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OPINION REVIEW

Anterior glenohumeral instability: Current review with technical pearls and pitfalls of arthroscopic soft-tissue stabilization

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Abstract

The glenohumeral joint (GHJ) allows for a wide range of motion, but is also particularly vulnerable to episodes of instability. Anterior GHJ instability is especially frequent among young, athletic populations during contact sporting events. Many first time dislocators can be managed non-operatively with a period of immobilization and rehabilitation, however certain patient populations are at higher risk for recurrent instability and may require surgical intervention for adequate stabilization. Determination of the optimal treatment strategy should be made on a case-by-case basis while weighing both patient specific factors and injury patterns (*i.e.*, bone loss). The purpose of this review is to describe the relevant anatomical stabilizers of the GHJ, risk factors for recurrent instability including bony lesions, indications for arthroscopic *vs* open surgical management, clinical history and physical examination techniques, imaging modalities, and pearls/pitfalls of arthroscopic soft-tissue stabilization for anterior glenohumeral instability.

Key Words: Arthroscopic; Soft-tissue; Anterior instability; Glenohumeral; Functional anatomy; Recurrent instability

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Core Tip: Management of the patient with anterior shoulder instability is a common yet complex condition for the orthopaedic clinician. To optimize the evaluation and management of these patients the clinician must ensure a detailed and thorough clinical and radiographic workup, have a thorough understanding of the dynamic, static, and bony stabilizers of the glenohumeral joint, and understand the common causes of failed surgical intervention in order to address these concerns when appropriate. This review

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INTRODUCTION

The unique structure of the glenohumeral joint (GHJ) allows for a wide range of motion, but also makes the joint particularly vulnerable to episodes of instability[1]. Anterior instability is the most common form, accounting for 80%-98% of all GHJ instability events among young, athletic populations particularly during contact sporting events with the shoulder in the abducted and externally rotated position[2-10]. In 2018, the MOON Shoulder Instability Study reported on the descriptive epidemiology of 863 patients who underwent surgical intervention for GHJ instability[11]. They found the mean age for the cohort was 24 years with males representing 82% of all patients. The primary direction of instability was most commonly anterior for male (74%) and female (73%) patients with football (24%) and basketball (13%) the most common sports during which the injury occurred. The etiology of instability events ranges from ligamentous laxity to traumatic dislocation events, with the latter being the most common with an overall incidence of 1.7%[7,12].

Many first time dislocators can be managed non-operatively with a period of immobilization and rehabilitation, however, certain patient populations are at higher risk for recurrent instability which can lead to substantial time loss from active participation/training and may require surgical intervention for adequate stabilization[4,13,14]. Operative techniques aimed at addressing GHJ instability are variable and range from arthroscopic soft-tissue stabilization, open soft-tissue stabilization, as well as techniques aimed at addressing bone loss such as the Latarjet procedure, autologous bone graft transfer, and allograft bone transfers. Determination of the optimal treatment strategy should be made on a case-by-case basis while weighing patient specific factors such as age, activity/sport/working status, goals, and previous history of instability events. Additionally, injury specific factors should also be considered such as acuity of injury and the degree of bone loss which will be discussed in more detail later in this text.

The purpose of this review is to describe the relevant anatomical stabilizers of the GHJ, risk factors for recurrent instability including bony lesions, indications for arthroscopic *vs* open surgical management, clinical history and physical examination techniques, imaging modalities, and pearls/pitfalls of arthroscopic soft-tissue stabilization for anterior glenohumeral instability.

FUNCTIONAL ANATOMY

GHJ stability is provided through a complex interplay of passive and dynamic stabilizers[1,15-19]. Passive stabilizers include the rotator interval [superior glenohumeral ligament (SGHL), coracohumeral ligament, and joint capsule], the middle glenohumeral ligament (MGHL), and most importantly the inferior glenohumeral ligament complex (IGHL)[20]. The glenoid labrum runs circumferentially along the glenoid rim and serves as the point of insertion for all of the GH ligaments[1]. The SGHL prevents inferior translation of the adducted shoulder, the MGHL resists anterior translation in the externally rotated shoulder in abduction up to 45 degrees, and the IGHL can be broken down into the anterior band which is the major restraint to anteroinferior translation in external rotation with abduction > 45 degrees and the posterior band which resists posterior translation in the flexed and internally rotated shoulder[1,20-25]. The labrum deepens the glenoid socket and acts as a physiologic bumper to prevent GHJ instability[1]. Furthermore, the fibrocartilaginous labrum which

circumferentially surrounds the glenoid and provides stabilization to the GHJ is tight in its anteroinferior attachment and loose in the superior attachment with a great deal of anatomic variation[1,21]. Acting in accordance with these ligamentous and capsular stabilizers are surrounding muscles providing dynamic stabilization which include the deltoid, biceps brachii, and the rotator cuff muscles. The basis for dynamic stability is the theory that instability occurs at end-range positions which place the GHJ at its maximum vulnerability in regards to dislocation. Muscular activity acts to compress the humeral head against the center of the glenoid fossa thereby stabilizing during these end-range motions[15,17-19,26].

While there are several ligamentous and muscular components to stability, the glenoid and humeral head add an additional osseous component for stabilization. Therefore, in the evaluation of GHJ instability a proper understanding of the bony anatomy and pathoanatomy is critical to determine an accurate diagnosis and treatment plan. When considering the size of the glenoid in comparison to the humeral head it is clear that even a small bony lesion can lead to significant instability by altering the bony articulation of the glenoid and humeral head[21,27-29]. The glenoid is a pear shaped bone which is widest in the inferior half and is tilted anteriorly[1,26]. Wide variability in the size and inclination of the glenoid make bony lesions related to instability especially challenging to treat. The articulation between the glenoid and humeral head is important to consider in the patient with recurrent anterior instability. Burkhart and Danaceau[30] described the "articular arc" between these bones and determined that defects in this arc could lead to engaging lesions and instability events.

A proper understanding of the anatomy related to the GHJ is critical to properly evaluate, diagnose, and treat anterior GHJ instability. The surgeon needs to have a precise understanding of both the normal and variant anatomy of the capsulolabral complex as well as the dynamic muscular stabilizers to properly evaluate and surgically manage injury. Additionally, an understanding of the bony anatomy of the glenoid and humeral head come into play as the clinician needs to thoroughly evaluate and manage these defects. These challenges will be described further in later sections of this text.

RISK FACTORS FOR RECURRENT GLENOHUMERAL INSTABILITY

Although GHJ instability is considered a relatively common event in young athletes and physically active patient populations, oftentimes first-time dislocators can be effectively managed non-operatively[3-6,31]. However, several proposed risk factors associated with recurrent instability events have been described. Of these reported risk factors, the most closely associated with recurrence include a history of instability events, age at the time of initial injury, contact sports, overhead athletes, and those with ligamentous laxity[4,7,21,32-36]. In addition, the most challenging injuries to treat are those with concomitant bony pathologies. During an anterior GHJ instability event there can be bony injury to the glenoid (referred to as a bony Bankart lesion), the humeral head (referred to as a Hill-Sachs lesions), or to both structures (bipolar lesions). Several studies have reported on the relationship between GHJ instability and bony deficits with recurrent instability rates in correlation with the size of the bony lesion[34,37]. In the past these injuries were managed with isolated soft tissue repairs, however growing evidence of recurrent instability raised questions as to the appropriate management of these injuries. An investigation performed by Burkhart *et al*[29] reported on 194 consecutive arthroscopic Bankart cases and found recurrence rates of 4% in those without significant bone defects as compared to 67% in those with humeral and/or glenoid lesions. These findings added evidence to the recurrent instability in those with untreated bony lesions and increased the awareness and treatment of these pathologies. In the management of patients with anterior GHJ instability it is important to think about the bony risk factors for recurrent instability and to modify these risk factors when possible to improve clinical results. Some of these potential risk factors related to bony defects have been researched in the literature and include.

Glenoid defects: The bony Bankart

Glenoid lesions have been reported to occur in 22%-41% of first time dislocation events and up to 86% of recurrent events[28,32,38,39]. Bony Bankart lesions occur during anterior GHJ instability as the dislocation of the humeral head creates a bony lesion on the anteroinferior aspect of the glenoid in addition to avulsion of the anteroinferior

labrum. Burkhart *et al*[29] described the normal glenoid to appear pear shaped with a wider diameter in the inferior aspect as compared to the superior aspect. They went on to describe the "inverted pear" phenomenon which was in reference to the pathologic appearance of the glenoid resulting from a bony Bankart injury where the superior aspect of the glenoid appeared wider in diameter as compared to the inferior aspect. This change disrupts the arc of motion while the arm is abducted and externally which places the GHJ at a higher risk of redislocation. This theory was then confirmed by the biomechanical work of Gerber *et al*[40] who reported that increasing loss of the anteroinferior glenoid arc was associated with decreased resistance to dislocation. Bigliani *et al*[28] further categorized glenoid lesions and provided prognostic factors as follows: Type 1 Lesions involve a non-displaced anterior glenoid fragment, type 2 Lesions involve a small anterior fragment detached from the labrum, type 3a lesions involve < 25% anterior glenoid deficiency, and type 3b lesions involve > 25% anterior glenoid deficiency.

Humeral head defects: The Hill-Sachs lesion

In addition to glenoid sided lesions, a bony lesion to the posterolateral aspect of the humeral head is referred to as a "Hill-Sachs" lesion and can also lead to GHJ instability. These bony defects following first time GHJ dislocation have been reported to be found in up to 70% of patients[32,41]. In their review of 91 patients, Boileau *et al*[35] found Hill-Sachs lesions to be significantly related to failure. The failures resulting from Hill-Sachs lesions are theorized to result secondary to the articular arc defect which causes engagement of the humerus against the anterior glenoid rim referred to as the "engaging Hill-Sachs" lesion[29,35]. In their investigation, Burkhart *et al*[29] reported recurrent anterior GHJ instability in 100% (n = 3) of patients found to have an "engaging" Hill-Sachs lesion treated with arthroscopic Bankart repairs for traumatic anteroinferior instability. Although the clinical correlation between humeral defects and recurrent dislocation has been reported, there is a lack of current information regarding the size of the defect and relation to instability.

The combined bony Bankart and Hill-Sachs injury

While bony Bankart and Hill-Sachs lesions can occur in isolation, these injuries may also occur concurrently. A recent cadaveric study by Arciero *et al*[42] reported on these combined injuries. The study developed models for bony lesions based on computed tomography (CT) scans from 142 consecutive patients presenting with GHJ instability. The authors found that combined glenoid and humeral lesions displayed an additive and negative effect on GHJ stability. More specifically, they found that in patients with moderate sized Hill-Sachs lesions (defined as 50th percentile within the population of 142 consecutive patients), a glenoid lesion as small as 2 mm significantly compromised the stability of a soft tissue Bankart repair. These findings led to the conclusion that combined glenoid and humeral head defects have an additive and negative effect on glenohumeral stability.

The "glenoid track" concept

This description of the zone of contact between the glenoid and humeral head during elevation of the arm is termed the "glenoid track"[43]. This concept was initially described by Yamamoto *et al*[43] in a cadaveric study focused on the location and width of this "glenoid track" during various degrees of abduction while maintaining maximum external rotation and horizontal extension. The investigators found that the zone of contact shifted from the inferomedial to the superolateral portion aspect of the humeral head. They determined the width of the track from the rotator cuff attachment site of the greater tuberosity to be 84% ± 14% of the width of the glenoid (assuming no bone injury to the glenoid) and used this concept to determine the risk of a Hill-Sachs lesion engaging the glenoid rim in cases with and without bony injury. If the bony injury to the humeral head is located within the width of the glenoid track then there is no opportunity for the Hill-Sachs lesion to over-ride the glenoid creating a potential instability event. However, in cases where the Hill-Sachs lesion extends beyond the width of the glenoid track this creates an opportunity for instability. Another important aspect of this concept is that the width of the glenoid track is determined solely on the width of the glenoid meaning that a bony Bankart directly correlates with a decrease in width of the glenoid track. This concept was not the first to describe bony lesions as they relate to anterior glenohumeral instability, however this provided a new concept to evaluate both humeral and glenoid sided lesions simultaneously as the authors concluded that if the medial margin of a Hill-Sachs lesion is more medial than the glenoid track then standard stabilization techniques are

unlikely to adequately address the bony sources of instability. Several investigations have identified "off-track" lesions to be at higher risk for recurrent instability[44-48]. Most recently, in a 2020 investigation by Yian *et al*[36] the authors reported on 540 patients undergoing primary arthroscopic Bankart repair and found "off-track" glenoid lesions to be statistically significantly associated with higher rates of recurrent instability (odds ratio, OR 2.86).

INDICATIONS FOR ARTHROSCOPIC *VS* OPEN SURGICAL MANAGEMENT

The purpose of surgical management of anteroinferior labral injuries is to reduce the risk of recurrent instability events. Historically, the rate of recurrent glenohumeral dislocations following open surgical repair have been lower (5%-9%)[49-51] as compared to arthroscopic interventions (5%-33%)[52-54]. Traditionally, open Bankart repair performed simultaneously with a capsular shift was considered the preferred management option, however improvements in arthroscopic techniques and implants have resulted in arthroscopic stabilization becoming the currently preferred technique for management of recurrent anterior GHJ instability[55-57]. One of the major advantages of the arthroscopic technique is that it does not violate the subscapularis which could potentially lead to functional deficits in external rotation[49]. Several high level investigations have reported similar rates of recurrent instability following arthroscopic *vs* open surgical intervention[53,55,58,59]. While these investigations found similar outcomes in results following both arthroscopic and open stabilization procedures, only short term outcomes were reported. Others have argued that outcomes between arthroscopic and open stabilization cannot be established in 2-3 years of followup[56]. Supporting this argument, longer-term studies have found much higher rates of recurrent shoulder instability following arthroscopic repair ranging from 17%-35% at 5-10 years[60-63]. This is in comparison to longer-term studies reporting on outcomes of open Bankart repairs with recurrence rates of 15%-17.5% at 10-20 years[61,62,64]. Although it may seem reasonable to utilize an open Bankart repair following initial failure of an arthroscopic technique, the current literature shows inferior outcomes in patients undergoing revision open Bankart compared to primary open Bankart[65-67]. Despite the abundance of clinical outcomes on this topic, indications for primary open Bankart repair remain controversial[56]. Some advocate for open Bankart repair in the setting of male collision athletes younger than 20 years, patients with subcritical (10%-20%) glenoid bone loss, patients with 10 or more shoulder dislocations, patients who have failed arthroscopic Bankart repair with less than 20% glenoid bone loss, and those with poor capsulolabral tissue[56].

When considering operative intervention it is also critical to evaluate associated bony injuries as discussed in previous sections of this manuscript. Amounts of bone loss initially thought to be adequately treated with Bankart repair is shrinking. Historically, anteroinferior glenoid bone loss of ≥ 25% of the inferior glenoid diameter is managed with glenoid bone grafting with a coracoid autograft (Latarjet), iliac autograft, or allograft[29,35,40,54,68-71]. Cadaveric investigations have shown that bone loss of > 21% has resulted in residual instability, resulting in some advocating for a threshold of 20% glenoid bone defect to be an indication for bony stabilization[54,72]. A 2015 investigation by Shaha *et al*[73] reported increased shoulder pain and decreased function in patients after arthroscopic Bankart repair with bone loss of 13.5%-19.8% of the inferior glenoid which they termed "subcritical" bone loss. This investigation led to the potential role of bony augmentation in patients with this "subcritical" bone loss of the glenoid. More recently, Pickett and Svoboda[54] reported their threshold for a Latarjet procedure to be 20% glenoid bone loss while also considering the procedure in contact athletes with "subcritical" (13%-19%) glenoid bone loss.

The clinical implications of Hill-Sachs lesions is not completely understood, original thought was that lesions > 16% of the humeral head diameter, those whose volume exceed 1000 mm^3, or patients who experienced a clunking sensation with the arm in 90 degrees of abduction and 90 degrees of external rotation required operative intervention[54,74]. Others advocated that defects > 20%-25% of the humeral head diameter required management with an allograft[54,75]. These investigations preceded the concept of the glenoid track by Yamamoto *et al*[43] which was discussed earlier in this text.

While many investigations have reported on glenoid or humeral sided bone lesions, in practice these injuries can occur concurrently. Di Giacomo *et al*[68] proposed an algorithm in patients with bipolar lesions with varying degrees of glenoid and humeral head involvement. The authors broke patients down into the following four

groups with their associated treatment: (1) Group 1: < 25% glenoid bone loss and on-track Hill-Sachs defect can be treated with an arthroscopic Bankart repair; (2) Group 2: < 25% glenoid bone loss and off-track Hill-Sachs defect can be treated with an arthroscopic Bankart repair and remplissage; (3) Group 3: > 25% glenoid bone loss and on-track Hill-Sachs defect require a Latarjet procedure; and (4) Group 4: > 25% glenoid bone loss and off-track Hill-Sachs defect require a Latarjet procedure and may need an additional bony procedure to address the humeral head.

It would seem practical to utilize the glenoid track concept to assist in surgical planning as it incorporates bony lesions to both the glenoid and humeral head. Due to the fact that this initial concept was described *in vitro*, some theorized it may not represent true conditions of recurrent instability due to its lack of including factors such as laxity of the capsulolabral complex. In theory, this could lead to a smaller sized Hill-Sachs lesion facilitating an engaging bipolar lesion causing recurrent instability[44,76]. However, there is growing evidence supporting clinical outcomes using the glenoid track concept while lowering the threshold for glenoid bone loss[48,77]. More specifically, Metzger *et al*[77] reported on 205 patients with recurrent anterior shoulder instability. The patients had a mean glenoid bone loss of 7.6% (range 0%-29%) with 22% of patients engaging on clinical exam under anesthesia (EUA). When comparing clinical EUA findings with radiographic findings, 84.5% of patients with radiographic findings suggestive of an engaging lesion displayed clinical evidence of an engaging lesion on EUA while only 12.4% clinically engaged during EUA without radiographic evidence of engagement (P < 0.001). The investigation demonstrated that gleno-humeral engagement was well predicted based on preoperative glenoid and humeral head bone loss measurements using the glenoid track concept. Supporting these findings, a 2016 investigation by Shaha *et al*[48] reported on 57 shoulders over a two year period treated with a primary arthroscopic Bankart reconstruction. The authors reported 10 instability recurrences (18%) with 4 (8%) failures in the on-track patients as compared to 6 (75%) in the off-track group (P = 0.0001). Importantly, they reported the positive predictive value (PPV) of an off-track measurement was 75% compared to a 44% PPV in those with glenoid bone loss of > 20%. They concluded that the application of the glenoid track concept was superior to using glenoid bone loss alone when predicting post-operative stability.

More recently, a 2018 Yang *et al*[76] investigated the relationship between the Hill-Sachs interval and the glenoid track. The investigators retrospectively reviewed 160 patients who underwent an arthroscopic Bankart repair with a minimum of 24 mo follow up. They reported that a Hill-Sachs interval to glenoid track width ratio (H/G ratio) of ≥ 0.7 was a significant predictor of higher risk for recurrent instability. This value was validated by the recent findings of Chen *et al*[44] who found the H/G ratio of ≥ 0.7 to be comparable to the instability severity index score (ISIS) for predicting an increased risk of recurrent instability after arthroscopic Bankart repair. The ISIS was initially developed by Balg *et al*[78] and utilizes a combination of clinical characteristics and radiographic findings to predict risk for recurrent instability. It has been validated by several studies as a useful tool in predicting recurrent instability[44,79-83].

CLINICAL HISTORY AND PHYSICAL EXAM

The history of injury should include a description of the position of the arm, force applied, and point of force[84]. The typical mechanism for an anterior GHJ dislocation is a force to an extended, abducted, and externally rotated upper extremity[84]. Clinical history elicited during the initial encounter should also include evaluation of other sources of instability such as connective tissue disorders or generalized joint laxity. Connective tissue disorders such as Ehlers Danlos or Marfan's syndrome should be ruled out by inspecting for skin hyper-extensibility, widened atrophic scarring, family history, personal history of instability events, and evaluation of joint hypermobility utilizing the Beighton criteria when clinically appropriate[85]. Evaluation should always include comparison to the contralateral shoulder.

Examination of the shoulder should include evaluation of the cervical spine, visualization of bilateral shoulders for evidence of muscular atrophy or deformities, active and passive range of motion, and a neurovascular exam with careful evaluation of the axillary nerve[32]. Finally, evaluation should include specific laxity and instability testing. It is important for the clinician to differentiate GHJ instability which is described as symptomatic and reproducible dislocation of the joint as compared to generalized joint laxity which is characterized by loose ligamentous tissue causing chronic pain and instability during minor events.

Tests specific to joint laxity include the load and shift test and the sulcus test. In the load and shift test an axial load is placed on the shoulder to center the humeral head onto the glenoid cavity and the examiner stabilizes the shoulder girdle with one hand while applying an anterior or posterior load to the proximal humerus with the other hand[32]. Increased translation in the anterior or posterior directions indicates joint laxity in that plane. The sulcus test is performed while the patient stands with their arm at the side while the examiner places a downward force onto the arm. It can be indicative of inferior laxity if a sulcus, or hollowing, occurs inferior to the acromion. Both of these tests should be performed in comparison to the contralateral side. In regards to testing for joint stability the clinician may perform the apprehension test and the jerk test. The apprehension test is performed with the patient in a supine or standing position. The arm is held in 90 degrees of abduction and in external rotation. The examiner places one hand behind the scapula for stabilization while simultaneously pulling back on the wrist putting the patient into further external rotation. The patient with anterior instability becomes apprehensive during this maneuver[84]. The jerk test is performed with the patient in internal rotation and flexed to 90 degrees. With one hand stabilizing the scapula the examiner grasps the elbow and places an axial load onto the humerus while simultaneously moving the arm horizontally across the body. The clinician is evaluating for a sudden "jerk" of the humeral head sliding off of the posterior glenoid followed by a "clunk" when the arm is brought back to the original positioning[84]. A positive jerk test is indicative of posterior instability.

Imaging

Initial radiographic workup of GHJ dislocation should include plain radiographs with anteroposterior (AP), infraspinatus outlet, and axillary views to evaluate for bony pathology and the version of the glenoid. Angled views such as the apical oblique view, Stryker notch view, and the West Point view could also be obtained to better visualize bony defects to the glenoid and posterolateral humeral head[84]. If there is further clinical or radiographic concern for bony pathology, or in cases of recurrent episodes of instability, computed tomography (CT) imaging with 3D reconstruction remains the gold standard for evaluation of bony injury[28,32]. In addition to evaluation of bony deficits, magnetic resonance imaging (MRI) is the preferred method for evaluation of the soft tissues of the shoulder joint, specifically for evaluation of the glenoid labrum and rotator cuff. Based on its location, the GHJ is inherently difficult to image and the best positioning is with the arm in a neutral or externally rotated position as internal rotation of the shoulder can cause labral and/or anteroinferior capsule redundancy which obscures tears[1,86]. In general, several consecutive images should be reviewed when evaluating an MRI and MR arthrography may also be utilized to increase visualization[1,87].

OPERATIVE PEARLS AND PITFALLS OF ARTHROSCOPIC BANKART REPAIR

Patient positioning

Based on the importance of the inferior anchor placement the clinician should consider the benefits and disadvantages of beach chair *vs* lateral decubitus positions. In regards to the beach chair positioning the benefits include easier conversion from arthroscopic to open, anatomic orientation of the joint, rotational control of the shoulder, and optimal visualization of the subacromial joint. Despite these advantages, the major difficulty with beach chair orientation is decreased visualization of the inferior aspects of the joint. In comparison, the lateral decubitus positioning allows for increased joint space as traction can be applied in addition to improved access and visualization to the inferior GHJ. Despite this advantage it's important to note that the disadvantages of lateral decubitus positioning include non-anatomic orientation, difficult conversion from arthroscopic to open, challenging positioning for the anesthesia team, and the possibility of traction related injury.

In regards to the optimized visualization/access to the inferior joint, a systematic review with meta-regression analysis conducted by Frank *et al*[88] on outcomes of arthroscopic anterior shoulder instability cases in beach chair *vs* lateral positioning. The study reported on 64 studies including 3668 shoulders and found the overall recurrent instability rates were 14.65% in the beach chair positioning patients as compared to 8.5% in the lateral decubitus positioning. Although the study reported

decreased recurrence rates within the lateral decubitus group the differences in range of motion, return to activity, and Rowe scores between groups were not significant. Although patient positioning may be related to recurrent instability events it is important to recognize that these results do not necessarily suggest a more or less successful surgery as clinical outcome scores were similar and the fact that recurrence is a difficult measure of operative success based on the wide spectrum inherit to the term "instability."

Portal placement

Optimal portal placement is crucial during the operative management of GHJ instability. With incorrect or inadequate portal placement the visualization into the joint can be severely compromised and can also dramatically increase the technical difficulty. Ideal placement of the portals allows for adequate visualization for proper diagnostic arthroscopy and eases the technical demands of anchor placement. Initial portal placement begins with standard posterior portal located roughly 2 cm inferior and 1 cm medial to the posterolateral corner of the acromion. Next, the anterosuperior (AS) portal is placed anterolateral to the edge of the acromion and lateral to the coracoid under direct visualization. Ideal intraarticular placement of this portal is just posterior to the insertion of the long head of the biceps. The primary purpose of the AS portal is to visualize the inferior, anterior, and posterior capsule while allowing for a thorough diagnostic scope to evaluate and recognize the anatomy of the shoulder. During this stage of the procedure the surgeon will evaluate the capsular volume, biceps tendon, glenohumeral ligaments, rotator cuff, and the anterior, posterior, and inferior labrum. Next, the anterior and posterior working portals can be created under direct visualization. During creation of these portals an "outside in" technique is utilized meaning a spinal needed is used to ensure ideal placement. For the anterior portal the needle should be placed between the acromioclavicular joint and the lateral coracoid. Intraarticularly the needed will ideally pierce the capsule just superior to the subscapularis tendon directly parallel to the surface of the glenoid. The posterior portal is created slightly inferior to the arch of the acromion and directed towards the coracoid process. Proper placement of these portals will allow the surgeon to visually appreciate the entire capsulolabral complex.

Labrum and glenoid preparation

Adequate labral preparation is a critical component of anterior GHJ instability repairs as error during this step may lead to recurrent instability due to inadequate capsulolabral plication. An elevator device can be used during this step to peel the labrum off the glenoid surface. After elevating the labrum from the glenoid neck a small shaver can be used to prepare the surface of the glenoid for anchor placement. Preparation of the labrum should be completed prior to preparation of the glenoid surface and anchor placement.

Anchor placement

Ideal anchor placement is below the 3 o'clock position placed 2-3 mm from the glenoid rim at a 45 degree angle relative to the anterior glenoid rim[21]. Anchors can then be placed approximately 7 mm apart. Based on the study performed by Boileau *et al*[35] at least 4 suture anchors should be utilized as 3 or fewer were found to be at higher risk for recurrent instability. During this stage of the procedure it is critical to achieve inferior anchor placement onto the glenoid. There are several portal positions and guides available to the surgeon to achieve this low placement however there remains no perfect option. A biomechanical study by Frank *et al*[89] reported on inferior anchor placement in 30 cadavers which were randomized into 3 test groups based on portal location and drill guide. The study found that there was no significant difference in ultimate load to failure among anchors placed *via* the 3 techniques. However, the authors did conclude that midglenoid portal anchors drilled with a straight or curved guide placed at the 5 o'clock position displayed significantly increased risk of opposite cortex perforation. Although the clinical applicability of these findings remained unclear, the study prompted discussion regarding ideal patient positioning in order to visualize the inferior glenoid in order to place the inferior anchor.

Rehabilitation

The authors prefer an abduction sling post-operatively in order to keep the shoulder in neutral positioning. Physical therapy then begins 7-10 d post-operatively with passive and active range of motion (ROM) for 4 wk (forward flexion to 130 degrees, external rotation to 30 degrees), ROM progression from 4-6 wk (forward flexion to 180 degrees,

external rotation to 60 degrees), followed by resistive strengthening from 8-12 wk, and return to full sports and activities at 4-6 mo[21].

CONCLUSION

Management of the patient with anterior shoulder instability is a common yet complex condition for the orthopaedic surgeon. To optimize the evaluation and management of these patients the provider must ensure a detailed and thorough clinical and radiographic workup, have a thorough understanding of the dynamic, static, and bony stabilizers of the GHJ, and understand the common causes of failed surgical intervention in order to address these concerns when appropriate.

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ORIGINAL ARTICLE

Observational Study

Ceramic-on-ceramic *vs* ceramic-on-polyethylene, a comparative study with 10-year follow-up

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Institutional review board statement: This observational prospective single-center cohort study with a 10-year follow-up was part of the normal follow-up of a documented series of elective THAs. Therefore, no ethical approval was needed for this study. Moreover, the analysis used anonymous data that were obtained after each patient agreed to the operation by written consent.

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Abstract

BACKGROUND

In press-fit total hip arthroplasty (THA) ceramic-on-ceramic (CoC) bearings are a potential for overcoming the wear that is seen in ceramic-on-polyethylene (CoPE) bearings, and can lead to wear-induced osteolysis, resulting in loosening of the implant. However, CoC bearings show disadvantages as well, such as squeaking sounds and being more fragile, which can cause ceramic head or liner fracture. Because comparative long-term studies are limited, the objective of this study was to determine the long-term difference in wear, identify potential predictive factors for wear, investigate radiological findings such as osteolysis, and evaluate clinical functioning and complications between these bearings.

AIM

To determine 10-year differences in wear, predictive factors for wear, and investigate radiological findings and clinical functioning between CoC and CoPE.

METHODS

This observational prospective single-center cohort study with a 10-year follow-up includes a documented series of elective THAs. Primary outcome was wear measured by anteroposterior (AP) radiographs. Secondary outcomes were potential predictive factors for wear, complications during follow-up, Harris hip

Informed consent statement: All study participants, or their legal guardian, provided informed written consent for the operation.

Conflict-of-interest statement: The authors declare that there is no conflict of interest.

Data sharing statement: No additional data are available.

STROBE statement: The authors have read the STROBE Statement-checklist of items, and the manuscript was prepared and revised according to the STROBE Statement-checklist of items.

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score (HHS), and radiological findings such as presence of radiolucency, osteolysis, atrophy, and hypertrophy around the cup. Due to the absence of wear in the CoC group, stratified analysis to identify risk factors for wear was only performed in the CoPE group by use of univariate linear regression analysis. HHS was expressed as a change from baseline and the association with bearing type was assessed by use of multivariate linear regression analysis, adjusted for potential confounders.

RESULTS

A total of 17 CoPE (63.0%) and 25 CoC (73.5%) cases were available for follow-up and showed a linear wear of respectively 0.130 mm/year (range 0.010; 0.350) and 0.000 mm/year (range 0.000; 0.005), which was significant ($P < 0.001$) between both groups. Wear always occurred in the cranial direction. Cup inclination was the only predictive factor for polyethylene (PE) wear. No dislocations, ceramic head, or liner fractures were seen. The HHS showed a mean change from baseline of 37.1 points (SD 18.5) in the CoPE group and 43.9 (SD 17.0) in the CoC group. This crude difference of 6.8 (range -5.2; 18.7) in favor of the CoC group was not significant ($P = 0.26$) and was not significant when adjusted for age, gender, and diagnosis either ($P = 0.99$). No significant differences in complications and radiological findings were seen between groups.

CONCLUSION

CoC bearing shows lower wear rates compared to CoPE at 10-year follow-up with cup inclination as a predictive factor for wear and no differences in complications, HHS, and radiological findings.

Key Words: Total hip arthroplasty; Press-fit; Bearing; Ceramic-on-ceramic; Ceramic-on-polyethylene; Wear

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Core Tip: Polyethylene wear of the acetabular insert can cause osteolysis and aseptic loosening of the implant in total hip arthroplasty. Ceramic-on-ceramic (CoC) bearing can overcome this problem, but comparative long-term data between ceramic-on-polyethylene (CoPE) and CoC are limited. This 10-year follow-up study showed higher wear rates in CoPE with cup inclination as a predictive factor for wear. No differences in complications, radiological findings, and clinical scores were seen. To confirm the potential benefits of CoC bearing focusing on wear and survival rates of the implant, more long-term data are needed.

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INTRODUCTION

Total hip arthroplasty (THA) is considered the operation of the century, but the search for the ideal articulation is still a point of discussion[1]. Several bearing surfaces have been developed in the past to reduce causes for revision. Polyethylene (PE) or highly cross-linked PE (HXLPE) inlay combined with a ceramic head still remains the option of choice[2]. Therefore, the use of a ceramic-on-polyethylene (CoPE) articulation increased with almost 20% in the last decade up to 63.4% of all THAs as seen in the Dutch Arthroplasty Register in 2019[3].

Wear rates of PE are widely investigated, since wear-induced osteolysis resulting in aseptic loosening still remains one of the main causes of late revision[4,5]. The threshold of 0.05 mm/year was eventually stated to eliminate osteolysis, but recent long-term results showed that even wear rates below this threshold in both PE and HXLPE are

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associated with osteolysis[6,7]. Ceramic-on-ceramic (CoC) bearings are a potential to overcome this problem, with lower wear rates and incidence of osteolysis than CoPE[8]. However, CoC bearings show disadvantages as well, such as a squeaking sound and being more fragile, which can cause fracture of both the head and the inlay and makes revision THA challenging[9,10].

Comparative long-term studies are needed to confirm if the aforementioned disadvantages of both bearings will be reflected in accompanying revision rates, clinical functioning, and radiological findings over time. Recent systematic reviews have shown that more data and especially more research focused on long-term are required to clarify clinical advantages of both bearings[11,12].

The objective of this study was to determine the long-term difference in wear, identify potential predictive factors for wear, investigate radiological findings such as osteolysis, and evaluate clinical functioning and complications between CoC bearing *vs* CoPE in THA when using the same implants with a 10 years follow-up.

Our hypotheses were that CoPE would show higher wear rates than CoC and no differences would be observed in radiological findings, clinical functioning and complications.

MATERIALS AND METHODS

Ethical approval/registration

No ethical approval was needed for this observational prospective cohort study because this documented series was part of the normal follow-up of elective THAs. Reporting was done in accordance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement. This research was conducted according to the Declaration of Helsinki.

Study design

This observational prospective single center cohort study with 10-year follow-up included a documented series of elective THAs performed between December 2003 and December 2004 comparing the EP-FIT PLUS press-fit cup system with ceramic insert (BIOLOX delta, Smith and Nephew) to standard PE acetabular inserts (Standard REXPOL, Smith and Nephew) with similar ceramic head (BIOLOX delta, Smith and Nephew) articulation. No randomization was performed in this study. The choice between PE or ceramic insert depended on patient characteristics and the experienced orthopedic surgeons' preferences. All patients included were seen in a standard follow-up scheme with X-rays at baseline, 3, 12, 36, 60, and 120 mo post-operatively. After surgery, a standard postoperative rehabilitation protocol under guidance of a physical therapist consisted of immediate weightbearing and crutches for 6 wk. All outcomes were analyzed by a reviewer and checked by a second researcher who were both not involved in the selection, surgery, and follow-up process.

Eligibility

All indications for THA included in this study were primary osteoarthritis (OA), degeneration due to rheumatoid arthritis or other inflammatory arthritis, avascular necrosis and hip dysplasia. Patients were included after completing verbal informed consent. Patients with secondary OA due to trauma, infection of the hip, osteoporosis or a prior osteotomy or arthroplasty were excluded from this study. No a priori power analysis was performed.

Surgical procedure

All THAs were performed at Slotervaart Medical Center by experienced orthopedic surgeons using a straight lateral approach under standard antibiotic prophylaxis. The surgical approach was according to the surgical technique described by the manufacturer of the implants. The same uncemented acetabular cup (EP-FIT PLUS, Smith and Nephew) was used in all patients. This cup is an equatorial flattened press-fit cup design with an open porous titanium vacuum plasma coating to increase roughness, with initial fixation by 2%-3% oversizing. A non-cemented Zweymuller titanium rectangular tapered shape femoral stem (SL-PLUS, Smith and Nephew) was used as femur component in all cases in combination with a ceramic head articulation (BIOLOX delta, Smith and Nephew). A 32 mm and 28 mm head were respectively used in CoC and CoPE bearing. The liner being used was either a ceramic insert (BIOLOX delta, Smith and Nephew) or a standard PE acetabular insert (Standard PE,

Smith and Nephew). Both the ceramic head and liner are made of a zirconia toughened alumina ceramic alloy, a fourth-generation ceramic material. The aimed leg length and femoral offset was measured accordingly to be identical to the contralateral side.

Outcomes

Patient demographics were recorded at baseline, including age, gender, body mass index (BMI), indication for surgery (primary OA or other diagnosis), and operation side. Information regarding the operation was recorded as well including articulation, head size, and cup inclination in degrees on direct post-operative radiographs. Perioperative and complications during follow-up like ceramic articulation fractures, squeaking and dislocations were directly registered.

The primary outcome was wear in mm/year measured by an independent orthopedic surgeon, by consecutive radiography using standard weightbearing anterior-posterior radiographs. By using the penetration and the size of the head, the thickness of the inlay was calculated. The method being used as demonstrated in Figure 1, is widely used and first described and validated by Charnley *et al*[13]. The width of the narrowest part of the inlay in the proximal weightbearing region (B) was subtracted from the widest part in the distal non-weightbearing area (A) and halved. With this formula, wear = (A – B)/2, wear was calculated as cranial migration in mm. These outcomes were used to calculate linear wear rates in mm/year. As an example, if no wear occurs, the thickness of the inlay is the same in all directions. Hereby the difference between the measurement of A and B is zero, meaning that there is no cranial migration and hereby no wear. If wear increases and more cranial migration is seen, the measurement of B will become lower and A will increase due to a wider distal part, resulting in a greater difference between both values (Figure 1). As a secondary outcome, potential predictive factors for wear such as gender, age, operation side, BMI, diagnosis (primary OA *vs* other), cup size, and cup inclination were determined. The Harris hip score (HHS) was used as a clinical questionnaire to measure patient reported outcomes[14]. Radiographs were evaluated by two researchers to determine presence of radiolucency, osteolysis, atrophy, and hypertrophy around the cup in Zones I-III according to DeLee *et al*[15].

Statistical analysis

Statistical analyses were performed with Statistical Package for Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, New York, United States). Normally distributed continuous variables are stated as mean with standard deviation (SD) and tested by use of Student's *t*-test. In case of non-normality medians with interquartile ranges are presented and a Mann-Whitney *U* test was used to asses for significant differences between both groups. Categorical data were compared by use of chi-squared tests. Due to the absence of wear in the CoC group, stratified analysis to identify risk factors for wear was only performed in the CoPE group by use of univariate linear regression analyses. HHS was expressed as a change from baseline and the association with bearing type was assessed by use of multivariate linear regression analysis, adjusted for potential confounders (*i.e.* age, sex, and diagnosis). Differences were stated significant if *P* values were less than 0.05. Complications and radiological findings were expressed as frequencies with percentage. All statistical methods in this study were done by a biomedical statistical expert (Inger N Sierevelt).

RESULTS

A total of 61 patients receiving THAs were included in this study at baseline (Figure 2). A significant difference in age and distribution of diagnosis (primary OA *vs* other) between both groups was observed (Table 1). A total of 17 CoPE (63.0%) and 25 CoC (73.5%) cases were available for 10-year follow-up. Intra-operative trochanteric fracture occurred in one case (4%) in the CoPE group and two (6%) in the CoC group, and were treated with a trochanteric wire. Delayed wound healing was seen in two (8%) and four (13%) patients in the CoPE and CoC group, respectively. Temporary peroneal nerve injury was observed in the CoPE group in two cases (7.4%). During follow-up, one periprosthetic joint infection (3%) was seen in the CoC group, which was initially treated with lavage and antibiotics; however, removal of the implant was done elsewhere after 3 years of follow-up. Femoral component loosening was the reason for one revision in both groups, treated by revision of the stem and inlay elsewhere in the CoC case and in our clinic in the CoPE patient. No dislocations,

Table 1 Baseline characteristics and operation information

	CoPE, *n* = 27 (100%)	CoC, *n* = 34 (100%)	*P* value
Female gender, *n* (%)	21 (78%)	22 (65%)	0.27
Right side, *n* (%)	19 (76%)	17 (50%)	0.11
Diagnosis, *n* (%)			0.01
Primary OA	23 (85%)	19 (56%)	
Other	4 (15%)	15 (44%)	
Age, in years, mean (SD)	64.2 (5.3)	55.7 (8.5)	< 0.001
BMI, in kg/m^2 mean (SD)	27.6 (4.1)	26.9 (4.1)	0.52
Cup size in mm, mean (SD)	52.1 (3.4)	53.6 (3.5)	0.10
Inclination cup in degrees, mean (SD)	46.8 (6.7)	44.6 (5.0)	0.22
HHS, mean (SD)	50.2 (13.3)	47.5 (13.4)	0.44

BMI: Body mass index; CoPE: Ceramic-on-polyethylene; CoC: Ceramic-on-ceramic; HHS: Harris hip score; OA: Osteoarthritis; SD: Standard deviation.

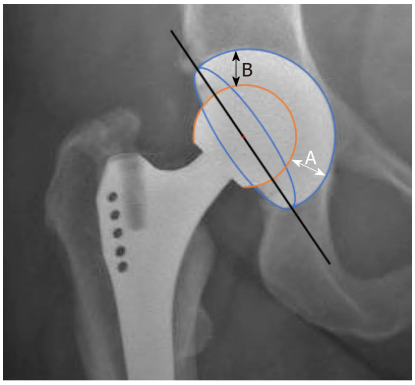


Figure 1 Method of wear measurement with center of rotation (red), boundaries of the cup (blue) and head (orange) and line for measurement of inclination angle (black). A: Widest distal part of inlay; B: Narrowest proximal part of the inlay.

squeaking, and fracture of the ceramic liner were observed. A total of two revisions were planned in the CoPE group after the 10-year follow-up due to complaints combined with excessive wear. All complications showed no significant differences between both groups.

Primary outcome

After 10 years of follow-up, the median linear wear of CoPE and CoC bearing was 0.130 mm/year (range 0.010; 0.350) and 0.000 mm/year (range 0.000; 0.005), respectively. Wear always occurred in the cranial direction. In two patients in the CoC group, wear of 0.05 mm was measured, in all other cases, no wear was observed. The difference in wear between both groups was significant ($P < 0.001$).

Secondary outcomes

The results of the stratified analysis to identify risk factors for wear in the CoPE group are shown in Table 2. Increased cup inclination was the only predictive factor for PE wear in CoPE bearing.

The HHS score showed a mean change from baseline of 37.1 points (SD 18.5) in the CoPE group and 43.9 (SD 17.0) in the CoC group. This crude difference of 6.8 (range -5.2; 18.7) in favor of the CoC group was not significant ($P = 0.26$). When adjusted for age, gender, and diagnosis (primary OA *vs* other), a mean difference of -0.02 (range -14.7; 14.7) was seen, which was not significant either ($P = 0.99$).

The radiological findings in the periacetabular cup zones are shown in Table 3. These outcomes showed no significant differences between both groups.

Table 2 Potential predictive values for polyethylene wear in beta-coefficient (range)

Potential predictive factors for PE wear	Beta-coefficient (95%CI)	*P* value
Gender	0.06 (-1.18; 1.29)	0.93
Age	-0.01 (-0.10; 0.08)	0.82
Operation side	-0.40 (-1.53; 0.73)	0.46
BMI	-0.05 (-0.20; 0.10)	0.46
Diagnosis, primary OA *vs* other	1.10 (-0.42; 2.61)	0.14
Cup size	-0.06 (-0.23; 0.12)	0.52
Cup inclination	0.08 (0.02; 0.15)	0.02

BMI: Body mass index; CI: Confidence interval; OA: Osteoarthritis; PE: Polyethylene.

Table 3 Radiological findings in DeLee and Charnley zones I, II and III at 10-yr

	CoPE, *n* = 17			CoC, *n* = 25		
Zones	**I**	**II**	**III**	**I**	**II**	**III**
Radiolucent lines	0	0	0	0	0	0
Osteolysis cup	0	1 (6%)	0	2 (8%)	3 (12%)	0
Atrophy	2 (12%)	3 (18%)	0	5 (19%)	5 (19%)	0
Hypertrophy	0	0	0	0	0	0

CoPE: Ceramic-on-polyethylene; CoC: Ceramic-on-ceramic.

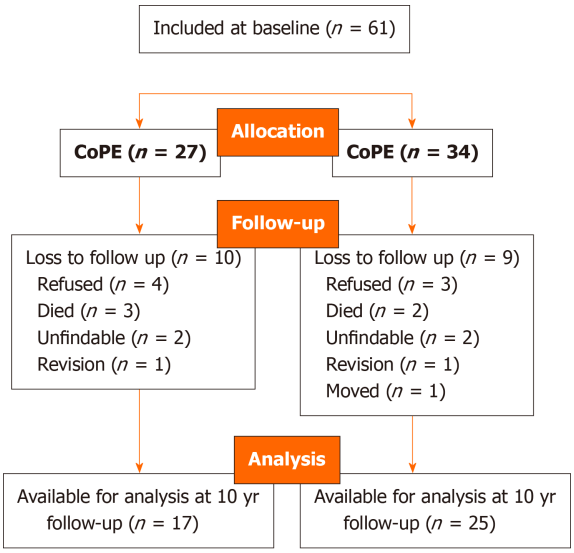


Figure 2 Flowchart of 10-year follow-up.

DISCUSSION

The main finding of this observational prospective cohort study of 61 THAs with 17 CoPE and 25 CoC cases available for 10-year follow-up was a significantly different degree of wear between the CoPE and CoC, with values of 0.130 mm/year (range 0.010; 0.350) and 0.000 mm/year (range 0.000; 0.005), respectively in the cranial direction. Comparable significant differences in wear rates were seen in the literature in both the short and long-term[8,16]. Conventional PE inlays have been improved by cross-linking to improve wear rates, but CoC bearings still show the lowest wear

rates[17-19]. Therefore, long-term follow-up is required to assess whether differences in wear will result in different survival rates. Although survival was not the focus of our study, to the best of our knowledge, the literature has only one comparative study with 12.6 years of follow-up showing no differences between CoC and CoHXLPE[18]. Studies that only focused on CoPE and CoHXLPE showed long-term survival rates of 86% and 100%, respectively, at 13 years and 88.3% and 93.8%, respectively, at 16 years[20,21]. Long-term studies that focused only on CoC showed divergent survival rates, with a 15-year follow-up study showing a survival rate of 92%, whereas another 20 years of follow-up showed a survival rate of 99.7%[22,23]. Our wear rate results combined with the revision rates in the literature indicated a possible advantage of ceramic coupling over PE, which needs to be confirmed with longer follow-up studies of at least 20 years.

The low wear and revision rates of CoC in the longer term become highly relevant since a rise in prevalence of THA and a shift to younger age is seen over the last decades[24]. Moreover, our study shows that patients receiving CoC articulation were significantly younger. Since life expectancy is still increasing worldwide, further research is needed to show if CoC can improve the longevity of THAs[25].

Our study showed that a higher inclination angle of the cup is a significant risk factor for wear. The same results are seen in the literature, with inclination angles above 45 degrees[26-28]. Since the mean angle of CoPE in our group was above this angle, it supports that acetabular positioning is highly important to reduce wear of CoPE.

In addition, inclination angles above 45 degrees are related to the higher incidence of squeaking in CoC[29,30]. In the literature, the incidence of squeaking is significantly higher in CoC than CoPE and varies between 0.5% and 20% and can influence the satisfaction of patients[11,12,31]. Although the mean angle of inclination in CoC in our study was just below the 45 degrees, no squeaking was reported.

Since the introduction of CoC, fracture of the ceramic, which was seen more often than in CoPE, was one of the greatest concerns against using this articulation[11,12]. A recent long-term meta-analysis showed that improvement of the ceramic over time led to lower fracture rates[32]. Additionally, in the literature, fourth-generation ceramic bearings showed no ceramic fracture when compared to third-generation CoC[33]. Since we used a fourth-generation ceramic bearing, this might be a reason that no head or liner fractures occurred in our study[32,33].

Another complication that influences long-term outcomes is dislocation, which can be caused by wear and malpositioning[34,35]. In the literature, a trend is seen in favor to CoC over CoPE[11,12]. Although no dislocations were seen in our study, the higher wear rate and wider angles of inclination presented in CoPE can indicate an increased risk of dislocation, which might become significant in the longer term.

In our study, no differences in radiological findings such as osteolysis were seen, which was supported by recent systematic reviews comparing CoC and CoPE[11,12]. Longer follow-up is needed to see if differences in osteolysis will occur over time.

No significant differences in clinical outcomes on the HHS were seen in our study. Since comparable scores on the HHS were seen in systematic reviews, there is no preference for one of the bearings based on functioning[11,12].

Finally, ceramic inserts are more expensive than PE, which might be an important issue in decision making in modern healthcare systems with an increasing focus on healthcare costs. Beaupre *et al*[36] stated that the costs of ceramic inserts were three times higher. To the best of our knowledge, no cost-analyses are performed in the literature between CoC and Co(HXL)PE. Long-term analysis needs to clarify if differences in outcomes, complication, and revision rates are cost-effective to the costs of both bearings.

A strength of our study is that we provided comparative results of a fourth-generation ceramic bearing, which are limited in the literature including wear, clinical, and radiological results. A limitation of our study was that no randomization was performed, which can have consequences for the comparability of the groups and might give indication bias. Moreover, a high loss to follow-up was seen in this study. Wear measurements were done using standard AP radiographs, which is a valid method, but is subsidiary to radiostereometric analysis (RSA)[37]. For example, we measured wear in two cases of CoC, which might be an error. Finally, no HXLPE was used, which is currently preferred when using a CoPE bearing.

CONCLUSION

In this study, higher wear rates were observed in CoPE compared to CoC bearing in

THA at the 10-year follow-up, with cup inclination as a predictive factor for wear for CoPE bearing, and no differences in complications, HHS, and radiological findings. More long-term comparative studies are needed to confirm potential benefits of CoC bearing, which might be the preference in THA focused on wear and survival rates, especially in younger patients.

ARTICLE HIGHLIGHTS

Research background

Ceramic-on-ceramic (CoC) bearing in total hip arthroplasty (THA) is presumed to give lower wear rates *in vivo*, compared to ceramic-on-polyethylene (CoPE).

Research motivation

More *in vivo* long-term studies are needed in literature, to confirm potential benefits or disadvantages of CoC over CoPE.

Research objectives

The objective of this study was to determine the 10-year difference in wear, identify potential predictive factors for wear, investigate radiological findings such as osteolysis, evaluate clinical functioning and complications between CoC bearing *vs* CoPE when using the same implants.

Research methods

An observational prospective single-center cohort study with 10-year follow-up of a documented series of elective THAs was performed with either a ceramic (BIOLOX delta, Smith and Nephew) or a standard PE acetabular insert (Standard REXPOL, Smith and Nephew) with a similar ceramic head (BIOLOX delta, Smith and Nephew) articulation.

Research results

Higher wear rates were observed in CoPE compared to CoC bearing after 10-year follow-up with cup inclination as a predictive factor for wear for CoPE bearing, and no differences in complications, Harris hip score, and radiological findings.

Research conclusions

The potential benefit of CoC over CoPE at the 10-year follow-up is less wear with cup inclination as a predictive factor for wear, without differences in clinical or radiological outcomes.

Research perspectives

Further investigation of wear, revision, and complication rates between CoC and CoPE, especially in the long-term, should be done, to confirm potential benefits of CoC over CoPE and to prove if it can improve the longevity of THAs. In addition, long-term analysis needs to clarify if differences in outcomes, complication, and revision rates are cost-effective to the costs of both bearings.

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ORIGINAL ARTICLE

Observational Study

Hello, can you hear me? Orthopaedic clinic telephone consultations in the COVID-19 era- a patient and clinician perspective

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Abstract

BACKGROUND

The coronavirus disease 2019 (COVID-19) pandemic has resulted in seismic changes in healthcare delivery. As a result of this, hospital footfall required to be reduced due to increased risk of transmission of infection. To ensure patients can safely access healthcare, we introduced orthopaedic clinic telephone consultations in our busy district general hospital.

AIM

To investigate patients' and clinicians' perspective of telephone consultations during COVID-19, and whether this method of consultation could be a viable option in the post- pandemic future.

METHODS

This is a single centre, prospective study conducted in a busy National Health Service district general hospital. In May 2020, 100 non- consecutive adult patients were contacted by independent investigators within 48 h of their orthopaedic clinic telephone consultation to complete a telephone satisfaction questionnaire. The questions assessed satisfaction regarding various aspects of the consultation including overall satisfaction and willingness to use this approach long term. Satisfaction and perspective of 25 clinicians conducting these telephone consultations was also assessed *via* an online survey tool.

RESULTS

93% of patients were overall satisfied with telephone consultations and 79% were willing to continue this method of consultation post- pandemic. Patients found telephone consultations to reduce personal cost and inconvenience associated with attending a hospital appointment. 72% of clinicians reported overall

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Data sharing statement: Technical appendix, statistical code, and dataset available from the corresponding author at anuhya.vusirikala@nhs.net. Participants consent was not obtained but the presented data are anonymized and risk of identification is low.

STROBE statement: The authors have read the STROBE statement-checklist of items, and the manuscript were prepared and revised according to the STROBE Statement- checklist of items.

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satisfaction with this service and 80% agreed that telephone consultations should be used in the future. The majority found it less laborious in time and administration in comparison to face to face consultations. Patients and clinicians expressed their desire for video consultations as a method of further improving their experience with remote consultations.

CONCLUSION

Our study has shown that telephone consultations are a safe and rapid method of adaptation to the COVID-19 pandemic, achieving the aim of reducing hospital footfall. This method of consultation has resulted in immense clinician and patient satisfaction. Our findings suggest that this tool has benefits in post pandemic healthcare delivery. It has also highlighted that telephone consultations can act as a steppingstone to the introduction of the more complex platform of video consulting.

Key Words: COVID-19; Telephone consultation; Orthopaedic clinic; Patient satisfaction; Patient perspective; Clinician perspective

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Core Tip: Telephone consultations are a safe and rapid method of adaptation to the coronavirus disease 2019 pandemic, achieving the aim of reducing hospital footfall. This method of consultation has resulted in immense patient and clinician satisfaction, suggesting that this tool has benefits in the post pandemic healthcare delivery. Telephone consultations can also act as a steppingstone to the safe introduction of the more complex platform of video consulting.

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INTRODUCTION

Severe acute respiratory syndrome coronavirus disease 2019 (COVID-19) was declared as a pandemic on 11th March 2020 by the World Health Organization and has had a profound effect on trauma and orthopaedic services in the National Health Service (NHS). Public Health England reported the burden of coronavirus in England as 157074 Lab- confirmed cases with 37266 confirmed deaths as of June 15, 2020[1]. In response to the rapidly spreading infection, the UK public were placed in lockdown on March 23, 2020.

The NHS England and NHS Improvement released clinical guidelines in delivering remote consultations in secondary care during the coronavirus pandemic to reduce the transmission of disease[2]. The British Orthopaedic Association also supported a pragmatic approach in dealing with trauma and orthopaedic patients in these extraordinary circumstances advocating conservative management for a wide range of injuries that may have been considered for operative management weeks' before[3].

Trauma and Orthopaedic clinics are one of the busiest clinical environments with each clinician seeing 15-20 patients on average per clinic session. With the high volume and rapid turnover of patient attendance, running these clinics with appropriate social distancing to reduce spread of infection was deemed challenging. Therefore, our trauma and orthopaedic department set up telephone consultations as a way of rapidly adapting to the new guidance provided to reduce hospital footfall and ensuring to deliver high quality patient care.

In the United Kingdom, telephone consultations are not a new concept and are used for primary care triage and have shown to reduce face to face (F2F) consultations[4,5]. In the last decade, digital health technologies have developed that allow virtual medical consultations such as GP at Hand by Babylon Health that is currently trialled as a

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virtual GP practise in NHS Hammersmith and Fulham Clinical Commissioning Group[6]. There is a long-term plan for digital services within the NHS in the future[7].

Telemedicine is well established within orthopaedics worldwide, especially useful for clinical management in remote locations. An American hospital followed up their trauma patients remotely when discharged from a level 1 trauma centre with high levels of satisfaction[8]. In elective orthopaedics, telemedicine has been used for elective paediatrics in Australia for their rural population[9] and also in American paediatric fracture management[10]. Post-operative carpal tunnel care has been conducted using telemedicine with good satisfaction and financial savings[11]. One prospective study found no difference in satisfaction between F2F consultations and telemedicine[12]. In the United Kingdom, the virtual fracture clinic is a common form of telemedicine used in orthopaedics, but the pandemic meant that there needed to be a rapid shift to telephone consultations without a pre-existing United Kingdom model to follow.

There are proven positive models of telemedicine consultations, however particularly in orthopaedics, limitations include the inability to carry out a thorough clinical assessment by physically examining a patient. This can be frustrating for both patients and clinicians. The purpose of this study was to assess patients' and clinicians' perspective of telephone consultations during COVID-19, and whether this could be a viable option in the post pandemic future.

MATERIALS AND METHODS

Study population and data collection

This is a single centre, prospective study at a busy NHS district general hospital in the United Kingdom. Telephone clinics were rapidly implemented at the start of the pandemic. In May 2020, 100 non- consecutive adult patients were contacted after their orthopaedic clinic telephone consultation by independent investigators (orthopaedic clinic healthcare professionals) and completed a telephone satisfaction questionnaire (Supplementary material 1) within 48 h of the consultation. We contacted new and follow-up patients from fracture and elective clinics across all trauma and orthopaedic subspecialties to avoid selection bias. Inclusion and exclusion criteria are summarised in Table 1.

These clinics were consultant-led clinics, with additional specialty registrar and core surgical trainee support. To assess suitability for telephone consultations, each patient was screened by a clinician, by reviewing their emergency department notes, or previous clinic letters and imaging. Any patients that required a wound check, plaster cast care or physical examination were deemed unsuitable for a telephone consultation and a F2F appointment was made.

We assessed the satisfaction and perspective of clinicians conducting the telephone consultations *via* an online questionnaire tool (Supplementary material 1). All clinicians who conducted the telephone consultation were included and were consultant or specialty registrar level.

The questionnaires for both clinicians and patients were designed by the authors and used a Likert scale. The questions aimed to assess satisfaction regarding various aspects of the consultation including overall satisfaction and willingness to use this approach long term. We broke down the telephone consultation into 3 sections and analysed satisfaction with each: (1) Satisfaction with the explanation of patient condition/ injury; (2) Satisfaction with the outcome received from the consultation; and (3) Satisfaction with the answers received to patient questions during the consultation.

Statistical analysis

Cronbach's Alpha coefficient of internal consistency was used as a measure of reliability for the results from the Likert scale used for questions 2 to 6 of the patient satisfaction questionnaire. Analysis was performed on SPSS Statistics version 27.

Fisher's exact test was used to assess differences in the level of patient satisfaction for age, gender and diagnosis of upper/lower limb injuries. A statistically significant level of $P < 0.05$ was set. Statistical analysis was performed on GraphPad Prism version 8.3.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Adult patients aged ≥ 18 years of age	Patients aged < 18 yr of age
Received orthopaedic clinic telephone consultation	If other members of the family responded on patient's behalf
Satisfaction questionnaire completed within 48 h from telephone consultation	Unable to consent to complete satisfaction questionnaire
	Communication difficulties (verbal or auditory) as stated in patient clinical notes
	Cognitive impairment as stated in patient clinical notes
	If patients did not answer their telephone on two occasions to complete the satisfaction questionnaire

RESULTS

Telephone satisfaction questionnaires were carried out from May 5, 2020 to May 20, 2020, equating to 12 working days. 23 clinics were held during this time with a total of 262 patients reviewed. Of these, 125 patients (47.7%) had a telephone consultation, and 100 patients were surveyed giving us a capture rate of 80%.

This was compared with the same time period 1 year prior (May 5, 2019 to May 20, 2019) which equated to a total of 10 working days. 36 clinics were held during this time with a total of 617 patients reviewed F2F. There were no telephone consultations taking place within the department prior to the pandemic.

There were 49 males and 51 females, capturing a wide age demographic from 18 to 85+, with the largest cohort (29%) 45-54 years of age. There was a total of 100 injuries in 100 patients. 50% of these were upper limb injuries, 44% lower limb injuries, 1% spine and 5% did not have a diagnosis recorded on the questionnaire.

Patient perspective

90 out of the 100 patients were happy to be reviewed *via* telephone consultation. 93% of patients were overall satisfied with telephone consultations with 91% of patients satisfied with the explanation of their condition and answers received to all their questions during the consultation. 79% of the patients were willing to continue this method of consultation in the future. Table 2 is a detailed summary of the level of patient satisfaction with each question. The results of the Likert scale used (very satisfied, satisfied, neutral, dissatisfied and very dissatisfied) for questions 2 to 6 in the patient satisfaction questionnaire revealed satisfactory reliability as shown by Cronbach's alpha coefficient of internal consistency 0.763.

Patients had the opportunity to provide free text comments at the end of their questionnaires. Table 3 is a summary of quotations which highlight both positive and negative feedback on telephone consultations. Positive comments were broadly categorized into convenience and efficiency, avoidance of hospital attendance during COVID-19 and mannerisms of the doctors. Negative comments included lack of visual feedback, inability to review images and non-adherence to appointment times.

We found no statistically significant difference ($P < 0.05$) in the level of satisfaction between age groups, gender and diagnosis of upper or lower limb injuries (Table 4). There was also no statistically significant difference between willingness for telephone consultations during the current pandemic and willingness for telephone consultations in the future.

Clinician perspective

The level of satisfaction of all orthopaedic surgeons carrying out telephone consultations within the department (17 consultants and 8 specialty registrars) was assessed. 72% of clinicians reported overall satisfaction with the use of telephone consultations during the pandemic, with 80% agreeing to continue this method in the future. Figures 1 and 2 compare patient and clinician satisfaction with telephone consultations and their willingness to continue this method of consultation in the future.

Clinicians did not find telephone consultations overly laborious. 80% stated that it took the same amount of time or shorter than traditional face to face consultations and 84% felt telephone consultations required the same or less amount of preparation compared to F2F.

In regard to the effectiveness of telephone consultations, 68% reported them as less

Table 2 Summary of patient satisfaction levels (%)

Scale	Explanation of condition	Outcome of consultation	Answers received to all questions	Overall satisfaction	Willingness for future telephone consultations
Very satisfied	51	47	46	56	44
Satisfied	40	45	45	37	35
Neutral	6	6	4	2	10
Dissatisfied	3	2	3	4	3
Very dissatisfied	0	0	2	1	8

Table 3 Free text feedback from patients

Positives		Negatives	
Logistical advantages	A better way to avoid coming to hospital during COVID-19	Lack of visual feedback	More explanation of X-ray required as I could not see it
	Good and efficient way to receive results		Video conferencing would be an improvement *e.g.*, Skype/Zoom
	Great service to be seen at home		Prefer F2F to show doctor the deformity
	Telephone consultations made the process quicker than attending the hospital for an appointment	Consultation timings	Was not expecting telephone consultation, a pre-warning text message may have helped
Overall Satisfaction	Very satisfied - doctor really listened and able to ask questions		No specific time given, better to have one hour slots or "window"
	Very clear and precise	Patient confidence	Would prefer F2F for first appointment
	Doctor was very helpful		Prefer F2F for more support with condition
	Doctor very friendly		Needed to guess whether exercises were being done correctly
	Pleasant doctor		With elderly patients important to advise to have someone accompany them on the telephone call on loudspeaker

Table 4 *P* values for Fisher's exact test in level of satisfaction between age, gender and diagnosis of upper or lower limb injuries

***P* value (≤ 0.05)**				
		Age	**Gender**	**Diagnosis of upper or lower limb injuries**
Question 1	Willingness for telephone consultation in the current pandemic	0.31	0.32	> 0.99
Question 2	Explanation of condition	> 0.99	0.09	0.25
Question 3	Outcome of consultation	0.71	0.48	0.25
Question 4	Answers received to all questions	> 0.99	0.31	0.14
Question 5	Overall satisfaction	> 0.99	0.11	0.41
Question 6	Willingness for future telephone consultations	0.81	0.33	0.43

comprehensive a medium to F2F consultations. However, the process of explaining the diagnosis and management plan, with subsequent patient questioning fared better. 60% found it the same or easy to explain the diagnosis and management over the telephone and 76% were satisfied with opportunities for patient questions.

Clinicians were also given an opportunity to provide free text suggestions at the end of their questionnaires (Table 5). The overarching suggestions included the need for video consultations which would help with the process of virtual examination, show patients their imaging so as to improve the overall understanding of their condition and subsequent management plan. Additionally, a notable point from a spinal consultant which can be extrapolated across specialties. ("It has to be noted that the public are currently accepting phone consultation as the best available option. This

Table 5 Free text suggestions from clinicians

Suggestions
Lack of visual feedback
Visual consultations would be a great improvement and improve quality of consultation
Video software that will also allow sharing of clinicians' screen would be more informative as imaging can be shown
Workload
Dedicated administrator for telephone consultation preparation would be useful
Lack of examination
Difficult to examine patients. Often reliant on family or patient's own interpretation of examination
Could be limited to follow ups only
Difficult to build rapport or trust

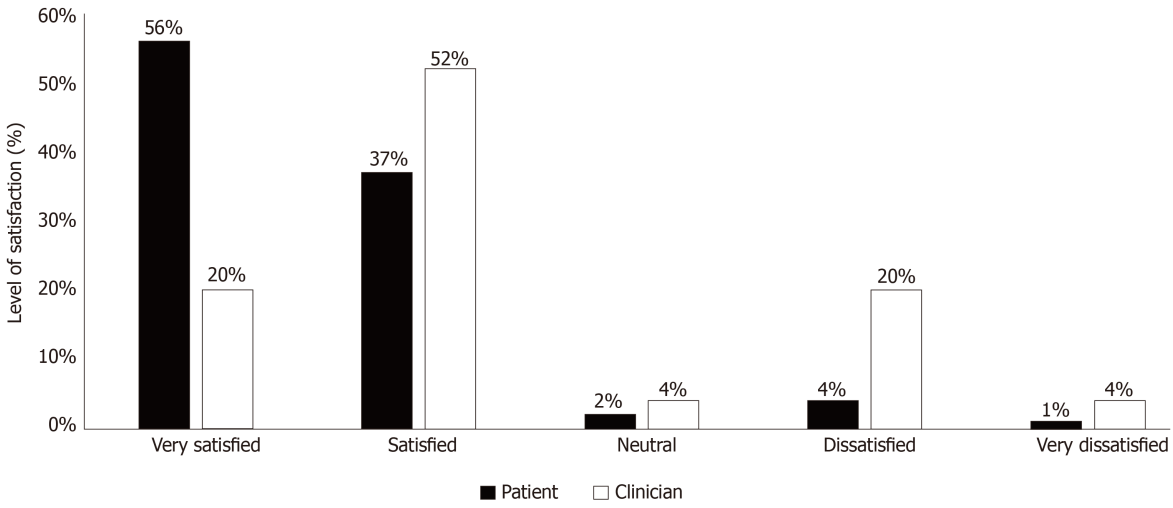


Figure 1 Compares patient and clinician overall satisfaction with telephone consultations.

view may change if it carries on for too long. In spine clinics many patients may find it difficult to be convinced that their cases are not suitable for surgical intervention without "hands on" clinic assessment").

DISCUSSION

This study investigated patient and clinician satisfaction with orthopaedic clinic telephone consultations. 93% of patients were overall satisfied with telephone consultations. Gilbert *et al*[13], recently published a quality improvement study which focused on the process involved in the implementation of virtual clinics in response to the COVID-19 pandemic. A secondary outcome from their study assessed patient satisfaction with telephone consultations using a single summative question, which resulted in a mean satisfaction score of 90 out of 100, which was similar to our study findings[13]. From our literature review, no previous United Kingdom based study assessed level of patient satisfaction with the various aspects involved in a telephone consultation. We divided the telephone consultation into 3 sections and analysed satisfaction with each: (1) satisfaction with the explanation of patient condition/injury; (2) satisfaction with the outcome received from the consultation; and (3) satisfaction with the answers received to patient questions during the consultation. Greater than 90% of patients were satisfied with each of the three areas within the consultation.

79% of patients agreed to future follow ups using this form of telemedicine. Patients felt they were able to obtain the required information from the comfort of their own home, avoiding exposure/spread of COVID-19 and reducing personal cost and

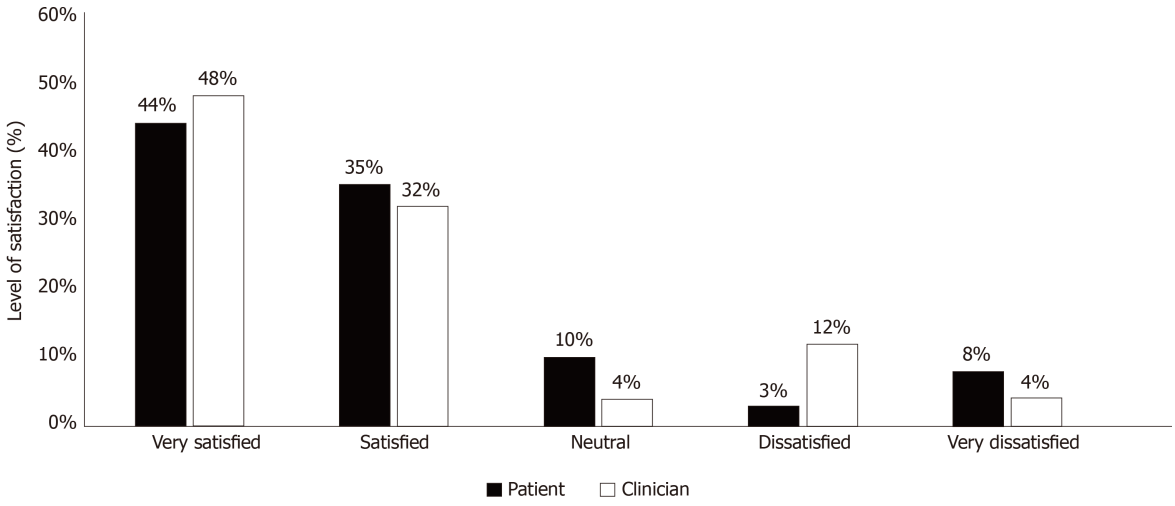


Figure 2 Compares patient and clinician willingness to continue this method of consultation in the post pandemic era.

inconvenience associated with attending a hospital appointment. In 2014, a study comparing web- based follow up to face to face consultations following joint arthroplasty found that patients in the web-based group incurred lower associated costs[14].

Remote consultations theoretically may be more cost-effective for the NHS. In our department, the average cost per appointment for all trauma and orthopaedic clinics (fracture and elective) are £206 for first time appointment and £165 for follow up appointments[15]. 80% of clinicians in our study found that telephone consultations took the same amount of time or less compared to F2F consultations. Unfortunately, at present, we are unable to comment on the cost-effectiveness of this new telephone consultation service because costing returns are carried out every 3 months. The main cost for an outpatient department is staff payroll. During the pandemic, staff base has not changed because many clinicians were deployed to carry out COVID related duties. Therefore, the base staff cost remained static. Marsh *et al*[16] in 2014, carried out an economic evaluation of web-based ($98 per patient) compared with in- person follow up ($162 per patient) and showed that service costs were significantly lower in the web-based group[16]. In the near future, if clinicians are back to their normal duties and telephone consultations continue then the average cost per appointment may reduce because more appointments will be carried out per clinician *via* the telephone and fewer staff may be required to review the same number of patients. This aspect of remote consultations is worthwhile to investigate to ascertain its costing benefits as the NHS is constantly under pressure to provide a cost- effective service but at the same time respond to the rising needs and demands of the population.

72% of clinicians were overall satisfied with telephone consultations. 80% agreed with continuing this method of consultation after the pandemic. Our findings were in contrast with a recent study published in Madrid where only 37.5% of clinicians agreed with continuing telephone consultations in the future because they felt this method of consultation may have limitations for first clinical appointments[17]. Even though our study did not differentiate between first and follow up appointments we had high satisfaction rates to continue this form of telemedicine consultation in the post pandemic era. We recognise that there is a need for further research in identifying the challenges related to first and follow up telephone consultation appointments.

Patients in our study highlighted the importance of clinician punctuality with appointment times. As a new method of consultation, there were wide variations in adherence to appointment times with some clinics being carried out earlier or later than scheduled. In most cases, patients were called by the administrative team in regard to their new date and time of appointment. To ensure future adherence to appointment times and better communication with patients in regard to changes to their appointments a patient text messaging service could be implemented[18].

We are aware that telephone consultations have limitations from both patient and clinician perspectives. They may not be suitable for all conditions but can be a useful tool to stratify risk for each patient. It will help identify those who can be provided advice over the telephone and signposted to resources online. But it will also help identify a clinical situation that necessitates a face to face consultation.

Both patients and clinicians report a lack of visual feedback with telephone consultations. Patients were frustrated that they were unable to visually demonstrate areas of pain or deformity and they could not confirm whether the rehabilitation exercises given to them were being carried out correctly. They also expressed wishes to be able to view their imaging to have a better understanding of their condition. These concerns were also echoed by the clinicians in our study. 68% felt that telephone consultations were not as comprehensive as face to face consultations and this may be due to the inability to examine the patient, review images with patients to explain their conditions and subsequent management in more detail.

Telephone consultations require a very different skill set in comparison to F2F consultations. Clinicians carrying out telephone consultations may adequately assess patients but inadequately reassure them due to the lack of visual cues. This may mean that clinicians may need to quickly adapt specific skills for effective telephone consultations.

In our study, due to the rapid implementation of telephone consultations, clinicians did not receive any formal training, yet, 91% of patients were satisfied with the explanation of their condition and 91% found that all their questions were appropriately answered during the consultation. A number of articles have been published providing guidance on effective telephone consultations, which have also stressed the importance of accurate documentation and stated that clinic letters that are normally sent to GPs should also be sent to patients to reinforce what was discussed and avoid misunderstandings[19,20]. It would be beneficial to review these articles by those carrying out this form of consultation.

Both patients and clinicians in our study suggested the need for video consultations to further improve their experience with remote consultations. A systematic review by Gilbert *et al*[21] in 2018, showed that patients preferred video consultations to telephone because they had visual feedback from their clinician. This increased their confidence with the information received during the consultation thus increasing their adherence to the medical advice given. They also found video consultations useful for those who have difficulty with verbal descriptions, and it was a good medium to receive rehabilitation as their exercises can be shown to them[21].

Video consultations can help overcome many challenges associated with telephone consultations. But it is important to recognise that implementation of a video consulting platform is a complex process which is resource heavy and requires the involvement of both national and local strategic leads[22]. The execution of a video consultation service requires a team of experts to install new software, adequately train clinicians and administration staff, set up videoconferencing programmes and equipment in patient's homes and be available for any technical issues that may occur. This process is difficult, requiring a lot of planning and if implemented at speed, service failure may occur.

During our study period in the midst of the pandemic, the number of trauma and orthopaedic clinics held was 1.5 times less (23 clinics *vs* 36 clinics) and the volume of patients reviewed in these clinics was approximately twice as less compared to the same time period in 2019 (262 patients *vs* 617 patients). The reduction in the volume of patients in our clinics is likely a reflection of a change in people's behaviour in response to COVID-19 and the nationwide lockdown. It would be important to assess whether satisfaction levels of telephone consultations amongst our patients remain high when we revert back to running clinics at the pre- pandemic capacity as there would be increased time pressure amongst the clinicians.

Due to the unforeseen circumstances of the COVID-19 pandemic, we had to introduce a safe alternative to F2F consultations quickly. Telephone consultations were easy to implement rapidly in a department with no pre-existing remote consultation model. They were found to be an acceptable method of communication irrespective of age, gender and diagnosis. A similar finding was found in a study carried out at 5 GP practises in South Yorkshire in the United Kingdom[23].

Telephone consultations act as a steppingstone to the introduction of the more complex platform of video consulting. Our department is currently in the process of introducing a video consultation service in a planned and safe manner to ensure a more effective and interactive healthcare service delivery to our patients in the post pandemic future.

Strengths and limitations

This study has several strengths. Firstly, it has shown that telephone consultations have been well received by both clinicians and patients across all ages. Patients had high satisfaction with the opportunity to discuss their condition and have had all their questions answered to an acceptable standard. Telephone consultations have shown to

be a safe and quick adaptation to the pandemic, achieving the aim of reducing hospital footfall. This study has also identified the need to further improve remote consultations by introducing video consultation services.

The rapid implementation of this method of remote consultation service within our department has resulted in this study having limitations. We were unable to put our patient and clinician questionnaires through the validation process, but we used a validated Likert scale[24] to assess satisfaction to reduce measurement error and we demonstrated satisfactory reliability of the results obtained as shown by Cronbach's alpha coefficient. Due to the time critical nature of this study, we were unable to compare satisfaction levels of telephone consultations with F2F consultations and we did not differentiate between first time and follow up clinic appointments, even though overall satisfaction amongst our patients was high. Our clinicians did not receive any specific training prior to carrying out telephone consultations but patients were satisfied with the information provided and subsequent management as a result of these consultations.

CONCLUSION

We are aware that telemedicine is not a novel approach in trauma and orthopaedics, but our study is a snapshot of patient and clinician satisfaction with the rapid implementation of telephone consultations in the midst of a pandemic. We understand that more detailed work needs to be completed to analyse the effectiveness and acceptability of telephone consultations as a form of safe healthcare delivery in the long term. But for now, it has proved an effective alternative in providing high quality healthcare during these unprecedented times.

ARTICLE HIGHLIGHTS

Research background

The coronavirus disease 2019 (COVID-19) pandemic resulted in seismic changes in healthcare delivery. Due to the high transmission risk of this infection, hospital footfall required to be reduced rapidly. Trauma and Orthopaedic clinics are one of the busiest clinical environments with high volume and rapid turnover of patient attendance. Running these clinics with appropriate social distancing to reduce the spread of infection was deemed challenging. To ensure patients can continue to safely access healthcare, we introduced orthopaedic clinic telephone consultations within our department in a busy district general hospital in England.

Research motivation

Telephone consultations were rapidly implemented within a department with no pre-existing remote consultation model in order to adapt to the COVID-19 pandemic. But in order to ensure patients received high quality care it was vital to obtain patient and clinician satisfaction with this method of remote consultation.

Research objectives

This study aimed to investigate patient and clinician perspective of telephone consultations during the COVID-19 pandemic, and whether this method of remote consultation could be a viable option in the post- pandemic future.

Research methods

This is a single centre, prospective study conducted in a busy National Health Service district general hospital. 100 non- consecutive adult patients were contacted within 48 h of their telephone consultation to complete a patient satisfaction questionnaire which assessed satisfaction with various aspects of the consultation including willingness to continue this method of consultation in the long term. Clinician perspective and satisfaction with conducting these telephone consultations was also sought.

Research results

93% of patients were overall satisfied with telephone consultations and 79% were willing to continue this method of consultation post- pandemic. Patients found telephone consultations to reduce personal cost and inconvenience associated with

attending a hospital appointment. 72% of clinicians reported overall satisfaction with this service and 80% agreed that telephone consultations should be used in the future. The majority found it less laborious in time and administration in comparison to face to face consultations. There was no statistically significant difference ($P < 0.05$) in the level of satisfaction between age groups, gender and diagnosis of upper or lower limb injuries. There was also no statistically significant difference between willingness for telephone consultations during the current pandemic and willingness for telephone consultations in the future.

Research conclusions

This study has proved that telephone consultations are an effective alternative that can be implemented rapidly to provide high quality healthcare during these unprecedented times. This method of consultation has resulted in immense clinician and patient satisfaction. Our findings suggest that this tool has benefits in the post-pandemic healthcare delivery.

Research perspectives

Although the number of patients and clinicians included was relatively small, this study provided a snapshot of patient and clinician satisfaction with the rapid implementation of telephone consultations, achieving the aim of reducing hospital footfall in response to the COVID-19 pandemic. It also highlighted the need to further improve patient experience of remote consultations with the safe and planned introduction of the more complex platform of video consultation services.

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META-ANALYSIS

Thirty-day mortality of patients with hip fracture during COVID-19 pandemic and pre-pandemic periods: A systematic review and meta-analysis

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Abstract

BACKGROUND

Timely intervention in hip fracture is essential to decrease the risks of perioperative morbidity and mortality. However, limitations of the resources, risk of disease transmission and redirection of medical attention to a more severe infective health problem during coronavirus disease 2019 (COVID-19) pandemic period have affected the quality of care even in a surgical emergency.

AIM

To compare the 30-d mortality rate and complications of hip fracture patients treated during COVID-19 pandemic and pre-pandemic times.

METHODS

The search of electronic databases on 1st August 2020 revealed 45 studies related to

mortality of hip fracture during the COVID-19 pandemic and pre-pandemic times. After careful screening, eight studies were eligible for quantitative and qualitative analysis of data.

RESULTS

The pooled data of eight studies (n = 1586) revealed no significant difference in 30-d mortality rate between the hip fracture patients treated during the pandemic and pre-pandemic periods [9.63% *vs* 6.33%; odds ratio (OR), 0.62; 95%CI, 0.33, 1.17; P = 0.14]. Even the 30-d mortality rate was not different between COVID-19 non-infected patients who were treated during the pandemic time, and all hip fracture patients treated during the pre-pandemic period (OR, 1.03; 95%CI, 0.61, 1.75; P = 0.91). A significant difference in mortality rate was observed between COVID-19 positive and COVID-19 negative patients (OR, 6.99; 95%CI, 3.45, 14.16; P < 0.00001). There was no difference in the duration of hospital stay (OR, -1.52, 95%CI, -3.85, 0.81; P = 0.20), overall complications (OR, 1.62; P = 0.15) and incidence of pulmonary complications (OR, 1.46; P = 0.38) in these two-time frames. Nevertheless, the preoperative morbidity was more severe, and there was less use of general anesthesia during the pandemic time.

CONCLUSION

There was no difference in 30-d mortality rate between hip fracture patients treated during the pandemic and pre-pandemic periods. However, the mortality risk was higher in COVID-19 positive patients compared to COVID-19 negative patients. There was no difference in time to surgery, complications and hospitalization time between these two time periods.

Key Words: Hip fracture; Femur neck fracture; Trochanter fracture; Mortality; Pandemic; COVID-19

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Core Tip: Timely intervention in hip fracture is essential to decrease the risks of perioperative morbidity and mortality. However, limitations of the resources, risk of disease transmission and redirection of medical attention to a more severe infective health problem during coronavirus disease 2019 (COVID-19) pandemic period have affected the quality of care even in a surgical emergency. This meta-analysis and systematic review compared the 30-d mortality rate and complications of hip fracture patients treated during COVID-19 pandemic and pre-pandemic times. The findings of the meta-analysis revealed whether the delay in surgery for hip fracture patients affected the outcome or not.

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INTRODUCTION

The health care delivery systems of most of the nations have been affected by the outbreak of coronavirus disease 2019 (COVID-19)[1]. In order to prevent the spread of the disease and to provide essential care to infected patients, many elective surgical procedures were postponed. Even emergency surgical procedures also got delayed because of the lack of human resources and operation theatre. Optimization of the patients before surgery also took a long time. Hip fracture is a surgical emergency. Despite mandatory lockdown during COVID-19 pandemic, hip fracture incidence has remained unaltered[2-5].

The most worrisome problem is that majority of these patients are elderly

Checklist.

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individuals with numerous comorbidities[6-10]. Management of such fractures in these vulnerable immunocompromised patients during COVID-19 pandemic time is a big challenge[11-29]. With the best possible care, the incidence of 30-d mortality in hip fracture has been reported between 9%-13% in the literature[14,15]. Those who survive usually have a poor functional outcome and quality of life[14,15]. During the pandemic time, when the entire medical services have focused on COVID-19 treatment, delaying of hip fracture surgery might cause increased complication and perioperative mortality. Although it was believed that COVID-19 infected patients with hip fracture might have more incidences of pulmonary complications, pneumonia and perioperative mortality, few studies reported similar mortality rates in both COVID-19 infected and non-infected patients[18,24]. The observational study by the Spanish HIP-COVID group reported a 10% incidence of in-hospital death among fracture patients who were negative for COVID-19[16]. Similar observations were reported by Kayani *et al*[18], who had a similar incidence of mortality in hip fracture among the COVID-19 infected and non-infected patients. Several cohort studies reported no significant difference in delay in surgery, treatment methods, complications, and 30-d mortality in the hip fracture between the pandemic and the pre-pandemic period[24,27]. Because of the small cohort of hip fracture patients during the pandemic time, such conclusion should be interpreted judiciously as it seems there is no ill-effect of COVID-19 infection *per se* on the patient and probably there is no severe consequence of slight treatment delay. Therefore, this systematic review and meta-analysis were designed to look for: (1) The 30-d mortality in hip fracture during the pandemic time *vs* the pre-pandemic time; and (2) the 30-d mortality rate between COVID-19 negative hip fracture patients and pre-pandemic era hip fracture patients. Similarly, delay in surgery, the length of hospital stay, and overall complication in the hip fracture patients in these two-time frames will be compared. We hypothesized that the 30-d mortality rate in hip fracture patients treated during the pandemic time is more than the pre-pandemic time.

MATERIALS AND METHODS

The recommendations of Preferred Reporting Items for Systematic Reviews and Meta-analyses was followed for reporting this systematic review/meta-analysis[30] (Figure 1). It was registered in PROSPERO (Regd. No.: CRD42020203581) before the data extraction and analysis.

Literature search strategy

A literature search was performed on 1st of August 2020 by two authors (Tripathy SK and Varghese P) to identify studies that have evaluated hip fractures during COVID-19 pandemic and pre-pandemic period. PubMed/Medline, Embase and the Cochrane Central Register of Controlled Trials (CENTRAL) databases were searched using the keywords "COVID", "COVID-19", "pandemic", "hip fracture", "trochanter fracture" and "femur neck fracture". The Boolean operators "and" or "or" was used with different combinations of the keywords. The search was not time-bound but limited to the English literature and human being. The exact search strategy of Medline database has been provided in Table 1. The title and abstract of the retrieved articles were assessed carefully for possible inclusion in this review. The references of the relevant articles and reviews were also searched to get more studies related to the topic. The opinion of a third author (Panda BB) was sought when there was any disagreement/discrepancy between the two authors (Figure 1).

Study selection

Any randomized controlled trial or observational prospective/retrospective study that mentioned the 30-d mortality rate of hip fracture patients (age > 18 years) in both pandemic and pre-pandemic periods were selected for this systematic review/meta-analysis. Studies that reported on open fracture or pathological fracture were not considered. If any study reported the 30-d mortality of hip fracture only for the pandemic period, it was excluded.

The hip fracture in this review included both intracapsular (neck femur fracture) and extracapsular fracture (intertrochanteric and subtrochanteric fracture). Patients who had clinical symptoms/signs of COVID-19 with reverse transcriptase-polymerase chain reaction positive nose or throat swab for severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) were considered as COVID-19 infected (COVID-19 +). Asymptomatic patient with negative throat and nose swabs were considered as

Table 1 Search strategy of Medline database

Keyword	Search strategy	No. of hits
COVID, COVID-19, Pandemic, Hip fracture, Trochanter fracture, Femur neck fracture	(("COVID"[All Fields] AND ("humans"[MeSH Terms] AND "medline"[Filter] AND "english"[Language]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) OR (("severe acute respiratory syndrome coronavirus 2"[Supplementary Concept] OR "severe acute respiratory syndrome coronavirus 2"[All Fields] OR "ncov"[All Fields] OR "2019 ncov"[All Fields] OR "covid 19"[All Fields] OR "sars cov 2"[All Fields] OR (("coronavirus"[All Fields] OR "cov"[All Fields]) AND 2019/11/01:3000/12/31[Date - Publication])) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND "english"[Language]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) OR (("pandemic s"[All Fields] OR "pandemically"[All Fields] OR "pandemicity"[All Fields] OR "pandemics"[MeSH Terms] OR "pandemics"[All Fields] OR "pandemic"[All Fields]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language]))) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language]) AND ((((("hip fractures"[MeSH Terms] OR ("hip"[All Fields] AND "fractures"[All Fields]) OR "hip fractures"[All Fields] OR ("hip"[All Fields] AND "fracture"[All Fields]) OR "hip fracture"[All Fields]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) OR (("femur"[MeSH Terms] OR "femur"[All Fields] OR "trochanter"[All Fields] OR "trochanters"[All Fields]) AND ("fractur"[All Fields] OR "fractural"[All Fields] OR "fracture s"[All Fields] OR "fractures, bone"[MeSH Terms] OR ("fractures"[All Fields] AND "bone"[All Fields]) OR "bone fractures"[All Fields] OR "fracture"[All Fields] OR "fractured"[All Fields] OR "fractures"[All Fields] OR "fracturing"[All Fields]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND "english"[Language]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language])) OR (("femoral neck fractures"[MeSH Terms] OR ("femoral"[All Fields] AND "neck"[All Fields] AND "fractures"[All Fields]) OR "femoral neck fractures"[All Fields] OR ("femur"[All Fields] AND "neck"[All Fields] AND "fracture"[All Fields]) OR "femur neck fracture"[All Fields]) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language]))) AND ("humans"[MeSH Terms] AND "medline"[Filter] AND 1000/01/01:2020/08/01[Date - Publication] AND "english"[Language]))	24

COVID-19: Coronavirus disease 2019.

COVID-19 non-infected (COVID-19 −). In cases where there was strong clinical suspicion, it was labelled as COVID suspect even though the swab tests were negative. For data analysis, all suspect patients were included in the COVID-19 + group. Similarly, patients who were not tested, and there was no clinical suspicion, were categorized as COVID-19 −.

Data extraction

The data from the included studies were extracted by two authors (Tripathy SK and Varghese P). The details (author, year of publication, study design, demographic properties, surgical details, follow-up, 30-d mortality, and complications) were filled up in a Microsoft Excel sheet for subsequent analysis. The opinion of a third author (Panda BB) was sought in case of disagreement.

The primary objective of this study was to look for the 30-d mortality of hip fracture in COVID-19 pandemic period and pre-pandemic period. The secondary objective was to compare 30-d mortality of hip fracture among COVID-19 negative patients and pre-pandemic hip fracture patients. The duration of hospital stay, complications and preoperative morbidity among the hip fracture patients during these two-time frames were compared.

Methodological quality and risk of bias assessment

The methodological quality and risk of bias of the observational studies were evaluated by two authors (Tripathy SK and Varghese P) using the Newcastle-Ottawa scale (NOS)[31]. The NOS evaluates a study in three domains (8 items with maximum score 9): Study group selection, comparability of the groups, and determining the outcome of interest for case-control and cohort studies[31]. A score of more than six was considered as a high-quality study. In case of disagreement between the authors, the opinion of a third author (Naik MA) was sought.

Statistical analysis

The Review Manager (RevMan) V.5.3 was used for data analysis[32]. Few studies provided the median value and interquartile range (IQR). The mean and SD value was calculated from the median and IQR as per the recommendation of Luo *et al*[33] and Wan *et al*[34]. The study, providing the previous two years of data (pre-pandemic) were evaluated jointly, and the mean (SD) was calculated using the RevMan calculator. Whenever feasible, data were pooled for analysis. For the comparison of binary data, the odds ratio (OR) and a 95% confidence interval (CI) were calculated. Similarly, the mean difference (MD) and 95%CI were estimated for continuous data. The *P* value of <

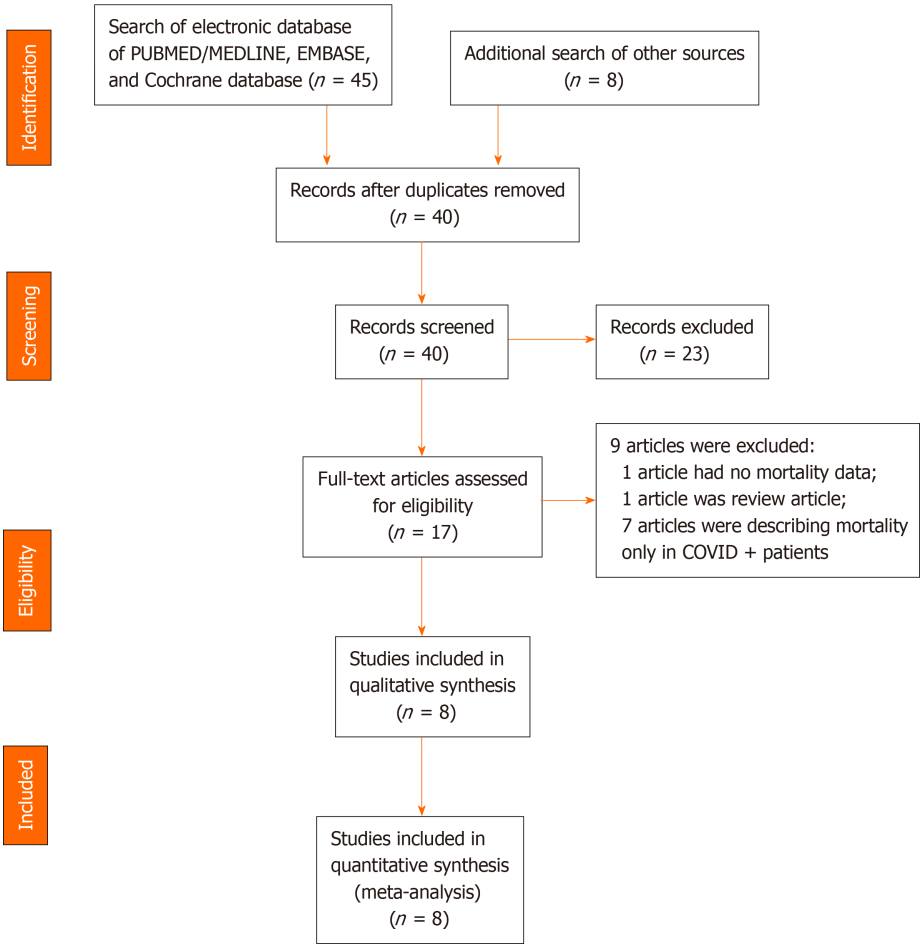


Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-analyses flow diagram showing methods of study recruitment.
COVID-19 +: Coronavirus disease 2019 infected.

0.05 was considered as statistically significant. The heterogeneity among the cohort studies was evaluated by Cochrane's Q (χ^2 P < 0.10) and quantified by I^2-Higgins test. The I^2 value of 25%, 50% and 75% were considered as low, moderate, and high grade of heterogeneity, respectively[35,36]. The random-effects model was applied to address the high grade of heterogeneity (I^2 > 50%)[37].

RESULTS

Selection of the study, quality assessment, and patient demographics

A total of 45 studies were retrieved after the search of electronic databases using the keywords; of which, eight studies were eligible for review after screening[9,19,20,27-29,38,39] (Figure 1). There were three prospective studies and five retrospective comparative studies. The inclusion and exclusion criteria were well defined in all studies. Assessment of quality of the studies using NOS revealed a low risk of bias in one study and moderate risk of bias in the remaining seven studies (Table 2). The data of 901 hip fracture patients who were treated during the pre-pandemic period (similar time in 2018 and 2019) was evaluated, and it was compared to 685 hip fracture patients treated during the pandemic period. There were 77 COVID-19 + patients and 608 COVID-19 − patients (Table 2). The mean/median age of the patients in all studies was above 75 years during both pre-pandemic and pandemic periods. The female patients had more incidences of hip fracture during both the time periods. The study by Macey *et al*[9] had age- and sex-matched hip fracture patient cohort from the pre-pandemic time. The body mass index and domicile status during both time periods have been provided in Table 2.

Table 2 Demographic properties, fracture type and surgical techniques in hip fractured patients treated during coronavirus disease 2019 and pre-coronavirus disease 2019 times (2020)

Study/country		Macey *et al*[9]/United Kingdom	Malik-Tabassum *et al*[38] /United Kingdom	Segarra *et al*[27] /Spain	Thakrar *et al*[19]/United Kingdom	Egol *et al*[20]/United States	Williams *et al*[28] /United Kingdom	Slullitel *et al*[39] /Argentina	Karayiannis *et al*[29] /United Kingdom
Study design		Retrospective study with prospective data collection	Retrospective observational studies	Longitudinal prospective cohort study	Prospective cohort study	Prospective cohort study	Retrospective observational study	Retrospective case-control study	Retrospective case-control study, multicentre
Sample size/ duration	Pre-COVID	76 (20th March 2019-24th April 2019)	174 [90 (23rd March 2018-11th May 2018); 84 (23rd March 2019-11th May 2019)]	70 (1st February 2019-15th April 2019)	99 [51 (15th March 2018-15th April 2018); 48 (15th March 2019-15th April 2019)]	115 (1st February 2019-15th April 2019)	15 (January 2020)	86 (1st December 2019-19th March 2020)	266 (18th March 2019-27th April 2019)
	COVID	76 (20th March 2020-24th April 2020)	68 (23rd March 2020-11th May 2020)	68 (1st February 2020-15th April 2020)	43 (15th March 2020-15th April 2020)	138 (1st February 2020-15th April 2020)	15 (March 2020)	74 (20th March 2020-31st May 2020)	203 (18th March 2020-27th April 2020)
	COVID +	10 (13.16%)	1 (1%)	2 (2.94%)	12 (27.9%)	31 (22.5%)	0	0	21 (10.35%)
	COVID –	66 (86.84%)	67 (99%)	66 (97%)	31 (72.1%)	107 (77.5%)	15 (100%)	74 (100%)	182 (89.65%)
NOS		8 (moderate risk)	8 (moderate risk)	7 (moderate risk)	8 (moderate risk)	9 (low risk)	7 (moderate risk)	8 (moderate risk)	7 (moderate risk)
Age (yr)	Pre-COVID	Median: 83 (IQR, 74-88)	2018: 82.9 ± 9.9; 2019: 83.8 ± 7.7	84 ± 7.8	2018: 81.6 ± 12.3; 2019: 84.0 ± 8.7	81.5 ± 10.7	86.6	Median: 86 (IQR, 78-90)	78.0 ± 12.8
	COVID	Median: 83 (73-87)	84.3 ± 8.9	82.4 ± 7.4	81.6 ± 11.3	83.0 ± 10.2	81.5	Median: 86 (IQR, 80–91)	81.3 ± 9.7
Sex, M:F	Pre-COVID	58:18	37:137	18:52	25:74	34:81	2:13	19:67	79:187
	COVID	58:18	25:43	21:47	23:20	50:88	3:12	9:65	65:138
BMI (kg/m^2)	Pre-COVID	NM	NM	NM	NM	24.6 ± 5.2	NM	Median 24 (IQR, 21.7–26.6)	NM
	COVID	NM	NM	NM	NM	24.4 ± 5.1	NM	Median 24.5 (IQR, 22.3-27.3)	NM
Domicile status	Pre-COVID	Home: 58 (79.45%); residential care: 10 (13.69%); hospital: 5 (6.84%)	Nursing care: 14 (8.04%); own home/sheltered housing: 135 (77.58%); residential care: 25 (14.36%)	NM	NM	NM	NM	NM	NM
	COVID	Home: 61 (80.2%); residential care: 11 (14.47%); hospital: 4 (5.26%)	Nursing care: 8 (11.8%); own home/sheltered housing: 52 (76.5%); residential care: 8 (11.8%)	NM	NM	NM	NM	NM	NM

ASA grade	Pre-COVID	1:2 (2.6%); 2:18 (24%); 3:42 (56%); 4:13 (17.3%); 5:0 (0%)	1:4 (2.29%); 2:53 (30.4%); 3:98 (56.3%); 4:19 (10.9%)	1:0; 2:22 (31.4%); 3:48 (68.6%); 4:0	NM	NM	NM	1 and 2: 22 (25.6%); 3 and 4: 64 (74.4%)	1 and 2: 66 (25.3%); 3, 4 and 5: 195 (74.7%)
	COVID	1:2 (2.6%); 2:12 (15.7%); 3:51 (67%); 4:9 (11.8%); 5:2 (2.6%);	1:0 (0.0%); 2:17 (25.0%); 3:47 (69.1%); 4:4 (5.9%);	1:0; 2: 29 (42.7%); 3:37 (54.4%); 4:2 (2.9%)	NM	NM	NM	1 and 2: 12 (16.2%); 3 and 4: 62 (84%)	1 and 2: 35 (17.2%); 3, 4 and 5: 168 (82.8%)
Anesthesia	Pre-COVID	GA: 51 (69.8%); SA: 22 (30.1%)	NM	NM	NM	GA: 78 (70.3%); SA: 33 (29.7%)	NM	NM	GA: 76 (29.1%); SA/nerve block: 185 (70.9%)
	COVID	GA: 36 (50%); SA: 36 (50%)	NM	NM	NM	GA: 82 (61.2%); SA: 52 (38.8%)	NM	NM	GA: 37 (18.2%); SA/nerve block: 166 (81.8%)
Time to surgery (h)	Pre-COVID	Median: 20 (IQR, 16-25); [1]mean: 20.35 + 6.80	2018: 26.5 ± 18.7; 2019: 28.2 ± 51.7	36 ± 38.4	NM	33.6 ± 19.2	21.8 (range, 8-48)	Median: 16.5 (IQR, 9-30); [1]mean 18.61 ± 15.83	< 24 h: 56 (21.4%); 24-48 h: 85 (32.6%); > 48 h: 120 (46.0%)
	COVID	Median: 23 (IQR, 18-30); [1]mean: 23.7 ± 9.06	21.8 ± 12.1	43.2 ± 31.2	51.2	33.6 ± 36	35.8 (range, 8.5-79)	Median: 24 (IQR, 24-48); [1]mean: 32.46 ± 18.14	< 24 h: 78 (38.4%); 24-48 h: 92 (45.3%); > 48 h: 33 (16.3%)
Fracture type	Pre-COVID	FN: 45 (59.2%); IT: 31 (40.7%)	FN: 101 (58.0%); IT: 66 (37.9%); ST: 7 (4.02%)	NM	NM	FN: 43 (37.4%); IT: 69 (60.0%); ST: 3 (2.6%)	NM	IT: 45 (52.33%); FN: 41 (47.67%)	FN: 266
	COVID	FN: 51 (67.1%); IT: 25 (32.8%)	FN: 44 (64.7%); IT: 21 (30.8%); ST: 3(4.41%)	NM	NM	FN: 71 (51.4%); IT: 60 (43.5%); ST: 7 (5.1%)	NM	FN: 33 (44.59%); IT: 41 (55.41%)	FN: 203
Surgical techniques	Pre-COVID	Nonoperative: 3 (3.9%); DHS: 26 (34.2%); IMN: 9 (11.8%); Hemi A: 31 (40.7%); THA: 7 (9.2%); CRPP: 0 (0%)	THA: 12 (6.8%); Hemi A: 77 (44.2%); CCS: 4 (2.29%); DHS: 48 (27.5%); IMN: 31 (17.8%); Nonoperative: 2 (1.14%)	Operative: 67 (95.7%); nonoperative: 3 (4.3%)	NM	IMN: 61 (54.9%); Hemi A: 22 (19.8%); THA: 10 (9.0%); DHS: 10 (9.0%); CRPP: 8 (7.2%); nonoperative: 4 (3.5%)	All operative (15)	CS: 11 (12.8%); Hemi A: 14 (16.3%); THA: 19 (22.1%); Girdlestone: 1 (1.1%); IMN: 41 (47.7%); nonoperative: 0	Hemi A: 115 (44.1%); DHS: 68 (26%); IMN: 43 (16.5%); THA: 35 (13.4%); conservative: 5 (1.9%)
	COVID	Nonoperative: 3 (3.9%); CRPP: 1 (1.31%); DHS: 14 (18.4%); IMN: 13 (17.1%); Hemi A: 42 (55.2%); THA: 3 (3.9%)	Nonoperative: 2 (2.94%); CCS: 3 (4.41%); DHS: 12 (17.64%); IMN: 11 (16.17%); Hemi A: 39 (57.35%); THA: 1 (1.47%)	Operative: 64 (94.1%); nonoperative: 4 (5.9%)	DHS: -7 (16.27%); CS: 3 (6.9%); Hemi A: 15 (34.8%); IMN: 13 (30.2%); THA: 1 (2.3%); Rev THA: 4 (9.3%)	IMN: 64 (46.3%); Hemi A: 42 (31.3%); THA: 6 (4.5%); DHS: 7 (5.2%); CRPP: 15 (11.2%); nonoperative: 4 (2.9%)	Operative:14; 1 patient expired before surgery	CS: 2 (2.75%); Hemi A: 20 (27%); THA: 10 (13.5%); Girdlestone: 0; IMN: 41 (55.4%); nonoperative: 1 (1.35%)	Hemi A:113 (55.7); DHS: 47 (23.1%); IMN: 36 (17.7%); THA: 7 (3.4%); conservative: 0

[1]Indicates that the mean has been calculated from the median value and interquartile range/range. NOS: Newcastle-Ottawa scale; M: Male; F: Female; ASA: American Society of Anesthesiologists Classification; COVID: Coronavirus disease 2019; IQR: Interquartile range; NM: Not mentioned; GA: General anesthesia; SA: Spinal anesthesia; FN: Femoral neck fracture; IT: Intertrochanteric fracture; DHS: Dynamic hip screw; IMN: Intramedullary nail; Hemi A: Hemiarthroplasty; THA: Total hip arthroplasty; CRPP: Closed reduction percutaneous pinning; ST: Subtrochanteric fracture; CS: Cannulated screw; CCS: Cannulated compression screw; Rev THA: Revision total hip Arthroplasty.

Preoperative morbidity, time to surgery and type of anesthesia

The preoperative morbidity status of the patients in both pandemic and pre-pandemic periods were compared using the American Society of Anesthesiologists (ASA) classification. Pooled analysis of five studies (n = 1159) revealed significantly increased number of severely morbid (ASA grade > 3) hip fracture patients who were treated during the pandemic period (OR, 1.43; 95%CI, 1.08, 1.89; P = 0.01)[9,27,29,38,39]. Egol *et al*[20] (2020) did not observe a significant difference in preoperative morbidity using the

Charlson Co-morbidity index between 2020 hip fracture cohort and 2019 hip fracture cohort.

After pooling of the data from five studies[9,20,27,38,39], it was observed that there was no difference in time to surgery following the injury (MD, 6.57; 95%CI, −0.25, 13.39; P = 0.06). The high grade of heterogeneity (I^2 = 88%) among the studies was addressed by the random effect model (Figure 2).

Only three studies (n = 874) had provided details about the type anesthesia (regional *vs* general anesthesia) used during surgery[9,20,29]. There was significantly less use of general anesthesia during the pandemic period (37.17% *vs* 44.86%; OR, 0.57; 95%CI, 0.42, 0.77; P = 0.0003) (Figure 2).

Mortality, length of hospital stay, complications

Pooled analysis of 30-d mortality from the eight studies (n = 1586) revealed a significantly increased death among hip fracture patients during the pandemic time (9.63% *vs* 6.33%; OR, 0.62; 95%CI, 0.33, 1.17; P = 0.14) (Table 3, Figure 3)[9,19,20,27-29,38,39]. There was no difference in 30-d mortality rate between COVID-19 negative patients who were treated during the pandemic time and all hip fractured patients treated during the pre-pandemic period (6.44% *vs* 5.74%; OR, 1.03; 95%CI, 0.61, 1.75; P = 0.91)[9,19,20,29,38]. However, a significant difference in mortality rate was observed between COVID-19 + and COVID-19 − patients with an OR of 6.99 (29.33% *vs* 5.73%; 95%CI, 3.45, 14.16; P < 0.00001) (Table 3, Figure 3)[9,19,20,29,38].

There was no difference in length of hospital stay among hip fracture patients treated during pandemic and pre-pandemic periods (OR, −1.52; 95%CI, −3.85, 0.81; P = 0.20)[9,20,38,39]. Similarly, major complications (17.98% *vs* 10.64%; OR, 1.62; P = 0.15) and the incidence of pulmonary complications (9.09% *vs* 6.78%; OR, 1.46; P = 0.38) among the hip fracture patients during these two-time frames were not different (Table 3, Figure 4)[9,20,38,39].

DISCUSSION

The main finding of the meta-analysis was that there was no difference in 30-d mortality in hip fracture patients between the pandemic and pre-pandemic periods. Even, the mortality risk was not different among the COVID-19 − patients of pandemic time and all hip fracture patients of pre-pandemic time. However, significantly increased 30-d mortality rate was observed in COVID-19 + patients. There was less use of general anesthesia during the pandemic period and patients with hip fracture treated during this time were severely morbid.

Early intervention in hip fracture reduces morbidity and mortality. A shorter hospital stay and minimal respiratory complications have been reported if the hip fracture surgery is stabilized within 24 h of admission[40,41]. During the pandemic, there was difficulty in treating these patients within the stipulated time[42,43]. Accordingly, a high incidence of 30-d mortality was expected, but the pooled analysis of the studies did not observe a significant difference in mortality among the hip fracture patients treated during the pandemic and pre-pandemic periods. However, the difference in the mortality was limited to the COVID-19 + patients as the analysis failed to notice a difference between COVID-19 − patients and pre-pandemic hip fracture patients. The respiratory compromise because of the COVID-19 infection in the perioperative period acts as a second hit phenomenon as the cytokines are already flared up by the traumatic hip fracture[18,20,24]. Prolonged recumbency, poor immunity and multiple comorbidities in the elderly individuals are also detrimental[43,44]. Nevertheless, asymptomatic COVID-19 − patients are not different from the typical elderly cohort. Accordingly, segregations of the hip fracture patients into the COVID-19 positive site or the negative site will minimize cross-infection, and it will help in early delivery of medical care to the non-infected patients[24,27]. The patient may be temporarily held up in a transition zone till COVID-19 test result is available.

The importance of patient segregation into two different sites has been evaluated by Chui *et al*[24] and Segarra *et al*[27]. Chui and his associate did not notice a significant difference in mortality between COVID-19 infected and non-infected patients as they could operate 61% of hip fractured patients within 36 h[24]. It has been reported that the respiratory symptoms have improved after femur fracture stabilization[23]. Catellani *et al*[23] advocated that the patients could be mobilized after surgery with general patient comfort, and there was an improvement in physiological ventilation. Few studies reported a slight delay (48-72 h) in providing care to the COVID-19 infected compared to non-infected patients because of the need for medical optimization of

Table 3 Mortality and complications in hip-fractured patients treated during coronavirus disease 2019 and pre-coronavirus disease 2019 times (2020)

Study/country		Macey *et al*[9] /United Kingdom	Malik-Tabassum *et al*[38] /United Kingdom	Segarra *et al*[27] /Spain	Thakrar *et al*[19] /United Kingdom	Egol *et al*[20] /United States	Williams *et al*[28] /United Kingdom	Slullitel *et al*[39] /Argentina	Karayiannis *et al*[29]/United Kingdom
30-d mortality	Pre-COVID	10 (13%)	12 (6.89%)	9 (12.9%)	6 (6.06%)	3 (2.7%)	1 (6.6%)	0	16 (6%)
	COVID	11 (14%)	6 (8.8%)	8 (11.8%)	7 (16.3%)	17 (12.3%)	2 (13.3%)	8 (10.8%)	7 (3.4%)
	COVID +	2 (20%)	1 (100%)	NM	4 (33%)	9 (52.9%) + 2 (14.3%); Total-11 (35.4%)	NM	NM	4 (57.14%)
	COVID −	9 (13.6%)	5 (7.4%)	NM	3 (9.6%)	6 (5.6%)	NM	NM	3 (42.86%)
In-patient mortality	Pre-COVID	NM	11 (6.32%)	NM	NM	1 (0.9%)	NM	NM	NM
	COVID	NM	4 (5.9%)	NM	NM	8 (5.8%)	NM	NM	NM
Length of hospital stay (d)	Pre-COVID	Median: 12 (range, 7-26); [1]mean: 14.25 ± 3.17	2018: 15.8 ± 11.4; 2019: 16.3 ± 11.4	NM	NM	5.8 ± 3.7	11.7	Median: 5 (IQR, 4-7); [1]mean: 5.35 ± 2.26	NM
	COVID	Median: 11.5 (range, 6-22); [1]mean: 12.75 ± 2.67	8.6 ± 4.6	NM	NM	5.8 ± 3.8	6.2	Median: 6 (IQR, 5-8); [1]mean: 6.35 ± 2.26	NM
Major complications	Pre-COVID	11 (14.5%)	17 (9.7%)	NM	NM	10 (8.7%)	NM	10 (11.6%)	NM
	COVID	17 (22.4%)	3 (4.5%)	NM	NM	28 (20.3%)	NM	16 (21.6%)	NM
Pulmonary complications/pneumonia/respiratory infection	Pre-COVID	8 (10.95%)	NM	NM	NM	NM	2 (13.3%)	2 (2.32%)	NM
	COVID	15 (20.54%)	NM	NM	NM	NM	0	0	NM
Deep vein thrombus/pulmonary embolism	Pre-COVID	1 (1.36%)	2 (1.14%)	NM	NM	NM	NM	0	NM
	COVID	0	1 (1.47%)	NM	NM	NM	NM	5 (6.75%)	NM

[1]Indicates that the mean has been calculated from the median value and interquartile range/range. COVID: Coronavirus disease 2019; COVID +: Coronavirus disease 2019 infected; COVID −: Coronavirus disease 2019 non-infected; NM: Not mentioned; IQR: Interquartile range.

these patients[18,20,24]. Whether this delay was responsible for increased mortality in the COVID-19 positive patients is unknown. Overall, there was no significant delay in time to surgery during this epidemic. It indicates the promptness of medical health care professionals in understanding the timely delivery of emergency care. Despite understanding the risk of disease transmission, the orthopedic surgeons have given priority to the patients' health and safety. In order to evaluate the impact of COVID-19 infection in the hip fracture patients, the mortality rate of these patients was compared with the national average mortality rate of the corresponding country that has been related to COVID-19 infection. The national statistics bulletin report of United Kingdom stated that 13.7% of all deaths that occurred in England (45439 deaths) between January and July 2020 was COVID-19 related and it was 10.8% in Wales (2274 deaths) for the same period. The age-standardized mortality rates for deaths due to COVID-19, per 100000 persons, in England for March, April and May 2020 (for the period under consideration in this meta-analysis), were 33.8, 623.2 and 244.8 respectively[45,46]. It is quite apparent that the death rate of hip fracture patients with the

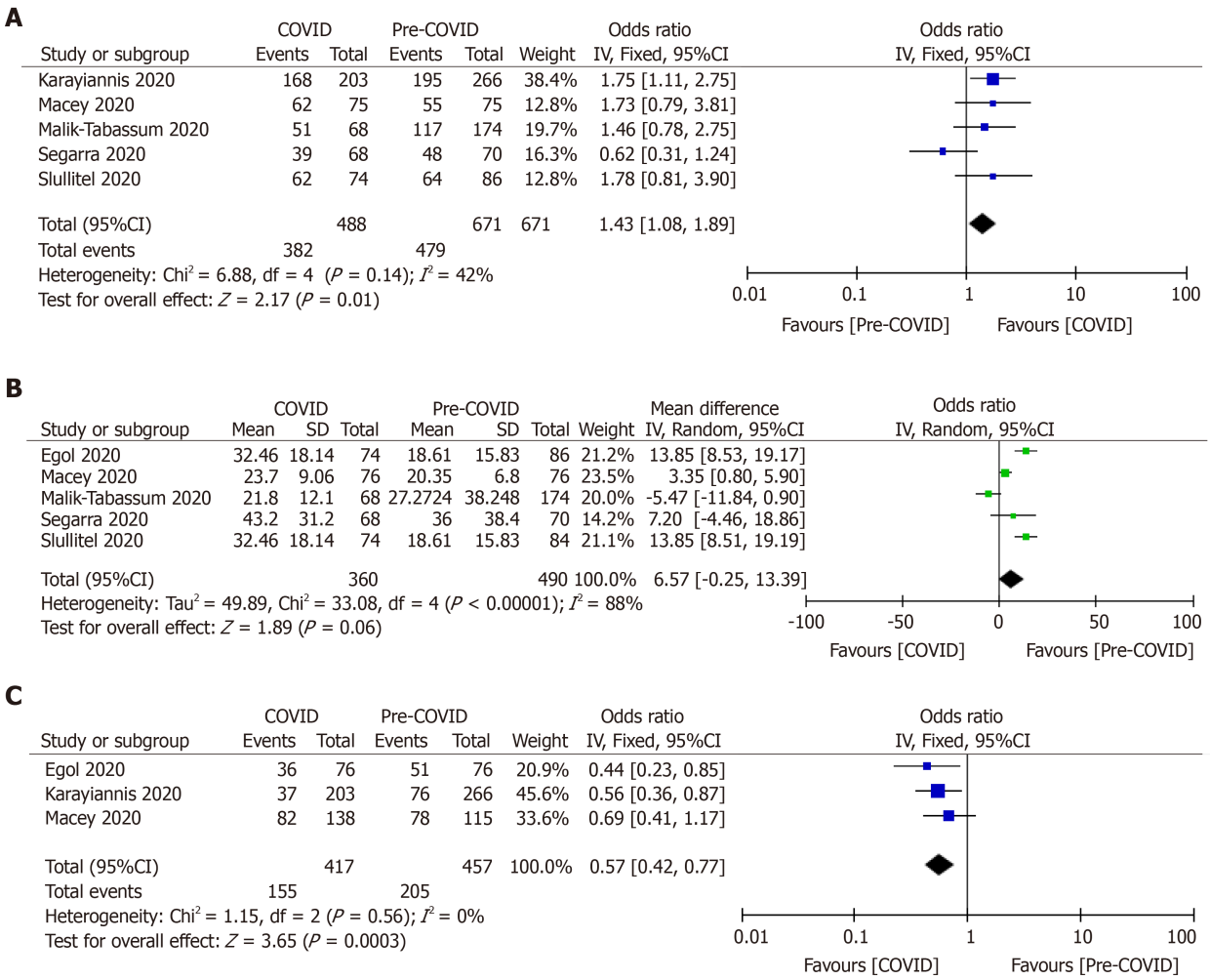


Figure 2 Forest-plot diagram showing preoperative morbidity, time to surgery and use of general anesthesia among hip-fractured patients during the pandemic and pre-pandemic periods. A: Preoperative morbidity (American Society of Anesthesiologists grade); B: Time to surgery; C: General anesthesia. COVID: Coronavirus disease 2019.

SARS-CoV-2 infection is very high (29.33% as per the current meta-analysis) compared to the national average death due to COVID-19 infection (13.7%, five studies are from the United Kingdom).

Previous literature revealed that COVID-19 patients with multiple associated comorbidities had an increased risk of death when admitted to the critical care service[18,20,24,45]. Deng *et al*[47] compared the clinical characteristics, blood parameters and morbidity of 109 COVID-19 + patients who died during hospitalization with 116 recovered patients. The risk of mortality increased from 41.5% to 72.5% ($P < 0.01$) in patients with associated pre-existing comorbidities[45]. The national statistics bulletin of England and Wales reported 50335 deaths involving COVID-19 between March and June 2020. About 91% of these patients had at least one pre-existing disease, and the remaining 9% had no associated comorbidity[45,46]. The average number of comorbidities for COVID-19 related death was 2.1 for patients of 0-69 years of age, and it was 2.3 for patients aged > 70 years[45,46]. Center for Disease Control and Prevention reported that 8 out of 10 COVID-19 deaths in the United States have been in the older individuals of age > 65 years[48]. Poor immunological status and multiple chronic pre-existing disease conditions such as hypertension, diabetes mellitus and chronic cardiorespiratory disorders were attributed for this high death rate[18,20,24,47,48]. The preoperative comorbidities, as reported using ASA grading system, showed increased premorbid patients during the pandemic time in this review. These patients had probably poor systemic baseline function and their physiological capability to endure the surgical procedure was limited[18,20,24]. The concomitant use of angiotensin-converting enzyme (ACE) inhibitors that up-regulates the expression of ACE-2 receptors hypothetically might have increased the virus-cell binding and thereby increased the virus transmission into the cell in the COVID-19 patients. The resultant

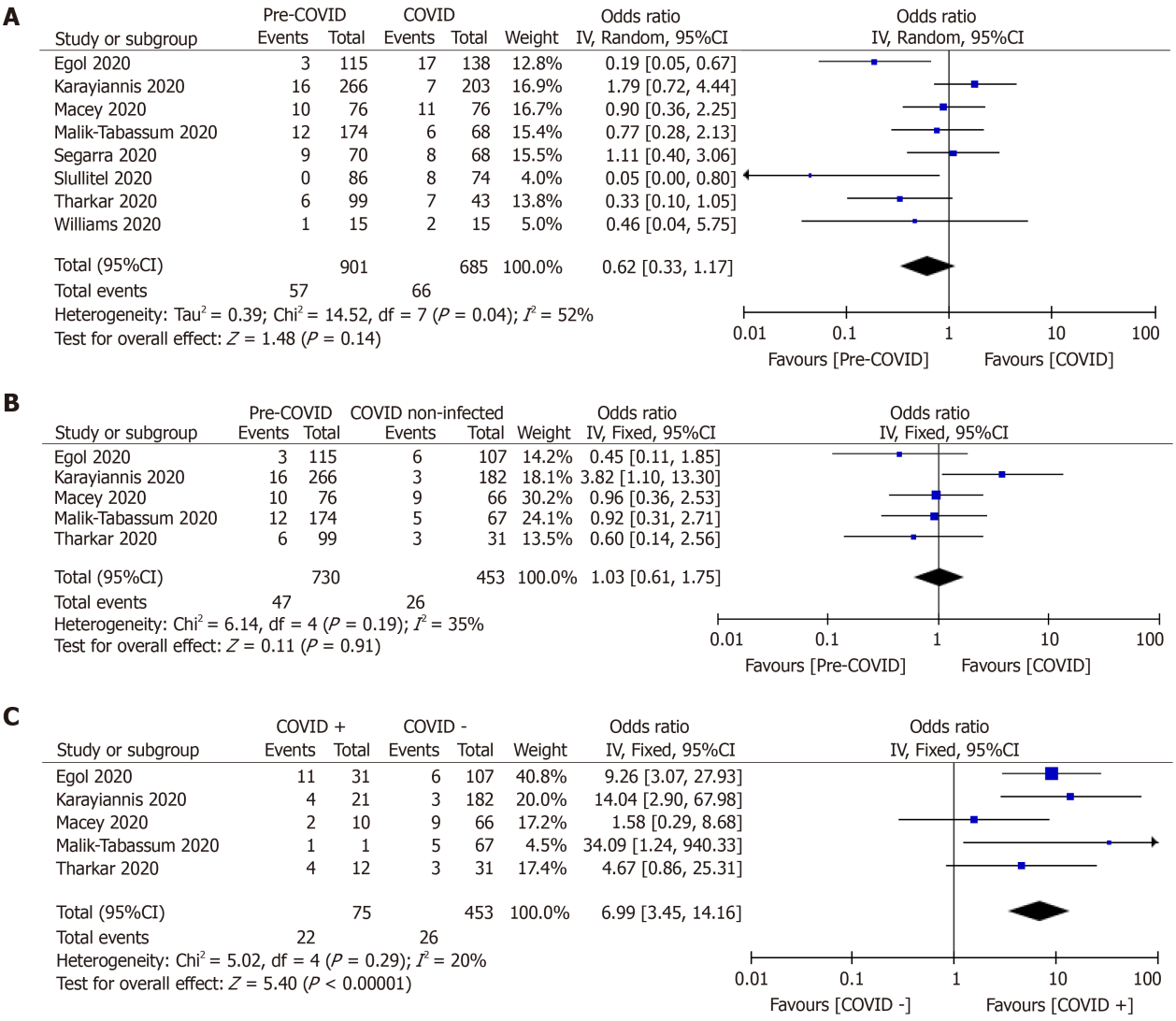


Figure 3 Forest-plot diagram showing 30-d mortality among hip-fractured patients in these two time frames. A: Thirty-day mortality rate in hip-fractured patient during pre-coronavirus disease 2019 (COVID-19) and COVID-19 periods; B: Thirty-day mortality rate in hip-fractured patient managed during pre-COVID-19 time *vs* COVID-19 non-infected hip-fractured patients managed during COVID-19 time; C: Thirty-day mortality rate in COVID-19 infected and COVID-19 non-infected hip-fractured patients managed during COVID-19 pandemic time. COVID: Coronavirus disease 2019; COVID +: COVID-19 infected; COVID –: COVID-19 non-infected.

increased viral load explains the increased rate of mortality[49]. Regarding the increased numbers of premorbid patients during the pandemic time, we believe that most of these old patients had not performed their regular check-up for chronic illnesses because of lockdown, and restriction of medical service for regular care. Despite the poorly controlled chronic disease conditions among all hip fracture patients, the increased mortality was selectively observed in the COVID-19 + patients.

General anesthesia increases the risk of aerosol exposure among health care workers and hence increases the chance of infection in them[16,18,20]. Besides, the general anesthesia also augments an inflammatory reaction within the lung parenchyma of the patients. Consequently, there was significantly less use of general anesthesia during the pandemic time compared to the pre-pandemic period. Despite the recommendation of regional anesthesia, Kayani *et al*[18] noted no difference in types of anesthesia between COVID-19 infected and non-infected patients in their series.

Many researchers reported increased early mortality, increased length of hospital stay, a higher incidence of major complications, and a greater incidence of respiratory complications in COVID-19 infected compared to the non-infected patients[16,18,20]. However, this meta-analysis did not perceive a significant difference in major complications, length of hospital stay and respiratory complication among hip fracture patients managed during the pandemic and pre-pandemic times. Probably the higher proportion of COVID-19 − patients (89%) in the evaluation controlled the result or,

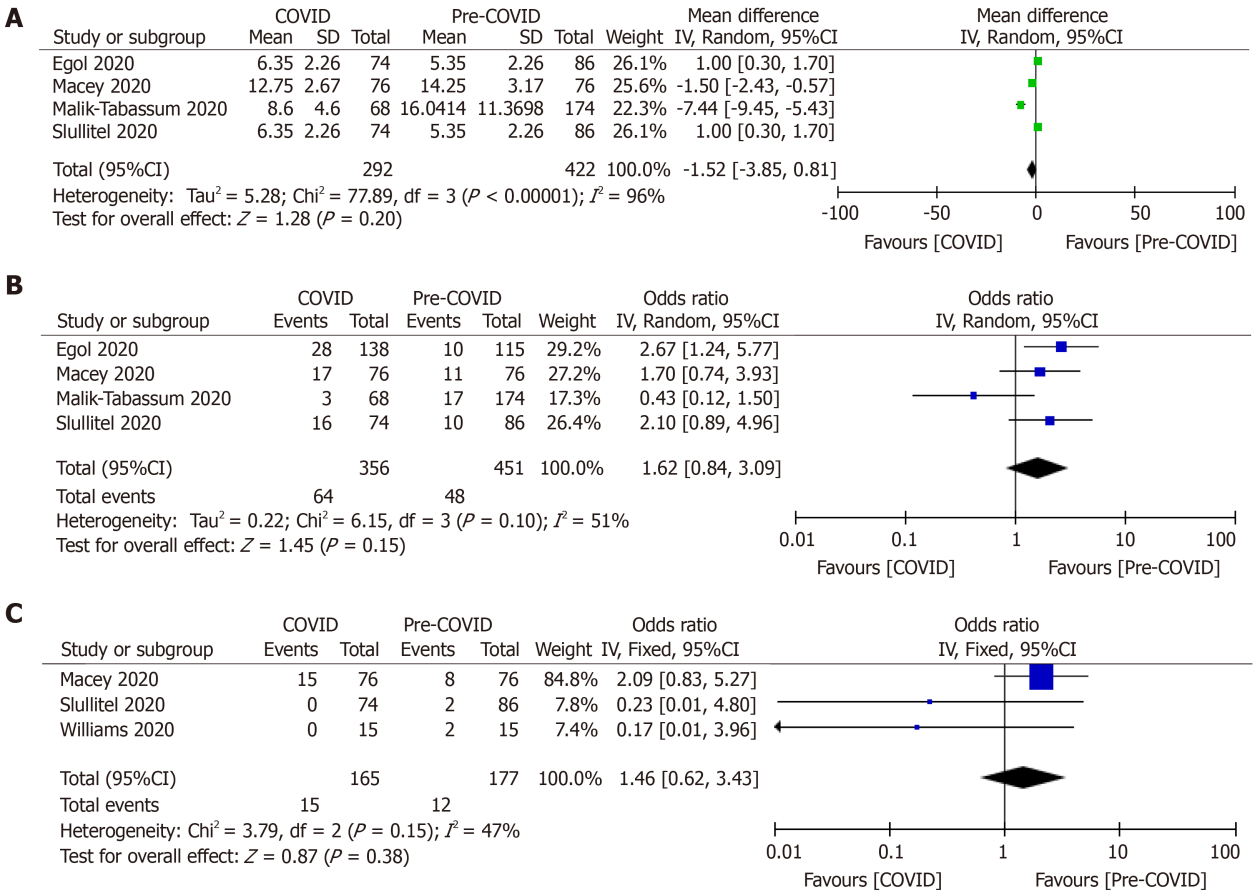


Figure 4 Forest-plot diagram showing length of hospital stay, overall complications, and respiratory complications among hip-fractured patients during the pandemic and pre-pandemic periods. A: Length of hospital stay; B: Major complications; C: Pulmonary complications. COVID: Coronavirus disease 2019.

most of the COVID-19 + patients were probably asymptomatic or minimally affected by the infection.

There were certain limitations to this meta-analysis. All these studies are from developed nations where the health care sectors are streamlined and protocol-based; hence it cannot be generalized to all nations. Only 30-d follow up has been studied in this review, so the outcome after one month is unknown. The retrospective study design and small patient cohort are also the main limitations for this meta-analysis. Despite that, this meta-analysis is first of its kind comparing the mortality and morbidity among hip fracture patients during the pandemic and pre-pandemic periods.

CONCLUSION

To conclude, there was no difference in 30-d mortality rate among hip fracture patients treated during the COVID-19 pandemic and pre-pandemic periods. The mortality risk was significantly high among COVID-19 + patients as compared to non-infected patients. With the development of better drug and better treatment protocol of COVID-19, the interpretation of this meta-analysis might change.

ARTICLE HIGHLIGHTS

Research background

During the coronavirus disease 2019 (COVID-19) pandemic time, the attention of the whole of the medical fraternity was diverted to the infective viral severe acute respiratory syndrome coronavirus-2 infection. There was a huge risk of infection

among the medical staffs and patients coming to the hospital for other serious problems. Limitations of the operation theatre and medical staff were other hurdles in tackling life-threatening emergency surgeries. Although the mandatory lockdown policy might have reduced the incidence of the road traffic accident, the incidence of fragility fractures remained unaltered. Hip fracture is a surgical emergency and needs urgent surgical intervention to reduce morbidity and mortality. The impact of the COVID-19 infection on hip fracture management has been studied by a few researchers.

Research motivation

This systematic review and meta-analysis were designed to look for the impact of COVID-19 infection on hip fracture management and outcome.

Research objectives

The objectives of this meta-analysis were to compare the 30-d mortality and complications of hip fracture management during COVID-19 pandemic time and pre-pandemic time.

Research methods

The search of electronic databases was performed to retrieve studies related to hip fracture management during COVID-19 pandemic and pre-pandemic times. A total of 45 studies were identified, of which eight studies were eligible for quantitative and qualitative analysis of data.

Research results

The pooled data of eight studies with 1586 patients showed no significant difference in 30-d mortality rate between the hip fracture patients treated during the pandemic and pre-pandemic periods [9.63% *vs* 6.33%; odds ratio (OR), 0.62; 95%CI, 0.33, 1.17; P = 0.14]. Even there was no difference in the 30-d mortality rate between COVID-19 − patients managed during the pandemic time *vs* all hip fracture patients managed during the pre-pandemic period (OR, 1.03; 95%CI, 0.61, 1.75; P = 0.91). A significant difference in mortality rate was observed between COVID-19 positive and COVID-19 negative patients (OR, 6.99; 95%CI, 3.45, 14.16; P < 0.00001). There was no difference in the duration of hospital stay (OR, −1.52; 95%CI, −3.85, 0.81; P = 0.20), overall complications (OR, 1.62; P = 0.15) and pulmonary complications (OR, 1.46; P = 0.38) in these two-time frames. Nevertheless, the preoperative morbidity was more severe, and there was less use of general anesthesia during the pandemic time.

Research conclusions

There was no difference in 30-d mortality rate between hip fracture patients treated during the pandemic and pre-pandemic periods. However, the mortality risk was higher in COVID-19 positive patients compared to COVID-19 negative patients. There was no difference in time to surgery, complications and hospitalization time between these two time periods.

Research perspectives

This meta-analysis showed that the COVID-19 infected patients with a hip fracture had a higher mortality rate, but the non-infected patients received the same level of care and they had similar mortality to that of hip fracture patient managed during the pre-pandemic period. The orthopedic trauma surgeons have learnt the ways to tackle the orthopedic emergency during the epidemic time.

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CASE REPORT

Hallux rigidus treated with adipose-derived mesenchymal stem cells: A case report

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Abstract

BACKGROUND

First metatarsophalangeal joint arthritis (FMTPA), also known as hallux rigidus, is the most frequent degenerative disease of the foot. Diagnosis is made through both clinical and radiological evaluation. Regenerative medicine showed promising results in the treatment of early osteoarthritis. The aim of the present study was to report the results of a case of FMTPA treated with the injection of autologous adipose-derived mesenchymal stem cells.

CASE SUMMARY

A gentleman of 50 years of age presented with a painful hallux rigidus grade 2 resistant to any previous conservative treatment (including nonsteroidal anti-inflammatory drugs and hyaluronic acid injections). An injection of autologous adipose-derived mesenchymal stem cells into the first metatarsophalangeal joint was performed. No adverse events were reported, and both function and pain scales improved after 9 mo of follow-up.

CONCLUSION

The FMTP joint injection of mesenchymal stem cells improved symptoms and function in our patient with FMTPA at 9 mo of follow-up.

Key Words: First metatarsophalangeal joint arthritis; Hallux rigidus; Stem cells; Regenerative medicine; Early osteoarthritis; Adipose derived-mesenchymal stem cells; Case report

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Checklist (2016), and the manuscript was prepared and revised according to the CARE Checklist (2016).

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Core Tip: Recently, the use of intra-articular injections of stem cells has been proposed as a promising treatment in early osteoarthritis. In particular, autologous adipose-derived stem cells (aASCs) have attracted considerable attention, considering the easy access to fat tissue and the absence of adverse events registered. These characteristics make aASCs one of the most promising cell types used in regenerative medicine. Hallux rigidus, is the most frequent degenerative disease of the foot. Patients with hallux rigidus present a history of pain, gait discomfort, articular effusion, and a reduction in range of motion. Different types of treatment are available, both conservative and operative, but both are often ineffective. aASCs might overcome the gap between these two methods of treatment.

Citation: Braile A, Toro G, De Cicco A, Cecere AB, Zanchini F, Schiavone Panni A. Hallux rigidus treated with adipose-derived mesenchymal stem cells: A case report. *World J Orthop* 2021; 12(1): 51-55
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INTRODUCTION

First metatarsophalangeal joint arthritis (FMTPA), also known as hallux rigidus, is the most frequent degenerative arthritis disease of the foot[1]. Depending on the severity of the disease, the symptoms in the case of FMTPA are pain, gait discomfort, articular effusion, and a reduction in range of motion. The diagnosis is generally completed by observing the typical findings of osteoarthritis (OA) revealed by X-rays. Coughlin and Shurnas proposed a classification for FMTPA based on both clinical features and imaging[2] (Table 1).

Different types of treatments had been proposed, both conservative [*i.e.*, orthosis, nonsteroidal anti-inflammatory drugs, hyaluronic acid (HA) injections] and operative (*i.e.*, cheilectomy, arthroplasty, arthrodesis)[3].

Recently, emerging evidence has supported the use of autologous adipose-derived mesenchymal stem cells (aAMSCs) for the treatment of early OA[4-7].

The aim of the present study was to report the clinical results of a case of FMTPA treated with the injection of aAMSCs.

CASE PRESENTATION

Chief complaints

A gentleman of 50 years of age presented with a painful FMTP joint in the left foot.

History of present illness

His symptoms were resistant to both nonsteroidal anti-inflammatory drugs and HA injections.

History of past illness

The patient was already scheduled for an aAMSCs injection due to right knee Kellgren-Lawrence grade 2 OA.

Personal and family history

Personal and family history were negative for foot pathologies.

Physical examination

The clinical examination showed a positive axial grind test and joint pain, exacerbated by the dorsiflexion that impaired the patient's ability to walk.

Laboratory examinations

Laboratory tests did not support the final diagnosis.

Table 1 Coughlin and Shurnas clinical and radiographic classification of hallux rigidus

Grade	Dorsiflexion	Radiographs	Clinical
0	40°-60°	Normal	No pain, stiffness with loss of motion
1	30°-40°	Dorsal osteophytes; Minimal narrowing; Minimal flattening	Mild pain and stiffness pain with maximum dorsiflexion/plantar flexion
2	10°-30°	Global osteophytes, mild/moderate narrowing	Moderate to severe pain and stiffness relatively constant, pain near extreme ROM
3	< 10°	Cystic changes	Nearly constant pain and stiffness, no midrange pain
4	< 10°	Same as grade 3	Grade 3 + midrange pain

Imaging examinations

Antero-posterior and latero-lateral standard X-rays showed FMTPA stage 2.

FINAL DIAGNOSIS

FMTPA stage 2 was diagnosed.

TREATMENT

The patient was already scheduled for an aAMSCs injection due to right knee Kellgren-Lawrence grade 2 OA, and therefore a similar injection was proposed to treat the hallux rigidus.

Concentrated aAMSCs were obtained from the abdomen, filtered as previously reported[5], and then injected into the FMTP joint after its distraction (Figure 1).

Protected weight bearing was prescribed during the first week after the procedure.

OUTCOME AND FOLLOW-UP

The patient was followed up at regular intervals. The clinical evaluation was completed using both the American Orthopedic Foot and Ankle Society (AOFAS) for hallux metatarsophalangeal-interphalangeal scale and the Visual Analog Scale (VAS).

No adverse effects were reported, excluding a transient pain in the FMPT joint in the first week after surgery. During the entire follow-up, an improvement in both VAS and AOFAS scales were observed (Table 2), leading to a final VAS scale of 0 and an AOFAS of 78 at 9 mo of follow-up.

DISCUSSION

Recently, the use of regenerative medicine principles has been proposed for various applications in both trauma and orthopedics, and especially for the treatment of early OA[4-6,8-11]. While conventional therapies for early OA (*i.e.* physical therapy, glucosamine and chondroitin sulfate supplementation) showed little benefits, regenerative medicine was demonstrated to be a promising option, due to the paracrine, anti-apoptotic, anti-inflammatory, and anti-aging effects of stem cells[12,13].

aAMSCs showed some theoretical advantages over other sources of stem cells. In fact, aAMSCs are easy to harvest, because of the wide availability of adipose tissue, and their sampling is generally associated with minimal discomfort, considering that it can be carried out using local anesthesia[7]. Moreover, aAMSCs demonstrated a high capacity for proliferation and fibroblastic differentiation[14]. Hass *et al*[15] showed that adipose tissue should be considered a primary source of cells for regenerative medicine as it contains 500 times more MSCs than the same volume of bone marrow.

Emerging literature has underlined the role of aAMSCs in the treatment of early OA. Schiavone Panni *et al*[5] conducted a study of 52 patients with early knee OA treated with arthroscopic debridement and aAMSCs injection, and showed improvement in both function and pain at an average of 15.3 mo of follow-up.

Table 2 American Orthopedic Foot and Ankle Society and Visual Analog Scale scores

	Pre-operatively	6-mo follow-up	9-mo follow-up
AOFAS score			
Pain	30	30	30
Function	35	40	40
Alignment	8	8	8
Total score	73	78	78
VAS	7	5	0

AOFAS: American Orthopedic Foot and Ankle Society; VAS: Visual analog scale.



Figure 1 Intraoperative picture showing the autologous adipose-derived mesenchymal stem cells injection into the first metatarsophalangeal joint.

Similarly, Song *et al*[16] reported the amelioration of pain, function and cartilage volume of the knee after multiple injections of aAMSCs. The efficacy of aAMSCs in OA was recently confirmed in a systematic review conducted by McIntyre *et al*[17].

FMTPA is a degenerative disease with an incidence of 2.5% in patients over 50 years of age. Its treatment might be frustrating for both the orthopedic and the patient, considering the conflicting outcomes reported after conservative treatment, including HA injections. Petrella *et al*[18] in their study of 47 patients with FTMPA, described the long-term improvement in both pain and function after multiple HA injections; however, Munteanu *et al*[19] in their randomized controlled trial did not observe any differences when HA was compared with placebo.

Pons *et al*[20] in a randomized study compared the use of sodium hyaluronate with triamcinolone acetonide in FMTPA, and reported an improvement in pain relief and function at 3 mo after the injections. However, a high percentage of patients in both groups required subsequent surgery after 1 year of follow-up, due to further progression of the disease with worsening of both pain and function.

To the best of our knowledge, this is the first report on the use of aAMSCs for FMTPA. A single injection was effective in treating FMTPA, improving both the AOFAS and VAS score at 9 mo of follow-up.

CONCLUSION

The present case report indicates that the injection of aAMSCs might be a promising treatment for FMTPA. Obviously, larger cohorts and longer follow-up studies are needed to confirm these findings.

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ABOUT COVER

Editorial Board Member of *World Journal of Orthopedics*, Dr. De Martino is an orthopaedic surgeon specializing in adult reconstruction and joint replacement in the Division of Orthopaedic Surgery, Fondazione Policlinico Universitario Agostino Gemelli IRCCS. He completed several fellowships at the Hospital for Special Surgery (New York City, United States) including in Biomechanics, Joint Replacement, Shoulder Surgery, and Complex Joint Reconstruction. In his clinical practice, Dr. De Martino specializes in orthopaedic procedures, including primary and revision total hip, knee and shoulder replacement, and partial knee replacement. He has a strong background in minimally-invasive surgery and new technologies, including robotics and computer-assisted navigation. As recipient of various national and international awards for excellence in clinical research, Dr. De Martino also has a strong research background in orthopedic surgery. (L-Editor: Filipodia)

AIMS AND SCOPE

The primary aim of *World Journal of Orthopedics* (*WJO*, *World J Orthop*) is to provide scholars and readers from various fields of orthopedics with a platform to publish high-quality basic and clinical research articles and communicate their research findings online.

WJO mainly publishes articles reporting research results and findings obtained in the field of orthopedics and covering a wide range of topics including arthroscopy, bone trauma, bone tumors, hand and foot surgery, joint surgery, orthopedic trauma, osteoarthropathy, osteoporosis, pediatric orthopedics, spinal diseases, spine surgery, and sports medicine.

INDEXING/ABSTRACTING

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EDITORIAL

New Year's greeting and overview of *World Journal of Orthopedics* in 2021

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Abstract

On behalf of the Editorial Office of *World Journal of Orthopedics* (*WJO*), we extend our sincere gratitude to our authors, subscribers, readers, Editorial Board members, and peer reviewers, thanking each and every one for their contributions to *WJO* in 2020 and with wishes for a Happy New Year. It was the support of all our Editorial Board members and peer reviewers that allowed the Baishideng Publishing Group Inc to successfully carry out the complete peer review, editing and publishing processes for *WJO* in 2020. We have analyzed the data of *WJO*'s manuscript submissions and article publications in 2020, the invited manuscripts for 2021, manuscript peer review, composition of Editorial Board, and citation of *WJO*'s articles, and present the findings here. We expect to be even more productive and to further raise the academic rank of *WJO* in 2021.

Key Words: *World Journal of Orthopedics*; Acknowledgments; New Year's message; Editorial Board; Journal development

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Core Tip: With the support of all Editorial Board members and peer reviewers, Baishideng Publishing Group Inc successfully carried out the complete peer review, editing and publishing processes for *World Journal of Orthopedics* (*WJO*) in 2020. We give thanks for their contributions to the *WJO* in 2020 and support their upcoming endeavors to be more productive and to raise the academic rank of *WJO* in 2021.

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INTRODUCTION

As editors of *World Journal of Orthopedics* (*WJO*), we extend our sincere gratitude to our authors, subscribers, readers, Editorial Board members, and peer reviewers, thanking them for their contributions to the *WJO* in 2020 and wishing them a Happy New Year. We also give thanks for the support of all Editorial Board members and peer reviewers, whose efforts allowed for the Baishideng Publishing Group Inc (BPG) to successfully carry out the complete peer review, editing and publishing processes for *WJO* in 2020.

ACADEMIC INFLUENCE OF *WJO*

The *WJO* was launched by the BPG on November 18, 2010, and since then has grown into a high-quality, online, open-access, peer-reviewed journal. While we are celebrating *WJO*'s 11-year anniversary, we are very proud to share with you that since its first publication, *WJO* has published 698 articles that have been cited 8676 times.

In 2020, *WJO* received a total of 154 manuscripts for consideration of publication. Among the 119 which received a first decision by the Science Editor Development Department, 54 were edited and processed and advanced to the second decision, 56 (36.4%, 56/154) were rejected, and 64 (41.6%, 64/154) were published online by the Production Department (Figure 1)[1]. Among the 64 published articles, 18 (28.1%, 18/64) were invited manuscripts and 46 (71.9%, 46/64) were unsolicited manuscripts; in addition, 28 (43.8%, 28/64) were original articles, 19 (29.7%, 19/64) were review articles, 15 (23.4%, 15/64) were case reports, 1 (1.6%, 1/64) was an editorial and 1 (1.6%, 1/64) was 'other' (Figure 2A). The authors of those articles hail from 24 countries or regions. Among them, 14 (21.9%, 14/64) were authored by researchers from the United States, 5 (7.8%, 5/64) from the United Kingdom, 5 (7.8%, 5/64) from the Netherlands, 4 (6.3%, 4/64) from Italy, and 36 (56.3%, 36/64) from other countries or regions (Figure 2B).

As of December 31, 2020, *WJO* has received a total of 204 titles submitted for invited manuscripts for consideration of publication in 2021, including 116 (56.9%) review articles, 80 (39.2%) original articles, and 8 (3.9%) editorials. Among them, 28 (13.7%) had been submitted online and 176 (86.3%) have not been submitted yet (Figure 3).

In 2020, 5609 invitations were sent out to peer reviewers and Editorial Board members to conduct peer review of *WJO* manuscripts, yielding 660 acceptances (11.7%, 660/5609), 603 declines (10.8%, 603/5609), and 4346 non-responses (77.5%, 4346/5609) (Figure 4). Among the peer reviewers and editorial board members who accepted invitations, 224 (33.9%, 224/660) submitted the peer review report on time, 425 (64.4%, 425/660) failed to submit the peer review report on time, and 11 have not submitted the peer review report yet.

The *WJO* Editorial Board is composed of 60 members[2], and the Editorial Office has received 32 new applications to evaluate for inclusion on the member list. The 60 Editorial Board members came from 27 countries or regions. Among them, 10 (16.7%) are from Italy, 6 (10%) from the United States, 4 (6.7%) from Germany, 4 (6.7%) from Iran, 4 (6.7%) from Austria, and 32 (53.3%) from other countries or regions (Figure 5), among which 40 (66.7%) have conducted peer review and 20 (33.3%) have yet to conduct their first peer review.

In 2020, the number of total visits to the *WJO* homepage was about 254463, of which 26.7% of those visits were from the United States, 10.8% from the United Kingdom, and 8.2% from China[3]. The number of total downloads to the *WJO* articles is about 176327, of which 47.9% of those visits have been from the United States, 11.2% from China, and 8.4% from Germany[4] (Figure 6).

As of January 4, 2021, according to data from the Web of Science, the *WJO* published 88 articles in 2018-2019 from authors in 27 countries or regions. Among them, 33 authors (37.5%, 33/88) came from the United States, 12 (13.6%, 13/88) from the United Kingdom, and 7 (8.0%, 7/88) from Italy. These 88 published articles included 83 classified as "article" or "review" and yielded total cites of 190 times in 2020.

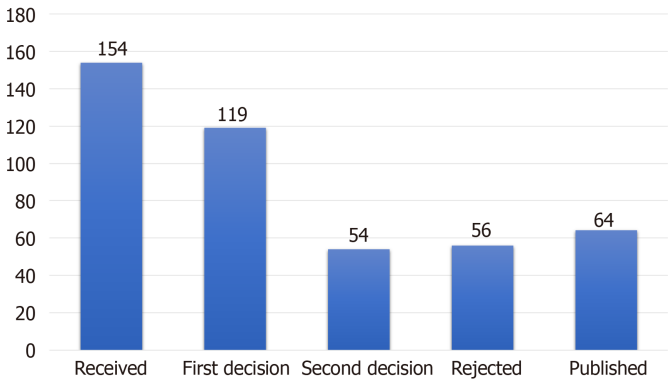


Figure 1 *World Journal of Orthopedics* 2020 manuscript processing. The numbers of manuscripts processed, from submission through publication, are presented.

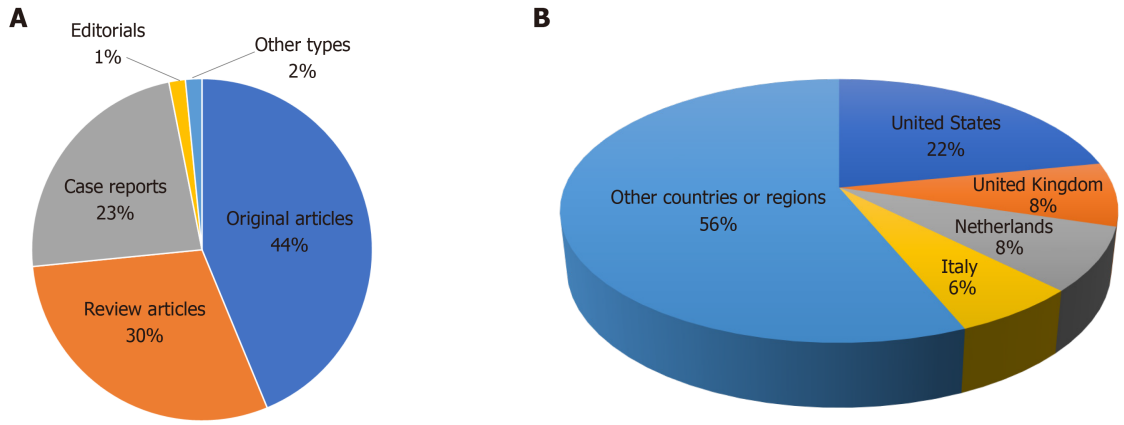


Figure 2 Bibliographic data for articles published by the *World Journal of Orthopedics* in 2020. A: Article types; B: Authors' countries.

According to data from Scopus, the *WJO*'s CiteScore for 2019 is 3.2 and Scopus CiteScore rank 2019: Orthopedics and sports medicine is 77/261 (Figure 7).

CONCLUSION

At present, *WJO* still has some problems to be solved, including: (1) A lower than desired number of manuscript submissions, especially of high-quality original and review manuscripts; (2) A lower than desired number of peer review reports received for each manuscript; (3) The academic quality of published articles should be further improved; (4) A lower than desired number of submissions of invited manuscripts from Editorial Board members; and (5) An insufficient number of Editorial Board members, which presents a challenge to the peer review process for some manuscripts.

With continued dedicated support from all our authors, reviewers, Editorial Board members and readers, we expect to be more productive in this new year. For our part, we commit to working with you all to raise the academic rank of *WJO* in 2021. In order to achieve these goals, we will invite more scientists in the field of orthopedics to join the *WJO* Editorial Board, more active scientists to conduct peer review for *WJO* manuscripts, and more scientists to contribute high-quality original and review manuscripts to *WJO*. By publishing more high-quality articles, the *WJO* will be able to make more substantive contributions to the development of basic medical and clinical research in the field of orthopedics.

We remain open to any suggestions that could improve *WJO*'s operation and publication. Please feel free to contact us at j.l.wang@wjgnet.com, if you have any questions or suggestions on *WJO*.

Once again, on behalf of the Editorial Office of *WJO*, we wish you and your families the best for the New Year.

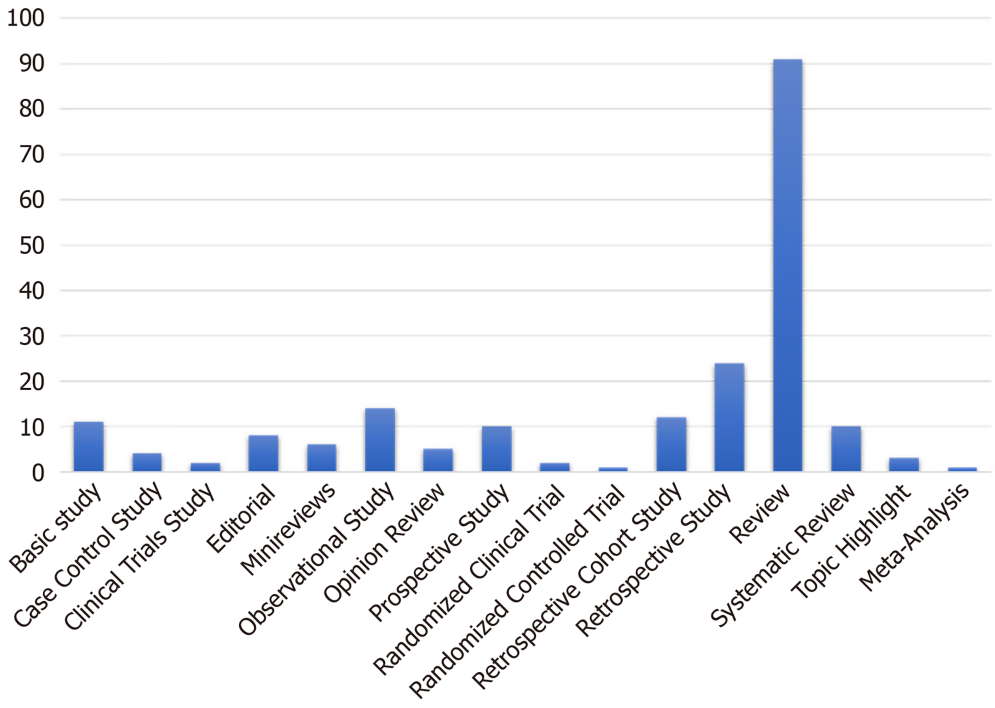


Figure 3 Titles of invited manuscripts submitted for the various types of articles for consideration of publication in 2021 by the *World Journal of Orthopedics*.

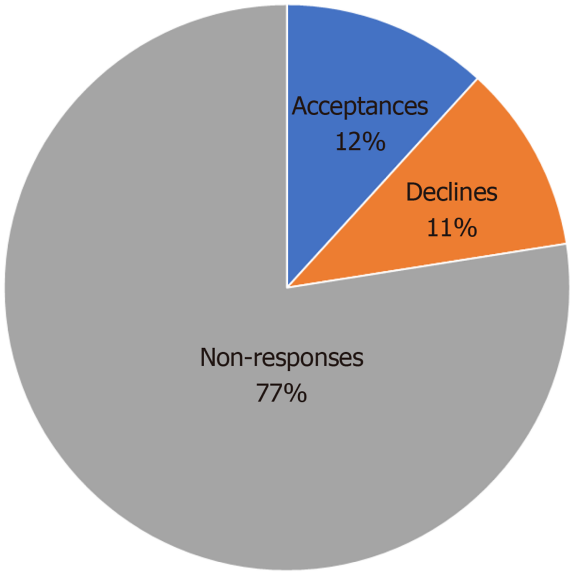


Figure 4 In 2020, 5609 invitations were sent out to peer reviewers and Editorial Board members to conduct peer review of *World Journal of Orthopedics* manuscripts.

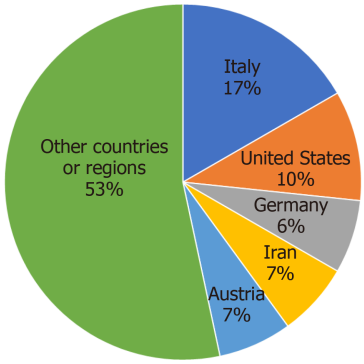


Figure 5 *World Journal of Orthopedics* Editorial Board members are from 27 countries or regions.

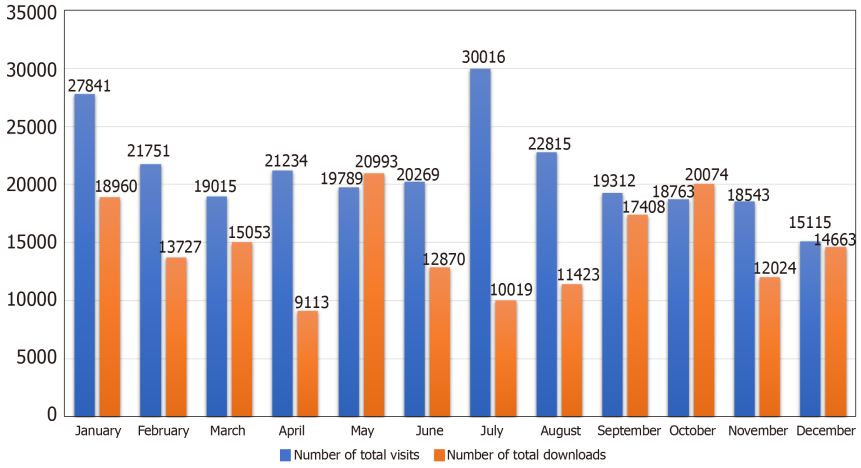


Figure 6 Number of total visits to the *World Journal of Orthopedics* homepage and number of total downloads of *World Journal of Orthopedics* articles in 2020.

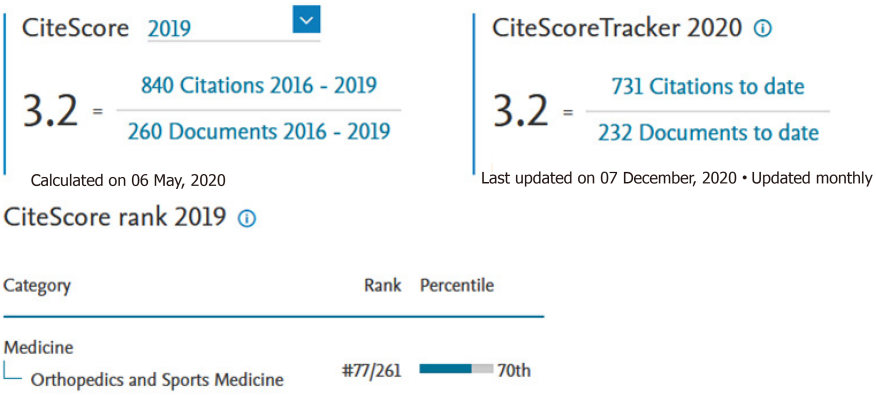


Figure 7 Formula for the anticipated 2019 CiteScore for the *World Journal of Orthopedics*.

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MINIREVIEWS

Diabetic foot: Which one comes first, the ulcer or the contracture?

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Abstract

Diabetic foot is among the most common complications of patients with diabetes. One of the known causes of foot ulceration is ankle equinus, which increases the pressure on the plantar surface during ambulation. Conversely, equinus contracture can be caused by a complicated wound, and it may be due to prolonged immobilization. In this paper, we reviewed the pathogenesis of both conditions and their clinical considerations. Poor glycemic control in patients with diabetes may result in angiopathy and neuropathy as an underlying condition. An ulcer can be precipitated by an injury, improper foot care, or increased biomechanical loading as seen in elevated plantar pressure following equinus contracture. Equinus contracture may be a direct effect of hyperglycemia or can arise in combination with another pathway, for example, involving the activation of transforming growth factor β. Static positioning resulting from any prior foot wound may develop fibrotic changes leading to contracture. Wound healing promoting factors can also result in overhealing outcomes such as hypertrophic scarring and fibrosis. The body's repair mechanism during the healing cascade activates repair cells and myofibroblasts, which also serve as the main producers and organizers of the extracellular matrix. Considering this intricate pathogenesis, appropriate interventions are essential for breaking the vicious cycle that may disturb wound healing.

Key Words: Diabetes; Ulcer; Contracture; Vicious cycle; Pathogenesis; Intervention

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Core Tip: There is a complex pathogenesis of diabetic foot ulcers, including many variables that are involved in a vicious cycle. This is the first review to analyze the relationship between contracture and ulcer formation, with the aim of formulating a more detailed pathogenesis and timeline for better treatment strategies.

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INTRODUCTION

The rising prevalence of diabetes represents a major public health and socioeconomic burden on society. Diabetic foot is one of the clinical manifestations of diabetes. Diabetic foot may develop in some diabetic patients as a consequence of advanced disease. It is defined as a structural or functional alteration of the foot that may manifest as ulcers, osteomyelitis, or gangrene, as a result of the interaction of different factors induced by sustained hyperglycemia and previous traumatic causes[1,2]. Diabetes-related foot complications have been identified as the single most common cause of morbidity among diabetic patients[3]. Recurrence rates of diabetic foot ulcers are high, and they remain an unresolved issue for many patients[4,5]. Pinpointing the exact cause is difficult; however, this is crucial for the management of diabetic foot as well as for the prevention of recurrences.

Neuropathy, deformity, callus, increased peak plantar pressure, peripheral arterial disease, penetrating trauma, and ill-fitting shoes account for 64% of all new diabetic foot ulcers; hence, their prevention is paramount in comprehensive diabetes management[6,7]. Once it occurs, diabetic foot may be managed with offloading, wound care utilizing various dressings, skin grafting or formal debridement.

One of the common causes of foot ulceration is ankle equinus, which increases the pressures on the plantar surface of the foot during ambulation[8]. Among diabetic patients, contracture of the triceps surae is thought to occur and this contributes to ulcer formation[9]. In patients with a high risk of recurrent ulcers and when traditional offloading methods have failed, surgical offloading may be an alternative option[10-12]. However, equinus resulting from limb contracture is known to be a complication of prolonged static positioning, specifically due to foot wounds, as the ulcer can be initially caused by external injuries as well[13]. In the late stage, it is difficult to determine which one came first: The contracture or the ulceration.

It is not clear in the current literature if the pathophysiology leading to equinus is the same between diabetic and nondiabetic patients[8]. In this paper, we review and analyze the contribution of equinus contracture to diabetic foot ulcers and vice versa. We also sought to formulate the possible timelines of both conditions during the natural course of diabetic foot ulcers.

CLINICAL CONSIDERATIONS

An equinus ankle is an ankle that will not go into more than 5 degrees of dorsiflexion with the knee extended. Most cases of equinus are associated with other biomechanically related disorders[14]. There are several possible causes for the limited range of ankle motion, including a bony block or soft tissue contracture. Limb contracture itself is a condition of shortening and hardening of the muscles, tendons, or other tissues, often leading to deformity and rigidity of the joints. In diabetic foot, contracture may ensue following prolonged immobilization due to the ulcers[13]. This is made worse by macro and microangiopathy, further deteriorating the soft tissue quality.

Initial management of ankle equinus involves stretching and physical therapy, balancing flexibility and power. However, in severe cases, surgery may be chosen to provide an immediate increase in the range of motion[15]. Several surgical techniques have been described. The type and level of surgery will be determined from a physical examination, specifically related to the affected structure. Achilles tendon lengthening is indicated if both the gastrocnemius and soleus are affected. Here, the tendon is either sectioned completely, Z-lengthened, or triply hemisectioned[15,16]. The increase in tendon length will reduce its tension and reduce the pressure on the plantar aspect of the foot by allowing it to dorsiflex. The pressure offloading relieves the abnormal pressure applied to the ulcer, promoting wound healing[17]. Lengthening the triceps surae complex should decrease the stress on the entire plantar forefoot. Lengthening other tendons may serve specific purposes: Peroneus longus tendon lengthening may

relieve pressure on the plantar surface of the first metatarsal head, while lengthening of the posterior medial tendon should reduce plantar flexion of the fifth metatarsal head. The literature has attested to the virtue of tendon lengthening when indicated[18]. In addition, correction of static deformity through various methods, including resectional arthroplasty or osteotomy, is beneficial to decrease the pressure overload on the prominences of the plantar surface[19]. Bony correction, such as arthroplasty or excision, may be helpful were deemed necessary. The drawbacks include the changes in the foot anatomy as well as the possible relocation of points of focal pressure to a different area of the foot[20].

PATHOGENESIS OF FOOT ULCERATIONS

Regardless of the anatomical location, the etiology of a diabetic foot wound is considered multifactorial. While the underlying cause is poor glycemic control resulting in angiopathy and neuropathy, the wound can be precipitated by injury, deformities, improper foot care, or elevated plantar pressure due to increased biomechanical loading[21,22].

Diabetic foot development occurs in phases: The first phase is callus formation, followed by multiple foot traumatization due to loss of the protective sensations secondary to neuropathy. Dry skin on the diabetic foot caused by autonomic neuropathy only worsens the condition. The ensuing subcutaneous hemorrhaging delivers the final insult to the skin, resulting in skin ischemia and then ulceration[23].

The presence of localized elevations of plantar pressure has been conclusively identified as the primary determinant of plantar ulceration[24]. Localized increases in pressure are sufficient to initiate ulceration[25]. Tightness or contracture in the triceps surae and foot intrinsic muscles contributes to the initiation of ulceration; triceps surae contracture plantarflexes the foot, increasing stress on the forefoot, while hammertoe and clawtoe resulting in intrinsic tightness cause the migration of the plantar metatarsal head fat[26]. Prior studies demonstrated that plantar pressures are higher in cases with active diabetic foot ulcers despite having a longer stance phase duration, which would be expected to lower plantar pressure. Hence, taking these condition into consideration, the prevention of diabetic foot ulceration requires offloading of pressure during ambulation despite a longer stance phase[27].

Charcot neuropathic osteoarthropathy, for which diabetic neuropathy is the most common etiology, is a condition affecting the bones, joints, and soft tissues of the foot and ankle, characterized by inflammation in the earliest phase. This inflammatory condition may lead to varying degrees and patterns of bone destruction, subluxation, dislocation, or deformity. The hallmark deformity is midfoot collapse, described as a "rocker-bottom" foot, that can result in persistent foot ulceration due to the pressure[28]. The contributing forces for this deformity include the contracture of the peroneal, anterior tibialis, and Achilles tendon.

Biological impairment and vasculopathy also play a significant role in the formation of diabetic foot and its ability to heal. Endothelial dysfunction is an inflammation of the endothelial cells due to hyperglycemia. During the hyperglycemic state, the endothelial cells switch from the utilization of nitric oxide to metabolize glucose, the depletion of which results in the inability to vasodilate. The inability to vasodilate increases intravascular pressure, causing injury and inflammation to the endothelial cells, which in turn causes the migration of inflammatory cells subintimally, forming atherogenic foam cells. Lytic enzymes released by inflammatory cells further damage the vessels in a condition called vasculopathy, which is responsible for both the initiation of ulceration as well as its impaired healing. Impaired activity of the white blood cells involving both B and T cell types in diabetic patients may also complicate the healing and treatment of these wounds[19]. Furthermore, ankle joint equinus has been reported to be associated with diminished venous blood flow in the lower extremity that is detrimental to wound healing[29].

PATHOGENESIS OF EQUINUS CONTRACTURE

Tendon diseases are increasingly common fibrotic disorders and they account for a third of all musculoskeletal complaints[30-32]. Fibrosis itself is characterized by extracellular matrix (ECM) accumulation and often by a change in the quality of the ECM. The morphological and biochemical disturbances of the ECM are directly related to a loss of function in the target organs[33].

In general, several pathophysiologic mechanisms appear to be involved in the development of contracture. The most frequent cause is immobilization, but it can also be caused by congenital deformities, muscle problems, ulcers, local trauma, diabetes, and hormone deficiencies[34]. Prior studies confirmed that levels of physical activity are low in the population with diabetes, and this inactivity is more commonly seen in older patients[35]. This inactivity can lead to contracture development through some conditions, including static positioning, muscle imbalance, and the aforementioned fibrosis.

Static positioning indicates that the position in which a joint is statically positioned influences the number of sarcomeres present in any given muscle. A statically positioned limb developing fibrotic changes within the muscle will develop contracture formation in the position of immobilization. In a supine position, bulky posterior muscles are at a physiologic disadvantage in maintaining flexibility. The imbalance between the flexor and extensor muscle groups has not been shown to be a major factor leading to contracture formation, but contractures are frequently observed when major muscle imbalance is present[13,36]. Thus, inactive patients tend to develop plantarflexion contracture without regular stretching or splinting. Intrinsic muscle tissue alterations in dystrophic myopathies also contribute to contracture formation, due to replacement of the functioning muscle fibers with collagen and fatty tissue in concert with a chronically shortened resting muscle length[13]. A situation of concern is when soft tissue changes that contribute to contractures begin very early after the onset of immobility. Protein synthesis within muscle fibers is reduced within 6 h after immobilization. Shortening of muscle fibers occurs within 24 h, and after 48 h, collagen infiltration of the perimysium is increased[37].

In diabetes patients, chronic hyperglycemia is a major factor causing various complications, since strict glycemic control reduces the end-organ complication incidence and the rate of progression[33]. Hyperglycemia can work through both metabolic and hemodynamic pathways to affect ECM turn-over[33]. Hyperglycemia is responsible for the presence of high levels of advanced glycation end-products (AGEs), which are able to directly stimulate the production of ECM[38]. In addition, AGEs significantly interact with the renin angiotensin aldosterone system (RAAS). Angiotensin II, the main physiological effector molecule of the RAAS, mediates fibrosis by stimulating the synthesis of ECM components. Generally, RAAS is known to be an important contributor to the pathogenesis of diabetic micro- and macrovascular complications by inducing various tissue responses, including not only fibrosis but also vasoconstriction, inflammation, oxidative stress, cell hypertrophy and proliferation[33]. Pathogenesis of fibrosis is also affected by transforming growth factor β (TGF-β). TGF-β regulates the expression of many matrix proteins, including ECM. TGF-β has been previously reported to be the main pro-fibrotic factor in diabetic nephropathy[39]. In the diabetic environment, there is upregulated TGF-β1 expression and bioactivity in glomerular mesangial and proximal tubule cells[33]. Certain comorbidities have been known to affect TGF-β expression, for example, cigarette smoking, in which sustained oxidative stress induces chronic inflammation and causes a further release of active TGF-β1[40].

Our body's repair mechanism during the healing cascade of the wound may also lead to fibrosis. Activated repair cells, myofibroblasts, are the main producers and organizers of ECM, which is needed to restore tissue integrity after injury. Too many fibroblasts working for too long can cause hypertrophic scarring and tissue contractures[41].

Nonhealing wounds resulting in an infection may cause a stress response in the body by increasing the amount of certain hormones, such as cortisol and adrenaline. In the liver, high cortisol levels increase gluconeogenesis and decrease glycogen synthesis[42]. These hormones work against the action of insulin, and as a result, the body's production of glucose and blood sugar levels are increased. Inflammatory stimuli that activate macrophages enhance the release of active TGF-β complexes that are secreted by plasma cells and then release active TGF-β into the extracellular fluid[43]. It is well established that TGF-β1 functions as a wound healing promoting factor, and when in excess it may lead to overhealing outcomes, such as hypertrophic scarring and fibrosis[44].

It can be concluded that there are multifactorial etiologies of ankle equinus contracture. Intrinsically, hyperglycemia and wound healing mechanisms are known to play a role in contracture development. In addition, static positioning due to a systemic health problem or the presence of an established wound may result in contracture as well.

CONCLUSION

Diabetic foot ulcer has been known to be associated with various factors, including equinus deformity ensuing from a triceps surae contracture. Although some light has been shed on the mechanism of both, the exact mechanisms and their interactions are still unclear. This is a situation that may seem like a chicken-or-egg condition, and which one comes first is puzzling.

In our experience, the patients came at different stages without any strict pattern of the pathogenesis. Some patients presented ulcers without contracture, and vice versa. It is also suggested not to consider hyperglycemia status as a sole determinant of the ulcerations of contracture development, as it is also depended on many factors as mentioned above.

Determining the timeline of each pathology is crucial, as shown in Figure 1. A contracture may contribute to wound development in the ulcer-prone feet. Recognizing and addressing the source of a triceps surae contracture is important to prevent subsequent ulcers. While chronic hyperglycemia can directly cause contractures through AGEs accumulation, it is not the sole etiology for this condition. Thus, other contributing factors must be identified and taken into consideration. Prolonged immobilization due to diabetic foot is seen as the bridge to triceps surae contracture in nonambulant patients. The body's wound healing cascade can contribute to further fibrosis that affects the joint. In patients presenting with long-standing wounds, it is difficult to determine which one came first. Thus, a thorough evaluation, including physical and adjunct examinations, must be conducted and interpreted wisely.

Identifying the pathogenesis of a specific pathology can lead to the correct and timely treatment. Assessments and interventions are essential in breaking the vicious cycle that may disturb wound healing.

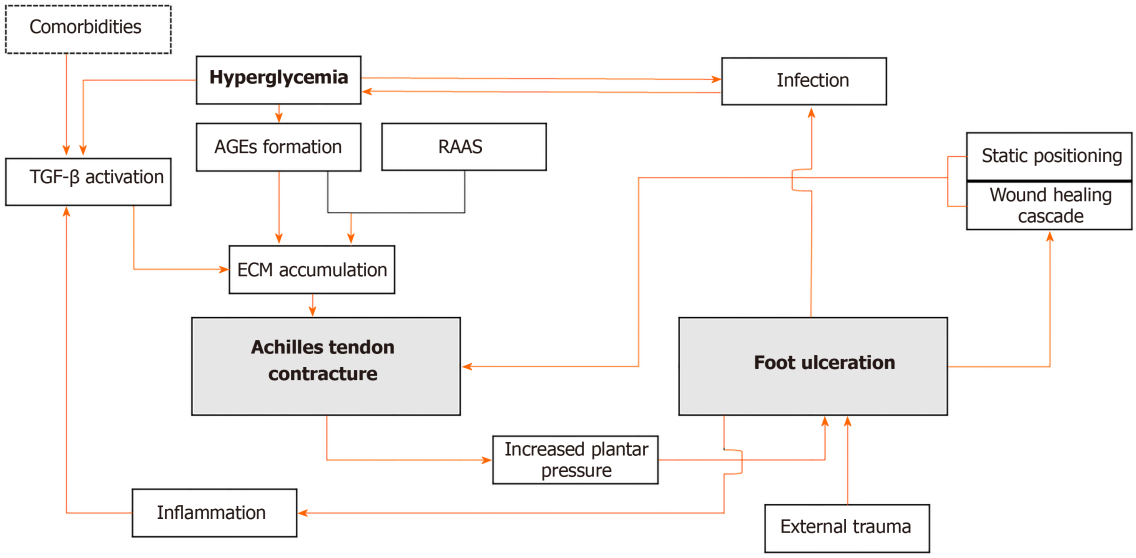


Figure 1 Schematic diagram indicating how a vicious cycle can occur between equinus contracture and foot ulceration in patients with diabetes. TGF-β: Transforming growth factor β; AGEs: Advanced glycation end-products; RAAS: Renin angiotensin aldosterone system; ECM: Extracellular matrix.

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ORIGINAL ARTICLE

Clinical Trials Study

Evaluation of joint awareness after acetabular fracture: Validation of the Forgotten Joint Score according to the COSMIN checklist protocol

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Institutional review board statement: This study was carried out in accordance with the Declaration of Helsinki and approved by the ethics committee at the University of Regensburg in December 2015 (Institutional Review Board Number 15-101-0241). We obtained written informed consent from all study

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Abstract

BACKGROUND

A fracture of the acetabulum is an uncommon, but serious injury. Established outcome tools do not reflect the patient's perspective after fracture of the hip joint. Originally designed for post-arthroplasty patients, the Forgotten Joint Score (FJS) is a patient-reported outcome measurement (PROM) tool evaluating the disease-specific health-related quality of life (HR-QoL).

AIM

To validate the FJS in patients after acetabular fracture.

METHODS

In a prospective mono-centric cohort study, we evaluated 100 patients at mean 5.2 ± 3.6 years after a fracture of the acetabulum. The validation study followed the complete COSMIN checklist protocol. For calculation of convergent validity, we used the Tegner-Activity Scale, the Western Ontario and McMaster Universities Osteoarthritis Index, the EuroQol-5D, and a subjective rating of change as an anchor variable.

RESULTS

We confirmed good internal consistency with a Cronbach's alpha of 0.95. With an intraclass correlation coefficient of 0.99 (95%CI: 0.97, 0.99), test-retest reliability of the FJS was excellent. Correlation coefficients between the questionnaires were moderate to high ranging from |0.56| to |0.83| (absolute value). No relevant

floor or ceiling effects occurred. Standard error of measurement was 3.2 and smallest detectable change (SDC) was 8.8. Thus, changes greater than 8.8 points between two assessments denote a real change in FJS.

CONCLUSION

The FJS is a valid and reliable tool for evaluation of patient-reported outcome in posttraumatic condition after acetabular fracture. The SDC indicating a real clinical improvement was 8.8 points in the FJS. We could confirm responsiveness of the FJS and found no relevant floor- or ceiling effects.

Key Words: Patient reported outcome measurement; Validation study; Hip joint; Forgotten Joint Score; Acetabulum fracture; COSMIN checklist

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Core Tip: A fracture of the acetabulum is a rare but serious medical condition. Patient-reported outcome measurement has rising impact on clinical decision-making and is of extraordinary value in research. Validation of measurement tools is an essential scientific contribution for further research. This study evaluates psychometric properties of the Forgotten Joint Score in posttraumatic condition after acetabular fractures.

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INTRODUCTION

A fracture of the acetabulum is an uncommon but severe injury to the hip joint. Initial management of these injuries is crucial regarding long-term outcome[1-7]. Persistent immobilizing pain and post-traumatic osteoarthritis are typical consequences in cases where the integrity of the acetabulum is not adequately reconstructed. Open reduction and internal fixation (ORIF) is the standard treatment for displaced acetabular fractures. Risk factors for a poor radiographic outcome like residual articular surface gaps and steps as well as involvement of the posterior wall and the quadrilateral surface are well known[2,4,8,9]. However, the impact of these radiographic parameters on Patient-reported outcome (PRO) is unclear. Conventional scoring systems like the Merle d'Aubigne-Postel Score are rather surgeon-based neglecting the patient's perception of the outcome[10].

The "Forgotten Joint Score" (FJS) was developed in 2012 as a PRO measurement tool in patients after arthroplasty of the knee or hip joint[11]. The concept that the patient rates the loss of awareness of the hip joint is revolutionary in patient-reported outcome measurement (PROM). Joint awareness in everyday life is seen as an important criterion in activity of daily living (ADL)[11-13]. The forgotten joint, a condition where the patient has no distracting sensation of the joint, is seen as the ultimate goal resulting in maximum patient satisfaction[11]. Currently, the Merle d'Aubigne-Postel Score and the Western Ontario and McMaster Universities Osteoarthritis Index-Visual Analog Scale (WOMAC-VAS) Score are most frequently used in functional outcome evaluation after acetabular fractures[2,4,8,9,14]. Other scales like the EuroQol-5D (EQ-5D-3L) and the Tegner Activity Scale (TAS) are tools to rate global health-related quality of life and sports activity for characterization of a patient population.

Studies on psychometric properties of outcome tools should meet highest standards regarding methodological quality[15]. The COSMIN checklist is based on an international Delphi study in 2010 reporting on a consensus-based checklist evaluating the quality of studies on psychometric properties of HR-QoL instruments[16]. The COSMIN checklist consists of ten items giving recommen-dations for design, conduction and interpretation of medical validation studies. Relevant characteristics

participants.

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Informed consent statement: We obtained consent for publication from all study participants.

Conflict-of-interest statement: The authors declare that there is no conflict of interest.

Data sharing statement: The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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are study design, content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, hypotheses testing for construct validity, and responsiveness.

Purpose of this study was to validate the FJS for mid- and long-term condition after acetabular fractures and to investigate the relation between perioperative parameters and score values of the FJS.

MATERIALS AND METHODS

Validation study

The ethics committee at the University of Regensburg approved this study in December 2015 (Institutional Review Board Number 15-101-0241). We obtained written informed consent from all study participants. The study was carried out in accordance with the Declaration of Helsinki.

In this prospective, mono-centric validating study, we identified 100 consecutive German-speaking patients with a history of an acetabular fracture between 07/2002 and 06/2016.

Inclusion criteria were: (1) Mid- and long-term condition after acetabular fracture; (2) Minimum follow up was 12 mo after trauma; (3) Age between 18 and 70 years; and (4) Sufficient German reading and comprehension capacity.

Exclusion criteria were: (1) Relevant concomitant injuries (*e.g.*, a fracture of the lower extremity or neurovascular injury leading to prolonged immobilization); (2) Preexisting mental disorder; and (3) Lack of consent to participate in this study.

Of initial 296 patients who were treated in a single institution for an acetabular fracture between 07/2002 and 06/2016, 32 patients had died until follow-up, 102 patients were lost to follow-up, 58 patients refused to give their informed consent. Four patients were excluded due to missing data. The patients were asked to complete the questionnaire at follow-up evaluation at mean 5.2 ± 3.6 years after the injury (time point T1). The patients received the questionnaire two weeks after the first questionnaire (time point T2) to evaluate the test-retest reliability and responsiveness. If the patients did not return the questionnaire form within four weeks, the patients were reminded at intervals of two weeks' time. 55 of 100 patients completed the questionnaire twice on average after 32 ± 71.4 d. Figure 1 shows the patient flow chart.

FJS

The Forgotten Joint score is a self-administrated questionnaire comprising of 12 items concerning on the patient's ability to forget the hip joint in everyday life[11]. Meanwhile, the loss of awareness of a joint is seen as the ultimate goal leading to maximum patient satisfaction. The FJS was developed in 2012. Several studies have proven high internal consistency, responsiveness, and construct validity in mid- and long term conditions after arthroplasty[11,13,17-19]. Originally, it was developed to evaluate PRO in patients after arthroplasty of the knee or hip.

The patients were asked to return the forms by mail. For evaluation of test–retest reliability, the patients were supposed to complete a second questionnaire after a minimum of two weeks. The patients received a reminding call if they did not answer within two weeks.

WOMAC-VAS

The WOMAC-VAS is a well-established standardized questionnaire to evaluate the disease-specific health-related quality of life of patients with osteoarthritis of the knee and hip comprising of 24 questions each rated on a VAS (0-100 mm)[20]. Following scores were computed: Subscale pain (0-500 mm), subscale stiffness (0-200 mm), subscale functional limitation (0-1700 mm), and a summary score (0-2400 mm). A WOMAC-VAS score of 0 indicates no pain, no stiffness, and full function. The higher the score is, the more problems the patient is facing. The WOMAC-VAS is validated in German[21].

TAS

The TAS is a well-established score reflecting the patient's highest level of physical activity on a 10 level scale[22]. The TAS is the most commonly reported tool for physical activity in patients with lower extremity disorders. A TAS score of ten reflects the functional capacity of a top-level athlete, a score of 0 reflects the inability to walk. A German adaption is available[23].

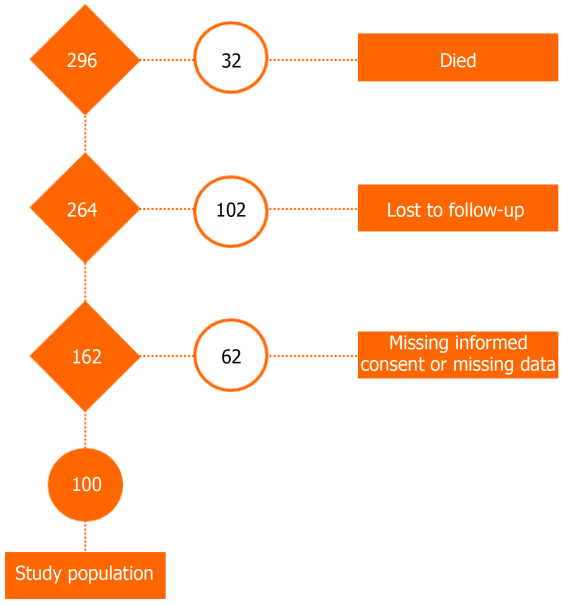


Figure 1 Patient flow-chart of study population.

EQ-5D-3L

The EQ-5D-3L is a HR-QoL questionnaire consisting of subscales regarding mobility, self-care, usual activities, pain/discomfort, and anxiety/depression[24,25]. Responses to each dimension were transformed into EQ index ranging from -0.21 (worst health) to 1.00 (best health). Additionally, the EQ-5D reports the patient's assessment of the current HR-QoL in a 100 mm visual analogue scale. This scale ranges from 0 (the worst health you can imagine) to 100 (the best health you can imagine).

Subjective assessment

We asked the patients to evaluate whether the condition of their hip joint had changed since primary evaluation (much better, somewhat better, unchanged, somewhat worse, much worse). For calculation of the responsiveness, the anchor variable was summarized to 'better', 'unchanged', or 'worse'.

Clinical data

We reviewed all digital patient charts to record relevant clinical data. Our institution is a level-one trauma-center specialized on management of pelvic injuries. Standard diagnostics at time of injury was a clinical evaluation and a computed tomography (CT) scan of the pelvis. The initial degree of initial and postoperative dislocation was rated according to the Matta scoring system for evaluation of dislocation after acetabular fracture[8]. There was an indication for conservative treatment in cases with no relevant dislocation (less than 2 mm and no involvement of the dome area) measured in the initial CT scan. We recorded clinical parameter like treatment modality (operative *vs* non-operative/fracture classification according to Letournel/surgical approach) and compared mean values of the FJS between the groups.

Statistical analysis

Statistical analysis was performed using the software package SPSS (Version 25, SPSS Inc, Chicago, IL, United States). The level of significance was defined at $P < 0.05$ for all tests. Analyses were exploratory, thus no adjustments of P values for multiple testing were conducted. Questionnaires were computed in accordance with guidelines. If not stated in questionnaire guidelines, missing values were not imputed.

Descriptive data were given as frequencies (n) and percentage (%) for categorical variables, mean ± SD or median and interquartile range (IQR) for continuous variables.

Methodological testing according to the COSMIN checklist

We evaluated the reliability (internal consistency, test-retest reliability, and measurement error), validity (convergent validity and clinical validity), responsiveness to change, and interpretability (data completeness and response distribution) of the FJS based on the COSMIN checklist.

Reliability

Reliability is the degree to which the measurement is free from measurement error[16].

Internal consistency

Internal consistency is the degree of interrelatedness among items[16]. Sufficient internal consistency iukrs assumed for a Cronbach's $\alpha \geq 0.70$[15].

Test–retest reliability

Test–retest reliability is the degree of which an outcome of the same patient in the same health condition remains unchanged over time. As the time interval between first and second testing were heterogeneous (0 to 385 d), intraclass correlation coefficient (ICC, two-way mixed model with absolute agreement, average measures) and its 95%CI was estimated indicating an unchanged health condition regarding their hip function compared to the primary evaluation. For an ICC ≥ 0.70 sufficient test-retest reliability was assumed.

Measurement error

The measurement error is the systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured[16]. For patients indicating no change in the condition of their hip joint, standard error of measurement (SEM) and smallest detectable change (SDC) were computed to estimate how much a score needs to change to be sure that a true change has occurred (sensitivity to change). SEM was computed by multiplying the standard deviation (SD, all assessments of patients with unchanged condition) by the square root of 1 minus reliability (ICC): $SD \times (1\text{-}ICC)^{1/2}$. SDC was computed by $SEM \times 1.96 \times 2^{1/2}$[15].

Validity

Validity is the degree to which a questionnaire measures the construct it purports to measure[16]. There is no gold standard in the measurement of PRO. Therefore, we rated validity as convergent and clinical validity. Convergent validity is the degree to which the score of the FJS is comparable with the scores of other functional questionnaires (TAS, WOMAC-VAS, EQ Index, EQ VAS). We measured convergent validity by Spearmen's rank correlation. With a correlation coefficients $|\geq 0.60|$ (absolute value), convergent validity was rated positive. Based on previous results, it is expected that FJS correlates negative and high ≤ -0.60 with WOMAC-VAS subscales and WOMAC-VAS summary score[11], correlates positive and moderate between 0.30 and 0.50 with EQ Index, EQ VAS and TAS[13]. We measured clinical validity of FJS by known-groups comparison using *U*-test to assess differences between patients with and without articular displacement. Just the first FJS measurement of patients without total hip arthroplasty was assessed.

Responsiveness

Responsiveness is the ability of a questionnaire to detect a change over time in the construct to be measured[16]. Changes in FJS were assessed by Wilcoxon tests separate for patients indicating improvement, no change or worsening of hip functioning. Moreover, Cohan's d effect size (ES) was computed for each patient group by the mean difference between measurement at T1 and T2 by the SD of measurement A: mean difference measure A and B/SD measure A. ES values of 0.2, 0.5, and 0.8 indicate small, moderate and large changes/ responsiveness[15,16]. To assess whether patients with different hip function development (improvement, no change, worsening) differed in baseline FJS, Kruskal-Wallis H-Test was computed.

Interpretability

Interpretability is the ability to transform a qualitative effect into a quantitative score[16]. Interpretability of the FJS was assessed by presenting data completeness and response distribution (floor and ceiling effects). Extreme outcome values might not be represented adequately if more than 15% of patients score lowest (0) value (floor effect) or highest (100) (ceiling effect) levels in the FJS. In cases of floor- or ceiling

effects, the questionnaire might also not be able to reflect changes[15].

RESULTS

Demographic data

Table 1 shows mean score values at initial assessment and demographic data. The cohort comprised of 79% men and 21% women. All patients had sustained an acetabular fracture 1 to 14 years before. 22% of these patients were treated conservatively; 78% required surgical treatment. Of 78 patients with surgical treatment, 55 patients required open reduction and internal plate fixation. In 37 cases, an anterior approach (25 × ilio-inguinal and 12 × intrapelvic approach) was necessary. 18 patients required posterior fixation *via* a Kocher-Langenbeck approach. We carried out operative management according to the Arbeitsgemeinschaft für Osteosynthesefragen (AO) principles (Figure 2). According to these recommendations, we aimed for anatomic reduction of the articular surface and internal fixation of the fragments. Aftercare was equal for all patients. We advised the patients to partial weight-bearing of 15 kg for 6 weeks and a step-wise increase of load of 10 kg per week until the patient's normal weight was reached. For patients with an involvement of the posterior wall, internal rotation of the hip was limited for 6 weeks postoperative. 54/100 patients had an initial articular surface step of more than 3 mm and 46 patients had an initial articular surface step of 3 mm or less. Regarding long-term complications, 4 of 100 patients required a total hip arthroplasty (THA) due to rapid progressive joint degeneration after the acetabular fracture. There were 2/54 patients in the displacement group and 2/46 patients in the other group requiring THA until follow-up evaluation. The time between accident (T0) and follow-up (T1) was 5.2 ± 3.6 years (range 0.2-13.5). The mean age at follow up (T1) was 57.9 ± 17.6 years (range 22-88). The second questionnaire (T2) was completed on average 31.2 ± 71.4 d (range 0-385) after the first.

Reliability

The internal consistency of the questionnaire is satisfying, with Cronbach's alpha = 0.95 for measurement at T1 (n = 83) and 0.97 for measurement at T2 (n = 50). Even with deleting an item, Cronbach's alpha was high raging between 0.95 and 0.97.

The test-retest reliability was excellent with an ICC = 0.99 (95%CI = 0.97-0.99). We included only patients indicating an unchanged functional condition regarding their hip joint (n = 24).

SEM was 3.2 and SDC was 8.8. Thus, changes > 8.8 points between two assessments denote real change in FJS and changes ≤ 8.8 denote for measurement errors and subject variability.

Validity

In both assessments, convergent validity between FJS and WOMAC-VAS, TAS, EQ Index as well as EQ VAS could be confirmed. Correlation coefficients were moderate to high ranging from |0.56| to |0.83| (absolute value). The higher the WOMAC-VAS (pain, stiffness, functional limitation and summary score), the lower the forgetting of the joint. The higher the TAS, EQ index and EQ VAS, the higher the forgetting of the joint (Table 2).

Clinical validity was assessed by comparing FJS scores between patients with articular displacement (> 3 mm, n = 54) and patients without articular displacement (≤ 3 mm, n = 46). Patients with (median = 3 8.6, IQR = 12.5/72.9) and without (median = 3 7.5, IQR = 16.6/67.8) articular displacement did not differ in FJS at follow-up evaluation T1 (Z = 0.005, P = 0.996).

We also evaluated clinical validity by comparing the different fracture patterns according to the Letournel classification. We found highest median values for anterior column and posterior hemi-transverse fractures (median = 12.5, n = 11), and lowest levels of the FJS in T-type fractures (median = 72.9, n = 3). However, there were only three patients with a T-type fracture within the study population. There was no significant difference in the FJS between the fracture types according to the Letournel classification (P = 0.795).

There was also no significant difference between the surgical approaches (P = 0.477). Lowest FJS levels (median = 15.6, n = 24) were found in patients undergoing ORIF *via* an ilio-inguinal approach whereas patients with a Kocher-Langenbeck approach reported highest FJS levels (median 33.3, n = 18).

There was a significant difference in FJS (P = 0.019) comparing patients after

Table 1 Patient characteristics at initial assessment (T1)

n = 100	Total
Sex	21 female/79 male
Mean age at follow up T1	57.9 ± 17.6 yr
Intra-articular step	54 > 3 mm/46 < 3 mm
Treatment	78 operative/22 conservative
Approach (open reduction only)	37 anterior/18 posterior
FJS	41.4 ± 29.7
WOMAC-VAS	60.6 ± 63.3
EQ-5D Index	0.90 ± 0.09
EQ-5D VAS	67.8 ± 23.0
TAS	3.6 ± 1.8

FJS: Forgotten Joint Score; WOMAC-VAS: Western Ontario and McMaster Universities Osteoarthritis Index-Visual Analog Scale; EQ-5D: EuroQol-5D; TAS: Tegner Activity Scale.

Table 2 Detailed data on correlation of functional scores indicating a positive rating for convergent validity (*r* = Spearmen's rank correlation coefficient) level of significance *P* < 0.05

FJS	WOM I	WOM II	WOM III	WOM total	EQ Index	EQ VAS	TAS
r	-0.69	-0.68	-0.70	-0.73	0.72	0.60	0.56
P value	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
n	96	96	96	96	96	95	94

FJS: Forgotten Joint Score; WOM: Western Ontario and McMaster Universities Osteoarthritis Score; EQ: EuroQol-5D; VAS: Visual Analog Scale; TAS: Tegner Activity Scale.

conservative treatment (median 68.7, n = 22) to surgically managed patients (median 33.3, n = 78).

Responsiveness

Patients with different hip function development did not significantly differ in FJS at initial assessment ($H_{2, 55}$ = 0.336, P = 0.845). In patients indicating improvement of hip function, the FJS significantly increased (mean difference = 9.4, Z = 3.465, P = 0.001, n = 21). This increase was higher than the SDC of 8.8 and had a small ES of 0.28. In patients indicating worsening of hip function, the FJS significantly decreased (mean difference = 17.1, Z = -2.402, P = 0.016, n = 10). This decrease was higher than the SDC of 8.8 and had a moderate ES of 0.59. Patients indicating no change in hip function did not show differences in FJS (mean difference = 1.1, Z = -0.328, P = 0.743, n = 24, ES = 0.03). Table 3 presents responsiveness data of the FJS.

Interpretability

The proportion of missing FJS item responses was 3.9% (47/1200) at first assessment and 1.2% (8/660) at second assessment. For four patients, the FJS at first assessment could not be computed as they had more than four missing responses and thus, these patients were excluded from data analyses.

There was no relevant floor effect [minimum score of 0: first assessment T1: n = 1 (1%), second assessment T2: n = 1 (1%)] and no relevant ceiling effect [maximum score of 100: first assessment T1: n = 1 (1%), second assessment T2: n = 2 (2%)] for the FJS.

DISCUSSION

The main result of this study is that the FJS is a valid and reliable tool for evaluation of

Table 3 Responsiveness of the Forgotten Joint Score based on the subjective rating of change

	n	FJS first assessment		FJS second assessment		Difference FJS first-second assessment		*P* value	SEM	SDC	ES
		m	SD	m	SD	m	95%CI				
Function improved	21	46.9	34.1	56.2	34.9	-9.4	-13.6–(-5.1)	0.001			0.28
Function unchanged	24	43.8	31.6	42.7	32.6	1.1	-1.9–4.1	0.743	3.2	8.8	0.03
Function worsened	10	37.7	29.0	20.2	13.1	17.1	0.7–33.4	0.016			0.59

FJS: Forgotten Joint Score; SEM: Standard error of measurement; SDC: Smallest detectable change; ES: Effect size.



Figure 2 Initial X-rays of a patient with a both column fracture of the right acetabulum and follow-up X-rays 3.6 years after injury.

PRO in posttraumatic condition after acetabular fracture. The SDC indicating a real clinical improvement after a change of 8.8 points between FJS assessments. We could confirm responsiveness of the FJS and found no relevant floor- or ceiling effects. This is the first study validating FJS in fractures of the hip joint according to the COSMIN checklist.

Study design and patient population

An acetabular fracture is an uncommon but serious injury to the hip joint[2,6,8,9,14,26]. The surgeon-based view on clinical and functional outcomes after acetabular fracture is well documented in literature[1,4,5,26-29]. Operative management has become the standard treatment for displaced fractures[2,6,8,26,28,30]. Even though technical advancements have led to major improvements in management of these injuries, there is still a relevant number of cases leading to poor clinical outcomes[5,6]. The presented outcome studies mainly reflect short-term outcomes with a focus on risk factors leading to early failure with posttraumatic rapid-progressive joint degeneration like quality of reduction or stability of the osteosynthetic fixation[2,4,5,7]. However, there is a variety of symptoms sensed by the patient and the patient's perspective are neglected by most studies on QoL after acetabular fracture[1,2,5,7,8,31]. We chose to include patients with a mid-term result as well as long-term condition in this validating study to represent as many conditions as possible. Demographic data of our patient population is comparable to

other studies on acetabular fractures with an average age of 57.9 years at time of injury[2,32,33]. Again, our population represents the broad spectrum regarding age distribution seen in acetabular fracture patients[33]. The FJS was originally designed for patients after arthroplasty of the knee and hip[11]. Therefore, it is compiled for an older, physically less active patient population. However, recent studies have proven reliability in younger patients[12,13,17-19,34]. The FJS measures the patient's ability to forget the joint in everyday life, which is seen as ultimate goal resulting in maximum patient satisfaction[11]. This concept seems to be a valid construct not just post arthroplasty. We found a mean FJS of 41.6 points in our patient population. Recently, Baumann *et al*[34] published a validation study on the FJS in long-term results of patients in a posttraumatic condition after tibial head fracture in 77 skiers. They found an increased joint awareness of 70.7 points in the FJS 9-13 years after injury. The mean score in the present study was 41 at first assessment indicating that the level of forgetting the joint after acetabular fracture is lower than in patients after tibial head fracture (70.7)[13], anterior cruciate ligament repair (70.1)[12] or even total hip arthroplasty (59.8)[11]. We included patients of all age groups and operative and non-operative treatment. The distribution of our population's Letournel classification of acetabular fractures reflects also typical fracture patterns. Therefore, we assume generalizability for this type of injury.

Validation

There is ongoing discussion about methodical standards in validation studies[15,16,35]. The validation process in the present study was processed following the COSMIN checklist[16]. Along with the prospective multicenter design, the study meets high methodological standards with a level of evidence Ib.

The FJS has been validated in English and has been adapted in French, Dutch, Danish, Japanese, and German language[11,13,17,18,35,36]. All of these publications gave a positive rating on internal consistency with a Cronbach's alpha of 0.95-0.97. We measured a Cronbach's alpha of at least 0.95 in our study. According to Terwee *et al*[15] internal consistency can be confirmed if Cronbach's alpha is greater than 0.70 and below 0.95. Greater values reflect higher correlations among the items and might be an indication for a redundancy of two or more items[15]. Cronbach's alpha is also dependent on the number issues a questionnaire contains; higher values for scores with a higher number of items. The FJS consists of only 12 items. Therefore, it seems that the concept of the FJS with measurement of the joint awareness for every question could be the reason for a high level of internal consistency.

Prior studies reported a test-retest reliability of the FJS between 0.80 and 0.97[13,18,36]. We found perfect test-retest reliability with an ICC of 0.99. We intended to include also patients with a long-term result years after injury. In these cases, we assumed a stable medical condition making the ICC robust. The long period of time between time points T1 and T2 in some cases leading to a SD of 71.4 days is a potential source of bias. However, the anchor-based method to include only patients with a subjective steady medical condition should lead to reliable results from a statistical point of view.

We expected the WOMAC-VAS, TAS, and EQ-5D-3L to be appropriate for evaluation of construct validity, because these scores are widely used and a German language version of all scores was validated for sports related injuries and arthroplasty patients[23,24,37]. We decided to use the WOMAC-VAS score as tool for evaluation of validity because it was used in the original publication of the FJS as well[11]. The FJS showed good correlation to the total score of the WOMAC-VAS as well as to the WOMAC-VAS subscales.

To investigate if a risk factors for rapid-progressive joint degeneration like a residual joint surface step of more than 3 mm might have an impact on patient-centered HR-QoL, we collected data from the initial CT scan in cases of conservative treatment and the post-operative CT scan in operatively treated patients. We expected that a complex fracture pattern or a residual articular step would lead to a lower level of forgetting the joint because of inflammation of the joint. However, we did not find any impact of the fracture pattern according to Letournel or an articular surface step of more than 3 mm in the CT scan on the FJS at time of the validation study. This is probably due to the long period mean time between injury and mean follow-up of more than 5 years. It is likely that the patients with a clinically relevant joint step develop joint degeneration within the first two years after injury (n = 4/100). The other patients with an initial articular step might have sustained a consolidation in functional joint kinetics to a sub-clinical degree. From our perspective, this is an interesting finding and is worth further investigating.

However, we did find a difference between surgical and conservative management. Patients after conservative management reported higher levels in the FJS than

surgically treated patients. We recommended conservative management with partial weight bearing only in cases with no dislocation of the fragments. We suspect that this reflects a potential selection bias for conservatively treated patients.

Another important issue for the use of PROMs for further prospective trials is responsiveness to change in medical condition. With a lack of gold standard, defining responsiveness is difficult. According to the COSMIN checklist, we assessed responsiveness in patients by Wilcoxon tests and ES[16]. The FJS score has shown good responsiveness in post-arthroplasty conditions longer than 12 mo post-operatively[11,13,38]. In this study, patients indicating no change in function of the hip, FJS scores did not significantly differ, and the mean differences was with 1.1 below the SDC of 8.8. In patients indicating a change in medical condition of the hip, FJS scores significantly differed between both assessments and the mean differences were above the computed SDC. Therefore, we could give a positive rating for responsiveness.

According to the guidelines of the original FJS publication in 2012, we refused to calculate the FJS if more than four items were missing. The overall proportion of missing items of the FJS was 4% at first assessment. Concordant to all prior studies on the FJS, there was no relevant floor- or ceiling effect[11,12,17,18,35,36,38].

Limitations

The findings of this study have to be seen in the light of some limitations. First of all, the limited number of cases. Acetabular fractures are uncommon and treatment is concentrated to large trauma centers. We assume that our population can be seen as reference population for most centers, since our age distribution is relatively broad and we included conservatively and operatively treated patients to reflect clinical reality. Another limitation is that the time span between first and second evaluation showed quite some variability. Although we put major efforts on guidance of the patients to assure highest methodical quality, there is a natural variation in the recorded data. Finally, calculation of ICC was based on only 24 patients. This was the number of patients who indicated no relevant clinical change in medical condition of their hip joint between T1 and T2. Further studies are needed to confirm the results based on longitudinal data.

CONCLUSION

This is the first study validating FJS in fractures of the hip joint according to the COSMIN checklist. The FJS is a valid and reliable tool for evaluation of PRO in posttraumatic condition after acetabular fracture. With a Cronbach's alpha of 0.95, internal consistency of the questionnaire was good. Test-retest reliability was excellent with an ICC of 0.99. Based on the anchor variable, the SDC indicating a real clinical improvement was 8.8 points in the FJS. We could confirm responsiveness of the FJS and found no relevant floor- or ceiling effects. Clinicians are suggested to use the FJS for evaluation of PRO after fractures of the acetabulum.

ARTICLE HIGHLIGHTS

Research background

Patient-reported outcome (PRO) measurement is gaining more and more importance in clinical decision-making. Evaluation of psychometric properties of PRO tools is essential to assure validity.

Research motivation

A fracture of the acetabulum is an uncommon but serious injury. Outcome evaluation tools in patients after acetabular fractures are outdated. However, research based on large registries are dependent on valid outcome tools to allow the comparability.

Research objectives

Aim of the study was to validate the Forgotten Joint Score (FJS) according the COSMIN checklist. The FJS is a novel PRO tool to disease-specific quality of life in musculo-skeletal disorders.

Research methods

The COSMIN checklist is a standard protocol to assure methodical quality of validation studies. The COSMIN checklist consists of ten items giving recommendations for design, conduction and interpretation of medical validation studies. Relevant characteristics are study design, content validity, structural validity, internal consistency, cross-cultural validity/measurement invariance, reliability, measurement error, criterion validity, hypotheses testing for construct validity, and responsiveness.

Research results

We found the FJS to be a valid and reliable tool for evaluation of PRO in posttraumatic condition after an acetabular fracture. With a Cronbach's alpha of 0.95, internal consistency of the questionnaire was good. Test-retest reliability was excellent with an ICC of 0.99. Based on the anchor variable, the smallest detectable change indicating a real clinical improvement was 8.8 points in the FJS. We could confirm responsiveness of the FJS and found no relevant floor- or ceiling effects.

Research conclusions

Clinicians are suggested to use the FJS for evaluation of PRO after fractures of the acetabulum.

Research perspectives

Further studies are needed to confirm the study results, especially concerning longitudinal data. Based on the study results, the FJS can now be used for further clinical studies on post-traumatic conditions after fractures of the acetabulum.

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ORIGINAL ARTICLE

Observational Study

Interobserver and intraobserver agreement for Letournel acetabular fracture classification system using 3-dimensional printed solid models

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Author contributions: Keltz E drafted the manuscript; Keshet D participated in study design, data collection and analysis, and was the coordinator of this multicenter research; Keren Y initiated the study, designed it and supervised it; Peled E and Norman D contributed in collecting cases and providing consultation; Zvi Y assisted in coordinating the multicenter logistics and drafting the manuscript.

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Abstract

BACKGROUND

Acetabular fractures pose diagnostic and surgical challenges. They are classified using the Judet-Letournel system, which is based solely on X-ray. However, computed tomography (CT) imaging is now more widely utilized in diagnosing these injuries. The emergence of 3-dimensional (3-D) printing technology in varying orthopedic fields has provided surgeons a solid model that improves their spatial understanding of complex fractures and ability to plan pre-operatively.

AIM

To evaluate the reliability of the Judet-Letournel classification system of acetabular fractures, when using either CT imaging or 3-D printed models.

METHODS

Seven patients with acetabular fractures underwent pelvic CT imaging, which was then used to create solid, 3-D printed models. Eighteen orthopaedic trauma surgeons responded to questionnaires regarding fracture classification and preferred surgical approach. The same questionnaire was completed using only CT imaging, and two weeks later, using only 3-D printed models. The inter- and intra-observer agreement rates were then analyzed.

RESULTS

receive any funding in any form for this study and related topics. There is no conflict of interest what so ever.

Data sharing statement: Technical appendix, statistical code, and dataset available from the corresponding author at erankeltz@gmail.com. Participants consent for data sharing was not obtained but the presented data are anonymized and risk of identification is low.

STROBE statement: The authors have read the STROBE Statement-checklist of items, and the manuscript was prepared and revised according to the STROBE Statement-checklist of items.

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Inter-observer agreement rates based on CT imaging or 3-D printed models were moderate for fracture classification: κ = 0.44, κ = 0.55, respectively ($P < 0.001$) and fair for preferred surgical approach: κ = 0.34, κ = 0.29, respectively ($P < 0.005$). Intra-observer agreement rates for fracture classification and preferred surgical approach comparing CT imaging or 3-D printed models were moderate: κ = 0.48, κ = 0.41, respectively. No significant difference in intra-observer agreement was detected when comparing orthopedic pelvic specialists to general orthopedic traumatologists.

CONCLUSION

The Judet-Letournel classification demonstrated only moderate rates of agreement. The use of 3-D printed models increased the inter-observer agreement rates with respect to fracture classification, but decreased it with respect to the preferred surgical approach. This study highlights the role of 3-D printed models in acetabular fractures by improving spatial understanding of these complex injuries, thus providing more reliable fracture diagnoses and alternative viewpoints for pre-operative planning.

Key Words: Acetabulum; Pelvic trauma; Acetabular fracture; Three-dimensional printing; Three-dimensional reconstruction; Judet-Letournel

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Core Tip: Three-dimensional (3-D) imaging and printing is an emerging technique in the field of orthopedic surgery. This study highlights the utility of 3-D printing in the treatment of complex acetabular fractures, as it relates to the traditionally used Judet-Letournel classification and the accustomed surgical approaches.

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INTRODUCTION

Acetabular fractures pose a great diagnostic challenge due to the complexity and variability of each fracture pattern. Treatment, whether conservative or surgical, is influenced by the initial diagnosis of the fracture pattern and classification. Therefore, it is essential that these fractures are accurately characterized before decision making[1-4]. The Judet-Letournel classification system for acetabular fractures is the current gold standard for describing these injuries. The system is based on the theory of anterior and posterior walls and columns within the acetabulum[5,6]. Based on this anatomical description, they described five elementary fracture patterns and five associated fracture patterns.

The Judet-Letournel classification system was described using specific pelvic radiographs, termed Judet views, which include iliac oblique and obturator oblique views[5]. However today, most trauma centers perform computed tomography (CT) for high-energy or polytrauma patients. Using these CT scans, three-dimensional (3-D) reconstructions are created, and have become standard diagnostic tools in many trauma centers (Figure 1). Studies have shown that using two-dimensional (2-D) and 3-D CT reconstructions enable improved understanding of fracture patterns and anatomy, in particular with complex pelvic and acetabular fractures[7,8]. Some novel CT-based classification systems have been proposed as well[9], challenging traditional methods.

3-D printing technology can utilize 3-D CT reconstructions to manufacture a tangible model out of a variety of materials, ranging from plastics to metals. This technology is becoming more widespread in various industries, thus making it more affordable and accessible[10,11]. 3-D printing first entered the field of medicine in the

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early 2000s, when dental implants and tailored prostheses were produced. The use of this technology had increased substantially in several areas of medicine, creating anatomic models, prostheses, implants, and other accessories[12,13].

In orthopedic surgery, 3-D printing has been used both for surgical planning as well as patient specific instrumentation (PSI). PSI utilizes 3-D printing to manufacture instrumentation that is unique to a patient's anatomy. Its use has been reported on in varying fields of orthopedics including arthroplasty, orthopedic oncology, trauma, and spine surgery. Several studies have demonstrated that the use of 3-D printed models and implants decreased operative time and improved patient outcomes[14-18].

The reliability of the Judet-Letournel classification has been investigated in several trauma centers. Previous studies evaluating inter-observer agreement of acetabular fractures based on CT scans demonstrated high variability between studies and their reported rates of agreement, with a range of $\kappa = 0.6\text{-}0.7$[7,19-21].

To our knowledge, the use of 3-D printed models to test the reliability of the Judet-Letournel classification system has not yet been reported on in the literature. Therefore, we raised the hypothesis that the use of 3-D printed models of acetabular fractures may improve the interobserver and intraobserver agreement of fracture classification, and influence surgeons' preferred surgical approach.

MATERIALS AND METHODS

Seven patients with varying acetabular fractures that were surgically treated at our institution were included. No initial attempt was made to characterize them according to Letournel's system. Each patient underwent non-contrast CT imaging of the pelvis with 3-D reconstructions. The CT images of each patient were de-identified and assigned a coded number (Figure 2). Each case was stored onto several portable drives and distributed to the reviewing physicians.

3-D printed models of the fractured acetabuli were produced, using a UP Plus 2 3-D printer (PP3DP, United States), using Acrylonitrile Butadiene Styrene (ABS), a chemical compound $(C_8H_8)_x \cdot (C_4H_6)_y \cdot (C_3H_3N)_z$. Technical limitations mandated a 0.6-0.8/1 ratio of model to real size. The models were engraved with serial numbers (Figure 3). An encoding table was created, with the legend available only to the statistician following data collection. This was a blinded study in that reviewing surgeons were unable to identify which CT scan corresponded to each 3-D printed model.

Eighteen orthopedic trauma surgeons from various hospitals in Israel were selected. Nine of those surgeons specialize in pelvic and acetabular injuries and routinely operate on these injuries. The other nine orthopedic trauma surgeons do not routinely operate on pelvic and acetabular injuries. Each participating surgeon completed the same questionnaire twice. Initial responses were based only off of CT images. They then completed the same questionnaire two weeks later using only the 3-D printed models. They were asked to answer the following two questions: (1) What is the fracture type according to Judet-Letournel classification system? and (2) What is the preferred surgical approach for each case?

Statistical analysis

In order to comply with previous literature, the (Cohen's) Kappa coefficient was used to evaluate Interobserver Agreement between all participants with respect to fracture classification and corresponding preferred surgical approach using either CT images or 3-D printed models. Intraobserver Agreement was also tested for each individual surgeon with respect to fracture classification and corresponding preferred surgical approach using either CT images or 3-D printed models. For each of these parameters a correlation test was performed between the two abovementioned groups of surgeons.

In order to calculate the inter-observer agreement between the various examiners with respect to fracture classification using either CT images or 3-D printed models, we compared each individual's responses to the remaining examiners' responses. This was done for each test that was performed. The number of matches was then correlated to the number of comparisons made (removing duplicate matches), and the results from each imaging method were compared using a Wilcoxon signed-rank test. Statistical analyses were performed using SPSS program (version 20, IBM), with a *P* value below 0.05 considered significant.



Figure 1 Computed tomography 3-dimensional reconstruction of an acetabular fracture.

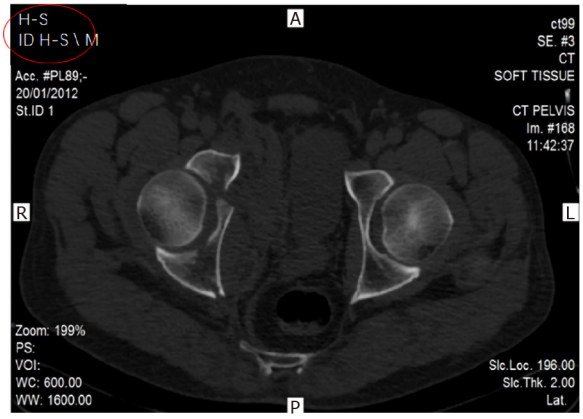


Figure 2 Computed tomography image: an axial cross-section illustrating a right acetabular fracture. Circled in red is the anonymously assigned coding of the case. All identifying details have been omitted from the test.



Figure 3 Three-dimensional printed models of acetabular fractures.

RESULTS

Seven cases of acetabular fractures were selected with differing levels of complexity, at the discretion of the authors. The eighteen participating surgeons examined all CT scans two weeks before the 3-D printed models were examined. The results from all questionnaires are shown in Tables 1-4 and Figures 4 and 5.

The inter-observer agreement regarding fracture classification based on CT and 3-D models was moderate: $\kappa = 0.44$ (SE range: 0.0-0.24) and $\kappa = 0.55$ (SE range: 0.0-0.22) respectively, with a statistically significant difference between the two modalities ($P <$

Table 1 Inter-observer agreement on classification, based on computed tomography or 3-dimensional printed models

Fx classification							
		CT			3-D model		
#Surgeon	Match pairs	Mean kappa	SE min	SE max	Mean kappa	SE min	SE max
Mean	153	0.44	0.00	0.24	0.55	0.00	0.22
1	17	0.06	0.06	0.20	0.54	0.17	0.21
10	17	0.22	0.04	0.23	0.41	0.15	0.20
7	17	0.24	0.04	0.20	0.65	0.15	0.22
4	17	0.35	0.06	0.21	0.58	0.15	0.20
12	17	0.36	0.17	0.22	0.26	0.14	0.22
16	17	0.40	0.13	0.22	0.61	0.15	0.20
17	17	0.41	0.11	0.22	0.68	0.15	0.21
14	17	0.42	0.11	0.24	0.60	0.14	0.21
8	17	0.45	0.14	0.22	0.56	0.16	0.20
9	17	0.48	0.10	0.24	0.69	0.00	0.21
6	17	0.50	0.11	0.24	0.54	0.17	0.21
15	17	0.52	0.14	0.22	0.51	0.16	0.21
3	17	0.56	0.11	0.24	0.55	0.15	0.21
11	17	0.57	0.00	0.22	0.69	0.00	0.21
18	17	0.57	0.00	0.22	0.40	0.16	0.21
2	17	0.60	0.00	0.24	0.69	0.00	0.21
5	17	0.60	0.00	0.24	0.44	0.14	0.21
13	17	0.66	0.00	0.24	0.58	0.15	0.20

CT: Computed tomography; 3-D: Three-dimensional; Fx: Fracture.

0.001). The inter-observer agreement regarding the preferred surgical approach based on CT and 3-D models was fair: κ = 0.34 and κ = 0.29 (SE range: 0.0-0.39), with a statistically significant difference between the two modalities ($P < 0.005$) (Tables 1 and 2, Figure 4).

The intra-observer agreement regarding fracture classification among all 18 surgeons when comparing the two imaging modalities was moderate: κ = 0.48. The surgeons specializing in pelvic and acetabular injuries demonstrated a slightly lower rate of agreement (κ = 0.45) when compared to the general orthopedic trauma specialists (κ = 0.50), though this difference was not statistically significant ($P = 0.592$). The intra-observer agreement regarding the preferred surgical approach among all the surgeons when comparing the two imaging modalities was moderate: κ = 0.41. The surgeons specializing in pelvic and acetabular injuries demonstrated a lower rate of agreement (κ = 0.37) when compared to the general orthopedic trauma specialists (κ = 0.50), though this difference was also not statistically significant ($P = 0.33$) (Tables 3 and 4, Figure 5).

After examining the 3-D printed models, surgeons changed their initial responses regarding fracture classification and preferred surgical approach 56 out of 126 times (44%), and 44 out of 126 times (35%), respectively (Table 4). There were no significant differences between the two groups of specialists in this respect (Table 3).

A large variability in responses amongst the cases was evident. For case 2, only three (17%) reviewers changed their decision regarding fracture classification, and only one (6%) reviewer with respect to preferred surgical approach. In contrast, for case 5, fourteen (78%) reviewers changed their response regarding fracture classification, and 9 (50%) reviewers with respect to preferred surgical approach (Table 4).

A total of 70 out of 126 (55.5%) responses regarding fracture classification using CT imaging alone were not changed after examination of the 3-D models. However, in

Table 2 Inter-observer agreement on surgical approach, based on computed tomography or 3-dimensional printed models

Surgical approach							
		CT			3-D Model		
#Surgeon	Match pairs	Mean kappa	SE min	SE max	Mean kappa	SE min	SE max
Mean	153	0.35	0.00	0.39	0.30	0.00	0.39
17	17	0.18	0.17	0.32	0.43	0.00	0.39
12	17	0.18	0.16	0.31	0.09	0.11	0.24
9	17	0.25	0.19	0.31	0.34	0.16	0.36
14	17	0.28	0.16	0.39	0.29	0.15	0.36
15	17	0.31	0.18	0.27	0.25	0.13	0.23
16	17	0.31	0.00	0.36	0.43	0.15	0.35
18	17	0.31	0.00	0.36	0.20	0.17	0.29
10	17	0.32	0.19	0.28	0.19	0.16	0.29
8	17	0.33	0.21	0.30	0.33	0.18	0.24
3	17	0.36	0.18	0.36	0.29	0.17	0.26
2	17	0.36	0.20	0.28	0.35	0.15	0.30
11	17	0.39	0.20	0.27	0.26	0.16	0.28
6	17	0.41	0.18	0.32	0.21	0.19	0.32
1	17	0.41	0.00	0.30	0.43	0.00	0.39
4	17	0.41	0.00	0.30	0.35	0.11	0.26
7	17	0.44	0.20	0.32	0.37	0.19	0.30
5	17	0.50	0.00	0.39	0.24	0.14	0.36
13	17	0.50	0.00	0.39	0.30	0.13	0.39

CT: Computed tomography; 3-D: Three-dimensional.

22.8% of these cases the examiners changed their responses regarding the preferred surgical approach. Of the remaining 56 out of 126 (44.5%) responses that were changed regarding fracture classification, 50% of these surgeons changed their response regarding the preferred surgical approach (Table 4 and Figure 5).

DISCUSSION

The primary outcome of this study demonstrated that 3-D printed models of 7 different acetabular fractures significantly increased inter-observer agreement with respect to fracture classification, while decreasing inter-observer agreement with respect to preferred surgical approach. The use of 3-D printed models did not demonstrate significant difference in intra-observer agreement for both fracture classification and preferred surgical approach. No significant difference in intra-observer agreement for fracture classification and preferred surgical approach was detected when analyzing responses from pelvic and acetabular specialists and general orthopedic traumatologists, separately.

The Judet-Letournel classification system for acetabular fractures is widely used and establishes an algorithm for surgical treatment. This classification system is based on X-ray imaging using Judet views[5]. However, with the prevalent use of CT imaging, most patients with pelvic or actebular injuries are not treated without review of this advanced imaging modality.

Numerous studies have evaluated the reliability and effectiveness of the Judet-Letournel classification system[7,8,19-21], using plain radiographs, 2-D and 3-D CT imaging. We've raised the hypothesis that 3-D printed solid models could contribute to the spatial understanding of these highly complex and variable fractures. The use of

Table 3 Intra-observer agreement on classification and surgical approach, between computed tomography and 3-dimensional printed models

#Surgeon		Fx classification					Surgical approach				
1	1	-0.02					0.70				
2	1	0.50					0.18				
3	1	0.50					0.32				
4	1	0.50					0.55				
5	1	0.83					0.36				
6	1	0.48					0.28				
7	1	0.32					0.77				
8	1	0.66					0.34				
9	1	0.67					0.22				
10	1	0.22					0.40				
11	1	0.50					0.58				
12	1	0.49					0.25				
13	1	0.66					1.00				
14	1	0.50					0.70				
15	1	0.64					0.15				
16	1	0.48					0.19				
17	1	0.32					0.16				
18	1	0.35					0.19				
		Mean	**Median**	**Min**	**Max**	***P* value**	**Mean**	**Median**	**Min**	**Max**	***P* value**
Total	18	0.48	0.50	-0.02	0.83	0.592	0.41	0.33	0.15	1.00	0.331
Pelvis	9	0.45	0.50	-0.02	0.83		0.37	0.25	0.15	1.00	
Trauma	9	0.50	0.50	0.22	0.67		0.45	0.36	0.18	0.77	

3-D printed models affords surgeons a more comprehensive spatial understanding of these injuries, thus improving their ability to plan pre-operatively. Advancement in 3-D printing technology has allowed a relatively simple way to create a real-size detailed model of a fractured acetabulum.

In contrast to previous studies involving a single medical center, this study recruited eighteen surgeons from numerous level 1 trauma centers in the nation, many of who regularly perform complex operations of the acetabulum. Our intention was to provide an accurate and generalizable picture regarding the reliability of the Judet-Letournel classification system. When we asked the surgeons to classify these fractures and provide their preferred surgical approach, our premise was that there is no "correct" answer, and that the agreement rate would be the sole reference.

Tables 1 and 2 demonstrates a moderate rate of agreement regarding the fracture classification based on CT imaging. This rate is lower than reported on previous literature[7,8,10]. One explanation might be that the fractures selected for this study were more complex and difficult to assess. Another explanation is the fact that the participating surgeons work at different medical centers. There's an element of habit and common practice at each medical center, or unified training under the same pelvic specialist, which may create a bias.

The degree of inter-observer agreement for the fracture classification based on the 3-D printed models was found to be only slightly higher, though still moderate. Although both imaging modalities were within moderate agreement, the difference between them was statistically significant ($P < 0.001$). The higher rate of agreement using the 3-D printed models is likely a result of the improved spatial visualization and understanding of each fracture and the possibility to examine each one from different viewpoints.

The inter-observer agreement rate among all the surgeons regarding the preferred

Table 4 Reviewers' change of decision (computed tomography *vs* 3-dimensional model)

#Surgeon	Total decisions	Fracture classification		Surgical approach	
		Number of decisions changed	% of decisions changed	Number of decisions changed	% of decisions changed
1	7	6	86	1	14
2	7	3	43	4	57
3	7	3	43	3	43
4	7	3	43	2	29
5	7	1	14	2	29
6	7	3	43	3	43
7	7	4	57	1	14
8	7	2	29	3	43
9	7	2	29	3	43
10	7	5	71	3	43
11	7	3	43	2	29
12	7	3	43	3	43
13	7	2	29	0	0
14	7	3	43	1	14
15	7	2	29	4	57
16	7	3	43	3	43
17	7	4	57	3	43
18	7	4	57	3	43
Total	126	56	44	44	35
Pelvis	63	29	46	20	32
Trauma	63	27	43	24	38

surgical approach according to CT imaging (Tables 1 and 2) was found to be fair. This is in contrast to a slightly lower, yet still fair, rate of agreement when using the 3-D models, which was statistical significant (P = 0.005). This can be explained by the fact that different surgeons may decide to approach the same fracture using different methods. Varying personal preferences among each surgeon can explain the lower rate of agreement when compared to that of fracture classifications. The higher agreement rate for the surgical approach when using CT *vs* 3-D models may be due to various options revealed to a surgeon when holding a model in his hand. We believe that, in this respect, use of the 3-D printed models raises a more innovative way of thinking and undermines previous decision making patterns. Simply put, one might say that more information may only contribute to a problem's complexity.

The intra-observer agreement regarding the fracture classification and the preferred surgical approach based on CT imaging *vs* 3-D printed models was moderate (Table 3), with no significant difference between pelvic and trauma specialists in both parameters. Table 4 demonstrates the variance between the cases chosen for the study. It can be assumed that in some cases, the complex fractures posed a greater diagnostic challenge for the reviewers and raised more questions regarding surgical approaches. Another explanation for this can be attributed to technical reasons. Some non-displaced fracture lines, which can be identified through CT imaging, might have been "obliterated" in the printing process and are difficult to identify in the solid models. A higher resolution printer, larger scales, or possibly other modalities (*e.g.*, 3-D holograms) may serve to reduce this effect.

Figure 5 illustrates the surgeons' decision-making process regarding the appropriate surgical approach for each classified fracture, once the 3-D printed models were examined. Although 56% maintained the same fracture classification, 13% of those surgeons decided to change their preferred surgical approach. In our view, this

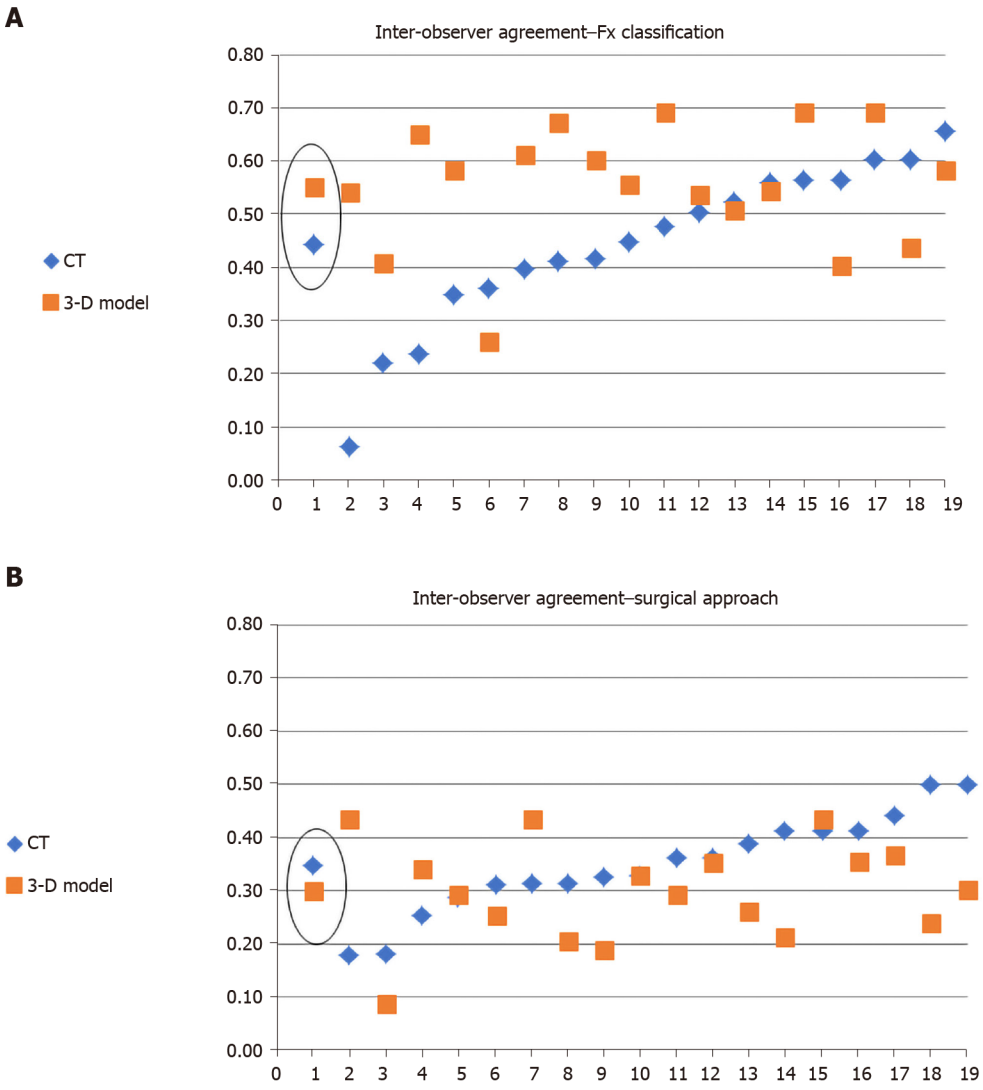


Figure 4 Mean Kappa rate describing agreement between reviewers regarding the fracture classification and preferred surgical approach using computed tomography and 3-dimensional printed models (mean kappa in circle). A: The fracture classification; B: The preferred surgical approach. CT: Computed tomography; 3-D: Three-dimensional; Fx: Fracture.

represents a significant insight into how a fracture is evaluated, and moreover, how it would be addressed surgically. Our findings demonstrate that the Judet-Letournel classification system does not comprise all the information surgeons need for their decision-making. It is likely that the 3-D printed models provide additional information that affects a surgeon's preferred surgical approach.

The collected data did not demonstrate significant differences between the pelvic specialists and general orthopedic traumatologists in all parameters. Presumably, as part of their work, trauma specialists who do not regularly operate on acetabular fractures are still thoroughly familiar with the theoretical material.

CONCLUSION

The results of this study indicate that the currently accepted Judet-Letournel classification system for acetabular fractures demonstrates only moderate rates of agreement by CT imaging alone. Use of 3-D printed models increased the interobserver agreement rates with respect to fracture classification, however decreased the interobserver agreement rates with respect to the preferred surgical approach. Due to the inherent anatomical complexity of acetabular fractures, these models allow for improved visuospatial understanding of these fractures and enable more accurate classification. Additionally, the 3-D printed models allow surgeons to examine a fracture from infinite perspectives and consider the best surgical approach

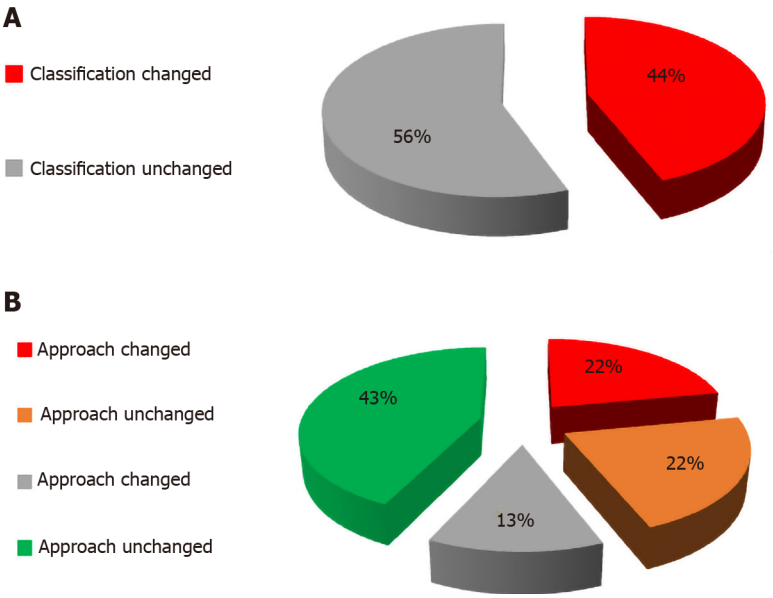


Figure 5 Decision change regarding the surgical approach. A: The effect of reviewing the 3-dimensional model; B: Division of the subgroups demonstrates a change in surgical approach in double rates when the classification is also changed.

before operating. The ability of a surgeon to hold a 3-D model in his hands as part of the preoperative planning process can improve their decision-making. This surgical aid may stimulate renewed thinking of fracture diagnosis and preferred surgical approaches for acetabular fractures, and may contribute to improved surgical outcome.

ARTICLE HIGHLIGHTS

Research background

There are numerous studies examining the reliability of the Judet-Letounel classification system for acetabular fractures using traditional radiographs and computed tomography (CT). However, 3-dimensional (3-D) printing is an emerging technology that hasn't been thoroughly investigated in the field of orthopedics in terms of imaging and pre-operative planning.

Research motivation

We evaluated the intra and inter-observer reliability of the Judet-Letournel classification system, with respect to fracture classification and preferred surgical approach. We compared the use of 3-D printed models of acetabular fractures to the current standard use of CT scans.

Research objectives

The study aims to illustrate the added value of 3-D printed models as a reliable method to more accurately characterize a patient's acetabular fracture, and aid in the decision regarding the preferred surgical approach.

Research methods

Seven patients with acetabular fractures underwent a CT scan with 3-D reconstructions. We then created 3-D printed models of the fractured acetabula. Eighteen trauma surgeons were surveyed to classify each fracture and identify their preferred surgical approach, on two separate occasions, using one of each imaging modality alone.

Research results

The inter-observer agreement regarding fracture classification based on CT and 3-D printed models was moderate for both: $\kappa = 0.44$ (SE range: 0.0-0.24), and $\kappa = 0.55$ (SE range: 0.0-0.22), respectively; this difference was statistically significant ($P < 0.001$).

The inter-observer agreement regarding the preferred surgical approach based on CT and 3-D printed models was fair for both: $\kappa = 0.34$, and $\kappa = 0.29$ (SE range: 0.0-0.39), respectively; this difference was statistically significant ($P < 0.005$). The intra-observer agreement regarding fracture classification among all 18 surgeons when comparing the two imaging modalities was moderate: $\kappa = 0.48$, as for the preferred surgical approach: $\kappa = 0.41$.

Research conclusions

3-D printed models improve the inter-observer reliability of the Judet-Letournel classification system, when compared to the use of standard CT scans. However, the inter-observer agreement regarding the surgical approach was decreased, likely due to the added perspective and visualization of the fractures.

Research perspectives

3-D printed models improve visuospatial understanding of complex fractures. Its utility and contribution for better patient outcomes should be investigated in future prospective randomized controlled trials.

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ABOUT COVER

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AIMS AND SCOPE

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OPINION REVIEW

COVID-19 and its effects upon orthopaedic surgery: The Trinidad and Tobago experience

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Abstract

The World Health Organisation (WHO) declared coronavirus disease 2019 (COVID-19) a pandemic on March 11, 2020. COVID-19 is not the first infectious disease to affect Trinidad and Tobago. The country has faced outbreaks of both Chikungunya and Zika virus in 2014 and 2016 respectively. The viral pandemic is predicted to have a significant impact upon all countries, but the healthcare services in a developing country are especially vulnerable. The Government of Trinidad and Tobago swiftly established a parallel healthcare system to isolate and treat suspected and confirmed cases of COVID-19. Strick 'lockdown' orders, office closures, social distancing and face mask usage recommendation were implemented following advice from the WHO. This approach has seen Trinidad and Tobago emerge from the second wave of infections, with the most recent Oxford COVID-19 Government Response Tracker report indicating a favourable risk of openness index for the country. The effects of the pandemic on the orthopaedic services in the public and private healthcare systems show significant differences. Constrained by shortages in personal protective equipment and inadequate testing facilities, the public system moved into emergency mode prioritizing the care of urgent and critical cases. Private healthcare driven more by economic considerations, quickly instituted widespread safety measures to ensure that the clinics remained open and elective surgery was not interrupted. Orthopaedic teaching at The University of the West Indies was quickly migrated to an online platform to facilitate both medical students and residents. The Caribbean Association of Orthopedic Surgeons through its frequent virtual meetings provided a forum for continuing education and social interaction amongst colleagues. The pandemic has disrupted our daily routines leading to unparalleled changes to our lives and livelihoods. Many of these changes will remain long after the pandemic is over, permanently transforming the practice of orthopaedics.

Trinidad and Tobago

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Core Tip: A government-led disciplined response to coronavirus disease 2019 (COVID-19) is an essential component in the fight against this pandemic. Orthopedic surgeons have been at the forefront of the struggle, maintaining essential surgical services while ensuring the safety of the public. Developing countries with under-resourced healthcare facilities have fared far better than many developed countries. In this war against COVID-19 the resilience and innovative spirit of the people may be our most effective weapons.

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INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 was first reported from Hubei province of the People's Republic of China in December 2019[1,2]. This highly infectious pathogen named coronavirus disease 2019 (COVID-19) rapidly spread throughout many countries, compelling the World Health Organisation to declare it a pandemic on March 11, 2020[3,4].

The beautiful islands of the Caribbean have not been spared the effects of COVID-19 with Trinidad and Tobago reporting its first case on March 12, 2020[5]. The Republic of Trinidad and Tobago is a twin-island state covering 1980 sq miles and located just 6.8 miles off the coast of northeastern Venezuela. Classified as a developing country, it has a population of 1363985 and is world-renowned for its colorful carnival, steelpan and Pitch Lake[6]. The healthcare system of Trinidad and Tobago includes both public and private sectors (Figure 1). Public healthcare is centrally funded, delivering its services, free at the point of access through five Regional Health Authorities; conversely the private sector operates on a fee for service basis[7,8] (Figure 2).

The response from the Government of Trinidad and Tobago (GoRTT) to the virus was quick and decisive, with infected cases and those persons exposed being placed in state quarantine. The country's international borders were closed on March 22, 2020 and a national stay-at-home order put in place from March 30, 2020, resulting in a "lockdown" of the country. A parallel public health system consisting of separate and independent tiered medical facilities, staff and laboratories was established to treat persons in state quarantine, while allowing the normal public health system to serve the needs of the rest of the population. These measures resulted in an initial flattening of the curve, and Trinidad and Tobago was ranked number one by the Oxford COVID-19 Government Response Tracker (OxCGRT) in a report published by the University of Oxford on May 1, 2020[9].

In an attempt to restart the economy the Prime Minister announced plans to lift restrictions on a six-tier phased basis beginning on May 10, 2020. The announcement of General Elections on July 3, 2020 signaled the start of an intense election campaign, marred by numerous breaches of the public health safety protocols. Leading up to Election Day, there was a gradual increase in daily confirmed cases and on August 15, 2020, five days after elections, the Chief Medical Officer confirmed that there was now community spread of COVID-19 in Trinidad and Tobago[10].

The GoRTT has maintained a lively response to the pandemic, with the OxCGRT derived Stringency Index trend for TnT mirroring the daily reported new cases of infection. At the time of writing we are emerging from the second wave of infections which started on July 20, 2020 with case 139, with a total of 7115 confirmed cases and 125 deaths (Figure 3). As our country returns to some semblance of normalcy we have seen a relaxation of the lockdown restrictions and our Risk of Openness Index (previously 'Lockdown Rollback Checklist') indicates a favorable environment to

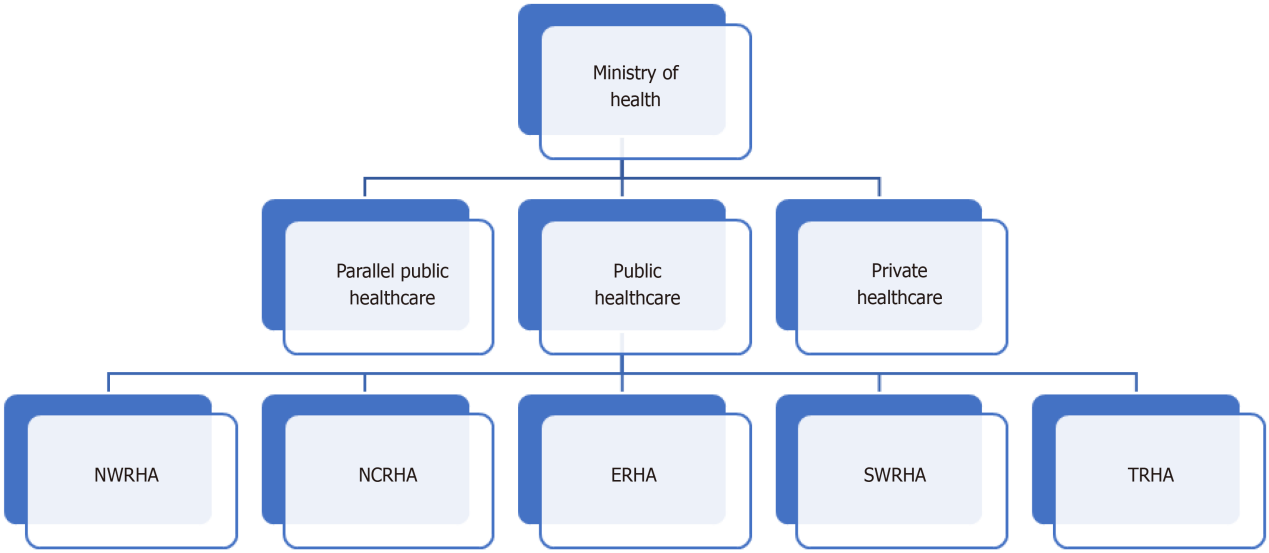


Figure 1 Organisation structure of the Trinidad and Tobago Healthcare System. NWRHA: North West regional health authority; NCRHA: North central regional health authority; ERHA: Eastern regional health authority; SWRHA: South West regional health authority; TRHA: Tobago regional health authority.

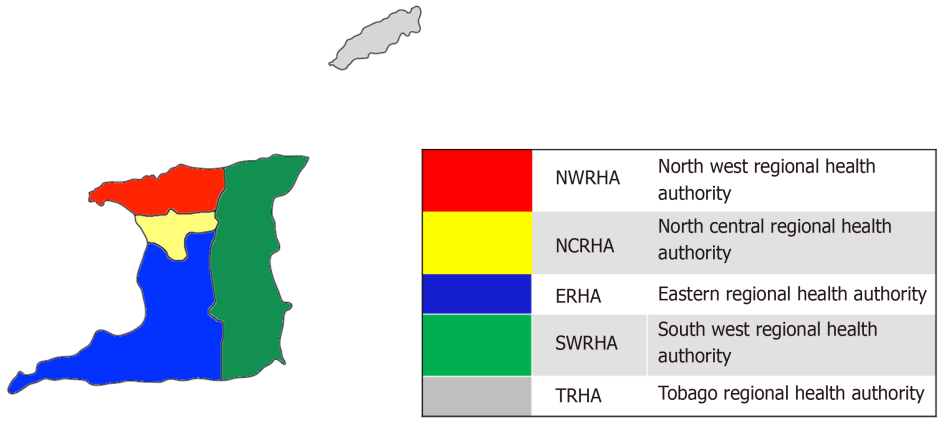


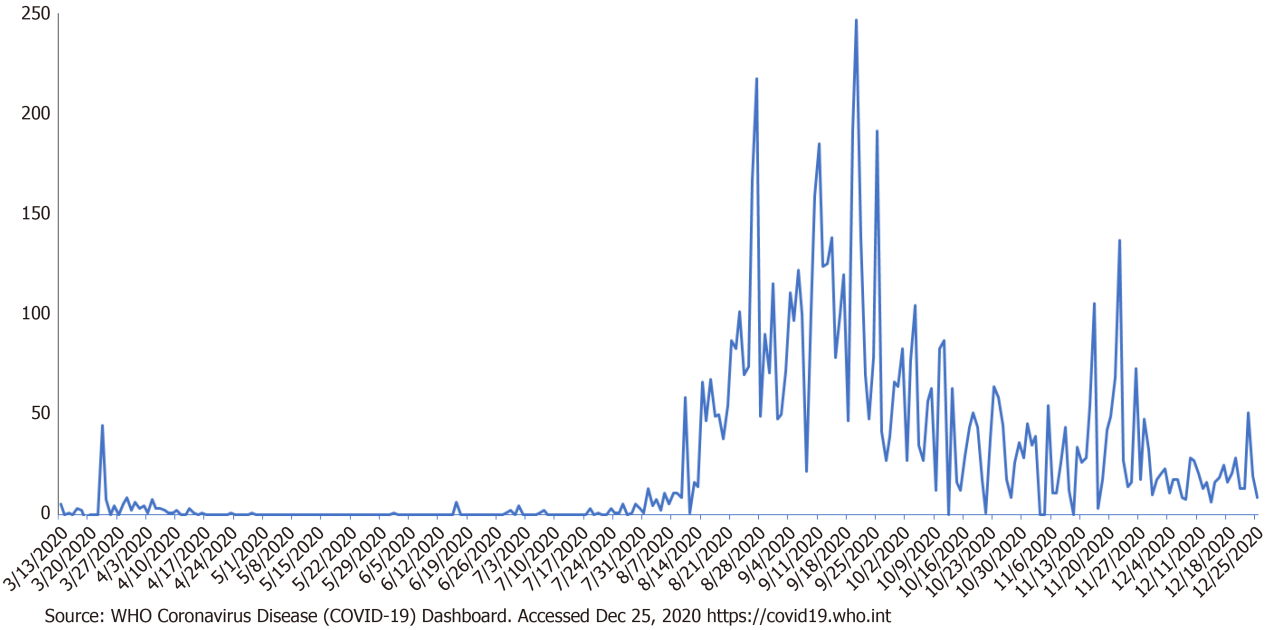
Figure 2 Map showing the geographic range of the Regional Health Authorities.

reopening[11].

Effects on public sector services

With the arrival of the first case of COVID-19 on the shores of Trinidad and Tobago, we noted a drop in clinic attendance as patients tended to avoid the hospital environment for fear of becoming infected. In addition, to reduce unnecessary crowding in the clinics, only patients requiring urgent consultation or follow up were given appointments. The patient medical records and referral letters were screened to identify such patients considered as high priority cases, which mostly consisted of patients with fractures, infections and cases of malignancy.

In accordance with public health recommendations, high visibility physical distancing signage was placed in the clinic waiting area and patients were required to wear face masks and wash their hands before being seen. Appointments in 20 min slots were also instituted to allow separation of persons by time. Only one family member was permitted to accompany a patient and children were not allowed in the clinic. Before entering the consultation room each patient had their temperature taken with an infrared scanner and medical personnel wore face masks and/or face shields during consultation. To further reduce patient traffic in the hospital, only essential imaging was requested and patients were encouraged to practice home based physical therapy. All non-urgent surgery was postponed and temporary measures such as



Source: WHO Coronavirus Disease (COVID-19) Dashboard. Accessed Dec 25, 2020 https://covid19.who.int

Figure 3 Daily confirmed cases of coronavirus disease 2019 in Trinidad and Tobago.

steroid injections and splints were used where applicable.

The national priority was to provide, at a minimum, basic orthopaedic services to the general community. Within the public sector the orthopaedic service is delivered by independently functioning teams. From the start, cross infection between teams of surgeons was identified as a major threat with the potential to destabilise our clinical infrastructure. To reduce risk we avoided unnecessary interaction between staff members of different teams, using electronic methods of communication *e.g.*, WhatsApp® for patient handovers and cancelling several departmental meetings including grand rounds and journal club presentations.

In the first wave of the pandemic, large numbers of COVID-19 positive cases and limited supplies of personal protective equipment (PPE) made it difficult to maintain the surgical services. To conserve scarce resources the Minister of Health in consultation with the Chief Medical Officer announced a temporary halt to all elective surgery in public hospitals on March 15, 2020[12]. To facilitate urgent and emergency cases, many surgeons purchased their PPE for use within the public hospital.

We are presently coming out of the second wave which has been characterised by community spread and rising mortality. To protect the healthcare workers, all patients, except those requiring immediate life-saving measures, must have a negative COVID-19 reverse transcriptase polymerase chain reaction (RT-PCR) test before undergoing surgery. Elective surgery has resumed although many lists have been cancelled due to a delay in obtaining tests results.

Effects on private sector services

The effect of the pandemic on the private sector differed from the public sector in several ways. Most private clinics continued to function with patients being reassured that safety measures were in place. Outdoor hand washing facilities, the provision of hand sanitiser and face masks for patients and staff were some of the additional preventative measures implemented in the private sector. Overcrowding in the waiting area was managed by having patients remain in their vehicles until the doctor was ready to see them. Despite this, doctors' practices reported low attendance rates with many appointments being cancelled.

As opposed to the public sector, there was a noticeable increase in the use of digital technology. Many practices took the opportunity to transition to a paperless office system, including the use of electronic payment to reduce interpersonal contact. Telemedicine for medical consultation was used infrequently, except by physical therapists where there has been early and wide adoption of the technology. A significant barrier to broader usage is the unavailability of a confidential and secure platform as well as an agreed billing and reimbursement method from payers[13].

With the predicted fall in revenue caused by the pandemic, many private hospitals introduced measures to preserve their financial viability. Critically, patient welfare

was the priority, and hospital administrators established major safety precautions to encourage confidence in the private health care system. This strategy has been successfully used in cardiac surgery at one of the private hospitals in Trinidad[14]. Additionally, many surgical procedures were transitioned to the outpatient setting, with savings to both the patient and hospital while maintaining surgical volume. Furthermore, the widescale digital transformation has improved billing and administrative processes, which is anticipated to result in future cost savings. A surprising but welcome source of additional revenue has come from an increase in both laboratory tests and imaging studies as the public seeks to remain healthy in the face of a deadly pandemic. Despite all these challenges, at the time of writing, no private hospitals have closed.

Most private hospitals derive the majority of their income from surgery, and unlike the situation in the public sector, elective surgery was encouraged. Initially, limited supplies of PPE in private hospitals led to some innovative methods to preserve stocks and protect staff. This included the use of industrial protective face shields and "double masking", in which two face masks were used in combination: a standard surgical mask over an N95 respirator mask to protect the latter from becoming soiled with blood during surgery (Figure 4).

To maintain confidence in the private sector, compulsory COVID-19 PCR tests before elective surgery was implemented very early, with the use of dedicated testing facilities and staff (Figures 5 and 6). Emergency cases are admitted only after a negative COVID-19 immunoglobulin (Ig) G/IgM antibody test and isolated from other inpatients. Unless urgent surgical intervention is required, these patients must also have a negative COVID-19 RT-PCR test preoperatively. Although the additional testing is both inconvenient and expensive, it has been well received by most patients who recognise the need for these safety measures.

Although several doctors have contracted COVID-19, to date there are no reports of COVID-19 related deaths amongst orthopaedic surgeons or COVID-19 related deaths or complications following orthopaedic surgery.

Orthopaedic education during COVID-19

The University of the West Indies (UWI) is one of only two regional universities in the world and is currently ranked by the Times Higher Education as the Caribbean's leading university[15]. The medical school of the Faculty of Medical Sciences (FMS) provides training for over 200 medical students who were affected by the pandemic. The FMS moved swiftly in response to the pandemic, ensuring that their teaching staff was well equipped to work in the new normal of online education, with workshops and webinars conducted by the Centre for Medical Sciences Education and the Centre for Excellence in Teaching and Learning.

The four-week undergraduate orthopaedic clerkship has been reorganised into a two-week online course which focuses on the acquisition of core knowledge using didactic lectures, problem-based learning and group discussion. E-learning has been shown to be an enjoyable and effective method of teaching in some studies[16]. The method is however novel to medical education at UWI, specifically orthopaedics and is currently the subject of a study proposal which would give greater insight into its usefulness. (UWI Campus Research Ethics Committee Application CREC-SA.0511/09/2020). The online component is to be complemented by a two-week face-to-face clinically oriented course which began on November 8, 2020, in step with national conditions allowing for a safe return to the clinical setting.

Resident education has been significantly affected by the pandemic. The June/July 2020 exit examination has been postponed and the enrolment of new residents deferred until 2021. Teaching has continued online with the use of Zoom® following the suspension of face-to-face teaching. Of great concern is the diluted clinical exposure caused by a reduction in elective surgery and low outpatient clinic attendance. Additionally, the trauma burden from motor vehicle accidents and sports injuries is significantly reduced, a phenomenon likely related to the population being required to limit outdoor activity.

The FMS understands its pivotal role in supporting the healthcare workforce of Trinidad and Tobago and has had to weigh this with its obligation to provide a safe working environment for students. Continuous dialogue with stakeholders has produced a blueprint for the resumption of clinical teaching; the document which has the support of the Minister of Health has been granted an exception from the national mandate to suspend all teaching until 2021.



Figure 4 A standard surgical mask over an N95 respirator mask to protect the latter from becoming soiled with blood during surgery. A: Double masking technique in which a standard surgical mask is used over a N95 respirator mask to avoid blood contamination of the latter; B: A face shield designed for agricultural purposes being used in the operating theatre.



Figure 5 Coronavirus disease 2019 screening station.



Figure 6 Drive thru coronavirus disease 2019 screening and swabbing station.

The caribbean association of orthopaedic surgeons

This short report on the effects of the pandemic upon the orthopaedic services of Trinidad and Tobago would be incomplete without mentioning The Caribbean Association of Orthopaedic Surgeons (TCOS). The association was founded in 2007 following an informal gathering of orthopaedic surgeons from the region, dubbed an "Orthopaedic Lime". Used in this context "lime", is a Trinidadian phrase meaning: to hang out or socialise in an informal relaxing environment especially with friends[17]. The executive of TCOS lost no time in responding to the pandemic. The discussion of clinical cases and the scientific concepts were promptly migrated to a social media platform. This rapidly developed into the hosting of monthly Clinical Symposia *via* Zoom, and a larger two-day event is planned for November 2020. These virtual meetings have been well attended, providing both educational opportunities as well as

a space for mental restitution. The connection with colleagues, socialization and sharing of experiences, are essential activities for mental wellbeing, providing a much-needed respite during these difficult times.

CONCLUSION

The COVID-19 pandemic has had an unprecedented effect upon the practice of orthopaedic surgery in Trinidad and Tobago. Amid the overwhelming negative impact of the pandemic, several noteworthy transformations have emerged. The rapid adoption of digital technologies in the workplace has improved efficiency, reduced waste and increased patient access to affordable healthcare. Similarly, the transition to online teaching has led to more consistent resident attendance and greater participation in discussion groups.

Surgeons have united in a spirit of teamwork and camaraderie as they face this novel viral threat. Hitherto unseen leadership qualities have emerged, with many examples of surgeons acting selflessly with courage, compassion and empathy. This COVID-19 pandemic will not last forever, but the role that we, as orthopaedic surgeons have played in facing the enemy will in perpetuity be part of our legacy.

Work safe, stay safe.

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MINIREVIEWS

Slacklining: An explanatory multi-dimensional model considering classical mechanics, biopsychosocial health and time

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Abstract

This paper aims to overcome slacklining's limited formulated explanatory models. Slacklining is an activity with increasing recreational use, but also has progressive adoption into prehabilitation and rehabilitation. Slacklining is achieved through self-learned strategies that optimize energy expenditure without conceding dynamic stability, during the neuromechanical action of balance retention on a tightened band. Evolved from rope-walking or 'Funambulus', slacklining has an extensive history, yet limited and only recent published research, particularly for clinical interventions and in-depth hypothesized multi-dimensional models describing the neuromechanical control strategies. These 'knowledge-gaps' can be overcome by providing an, explanatory model, that evolves and progresses existing standards, and explains the broader circumstances of slacklining's use. This model details the individual's capacity to employ control strategies that achieve stability, functional movement and progressive technical ability. The model considers contributing entities derived from: Self-learned control of movement patterns; subjected to classical mechanical forces governed by Newton's physical laws; influenced by biopsychosocial health factors; and within time's multi-faceted perspectives, including as a quantified unit and as a spatial and cortical experience. Consequently, specific patient and situational uses may be initiated within the framework of evidence based medicine that ensures a multi-tiered context of slacklining applications in movement, balance and stability. Further research is required to investigate and mathematically define this proposed model and potentially enable an improved

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understanding of human functional movement. This will include its application in other diverse constructed and mechanical applications in varied environments, automation levels, robotics, mechatronics and artificial-intelligence factors, including machine learning related to movement phenotypes and applications.

Key Words: Slacklining; Model; Human movement; Biopsychosocial; Time

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Core Tip: Slacklining's is achieved through optimizing energy expenditure and dynamic stability, but limited explanatory models exist. These 'knowledge-gaps' are overcome through a new explanatory multi-dimensional model that considers entities from: self-learned movement patterns; classical mechanical forces governed by Newton's physical laws; biopsychosocial health; and time's multi-faceted perspectives as a quantified unit with spatial and cortical experience. Consequently, evidence-based situational uses will ensure a multi-tiered context for slacklining's applications in movement, balance and stability. Further research must consider diverse constructed and mechanical applications in varied environments, with automation levels, artificial-intelligence, and machine-learning related to movement phenotypes and applications.

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INTRODUCTION

Slacklining is a complex neuromechanical task where functional independence is achieved while dynamic stability is maintained from balance retention while treading on an unstable, three-dimensional, moveable, tightened webbing-band fixed at each end. This requires interactions between the individual's whole-body internal dynamics that drive the response to external environmental changes[1,2]. The individual adopts self-learned-strategies to ensure an optimal balance between energy expenditure and maintaining dynamic stability in the presence of perturbations[3,4]. Despite its extensive historical background[5], research into slacklining models that fully define the activity are limited[6], particularly in relation to a model's clinical rehabilitation implications and formulated explanations. This is predominantly due to incomplete descriptions of the neuromechanical control strategies not accounting for the biopsychosocial (BPS) health model or the multiplicities of time[7]. This leaves 'knowledge-gaps' that question areas of application extrapolation and detailed explanation and an expanded and evolved model that satisfies these requirements. The model must also have potential relevance to other diverse areas like construction and mechanical engineering in varied environments including automation, robotics and artificial-intelligence (AI) driven locomotion.

Consequently, the aims of this paper are to: summarize existing slacklining models; then expand and progress these to overcome existing 'knowledge-gaps' that explain the broad circumstances of use, through a multi-dimensional model (MDM); for the individual's capacity to employ control strategies that achieve functional movement and stability; and highlight potential applications to other diverse areas.

An overview of current models

Most models of self-balancing consider the duality of mathematical mechanical precision with supplementary neural control of sensory-motoric systems[3,8]. However, human motion strives to be a harmonious functional movement (HFM), 'the inter-relation of neural and muscular components to facilitate stable harmonized full-body functional movement'[9]. Most human movement models do not consider this need for full body HFM and are generally hypothesized about a stable or fixed base. This is inadequate for slacklining where the body is dynamically coupled with external

changes and response actions[1]. Consequently, slacklining stability[6,10] and balance-control[11] is currently modelled as being achieved through: Self-learned patterns[12]; encompassing neuromechanical control strategies; within a 'saddle-shaped' interactive 3-dimensional (3D) task space that is concave horizontal-X for the slackline, and convex laterally-Y for shift, and vertically with sag-Z)[13]; with defined variables and significant degrees of freedom (DoF). These contribute *via* central nervous system (CNS) control[4] to specific movements[10] that amalgamate mobility and stability[9].

This use of classical mechanics acknowledges spatial orientation and subsequent corrective stabilization actions. This envisages a self-balancing mechanical model of an inverted pendulum (the person)[11], on a cart (the slackline), moving on an elliptical track[1] (the physical 3D space movement limitations), to a maximal distance from slackline contact[3], during instantaneous stability. Concurrently, the arms and trunk are decoupled from the stance leg/s by muscular co-contraction at the hips, but dynamically direct the vector forces that enable angular momentum control[6]. The forces are both pro-active and re-active to those of the slackline's 3D reciprocal forces at and through a point/s of fixed contact[3]. They form within the 'high-dimensional manifold' '… in which the subjects have to stay in order to maintain balance'[4].

However, this mechanical model has a 'knowledge gap' that requires evolution and expansion. It must acknowledge the framework of the BPS health model[14,15], and the multiplicity of possible time constructs[16,17].

Factors that necessitate change to existing classical mechanical models of slacklining

The summarized models of self-balance and HFM account for the available DoFs found with unpredictable dynamic movement on unstable 3D surfaces that consider both inter-segmental coordination and kinematic redundancy - summarised in a further article reviewing the literature and background to slacklining as "an integrated mathematical mechanical precision model, bound by classical mechanics equations in parity with sensory and motoric neural controls, that approximates a dynamic 'saddle-like' phase-space, high-dimensional manifold characterized by two internal competing manifolds of convergent and divergent motion".

The resultant "knowledge gap" arises from the lack of additional perspectives on HFM that involves complex actions and unstable surfaces[18]. These perspectives include: The BPS health model, accounting for physical, mental and social circumstances[14]; and the multiple perspectives of time from the basic neurophysiological effects of aging such as neuro-motoric delay, through to concepts inspired by a qualitative understanding of relativity-theory. Time must be considered and reflected as a physical continuum with epistemological relevance[19], how it relates to individual momentary status accounting concurrently for past experience and future intentions, the transience of 'this' moment, and its' interposition between external physical mechanical time and temporal internal or cortical time. By considering slacklining as a representative highly skilled and complex activity, as compared to quiet-standing, the proposed MDM can encompass both current and potential HFM situations involving equilibrium and self-balance, and their application to other diverse fields.

OVERLYING BIO-PSYCHO-SOCIAL INFLUENCE: A FURTHER DIMENSION

The BPS health model was proposed in 1977 being generally and widely preferred to the traditional 'bio-medical model' by virtue of its basic principles, that the individual's dimensional BPS triad reflects a holistic organism, not isolated organs[14,20]. Consequently, health, medical, and science practitioners are encouraged to adopt a holistic approach and account for individuality in personality, emotion, social situations, and environmental conditions. This has ensured greater emphasis on an empathetic and compassionate 'person-centered diagnostic approach'[20]; however, this has not fully penetrated basic science research and theory, yet.

The BPS factors contribute as a consequence of their context, setting, and the individual's social interaction support networks[15]. With slacklining, this can include prior experience, for example: Biologically - a beginner *vs* an expert; psychologically - positively for enjoyment, or negatively from an experienced injury when participating; and socially - the physical/psychological setting when participating[2,7]. This BPS approach incorporates the reason for participating. This may be obligatory rehabilitation within a clinical setting[7,21,22], or a high-performance training institute[23], at a height or a very low line-tension which accentuate the challenge, or recreationally

with friends[5]. These BPS influences cast additional layers of control over the physical activity and its governance by physical laws that are not addressed in existing models. These contributors will influence subsequent learned movement patterns, so that no individual/s will adopt exactly the same movement and balance strategy at any given time point[8,9].

Criticisms of the BPS model predominate in four areas: (1) It is neither a scientific or a philosophical model; (2) Provides no answers on how a condition/disease is expressed by the three BPS components interactions; (3) Has no guidelines on when it should be applied; and (4) Recommends no definitive therapies and interventions. Noted disadvantages are that because it is multi-faceted it is complicated, making it problematic for education. It assigns no responsibilities, making it difficult to coordinate. It lacks concise theoretical framework related to content and how it functions[15]. But, the BPS health model enables more effective management! It connects science and humanism by facilitating collaborations between clinicians, patients, their families, and social support systems. Consequently, it remains a valued approach offering beneficial clinical, educational, and research services, while concurrently contributing to health and medicine policy and practice formation[15].

This multi-faceted BPS approach has evolved through the introduction of: semiotics - the language allowing the description of relationships between individuals and environments; and constructivism - how organisms perceive their environments. These explain the lack of uniformity in individual reaction to any defined physical or chemical stimulus. Stimuli are "... imprinted with a meaning [and] designated as a sign (that has no actual representation) ..." with the imprinting dependent on the individual's holistic "… motives, relationship needs, metabolic conditions, thoughts, and fantasies"[20]. Effectively, individuals construct their own environment and the imprinted meaning on the receptors "encompasses the individuals' unconscious, preconscious, and conscious memories in the implicit-, the working-, and the autobiographic - memory"[20]. Consequently, the two-link mechanistic model of cause and effect gains a third 'interpretation' stage: (1) *Cause* - the 'carrier' stimulates the receptors with a sign; (2) *Interpretation* - the 'interpretant' (the psycho-biological system developing during an individual's ontogenesis) which imprints this stimulated receptor with a meaning, or imprinted mark, prompts the organism to interpret the sign; and (3) Effect - the 'effect mark ... impregnates" the individual's environment[20].

The BPS model encompasses both the circumstances of 'emotional reactions' and 'somatic symptoms' as it is inclusive of the individual and their existing health status. It accounts for any affecting conditions by virtue of its paradigm's six specific supporting aspects[14]: (1) Illness based on biological changes indicate disease potential, not current circumstances; (2) Establishing relationships between physiological status and clinical presentation, both behavioral and psycho-social; (3) Living conditions significantly influence when conditions are reported and how they vary; (4) Psycho-social factors critically influence when and if individual's allow themselves and others to view them as sick; (5) "Rational treatment" directed at biological abnormality will not restore optimal status even when the condition is alleviated and correction documented; and (6) Provider's behavior and relationship with the individual influences the therapeutic outcome both positively and negatively.

Including BPS health as a dimensional input considers the 'individual' in any HFM and self-balance context. It creates an influence generally not accounted for, but required as it affects individual patterned responses as expanded upon below.

Biological contributors

The BPS model *biological* contributors to HFM provide insight into movement variability within and between individual/s, with many aspects well documented for 200 years, and some for 2000 years, consequently relevant historical references are provided. Biological attributes are specifically applicable in the presence of irregular inputs, both internal (ageing, fear, pain, …), and external (weather conditions, indoors *vs* outdoors, unstable surface contact, reason/motivation for training, fun, or rehabilitation …). These inputs cause physiological, sensory, and motor processing interactions[24], with specific biological relevance to nervous system processing, neuroplasticity, and 'reflex inhibition' or 'inhibition of reflexes' related to muscle activation.

Nervous system processing

There are significant variations in tissue-specific neural conductive paths[19] and subsequent delays that affect response times[18]. The CNS receives detected changes in position and orientation, and reacts in an integrated manner that maintains functional balance-control through a closed-loop feedback system with varied constraints on the

sensory integration process, including "sensory weighting"[24]. Changes in motor activity or movement occur after nervous system processing[12], being primordially protective or survival responses designated to prevent injury in the presence of threat by facilitating the least detrimental choice. This is achieved through behavioral organization of 'action' or 'inhibition of action'[25]. The individual's response will vary in size and duration as a function of the input and individual experience[12]. Subsequent changes then input to the CNS feedback-loop as multiple sensory signals, body awareness, or environmental factors that add processing, further adaptation and changes to the initial movements. These are facilitated, inhibited, or further altered ... and the loop continues[26], but complexity will increase delays[6,8] unless the signals are 'packaged' as single unit from learned response[24]. However, a finite neural delay is required and determined by the brain's 'time available processing'[27] which is optimized during complex integrated neuro-motoric control, like slacklining. The CNS allocates 'weights' to each sensory system's incoming signals, to ensure each contribution is comparatively represented[28]; and employs 'muscle synergies', that combine muscle groups responses as a common neural signal that simplifies motor-control[29]. Altered movements are essential in the early protective phase of recovery and rehabilitation, but if not modified appropriately through learned-control they lead to mal-adaptation[12]. Slacklining, as a learned activity, is an explicit example and can only occur through HFM, which when achieved can override or modify the maladaptive movements.

Inhibition of reflexes and muscle activation

There is a duality in the term 'reflex inhibition' which describes two separate but independent centrally mediated phenomena: The 'inhibition of a spinal reflex' at the spinal level *i.e.,* the stretch and Hoffman reflex (H-reflex); and 'a reflex body response that causes inhibition to occur' at the central level thereby affecting muscle activation[30,31], essentially causing arthrogenic muscle inhibition (AMI)[32,33]. Both actions are reduced during slacklining due to refined or regressed levels of down regulation[7,34] from learned regulatory control of the external stimuli[23,35]. This is likely from increased striatal-network efficiency[36] from the hippocampus and other 'primitive' brain areas[18] leading to pre-synaptic inhibition in supraspinal centers. These predominantly affect reflex inhibition driven movement control[37] leading to neuroplastic change[38].

The ability to both 'compensate for' and 'coordinate with' these sensory-motoric induced physical delays and their variability[27] is influenced by integrated interplay[39]. This includes "visual prediction" and motor planning, where each retains some semi-autonomous compensatory control, but ostensibly under CNS hierarchical influence[18]. These changes remain in constant flux dependent on the individual's life status circumstances. Since motoric activity changes occur subsequent to CNS processing, this provides the initial opportunity for individual adaptation to afferent input, and any adaptation to movement patterns previously used. Changes in movement are essential aspects of response and experience. Their prediction cannot be only through physiological, sensory or motor considerations[26].

Other biological considerations include normal ageing and pathological declines in the body's mechanical structures[8,40] and neural system[41] and age-associated contrasts between early and later age learning, absorption and capacity. This includes cortical, subcortical[27], and neocortical tissue[38] plus limbic hippocampal-striatal representations and information processing; all of which contribute to memory and spatial learning fluctuations and age-deteriorations[41]. There is also the variable rise and ebb in white matter microstructure associated with cognition[42]. These aspects are further compounded by the mental state, such as deterioration with dementia, traumatic brain injury (TBI), Alzheimer's and Parkinson's disease[43]. They in turn contrast with the BPS health model perspectives, such as emotion, motivation and experience[15].

Neuroplasticity

Neuroplasticity is vital to this MDM of slacklining as neural tissue adaptive changes can be virtually instantaneous[44,45] or occur rapidly after a complex balance-task, like slacklining[27,46]. Neuroplastic changes can also be sustained for weeks or even years[47] being task-specific[23] and functionally transferable to activities of daily living (ADL)[48].

Anatomically, neuroplastic change occurs in different cerebral structures at variable rates. The duration of sustained change depends on the tissue and cellular components[45]. The triggered changes are activity-driven, rapid, and specific to dynamically regulated white matter (primarily myelinated axons which form the connections between cortico-cortical and cortico-subcortical regions and is critical for prefrontal cortex functioning)[40], and gray matter (primarily densely packed neuronal

cell bodies, dendrites, and synapses)[49]. However, this dichotomous classification is overly simplistic as myelin in both the white and gray matter is derived from the neuroglial cells of oligodendrocytes developing from oligodendrocyte precursor cells (OPCs). To fully appreciate how dynamic myelination influences overall nervous system function during a complex whole-body activity, like slacklining, a circuit-level approach is required with integrating analysis of myelin dynamics and direct measurement of circuit function[45]. The measurable macro-level changes found with neuroplasticity, that indicate a re-sculpturing of brain structure, occur from increased underlying cellular and systems level cross-talk[36].

Neuroplastic-specific research of such changes has predominantly been on simple balance-based challenges (single-leg and tandem-standing), or dynamic (balance boards and moveable platforms)[50]. However, the balance-task difficulty for such activities is notably lower than that required to achieve and maintain a stable position when slacklining, which requires complex physical, neurological and whole body involvement[35]. Consequently, it can be extrapolated that changes found in simple and dynamic balance tasks will also be found in the more complex balance-task of slacklining[51]. The determined neuroplastic change can be latently reflected as both sensori-motor homunculus smudging[52] and as global concurrent functional change[48].

In considering the neurophysiological basis for neuroplastic change the white matter myelin support and insulate the axons and can alter their cell numbers, length, and penetration extent into the surrounding tissue[40]. They can be either modified through remodeling in situ or regenerated[49]. These include variable changes[45] to composition[38], distribution, and sheath[40]; the nodes of Ranvier size, length and spacing[53] which influence conduction velocity and by consequence reaction time. The gray matter neuroglial cells undergo multiple area morphological changes that include the fronto-parietal regions[47]; the limbic system from the hippocampal and para-hippocampus[46,50]; brain visual areas, lingual and fusiform gyri[26,48]; putamen and caudate nuclei that form the corpus and dorsal striatum; the cingulate gyrus and the precuneus in the superior parietal lobe and the supra-marginal gyrus[47]. Consequently, with slacklining, training-induced neuroplastic brain-tissue changes are specifically demonstrated by both structural and functional magnetic resonance imaging (fMRI)[47].

Such functional and morphological changes in brain structure subsequent to a complex balance oriented motor-learning task, like slacklining, has training-effects that result in activation and alteration of the primary motor cortex (M1), pre-motor cortex (PMC), supplementary motor cortex (SMA), cerebellum, and subcortical structures[26,54]. Connectivity reduces between other brain areas and the striatum during the training period, effectively increasing striatal network efficiency[47]. It is recognised that the fronto-parietal brain networks are responsible for coding acquired motor skills, but this appears to be a two-stage process[55]. Immediately post balance-training, functional connectivity is increased, then latently after several weeks structural changes that are induced by training can be visualized under both structural and fMRI. The task subsequently changes both the functional resting-state networks and the corresponding sub-cortical and cortical brain structures with time-related performance improvements[55]. Dynamic balance motor-training sessions initiate fronto-parietal network functional connectivity increases with the white matter after 1-wk[23] which continues consistently with micro-structural alterations over 6-wk with repeated training. In contrast, grey matter alterations and functional connectivity changes in prefrontal and supplementary-motor areas peaks at 3-wk[55].

Further, at the gross structural brain-tissue level, rapid and specific M1 gray matter changes triggered by balance-specific motor learning are visualized by MRI and diffusion tensor imaging (DTI). This includes increased cortical thickness from 1-session and is independent of resting cerebral blood-flow changes and repetitive leg use[50]. At the tissue and cellular level, neuronal processes re-modeling occurs at the pre-synaptic terminals that form synapses with dendritic spines. The gray matter induced changes include the SMA/pre-SMA, that reflect total dendritic spine alterations. Hence, both gray and white matter changes occur in the left anterior prefrontal lobe[56] from anatomical and functional connections *via* the cingulum bundle causing structural brain plasticity change across the entire cerebrum. This indicates large-scale networks comprising interconnected regions are positively affected leading to functional adaptation[55]. This strong systems level correlation between training-induced functional and structural brain plasticity changes suggests intrinsic brain activity has functional relevance for human brain morphological adaptations[55].

The exact time-scales accompanying structural remodeling and neuroplastic changes from high-demand balance training are not definitive[44]. The neural tissue cellular rearrangement and alteration occurs locally but at varying time-frames from activity specific stimulus[47]. The changes remain in flux, responding to variable

internal[49] and external functional stimuli[42,50] that requires adopting new neural and motor sequences[57]. They are induced and maintained instantaneously, rapid short-term (hours-days) to medium-term (days-weeks), or long term (months-years).

Instantaneous neuroplastic initiation of cerebral change is instigated by sensori-motor[4,44] and psycho-social inputs[46]. These are assimilated by constant neural system adaptation[40] to provide solutions through new and modified pathways[45]. With challenging balance and postural tasks like slacklining, supraspinal sites exhibit pre-synaptic inhibition rather than post-synaptic actions as a predominant adaptation[26]. This is partially driven by corticospinal excitability from muscle and joint feedback that accentuates CNS modulation and corticospinal drive. This overrides pre-synaptic inhibition and enables a counteraction to the α-motoneuron inhibition[58].

With spinal 'reflex inhibition' the Ia afferent excitation is not fully transmitted to post-synaptic α-motoneurons which allows subsequent 'inhibition of the spinal reflex' to occur at the spinal level, including the stretch and H-reflex[51]; and a reduction in the reflex size without affecting the supraspinal input to the α-motoneuron pool. This reduced reflex size, without concurrent change to the background muscular activity, indicates modified spinal processing of afferent information[26].

Conversely, with AMI, trauma causing peripheral nociceptive afferent inputs to the CNS inhibits the α-motoneuron pool as a form of self-protection that deactivates local and stabilizing muscles, *e.g.*, quadriceps and multifidus[33]. With ongoing neural inhibition the CNS is prevented from fully activating affected muscles[58], which if sustained becomes detrimental[12]. Consequently, this form of 'reflex inhibition' is 'inhibition that occurs as a reflex body response' at the central level, and is a negative adaptation, where the down-regulation effect must be inhibited to restore normal function[37]. This instantaneous neuroplastic change is postulated to occur by reduced neurotransmitter release from central inhibition, which enables the Ia afferent excitation to be fully transmitted to post-synaptic α-motoneurons. This minimizes neural signal output reduction that maximizes normal supra-spinal input to the α-motoneuron pool which enables muscle activation that is otherwise dormant or 'reflex inhibited' from central influence[31], but does not affect 'disuse atrophy'[33,59].

Rapid short to medium-term neuroplastic change subsequently, occurs when the brain adopts new procedural rule sequences, or memorizes cascades of new reactions or events[44]. This includes: Specific memory and spatial orientation and mapping interpretation tasks, as with expert navigation[60]; and motor processing with complex movements, like slacklining[4,50]. These changes are in two formats: (1) Measurable neural tissue cellular rearrangement, and (2) Cellular remodeling as occurs with oligodendrocytes and OPCs[49]. They occur within hours of task performance due to the necessity to achieve activities with hippocampal formation-dependent non-spatial memory components[48] that require spatial separation of the vestibular and visual processes, as non-visual-dependent spatial orientation[44]. The spinal reflex reactions are strong in the initial learning stages, which creates instability that prevents control, *e.g.*, slacklining has uncontrolled ankle reciprocal agonist-antagonist cyclic contraction to eversion-inversion. With slackline training, learned activity has positive functional adaptation from centrally induced 'reflex inhibition' from reduced pre-synaptic neurotransmitter release[39] that dampens and overrides spinal reflexes.

Consequently, motor learning through complex balance training triggers neuroplastic 'rapid and specific gray matter changes in M1'[50] exhibited as selective brain-volume changes[60] and shown on MRI and DTI[43]. This includes microstructural changes in the limbic system (hippocampus and para-hippocampus)[44] and balance-control motor cortical effector representations of the trunk and lower limb that cause the noted increased cortical thickness. Further, they appear not to be isolated to high-level complex movement tasks, however the degree of change and its duration of retention is[50].

Longer term change results from motor learning and adopting automated task behavior[54]. The white matter myelin has increased conduction speed through new and remodeled oligodendrocytes and OPCs[45], including increasing cell size and length, and the size of and distance between nodes of Ranvier[53]. For the gray matter, the motor cortex changes at multiple areas, including the effector representations primarily responsible for the trunk and lower limb[50], with increased cortical thickness and sensori-motor homunculus smudging[52]. It is also postulated that changes are due to neuronal size, dendritic or axonal arborization, or neurogenesis[60]. There is also reduced cortex excitability[26] with subsequently, reduced spinal reflex excitability from spinal reflex processing of afferent inputs, including the H-reflex and stretch reflex[51,61]. At the macro-level, change favors: A smaller anterior hippocampal volume supported by associated reduction in the parieto-insular vestibular cortex; concurrent enlarged posterior hippocampal formation volumes and increased brain visual areas;

and enlarged lingual and fusiform gyri from increased visual cue usage[48]. During a training period, decreased gray matter connectivity can be shown[57] between the caudate nuclei and caudal anterior cingulate gyrus, precuneus in the superior parietal lobe, supra-marginal gyrus, and between the putamen and SMA and the supra-marginal gyrus[47].

Psycho-social contributors to the bio-psycho-social effect/dimension

Psychological contributors affect an individual's purpose for performing an activity and include expectations and self-motivation, daily life experiences, personal interactions, and stress. The social aspects include personal enjoyment, human social/technical interaction, rehabilitation, performance, and adjunct training[20]. Other important psycho-social factors include poor recovery expectations, pre-traumatic and post-traumatic psychological symptoms[15], and age related change[42].

Stress occurs within the context of occupational activities of work-load requirements, multi-tasking, hazards or negative customers, for example with taxi drivers, first responders and military personnel[60]. Other considerations are fatigue and sleep deprivation as with jet lag or work/life-stress related activities. These produce spatial cognitive deficits and temporal lobe atrophy from both gray and white matter differences, such as regional and total volume and neuroplastic change[45], that parallel biological causes.

In the gray matter new spatial memory and volume acquisition is influenced, particularly the anterior hippocampus, that affects processing ability[43,45]. This plays a key role in slackline performance and progression within settings that are contextual, declarative, and episodic. Further, the hippocampus role in vegetative and autonomic functioning affects the secretion of multi-adrenocorticotropic hormone[62]. These levels are determined by an intricate interaction and feedback system involving the hypothalamus, pituitary and adrenal (HPA) axis, all of which are directly affected by the stress response. The HPA axis is driven primarily by neural mechanisms causing glucocorticoids (GCs) secretion. These regulate hippocampal synaptic plasticity, gene expression and neuronal metabolism, which redirects' energy resources to meet real or anticipated demand within multiple organ systems[62]. These GCs cause cortisol elevation that is detectable in the plasma and saliva which, if prolonged or chronically elevated, is associated with reductions in hippocampal volume affecting spatial and hippocampal-dependent learning and memory task capacity. All forms of repeated or sustained BPS stress can lead to increased GCs and cortisol, with resultant negative hippocampus effects on learning, memory, and modified or inhibited functional activity task performance capacity. Structurally, the stress leads to hippocampus remodeling through three actions: hormonal influences (particularly estrogen in females), dendrite atrophy in the Cornu-Ammonis region, and suppression of the adjacent dentate gyrus neurogenesis of granule neurons in the hippocampus[62].

In the white matter, 'hyper-intensities' (WMH) can be critical as these indicate reduced tissue integrity associated with reductions in cognitive domains[42]. In particular, WMH affect executive function and attention, including working memory, mental flexibility, fluency, planning, set shifting, inhibition, and distinctive cognitive processes. These reduction effects are prominent with ageing and age-related disorders such as medial temporal lobe atrophy (MTA). For functional performance activities like slacklining, this significant MTA negativity reduces active ability as both MTA and periventricular hyper-intensities predict performance inhibition independently[42].

These vulnerable regions affect global reactions to repeated stress, trauma, and ageing[36]. This in-turn affects capacity and progression in learning and achievement of balance activities, with slacklining as an example[50]. Consequently, each individual's circumstance will vary on each occasion of each activity due to progression/regression within their given situation; where each are in-turn affected by their level of motivation, mental functioning, and cognitive status at the time. This is definitive in explaining why psycho-social factors must be accounted for in any model of HFM, particularly with complex balance tasks like slacklining. The BPS model of health explains this phenomenon in terms of factors associated with recovery that are not bio-medical[15,20].

TIME MULTIPLICITY: A CRITICAL DIMENSION OF THE MODEL

Overview of the influence of time

The multiplicity of 'time' is an integral dimension in any hypothetical human

functional model that explains slacklining. The 'spatial' aspect of time remains implicit within the diverse biological movements that define slacklining. Our focus is the fundamental aspect of an identity between space and time, which facilitates consideration of a multiplicity of times. Although a unique time and a unique space may be defined by physicists for communication within social groups, in this paper the multiplicities of time are considered, and how they, each and together, are critical in affecting the MDM.

As a species, humanity has contemplated the transience of time from the perspectives of philosophers to scientists, but rarely from that of health professionals when considering movement and rehabilitation. The relevance is that time does not exist alone as an invisible substance that encapsulates everything[16], rather it has a multiplicity of forms that must be considered separately, yet concurrently integrated to explain and understand slacklining as an example of complex HFM.

Both time and space are inseparable 'movement relations', as designated and encouraged by the theory of relativity. Similarly, we contrast spatial relations with temporal relations, or immobility relations with mobility. From the psychological perspective of the individual's internal-cortical time, for a human subject moving in space, future events feel closer than past events that occurred in similar time durations[63]. This asymmetry is a consequence of future events approaching, whereas past events recede and provide apparent differences in the subjective experience of movement through time. This is mirrored in the physical experience of movement through space. However, if the experience is experimentally reversed, then past-future asymmetry is eliminated[63]. This may indicate that during slacklining, as a complex and dynamic functional movement, the concepts of relativity theory may qualitatively apply, though conditional on being viewed from a new perspective. The quantitative assessment of this effect requires knowing the "spatial velocity of the future progression", that takes the place of light velocity in the Lorentz transformation (a linear transformation of one coordinate system to another which is moving at constant speed relative to the other).

However, in hypothesizing a MDM of movement, the separate entities must be acknowledged and considered, yet integrated as a whole that encompasses the achievement of the final action, that of stable HFM. With the development of relativity theory, partially as a consequence of the determination of electromagnetism, the need to understand the deeper connection between space and time variables appeared. The role of different observers in relation to moving reference frames was stressed, together with the loss of absolute space and time[64]. Subsequently, when extending the inspiration of relativity theory, emphasis has been placed on the constructed and conventional characteristics of time, and on the equally legitimate properties of the duality of external-physical clocks and an individual's internal-cortical experienced time/s. This will help resolve the issues of time perception and its potential multiplicities, and how they are to be considered within this proposed MDM of slacklining[16,17].

The relevance of 'external-physical' time and 'internal-cortical' times

A duality of time is the first manifestation of *multiplicity*, being an integrated reflection of the individuals given spatial and cortical recognition[16,65]. Here, '*external-physical*' time, often considered as 'true time', is that computed by physicist's clocks, and 'estimated' by human subjects. '*Internal-cortical*' time is that constructed within the brain and referred to as 'perceived' time[66]. Experiments show that internal times have a direct relationship with neural connections and reflexes that provide the subsequent human pre-emptive and causative physical reactions. These include cortical integration and musculoskeletal responses that occur within quantifiable time frames. These were first measured in the 1850s[67] being described as 'psycho-physiological time'[18], and demonstrated to vary dependent on the stimulus itself. Sound or touch propagated a neural interval of 150 ms compared to light at 200-250 ms, while other physical stimuli required longer durations, but all within the range of 100 ms-5 s[19]. The early research also considered 'internal time' as a metaphysical contemplation[67]; but stipulated a distinction between durations requiring significant computational neural processing time that occurred "unconsciously ... before precepts' emerge", and that this did not imply that neural substrates were unrelated to consciousness[18].

Relevance of neuronal conduction and processing within times perspective

A further consideration of differentials between 'external' and 'internal' is neural transmission systems' physiological limitations. As time-varying events occur in a physical state there are concurrent delays in the registered instantaneous *vs* the external state, with discrepancies between the two perspectives[18]. This is complicated

further by the discreteness of the level of stimulation which determines the time delays for both neural delay and response, as there is a time differential between stimulation and a change in the target site's neural activity[18]. Furthermore, the individual's BPS status will influence the perspectives of both cortical and external time through current levels of excitation and preparedness due to motivation, social and psychologically influenced behavioral perspectives. Consequently, neuronal conduction and processing occurs in three distinct orders of duration on the external-physical time continuum; but do not epistemologically hold the same status: (1) < 100 ms, is 'instantaneity' and without 'time'; (2) 100 ms-5 s, is the 'present'; and (3) > 5 s, involves memory and duration estimation[19]. Within each perceived category separate subgroups are identified. Within 'instantaneity', 20 ms is the threshold for perceived succession or continuous presence, and approximately 40 ms is the minimum latency for reflex behaviors requiring only the spinal cord, *e.g.*, tendon-jerk responses. By contrast, learned motor 'voluntary response' with longer neural pathways are approximately 100-120 ms[67]. Lastly, 'choice response' behaviors involve additional cortical processing and slow to approximately 200-350 ms.

Consequently, simple reaction time is directly related to the delays in the single neurons or neural chains input-output actions, as variations depend on both the cell type and the modality of transmission-transduction; *e.g.*, sound-burst reaction-time is shorter than light-flash[65]. For complex functional balance tasks like slacklining, concurrent brain tasks result in a distinction between task processing and achievement that occur concurrently but with different durations. The implications being that the brain cannot maintain the required global task of balance by means of 'set and forget', addressing joint stiffness by postural adjustment from visual inputs[28]. This leads to an integrated global system where task success is determined by processing, accounting for time multiplicities, and adapting physiologically. This happens through concurrent neuroplastic change, down-regulation modification from hippocampal dampening, and spatial mapping within a learned and time-sensitive-adaptive experienced environment. To further complicate time's multiplicity is normal and pathological human ageing on the brain[41]. In early age we absorb, develop, and learn quickly, in later age the hippocampal-striatal circuitry for memory and spatial learning deteriorates[41].

Accordingly, the multiplicity of time is reflected in the learning and conducting of a complex balance task like slacklining by: the biological neuronal delay, the physical external time elapsed during the task, the perceived cortical time of the slackliner, and the process delays of choice action responses. Additional examples of time-multiplicity may also occur when temporal goals are set (*e.g.*, remain on the slackline for > 10 s); or when subjects receive instantaneous or delayed feedback during the elapsed-time standing on the slackline. The induced improvements in balance performance acquired during training are associated directly with increased striatal network efficiency[50]. These can be demonstrated on MRI, where connectivity between the striatum and other brain areas is decreased at varying rates[47] to enable the dampening process through increased reaction speed and selectively reduced input from multiple brain functional performance contributors.

Immediate relevance of time's multiplicity to slackline task performance

To remain stable and in balance, like slacklining, an individual either reverts to or progresses from a prior successfully learned strategy[6]. They employ learned control techniques that have become achieved movement patterns[68] that occur on multiple body-response time-scales[1]. However, on each new attempt to maintain an existing or progress to a higher level of competence, the integrated body-action occurs with the advantage of additional knowledge and experience[2,34], accompanied by accrued training[69], and the existing social structure determining why they perform this task[7]. Further, deviation from the stable upright position requires input from the three sensory contributors, each with different conduction latent time delays: (1) Proprioception *via* the joints; (2) Vision *via* the eyes; and (3) Vestibular *via* the labyrinthus[24]. These facilitate self-balance against gravity's inertial and ground-born vibration effects on head movements, particularly if vision is impeded. This provides at least six DoF: Three in the X, Y, and Z planes from the head's linear acceleration and static displacement giving translational motion sensed by the 'otolith organs'; and three from body rotation related to the X,Y, Z axes giving roll, pitch, and yaw as rotational motion sensed by the 'semicircular canals'. These inputs occur within the subsequent physical time delays present in the human sensory[39] and motoric[27] neural pathways. The delays limit the achievement of stabilization[51] but are minimized by having input from three separate systems 'packaged'[24] which enables responses to be assessed and adjusted based on how these inputs contribute to the 'total balance

system'[28]. The subsequent physical time delay is differentially present at the levels of neural conduction[40], central processing[1], and motor response[27]. This causes a difference between what is experienced and what was intended[65,66].

Changes in motor activity or responsive movement patterns occur after CNS processing, by which time the reactionary response needed will be different to that produced post-processing[12], and that which is experienced[66]. A further confounding contributor of 'packaged' information is task complexity. This encroaches on time's multiplicity as actions in the sensory systems support each other through a feedback loop that provides' the signaling for the control task/s'[6]. As tasks become more complicated[8], *e.g.*, slacklining compared to quiet standing[13], delay increases within the system leading to greater disparity between the reactionary time measure and the time experience. This disparity is amplified by the increasing differences that task complexity causes between the intention (future), the actualized (current experienced), and the reflective (past) responses the individual attempts to assimilate and integrate[4]. Consequently, the brain continuously receives functional input that instigates change[44], constantly adapts, and provides new and modified paths[45].

These pathways will influence the multiplicity of measured time. The adopted strategy selected for HFM as an intended strategy will not be replicated exactly. This means that slacklining as a learned activity will be: maintained by a minimum level of practice, progresses only with further appropriate practice, and regresses with none[69]. Hence, as the individual seeks to repeat a positive or successful 'time-experience', they employ a retrospective time point intended to be imposed on a future time point, that will then become the current measurable time point from the physical perspective[16] and the experience[65]. This leads to the new adopted strategy and will in-turn become a new time point from which they will progress, or attempt to prevent further regression, to regain and progress their previous successful time-experience strategy. However, as each time point is reached, it is no longer simply a current-measurable physical property, but one that is transformed to an 'experience'.

This 'integrated experience' then fluctuates at the CNS and physical 3D level between: Transitionary perspectives of anticipatory and preparatory actions; reflection on both positive and negative effective intentions; and the existing current moment of experience[9]. During this 'current moment' it is recognized that time, as a context, is different and that this 'current moment' is perceived to change[17]. Time is reflected as a physical measure[16] to that which the individual has achieved as the experienced entity, and which is and always was intended to be replicated, regressed or progressed[19].

When the BPS health model was introduced[14] it highlighted time's importance within multiple perspectives, *e.g.*, "at all 'times' in history". As such, "time is not discovered, it is constructed"[16], as the brain, being the focal source of the human entity, "does not process information, but creates it"[70]. The brain constantly learns by enquiry and examination of the consequences and outcomes of action-based interactions, to test the hypotheses within its environment. This is achieved through control of the body as it explores and seeks, rather than simply acting as a coding device for information-absorption[70]. Over time, the brain can foretell the likely consequences of its actions through cognition, as experience ensures our systems are calibrated, which enables past actions to acquire meaning. Information and experience is assimilated to become the present, and construct the future, through the ability to 'disengage from … sensors and actuators'[70]. This cognitive loop replicates and parallels the precise physiological, neural, and mechanical-versus-control feedback loops which are influenced by our age-time physical and mental state. These existing models, described by infinite-dimensional mathematical differential-equations whose analysis ensures balance and stability, are governed by the essential limitations of sensory-motoric reflex delays[8]. The consideration of the multiplicity of time provides an overlaid encompassing dimension, and an enhanced paradigm within which any model of movement must be considered. This is particularly so for complex functional actions like slacklining, and by consequence, several time parameters may intervene in the equations.

CONSEQUENCES OF THE POINT OF VIEW PRESENTED

Slacklining facilitates a maintenance or improvement in balance-control that is explained by existing mathematical manifold models[1,4,6]. These models describe an expanding manifold, where a higher available range of motion is present before the manifold edges are reached[4], and balance is lost. With repeated training, individual

learning facilitates an expansion of these manifold edges[1]; though to a finite limit which appears to be in the order of 10 cm laterally from the foot/feet for beginner and intermediate slackliners[3], but may be greater for expert level slackliners[4]. Consequently, balance stability is specifically discussed within existing models as a functional relation to the slackliner's contact point with the line; which enables the existing models manifold to be expanded in the future.

As control improves, the reactionary forces of the slackline[4] represents a unique dimensional contributor that pushes back against the weight and force of the slackliner[6]. This reaction force will reciprocate and remain incompatible with the slackline until a point of stabilisation is again reached. Further, this must also coincide with the individual's cortical and cerebral inputs, including those from the hippocampus[46,48], as well as the motivational and emotional centers[15]. These neurological aspects represent further dimensional contributors that have both preparatory and responsive actions that will assist closure of the manifold to a stable model, once all dimensional factors are equal and in harmony. This will represent a point of complete stability that is likely to last only briefly, till the imbalance of forces reoccurs and a state of entropy ensues. This is initiated by the combination of the individual's internal reactionary forces and the external forces of the environment that include the slacklines stored kinetic energy. However, the expert slackliner can prolong this period of equilibrium and exhibit a greater capacity to achieve and maintain stability and HFM.

To fully comprehend this proposed MDM, BPS health is considered along with each dimensional contributor. Within the three planes of movement, simple physics is accounted for within a physical, topographical, ordinary equivalent space. From the dimensional perspectives of forces and action-reaction resulting from the individual's physical interactions with the slackline and the environment, these are explained by classical mechanics. However, indirectly these recognized contributing forces are constrained by components of the BPS health model, and concurrently subjected to the multiplicity of time. Each force action is generated by the individual through the process of voluntary and involuntary muscular activity. It is a consequence of a balance reaction that is controlled from the three CNS levels, peripheral, spinal, and central. The central contributor includes cortical and cerebral inputs at the conscious and subconscious level[43], and the concurrent variations in motor cortex neural recruitment and neuroplastic changes[52].

The balance overlay affecting the dimensional input within the BPS health model entails that the biological, psychological, and social experiences of life perspectives are integral to HFM. The necessity of the given situation at hand, namely 'not falling over', is in itself a primordial imperative postural behavior[25] determined by postural orientation and postural equilibrium[71]. These inputs directly affect the dimensional forces generated and reciprocated to ensure that slacklining is achieved, and overlies the physical aspects of motion, function, and action or action-inhibition[25]. The sensory information is packaged and integrated[28], with or without a finite neural delay from time available processing[27] following input from the somatosensory, vestibular, and visual systems[24]. This in-turn determines the physical load perspectives and a muscular action at all levels of the body, employing muscle synergies as required to simplify motor-control[29], and achieve the necessary forces to retain balance and achieve HFM[50].

However, these loads are themselves determined by the goals of the movement task at hand and the context of the environment it is in[71], the fight-flight-freeze response[25], amusement[5] or physical endeavour[61]; and the skill and age of the individual[72]. These perspectives of the individual's goals and expectations are also affected by their prior life experience. This in-turn leads to both physical as well as emotional and psychological determined experience[20]. They are also affected by the multi-dimensional aspects of time in relation to space[16], perceived position[24], the stage of learning[4], and the individuals' position related to the anticipatory neurological reaction. These anticipatory postural adjustments maintain postural stability by compensating for destabilizing forces associated with moving a limb[69]. When the anticipatory movements align with the physical movement requirement and the psychological anticipatory experience related requirements, then the point of stability is facilitated. Consequently, the retention of balance on the webbing band to achieve slacklining is an integrated response of multi-dimensional inputs that is determined from: The amount of cognitive processing necessary for postural control, as established by the complexity of the task at hand, and the capability of the individual to provide the control (Table 1).

Table 1 Summary table of the proposed concept-model

Additional dimensionality		Multiple levels	Description
Time multiplicity: physical/external versus cortical/internal. These can include: (1) Biological neuronal delay; (2) Learning; (3) Process delays of choice; (4) Action responses; (5) Physical external time elapsed; (6) Perceived cortical time; (7) Temporal goal setting; and (8) Instant feedback	Biopsychosocial constraints, these can include: (1) Motivation; (2) Attitude; (3) Context; (4) Experience/Skill (neuroplasticity); (5) Fatigue; (6) Muscle properties; (7) Injury; and (8) Age	4: Neural activity	The manifold of different muscle activity strategies leading to HFM slacklining are the result of a complex integration of top-down control loops, bottom-up reflexes, neural latencies, inhibition loops *etc.*
		3: Muscle activity	Various muscle activation strategies can be used to control the multi-DoF joint kinematics and stay within the manifold of level 2 (co-contraction to control joint stiffness, agonist/antagonist tuning)
		2: Multi-DoF joint kinematics	Keeping within the manifold of level 1 can be attained through multiple solutions of joint kinematic strategies (abundant movement system). Different positions and orientations of the segments of the extremities and trunk can give the same CoM coordinates; vice versa the same point in the CoM phase space can be obtained through various joint kinematics. The (infinite) set of joint kinematic strategies form a manifold themselves within a high-dimensional topographical space
		1: CoM phase space	At the whole-body level there is > 6D phase space for CoM (position, orientation and velocity relative to the base of support, limbs and diverse body parts) contains a manifold in which the objective of slacklining (level 0) is achieved. There are physical limits to the extent the CoM can deviate from the base of support and to the velocities that can be counteracted. Higher velocities can be counteracted in regions of the manifold where deviation from the base of support is small
		0: HFM slacklining	The basic objective of slacklining is harmonious functional movement on a tightened rope: smooth dynamic stability

The slacklining multi-dimensional model presented above illustrates: the two added dimensions of 'time multiplicity' and 'biopsychosocial constraints', in the left 2-columns in descending hierarchical order; and the subsequent multiple levels at which these influence the body's response are presented in the 5-Rows and read from bottom to top in ascending hierarchical order. MDM: Multi-dimensional model (of slacklining); HFM: Harmonious functional movement; CoM: Centre of mass; DoF: Degrees of freedom.

FURTHER RESEARCH DIRECTIONS

Future research should investigate this slacklining MDM as a high-dimension mathematical manifold that details and discusses the multiple proposed contributing dimensions/constructs. There should include specific model applications that enable an improved understanding of HFM, stability, and balance-control. This may provide new/evolved evidence based recreational, performance, and rehabilitation slacklining applications and techniques as well as general stability-balance models. The MDM role in areas requiring development and utilization of stability, such as applications for machine learning for identifying pattern recognition of movement phenotypes. These applications may also extend to prostheses, mechanized automation, altered gravitational environments, robotics, mechatronics, and AI driven locomotion.

CONCLUSION

The successful strategy an individual employs to achieve slacklining is optimally explained by a hypothesized MDM. The strategy encompasses self-learned movement patterns that involve active and reactive generated forces that are integrated with gravity and the slackline's elastic reactive properties, governed by classical mechanics, occurring within a 3D defined space. These actions are subject to the BPS health model that integrates biological criteria, under psychologically experienced and motivated influences, affected by socially determined inputs. Concurrently, the multiplicity of time pervades and integrates all contributors as a measurable unit and integrated spatial and cortical experience. Dynamic stability is transitory and momentary, and acquired through the integration of all dimensions. It is higher in those with greater skill, but always returns towards entropy with movement away from, back to, and only momentarily crossing the point of fully integrated stability, a duration that lasts

longer as skill increases. This multi-tiered context facilitates multiple slacklining applications in movement, balance and stability. Further research is required to investigate this proposed model and potentially enable an improved understanding of HFM and its application in other diverse constructed and mechanical applications, varied environments and automation, robotic, mechatronics and AI factors.

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MINIREVIEWS

Dual antibiotic loaded bone cement in patients at high infection risks in arthroplasty: Rationale of use for prophylaxis and scientific evidence

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Abstract

In view of the demographic changes and projected increase of arthroplasty procedures worldwide, the number of prosthetic joint infection cases will naturally grow. Therefore, in order to counteract this trend more rigid rules and a stricter implementation of effective preventive strategies is of highest importance. In the absence of a "miracle weapon" priorities should lie in evidence-based measures including preoperative optimization of patients at higher infection risks, the fulfilment of strict hygiene rules in the operating theatre and an effective antibiotic prophylaxis regimen. Instead of a "one size fits all" philosophy, it has been proposed to adjust the antibiotic prophylaxis protocol to major infection risks taking into account important patient- and procedure-related risk factors. A stronger focus on the local application mode *via* use of high dose dual antibiotic-loaded bone cement in such risk situations may have its advantages and is easy to apply in the theatre. The more potent antimicrobial growth inhibition *in vitro* and the strong reduction of the prosthetic joint infection rate in risk for infection patients with aid of dual antibiotic-loaded bone cement in clinical studies align

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with this hypothesis.

Key Words: Prosthetic joint infection; Antibiotic-loaded bone cement; Single low dose antibiotic-loaded bone cement; Dual high dose antibiotic-loaded bone cement; Antibiotic prophylaxis; Risk-for-infection patients

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Core Tip: The objective of an effective antibiotic prophylaxis in arthroplasty may be best achieved through the combination of a systemic and local application route *via* antibiotic-loaded bone cement. Based on the observation of strong synergistic effects in antibiotic elution and antimicrobial efficacy of dual antibiotic-loaded bone cements, the hypothesis of a clinically more meaningful prophylaxis has been tested against gentamicin-only containing bone cements. Evidence is provided that this easy-to-apply strategy might be successful, if important comorbidities or procedure-related factors predispose patients to higher infection risks than usual.

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INTRODUCTION

Prosthetic joint infection (PJI) is one of the most dreadful complications of arthroplasty. Effective prophylactic strategies are essential to reduce the incidence of these difficult to treat and burdensome infections. The mode of prophylactic use of antibiotic-loaded bone cement (ALBC) is a frequent surgical practice in cemented hip and knee replacement. The idea behind delivering antibiotics directly into the vulnerable joint compartment is that local concentrations well above the minimum inhibitory concentration of the pathogen can be achieved without exposing the patient to major risks of side effects. With this mechanism ALBC may form an additional antimicrobial frontline *in situ* and complement the routine systemic antibiotic prophylaxis. The combined systemic and local antibiotic administration may be even more important in situations where the efficacy of the systemic prophylaxis is experiencing increasing limitations due to the spread of resistant bacteria to the commonly used perioperative antibiotics cefazolin or cefuroxime[1,2]. The Scandinavian registries and, most recently, the National Registry of United Kingdom have demonstrated that the additional use of ALBC reduces the revision risk in cemented hip and knee replacement[3-6]. It can be further speculated that this effect is more significant if specific cement brands are analyzed due to different antibiotic elution capacities of the cement polymers in commercial ALBC brands[7,8].

In view of the demographic changes, arthroplasty surgeons today face the challenge to operate on an increasing number of older patients suffering from several major comorbidities. Numerous clinical studies have provided evidence that important patient-related disorders predispose patients to a higher operational risk of infections than on average[9-11]. This is also true for the more complex surgical procedures of revision arthroplasty which is frequently associated with longer operation times and a higher invasiveness leading to a PJI incidence of 5% and more[12]. Significantly increased infection rates of 4%-6% are also reported in the frail cohort of femoral neck fracture (FNF) patients on an emergency trauma track which does not leave time for preoperative health optimization strategies or for decolonization protocols of multi-drug resistant bacteria[13,14]. In order to counteract the higher infection risks in such patient cohorts, one may hypothesize that a more optimized and risk-adjusted antibiotic prophylaxis strategy may have a positive impact on the PJI incidence. This may include (1) modification of the routine perioperative antibiotic prophylaxis regimen by either extending the duration[15] or by adding a second antibiotic to the standard drug (*e.g.*, vancomycin or teicoplanin to a cephalosporin)[16] or (2) use of high

dose local antibiotic combinations. Given the controversial outcomes regarding the first option and the substantial risks of side effects associated with prolonged systemic antibiotic exposure[17], a risk-adjusted strategy with dual ALBC might be a more attractive and "easy-to-apply" option in the theatre. The more potent antimicrobial growth inhibition found *in vitro* and the significantly reduced PJI rates in high infection risk patients receiving dual ALBC strongly argue for the latter option. This review summarizes the literature and evaluates the evidence from preclinical and clinical studies for the use of dual ALBC for PJI prevention in risk for infection patients and orthopaedic risk procedures. For that purpose, the PubMed and EMBASE literature databases were screened for publications pertaining to the clinical utilization of dual antibiotics in cement for infection prophylaxis. Use of dual ALBC in treatment of septic cases was excluded from the evaluation. Only four *in vitro* and five original clinical studies were identified which met the inclusion criteria. The latter were also stratified by level of clinical evidence (I-IV). The combination of gentamicin and clindamycin in commercial bone cement was the only referenced dual ALBC in these clinical studies. To the best of our knowledge there are no clinical outcome studies published which have compared the PJI rate in hand-made (theatre-admixed) dual ALBC *vs* single ALBC.

COMMERCIALLY PREMIXED *VS* HAND-MIXED DUAL ALBC

There are several Food and Drug Administration and European Medicines Agency approved ALBC which are available as "ready-to-use" commercial products. According to their antibiotic contents they can be grouped in single low dose ALBC [*e.g.*, impregnated with either 0.5 g or 1 g of gentamicin or loaded with 1 g of tobramycin in 40 g polymethyl methacrylate (PMMA) powder] or in dual high dose ALBC (*e.g.*, impregnated with 1 g of gentamicin and 1 g of clindamycin or loaded with 0.5 g of gentamicin and 2 g of vancomycin). In addition, there is widespread non-standardized, off-label and surgeon-directed use involving hand-mixing various antibiotics into bone cement. Reasons for this practice are economic considerations, lack of availability of specific ALBC, limited local regulatory approval or need for specific customized solutions in septic revision arthroplasty[18]. However, manual admixture of antibiotics into bone cement has raised some concerns with regards to unknown elution kinetics, toxicity, efficacy and mechanical stability of such in-theatre made ALBC[18]. The latter aspect is particularly important if the cement is intended for fixation. In fact, the manual addition of higher amounts of some antibiotics in powder- or in liquid-form has been shown to affect the fatigue strength of PMMA prompting fears of premature aseptic loosening of the joint[19]. It should also be noted that some antibiotics are not stable at the bone cement curing temperature (*e.g.*, many beta-lactam antibiotics) or chemically interfere with the polymerization process (*e.g.*, rifampicin)[20]. Given these uncertainties, the majority of surgeons still prefer the use of commercial single or dual ALBC for prosthesis fixation.

STRONGER ANTIMICROBIAL ACTIVITY WITH THE DUAL ALBC COPAL GENTAMICIN + CLINDAMYCIN *IN VITRO*

Gentamicin is the most frequently used antibiotic for impregnating bone cement because of its broad and concentration-dependent bactericidal effect, its relatively good elution in comparison to other antibiotics and its ability to withstand the high temperatures reached during polymerization of the bone cement[21]. Its antimicrobial spectrum covers non-gentamicin resistant gram-positive staphylococci, enterococci and several gram-negative bacilli[22]. Clindamycin is also an attractive antibiotic for local delivery which shares several features of gentamicin, but shows in addition a potent antimicrobial activity against intraosteoblastic *Staphylococcus aureus*[23]. Its spectrum overlaps with gentamicin on staphylococci and furthermore covers non-clindamycin resistant streptococci and anaerobic bacteria[24]. In combination, both antibiotics may target up to 90% of all pathogens typically found in PJI[25,26]. Given these antibiotic properties it is therefore not surprising that a dual ALBC bone cement using these antibiotics has been developed. This bone cement COPAL G+C (gentamicin + clindamycin) (Heraeus-Medical GmbH, Wehrheim, Germany) is simultaneously loaded with 1.68 g of gentamicin sulfate (= 1 g of active gentamicin) and 1.18 g of clindamycin hydrochloride (= 1 g of active clindamycin) within the

polymer basis of the successful PALACOS bone cement. Soon after the commercialization of COPAL G+C, Kuehn *et al*[7] and Neut *et al*[27] compared the antibiotic elution from this product with several single antibiotic loaded low dose cement brands on the market in two independent studies. It was found that COPAL G+C exhibited a much stronger synergistic release of both antibiotics exceeding that of gentamicin alone in single ALBC by a factor of at least 10[7,27].

Ensing *et al*[28] then combined these elution experiments with antimicrobial growth inhibition tests comparing the dual high dose COPAL G+C and the single low dose PALACOS R+G cement (containing 0.5 g of gentamicin). For that purpose, antibiotic-containing eluates from bone cement samples were collected at different time points and spotted onto agar plates which had been priorly inoculated either with a gentamicin-sensitive *Staphylococcus aureus* or with a gentamicin-resistant coagulase-negative *Staphylococcus epidermidis* strain. Both bacterial test strains were originally derived from PJI patients. COPAL G+C was observed to inhibit bacterial growth much more strongly when compared to PALACOS R+G. In more detail, the single low dose ALBC was effective in inhibiting growth of the gentamicin-sensitive *Staphylococcus aureus* for a period of 72 h of elution. However, the G+C containing cement yielded a stronger and more prolonged bacterial inhibition for at least 28 d, which was the entire duration of the experiment. In case of the gentamicin-resistant *Staphylococcus epidermidis* strain PALACOS R+G was not able to inhibit the bacteria while COPAL G+C prevented growth of these bacteria at all times after elution.

Cara *et al*[29] expanded on these studies and compared the inhibitory effect on staphylococcal biofilm formation of plain cement (no antibiotic) with the three ready-to-use commercial ALBC brands PALACOS R+G, COPAL G+C and COPAL G+V (the latter contains a combination of 0.5 g gentamicin and 2 g vancomycin, Heraeus Medical GmbH, Wehrheim, Germany). In total, ten different strains of *Staphylococcus aureus* and *Staphylococcus epidermidis*, some with specific resistance to gentamicin, were analyzed. It was observed that all the tested ALBC can inhibit biofilm formation of methicillin-susceptible staphylococci (without antibiotic resistances) up to day 9 (end of observation period). However, the inhibition of the dual ALBC brands at day 9 appeared more potent and sustained than that of the single ALBC product (Figure 1A). Strong antimicrobial effect of all 3 ALBC - at least up to day 3 - was also evident for methicillin-resistant staphylococci if they were still susceptible to gentamicin. However, a strong difference could be noticed for such strains which were highly resistant to gentamicin. In these cases, only the dual loaded products were able to exert a potent anti-biofilm activity with a tendency of even stronger and longer lasting inhibition for the G+C combination (Figure 1B). The most reliable and most sustained inhibition effect of the G+C combination against gentamicin-resistant coagulase-negative staphylococci is of important clinical relevance since regular antibiotic surveillance data from several countries point to an increasing gentamicin resistance level of these bacteria[30].

LOWER PJI RATE WITH DUAL ALBC (COPAL G+C) - HEMIARTHROPLASTY IN FNF PATIENTS

These promising *in vitro* observations with dual ALBC prompted surgeons at the Northumbria NHS Trust hospitals in the United Kingdom to test the hypothesis of a clinically more meaningful infection prophylaxis with COPAL G+C in the setting of a randomized clinical trial. For this they chose the particularly frail patient cohort of FNF patients known to suffer from higher infection risks. The study comprised of 848 patients with intracapsular fractures who were treated with cemented hemiarthroplasty according to the United Kingdom trauma guidelines. It was found that the primary study endpoint, incidence of deep surgical site infections (SSI), was significantly lower in the intervention group receiving the dual ALBC COPAL G+C (1.1% deep SSI rate) compared to the standard group receiving the single low dose ALBC PALACOS R+G (3.5% deep SSI rate, $P = 0.041$, evidence level I, Figure 2)[31]. If also considering the number of superficial SSI occurring in both groups, the difference was even more significant (1.7% in the intervention group *vs* 5.3% in control group). Tyas *et al*[32] later extended the patient number from this randomized study and analyzed 1941 FNF-patients in the same way. The lower PJI rate in the dual ALBC group was maintained (1.2% *vs* 3.4%). Savage *et al*[33] independently reported a PJI rate of 0% in the dual ALBC FNF-patient cohort *vs* 2.9% in the single ALBC group. This study compared bone cements from two different manufacturers in a mixed prospective and retrospective study design ($n = 206$), (evidence level II).

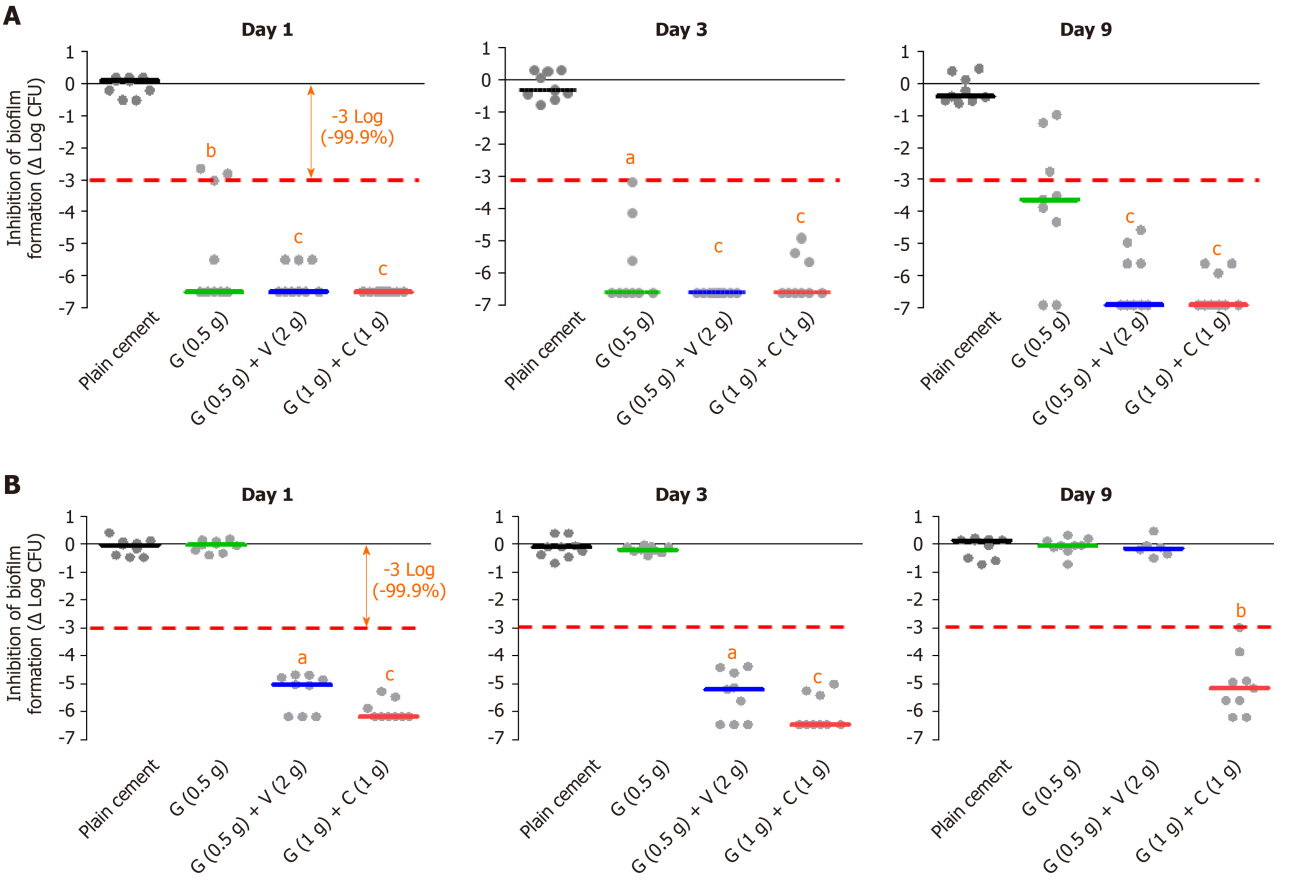


Figure 1 *In vitro* biofilm inhibition experiments with different bone cement types (plain, single and dual antibiotic-loaded bone cement). A: Prophylactic anti-biofilm effect of three different antibiotic-loaded bone cements against a gentamicin and methicillin-susceptible *Staphyloccus aureus* strain at day 1, day 3 and day 9 on basis of three independent experiments; B: Prophylactic anti-biofilm effect of three different antibiotic-loaded bone cements against a gentamicin- and methicillin-resistant *Staphylococcus epidermidis* strain on basis of three independent experiments. $^{a}P < 0.05$, $^{b}P < 0.01$, or $^{c}P < 0.001$ respectively in comparison with PALACOS R (cement without antibiotic). G: Gentamicin; C: Clindamycin; V: Vancomycin.

Concerns that the use of a dual antibiotic loaded cement with higher drug content may trigger more antibiotic-mediated side effects in these fragile patient cohorts could not be confirmed. In fact, the comparison of complications including renal failure or percentage of *Clostridium difficile* infections did not reveal differences between the standard and intervention group[31]. There was even a statistically significant decrease in the need for critical care treatment in the COPAL G+C group (0.5% *vs* 4.7%) reflecting the clinical impact of the much lower PJI rate in the intervention group receiving dual ALBC[31].

LOWER PJI RATE WITH DUAL ALBC (COPAL G+C) - ASEPTIC KNEE REVISION ARTHROPLASTY

Inspired by the promising results from the FNF studies, Sanz-Ruiz *et al*[34] tested the study hypothesis of a more potent infection prophylaxis with the dual ALBC COPAL G+C in the field of aseptic revision knee arthroplasty. All septic and oncologic revision causes were excluded in this study. On basis of 246 patients analyzed in this retrospective study no case of PJI was observed in the COPAL G+C group compared to six cases occurring in the PALACOS R+G group (PJI rate = 4.1%, $P = 0.035$, evidence level III). The use of the dual ALBC in all patients undergoing aseptic revision arthroplasty was further found to be cost-effective despite the additional cost of dual ALBC. A hospital saving of approximately 1200 € per patient was calculated due to 3.9 avoided PJI cases per 100 aseptic knee revision patients[34].

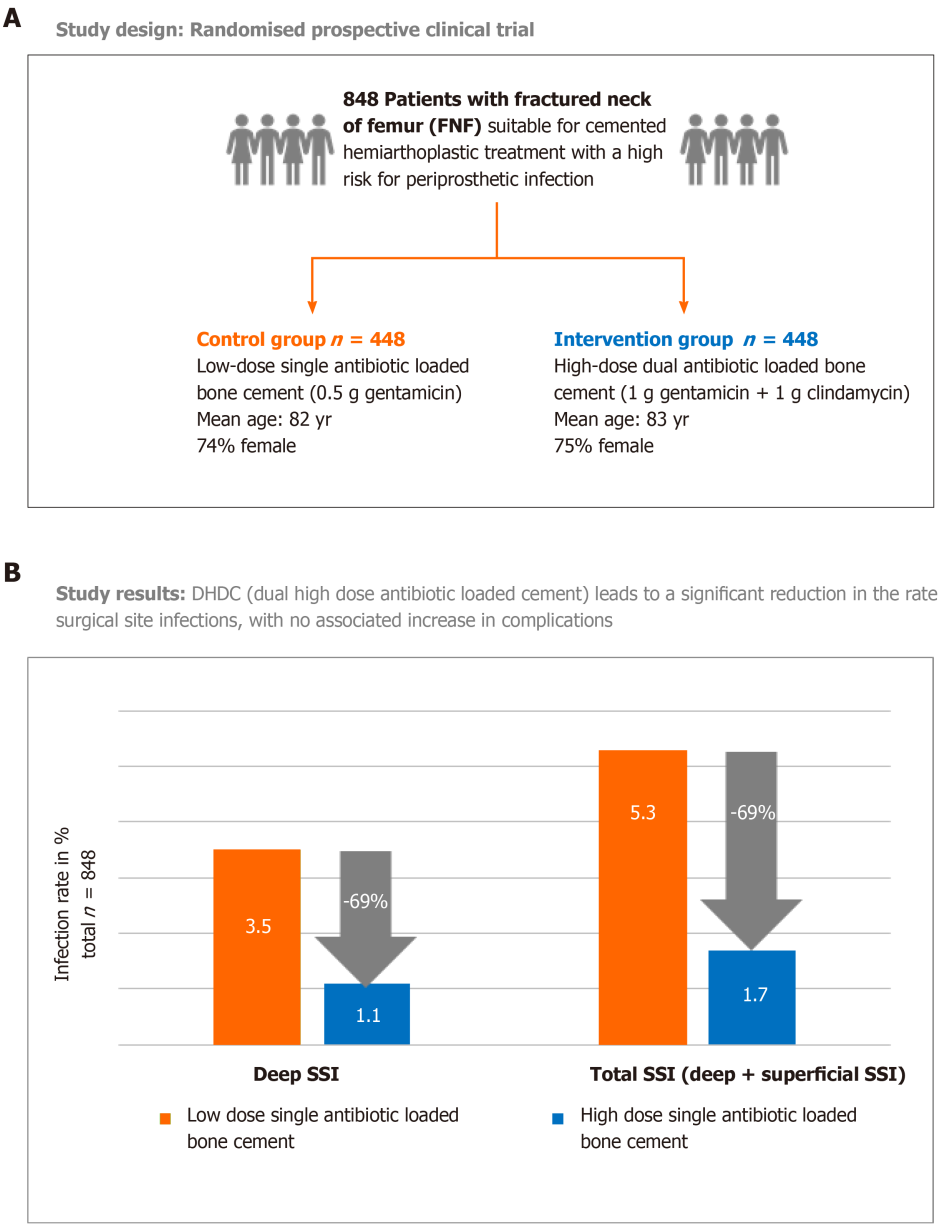


Figure 2 Randomized clinical trial in femoral neck fracture patients comparing prosthetic joint infection rate in low dose single antibiotic loaded bone cement group with high dose dual antibiotic loaded bone cement group. A: Study design, 848 patients were randomised to receive either hemiprostheses cemented with a low dose single antibiotic-loaded bone cement (PALACOS R + gentamicin = control group) or with a high dose dual antibiotic-loaded bone cement (COPAL gentamicin + clindamycin = intervention group); B: Study results: Primary endpoint was the deep surgical site infection rate (SSI) in the observation period of ≥ 1 yr in each group. Secondary endpoint was the rate of superficial SSI. For the calculation of the total SSI, both deep and superficial SSI cases in each group were combined. SSI: Surgical site infection.

LOWER PJI RATE WITH DUAL ALBC (COPAL G+C) - RISK FOR INFECTION PATIENTS IN PRIMARY ARTHROPLASTY

Sanz-Ruiz and Berberich[35] further analyzed the infection rate in presumed risk for infection patients by comparing the influence of single ALBC *vs* dual ALBC on the PJI incidence after primary cemented joint replacement. Patients were defined as risk for infection individuals if they presented a combination of at least two or three major risk factors for total hip arthroplasty and total knee arthroplasty, respectively, using a simple scoring system. The risk algorithm included specific patient-related comorbidities (*e.g.*, severe anemia, severe obesity, diabetes mellitus, chronic immunosuppression) and further general risk factors (*e.g.*, hip-fractures or prior arthroplasty surgeries)[35]. The study analyzed 2551 patients and found a trend towards fewer PJI cases in the dual ALBC (COPAL G+C) group containing exclusively patients at higher infection risk compared to the mixed risk profile (low and high risk) in the single ALBC (PALACOS R+G) group (PJI rate 2.45% *vs* 3.7%) (level of evidence

III/IV). This was a particularly interesting observation as one would expect an even higher PJI incidence in the higher infection risk cohort of patients. Further studies are needed to confirm whether this trend to fewer PJI cases in presumed risk for infection patients can be generalized on a broader basis for dual ALBC.

LOWER RATE OF RE-REVISIONS WITH DUAL ALBC IN SPACER AND/OR FIXATION CEMENT FOR REVISION PROSTHESIS - SEPTIC REVISION ARTHROPLASTY

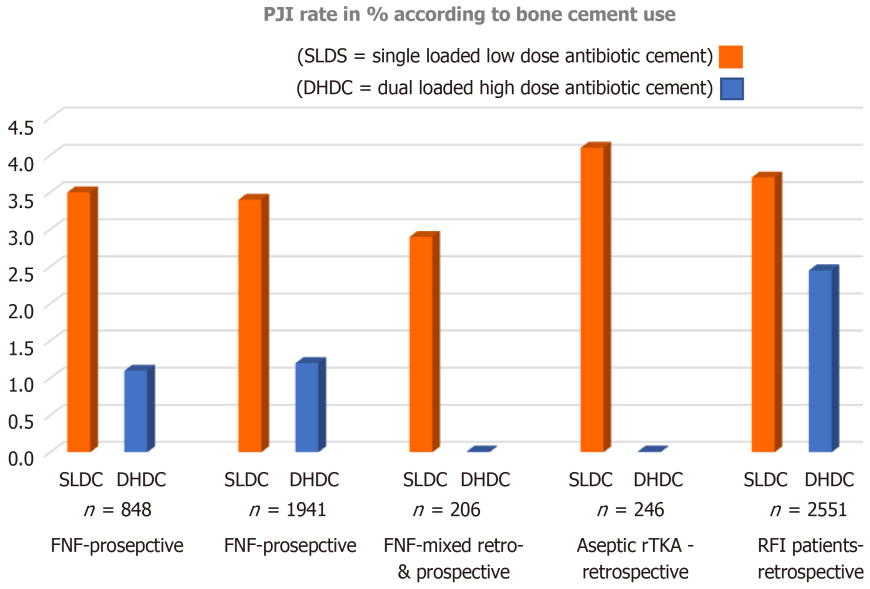
For many surgeons it is common clinical practice to use ALBC for the manufacture of block or articulating spacers in staged PJI treatment protocols and/or for the fixation of the revision prosthesis. Such ALBC spacers are meant to prevent bacterial recolonization of the foreign body and assist in the successful eradication of the infected joint in combination with systemic antibiotics. In order to increase the depot effect of the local antibiotics and to counteract the risk of antibiotic resistances in septic cases, the use of combinations of local antibiotics has been suggested[36]. The selection of antibiotics should be based on the antibiogram of the PJI organisms found after culture of synovial fluid and tissue biopsies. Vancomycin is the most common antibiotic added to aminoglycoside-containing single ALBC either in form of commercial dual ALBC brands or manually admixed in the theatre. The rationale of its use is to further target gentamicin-resistant methicillin-resistant *Staphylococcus aureus* (MRSA) and methicillin-resistant *Staphylococcus epidermidis* (MRSE). pathogens which are frequent in some regions, such as the United States[37]. Although several questions remain regarding optimal dosage for the possible therapeutic effects on biofilm-bacteria and/or contribution to renal injury if admixing large amounts of antibiotics into cement[18,36], its contribution to successful infection eradication appears conclusive[38]. Wouthuyzen-Bakker *et al*[39] have recently demonstrated on a large number of PJI cases to which extent the addition of vancomycin into the cement spacer influences the amount of growth-positive cultures taken at reimplantation of the revision prosthesis. The rate of unsterile biopsies dropped from 21.7% to 9.5% if combinations of vancomycin and gentamicin in the cement were used instead of aminoglycoside monotherapy spacers. On a single bacteria level, the strongest antimicrobial effect by such dual ALBC spacers was evident for coagulase-negative staphylococci (reduction of growth-positive samples from 13.3% to 2.5%).

Abdelaziz *et al*[40] have also provided evidence that the strategy of using the broad spectrum dual ALBC COPAL G+C (with or without additional admixing of vancomycin or ofloxacin) led to complete cure of PJI in one-stage treatment protocols. At five years follow-up, no patient required a repeated revision arthroplasty with exchange of the cemented prosthesis because of either infection or loosening. This was particularly remarkable as 33% of the included PJI cases in this study were caused by polymicrobial infections.

CONCLUSION

The current literature including *in vitro* and *in vivo* studies supports the additional benefits of dual ALBC, with synergy of drug elution and improved antibacterial activity on a wide range of pathogens related to orthopedic infections. While its therapeutic efficacy on mature biofilm-bacteria is still not entirely clear, more and more data have now demonstrated that it may confer better protection from infection in particularly vulnerable patients or in higher risk procedures (see Figure 3 for summary of clinical evidence). However, this conclusion is based on a mix of prospective and retrospective cohort studies, the latter with a lower evidence level and inherent limitations with regard to possible study bias and higher risk of confounding factors. A generalization of the observed effect of a stronger antibiotic prophylaxis by dual ALBC may also be problematic given that the ready-to-use brands of bone cements differ in their antibiotic elution properties as well as in the nature and amount of pre-mixed antibiotics.

The idea of an infection risk-adapted antibiotic prophylaxis strategy may be one interesting option among other preoperative optimization protocols to decrease the burden of PJI. In addition to the use of dual ALBC this can also be achieved by temporary or permanent antibacterial implant coatings including surface modifications with silver ions or manual spreading of a fast-resorbable, antibiotic-



Ref.	Sprowson *et al*[31] 2016	Tyas *et al*[32] 2018	Savage *et al*[33] 2019	Sanz-Ruiz *et al*[34] 2020	Sanz-Ruiz *et al*[35] 2020
Indication and study design	Femur fracture, randomized prospective trial	Femur fracture, randomized prospective trial	Femur fracture, retro-& prospective study	Aseptic rTKA, retrospective study	Primary TKA & THA (RFI-patients), retrospective study
Number of patients included	*n* = 848	*n* = 1941	*n* = 206	*n* = 246	*n* = 2551
Study arms	SLDC *vs* DHDC	SLDC *vs* DHDC	SLDC *vs* DHDC	SLDC *vs* DHDC	SLDC *vs* DHDC
Evidence level	level I	level I	level II	level III	level III/IV
PJI rate in %	**3.5 *vs* 1.1**	**3.4 *vs* 1.2**	**2.9 *vs* 0**	**4.1 *vs* 0**	**3.7 *vs* 2.45**

Figure 3 Overview of published clinical study results comparing prosthetic joint infection rate in patients in single low dose cement and dual high dose cement group across different indications. The table below lists the main study authors, indication and study design, number of patients included, evidence level of clinical study and prosthetic joint infection rate in % in both study groups. PJI: Prosthetic joint infection; SLDC: Single low dose cement = PALACOS R+G (containing 0.5 g of gentamicin); DHDC: Dual high dose cement = COPAL G+C (gentamicin + clindamycin); FNF: Femoral neck fracture; rTKA: Revision total knee arthroplasty; RFI: Risk for infection; THA: Total hip arthroplasty.

loaded hydrogel[41]. Both strategies have been shown to reduce early post-surgical infections in uncemented implants in orthopedic surgery. Further studies are needed to truly elucidate the effect of dual ALBC and other local antibiotic delivery systems for infection prevention and to weigh possible benefits against potential adverse effects and costs.

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MINIREVIEWS

Advantages of preoperative planning using computed tomography scan for treatment of malleolar ankle fractures

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Abstract

Malleolar ankle fractures have been classified using plain radiographs, and there is no consensus regarding the role of computed tomography (CT) scans in preoperative planning. We analyzed critical aspects, such as limits of standard radiographs, types of injury, classification methods and cost/benefit evaluations. CT scans allow a 3D analysis of the fracture to be obtained and consequently assess the indication for surgical procedure, surgical access and the type of fixation devices required. This exam is useful for detecting lesions that may go unnoticed on radiographs and will help surgeons to clarify the pathoanatomy of ankle fractures. According to Arbeitsgemeinschaft fur Osteosynthesefragen/ Orthopaedic Trauma Association (AO/OTA) classification, CT scan is recommended in medial malleolar fractures with vertical rim, type 44B fractures with posterior malleolar involvement and all type 44C fractures (according to AO/OTA). Also Tillaux-Chaput fractures (43-B1 according to AO/OTA), malleolar fractures in the presence of distal tibial fractures (43 according to AO/OTA) and distal tibia fractures in adolescents should be studied with CT scans.

Key Words: Computed tomography scan; Malleolar fractures; Planning; Trauma; Imaging

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Core Tip: Computed tomography scan is recommended in medial malleolar fractures with vertical rim, type 44B fractures [according to Arbeitsgemeinschaft fur

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Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification] with posterior malleolar involvement. All type 44C fractures (according to AO/OTA), Tillaux-Chaput fractures (43-B1 according to AO/OTA), malleolar fractures in the presence of distal tibial fractures (43 according to AO/OTA) and distal tibia fractures in adolescents should be studied with computed tomography scans.

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INTRODUCTION

Ankle fractures represent 10.2% of all fractures[1] and are the most common fractures of the lower extremity after proximal femur fractures[2]. The incidence number is approximately 1000 out of 1000000 people per year[3] with higher rates reported in the European literature[3,4]. Single malleolar fractures are the most frequent followed by bimalleolar fractures (25% of ankle fractures) and trimalleolar fractures (5%-10%)[5].

Isolated posterior malleolar fractures are rare[6] because they are usually associated with other bone or ligament injuries[7]. Ankle syndesmosis injury occurs in 10%-13% of cases, and 20% of cases require surgical treatment[8,9]. Malleolar fractures, in some cases, are associated with tibial pilon injuries[10-13].

The Arbeitsgemeinschaft fur Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) fracture and dislocation classification is one of the most used classifications. Malleolar segments are categorized as 44 and are based on the direction of the fracture lines and of the fracture degree of comminution (A-C)[14]. This classification is based on standard plain radiographs, although often this diagnostic assessment can underestimate the nature, extent and severity of the injury because of the complex three-dimensional anatomy of the joint[15].

Compute tomography (CT) scan is used in some cases in order to obtain a 3D analysis of the fracture and to consequently assess the indication for the surgical procedure, surgical access and type of fixation devices required. The anatomical reduction of fractures demonstrated higher functionality and improved long-term outcomes[16].

However, approximately one-third of patients aged 10-21 years with bimalleolar and trimalleolar fractures presented clinical signs of post-traumatic arthritis, and more than 97% showed pathological radiological findings[17-19]. Possible causes are due to minor inconsistencies, axial malalignment and syndesmosis instability. This study aims to identify the cases in which a CT scan is recommended in order to avoid or reduce the risk of long-term complications.

CRITICAL ASPECTS

Plain radiographs

Radiological assessment, usually performed in the emergency room, presents noncanonical projections because of patient pain or the presence of immobilization devices[2,16]. Furthermore, it is subject to the variable accuracy of the action and the scarce penetration of the radiations. Therefore, it is difficult to determine if the diagnostic assessment is adequate to perform a surgical fixation procedure with satisfying results. CT scan study does not replace an adequate plain radiograph study. Instead, it can provide precious information regarding the assessment of the fracture lines pattern and the number of fragments.

High-energy injuries

CT is fundamental to determine if surgical treatment is required due to the increase of the energy of the injury, which consequently increases the possibility of associated dislocations as well as complex injuries secondary to rotation flexion. Kumar *et al*[16]

reported that in ankle fracture cases the increase of malleolar involvement and the increase of the severity of the injury led to a different type of treatment strategy (that is surgical procedure) after CT scan study was performed. Hence, the presence of occult fractures and complex fracture lines is more likely in such injuries. The severity of the fracture is predictive of the increased risk of intra-articular abnormality[20,21], and in such cases preoperative CT scan assessment could identify additional lesions and mobile bodies requiring surgical treatment. The global change of the management plan rate was 23.2%, which was comparable with another retrospective study[2].

Classification methods

The most used classifications in the literature are AO/OTA, Weber or Lauge-Hansen classifications and are all based on standard plain radiographs. Clinical studies report that such classifications are not correlated with the fracture mechanism[22,23] and are not predictive of the sequence of bone and ligament injuries like CT, magnetic resonance imaging and surgical exploration are[24,25].

Cost/benefit analysis

Currently, CT scan studies represent the standard of care for all lower extremity joint fractures, especially acetabular fractures[26], femoral head fractures[27], distal femur fractures[28], tibial plateau fractures[29], tibial pilon fractures[30], talar fractures[31], calcaneal fractures[32], metatarsal fractures[33] and tarsometatarsal fractures[34]. Therefore, the CT scan study is by definition higher and larger than radiological analysis, although it is not assumed that it is required in all types of malleolar fractures[2].

CT requires higher costs, timing and exposure to radiation. Medical facilities are unfortunately more sensitive to cost and timing containment due to the constant increase of the demand for services; for this reason, it is essential to determine when a CT scan assessment is required. Radiation exposure is a sensitive aspect, particularly in pediatric patients. It was reported that the actual dose of an ankle CT scan study (0.07 mSv) was low and equivalent to a plain radiograph with anterior-posterior planes of the chest[35]. This value is ten times lower than the required dose of a CT scan study of the chest, abdomen and pelvis. It could be further reduced by limiting the exposed body segment or using a cone-beam CT scan and other protocols without the risk of losing essential information[36-38].

ADVANTAGES OF CT ANALYSIS

The advantages of using CT in the preoperative planning of malleolar fractures are: more accurate planning to determine the conservative/surgical approach and the type of fixation device required (and this is the major advantage because of the long-term results in spite of the surgical treatment[17-19]); the identification of unknown lesions in order to obtain a more accurate prognosis, including the detection of tibial pilon fractures; and more diffuse use of CT in the preoperative planning could clarify some unresolved biomechanical aspects regarding the relationship between the mechanism of injury and the pattern of fracture.

The most used classification, among the studies regarding the use of CT in the preoperative planning is the Danis Weber–AO classification, limited only to the three main categories: infrasyndesmotic (44-A according to AO/OTA classification), transsyndesmotic (44-B according to AO/OTA classification) and suprasyndesmotic (44-C according to AO/OTA classification). However, there is no absolute consensus among the authors[2,16,39]. This classification is attractive for clinicians because it is simple. The disadvantage of this system is that it does not incorporate a staging system to allow the degree of injuries falling only under one heading in terms of severity[40].

In our opinion this system is extremely simple and does not allow the differentiation of significant varieties within each group. Therefore, we reassessed the published system in order to determine a more detailed algorithm specifically referring to the Danis Weber subclassifications.

In our revision of the literature, the Lauge-Hansen classification was useful and significant in the evaluation of the importance of CT in the preoperative planning[7,41]. The classification is based on the rise of the mechanic forces, and there is a direct correlation between the increase of the energy of the injury and the usefulness of the preoperative CT study[2].

Infrasyndesmotic fractures (44-A according to AO/OTA classification)

Isolated lateral malleolar fractures [type 44-A1; Lauge-Hansen supination adduction (SA) stage I] and isolated medial malleolar fractures (type 44-A2.1/2; Lauge-Hansen SA stage II) are largely caused by injuries with no associated lesions. The use of CT is not recommended in this type of case. In a retrospective study[2] of 100 patients, no significant changes were noted regarding the treatment option (only 1 patient out of 24 cases of infrasyndesmotic fractures) following a CT scan study compared to the plain radiograph analysis[2].

The vertical medial malleolar fracture (Lauge-Hansen SA stage II) represents a particular condition because a medial tibial pilon injury can occur in the case of persistent energy of injury in adduction[11,42]. This type of lesion was described in 61% of SA stage II in the retrospective study conducted on 120 patients by Alluri *et al*[43]. In such cases, CT is recommended because the ideal treatment should provide the specific approach with elevation and bone grafting to significantly improve the prognosis[44]. In our opinion, the angulation of the line of fracture increases or decreases the suspected rate of tibial pilon injuries.

The above described subjects regarding the study of medial malleolus can be applied to bimalleolar fractures type 44-A2.3 (Lauge-Hansen stage II). In fracture type 44-A3 with a medial malleolus involvement associated with part of the posterior malleolus, a CT scan study is always recommended.

The importance of the preoperative CT scan study in the case of posterior malleolus fractures is documented by numerous publications in the literature. In fact, classifications based on CT scan studies have been proposed[13,45,46]. CT images allow the identification of impacted fracture fragments not visualized with conventional plain radiographs and with possible changes to the preoperative planning.

Black *et al*[2] and Magid *et al*[47] demonstrated that the use of CT scan study varies between 24.0% and 38.7% of the treatment planning compared to simple plain radiographs in cases of trimalleolar fracture[2,47]. Donohoe *et al*[48] and Palmanovich *et al*[49] reported that CT scan images increased the diagnostic accuracy and the intraobserver and interobserver agreement compared to conventional radiographs[48,49]. Furthermore, Evers *et al*[50] showed that in 25.1% of cases (430/1710), the planning was revised after CT scan study was performed with an increase of surgical indications and fixation device technique[50].

Transsyndesmotic fractures (44-B according to AO/OTA classification)

In transsyndesmotic fractures of isolated fibular fractures (type 44-B1 and B2) or bimalleolar fractures, the preoperative CT scan study does not significantly change the surgical treatment option[11,51]. This could be related to the fact that the standard radiographs are sufficient to adequately detect this type of fracture.

This assumption cannot be applied to transsyndesmotic fracture of posterior malleolar fracture (type 44-B3). In this case the study of posterior malleolus, as in fractures type 44-A3, cannot be based only on plain radiographs (Figures 1-3).

Suprasyndesmotic fractures (44-C according to AO/OTA classification)

In suprasyndesmotic fractures, despite the degree of fracture (C1, C2, C3 Lauge-Hansen PER stage 1-4), CT is always recommended. This study allows the evaluation of the syndesmosis and the possible involvement of the Tillaux-Chaput fragment[52,53]. Plain radiographs are not sufficient for syndesmosis evaluation because of the extreme variability among the individuals[54,55], whereas axial CT scan images allow a correct diagnosis as well as a determination of the best direction of the transsyndesmotic screw placement.

Tillaux-Chaput fractures (43-B1 according to AO/OTA classification) and malleolar fractures in the presence of distal tibial fractures (43 according to AO/OTA classification)

Conventional plain radiographs did not detect the Tillaux-Chaput fragment, which is more frequently present in fractures type B and C according to AO/OTA classification, in the studies conducted by Black *et al*[2] and Kumar *et al*[16]. This suggests an absolute advantage of the use of CT in fractures involving the anterior tibial tubercle[44] or in suspected cases considering the above-mentioned posterior malleolus fractures. The fixation of the anterolateral fragments re-establishes the anterior incisure and provides the stability of the anterior syndesmosis[56] (Figures 4 and 5).

The presence of occult fractures of the medial malleolus in fractures of the distal shaft of the tibia are described by some authors[57-60]. In the study by Jung *et al*[57], 89% of

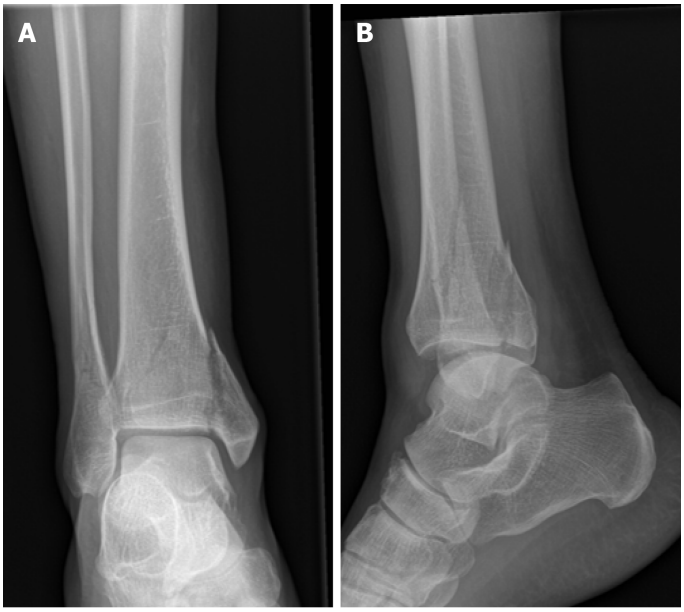


Figure 1 Transsyndesmotic fracture (44-B3). A: Anteroposterior; B: Lateral view.

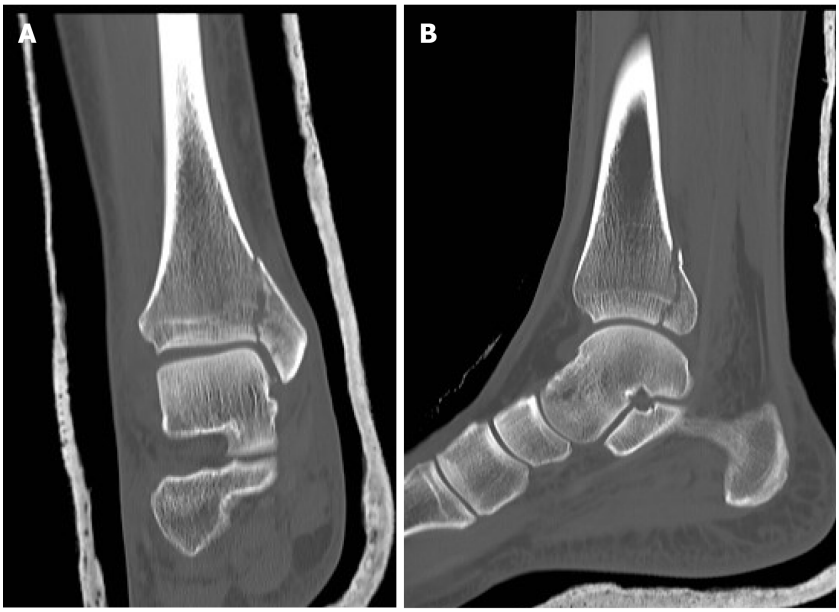


Figure 2 Computed tomography scans of the coronal plane and sagittal plane allow detection for the best screws direction. A: Coronal plane; B: Sagittal plane.

patients with distal tibia spiral fracture (type 43 according to AO/OTA) associated with malleolar fracture underwent surgical fixation. The importance of the preoperative identification derives from the risk of intraoperative decomposition during a surgical procedure of nailing with a consequent increase of surgical difficulties and duration of surgical treatment.

CT is additionally recommended in distal fracture of the leg because the line of fracture (even closed fracture) involves the epiphyseal/malleolar regions.

Malleolar ankle fractures in adolescents

The preoperative CT scan study represents the gold standard in malleolar ankle fractures in adolescents. Plain radiographs tend to underestimate this type of fracture. It is noted that consolidating fractures of the distal tibia present some features because the ossification of the growing cartilage is medial-lateral and posterolateral. This implies extraordinarily complex patterns of fractures (*i.e.* triplane fractures) and only with axial, sagittal and coronal planes is it possible to obtain adequate treatment

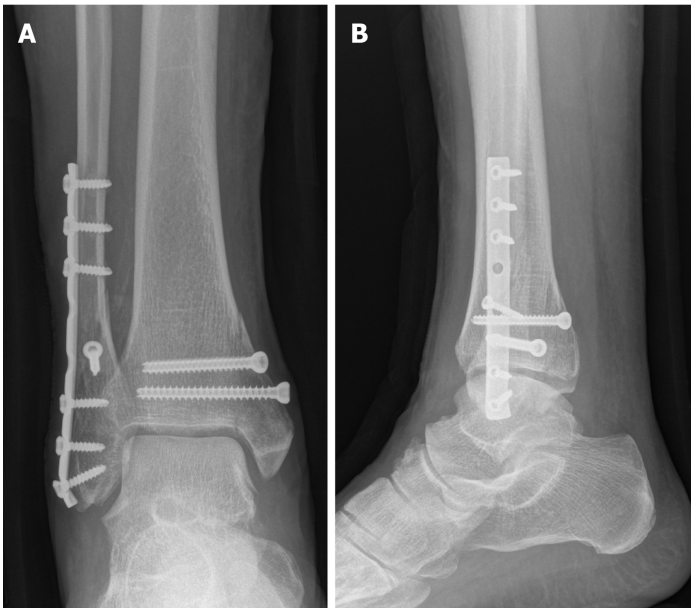


Figure 3 Postoperative X-rays in the anteroposterior and lateral view. Fractures treated with plate and screw fixation. A: Anteroposterior view; B: Lateral view.

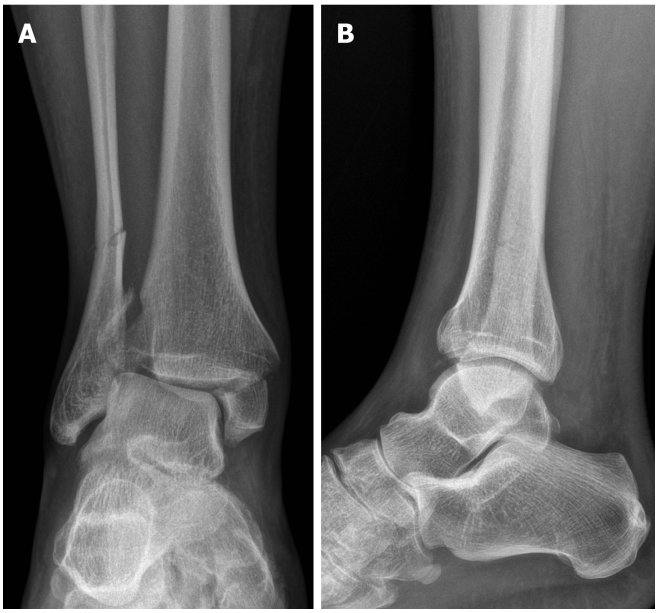


Figure 4 Suprasyndesmotic fracture (44-C2). A: Anteroposterior; B: Lateral view.

planning[11,61] (Figures 6-8).

CONCLUSION

The aim of malleolar fracture treatment is the anatomical reduction of the articular surfaces and of the syndesmosis. The use of CT in the preoperative planning could improve the clinical outcomes and reduce the risk of intraoperative difficulty and surgical duration in vertical medial malleolar fractures, in fractures type 44B with posterior malleolus involvement and in fractures type 44C. A CT scan study is mandatory in cases of Tillaux-Chaput fracture, malleolar fractures associated with the distal third of the leg and in adolescent patients. Additional large-scale clinical studies with cost/benefit analysis are required to confirm this hypothesis.

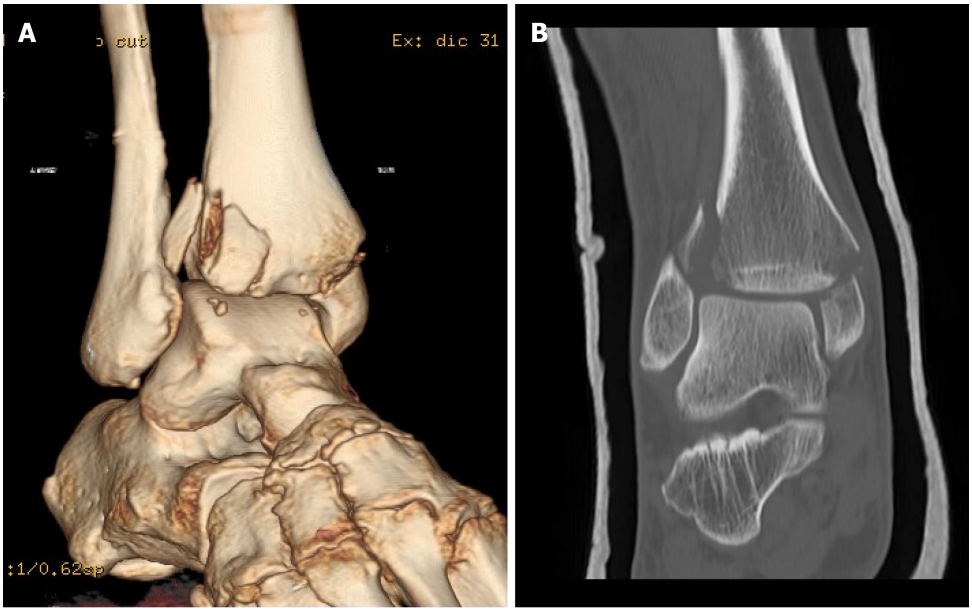


Figure 5 Computed tomography scans shows the involvement of the Tillaux-Chaput fragment. A and B: Tillaux-Chaput fragment.



Figure 6 Ankle fracture in adolescent. A: Anteroposterior view; B: Lateral view.

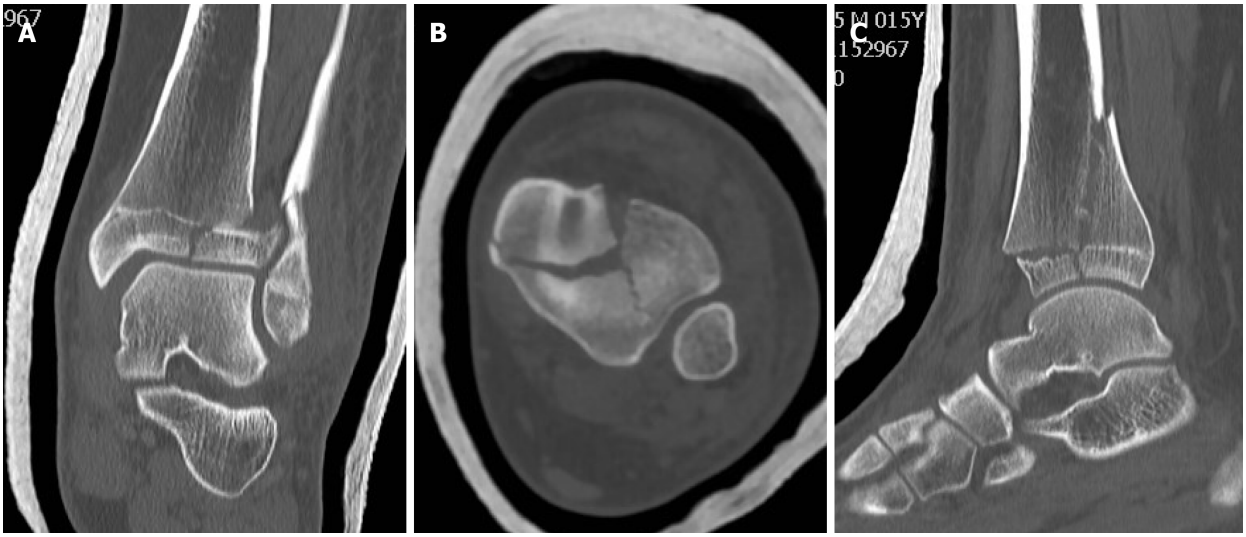


Figure 7 Computed tomography scan shows a triplane fracture. A: Coronal plane; B: Axial plane; C: Sagittal plane.



Figure 8 Postoperative X-rays in the anteroposterior view. Fractures treated with screws.

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ORIGINAL ARTICLE

Retrospective Study

Proximal tibial osteotomy for genu varum: Radiological evaluation of deformity correction with a plate *vs* external fixator

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Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

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Abstract

BACKGROUND

High tibial osteotomy (HTO) is a well-known procedure for the correction of knee varus. The purpose of this study was to compare the radiological results and accuracy of deformity correction performed using two different techniques: acute opening wedge correction using a plate and gradual correction with a monolateral external fixator.

AIM

To compare of the radiological results of two different techniques: acute opening wedge correction (a plate and screw) and gradual correction (external fixator).

METHODS

A total of 43 patients with plates and 36 patients with external fixators were included. All patients had moderate uniplanar varus deformities. We measured radiographic parameters, including the mechanical axis deviation (MAD), medial proximal tibial angle (MPTA), Caton-Deschamps Index (CDI), posterior proximal tibial angle, and joint line obliquity angle (JLOA). The accuracy of MAD correction was calculated based on a correction goal of neutral or overcorrection for medial compartment arthritis.

RESULTS

Demographics including age, body mass index, sex, and preoperative deformities were similar between the groups. The MAD significantly improved from 23.6 mm medial to the midline (SD = 8.2 mm) to 6.9 mm lateral to the midline (SD = 5.4 mm) ($P < 0.001$). The accuracy of MAD correction did not differ between the groups and was 96.1% (SD = 8.1%) in the plate group and 98.2% (SD = 5.2%) in the external fixator group ($P = 0.18$). The MPTA significantly improved from 83.9° (SD = 2.9°) to 90.9° (SD = 3.3°) ($P < 0.001$), and the change was similar between the groups. Differences were noted in patella height, with a CDI change of -19.2% (SD

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= 13.7%) and 3.1% (SD = 8.0%) for the plate and external fixator groups, respectively ($P < 0.001$). The change in JLOA was 1.6 degrees (SD = 1.1 degrees) and 0.9 degrees (SD = 0.9 degrees) for the plate and external fixator groups, respectively ($P = 0.04$).

CONCLUSION

Reliable correction of moderate varus alignment was achieved with both the acute opening wedge technique with a plate and the gradual monolateral external fixator technique. The patellar height decreased with the open wedge plate technique. Joint line obliquity decreased to a greater degree with the open wedge plate technique, perhaps as a result of medial collateral ligament release. The appropriate technique should be selected based on surgeon and patient preferences; however, external fixation may be a better choice when the preservation of patellar height is deemed important.

Key Words: High tibial osteotomy; External fixator; Gradual correction; Plate and screw; Genu varum; Radiological

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Core Tip: Open wedge high tibial osteotomy with plate and screw fixation is feasible and an appealing operation for surgeons. Overcorrection or under correction of the deformity leads to the persistence of pain. Patellar height changes affect patients with patellofemoral injuries. With the external fixator technique, the residual deformity can be corrected after surgery, and patellar height changes can be prevented. This is a retrospective study that was conducted to compare the accuracy and radiological outcomes of monolateral external fixation and internal fixation for proximal tibial varus deformity correction.

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INTRODUCTION

High tibial osteotomy (HTO) is a well-known procedure for the correction of knee deformities. This operation was introduced by Jackson in 1958 for the treatment of knee osteoarthritis (OA)[1]. In genu varum deformities, the load is transferred to the medial compartment of the knee, thus leading to the progression of medial compartment deterioration. HTO realigns the mechanical axis of the lower extremity, and this realignment decreases the load on the medial compartment and slows the progression of OA[2,3].

An abnormal biomechanical axis of the lower extremity not only causes damage to the cartilage of the knee but also affects the outcome of knee ligament reconstruction surgery. The degree of pain relief experienced after varus deformity correction depends on the accuracy of deformity correction. Inaccurate correction may cause pain to persist[4].

There are different techniques for genu varum knee deformity correction, including gradual correction with monolateral external fixation and acute opening wedge correction with internal fixation. HTO with monolateral external frame fixation is a minimal incision technique where the fibula and lateral cortex of the tibia are left intact during the osteotomy[5]. Gradual distraction of the medial cortex is performed with hinging on the intact lateral cortex, leading to realignment.

HTO with internal fixation and acute deformity correction may be performed with different approaches. Closing wedge HTO (CWHTO) and opening wedge HTO (OWHTO) are the two most well-known techniques for knee deformity correction. With OWHTO, patellar height changes can occur, which may adversely affect the

patellofemoral cartilage[2,6]. Changes in the posterior tibial slope (PTS) are another possible problem of OWHTO[7-11]. Although CWHTO does not seem to affect the posterior slope, achieving an accurate correction is more difficult with CWHTO than with OWHTO, and there is an increased risk for peroneal nerve injury[12,13]. There is no consensus on which technique is superior.

In this study, we compared OWHTO with a plate to gradual correction with a monolateral fixator in a group of patients with moderate varus deformities of less than 10 degrees. In our practice, complex deformities (greater than 11 degrees or multiplanar deformities) are usually approached with a hexapod frame. The radiological outcome data included the accuracy of coronal plane realignment and the effect on patella height and posterior slope.

MATERIALS AND METHODS

This study was a retrospective, nonrandomized study (level III). The study was reviewed and approved by our institutional review board. We identified 79 consecutive patients who underwent genu varum deformity correction surgery either by internal fixation with opening wedge correction (43 patients) or a monolateral external fixator (36 patients). The inclusion criteria were patients who required less than 11 degrees of correction, patients aged 18 years or older, and patients who did not have an accompanying femoral deformity. Patients with Blount disease and those undergoing revision surgery were excluded from the study. All the surgeries were performed by the senior authors. The different approach for similar patients represents an evolution of practice with a move away from external fixation to OWHTO with a locked plate.

We used the Kellgren-Lawrence classification (KL) system for OA[14]. The severity of arthritis was graded by X-ray as follows (KL): 0, no narrowing of the joint space or reactive changes; 1, doubtful narrowing of the joint space with possible osteophyte formation; 2, possible narrowing of the joint space with definite osteophyte formation; 3, definite narrowing of the joint space, moderate osteophyte formation, some sclerosis, and possible deformity of the bony ends; and 4, large osteophyte formation, severe narrowing of the joint space with marked sclerosis, and definite deformity of bone ends.

Our goal was to correct the mechanical axis in the patients without OA (KL ≤ 2) to normal anatomical alignment and to overcorrect the axis to 10 mm valgus in the patients with OA (KL > 2)[15].

Each patient obtained a bilateral hip-to-ankle X-ray, anteroposterior (AP) view of the knee, and lateral view of the knee both before surgery and six months after surgery. mechanical axis deviation (MAD) and medial proximal tibial angle (MPTA) measurements were performed before and six months after the operation to evaluate the status of deformity correction in the coronal plane. The other radiological parameters used for the evaluation included posterior proximal tibial angle (PPTA), and joint line obliquity angle (JLOA).

To quantify MAD, we measured the distance of the mechanical axis (center-of-hip to center-of-ankle line) from the center of the tibial plateau either laterally or medially. The lateral knee X-ray was used to measure the patellar height. We used the Caton-Deschamps Index (CDI) to evaluate the patella height before and 6 mo after the surgery (Figure 1). On the lateral view, the CDI was calculated as the distance from the upper part of the tibial plateau to the inferior pole of the patella divided by the length of the patella from the upper pole to the lower pole (Figure 1). All the measurements were performed by limb reconstruction fellowship-trained surgeons.

We measured PPTA to evaluate the PTS in the lateral view before and 6 mo after the surgery. We drew a line from the center of the diameter of the tibia in the lateral view and a line tangent to the tibial plateau. The angle between these lines was the PTS.

Surgical technique

Acute genu varum deformity correction using OWHTO and plate and screw fixation was performed through an incision over the medial surface of the proximal tibia. After incising the pes anserine insertion over the tibia, the superficial fibers of the medial collateral ligament (MCL) were released from the tibia. An oblique wire was inserted from the medial cortex toward the head of the fibula 1.5 cm distal to the lateral tibial plateau. The osteotomy was done along the wire making sure to leave the lateral cortex intact. The posterior half of the osteotomy ended near the tibial tuberosity. This region was connected to the anterior half of the osteotomy, which was performed in an

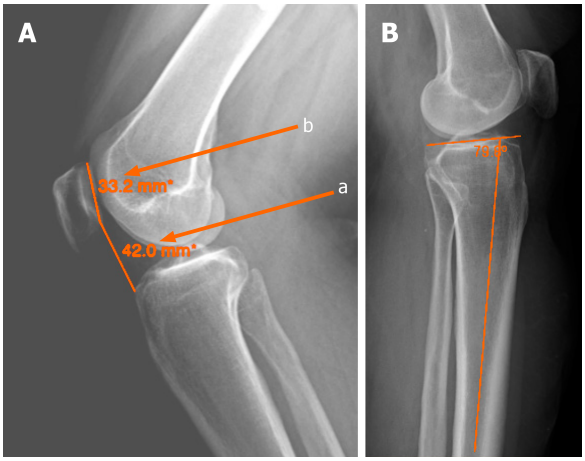


Figure 1 Knee X-ray images. A: Caton-Deschamps Index (a/b) for evaluation of the patella height; B: Posterior proximal tibial angle.

oblique fashion below the tibial tuberosity and continued to the anterior cortex of the proximal tibia. The lateral cortex was left intact, and the cut was stopped 1 cm medial to the lateral cortex. A laminar spreader was used in the posterior part of the osteotomy site to retract the two parts, stretching the soft tissue for several minutes and gradually opening the gap to achieve the preplanned measurement. A metal trial was inserted with a base height matching the preoperative plan. Care was taken to ensure that the opening wedge height was equal between the anterior and posterior parts to avoid unintentional flexion. The alignment of the lower extremity was confirmed during the surgery with a long rod from the hip to the ankle and C-arm fluoroscopy. A tri-cortical allograft was then inserted into the gap after the trial wedge was removed. The graft was not tapped into the osteotomy site to avoid graft fracture. The osteotomy site was then fixed with the plate and screws consisting of four 5-mm locking screws in the proximal segment and three to four locking and nonlocking 4.5- to 5-mm screws in the distal segment. The remaining space in the opening wedge was filled with freeze-dried allograft chips and demineralized bone matrix putty. In the postoperative follow-up period, the OWHTO patients were evaluated in the clinic 2 wk and 6 wk after surgery, and monthly thereafter for 6 mo after surgery (Figure 2). The patients were non weight bearing for 6 wk after surgery and then they were transferred to the partial weight bearing.

Gradual genu varum deformity correction with a monolateral external fixator procedure was performed through a small incision over the medial surface of the tibia just below the tibial tubercle. A monolateral frame external fixator with a hinge at the osteotomy level was placed over the medial side of the tibia and connected to the bone with two half-pins proximally and three half-pins distally. The hinge was carefully oriented in the coronal plane. The fixator was positioned parallel to the tibia in the sagittal plane to avoid unintentional flexion during distraction. The 6 mm pins were made of stainless steel and covered with hydroxyapatite. An osteotomy in the tibia was made with multidirectional drilling in a direction perpendicular to the axis of the tibia. A narrow osteotome was used to complete the osteotomy at the medial side. The lateral cortex and fibula remained intact. Distraction at the osteotomy site was started 7 d after the surgery with a rate of 0.25 mm four times a day. Adjustment was evaluated by X-ray 1 wk after starting the distraction, and the distraction gap was reassessed by the senior authors. After the adjustment schedule was completed, a new hip-to-ankle X-ray was taken for the final alignment measurement. For patients with residual malalignment, a new schedule was created to continue correction; this process was continued until the intended final result was achieved.

The patients were non weight bearing for 2 wk after surgery, and then transferred to the partial weight bearing. These patients were evaluated in the clinic every month until frame removal. After frame removal, they were seen 6 mo after surgery (Figure 3).

RESULTS

There were 43 patients in the plate and screw group and 36 patients in the external

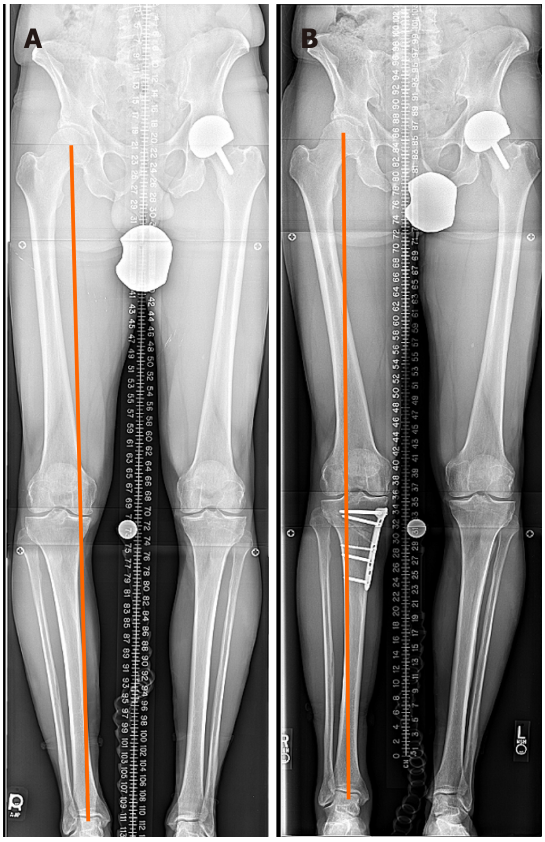


Figure 2 High tibial osteotomy with plate and screws. A: Pre-operation; B: Post-operation.

fixator group, and these groups were further subdivided based on whether the intraoperative correction goal was neutral alignment or overcorrection.

Age, body mass index, and sex were similar between the plate and external fixator groups (Table 1). We also compared the subgroups of each arm of this study as well as the subgroups within each arm (Table 2). The intra-arm comparison demonstrated several significant results, leading us to conclude that subgrouping and intergroup comparisons were appropriate.

For the MAD measurements, we included 40 patients in the plate and screw group and 36 patients in the external fixator group. In all the patients who underwent plate and screw fixation, the mechanical axis was transferred from the medial side to the lateral side. The patients who underwent external fixation were divided into two subgroups. In the external fixator group with an overcorrection goal, the mechanical axis of 1 of the 13 cases remained on the medial side. In the external fixator group with a neutral goal, the mechanical axis of all the cases shifted to the lateral side or neutral position (Table 3).

Among all patients, the MAD significantly improved from 23.6 mm medial to the midline (SD = 8.2 mm) to 6.9 mm lateral to the midline (SD = 5.4 mm) ($P < 0.001$, results not shown in the table). The mean MAD before surgery in the plate and screw group with a neutral goal was 24.5 mm medially and 4.3 mm laterally after surgery (Table 3). In the plate and screw group with an overcorrected goal, the MAD was 25.9 mm medially preoperatively and 12.7 mm laterally postoperatively. For the external fixator group, the patients with a neutral goal had an average MAD of 21.3 mm medially preoperatively and 3.5 mm postoperatively (no medial *vs* lateral because average of absolute value). The overcorrected subgroup of patients with external fixators had 23.0 mm of medial MAD before surgery with 9.5 mm after. The results between the two groups were not significantly different.

Among all patients, the MPTA significantly improved from 83.9° (SD = 2.9°) to 90.9° (SD = 3.3°) ($P < 0.001$, results not shown in the table). The changes in MPTA between the plate and screw patients *vs* the external fixator patients were not significantly different between the subgroups (Table 4). The plate and screw patients' MPTA increased 6.8 degrees in the neutral group compared to 5.7 degrees in the external fixator's neutral group. For the respective overcorrected subgroups, these changes were 9.6 degrees and 6.2 degrees.

Table 1 Patients demographic

Demographics	Plate and screw (*n* = 43)		External fixator (*n* = 36)		*P* value
	n	Mean (range)	*n*	Mean (range)	
Age (yr)	43	46.3 (19-68)	36	42.1 (24-67)	0.14
BMI (kg/m^2)	39	26.0 (18.7-35.0)	11	30.0 (20.3-39.1)	0.08
Sex (female)	43	32.6%	36	47.2%	0.16

BMI: Body mass index.

Table 2 Patients demographic

Demographics	Plate and screw (*n* = 43)				External fixator (*n* = 36)				*P* value			
	N[1] (*n* = 25)		O (*n* = 18)		N (*n* = 23)		O (*n* = 13)		N *vs* N	O *vs* O	N *vs* O (plate and screw)	N *vs* O (ex fix)
	n	Mean (range)	*n*	Mean (range)	*n*	Mean (range)	*n*	Mean (range)				
Age (yr)	25	41.7 (19-68)	18	52.7 (32-67)	23	39.9 (24-55)	13	46.1 (30-67)	0.61	0.12	< 0.01	0.11
BMI (kg/m^2)	23	24.1 (18.7-33.5)	16	28.8 (22.4-35.0)	8	27.6 (20.3-39.1)	3	36.4 (33.1-38.4)	0.15	0.03	< 0.001	0.01
Sex (female)	25	36.0%	18	27.8%	23	47.8%	13	46.2%	0.41	0.25	0.57	0.92

[1]In this table and all subsequent ones. T: Total group; N: Neutral goal; O: Overcorrected; BMI: Body mass index.

Table 3 Mechanical axis deviation changes

MAD	Plate and screw		External fixator		*P* value	
	N	O	N	O	N *vs* N	O *vs* O
	Mean (range)	Mean (range)	Mean (range)	Mean (range)		
MAD pre-op (mm)	24.5 med (14 med to 42 med)	25.9 med (11 med to 37 med)	21.3 med (9 med to 42 med)	23.0 med (11 med to 42 med)	0.15	0.38
MAD post-op (mm)	4.3 lat (1 lat to 13 lat)	12.7 lat (3 lat to 20 lat)	3.5 (7 med to 10 lat)	9.5 (5 med to 20 lat)	0.40	0.08

MAD: Mechanical axis deviation; N: Neutral goal; O: Overcorrected; op: Operation.

Table 4 Medial proximal tibial angle changes

MPTA	Plate and screw		External fixator		*P* value	
	N	O	N	O	N *vs* N	O *vs* O
	Mean (range)	Mean (range)	Mean (range)	Mean (range)		
ΔMPTA (degree)	6.8 (0-13)	9.6 (3-14)	5.7 (2-10)	6.2 (-4 to 15)	0.25	0.05

MPTA: Medial proximal tibial angle; N: Neutral goal; O: Overcorrected.

To determine the accuracy of correction, we first defined the error. The error of the correction was calculated as a ratio. The acceptable range from the MAD goal was considered 5 mm. The numerator was the distance from the limits of the acceptable range: 5 mm medial to 5 mm lateral for the neutral goal and 5 mm lateral to 15 mm lateral for the overcorrected goal (15). The denominator was the difference between the MAD preoperatively and the median of the acceptable MAD range postoperatively: 0

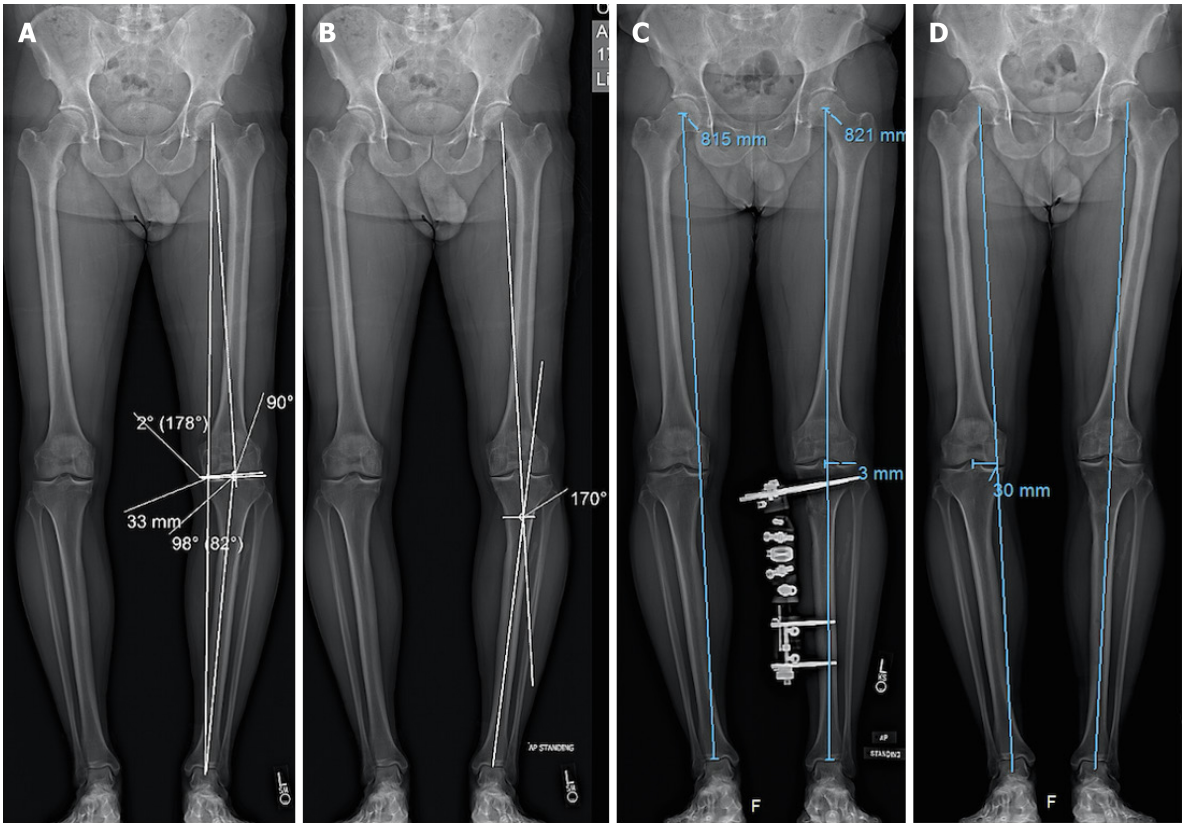


Figure 3 High tibial osteotomy with external fixator. A and B: Before correction medial proximal tibial angle: 82, joint line obliquity angle: 2, mechanical axis deviation: 33 mm, lateral distal femoral angle: 90; C: After correction with external fixator; D: After removal of external fixator.

mm in the neutral subgroup *vs* 10 mm lateral in the overcorrection subgroup. The accuracy for each patient was calculated by subtracting the error from 1[5,16,17].

The accuracy was quite high for every subgroup (Table 5). There were no statistically significant differences between the two arms' respective subgroups.

The mean preoperative CDI for the patients in the plate and screw group was 1.1, and that for the patients in the external fixator group was 1.0 (Table 6). This difference was not statistically significant. The postoperative measurements were 0.9 for the plate and screw group and 1.1 for the external fixator group, which was statistically significant. The absolute changes for the two groups were a decrease of 0.2 and an increase of 0.02 respectively for the two groups, and the percent changes were a decrease of 19.2% and an increase of 3.1%. These differences were statistically significant.

The average change of the plate and screw patients' PPTA was a decrease of 3.3 degrees *vs* a mean decrease of 1.7 degrees of external fixator patients' change in PPTA (Table 7). The percent changes were -4.1% *vs* -2.0%. None of these results were statistically significant.

The mean absolute value of the change in JLOA preoperatively to postoperatively was an increase of 1.6 degrees for the plate and screw group and a 0.9 degree increase for the external fixator group (Table 8). This difference was statistically significant.

There was a major complication in the external fixator group with one patient with loss of reduction and collapse in the regenerated bone at the osteotomy site after the removal of the external fixator. Subsequent open reduction and internal fixation with plates and screws were performed for this patient. Some of the patients in the external fixation group had discharge and superficial infections around the half-pin that were successfully treated with oral antibiotics. There were no cases of neurovascular injury, neuropraxia, nonunion, deep infection, or osteomyelitis in either group. There was no significant change in knee range of motion in either group at the last follow-up as compared to the pre-operative baseline measurement.

Table 5 Accuracy of mechanical axis deviation correction

Accuracy	Plate and screw			External fixator			*P* value		
	T	N	O	Total	N	O	T *vs* T	N *vs* N	O *vs* O
	Mean (range)	Mean (range)	Mean (range)	Mean (range)	Mean (range)	Mean (range)			
Accuracy (%)	96.1 (60 to 100)	94.8 (60 to 100)	97.7 (87 to 100)	98.2 (79 to 100)	98.2 (82 to 100)	98.2 (79 to 100)	0.18	0.17	0.82

T: Total group; N: Neutral goal; O: Overcorrected.

Table 6 Changes in Caton-Deschamps Index

CDI	Plate and screw	External fixator	*P* value
	Mean (range)	Mean (range)	
CDI pre-op (unitless)	1.1 (0.7-1.6)	1.0 (0.8-2.1)	0.77
CDI post-op (unitless)	0.9 (0.4-1.1)	1.1 (0.8-1.9)	0.01
ΔCDI (unitless)	-0.2 (-0.5 to 0.2)	0.02 (-0.2 to 0.2)	< 0.001
%ΔCDI (%)	-19.2 (-47.0 to 21.9)	3.1 (-8.1 to 25.0)	< 0.001

CDI: Caton-Deschamps Index.

Table 7 Posterior proximal tibial angle changes

PPTA	Plate and screw	External fixator	*P* value
	Mean (range)	Mean (range)	
ΔPPTA (degree)	-3.3 (-9 to 1)	-1.7 (-11 to 4)	0.14
%ΔPPTA (%)	-4.1 (-11.3 to 1.3)	-2.0 (-12.8 to 5.1)	0.11

PPTA: Posterior proximal tibial angle.

Table 8 Joint line obliquity angle changes

JLOA	Plate and screw	External fixator	*P* value
	Mean (range)	Mean (range)	
ΔJLOA (degree)	1.6 (4 med to 3 lat)	0.9 (3 med to 2 lat)	0.04

JLOA: Joint line obliquity angle.

DISCUSSION

HTO is an appropriate procedure for genu varum deformity correction to correct MAD. The procedure alleviates pain in patients with OA of the medial compartment of the knee. In this study, we compared the results of acute correction with OWHTO to those of gradual correction with an external fixator for knee varus deformities. The reported indication for HTO surgery is varus alignment of the knee combined with any of the situations, such as medial compartment OA, medial compartment overloading (such as post medial meniscectomy), knee instability or osteochondral lesions[18].

The indications for HTO surgery in our study were a varus deformity greater than 5 degrees and knee pain. If there was radiographic medial joint space narrowing, then the goal was overcorrection. If there was no radiographic medial joint space narrowing, then the goal was neutral alignment.

Our results showed that while the re-alignment was substantial, there were not

significant differences between the two groups in MAD and MPTA changes, and the accuracy of correction. The PPTA changed less in the external fixator group than the plate and screw group, but this change was not significant.

Patella baja may be a concern after OWHTO[19]. Patella baja causes anterior knee pain and crepitus[4,20]. Because of the transfer of the tibial tuberosity distally and laterally, the biomechanical axis of the patellofemoral joint changes after surgery[8]. One biomechanical study showed that OWHTO tilts the patella medially and increases the pressure over the lateral surface of the patella[21]. It has also been reported that the pressure over the patellar cartilage increases after OWHTO[6].

The literature has shown that there is a significant increase in patellofemoral joint pressure with genu varum knee deformity correction of more than five degrees[6]. Previous work has evaluated the effect of shortening the patellar height over the patellofemoral articular cartilage[7,22]. Researchers have demonstrated that shortening the patellar tendon after OWHTO accelerates the development of patellofemoral OA. Chondral lesions increased in long-term follow-up and likely causes anterior knee pain[23].

In our external fixator group, the patellar tendon height changed less than that in the plate group after surgery. The osteotomy performed in the external fixator group at the distal tibial tuberosity did not affect the patellar height. Additionally, when a varus deformity is gradually corrected, the soft tissue around the knee lengthens gradually, and the patellar tendon length does not change after varus deformity correction. For this reason, this technique may be preferred for genu varum deformity patients with OA of the patellofemoral joint. Also, the JLOA changed less in the external fixator group compared to the plate and screw group. Gradual correction of the deformity may allow the ligaments to stretch more slowly, having less of an effect on the JLOA. Additionally, the medial collateral ligament is released during the acute correction of OWHTO, which may decrease the JLOA. The clinical outcomes were similar between the two groups.

Correction of the knee genu varum deformity is important before anterior cruciate ligament (ACL) reconstruction[13]. The PTS is one of the factors that affects the outcome of ACL reconstruction. Increasing the PTS results in a transfer of the loading to the anterior part of the knee, and this overload may affect the outcome of ACL reconstruction surgery. OWHTO has been shown to increase the PTS[12,24]. Every 10-degree increase in the PTS causes a 6-mm translation of the anterior tibial load axis[4]. Our results show that there was a smaller change in the PTS in the external fixator group than in the OW group. However, the difference in PPTA change between the groups was not significant.

The results of some modifications of open wedge HTO have been reported. One study showed no differences in patellar height or PTS between an ascending *vs* descending OWHTO, a technique requiring leaving the tuberosity attached to the distal tibia or proximal tibia, respectively[23]. Some surgeons advise releasing the posterior soft tissue to prevent an increase in PTS[4]. Another study recommends against the release of the soft tissue and medial ligament[25]. In this biomechanical study, it was shown that cutting the anterior fiber of the MCL affects the stability of the medial side in HTO[25].

Evaluation of the changes in the MAD and MPTA in both groups showed there was no significant difference in correction of the genu varum deformity between the both groups. The accuracy of the correction was 96.1% (60%-100%) in the plate and screw group and 98.2% (79%-100%) in the external fixator group. Both techniques led to accurate genu varum deformity correction, and there was no significant difference between the two groups.

Undercorrection, or sometimes overcorrection, may compromise the outcome of genu varum deformity correction surgery[4]. Preoperative measurement planning is helpful to achieve optimal alignment correction. However, sometimes, the laxity around the knee that appears on weight-bearing X-rays is not as obvious when the patient is in the supine position intraoperatively[26]. With our external fixator technique, we have the opportunity to continually correct residual deformities after surgery, making it a helpful procedure in patients with soft tissue laxity in the knee. Additionally, because the external fixator allows gradual correction, the formation of bone is well controlled, the rate of lengthening can be adjusted, and nonunion or malunion can be prevented[16,17,27,28].

There are some limitations of our study. First, these operations were performed by experienced surgeons, which may affect the results of the operations and may have reduced the rate of complications after the operations. External fixator adjustments require experience and expertise; thus, these results may be hard to generalize to a large variety of practices. Second, this study is a retrospective study with a limited

number of patients. As mentioned above, there were some demographic differences between some subgroups, and we evaluated the radiological outcomes of the two techniques. Future works would be helpful if they evaluate these results in a larger number of patients. Third, this study was a radiological comparison of the two techniques, and a study comparing the early and late clinical outcomes in both groups in a larger number of patients would be helpful to determine the clinical performance of these techniques. Fourth, our patients were confined to those with varus deformities of less than ten degrees. We suggest future studies evaluating patients with larger-degree varus deformity corrections.

CONCLUSION

Reliable degrees of correction of moderate varus alignment were achieved with both the acute opening wedge technique with a plate and the gradual monolateral external fixator technique in patients undergoing HTOs. The appropriate technique should be selected on the basis of the surgeon and patient preferences; however, external fixation may be a better choice when maintenance of patellar height is deemed important.

ARTICLE HIGHLIGHTS

Research background

High tibial osteotomy (HTO) for the correction of painful varus knee deformities is a known surgery. Different HTO techniques have been reported in the literature, including open and closed wedge osteotomies. In this study, the radiological efficacy of the gradual and acute correction of varus deformities with two different fixation methods (external fixator and plate screw) was evaluated.

Research motivation

We aimed to compare the radiological accuracy of the gradual correction of varus deformities with HTO with an external fixator and that of acute correction with a plate and screw.

Research objectives

The changes in radiological parameters (mechanical axis deviation, medial proximal tibial angle, posterior proximal tibial angle, joint line obliquity angle, Caton-Deschamps Index) were evaluated after both acute and gradual correction to determine the accuracy of correction achieved with the two techniques.

Research methods

Retrospective, nonrandomized study (level III).

Research results

Both acute correction (opening wedge and plate and screw) and gradual correction (external fixator) yield reliable degrees of correction of moderate varus alignment. The changes in the radiological parameters achieved with and accuracy of the two techniques are reasonable. There were changes in the patellar height after acute correction with a plate and screw.

Research conclusions

Both techniques (HTO with plate and screw and external fixator) are reliable for the correction of varus deformities, and external fixation may be a better choice when the preservation of patellar height is important.

Research perspectives

Studies with a larger number of patients and evaluations of the early and late clinical outcomes of both techniques are suggested.

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ORIGINAL ARTICLE

Prospective Study

Pain and function deteriorate in patients awaiting total joint arthroplasty that has been postponed due to the COVID-19 pandemic

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Abstract

BACKGROUND

Elective total joint arthroplasty (TJA) procedures have been postponed as part of the coronavirus disease 2019 (COVID-19) response to avert healthcare system collapse. Total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures comprise the highest volume of elective procedures performed at health care facilities worldwide.

AIM

To determine the demand for TJA despite the pandemic and the impact of surgery postponement on physical and mental health.

METHODS

We conducted a prospective cross-sectional telephonic interview-based study on patients awaiting THA and TKA at an academic institution in South Africa. The questionnaire consisted of four sections. The first section recorded baseline demographic data and medical co-morbidities, the length of time spent awaiting TJA, and the patients' desire to undergo elective surgery despite the COVID-19 pandemic. Section 2 and Section 3 assessed the patients' current physical and mental health, respectively, as a consequence of deferred surgical intervention. The last section established the patients' perception of the healthcare system's response to the COVID-19 pandemic and necessity to postpone elective surgery. Patients received counseling and education on the current state of surgery during

indirectly related to this study.

Data sharing statement: Technical appendix, statistical code, and dataset available from the corresponding author, JRT Pietrzak at jrtpietrzak@yahoo.com.

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the COVID-19 pandemic and associated risks. Thereafter, patients were once again asked about their desire to undergo TJA during the COVID-19 pandemic.

RESULTS

We included 185 patients (65.95% female; mean age: 50.28 years) awaiting TJA for a mean of 26.42 ± 30.1 mo. Overall, 88.65% of patients wanted TJA despite the COVID-19 pandemic. Patients awaiting TJA for 1-3 years were 3.3-fold more likely to want surgery than those waiting < 1 year ($P < 0.000$). Patients with comorbidities were 8.4-fold less likely to want TJA than those with no comorbidities ($P = 0.013$). After receiving education, the patients wanting TJA decreased to 54.05%. Patients who changed their opinion after education had less insight on the increased morbidity ($P = 0.046$) and mortality ($P = 0.001$) associated with COVID-19. Despite awaiting TJA for shorter period (24.7 ± 20.38 mo), patients who continued to demand TJA had greater pain ($P < 0.000$) and decreased function ($P = 0.043$) since TJA postponement.

CONCLUSION

There is deterioration in health for patients, who have had elective procedures postponed during the COVID-19 pandemic. Waiting lists should be prioritized for urgency with the re-initiation of elective surgery.

Key Words: Total hip arthroplasty; Total knee arthroplasty; Elective surgery; COVID-19; Waiting lists; Primary total joint arthroplasty

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Core Tip: This was a prospective cross-sectional study of patients awaiting elective total joint arthroplasty (TJA) that was postponed during the coronavirus disease 2019 (COVID-19) pandemic. We investigated the demand for elective TJA, impact of surgery postponement on overall health, and the role of patient education regarding the healthcare system's response during the COVID-19 era. After receiving counseling about the peri-operative risks of COVID-19 infection, patients who continued to demand elective TJA had greater pain and decreased function compared to other patients, despite awaiting surgery for the shortest length of time. Waiting lists should be prioritized for urgency with the re-initiation of elective surgery.

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INTRODUCTION

The infectious disease caused by the novel severe acute respiratory syndrome coronavirus 2 virus (coronavirus disease 2019 [COVID-19]) was declared an international pandemic by the World Health Organization in March 2020[1-3]. In response, a moratorium was declared on the performance of elective surgery in many countries to avert healthcare system collapse, preserve equipment, and maintain resources and hospital capacity[4-8]. Approximately 28 million elective operations were cancelled or postponed worldwide during the peak 12 wk of this global pandemic[7,8]. Total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures comprise the highest volume of elective procedures performed at health care facilities worldwide[4,8]. A survey of the European Hip Society and the European Knee Associates from 40 different countries reported a near total shutdown of total joint arthroplasty (TJA) with 92.6% of primary TJA procedures being cancelled[7]. The demand for TJA is already high and waiting lists continue to rise with approximately 150000 elective procedures performed per month in the United States cancelled at some time due to the COVID-19 response[3,7,8]. The prolonged postponement of elective

TJA has had devastating economic implications on the healthcare system. It is estimated that the process of re-initiation of elective procedures following the COVID-19 pandemic in developing countries would result in an approximate loss of $700 billion[9].

In addition to the growing economic burden, patients awaiting surgery for more than 180 d have demonstrated increased risks for poor outcomes after TJA[10,11]. Patients with hip and knee osteoarthritis on extended waiting lists for surgery deteriorate with time on the pain and physical function on the Western Ontario McMasters Universities Osteoarthritis index scores and joint-specific Oxford scores[10,11]. Poor pre-operative baseline function is also associated with worse pain and functional outcomes up to 24 mo after TJA[10-12].

The aim of this study was to gain insight into patient perceptions in the setting of a waiting list for TJA at an academic institution in the COVID-19 era. Through a questionnaire-based telephone interview, we assessed patient demand for elective TJA and evaluated the impact of the postponement of TJA on function and mental health. Lastly, we assessed the effect of purposeful patient education and counseling about the reasoning behind postponement of elective surgery on patient demand for TJA[13].

MATERIALS AND METHODS

We conducted a prospective cross-sectional telephonic interview-based study of 227 patients awaiting TJA at a single, referral academic institution in Johannesburg, South Africa during the COVID-19. There were 118 patients and 109 patients planned for elective primary TKA and THA respectively, during this time who had their surgery postponed. Patients requiring emergency surgery for hip fractures, periprosthetic fractures, joint dislocation, or periprosthetic joint infections were excluded. Institutional review board ethics approval was obtained (M190528) before commencement of the study. Contact information was obtained for all patients from the institution's TJA waiting list. This waiting list generally operates on a first-in first-out basis with exceptions for cases that are deemed clinically urgent. The list has been used to capture data of patients who qualify for and consent to TJA. It is used to plan and prepare surgical lists and has been operational since 2004.

Interviews were conducted from 20 June to 10 July 2020, a full 6 wk after all elective surgery in both private and public hospitals in South Africa had been cancelled in response to the global COVID-19 pandemic as mandated by the South African Disaster Management Act. At the time of initiation of patient interviews, our institution had already made the decision to only revisit resumption of elective procedures after the 1st of October 2020, a period of 32 wk. Interviews were all conducted telephonically by two post-graduate orthopedic surgery students, and all interviews were recorded. The interviewers were fluent in all major South African language groups and all patients were, to the extent possible, interviewed in their first language. A single, standardized and structured questionnaire was used for all interviews, and all interviews were recorded. Patients were given the option to provide verbal voluntary consent or refusal to participate in the study after being informed of its purpose. The questionnaire consisted of four sections.

The first section recorded baseline demographic data including age, gender and medical co-morbidities including heart disease, diabetes mellitus and human immunodeficiency virus infection. The time that each patient had spent waiting for elective, primary TJA was calculated from the date the patient was first added to the waiting list until the date of suspension of all elective surgery lists, 20 March 2020. Lastly, we ascertained the patients desire to undergo elective TJA procedures despite the COVID-19 pandemic.

Section 2 assessed the patients current disease state as a consequence of the deferred surgical intervention. A 5-point Likert scale was used to determine the degree to which the patient felt the postponement of surgery had affected their pain, numerical rating scale (NRS) pain score, functionality and need for analgesia. Section 3 was an evaluation of mental health. Depressive symptoms including weight gain and loneliness were recorded. A 5-point Likert scale was used to evaluate the patients' anxiety regarding TJA during the COVID-19 pandemic.

Section 4 endeavored to establish the patients' perception of the healthcare system's response to the COVID-19 pandemic and necessity to postpone elective surgery. We assessed patients' knowledge of basic coronavirus transmission prevention measures such as the wearing of face masks, general hand hygiene, and social distancing. We attempted to assess the extent of insight that patients had regarding the response of

the healthcare system to the COVID-19 pandemic. This included the patient's knowledge of infection control procedures that have been implemented to minimize disease spread. Thereafter, patients were counseled regarding the current state of surgery during the COVID-19 pandemic. Patients were educated on the introduction of routine testing for COVID-19 prior to admission and preclusion of visitors during their hospital stay. Patients were then counseled with respect to poor clinical outcomes in COVID-19 infected patients undergoing surgery including the possibility of death and the risk of contracting COVID-19 as an inpatient. Upon conclusion of this patient education patients were once again asked about their desire to undergo TJA during the COVID-19 pandemic.

Results were tabulated with mean and standard deviation calculated for integer variables. Chi-squared testing was used to compare relationships between categorical variables. Patient age and period awaiting TJA were categorized and responses were compared across sub-groups. Additional categorical variables that responses were compared across included comorbidities and demand for TJA despite COVID-19 pandemic both before and after patient education and counseling. Odds ratios (ORs) were calculated using logistics regression for binary outcomes. Statistical significance was set at $P < 0.05$. The statistical software used for analysis was *R* 4.0.2 for Windows Copyright (C) 1989, 1991 Free Software Foundation, Inc with interface *R* Studio Version 1.3.959.

RESULTS

Sample population and demographic data

There were 185 patients (81.5%) included in the study (Figure 1). The mean age was 50.28 years (range: 33-69) with 122 female patients (65.95%). There were 106 (57.3%) patients awaiting surgery for TKA and 79 (42.7%) for THA, respectively. The overall mean length of time for patients awaiting TJA was 26.42 mo (standard deviation [SD]: 30.1; range: 3-264 mo). The mean length of time for patients awaiting THA was 28.29 mo (SD: 34.87; range: 3-264 mo) and TKA was 25.03 mo (SD: 26.07; range: 4-200 mo), respectively. There were 126 patients (68.11%) with one or more comorbidities. Additional demographic details and results for the questionnaire are depicted in Table 1.

Patient demand for TJA

There were 164 patients (88.65%) who wished to undergo TJA and 21 patients (11.35%) that did not want elective TJA, respectively at the earliest opportunity despite the COVID-19 pandemic. Patients awaiting TJA for more than 3 years were 4.3-fold more likely to want surgery compared to those awaiting surgery for less than 1 year (OR > 3 years 6.15; < 1 year 1.41; $P = 0.029$). Patients awaiting TJA between 1 and 3 years were 3.3-fold more likely to want surgery compared to those awaiting surgery for less than 1 year (OR: 1-3 years 4.71; < 1 year 1.41; $P < 0.000$). Patients with more than one comorbidity were 8.4-fold less likely to want elective surgery during the pandemic compared to those with no comorbid conditions (OR > 1 comorbidity 0.24; no comorbidities 3.38; $P = 0.013$).

Pain and function since the postponement of surgery

There was increased joint pain experienced by 101 patients (55.49%) since the postponement of their TJA. The responses for pain and function were compared between patients that wanted TJA despite the COVID-19 pandemic to those who did not want surgery at the earliest opportunity (Table 2). Increased joint pain was experienced by 58.28% ($n = 95$) of patients that wanted TJA despite the COVID-19 pandemic compared to 31.58% ($n = 6$) of patients that did not want elective surgery at the earliest opportunity ($P = 0.037$). The mean NRS pain score overall was 7.37 (SD: 2.24; range: 0-10).

There were 123 patients (67.21%) who felt their functionality due to joint pain had decreased since the postponement of surgery. There were 73 (78.5%) patients between the age of 45 to 60 years who had decreased functionality since the postponement of surgery compared to 25 (46.3%) and 24 (68.6%) patients under 45 years and over 60 years of age, respectively ($P = 0.015$). There was decreased function for patients that wanted TJA compared to those who did not, demonstrated by significant differences in decreased functionality due to joint pain (70.99% *vs* 38.1%; $P = 0.002$) and decreased walking distance (50.3% *vs* 28.58%; $P = 0.034$) respectively.

Table 1 Coronavirus disease 2019 arthroplasty waiting list questionnaire response results

Section I: Demographic data	
Age in yr, mean ± SD	50.28 ± 8.9
Gender, *n* (%)	
Male	63 (34.05)
Female	122 (65.95)
TJA, *n* (%)	
TKA	106 (57.3)
THA	79 (42.7)
Awaiting TJA in mo, mean ± SD	26.42 ± 30.1
Number of comorbidities, *n* (%)	
0	59 (31.89)
1	95 (51.35)
2	29 (15.68)
3	2 (1.08)
Comorbidities, *n* (%)	
DM	27 (14.59)
HPT	89 (48.11)
TB	5 (2.70)
Cardiac disease	9 (4.86)
Asthma	12 (6.49)
Lung disease	5 (2.70)
HIV	18 (9.73)
Demand for TJA despite COVID-19 pandemic, *n* (%)	
Yes	163 (88.11)
No	22 (11.89)
Section II: Pain and function	
Joint pain since postponement of TJA, *n* (%)	
Decreased	23 (12.64)
Same	58 (31.87)
Increased	101 (55.49)
Access to pain medication, *n* (%)	
Yes	90 (72)
No	35 (28)
NRS pain score, mean ± SD	7.37 ± 2.24
Current state in comparison to before TJA postponement	*n* (%)
Functionality due to joint pain	
Much less	24 (13.11)
Less	99 (54.1)
Same	50 (27.32)
More	5 (2.73)
Much more	5 (2.73)
Walking distance	

Much less	30 (16.3)
Less	59 (32.07)
Same	88 (47.83)
More	6 (3.26)
Much more	1 (0.54)
Sitting	
Much less	18 (9.89)
Less	57 (31.32)
Same	101 (55.49)
More	6 (3.3)
Much more	0 (0)
Sleep	
Much less	25 (13.59)
Less	25 (13.59)
Same	104 (56.52)
More	20 (10.87)
Much more	10 (5.43)
Need for pain medication	
Much less	8 (4.57)
Less	12 (6.86)
Same	74 (42.29)
More	47 (26.86)
Much more	34 (19.43)
Section III: Mental health	*n* (%)
Weight change since TJA postponement	
Lost	33 (25.98)
Same	56 (44.09)
Gained	38 (29.92)
Feelings of isolation or loneliness	
Yes	59 (32.78)
No	121 (67.22)
Anxiety to get infected with COVID-19	
No	28 (15.3)
Minimal	20 (10.93)
Neutral	22 (12.02)
Moderate	47 (25.68)
Severe	66 (36.07)
Anxiety to spread COVID-19 to relatives	
No	28 (15.64)
Minimal	17 (9.5)
Neutral	14 (7.82)
Moderate	39 (21.79)
Severe	81 (45.25)

Anxiety about Finances due to COVID-19	
No	18 (10)
Minimal	20 (11.11)
Neutral	82 (45.56)
Moderate	40 (22.22)
Severe	20 (11.11)
Section IV: Insight	
Understanding of healthcare system response to COVID-19	*n* (%)
Aware no elective surgery	
Yes	137 (74.05)
No	48 (25.95)
Fair no elective surgery	
Yes	157 (84.86)
No	28 (15.14)
Important to delay elective surgery	
Yes	162 (87.57)
No	23 (12.43)
Knowledge of preventative measures	*n* (%)
Hand washing	
Yes	124 (67.03)
No	62 (32.97)
Social distancing	
Yes	124 (67.03)
No	62 (32.97)
Wearing mask in public	
Yes	123 (66.49)
No	63 (33.51)
Peri-operative patient considerations for COVID-19	*n* (%)
Routine pre-operative screening	
Yes	122 (89.1)
No	15 (10.9)
Increased morbidity if COVID-19 positive	
Yes	120 (88.9)
No	15 (11.1)
No visitors allowed	
Yes	114 (87)
No	17 (13)
Increased mortality if COVID-19 positive	
Yes	92 (67.2)
No	45 (32.8)
Patient education and counselling	
Still demand TJA despite COVID-19 pandemic	*n* (%)
Yes	100 (54.05)

No	85 (45.95)

COVID-19: Coronavirus disease 2019; DM: Diabetes mellitus; HIV: Human immunodeficiency virus; HPT: Hypertension; NRS: Numerical rating scale; SD: Standard deviation; TB: Tuberculosis; THA: Total hip arthroplasty; TJA: Total joint arthroplasty; TKA: Total knee arthroplasty.

Mental health during the COVID-19 pandemic

There were 113 patients (61.75%), who experienced increased anxiety about getting infected with COVID-19 should they get their elective TJA during this time. There were 120 patients (67.04%) who experienced increased anxiety about subsequently spreading COVID-19 to relatives. The responses for mental health were compared between patients that wanted TJA despite the COVID-19 pandemic to those who did not want surgery at the earliest opportunity (Table 3). The increased anxiety of getting infected with COVID-19 was found in 64.19% (n = 104) of patients who wanted TJA compared to 42.86% (n = 9) of patients that did not want surgery at the earliest opportunity (P = 0.013). Similarly, there was increased anxiety to spread COVID-19 to relatives for 110 patients (69.62%) that wanted TJA and 10 patients (47.62%) that did not want elective surgery, respectively (P = 0.016). There were no significant differences between patients when compared between age groups and presence of comorbidities.

Patient insight and impact of patient education

There were 162 patients (87.57%) that accepted the reasoning behind the delay of elective surgery in response to the COVID-19 pandemic. The detailed results for the assessment of patient insight are depicted in Table 1. After receiving patient education there were 100 patients (54.05%) that still wanted TJA despite the COVID-19 pandemic and 85 patients (45.95%) that did not want elective surgery at the earliest opportunity (Figure 2). Over half the patients (100 patients/54.05%) wanted TJA despite the COVID-19 pandemic (continued demand group) after counseling. There were 21 patients (11.35%) that opted out of surgery as the earliest opportunity despite COVID-19 (defer group) both before and after patient education. There were 64 patients (34.59%) that changed their opinion after receiving patient education (receptive group).

The receptive group previously wanted TJA despite the COVID-19 pandemic and subsequently opted out of elective surgery after receiving patient education. The results for questions regarding patient insight were compared between the continued demand group, the defer group and the receptive group (Table 3). The importance to delay elective surgery was recognized 81.97% of the receptive group compared to 91.4% and 100% of the continued demand and defer groups, respectively (P < 0.000). Similarly, 76.67% of the receptive group were aware of the increased risks associated with COVID-19 if infected peri-operatively, compared to 91.75% and 100% of patients from the continued demand and defer groups, respectively (P = 0.046). There were 44 patients (73.33%) from the receptive group that understood there would be no visitors allowed to see them in hospital after surgery compared to 85 (91.75%) and 20 (95.24%) patients from the continued demand and defer groups, respectively (P = 0.018). Lastly, 43.33% of the receptive group were aware of the increased risks for death associated with COVID-19 compared to 77% and 85.71% of patients from the continued demand and defer groups, respectively (P = 0.001).

Continued demand for TJA despite the COVID-19 pandemic

The patient characteristics and perception of pain and function since the postponement of TJA was of interest regarding the continued demand group. The results for questions regarding pain and function were compared between the continued demand group, the defer group and the receptive group (Tables 4 and 5). Patients in the continued demand group were awaiting TJA for a mean period of 24.7 mo (SD: 20.38, range: 3-132 mo). The mean length of time for patients awaiting TJA in the Defer group was 25.32 mo (SD: 40.54, range: 4-200 mo) and in the receptive group was 28.91 mo (SD: 37.82, range: 4-264 mo), respectively. Increased joint pain was experienced by 60.61% of the continued demand group compared to 33.33% and 53.12% of defer and receptive groups, respectively (P = 0.035). The mean NRS pain score for the continued demand group was 7.68 (SD: 2.14; range: 2-10) compared to 5.9 (SD: 3.2; range: 0-10) and 7.24 (SD: 1.8; range: 2-10) for defer and receptive groups, respectively (P < 0.000). There was decreased functionality due to joint pain for 75.51% of the continued demand group since the postponement of surgery compared to 50% and 60.94% of

Table 2 Pain and function responses compared between patients that wanted total joint arthroplasty despite the coronavirus disease 2019 pandemic (Yes) to patients that did not want elective surgery as soon as possible (No)[1]

Current state in comparison to before TJA postponement	Want TJA despite COVID-19 pandemic		*P* value
Function	Yes, *n* (%)	No, *n* (%)	
Functionality due to joint pain			0.002
Much less	26 (16.05)	0 (0)	
Less	89 (54.94)	8 (38.1)	
Same	42 (25.93)	8 (38.1)	
More	2 (1.23)	4 (19.05)	
Much more	3 (1.85)	1 (4.76)	
Walking distance			0.034
Much less	27 (16.56)	3 (14.29)	
Less	55 (33.74)	3 (14.29)	
Same	77 (47.24)	11 (52.38)	
More	3 (1.84)	4 (19.05)	
Much more	1 (0.61)	0 (0)	
Sitting			0.63
Much less	15 (9.2)	3 (15.97)	
Less	53 (32.52)	4 (21.05)	
Same	90 (55.21)	11 (57.89)	
More	5 (3.07)	1 (5.26)	
Sleep			0.572
Much less	21 (12.88)	4 (19.05)	
Less	21 (12.88)	4 (19.05)	
Same	94 (57.67)	10 (47.62)	
More	19 (11.66)	1 (4.76)	
Much more	8 (4.91)	2 (9.52)	
Pain	Yes, *n* (%)	No, *n* (%)	
Joint pain			0.037
Decreased	20 (12.27)	3 (15.79)	
Same	48 (29.45)	10 (52.63)	
Increased	95 (58.28)	6 (31.58)	
Access to pain medication			0.714
No	30 (27.03)	5 (35.71)	
Yes	81 (72.97)	9 (64.29)	
Need for pain medication			0.05
Much less	6 (3.87)	2 (10)	
Less	8 (5.16)	4 (20)	
Same	65 (41.94)	9 (45)	
More	44 (28.39)	3 (15)	
Much more	32 (20.65)	2 (10)	
	Yes, mean (± SD)	No, mean (± SD)	*P* value

NRS pain score	7.54 ± 2.02	3.09 ± 3.27	< 0.000

[1]Yes (n = 164); No (n = 21). COVID-19: Coronavirus disease 2019; NRS: Numerical rating scale; SD: Standard deviation; TJA: Total joint arthroplasty.

Table 3 Mental health responses compared between patients that wanted total joint arthroplasty despite the coronavirus disease 2019 pandemic (Yes) to patients that did not want elective surgery as soon as possible (No)[1]

Mental health responses	Want TJA despite COVID-19 Pandemic, *n* (%)		*P* value
	Yes	No	
Weight change since TJA postponement			0.423
Lost	30 (27.03)	3 (18.75)	
Same	50 (45.05)	6 (37.50)	
Gained	31 (27.93)	7 (43.75)	
Feelings of isolation or loneliness			0.89
Yes	51 (32.48)	8 (34.78)	
No	106 (67.52)	15 (65.22)	
Anxiety to get infected with COVID-19			0.133
No	15.43	14.29	
Minimal	10.49	14.29	
Neutral	9.88	28.57	
Moderate	26.54	19.05	
Severe	37.65	23.81	
Anxiety to spread COVID-19 to relatives			0.016
No	26 (16.46)	2 (9.52)	
Minimal	13 (8.23)	4 (19.05)	
Neutral	9 (5.7)	5 (23.81)	
Moderate	35 (22.15)	4 (19.05)	
Severe	75 (47.47)	6 (28.57)	
Anxiety about finances due to COVID-19			0.785
No	16 (10.06)	2 (9.52)	
Minimal	36 (22.64)	4 (19.05)	
Neutral	70 (44.03)	12 (57.14)	
Moderate	19 (11.95)	1 (4.76)	
Severe	18 (11.23)	2 (9.52)	

[1]Yes (n = 164); No (n = 21). COVID-19: Coronavirus disease 2019; TJA: Total joint arthroplasty.

patients in the defer and receptive groups, respectively (P = 0.043).

DISCUSSION

In our study, 88.65% of patients awaiting TJA wanted elective surgery as soon as possible despite the current COVID-19 pandemic. Similarly, a study by Brown *et al*[14] in the united states demonstrated that almost 90% of patients wanted to reschedule elective TJA as soon as possible. A study conducted in the United Kingdom found that only 56.8% of patients for TJA wanted their elective surgery as soon as possible[15]. Additionally, Brown *et al*[14] reported that 85% of patients agreed with the decision to cancel elective surgery in response to the COVID-19 pandemic in the united states.

Table 4 Pain and function responses compared between the continued demand group, defer group and receptive group[1]

Current function in comparison to before TJA postponement	Continued demand group, *n* (%)	Defer group, *n* (%)	Receptive group, *n* (%)	*P* value
Functionality due to joint pain				0.043
Much less	15 (15.31)	0 (0)	9 (14.06)	
Less	59 (60.20)	10 (50)	30 (46.88)	
Same	19 (19.39)	6 (30)	24 (37.5)	
More	2 (2.04)	3 (15)	0 (0)	
Much more	3 (3.06)	1 (5)	1 (1.56)	
Walking distance				0.118
Much less	21 (21.21)	2 (10)	7 (10.94)	
Less	29 (29.29)	4 (20)	25 (39.06)	
Same	46 (46.46)	11 (55)	31 (48.44)	
More	2 (2.02)	3 (15)	1 (1.56)	
Much more	1 (1.01)	0 (0)	0 (0)	
Sitting				0.518
Much less	12 (12.12)	2 (11.11)	4 (6.25)	
Less	29 (29.29)	4 (22.22)	23 (35.94)	
Same	53 (53.54)	11 (61.11)	37 (57.81)	
More	5 (5.05)	1 (5.56)	0 (0)	
Sleep				0.643
Much less	13 (13.13)	3 (15)	9 (14.06)	
Less	15 (15.15)	4 (20)	6 (9.38)	
Same	50 (50.51)	10 (50)	43 (67.19)	
More	14 (14.14)	1 (5)	5 (7.81)	
Much more	7 (7.07)	2 (10)	1 (1.56)	
Current pain in comparison to before TJA postponement	Continued demand group, *n* (%)	Defer group, *n* (%)	Receptive group, *n* (%)	*P* value
Joint pain				0.035
Decreased	10 (10.10)	3 (16.67)	10 (15.62)	
Same	29 (29.29)	9 (50)	20 (31.25)	
Increased	60 (60.61)	6 (33.33)	34 (53.12)	
Access to pain medication				0.792
No	19	5	11	
Yes	51	9	30	
Need for pain medication				0.068
Much less	5 (5.26)	2 (10.53)	1 (1.67)	
Less	7 (7.37)	4 (21.05)	1 (1.67)	
Same	34 (35.79)	9 (47.37)	31 (51.67)	
More	26 (27.37)	3 (15.79)	17 (28.33)	
Much more	23 (24.21)	1 (5.26)	10 (16.67)	
NRS pain score, mean (± SD)	Continued demand group	Defer group	Receptive group	*P* value
	7.68 ± 2.14	5.9 ± 3.2	7.24 ± 1.8	< 0.000

[1]Continued demand (n = 100); Defer (n = 21); Receptive (n = 64). NRS: Numerical rating scale; SD: Standard deviation; TJA: Total joint arthroplasty.

Table 5 Responses for Insight Perception Regarding coronavirus disease 2019 compared between the continued demand group, defer group and receptive group[1]

Insight responses	Continued demand group, *n* (%)	Defer group, *n* (%)	Receptive group, *n* (%)	*P* value
Healthcare system response to COVID-19				
Aware no elective surgery				0.951
Yes	73 (74.49)	15 (75)	48 (75)	
No	25 (25.51)	5 (25)	16 (25)	
Fair no elective surgery				0.710
Yes	82 (82.83)	17 (85)	57 (89.06)	
No	17 (17.17)	3 (15)	7 (10.94)	
Important to delay elective surgery				< 0.000
Yes	85 (91.4)	21 (100)	50 (81.97)	
No	8 (8.6)	0 (0)	11 (18.03)	
Knowledge of preventative measures				
Hand washing				0.441
Yes	69 (69.70)	14 (66.67)	41 (64.06)	
No	30 (30.30)	7 (33.33)	23 (35.94)	
Social distancing				0.441
Yes	69 (69.70)	14 (66.67)	41 (64.06)	
No	30 (30.30)	7 (33.33)	23 (35.94)	
Wearing mask in publicYes	68 (68.69)	14 (66.67)	41 (64.06)	0.489
No	31 (31.31)	7 (33.33)	23 (35.94)	
Peri-operative patient considerations for COVID-19				
Routine pre-operative screening				0.016
Yes	94 (94)	18 (85.71)	44 (73.33)	
No	6 (6)	3 (14.29)	16 (26.67)	
Increased morbidity if COVID-19 positive				0.046
Yes	89 (91.75)	21 (100)	46 (76.67)	
No	8 (8.25)	0 (0)	14 (23.33)	
No visitors allowed				0.018
Yes	85 (91.4)	18 (85.71)	44 (73.33)	
No	8 (8.6)	3 (14.29)	16 (26.67)	
Increased mortality if COVID-19 positive				0.001
Yes	77 (77)	18 (85.71)	26 (43.33)	
No	23 (23)	2 (14.29)	34 (56.67)	

[1]Continued demand (n = 100); Defer (n = 21); Receptive (n = 64). COVID-19: Coronavirus disease 2019.

This is reflected in our study of a sub-Saharan Africa population with 87.57% of patients accepting the need to delay elective TJA procedures. There is a demonstrated need to postpone elective surgery, particularly in high-risk patients and re-initiation

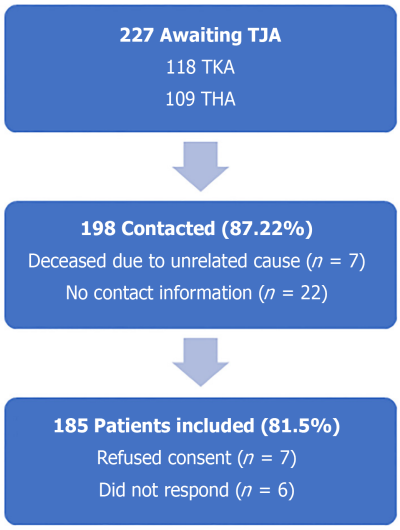


Figure 1 Flowchart of the study cohort. THA: Total hip arthroplasty; TJA: Total joint arthroplasty; TKA: Total knee arthroplasty.

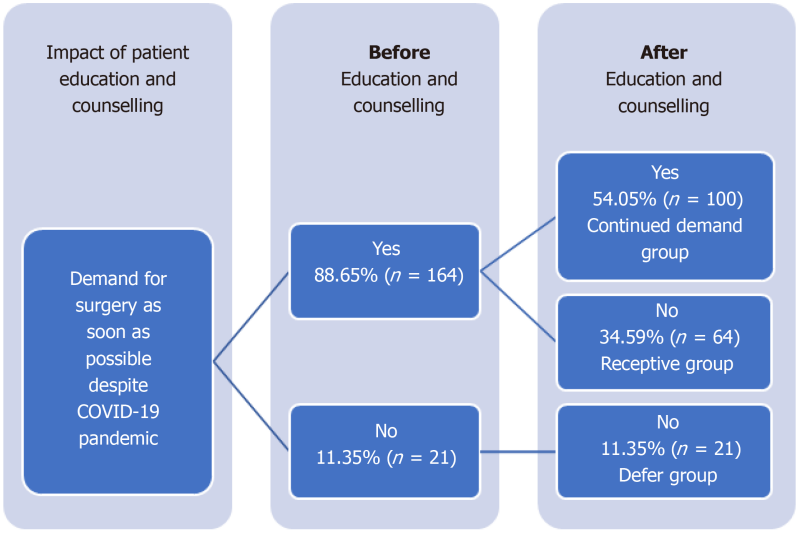


Figure 2 Patient demand for total joint arthroplasty before and after receiving education and counseling. COVID-19: Coronavirus disease 2019.

should be careful and gradual.

Patients with comorbidities, particularly those with cardiac diseases, hypertension and diabetes mellitus, have increased risks for morbidity and mortality if infected with COVID-19[16,17]. In our study, patients with comorbidities were 8.45-fold less likely to want elective surgery at the earliest opportunity compared to those with no comorbid conditions (P = 0.0128). Similarly, Chang *et al*[15] reported that patients classified ASA I (60.5%) and ASA II (60.0%) were more likely to agree to undergo earlier elective TJA after the COVID-19 pandemic compared to ASA III (44.4%) and ASA IV (0%) patients (P = 0.01). A multicenter study by Kayani *et al*[16] assessed the impact of COVID-19 infection on peri-operative outcomes for patients undergoing surgical treatment for hip fractures. COVID-19 positive patients had increased post-operative mortality rates (P < 0.001), increased risk of post-operative complications (P < 0.001) and more critical care unit admissions (P < 0.001) compared to COVID-19 negative patients[16]. Furthermore, COVID-19 positive patients with greater than 3 comorbidities had a significantly higher risk for mortality compared to those with no comorbidities (P < 0.001)[16].

The waiting period for elective TJA is high in our sub-Saharan setting when compared to other reported rates worldwide. In our study, the mean length of time for patients awaiting THA was 28.29 mo and 25.03 mo for TKA. In 2018, the average median worldwide waiting time for elective THA was 113 d (range: 50-282 d) and 189 d (range: 45-839 d) for TKA with wide variation, across countries[18]. Initially, longer

waiting period was associated with increased patient demand for elective surgery at the earliest opportunity despite the COVID-19 pandemic in our study. Patients awaiting TJA for between 1 and 3 years were 3.34-fold more likely to want elective surgery at the earliest possibility compared to those awaiting surgery for less than 1 year ($P < 0.000$). A systematic review including 15 studies of patients awaiting TJA for osteoarthritis was conducted to assess the impact of wait times on pain and functional status[19]. There was a mean waiting period between 42-399 d with strong evidence that pain and WOMAC score did not deteriorate for patients waiting less than 180 d[19]. Similarly, a multicenter study with a mean wait time of 5.07 mo by Vergara *et al*[20] observed that patients waiting less than 3 mo had a greater likelihood of achieving successful post-operative outcomes on the WOMAC scale and the 36-item short form survey scores. Furthermore, a multicenter study including 7151 patients found that longer waiting periods were significantly associated with a lower Oxford Hip Score at 12-mo follow-up after THA[21]. Patients waiting 12 and 24 mo had a post-operative mean difference of 2.6 and 4.2 Oxford Hip Score points, respectively compared to those waiting less than 6 mo[21].

In our study, 55.49% of patients had increased joint pain and 67.2% of patients had decreased functionality respectively, since the postponement of their TJA. Patients that wanted TJA despite the COVID-19 pandemic experienced significantly greater decrease in function compared to those who were prepared to wait. This was demonstrated by significant differences in decreased functionality due to joint pain ($P = 0.002$) and decreased walking distance ($P = 0.034$) respectively. Additionally, patients between the ages of 45 to 60 years had significantly more decreased functionality due to joint pain compared to patients younger than 45 years of age (78.5% *vs* 46.3%; $P = 0.015$). Brown *et al*[14] in their survey of TJA patients in the united states reported that joint pain had increased for 54% of patients and activity levels had decreased for 50% of patients, respectively since their surgery cancellation. This has long-term implications as several studies have demonstrated significantly less improvement in WOMAC and 36-item short form survey scores for patients with lower baseline function compared to those with higher baseline function persisting through 24 mo follow-up after TJA[12,13]. A recent study by Scott *et al*[11] demonstrated that patients with low scores on the Euro Qol five-dimension general health questionnaire achieved significantly worse joint-specific Oxford scores and satisfaction rates 1 year after TJA, compared with those with higher scores pre-operatively ($P < 0.001$).

Patient consent prior to elective surgery during the COVID-19 pandemic must focus on counseling and education, particularly for high-risk patients. Our study found that the percentage of patients who wanted elective surgery at the earliest opportunity decreased from 88.65% to 54.05% after receiving patient education about the COVID-19 pandemic. Patients in our study that were in the receptive group had significantly less insight on the impact of COVID-19 regarding both their individual health and the response of the healthcare system. Patients in the receptive group were less likely to be aware of the increased morbidity ($P = 0.046$) and mortality ($P = 0.001$) associated with COVID-19 if infected peri-operatively when compared to non-infected patients. A purposeful patient education program was implemented by the orthopedic department of the New York University Langone Health in response to the COVID-19 pandemic[6]. Orthopedic surgeons counseled patients regarding need for the postponement of surgery due to the COVID-19 pandemic and addressed patient concerns and questions which alleviated their anxiety[6].

In our study, the continued demand group had been awaiting surgery for a shorter length of time (24.7 mo) than the defer group (25.32 mo) and the receptive group (28.91 mo). Despite the shorter waiting period, the continued demand group experienced significantly greater pain than other patients. The continued demand group had a higher mean pain score ($P < 0.000$) and the greatest proportion of patients with increased joint pain ($P = 0.035$) since the postponement of surgery compared to the other patient groups.

There are unique challenges that must be considered during the re-initiation of elective surgery. Rizkalla *et al*[22] proposed that the decision to proceed with either primary or revision hip arthroplasty should be assessed for urgency. The urgency to proceed with hip arthroplasty should be based on both the potential harm of delaying surgery and the potential risk of performing surgery in the context of COVID-19[22]. In addition to patient outcomes, the economic implications of the postponement of elective surgery place an increasing burden on healthcare systems[23,24]. There have been several guidelines developed to facilitate the return of elective surgery in many parts of the world[23,24]. The reinstitution of elective surgery must be carefully implemented to ensure patient and staff safety and the responsible management of

healthcare resources and equipment[23,24]. Waiting lists should no longer operate on a first-in, first-out basis as was previously used in our institution. The effect of TJA postponement on patients should be assessed on an individualized basis and waiting lists should be prioritized for urgency.

One of the weaknesses of our study is that the waiting period was already long in comparison to worldwide rates. An additional limitation is that the interview was done telephonically, however, to mitigate this there were two individuals conducted interviews and all conversations were recorded.

CONCLUSION

Patient education and counseling are essential for those who have had elective procedures postponed during the COVID-19 pandemic. South Africa has longer waiting periods for TJA in comparison to international reports and the further postponement of surgery increases the risk of poor post-operative outcomes. There is deterioration in patients' physical and mental health whilst awaiting TJA and should be individually reassessed before rescheduling their surgery. Waiting lists should be prioritized for urgency with the re-initiation of elective surgery based on their current overall health status.

ARTICLE HIGHLIGHTS

Research background

The postponement of elective surgery in response to the coronavirus disease 2019 (COVID-19) pandemic resulted in a total shutdown of total joint arthroplasty (TJA). The impact of elective surgery postponement has resulted in the cancellation of approximately 92.6% TJAs in Europe. The demand for TJA is already high and waiting lists continue to grow with 150000 procedures per month postponed in the United States.

Research motivation

There is wide variation across countries worldwide; with the average median waiting time of 113 d (range 50-282 d) for total hip arthroplasty and 189 d (range 45-839 d) for total knee arthroplasty respectively. Patients awaiting surgery longer than 6 mo and those with poor pre-operative baseline function have demonstrated increased risks for poor outcomes after TJA. The unprecedented postponement of elective TJA in response to the COVID-19 pandemic may impact patients awaiting surgery.

Research objectives

Our aim was to assess the impact of TJA postponement on the physical and mental health of patients awaiting elective surgery. We secondarily sought to determine the demand for TJA and average waiting time for our South African population. Additionally, we investigated the role of patient insight after providing education and counseling regarding the healthcare system's response to the COVID-19 pandemic. The effect of TJA postponement on patients should be considered with the re-initiation of elective surgery and waiting lists should be prioritized to optimize outcomes.

Research methods

A prospective cross-sectional telephonic interview-based study of patients awaiting TJA at an academic referral institution in South Africa during the COVID-19 pandemic. We recorded baseline demographic data and length of time awaiting surgery and demand for TJA. A 5-point Likert scale was used to determine the degree to which the patient felt the postponement of surgery had affected various characteristics of their physical and mental health. We assessed patient insight regarding elective surgery cancellation in response to the COVID-19 pandemic and subsequently re-evaluated demand for TJA after providing education and counseling.

Research results

Patients with comorbidities were 8.45-fold less likely to want elective surgery at earliest possibility compared to those with no comorbid conditions (P = 0.013). In our study in South Africa, the mean length of time for patients awaiting total hip

arthroplasty was 28.29 mo and total knee arthroplasty was 25.03 mo, respectively. Before and after receiving patient education, the number of patients who demanded elective TJA decreased respectively, from 164 patients (88.65%) to 100 patients (54.05%) (continued demand group). The continued demand group had a higher mean pain score ($P < 0.000$) and the greatest proportion of patients with increased joint pain ($P = 0.035$) since the postponement of surgery compared to the other patients.

Research conclusions

The effect of TJA postponement on patients should be assessed on an individualized basis and waiting lists should be prioritized for urgency. Patient consent prior to elective surgery during the COVID-19 pandemic must focus on counseling and education, particularly for high-risk patients, to ensure optimal outcomes. The urgency to proceed with TJA should be based on both the potential harm of delaying surgery and the individual risk profile of performing surgery incurred by each patient, respectively, in the context of the COVID-19 pandemic.

Research perspectives

There is a demonstrated need to postpone elective surgery in response to the COVID-19 pandemic, particularly in high-risk patients. Patients should be reassessed and thoroughly counseled prior to rescheduling their elective procedures, particularly those at increased risk for morbidity and mortality if infected with COVID-19 perioperatively. In addition to the potential negative impact on patient outcomes, the economic implications of the postponement of elective surgery place an increasing burden of healthcare systems worldwide. The reinstitution of elective surgery must be carefully implemented to ensure patient and staff safety and the responsible management of institutional resources.

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SCIENTOMETRICS

Bibliometric analysis of research on the effects of human immunodeficiency virus in orthopaedic and trauma surgery

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Abstract

BACKGROUND

There is little research investigating how human immunodeficiency virus (HIV) affects outcomes in orthopaedic surgery. With advances in treatment, HIV has become a chronic health problem and the chance of orthopaedic surgeons encountering it in clinical practice is increasing.

AIM

To ascertain the quantity and quality of peer-reviewed publications in orthopaedic journals about HIV.

METHODS

A search of the Web of Science database was carried out, identifying any articles relating to HIV published in orthopaedic journals. These were assessed for geographic origin and level of evidence.

RESULTS

Of 48.7% of orthopaedic journals listed on the Web of Science database had

Specialty type: Orthopedics

Country/Territory of origin: South Africa

Peer-review report's scientific quality classification

Grade A (Excellent): 0
Grade B (Very good): 0
Grade C (Good): C, C
Grade D (Fair): 0
Grade E (Poor): 0

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published articles relating to HIV. There were 168 articles about HIV in orthopaedic journals with only 40.5% (n = 68) published in the time frame we analysed (January 2007 to September 2017). Very few articles came from low-income countries and any articles published from that setting were collaborations. All of the articles were low level of evidence.

CONCLUSION

There is a need for more high level orthopaedic and trauma research investigating the effects of HIV, particularly research from low-income countries, where higher level research will help to guide improvements in their treatment of its musculoskeletal manifestations and complications.

Key Words: Human immunodeficiency virus; Research; Bibliometric analysis; Analysis; Orthopaedic

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Core Tip: This paper looks in to the research being carried out in orthopaedic journals regarding human immunodeficiency virus and how it affects outcomes in orthopaedic and trauma surgery. We have shown that there is a significant lack of research in to this subject despite the fact there is a high prevalence of the disease in the setting which has the greatest burden of disease from trauma. Our findings highlight the need for further research to improve outcomes in trauma and orthopaedic surgery in these settings.

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INTRODUCTION

The World Health Organization in 2018 estimated that there are 37.9 million people globally living with human immunodeficiency virus (HIV), with well over half of these people (25.7 million, 69.8%) living in sub-Saharan Africa[1].

The introduction of antiretroviral therapy (ART) in 1997 has altered the course and nature of patients infected with HIV by increasing the duration of asymptomatic infection and, consequently, patients with HIV are attaining close to normal life spans[2]. Because individuals are now living longer, they commonly present with complications that result from the virus directly or the ART used to treat it[3].

HIV can present with a number of different orthopaedic pathologies, including osteonecrosis of the hip or knee, osteoporosis, septic arthritis and primary HIV arthropathy[4]. Furthermore, ART treatment is also associated with osteonecrosis and increase in risk of osteoporosis, potentially resulting in increased risk of sustaining a fracture[5,6]. With the increasing availability of ART and the major decline in HIV-related mortality levels[7], orthopaedic surgeons are more likely to encounter patients with HIV in their surgical practice. This is particularly relevant for orthopaedic surgeons operating in sub-Saharan Africa and in low-income countries (LIC), where HIV is more prevalent[1].

In the current orthopaedic literature, there has been little research investigating the effects of HIV on outcomes in orthopaedic surgery[8]. We found in a previous study that, despite a significant proportion of the global burden of disease from musculoskeletal disease and trauma occurring in LIC, there was little musculoskeletal disease and trauma research being produced in that setting[9]. Similarly, LIC have a much higher prevalence of HIV[1] but the current literature would suggest that orthopaedic research into how HIV may impact outcomes in musculoskeletal disease and trauma, is being conducted outside of the setting where it is most needed.

The aim of this paper was to ascertain the number of peer-reviewed articles being published in orthopaedic journals across all sub-specialties within orthopaedic surgery

that related to HIV. We also sought to determine the geographic origin of the research and what proportion was being conducted in LIC, the setting that would most benefit from the research.

MATERIALS AND METHODS

We searched the 'Clarivate Analytics' Web of Science database to obtain all indexed articles regarding HIV published in all orthopaedic journals listed on the database. We then filtered this to search just the last 10 years, going back from the time point the search was conducted (January 2007 to September 2017). Inclusion criteria consisted of articles limited to English language publications. We used Web of Science as it is possible to filter journals so only English language orthopaedic journals are included.

Search terms used on the database consisted of the following: 'human immunodeficiency virus' OR 'HIV'. We then recorded the number of articles returned for each journal. Subsequently, abstracts and full texts were reviewed for each article to determine its relevance. This was done by two of the researchers (Brennan C and Graham SM).

Articles were included if the main focus of research was HIV. Excluded articles were those that had no relevance to HIV or had an additional focus such as tuberculosis, as well as letters or comments.

All relevant indexed articles were analysed for the following information: journal title, year of publication, geographic location and country, level of evidence and number of citations. The level of evidence was determined in accordance with the criteria established in the *Journal of Bone and Joint Surgery American Volume*[10,11] following review of abstracts and full texts.

Countries producing research were categorised into high-income countries (HIC), upper and lower middle-income countries (UMIC/LMIC) and low-income countries (LIC) according to the World Bank data for the current 2020 fiscal year[12] (Table 1).

RESULTS

There are 76 orthopaedic journals listed on the Web of Science database. Initial searches showed that there were 168 published articles relating to HIV across 37 different orthopaedic journals (48.7% of the listed journals).

Of these 168 articles, 68 (40.5%) were published in the time frame analysed for this paper (January 2007 to September 2017), in 26 different orthopaedic journals (34.2%). (See Table 2 for full list of journals).

The 5 orthopaedic journals with the most papers relating to HIV in that time period each had 5 published articles. These were: *The Journal of Bone and Joint Surgery-American volume*; *Journal of Arthroplasty*; *Injury*; *Skeletal Radiology* and *The Journal of the American Podiatric Medical Association*.

The 68 articles originated from 20 different countries (See Table 3 for full list of countries).

The majority of publications originated from the United States (n = 34, 50%), with the next four highest yield countries being: United Kingdom (n = 7, 10.3%), South Africa (n = 6, 8.8%), Malawi (n = 5, 7.4%) and Ireland (n = 4, 5.9%) respectively. Of the 68 articles, 9 (13.2%) were collaborations between authors or groups from different countries.

Of the 20 countries producing research into HIV in orthopaedic surgery, research from 5 countries was solely collaborative and there was no individual research output from that country. These countries were Malawi (5 collaborative articles), Norway (2 collaborative articles), Australia, Canada and Japan (each with 1 collaborative article).

The majority (13/20, 65%) of research output, including the collaborative research, was from HIC. They accounted for 78% (46/59) of the non-collaborative articles, as well as 100% of the collaborative articles. Only 4 countries (20%) were UMIC, with a research output of 12 of the 68 articles (17.7%) and 2 collaborative articles. There were just 2 (10%) LMIC, which produced 3 articles (4.4%), none of which were collaborative research papers. Finally, only 1 country (5%) was a LIC. This was Malawi, and 100% of the research from there was collaborative and with authors from HIC.

Collaborative research was conducted between: HIC and HIC, HIC and UMIC or HIC and LIC (See Table 4 for a full list of the countries participating in collaborative studies).

Sixty-six of the 68 included articles (97.1%) were low level of evidence articles (IV or

Table 1 Countries divided by their economic status, as per World Bank classifications (10)

High-income countries	Upper middle-income countries	Lower middle-income countries	Low-income countries
Australia	Brazil	Cameroon	Malawi
Canada	China	Nigeria	
France	South Africa		
Germany	Turkey		
Ireland			
Italy			
Japan			
Netherlands			
Norway			
South Korea			
Spain			
United Kingdom			
United States			

V) and there were no level I or II high evidence studies. The remaining 2 articles were level III evidence and none were from LIC. One was a systematic review and meta-analysis of observational studies looking into gait and balance impairments as a result of HIV infection[13] and was a collaborative paper from South Africa and Germany. The other being a systematic review of studies looking at correlation between osteopaenia and HIV from Brazil[14]. The vast majority of low level of evidence articles (IV or V) was case reports or case series.

DISCUSSION

This study has shown that there is little research conducted into HIV and its impact on orthopaedic surgery. Fewer than half of all the orthopaedic journals have any published research on the subject and less than half of this has been produced in the preceding 10-year period analyses in this research paper.

People living with HIV in all income settings are living longer[15,16] and therefore there is a call for more research to be conducted to facilitate the practice of evidence based medicine in treating these patients. Studies have shown equivocal evidence as to whether HIV is an independent risk factor for outcomes in orthopaedic surgery such as post-operative infection or fracture union, again highlighting the need for further research to be carried out to further evidence based practice[17-20]. A good example of this is seen in the systematic review by Wijesekera *et al*[8], which showed no statistically significant difference between infection rates following surgery in HIV-positive patients compared to control groups in 3 different studies, but one smaller cohort study did report a significantly higher infection rate in the HIV-positive group compared to controls. This highlights a need for more higher level of evidence research to be conducted.

Despite the fact that the vast majority of people living with HIV are located in low- and middle-income countries, with an estimated 68% living in sub-Saharan Africa[21], the majority of publications focusing on HIV in orthopaedic literature originate from high-income countries. South Africa has the world's largest HIV positive population[22], yet we have found that less than 10% of research looking in to this subject originated from South Africa. The overriding majority of research came from the United States which has 7 times fewer people living with HIV compared to South Africa[21]. There were only 2 LMIC countries, Cameroon and Nigeria, that had any published research on HIV amongst the orthopaedic journals listed and both of these were low level of evidence. Only 1 LIC, Malawi, had any articles in the orthopaedic journals on the database and these were all collaborative studies with HIC but once again were all low level of evidence. This shows a struggle for LIC and LMIC to publish research, particularly high level of evidence studies, in a subject that has a

Table 2 Orthopaedic journals with published articles on human immunodeficiency virus in the last 10 years

Journal name	Number of articles
Journal of Bone and Joint Surgery-American Volume	5
Journal of Arthroplasty	5
Injury	5
Skeletal Radiology	5
Journal of the American Podiatric Medical Association	5
Clinical Orthopaedics and Related Research	4
Physical Therapy	4
Spine	4
BMC Musculoskeletal Disorders	4
Acta Orthopaedica	3
Spine Journal	3
Archives of Osteoporosis	3
Orthopedics	3
International Orthoapedics	2
Bone and Joint Journal	2
Journal of the American Academy of Orthopaedic Surgeons	1
Journal of Shoulder and Elbow Surgery	1
Journal of Orthopaedic Research	1
European Spine Journal	1
Osteoarthritis and Cartilage	1
Foot and Ankle International	1
Journal of Pediatric Orthopaedics	1
Orthopaedics & Traumatology – Surgery and Research	1
Indian Journal of Orthopaedics	1
Acta Orthopaedica Belgica	1
Acta Ortopedica Brasileira	1
Total = 26	68

greater impact on their patient demographic than those in HIC.

Possible reasons for this are the barriers faced by LIC in implementing research studies such as issues with funding, lack of expertise in conducting high level research or reluctance of journals to publish research from LIC. The lower publication rate from LIC could also be due to authors in this setting not being well informed about how to get published even in the context of higher quality research.

The Lancet report[23], "Global Surgery 2030: Evidence and solutions for achieving health, welfare and economic development", highlights the need for financial support in helping LIC and LMIC achieve the surgical care to meet population demand. This also includes improving research capabilities in these countries to improve overall surgical care. We found in this study that research in HIV and orthopaedics coming from LIC was through collaborative efforts with HIC. The Lancet report also highlights the need to develop effective research collaborations to maximise the impact of research outcomes.

As well as funding, the capacity for LIC to be able to carry out high level research is hindered by the fact their physicians are required to serve a much greater population with fewer resources. World bank data[24] on the number of physicians per population show that a LIC such as Malawi has only 0.016 doctors per 1000 people (as of 2016), whereas a HIC like the United Kingdom has 2.806 doctors per 1000 people (as of 2017). This, combined with the fact the burden of trauma is greater in LIC[25], make high

Table 3 Countries of origin for articles on human immunodeficiency virus in the last 10 years

Publication country of origin	Number of articles (collaborations)
United States of America	34 (2)
United Kingdom	7 (3)
South Africa	6 (2)
Malawi	5 (5)
Ireland	4 (1)
Brazil	3 (0)
Cameroon	2 (0)
China	2 (0)
Germany	2 (0)
Norway	2 (2)
Australia	1 (1)
Canada	1 (1)
France	1 (0)
Italy	1 (0)
Japan	1 (1)
Netherlands	1 (0)
Nigeria	1 (0)
South Korea	1 (0)
Spain	1 (0)
Turkey	1 (0)

Table 4 Collaborative research by country of origin and economic status

HIC: HIC	HIC: UMIC	HIC: LIC
United States: Ireland	United Kingdom: South Africa	United Kingdom (+Australia): Malawi
United States: Japan	Germany: South Africa	United Kingdom: Malawi
United Kingdom: Australia (+Malawi)		Norway: Malawi
		Norway: Malawi
		Canada: Malawi

HIC: High-income countries; UMIC: Upper middle-income countries; LIC: Low-income countries.

orthopaedic research output in these settings difficult. This again highlights the need for greater collaborative effort in producing high evidence research between HIC with more resources and LIC, where exists the larger population of HIV positive patients.

Lastly, readers of journals are more likely to be from HIC settings due to access and availability of resources. This can result in a reluctance of journals wanting to publish research from LIC as it can often be less relevant to their target audience.

Limitations

A limitation of the study is the fact that our Web of Science database search methodology selected solely orthopaedic journals and therefore any articles in journals not listed on their database as an orthopaedic journal would not have been included in the search results. This includes any orthopaedic publication in non-orthopaedic journals, such as the *Lancet*, or in virology focused journals, such as the *Journal of Medical Virology*. Furthermore, in clinical practice and in literature in low-income countries, trauma and orthopaedics is often grouped with other surgical specialties

and publications such as the *Tropical Doctor* and *East and Central African Journal of Surgery*, which are not included on the Web of Science database. This may have led to an underestimate of the number of orthopaedic research articles published on the topic of HIV.

CONCLUSION

People living with HIV are living longer and are becoming more prone to various musculoskeletal and orthopaedic complaints, as a result of both their treatment and age-related conditions. We have found that there is little research conducted looking at how HIV affects outcomes in orthopaedic surgery and that the research that is being done is preferentially carried out in HIC rather than LIC, where these problems are more prevalent. Current research tends to be of a low level of evidence. Collaborative research between LIC and HIC has proven to be a useful method for increasing research output in the LIC setting. This article highlights a greater need for high level of evidence research in this field to be carried out and done so in the LIC setting where it is of most benefit. One way this can be achieved is through more collaborative efforts with HIC.

ARTICLE HIGHLIGHTS

Research background

Human immunodeficiency virus (HIV) has become a chronic health problem with advances in treatment, and the chance of orthopaedic surgeons encountering it in clinical practice is increasing. It is also known that HIV may present with various musculoskeletal manifestations or treatment may result in a number of orthopaedic pathologies. There is little research in the current literature investigating how HIV effects outcomes in orthopaedic surgery.

Research motivation

The current literature highlighted a lack of research looking at the effects of HIV in trauma and orthopaedic surgery, particularly coming from geographic areas most in need of this evidence base for clinical practice. By highlighting this gap in the literature, it should pave the way for future research to be conducted in the appropriate setting to help improve outcomes in this patient cohort.

Research objectives

This study aimed to investigate the quantity and quality of peer-reviewed publications in orthopaedic journals about HIV.

Research methods

A bibliometric analysis was conducted using the 'Clarivate Analytics' Web of Science database. All articles in orthopaedic journals relating to HIV were identified. All relevant articles were analysed for the following information: journal title, year of publication, geographic location and country, level of evidence and number of citations. This is a novel research method for determining the volume and quality of publications about HIV in trauma and orthopaedic surgery.

Research results

Less than half of orthopaedic journals listed on the Web of Science database had articles published relating to HIV. Only 168 articles were identified in the literature, with only 40.5% (n = 68) published in the time frame analysed in the study (January 2007 to September 2017). These articles tended to be low level of evidence papers. The majority of research output came from high-income countries and any articles published from low-income countries were collaborations.

Research conclusions

The findings of this study show that there is a need for more research to be carried out on how HIV affects outcomes in orthopaedic and trauma surgery. This further research should be carried out in the area of greatest clinical need, particularly in low-income countries, where the burden of disease is higher. One way to achieve, as

shown from the results of this study, is with greater collaborative research efforts between high-income and low-income countries.

Research perspectives

The direction of future research should be focused on larger scale clinical trials, including collaborative studies, investigating the effects of HIV in orthopaedic and trauma surgery to produce high level of evidence research, to improve clinical outcomes.

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REVIEW

Slacklining as therapy to address non-specific low back pain in the presence of multifidus arthrogenic muscle inhibition

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Abstract

Low back pain (LBP) represents the most prevalent, problematic and painful of musculoskeletal conditions that affects both the individual and society with health and economic concerns. LBP is a heterogeneous condition with multiple diagnoses and causes. In the absence of consensus definitions, partly because of terminology inconsistency, it is further referred to as non-specific LBP (NSLBP). In NSLBP patients, the lumbar multifidus (MF), a key stabilizing muscle, has a depleted role due to recognized myocellular lipid infiltration and wasting, with the potential primary cause hypothesized as arthrogenic muscle inhibition (AMI). This link between AMI and NSLBP continues to gain increasing recognition. To date there is no 'gold standard' or consensus treatment to alleviate symptoms and disability due to NSLBP, though the advocated interventions are numerous, with marked variations in costs and levels of supportive evidence. However, there is consensus that NSLBP management be cost-effective, self-administered, educational, exercise-based, and use multi-modal and multi-disciplinary approaches. An adjuvant therapy fulfilling these consensus criteria is 'slacklining', within an overall rehabilitation program. Slacklining, the neuromechanical action of balance retention on a tightened band, induces strategic indirect-involuntary therapeutic muscle activation exercise incorporating spinal motor control. Though several models have been proposed, understanding slacklining's neuro-motor

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mechanism of action remains incomplete. Slacklining has demonstrated clinical effects to overcome AMI in peripheral joints, particularly the knee, and is reported in clinical case-studies as showing promising results in reducing NSLBP related to MF deficiency induced through AMI (MF-AMI). Therefore, this paper aims to: rationalize why and how adjuvant, slacklining therapeutic exercise may positively affect patients with NSLBP, due to MF-AMI induced depletion of spinal stabilization; considers current understandings and interventions for NSLBP, including the contributing role of MF-AMI; and details the reasons why slacklining could be considered as a potential adjuvant intervention for NSLBP through its indirect-involuntary action. This action is hypothesized to occur through an over-ride or inhibition of central down-regulatory induced muscle insufficiency, present due to AMI. This subsequently allows neuroplasticity, normal neuro-motor sequencing and muscle re-activation, which facilitates innate advantageous spinal stabilization. This in-turn addresses and reduces NSLBP, its concurrent symptoms and functional disability. This process is hypothesized to occur through four neuro-physiological processing pathways: finite neural delay; movement-control phenotypes; inhibition of action and the innate primordial imperative; and accentuated corticospinal drive. Further research is recommended to investigate these hypotheses and the effect of slacklining as an adjuvant therapy in cohort and control studies of NSLBP populations.

Key Words: Slacklining; Arthrogenic muscle inhibition; Low back pain; Therapy-intervention; Multifidus; Hypothesis

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Core Tip: Non-specific low back pain (NSLBP) is the leading problematic musculoskeletal condition for individuals and society. With no consensus definition, depleted lumbar multifidus stabilization is recognized with fatty infiltration and wasting, where arthrogenic muscle inhibition is a probable cause. With no gold-standard therapy, management consensus recommends cost-effective, self-administered, exercise-based multi-modal approaches. 'Slacklining' addresses these criteria as an adjuvant therapeutic rehabilitation exercise, rationalized by a hypothesized over-ride of central down-regulatory induced muscle insufficiency. This allows neuroplasticity, normalized neuro-motor sequencing and muscle re-activation for stabilization. Four neuro-physiological pathways are proposed with further research required into the hypotheses and slacklining's potential NSLBP rehabilitation role.

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INTRODUCTION

Low back pain (LBP) is a major global health and economic concern due to its prevalence, heterogeneous classification and multiple causes and diagnoses. It affects more individuals than any other musculoskeletal condition[1], but is mostly 'non-specific' (approximately 85%), as the source of abnormality and symptoms is undefined[2]. Non-specific LBP (NSLBP) is characterized by factors that cross biophysical, psychological and social domains, and presents on a spectrum from neuropathic to nociceptive pain[3]. The neuropathic component is predominantly from nerve root compression within or adjacent the spinal canal from several potential causes, whereas nociceptive is associated with mechanical stress[4] and non-neural tissue damage[5,6]. This leads to broad problems for the individual's function, ability, activities of daily living (ADL), societal participation, and economic situation. There are also societal demands on health-care and support networks, that vary considerably

within and between countries, due to local approaches, social attitudes, and legislative influences[1,2]. The most widely used categorization of NSLBP is acute (< 6 wk), subacute (6-12 wk), or chronic (> 12 wk), causing symptoms in > 50% of days[3,7,8].

However, there is no 'gold standard' management that demonstrates a strong, cost efficient, evidence-based effect[2]. This is partly because consensus is divided on the terminology used and the approaches advocated. Different terms such as mechanical or axial LBP refer to the same condition, causing inconsistency in nomenclature due to varied interpretations by clinicians, researchers, and society in general; while the many diverse and conflicting approaches and interventions recommended perpetuate the perplexity[6]. Systematic reviews and meta-analyses indicate the different interventions show markedly varied levels of cost efficiency and supportive evidence, both between and within approaches[2]. One area with general agreement is that spinal stability[9-11] is critically important, particularly at the segmental level[12,13] where the abdominal and lumbar muscles[6] contribute significantly[14,15], with the multifidus (MF) muscle having a strategic functional role[12]. Accordingly, any condition that disrupts and compromises this lumbo-pelvic stabilization capacity, such as myocellular lipid (MCL) infiltration and wasting leading to depletion of the MF stabilizing role, should be investigated and addressed[6,16,17].

One such causative condition is arthrogenic muscle inhibition (AMI)[17-22], which is summarily defined as "… a neural activation deficit [of the muscles]"[23] (see Supplementary material, Appendices 1-3. Consequently, AMI has gained increasing recognition and research interest over recent decades as a primary contributor to NSLBP[5,6,17]. Therefore, intervention techniques that address MF deficiency induced through AMI (MF-AMI), use direct/indirect muscle activation approaches that target the MF through voluntary/involuntary activation, and are clinically important[24], particularly if they are self-directed, and cost effective[13,15].

Within this clinical framework of self-directed, cost effective interventions addressing MF deficiency, any new techniques are encouraged[15]; with a very recent paradigm being indirect-involuntary muscle activation, where slacklining is a specific example. Slacklining, 'the neuromechanical action of balance retention while standing on a tightened webbing band'[25-28], has been introduced over recent decades as a strategic musculoskeletal and neurological therapeutic pre- and re-habilitation exercise[29,30]. However, published slacklining research is recent and available evidence remains limited[31-33], particularly for clinical rehabilitation implications[30,34-36], and formulated explanatory models[28,31], despite slacklining's ancient origins[37]. Slacklining invokes a moderated indirect muscle activation that occurs involuntarily and facilitates achieving optimum balance according to the needs of the motor task through muscle, joint, and subsequent limb and body control[31,38]. It has been clinically demonstrated to overcome AMI during rehabilitation in peripheral regions and joints, particularly the knee and ankle[23,30,39], and is recently reported as potentially showing promising clinical results in reducing MF-AMI induced NSLBP[17].

Consequently, this paper aims to rationalize why and how slacklining, as an adjuvant therapeutic exercise, may positively affect patients with NSLBP that is due to MF-AMI induced depletion of spinal stabilization. We consider slacklining's centrally mediated pre-synaptic actions that provide either an over-ride or inhibition of the down-regulatory induced MF insufficiency that occurs as a consequence of AMI. This action will, consequently, allow neuroplasticity, the restoration of normal neuro-motor sequencing that enables MF re-activation, subsequent spinal stabilization, and the resultant improvement in symptoms and function. This in-turn addresses and reduces NSLBP and its concurrent symptoms and functional disability.

This action is hypothesized to occur through one or a combination of four neuro-physiological processes that occur within the following pathways: (1) Finite neural delay accompanying 'time available' processing; (2) Movement control phenotypes affected by an exercise reasoning hypothesis; (3) The inhibition of action and the innate primordial imperative; and (4) Accentuated corticospinal drive. To comprehend these actions and understand their implications requires a step-wise rationalization that involves a process of: presenting a summary review of NSLBP and spinal stability; the MF stabilizing role; how AMI depletes this stabilization; recognized NSLBP rehabilitation methods; slacklining as an adjuvant therapeutic exercise; and, subsequently, slacklining's neuro-physiological effects of centrally mediated pre-synaptic actions that provide either an over-ride or inhibition of the down-regulatory induced MF, that counter the local stabilization inadequacies that result in NSLBP.

NSLBP AND SPINAL STABILITY

The classic Panjabi spine-stability model[9,10] hypothesizes that NSLBP originates from the embedded mechanoreceptors of passive spinal support structures (ligaments, disc-annulus, and facet-capsules), which are subject to large-singular or cumulative-micro trauma causing sub-failure injuries. This model was initially amended to include the thoracolumbar fascia[40], then further adapted to integrate mobility[11]. The injury-affected structures generate corrupted transducer signals that alter the neuromuscular control units response patterns, which disrupts muscular onset-shutoff coordination and force magnitude characteristics[6,9,10]. Lumbar spine vertebral joints are over-loaded[4] from 'functional instability' due to 'motor-control system anomalies'[9,11,16]. These are both a cause and effect of neuroplastic changes in sensorimotor control[41-43] and impaired lumbar MF corticomotor control[6,44]. Addressing these factors involves muscle activation, such as 'motor control exercises' (MCE) at the local and or global level, which aim to restore coordinated and efficient use of the muscles that control and support the spine[13,45]. These target the 'core' stabilizing muscles, transversus abdominus (TrA), erector spinae (ES), pelvic floor (PF), and MF[6,46]; however, only MF provides segmental stability[12,13].

The use of MCE therapy aims to restore muscle activation to the disrupted MF, either alone or in combination with the other core muscles[6,46], though with conflicting available evidence[47,48]. Systematic reviews of characteristic macroscopic structural MF changes in NSLBP patients indicate "… a loss of muscle size … [especially] in the lower lumbar levels …"[49]; and distinct differences in muscle size and levels of fat infiltration compared to age and gender related norms[12,50,51]. However, correlation of these changes with clinical outcome improvement varies[48], as supportive evidence is low-moderate in higher quality studies[16,47], while lower quality studies overestimate MCE effectiveness[45]. Consequently, MCE can be considered as supported, but without a unified consensus approach[13].

LUMBAR MF ROLE IN SPINAL STABILIZATION

Researching trunk muscles structure, particularly MF, and their contributions to spinal stability and the clinical association with NSLBP, has continued for over 50 years[45]. The MF has a specific segmental stability role[10-12], and is the muscle with the strongest influence on lumbar stability against applied forces, especially in flexion and extension[12,13], the two predominant motor control impairment clinical directional subgroup classifications[52,53]. A lack of adequate segmental stability results in abnormal stress on ligaments, muscles, and mechanoreceptors; which leads to excessive facet joint loading[10,13]. Since spinal ligaments have inherently poor healing, disc and facet joint degeneration accelerates. Persistence of such abnormal conditions results in NSLBP from: neural tissue inflammation, changes to biochemistry, nutrition, stem cells immune factors, endplate structure and composition, discs, and neural tissues with ingrowth into the intervertebral discs[10]. In this situation, the MF's stabilizing role is depleted and hypothesized as due to AMI[5,6,17]; with supportive evidence from MCE therapy[13,14,24,45,54], and the effects of localized neuromuscular electrical stimulation (NMES) which directly induces involuntary episodic MF-contraction[5,6,16,55].

The links between NSLBP, lumbar muscle wasting, and fatty infiltration by macroscopic MCLs was recognized over 25 years ago[12,14], though there has been both subsequent support for the model, and questioning of whether these links have consistent correlations[49]. The attribution of this lumbar MF wasting to AMI was first speculated in 2002[56], while acceptance of AMIs contribution to NSLBP is only quite recent[5,6,16]. Recognizing MF-AMI is a clinical diagnosis, but supported by physical measures of wasting on ultrasound (US) imaging[44], and MCL infiltrates on dual/multi-echo magnetic resonance imaging (MRI) and MR-spectroscopy[51]. The latter also provides muscular-MCL composition and distinguishes between extra-MCLs (EMCLs), associated with age-related change, and intra-MCLs (IMCLs) associated with NSLBP[17,51]. Consequently, IMCLs and changes in their percentage presence may enable: the described diagnostic techniques to function as a proxy for MF-AMI induced NSLBP; and act as prognostic markers for the efficacy of NSLBP rehabilitation management techniques directed at MF activation/stimulation for spinal stabilization[6,17].

ARTHROGENIC MUSCLES INHIBITION — CURRENT CONCEPTS

The introductions summary definition of AMI as "… a neural activation deficit [of the muscles]"[23], can be further expanded and detailed through the current descriptive consensus of: Periarticular muscle inhibition, often with associated atrophy, from modulation of motor neuron pools within the uninjured muscle/s, that prevents voluntary recruitment about a damaged or distended joint[21,57], and may include the contralateral unaffected side[23]; where motor insufficiency and activation failure is a consequence of a presynaptic reflex reaction through neural inhibition and ongoing neural activation deficit of the muscles, due to compromised efferent drive in the local, spinal and supra-spinal pathways, resulting from aberrant afferent discharge from joint mechano-sensory receptors, which serves as a natural response to protect from further damage[18-23,57-60].

The distinction of AMI from 'disuse atrophy', which has no central nervous system (CNS) or reflex basis[58], has been made since Hippocrates around 400BC[61]. However, the specific mechanism eliciting and controlling AMI remains unclear in all recent publications[22,62], and has predominantly been postulated from the recognized actions and effects following knee joint injury[6,23]. Consequently, though the physiological neuro-motor basis of AMI remains poorly understood, significant investigation continues, particularly research into the cerebral-based mechanisms of AMI[22,63].

Clinically AMI results in an inability to completely activate the periarticular muscles as the available volume of motor units is reduced[20,21]. This leads to a 'vicious circle'[19] of atrophy, weakness, damage, and dysfunction[59]. Consequently, AMI is consistent across different joints and joint pathologies throughout the body, and often most severe in the acute stage of joint damage[21]. The level of afferent discharge from changes in the articular sensory receptors is determined by several factors. Consequently, the mechanisms that drive the severity of AMI presentation are: the severity of the damage to the joint, distention due to inflammation and effusion, joint laxity[6,20,23], the angular position of the affected joint/s, and time-duration since the injury[21]. These factors, subsequently, initiate changes at all levels of the CNS[21], and is expanded on below and in Supplementary material, Appendix 2.

AMI — neurophysiology of AMI actions within the CNS

The mechanisms of action for AMI initiated by neural pathways at the local/peripheral, spinal, and supra-spinal/central levels of the CNS are summarized as follows.

Local/peripheral level changes: These are a consequence of sustained tissue damage that alters muscle resting motor thresholds, and articular sensory receptor afferent discharge[6,19,20,58,64]. These predominantly include loss or irregularity of the affected articular sensory receptors themselves, joint laxity, and joint damage from distention due to swelling and/or inflammation[21].

For articular sensory receptors, the degree of joint structural trauma affects the level of damaged local nerve endings, with decreases in afferent output when the sensory endings are damaged[59,65], but increases with distention and joint laxity, which accounts for the strong association with AMI[21]. With joint laxity there is altered sensory receptor activation. The presence of structural damage, and/or degenerative change, enables increased intra-articular movement and joint surface translation, which increases mechanoreceptor and nociceptor activation. This in-turn signals the joints range of movement limits. Consequently, anomalous sensory receptor firing during joint movement will be present.

With joint distention from swelling, including clinically undetectable effusions, intra-articular pressure (IAP) is raised. This increases Group II afferent discharge from the joint through stimulation of pressure sensitive and stretch mechanoreceptors. This strongly inhibits the periarticular muscles, as the Group-I non-reciprocal (Ib) inhibitory interneurons in the spinal cord in-turn inhibit localized muscle α-motoneurons, which prevents full muscle activation. This results in significant AMI, as shown directly in the quadriceps[23,62], and can be implied for the local MF from studies on disc and nerve root trauma[66]. With joint distention from inflammation, the presence of AMI is distinguished by peripheral sensitization and resultant nociceptive signaling. Prolonged local tissue and joint sensitivity changes occur as a result of a reduced activation threshold in the articular free nerve endings supplied by Group III and IV joint afferents[67]. Consequently, normal non-noxious mechanical movement and activity causes articular structure stimulation which results in notable Group III and IV afferent discharge[67]. The release of inflammatory mediators increases this joint afferent discharge by sensitizing the free nerve endings innervated by Group III and

IV afferents. This is independent of nociceptive signals, as reducing pain does not necessarily reduce AMI's severity[21,62]. This action and the resultant reflex inhibition indicative of AMI, is also demonstrated for the lumbar MF at adjacent joints as well as the specific neural innovation levels, and in the presence of disc prolapse[66]. Both distention scenarios support the historical and recent recognition that AMI can occur regardless of the presence of structural damage[23,58,61,62] or inflammation[19,68,69].

Spinal pathways implicated in AMI: The spinal pathways are particularly associated with abnormal afferent discharge from the affected joint/s that can alter the excitability of the reflex pathways within the cord. This particularly affects the Group Ib inhibitory pathway and the associated Group Ia, II, III, and IV, the flexion reflex, and the gamma (γ)-loop[21]. However the neural connectivity at this level is able to show local neuroplastic change. A marker of observable neural change at the spinal level, the Hoffmann reflex (H-reflex), is measurable at the soleus through amplitude variations[70]. The H-reflex can be used to compare training effects in relation to the learning of a new skilled task, such as slacklining, with measures pre-activity (baseline), immediate post-activity (acquisition), and 24 h post-activity (retention). After 'acquisition' of a new skilled task, changes at the spinal level are general, but by 24 h these become task-specific. Consequently neural reorganization and generalization of spinal adaptations appears to be time dependent with the task specific adaption occurring after one day[71].

The Group Ib non-reciprocal inhibitory pathway utilizes signal relay actions to integrate sensory-motor information. Afferent musculo-tendinous junction neuronal signals are supplemented by Group Ia sensory fibers from the muscle-spindle stretch receptor, joint and peripheral sensory receptors through Group II, and unmyelinated/thinly myelinated Group III and IV fibers[72]. In turn motor-efferent neuron actions are influenced. Consequently, these dual capacities influence the Ib fibers signaling where effusion increases Group II output, which increases AMI through facilitated muscle motoneuron pool inhibition[21,72].

The flexion reflex in contrast is a polysynaptic pathway with facilitated agonist excitability and concurrent reciprocal extensor inhibition that may cause AMI[68]. The distinction of the γ-loop spinal reflex circuit is that it enables automatic muscle tension regulation that ensures full activation during voluntary muscle contractions[21,73]. Consequently, γ-loop dysfunction will contribute to AMI[21] as joint injury reduces excitatory afferent output to the muscle γ-motoneuron pool which reduces discharge. This results in enhanced presynaptic inhibition of the muscle α-motoneuron pool *via* Ia afferent fibers[74]. The spinal inhibitory interneurons projecting into the Ia afferent fibers synaptic terminals adjust the neurotransmitter release levels in response to the afferent input, which, subsequently, modulates the synaptic efficacy[74].

Supra-spinal/ Central pathways implicated in AMI: These pathways are hypothesized as supra-spinal projections from the joint afferents that influence AMI[21,75]. The changes include four main areas: (1) Cortico-spinal excitability/activity affecting the somatosensory cortex[22]; (2) Brainstem descending pathways[76] and the flexion reflex[75], with efferent commands modulated by afferent input; (3) Individual voluntary effort[21]; and (4) 'Informed awareness' that amalgamates behavior and 'flow-experience'[77]. These supra-spinal actions affect both neuroplasticity[42,43,78] and movement-fluency[79] to facilitate global equilibrium control. Consequently, centrally mediated sources override existing down regulatory inhibition, through concurrent control of active spinal reflexes. This enables muscular re-activation that is repressed by central inhibition in response to negative afferent input from traumatized and/or distended joints.

AMI knowledge: Based on peripheral findings, particularly at the knee

Despite AMI's specific mechanism remaining unclear and the majority of knowledge being derived from recognized attributes post-trauma about the knee[22,62], ongoing research into AMI's physiological neuro-motor basis continues[5,6,17,22,23,63]. It is already well accepted that, in acute knee trauma maximizing available quadriceps activation through isometric exercises in the lowest IAP range is effective[80], however this is not always recognized as occurring when addressing AMI[23,68]. Consequently the focus in new research is on the CNS, particularly modification of the connectivity within the sensory-motor network[63]. This includes efferent corticospinal excitability alterations post joint injury that facilitate local muscle inhibition at the knee[81], and investigations in ACL injury related to therapeutic effectiveness in reducing AMI[22]. The verification of the consensus assumption that central brain origin output and inhibition is the primary explanation for quadriceps AMI[22,23,63], is demonstrated by brain motor area

activation variations, found under MRI, between individuals with and without quadriceps AMI[69]. As these understandings improve, become recognized and accepted, the ability to progress and extrapolate such findings to the spine and MF-AMI depleted stabilisation will increase; as will the potential for management of NSLBP though AMI directed intervention to similarly evolve[5,6,17].

AMI knowledge: NSLBP implications and hypothesis evolved from the peripheral context

Using the knowledge and precedent understanding of AMI at the peripheral joints, particularly the knee[22,23,68], along with recent work from MF NMES[5,6,16], and understanding MF MCLs[17,51], the underlying basis of spinal MF-AMI can not only be implied but also understood through quantitative research.

This is supported by examples within the CNS neurophysiology, detailed above. This includes the analogous comparison of MF and quadriceps in the polysynaptic pathway of the flexion reflex with agonist flexion reflex excitability and concurrent reciprocal extensor inhibition[68]. Also the neuroplastic change, as a response to neuromotor sequencing and muscle re-activation, that advantageously facilitates innate spinal stabilization[42,78]. Similarly the altered efferent corticospinal excitability following both joint injury and local manual intervention associated with local spinal muscle inhibition[82] supports this premise.

It seems then a logical understanding to extrapolate the knowledge of peripheral AMI, particularly the knee, to the spine, as a recognized mechanism where central brain origin output and inhibition is a primary explanation. Consequently this would be, at least in part, an indicative explanation of the MF deficiency[6], and by consequence that interventions directed at MF-AMI would facilitate NSLBP management[5,17].

NSLBP: RECOGNIZED THERAPEUTIC INTERVENTIONS

Medical, general, non-surgical, and surgical interventions

Patients with LBP seek and are recommended in clinical practice guidelines to use symptom relief in a stepped approach stratified by duration[3,7,8,48]. This approach is initially simple and non-interventional with moderate-quality evidence for advice, reassurance, and self-management. If improvement is insufficient, then more complex interventional techniques are considered including heat, massage, spinal manipulation, and acupuncture in the acute-subacute phase, which have low-quality evidence[3,7,48]. Progression to medications, such as non-steroidal anti-inflammatory drugs (NSAIDs), but not Paracetamol or muscle relaxants, has moderate-quality evidence, being initiated only if non-pharmacological therapies are unsuccessful. This is advised to be under medical guidance and with caution, particularly if further medication progression is made to antidepressants, opioids, or for any prolonged medication use, which have moderate-quality evidence, and anticonvulsants or other (new) drugs, which have insufficient-quality evidence[7,48,83]. At week 12, persistent pain is recognized and the recommended progression is stratified using a biopsychosocial (BPS) approach that employs patient reported questionnaires that screen for the risk of persistent problems and pain[3,7,84,85]: where low risk indicates simpler less intense support with continued therapy and group exercises[7]; while higher risk[84] indicates structured exercise regimes[86], psychological therapies including cognitive behavioral therapy[82], and a multimodal[7,85] and multidisciplinary approach, though the 'dosage' of input has no quality of evidence for a determined recommendation[3,7,47,48]. With suspicion of radiculopathy or specific pathology, or non-improvement following four weeks of additional therapy, a specialist referral is recommended[83].

This overall approach has gained consensus to achieve best practice[8] in NSLBP and reflects general musculoskeletal problems. The approach is supported by recent systematic reviews with 11 'musculoskeletal pain care' summarized recommendations[87] that parallel the stated NSLBP management[6,7,85]. However, only three recommendations were specific to interventions, (education/information, physical activity/exercise, and adjuvant manual therapy treatment), but they were supplemented with a BPS approach (activity through work)[87].

Other non-invasive, non-pharmacological interventions have mixed evidence in their effect. There is no evidence for therapeutic traction, heat, and US[5,48]; insufficient[48] or limited evidence for massage, non-structured exercise[86], and transcutaneous electrical nerve stimulation (TENS)[6]; and low to moderate evidence for photo-biomodulation (or laser therapy) and information/education alone[48]; but

information/education improves significantly when combined with other therapies, particularly manual therapies[16,48] and therapeutic exercise[82], of which slacklining would be an example.

Invasive interventions have similar mixed findings in the evidence of their effect. These include: radiofrequency neurotomy, facet and nerve blocks, which have similarly varied findings with most recent meta-analyses questioning their use[88]. Similarly spinal cord stimulation (SCS) is questioned, though high frequency multi-column-SCS added to optimal medical management has higher evidence for gained effects, particularly individuals with multi-level non-specific changes and central sensitization[89]. Consequently, there remains a patient subgroup with significant symptoms and/or disability that fail with conventional management therapies and potentially require additional medical and invasive interventions[6].

AMI specific interventions for NSLBP

Several therapeutic interventions are demonstrated as effective in countering the presence of MF-AMI, though evidence is predominantly derived from effectiveness determined in musculoskeletal settings, particularly the lower limb and the quadriceps post knee trauma[23]. These techniques are generally achieved through a focus on local processes within two broad categories: (1) Modulation of joint afferent discharge; or (2) Muscle stimulation[20,22] as detailed below (in Supplementary material, Appendix 3), and summarized in Table 1. Consideration of management strategies for the lumbar MF-AMI that parallel those used for other AMI affected muscles, particularly quadriceps AMI at the knee, has occurred only recently through: involuntary-direct therapy *via* surgically introduced NEMS interventions[5,16]; while conservative approaches look to explain and utilize existing voluntary-direct and voluntary-indirect MCE therapy[6], and potentially involuntary-indirect therapeutic approaches, such as slacklining[17].

Joint afferent modulation to reduce discharge: The joint afferent modulation techniques reduce the neural signaling such that the CNS receives a lower degree of neural information and, subsequently, lowers the muscles inhibitory levels. Some of these therapies appear transferable to other body regions, such as the lumbar MF, and include: very low evidence for US[60] and vibration; low evidence for TENS[6], disputed evidence for NEMS[5,16] with reported findings both negative and positive[5,16], and moderate to strong evidence for cryotherapy[90].

Muscle stimulation and activation: The muscle stimulation techniques are achieved through four combinations of direct/indirect activation through voluntary/involuntary mechanisms. These target the restoring of stability, predominantly through the MF segmental stabilizing action[6,54], either alone[12] or with other 'core' muscles as previously noted[14,15]. This includes open/closed/composite kinetic-chain resistance[91] with fatiguing of the antagonist. However, many peripherally directed interventions for AMI may not be transferable to MF-AMI due to the MF diffuse fibers network, depth, additional overlying muscles, and that MF-AMI is virtually impossible to voluntarily activate[6].

Consequently, there is no definitive consensus on which specific therapeutic intervention/s demonstrate the most effective management for NSLBP, including that due to MF-AMI[6,13,85]. Ongoing disputes remain in the systematic reviews, meta-analyses, and RCTs, with discrepancies in guidelines[7,8,48], even within the same author group[83]. However, one area of consensus is management goals and aims, with recognition that for all NSLBP, including AMI affected joints and regions[5,6], low cost, self-administered interventions, such as adjuvant therapeutic exercise with the potential to alleviate symptoms and disability, should be considered and investigated[22,68].

Using published and current AMI cerebral-based research on peripheral joints, particularly the knee and the lower limb kinetic chain generally, the known positive effects from dis-inhibitory therapies that alter motor excitability, as cited in mild to moderate definitive scoping and systematic reviews[22], can be used and extrapolated to provide relevant applications to NSLBP. This leaves slacklining as a unique rehabilitation exercise, in that it addresses the entire affected lower limb kinetic chain coupled with the lumbo-pelvic region as a single unit[31,92], with the potential to overcome the presence of MF-AMI. This potential rehabilitation relationship between slacklining and MF-AMI for NSLBP management is significant, as slacklining presents an indirect-involuntary exercise therapy to address MF activation through a centrally mediated neural mechanism.

Table 1 Interventions that counter the effects of arthrogenic muscle inhibition

Modulation of joint afferent discharge		
Joint aspiration; intra-articular corticosteroid injection; nonsteroidal anti-inflammatory drugs; local anesthetic; cryotherapy; transcutaneous electrical nerve stimulation-TENS; electro-acupuncture; altering fluid distribution/capsular compliance		
Muscle stimulation		
	Voluntary activation	**Involuntary activation**
Direct	Therapeutic exercise; motor control exercise therapies: (1) Biofeedback/ultrasound guided; and (2) Individualized tailored hybrid convergence and divergence exercise-based approach of specific treatment of problems of the spine including: 'movement system impairment'; 'mechanical diagnosis and therapy' (MDT); 'integrated systems model' incorporates 'regional interdependence model'	(1) Neuromuscular electrical stimulation: (a) surgically implanted-effective; and (b) transcutaneous-ineffective; (2) Transcranial magnetic stimulation; and (3) Peripheral magnetic stimulation
Indirect	Therapeutic exercise: (1) Global/non-specific 'core stabilization exercise'; and (2) Specific 'core stabilization exercises' including: 'modern mind body' incorporating: Yoga, Tai Chi, Qigong, Pilates, Alexander, Feldenkrais, Bounce-Back, Calisthenics, Gyrokinesis, Gaga, Core-Align and Human Harmony; and MDT	Slacklining—possibly, *via* reducing down regulatory inhibition

TENS: Transcutaneous electrical nerve stimulation.

SLACKLINING AND ADJUVANT THERAPEUTIC EXERCISE

What is slacklining

A complete understanding of the full neuro-motor mechanism of slacklining remains incomplete, though several hypothetical models are proposed[28,92-95]. Most recently these models have been updated in an in-depth review with a revised paradigm proposed[31]. The summary slacklining definition presented in this paper's introduction can be expanded to include: Neuromechanical balance retention on a tightened webbing-band, fixed at each end, moveable in three dimensions during achievement of functional independence and dynamic stability from the interactions of the individual, where whole-body internal dynamics drive innate and learned responses to external environmental changes, that require adopting strategies that seek a compromise between maximum stability and minimal energy expenditure[26,28,31].

Consequently as a complex task[28,92], the individual learns, adapts, and adopts techniques that are self-developed neural strategies in response to the challenged balance and equilibrium[30], and can be quantified using self-organizing maps, a class of vector learning algorithms with the capacity to explain visualization techniques, topological retention and high-dimensional data-sets[94,96]. This results in lower-limb and core muscle activation as a primordial response[97,98] for balance retention to ensure postural stability[25,31] as a critical physical function[99]. This is achieved through a combination of: neurological system controls from centrally derived dampening of the down-regulation that causes reflex inhibition at both the central[78,100] and spinal segmental level[71]; and learned motor skills, from muscle recruitment through higher demand[78,101], that, subsequently improves coordination of movement and control[11,31]. However, there is also the consideration of mindfulness and flow-experience[77], the mind-body interaction that enables the movement-fluency[79] required to achieve and pursue slacklining as a tool for social, pleasure, pre- or re-habilitation purposes[29,37].

Efficacy of slacklining on AMI in NSLBP therapy

Slacklining has shown therapeutic promise in the clinical setting, particularly for the quadriceps AMI-inhibited post-trauma knee[25,26,30]. Slacklining may induce over twice the activation of four standardized quadriceps exercises with less than half the effort[30]. In employing this hypothesized basis, as previously detailed (presynaptic inhibitory actions on the CNS to over-ride central down-regulation induced muscle insufficiency[31,78,100]), for AMI-MF NSLBP case studies[17], the same neurophysiological, therapeutic-based reasoning of slacklining's action applies to the lumbo-pelvic musculature. The AMI-MF is targeted, in unison with other core stabilizing muscles[31], through an indirect-involuntary activation as a part of a whole body therapeutic exercise approach[79]. Though the therapeutic practice and research is still in its infancy and definitive evidence are lacking, the concept appears viable[17].

The consideration and inclusion of slacklining with other prevention and rehabilitation themes into NSLBP management derives from the sensory system's contributing triad of, proprioception, vision, and vestibular somatosensory inputs[102]. This is a consequence of slacklining's unique properties[30,31]: being a composite-chain

activity, *i.e.*, there is a weak link in the kinetic chain resulting in abnormal motor synergy patterns due to the contact surface of the loaded limb/s having free, partially supported, but unstable three-dimensional movement on a recoil resistance surface[31,91]; and actions being distinctly different from other conventional balance activities[27] and apparatus[25,33]. The synergy of these qualities coupled with CNS contributions results in four integrated qualities[30,31]: balance—equilibrium control of dynamic movement and center-of-mass within the base of support[25]; postural control—positional control in space[25]; muscle strength- muscular generated forces[33]; and neuromechanical demand—integration of neurobiology and biomechanics[28].

Evidence of the efficacy of slacklining in therapy and rehabilitation

The therapeutic direction of slacklining has progressively evolved. In particular the past decade has shown increased recognition of its adjuvant role in both the prevention and management of injury. In prehabilitation this is demonstrated in falls prevention in the elderly[26], and specific sports including judo[103], basketball[33], badminton[104], handball[105], and football/soccer[106]. In rehabilitation this is demonstrated in orthopedics[17,30], neurology[31,34,107] including systematic review support for reduction of falls and freezing of gait for Parkinson's disease[36], sports training[95], general physical training[106], physical performance[33,103], and recreation[37].

For all forms of LBP the current recommendations for therapeutic exercise interventions suggest an individually tailored hybrid approach[108] that accounts for individual preferences and abilities, and considers aligning areas of convergence and divergence that incorporate MCE[14]. These approaches utilize a 'specific treatment of problems of the spine' (STOPS) approach[109], where the key application principles are derived from four diverse areas. These are established evidence based/informed clinical physical therapy approaches where motor control is either a central or adjuvant feature[14,108]: the kinesiopathologic mechanical LBP model of 'movement system impairment'[110]; McKenzie's model of 'mechanical diagnosis and therapy'[111]; individually tailored MCE for areas with assessed suboptimal features[12]; and the 'integrated systems model'[14] which is compatible with the musculoskeletal 'regional interdependence model'[14]. This STOPS approach serves to guide clinicians and provide the platform for the proposed hybrid model[14,108]. Consequently, slacklining can be seen to fit comfortably within a hybrid model[14,108] as part of the STOPS approach[109].

The inter-related effects of slacklining and AMI on NSLBP

To understand the hypothesized paradigm for how slacklining can address MF-AMI related NSLBP from the neuro-physiological perspective, it is critical to understand that AMI's defined CNS actions are present at each of the three levels[21,23] as discussed previously. The presence of AMI, as a centrally derived presynaptic inhibitory action[18,19,23], modifies existing down-regulation control with consequential local MF-AMI deficiency[78,100]. This paradigm is particularly significant for exercise based NSLBP rehabilitation therapies that aim to facilitate normal neuro-motor sequencing[93,94] for neuromuscular and proprioceptive impairments[11,31,79], as similarly targeted in other musculoskeletal problems with cortical excitability deficits that alter function. Slacklining's action as an adjuvant therapy within rehabilitation simultaneously addresses this neural compromise by providing an override of central inhibition that enables indirect activation of the local neuro-motor inhibited muscles, where the presence of the lowest available IAP joint range inhibition initiates AMI through central mediated processes. This occurs immediately and directly at all CNS levels with significant implications for the MF-AMI related NSLBP, and the use of therapeutic slacklining. This therapeutic slacklining can be achieved with minimal required learning or therapist input[30] to induce normalized function[11,79] of the descending inhibition alterations[21,31,59] and facilitate neuroplastic change[41,94]. Consequently, in the presence of AMI there is "… the need to address cortical function early in rehabilitation ..."[62].

This leaves an open and potential role for slacklining to be considered within 2-4 wk of any LBP rehabilitation initiation; but particularly NSLBP, when natural response progression falters, not simply as an alternative therapy and option of potential last resort. This therapeutic use could prevent the descent into persistent pain[5,6], particularly in circumstances such as soft tissue trauma and operative interventions, where AMI is likely to ensue[21,62]. The proposed model and paradigm shift on potential muscle specific activation, that this paper presents, can assist in closing what appears to be a 'knowledge gap', but may simply be a matter of interpretation, and consequently an 'implementation gap'[112].

A practical implementation of therapeutic slacklining exercises can be derived from

the operational definition of 20-steps over 5-stages provided in previous publications[30]. These progressive stages enable the patient and clinician to both document and sequentially progress the slackline exercise capacity as an adjuvant to other incorporated and multi-modal and multi-practitioner approaches in a manner that is both self-taught and self-progressed. The sequence of steps and stages act as a guide and can be followed or altered for the individual (Table 2).

SLACKLINING'S NEURO-PHYSIOLOGICAL ACTIONS THAT POTENTIALLY COUNTER MF AMI INDUCED NON-SPECIFIC LBP

As presented above and per the aims, to rationalize why and how slacklining should be effective in reducing NSLBP symptoms, the ameliorating capacity is a consequence of slacklining's neuro-motor action that addresses the basis of MF-AMI[6,18-21,59], facilitating a reduction in down-regulated inhibition[31,78,100]. Consequently, this reductive capacity causes signal redundancy in the cerebral pre-synaptic inhibition section of the neuro-motor closed loop feedback system[102]. The action/s enable/s the brain to recourse to the normal or primordial signaling action[97,98,113] of neural flow through the spinal cord to the peripheral nerves and the local musculature, subsequently reducing the effect of AMI. This mechanism is supported by studies suggesting that central sensitization is influenced by impaired descending inhibition signaling[41]. This causes alterations in the individual's conditioned pain modulation (CPM) which is found in NSLBP patients. This slacklining action is hypothesized to occur through one or several of the four established neuro-physiological pathways detailed below[41,114].

Finite neural delay

The finite neural delay system occurs within the brain's limits for 'time available processing'[113,115]. To facilitate optimal use of available processing time during complex integrated neuro-motor control, such as that present with slacklining, the CNS combines and integrates: incoming/efferent signals through 'sensory weights', to ensure the required representation of all comparative contributions of each sensory system; and simplifies subsequent motor control through 'muscle synergies', where groups of muscles are combined as a common neural signal to control a range of movements, which simplifies motor-control[102,116]. Further, these neuromuscular strategies can be adapted and modulated by the individual to the required capacity necessary to facilitate stability[116]. However, despite these efficiency strategies, a significant neural load remains[117]. Consequently, the total information is interpreted as a 'package'[102], and as such requires processing time that exceeds the available finite neural delay; this consequently allows an override of existing down regulatory inhibition. Slacklining, being one such complex neuro-motor action, could induce such sequence override[31].

This is further supported by the understanding that nervous system processing is a principle consideration in relation to neural delay. This is due to the variations in different tissue-specific neural conductive pathways[118] and subsequent delays that result in varied reaction times[119] under different stressful situations[120]. These systems detect changes in desired positional orientation and react in an integrated manner. This maintains functional balance-control through a closed-loop feedback system with varied constraints on the sensory integration process, including that of the 'sensory weighting' discussed above[102,116]. Consequently, changes in motor activity or movement occur after nervous system processing[121], and are predominantly primordially protective responses designated to prevent injury[97,98,113].

NSLBP movement-control phenotypes, exercise reasoning hypothesis

The presence of two trunk movement control phenotypes[54] has been proposed as a model to facilitate the understanding of the inter-relation within trunk motor control between muscle activity and kinematics in LBP individuals[122]. In such a model there is a proposed spectrum continuity anchored at each end by control that is 'tight' and 'loose'. This may also be influenced by CPM response strategies that have a bias toward a pro-nociceptive phenotype in individuals presenting with NSLBP. Both the 'tight' and 'loose' control models are proposed to have beneficial effects, where 'tight' control protects against large tissue strains from uncontrolled movement, whereas 'loose' control protects against high muscle forces and resultant spinal compression[54]. This concept is consistent with Panjabi[9]'s modified model of spine stability that was

Table 2 Slacklining progressive competency phases—5 stages and 20 steps[30]

Stage and steps	Description of position
1—Beginner: Stand	Each description of stages 1-4 is for the slackliner standing on a slackline of 3 m length at strong tension anchored at each end 25 cm above soft terrain such as sand or grass
1	Single leg stand—on the dominant leg
2	Single leg stand—on the non-dominant leg
3	Single leg stand—on dominant leg, other foot touching the side of the line 1 foot length in front of the weight-bearing foot
4	Single leg stand—on dominant leg, other foot touching the side of the line 1 foot length behind of the weight-bearing foot
5	Single leg on non-dominant leg, other foot touching the side of the line 1 foot length in front the weight-bearing foot
6	Single leg on non-dominant leg, other foot touching the side of the line 1 foot length behind of the weight-bearing foot
2—Moderate: Walk	
1	Walk forward along the line with minimal to no pause between steps
2	Walk backward along the line with minimal to no pause between steps
3	Tandem stance with the dominant leg back or closest to the anchor point
4	Tandem stance with the dominant leg forward or furthest from the anchor point
3—Intermediate: Tandem	
1	Tandem stance with the dominant leg behind, then turn or pivot 180° on both feet to the natural side so that the dominant then becomes forward
2	Tandem stance with the dominant leg forward then turn or pivot on both feet to the non-natural side so that the dominant leg is behind
3	Tandem stance with the dominant leg behind, then turn or pivot 180° on the dominant foot to the non-natural side so that the non-dominant foot crosses over and returns to the forward position
4	Tandem stance with the dominant leg in front, then turn or pivot 180° on the non-dominant foot to the non-natural side so that the dominant foot crosses over and returns to the forward position
5	Side stand 'surf posture'—feet perpendicular to slackline and balance
4—Advanced: Squats	
1	'Surfer' position and squat down feet perpendicular to the line approaching buttocks to the line
2	Squat in tandem, dominant leg behind—feet along the line approaching buttocks to the line
3	Squat in tandem dominant leg in front—feet along the line approaching buttocks to the line
4	Single leg squat all weight on the dominant leg—approaching buttocks to the line
5	Single leg squat all weight on the non-dominant leg—approaching buttocks to the line
5—Extreme	Without using arms, without sight, bouncing
Other—tricks: Performance	Heel raises, walking on toes, jumps, spins, somersaults on line or as dismounts
	External focus (*e.g.*, throwing ball, juggling ball)
	Surfing (on very slack line) with oscillations or swinging perpendicular to the line

Slackline length and tension can be changed to modify the difficulty level.

evolved to include motor control[11]. Should these proposed differential movement control phenotypes exist, then interventions using different motor-control exercises would be required, or a single exercise that provides the ability to address both forms[54,122], particularly if they truly are parts of the same spectrum[14]. Slacklining as a unique complex neuromechanical action could potentially be such an exercise with this dual capacity[30,31].

The inhibition of action and the innate primordial imperative

A primary brain function is behavioral organization to determine 'action' or 'inhibition of action'[98]. This involves activation of the behavioral inhibition system (BIS)[97], which occurs in the presence of threats and endangered health, to enable choice of the least

detrimental option, *e.g.*, injury is preferred to death. It also, additionally, occurs in three circumstances when: no previous response pattern exists; danger cannot be predicted; or the instinctive fight/flight/freeze response (FFFR) is impossible[97]. The FFFR is instigated by fear and relates to individual underlying differences and experiences that, consequently, affect the level of adrenaline production. All three additional BIS circumstances would essentially be present in an initial exposure to slacklining[30,31]. Consequently, this BIS activation pathway may explain the pre-synaptic AMI override, but such an assumption must be taken within the context of reinforcement sensitivity theory (RST). This RST predicts that the BIS role in coping-motivated problem solving through its central role in anxiety is moderated by the behavioral approach system[97]. Further, it is important to recognize that BIS activation causes neuroendocrine responses; these involve multi-adrenocorticotropic hormone production by the hypothalamus, pituitary and adrenal axis, as part of the stress response. This in turn leads to glucocorticoid secretion and elevated cortisol levels, which if prolonged or chronically elevated have detrimental consequences including reductions in hippocampal volume which, subsequently, effect spatial and hippocampal-dependent learning and memory task capacity[15].

Preservation of existence is every organism's primordial imperative[97] as the brain's purpose is to ensure survival, through this aforementioned action, or inhibition of action[97]; not simply to think, but to act. This is because humans exist to maintain the structures that sustain life[98] and to reproduce for the optimal potential of natural selection through self-organization. The nervous system, consequently, enables species to act both within and upon their environment with the intended purpose of survival[99]. As such, the actions of slacklining through pre-synaptic inhibition could result from the consequential role of the inhibition of action and the innate primordial imperative[97,98].

Accentuated corticospinal drive

Positive influence on corticospinal excitability occurs in the presence of individual muscular feedback and joint pathology[68]. These cause an accentuated modulation in the CNS corticospinal drive[21]. The consequential effect is an override of pre-synaptic inhibition that enables a counteraction to the α-motoneuron inhibition by the spinal reflex pathways[23]. This positive influence on local AMI influenced muscles[69], particularly as demonstrated in the knee[22,23,30,31], could account for the capacity to initiate MF activation through the various direct and indirect, voluntary and involuntary mechanisms previously discussed.

CONCLUSION

Slacklining is a strategic indirect-involuntary therapeutic exercise that can facilitate the activation of MF-AMI deficient muscles; however, a thorough understanding of its neuro-motor mechanism of action remains incomplete. Slacklining has demonstrated clinical effects that overcome AMI in peripheral joints and recent case-studies indicate slacklining's potential in reducing MF-AMI related NSLBP. Slacklining's actions of effect are proposed to be provided by an: over-ride and inhibition of CNS down-regulatory induced MF-AMI, which normalizes the MF neuro-motor sequencing and muscle re-activation. These actions in-turn suggest slacklining as a potential adjuvant therapy that may address and reduce NSLBP symptoms and disability. Slacklining is simple to administer, use, and progress. Existing slacklining research on the neurological basis of effect, particularly in relation to AMI, has adequate acceptance to facilitate its introduction into NSLBP rehabilitation. However, what appears as a 'knowledge gap' could simply be interpretive, and merely an 'implementation gap' where the rehabilitation clinicians prescribing protocols are yet to recognize the full potential of this ancient excise and take it back to the future. Further investigation is required in research, cohort, and clinical populations to determine slacklining's efficacy, dose-response, and optimal time of implementation during pre- re-habilitation in managing MF-AMI deficient NSLBP.

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MINIREVIEWS

Lateral unicompartmental knee arthroplasty: A review

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Abstract

Isolated lateral compartment osteoarthritis of the knee is a rare condition affecting approximately 1% of the population, which is ten times less common than osteoarthritis affecting only the medial compartment. Unicompartmental knee arthroplasty (UKA) has many potential advantages over total knee arthroplasty. The benefits of UKA include a smaller incision, preservation of more native tissue (including cruciate ligaments and bone), decreased blood loss, and better overall proprioception. When UKA was first introduced in the 1970s, the outcomes of medial UKA (MUKA) were poor, but the few cases of lateral UKA (LUKA) showed promise. Since that time, there has been a relative paucity of literature focused specifically on LUKA given it is a rare procedure. Refinements in patient selection criteria, implant design, and surgical technique have been made leading to increased popularity. A review of the recent literature reveals that LUKA is associated with excellent long-term clinical outcomes and implant survivorship when performed in properly selected patients. Implant design options include fixed *vs* mobile bearing as well as metal backed *vs* all polyethylene tibial component, with improved outcomes noted with fixed bearing designs. Three reasons cited for revision (*i.e.*, fracture of the femoral component, fracture of the tibial component, and valgus malalignment) had been reported in past literature but not recently. Presently, while rare, the most common cause of failure and need for revision are osteoarthritis progression and aseptic loosening. Despite the need for an occasional revision procedure, the survivorship of LUKA is comparable to MUKA, although it should be noted that outcomes of MUKA have been notably varied. Continued pursuit of improved techniques and implant designs will continue to show LUKA to be an excellent procedure for appropriately indicated

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Core Tip: Lateral unicompartmental knee arthroplasty (LUKA) is an uncommon procedure, that when indicated appropriately, shows promising results for patients with isolated lateral compartment osteoarthritis. Recent literature has shown good long-term outcomes for LUKA. Continued pursuit of improved techniques and implant designs will continue to show LUKA to be an excellent procedure for appropriately indicated patients. This paper reviews patient selection, surgical techniques, and outcomes for LUKA.

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INTRODUCTION

Isolated lateral compartment osteoarthritis of the knee is a rare condition affecting approximately 1% of the population, which is ten times less common than osteoarthritis affecting only the medial compartment[1]. The clinical outcome of unicompartmental knee arthroplasty (UKA) has been a topic of renewed interest in the orthopaedic literature. Initial studies indicated poor outcomes following UKA; however, patient selection, surgical technique, and implant design changes have changed over the years[2-6]. This has led to many potential advantages over its total knee arthroplasty (TKA) counterpart. Performing a UKA allows for a smaller incision, less bone and soft tissue resection, less blood loss, and improved proprioception[7-11]. In addition, patients show decreased rates of post-operative infection and thromboembolic disease, decreased pain, and improved range of motion[9,11]. Furthermore, improvements have been seen in the form of shorter hospital stays as well as quicker rehabilitation[9,12,13]. Registry studies have indicated higher revision rates after primary UKA when compared with TKA. In contrast to the registry data, multiple studies have shown UKA implant survivorship to be comparable TKA[9,12,14,15]. Other studies have also indicated improved patient satisfaction likely a result of perceived normal knee function[16,17]. Biomechanical studies have confirmed that tibial axial rotation and femoral rollback following UKA more closely recapitulate normal knee kinematics than that following TKA[18].

Even though multiple studies have documented the success of lateral UKA (LUKA), it is not commonly performed. In fact, medial UKAs (MUKAs) are performed ten times more often than LUKAs. Overall, LUKA accounts for less than 1% all of knee arthroplasty procedures[19].

The small number of LUKAs performed since the development of the procedure many years ago is surprising. The original reports from that era implied that MUKA was not a great long-term option for treatment of unicompartmental osteoarthritis, while LUKA appeared to be much more promising[3-6]. Following refinements in patient selection criteria, surgical technique, and implant design, improved results for both medial and LUKA were seen in the 1980s[2]. Improved survivorship was noted at ten years and reported to be only slightly less than that seen for TKA at the time[20-22]. Studies on long-term outcomes following LUKA are hard to come by. However, more recent studies on LUKA show 100% survivorship at mid-term and long-term follow up[23,24]. These reports suggest that outcomes of LUKA are at least comparable to, if not superior to, those of MUKA. Recently, a meta-analysis of survival between medial and LUKAs showed no difference in short, mid-term, and long-term survival. In addition, there was no difference in pain relief or functional improvement between the two procedures[25].

BIOMECHANICS OF THE LATERAL KNEE

The lateral compartment of the knee is significantly different than the medial compartment in regard to the anatomy and biomechanics. Implants and surgical techniques must be specific to the lateral compartment, thus accounting for its unique characteristics.

Anatomic differences between the medial and lateral compartments include differences in posterior tibial slopes and anteroposterior (AP) dimensions in tibial plateaus[26,27]. In addition, the lateral plateau is convex and sits slightly more proximal than the medial plateau. Furthermore, the C-shaped lateral meniscus is more mobile allowing for more movement within the lateral compartment compared with the medial during normal knee kinematics. In normal knees, the femur rotates externally with flexion when the foot is left in neutral. At 40° of flexion, the flexion facet centers of the femur displace 4-5 mm in the AP plane such that there is anterior translation on the medial femoral condyle and posterior translation of the lateral femoral condyle[28]. Furthermore, the degree of femoral rollback is greater in the lateral knee than the medial knee[29].

As a result of these differences in anatomy and biomechanics, contact stresses develop in different regions as arthritis develops in the medial and lateral compartments. Weidow *et al*[29] localized regions of cartilage wear for cases of medial and lateral compartment arthritis. In medial osteoarthritis, tibial cartilage wear is located anteriorly, while in lateral osteoarthritis, wear is greater in central and posterior regions.

INDICATIONS

Over the years, different criteria have been included to pin point the perfect candidate for LUKA in order to improve outcomes. Most authors tend to refer to similar parameters, however they often disagree on specific cutoffs and values. Indications and contraindications proposed by Scott[19] are listed in Table 1.

Isolated lateral compartment osteoarthritis with axial deviation less than 10°-20° from neutral mechanical axis is a primary indication for LUKA. Radiographic evaluation should confirm the absence of advanced osteoarthritis in the medial and patellofemoral compartments. If joint space is preserved in the medial compartment, chondrocalcinosis or osteophytes are not an absolute contraindication. Provided the patient is not symptomatic for patellofemoral symptoms, radiographic evidence of patellofemoral osteoarthritis is also in itself not a contraindication. Burger *et al*[30] demonstrated that mild to moderate preoperative radiological degenerative changes and malalignment of the patellofemoral joint are not associated with poor patient reported outcomes at midterm follow up after lateral fixed bearing UKA.

Other commonly reported prerequisites are pre-operative range of knee flexion greater than 90°-100°, full knee extension, and tibiofemoral angles between physiological valgus and 10° varus without subluxation[31]. Some of the other indications have been adopted from literature based on MUKA. Ideal patient characteristics include an intact anterior cruciate ligament (ACL), weight less than 82 kg, and absence of significant inflammatory synovitis[32]. A fixed flexion deformity greater than 10° that cannot be corrected by ligamentous release nor removal of osteophytes is also considered a relative contraindication[24,33], especially given that a UKA relies heavily on normal knee biomechanics in order to maintain function and stability. Motion and stability are based on balance between static and dynamic support around the knee. If the release of soft tissue and osteophytes does not correct the deformity, larger bone cuts would need to be made in order to gain full extension, thus altering the normal kinematics of the knee.

EXPANDING INDICATIONS

While well-established guidelines have improved overall outcomes, expansion of traditional criteria has been favorable with no obvious decline in quality. Age and body mass index of patients at time of surgery have been expanded. While there is not any specific study looking at survivorship based on age as their primary outcome, there are some studies that indicate age is not a factor in outcomes. Lustig *et al*[34] showed excellent pain relief, improved function, and survivorship of 100% at 5 years and 10 years in patients with an average age of 50 years old (range 25-67). In a

Table 1 Traditional indications and contraindications

Indications
Predominantly isolated lateral compartment osteoarthritis
Angular deformity < 10°
Body weight < 80 kg
Contraindications
Flexion contracture > 15°
ACL and/or MCL insufficiency
Inflammatory synovitis

ACL: Anterior cruciate ligament; MCL: Medial collateral ligament.

retrospective review that included 31 LUKA, Xing *et al*[35] showed that the outcome was not influenced by the patients age.

Body mass index continues to be a topic of discussion in regard to success of knee arthroplasty. Multiple authors have shown based on long-term survivorship of LUKA that obesity alone should not be a contraindication[16,33]. In a study that included a cohort of obese patients, Swienckowski and Pennington[23] showed LUKA survivorship to be 100% at 12.4 years. In addition, Xing *et al*[35], found no correlation with obesity and LUKA outcomes. In a study that included 55 patients that underwent LUKA, Cavaignac *et al*[36] showed that weight and body mass index did not influence the outcome or survival. In fact, their results trended in the direction that weight plays a part in reducing the risk of revision, although their results were not significant.

Traditionally, the lack of a functional ACL was a contraindication for LUKA. This is a result of greater translation between the tibia and femur in the lateral compartment when the ACL is deficient. Therefore, this leads to abnormal kinematics and increased contact stresses, thus creating a higher implant failure rate[37]. However, Volpi *et al*[38] proposes that ACL insufficiency in patients over 70 years of age is not a reason to avoid LUKA. In his study, he reported on 3 patients with deficient ACLs that underwent LUKA, and they had excellent Hospital for Special Surgery scores at mid-term follow-up (range 2-5 years). While this study does show promising results of a LUKA in an ACL deficient knee, 3 patients is not enough to offer strong conclusions regarding its efficacy, and has only been found in a specific patient population of patients over age 70. Future research may offer more insight into the benefits of LUKA in ACL deficient knees; however, no formal conclusions can be made at this time. As technology improves, implants are moving toward restoring more native kinematics of the knee, thus offering a more stable implant even in the setting of an ACL deficient knee.

In addition to osteoarthritis as a diagnostic indication, the presence of primary osteonecrosis and post-traumatic arthritis are also indications for LUKA. Multiple studies have indicated excellent long-term survivorship in the setting of osteonecrosis and post traumatic arthritis[16,33,34]. Secondary osteonecrosis and inflammatory arthritis have been reported as contraindications to LUKA due to the fact they are likely going to involve the other knee compartments leading to early failure[39].

PRE-OPERATIVE ASSESSMENT

The pre-operative evaluation of a patient should be focused and intent on elucidating key pieces of information in the patients' history that would help the physician indicate the patient for a LUKA. A detailed history and physical exam should focus on location of the pain, timing and length of symptoms, and previous knee injuries/surgeries. Pain localization to the lateral joint line is imperative and indicates lateral joint pathology. Pain that is general or localized to other parts of the knee should be examined closer, as the patient may have pathology in other compartments and would therefore not be indicated for a LUKA. According to Bert[40]'s "one finger test", the patient points with one finger to the lateral compartment of the knee. In addition, the patient should be questioned about knee stiffness, mechanical instability, progression of functional limitations, and daily functional demands. On physical

exam, evaluation should consist of overall limb alignment with comparisons made with the opposite knee. Range of motion, gait analysis, and presence or absence of effusion should also be evaluated during the initial exam.

Four different radiographic views are recommended as part of the initial evaluation: weight-bearing anteroposterior, lateral, patellofemoral skyline, and a 45°-flexed knee tunnel view. In addition, stress radiographs can assist in making an accurate diagnosis and development of an appropriate preoperative plan. Gibson and Goodfellow[41] noted that if a stressed knee retains a width of 5 mm or more in the compressed compartment, the cartilage within that compartment is normal. Stress radiographs will also provide additional information on the reducibility of any deformity that may assist in determining if a LUKA is the correct procedure for the patient. Magnetic resonance imaging is typically not needed; however can be useful to further identify soft-tissue injuries.

Following a thorough examination and review of radiographic images, the decision to perform a LUKA *vs* perform a TKA should be determined prior to surgery, however being ready to convert to a TKA is imperative as plans may change after direct visual inspection of other compartments intra-operatively.

APPROACHES

Medial and lateral parapatellar approaches have been described for LUKA and offer good results. A lateral parapatellar approach provides direct visualization into the lateral compartment, thus allowing for a potentially smaller incision and less technically demanding than a medial approach. A main drawback on the lateral approach is that many orthopaedic surgeons are less familiar with this approach, which may lead to increased surgical time. In addition, there may be a concern for devascularization of the patella if a future medial parapatellar incision is needed. Despite all this, a lateral parapatellar approach has shown to be successful in LUKA. Swienckowski and Pennington[23] showed excellent long-term results using a lateral approach to the knee. In addition, Lustig *et al*[34] had a 100% survivorship at 10 years using a lateral parapatellar approach.

A medial parapatellar approach is another option for performing a LUKA. It is much more widely familiar to most orthopaedic surgeons and thus provides a level of comfort when performing the procedure. Sah and Scott[24] utilized a medial parapatellar approach and showed excellent outcomes at 5.2 years postoperatively. They showed that while a lateral parapatellar arthrotomy is more common to enter the lateral compartment, performing a LUKA through a medial approach provides a safe, effective, extensile and viable alternative.

When medial and lateral approaches were compared, Edmiston *et al*[42] showed improved postoperative flexion and greater improvement in flexion from preoperative measurements in the lateral approach group. Despite these findings, they also showed no difference between medial and lateral approaches in regard to revision rates or clinical outcome[42]. Both medial and lateral approaches offer excellent results. The approach used should be based on surgeon preference taking into consideration patient specific factors that may be present at the time of surgery.

OUTCOMES

Table 2[6,16,23,24,33,34,43-50] indicates the literature available for the survivorship of LUKA and the need for revision procedures. Of note, over the years there has been many different implant designs which is reflected in the literature laid out in Table 2. These studies include tibial components that are fixed *vs* mobile bearing as well as metal backed or all-polyethylene. Prior studies comparing these two tibial designs have focused on MUKAs with much more limited research on LUKA. Studies based on MUKAs show a superiority of metal back tibial designs over an all poly designs[51,52]. van der List *et al*[51] reported improved functional outcomes when using metal back implants and Koh *et al*[52] showed an increased failure rate within 2 years of all poly implants. While these studies show better results with metal backed implants, it is important to note these studied on MUKA and not LUKA. As discussed, the lateral compartment has different anatomy and biomechanics and therefore these benefits may or may not be seen in LUKA. There is very little literature comparing metal backed *vs* all poly tibial designs. Based on the few studies reported to date, no significant differences can be observed between metal backed or all-polyethylene tibial components[23,24,43]. However, it is

Table 2 Survivorship of lateral unicompartmental knee arthroplasty

Ref.	Number of UKA	Type of implant	Mean follow-up (yr)	Survivorship (number of revisions)
Scott and Santore[6] (1981)	12	Cemented, all poly tibia	3.5 (2-6)	83% at 3.5 yr (2)
Marmor[47] (1984)	14	Cemented, all poly tibia	7.4 (2.5-9.83)	NA (2)
Gunther *et al*[48] (1996)	53	Cemented, metal-backed, mobile-bearing	5 (2.5-9.83)	82% at 5 yr (11)
Ohdera *et al*[49] (2001)	18	Four different designs	8.25 (5-15.75)	NA (2)
Ashraf *et al*[33] (2002)	83	Cemented all poly tibia	9 (2-21)	74% at 15 yr (15)
O'Rourke *et al*[50] (2005)	14	Cemented all poly tibia	24 (17-28)	72% at 25 yr (2)
Swienckowski and Pennington[23] (2004)	29	Cemented, metal-backed (75%); all poly tibia (25%)	12.4 (3.1-15.6)	100% at 12.4 yr (0)
Sah and Scott[24] (2007)	49	Three different designs	5.2 (2-14)	100% at 5.4 yr (0)
Argenson *et al*[16] (2008)	38	Four different designs	12.6 (3-23)	84% at 16 yr (5)
Lustig *et al*[43] (2011)	54	Cemented, all poly tibia	8.4 (5-16)	98% at 10 yr (1)
Lustig *et al*[34] (2012)	13	Three different designs	10.2 (3-22.1)	100% at 5 yr; 80% at 15 yr (3)
Heyse *et al*[44] (2012)	50	Full poly, metal-backed cemented, metal-backed uncemented	10.8 (5-16)	91.8% at 10 and 15 yr
Fornell *et al*[45] (2018)	41	Cemented, metal-backed, mobile bearing design	4.1 (2-7)	97.5% at 5 yr
Zambianchi *et al*[46] (2020)	67	Fixed bearing metal backed design	3	100% at 3 yr (0)

UKA: Unicompartmental knee arthroplasty; NA: Not available.

reported that there is an increase in polyethylene dislocations associated with mobile bearing designs which has an effect on outcomes. When using a mobile bearing designed implant, Gunther *et al*[48] showed a 10% rate of inlay dislocations. This is likely due to greater translation of the lateral femoral condyle on the lateral tibial plateau during knee range of motion[18]. More recently, domed shaped mobile bearing implants were designed to imitate the native convexity of the lateral tibial plateau however more data is needed on this type of design to make a judgement on its effectiveness. A recent systematic review noted mobile bearing LUKAs had a higher rate of revision compared to fixed bearing designs with regard to short to mid-term survivorship, however clinical outcomes were similar[53]. At present, fixed bearing implant design is preferable given the survivorship and low failure rate.

Table 2 also shows three more recent publications that are important to highlight[23,24,34]. Swienckowski and Pennington[23] and Sah and Scott[24] showed 100% survivorship of LUKA at long-term (12.4 years) and mid-term intervals (5.2 years), respectively. Lustig *et al*[34] also had similar results and showed survivorship to be 100% at mid-term follow up and 80% at long-term follow-up after undergoing LUKA for post-traumatic arthritis secondary to lateral tibial plateau fractures. Heyse *et al*[44] showed a survivorship of LUKA to be 91.8% at 10 years and 15 years in patients less than 60 years old at the time of the index operation. They also found revision rates to be comparable to those in which UKA was performed in the elderly population. In addition, Fornell *et al*[45] showed 97.5% survival at 5 years. Overall survivorship of LUKA has improved since it was first attempted. Literature shows excellent survivorship at the 5- and 10-year time intervals with only minor drops at long term intervals.

More recently, the literature has investigated robot assisted LUKA to improve the quality of the procedure. Zambianchi *et al*[46] found 100% survival rate in 67 patients receiving LUKA when a robotic arm assisted procedure was performed. In a retrospective study comparing robotic assisted LUKA with a conventional technique, Canetti *et al*[54] showed that a robotic assisted surgical technique provide a quicker return to sports at an average of 4.2 mo *vs* 10.5 mo for the conventional technique (*i.e.*, hiking, cycling, swimming, skiing). While this was a small cohort of 28 patients who underwent LUKA, both groups were comparable preoperatively. Decisions about while whether to use robot assisted technique *vs* conventional were determined by robot availability as opposed to patient specific differences. The overall return to

sports was high and comparable between both groups.

Argenson *et al*[16] reported a survivorship of 84% at 16 years after undergoing LUKA for osteoarthritis. While these results are disappointing, it is important to note that this retrospective review included cases from February 1982 and December 2004. As discussed above, there have been many changes to surgical technique, implant design, indications, and contraindications. In this study, 4/5 revision surgeries were completed prior to 1989, when patient selection criteria were not nearly as strict as it is today. In addition, previously surgical instrumentation was not as refined and therefore much of the procedure relied on handmade cuts for proper placement of the implants. Implant choice may have also contributed implant failure. Gunther *et al*[48] reported a 21% failure rate in the lateral compartment with a 10% rate of bearing dislocation with the use of a mobile-bearing Oxford unicompartmental prosthesis. While this is cause for concern, this high failure rate in mobile bearing componenets has not been reproduced in more recent studies[45].

FAILURE AND REVISION SURGERY

Following LUKA, revision surgery is occasionally needed. In a recent systematic review by Ernstbrunner, they cited the most common cause of failure in LUKA was osteoarthritis progression and aseptic loosening noted in 30% and 22% respectively. Other causes of failure included instability, unexplained pain, infection, polyethylene wear, and bearing dislocation. In addition, they noted that bearing dislocation was the most common cause of early failure and the most common cause of failure when mobile bearing implants were used. Late failures were most commonly caused by osteoarthritis progression[55]. In a different systematic review investigating both cohort and registry data, van der List *et al*[56] noted the most common modes of failure to be osteoarthritis (29%), aseptic loosening (23%), and bearing dislocation (10%). In an evaluation of a Dutch arthroplasty register Burger *et al*[57] found a 12.9% 5 year revision rate for LUKA, citing progression of osteoarthritis as the main reason for revision. In addition, in a cohort that included 32 patients, Walton reported progression of osteoarthritis in 18%-34% of LUKAs[58]. While some authors admit to progression of osteoarthritis to other compartments, they tend to believe it remains clinically asymptomatic and therefore revision is not needed[31]. Two studies highlighted the need for revision surgery due to progression of osteoarthritis. Ashraf *et al*[33] revised 9/15 LUKAs and Argenson *et al*[16] revised 4/5 for osteoarthritis progression to other compartments.

Other reasons for revision that have been cited are fracture of the femoral or tibial component and valgus malalignment. These complications have not been found in recent literature and are therefore likely the result of past poor patient selection, surgical technique, and implant design. For example, Ashraf *et al*[33] completed 4 revisions prior to 1988 for a fractured femoral component. Subsequent design alterations have made the femoral component stronger making this complication rare. Argenson *et al*[16] revised 1 implant for a tibial plateau fracture that was likely caused by a technical error at the time of surgery. Valgus malalignment was another common cause for poor results following LUKA during its early days of development. Cameron *et al*[59] reported difficulty correcting valgus malalignment as a cause for poor results in 9/20 LUKA. Improvements in patient selection have since been modified to include fixed valgus deformity as a contraindication due to previous poor results.

Despite increasing literature regarding revision surgery from a LUKA, it remains controversial. Ease of revision often favors performing a UKA[60]. In a study of 54 patients undergoing revision to TKA after a UKA (9 lateral, 45 medial), Châtain *et al*[60] found better results with revision from a UKA to a TKA *vs* patients who underwent a tibial valgus osteotomy. In turn they also found less satisfactory results when a UKA was converted to a TKA than a primary TKA initially[60]. Lewold *et al*[61] found that the risk of having a second revision was greater than 3 times higher for failed UKAs revised to a new UKA than for those that were originally revised to a TKA. The re-revision rate was reduced to 7% after converting the initial UKA to a TKA[61]. Robertsson and W-Dahl[62] indicated a significantly higher risk of revision after a TKA in patients that previously underwent a UKA or closed wedge HTO. While it has been well documented that TKA's are more reliable in terms of survivorship and less complications overall, there is still a lot of debate on whether undergoing a UKA is advised over a TKA at the index procedure. It should be noted that a revision of a UKA can often be done with primary TKA implant without then need for revision stems, whereas a revision of a primary TKA would require a more involved and

invasive procedure. In many cases, a LUKA offers a great option for patients that meet the indications; however, they do need to be advised on the comparison between that and undergoing a TKA.

CONCLUSION

Although LUKA is sparingly utilized, the procedure does lead to excellent clinical outcomes and high long-term implant survivorship rates. The increase in survivorship and decrease in revision rates of LUKA can be attributed to better-defined patient selection criteria, improvements in surgical technique and instrumentation, and modifications of implant design to better accommodate the lateral compartment. Currently the literature supports improved outcomes when using fixed bearing designs. Given the paucity of literature on the topic, the superiority of metal backed *vs* all polyethylene tibial components has not been borne out despite the superiority of metal backed implants for MUKA. The breadth of research into LUKA has flourished within the last 10 years and will likely continue along that path as the procedure is becoming more frequent. LUKA now has similar survival rates and functional outcomes to MUKA within the literature. Continued pursuit of improved techniques and implant designs will continue to show LUKA to be an excellent procedure for appropriately indicated patients.

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MINIREVIEWS

Fracture of ossified Achilles tendons: A review of cases

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Abstract

Fracture of an ossification of the Achilles tendon (OAT) is a rare entity, and its etiology, pathology, and treatment remain unclear. We reviewed and scrutinized 18 cases (16 articles) of the fracture of an OAT. The most common etiologies of the ossifications include previous surgery and trauma. The fractures often occur without any trigger or with minimal trigger. The long, > 5 cm, ossification in the body of the Achilles tendon may have a higher risk of fracture. The OAT itself is often asymptomatic; however, its fracture causes severe local pain, swelling, and weakness of plantar flexion, which forces patients to undergo aggressive treatments. Regarding the treatments of the fractures, nonoperative treatment by immobilizing ankle joint could be an option for elderly patients. However, because it often cannot produce satisfactory results in younger patients, surgical treatment is typically recommended. Excision of the fractured mass and repairing the tendon is applicable if the remnant is enough. If there is a defect after the excision, reconstruction with autologous grafts or adjacent tendon transfer is performed. Gastrocnemius fascia turndown flap, hamstring tendon and tensor fascia lata are used as autologous grafts, whereas peroneus brevis and flexor hallucis longus tendons are used for the tendon transfer. If the fracture of an OAT is treated properly, the functional result will be satisfactory.

Key Words: Achilles tendon; Ossification; Fracture; Tissue grafting; Tendon transfer; Treatment

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Core Tip: This review paper aims to provide an overview of the fracture of an

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ossification of the Achilles tendon. This fracture is distinct in that it occurs with minimal or no triggers. Nonoperative treatments may offer acceptable results for the elderly; however, surgeries should be recommended in younger patients. Following excision of the fractured mass, repairing the tendon is only applicable if the remnant is enough. If there is a defect after the excision, reconstruction with auto-grafts or adjacent tendon transfer is performed. Various kinds of tissues are used for the reconstruction. Treated properly, the functional result will be satisfactory.

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INTRODUCTION

Ossification of the Achilles tendon (OAT) is a rare entity. Among them, fracture of an OAT (FOAT) is exceptionally rare. Therefore, perspectives of the etiology, pathology, and the treatment of the FOAT have not yet been unified. This review aims to summarize and evaluate the current literature on the FOAT and describe current concept of etiology, pathology, and treatment of this condition.

LITERATURE SEARCH

Systematic searches of PubMed were performed in August 2020 to identify studies relating to FOAT. The outline of the search strategy is shown in Figure 1. First, we identified 54 relevant articles by using the specified terms shown in Figure 1. Second, we excluded the articles which were not written in English. Third, articles were screened based on their title and abstract. Fourth, articles were further screened based on the full text and those that described the FOAT cases were selected. Finally, we scrutinized the reference lists of the included 15 articles and added one proper article. As a result, we identified 16 articles. All of them were case reports and included cases of 18 fractures in 16 patients (two patients had the fracture on both sides[1,2]). We show the summary of all the 16 articles in Table 1.

ETIOLOGIES OF OAT

Past studies revealed that OAT occurred more frequently in men than in women[1,3,4]. Although the exact mechanism of ossification is unclear, the most commonly known etiologies are previous trauma and surgery[4]. In addition, infectious, metabolic, and systemic diseases such as syphilis, gastrocnemius abscess, osteomyelitis of the calcaneum, gout, diabetes, Wilson's disease, ochronosis, diffuse idiopathic skeletal hyperostosis, Reiter's syndrome, and ankylosing spondylitis may also cause ossification[3,5-9].

ETIOLOGIES OF FOAT

Only a small number of patients with OAT experience the FOAT. We show the summary of all the FOAT cases in Table 1. Etiologies of FOAT are similar to those of OAT. Among the 16 patients with the FOAT, 10 were men and 6 were women. Six patients had a history of previous surgery and 5 had a history of previous trauma. Among the 6 cases, who had experienced previous surgeries, the most common underlying cause was talipes equinovarus (5 cases)[1-3,5,10], followed by poliomyelitis (1 case)[11]. Achilles tendon rupture[12], ankle dislocation[9], distal tibial fracture[13], deep laceration of the calf[6] and soft tissue injury of the calf[14] were described as the details of the previous trauma.

Table 1 Summary of reported cases of the fracture of an ossification of the Achilles tendon

Ref.	Patient		Size	Cause of ossification			Onset of fracture	Treatment	Histology	Follow-up period	Result
	Age	Sex		Previous trauma	Previous surgery	Other factors					
Lotke[1] (1970)	61	F	NA	-	+	-	Standing at the sink	Surgery (excision and repairing the tendon)	Mature bone with fibrosis of the marrow space	15 mo	Good
	66	F	NA	-	+	-	Unspecified	Surgery (excision and repairing the tendon)	Mature bone with fibrosis of the marrow space	12 mo	Good
Weseley *et al*[11] (1976)	58	M	NA	-	+	-	None (spontaneous occurrence)	Nonoperative (immobilization for 6 wk)→Surgery (excision and transferring peroneus brevis)	Mature bone	3.5 mo	Nonoperative: poor; surgery: good
Brotherton and Ball[14] (1979)	71	M	12.5 cm	+	-	-	Walking uneven ground	Surgery (reduction and holding with a figure of eight wire)	Partly woven and partly lamellar bone, forming a cancellous structure	4 mo	NA
Fink and Corn[8] (1982)	42	F	8 cm	-	-	Hypertension, hypothyroidism, obesity	Stumbling on level ground	Surgery (excision and reconstruction with gastrocnemius fascia flap)	NA	4 mo	Good
Kernohan and Hall[17] (1984)	64	M	20 cm	-	-	Manual worker	NA	Surgery (Achilles tendon graft interposition)	NA	5 mo	Good
Suso *et al*[16] (1988)	20	M	10 cm	-	-	Long-distance runner	Long-distance run	Surgery (excision and direct repair)	Bony trabeculae, separated by fibrous tissue areas	3 mo	Good
Resnik and Foster[10] (1990)	36	M	NA	-	+	-	Stepping in a hole	Nonoperative (immobilization for 6 wk)→Surgery (excision and reconstruction with tensor fascia lata graft)	NA	NA	Nonoperative: poor; surgery: good
Friedman[13] (1991)	41	F	NA	+	-	-	Twisting the ankle	Surgery (excision, unspecified)	NA	NA	Good
Goyal and Vadhva[3] (1997)	84	M	6 cm	-	+	-	Crossing a road	Nonoperative (immobilization for 12 wk)	NA	12 mo	Good
Aksoy and Surat[6] (1998)	44	M	7 cm	+	-	-	Climbing upstairs	Surgery (excision and reconstruction with proximal Achilles tendon flap)	NA	24 mo	Good
Parton *et al*[5] (1998)	84	M	NA	-	+	-	Hurrying across a crossing	Nonoperative (immobilization for 8 wk)	NA	3 mo	Good
Haddad *et al*[15] (1999)	67	F	NA	-	-	Hypertension, obesity	Tripping in the garden	Nonoperative (immobilization for 6 wk)	NA	6 mo	Good
Mády and Vajda[2] (2000)	57	M	5 cm (bilateral)	-	-	History of treatment for clubfeet by serial plaster casts	None (spontaneous occurrence)	Surgery (interosseous polydioxanone suture which was reinforced by a local tendon flap)	Mature osseous tissue	84 mo	Good
Battaglia and	55	M	NA	+	-	Hypertension,	Strained while	Nonoperative (immobilization for 12	Osseous composition	6 mo	Nonoperative: poor;

Chandler[12] (2006)						dyslipidemia	pruning a tree	wk)→Surgery (excision and transferring flexor hallucis longus)			surgery: good
Ishikura *et al*[9] (2015)	50	F	14 cm	+	-	-	Climbing upstairs	Surgery (excision and reconstruction with hamstring tendon graft and gastrocnemius fascia flap)	Lamellar bone, which is covered by a number of osteoblasts in some areas	12 mo	Good
Gendera *et al*[18] (2020)	70	M	12 cm	-	+	-	None (spontaneous occurrence)	Surgery (excision and reconstruction with fascia lata graft)	Broad trabeculae of lamellar bone tissue with vital osteocytes	12 mo	Good

F: Female; M: Male; NA: Not available.

As for the patients who had no previous trauma or surgery, an obese person[15], a long-distance runner[16] and a manual worker[17] were included in the cases examined. The repetitive stresses from the overweight or overload might have led to the OAT. In that sense, repetitive stresses through obesity or an overactive state might be included in the concept of "previous trauma."

The mean period between the previous trauma or surgery and the occurrence of FOAT was 44.3 ± 20.8 years (n = 10, 15-78 years). This implies it takes a considerable amount of time for the ossification to grow big enough to fracture.

SIZE AND LOCATION OF THE OSSIFICATION

According to the previous reports about the OAT, a variety of sizes have been reported[4]. However, as for the FOAT, the length is 5 cm or more in all the mentioned cases[2,3,6,8,9,14,16-18].

OAT can occur in the body of the tendon or at its insertion into the calcaneus[1,4,6,14]. In the cases reviewed, the site of ossification could be detected by plain radiographs in 15 cases. The ossifications were located within the body of the tendon in 13 cases. In the remaining 2 cases, the ossification was present at the insertion of the calcaneus[12,15].

Considering these tendencies, ossifications in the body of the Achilles tendon that are > 5 cm long may have a higher risk of fracture. However, additional studies are needed to confirm this hypothesis.

CAUSE OF FOAT

In general, rupture of an unaffected Achilles tendon occurs in sports with abrupt repetitive jumping and sprinting activities[19]. By contrast, FOAT occurs without any trigger or with minimal trigger such as climbing upstairs and crossing a road[2,3,6,9,11,18]. This fact probably reflects the fragility of the OAT. This fragility may be attributable to

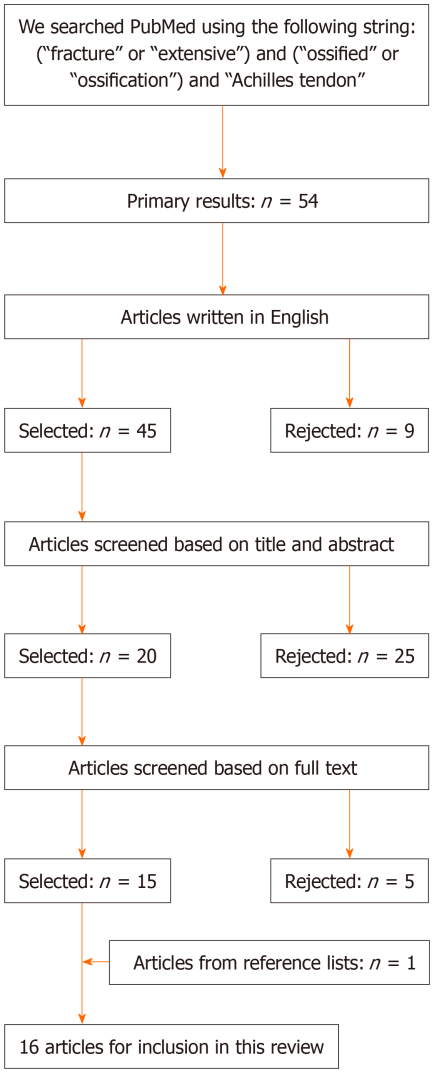


Figure 1 Search strategy for this study.

its histological structure described in the "Histology of FOAT" section.

DIAGNOSIS OF FOAT

Although an OAT is usually asymptomatic[10,12], it can sometimes cause pain if the inflammation exists around the ossified area[4]. Meanwhile, once the ossified mass fractures, it causes symptoms including severe local pain, swelling, and weakness of plantar flexion[10,12]. Therefore, if the patients with an OAT suddenly experience pain, a fracture should be suspected[14].

As for the physical examination, it should be noted that Thompson calf squeeze test is sometimes negative despite the presence of the fracture[12,17]. It is probably because of the retained continuity of Achilles tendon component around the fractured ossification. Therefore, plain radiographs should be used to obtain precise diagnosis. Magnetic resonance imaging is also used to evaluate the hemorrhage, edema, and soft tissue condition around the fracture site[5,9].

TREATMENT OF FOAT

According to previous reports, FOAT is treated either nonoperatively or surgically. In elderly patients, the nonoperative treatments are one of the options, because it can bring satisfactory results in some cases[3,5,15]. However, in 3 cases of younger patients, it has not produced the desired functional outcome. Resnik and Foster[10] reported a case

of a 36-year-old man who underwent nonoperative treatment for FOAT but experienced persistent pain and swelling even after the treatment. He eventually underwent surgical excision of the bony mass and tendon reconstruction. Weseley *et al*[11] and Battaglia and Chandler[12] reported similar cases of male patients in their 50s who experienced failure of the nonoperative treatment modality and, subsequently, underwent the surgical treatment. Given these results, only limited outcomes should be expected from nonoperative treatment modalities, particularly in younger patients.

The surgical procedures for the treatment of the FOAT include internal fixation[2,14] and excision of the fractured mass, followed by the reconstruction with autografts[6,8-10,18] or adjacent tendon transfer[11,12]. Although internal fixation of the fractured mass reportedly offers the prospect of bone union[2,14], the applicable cases should be limited because this treatment does not eradicate the risk of non-union and refracture. Meanwhile, when the fractured mass was excised, diverse procedures have been conducted to cover the defect. If the ossification does not involve all layers of the Achilles tendon, direct repair of the tendon could be applicable[1,16]. However, if the ossification has infiltrated almost all layers of the tendon and there is a defect after excision, various kinds of grafts including gastrocnemius fascia turndown flap, hamstring tendon and tensor fascia lata grafts have been used to cover the defect[6,8-10,18]. For the adjacent tendon transfer, the peroneus brevis and flexor hallucis longus tendons have been used[11,12].

These procedures of reconstruction are also performed to treat chronic Achilles tendon ruptures[20-23].

HISTOLOGY OF FOAT

Ossification, not calcification, typically accounts for a great majority of patients with Achilles tendon mineralization[4]. This tendency is consistent with our FOAT cases. All the patients whose histological appearances were available in this study showed bone tissues instead of calcification[1,2,9,11,12,14,16,18]. Lamellar bone, or combination of lamellar bone and woven bone was reported. In one of the cases examined here, histological sections stained with hematoxylin and eosin revealed that the tendon tissue underwent cartilaginous metaplasia and was gradually replaced by lamellar bone, which is surrounded by a number of osteoblasts[9]. These histological findings suggest the occurrence of endochondral ossification, which is consistent with the observation of heterotopic ossifications in other studies[24,25]. In that sense, histology of FOAT is quite similar to that of the heterotopic ossification. However, in our FOAT cases, the bone structures are often separated by fibrous tissues[1,16]. Such a mixed structure may be responsible for its fragility and this might be the distinct feature of FOAT. Given this histological finding, leaving the ossified mass in the FOAT patients may entail the risk of refracture. Therefore, the fundamentals of treating FOAT should include excision of the ossified mass as much as possible, followed by repairing or reconstructing the tendons. Past studies also reported the cases describing the combination of endochondral and intermembranous ossification[26,27]. However, the exact mechanism of the ossification in the FOAT patients were not suggested in many cases. Further studies are needed to accumulate the histological findings and elicit the exact mechanism of the ossification and its fracture.

CONCLUSION

This review provides an overview of the FOAT. Many of the affected patients had a history of previous surgery or trauma. This fracture is distinct in that it occurs without any triggers or with minimal triggers. Nonoperative treatments offer only limited effects and surgeries are often performed. When the fractured mass was excised, repairing the tendon is applicable if the remnant is enough. If there is a defect after the excision, reconstruction with autografts or adjacent tendon transfer is performed. Treated properly, the functional result will be satisfactory.

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ORIGINAL ARTICLE

Basic Study

Osseointegration of porous titanium and tantalum implants in ovariectomized rabbits: A biomechanical study

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Abstract

BACKGROUND

Today, biological fixation of uncemented press-fit acetabular components plays an important role in total hip arthroplasty. Long-term stable fixation of these implants depends on the osseointegration of the acetabular cup bone tissue into the acetabular cup implant, and their ability to withstand functional loads.

AIM

To compare the strength of bone-implant osseointegration of four types of porous metal implants in normal and osteoporotic bone in rabbits.

METHODS

The study was performed in 50 female California rabbits divided into non-ovariectomized (non-OVX) and ovariectomized groups (OVX) at 6 mo of age. Rabbits were sacrificed 8 wk after the implantation of four biomaterials [TTM, CONCELOC, Zimmer Biomet's Trabecular Metal (TANTALUM), and ATLANT] in a 5-mm diameter defect created in the left femur. A biomechanical evaluation of the femur was carried out by testing implant breakout force. The force was

gradually increased until complete detachment of the implant from the bone occurred.

RESULTS

The breakout force needed for implant detachment was significantly higher in the non-OVX group, compared with the OVX group for all implants (TANTALUM, 194.7 ± 6.1 N *vs* 181.3 ± 2.8 N; $P = 0.005$; CONCELOC, 190.8 ± 3.6 N *vs* 180.9 ± 6.6 N; $P = 0.019$; TTM, 186.3 ± 1.8 N *vs* 172.0 N ± 11.0 N; $P = 0.043$; and ATLANT, 104.9 ± 7.0 N *vs* 78.9 N ± 4.5 N; $P = 0.001$). In the OVX group, The breakout forces in TANTALUM, TTM, and CONCELOC did not differ significantly ($P = 0.066$). The breakout force for ATLANT in the OVX group was lower by a factor of 2.3 compared with TANTALUM and CONCELOC, and by 2.2 compared with TTM ($P = 0.001$). In the non-OVX group, the breakout force for ATLANT was significantly different from all other implants, with a reduction in fixation strength by a factor of 1.9 ($P = 0.001$).

CONCLUSION

TANTALUM, TTM, and CONCELOC had equal bone-implant osseointegration in healthy and in osteoporotic bone. ATLANT had significantly decreased osseointegration ($P = 0.001$) in healthy and in osteoporotic bone.

Key Words: Animals; Bone-implant interface; Osteoporosis; Femur; Tantalum; Titanium

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Core Tip: In an *in vivo* model of osteoporosis, it was found that some types of porous acetabular components are more compatible with osteoporotic bone. The study results can help to select the right choice of acetabular components for hip replacement in patients with low bone mass.

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INTRODUCTION

Today, biological fixation of uncemented press-fit acetabular components plays an important role in total hip arthroplasty. Long-term stable fixation of these implants largely depends on the osseointegration of bone tissue into the acetabular cup implant and their ability to withstand functional loads[1,2].

It has been established that both the implant surface and the condition of bone tissue are of great importance in the process of osseointegration[3]. Implant qualities including structure, strength, stiffness, porosity, coefficient of friction, and surface roughness have significant impact on the quality and quantity of bone osseo-integration as well as the long-term survival of press-fit implants[4,5]. In patients with osteopenia and osteoporosis, both qualitative and quantitative properties of bone tissue deteriorate, leading to a weakening of bone metabolism that then leads to accelerated osteoclastogenesis and bone resorption[6,7]. The above situation is an unfavorable condition for the implantation of uncemented press-fit acetabular components[8].

In a previous experimental animal study utilizing a rat model, it was shown that osseointegration of current porous acetabular implant materials, as well as the possibility of successful implantation and osseointegration in osteoporotic bone, directly depends on the structural characteristics of the porous implant[9]. However, there is a lack of comparative data of the strength and stability of the bone-metal osseointegration of current porous materials used in acetabular components in both normal and in osteoporotic bones.

followed. The *in vivo* study was approved by the Ethical Clearance Bioethics Committee State Institution "Sytenko Institute of Spine and Joint Pathology NAMS of Ukraine", Kharkiv, Ukraine (Protocol No. 175 of 26 Feb 2018).

Conflict-of-interest statement: Bondarenko S, Filipenko V, Karpinsky M, Karpinska O, Ivanov G, Maltseva V, and Badnaoui AA declare that they have no conflict of interest. Schwarzkopf R has potential competing interests; he is a paid consultant of Smith & Nephew, Memphis, TN, United States.

Data sharing statement: No additional data are available.

ARRIVE guidelines statement: The authors have read the ARRIVE guidelines, and the manuscript was prepared and revised according to the ARRIVE guidelines.

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The study aim was to carry out a comparative analysis of the strength of the formed bone-metal osseointegration among four types of porous metal implants in an *in vivo* animal model with both normal bone and after the simulation of osteoporosis. Our hypothesis was that there will be a difference in the strength between the formed bone metal osseointegration between normal and osteoporotic bone models.

MATERIALS AND METHODS

Animals

Fifty female California rabbits 6 mo of age and weighing 4.5-5.0 kg) were kept in conditions of 24 °C, 12/12 h light/dark, and 60% humidity, with *ad libitum* access to food and water, and a standard diet. All surgeries (ovariectomy and implantation of materials) were performed under general intramuscular anesthesia (xylazine hydrochloride 15 mg/kg and ketamine 50 mg/kg). Euthanasia was carried out by overdosing of ketamine (50 mg/kg) and subsequent air embolism. All experiments were performed according to the national guidelines and all appropriate measures were taken to minimize pain or discomfort to the animals. The study design was approved by the local Bioethics Committee.

Study design

Rabbits were randomly divided into healthy control non-ovariectomized (non-OVX) and ovariectomized (OVX) groups of 25 each. To simulate osteoporosis, ovariectomy was performed in the OVX group. After 3 mo, 10 rabbits (5 non-OVX and 5 OVX) were sacrificed to confirm of osteoporosis development. For the remaining rabbits, (n = 40) one of the four types of porous materials were implanted. All rabbits with implants were sacrificed 8 wk after implantation.

Implants

The four types of implants used in this study were of comparable 80% or greater porosity. Three were Ti6-Al4-V titanium alloys: TTM (AK Medical, Beijing, China), CONCELOC (Smith & Nephew, Memphis, TN, United States), ATLANT (TITAN-MED, Kyiv, Ukraine). The fourth was porous Zimmer Biomet's Trabecular Metal (TANTALUM) (Zimmer, Warsaw, United States). The elastic moduli are 3 GPa for TANTALUM[10], 12.9 for GPa[11], 4.3 GPa for CONCELOC[12], and 113 GPa for ATLANT. A 1.2 mm diameter hole was drilled on one side of the implants to allow mounting of the testing jig. The testing jig that was attached to the implant was used to test breaking strength during the study (Figure 1A). Prior to implantation, the biomaterials were sterilized by autoclaving at 132 °C for 20 min.

Surgical procedures

Ovariectomy (n = 25) was performed under general anesthesia by two dorsolateral 2.5 cm incisions of the skin and muscles following the method described by Wanderman *et al*[13].

Implantation of materials: Each type of porous material was implanted in 5 healthy and 5 ovariectomized rabbits (n = 40) under general anesthesia under sterile conditions. The surgical field in the proximal part of the left femur was treated with Betadine antiseptic solution, after which the skin was incised from the lateral approach along the anterior femoral region above the greater trochanter. The musculus tensor fasciae latae and musculus quadriceps femoris were bluntly dissected and sequentially fixed. The greater trochanteric area was perforated by a burr to create a bone defect to match the biomaterial samples (diameter of 5 mm, length of 6 mm). After that, the wound was sutured in layers and the skin was treated with Betadine antiseptic. As postoperative pharmacological therapy, benzylpenicillin, dihydrostreptomycin (combikel 40) and meloxicam were administered.

X-ray radiographic evaluation

Radiographic evaluation was performed three times. Three months after ovariectomy to control osteoporosis development in 5 OVX and 5 non-OVX rabbits, immediately after implantation to evaluate the position of implants, and at 8 wk after implantation for all 20 OVX and 20 non-OVX rabbits (Figure 2). In all cases, a digital X-ray diagnostic system (OPERA T90cex; General Medical Merate S.p.A., Italy) was used.

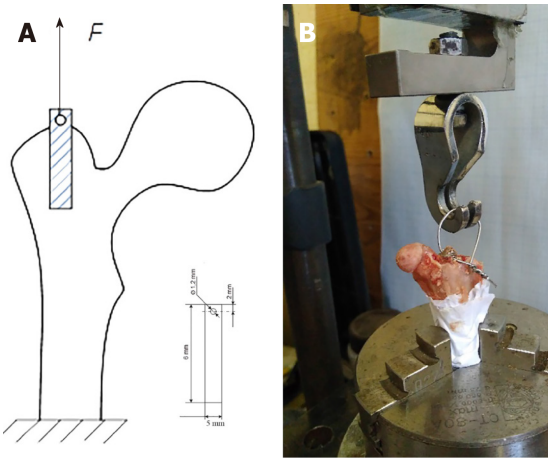


Figure 1 Scheme of biomechanical testing and biomechanical testing. A: The geometric dimension of the implants; B: Rabbit femur with implant on the stand during testing.

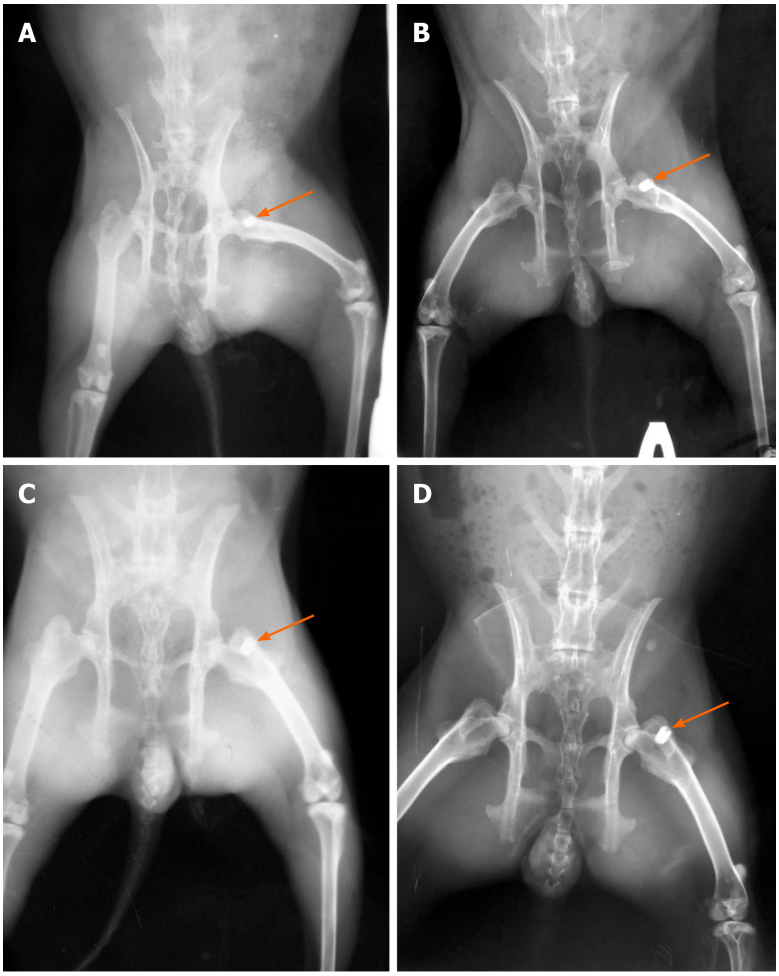


Figure 2 X-ray images of rabbits after implanted CONCELOC material (arrow) in the proximal femur. A: Non-ovariectomized (non-OVX) rabbit after surgery; B: Non-OVX rabbit at 8 wk after surgery; C: Ovariectomized (OVX) rabbit after surgery; D: OVX rabbit at 8 wk after surgery.

The analysis of cortical thickness index

Radiographs of the femur was obtained in 10 rabbits (5 OVX and 5 non-OVX) before implantation of materials to verify the osteoporosis model (Figure 3)[14]. This method is used as an alternative to measurement of bone mineral density in diagnosis of osteoporosis[14]. Using "X-Rays" software (Kharkiv National University of Radioelectronics, Ukraine)[15,16], the cortical thickness index was automatically

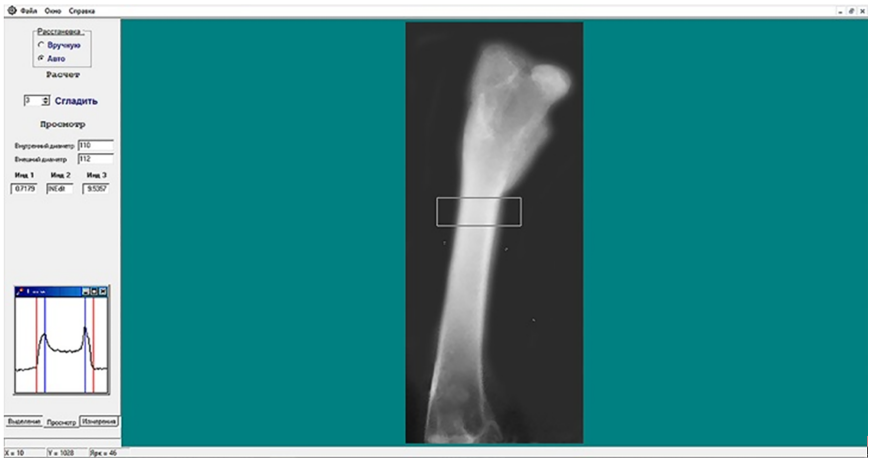


Figure 3 Evaluation of the cortical thickness index of the proximal femur of rabbit with "X-Rays" software (Kharkiv National University of Radioelectronics, Ukraine) 3 mo after ovariectomy.

calculated based on the measurement of the thickness of the cortical layer of the femur under the lesser trochanter in 10 rabbits. This software allows performing a coordinate-brightness analysis of digital radiographs, and provides spatial sampling with 0.042 mm elements and brightness quantization with a grayscale of 256 intensities. The analysis was performed by two independent experts.

Biomechanical testing

The implanted materials were rigidly fixed to the testing jig and breakout force testing was performed to detach the implant from the bone tissue (Figure 1B). We applied a breakout force to the implant at a constant speed of 1 mm per minute, which was gradually increased until complete detachment of the implant from the bone. The maximum value of the breakout force (N) was recorded with a strain gauge (SBA-100L) and a CAS type CI-2001A registration device (South Korea) (Figure 4).

Statistical analysis

Data were reported as means ± SD. Unpaired *t*-tests were used to evaluate the effect of osteoporosis on the stability of the same type of implant. Unpaired *t*-tests were performed for verification of osteoporosis model. To analyze the effect of the type of material on the strength of osseointegration in the non-OVX and OVX groups, one-way analysis of variance (ANOVA) was carried out with the post-hoc Duncan test. The critical level of significance was accepted as 0.05. The analysis was performed with IBM SPSS Statistics 19.0 software. The statistical methods were reviewed by Olena Karpinska and Michael Karpinsky of the Department of Biomechanics, Sytenko Institute of Spine and Joint Pathology, National Academy of Medical Sciences of Ukraine.

RESULTS

Analysis of cortical thickness index

In the OVX group (n = 5), the cortical thickness index of the proximal femur was 1.4 times lower (P = 0.001) than that in the non-OVX group (n = 5) (0.482 ± 0.033 *vs* 0.660 ± 0.007, unpaired *t*-test).

Biomechanical testing

Data were obtained on the maximum breakout force that led to detachment of the implant from the femoral bone in both normal and osteoporotic bone tissue. The strength of the implant attachment in the femoral bone tissue was significantly higher in non-OVX group (n = 20), compared with the OVX group (n = 20) for all materials (Figure 5, unpaired *t*-test). When evaluating each implanted material, the breakout force was higher in the non-OVX group by a factor of 1.1 for TANTALUM (194.7 ± 6.1 N *vs* 181.3 ± 2.8; P = 0.005); CONCELOC (190.8 ± 3.6 N *vs* 180.9 ± 6.6 N; P = 0.019); and TTM (186.3 ± 1.8 N *vs* 172.0 ± 11.0 N; P = 0.043), and by a factor of 1.3 (104.9 ± 7.0 N *vs*



Figure 4 Device for recording breakout force with a strain gauge.

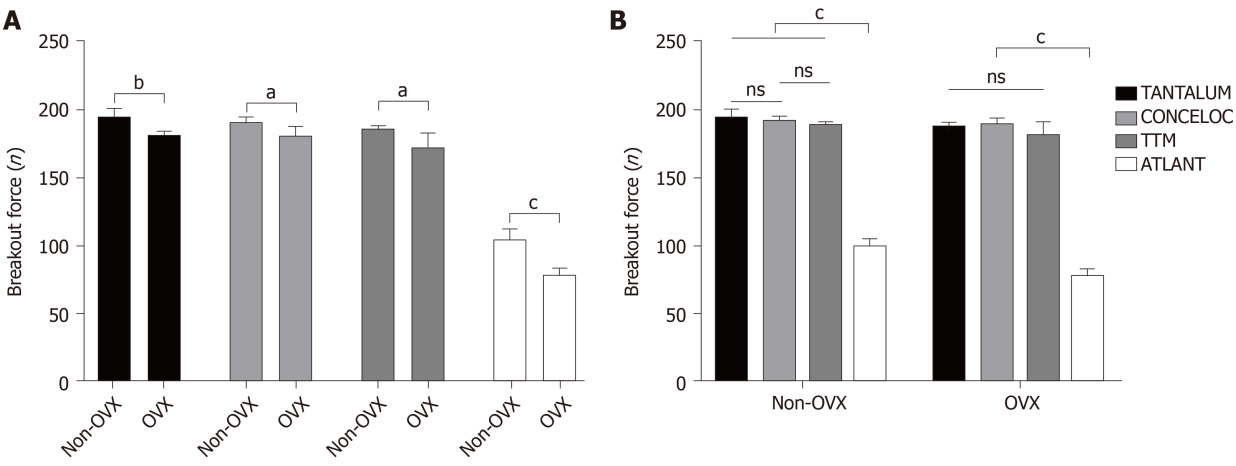


Figure 5 Results of breakout force testing of four types of porous materials in ovariectomized (OVX, *n* = 20) and healthy rabbits (non-OVX, *n* = 20) 8 wk after implantation. A: Unpaired *t*-test: Analysis of the effect of osteoporosis (OVX group) on the bone-implant strength and osseointegration for the same type of implant; B: ANOVA with post-hoc Duncan test evaluation of the effect of the implant material on bone-implant strength and osseointegration in ovariectomized and non-ovariectomized rabbits. $^{a}P < 0.05$; $^{b}P < 0.01$; $^{c}P < 0.001$. ns: not significant; non-OVX: non-ovariectomized; OVX: ovariectomized.

78.9 ± 4.5 N; $P = 0.001$) for ATLANT, compared with the OVX group.

TANTALUM implants had the highest breakout strength in osteoporotic bone tissue at a load of 181.3 ± 2.8 N and in normal bone tissue at a load of 194.7 ± 6.1 N (Figure 5). The lowest breakout strength was shown in ATLANT implants. Failure was observed in normal bone tissue at a load of 104.9 N ± 7.0 N and in osteoporotic bone at 78.9 ± 4.5 N. In the OVX group (osteoporotic bone), the breakout forces of TANTALUM, TTM, and CONCELOC did not differ significantly ($P = 0.066$, Figure 5, one-way ANOVA). On the contrary, The breakout force of ATLANT implants was lower by a factor of 2.3 compared with TANTALUM and CONCELOC and by a factor of 2.2 compared with TTM ($P = 0.001$). Results in the non-OVX group (normal bone) were similar to those in the OVX group with minor differences (Figure 5, one-way ANOVA). The breakout force for TANTALUM and CONCELOC implants did not differ significantly ($P = 0.239$). ATLANT implants were significantly different from all other implants, with a reduction in fixation strength of approximately 1.9 times ($P = 0.001$).

DISCUSSION

In this biomechanical study, we examined the strength of osseointegration of three porous titanium and one porous tantalum materials. We studied the breakout strength of the implanted materials 8 wk after their implantation in the metaphysis of the greater trochanter of the femur in an *in vivo* rabbit model. Three of the studied

materials in this study (TANTALUM, CONCELOC, TTM) are used in the manufacture of acetabular components for total hip replacement and are currently used in clinical practice. The fourth studied sample (ATLANT) is a new material used in the manufacture of acetabular cups. A unique aspect of our study is the comparison of the breakout strength among the four studied materials in both normal and osteoporotic bone in a rabbit ovariectomy model.

The importance of bone quality for osseointegration of porous implants has been shown both in cadaver studies[17,18] and in an animal model[19]. Beckmann *et al*[18] reported the results of a biomechanical study (multi-axial testing machine) that examined the mobility of an acetabular titanium cup with a porous surface in 10 cadaveric pelvises. They found an inverse relationship between the bone mineral density (BMD) of the femoral neck and the mobility of the acetabular cup. Similar data were obtained when using an additional acetabular porous augment[18]. The differences in osseointegration and breakout strength between different commercial acetabular cup materials are especially important in patients with low BMD. It has been found that patients with low BMD have an increased risk of migration of uncemented hydroxyapatite-coated titanium alloy acetabular cups 3–12 mo after total hip arthroplasty (THA) compared with patients with normal BMD[8]. According to a clinical study of 283 patients evaluated 2 years after revision THA, it was found that porous tantalum acetabular cups were more stable than porous titanium cups in patients with low BMD[20]. However, the long-term survivorship of acetabular cups in patients with osteoporosis is poorly understood in comparison with patients with normal BMD[21].

According to our data, the stability of implants in the OVX group was lower for all materials studied compared with the non-OVX group. Similar results were obtained by Fujimoto *et al*[19] when evaluating titanium implants in an experimental model of glucocorticoid-induced osteoporosis in rabbits. Similar to our results of the non-OVX group, Duan *et al*[22] presented biomechanical testing (push-out test) of medical Ti-6Al-4V substrates with titanium and tantalum coated implants. Their results showed that at 9 wk after implantation, the titanium and tantalum implants had similar push-out strengths when evaluated in New Zealand white rabbit femurs.

Our findings of similar breakout forces in tantalum (TANTALUM) and titanium implants (TTM and CONCELOC) in the OVX group may have occurred because the evaluated titanium implants had similar porosity, highlighting the importance of high porosity percentage in these implants. It has been shown that high porosity improves osseointegration compared to nonporous implants[23,24]. Pore size is also an important factor affecting osseointegration of the implant[23,24]. These variables probably explain the lower values of breakout force exhibited by the ATLANT component material compared with the other implants in both OVX and non-OVX models. A recent study in rabbits that compared titanium implants manufactured by additive technology and with three different pore sizes (500 μm, 700 μm and 900 μm)[25] showed that the best interfacial strength was achieved when the pore size was 700 μm, when evaluated by a push-out test at weeks 4 and 12 after implantation. This emphasizes the importance of the material pore size for its osseointegrative qualities. This knowledge may help manufacturers design materials made with similar technology and from different alloy materials. Nevertheless, when comparing tantalum and titanium implants with the same 500 μM pore size and 70% porosity in a rabbit model, the authors did not find any differences in the push-out test indices at 2 wk, 4 wk, and 8 wk after implantation[26]. The same results were reported in a similar study by Su *et al*[27] when comparing tantalum and titanium implants with the same pore size.

A limitation of our study was the use of one type of test to evaluate implant stability. However, our study is one of the few studies comparing tantalum and titanium materials in a low bone-mass model. Thus, these results will help expand the current knowledge of the stability of the studied materials in cases of osteoporosis.

CONCLUSION

TANTALUM, TTM and CONCELOC had equal bone-implant osseointegration in both healthy and osteoporotic bones. ATLANT showed a significant decrease in osseointegration (P = 0.001) in both healthy and osteoporotic bone.

ARTICLE HIGHLIGHTS

Research background

Highly porous metal acetabular components are widely used in patients with low bone mass, but the strength of osseointegration may differ.

Research motivation

There is a need to perform studies to compare the strength of osseintegration of new porous metal biomaterials used in total hip arthroplasty of patients with low bone mass.

Research objectives

The objective of this study was to compare the strength of the formed bone-metal osseointegration among four types of porous metal biomaterials in an *in vivo* animal model with both normal bone and after simulation of osteoporosis

Research methods

The experimental study was performed in a rabbit model of postmenopausal osteoporosis. Biomechanical evaluation of the femur was carried out by testing the implant breakout force 8 wk after implantation of four types of biomaterials: TTM, CONCELOC, Zimmer Biomet's Trabecular Metal (TANTALUM), and ATLANT. The force was gradually increased until complete detachment of the implant from the bone.

Research results

The breakout force needed for implant detachment was significantly higher in healthy controls, compared with the ovariectomized group for all implants. The breakout force for ATLANT in the ovariectomized group was lower than that observed with TANTALUM, CONCELOC' and TTM.

Research conclusions

TANTALUM, TTM and CONCELOC had equal bone-implant osseointegration in healthy and osteoporotic bones. ATLANT showed a significant decrease in osseointegration in healthy and osteoporotic bone.

Research perspectives

Further studies on the use of other biomechanical methods will expand the knowledge of the strength of osseointegration of modern porous materials, which will help in choosing optimal materials for acetabular implants when performing total hip arthroplasty in patients with osteoporosis.

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ORIGINAL ARTICLE

Retrospective Study

Predictors of clinical outcomes after non-operative management of symptomatic full-thickness rotator cuff tears

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Abstract

BACKGROUND

Previous studies have shown that non-surgical management can be an effective treatment strategy for many patients with rotator cuff tears. Despite the prevalence of rotator cuff disease, few studies have examined the patient and tear related factors that predict outcomes of nonsurgical management in this cohort of patients.

AIM

To identify factors that are associated with changes in patient reported outcomes over time in individuals with full-thickness rotator cuff tears treated without surgery.

METHODS

A cohort of 59 patients who underwent non-surgical management of full thickness rotator cuff tears with a minimum of 1-year follow-up were identified from our institutional registry. Patient demographics, comorbidities and tear characteristics were collected at initial presentation. Outcome measures were collected at baseline and at each clinical follow-up, which included Western Ontario Rotator Cuff (WORC) index, American Shoulder and Elbow Surgeons score, Visual Analog Scale for pain and Single Assessment Numerical Evaluation. Multi- and univariate regression analyses were used to determine the impact of each patient and tear related variable on final WORC scores and change in WORC scores throughout the study.

RESULTS

In this non-surgical cohort, all patient-reported outcome measures significantly improved compared to baseline at 1 and 2-year follow-up. There was no significant difference in outcomes between 1 and 2 years. The average improvement surpassed the published minimal clinically important differences values for WORC, American Shoulder and Elbow Surgeons, Visual Analog Scale

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pain and Single Assessment Numerical Evaluation scores. Regression analysis identified female gender (β = - 19.88, *P* = 0.003), smoking (β = -29.98, *P* = 0.014) and significant subscapularis fatty infiltration (β = -15.35, *P* = 0.024) as predictors of less favorable WORC scores at 1 year, and female gender (β = -19.09, *P* = 0.015) alone as a predictor of lower WORC scores at 2 years. Patients with symptom duration greater than 1 year at presentation reported less improvement in WORC scores at 1-year follow-up (β = -14.63, *P* = 0.052) and patients with traumatic tears reported greater improvements in WORC scores at 2-year follow-up (β = 17.37, *P* = 0.031).

CONCLUSION
Patients with full thickness rotator cuff tears can achieve and maintain clinically meaningful benefit from non-surgical management through 2-year follow-up. Female patients, smokers, and those with significant subscapularis fatty infiltration tend to have lower overall WORC scores at 1-year follow-up, and females also have lower WORC scores at 2-year follow-up. Patients presenting with symptoms greater than 1 year had less clinical improvement at 1-year follow-up, and those with traumatic tears had greater clinical improvement at 2-year follow-up.

Key Words: Rotator cuff tear; Conservative treatment; Patient reported outcome measures; Shoulder injuries; Shoulder pain

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Core Tip: This clinical study examines the factors, both patient and tear-related, that predict patient reported outcome measures in a cohort of 59 patients with symptomatic, full-thickness rotator cuff tears who are treated non-surgically. All patients included in this study presented with magnetic resonance imaging scans which were used to measure several important characteristics including tear size, associated fatty infiltration and the supraspinatus tangent sign. Linear regression analyses were performed to determine which factors independently predicted patient reported outcome measures.

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INTRODUCTION

Rotator cuff disease represents the most common etiology of shoulder dysfunction in the aging population, with an estimated 4.5 million physician office visits annually in the United States dedicated to its treatment[1,2]. The prevalence of rotator cuff disease increases with age, with over 60% of patients over the age of 80 exhibiting evidence of rotator cuff pathology[3]. Despite its prevalence, the ideal management of full-thickness rotator cuff tears has yet to be clearly defined. There have been several randomized controlled trials comparing surgical and non-surgical management of rotator cuff tears with conflicting results supporting both treatment options[4-6]. Although non-surgical management does not lead to rotator cuff healing, it has been shown to be an effective treatment option in many patients, leading to improvements in function and patient-reported outcomes[7-11].

Despite the generally positive outcomes, few studies have investigated the factors that predict outcomes after non-surgical management of rotator cuff tears. The Multicenter Orthopaedic Outcomes Network (MOON) shoulder group identified patient expectations related to physical therapy, smoking status and activity level to be predictive of outcomes in their prospective cohort of patients with full thickness rotator cuff tears[12]. Boorman *et al*[13] found that only the rotator cuff quality-of-life

index predicted treatment failure in their non-surgical cohort. Both of these studies defined treatment failure as patients who decided to undergo surgical intervention.

The objective of this study was to identify patient characteristics at initial presentation that might be predictive of patient-reported outcomes after non-surgical management of full thickness rotator cuff tears.

MATERIALS AND METHODS

Patient enrollment

This study was approved by our institutional review board. Patients who presented to our institution between 2009 and 2015 with full thickness rotator cuff tears were prospectively enrolled into our research registry. The inclusion criteria for this registry included patients at least 18 years old who were diagnosed with a full thickness rotator cuff tear proven by magnetic resonance imaging (MRI) or ultrasound. Exclusion criteria included patients with isolated subscapularis tears, those with a history of prior ipsilateral shoulder surgery, fracture, dislocation, infection, inflammatory joint disease, or those who had already undergone more than 4 wk of formal non-operative treatment modalities.

Baseline demographic data were obtained, including factors pertinent to rotator cuff pathology [age, sex, body mass index (BMI), smoking, diabetes]. Patients documented whether their symptoms were related to an injury (traumatic *vs* atraumatic) and how long their symptoms had been present. For the purpose of our analysis, symptom duration was categorized as less than 1 year and greater than 1 year.

Treatment allocation was determined by shared decision making between the surgeon and patient after a thorough clinical exam and discussion of the risks and benefits of operative and non-operative management. No specific criteria were formally utilized to determine the treatment arm, as each decision was individualized for the specific patient. A previous study by Kweon *et al*[14] analyzed this same patient registry and found that there were some patient factors which predicted allocation to surgical management, including younger age, lower BMI and duration of symptoms less than 1 year. Other relevant factors including sex, tear size, functional comorbidity score or any patient reported outcome measure were no predictive of treatment allocation in this same study. Patients who chose to pursue non-operative management in this registry were enrolled in formal physical therapy with a standardized rotator cuff rehabilitation protocol. This therapy involved shoulder stretching, rotator cuff resistance band strengthening and scapular stabilizing exercises. These patients were also treated with anti-inflammatory medications and occasional steroid injections as needed for pain control.

We identified 151 patients in the registry who underwent non-operative management with a minimum of 1-year follow-up. Fifty-nine of these patients had adequate pre-treatment imaging studies to evaluate rotator cuff muscle grading. Forty-three of the patients were followed for 2 years and the remaining 16 patients had 1 year of follow-up. Of note, there were a total of 316 patients in the registry treated for rotator cuff tears during this study period, signifying that 47.8% (151/316) of the total patients were treated non-operatively.

Patient-reported outcome measures

Upon enrollment into the registry, patients completed a demographic questionnaire as well as several patient-reported outcome measures including the Western Ontario Rotator Cuff (WORC) index[15], American Shoulder and Elbow Surgeons (ASES) score[16], Single Assessment Numerical Evaluation (SANE)[17] and Visual Analog Scale for pain[18]. The WORC index was used as the primary outcome measure for this study as it was developed and validated specifically for patients with rotator cuff tears[19]. The normalized version of the WORC index (WORCnorm) was utilized for this study, which converts the scores to a 0-100 point scale, with 100 representing the highest possible score. Outcome measures were collected at 6 and 12 mo, then at annual intervals. For the purpose of our study, the patients' last documented outcome measures (either 1 or 2 years) were used as their final outcome.

MRI evaluation

All patients included in this study underwent an MRI with at least a 1.5T magnet. These MRI studies all included a T1 sagittal oblique sequence which was used to evaluate the rotator cuff musculature. The maximal anterior-posterior and medial-lateral dimensions of the rotator cuff tear were multiplied to obtain the cuff tear index

(CTI)[20]. Of note, CTI was originally described using arthroscopic measurement techniques, but MRI based measurements were substituted in this non-surgical cohort. Fatty infiltration was graded on a scale of 0 to 4 as originally described in a computed tomography study by Goutallier *et al*[21]. Sagittal oblique T1 sequences were used to calculate the grade of fatty infiltration, as described in a subsequent MRI based study by Fuchs *et al*[22]. For the purpose of analysis, fatty infiltration was grouped by grades 0 and 1 *vs* grade 2 and higher. The supraspinatus tangent sign was also measured on this sequence, in accordance with the methods proposed by Zanetti *et al*[23]. MRI analysis was performed independently by two orthopaedic surgery sports medicine fellows, and any discrepancies between graders were resolved by an additional assessment performed by the senior author. Both inter-rater and intra-rater reliability were also assessed for this dataset and published previously by Naimark *et al*[24].

Statistical methods

Descriptive and inferential statistics were analyzed using Statistic Package for Social Science v22.0 (IBM) and STATA/MP 14.2. Differences in patient reported outcome measures at each time point were obtained using univariate analysis of variance post-hoc testing using Tukey's test was utilized to check for significant differences between specific time points. *P* values less than 0.05 were considered significant. Baseline demographic data are presented as the mean ± SD or a percentage within groups. An a priori power and sample size analysis using a moderate effect size estimate was calculated and produced a requirement of 21 patients for a power of 0.80 at 95%CI.

Linear regression analyses were conducted for all continuous dependent variable, change in the WORC score and total normalized WORC scores at 1 and 2-year follow-up. Predictor variables included gender, age, BMI, smoking status, diabetes, CTI, traumatic or atraumatic tears, duration of symptoms greater than or less than 1 year, tangent sign, infraspinatus fatty infiltration, and subscapularis fatty infiltration. Multivariable models were completed, then an elimination analysis was performed, removing the least significant variable each time before running the analysis again. This elimination analysis was continued until only statistically significant variables remained. *P* values less than 0.1 were considered significant.

RESULTS

Fifty-nine patients met the inclusion criteria for this study. The baseline characteristics of these patients are displayed in Table 1. All patient-reported outcome measures improved over the course of the study compared to baseline values, as shown in Table 2. Statistically significant improvements were noted between baseline and 1 year and between baseline and 2-year outcomes. There was not a statistically significant improvement in any patient reported outcome between 1 and 2 years (Figure 1).

Multivariable linear regression models using final WORC scores at 1 and 2 years as the clinical outcome measure are shown in Table 3. At 1-year follow-up, female gender, smoking and advanced subscapularis fatty infiltration were found to be predictive of worse WORC scores. These factors predicted fairly substantial decreases of nearly 20, 29 and 15 points respectively. At 2-year follow-up, only female gender remained predictive of worse scores, with a similar decrease of 19 points on the normalized WORC score.

In addition to analyzing final WORC scores, multivariable analyses were also performed using the overall change in WORC scores at 1 and 2 years compared to baseline values. These results are shown in Table 4. At 1-year follow-up, patients with chronic symptoms (> 1 year) were predicted to have significantly less improvement in WORC scores by nearly 15 points. At 2-year follow-up, patients with traumatic tears were predicted to have over a 19-point greater increase in WORC scores. Age was also found to be a significant predictor of worse WORC scores at 2-year follow-up, although not likely clinically significant with a β value of less than 1 point. The mean improvements in WORC score at 2-year follow-up for patients with traumatic *vs* atraumatic and acute *vs* chronic tears are shown in Table 5.

DISCUSSION

Few studies have examined the factors associated with positive patient-reported outcomes after non-surgical management of full thickness rotator cuff tears. In this

Table 1 Baseline characteristics

Baseline characteristics	
Age	63.85 ± 8.48
Male, *n* (%)	37 (62.71)
BMI	29.63 ± 5.58
CTI	4.77 ± 4.47
Diabetes, *n* (%)	5 (8.47)
Smoking, *n* (%)	4 (6.78)
Traumatic, *n* (%)	40 (67.8)
Duration > 1 yr, *n* (%)	17 (28.81)
Tangent sign, *n* (%)	21 (35.59)
Supra FI ≥ 2, *n* (%)	27 (45.76)
Infra FI ≥ 2, *n* (%)	21 (35.59)
Subscap FI ≥ 2, *n* (%)	20 (33.9)
ASES baseline	54.91 ± 20.85
SANE baseline	31.13 ± 25.39
WORCnorm baseline	46.05 ± 21.61
VAS pain baseline	50.13 ± 26.39

Except as noted, values are expressed as mean ± SD. BMI: Body mass index; CTI: Cuff tear index; FI: Fatty infiltration; ASES: American Shoulder and Elbow Surgeons score; SANE: Single Assessment Numerical Evaluation; WORC norm: Normalized Western Ontario Rotator Cuff index; VAS: Visual analog scale.

Table 2 Change in outcome scores

	Baseline	Final follow-up	Change
WORCnorm	46.05 ± 21.61	63.58 ± 25.6	17.53 ± 6.87
ASES	54.91 ± 20.85	70.1 ± 25.03	15.19 ± 6.77
SANE	31.13 ± 25.39	59.4 ± 29.45	28.27 ± 7.41
VAS pain	50.13 ± 26.39	29.17 ± 26.68	-20.96 ± 7.28

Values are expressed as mean ± SD; WORCnorm: Normalized Western Ontario Rotator Cuff index; ASES: American Shoulder and Elbow Surgeons score; SANE: Single Assessment Numerical Evaluation; VAS: Visual Analog Scale.

study, we demonstrated that clinical outcome measures in a selected population of patients were significantly improved at 1 year. These results were durable at 2 years, with no statistically significant change between the 1 and 2-year follow-up. The average improvements in WORC, ASES, SANE and Visual Analog Scale pain scores all surpassed their published minimal clinically important differences (MCID) at final follow-up[25-27].

These results are consistent with previously published literature regarding non-surgical management of rotator cuff tears. Patients treated non-operatively in the MOON shoulder cohort were noted to have improvements of 22.5, 29.2 and 23.7 points in the WORC, ASES and SANE scores respectively, at 12-wk follow-up[10]. These are comparable to our cohort's improvements of 17.5, 15.2 and 28.3 points on these same scales respectively.

Based on our multivariable regression analyses, female gender, smoking and significant subscapularis fatty infiltration were found to be predictors of worse clinical outcomes at 1-year follow-up in our primary outcome measure, the normalized WORC score. These variables were not only statistically significant, but also clinically significant with magnitude of change with β values ranging between 15 and 30 points (WORC MCID = 11.7). At 2-year follow-up only female gender remained a significant

Table 3 Multivariable regression elimination analysis and for change in Western Ontario Rotator Cuff index score at 1 year and 2 year

	β	*P* value	95%CI
1 yr			
Female gender	-19.88	0.003	-32.82 to -6.95
Smoking	-28.98	0.014	-51.9 to -6.05
Subscap FI ≥ 2	-15.35	0.024	-28.62 to -2.07
2 yr			
Female gender	-19.09	0.015	-34.26 to -3.92

WORC: Western Ontario Rotator Cuff index; FI: Fatty infiltration; CI: Confidence interval.

Table 4 Multivariable regression elimination analysis for change in Western Ontario Rotator Cuff index score at 1 year and 2 year

	β	*P* value	95%CI
1 yr			
Duration > 1 yr	-14.63	0.052	-29.4 to 0.13
2 yr			
Age	-0.82	0.08	-1.75 to 0.10
Traumatic	19.06	0.017	3.65 to 34.48

WORC: Western Ontario Rotator Cuff index; CI: Confidence interval.

Table 5 Change in Western Ontario Rotator Cuff index score at 2-year follow-up

	Mean	SD	95%CI
Traumatic	26.82	27.3	16.39 to 37.25
Atraumatic	9.45	19.06	-0.49 to 19.38
Duration < 1 yr	24.61	24.72	16.04 to 33.18
Duration > 1 yr	5.71	24.84	-11.01 to 22.44

WORC: Western Ontario Rotator Cuff index; CI: Confidence interval; SD: Standard deviation

predictor of WORC scores, suggesting smoking status and subscapularis fatty infiltration may not be as clinically important for determining long-term prognosis.

Female gender has been shown in several other studies to negatively affect pain and clinical outcomes scores after rotator cuff repair surgery, however to our knowledge the same has not been shown in non-surgical cohorts[28-30]. This result may be further explained by the lower baseline WORC scores in females *vs* males in our cohort (35.5 *vs* 52.7), as the subsequent regression analyses evaluating change in WORC scores did not find female gender to be a predictor of less improvement throughout the study.

Smoking has also been shown in several studies to be a risk factor for worse clinical outcomes and decreased healing rates after rotator cuff repair[31-33]. In contrast, a study by Dunn *et al*[12] found that non-smokers were actually more likely to fail non-operative management of rotator cuff tears, however treatment success was defined as avoidance of surgical intervention rather than patient reported outcome measures. There may have been some selection bias introduced into this study outcome as well, as surgeons may have been more willing to offer surgery to non-smokers.

Although patients with isolated full thickness subscapularis tears were excluded from this study, over 1/3 of the patients in our cohort (20/59) did exhibit grade 2 or higher fatty infiltration in the subscapularis, indicating an anterosuperior variant rotator cuff tear. These tears have been associated with worse clinical outcomes in surgical cohorts in previous studies, especially when associated with higher grades of

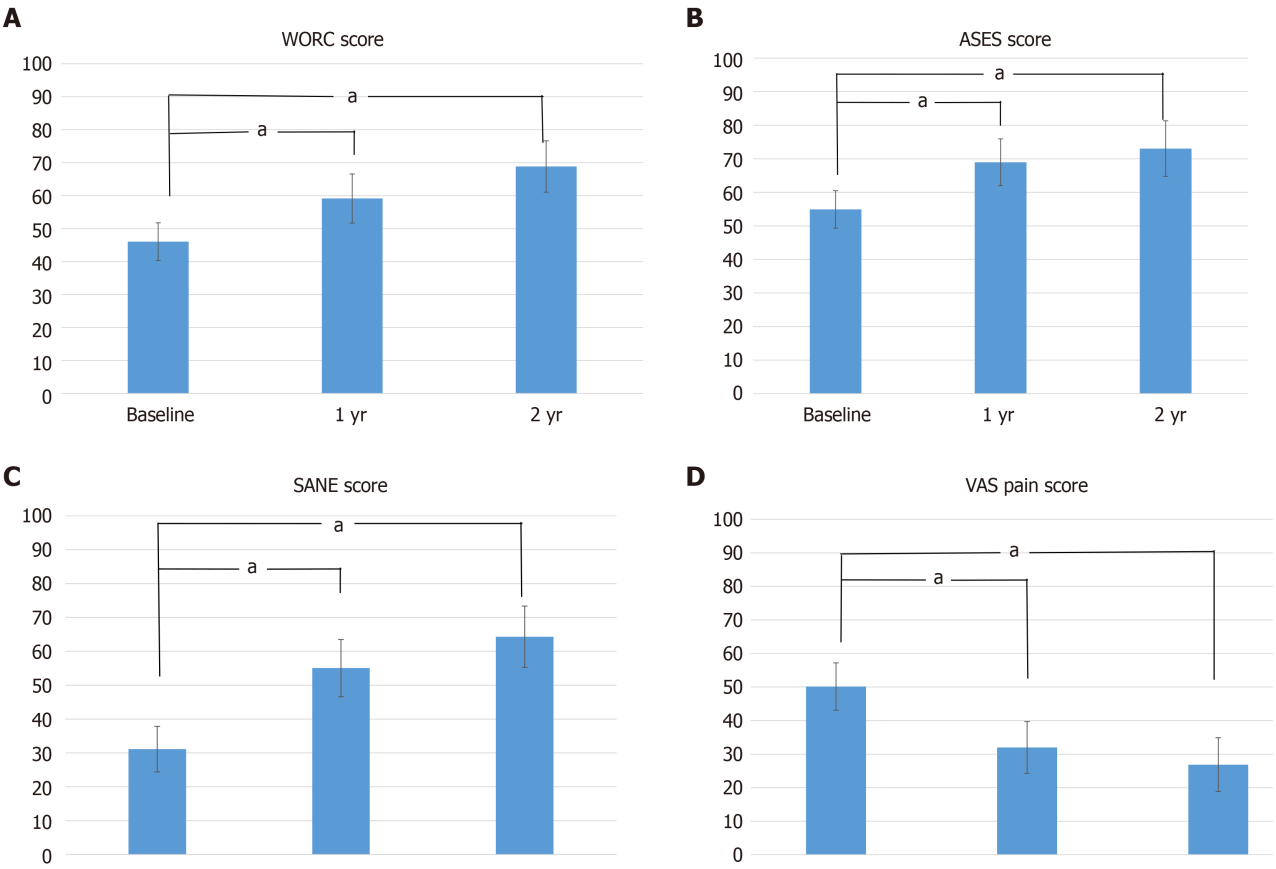


Figure 1 Patient-reported outcome measures. A: Western Ontario Rotator Cuff index; B: American Shoulder and Elbow Surgeons score; C: Single Assessment Numerical Evaluation; D: Visual Analog Scale. Indicates statistical significance ($^{a}P < 0.05$). WORC: Western Ontario Rotator Cuff index; ASES: American Shoulder and Elbow Surgeons score; SANE: Single Assessment Numerical Evaluation; VAS: Visual Analog Scale.

subscapularis fatty infiltration[34,35]. The results of our study mirror these results, with increased grades of subscapularis fatty infiltration portending worse WORC scores at 1-year follow-up.

In addition to the aforementioned factors that were predictive of final WORC scores in our study, we also analyzed the factors that impacted the amount of improvement patients achieved during the study period. We feel that both of these outcomes are worth examining, as they answer different clinical questions. Some patients may be more interested in the degree to which they will improve with a specific intervention rather than the final outcome they will achieve, and vice versa.

With this idea in mind, we performed additional regression analyses using the change in WORC score from baseline at 1 and 2-year follow-up as the clinical outcome measure. We found that patients presenting with symptom duration greater than 1 year achieved significantly less improvement at 1-year follow-up, and those with a traumatic onset of pain achieved significantly greater improvement at 2-year follow-up. Specifically, those with a traumatic onset of shoulder pain improved over 17 points more at 2-year follow-up than those with an atraumatic onset of pain, and those with symptoms less than 1 year at the onset of the study improved nearly 19-points more than those with symptoms greater than 1 year. Considering the MCID for normalized WORC scores has been published at 11.7 points, these variables predicted a fairly impactful magnitude of change.

The considerable effect of tear chronicity on improvement with non-surgical management may be explained by the idea that patients with long-standing symptoms have already gained some positive effects from some form of self-directed rehab, or simply by performing their day-to-day activities. These patients with chronic tears may have also developed some irreversible changes within their rotator cuff musculature, or within the glenohumeral joint itself due to altered mechanics. It is possible that these secondary changes may predispose them to worse outcomes with non-surgical management.

The explanation of the predictive impact of traumatic tears on the magnitude of

improvement in this study is less clear. It may be theorized that patients with degenerative rotator cuff tears have a more diffuse underlying problem within the remainder of their intact cuff tendons, *vs* those who suffered acute traumatic tears. It may also be possible that there is an inherent difference in the population of patients who suffer a traumatic *vs* atraumatic tear, which may impact their ability to successfully rehab their ailing shoulders. Furthermore, there may be some overlap between tear mechanism and symptom duration at presentation. Specifically, those patients who sustain traumatic tears may be more likely to present for care acutely than those with an insidious onset of symptoms. An additional consideration is that while patients self-reported a traumatic onset of pain, many of these patients could have had pre-existing rotator cuff tears prior to these traumatic events. Their initial magnitude of symptom improvement may be related to resolution of pain related to temporary contusions or sprains related to these traumatic events. No pre-injury imaging studies exist in these patients to determine whether they truly suffered a traumatic rotator cuff tear, or simply trauma in the setting of an existing tear. These concepts warrant further investigation.

Several factors that have been identified as important predictors of outcomes in surgically managed rotator cuff tears, such as tear size, tangent sign, fatty infiltration in the posterosuperior cuff muscles, and diabetes, did not have an apparent impact on the outcomes of our non-surgical cohort[24,36,37]. Many of these factors may be related to tissue healing capacity, which presumably would be less critical in those patients being treated non-surgically. Other studies evaluating outcomes with non-operative management have also found these patient and tear related factors to be unrelated to clinical outcomes[12,13].

Our study was not without limitations. Although the data was collected prospectively, this study was retrospective in nature. Also, treatment allocation into this non-surgical cohort was not randomized. Patients had the ability to choose between surgical and non-surgical management, which could introduce some selection bias into the study. Outcomes of this cohort may not be entirely generalizable to all patients presenting with full thickness rotator cuff tears. The cohort included in this study was also smaller than other similar studies which included multiple centers, such as the MOON group studies[10,12]. Also, although many variables were included in the regression analyses as potential predictors of patient outcomes, other potentially significant factors may have been neglected, such as workers compensation status, tear retraction, or concomitant biceps tendon pathology. Also, standardized physical exam findings were not available for review, and could have impacted patient outcomes. Although fatty infiltration of the various rotator cuff muscles was used as a surrogate of tear location (*i.e.*, anterosuperior *vs* posterosuperior), the specific location and tendons involved in each rotator cuff tear were not specifically categorized, which may have affected the interpretation of these tear subtypes. Other limitations include the lack if information regarding patient compliance with physical therapy and the lack of any follow up imaging studies to assess progression of tear size or fatty infiltration. These morphologic characteristics may be important when considering the long-term outcomes in these patients.

CONCLUSION

This study demonstrated that non-operative management of full thickness rotator cuff tears results in clinically meaningful and statistically significant improvements in patient reported outcome measures at 2-year follow-up. Female gender, smoking and advanced subscapularis fatty infiltration were predictive of lower WORC scores at 1-year follow-up; only female gender was predictive of lower WORC scores at 2-year follow-up. Patients with symptom duration greater than 1 year at presentation were found to have less improvement in WORC scores at 1-year follow-up, and those with traumatic tears demonstrated significantly greater improvements at 2-year follow-up. These outcome measures and patient related factors can be used to counsel patients with rotator cuff tears who are contemplating their treatment options.

ARTICLE HIGHLIGHTS

Research background

Rotator cuff tears are extremely prevalent in the general population, and many

patients with rotator cuff tears can be treated successfully without surgical intervention. Little data exists in the literature regarding patient and pathology related factors which predict the outcomes after nonsurgical management.

Research motivation

By evaluating the patient reported outcomes in a cohort of patients who underwent nonsurgical management for full-thickness rotator cuff tears, we hope to uncover important factors which may refine treatment indications for this subset of patients.

Research objectives

The objectives of this study were to evaluate the outcomes of nonsurgical management in patient with full thickness rotator cuff tears, and to identify patient and tear related characteristics which may predict outcomes. These findings could have a significant impact on the treatment of patients with rotator cuff tears in the future.

Research methods

Patients in our institutional registry who underwent nonsurgical management for full thickness rotator cuff tears were identified. Pre-treatment magnetic resonance imaging scans were evaluated for tear size and related muscle atrophy and fatty infiltration. Patient reported outcomes were evaluated at 1 and 2 years after treatment began and regression analyses were performed in order to identify any predictors of patient reported outcomes in this cohort.

Research results

Patient reported outcome measures improved significantly at 1 and 2 year follow up after nonsurgical management. Patients who presented with chronic symptoms showed less improvement in patient reported outcome scores, and those with traumatic tears were noted to make greater improvements over the course of the study.

Research conclusions

Patients with full thickness rotator cuff tears can achieve significant clinical improvement with nonsurgical management. Several factors may affect the amount of improvement they achieve, including the duration of their symptoms at presentation and the mechanism of their pain at the onset of symptoms. Additional factors likely exist that may impact patient outcomes in the setting of rotator cuff pathology.

Research perspectives

Future studies should consider additional factors that may be relevant in predicting outcomes in patients with rotator cuff tears including pertinent physical exam findings and concomitant shoulder pathology such as biceps tendon involvement. Prospective comparative studies of surgical and nonsurgical management will also help clarify the ideal surgical and non-surgical indications in this cohort of patients.

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SYSTEMATIC REVIEWS

Hanging up the surgical cap: Assessing the competence of aging surgeons

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Abstract

BACKGROUND

As the average age of surgeons continues to rise, determining when a surgeon should retire is an important public safety concern.

AIM

To investigate strategies used to determine competency in the industrial workplace that could be transferrable in the assessment of aging surgeons and to identify existing competency assessments of practicing surgeons.

METHODS

We searched websites describing non-medical professions within the United States where cognitive and physical competency are necessary for public safety. The mandatory age and certification process, including cognitive and physical requirements, were reported for each profession. Methods for determining surgical competency currently in use, and those existing in the literature, were also identified.

RESULTS

Four non-medical professions requiring mental and physical aptitude that involve public safety and have mandatory testing and/or retirement were identified: Airline pilots, air traffic controllers, firefighters, and United States State Judges. Nine late career practitioner policies designed to evaluate the ageing physician, including surgeons, were described. Six of these policies included subjective performance testing, 4 using peer assessment and 2 using dexterity testing. Six objective testing methods for evaluation of surgeon technical skill were identified in the literature. All were validated for surgical trainees. Only Objective Structured Assessment of Technical Skills (OSATS) was capable of distinguishing between surgeons of different skill level and showing a relationship between skill level and post-operative outcomes.

CONCLUSION

Specialty type: Orthopedics

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A surgeon should not be forced to hang up his/her surgical cap at a predetermined age, but should be able to practice for as long as his/her surgical skills are objectively maintained at the appropriate level of competency. The strategy of using skill-based simulations in evaluating non-medical professionals can be similarly used as part of the assessment of the ageing surgeons' surgical competency, showing who may require remediation or retirement.

Key Words: Aging surgeon; Competency; Surgical skill; Surgeon retirement

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Core Tip: A surgeon should not be forced to hang up his/her surgical cap at a predetermined age, but should be able to practice for as long as his/her surgical skills are objectively maintained at the appropriate level of competency. The strategy of using skill-based simulations in evaluating non-medical professionals can be similarly used as part of the assessment of the ageing surgeons' surgical competency, showing who may require remediation or retirement.

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INTRODUCTION

The aging surgeon has remained a contentious patient safety issue, as the average age of surgeons continues to rise. The number of physicians exceeding the age of 65 has more than quadrupled in almost 40 years, and surgeons are no exception[1]. Currently, 38% of surgeons working in Canada and over 46% of the surgeons in the United States are above the age of 55 and 16% of Canadian surgeons are over the age of 65[2-4]. When should an older surgeon stop operating? This becomes an important issue when we consider that the surgical profession is highly dependent on memory, sensory acuity, clinical decisiveness, technical skills and physical stamina; skills and abilities that may decrease with age.

Like all professionals, surgeons are fallible and vulnerable to the natural process of aging in which cognitive and physical skills experience a decline. The relationship between surgeon age and operative risk is controversial and uncertain, with some studies showing worse outcomes and some showing reasonable, or even better outcomes[3,5-7]. Even so, there are accounts of prominent older surgeons struggling with simple fine motor skills and clinical decision making; while various studies have demonstrated that senior surgeons have worse outcomes than their younger colleagues, suggesting surgeon age is an operative risk factor[2,8-12]. In the past two decades, more research has been dedicated to studying the aging surgeon and trying to find more effective ways to help surgeons experiencing age-related decline[8,13-15].

Although age has been identified as a possible occupation hazard in the surgical profession[9,10], other professions within the public sector have maintained a more proactive approach with their aging workforce. These strategies include enforcing strict certification and mandatory retirement. Currently, retaining certification in a surgical field is not as rigorous a process and retirement of surgeons remains largely at their discretion, relying on the assumption that they are fully capable of identifying their own cognitive and physical regression[1,2]. Both the American College of Surgeons (ACS) and American Medical Association (AMA) recognize the safety implications of the aging physician and surgeon; and have recommended practitioners aged 65 to 70 undergo voluntary physical examination and visual testing, in addition to peer-reviewed performance evaluation for re-credentialing[1,2]. Programs have been developed to assess the competence of aging surgeons and guide them depending on their incapacities or capacities[16,17]. However, no standardized approach to address age-related deterioration in surgeons exists at this time.

In order to address this issue, we performed a scoping review of well-established

and accepted policies of testing for competency of aging non-medical professionals from the industrial workplace. In particular we sought to identify strategies used to determine competency that could be transferrable in the assessment of aging surgeons. In addition, we reviewed the present testing of senior surgeons by hospitals to determine if the testing specifically addresses the skills, other than knowledge, required to maintain their competency to perform surgery.

MATERIALS AND METHODS

In order to identify mandatory testing of non-medical professions, where cognitive and physical competency are necessary for public safety, we conducted scoping review of the literature in PubMed, EMBASE, Google Scholar and Google using the terms mandatory retirement, mandatory retirement testing, retirement, mandatory retirement ages, surgeon retirement. The Google search engine was used to locate websites describing these professions within the United States. The mandatory age and certification process, including cognitive and physical requirements, were reported for each profession.

Google Scholar and the Google search engines were used to search for current policies, at health institutions in the United States, that are being used to evaluate older physicians and surgeons with regard to their ability to provide safe and high-quality care. The search queries used were: Late career practitioner policy, late career practitioner, assessing late career practitioners, aging physician policy, and aging surgeon policy. These policies were described based on their objectives, candidates, examination procedures, and modification of privileges.

Methods for determining surgical competency currently in use or practice as well as those existing in the literature were identified. Licensing bodies and subspecialist certification boards were described, along with their use of Continuing Medical Education (CME) and Maintenance of Certification (MOC) as a means of assessment. These agencies were selected as they are invested in ensuring the clinical competency of practicing physicians for the welfare of the general public[18,19]. The published literature was reviewed for objective assessments of surgical technical skills that were shown to be valid and reliable, as well as predictive of surgeon competency and improved patient outcomes for surgeons. Studies were identified through a search of databases, including PubMed, EMBASE, and Google Scholar. Search queries were developed from the following keywords: Technical skill, surgery, assessment, surgical training, surgical skill. Objective assessment tools identified in the database search were described if studies evaluating these tools were written in English, evaluated participants performing surgical tasks, and analyzed the validity and reliability of the objective assessment. Review articles found were used to identify studies assessing the reliability and validity of the objective assessment tools. Virtual reality simulators were excluded as assessment tools as they are often used primarily to determine the validity and reliability of the performance tools in mock surgical procedures, rather than for assessment of surgical skills. All search queries were completed by May 20, 2020.

RESULTS

Non-medical professionals

Four non-medical professions requiring mental and physical aptitude that involve public safety and have mandatory testing and/or retirement were identified: Airline pilots, air traffic controllers, firefighters, and United States State Judges (Table 1). The nature of their work is such that any condition which compromises their competency, such as knowledge; cognition; illness or physical stamina; can put many members of the public at risk. As a result, these professions have mandatory retirement at specific ages, as well as strict recertification and licensing programs. A mandatory retirement age, which is different for each occupation, is enforced in all 4 professions. An annual medical exam is required for 3 of these professions; a skills refresher course and assessment in two of the professions; and a physical ability test in one to maintain the professional's ability to continue working. These skill assessments, knowledge or physical, are designed to reflect the competency and proficiency standards of their profession. They entail simulated situations one may expect to encounter as part of their profession.

Table 1 Surgeon certification compared to non-medical professions

Occupation	Mandatory retirement age (yr)	Certification based on cognitive and/or physical requirements
Surgeon[33]	None	Complete residency and board examination. Continuous self-learning or medical education (CME) for credit with periodic examination for certification. May have case list peer-reviewed and be evaluated by in-hospital staff. No physical exam or performance-based skills currently defined
Airline pilot[34,35]	65	Every 24 mo, complete flight review with instructor: Ground/flight training. Must demonstrate proficiency, competency, and sound judgement within approved standards during training. Medical certificate every 12 mo or every 6 mo if age > 40 yr
Air traffic controller[36-38]	56, 61 with exception	Apply at < 31 yr. Medical exam. Pass biographical assessment, pass the ATSA, and pass training course at FAA academy. The ATSA is designed to measure the cognitive, visuospatial reasoning, and psychomotor abilities of candidates. Must submit to yearly physical exam, and job performance twice a year, with periodic drug screenings. Certificate valid until surrendered, suspended, or revoked
Firefighter[39,40]	57	Complete CPAT. Complete annual medical exam and physical testing, depending on department discretion. Physical testing consists of exercises related to firefighting such as step tests, and leg lifts
United States State Judge[41,42]	70-75	Obtained law degree and passed Bar examination. State court often requires mandatory retirement for state court judges

ATSA: Air traffic controller specialists skills assessment battery; CPAT: Candidate Physical Ability Test; CME: Continuing medical education; FAA: Federal Aviation Administration.

Late career practitioner policies

There are currently no mandatory retirement criteria for all surgeons in North America. We identified 9 late career practitioner policies designed to evaluate the ageing physician, including surgeons. One of the policies, the Aging Surgeon Program at Sinai Hospital, specifically targets the aging surgeons, but is identical to the Hospital's evaluation of medical doctors, and has no specific testing of surgical skills (Table 2). All nine of these policies vary according to their trigger for assessment, the assessments being utilized (medical exam and performance testing), and their influence on hospital privilege modification. Eight of the policies use age to identify physicians that require cognitive and physical testing, starting typically at the age of 70 years, with repeated testing required every 1 or 2 years. All 9 physician monitoring programs have a medical exam component, focusing on general health, cognition, vision, and hearing testing, although the evaluation process does vary from program to program. Performance testing is part of the evaluation in 6 of the health systems and is done by peer assessment in 4, and only done by dexterity testing in 2. In the peer review assessment, two policies address the technical and procedural competencies required by surgeons to safely and effectively perform surgery. The evaluation of these technical competencies is subjective in nature, where candidates are rated on scale from "significant concern" to "outstanding" clinical competence. Observed performance or behavior that influenced the peer assessment must be commented if labeled "significant concern" or "minor concern". The results of the testing could be used to modify the physician's privileges in 7 of the 9 health systems identified.

Competency assessments in the workplace

Licensing bodies and certification boards in the United States and Canada use CME and MOC as assessment methods to ensure continued clinical competency in the surgical workplace of board-certified surgeons (Table 3). However, these competency evaluations only address knowledge and do not take into account surgical skills, and to some degree judgment. State and provincial licensing bodies can initiate a competency evaluation by independent evaluator if a surgeon has been identified to the licensing body as performing below the accepted level of competency. Within the hospital setting, the surgeon-in-chief is primarily responsible to the community for the safety of the operating room and the competence of surgeons on the staff.

Several tools using surgical simulation or direct observation are currently being used on practicing surgeons to evaluate performance and technical skills needed for a surgical specialist (Table 3). Six of these tools reliably and accurately detect different level of technical skills among study participants, consisting of surgical trainees, fellows, and staff. All of these methods were validated for surgical trainees. Objective Structured Assessment of Technical Skills (OSATS) is the only method capable of distinguishing between surgeons of different skill level and showing a relationship

Table 2 Late career practitioner policies adopted at health institutions

Program	Objectives	Candidates	Medical exam	Performance testing	Modification of privileges
Stanford Health Care[16,17]	To ensure high quality care for patients and protect them harm and identify health concerns of practitioners	74.5 years old and every 2 yr thereafter	Comprehensive history and physical examination including vision, hearing, neurological, and cognitive testing	Peer assessment by hospital staff of technical and procedural competencies, relative to Stanford expectations	Yes, if non-compliant or unsafe practice patterns
Aging Surgeon Program at Sinai Hospital, Baltimore, MD[43]	Designed to protect patients from unsafe surgeons and guard surgeons from arbitrary or unreliable methods of assessing competence or cognitive capacity. The program can identify potentially treatable or reversible disorders that, if properly treated, could restore or improve functional capacity	No mandatory age. Requested from surgeons, hospitals or licensing bodies of all surgical sub-specialties	Evaluation of general health, vision, hearing, neurocognition, visual-spatial and fine motor capability	None	No
Hartford Health Care[44]	To ensure patient safety and high-quality medical care	70 years old and above, and annually thereafter	Annual physical exam, vision, neurological testing and neuropsychological screening	OPPE. FPPE if needed, to identify patterns that may negatively impact quality and safety of care	Yes, discussion with department Chief ± Credentials Committee if deemed unable to safely exercise privileges
YNHH[21,45]	To protect patients from harm and safeguard fair physician assessment	70 years old and above	Ophthalmologic exam and 16 test neuropsychologic screening battery	None	Yes, MSRC suggestions based on screening results
Legacy Health, OR[46]	To assess physicians to ensure patient safety and physician wellness	70 years old and above, and every 2 yr thereafter	Physical capacity by occupational therapy and neuropsychological testing	Peer review assessment	Yes, determined by Credentials Committee, if health problems interfere with safe practice
Driscoll's Children's Hospital, Corpus Christi, TX[17]	To assure that patient safety and quality are adequately supported by carefully assessing the capabilities, competencies and health status of each practitioner	70 years old and above	Comprehensive examination addressing physical and mental capacity by a physician	Peer review assessment may be required. Must meet technical and procedural competencies	Yes, determined by Credentials committee, if practice unsafe or incompetent
University of Virginia Health System[17]	To assess each physician's capacity to perform requested privileges	First assessment at age 70. Annual assessment after 75 years of age	Comprehensive examination addressing physical and mental capacity under the Physician Wellness Program	None	Yes, as determined by Department Chair
UC San Diego LCHS[47,48]	To detect any physical or mental health problems that may affect a physician's ability to practice	70 years old and above. At request of hospital or medical group	History and physical exam. Cognitive and mental health screen	Dexterity tests for proceduralists/surgeons	No
Tahoe Forest Health System, CA[49]	To fairly and accurately evaluate physician performance and capabilities	70 years old and above. Required to partake in LCHS	See LCHS	See LCHS	Yes, after consultation with department Chair if adjustment is required

OPPE: Ongoing Professional Practice Evaluation; FPPE: Focused Professional Practice Evaluation; YNHH: Yale New Haven Hospital; MSRC: Medical Staff Review Committee; LCHS: Late Career Health Screening for Physicians and Healthcare Professionals.

between skill level and post-operative outcomes.

Surgical procedures and/or skills are evaluated by an expert, or non-medically trained reviewers with regards to Crowd-Sourced Assessment of Technical Skills (C-SATS), using a paper-based tool in six of the object assessments, blinded to the post-graduate year of the participant. The objective assessments were designed for common surgical procedures extending over multiple specialties, including laparoscopic cholecys-tomy, open reduction and internal fixation (hip, wrist, or ankle), arthroplasty, and robotic prostatectomy. Global Operative Assessment of Laparoscopic Skills (GOALS) and Global Evaluative Assessment of Robotic Skills (GEARS), however, target laparoscopic and robotic surgery only. The last tool, Direct Objective

Table 3 Existing methods for determining surgical competency

Method	Basic structure	Assessment	Procedure examples	Validated[1] for	
				Practicing surgeons	Surgical trainees
Licensing bodies assessments					
State Medical Boards[50-52]	Mandatory to practice. Required to demonstrate competency through CME. However, states individually may evaluate professional conduct when a physician fails to provide appropriate quality of care	Must regularly participate in CME activities and may require board certification. May have competency evaluation by independent evaluator or approved assessment program if signs of dyscompetence	-	Unclear	-
ABMS[18,19]	Voluntary certification to show knowledge of standards of practice. Rigorous process of evaluation every 10 yr with MOC	MOC consists of 4-part assessment: Licensure/professional standing, participation in CME programs, cognitive expertise through examination, and documentation of quality of care and/or audits or peer review	-	Unclear	-
Provincial Licensing Bodies in Canada[53-55]	Mandatory to practice. Required to demonstrate competency through CME. Provincial licencing bodies identify those with deficiencies in competence, requiring peer review	Must regularly participate in CME activities. If evidence of dyscompetence, rigorous individualized assessment of the surgeon's practice is performed, with emphasis on quality of care	-	Unclear	-
Fellows of the RCPSC[56,57]	Voluntary certification to show commitment to competent practice. Evaluation and successful completion of MOC program every 5 yr	Must participate in CPD activities. MOC based on 3 section framework: Group learning, self-learning, and assessment	-	Unclear	-
Non-licensing bodies assessments					
OSATS[58-61]	Multi-station and timed with bench and live model simulations or surgical procedures. Peer evaluated with rating scale	Checklist and global rating scale by expert examiner to evaluate technical skill. Does not assess decision making or concrete surgical aspects	Laparoscopic Gastric Bypass Saphenofemoral dissection. Meniscectomy transtibial or anteromedial femoral tunnel	Yes	Yes
C-SATS[26,31]	Video recorded surgical performance and evaluated with validated with rating scale	Crowds of anonymous and independent reviewers, including those nonmedically trained, evaluate surgical skill with validated performance tools such as OSATS	Urinary bladder closure. Robotic surgery skills	No	Yes
O-SCORE[27,62]	Surgical procedure peer evaluated with rating scale	Surgical experts rate performance with 9 item tool and scaling system to assess competence to perform procedure independently	Open reduction internal fixation of hip, wrist, or ankle. Arthroplasty (total hip or hemi). Knee arthroscopy	No	Yes
GOALS[63,64]	Laparoscopic procedure peer evaluated with rating scale	Surgical experts evaluate performance with 5-point rating scale of 5 items unique to laparoscopy	Laparoscopic cholecystectomy	No	Yes
GEARS[65,66]	Robotic procedures peer evaluated with rating scale	Surgical experts evaluate performance with 5-point rating scale of 6 items unique to robotic surgery	Inanimate simulators–continuous suturing. Prostatectomy	No	Yes
Direct Objective Metric Measures[67,68]	Skill/surgical procedure measured with concrete aspects	Measurement of stiffness and failure load for each repair construct, with comparison to expected rehabilitation loads	Tibial plafond fracture reduction. Distal radius fracture reduction	No	Yes

[1]To note: Methods to determine surgical competency are deemed valid for (1) Experienced surgeons; or (2) Residents/trainees if the assessment (continuing medical education, maintenance of certification or rated technical skill) correlated with experience level and/or with patient outcomes. Validity was shown for specific procedures within specific subspecialties. For example, experienced bariatric surgeons who had higher rated technical skill in laparoscopic gastric bypass surgery had patients with fewer post-op complications[46]. Generalized validity has yet to be shown in literature with regards to the technical skill assessments, although validity was typically demonstrated across several procedures. ABMS: American Board of Medical Specialties;

CME: Continuing medical education; MOC: Maintenance of certification; RCPSC: Royal College of Physicians and Surgeons of Canada; CPD: Continuing professional development; OSATS: Objective structured assessment of technical skill; C-SATS: Crowdsourced assessment of technical skills; O-SCORE: Ottawa Surgical Competency Operative Room Evaluation; GOALS: Global operative assessment of laparoscopic skills; GEAR: Global evaluative assessment of robotic skills.

Metric Measures, uses measurable metrics to determine skill level instead of technique. Direct Objective Metric Measures investigate the stiffness and failure load of the final surgical product, which are critical within the orthopaedic field.

DISCUSSION

For almost all of history, people worked until they died. Retirement is a recent phenomenon, starting during the Great Depression when governments, unions, and employers, desperate to make room in the workforce for young workers institutionalized retirement programs as we know them today, complete with social security and pension plans. Initially, the designated retirement age of 65 was longer than the life expectancy, but as life expectancy has increased, retirement age in certain professions has become more arbitrary. Surgeons may continue to work longer than other professionals because of their satisfaction and gratification in treating patients, because their work connects the surgeon to an identity or for financial reasons. Surgeon's retirement age remains a contentious issue and presently there is no mandatory retirement age for surgeons. Furthermore, we could not find any universal, well-established and accepted policies of testing for competency of aging surgeons.

Although a review of 65 studies of physicians' retirement planning found that most physicians retire between ages 60 and 69 years, some surgeons delay retirement because of financial insecurity, lack of other interests or fear of change in their personal lives and identity[20]. Despite the well-recognized decline of cognitive and physical skills with ageing, most surgeons only require verification of their CME to maintain their medical license to practice, in the absence of skill-based simulations that regulate non-medical professionals. Airline pilots, air traffic controllers, firefighters, and United States State Judges were found to have thorough medical examinations and skill assessments during their practice. Regardless of inherent ability, they are further subjected to mandatory retirement ages. Although the United States Age Discrimination and Employment Act of 1967 protects individuals at or above the age of 40 from mandatory retirement ages, employers have established a legitimate age-based criterion referred to as a bona fide occupational qualification (BFOQ), allowing them to justify an age-based BFOQ for certain professions.

Despite age being a variable process, the potential association within the surgical profession between increasing age and poorer operative outcomes has been reported in some studies[9-12]. The mandatory late career practitioner policies identified in this study begin to address the competency of the surgical workforce, through cognitive and physical testing. Performance testing consisted of peer-review assessment and varied across the different health institutions. In the absence of standardized technical skill assessments and continued legal challenges[21], age may not be the most reliable and objective performance indicator.

Surgeons, like other medical specialties, need to regularly engage in activities that keep them up to date with standards of care. However, the requirements to be certified or licensed are highly dependent on the standards developed by individual states, provinces or specialty boards. Furthermore, the validity of CME and MOC, defined as the ability to distinguish expertise level and effects on patient outcomes, was noted as unclear based on available literature. CME, such as didactic educational meetings, were shown to have only a small effect on clinical practice and patient outcomes[22,23]. Completion of MOC is not associated with differences in complication rates in specific surgical subspecialties[24]. In fact, surveyed surgeons were in favor of improving MOC with additional testing such as cognitive assessments or review of cases for older surgeons, in place of a mandatory retirement age[25]. Meeting CME or MOC requirements alone does not guarantee a successful surgical practice, despite being used to certify surgeon competency.

Similar to the testing of pilots and air traffic controllers, there are surgical simulators designed to provide an objective assessment of surgical technical skills. Although these simulators have been used primarily for surgical residents to gauge their level of training, surgical simulators can equally be used to evaluate practicing surgeons by

their peers or recognized experts[26,27]. These simulators may then be used to assess surgical competency among, not only older surgeons, but all surgeons as part of their medical education, showing who may require remediation or retirement. However, one of the most significant limitations in the use of simulation for assessing competence for aging surgeons–namely the ability to evaluate the most important skill that dictates surgical expertise and competence: Intra-operative cognitive skills. To date, very few if any surgical simulations have demonstrated the ability to assess advanced mental processes such as decision-making and judgment; and pattern recognition. These cognitive behaviors (or "thinking skills") are some of the most important aptitudes that dictate performance in the operating room and better methodologies are required to measure them[28]. In addition, the use of simulators would need to be specialty specific and the specialty societies have not yet built these programs.

While this study demonstrated that current competency assessment methods for older surgeons require improvement, the study was limited by various factors. This study is a scoping review, thereby providing an overview of an important topic, without describing every possible assessment tool. Information regarding non-medical specialties was constrained to predefined professions, weakening the comparative analysis between these professions and surgeons. Other non-medical professions were not investigated, although the ones presented are commonly known. The number of late practitioner policies identified was also small, as they needed to be accessible online. It is clear that other policies exist, some of which have been referenced to online, such as Sharp Rees-Stealy Medical Group, Intermountain Healthcare in Utah, Scripps Health network in San Diego, Arkansas Children's Hospital, Cooper University Hospital, University of Pittsburgh Medical Center, and Virtua Health[29,30]. However, their policies are not explicitly described so that it is unclear whether or not these policies address older surgeon competence in a similar manner to the policies discussed in this study, or in a manner separate from cognitive testing or peer-assessment. As well, there are likely other late practitioner policies that exist but are not present online. In addition, the non-licensing body surgical simulators have been studied across different procedures within different specialties, but the generalizability remains in question. For example, Crowd Sourced Assessment of Technical skills (C-SAT) was shown to be valid for robotic skills amongst urology residents but whether it is valid in orthopaedics or other specialties is not known[26,31]. And given that these surgical simulators have largely been validated for distinguishing skill among surgical residents, more studies need to evaluate the validity and reliability of these simulators for staff surgeons before even considering implementation. In addition, even when there is a valid technique for objective assessment of competence in the execution of particular operations by surgeons, such as the assessment of intraoperative videos, there has been low utilization due to its labor-intensive nature involving human factors (cognitive engineering) expertise[32].

CONCLUSION

Surgery is a profession that requires good surgical judgment, as well as manual dexterity and physical skills for performing an operation. Age alone is not an indication of surgical competence, so testing of these attributes is necessary to ensure that the ageing surgeon remains competent. This requires regular periodic review of the surgeon's outcomes and skills to ensure that the ageing surgeon has the competency to meet the standards of the profession. The strategy of using skill-based simulations in evaluating non-medical professionals can be similarly used as part of the assessment of the aging surgeons' surgical competency. While more studies investigating the validity of these simulators is needed, future implementation of these simulators may ensure all aging surgeons maintain an appropriate professional standard for patient safety. A surgeon should not be forced to hang up his/her surgical cap at a predetermined age, but should be able to practice for as long as his/her surgical skills are objectively maintained at the appropriate level of competency. For those aging surgeons with a diminishing skillset, there other potential options to integrate these surgeons into important aspects of surgical care such as assisting younger surgeons for more complex cases, teaching and training the next generation of surgeons, coaching surgeons in practice, being involved in quality-improvement and leadership roles.

ARTICLE HIGHLIGHTS

Research background

The aging surgeon has remained a contentious patient safety issue, as the average age of surgeons continues to rise.

Research motivation

When should an older surgeon stop operating? This becomes an important issue when we consider that the surgical profession is highly dependent on memory, sensory acuity, clinical decisiveness, technical skills and physical stamina; skills and abilities that may decrease with age.

Research objectives

The aim of this scoping review study was to investigate strategies used to determine competency in the industrial workplace that could be transferrable in the assessment of aging surgeons and to identify existing competency.

Research methods

Scoping review.

Research results

Surgeon's retirement age remains a contentious issue and presently there is no mandatory retirement age for surgeons. Furthermore, we could not find any universal, well-established and accepted policies of testing for competency of aging surgeons.

Research conclusions

A surgeon should not be forced to hang up his/her surgical cap at a predetermined age, but should be able to practice for as long as his/her surgical skills are objectively maintained at the appropriate level of competency.

Research perspectives

More studies need to evaluate the validity and reliability of these simulators for staff surgeons before even considering implementation.

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CASE REPORT

Salmonella infection after anterior cruciate ligament reconstruction: A case report

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Abstract

BACKGROUND

Infections after anterior cruciate ligament reconstruction (ACLR) are rare. No cases of *Salmonella* infection have been described to our knowledge.

CASE SUMMARY

We describe a rare case of *Salmonella* infection in a 23-year-old patient following an ACLR. The patient presented with subacute septic arthritis, 26 d after a hamstring autograft ACLR. The pathogen, *Salmonella enterica typhimurium* was isolated by bacteriological sampling of the first arthroscopic lavage. Two arthroscopic lavages were required, with intravenous antibiotic therapy for two weeks with cefotaxime and ciprofloxacin, followed by oral antibiotics with amoxicillin and ciprofloxacin for a total duration of three months. This approach treated the infection but two years after the septic arthritis, faced with ongoing knee instability due to graft damage, a revision ACLR with a bone-tendon-bone graft was performed. At the last follow-up, full range of knee motion had been achieved and sports activities resumed.

CONCLUSION

Infection after ACLR is rare and requires an early diagnosis and management in order to treat the infection and prevent arthritis-related joint cartilage destruction and damage to the graft.

Checklist (2016), and the manuscript was prepared and revised according to the CARE Checklist (2016)

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Core Tip: Infection after anterior cruciate ligament reconstruction (ACLR) is uncommon, with staphylococci found in more than 90% of cases. We present herein, an exceptional case of *Salmonella* infection after ACLR. This case highlights the importance of early diagnosis and management: arthroscopic washing for acute infections or arthrotomy for late infections and appropriate antibiotic therapy. The purpose of the surgical treatment is to prevent arthritis-related joint cartilage destruction and to protect the graft.

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INTRODUCTION

Septic arthritis after anterior cruciate ligament (ACL) reconstruction (ACLR) is a rare but severe complication, with an incidence between 0.3% and 1.7%[1-3]. The main responsible pathogens are *Staphylococci* (coagulase-negative and *S. aureus*) and *Streptococci*[2,4-6].

Salmonella spp are Gram-negative bacilli, belonging to the enterobacteriaceae family and responsible for digestive infections. Contamination is mainly caused by the consumption of raw or undercooked food (meat, eggs, and dairy products), or food contaminated by the excreta of carrier animals (more rarely by direct animal contact). After a short incubation period, these pathogens are responsible for an inflammatory intestinal syndrome with mucoid bloody diarrhea. Extra-intestinal complications, including osteo-articular complications, are rare (< 1%) and associated with haematogenous spread[7]. Typhoid fever is caused by *Salmonella spp* and osteo-articular complications occur in less than 1% of cases, arising in one of three possible ways: haematogenous spread, contiguous source, or as a result of vascular insufficiency[8]. The risk factors include sickle cell anaemia, diabetes, systemic lupus erythematosus, lymphoma, liver diseases, previous surgery or trauma, those at extremes of age, and steroid use[9].

We report herein a rare case of *Salmonella enterica typhimurium* following ACLR. To our knowledge, this is the first case of septic knee arthritis after ACLR due to *Salmonella spp*.

CASE PRESENTATION

Chief complaints

Twenty-six days after an ACLR, a 23-year-old man showed a deterioration in his general state (asthenia, fever and chills) and local signs of an early knee septic arthritis: pain, heat, redness, and edema.

History of present illness

The patient reported an episode of abdominal pain associated with mucoid bloody diarrhea 10 d before the onset of the arthritis symptoms, which quickly resolved within 48 h. Further questioning on risk factors for *Salmonella spp* revealed the patient had eaten an egg-based picnic 24 h before these symptoms appeared.

History of past illness

This patient was suffering from chronic instability in his right knee, following a soccer injury. An isolated ACL injury was reported on magnetic resonance imaging (MRI).

Three months after the injury, an ACLR was performed, using a hamstring autograft (semi-tendinosus and gracilis). The procedure was performed under general anesthesia with a tourniquet at the proximal thigh for duration of 40 min. An outside-in drilling technique was used for the femoral tunnel. Femoral and tibial fixation was with interference screws.

The patient followed a standardized post-operative rehabilitation protocol aimed at controlled restoration of range of motion, muscle strength and proprioception. He was discharged the same day full weight bearing assisted with crutches. At 15 d after surgery, a routine consultation was performed to verify the absence of pain, hematoma, wound inflammation and/or serous or purulent discharge.

Personal and family history

The patient had a free previous medical history.

Physical examination

A collection in the external femoral approach site was confirmed.

Laboratory examinations

A biological inflammatory syndrome was found with an initially raised C-reactive protein (CRP) of 51 mg/L increasing to 130 mg/L over the first 24 h (Figure 1), alongside a white blood cell count increase from 11000/mm^3 to 13300/mm^3 during the same period.

The joint fluid aspiration performed in the emergency room showed neutrophils at direct examination and was followed by administration of intravenous antibiotic therapy – oxacillin 2 g every 8 h and gentamycin – 270 mg/d.

Imaging examinations

A knee ultrasound examination reported an intra-articular effusion. X-rays showed no fracture.

FINAL DIAGNOSIS

Salmonella enterica typhimurium arthritis following an ACLR.

TREATMENT

An urgent arthroscopic joint lavage was performed the same day. The joint fluid was serous, not purulent. with few false membranes but without a clear inflammation of the synovial tissue. A surgical approach centered on the scar for the femoral tunnel, was also performed and revealed a separate collection apparently extra-articular. Multiple samples were taken for bacteriological analysis. Intravenous antibiotic therapy with oxacillin at a dose of 2 g every 8 h and gentamycin at a dose of 270 mg per day was continued pending bacteriological results.

The stool and blood cultures returned negative. Samples of joint fluid aspiration and arthroscopic lavage both grew *Salmonella typhimurium* on aerobic cultures.

This result was also confirmed by polymerase chain reaction (PCR) DNA 16S. Antibiotic therapy was modified to cefotaxime at a dose of 3 g every 6 h and ciprofloxacin at a dose of 400 mg every 8 h.

The clinical and biological evolution was not favorable, on the 6th post-operative day, a knee effusion and a collection in the external femoral approach was seen, as well as a biological inflammatory syndrome, with a CRP increase up to 450 mg/L (Figure 1). Therefore, a second arthroscopic lavage was performed. The external femoral approach was again opened and now revealed a purulent collection, communicating with the joint. Arthroscopy showed purulent joint effusion with false membranes and an inflammatory synovial tissue (Figure 2).

Multiple bacteriological samples were taken, followed by lavage. The samples returned sterile and 16S DNA PCR was negative.

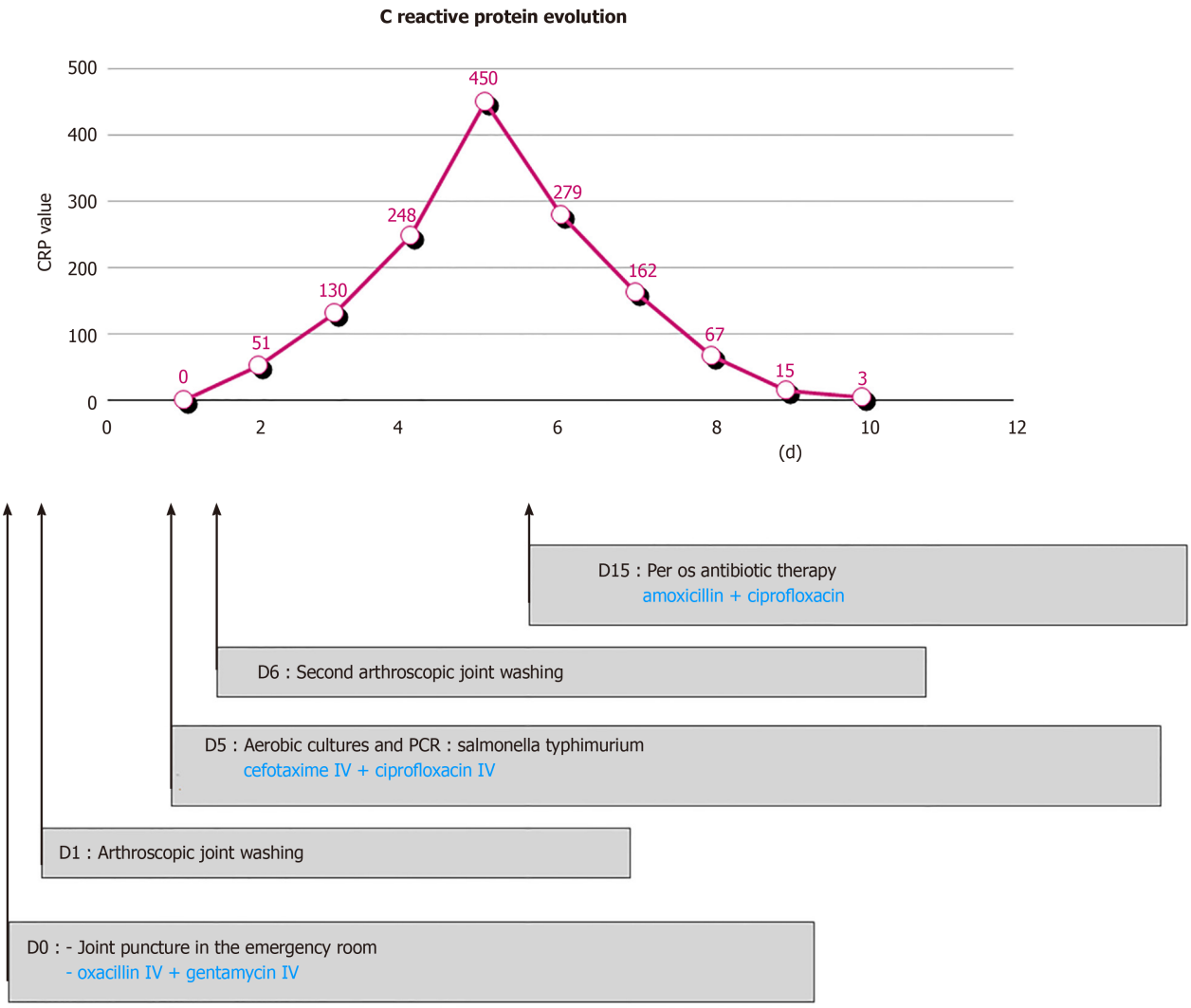


Figure 1 C reactive protein evolution and therapeutic management. CRP: C-reactive protein; PCR: Polymerase chain reaction; IV: Intra venous.

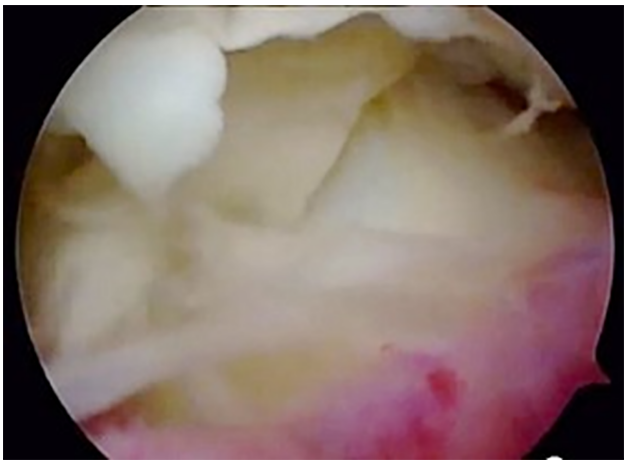


Figure 2 Second arthroscopy, showing false membranes and synovitis.

OUTCOME AND FOLLOW-UP

Over the subsequent days, a decrease in local inflammation as well as a decrease in biological inflammatory syndrome was seen, with a normalized CRP (< 5 mg/L) at 1 mo (Figure 1).

A total of 3 wk of hospitalisation was required, with oral antibiotic therapy started after 15 d of intravenous treatment with amoxicillin at a dose of 1 g, 3 times daily and ciprofloxacin at a dose of 500 mg, twice daily for a total of 3 mo of antibiotic therapy.

Two years after the septic episode, the infection was considered cured but a persistent knee instability (with positive Lachmann-Trillat and jerk-tests) persisted. Furthermore, MRI showed a partial rupture of the graft. In order to meet the patient's desire to resume a pivotal sports activity, a revision ACLR was scheduled, using a bone-tendon-bone graft reconstruction combined with a Lemaire procedure. Intra-operatively, a distended and non-functional ACL graft was found. Prophylactic antibiotic therapy with amoxicillin at a dose of 150 mg/kg/d in 4 injections was initiated pending the microbiology results of tissue samples. Antibiotic therapy was stopped on day 5, due to the sterility of the bacteriological samples.

Final follow-up at three years after the surgical revision revealed a full range of stable knee motion, with function similar to the contralateral knee, allowing pivoting sports activities (soccer).

DISCUSSION

We report an uncommon case of *Salmonella enterica typhimurium* arthritis in a young patient, following an ACLR.

Infections after ACLR are rare, and no cases of *Salmonella* infection have been described to our knowledge. The main responsible pathogens are *Staphylococci* (coagulase-negative and *S. aureus*) and *Streptococci*[2,4-6]. This case occurred early after ACLR, however given the history, haematogenous spread from the primary bowel infection is presumed.

Salmonella non typhi have been rarely reported as agents of arthritis. *Salmonella* is a Gram-negative *Bacillus Enterobacteriaceae* responsible mainly for digestive infections. The prevalence of joint infections with *Salmonella* is only 1%[7]. It mainly affects the native hip in children[10]. Some cases of *Salmonella* arthritis after total hip or knee arthroplasty have been described in the literature (Table 1).

Risk factors for bacterial blood-borne knee infections (old age, diabetes, polyarthritis and other immunodeficiency diseases as well as intravenous drug abuse) were not found in this patient, nor were other described risk factors such as concomitant meniscus resection or a history of surgery on the same knee[11].

For ACLR, hamstrings autograft has been reported to be a risk factor for surgical site infection compared to bone-tendon-bone graft reconstruction[5].

Septic arthritis is an orthopedic emergency. The gold standard of treatment is joint debridement and antibiotic therapy according to the culture results. Smith *et al* reported that enzymatic destruction begins by the eighth hour after the inoculation. By the 48th hour, 40% of the glycosaminoglycan is lost, and collagen breakdown occurs in a period of few days in septic arthritis[12]. Several studies have shown that the duration between the beginning of symptoms and surgical intervention is the most important prognostic factor for septic arthritis[13,14]. Early diagnosis and management are essential to minimize the risk of graft failure and osteo-articular lesions, which cause stiffness and chronic pain. It is recommended to hospitalise the patient and give the appropriate treatment within 24 h[1,15-17]. The reference treatment is as follows (Figure 3) : first surgical treatment by knee debridement and lavage with attempts to protect the graft in most cases and then medical treatment by intravenous antibiotic therapy with penicillin (cloxacillin), initially targets the most frequently encountered pathogens (*Staphylococcus aureus*, *enterobacteria* and *streptococci*).

Blind joint fluid aspiration is not described in the optimal management of infection after ACLR and antibiotic therapy initiated before the first arthroscopic lavage in our patient could have negated the results of bacteriological samples, resulting in a delay in optimal management and therefore decreasing the chances of saving the graft[16]. For acute (less than 2 wk postoperatively) and subacute (between 2 and 8 wk) infections, arthroscopic debridement and lavage can be proposed, while for chronic infections (after 8 wk postoperatively) an open lavage *via* an arthrotomy has been recommended. Additional lavage may be necessary if the initial treatment fails. The modalities of management, in this case, are ambiguous: some would perform a second lavage

Table 1 Literature review on *Salmonella* infection after total hip or knee arthroplasty

Ref.	Prosthetic joint	Prosthesis age at time of infection	Symptoms	Microbiology	Surgical treatment	Antibiotic therapy	Failed treatment
Chong and Sporer[20], 2005	THA	8 mo	Purulent flow	*Salmonella choleraesuis*	Two-stage revision	IV vancomycin oral ciprofloxacin 6 wk	No
Gupta *et al*[21], 2014	TKA	3 yr	Deep joint pain, discomfort for 4 mo	*Salmonella enterica serovar Enteritidis*	Removal, debridement and arthrodesis after aspiration failed and oral TMP-SMX 12 wk	Oral TMP-SMX 8 wk	No
Gupta *et al*[21], 2014	THA	7 yr	Pain	*Salmonella enterica serovar Enteritidis*	Removal, debridement and arthrodesis after debridement failed and oral amoxicillin 10 mo	IV ampicillin 4 wk	No
Gupta *et al*[21], 2014	THA	5 mo	Fever, pain, joint swelling	*Salmonella enterica serovar Choleraesuis*	Two-stage revision after aspiration failed and oral ampicillin 8 wk	Oral ampicillin4 wk	No
Gupta *et al*[21], 2014	THA	4 yr	Fever, pain, swelling	*Salmonella enterica serovar Enteritidis*	Two-stage revision	Oral ciprofloxacin8 wk	No
Gupta *et al*[21], 2014	THA	5 mo	Fever, pain	*Salmonella enterica serovar Enteritidis*	Two-stage revision	IV ceftriaxone 6 wk	No
Gupta *et al*[21], 2014	THA	9 yr	Pain	*Salmonella bongori*	Two-stage revision after aspiration failed and oral ciprofloxacin 8 wk	IV ceftriaxone 6 wk	No
Toth *et al*[10], 2010	THA	2 yr	Pain	*Salmonella enteridis*	Two-stage revision	Oral ciprofloxacin 6 wk	No
Toth *et al*[10], 2010	THA	7 yr	ARDS caused by sepsis and increased uptake aroud the THA (autolog leukocyte scintigraphy)	*Salmonella cholerae-suis*	Two-stage revision	Oral ciprofloxacin 6 wk	No
Sebastian *et al*[22], 2017	TKA	4 yr	Pain, swelling, scare discharge, limitation of range of motion	*Salmonella typhimurium*	Two-stage revision	Oral ciprofloxacin 6 wk	No
Carlile *et al*[23], 2010	TKA	5 yr	Pain, swelling, fluctuant swelling, night sweats and shivering	*Salmonella enterica choleraesuis*	Two-stage revision	IV cefotaxim 7 d. Oral ciprofloxacin 3 wk	No
Jeroense *et al*[24], 2014	THA	5 d	Fever	Group E *Salmonella*	One-stage revision after lavage failed and ciprofloxacin 4 wk	Oral ciprofloxacine 5 mo	No
Jeroense *et al*[24], 2014	THA	13 years	Pain, abscess at the ultrasound	*Salmonella enteritidis*	One-stage revision	Oral ciprofloxacine 3 mo	No

IV: Intra venous; THA: Total hip arthroplasty; TKA: Total knee arthroplasty; TMP-SMX: Trimethoprim and sulfamethoxazole.

arthroscopically and others would prefer an arthrotomy[16,18].

The presence of an abscess in the surgical wound, backed by a CRP increase despite the surgical and antibiotic treatment, justified a second lavage in order to reduce the bacterial inoculum. In this patient case, the subacute infection justified the use of an arthroscopic approach instead of an arthrotomy. An open arthrotomy could also have been performed if arthroscopic treatment had failed. In this case, iterative arthroscopic management has been successful to control the infection. Antibiotic therapy is adapted after analysis of antibiotic sensitivity, and continued until the clinical-biological evolution is satisfactory, an antibiotic treatment of at least 6 wk is recommended[19].

The initial antibiotic therapy used in this patient was appropriate because it is effective for the most frequent pathogens (*i.e.*, *staphylococci*). It was adapted after antibiotic sensitivities. *Salmonella* is sensitive to third generation cephalosporins and fluoroquinolones, which were administered to our patient once the bacteriological results were obtained[7,11].

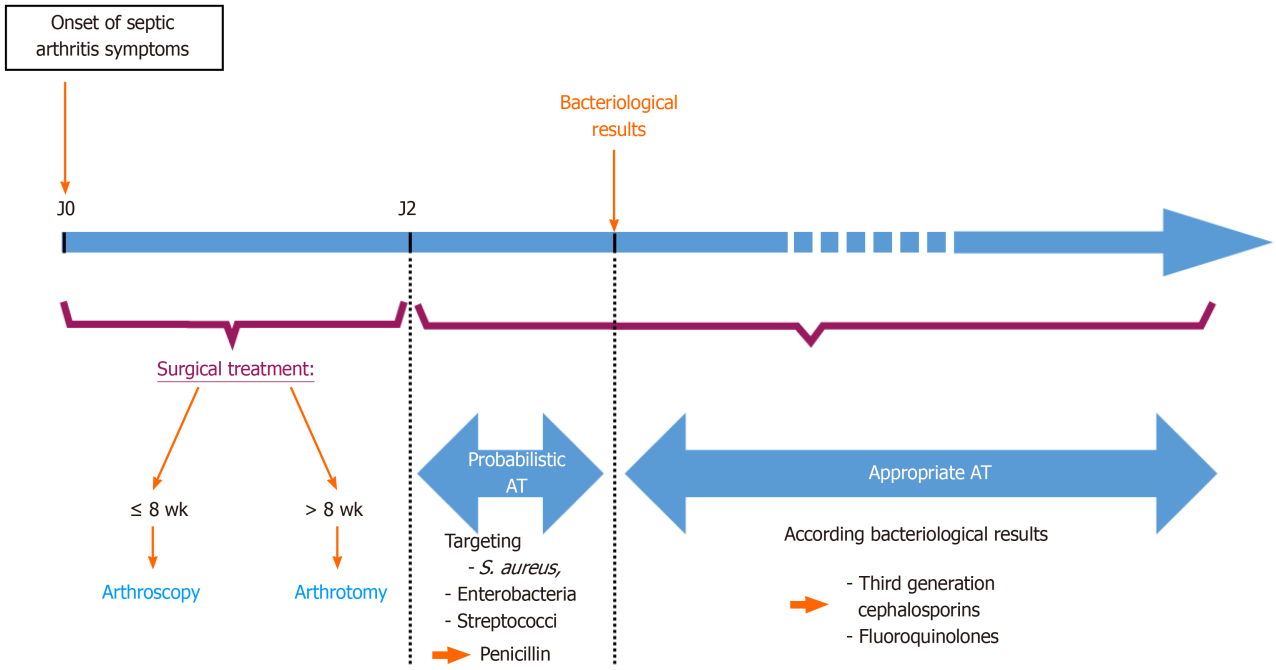


Figure 3 Therapeutic management schema. AT: Antibiotic treatment.

Graft failures are rare in early management of infection[16]. For this patient, the causes may have been as follows: The 24 h delay in treatment due to the aspiration, the absence of graft debridement, the pathogen (since no cases of *Salmonella* septic arthritis after ACLR are described), but likely primarily due to the two successive surgical procedures that could have compromised the integration of the graft.

CONCLUSION

Infection after ACLR is uncommon, with staphylococci found in more than 90% of cases. This case highlights the importance of early diagnosis and management: arthroscopic lavage for acute infections or arthrotomy for late infections and appropriate antibiotic therapy. Like any septic joint, early aggressive surgical treatment is required, also aiming to reduce the risk of arthritis-related joint cartilage destruction and damage to the graft.

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REVIEW

Fibula fractures management

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Abstract

Isolated distal fibula fractures represent the majority of ankle fractures. These fractures are often the result of a low-energy trauma with external rotation and supination mechanism. Diagnosis is based on clinical signs and radiographic exam. Stress X-rays have a role in detecting associated mortise instability. Management depends on fracture type, displacement and associated ankle instability. For simple, minimally displaced fractures without ankle instability, conservative treatment leads to excellent results. Conservative treatment must also be considered in overaged unhealthy patients, even in unstable fractures. Surgical treatment is indicated when fracture or ankle instability are present, with several techniques described. Outcome is excellent in most cases. Complications regarding wound healing are frequent, especially with plate fixation, whereas other complications are uncommon.

Key Words: Fibula fracture; Lateral malleolus; Distal fibula; Management; Treatment; Ankle

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Core Tip: Isolated fibula fractures are very common injuries. Diagnostic exams must rule out ankle instability. Surgical treatment must be considered in the case of associated ankle instability. Risk factors for wound related complications must be considered when choosing the surgical technique.

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INTRODUCTION

Ankle fractures are frequent injuries[1], increasing in elderly patients as a consequence of osteoporosis[2]. In most literature reports, distal fibula fractures represent the majority of ankle fractures[3]. These fractures are often the result of a low energy trauma with an external rotation and supination mechanism.

Many authors recommend conservative treatment for isolated fibula fractures without signs of ankle instability as good clinical results are obtained in most cases[1-3]. However, the trend in recent years is headed towards surgical treatment, with advantages in terms of anatomic restoration and earlier recovery[1-3].

Depending on fracture type, displacement and degree of instability, several surgical treatment techniques have been described. These include lateral *vs* posterolateral plating, nonlocking *vs* locking plate fixation, isolated screws and intramedullary fixation[4].

The aim of the present paper is to review the most recent literature about the epidemiology, mechanism of injury, diagnosis, classification, management and complications of isolated distal fibula fractures treatment.

EPIDEMIOLOGY

Ankle fractures are frequent injuries, accounting for about 9% of all fractures[1]. Moreover, there has been a sharp increase in osteoporosis related ankle fracture incidence in recent years. Isolated distal fibula fractures represent the most frequent ankle fracture type[3,4]. Elsoe *et al*[2] recently reported the epidemiology of 9767 ankle fractures, identifying distal fibula fractures as the most common fracture type, accounting for 55% of cases. Furthermore, according to the Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) classification, type B is generally reported to be the more common distal fibula fracture type. Court-Brown *et al*[5] reported the following distal fibula fracture type distribution among 1500 ankle fractures: 52% type B trans-syndesmotic fractures, 38% type A infra-syndesmotic fractures and 10% type C supra-syndesmotic fractures[5]. Age and gender-related differences in ankle fracture epidemiology have been reported. Distal fibula fractures are more frequent in young active male patients. Werner *et al*[6] reported an incidence of isolated distal fibula fractures reaching 83% of cases among a population of National Football League athletes reporting ankle fractures. Conversely, Hasselman *et al*[7] found isolated fibular fracture to cover 57.6% of cases in elderly (> 65 years) women reporting ankle fractures.

MECHANISM OF LATERAL MALLEOLUS FRACTURE

Stability of the ankle mortise is determined by bony components (fibula, tibia and talus) and ligamentous structures (syndesmosis complex and lateral and medial collateral ligaments). Dynamic musculotendinous stabilizers, which exact function is less understood, also play a relevant role. There is on-going research on interactions between these structures and mechanisms that cause fracture.

Ankle sprains/torsion injuries, accidental falls and sports related accidents are the most frequently reported causes of distal fibula fracture, with different rates according to the different AO/OTA types. In type A fractures the main cause is represented by torsion (32%) followed by falls (23%) and sports related trauma (22%). In type B fractures the trend is similar, with reported rates of 27% for torsion, 37% for falls and 13% for sports related trauma. For type C the trend is slightly different because torsion represents only 3.7% of cases while falls and sports related trauma represent 28% and 21% of cases, respectively.

The most frequently described traumatic mechanism is supination-external rotation (SER). In this type of trauma, the talus rotates pushing the tibia and fibula apart, rupturing the anterior-inferior tibiofibular ligament and causing a simple ankle sprain.

Further progression of deforming force causes a simple oblique fibula fracture at the level of the syndesmosis, equivalent to the AO/OTA type B fracture. In the second most frequent mechanism, supination-adduction, adduction of the hindfoot causes either talofibular ligament rupture (ankle sprain) or an avulsion fracture of the distal fibula, equivalent to the AO/OTA type A fracture. As reported by Lauge-Hansen[8], lateral structures are damaged after the medial side when traumatic forces act in pronation.

Nonetheless, a recent *in vivo* study by Kwon *et al*[9] analyzing injury videos posted on YouTube and matching them to their corresponding X-rays, found that the Lauge-Hansen system was only 58% overall accurate in predicting fracture patterns from deforming injury mechanism.

DIAGNOSIS

Clinical examination

Clinical signs of an isolated fracture of the distal fibula are not specific and may not be distinguishable from a severe ankle sprain. These signs include swelling, bruising, pain, ecchymosis, tenderness and reduced range of motion (ROM). Swelling is the most common reported sign and was found to be a constant feature of all ankle fractures[10]. Because most isolated distal fibula fractures are stable, weight bearing is usually possible[11], thus patients might be ambulating at clinical presentation. There are no specific clinical tests for this fracture. Nonetheless, it is essential to evaluate medial ankle structures stability to choose the correct management. In C type fractures, the syndesmosis complex integrity must also be investigated. However, clinical examination alone is not diagnostic in most cases because pain, edema and muscle contracture can hinder correct evaluation[12,13].

Radiographic evaluation

Standard ankle X-rays are the mainstay of instrumental diagnosis for all ankle fractures. However, ankle sprains that might possibly cause a fracture might not deserve radiographic examination in all cases. In fact, due to the already described unspecific clinical presentation, other criteria should be considered to reduce the number of unnecessary exams and length of hospital stay[14,15]. The Ottawa Criteria were introduced for this purpose, despite some studies questioning their clinical validity[16].

When cases amenable for radiographic evaluation are selected, three radiographic views should always be obtained according to the American College of Radiology guidelines: antero-posterior (AP), lateral and mortise view[17].

The AP view is performed along the long axis of the foot. In isolated fibula fractures, this view is particularly useful to evaluate signs of associated ankle and/or syndesmotic instability through the analysis of talus coronal inclination, tibio-fibular overlap, tibio-fibular clear space and medial clear space (MCS)[18].

In the lateral view, the talar dome must be centered and congruent with the tibial plafond. This view is useful in isolated fibula fractures to demonstrate AP displacement and external rotation type fractures[19].

The mortise view is taken by placing the foot on the table with about 15° of internal rotation. This visualization is useful in isolated fibula fractures to detect signs of associated syndesmosis instability and to obtain a clear view of the lateral malleolus without other overlapping structures. It is especially useful in undisplaced and incomplete fractures[18,20].

Theoretically, these views are sufficient to identify an isolated distal fibula fracture in almost all cases. As demonstrated in several clinical and cadaveric studies[21-23] in standard radiographic evaluation, a MCS increase in isolated distal fibula fractures is a typical sign of rupture of the deltoid ligament with consequent talar lateral shift. These factors suggest a possible mortise instability, which is fundamental to define treatment modality. However, reliable radiographic determination of deltoid ligament rupture in such uncertain cases is difficult in clinical practice[24]. To adequately evaluate mortise stability, different modalities to obtain stress radiographs have been described.

The manual stress view has been considered the method of choice for years. However, being an operator dependent exam, reproducibility and radiation exposure to the physician are a concern. Moreover, it is not clear in the published data which MCS values are to be considered as a cut off to identify a clinically relevant deltoid ligament rupture.

Michelson *et al*[25] described for the first time in 2001 the gravity stress view to investigate ankle joint instability. The patient is placed in the lateral decubitus position with the distal half of the leg off the end of the table. Then a standard AP and mortise view is taken. Gravity stress views proved to be just as effective as manual stress views to detect deltoid ligament injury in association with an isolated distal fibula fracture[26-28]. Many advantages, such as no radiation exposure to the physician and less pain to the patient are described. Moreover, the constant force of gravity makes the exam reproducible[27].

Nonetheless, manual and gravity stress radiographs can overestimate the need for surgical fixation by showing MCS widening in partial deltoid ligament lesions that might uneventfully heal with conservative treatment[29-31]. For this reason, in the literature many authors described the weight bearing radiographs as an alternative method to identify ankle instability in isolated distal fibula fractures. As proposed by Weber *et al*[32], these radiographs should be performed with the patient standing on both legs as pain allows. An AP, lateral and mortise view is then taken with the weight ideally distributed equally on both ankles[32]. The disadvantage of this technique is the possible variability in weight distribution between healthy and injured side that could hide the degree of ankle instability in some cases.

Finally, magnetic resonance imaging is not indicated in the acute diagnosis of isolated distal fibula fractures. Its use in these lesions is very limited because traditional and stress radiographs proved to be equally effective in identifying the severity of associated deltoid ligament injury[33]. Conversely, magnetic resonance imaging might be useful to detect associated chondral injuries or to diagnose a fracture when conventional radiographs are inconclusive, and clinical suspicion is very high[34].

CLASSIFICATION

Although the fibula carries only 10% of the body weight (compared to 90% carried by the tibia)[35], its role is crucial in the stability of the ankle mortise. Based on this statement, to define an ankle with isolated fibula fracture as stable or unstable is crucial to guide proper treatment. Nonetheless, there is still debate in the literature on which are the most suitable clinical and radiological criteria to obtain this goal. The optimal management is based on an accurate knowledge of the fracture. For a comprehensive assessment of the fracture, a reproducible classification method is essential.

Different classifications have been proposed through the years. Lauge-Hansen and Danis-Weber classifications are the most used. They are based on standard AP, lateral and mortise radiographic views of the ankle. Their aim is to describe the mechanism of injury, predict soft tissue conditions and finally guide treatment.

The Lauge-Hansen classification, developed in 1954, is based on the position of the foot at the time of injury (supination or pronation) and on the deforming forces acting on the foot (abduction, adduction or external rotation)[36]. This results in a combination of four categories and thirteen patterns of ankle fracture. Isolated distal fibula fractures usually occur in the supination-external rotation type II and supination-adduction Lauge-Hansen types. In the other classes (pronation-abduction and pronation-external rotation) an isolated fibula fracture might occur above the level of the syndesmosis in association with a medial ligament injury. The main limitation of the Lauge-Hansen classification is the poor interobserver agreement that is instead very high in the Danis-Weber classification due to its simplicity.

The Danis-Weber classification (Figure 1) was first described by Robert Danis in 1949 and later modified by Bernhard Georg Weber in 1966. It was then adopted by the AO/OTA Group. It evaluates the location of the main fibular fracture in relation to the syndesmosis. Type A fractures are generally stable injuries occurring below the level of the syndesmosis. Type B fractures occur at the level of the syndesmosis and might be unstable in some cases. Type C fractures are usually unstable injuries occurring above the level of the syndesmosis[37].

However, differentiating fracture types in relation to the syndesmosis might lead the medial side of the ankle to be overlooked. Moreover, injury extent in the tibiofibular syndesmosis is often not predictable. These findings are crucial to detect tibio-talar instability and consequently to decide between surgical and nonsurgical management, especially for type B fractures[38]. Probably, as suggested by Lampridis *et al*[39], a combination of the two main systems is the correct approach. Nonetheless, the limits of these classification systems are reported by several studies in the literature, especially their poor prognostic and therapeutically predictive capabili-



Figure 1 Danis-Weber classification of distal fibula isolated fractures. A: Type A; B: Type B; C: Type C.

ties[40-42].

MANAGEMENT

Clinical and biomechanical data indicate that maintenance of talar reduction is the most important factor for the prognosis of ankle fractures[43,44]. A residual dislocation leads to a series of complications including impaired healing, early osteoarthritis and residual instability.

Shortening and external rotation of the fibula can cause talar lateral shift, reducing the tibio-talar contact area and increasing peak pressure in the articular cartilage[45,46]. Many authors believe that the deltoid ligament is the most important structure to maintain the position of the talus when the fibula is fractured[47-49].

An isolated distal fibula fracture is considered stable when less than 2 mm of displacement occurs, and no deltoid ligament rupture is detected (MCS < 4 mm)[50,51]. Several clinical studies have shown that in isolated fractures without concomitant medial injury, conservative treatment leads to excellent long-term results[52,53].

Conversely, many clinical studies have shown significantly better results in ankle fractures with mortise instability and talus displacement when an accurate fracture reduction is achieved[54]. However, unlike cases associated with gross instability, proper management of isolated fibula fractures that demonstrate instability only after stress radiographs is still a matter of debate in the literature[55]. In many authors' opinions, stress radiographs can overestimate the need for surgical fixation[29-31]. Hoshino *et al*[31] analyzed 36 patients with isolated distal fibula fracture demonstrating MCS widening at external rotation stress radiographs. All patients were treated with nonsurgical treatment initially. After 7 d, only one (3%) patient had an unstable ankle mortise on weight bearing radiographs, thus requiring operative treatment. All patients demonstrated good to excellent functional scores at 1 year follow-up[31].

NONOPERATIVE TREATMENT

Conservative treatment is indicated for isolated distal fibula fractures with a stable ankle mortise. As far as fracture displacement is concerned, Lesic *et al*[56] set 2 mm as the threshold between conservative and surgical treatment. However, there is no strong evidence in the literature advocating surgery for fracture displacement more than 2 mm[57]. Other studies suggest that radiographic displacement might not be reliable as it is mostly a rotational displacement[58-60].

Nonetheless, minor radiographic displacement seems not to affect clinical outcome[61]. Two studies have shown a high percentage of good results even when the fibula is posteriorly displaced up to 5 mm[41,62]. Hence, any isolated distal fibula fracture with a stable ankle can be treated conservatively (Figure 2).



Figure 2 Lateral, mortise and antero-posterior radiographic views of a Danis-Weber type B left distal fibula fracture. Conservative treatment is the correct choice for this case because minimal displacement of the fracture and absence of associated ankle instability are demonstrated.

Weber type A fractures can be considered equivalent to a ligamentous ankle injury. Likely, satisfactory results with nonoperative treatment can be achieved as in ligament ruptures[63].

In the literature, randomized and nonrandomized studies show satisfactory outcomes for conservative treatment in minimally displaced or nondisplaced Weber B type fractures[41,61,62,64]. Dobbe *et al*[65] reported that 13% of 108 conservatively treated infra-syndesmotic fractures had difficulties with work- and life-related activities. However, no relationship was identified between outcomes and the degree of articular displacement or fragment width[65]. These results might suggest the need to adapt treatment according to age and activity level. Sanders *et al*[54] suggested operative intervention in younger individuals, with the aim to reduce the risk of malalignment and improve outcomes. Conversely, a different management can be reserved for older and less active patients, which can be safely treated with cast immobilization even in unstable fracture patterns[54].

While there are several studies that describe conservative treatment for Weber type B fractures, a recent review comparing different managements for Weber type C fractures found only one study included conservative treatment. This demonstrates the widespread preference for surgical management in these cases[66]. Donken *et al*[67] compared the results of nonoperative and operative treatment for Weber type C fractures, with conservative treatment reserved to cases that demonstrated joint congruity, no signs of deltoid ligament injury and no medial malleolus fractures. Clinical results were comparable with most patients reaching high-level functional results[67].

Nonoperative treatment modality is chosen based on patients' symptoms, bone and skin quality, time lapse from injury to clinical presentation and risk factors for impaired healing (Table 1). Different conservative treatment modalities are described in the literature, ranging from cast immobilization without weight bearing to immediate full weight bearing without cast or brace. Historically, treatment in a plaster cast for several weeks was recommended. This strategy arises from the evidence that 6 wk are needed for any fracture to tolerate weight bearing[41,61,62,68]. Although a high rate of fracture union was demonstrated, a prolonged immobilization can result in ankle stiffness and higher risk of deep vein thrombosis[69-73]. To overcome these complications, Kortekangas *et al*[74] recently showed that a 3-wk period of immobilization is noninferior to 6 wk in the treatment of an isolated stable Weber B type fracture.

Alternative methods of immobilization with immediate weight bearing have been proposed through the years. In 1979, Stover *et al*[75] proposed a bivalve pneumatic air stirrup in the management of ankle fractures. Stuart *et al*[71] in 1989 showed the brace to improve patient comfort, post fracture swelling, range of ankle motion at union and time to full rehabilitation. Similar findings were reported by Brink *et al*[76], who advocated the use of a hinged short-leg boot with good results in pain relief, increased ROM and earlier return to ambulation. It has been suggested that an ordinary elastic bandage is equally safe and beneficial[52], and no difference in the amount of pain experienced has been found between early mobilization or plaster cast[77]. Ryd *et al*[52] described 49 patients treated only with elastic bandage for isolated distal fibula fractures displaced less than 2 mm and without medial tenderness. All of them had excellent clinical outcomes and were back to normal activity in about 4 mo[52].

Table 1 Summary of main criteria for conservative indication in isolated distal fibula fractures treatment

Nonoperative treatment	
Displacement	< 2 mm
Medial stability	MCS < 4 mm in AP/mortise view and/or in dynamic radiographs view
Poor bone and skin quality	
Long time lapse from injury	
Advanced age, low functional demand	
High risk of local and general complications	

AP: Antero-posterior; MCS: Medial clear space.

The functional treatment of stable ankle fractures is also supported by van der Berg *et al*[78], who showed better Visual Analogue Scale score and total ROM with a brace rather than with a cast after 6 wk, while no significant difference was found at 1 year.

SURGICAL TREATMENT

Open reduction and internal fixation is the most common treatment for unstable ankle fractures (Table 2). There are several fixation methods described for distal fibula fractures fixation, including one-third tubular plate (Figure 3), dynamic compression plate and locking plate with or without an independent lag screw[79-81]. The most used plates are angular stable metaphyseal or anatomic distal fibula plates (Figure 4)[82]. They can serve as bridging plates, compression plates, tension band plates or neutralization plates. Most studies comparing locking plates and conventional one third tubular plates show no differences in clinical and radiographic outcomes as well as in wound complications incidence[79,83-85]. However, these fixation techniques have a complication rate of up to 30% of cases, with wound complications being the most common[86-88]. This is attributed to the surgical trauma occurring in an already injured area with limited soft tissue cover. This range increases in smokers, in elderly patients and in patients with comorbidities such as diabetes and peripheral vasculopathy[87-90]. Minimally invasive plate osteosynthesis is a suggested alternative to prevent periosteal damage and major soft tissues dissection. This technique allows plate insertion through a small incision and better respects fracture biology[79]. However, anatomic restoration is more technically demanding for the surgeon, and the technique is suitable for only a small amount of fracture patterns.

Distal fibula fractures in elderly patients are often comminuted and present with impaired soft tissues coverage. Consequently, the correct management of ankle fractures in these patients must account for bone quality and the risk of soft tissue complications[80,86,89]. Locking plates provide a biomechanical advantage in cases of poor bone quality and are therefore recommended over nonlocking plates in osteoporotic patients when surgical management is chosen[86,80].

Fibular nailing is considered a valid alternative method of fixation for distal fibula fractures. The use of intramedullary fibula fixation was first introduced in the mid-1980s to reduce complications of the traditional plating techniques[91]. However, early attempts in intramedullary fibula fixation, such as using rush rods, Inyo nail, K. wires, *etc*., showed several complications and failures due to poor rotational and longitudinal stability, which led to loss of reduction, malunion and nail migration[92-94]. As a result, modern locking fibula nails have been developed to reduce such complications[93]. Modern fibula nails are designed with proximal and distal locking fixation systems. The use of proximal and distal locking screws as well as of intersyndesmotic screws (Figure 5) if needed, allows optimal fracture stability with consequent advantages on early weight bearing[93,95]. The use of a modern fibula intramedullary nail should be considered especially in cases of suffering skin and/or patients with severe comorbidities[93-95]. Several authors compared the results of plating and nailing for internal fixation of the fibula in ankle fractures, and most of them show no differences in functional outcome[96,97]. Successful results with lower rates of wound breakdown and hardware prominence compared with standard open reduction and plating have been reported[93-96]. On the other hand, the main criticisms of this

Table 2 Summary of main criteria for surgical indication in isolated distal fibula fractures treatment

Surgical treatment	
Displacement	> 2-5 mm
Medial instability	MCS > 4 mm in AP/mortise view or in dynamic radiographs view
Type C	Any displacement

AP: Antero-posterior; MCS: Medial clear space.



Figure 3 Radiographic and clinical results at 3 mo from a one-third tubular plate fixation of a Danis-Weber type B left distal fibula fracture.

technique reside in the difficult management of rotational displacement, especially in type B fractures and in the absence of compression at the fracture site in simple oblique and spiral fracture patterns with a theoretical risk of delayed healing[93,95]. However, the minimally invasive approach that preserves fracture biology and periosteal blood supply might overcome this aspect[94,98].

COMPLICATIONS

Nonunion

Nonunion in ankle fractures is an extremely rare complication[99-103]. Distal fibula fractures usually heal uneventfully even with nonsurgical treatment. However, because most nonunions in this area are asymptomatic, the exact incidence of this complication is uncertain[99-103].

A higher incidence of fibular nonunion has been described when associated with medial instability. Sneppen *et al*[99] demonstrated a 0.7% incidence of fibular nonunion in ankle fractures involving the medial malleolus *vs* a 0.1% incidence in isolated fibular fractures. Complete nonunion was mostly seen in type A (Figure 6) and C fractures[100], whereas incomplete nonunion was described in Weber type B fractures[101].

Treatment is based on the type of nonunion, symptoms, initial fracture pattern, associated injuries and patient expectations. Asymptomatic nonunions are treated conservatively, with reports of spontaneous healing even several years after the initial injury[102]. For symptomatic nonunion, open reduction and internal fixation with or without bone grafting represents the best treatment choice resulting in successful outcomes in most cases[103].

Malunion

Angular malalignment occurs when the distal fibula heals in shortening or external rotation. This causes a lateral subluxation of the talus with ankle kinematics alteration leading to arthritis[44]. Most cases of angular malalignment occur after conservative treatment[104]. However, surgical treatment might be a cause of malunion if anatomic reduction is not achieved intraoperatively. Moreover, technical errors, suboptimal stability of fixation and unrecognized associated ligamentous instability might lead to loss of reduction and consequent malunion (Figure 7)[105]. Several radiographic parameters have been described to identify the correct length and rotation of the fibula



Figure 4 Clinical and radiographic results at 3 mo from surgical treatment of a Danis-Weber type B right distal fibula fracture with an anatomic angular stable plate.

in the ankle mortise: the Weber circle, the Shenton's line, the talocrural and bimalleolar angles[106]. These parameters can help the clinicians to more easily identify a malalignment that could cause continuous pain to the patient even after several months.

Surgical treatment is a demanding procedure, as anatomic reconstruction usually requires both fibula osteotomy and soft tissues release. Plate osteosynthesis is then required for fixation[107]. In several studies, the results of surgical treatment for malalignment were excellent. Yablon *et al*[108] reported good results over 7 years of follow up in 23 of 26 patients with fibular malalignment surgically treated 6 years after trauma. Ward *et al*[109] reported similar results in ankle fracture malunions treated with lengthening osteotomy of the fibula.

Wound dehiscence and infection

The distal fibula is subcutaneous and lacks a layer of overlying muscles. Thus, wound healing complications are the most common adverse events related to distal fibula fixation. Wound edge necrosis, wound dehiscence and superficial and deep infection have all been reported[110]. In the literature, the overall wound complication rate varies from 8.4% to 40.0% among studies[111-113] . The deep surgical infection rate is significantly lower, about 1.2% to 2.8% according to different reports[111,114,115].

The genesis is multifactorial as it depends on soft tissue compromise at admission, timing of surgery, fracture type and patient characteristics. Age, diabetes, steroid intake, smoking and peripheral vascular disease are associated with a greater risk of wound complications[88,112,116-118].The type of implant also might have a role. Schepers *et al*[119] reported in a retrospective study of 165 patients a higher wound complication rate with locking plates (17.5%) than with thinner one third tubular plates (5.5%). Conversely, Tsukada *et al*[84] in two different trials did not find any difference in complication rates between locking and nonlocking plates[84,115].



Figure 5 Clinical case of a Danis-Weber Type B left distal fibula fracture treated with locked nailing. A: Intraoperative image demonstrating fibula nail insertion with guided instrumentation; B: Detail of the clinical result of minimally invasive approach for fibular nail insertion; C: Antero-posterior X-rays demonstrating fracture fixation with fibular nail completed with two guided intersyndesmotic screws.



Figure 6 Lateral and antero-posterior view X-rays taken 4 mo after conservative treatment of a Danis-Weber type A distal fibula fracture. Despite the radiographic evidence of nonunion the patient is completely asymptomatic, and no further treatment is indicated.

The incidence of this complication can be minimized by treating the fracture as soon as reasonably possible[110] or postponing the surgery until the edema is resolved. The latter strategy has gained more and more popularity with the advent of damage control techniques. Whatever the timing, limiting the use of the tourniquet and closing the wound without tension is also advisable.

ROM limitation

Most patients after isolated distal fibula fractures recover with a completely functional ROM. When stiffness occurs, dorsiflexion deficit is more common. Lin *et al*[120] reported that in a population of 306 patients a 19% rate of plantar flexion limitation (only 2% > 10 degrees) occurred, while 41% of cases had restriction in dorsiflexion. In a review of 31 randomized trials about rehabilitation of ankle fractures, the authors found a positive effect on ankle ROM form early mobilization, early weight bearing and the use of a removable immobilization device. However, there is limited evidence supporting this strategy as patient compliance seems to play a significant role[120].

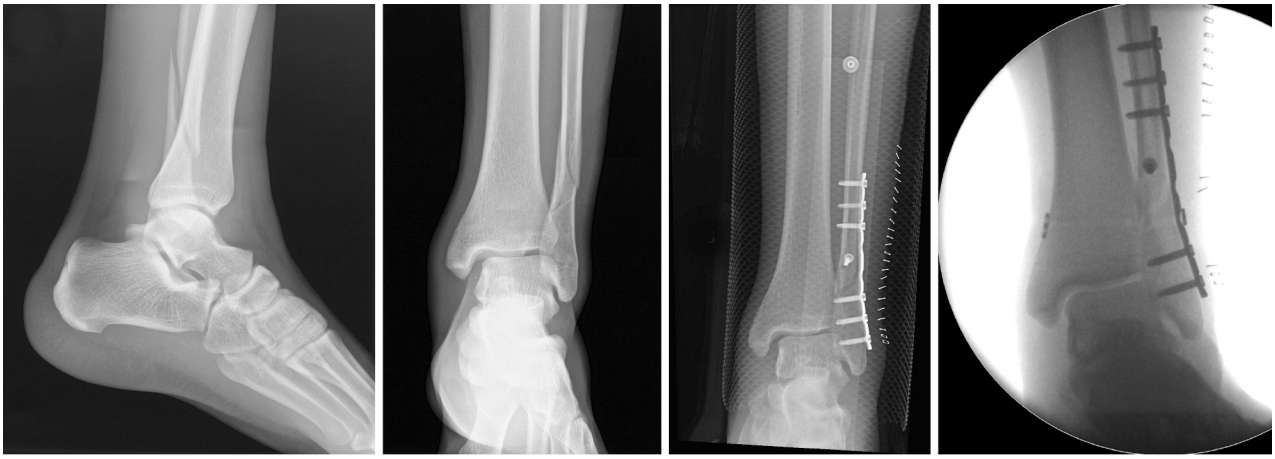


Figure 7 Clinical case of a Danis-Weber type C left distal fibula fracture treated with a one-third tubular plate. At post-op X-rays, malreduction with residual medial displacement is demonstrated. A dedicated adjustable tibio-fibular suture button fixation was added to obtain anatomic reduction and correction of associated ankle instability.

Early arthritis

Trauma is the most common cause of ankle osteoarthritis[121]. Arthritis results from a combination of direct cartilage damage and biomechanical alterations that affect joint kinematics[122]. It becomes evident 2 to 3 years after trauma and is often symptomatic. It is more frequent in higher grade fractures according to the Lauge-Hansen classification. Lübbeke *et al*[105], evaluating risk factors for development of ankle osteoarthritis, found a Weber type C or a fibula fracture with an associated fracture of the medial malleolus as the most important risk factors for the development of symptomatic radiographically advanced osteoarthritis. Surgical treatment seems to reduce the incidence of osteoarthritis by means of anatomic reduction and ankle stability restoration.

CONCLUSION

Isolated fibula fractures are very common injuries. Diagnostic exams must rule out ankle instability. Conservative treatment yields good results in stable fractures with stable ankle mortise. Open reduction internal fixation is indicated in case of associated ankle instability. Risk factors for wound related complications must be considered when choosing a surgical technique.

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MINIREVIEWS

Acute syndesmotic injuries in ankle fractures: From diagnosis to treatment and current concepts

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Abstract

A stable and precise articulation of the distal tibiofibular syndesmosis maintains the tibiofibular relationship, and it is essential for normal motion of the ankle joint. The disruption of this joint is frequently accompanied by rotational ankle fracture, such as pronation-external rotation, and rarely occurs without ankle fracture. The diagnosis is not simple, and ideal management of the various presentations of syndesmotic injury remains controversial to this day. Anatomical restoration and stabilization of the disrupted tibiofibular syndesmosis is essential to improve functional outcomes. In such an injury, including inadequately treated, misdiagnosed and correctly diagnosed cases, a chronic pattern characterized by persistent ankle pain, function disability and early osteoarthritis can result. This paper reviews anatomical and biomechanical characteristics of this syndesmosis, the mechanism of its acute injury associated to fractures, radiological and arthroscopic diagnosis and surgical treatment.

Key Words: Ankle; Fracture; Injury; Distal tibiofibular joint; Trauma; Syndesmosis

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Core Tip: Patients with unstable distal tibiofibular syndesmosis injuries associated with fractures require surgical stabilization. The aim of surgical treatment is to restore joint

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congruency and to maintain the stability of the syndesmosis until the ligaments have healed. Satisfactory results depend on correct management from diagnosis to treatment. Static and dynamic fixation systems have similar long-term clinical and radiological outcomes.

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INTRODUCTION

The distal tibiofibular syndesmosis (DTS) complex is critical for maintaining the congruency of the ankle mortise[1] and is the most important supporter of this joint[2]. DTS injuries of sufficient severity can disrupt the normal stability of the ankle and they may occur in many forms, commonly classified into isolated or, more frequently, with an associated malleolar fracture[3]. They are consequent to an external rotation force applied to the foot that leads to eversion of the talus within the ankle mortise[4-6]. Ankle fractures occur with an incidence of 107-148 per 100000 in the adult population[7-9]. About 10% of all are associated to syndesmotic injury, and this percentage is twice as high in patients who require internal fixation[10]. Therefore, it is crucial that surgeons adequately diagnose these lesions, which are present in up to 40% of all type B injuries according to Danis-Weber classification and up to 80% of all type C[11]. Persistent ankle pain, function disability and early osteoarthritis are potential problems related to misdiagnosed or inadequate treatment[12-14], and for this reason it is necessary to acquire an accurate diagnosis and maintain syndesmotic reduction when treating ankle fractures with concomitant syndesmotic disruption.

Patients with unstable injuries require surgical stabilization[15]. Various fixation techniques have been introduced over recent decades (metallic and bioabsorbable screws, staples, polyester bands, syndesmosis hooks, Kirschner wires and suture-button fixation)[2,16-18]. Static fixation (SF) with one or more cortical screws is the reference standard fixation method. However, some significant issues should be considered. Screw loosening, breakage[19], discomfort, pain related to overcompression, the need for a reoperation for screw removal and the risk of late diastasis after early removal are potential drawbacks of this type of fixation[20-24]. An alternative dynamic method of fixation (DF) uses an implanted suture-button device; it consists of a nonabsorbable synthetic suture between two metallic buttons implanted across the DTS[25]. Recently, this technique has become increasingly popular because it allows a more physiological articular movement, early rehabilitation, satisfactory functional outcomes and no requirement for implant removal[2,25]. However, there is no unique consensus on whether DF methods are superior to the static ones in terms of functional outcomes, change in range of motion, complication rates and incidence of reoperation[26,27]. The aim of this study is to review anatomical and biomechanical characteristics of DTS, the mechanism of its acute injury associated to fractures, radiological and arthroscopic diagnosis and surgical treatment.

ANATOMY AND BIOMECHANICS

The bony anatomy of the distal tibia and fibula is important for the osseous stability of the tibiofibular joint, which is a syndesmosis formed by the medial rough convex surface of the distal fibula which articulates with the lateral triangular fibular notch of the distal tibia[1,28]. The lateral ridge of the distal tibia bifurcates into an anterior and posterior margin, forming a larger anterior (Chaput's tubercle) and a smaller posterior tubercle (Volkman's tubercle). These tubercles represent the tibial attachment sites respective of the anterior and posterior syndesmotic ligaments. Posterior tubercle functions as a fulcrum during external rotation injury, and the fibula spins around its longitudinal axis. Between the anterior and posterior margins of the tibia there is a triangular concave notch, named incisura tibialis, where the convex medial margin of

the distal fibula rests. In about 75% of ankles, there are cartilage covered facets at the tibiofibular contact zone, forming a true synovial joint[29]. This articulation can act as a guide for the alignment of the ankle mortise in ankle fracture fixation or in syndesmosis reconstruction.

The ligamentous structures of the syndesmosis (Figure 1) function in addition to the bony support to provide syndesmotic stability by resisting the axial, rotational and translational forces. The distal syndesmosis complex may be further divided into its four components as follows[30].

The anterior inferior tibiofibular ligament (AITFL) traverses the joint at an oblique 45° angle from the Chaput's tubercle of the tibia to the Wagstaffe-Le Forte tubercle of the fibula. It is often composed of three bundles forming a trapezoidal shape. Rarely, an accessory anteroinferior tibiofibular ligament (Bassett's ligament) runs parallel and inferior to the AITFL. AITFL is the weakest of the syndesmotic ligaments and is the first ligament subjected to stress during an external rotation force of the fibula around its longitudinal axis.

The posterior inferior tibiofibular ligament (PITFL) is the strongest portion of the complex, and it lies in the posterior surface of the syndesmosis. From its origin, at the Volkman's tubercle, it descends posterolaterally to insert in the posterior aspect of the distal fibula. Tear of PITFL can occur in Lauge-Hansen supination-eversion, pronation-abduction or pronation-eversion injury. However, in these cases, forces usually result in a posterior malleolar avulsion fracture due to the ligament strength[31].

The interosseous ligament is formed by a thickening of the lowermost end of the interosseous membrane. This ligament functions as a "spring" to accommodate slight separation of the mortise during dorsiflexion of the ankle. The interosseous membrane connects the tibia and fibula throughout their length and plays a minimal role in syndesmotic stability[32].

The transverse tibiofibular ligament extends horizontally from the proximal margin of the fibular malleolar fossa to the dorsodistal rim of the tibia distal to the PITFL; it may protract to as far as the dorsal aspect of the medial malleolus[31]. It has a fibrocartilagineous appearance that functions as a labrum to deepen the posteroinferior rim of the tibia. The presence of another ligament, the posterior intermalleolar ligament, is still controversial. Its occurrence varies from 19% in magnetic resonance imaging to 82% in dissected anatomical specimens[33]. Although the posterior intermalleolar ligament has been neglected in the anatomy literature, the existence of this ligament has been revealed recently to be a cause of posterior impingement syndrome that brings about posterolateral ankle pain during plantar flexion[34,35]. Furthermore, radiological studies have demonstrated that this ligament is an almost invariably present anatomical entity[36,37]. However, its anatomical role is still unknown.

In a study based on computed tomography (CT) imaging of 100 normal syndesmosis, Elgafy *et al*[38] showed variation of the articulation between genders, with variation between the anterior and posterior dimensions within the syndesmosis. This diversity of the articulation poses both diagnostic and operative challenges to the practitioner.

Despite a small amount of motion, DTS has a very important role in ankle joint biomechanics even if only very small rotations and displacements are detected indicating that the fibula is closely attached to the tibia. With the ankle in external rotation, the fibula translates medially (0-2.5 mm) and posteriorly (1.0-3.1 mm) and externally rotates (2°-5°), even though this little displacement cannot be estimated on radiographs[39]. While moving from plantar flexion to dorsiflexion, Peter *et al*[40] reported a 2° external rotation and 1.25 mm lateral translation of the lateral malleolus to accommodate the irregularly shaped talus.

The disruption of ligamentous structures around the ankle modifies this "equilibrium." Anatomical study suggested the relative importance of any syndesmotic ligament to the overall syndesmotic stability (35% by AITFL, 22% by interosseous ligament, 9% by superficial PITFL and 33% by deep PITFL)[41]. Sectioning of the AITFL results in the greatest reduction in resistance to external rotation, although there is a significant decrease in resistance with each sequential ligament sectioned. In contrast, sectioning of the PITFL results in the greatest decrease in resistance to internal rotation[42]. Additionally, the deltoid ligament confers secondary stability by resisting lateral shift of the talus[43]. Ramsey *et al*[44] reported that when the deep horizontal part of the deltoid ligament is cut, this diastasis increases to 3.7 mm and described that when the talus moves laterally by 1.0 mm, the contact area in the tibiotalar articulation is decreased by 42%.

Moreover, Burns *et al*[45] showed that a complete disruption of syndesmosis with a deltoid ligament tear caused a 40% decrease in the tibiotalar contact area and a 36% increase in the tibiotalar contact pressure. Therefore, a precise and stable articulation is

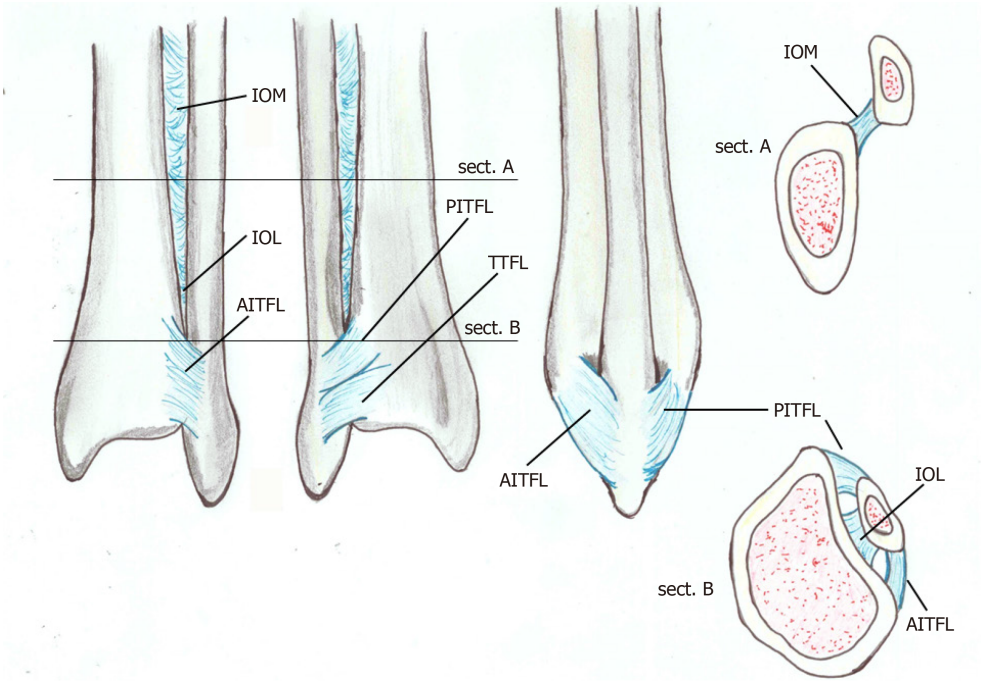


Figure 1 Anatomy of the distal tibiofibular syndesmosis: anterior view, posterior view, lateral view and proximal and distal coronal view. AITFL: Anterior inferior tibiofibular ligament; IOL: Interosseous ligament; IOM: Interosseous membrane; PITFL: Posterior inferior tibiofibular ligament; TTFL: Transverse tibiofibular ligament.

required for normal motion of the ankle.

MECHANISM OF INJURY AND CLASSIFICATION

Although the precise mechanism of injury in the DTS often remains unclear, it has been demonstrated that these lesions occur more frequently with some types of rotational ankle fractures such as in pronation-external rotation and pronation-abduction and less frequently in supination-external rotation[34].

The most frequently used ankle fracture classifications are the Danis-Weber, AO-Müller, and Lauge-Hansen. The Weber classification (Figure 2) is based on the position of the distal fibular fracture in relation to the syndesmosis. Weber A includes fractures below the level of the syndesmosis, those at the level of the syndesmosis are Weber B, and Weber C includes fractures above the level of the syndesmosis. Type C also includes rotational ankle traumas with high fibular rupture, the so-called "Maissoneuve fractures," which are usually associated to syndesmotic disruption. The syndesmosis is rarely involved in Weber A fractures, although it is torn in up to 80% of all type C injuries[7,12]. In this case, we have disruption of the deltoid ligament caused by external rotation and peroneal fracture above the level of distal syndesmosis. The status of the syndesmosis is unclear in Weber B lesions caused by an external rotation mechanism, but some studies report lesions in up to 40% of cases[7,12].

In the AO/OTA classification, ankle fractures are classified as infrasyndesmotic (correlating to Danis-Weber Type A injuries), trans-syndesmotic (correlating to Danis-Weber Type B injuries) or suprasyndesmotic (correlating to Danis-Weber Type C injuries) with other subsets based on the presence or absence of medial or posterior malleolar injuries[46,47]. This contrasts with the Danis-Weber classification that ignores the medial and posterior structures. AO/OTA classification system also includes the fracture patterns described by Lauge-Hansen and Danis-Weber[47].

The Lauge-Hansen classification system instead gives more information about the mechanism of injury and anatomic structures involved, and it divides these fractures in four categories and other subgroups. It includes mechanism (with the position of the foot supinated or pronated), the direction of the force at the moment of the trauma (a force causing abduction, adduction or external rotation) and has multiple stages for each type depending on severity[48]. Lauge-Hansen used amputated limbs to divide ankle fractures in which the position of the foot at the time of the traumatic event and to the direction of the forces were crucial points for the injury mechanism knowledge.



Figure 2 Radiographs representing the three types of ankle fractures according to Danis-Weber. A: Infrasyndesmotic; B: Trans-syndesmotic; C: Suprasyndesmotic.

In supination external rotation injuries, the most commonly occurring of Lauge-Hansen's categories, the lateral structures are under stress, and the medial structures are finally compromised. In Stage 1 the talus rotates laterally and pushes the lateral malleolus posteriorly stressing the AITFL that is injured. In Stage 2 progressive external rotation in supination and lateral rotation of the talus results in an oblique or spiral fracture of the distal fibula. Stage 1 and stage 2 are considered stable injuries or fractures. With more force, in Stage 3, the PITFL is injured, or the posterior malleolus (PM) is fractured. Finally, in Stage 4, the medial malleolus is fractured, or the deltoid ligament is disrupted.

Supination adduction injuries are caused by compression force under the medial ankle structures and traction of the lateral ankle structures. In stage 1 either a transverse fracture of the lateral malleolus below the level of the tibial plafond is produced, or the lateral ligaments of the ankle are avulsed of the distal fibula. In Stage 2, either a vertical medial malleolus fracture or injury to the deltoid ligament occur.

In pronation external rotation lesions the foot is pronated, and the deltoid ligament is stressed; this mechanism produces injury of the medial ankle structures. In addition, the external rotation involves the lateral and posterior ankle structures. This results in fibula and PM fractures. In Stage 1 with either deltoid ligament rupture or avulsion, fractures of the medial malleolus are evident. Injuries of the AITFL occur in Stage 2, oblique or spiral fibula fractures proximal to the level of the tibial plafond are observed in Stage 3, and fractures of the PM or injury to the PITFL occur in Stage 4.

In pronation abduction injuries the abduction of the talus causes traction of the medial ankle structures. Stage 1 injuries involve rupture of the deltoid ligament or transverse fractures of the medial malleolus, whereas Stage 2 injuries are associated with damage to the AITFL. In Stage 3, transverse or comminuted fibula fractures were observed above the level of the tibial plafond[47-49].

In conclusion, ankle fractures that are more frequently associated to DTS injuries are those localized over the syndesmosis. Less frequently, these lesions are present in fractures at the level of the syndesmosis and rarely in those positioned under. Concomitant traumas of the medial structures may influence the correct reduction of the fibula inside the tibia at this level and consequently the prognosis.

CLINICAL AND INSTRUMENTAL EXAMINATION

Patients affected by syndesmotic injuries associated to fractures are characterized by swelling, instability and pain at rest that makes loading impossible and is exacerbated by palpation and compression[50].

Several specific syndesmosis tests have been described. The squeeze test consists of compressing the tibia against the fibula at the mid-point of the calf, thus inducing a movement separating the two bones distally[51]. The test is considered positive when it produces a distal pain around the interosseous ligament[52].

The Frick test is performed by applying an external rotation to the foot and ankle with the knee flexed 90°[53]. The ankle is dorsiflexed, and the external rotation of the foot replicates the mechanism of the injury. Pain indicates a positive test[54].

In the Cotton test, medial and lateral forces are applied to the talus; the increased pain in medial-lateral plane translation indicates a positive test result[55].

Finally, in the crossed-leg test the patient is in a sitting position, and the mid fibula of the injured leg is placed on the knee of the healthy leg. The knee is then pushed on the injured leg toward the ground; syndesmosis pain demonstrates a positive result[54].

Unfortunately, none of these examinations are directive in the diagnosis, especially if a fracture is present, because induced pain can limit its development. For this reason, the diagnosis should not only be made based on medical history and physical examination but in conjunction with imaging (also helpful for the preoperative planning) and intraoperative evaluation[55].

Generally, anteroposterior (AP), laterolateral and mortise views are used during radiographic examination. The AP view is useful for evaluating the distal epiphyseal portion of the fibula and tibia. The mortise projection is a variant of the AP projection (obtained with the internal rotation of the foot by 10-15°). The lateral view allows a good evaluation of the posterior tibial tuberosity (Figure 3). Three radiographic parameters have been established to evaluate diastasis of the distal tibiofibular joint: tibiofibular clear space (TFCS)[56,57], tibiofibular overlap (TFO)[56,57] and medial clear space (MCS)[58] (Figure 4).

The TFCS is the distance between the lateral border of the posterior tibial malleolus and the medial edge of the distal epiphysis of the fibula, measured about 10 mm above the tibial plafond in both the AP projection and in the mortise view. Most authors believe that TFCS is the most reliable parameter to suspect a syndesmotic lesion and consider a TFCS greater than 6 mm as pathological[51,59]. Schoennagel *et al*[60] have shown that by setting a TFCS cut-off of 5.3 mm and considering values greater than 5.3 mm as indicative of syndesmotic lesions and values lower than 5.3 mm as not indicative of such lesions, is possible to have a diagnostic accuracy with a specificity and sensitivity of 75% and 82%, respectively.

The TFO is the distance between the lateral edge of the anterior tibial tubercle and the medial edge of the distal epiphysis of the fibula. In normal conditions it should be > 6 mm in the AP projection and > 1 mm in the mortise view. It has been demonstrated that the TFO value has a high degree of variability depending on the rotation of the foot at the time of the X-ray acquisition and that the only parameter that does not vary, according to the rotation of the foot, is the TFCS[51,61].

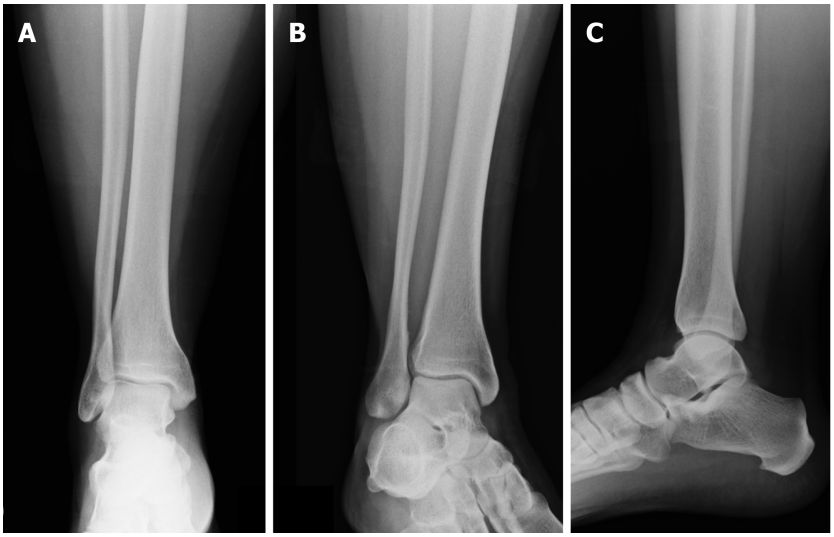


Figure 3 X-ray of the right ankle: standard projections. A: Anteroposterior; B: Mortise; C: Laterolateral views.

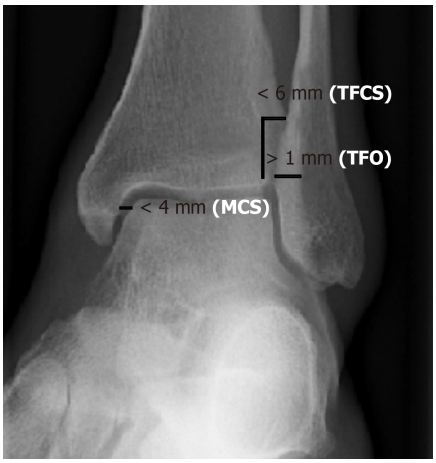


Figure 4 Normal values of tibiofibular clear space, tibiofibular overlap and medial clear space in left ankle mortise projection. MCS: Medial clear space; TFCS: Tibiofibular clear space; TFO: Tibiofibular overlap.

The MCS, measured in the projection of the mortise, is the widest distance between the lateral edge of the medial tibial malleolus and the medial edge of the talus. In normal conditions the MCS should be equal to or less than the space between the tibial plafond and the talar dome[51]. Like the TFO, the value of the MCS varies depending on the rotation of the foot at the time of acquisition of the radiograph[61]. Schoennagel *et al*[60] demonstrated that using the distance of 2.8 mm as a cut-off is possible to discriminate between patients with syndesmotic lesions and patients without syndesmotic lesions with a specificity and sensitivity of 59% and 73%, respectively, and if both TCFS and MCS values were altered, the specificity increased to 86%. Grath *et al*[62] affirmed that it may also be useful to compare the MCS of the affected side with the contralateral and that differences greater than 2 mm may be indicative of syndesmotic lesions.

However, due to the interobserver variation, wide anatomic variability in the depth of the peroneal groove and the shape of the tibial tubercles, these measurements are not reliable unless there is significant disruption of the DTS[1]. If the measurements obtained by radiography are ambiguous, bilateral CT can be useful (Figure 5). Horizontal slices allow measurement of the intertibiofibular gap. With a threshold of 4 mm, the anterior gap (selectivity, 56.5%; specificity, 91.7%) and medial gap (selectivity, 74.4%; specificity, 78.4%) are reproducible measurements, unlike the posterior gap. AP translation of the fibula and rotation with respect to the tibia, TFCS and TFO can also be assessed, and peroneal groove anatomy can be evaluated[51].

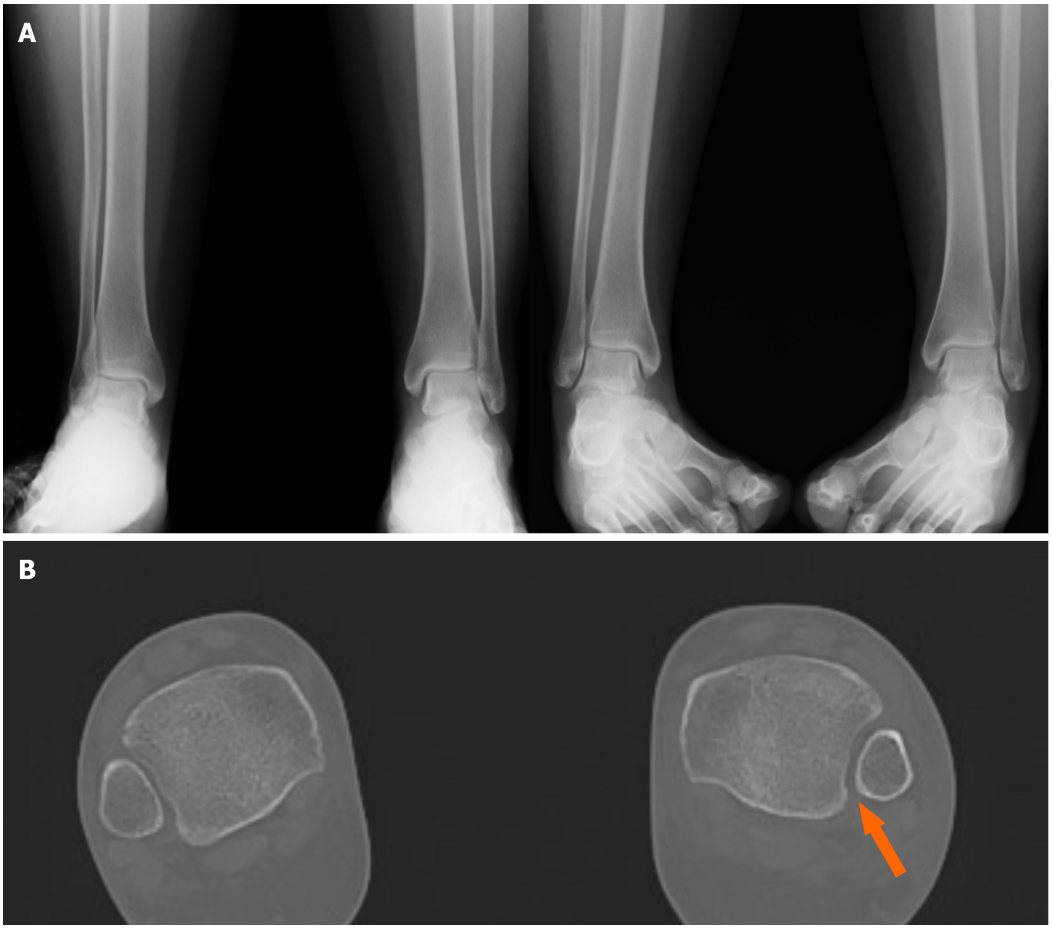


Figure 5 Suspect of a left syndesmotic lesion. A: Comparative X-ray and based on the measurements of the tibiofibular clear space, tibiofibular overlap and medial clear space, the exam was considered negative; B: Computed tomography assessment showed a difference (> 2 mm) between both sides (arrow), demonstrating the presence of a syndesmotic lesion.

In those cases of DTS injuries associated with fractures, preoperative CT should be useful to better study the morphology of the fracture, determine the correct size and shape of the PM fracture, which will determine if the associated plan is the correct surgical procedure[63,64]. In addition, comparative CT can be used in the postoperative evaluation of the correctness of the reduction of the diastasis (Figure 6). The current trend is in favor of stress X-rays and stress CT (external rotation and dorsiflexion) or CT in weight-bearing[51], especially in the detection of chronic disruptions. Magnetic resonance imaging has added benefit to assess the soft tissue condition directly, but it has been found to be useful in both acute and chronic isolated syndesmotic injuries[1,65,66].

Furthermore, the modified Cotton test is largely used during surgery, and it consists in laterally fibula distraction with the use of a bone hook or reduction clamp (Figure 7). An intraoperative fluoroscopic mortise view of the ankle that shows a widening more than 2 mm in the syndesmosis suggests an unstable injury that necessitates fixation[67]. Another intraoperative specific test for the deltoid lesion is the external rotational stress test that is performed after lateral fibular fixation. If there is a talar tilting leading to MCS more than or equal to 5 mm, then the test should be considered positive[68].

Finally, ankle arthroscopy also enables diagnosis of syndesmosis instability, and it can be used as a diagnostic and therapeutic tool[51]. The syndesmosis is judged unstable as of 2 mm diastasis, which is commonly tested by introducing an arthroscopic palpation hook into the tibiofibular joint line[58,59]. If fixation is indicated, then arthroscopy may guide extra-articular stabilization[51].

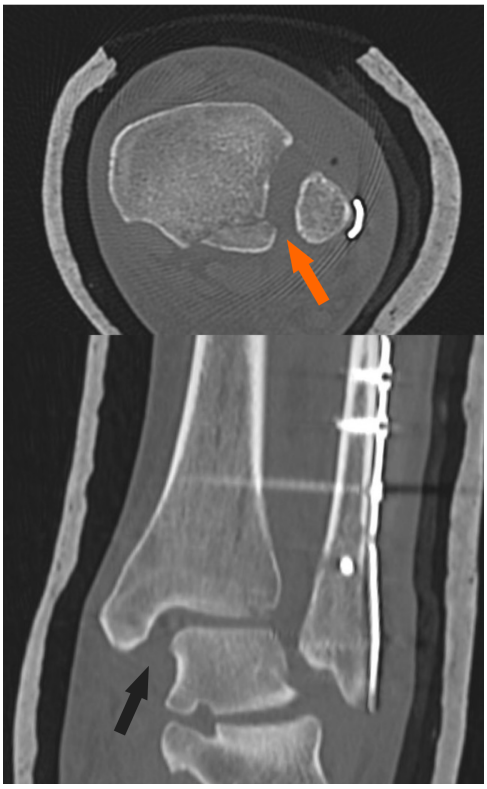


Figure 6 Postoperative computed tomography scans of a syndesmotic lesion showing a widened tibiofibular space (arrows) indicative of an inadequate reduction.

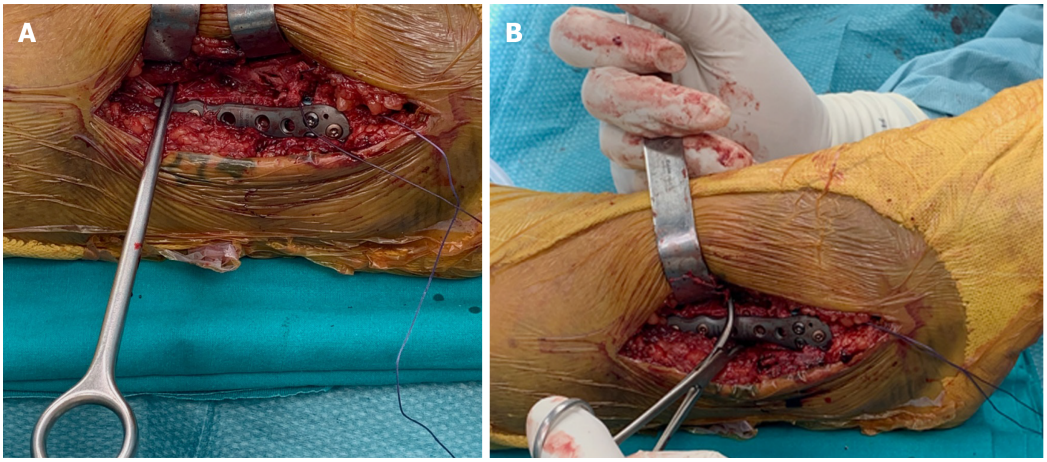


Figure 7 Intraoperative view. A: Modified Cotton test with hook; B: Modified Cotton test with reduction clamp.

SURGICAL TREATMENT AND POSTOPERATIVE CARE

All injuries with evident diastasis require surgical stabilization[69,70]. The goal of treatment is to restore joint congruency and to maintain the stability of the syndesmosis until the ligaments have healed. The ideal implant should stabilize the joint but also allow its physiological movements and that of the ankle, thus guaranteeing an early mobilization.

Surgery initially involves stabilization and restoration of the fibular length, followed by the fixation of the PM and finally of the tibia. The indications for fixation of the PM remain controversial. Historically, these included fractures involving > 25% to 33% of the joint surface, displacement > 2 mm, ankle instability in association to syndesmotic lesion and persistent posterior subluxation of the talus[71,72].

However, up to now, there has not been any strong clinical evidence for this practice, and the percentage of articular surface of PM has been questioned, as studies

have demonstrated the importance of even small posterior malleolar fragments to ankle stability, and surgical indications have expanded. The historic criteria based on size could underestimate the number of fractures that requires operative intervention[73].

In a prospective study of outcomes of syndesmotic injuries with posterior malleolar fractures, Miller *et al*[74] found that posterior malleolar fixation was equivalent to fixation with syndesmotic screws or combined fixation. The results of these studies would lead to the conclusion that even small posterior malleolar fractures should be repaired in ankle fractures with syndesmotic disruption. Anatomic reduction of the PM additionally recreates the incisura fibularis, the congruity of the articular tibial surface and should minimize the risk of posterior translatory malreduction of the syndesmosis as the PITFL is intact.

Warner *et al*[75] went so far as to say ligamentous repair of the PITFL is critical in ankle fractures. They studied PITFL injuries in the absence of the PM fracture and found that most lesions occur as a delamination of the ligament from its attachment to the PM. In conclusion, they suggested that repair techniques to fix the PITFL to its footprint on the PM may provide an effective stabilization of the syndesmosis and that this approach could potentially obviate the need for further DTS stabilization.

Different surgical approaches and techniques for internal fixation of PM fractures [percutaneous anterior to posterior screw fixation or open reduction and internal fixation using screws or buttress plates from posterior to anterior] have been reported[76]. Indirect reduction and stabilization with AP screws remain the early common method[76,77]. The disadvantages of this type of fixation of the PM are that anatomical reduction is more difficult due to the interposition of soft tissues or loose bony fragments, which is hard to assess reduction satisfactorily using an image intensifier, and the fixation of small or comminuted fragments is technically difficult. Furthermore, symptomatic tibial nerve entrapment syndrome has been described[78].

For this reason, several surgeons prefer open and anatomical reduction. The choice of the surgical approach must be guided by the characteristics of the ankle's fracture thus including the PM. Precise classifications of PM fractures, based on CT examination, are undoubtedly helpful as different studies have shown inadequacy of radiographs in assessing the shape and the size of the PM detached but also the real involvement of the fibular notch and of the medial malleolus[63,79,80]. In this context the most utilized classification systems are from Haraguchi[64], who conducted a CT study to clarify the pathologic anatomy of the PM fractures, and from Bartoníček[63].

The posterolateral approach has been described in the literature and has received much attention. Surgery is usually performed in the prone position. Most surgeons prefer an incision between the peroneal and Achilles tendons, but others did perform the incision just medial to the posterior border of the fibula[81]. This approach allows a direct visualization and reduction of the posterior fragment, even if addressing the posteromedial malleolar fracture is more difficult. In this case an incision immediately laterally to the Achilles tendon can facilitate fixation of the more medial part of the PM fracture. On the other hand, posterolateral approach has the potential to cause sural nerve injuries and that prone position may render open reduction and internal fixation of the medial malleolus more challenging[76].

Another possible approach is the posteromedial, which allows fixation of the medial and PM through the same incision, even if for a typical posterolateral fragment it would seem suboptimal[82].

In types II and IV fractures according to Bartoníček, which correspond to type I of Haraguchi's classification, a posterolateral approach with mobilization of the peroneal tendon is used almost exclusively. For fixation of type III lesions, which corresponds to type II of Haraguchi's classification, a posteromedial approach is preferred. In selected cases, in which the reduction of both posterior fragments is not possible, a combined posteromedial and posterolateral approach have been utilized[83,84].

Definitive osteosynthesis of PM fragments depends on the number and size of the fragments and on quality of the bone. Later, the surgeon must decide the necessity of an additional syndesmotic fixation. This choice depends on DTS stability and must be evaluated manually and fluoroscopically during surgery[21]. Various stabilization modalities of DTS have been used[2]. They can be divided by SF techniques (metallic or bioabsorbable screws, staples, syndesmosis hooks, Kirschner wires) and DF techniques (suture-button)[2,16-18].

SF with cortical screws is the reference standard fixation method. However, some significant issues should be considered. Screw loosening, breakage (Figures 8 and 9), discomfort, pain related to overcompression, the need for a reoperation for screw removal and the risk of late diastasis after early removal are potential drawbacks of this type of fixation[20-24]. Syndesmotic screw is the oldest surgical device utilized,

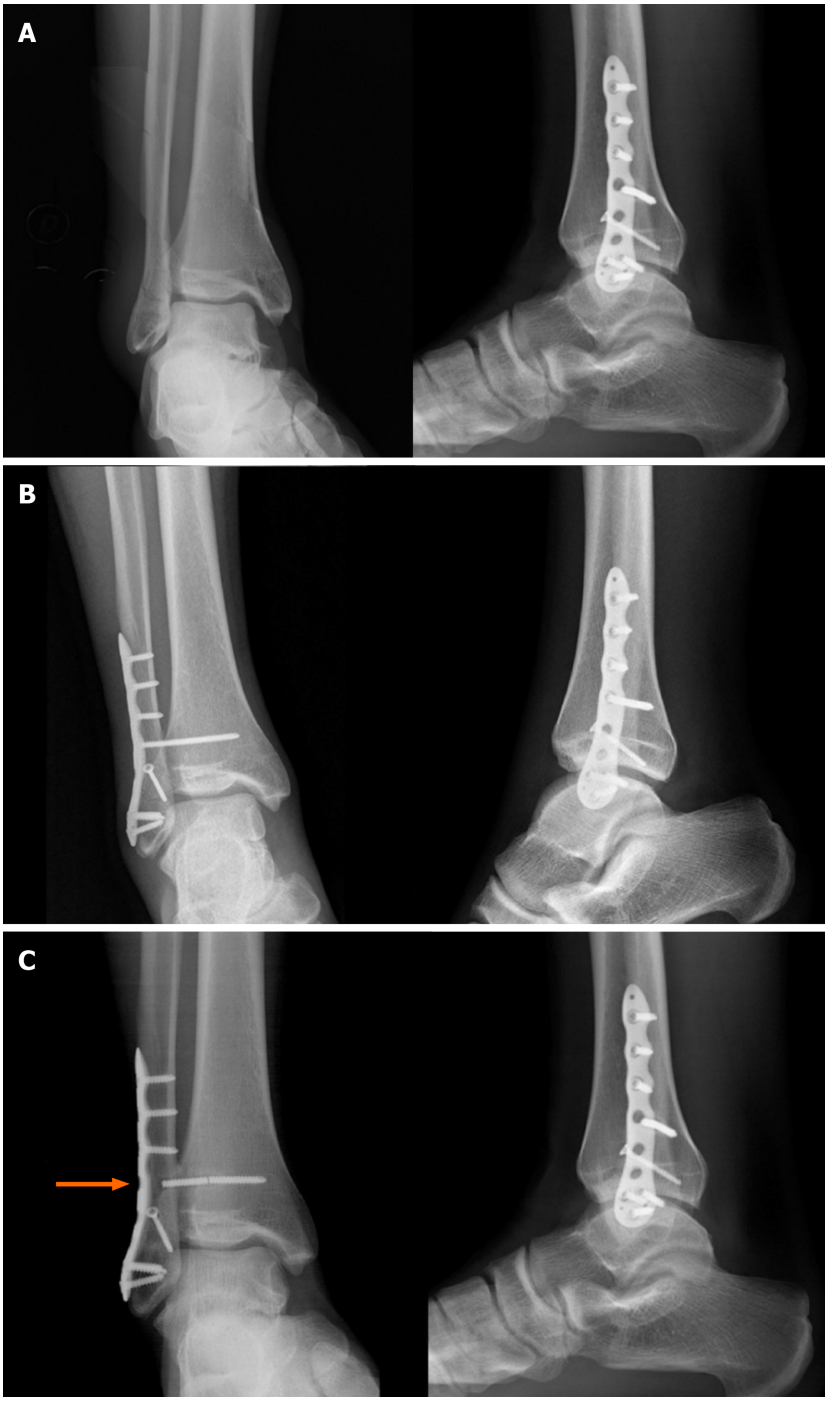


Figure 8 Type B ankle fracture. A: Preoperative X-rays; B: Radiographs 1 mo after surgery; C: Radiographs 2 mo after surgery following removal of the screw that was discovered broken (arrow) during the second procedure.

and it was first described by Burwell *et al*[70] in 1965. In the literature there is a wide debate about the type, size and number of screws to be placed, the optimal distance from the tibial plafond, the optimal number of cortices to cross, the position of the foot during fixation, the timing and real need for screw removal.

The screw that is more frequently used is metallic. As mentioned, it stabilizes the joint allowing the injured ligaments to heal. However, this fixation does not completely permit the physiological reciprocal movement between the fibula and tibia. It often requires removal, with the associated increased risk of complications (infections and recurrence of diastasis) and higher costs. For these reasons, bioabsorbable devices have been developed, first produced in polyglycolic acid, subsequently in polylactic acid and currently in polylevolactic acid. These devices gradually reabsorb by hydrolysis, thus allowing a progressive recovery of the syndesmosis function[85]. The bioabsorbable screw has shown the same efficacy in maintaining stability, and the incidence of rupture and infection is similar to that of



Figure 9 Type C ankle fracture and dislocation. A: Preoperative X-rays; B: Postoperative X-rays; C: Radiographs performed 3 mo after trauma with breakage of the proximal intersyndesmotic screw (arrow).

the metal one. The reoperation rate is lower, and in about 13% of cases there is a foreign body reaction that can last for months. In some cases, it can lead to a second intervention[86,87].

One or two 3.5 mm or 4.5 mm diameter screws can be used, and there are no statistically significant differences in short and long-term outcomes and functionality between these two diameters. Biomechanical studies have shown that the breaking load is higher in 4.5 mm screws and that the presence of two screws ensures greater biomechanical stability. Nevertheless, these differences have no clinical significance because it has been demonstrated that the single 3.5 mm diameter screw is able to maintain adequate stability *in vivo*[88,89].

Tricortical and quadricortical screws have been compared in terms of stability and outcomes. Tricortical fixation is a less rigid system for stabilizing a syndesmosis, and it recreates a more similar syndesmosis biomechanism with less breakage risk. However, quadricortical fixation, with one or two screws, is characterized by less occurrence of syndesmotic widening during the healing period, although it is more rigid. In any case, fixation after reduction should be performed 2-4 cm above and parallel to the joint line and perpendicular to the distal tibiofibular, from posterior to anterior through the fibula and tibia with an inclination of 25°-30°[90,91].

The influence on the short and long-term outcomes of the foot position to be maintained during fixation is still unclear. Olerud *et al*[92] suggested placement of the syndesmotic screw with the foot in dorsiflexion to avoid limitations of this movement. Other authors instead have recently demonstrated that the most important aspect of fixation is anatomic reduction of the syndesmosis, and dorsiflexion during fixation has less importance. They concluded that foot position does not influence long-term outcomes[93]. However, the possibility of excessive compression and, consequently of a limitation of dorsiflexion, is described, but it is observed when the screw is tightened too hard, or it is attributable to the excessive force applied with the reduction clamp at the time of positioning the screw, which does not depend on the foot position[94].

The optimal force that should be applied with a clamp to reduce the syndesmosis is currently unknown. Fluoroscopy is typically used for intraoperative assessment of the reduction of the syndesmosis. However, the use of other intraoperative imaging studies have been evaluated (intraoperative CT). Obtaining intraoperative mortise and perfect lateral fluoroscopic views of the talar dome of both ankle before fixation could help in determining the relationship between the fibula and tibia in the ankle and to reduce the risk of overcompression[93].

The real need for the removal of the intersyndesmotic screw is a topic that has been the subject of debate for years. The authors that suggest to always remove the screw maintain that otherwise the biomechanics of the ankle joint and its dorsiflexion could be hindered, and the load could therefore lead to the breaking or mobilization of the screw[95]. Other authors instead have shown that patients with retained or broken devices do not show significant differences in terms of outcomes and complications compared to those with intact ones[96]. Furthermore, their removal, especially in patients who present a delayed healing of the surgical wound following the first operation, is subject to a higher rate of infection. For these reasons, the percentage of patients in which the screw has not been removed has passed from 8% in 2004, to 14% in 2008, to over 35% in 2010[97], and as a consequence the routine screw removal is not recommended now. However, this procedure may be indicated in cases of intolerance, poor joint reduction and when it is indicated to remove the synthesis hardware of the associated malleolar fracture[98]. In these cases, extraction should be scheduled no earlier than 8 wk (preferably 10-12 wk) as it has been amply demonstrated that removal within the first 8 wk is burdened by a higher incidence of loss of reduction and recurrence of diastasis[99].

In any case, one of the main problems in screw maintenance cases is the management of the patient in the postoperative period. In many cases, the patient struggles to accept the idea of being able to weight bear on a retained screw, and similarly he/she does not accept the idea of maintaining a screw that is broken (although this does not involve any risk)[100]. Consequently, if the surgeon decides to maintain the screw, it is therefore necessary to adequately explain to the patient the risk of rupture of the screw and that any breakage does not lead to more complications.

To overcome the excessive joint stiffness and the increased stress on the interosseous membrane that a static stabilizer causes, an alternative system of dynamic stabilization with an implanted suture-button device has been developed. It consists of a nonabsorbable synthetic suture between two metallic buttons implanted across the DTS[4,25], and it is characterized by less risk of hardware pain and recurrent syndesmotic diastasis, quicker return to mobility, maintenance of physiologic movement while retaining reduction, earlier rehabilitation and no need for removal[101,102]. It has also been shown that the position of the foot at the time of implant fixation does not affect stability, postoperative range of motion and outcomes[103]. Several literature reviews and meta-analyses confirmed these significant clinical advantages, but sometimes a greater residual diastasis is described. Instead, syndesmosis screws provide more rigid assembly but a higher rate of poor reduction (12%-39%), ablation (40%-50%), breakage (up to 30%) and more local discomfort[104]. Nevertheless, there is no agreement on whether DF methods are superior to SF methods in terms of long-term functional outcomes, change in range of motion, complication rates and incidence of reoperation[26,27,105].

Equally important is the postoperative treatment. To prevent the equinus of the foot, the ankle is kept at rest with the foot at 90° by means of a plaster splint applied posteriorly. The patient is encouraged to move the toes early. If the wounds are satisfactory, then passive and active mobilization of the ankle under the control of the therapist can begin after 24-48 h. Once active dorsiflexion is achieved, the decision to leave the ankle free or to keep it still with the plaster cast depends on various factors, such as the stability of the internal fixation obtained by the surgeon, the patient's general mobility and the prospects for adhesion to the chosen postoperative regimen. It has been shown that long-term results are similar with both the immobilized and the free ankle, during the first 6 wk after surgery[106]. Loading decisions, with or without plaster, also largely depend on the stability of the fixation obtained and the patient's cooperation. Most authors recommend avoiding weight-bearing for 8-10 wk whether the screw is removed or left in place[15].

AUTHORS PREFERRED SURGICAL METHOD

Patients are positioned with a tourniquet applied, and the surgical procedure is done under fluoroscopic control. In the cases of trimalleolar fractures, we initially stabilize and restore the fibula length and consequently synthesize the PM and finally the tibia. We prefer open reduction of posterior malleolar fragment through a posterolateral approach in types II and IV and a posteromedial approach in type III fractures according to Bartoníček classification. In selected cases, when reduction and fixation of both posterior fragments is difficult to achieve, we have opted for a combined posteromedial and posterolateral approach (Figure 10).

The choice of the fixation devices (screws or plates) depends on the intraoperative characteristics of the fractures and the quality of the bone. The decision to stabilize the DTS depends on the positivity of the modified Cotton test. We prefer the use of reduction clamp instead of bone hook because of its minor aggressiveness towards the soft tissues between tibia and fibula.

We obtain DTS fixation with one tricortical 3.5 mm screw that is positioned approximately 2.5-3.0 cm proximal and parallel to the tibiotalar joint with the foot in dorsiflexion at 90° (Figure 11).

In most cases the simple screwing determines the closure of the DTS. If this does not happen, then we first try to reduce the diastasis with forceps before placing the screw. If despite this maneuver the DTS reduction is not sufficient, then we perform a medial surgical exploration to verify if the deltoid ligament is detected between the malleolus and the talus.

In the immediate postoperative period, a plaster cast with the foot at 90° is applied for 48 h. After this period, if the stability of the fixation obtained is good, the wound healing is positive and the patient is collaborative, then the cast can be replaced by a removable bivalve ankle brace with the aim to begin early active and passive progressive mobilization under the control of the therapist. We recommend avoiding weight-bearing for 8-10 wk whether the screw is removed or left in place.

Until 5 years ago, the authors always removed the screw after 8-10 wk from surgery. Based on recent findings in the literature, they currently rarely remove this device. The patient is informed regarding the possibility of screw rupture and that this occurrence does not compromise the long-term functional result.

Intolerance, pain, poor reduction obtained and necessity to remove malleolar fracture hardware does lead us to consider this second surgery. Screw removal is then performed under local anesthesia and fluoroscopic control. Antibiotic prophylaxis with first generation cephalosporin (cefazoline) is always administered.

CONCLUSION

The stability and correct anatomy of the DTS is essential for normal biomechanics of the ankle. Syndesmosis injuries occur following spraining trauma especially in external rotation, and they can be isolated or, more frequently, associated with malleolar fractures. In the latter case, specific clinical tests for the evaluation of syndesmosis are not reliable due to the important painful symptoms of the fracture. Consequently, preoperative imaging and specific intraoperative tests, performed after completing the synthesis of the associated malleolar fractures, are essential for the definitive diagnosis and indication for stabilization of the DTS. In this context, the Danis-Weber radiological classification and the modified Cotton test are the most used and complete.

Furthermore, especially if the images obtained by radiography are not conclusive, preoperative CT is mandatory in order to better evaluate the size, shape and location of fracture fragments and to assess the stability of the tibiotalar joint through more precise measurements and the integrity of the fibular notch[63,74,76,107]. In those cases where after fracture stabilization the DTS remains unstable, the different treatment options include SF and DF techniques. To this day, the intersyndesmosis screw remains the most widely used method of stabilization.

Despite the numerous anatomical, biomechanical and comparative studies performed, there is still a wide debate as to which surgical technique is the best. From the analysis of the literature, it emerged that the type, size and number of screws, the number of cortices to cross, the distance from the tibial plafond and the position of the foot during fixation do not significantly affect the short and long-term results.

It will be a choice of the surgeon in accordance with the patient whether to remove or maintain the screw. The removal is indicated in those cases characterized by

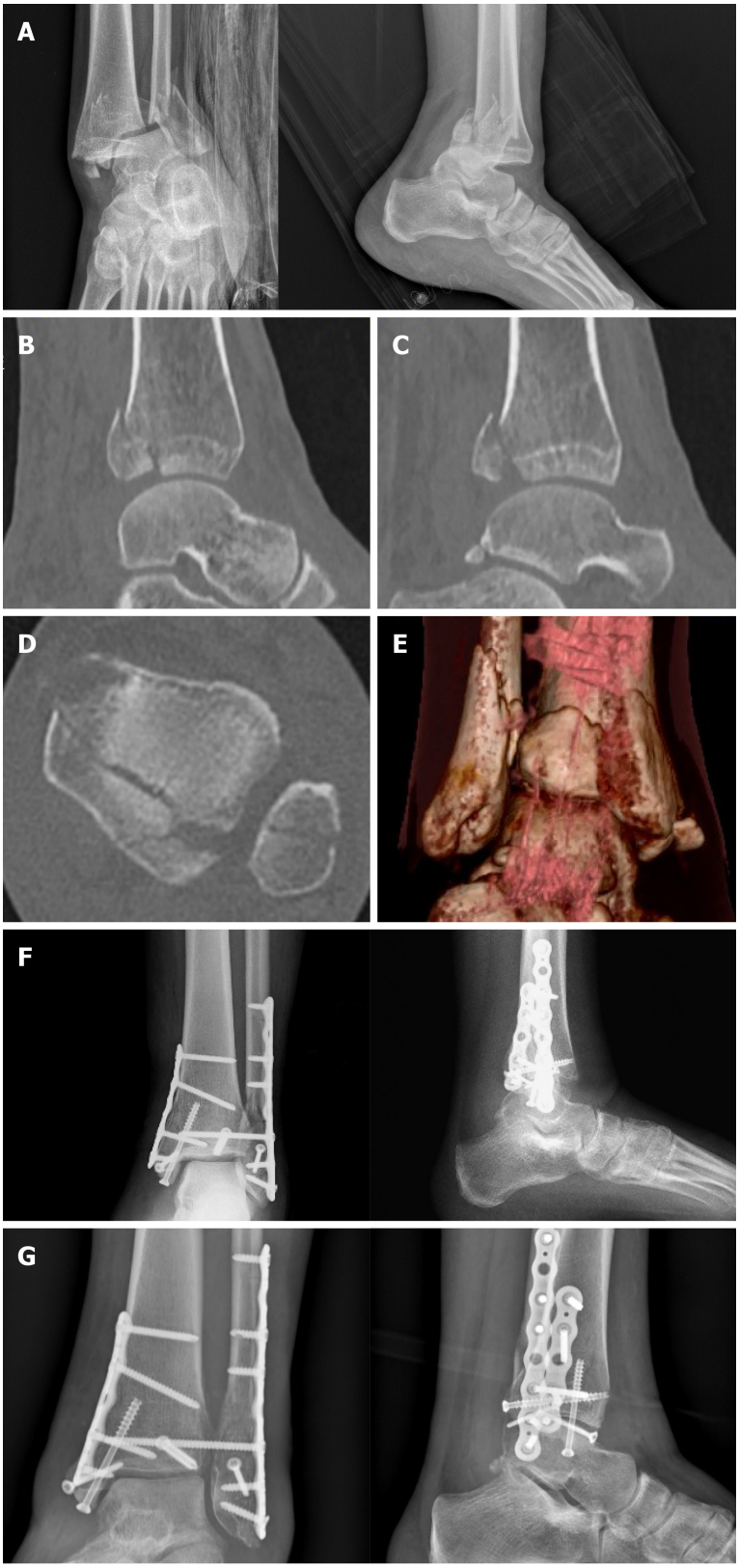


Figure 10 Trimalleolar right ankle fracture associated with dislocation. A: Preoperative X-rays; B and C: Computed tomography sagittal views with posterior malleolar fracture [tibial portion (B) and peroneal portion (C)]; D: Computed tomography axial view; E: Three dimensional computed tomography; F: Postoperative radiographs after fixation of the fibula and of the lateral part of the posterior malleolus with a P-A screw through a posterolateral approach and of the medial malleolus and of the tibial part of the posterior malleolus through a posteromedial approach (plates and screws); G: X-rays 8 mo following surgery with consolidation.

intolerance, pain, malreduction or if it is necessary to remove the hardware implanted for associated malleolar fractures. In this regard, it is important to emphasize that screw rupture does not negatively influence the clinical results. If removal is



Figure 11 Type C ankle fracture. A: Preoperative X-rays and computed tomography performed after closed reduction with diastasis (asterisks); B: Intraoperative positioning of the 3.5 mm intersyndesmotic screw with the foot positioned at 90° of dorsiflexion; C: Postoperative radiographs; D: Removal of the screw 2 mo after surgery; E: Views 6 mo after trauma with fracture consolidated.

performed, then it must be scheduled after at least 8 wk to avoid the risk of recurrence of the diastasis. However, it is well established that in this type of fixation the possibility of screw loosening, breakage, discomfort, the need for a reoperation for screw removal and the risk of late diastasis after early removal should be considered.

These drawbacks seem to be canceled by dynamic fixation with the endobutton, which has become increasingly popular as it allows a more physiological articular movement, early rehabilitation, satisfactory functional outcomes and no requirement for implant removal. Nevertheless, there is no unique consensus on whether DF methods are superior to the static ones.

Another frequent complication of DTS stabilization associated with fractures is malreduction. This is the consequence of an inadequate closure of the malleolar forceps, of an abnormal anteriorization or posteriorization of the fibula with respect to the tibia or of a rotational fibular malalignment. For this reason, if the simple screwing does not close the DTS, then the authors suggest trying to reduce the diastasis with forceps before placing the screw, considering that an excessive tension of the forceps can favor the anterior translation of the fibula. If despite this maneuver the DTS reduction is not sufficient, then they perform a medial surgical exploration to verify if the deltoid ligament is detected between the malleolus and the talus. In doubtful cases, a bilateral postoperative CT is helpful for evaluating the correct reduction.

In addition to malreduction, the development of heterotopic ossification and more rarely tibiofibular synostosis is reported. Functional consequences of these complications are questionable and often no special treatments are needed due to real symptoms[108]. Alternatively, in rarer cases persistent pain related to heterotopic ossification and synostosis required surgical treatment[67].

Finally, the authors are confident that postoperative care is another important aspect for positive outcomes. They agree with most authors that loading is not recommended until the screw is removed, or if it is not removed, then for 8-10 wk after surgery, depending on the stability of the synthesis obtained and the patient's characteristics. Active and passive exercises of the ankle are allowed immediately after surgery.

In conclusion, patients with unstable injuries require surgical stabilization [15,95,105,109]. The aim of surgical treatment is to restore joint congruency and to maintain the stability of the syndesmosis until the ligaments have healed. Satisfactory results depend on a correct management from diagnosis to treatment. SF and DF systems have similar long-term clinical and radiological outcomes.

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ORIGINAL ARTICLE

Retrospective Study

Reducing unnecessary crossmatching for hip fracture patients by accounting for preoperative hemoglobin concentration

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Abstract

BACKGROUND

Maximum surgical blood order schedules were designed to eliminate unnecessary preoperative crossmatching prior to surgery in order to conserve blood bank resources. Most protocols recommend type and cross of 2 red blood cell (RBC) units for patients undergoing surgery for treatment of hip fracture. Preoperative hemoglobin has been identified as the strongest predictor of inpatient transfusion, but current maximum surgical blood order schedules do not consider preoperative hemoglobin values to determine the number of RBC units to prepare prior to surgery.

AIM

To determine the preoperative hemoglobin level resulting in the optimal 2:1 crossmatch-to-transfusion (C:T) ratio in hip fracture surgery patients.

to disclose.

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METHODS

In 2015 a patient blood management (PBM) program was implemented at our institution mandating a single unit-per-occurrence transfusion policy and a restrictive transfusion threshold of < 7 g/dL hemoglobin in asymptomatic patients and < 8 g/dL in those with refractory symptomatic anemia or history of coronary artery disease. We identified all hip fracture patients between 2013 and 2017 and compared the preoperative hemoglobin which would predict a 2:1 C:T ratio in the pre PBM and post PBM cohorts. Prediction profiling and sensitivity analysis were performed with statistical significance set at $P < 0.05$.

RESULTS

Four hundred and ninety-eight patients who underwent hip fracture surgery between 2013 and 2017 were identified, 291 in the post PBM cohort. Transfusion requirements in the post PBM cohort were lower (51% *vs* 33%, $P < 0.0001$) than in the pre PBM cohort. The mean RBC units transfused per patient was 1.15 in the pre PBM cohort, compared to 0.66 in the post PBM cohort ($P < 0.001$). The 2:1 C:T ratio (inpatient transfusion probability of 50%) was predicted by a preoperative hemoglobin of 12.3 g/dL [area under the curve (AUC) 0.78 (95% confidence interval (CI), 0.72-0.83), Sensitivity 0.66] in the pre PBM cohort and 10.7 g/dL [AUC 0.78 (95%CI, 0.73-0.83), Sensitivity 0.88] in the post PBM cohort. A 50% probability of requiring > 1 RBC unit was predicted by 11.2g/dL [AUC 0.80 (95%CI, 0.74-0.85), Sensitivity 0.87] in the pre PBM cohort and 8.7g/dL [AUC 0.78 (95%CI, 0.73-0.83), Sensitivity 0.84] in the post-PBM cohort.

CONCLUSION

The hip fracture maximum surgical blood order schedule should consider preoperative hemoglobin in determining the number of units to type and cross prior to surgery.

Key Words: Hip fracture; Transfusion; Blood conservation; Hemoglobin; Type and cross; Maximum surgical blood order schedule

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Core Tip: Implementation of patient blood management programs has led to a decrease in transfusion needs in hip fracture surgery patients. Preoperative hemoglobin plays a significant role in determining transfusion needs in these patients. Maximum surgical blood order schedules should be adjusted based on preoperative hemoglobin values to reduce unnecessary blood product waste and conserve resources.

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INTRODUCTION

Patients with hip fractures constitute a particularly frail patient population due to their elevated comorbidity burden[1]. Given the nature of the injury and poor health status of this population, many of these patients require perioperative allogeneic red blood cell (RBC) transfusions[2,3]. Transfusions in this population are not without risk as they are independently associated with surgical site infection and 1-year mortality and also represent a limited resource[4-7]. As such, substantial focus has been placed upon reducing the use of allogeneic RBCs in this population[8]. Several measures including quicker time to surgery, conservative transfusion practices, and use of anti-fibrinolytic agents have been employed to successfully to reduce the transfusion incidence from 50% of patients to 30%-35% more recently[8-13].

As blood transfusion rates have decreased, adjusting the number of units preoperatively cross-matched is an important consideration. Over-crossmatching increases both the number of units taken out of the available blood bank inventory and the likelihood of discarding those units as they become closer to their storage duration limit[14]. To successfully reduce unneeded type-and-cross (T&C) of blood prior to major surgical procedures, maximum surgical blood order schedules (MSBOS) have been widely adopted[15]. Several algorithms for calculation have been employed with a consensus placed on optimum crossmatch to transfusion (C:T) ratio of 2:1 for any surgical procedures[14,16,17]. These base crossmatching recommendations on surgical procedure to be performed without incorporation of patient specific variables [19]. Patient specific factors have been previously shown to better predict RBC needs but are not employed in MSBOS[19-21].

Nationally, most institutions practice crossmatching 2 units RBC ahead of hip fracture surgery[17]. These guidelines may be based on RBC utilization with a transfusion threshold of < 8 g/dL, as recommended by the American Association of Blood Banks and American Academy of Orthopaedic Surgeons[23,24], however, an increasing body of recent literature has demonstrated that transfusion thresholds of Hgb < 7 g/dL are safe in this population[10]. As such, using this crossmatch generalization for all hip fracture patients inadvertently results in over-crossmatching for many patients, while potentially under cross-matching for a small subset of very frail patients. It stands to reason that more accurate cross-matching practices could be determined by using broadly understood patient specific factors, including preoperative hemoglobin, which, although not typically considered in the MSBOS, has been identified as one of the strongest predictors of transfusion requirements[2,25-27].

In an era of increased emphasis on value-based care, incorporation of simple, predictive patient factors is necessary to prevent unneeded crossmatching. With our implementation of a widely utilized restrictive transfusion strategy (hemoglobin transfusion threshold of < 7 g/dL in asymptomatic patients, < 8 g/dL in history of coronary artery disease, and single RBC unit per occurrence) we sought to redefine clinically significant anemia (the Hgb level which predicts a 50% transfusion rate) to reduce the number of units crossmatched for this population.

MATERIALS AND METHODS

Institutional review board approval was obtained for this study. Documentation of consent was waived by our institutional review board as this was a minimal risk retrospective review of electronic medical record data.

We reviewed the medical records of 498 consecutive patients admitted to our level 2 trauma center from January 2013 to May 2017. Patients with *Arbeitsgemeinschaft für Osteosynthesefragen* classification fractures of 31A1, 31A2, 31A3, 31B1, 31B2, 31B3, 31C1, 31C2, 31C3 were eligible for inclusion. Patients were excluded if they were both admitted and discharged by the acute care general surgery trauma service or if the fracture was oncologic in nature. The prior exclusion criteria were based on the high likelihood of additional, nonorthopaedic, surgical procedures in these population per our institutional admitting guidelines.

Beginning in January 2015 a patient blood management (PBM) program was implemented at our institution. This program included lowering postoperative RBC transfusion threshold to Hgb < 7 g/dL in hemodynamically stable patients and < 8 g/dL in patients with a history of coronary artery disease or symptomatic anemia (hypotension and/or tachycardia refractory to fluid management, lightheadedness, and lethargy), and single-unit pRBC transfusions followed by reassessment before transfusion of additional units. Antifibrinolytic agents such as tranexamic acid were not used in our patient population. Based on the implementation date of January 1, 2015, patients were stratified into a pre-PBM group (January 2013 through December 2014, n = 201) and a post-PBM group (January 2015 through May 2017, n = 297) for analysis.

Pre-, peri- and post-operative outcomes were analyzed. The primary outcome was the admission hemoglobin which predicted the 2:1 C:T ratio (50% probability of a transfusion event during the entire hospital stay) in the pre- and post-PBM cohorts. The secondary outcome was the admission hemoglobin which predicted a 50% probability of multiple unit transfusion in the pre- and post- PBM cohorts. The mean RBC units transfused per patient was calculated for the pre- and post-PBM cohorts and compared using the Kruskal-Wallis test. Predictive modeling was utilized to generate a receiver operating curve and determine the pre- and post-PBM hemoglobin

threshold which predicted a 50% transfusion event rate during the entire admission. This is consistent with previously described methods[16,28]. 95% confidence intervals (CI) were reported for each area under the curve (AUC) value. Two-sided t-tests were used for univariate analysis of continuous variables, and chi-square tests were used for categorical variables. A value of $P < 0.05$ (two-sided) was considered statistically significant. Analyses were performed using JMP, version 13.0.0, software (SAS Institute, Cary, NC).

RESULTS

Demographics

Preoperative characteristics of the two cohorts are demonstrated in Table 1. The post-PBM cohort had a slightly higher rate of congestive heart failure. There were no differences in preoperative use of anticoagulation, dual antiplatelet therapy, cardiopulmonary risk factors, need for transfusion at Hgb < 8 g/dL instead of < 7 g/dL, fracture location, or treatment type. The preponderance of patients in both cohorts had intertrochanteric fractures treated by cephalomedullary nailing.

Transfusion utilization

The mean RBC units transfused per patient in the post-PBM cohort was 0.66, significantly lower than the 1.15 RBC units per patient in the pre-PBM cohort ($P < 0.001$). In the post-PBM cohort, both the percentage of patients requiring one or more units of RBCs declined significantly (51% *vs* 33%, $P < 0.0001$) (Table 1).

Primary outcome

With implementation of the PBM program, a 50% probability of a transfusion event in the post PBM cohort was predicted by a preoperative hemoglobin of Hgb 10.7 [AUC 0.78 (95%CI, 0.73-0.83), Sensitivity 0.88]. For those patients in our study with a preoperative hemoglobin of > 10.7 g/dL, implementation of a single unit crossmatch policy would have resulted in 6.3% of our population initially undercrossmatched by 1 pRBC and 5.2% by > 1 unit. For the pre-PBM cohort a 50% probability of transfusion event was predicted by a preoperative Hgb of 12.3 [AUC 0.78 (95%CI, 0.72-0.83), Sensitivity 0.66] (Figure 1).

Secondary outcomes

Multiple unit transfusion status was substantially different between the two cohorts. The pre-PBM cohort had a 50% probability of multiple unit transfusion at a preoperative hemoglobin of 11.2 [AUC 0.80 (95%CI, 0.74-0.85), Sensitivity 0.87] (Figure 2) whereas this value was hemoglobin 8.7 [AUC 0.78 (95%CI, 0.73-0.83), Sensitivity 0.84] (Figure 2) in the post-PBM cohort. For those patients in our study with a preoperative hemoglobin of > 8.7 g/dL, use of a 2:1 unit crossmatch policy would have resulted in undercrossmatching 4.3% of our population by 1 unit and 2.9% by > 1 unit for the entire hospitalization.

DISCUSSION

With PBM programs and improvements in peri-operative care of hip fracture patients, the RBC transfusion requirements of this population have declined. Thus, the routine crossmatch of 2 units preoperatively may not be necessary. Our data suggest that with a restrictive transfusion threshold of Hgb < 7 g/dL and single unit per transfusion occurrence, a substantial number of patients require only a type-and-screen (T&S), or T&C of one RBC unit during their inpatient hospitalization. Specifically, the ideal preoperative blood orders may be a T&C of 2 units with a preoperative Hgb < 9 g/dL, a T&C of 1 unit with a preoperative Hgb < 11 g/dL, and a T&S when the preoperative Hgb is > 11 g/dL.

Though the hip fracture patient population is well-studied in the literature, data regarding hemoglobin thresholds for optimal preoperative blood ordering are relatively scarce. Multiple studies have found that preoperative hemoglobin values of 7-12 g/dL predict perioperative transfusion, though few have used this information to determine a cross-matching algorithm[27,29,30]. To our knowledge, only one study has risk stratified the number of units to crossmatch preoperatively based on starting preoperative hemoglobin for patients with hip fracture. The 2002 study advocated for

Table 1 Preoperative characteristics of 498 hip fracture cases before *vs* after implementation of a patient blood management program, *n* (%)

Variable	Pre-PBM (*n* = 201) (January 2013 – December 2014)		Post-PBM (*n* = 297) (January 2015 – May 2017)		*P* value
	mean ± SD		mean ± SD		
Age (yr)	77 ± 15		76 ± 16		0.68
Case mix index[1]	1.9 ± 0.6		1.9 ± 0.9		0.36
Preoperative Hb, g/dL	12.1 ± 1.9		12.1 ± 2.0		0.96
Male sex		58 (29)		110 (37)	0.26
Cardiac disease		42 (20.3)		67 (23.0)	
Congestive heart failure		11 (5.3)		19 (6.5)	0.04
Pacemaker		18 (8.7)		37 (12.7)	0.57
Chronic kidney disease		18 (8.7)		37 (12.7)	0.15
COPD		30 (14.5)		47 (16.2)	
Requiring home oxygen		9 (4.3)		14 (4.8)	
Anti-platelet agent use		80 (38.7)		103 (35.4)	0.57
Anticoagulation use		27 (12.0)		48 (16.5)	0.29
Extracapsular Fracture		127 (61)		169 (58)	0.46
Independent in ADL		152 (73.4)		215 (73.9)	0.91
Cephalomedullary nail		122 (59)		161 (55)	0.78

[1]Case mix index is the weighted all patients refined diagnosis related group score. COPD: Chronic obstructive pulmonary disease; ADL: Activities of daily living; PBM: Patient blood management.

crossmatching of 2 units for Hgb > 12.5 g/dL and 4 units for Hgb 10-12.5 g/dL. Given the vast aforementioned improvements in the care of patients with hip fracture of the past decade and the transfusion threshold of 10 g/dL utilized in this 2002 study, these recommendations are likely not suitable for current practice[31].

While there are many individual preoperative patient characteristics that can be utilized to predict transfusion requirements, the use of preoperative hemoglobin is likely the simplest marker which is well understood by all ordering providers. Though time to surgery[32], fracture site (intra-capsular *vs* extra capsular)[3,12], and anesthesia type[33] predict blood utilization, the associations have not been documented as thoroughly as that of preoperative hemoglobin[32]. Moreover, the decision to preoperatively allocate blood products is considered by multiple independent practitioners (emergency medicine, anesthesiology, internal medicine, and surgeons). Incorporating the aforementioned factors, which are not as easily obtainable as preoperative hemoglobin, may not be reasonable and may result in reversion to generalized cross matching practices for all patients.

The benefits to both the patient and health system with reduction of unneeded preoperative crossmatching are substantial. Unneeded crossmatching removes RBC units from the available inventory for the general population placing increasing strain on blood banks by requiring a larger volume of stored RBCs, and pushes blood products closer to their expiration date[34]. Although longer RBC storage duration does not appear to influence clinical outcomes[35,36], wastage of product reaching the expiration date could be problematic.

This study is not without limitations. First, our study is also retrospective in nature and requires prospective validation. We do not advocate for proceeding to the operating room without obtaining a T&S, which at our institution costs 5-fold more than a crossmatch. Second practitioners may fear underordering products in the event there is a need for emergency release (uncrossmatched type-O) blood. However, implementation of a restrictive MSBOS has been shown to not increase the rate of emergency release transfusions[37]. Moreover, data suggest less than 5% of hip fracture patients require intraoperative transfusion, and that these 5% of patients are highly predictable with multiple independent risk factors[30]. Additionally, with

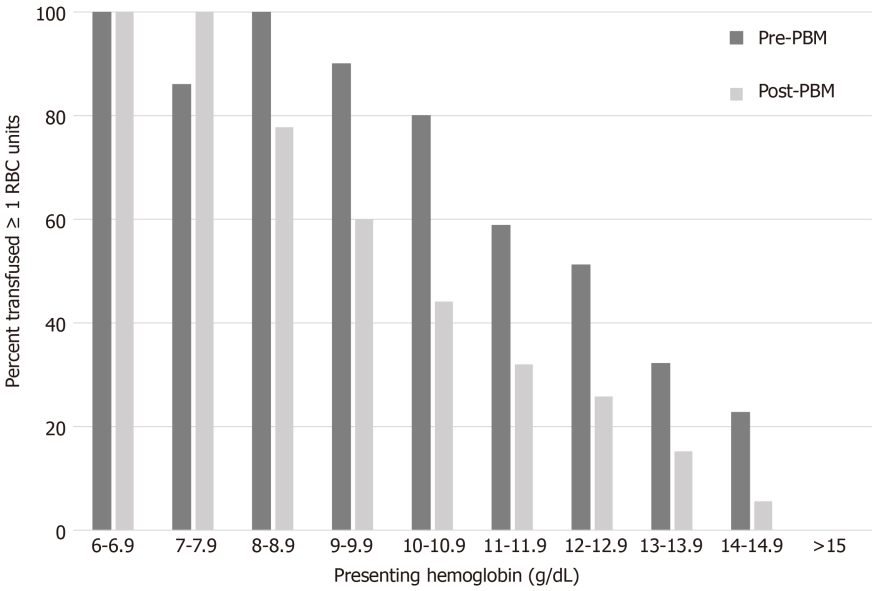


Figure 1 Percentage of patients transfused ≥ 1 red blood cell units in the pre (*n* = 201) and post (*n* = 297) patient blood management cohorts stratified by pre-operative hemoglobin. RBC: Red blood cell; PBM: Patient blood management.

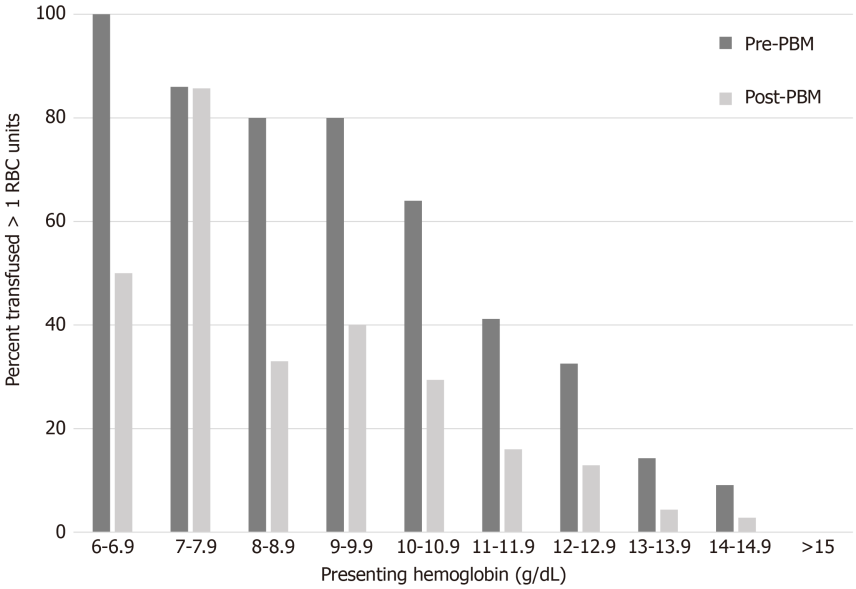


Figure 2 Percentage of patients transfused > 1 unit red blood cell in the pre (*n* = 201) and post (*n* = 297) patient blood management cohorts stratified by pre-operative hemoglobin. RBC: Red blood cell; PBM: Patient blood management.

electronic remote blood issue and electronic crossmatching the time from the need for urgent blood products in the OR to delivery has been reduced substantially[38-39]. Should emergent release blood be needed, type-O blood has been shown in multiple studies to be exceedingly safe in all patients[37,40,41]. Type-O blood is associated with a 0.2% incidence of mild delayed hemolytic reaction which is lower than the risk of major ABO transfusion reaction due to clerical errors and wrong unit transfusion[37], the decision to obtain only a type and screen ahead of the OR as opposed to crossmatching 1 unit may cause concern for delays in availability, however the electronic crossmatch has mitigated this problem for patients with a negative antibody screen[39].

CONCLUSION

Our findings suggest that a hemoglobin < 11 g/dL and < 9 g/dL warrants a T&C of only 1 and 2 units, respectively, and a hemoglobin > 11g/dL warrants consideration of only a T&S. The MSBOS may over allocate RBC units in the era of restrictive transfusion thresholds and we propose that preoperative hemoglobin levels should be considered in determining the number of units to type and cross prior to surgery.

ARTICLE HIGHLIGHTS

Research background

Blood product utilization is becoming increasingly scrutinized in orthopaedic surgery as restrictive transfusion triggers and conservative blood management strategies have become more common.

Research motivation

As transfusion frequency decreases through implementation of restrictive blood management practices, a rethinking of preoperative blood product allocation is required. Rather than using standardized maximum surgical blood order schedules (MSBOS), we wanted to investigate the ideal type and cross ratios for hip fracture patients while accounting for preoperative hemoglobin values.

Research objectives

The aims of this study were to characterize and compare the ideal 2:1 crossmatch to transfusion ratio in hip fracture patients before and after the implementation of a restrictive blood management policy at our institution.

Research methods

A retrospective review was conducted of all operatively treated hip fractures at our institution from January 2013 through May 2017. Cases were split up based on whether they occurred before or after implementation of a patient blood management (PBM) program (January 2015). Receiver operating curve analyses were used to determine the preoperative hemoglobin levels predicting 50% transfusion events in the pre- and post-PBM cohorts.

Research results

Implementation of the PBM resulted in a significant decrease in transfusion requirements from the pre- to post-PBM cohorts (51% *vs* 33%, $P < 0.0001$). Additionally, the post-PBM cohort was much less likely to receive multiple transfusions. Compared to the pre-PBM cohort, the post-PBM cohort had a much lower preoperative hemoglobin value that predicted a 50% transfusion probability.

Research conclusions

In order to more appropriately allocate blood product resources, hip fracture MSBOS should be updated to reflect current restrictive transfusion strategies and should consider preoperative patient hemoglobin values.

Research perspectives

Further study at other institutions is warranted to validate the generalizability of our findings. To help conserve resources, additional MSBOS studies are warranted in other orthopaedic trauma surgery procedures as well.

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ORIGINAL ARTICLE

Retrospective Study

Usefulness of computed tomography based three-dimensional reconstructions to assess the critical shoulder angle

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Author contributions: Mah D designed and performed the research, and wrote the paper; Chamoli U designed the research, and contributed to the analysis; Smith GCS designed and performed the research, and supervised the report.

Institutional review board statement: This study was reviewed and approved by the Ethics Committee of the University of New South Wales.

Informed consent statement: The private patients of Dr Geoffrey Smith sign a consent form for their deidentified radiographic imaging data and intra-operative images to be used for teaching, medical education and research purposes (including computer modelling).

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Abstract

BACKGROUND

The critical shoulder angle (CSA) is a radiographic measurement that provides an assessment of both glenoid inclination and acromial length. Higher values may correlate with the presence of rotator cuff tears. However, it is difficult to obtain a high-quality true anteroposterior (AP) radiograph of the shoulder, with any excess scapular version or flexion/extension resulting in deviation from the true CSA value. Three-dimensional (3D) bony reconstructions of computed tomography (CT) shoulder scans may be able to be rotated to obtain a similar view to that of true AP radiographs.

AIM

To compare CSA measurements performed on 3D bony CT reconstructions, with those on corresponding true AP radiographs.

METHODS

CT shoulder scans were matched with true AP radiographs that were classified as either Suter-Henninger type A or C quality. 3D bony reconstructions were segmented from the CT scans, and rotated to replicate an ideal true AP view. Two

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observers performed CSA measurements using both CT and radiographic images. Measurements were repeated after a one week interval. Reliability was assessed using intraclass correlation coefficients (ICCs) and Bland-Altman plots [bias, limits of agreement (LOA)].

RESULTS

Twenty CT shoulder scans were matched. The mean CSA values were 32.55° (± 4.26°) with radiographs and 29.82° (± 3.49°) with the CT-based method [mean difference 2.73° (± 2.86°); $P < 0.001$; bias +2.73°; LOA -2.17° to +7.63°]. There was a strong correlation between the two methods ($r = 0.748$; $P < 0.001$). Intra-observer reliability was similar, but the best intra-observer values were achieved by the most experienced observer using the CT-based method [ICC: 0.983 (0.958-0.993); bias +0.03°, LOA -1.28° to +1.34°]. Inter-observer reliability was better with the CT-based method [ICC: 0.897 (0.758-0.958), bias +0.24°, LOA -2.93° to +3.41°].

CONCLUSION

The described CT-based method may be a suitable alternative for critical shoulder angle measurement, as it overcomes the difficulty in obtaining a true AP radiographic view.

Key Words: Critical shoulder angle; Computed tomography; Osteoarthritis; Rotator cuff tear; Acromioplasty; Arthroscopic lateral acromial resection

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Core Tip: The critical shoulder angle (CSA) is a radiographic measure which correlates with the presence of rotator cuff tears. However, it is difficult to obtain high-quality true anteroposterior radiographs that are suitable for CSA measurements. Three-dimensional bony reconstructions may be produced from computed tomography shoulder scans and be rotated to replicate a more ideal true anteroposterior view, and hence obtain a more accurate CSA measurement. This retrospective study demonstrated its improved intra-observer and inter-observer reliability, compared to the standard radiographic method.

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INTRODUCTION

The critical shoulder angle (CSA) is a radiographic measurement that provides an assessment of both glenoid inclination and acromial length[1]. It is defined as the angle between a line joining the superior and inferior bony margins of the glenoid fossa, and the line joining the inferior margin of the glenoid fossa and the most inferolateral aspect of the acromion on a true anteroposterior radiograph of the shoulder (Figure 1) [2]. CSA values greater than 35° and less than 30° are associated with degenerative rotator cuff (RC) tears and primary glenohumeral osteoarthritis (GHOA), respectively [2]. If reduced, this may lower the risk of non-healing or re-tear after RC repair. Thus, this radiological measure may be useful in clinical practice for the preoperative evaluation of RC tears, particularly in the consideration of lateral acromioplasty as an adjunct to RC repair[3].

However, the precision and reliability of the CSA measurement is dependent on the quality of the true anteroposterior (AP) radiograph which should show "visible joint space and only minimal overlap between the posterior and anterior rim of the glenoid"[2,4]. Suter *et al*[5] demonstrated that any excess scapular ante-/retro-version (+5°/-8°) or flexion/extension (+15°/-26°) results in > 2° deviation of the measured CSA compared with the true value. They consequently defined the Suter-Henninger

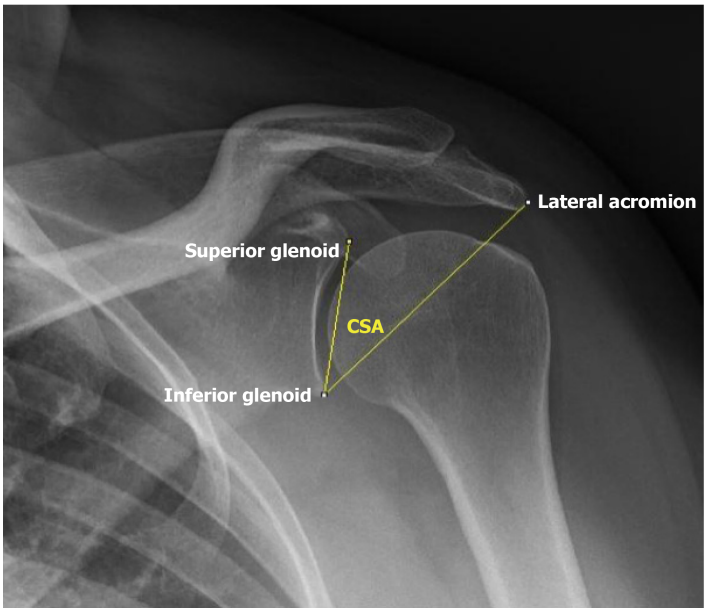


Figure 1 Radiograph: Measurement of the critical shoulder angle on a true anteroposterior radiograph, classified as Type A using the Suter-Henninger criteria[5].

(SH) criteria, which classifies the radiographic image according to the degree of overlap of the anterior and posterior glenoid rims (Types A-D) and the location of the coracoid process relative to the superior glenoid (Types 1-3)[5].

Unfortunately, it is difficult to gain a high-quality true AP radiograph. A previous study reported the rate of acquisition of SH Type A1 radiographs to be 57%[6]. The use of cross-sectional imaging offers a potential alternative to plain radiographs, as it may eliminate the need for the accurate patient and imaging gantry positioning required to achieve SH Type A or C radiographs. Computed tomography (CT) has shown promising reproducibility in CSA measurements[7]. The use of three-dimensional (3D) bony CT reconstructions of scapulae may offer an alternative, which theoretically can be rotated to a similar view to that of true AP radiographs. The present study aimed to evaluate CSA measurements performed on 3D bony reconstructions of shoulder CT scans, and to correlate the results with conventional measurements of the CSA using true AP radiographs.

MATERIALS AND METHODS

This study was approved by the University of New South Wales Human Research Ethics Committee (HC180427). In the absence of pre-existing data on using a 2D angle measurement on 3D reconstructions of CT scans, it was not possible to conduct an a priori power calculation. Previous studies that compared imaging modalities for CSA measurements used sample sizes of 30-60[7,8]. To maximise the sample size, we used all the imaging data available over a 5-year period from the private clinical practice of the senior author (Smith GCS).

A retrospective review of the private medical records from the clinical practice of GS was performed for patients who had non-arthrographic CT shoulder scans performed between June 2013 and June 2018. The earliest CT scan was used if multiple scans of the same patient were available in the database. Identified patients were then similarly searched for radiographic series of the same shoulder side with a true AP view. Prior to the study commencement, two of the authors (Mah D, Smith GCS) trained together using five illustrative cases to establish a routine method of measurement, as described below. In total, there were 96 shoulders (93 patients) with paired imaging identified.

The quality of the AP radiographs was assessed according to the SH criteria by the senior author (Smith GCS). Only SH Type A and C radiographs were included. The CSA was measured radiographically with image processing software ImageJ (ver. 1.51, United States National Institutes of Health, Bethesda, MD, United States) according to the technique described initially by Moor *et al*[2] (Figure 1). Identifiable osteophytes were not included in angular measurements in patients with GHOA. Of the 96

consecutive shoulders with paired imaging identified, only 20 (21%) had radiographs that were of sufficient quality for inclusion (SH Type A: n = 18; SH Type C: n = 2).

The median age of patients at the time of their CT shoulder scan was 56 years (range: 17-77 years). There were 12 males and 8 females. The median time between CT and radiographic imaging was 113.5 d (range: 0-534 d). The clinical diagnoses were: glenohumeral instability (n = 8), primary GHOA (n = 6), proximal humeral fracture (n = 4), secondary GHOA due to avascular necrosis (n = 1), and humeral tumour (n = 1).

The Digital Imaging and Communications in Medicine files of the remaining paired CT scans were imported into the image processing and 3D reconstruction software Amira (ver. 5.4, Visage Imaging, San Diego, CA, United States). Scapulae were semi-automatically segmented from the CT image data and semi-transparent 3D reconstructions of the bone surfaces were generated. The 3D reconstructions of the scapulae were then rotated, such that the glenoid was orthogonal to the plane of view with minimal overlap of the anterior and posterior margins of the glenoid, and with the midpoint of the coracoid process intersecting the upper margin of the glenoid. This process replicated the view of an ideal SH Type A1 radiographic image. Once the desired position was obtained, a snapshot was taken, and the CSA was measured on the snapshot using ImageJ (Figure 2).

The CSA measurement methods described above were performed by two observers: an experienced shoulder surgeon (Observer 1; Smith GCS) and a final-year medical student (Observer 2; Mah D). All measurements were repeated by both investigators after a one-week interval to assess intra-observer reliability.

Statistical analysis

Statistical analyses were performed using the statistical software SPSS (ver. 25, IBM Corporation, Armonk, NY, United States). Data were tested for normality using the Kolmogorov-Smirnov test. As the data were normally distributed, the distribution of variables was expressed using mean and standard deviation values. Age and gender group differences were evaluated using independent-samples t-tests. Inter-method comparison was performed using paired-samples t-tests, Pearson correlation coefficients and Bland-Altman plots[9]. Hypothesis tests were conducted at a significance level of 0.05.

The inter-observer and intra-observer reliability of each CSA measurement method was evaluated using two-way mixed consistency single-measures intraclass correlation coefficients (ICCs). The ICCs were classified according to the method described by Koo and Li[10], where values < 0.50, 0.50-0.75, 0.75-0.90, and > 0.90 indicated "poor", "moderate", "good", and "excellent" reliabilities, respectively[10]. The reliabilities were further assessed using bias and limits of agreement (LOA) on Bland-Altman plots.

RESULTS

Table 1 displays the mean CSA values obtained by each method and observer, as well as the absolute difference and Pearson correlation between them. Additionally, there were no statistically significant differences in measured CSA values between age groups (≤ 55 years and > 55 years; P = 0.550) and gender groups (male/female; P = 0.698).

Correlation between measurements from the two methods

There was a positive inter-method correlation between the CSA values obtained using the CT-based method and the conventional radiographic method (Pearson's r = 0.748; P < 0.001; Figure 3). The bias between the two methods was +2.73° (LOA: –2.17° to +7.63°).

Intra-observer reliability

The intra-observer ICC values of the CSA measured using the conventional radiographic method were "excellent" for both observers [Observer 1: ICC: 0.946 (0.870-0.978); Observer 2: ICC: 0.970 (0.925-0.988)]. The bias within observers was +0.35° (LOA: –2.15° to +2.85°; Figure 4A). Similar LOAs were observed for Observer 1 (bias +0.20°; LOA: –2.78° to +3.18°) and Observer 2 (bias +0.50°; LOA: –1.43° to +2.43°).

The intra-observer ICC values of the CSA measured using the CT-based method were "excellent" for Observer 1 [ICC: 0.983 (0.958-0.993)] and "good" for Observer 2 [ICC: 0.887 (0.738-0.954)]. The bias within observers was +0.34° (LOA: -2.15° to +2.83°; Figure 4B). A wider LOA was observed in Observer 2 (bias +0.66°; LOA: -2.54° to

Table 1 Comparison of critical shoulder angle measurements between methods and observers

	Observer 1 (Smith GCS)	Observer 2 (Mah D)	Combined
Means (SD)			
Radiographs	32.42° (4.58°)	32.88° (3.96°)	32.55° (4.26°)
CT-based method	29.86° (3.61°)	29.79° (3.41°)	29.82° (3.49°)
Inter-method			
Difference (LOA)	[1]2.46° (-3.05° to +7.24°)	[1]2.99° (-3.15° to +7.97°)	[1]2.73° (-2.17° to +7.63°)
Pearson's *r*	[1]0.769	[1]0.725	[1]0.748

[1]Indicates $P < 0.001$. LOA: Limits of agreement.

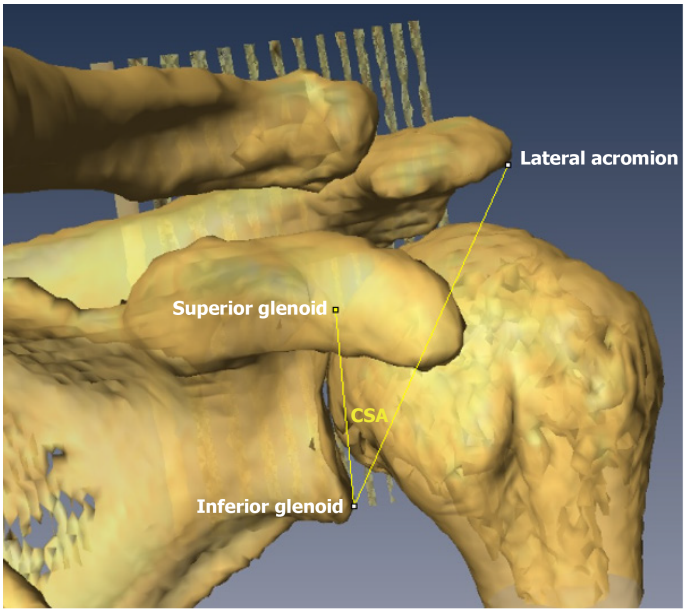


Figure 2 Computed tomography: measurement of the critical shoulder angle on a semi-transparent three-dimensional reconstruction of computed tomography data.

+3.85°), compared to Observer 1 (bias +0.03°; LOA: –1.28° to +1.34°).

Inter-observer reliability

The inter-observer reliability of CSAs measured using the conventional radiographic method was "good" [ICC: 0.864 (0.688-0.944)]. The bias between the two observers was +0.31° (LOA: -4.10° to +4.72°; Figure 5A).

The inter-observer reliability of CSAs measured using the CT-based method was also "good" [ICC: 0.897 (0.758-0.958)]. The bias between the two observers was +0.24° (LOA: -2.93° to +3.41°; Figure 5B). This achieved slightly better inter-observer reliability than the radiographic method.

DISCUSSION

The most important finding of this study is its support of the potential use of 3D bony reconstructions of CT shoulder scans to perform CSA measurements. Whilst radiographs have the advantage of being cheap, low-radiation and accessible (and hence are the primary investigation for a variety of shoulder conditions), a recent meta-analysis demonstrated that radiographic quality is a source of heterogeneity in studies that investigate the link between CSA and RC tears and primary GHOA[11]. Poor radiographic quality was found to contribute to differences in the measured CSA found in both symptomatic RC tear patients and primary GHOA patients. In our

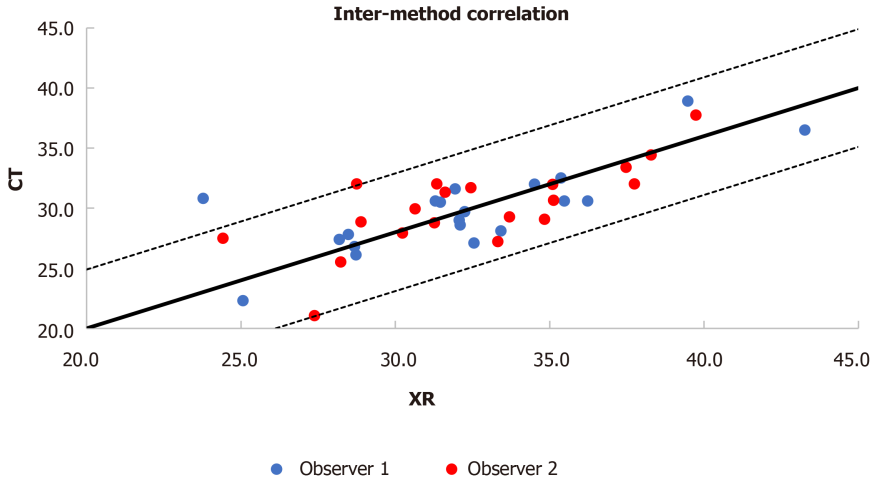


Figure 3 Inter-method correlation: Critical shoulder angle measurements compared between radiographic and computed tomography-based methods. CT: Computed tomography.

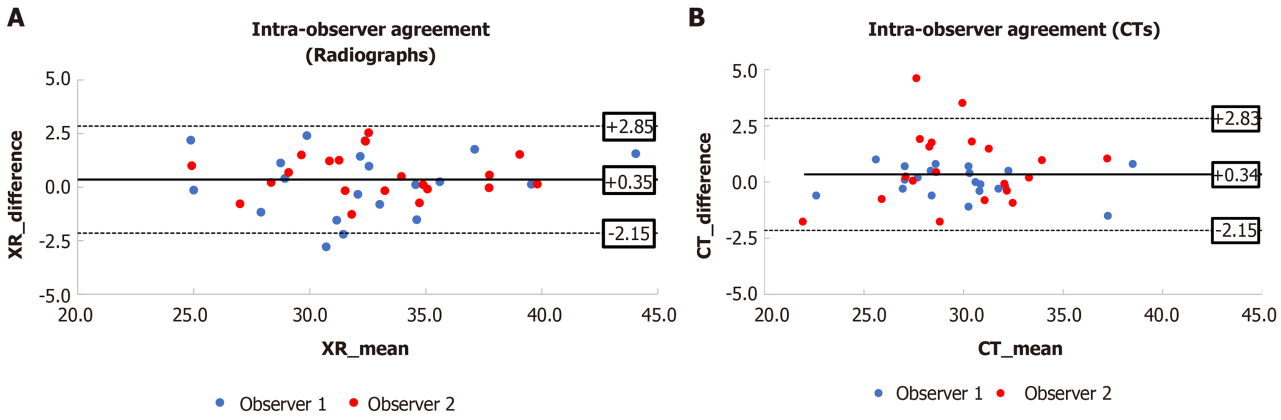


Figure 4 Intra-observer agreement (radiographs) (Bland-Altman plots): Critical shoulder angle measurements repeated after a one-week interval. A: Radiographs; B: Computed tomography-based method. CT: Computed tomography.

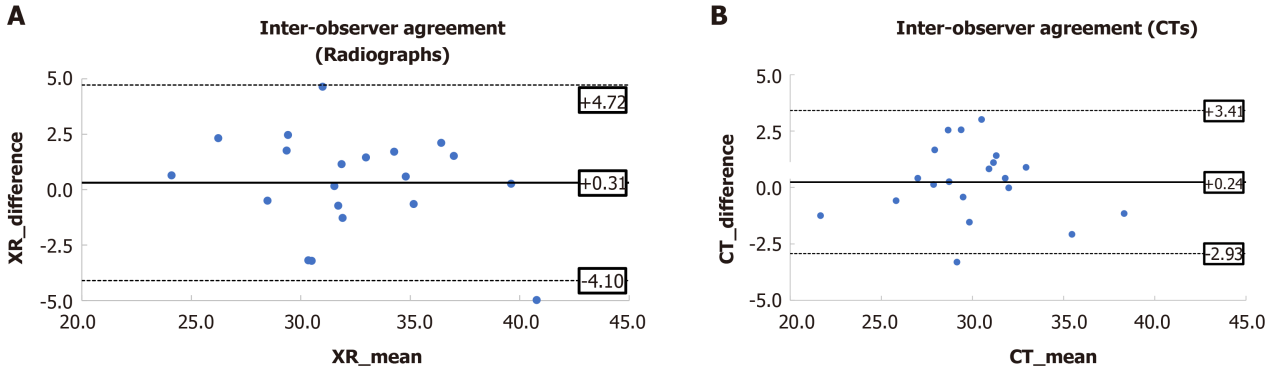


Figure 5 Inter-observer agreement (radiographs) (Bland-Altman plots): Critical shoulder angle measurements compared between Observers 1 and 2. A: Radiographs; B: Computed tomography-based method. CT: Computed tomography.

study, only 21% of the shoulders with paired imaging had true AP radiographs of SH Type A or C, thus highlighting the difficulty in obtaining such high-quality radiographs in routine clinical practice. While fluoroscopy may be able to assist, it is associated with increased radiation exposure and is not available in most locations outside the operating theatre.

Instead of radiographs, a true AP view of the shoulder can theoretically always be obtained using 3D bony reconstructions from CT scan data. Low-dose CT imaging may reduce the radiation dose by 50%, without compromising the diagnostic performance[12]. In our study, there was a strong positive correlation between CSA values obtained using the CT-based method and the conventional radiographic method. Previous authors have suggested that a 2° difference in the measured CSA is clinically unimportant and that LOA values of -2° to +2° for intra- and inter-observer reliability for the measurement of CSA are excellent[2]. Both the intra- and inter-observer reliabilities of each method were slightly worse than, but approximate to this range. The CT-based method demonstrated superiority in terms of inter-observer reliability over the radiographic method. It also yielded statistically significant lower CSA values compared to the conventional radiographic method, which was present regardless of the observer's clinical experience. This may reflect the ability to always create a SH A1 image, eliminating measurement inaccuracy due to scapular version and flexion/extension[5].

A systematic review concluded that a high CSA is associated with RC re-tear rates and worse clinical outcomes after RC repair[13]. After first being trialled in cadaveric studies, several authors have also described the use of an arthroscopic lateral acromioplasty with the aim of reducing the CSA[14,15]. While it is not currently widely used in the investigation of RC tears, the use of CT would have the additional advantage of allowing accurate preoperative planning of a lateral acromioplasty, with the aim of reducing the CSA to the normal range (30°-35°). This could improve the efficacy of lateral acromioplasty, and reduce the potential compromise of the deltoid origin.

The present study also highlights particular drawbacks with using the CT-based method. Firstly, the intra-observer reliability of the CT-based method was compromised to some degree when the less clinically experienced observer (Mah D) utilised the 3D reconstruction. This suggests a difficulty with obtaining an orthogonal plane of view, likely due to less familiarity with scapular anatomy. This effect was more pronounced at CSA < 30°, suggesting that the presence of osteophytes may affect the reliability of the CT-based method when performed by a less clinically experienced observer. Secondly, although the present study used an image processing software (Amira) that does allow free rotation of the 3D reconstructions in any plane, not all picture archiving and communication system software currently allow the free rotation of images in different planes. This may affect the ability to generate an SH Type A or C view.

Subtraction of the humerus was not undertaken, due to technical difficulties that would also not be able to be practically resolved in a clinical setting. When the 3D reconstructions were rotated to create an overlap of the coracoid process and superior glenoid (and hence a SH Type A1 view), this often obscured the upper margin of the glenoid during CSA measurement which may have affected the measured value and the intra-observer and inter-observer reliabilities to an extent, even with semi-transparent images. However, due to the concave shape of the glenoid, measurement error would tend to have generated an erroneously high CSA using the CT-based method, whereas a lower value was found in this study. Nevertheless, we believe that segmentation and subtraction of the humerus, and the ability to render the resultant image of the scapula radiolucent such that the upper border of the glenoid can be visualised through the coracoid process, would further improve the accuracy of the CT-based method in measuring the CSA.

A limitation of the present study is the small sample size of CT shoulder scans that were appropriately matched with true AP radiographs classified as SH Type A or C. This is a reflection of the difficulty in obtaining high-quality true AP radiographs in clinical settings. Additionally, none of the CT shoulder scans in our analysed population were ordered for RC tear indication, and therefore, the number of patients with a CSA of more than 35° was relatively low. However, the aim of this study was to evaluate the CSA measurement method using 3D reconstructions of CT scans of the shoulder. We do not believe that the outcomes would have been affected by including subjects with a higher CSA.

CONCLUSION

In conclusion, the use of 3D bony reconstructions from CT scan data may offer a viable alternative to plain radiographs in the measurement of the CSA. The CT-based method is potentially advantageous for measurement of the CSA on 3D reconstructions and

presurgical planning for acromioplasty, given the challenges associated with obtaining true AP radiographs.

ARTICLE HIGHLIGHTS

Research background

The critical shoulder angle (CSA) is a radiological measure that assesses both glenoid inclination and acromial length, with higher values being associated with rotator cuff (RC) tears.

Research motivation

It is difficult to obtain a high-quality true anteroposterior (AP) radiograph of the shoulder, with any excess scapular version or flexion/extension resulting in deviation from the true CSA value. This may be overcome by using three-dimensional (3D) bony reconstructions from computed tomography (CT) shoulder scans, which can be rotated to replicate an ideal true AP view.

Research objectives

This study aimed to evaluate CSA measurements performed on 3D bony reconstructions of shoulder CT scans.

Research methods

CSA measurements were performed on 3D bony reconstructions of shoulder CT scans and corresponding true AP radiographs. Measurements were performed by two observers, on two separate occasions.

Research results

There was a strong positive correlation between the two methods. Better intra-observer and inter-observer reliability was seen when using the 3D bony CT reconstructions to measure the CSA.

Research conclusions

The use of 3D bony reconstructions from CT shoulder scans may offer a viable alternative to plain radiographs in the measurement of the CSA.

Research perspectives

Future research should consider the use of 3D CT bony reconstructions in the preoperative evaluation of RC tears, particularly in the consideration of lateral acromioplasty as an adjunct to RC repair.

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ORIGINAL ARTICLE

Observational Study

Potential contribution of pedicle screw design to loosening rate in patients with degenerative diseases of the lumbar spine: An observational study

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Abstract

BACKGROUND

The majority of published data report the results of biomechanical tests of various design pedicle screw performance. The clinical relevance and relative contribution of screw design to instrumentation stability have been insufficiently studied.

AIM

To estimate the contribution of screw design to rate of pedicle screw loosening in patients with degenerative diseases of the lumbar spine.

METHODS

This study is a prospective evaluation of 175 patients with degenerative diseases and instability of the lumbar spine segments. Participants underwent spinal instrumentation employing pedicle screws with posterior only or transforaminal interbody fusion. Follow-up was for 18 mo. Patients with signs of pedicle screw loosening on computed tomography were registered; logistic regression analysis was used to identify the factors that influenced the rate of loosening.

RESULTS

Parameters included in the analysis were screw geometry, type of thread, external and internal screw diameter and helical pitch, bone density in Hounsfield units, number of levels fused, instrumentation without anterior support, laminectomy, and unilateral and bilateral total facet joint resection. The rate of screw loosening decreased with the increment in outer diameter, decrease in core diameter and helical pitch. The rate of screw loosening correlated positively with the number of fused levels and decreasing bone density. Bilateral facet joint removal signifi-

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cantly favored pedicle screw loosening. The influence of other factors was insignificant.

CONCLUSION

Screw parameters had a significant impact on the loosening rate along with bone quality characteristics, the number of levels fused and the extensiveness of decompression. The significance of the influence of screw parameters was comparable to those of patient- and surgery-related factors. Pedicle screw loosening was influenced by helical pitch, inner and outer diameter, but screw geometry and thread type were insignificant factors.

Key Words: Degenerative diseases; Lumbar spine; Pedicle screw design; Pedicle screw loosening

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Core Tip: The published data on the contribution of pedicle screw design to pedicle screw stability remain controversial. According to the study results, the influence of screw parameters was comparable to that of patient- and surgery-related factors. The rate of pedicle screw loosening was influenced by helical pitch, inner, and outer diameter, but the influence of screw geometry and thread type was not significant.

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INTRODUCTION

Severe symptomatic degenerative diseases of the lumbar spine are frequently encountered morbid conditions, for which clinically significant improvement can only be achieved by pedicle screw fixation and fusion. Pedicle screw fixation, however, is associated with frequent complications, notably screw loosening, which has an overall reported rate of from 0.8% to 27% and over 50% in patients with osteoporosis[1-4]. Taking into account complication-related concerns, several strategies have been suggested to reduce the risk of implant failure, among which optimal screw design might play a considerable role[5].

Although the potential impact of screw design on pedicle screw instrumentation failure is a topic of interest in the literature, the pros and cons of each design alteration are still unresolved[5]. The most frequently used strategy is an increase in external diameter with an optimal thread depth[6,7]. Also, it is widely assumed that a conical screw geometry provides additional pullout resistance[8-10]. While some authors expect that an optimal screw shape and helical thread pitch may provide additional bone purchase benefit, screw performance in normal and osteoporotic models remains controversial[5,8,9].

Among the many factors that affect pedicle screw fixation stability, the most thoroughly studied is bone quality. At present, there is growing evidence that bone radiodensity in Hounsfield units (HUs) can be used to predict implant failure and pseudoarthrosis[4,11,12]. The extension of fixation, anterior support with interbody cages, screw insertion technique including depth and angulation may strongly influence the pedicle screw loosening rate, potentially blurring the results of *ex-vivo* studies[3,13-15]. Applying the results of *ex-vivo* experiments is problematic, because in the vast majority of studies, pullout tests barely mimic the biomechanics of screw loosening[7,16]. Finally, the reported data on pedicle screw loosening remain controversial because of differences in the criteria used as indicators for implant loosening and heterogeneity of the enrolled groups[3].

The study aim was to estimate the contribution of screw design to the rate of pedicle screw loosening and its interrelation with other risk factors in patients with

degenerative diseases of the lumbar spine.

MATERIALS AND METHODS

Study population and data collection

This study was a single-center prospective evaluation of 175 nonconsecutive patients with degenerative diseases of the lumbar spine with instability of spinal segments including 60 men and 115 women with a male-to-female ratio of 0.52. The average age of the participants at the time of surgery was 54 years (standard deviation = 14.12; range 28-76 years). Patients with only axial pain and those who presented with neurological symptoms associated with spinal stenosis were enrolled. Participants underwent spinal instrumentation employing pedicle screw fixation with posterior fusion stand-alone or with transforaminal interbody fusion supplementation during the years 2012 to 2017. The duration of follow-up was 18 mo. Radiographic criteria of pedicle screw loosening were used to assess outcomes as numeric scores can be biased by causes not associated with the surgery. The study was reviewed and approved by the local institutional review board, given that no additional risks were anticipated.

Inclusion and exclusion criteria

The inclusion criterion was presence of degenerative disease of the lumbar spine with unstable spinal segments and confirmed by functional radiograms or the presence of low-grade symptomatic unstable spondylolisthesis. Indications for spinal instrumentation were: (1) Neurological deficit associated with spinal stenosis; (2) Neurogenic claudication; (3) Evidence of spinal segment instability; (4) Axial and radicular pain syndromes with a visual analog scale score of over 4 (0-10); and (5) An Oswestry Disability Index score of over 40% and resistant to repeated conservative treatment for 3 mo.

The exclusion criteria were: (1) High-grade spondylolisthesis (grades 3 and 4); (2) Degenerative deformities that required fixation of more than five segments or spinopelvic fixation; (3) Tumor-related lesions of the lumbar spine; (4) Sagittal and frontal imbalance and spinopelvic parameter mismatches that required more than five-segment fixation and spinopelvic fixation; (5) Hospitalization for revision surgery; (6) Screw malposition and redirection detected on postoperative computed tomography (CT) images; (7) Different types of fusion applied on different levels; and (8) Different screw designs and sizes applied for pedicle screw fixation. This exclusion criterion was the reason why the study cohort was not consecutive.

Preoperative assessment

Before the procedure, all patients underwent functional X-ray imaging and CT evaluation. The criterion for spinal instability was anterior translation greater than 3 mm or rotation more than 10°[17]. CT was used as a part of the preoperative work-up. The CT scans were performed from the T12-L5 levels using a single CT scanner (Aquilion 32, Toshiba Corporation). The scans used a slice thickness of 0.5 mm and covered a scan area of 50 cm. The scan parameters included tube voltage 120 kV, tube current 300 mA, auto mAs range 180 to 400; 1.0 s/3.0 mm/0.5 × 32, helical pitch 21.0. Integrated software was used for calculations of bone density (Vitrea Version 5.2.497.5523) incorporating a window width/window level ratio of 2000/500. During CT evaluations, measurements of a vertebral body cancellous bone radiodensity in HU were obtained at standard level of L3 in the sagittal, axial, and coronal planes; those measurements were taken by two independent radiologists. Measurements in the axial plane were taken at the level of the middle of the pedicles while those in the sagittal and coronal planes were taken along the geometric center of the vertebral body. Oval-shaped trabecular bone samples were selected using the maximal achievable diameters without traversing into cortical bone to calculate bone density in each plane. Using those values, an average radiodensity was calculated for each case.

Operative techniques

Pedicle screw fixation with different types of polyaxial screws was used, either to augment posterolateral fusion alone or with interbody fusion. Screws with a conical core and thread (con/con), cylindrical core and thread (cyl/cyl), or cylindrical thread and conical core (cyl/con), with either V-shaped or buttress threads were used. The size of the pedicle screws was 6, 6.5, 7, or 7.5 mm. The applied technique was a standard strait trajectory for screw placement and either Wiltse or conventional open

screw placement. The surgeon qualification was at least 7 years of experience. Pedicle screws were introduced at least to the anterior third of a vertebral body; bicortical screw placement was not used in the enrolled patients. Transforaminal lumbar interbody fusion (TLIF) with a single cage, or posterior fusion only were used in this study. Only autografts of locally harvested bone was used to perform TLIF and posterior fusion. If indicated, decompression of the nerve roots and spinal cord was performed. The extent of the applied decompression was classified by structures removed (*i.e.* unilateral facet joint removal, bilateral facet joints with interspinous ligament removal, and laminectomy).

Follow-up protocol

The duration of follow-up was 18 mo. All patients underwent CT evaluation at the 6, 12, and 18 mo after surgery. Patients with pedicle screw loosening detected on CT images were registered. The criterion for screw loosening was a 1 mm or greater radiolucent zone around the screw, a double halo sign, or both[3]. Figure 1 includes a CT image in a patient with signs of pedicle screw loosening. Finally, patient outcomes were reported in a dichotomized scale either with the presence signs of pedicle screw loosening regardless the number of the involved screws, or absence of this complication.

Statistical analysis

Power analysis employing a Monte-Carlo method with 2000 simulations was used to calculate the required sample size (NCSS PASS 2008 v8). The association between screw loosening rate (dichotomized scale) and potential risk factors (both, continuous and dichotomized) was assessed with a general multivariate logistic regression model (Statistica 12, SPSS 22).

RESULTS

The characteristics of the enrolled group are shown in Table 1. By the end of the follow-up period, CT signs of pedicle screw loosening were present in 71 (40.6%) patients, 29 (16.6%) of whom presented with axial pain and Oswestry Disability Index scores over 40; the other 29 patients underwent revision surgery. The high prevalence of CT loosening signs can be explained by a considerable proportion of patients with radiodensities below 110 HU, which has a 90% specificity of osteoporosis detection. The screw parameters used in the analysis were con/con, cyl/cyl, cyl/con designs, V-shaped *vs* buttress thread, external, internal screw diameter, and helical pitch. The characteristics of screws used in this study are shown in Table 2.

Patient- and surgery-related factors were bone density measured in HU, number of fused levels (the extension of fixation), posterior fusion performed without anterior support *vs* anterior support applying TLIF, and the extent of decompression (from no decompression performed, to laminectomy, unilateral and bilateral total facet joint resection). The parameters included in the general multivariate logistic regression model with highest explanatory value are shown in Table 3.

The most significant non-implant-related factors contributing to pedicle screw loosening were the number of fused levels and radiodensity. The rate of screw loosening correlated positively with the number of fused levels and decreasing bone density. Bilateral facet joint removal significantly contributed to pedicle screw loosening and the impact of laminectomy was not significant. Technical solutions with pedicle screw fixation and posterior fusion only *vs* cases supplemented with TLIF were not significantly associated with the loosening rate.

We found that screw parameters also strongly influenced the frequency of loosening. The rate of pedicle screw loosening decreased with increase in outer diameter and decrease in core diameter. A small helical pitch was associated with a decrease in the pedicle screw loosening rate. Neither thread type or screw design (con/con, cyl/con, cyl/cyl) had a significant influence on pedicle screw loosening. The overall goodness of fit of estimated general multivariate model was $\chi^2 = 64.5554$, $P < 0.0001$. The model correctly classified 78.86% of cases and had a 86.54% specificity and 67.61% sensitivity.

Table 1 Characteristics of the study patients, *n* (%)

Characteristic	Patients, *n* (%)
Number of levels fused	
1 level	115 (65.7)
2 levels	47 (26.9)
3 levels	16 (9.1)
4 levels	1 (0.6)
5 levels	1 (0.6)
Fusion type	
Posterior fusion only	25 (14.3)
TLIF	150 (85.6)
Amount of decompression	
No resection of posterior structures	18 (10.3)
Laminectomy	46 (26.3)
Unilateral total facet joint removal	108 (61.7)
Bilateral total facet joint removal on at least one level	46 (26.3)
Bone characteristics	
Radiodensity, HU	M = 126.25 ± 3.20 SD = 42.31, range 43.17-282.07

HU: Hounsfield units; TLIF: Transforaminal lumbar interbody fusion.

Table 2 Characteristics of the screws used in this study

Design	External diameter (max)	Internal diameter (max)	Helical pitch	Type of thread	*n* (%)
cyl/cyl	6.5	4.0	3.0	Buttress	6 (3.4)
cyl/cyl	7.5	4.5	3.0	Buttress	9 (5.1)
cyl/con	6.5	4.0	2.5	Buttress	40 (22.9)
cyl/con	7.5	5.0	2.5	Buttress	4 (2.3)
con/con	6.0	4.0	3.0	V-shape	48 (27.4)
con/con	7.0	4.5	3.0	V-shape	5 (2.9)
con/con	6.0	4.5	2.5	V-shape	49 (28.0)
con/con	7.0	5.5	2.5	V-shape	14 (8.0)

con/con: Conical core and thread; cyl/con: Cylindrical thread and conical core; cyl/cyl: Cylindrical core and thread.

DISCUSSION

Among the few surgical means of achieving clinically significant results, pedicle screw fixation is associated with various implant-related complications, and one of the most frequently reported is pedicle screw loosening[3]. Along with degenerative diseases of the spine, osteoporosis is also a frequently encountered morbid condition in older-adult populations. Even though altered bone quality is not an absolute contraindication for spinal surgery with pedicle screw fixation, it may increase the risk of implant instability, with reported rates as high as 50%-60%[1,3]. One of the approaches intended provide maximal stability of pedicle screw fixation is an alteration of screw design including differences in geometry, type of thread and helical pitch, and in the ratio of internal to external diameter[5,8-10,18]. Despite a considerable amount of research published on this topic, the reported results remain controversial[5].

Table 3 Parameters included in the general logistic regression model

Parameter	Regression coefficient	OR per unit change with 95%CI
Intercept	−4.819065; P = 0.3617	-
Radiodensity, HU	−0.0271586; P < 0.0001	0.9732 (0.9623-0.9842)
Number of fused levels	1.111651; P < 0.0001	3.0394 (1.7566-5.2590)
Bilateral total facet joints removal (at least one level)	1.124871; P = 0.4359	3.0798 (1.0023-9.2781)
Laminectomy	0.4418158; P = 0.5333	1.5555 (0.5090-4.7533)
Posterior fusion performed without interbody fusion	−0.4247137; P = 0.4550	0.6540 (0.2128-2.0097)
Maximal external screw diameter	−5.966555; P = 0.3798	0.0026 (0.000009-0.7153)
Maximal internal screw diameter	6.430714; P = 0.0253	620.61 (2.2363-172234.6)
Helical pitch	4.611687; P = 0.0081	100.6538 (3.3668-3009.1310)
Thread type (buttress *vs* V-shape)	−1.034237; P = 0.9949	0.1070 (0.0090-1.2659)
Design cyl/cyl	0.1446205; P = 0.8568	1.1566 (0.2378-5.6156)
Design cyl/con	−1.731799; P = 0.2767	0.1769 (0.0077-4.0602)
Design con/con	0.2718265; P = 0.7594	1.3124 (0.2282-7.5451)

CI: Confidence interval; con/con: Conical core and thread.; cyl/con: Cylindrical thread and conical core; cyl/cyl: Cylindrical core and thread; HU: Hounsfield unit; OR: Odds ratio.

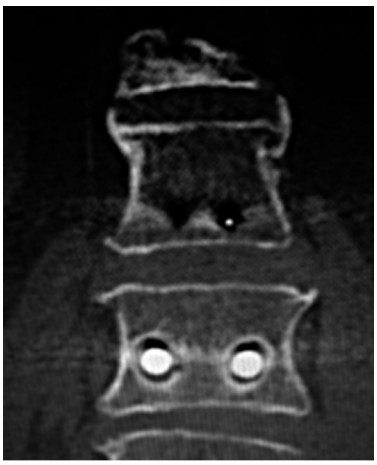


Figure 1 Computed tomography image of the lumbar spine in the coronal plane. Bilateral double halo sign is evident as a radiolucent zone around pedicle screws surrounded by sclerotic bone.

It has been shown in *ex-vivo* experiments that an increase in external diameter enhances the pullout strength of a screw although pedicle size and the risk of pedicle fracture limit application of this strategy[5,18-20]. By additionally increasing the depth of thread the interface of bone and screw can be considerably strengthened, however this effect can be achieved only if internal diameter is decreased[19]. The results of our study are in agreement with previously reported data and demonstrate that the rate of pedicle screw loosening declined with increase in outer diameter and decrease in core diameter. Surprisingly, helical pitch turned out to be a parameter that had a statistically significant influence on the pedicle screw loosening rate. According to the regression analysis results, a decrease of the helical pitch was associated with a decline in the pedicle screw loosening rate. The potential influence of helical pitch on bone and screw interface strength is still debated in the literature. In theory, pedicle screws with a small helical pitch provide a maximal contact area between the screw thread and bone[5,10,18,19]. On the other hand, it has been reported that pedicle screws with a small helical pitch sometimes have a decreased resistance to pullout forces[5,21]. The explanation for the observed discrepancies is that a smaller helical pitch results in an increase in coverage between bone and thread enhancing pullout strength only until

the bone is damaged[5,21].

The potential influence of thread type and screw geometry is frequently discussed in the literature, but the results remain controversial to some extent. It has been reported that conical screws are superior to cylindrical screws because of additional compression of the surrounding bone[5,9,10]. Some studies have reported that pedicle screws with a cylindrical thread and conical core provided maximal pullout resistance[8]. Screws with a buttress thread might be expected to provide increased strength at the bone-screw interface because of its geometry, however pedicle screws with a V-shaped thread were found to have superior pullout strength in foams that mimic osteoporotic bone[8]. On the other hand, buttress and V-shaped threads had about the same pullout strength in foam that reproduced normal bone density[8]. The results of those studies demonstrate that the effect of different thread types might depend on bone quality. The results of our study demonstrate, that in a cohort of patients with having nonstandardized bone quality, the geometry of screw and thread type turned out to be insignificant factors.

A potential source of controversies related to screw design is the way screws are tested *ex-vivo*. Even though the most frequently used pullout test can be easily standardized and reproduced, it has limited relevance to screw loosening mechanisms *in vivo* because cases with pullout failure account for only 0%-1.3% of the causes[7]. The surgical technique may also interfere with the results of screw testing in clinical trials. It has been reported that multilevel fusion may favor pedicle loosening because of an increased load on the pedicle screws[1,3,14]. It has been clearly shown that excessive resection of ligaments, facet joints, and laminectomy are associated with the increased range of movements in a spinal segment[22,23]. Taking into account that the most reliable mechanisms of screw loosening were considered cyclic caudocephalad toggling and rotational stress causing micromovements between the vertebral body and screws, extensive decompression may favor screw loosening[16,24]. It has been reported that the lack of anterior support and even fusion type may also impact the stability of spinal instrumentation[3,25,26]. For those reasons, those factors were also taken into account to assess their relative contribution to pedicle screws loosening. Finally anterior support did not significantly influence the screws loosening rate in our study.

Measurements of bone density in HU was used in this study as a predictor because of growing evidence that those figures can be used to predict implant failure and pseudoarthrosis. Furthermore if a 120 kV tube is used, then HU values can be converted to mineral density[4,11,12,27,28]. The results of our study demonstrate that the radiodensity of vertebral body cancellous bone and the extensiveness of fixation were the most significant nonimplant-related contributing factors to pedicle screw loosening. The rate of screw loosening was positively correlated with the number of fused levels and with decreasing bone density, which is in agreement with previously reported data. The results of this analysis confirmed that total removal of bilateral facet joints slightly increased the pedicle screw loosening rate and that the impact of laminectomy was not significant. The influence of fusion by TLIF *vs* posterior fusion only on the pedicle screw loosening rate was not significant.

Finally the study results demonstrate the clinical relevance of previously reported biomechanical findings and provide additional evidence that screw parameters may have a considerable influence on the loosening rate. The significance of the contribution of screw parameters was comparable to that of patient- and surgery-related factors.

Limitations

This study limitations include enrollment of a nonconsecutive patient cohort because individual patients with different screw types and sizes were excluded. The prevalence and significance of pseudoarthrosis was not studied because that aim would have required a different study design. Collinearity of some screw parameters may have influenced the results of the analysis. On the other hand, the study provides evidence sufficient to conclude that screw parameters strongly influenced the rate of pedicle screw loosening.

CONCLUSION

Screw parameters have a significant impact on pedicle screw loosening rate along with bone quality characteristics, the number of levels fused, and the extent of decompression. The significance of the impact of screw parameters was comparable to

the influence of patient and surgery-related factors. The complication rate is influenced by helical pitch and inner and outer screw diameter. The impact of screw geometry and thread type was not significant.

ARTICLE HIGHLIGHTS

Research background

Because of aging populations worldwide the number of spinal instrumentations performed annually is increasing dramatically. The most frequently encountered comorbidity in elderly adults is osteoporosis, which is a main reason for development of pedicle screw instability. Strategies to increase pedicle screw fixation stability include changes in pedicle screw design, but evaluations of pedicle screw loosening are controversial because of differences in the criteria used as indicators for implant loosening and heterogeneity of study groups.

Research motivation

It has be assumed that pedicle screw design influences the stability of the bone-screw interface and it has been extensively studied. The weak points of those studies is in the extrapolation of mechanical data and the results of pullout tests that to clinical practice. It is clear that pullout forces cause minority of cases of pedicle screw instability and that and bone characteristics influence the performance of screws. The strong point of our study is that the influence of screw parameters were tested.

Research objectives

The study aim was to test the impact of a screw design on loosening rate and to assess how screw parameters interfere with patient- and surgery-related factors.

Research methods

This study was a prospective evaluation of 175 patients with degenerative bone diseases and instability of lumbar spine segments. Participants underwent spinal instrumentation employing pedicle screws with posterior only or transforaminal interbody fusion. Follow-up was for 18 mo. Patients with signs of pedicle screw loosening signs on CT were registered; logistic regression analysis was used to identify the factors associated with loosening, including screw parameters, bone characteristics, and surgery-related factors.

Research results

Parameters included in the analysis were screw geometry, thread type, external and internal screw diameter and helical pitch, bone density in HUs, the number of levels fused, instrumentation without anterior support, laminectomy, and unilateral and bilateral total facet joint resection. The rate of screw loosening decreased with an increase in outer diameter, decrease in core diameter, and helical pitch. The rate of screw loosening was positively correlated with the number of fused levels and with decreasing bone density. Bilateral facet joint removal significantly favored pedicle screw loosening. The influence of other factors was not significant. The overall contribution of screw design to loosening rate was comparable to that of patient and surgery-related factors.

Research conclusions

Screw parameters had a significant impact on loosening rate along with bone quality characteristics, the number of levels fused, and the extent of decompression. The significance of the influence of screw parameters was comparable to that of patient- and surgery-related factors. The pedicle screw loosening rate was influenced by helical pitch, inner, and outer screw diameter. The influence of screw geometry and thread type was not significant.

Research perspectives

We assume that the rational application of implants of various designs can result in a decrease in implant-related complications, but the design characteristics may interfere with patient- and surgery-related factors. To identify additional effects, including those of higher order, and to address the potential bias relevant to collinearity, a cohort study with enrollment of more patients is required. Multivariate analysis can help in the design of randomized case-control trials that can address potential sources

of study bias.

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SYSTEMATIC REVIEWS

Endoscopic fasciotomy for chronic exertional compartment syndrome of the forearm: Systematic review of outcomes and complications

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Abstract

BACKGROUND

Endoscopic fasciotomy of the forearm for chronic exertional compartment syndrome (CECS) has gained popularity recently.

AIM

To systematically review the literature of endoscopic fasciotomy for CECS of the forearm, aiming to assess the outcomes and complications of the different endoscopic fasciotomy techniques described in the literature.

METHODS

On January 18, 2021, PubMed and EMBASE were searched by 3 reviewers independently, and all relevant studies published up to that date were considered based on predetermined inclusion/exclusion criteria. The subject headings "endoscopic fasciotomy" and "compartment syndrome" and their related key terms were used. The Preferred Reporting Item for Systematic Reviews and Meta-Analyses statement was used to screen the articles.

RESULTS

A total of seven studies including 183 patients (355 forearms) were included. The mean age of the patients was 31.2 years (range: 15-42 years). The postoperative follow-up duration ranged from 6 wk to 4.9 years. All patients were able to return to sport activities between postoperative weeks 1 to 8. Recurrence of the compartment syndrome occurred in three patients, giving a rate of 1.6% per patient and 0.8% per forearm. The overall complication rate was 8.7% per patient, and 4.5% per forearm. The most common reported complication was hematoma (7 forearms; 2.0%).

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CONCLUSION

Endoscopic fasciotomy for CECS of the forearm has favorable short- and mid-term outcomes with very low recurrence and complication rates. This, however, needs to be confirmed in larger, long-term follow-up, prospective, comparative studies between open, mini-open and endoscopic fasciotomy techniques.

Key Words: Exertional compartment syndrome; Compartment syndrome; Fasciotomy; Forearm; Endoscopy

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Core Tip: Endoscopic fasciotomy of the forearm for chronic exertional compartment syndrome (CECS) has gained popularity recently. This study reviewed the literature of endoscopic fasciotomy for CECS of the forearm, summarizing the outcomes and complications of the different endoscopic fasciotomy techniques described.

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INTRODUCTION

Chronic exertional compartment syndrome (CECS) is a condition where there is an exercise-induced increase in pressure within fascial compartments after muscle hyperemia and expansion, resulting in poor tissue perfusion followed by ischemic pain, functional loss, and possible neurologic compromise[1,2]. The symptoms of this condition are exercise-induced, and typically resolve when the activity ceases leaving no permanent damage to the tissue[1,2]. During exercise, the intramuscular pressure elevates to a point that the tissues within the affected compartment become swollen, tight, and painful, preventing further activities[1-3]. While the leg is the most involved, CECS can affect the shoulder, arm, forearm, hand, gluteus, thigh, and foot[1].

In the forearm, CECS is seen in people who perform activities and sports that require prolonged, repetitive and forceful gripping, such as cyclists, arm wrestlers, rowers, rock climbers and weightlifters[2-5]. Patients with CECS present with predictable and reproducible atraumatic exercise-induced pain, cramping and tightness that is typically localized to the affected compartment[1-3]. They may also complain of transient numbness, tingling, or weakness (*e.g.*, loss of grip strength) in the distributions of nerves within the involved compartment, which usually resolve with rest[1-3]. In severe cases of CECS, these symptoms can significantly affect the quality of life, and can be dangerous occasionally (*e.g.*, motocross riders may be unable to hold the handlebar grips while riding)[2,3].

Although the diagnosis of CECS can be made based on history and physical examination, few diagnostic tests can help confirm it[1-3,6-11]. Dynamic intra-compartmental pressure measurement (*i.e.* at rest and after exercise) is widely used as an objective diagnostic test of CECS of the forearm; however, no clear consensus on the cut-off diagnostic values exist[3,6-9]. Intracompartmental pressure of ≥ 30 mmHg at 5 min after exercise and/or ≥ 30 mmHg difference between the intracompartmental pressure and the diastolic blood pressure is the most commonly used criteria to diagnose CECS of the forearm[3,8,9]. In addition to compartment pressure measurements, few authors reported the use of ultrasonography and magnetic resonance imaging (MRI) to help establish a diagnosis of CECS, nevertheless, the findings of these radiologic tests are not specific[1-3,10-12].

The treatment of CECS can be nonsurgical or surgical[1-3]. Nonsurgical treatment in the form of activity modification, physical therapy and pain control can be successful in up to 80% of the cases[3,13]. Patients who have no improvement in symptoms after at least 3 mo despite nonoperative treatment are usually indicated for surgical management in the form of forearm fasciotomy[1-3]. Regardless of the surgical

technique used to perform the fasciotomy, the rate of resolution of symptoms and return to sports activities reaches 90%[1-3].

Recently, endoscopic fasciotomy of the forearm for CECS has gained popularity[10,11,14-16]. Authors suggest that this surgical technique result in reduced time to return to competitive sports and decreased surgical scarring and complications[1-3]. Endoscopic fasciotomy techniques have evolved because the expansile muscle bellies which result in the compartment syndrome when swollen lie in the proximal third of the forearm, thus, fasciotomies distal to this region might not be required[2]. In this study, we aim to systematically review the literature of endoscopic fasciotomy for CECS of the forearm. We intend to assess the outcomes and complications of the different endoscopic fasciotomy techniques described in the literature. We hypothesize that overall outcomes are favorable in regards of return to sports and functional outcomes, as well as rate of recurrence and complications is low.

MATERIALS AND METHODS

Search strategy

PubMed and EMBASE databases were searched independently by three authors (Marwan Y, Addar A, Algarni N) for relevant articles on January 18, 2021. The search was limited to English language only. The subject headings "endoscopic fasciotomy" and "compartment syndrome" and their related key terms were used. The articles were screened based on the Preferred Reporting Item for Systematic Reviews and Meta-Analyses statement.

Inclusion and exclusion criteria

The following inclusion criteria were used in our systematic review: (1) Clinical studies; (2) All level of evidence; (3) Endoscopic fasciotomy done for CECS of the forearm; (4) All endoscopic fasciotomy techniques; and (5) No restriction to date of publication. Studies were excluded if they met any of the following criteria: (1) Non-English articles; (2) Open fasciotomy; (3) Endoscopic fasciotomy of other anatomic regions (*e.g.*, leg and foot); (4) Articles published in abstract form only; (5) Review articles; (6) Technique articles; and (7) Cadaveric studies.

Data collection/extraction

Independent screening of the titles and abstracts of the included studies were carried out by the same three authors (Marwan Y, Addar A, Algarni N). Articles were included in the full-text review stage if any of the three authors believed it should, and more were excluded during this stage. The data was then retrieved from the included studies and entered/organized in Microsoft Excel 2013 (Microsoft, Redmond, WA, United States) independently by the same three authors. The information was categorized into basic background/clinical data (*e.g.*, title, authors, year of publication, country of publication, sample size, gender, age, sports, risk factor and preoperative assessment), surgical technique (*e.g.*, equipment, incision and other surgical details) and postoperative outcomes and complications (*e.g.*, follow-up duration, recurrence, complications, return to sports, pain and functional scores). The primary outcome of this review was the recurrence rate, while return to sports, pain improvement, functional scores improvement and complications were the secondary outcomes. Meta-analysis was not done due to the heterogeneity of the included studies; however, a qualitative assessment of the data was done.

RESULTS

The initial search revealed a total of 59 article (Figure 1). A total of 39, 8 and 5 articles were excluded after title, abstract and full-text review, respectively. Therefore, seven articles were included for final analysis[10,11,14-18]. These articles were published from Asia, Europe and the United States. Additional screening of the references of the seven articles did not reveal more relevant studies that meet our inclusion criteria. The three reviewers (Marwan Y, Addar A, Algarni N) had no disagreements throughout the stages of the systematic review.

Table 1 summarizes the background information and clinical features of the included studies and patients. A hundred and eighty-three patients (355 forearms) underwent endoscopic fasciotomy for CECS of the forearm, of whom 178 (97.3%) were

Table 1 Background and clinical information of patients with chronic exertional compartment syndrome of the forearm who underwent endoscopic fasciotomy

Ref.	Sample size	Gender	Age (mean and range)	Sport/risk factor	Diagnostic investigations	Preoperative VAS score (mean and range)	Preoperative DASH score (mean and range)	Preoperative quick DASH score (mean and range)
Abe and Fujii[10], 2017	1 (unilateral)	1 F	15	Tennis; This case involved the mobile wad only	Compartment pressure measurements (at rest, under stress and after stress) US and MRI	--	--	--
Hijjawi and Nagle[14], 2010	1 (unilateral)	1 M	33	Truck driver	Compartment pressure measurements (at rest and after stress)	--	--	--
Jans *et al*[11], 2015	154 (all bilateral)	151 M; 3 F	32.7; 16-42	Motocross racers	MRI after flexor loading (repetitive grip until exhaustion for 15 minutes)	1.1 ± 0.3 at rest and 7.4 ± 1.5 after stress (used scale of 1 to 10)	--	--
Miller *et al*[17], 2017	2 (1 bilateral)	2 M	24.5; 23-26	Motocross racers	Compartment pressure measurements (at rest and after stress)	9.5; 9-10 (used scale of 0 to 10)	--	--
Pegoli *et al*[15], 2016	3 (1 bilateral)	3 M	25.3	Motorcycle drivers	Compartment pressure measurements (at rest, under stress and after stress)	4.5; 3-6 (used scale of 0 to 10)	21.71%; 18.42-25.00%	--
Ruyer *et al*[16], 2020	21 (15 bilateral)	21 M	28; 14-42	Motorcycle road racing (n = 20), off-road motorcycle racing or enduro (n = 11), quad racing (n = 4) and mountain biking and water skiing (n = 1)	Compartment pressure measurements (pre- and post-stress)	--	--	23 ± 10%; 7-45%
Seiler *et al*[18], 2011	1 (bilateral)	1 F	19	Swimmer	Compartment pressure measurements (after stress)	--	--	--

DASH: Disabilities of the Arm, Shoulder and Hand; F: Female; M: Male; MRI: Magnetic resonance imaging; US: Ultrasound; VAS: Visual analogue scale.

males. The mean age of the patients was 31.2 years (range: 15-42 years). Only four (2.2%) patients were not motorcycle/motocross riders/racers. To help in establishing the diagnosis of CECS, six out of the seven studies used compartment pressure measurements (29 patients; 15.8%), while MRI was used in two studies (155 patients; 84.7%). The visual analogue scale (VAS) score was used to assess the severity of pain in three out of the seven studies (159 patients; 86.9%); however, scale range differed among these studies (one used a scale of 1 to 10, while two used a scale of 0 to 10). On the other hand, the Disabilities of the Arm, Shoulder and Hand (DASH) score was used in a single study (3 patients; 1.6%), and the quick DASH score was used in another study (21 patients; 11.5%).

Table 2 demonstrates the surgical techniques used in the included studies. Each group of surgeons used different set of tools; however, the basic setup consisted of an endoscope and a cutting instrument like blade or electrocautery. Skin incision ranged from one to three, based on surgeon preference, surgical set used and the involved compartment. Interestingly, the largest series of patients underwent fasciotomy of the

Table 2 Surgical technique used for endoscopic fasciotomy of the forearm for chronic exertional compartment syndrome

Ref.	Sample size	Surgical technique		
		Special tools	Incisions	Other surgical notes
Abe and Fujii[10], 2017	1 (unilateral)	2.3 mm endoscope with 30° angle	1 cm single incision, 2 cm proximal to the point of tenderness	Release of brachioradialis fascia (case involved mobile wad only)
Hijjawi and Nagle[14], 2010	1 (unilateral)	4.5 mm 30° endoscope and probe blade from Chow dual-port endoscopic carpal tunnel set	2 incision: 2 cm transverseincision was made at the junction of the middle and distal thirds of the forearm in line with the flexor-pronator muscles; another 2 cm incision made 4 cm distal to the elbow crease	--
Jans *et al*[11], 2015	154 (all bilateral)	The single-use Vasoview 7 Endoscopic Vessel Harvesting System (Maquet–Getinge Group, Rastatt, Germany)	Single 3 cm volar incision between flexor carpi radialis tendon and palmaris longus tendon made 4 cm proximal to the wrist	Decompression of the superficial flexor compartment done up to 3 cm distal to cubital fold
Miller *et al*[17], 2017	2 (1 bilateral)	EndoRelease (Integra LifeSciences Corporation,Plainsboro, New Jersey) system	Single incision over the subcutaneous border of the ulna midway between olecranon and ulnar styloid	--
Pegoli *et al*[15], 2016	3 (1 bilateral)	STORZ endoscopy set	Single 2 cm volar incision: Line drawn between medial epicondyle to wrist flexion crease ulnar to palmaris longus tendon, then divided into 4 parts. Incision is made between first and second quarters proximally	Fasciotomy between flexor carpi radialis/palmaris longus tendons laterally and flexor carpi ulnaris medially
Ruyer *et al*[16], 2020	21 (15 bilateral)	SmartRelease® (previously Agee®) endoscopic system (Micro- Aire Surgical Instruments, VA, United States)	Incision based on the involved compartments: Line drawn between medial epicondyle to middle of wrist flexion crease anteriorly, and between lateral epicondyle and Lister's tubercle posteriorly. 2 or 3 small incisions are made along the lines to fit the 6 cm long endoscopic knife	--
Seiler *et al*[18], 2011	1 (bilateral)	0° endoscope and electrocautery forceps	3 incisions: dorsal incision just proximal to extensor retinaculum along a line between lateral epicondyle and Lister's tubercle; volar incision made along a line between palmaris longus tendon and biceps tendon, proximal incision made 1 cm distal to the midline of the antecubital fossa, and distal incision at the wrist crease just ulnar to palmaris longus tendon	--

superficial flexor compartment only without consideration of releasing other compartments of the forearm[11]. A single case had compartment syndrome of the mobile wad only, therefore, release of the brachioradialis fascia was done only[10].

The outcomes and complications of endoscopic fasciotomy for CECS of the forearm are demonstrated in Table 3. The follow-up duration of the 183 patients ranged from 6 wk to 4.9 years. In two studies (5 patients; 2.7%), the mean VAS score at final follow-up ranged from 0.0 to 0.75 out of 10. Another study (154 patients; 84.1%) reported a final follow-up mean VAS score of 1.0 out of 10 at rest and 1.7 out of 10 following stress. In addition, the postoperative DASH score ranged from 2.15% to 5.39% in two studies (4 patients; 2.2%), and the mean quick DASH score was 1% in a single study (21 patients; 11.5%). All patients were able to return to sport activities, and this was between postoperative week 1 to 8. Recurrence of the compartment syndrome occurred in three patients, giving a rate of 1.6% per patient and 0.8% per forearm. The overall complication rate was 8.7% per patient, and 4.5% per forearm. The most common reported complication was hematoma (7 forearms; 2.0%).

Table 3 Outcomes and complications of endoscopic fasciotomy of the forearm for chronic exertional compartment syndrome

Ref.	Sample size	Follow-up duration	Postoperative VAS score (mean and range)	Postoperative DASH score (mean and range)	Postoperative quick DASH score (mean and range)	Return to sports	Other outcomes	Recurrence	Complications
Abe and Fujii[10], 2017	1 (unilateral)	7 mo	--	--	--	Returned 2 mo postoperatively	Pain free at 4 mo postoperatively	None	None
Hijjawi and Nagle[14], 2010	1 (unilateral)	6 mo	--	--	--	--	Pain free at final follow-up	None	None
Jans *et al*[11], 2015	154 (all bilateral)	6 wk	1.0 ± 0.2 at rest and 1.7 ± 0.9 after stress (used scale of 1 to 10)	--	--	All returned 6 wk postoperatively	--	1 recurrence 8 mo postoperatively	5 hematomas requiring drainage
Miller *et al*[17], 2017	2 (1 bilateral)	1 mo (only specified for 1 case)	0.0	--	--	Both returned 1 wk postoperatively	Improved grip strength and wrist ROM	None	1 case had small seroma resolved with compressive wrapping at 2 wk postoperatively
Pegoli *et al*[15], 2016	3 (1 bilateral)	45.80 mo (34-55)	0.75; 0-2 (used scale of 0 to 10)	5.39%; 2.15-10.05%	--	All returned 3 wk postoperatively	--	None	None
Ruyer *et al*[16], 2020	21 (15 bilateral)	4.9 ± 2.7 yr (range: 1.0-10.2)3 patients lost follow-up	--	--	1 ± 2%; 0-9%	Returned at 4.3 ± 1.8 wk (range: 3-8 wk) postoperatively	14 were very satisfied with the procedure, 3 were satisfied, and 1 was moderately satisfied.	2 recurrence due to fibrous scar tissues requiring revision fasciotomy; revision was open for one of them	2 superficial vascular injury, 1 superficial sensory nerve injury, 2 hematomas (1 requiring drainage), 3 transient hypoesthesia (recovered at 3 mo postoperatively). 2 lateral epicondylalgia
Seiler *et al*[18], 2011	1 (bilateral)	9 mo	--	5.0%	--	Returned 3 wk postoperatively; full level at 6 wk postoperatively	Pain free at final follow-up	None	None

DASH: Disabilities of the Arm, Shoulder and Hand; VAS; Visual analogue scale.

DISCUSSION

The current systematic review has explored the outcomes and complications of endoscopic fasciotomy for CECS in 355 forearms of 183 patients. Regardless of the technique/equipment used to perform the endoscopic fasciotomy, the outcomes were excellent. The recurrence and complication rates were less than 1% and less than 5% per forearm, respectively. No serious complications were reported. Additionally, no patients were unable to return to their preoperative level of sports activities, and

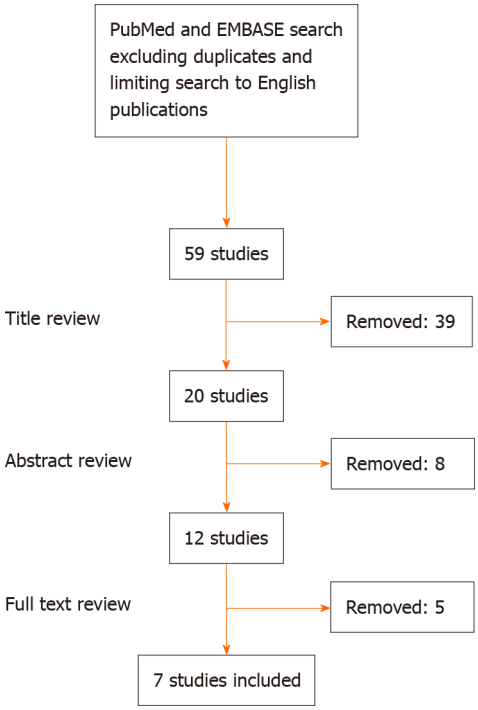


Figure 1 Flow diagram of the systematic search strategy.

return to sports was between 1 wk to 8 wk postoperatively. Resolution of pain and improvement in functional scores were also excellent.

Surgical treatment for CECS has high success rate, regardless of the surgical technique used[1-3]. Compared to patients who undergo surgical intervention for CECS of the forearm, authors have shown that all patients who underwent nonoperative management continued to struggle and were no longer able to perform sports and activities at the same level of their pre-morbid condition[1,19]. Surgical intervention is, therefore, recommended for those who wish to continue to practice high level of sports activities.

Wide open fasciotomy of the forearm is thought to be the best surgical intervention for CECS, allowing full release of the fascia, better visualization of neurovascular structures, and peripheral nerve decompression if needed; thus, may have lower rate of complications[1-3,20,21]. Based on the available literature on open forearm fasciotomy for CECS and our current systematic review of endoscopic fasciotomy, this is not necessarily true. The rate of patients with full resolution of CECS symptoms following open or mini-open fasciotomy of the forearm ranged between around 85% to 98%[2,9,20-23], while the rate after endoscopic fasciotomy was around 99% [2,10,11, 14-18]. Moreover, complication rate of open and mini-open fasciotomy ranged between around 14% to 21%[2,9,20-23], while the rate following endoscopic fasciotomy was less than 10%[2,10,11,14-18]. Although these differences have not been proven with high-quality, comparative, prospective studies, endoscopic fasciotomy may provide superior outcomes compared to open fasciotomy.

Although this study provides valuable information, several limitations exist. The studies found in the literature and included in the current systematic review are either case series or case reports. Despite the lack of high-quality, high-level of evidence studies, valuable information has been extracted which should help guide future research about endoscopic forearm fasciotomy. Also, as most of the available studies were case reports, cases with unsatisfactory outcomes might have been underreported. Another limitation is that the short period of postoperative follow-up for some of the included studies. A long-term follow-up is needed specially to determine recurrence of the CECS after resuming sports for a longer period post endoscopic fasciotomy. In addition, poor documentation of relevant functional outcomes was noted in the available studies.

CONCLUSION

Endoscopic fasciotomy for CECS of the forearm has favorable short- and mid-term outcomes with very low recurrence and complication rates. This, however, needs to be confirmed in larger, long-term follow-up, prospective, comparative studies between open, mini-open and endoscopic fasciotomy techniques.

ARTICLE HIGHLIGHTS

Research background

Chronic exertional compartment syndrome (CECS) of the forearm can limit the quality of life and sport activities. Endoscopic forearm fasciotomy has been described to manage this condition.

Research motivation

The literature of endoscopic forearm fasciotomy for CECS has not been analyzed in detail.

Research objectives

To systematically review the literature if endoscopic fasciotomy for the management of CECS of the forearm.

Research methods

PubMed and EMBASE were searched, and all relevant studies were considered for analysis based on predetermined inclusion/exclusion criteria. The subject headings "endoscopic fasciotomy" and "compartment syndrome" and their related key terms were used.

Research results

A total of seven studies including 183 patients (355 forearms) were included. All patients were able to return to sport activities between postoperative week 1 to 8. Recurrence of the compartment syndrome occurred in three patients. The overall complication rate was 8.7% per patient, and 4.5% per forearm.

Research conclusions

Outcome of endoscopic fasciotomy for CECS of the forearm are favorable, with low recurrence and complication rates.

Research perspectives

Future larger, long-term follow-up, prospective, comparative studies between open, mini-open and endoscopic fasciotomy techniques are needed.

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CASE REPORT

Rare shear-type fracture of the talar head in a thirteen-year-old child — Is this a transitional fracture: A case report and review of the literature

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Author contributions: Monestier L and Faoro L were the patient's surgeons; Monestier L, Riva G, Faoro L reviewed the literature and contributed to manuscript drafting; Monestier L analyzed the imaging findings; Surace MF, Monestier L and Riva G were responsible for revision of the manuscript for important intellectual content; all authors issued final approval for the version to be submitted.

Informed consent statement: The informed consent statement has been correctly acquired. The file was previously sent to the reviewer.

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Abstract

BACKGROUND

Talar fractures are exceedingly rare in childhood. There are very few studies on the clinical aspects, the long-term outcomes and the appropriate treatment of these fractures in pediatric patients. The mechanism of trauma consists of the application of a sudden dorsiflexion force on a fully plantar-flexed foot. Traumatic mechanism, symptoms and imaging of injuries of the talar head are similar to transitional fractures that are normally described at the distal epiphysis of the tibia: the so-called transitional fracture is defined as an epiphyseal injury when the growth plate has already started to close.

CASE SUMMARY

A thirteen-year-old girl reported a high-energy trauma to her right foot, due to falling from her horse. X-rays at the Emergency Department were negative. Because of persistent pain, the patient was assessed by an orthopedic surgeon after two weeks and computed tomography scans revealed a misdiagnosed displaced shear-type fracture of the talar head. Hence, surgical open reduction and fixation with two headless screws was performed. The girl was assessed regularly, and plain films at follow-up revealed complete healing of the fracture. Within six months after surgery, the patient returned to pre-injury sport activities reporting no complications.

CONCLUSION

Injuries of the talar head in childhood should be considered as transitional fractures. Open reduction with internal fixation aims to reduce malalignment and

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osteoarthritis. Computed tomography scans are recommended in these cases.

Key Words: Head; Talus; Transitional fracture; Child; Surgical treatment; Case report

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Core Tip: Fractures of the talar head in childhood must be judged as transitional fractures. These injuries, typically occurring at the distal tibia, are defined as an epiphyseal injury when the growth plate has already started to close. This crucial aspect should be considered by orthopedic surgeons: surgical treatment is preferred in order to reduce malalignment and osteoarthritis.

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INTRODUCTION

Talar fractures are exceedingly rare in childhood, with an estimated incidence of 0.01%-0.08% among all pediatric fractures[1-6]. This rarity is due to skeletal immaturity making the bone more resistant to bending and torsional forces without subsequent fracture[2,4,5,7-9].

In the talus, the neck is usually involved, followed by the body and the head: the latter is protected by ligaments and capsule of the talar-navicular joint[4,10]. Talar fractures are often related to high-energy trauma (high-altitude fall, sport injuries, car accidents)[8,11,12]. The mechanism of trauma generally consists of the application of a sudden dorsiflexion force on a fully plantar-flexed foot: compressive forces through the talar head result in compression of the talar head against the anterior tibial edge[11]. Participation in high-impact sports may increase the incidence of talus fractures in children[12].

Despite the improvements in surgical procedures, complications of these fractures are extremely frequent: osteonecrosis, post-traumatic osteoarthritis and foot deformity are the most common[3,8,11,13]. In the past, fracture displacement and delayed surgery were considered the main risk factors; thus, immediate open reduction with internal fixation (ORIF) was recommended[14,15]. However, the most recent literature has shown that there is no significant correlation between time of surgery and development of osteonecrosis or osteoar-thritis[16,17].

Relatively little is known about talar injuries in childhood, as there are only a small number of studies in the literature. Due to their rarity, there are very few studies on the clinical aspects, the long-term outcomes, and the appropriate treatment in pediatric patients[18].

Here we report the rare case of a shear-type fracture of the talar head in a female adolescent, initially misdiagnosed in the emergency room.

CASE PRESENTATION

Chief complaints

A 13-year-old female came to the Emergency Department (ASST Settelaghi-Fondazione Macchi, Varese, VA, Italy) with a possible dislocation of the right ankle after a fall from her horse.

Physical examination

At clinical examination, an antero-medial tenderness of the foot, local pain and inability to bear weight on right foot were observed.

Laboratory examinations

Laboratory examinations were normal.

Imaging examinations

A trauma X-ray series was performed, with no evidence of fractures (Figure 1).

FINAL DIAGNOSIS

Shear-type fracture of the talar head.

TREATMENT

The patient was released from the hospital without evaluation by an orthopedic surgeon and was prescribed rest, no weight-bearing for a week, non-steroidal anti-inflammatory drugs and ice.

As local pain and inability to weight-bear was protracted with no further trauma, the patient came to our Trauma Unit after fifteen days. Pain at palpation and minimal swelling were found in her right foot. Hence, the orthopedic surgeon requested a computed tomography (CT) scan which revealed a displaced shear-type fracture of the talar head (Figure 2). This fracture was described as type-2, as defined by Canale *et al*[19].

It was decided to perform ORIF due to displacement and involvement of the articular surface. Surgery was performed two days later (seventeen day after trauma).

Open reduction was performed through an anteromedial approach and the fracture was fixed using two divergent BSS headless screws (Medartis AG, Basel, Switzerland), favoring compression and avoiding rotation of the fragment (Figure 3).

Postoperatively, the ankle was protected by a below-knee cast and no weight-bearing was allowed. Enoxaparin was prescribed for thromboprophylaxis. Pulsed electromagnetic field therapy was indicated for 4-6 h per day (IGEA Clinical Biophysics, Carpi, Italy).

OUTCOME AND FOLLOW-UP

At one-month follow-up, we found no local edema or wound complications, and the patient had minimal pain [(numeric rating scale) NRS = 2]. Plain films revealed initial healing of the fracture (Figure 4). The cast was substituted with a removable air-cushioned ankle orthosis (Bauerfiend© AirLoc) to avoid foot pronation and supination. We believe it was crucial to protect the cartilaginous surface of the talar head. Weight-bearing was not permitted. A rehabilitation protocol was begun with active/passive dorsiflexion and plantarflexion. At six weeks, foot pronation and supination exercises were introduced, as weight off proprioception and exercises in the pool.

At two months follow-up, range of motion was restored without pain (NRS = 0), 50% partial weight-bearing was indicated for two weeks, and then complete weight-bearing as tolerated. A rehabilitation protocol was deployed (Figure 5). Running and atraumatic sport activities were reintroduced at three months.

At six months, the young patient practiced every sport, and specifically horse riding, without any complications (NRS = 0). Range of motion was completely restored, and the patient showed no postoperative foot deformities or neurovascular deficits. Plain films revealed healing of the fracture with no osteonecrosis or osteoarthritis (Figure 6).

DISCUSSION

Talar fractures are exceedingly rare in childhood with an estimated incidence of 0.01%-0.08%[1-6]. This rarity is due to skeletal immaturity making the bone more resistant to forces without subsequent fracture [2,4,5,7-9].

When comparing children (< 12 years) and adolescents (> 12 years), Ebler reported a higher incidence of talar fractures in the latter, probably due to skeletal development: in younger children, the immature portion of the talus shows more resistance to



Figure 1 X-rays of the patient at the emergency department. A: The foot was investigated by A-P view; B: Oblique view; C: Ankle on lateral view; and D: A-P view.

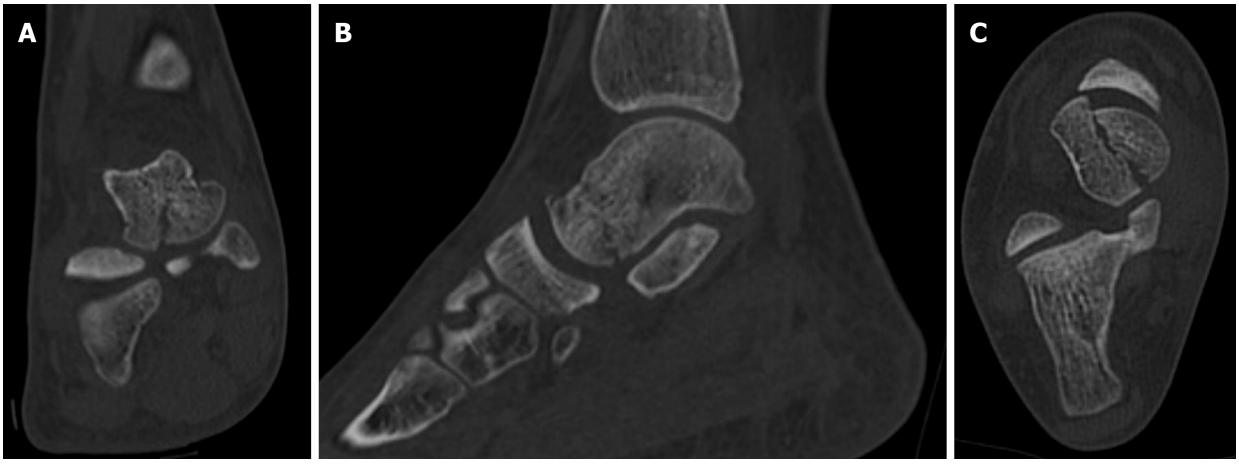


Figure 2 Pre-operative computed tomography images of the shear-type fracture. A: Coronal, B: Sagittal; and C: Axial view are shown.

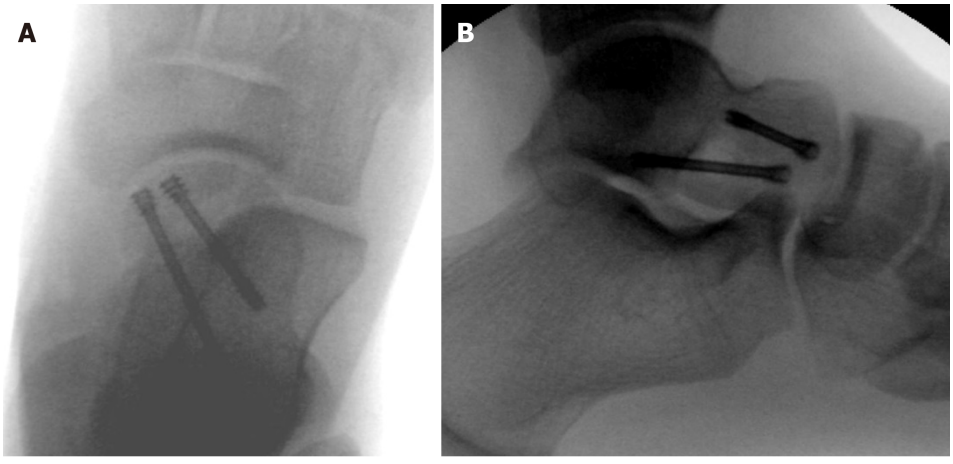


Figure 3 Intraoperative X-rays. Two headless screws were used for fixation. A: Anteroposterior view; B: Lateral view.

bending or compressive forces[11]. The severity of these fractures has been demonstrated to be greater in older patients[6,12].

Talar fractures are often related to high-energy trauma (high-altitude falls, sport injuries, car accidents). First described by Anderson in 1919, the mechanism of trauma generally consists of the application of a sudden dorsiflexion resulting in compression

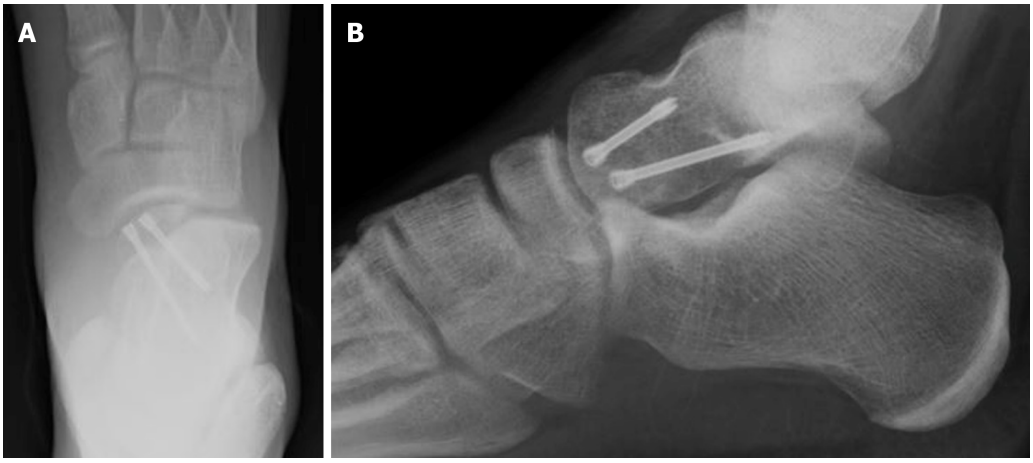


Figure 4 Plain films at one-month postoperative follow-up: the fracture is healing. A: Anteroposterior view; B: Lateral view.

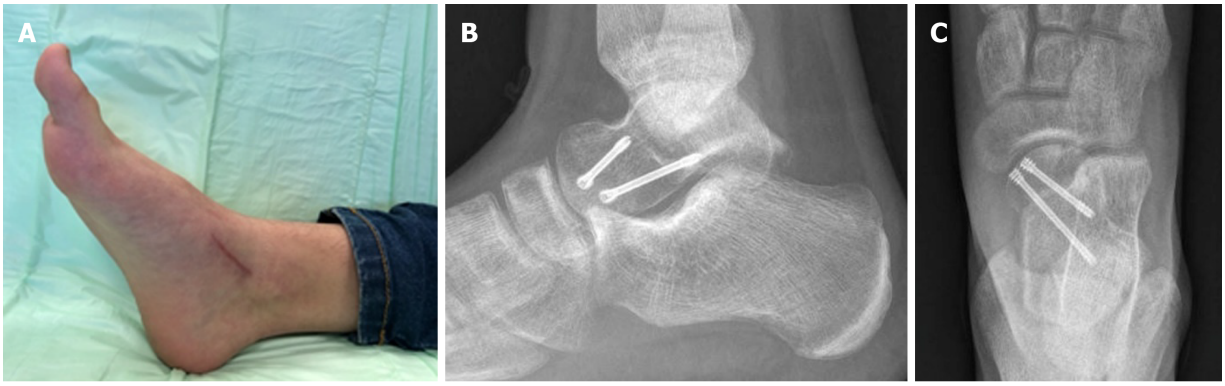


Figure 5 Follow-up at two months: the foot is shrunken and the surgical wound healed. Plain films revealed a healed fracture. A: Clinical assessment; B: Lateral view; and C: Anteroposterior view.

of the talar head against the anterior edge of the tibia[18]. This theory was successively confirmed[8,11,12].

The rarity of these fractures in childhood and the difficulty in their diagnosis on plain films often result in misdiagnosis. Our patient was diagnosed after two weeks only because a CT scan was requested due to protracted pain and inability to walk. Hence, we emphasize the importance not only of a careful clinical assessment of the foot and ankle at the Emergency Department, but also of a meticulous examination of the medical history of the patient and of the trauma mechanism. In the case of a pediatric patient with high energy trauma, despite no recognizable fractures on plain films, CT or magnetic resonance imaging (MRI) scans are strongly suggested.

CT scanning has several advantages over MRI: CT is useful for precisely analyzing the degree of injury, specifically articular involvement, and to plan accurate surgical treatment[20]. CT permits rapid acquisition of scans, optimal visual resolution and three dimensional-acquired images. Moreover, sedation and anesthesia are not required. Conversely, MRI eliminates the exposure to radiation in pediatric patients. This issue should not be underestimated as compared to adults, children show more sensitivity of tissues to ionizing radiation and their longer lifetime allows the development of several tumors. For this reason, in the last decades several studies evaluated the effects of exposure to radiation in children, introducing the notion of "as low as reasonably achievable" dose[21-25]. The use of low-dose CT or ultra-low-dose CT, digital acquisition of images and more accurate protective devices have significantly reduced the exposure of pediatric patients to ionizing radiation: with regard to fractures, ultra-low-dose CT has been demonstrated to expose patients to lower doses than plain films[24]. Hence, we strongly believe that a CT scan at the Emergency Department is necessary in the case of high energy trauma involving children. Our statement regarding the necessity of CT scans in pediatric ankle fractures is supported by the literature[26-29].



Figure 6 Follow-up at six months: complete range of motion was restored. A: Clinical assessment; and B: Fracture healed without osteonecrosis or osteoarthritis.

With regard to the pediatric population, ossification of the talus and the mechanism pattern, an important question emerges: could these injuries be transitional fractures?

Talus development is based on endochondral ossification. The ossific nuclei of the talus compares to the neck during the 26th-28th gestational week. In newborns, up to 24% of the talus consists of bony tissue[30,31]. Frisch described two periosteal collars: the first forms the roof of the sinus tarsi; the second is situated at the top of the ossification center and is covered by a layer of fibrocartilage-like tissue, a layer of dense connective tissue and the synovial membrane of the tibiotalar joint[30]. Complete talar maturity occurs during adolescence (12-22 years). However, because the talus has no epiphysis, it is difficult to determine the maturity of the talus; hence, its development is usually defined by the closure of metatarsals (14-21 years)[32].

The so-called transitional fracture is defined as an epiphyseal injury when the growth plate has already started to close (Figure 7 shows closure of the distal tibial physis). The most involved site is the distal tibia: transitional fracture occurs because of the combination of relative weakness of not yet mineralized epiphyseal areas and the great resistance of mature bone, stabilized by tibiotalar ligaments. The distal epiphysis of the tibia is prone to fracture as it shows a uniform and eccentric closure pattern of the growth plate[33].

Could the fracture of the talar head/neck edge be considered a transitional fracture? Presumably, yes. The mechanism could be compared to that which occurs at the distal tibia. As described above, the enchondral ossification of the talus concludes in adolescence. The weakness of unfused talar areas on the one hand, the increased stability of the already mineralized parts and the strength of the talonavicular joint on the other hand, tend to facilitate fracture at this site when a torsional or compressive force is applied to the foot.

The treatment is conservative for nondisplaced transitional fractures. The tolerance limit is a fracture displacement greater than 2 mm and/or a joint step[33]. The purpose of surgical treatment is anatomical joint reconstruction. Several authors disputed whether an open reduction or percutaneous closed reduction is required[33-35].

With regard to the distal tibia, Schneidmueller *et al*[33] suggested ORIF should be performed as capsule incision ensures the evacuation of hemarthrosis reducing intraarticular pressure, and permits a direct view of the fracture. Fixation is performed with cannulated screws[33].

The treatment of a transitional fracture aims to reduce complications, physeal malalignment, growth disturbances and post-traumatic osteoarthritis. However, closure of the physeal plate is not sufficient in adolescents to cause significant growth-related problems and ORIF is indicated mostly to reduce articular malalignment leading to osteoarthritis.



Figure 7 Postoperative plain film: The orange arrow shows that the physis of the distal tibia has started to close.

These principles can all be applied to fractures of the talar head.

In the present case, we decided to perform ORIF using two headless screws. A displaced shear-type fracture of the talar head could result in midfoot deformity and osteoarthritis of the talonavicular joint. Open reduction was necessary as we performed surgery on the seventeenth day after the trauma. At follow-up, no signs or symptoms were observed in our young patient.

Talar fractures in pediatric patients must be treated similar to those in adults[5,36]. Nondisplaced fractures of the talus can be treated non-operatively by using cast immobilization, while displaced fractures require operative intervention[5,11]. Godoy-Santos *et al*[8] and Rammelt *et al*[20] highlighted the limitations of the talar spontaneous remodeling capacity during growth; thus, these authors indicated ORIF for all displaced fractures[8,20]. If a few attempts of closed reduction appear unsuccessful, open reduction should be performed[8].

Kruppa *et al*[6] demonstrated worse injuries with high rates of complications (nonunion, osteonecrosis, osteoarthritis, deformities) and disabilities in adolescents: in general, older children and adolescents were more likely to benefit from surgical treatment[6].

The purpose of treatment is to reduce the rate of complications: osteonecrosis, osteoarthritis and foot deformities are the most frequent and dangerous[3,5,8,11-13]. With regard to the talar head specifically, unreduced fractures may result in post-traumatic arthritis and three-dimensional deformities: the foot function can be severely restricted by the medial column displacement and subluxation in the talonavicular joint[8,13]. Hence, immediate ORIF was traditionally considered crucial[14,15]. Nonetheless, the most recent literature has shown that there is no significant correlation between time of surgery and development of osteonecrosis or osteoarthritis[16,17].

CONCLUSION

Talar head fractures represent severe injuries, including in the pediatric population. Open reduction and internal fixation are necessary in the case of displacement. Injuries of the talar head in children and adolescents should be considered as transitional fractures; hence, the treatment aims to reduce malalignment and osteoarthritis. Due to the frequent misdiagnosis of these fractures, CT scans are recommended in children describing high energy trauma.

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CASE REPORT

Three-dimensional printing technology for patient-matched instrument in treatment of cubitus varus deformity: A case report

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Author contributions: Sri-utenchai N and Sa-ngasoongsong P were the main researchers who conceptualized and performed the study, and prepared the manuscript; Pengrung N was the orthopedic surgeon who assisted in the data collection; Srikong K, Puncreobutr C, and Lohwongwatana B were the experienced engineer team who performed the computer simulation and assisted in the customized osteotomy guide and patient-matched monoblock crosslink plate design and manufacture; all authors have read and approved the final manuscript.

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Abstract

BACKGROUND

Recently, medical three-dimensional printing technology (3DPT) has demonstrated potential benefits for the treatment of cubitus varus deformity (CVD) by improving accuracy of the osteotomy through the use of an osteotomy guide, with or without a patient-mated plate. Here, we present an interesting CVD case, involving a patient who was treated with corrective biplanar chevron osteotomy using an innovative customized osteotomy guide and a newly designed patient-matched monoblock crosslink plate created with 3DPT.

CASE SUMMARY

A 32-year-old female presented with a significant CVD from childhood injury. A computer simulation was processed using images from computerized tomography scans of both upper extremities. The biplanar chevron osteotomy was designed to create identical anatomy between the mirror image of the contralateral distal humerus and the osteotomized distal humerus. Next, the customized osteotomy guide and patient-matched monoblock crosslink plate were designed and printed. A simulation osteotomy was created for the real-sized bone model, and the operation was performed using the posterior paratricipital approach with k-wire positioning from the customized osteotomy guide as a predrilled hole for screw fixation to achieve immediate control of the reduction after osteotomy. Our method allowed for successful treatment of the CVD case, significantly improving the patient's radiographic and clinical outcomes, with satisfactory result.

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CONCLUSION

3DPT-created patient-matched osteotomy guide and instrumentation provides accurate control during CVD correction.

Key Words: Cubitus varus deformity; Post-trauma reconstruction; Three-dimensional printing technology; Biplanar chevron osteotomy; Customized osteotomy guide; Patient-matched implant; Case report

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Core Tip: To the best of our knowledge, this case report introduces a new insight for the clinical application of three-dimensional printing technology in the treatment of cubitus varus deformity. Successful outcome of cubitus varus deformity correction is dependent upon precise preoperative planning and the accuracy of osteotomy and fixation. The treatment procedure itself can be performed safely, with high chance of alignment correction by means of three-dimensional printing technology to generate a well-designed customized osteotomy guide and patient-matched plate.

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INTRODUCTION

Cubitus varus deformity (CVD) is the most common late complication after supracondylar fracture of distal humerus in children[1] and, if left un-intervened, results in multiplanar deformity (varus, hyperextension, and rotation)[2]. The current standard treatment for CVD is corrective supracondylar osteotomy of the humerus, using a plethora of surgical correction techniques[3]. However, previous studies have shown that the conventional corrective osteotomy can result in poor functional outcomes-such as, unsatisfactory correction and residual deformity, and lateral condyle prominence with poor cosmetic appearance[4].

Recently, three-dimensional printing technology (3DPT) has been developing and is one the most exciting and fastest growing fields of healthcare due to its excellent accuracy from using preoperative computed tomography (CT) evaluation and advanced computer software, enabling of personalized treatment, having a wide range of potential uses including in the clinical application of orthopaedic surgery[5]. Regards the treatment of cubitus varus deformity, previous studies showed that 3DPT is beneficial for preoperative planning[6], design of individualized surgical guide[7-9], preparation of the prebent plate with real-sized plastic bone model[10], and patient-matched plate[11,12]. However, through our knowledge, the application of 3DPT in the cubitus varus deformity is still limited to design of osteotomy guide for the simple technique as lateral closed wedged osteotomy and mostly fixation with conventional implants.

This study aimed to present a novel surgical technique based on 3DPT applied to a 32-year-old female with CVD *via* corrective biplanar chevron osteotomy using a 3DPT-generated customized osteotomy guide and patient-matched monoblock crosslink plate.

CASE PRESENTATION

Chief complaints

A 32-year-old female presented to our clinic with deformity of the left elbow that was progressively worsening.

History of present illness

At 7 years of age, the patient had suffered an injury to the left elbow, which had been treated by a nonoperative method. Since then, the patient experienced a progressive gunstock deformity of the left elbow, but without pain, numbness, or weakness in the left upper extremity.

History of past illness

The patient had previous good health.

Personal and family history

The patient reported that no family member had suffered from this symptom before.

Physical examination

Physical examination showed a 20° varus deformity, with elbow range of motion (ROM) as flexion of 125°, extension of -10°, supination of 85°, and pronation of 80° (Figure 1A). There was no muscle atrophy of the left hand, and the distal neurovascular status of the left upper extremity was intact.

Laboratory examinations

All laboratory tests yielded results within normal range.

Imaging examinations

Preoperative radiography and 3D-CT (Figure 1B and C) showed a 15° varus deformity and 10° hyperextension deformity, without rotational deformity.

FINAL DIAGNOSIS

Cubitus varus and recurvatum deformity of the distal humerus.

TREATMENT

After detailed discussion regarding the treatment option of corrective biplanar chevron osteotomy, an approach was formulated that would involve the use of a 3DPT-generated customized osteotomy guide and an innovative patient-matched monoblock crosslink titanium plate. The customized osteotomy guide was specifically designed to ensure the position of k-wire fixation at the same position of the screw holes on the patient-matched plate. Through these aspects, this specific design was expected to assist the surgeon with bone reduction after osteotomy *via* application of the plate through the k-wire position, which featured a predrilled hole for screw insertion. Moreover, we also designed the plate configuration as a monoblock crosslink plate, by placing the plate on the medial and posterolateral side of the distal humerus with the built-in metal crosslink between both sides. This plate design was expected to aid in the reduction osteotomy, according to its features of easier and better intraoperative plate position adjustment compared to the conventional dual plating technique. We also intended the crosslink to provide improved biomechanical properties of the plate and stability after fixation, as compared to separate dual plates, as reported for spinal surgery[13]. Therefore, use of the innovative plate design, with its described advantages, and the 3DPT technology for its customized generation would benefit the complex osteotomy operation by reducing operative time related to the bone reduction step and improving accuracy of the osteotomy itself.

Preparation of the customized osteotomy guide and patient-matched monoblock crosslink plate

A simulation of the deformity correction was first performed through 3D reconstruction and image processing of DICOM files, taken from CT scans, *via* Avizo software (Thermo Fisher Scientific, Waltham, MA, United States). A corrective biplanar chevron osteotomy was planned, as illustrated in Figure 2A, to divide the affected bone into three separated fragments. The distal fragment of bone was then reduced to match the mirrored image of the contralateral bone. The designs of the customized osteotomy guide and the patient-matched monoblock crosslink plate were then developed based on the patient's anatomical bone geometry and the surgeon's

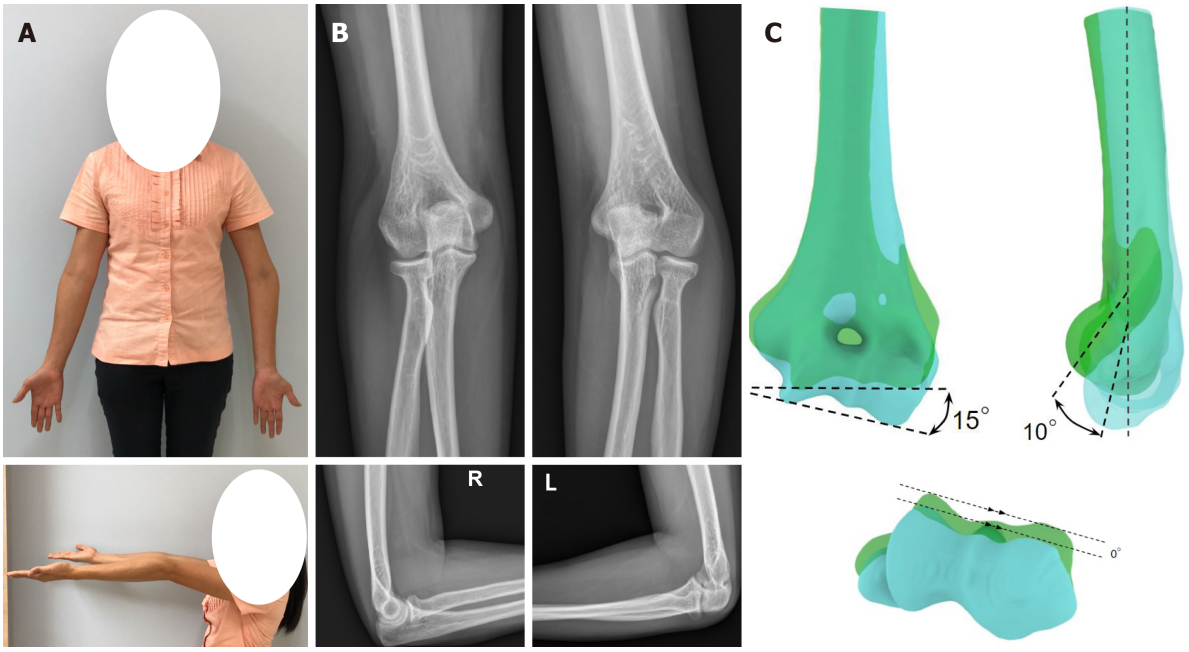


Figure 1 Preoperative evaluation. A: Clinical pictures showing the cubitus varus and hypertension deformity of the left elbow; B: Preoperative radiographs in antero-posterior and lateral views showing a humerus-elbow-wrist angle of 15º varus and a shaft condylar angles of 35º on the left side, and those of 13º valgus and 45º, respectively; C: Three-dimensional computed tomography analysis with overlapping of the mirror image model from the right humerus (green color) and the deformed model from the left humerus (blue color). Anterior view showing a 15º-degree varus deformity. Lateral view showing a 10º-degree hyperextension deformity. Axial view showing no rotational deformity.

requirements using ANSYS software (Ansys Inc., Canonsburg, PA, United States).

The osteotomy guide was designed to fit over the distal surfaces (posterior, lateral, and medial supracondylar ridge) of the defected bone, excepting the area over the olecranon fossa (Figure 2B). The cutting slots and drilling sleeves were designed to match the cutting planes and the plate's screw holes, respectively. The patient-specific plate with the monoblock crosslink was designed to fit over the corrected humerus bone, with an overall thickness of 2 mm (Figure 2C). The structural strength of the plate was also confirmed by finite element analysis.

Upon the surgeon's approval of the design, the patient-specific implant was 3D-printed by selective laser melting using medical grade Ti-6Al-4V alloy (Meticuly Co., Ltd., Bangkok, Thailand). The processing parameters set for the SLM machine (Mlab 200R, Concept Laser GmbH, Germany) were 180 W of laser power and 1250 mm/s of scanning rate. This process was operated under 99.999% Ar atmosphere. Subsequent post-processing techniques, including surface polishing and sterilization, were performed according to routine standards. For osteotomy guides and bone models, fused filament fabrication was used for the 3D printing of biocompatible high-impact polystyrene. The entire fabrication process was certified by the ISO13485 standard for the design, manufacturing, and sterilization of medical devices. Finally, the customized osteotomy guide was printed, and a trial osteotomy was simulated on the real-sized plastic bone model (Figure 2C). The dimensions of the customized osteotomy guide and the patient-specific plate were given in Supplementary Figures 1 and 2.

Surgical technique and postoperative care

After administration of combined general anesthesia and an ultrasound-guided supraclavicular nerve block, the patient was placed in the right lateral decubitus position. The operation was performed using a standard posterior paratricipital surgical approach, with a 20-cm posterior midline incision. The triceps muscle was exposed and elevated from the posterior surface of the distal humerus, and then the ulnar nerve was identified. The customized osteotomy guide was placed and fixed with multiple K-wires. After complete osteotomy, the guide and bone blocks were removed, and the plate was inserted under the triceps using the screw fixation based on the predrilled screw holes (Figure 2D).

The intraoperative flexion/extension ROM was 135º/0º. The intraoperative fluoroscopic images were checked to confirm the post-reduction alignment (Figure 2E) before wound closure (without nerve transposition). The total operative time was 116

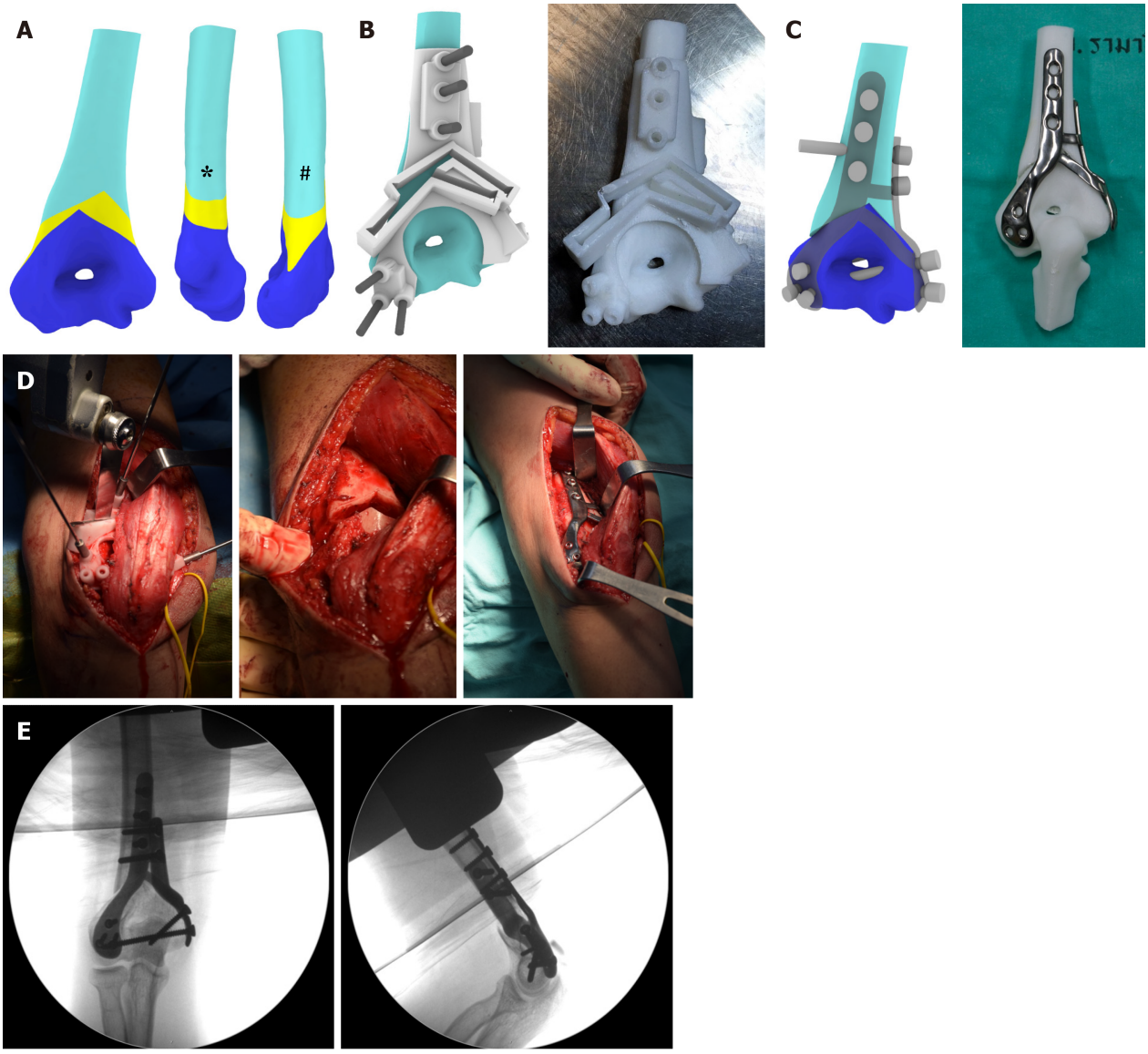


Figure 2 Preparation of the customized osteotomy guide and patient-matched plate. A: The biplanar chevron osteotomy was designed, and the osteotomy block in antero-posterior and lateral views from medial (*) and lateral (#) were demonstrated; B: The proximal, osteotomized, and distal fragments are shown in light green, yellow, and dark blue color respectively. The customized osteotomy guide was designed and printed accordingly; C: The patient-matched monoblock crosslink plate was innovated and made by using the same holes for k-wire and screw fixation; D: Intraoperative surgical steps for the customized osteotomy guide placement, osteotomy, and fixation respectively with the patient-matched implant; E: Intraoperative fluoroscopic images after fixation.

min. The initial postoperative radiographs showed good alignment and adequate fixation stability in both antero-posterior and lateral views.

OUTCOME AND FOLLOW-UP

After surgery, the patient was immobilized with an arm sling for 6 wk and was allowed to perform active assisted-ROM exercises of the wrist, elbow, and shoulder joints, as tolerated. During admission, she reported only minimal pain on motion, with mild paresthesia affecting the ulnar side of the left hand. She was discharged from the hospital 3 d postoperative and was scheduled for follow-up visits at the orthopedic clinic.

At first follow-up, the clinical examination showed nearly normal alignment of the left elbow (compared to the right side). Normal sensation had completely returned by 6 wk postoperative, and the flexion/extension and pronation/supination ROMs of the left elbow were 130°/0° and 90°/90° respectively. The osteotomy healed uneventfully by 3 mo postoperative. The postoperative radiographs demonstrated improved humerus-elbow-wrist angle, from 15° varus to 7° valgus (compared to 8° valgus on the

right side) (Figure 3). At the last follow-up visit, at 18 mo postoperative, the patient reported being highly satisfied with the clinical outcome and did not report feeling any pain, swelling, or implant irritation. Therefore, we did not advise removal of the implant in this case.

DISCUSSION

Medical 3DPT has recently fueled new hope for an effective treatment of CVD. Especially promising is that the technology enables highly accurate control of the plane and the angle of osteotomy, resulting in higher overall operating accuracy and lower risk of complications.

Regarding the development of a customized osteotomy guide for the CVD, Murase *et al*[14] first reported performing a 3D corrective osteotomy on 22 patients with malunited fractures of the upper extremities (including 4 cases with CVD) by using custom-made osteotomy template and reduction guide on the bone surface of lateral side of distal humerus metaphysis and fix with k-wire. Then the closed wedged osteotomy was performed by cutting through a slit on the template and using the reduction guide to align the bone. Since then, many researchers have worked towards developing an individualized navigation template for lateral closed-wedge osteotomy to treat CVD, and showed the advantages of this technique as to determine the osteotomy angle, osteotomy plane, and rotational angle[8,11,12,15]. In this study, we innovatively designed a customized osteotomy guide to place on the posterior surface of our patient's distal humerus, to address the need for a posterior slit for the biplanar chevron osteotomy. Although this design might be larger than the previously mentioned lateral-side template, our customized osteotomy guide provided predrilled holes for medial plate placement, resulting in easier placement of the 3D patient-matched plate in the later steps of the procedure. Moreover, performing the osteotomy through a posterior slit would better minimize the risk of ulnar nerve injury that is faced by osteotomy performed through a lateral slit.

Concerning the development of the patient-matched plate for the cubitus varus deformity, there were only two studies by Omori *et al*[11] in the cadaveric study and Oka *et al*[12] in the prospective multicenter study. In these studies, both patient-matched plate designs were made from titanium and placing on the lateral side of distal humerus. Although there was no control group in the prospective study by Oka *et al*[12], they showed that the patient-matched implants resulted in highly accurate correction with an average residual maximal deformity angle of 3.3° and average 3D correction error of < 1.0° and < 1 mm, with high patient satisfaction and no serious complication[12].

Our study has some limitations that must be considered when interpreting our results. First, the present study was based on a single case, without control group patients for comparison. Nonetheless, we believe our method is reliable; our method also showed high accuracy, like the other methods used in previous studies. Second, due to the osteotomy and implant design, our method requires a posterior paratricipital approach, to provide for a medial and lateral soft tissue window and elevation of the triceps muscle. However, this posterior approach allows the surgeon to explore and protect the ulnar nerve, making the overall procedure safer for patients with the type of severe and complex anatomy present with CVD. Moreover, the surgical scar on the posterior side resulting from this approach will be more cosmetically acceptable for patients, especially for younger individuals. Lastly, as with previous studies using the 3DPT technology, our method requires patients to be exposed to radiation from the CT scans required for both upper extremities. Additionally, the materials used for patient-specific plate in this study was designed as Ti-6Al-4V alloy as same as the previous studies. Although Ti-6Al-4V alloy is a well-established biomaterial for orthopaedic implant with high biocompatibility and corrosion resistance as same as commercially titanium implants, it can release a very low concentration of potentially toxic metal ions as aluminum and vanadium ions that had been linked to some health problems such as Alzheimer's disease, neuropathy and osteomalacia with chronic exposure[16]. Therefore, implant removal after fracture healing or long-term follow up for side effect monitoring are necessary.

CONCLUSION

This study showed that using of 3DPT is an alternative and noteworthy option for

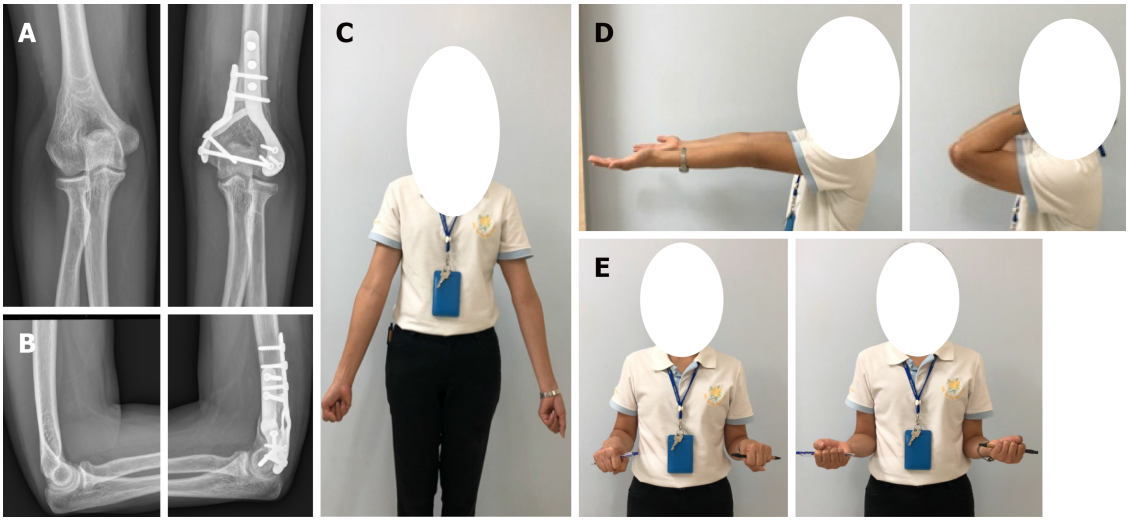


Figure 3 Postoperative radiographic and clinical outcomes. A and B: The 3-mo postoperative radiographs of both elbows in antero-posterior (A) and lateral (B) views showing nearly anatomical alignment of the left elbow compared with the right elbow; C-E: The 3-mo postoperative clinical examination revealed nearly identical alignment of both elbows (C), with the same flexion/extension (D) and pronation/supination range of motion (E).

achieving satisfactory outcome in the treatment of CVD. We believed that our method to generate a customized osteotomy guide and patient-matched monoblock crosslink plate provides a new insight for accurate control of the deformity correction by improving the accuracy of osteotomy and stability of fixation, and therefore, avoiding a prolonged operative time and unnecessary blood loss, and decreasing the risk of postoperative complications.

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REVIEW

Developing an enhanced recovery after surgery program for oncology patients who undergo hip or knee reconstruction surgery

Maria Bourazani, Eleni Asimakopoulou, Chrysseida Magklari, Nikolaos Fyrfiris, Ioannis Tsirikas, Giakoumis Diakoumis, Martha Kelesi, Georgia Fasoi, Theodoros Kormas, Gunhild Lefaki

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Abstract

Enhanced recovery after surgery (ERAS) protocols are applied in orthopedic surgery and are intended to reduce perioperative stress by implementing combined evidence-based practices with the cooperation of various health professionals as an interdisciplinary team. ERAS pathways include pre-operative patient counselling, regional anesthesia and analgesia techniques, post-operative pain management, early mobilization and early feeding. Studies have shown improvement in the recovery of patients who followed an ERAS program after hip or knee arthroplasty, compared with those who followed a traditional care approach. ERAS protocols reduce post-operative stress, contribute to rapid recovery, shorten length of stay (LOS) without increasing the complications or readmissions, improve patient satisfaction and decrease the hospital costs. We suggest that the ERAS pathway could reduce the LOS in hospital for patients undergoing total hip replacement or total knee replacement. These programs require good organization and handling by the multidisciplinary team. ERAS programs increase patient's satisfaction due to their active participation which they experience as personalized treatment. The aim of the study was to develop an ERAS protocol for oncology patients who undergo bone reconstruction surgeries using massive endoprosthesis, with a view to improving the surgical outcomes.

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Core Tip: Enhanced recovery after surgery (ERAS) pathways are applied to oncology patients undergoing primary total hip replacement or total knee replacement; and through evidenced practices are used by the multidisciplinary team, with the aim of reducing the perioperative stress and its effects. ERAS protocols have been reported to promote early recovery, early mobilization, early feeding, and better pain management with multimodal analgesia. ERAS pathways in orthopedic surgery, also, reduce postoperative length of stay, postoperative complications and mortality by 30 d after surgery, hospital costs, and readmission rate by 30 d after discharge.

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INTRODUCTION

Orthopedic prosthesis has been used globally since the 1960s. The aim is to restore the function of the joint replaced and to improve the patient's quality of life[1]. The first primary hip arthroplasty with a metal prosthesis was performed in 1953 by the Englishman George McKee[2]. Since then, different interventions have been developed varying in terms of their design and construction material, for a number of joints, revolutionizing the specialty of orthopedics[3,4]. Nowadays, the use of orthopedic prostheses is very common. It is estimated that more than 600000 knee arthroplasties are performed in the United States each year[5].

Endoprostheses are used in two areas of orthopedics: (1) In reconstructions of joints, which have been damaged by trauma, degenerative or systemic diseases and need to be replaced by metal endoprosthesis (semi- arthroplasty of the hip, knee and shoulder, total ankle arthroplasty and total hip and knee arthroplasty) for better functional and long-term results[6]; and (2) In orthopedic oncology after tumor resection due to malignancies or, less often, benign diseases, where bone and tissue deficits are restored with extensive prosthesis. Until about 1970, the only treatment for bone tumors and soft tissue sarcomas was amputation, without improving patient survival though. Since then, rapid advances in prosthesis technological has allowed the rescue of limps, which in combination with chemotherapy have significantly improved the survival rate[7].

The idea of enhanced recovery pathways was first introduced by Kehlet in the late 1990s, improving the mental and physical effects of post-operative stress on the recovery and general clinical condition of a patient undergoing surgery[8,9]. The concept of fast-track surgery, as it is widely known, included a combination of minimally invasive surgical techniques, combined anesthesia and analgesia, early feeding and early mobilization[10,11]. It was initially applied to colorectal surgery and later to almost all general surgeries[12,13].

Nowadays, fast-track programs have evolved into enhanced recovery after surgery (ERAS) protocols applied by a variety of surgical specialties, including orthopedics. Studies have shown that ERAS protocols reduce length of stay (LOS) without increasing mortality, readmissions or complications rates, decrease hospital cost and enhance patient satisfaction[14,15].

ERAS protocols are intended to reduce perioperative stress, which causes metabolic and immune changes with side effects on the various body systems and increases susceptibility to post-operative infections[14,16,17]. This is achieved through a combination of multifactorial evidenced-based practices performed by various health

specialties collaborating in an interdisciplinary team (surgeon, anesthesiologist, nurse, physiotherapist, *etc*.). An ERAS protocol is divided into three phases: Pre-operative, intraoperative, and post-operative (Table 1). It often begins before the patient's admission to the hospital and continues after discharge. The active participation of patients is required throughout the program[17-19].

According to ERAS protocols, there are several components of perioperative care that affect stress response and accelerate recovery. These include pre-surgical counselling, short fasting period, early mobilization, bowel and bladder preparation, anesthesia and analgesia, thrombocytopenia, prevention of nausea and vomiting and fluid management[20].

PRE-OPERATIVE PERIOD

Informed consent

In order for the patient to follow an ERAS protocol, it is necessary to be informed about all the care practices they will receive, the expected results of their care and the active role they will play in the program, and be acquainted with all the members of the interdisciplinary team. Some patients feel reticent about new practices out of either ignorance or fear, so they disagree or need time to decide. The interdisciplinary team should answer each question of the patient and give them the written protocol instructions[16,20,21].

Patient's medical history and determination of vital signs

After the diagnosis and before the surgery is decided by the surgeon, the multidisciplinary team meets the patient to determine their vital signs and identify any health conditions they may have that may be improved until the planned surgery[22,23]. Patients at high risk for post-operative complications are identified by calculating individual risk based on family history, symptoms, and health status measurement using specific questionnaires[24,25]. One such tool is the Revised Cardiac Risk Index (Lee Criteria), which assesses the risk of more serious heart events based on a history of ischemic heart disease, heart failure, stroke, insulin-dependent type II diabetes, serum creatinine > 177 μmol/L and high risk surgery[24,26-28]. There are many specialized tools for measuring a patient's physical function, severity of surgery and anesthesia, post-operative mortality and morbidity, as well as various measurements of frailty related to clinical outcomes from surgery, supported by the American Society of Anesthesiologists[26-28].

Counseling

ERAS protocols aim to increase the patient's physiological and functional reserves before surgery, which is, in fact, their main difference from fast-track proto-cols[11,29,30]. Studies have demonstrated the effectiveness of targeted pre- operative counseling. In particular, to reduce the risk of respiratory complications, such as infection or atelectasis, and the risk of post-operative wound inflammation, pre-operative smoking cessation within 2-4 wk of surgery is recommended[31,32]. If this is not possible, then it is recommended to reduce the number of cigarettes *per* day rather than quitting smoking, as this would result in a reflex increase in secretions that would have the opposite effect. Patients who consume alcohol have a slow recovery and increased rates of post-operative complications, so it is recommended to follow alcohol withdrawal programs before surgery when possible[33-35].

Pre-operative fasting

According to ERAS protocols, the routine of "being nil by mouth" from midnight before surgery to patients who are going to be operated is considered obsolete and incorrect. Fasting increases the peri-operative stress and its adverse effects as catabolism, insulin resistance and hyperglycemia[36,37]. ERAS protocols recommend shortening the pre-operative fasting time; clear fluid fasting for 2 h and solid food fasting for 6 h before surgery are enough for most patients. Patients with gastroparesis, esophageal achalasia or previous upper gastrointestinal surgery, morbid obesity and previous history of post-operative nausea and vomiting are excluded[38,39]. Pre-operative administration of oral carbohydrate drinks has been studied in recent years and shown to significantly improve insulin resistance without significant impact on the recovery time of patients undergoing hip or knee replacement surgery[40-42]. Although carbohydrate intake in orthopedic surgery has been shown to improve

Table 1 Summary of enhanced recovery after surgery pathways for oncology patients who will undergo hip or knee reconstruction surgery

Preoperative approach	
Informed consent	Patient should be informed and consented about all the care practices he/she will receive, the expected results from his/her care, the active role he/she will have in the program and to meet all the members of the interdisciplinary team
Health history and determination of the patient's vital function	To determine patient's vital function and to identify any health conditions that can be improved prior to surgery. Patient of high risk are identified by calculating individual risk based history, symptoms, health status using specific questionnaires
Counseling	Targeted preoperative counseling. It is recommended to quit smoking 2-4 wk and drinking alcohol 4 wk prior to surgery
Preoperative fasting	ERAS protocols recommend 2 h of fasting from clear fluids and 6 h of solids prior to induction of anesthesia
Preoperative anemia management	Preoperative anemia should be evaluated and treated before surgery
Intraoperative phase	
Anesthesia protocol	Standard Anesthetic Protocol and neuraxial techniques as a part of a multimodal approach
	GA with TIVA using continuous drip infusion of Propofol and Remifentanil is recommended by ERAS pathways
Neuraxial anesthesia	The gold-standard of ERAS programs is the use of epidural or spinal anesthesia, but especially for hip or knee replacement surgery is not recommended as a routine alone
RA/analgesia	A multimodal approach to pain management with RA and MA is supported by ERAS protocols. Should not be considered as an alternative technique to GA, but as a complement to an integrated strategy
Intraoperative analgesia	The use of NSAIDs or COX-2 inhibitors is recommended for the treatment of pain, in combination with paracetamol, in order to significantly reduce the use of opioid drugs in the context of a MA
Optimal intraoperative fluid management	Optimal fluid balance is necessary to avoid over or under hydration. Intraoperative isotonic crystalline fluids are administered to maintain the homeostasis and the electrolyte balance at a rate of 3-5 mL/kg/h
Prevention and treatment of perioperative nausea and vomiting	It is recommended to administer IV ondansetron 4 mg before induction to anesthesia and metoclopramide 30 min before awakening. Especially for high-risk patients, a combination of 2-3 antiemetics is recommended (ondansetron, dexamethasone, droperidol)
	Chewing gum postoperatively appears to help mobilize the gastrointestinal system
Normothermia	Normal body temperature is achieved by the use of electric hot air devices (for the patient's body) and fluid warmer devices for the IV fluids or blood agents to 37-40 °C
	The temperature of the operating room should not be under 21 °C
Prophylactic anticoagulant treatment	Rapid mobilization, elastic anticoagulant socks and low molecular weight heparin anticoagulant therapy for 28 d in hip surgery and 14 d in knee surgery, are recommended
Antimicrobial prophylaxis	The most suitable antibiotic for prophylactic antimicrobial treatment is 1st or 2nd generation cephalosporin (cefazolin or cefuroxime) intravenously 30-60 min before the skin incision, as a single-dose, depending on the patient's weight (weight-adjusted dose)
Surgical management	The ERAS Society makes no recommendations for surgical technique
	However, it recommends avoiding the use of tourniquets and drains as a routine in all operations
Postoperative phase	
Postoperative analgesia	Effective postoperative pain management includes a combination of analgesic drugs with central and peripheral action
	Postoperative analgesia is determined and depends on the intraoperative analgesia plan and follows the same method used
	The use of paracetamol 1 gr in combination with lornoxicam or celecoxib/parecoxib is recommended
	Oral analgesia as soon as patients begins to eat
Postoperative fasting	Clear fluids or jelly 4-6 h post-surgery. Return to normal diet as soon as possible
Prevent falls after surgery	Many factors can contribute to the fall after TKA and THA, such as reoperation, elderly, female gender and comorbidities, which highlights the importance of establishing a multidisciplinary fall prevention program at every orthopedic ward
Physiotherapy approach	Physiotherapy, Kinessiotherapy, Strengthening
	Physiotherapy rehabilitation of the patient undergoing TKA or THA should begin much earlier than the day of surgery, as counseling

	After the physical evaluation, interventions are made to reduce BMI and increase muscle strength by increasing physical exercise and activity
	The procedure can be started up to 4 wk before scheduled surgery, with regular sessions aimed at early mobilization
	Respiratory physiotherapy with 3-flow spirometer

ERAS: Enhanced recovery after surgery; TIVA: Total intravenous anesthesia; BMI: Body mass index; GA: General anesthesia; MA: Multimodal analgesia; NSAIDs: Nonsteroidal anti-inflammatory drugs; COX-2: Cyclooxygenase-2; TKA: Total knee arthroplasty; THA: Total hip arthroplasty; RA: Regional anesthesia.

patients' well-being, metabolism, and post-operative pain, it is not recommended as a standard practice[17,43,44].

Pre-operative anemia management

Pre-operative anemia should be evaluated and treated before surgery. Pre- operative anemia is associated with increased rates of allogeneic transfusion, longer stay in hospital, increased risk of post-operative infection, higher post- operative morbidity, complications and readmissions[45,46]. Clinical intervention studies about pre-operative and post-operative treatment with iron (Fe) or erythropoietin have reported statistically and clinically significant reduction in allogeneic blood transfusions[46-48]. The algorithm used to detect and correct pre- operative anemia by ERAS certified centers was associated with a reduction in the rate of transfusions, LOS, hospital readmissions, admissions to intensive care units and hospital cost[49].

INTRA-OPERATIVE AND POST-OPERATIVE PERIODS

Anesthetic protocol

In order to extract comparable results from an ERAS protocol, a standard anesthetic protocol must be followed. However, this is not always possible (for various reasons), which causes problems with regard to the homogeneity of parameters and the quality of the study methodology, thus challenging its reliability[50,51]. General anesthesia (GA) with total intravenous anesthesia using continuous drip infusion of Propofol and Remifentanil is recommended by ERAS pathways. In vitro studies have shown the properties of propofol as an anti-inflammatory agent and as a stimulant of immune response with beneficial effects on cancer recurrence prevention[52-55]. Oncology patients have peculiarities compared to the rest of the population. They are usually patients with metastatic or primary disease who have undergone chemotherapy and/or radiotherapy and have increased risk of intraoperative complications, especially during bone reconstruction with endoprosthesis and use of bone cement [56]. After a systematic review and meta-analysis of anesthesia techniques used for total knee replacement (TKR) and total hip replacement (THR) in non-cancer patients, the choice of anesthesia type was based on the type of surgery and the patient's general condition[57]. The level of evidence was low for GA or neuraxial anesthesia (NA), but the recommendation strength for both types of anesthesia was strong for patients undergoing hip or knee arthroplasty[52,58].

Neuraxial Anesthesia

The gold-standard of ERAS programs is the use of epidural or spinal anesthesia, but it is not recommended as a routine specifically for hip or knee replacement surgery[57, 59,60]. There is a strong recommendation from the ERAS society not to inject high doses of opioids into epidural or spinal cord to avoid the risk of respiratory depression, post-operative nausea-vomiting (PONV), pruritus and urinary retention [61-63]. Morphine in low doses (0.1-0.18 mg) prevents the risk of respiratory depression and provides an adequate analgesic effect compared with continuous local anesthetic infusion after peripheral nerve blocks (PNB). NA with morphine promotes early patient mobilization[64]. Recent clinical trials using non- opioid formulations, such as bupivacaine, have shown excellent results with minimal risk of complications [51,65].

In ERAS protocols for hip or knee replacement, NA is recommended for its superiority over GA in reducing the stress response and the insulin resistance[19,66]. NA offers great analgesic benefits and reduces LOS and hospital costs, but may cause side effects such as respiratory depression, PONV and pruritus, therefore not

recommended as a routine[19].

Regional anesthesia/analgesia

Regional anesthesia (RA) can reduce the incidence of cancer recurrence due to reduced need for opioids, suppression of the sympathetic nervous system, reduction of perioperative stress, and immediate anti-inflammatory and anticancer effect on immune system[54,67,68]. Although there are many studies that support the positive effects of RA on cancer recurrence, more studies are needed to determine the effects of RA on orthopedic cancers. Data may be incomplete, as orthopedic oncology procedures often involve resection of large bones and/or muscle groups and can take up to 12 h, making GA more common[69]. However, these resections can be performed using RA, either alone or in combination with GA[55,69].

RA provides a greater advantage in joint reconstruction as it delivers sufficient anesthesia for orthopedic surgery and great post-operative analgesia, inhibits the release of stress hormones and reduces insulin resistance. A multimodal approach to pain management with RA and multimodal analgesia (MA) is supported by ERAS protocols[17,68]. RA always plays an important role in minimizing the intra- operative requirements for opioids and should not be considered as an alternative to GA, but rather as a complement to an integrated strategy[68].

Morphine has a negative effect on the functioning of the immune system and it is strongly recommended to minimize doses[70-72]. MA is of paramount importance in the perioperative period, because it helps to reduce the need for opioids[73]. Opioid sparing analgesia based on intravenous lidocaine, nonsteroidal anti-inflammatory drugs (NSAIDs) and ketamine has been found to maintain immune function[73].

RA seems to benefit most elderly and debilitated or seriously ill patients or those undergoing major orthopedic and thoracic surgeries[74]. Recent studies have shown that total arthroplasty may be possible with the use of RA in all age groups, regardless of the severity of the comorbidity[58,67].

ERAS programs significantly reduced the incidence of post-operative complications, such as myocardial ischemia and mortality, over a period of 30 d compared to conventional treatment[58,66].

Intra-operative analgesia

For purpose of pain management, using a combination of NSAIDs or inhibitors of cyclooxygenase-2 (COX-2) with paracetamol (acetaminophen) is recommended to significantly reduce the administration of opioid drugs in the context of a MA[21,75,76]. Concomitant use of paracetamol and NSAIDs is the main axis of perioperative MA and one of the most important components of ERAS[73,76]. Studies have shown that MA has great analgesic effects on moderate pain and reduces the additional use of opioids after TKR and THR[57,77]. NSAIDs and COX-2 inhibitors are not recommended for patients with contraindications (allergy, pre-existing kidney disease, *etc.*)[78].

Optimal intra-operative fluid management

Intravenous fluids and maintenance of normovolemia are very important for perioperative patients. Failure to maintain normovolemia may lead to increased morbidity/mortality, affect tissue oxygenation, increase post-operative cardiopulmonary complications, increase trauma inflammation and prolong hospital stay[17,19,21]. Intra-operative isotonic crystalline fluids are administered to preserve homeostasis and the electrolyte balance at a rate of 3-5 mL/kg/h. ERAS society recommends early transition from IV to PO fluid therapy within 24 h for patients undergoing major surgery[79].

Prevention and treatment of PONV

PONV is undoubtedly an unpleasant adverse effect, which is experienced by 20%-30% of surgical patients and 70% of high-risk patients (patients with gastroparesis, esophageal achalasia, dysphagia, neurological diseases, gastrointestinal surgery, Whipple procedure, gastrectomy, *etc.*)[38]. For the prevention and treatment of PONV, it is recommended to administer 4 mg IV infusion of ondansetron before induction of anesthesia and metoclopramide half an hour before awakening. Especially for high-risk patients, a combination of 2-3 antiemetics is recommended. Such a combination may be ondansetron 4mg overnight, dexamethasone 4-5 mg after induction of anesthesia and droperidol 0.625-1.25 mg at the end of surgery[17,19,21,80]. Caution is needed in the use of dexamethasone as an antiemetic in oncology patients because of its potential immunosuppressive and hyperglycemic effects[81]. A recent study has

shown that dexamethasone significantly decreased the incidences of PONV as well as pain, improved respiratory parameters, and reduced the need for additional post-operative analgesic and antiemetic drugs[81]. It is worth noting that Gan *et al*[80] and Sherif *et al*[82] created a simplified PONV probability scoring system using only four risk factors: (1) Female gender; (2) Previous PONV history; (3) Smoking; and (4) Opioid analgesics[80,82]. Therefore, a combination of two drugs is recommended for patients with one or two risk factors, while for patients with more than two factors the recommendation is a combination of three drugs[80,83]. Finally, chewing gum post-operatively appears to help mobilize the gastrointestinal system[84].

Normothermia

Hypothermia affects over 60% of patients. Maintaining body temperature at normal levels throughout the surgery has been shown to help reduce post- operative wound infection, intraoperative bleeding, cardiovascular complications, post-operative stress and its metabolic effects[85,86]. Prevention of perioperative hypothermia is achieved by using electric hot air devices for the patient's body and fluid heating pumps to administer intravenous fluids or blood products at 37-40 ℃ intraoperatively. The temperature in the operating room should be 21 ℃ for total joint surgeries[19,86-89].

Prophylactic anticoagulant treatment

There is a significant correlation between deep vein thrombosis, pulmonary embolism and hip and knee replacement surgery, which can lead to post- thrombotic syndrome or even death[90]. The NICE guidelines recommend early mobilization and fast return to baseline activity[61], as well as low-molecular-weight heparin anticoagulant therapy for 28 d in hip surgeries and 14 d in total knee operations[90-92].

Antimicrobial prophylaxis

One of the most serious and harmful post-operative complications in orthopedic surgery is bone tissue and prosthetic joint infections. Infection after THR or TKR surgery is called osteomyelitis and remains to date the worst complication to treat[21, 93]. Bone infection treatment often requires removal of the prosthesis in order to reduce osteolysis and inflammation[94-97]. Recommendation for prophylactic antimicrobial therapy is 1st or 2nd generation cephalosporin (Cefazolin, Cefuroxime) 30-60 min before the skin incision as a single-dose, depending on the patient's weight (weight-adjusted dose)[98].

Surgical management

Although there are many comparative studies on surgical techniques and approaches to TKR and THR, we cannot conclude with certainty which technique is superior to all. ERAS society does not recommend a specific surgical technique[16].

ERAS protocols recommend avoiding the use of tourniquets and drains as a routine. It seems that tourniquet does not reduce the total blood loss from surgery, while increasing the risk of thromboembolic events, edema and complications[99-101]. Regarding wound drainage, studies show that not only does it not help prevent hematomas, but it also increases the risk of inflammation and blood loss because it eliminates the tamponade effect and may cause a retrograde infection[102-104].

Post-operative analgesia

Effective post-operative pain management includes a combination of analgesic drugs with central and peripheral action, aimed at early mobilization and feeding. Once the patient begins to eat solid food, the IV analgesic regimen should be administered *per* os[19,36]. In ERAS protocols, MA is very important for pain management, enhanced recovery and patients discharge. MA significantly reduces the opioid requirements and helps reduce PONV, post-operative stress and the risk of complications[16,19]. The use of paracetamol in combination with lornoxicam or celecoxib/parecoxib is recommended. Paracetamol is very effective in acute post-operative pain without significant side effects and constitutes a key component of MA in all ERAS guidelines [17,78,105].

Prevention of in-hospital falls after surgery

RA is responsible for in-hospital falls in post-operative patient after TKR and THR. Patients with GA have a higher rate of in-hospital falls compared to NA. The group of PNB has not been significantly associated with patients' falls[67], while PNB-induced quadriceps insufficiency is not the only cause for in-hospital falls[106]. Many factors can contribute to an in-hospital fall after TKR and THR, such as re-operation,

advanced age, female gender and comorbidities, which highlights the importance of establishing a multidisciplinary in-hospital fall prevention program in every orthopedic ward[35,107,108].

Multimodal post-operative analgesia, including RA or PNB techniques, in combination with goal-directed rehabilitation are important components that prevent in-hospital falls. This approach accelerates functional recovery and minimizes the risk of in-hospital falls, increases patient satisfaction and reduces overall hospital stay and costs[109,110].

PHYSIOTHERAPY REHABILITATION

Physiotherapy rehabilitation of patients after TKR or THR surgery should begin much earlier than the day of surgery, in the form of counseling. After the physical evaluation, interventions are made to reduce body mass index and increase muscle strength by increasing physical exercise and activity[71,111]. The procedure can be started up to 4 wk before scheduled surgery, with regular sessions aimed at early mobilization. Patients are initially informed in detail about the surgery and the post-operative stage even with appropriate leaflets. If possible, patient counseling can be performed simultaneously to a group of people who will undergo surgery on the same day. At the same time, an exercise and stretching program can be implemented to strengthen the muscles of the lower extremities of patients, who learn how to perform it on their own[112,113].

Patients who have followed a counseling program delivered by the physiotherapist, have become more comfortable with the use of walking-aid, made the suggested interventions in the configuration of their residence so that it is safe for a faster return home and have returned home on the 3rd post-operative day without complications [114,115].

The strengthening part is very important because patients who are going to undergo TKR or THR surgery, already have deficient function of the quadriceps due to arthritis or cancer. This is caused by reduced functional use of the joint due to pain and atrophy. Muscle strengthening with progressively increasing resistance and neuromuscular electrical stimulation perioperatively have been shown to improve the functional performance of the quadriceps[116].

Pre-operative mobilization and strengthening seems to be crucial because there is a significant reduction in muscle strength and ability to perform the leg press test within the 1st week after surgery[117]. In fact, the decrease is not due to objective findings (inflammation, swelling) but subjective symptoms (insecurity, pain), which subside to such an extent when applying the pre-operative approach and early mobilization, that patients are discharged earlier and, in some cases, do not need post-operative physio-therapy other than an exercise routine they are trained to perform at home[118,119].

Psychological support of the patients from the interdisciplinary team is necessary, because it increases their sense of security and satisfaction[120]. The team reports on the benefits of early mobilization within 8-12 h after the surgery. Even patients who disagree or hesitate to follow the instructions of physiotherapists should at least agree to cooperate. Their initial reluctance is followed by surprise, as they experience less pain than they thought during the recovery period and are satisfied with their post-operative progress[121].

Early mobilization reduces the LOS as patients can be discharged sooner without increasing the risk of complications. Depending on the pain experienced by the patient, he or she may be able to stand or walk without aid on post- operative day 1 if the visual analogue scale score is lower than 5[122].

Pain management, reduced swelling, autonomous movement and normal mobilization with walking-aids are criteria for the patient's discharge from the hospital. Indicatively, following TKR the aim is for the patient to be able to lift their limb with stretched knee and achieve pain-free flexion to 90 degrees, while safe and controlled walking to and from the bed suffices after THR surgery[111,115,122]. Post-operatively, standard physiotherapy (kinesiotherapy) as well as other methods, including electrical stimulation, are applied in order to strengthen the muscles, increase the range of motion, reduce swelling and enhance independent gait[123,124].

All of the above ERAS pathways that developed for the rapid postoperative recovery of oncological patients undergoing Total Knee or Hip Reconstruction are summarized in Table 1.

CONCLUSION

ERAS programs undoubtedly reduce hospitalization days without increasing the risk of complications or relapses and reduces hospital costs. These programs require good organization and handling by the multidisciplinary team. Nurses have a central role in the implementation of ERAS programs. ERAS programs increase the patient's sense of satisfaction due to their active participation which they experience as an individualized treatment. However, their implementation is not common practice in Greece, so additional multicenter clinical trials at are required.

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REVIEW

Slacklining: A narrative review on the origins, neuromechanical models and therapeutic use

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Abstract

Slacklining, the neuromechanical action of balance retention on a tightened band, is achieved through self-learned strategies combining dynamic stability with optimal energy expenditure. Published slacklining literature is recent and limited, including for neuromechanical control strategy models. This paper explores slacklining's definitions and origins to provide background that facilitates understanding its evolution and progressive incorporation into both prehabilitation and rehabilitation. Existing explanatory slacklining models are considered, their application to balance and stability, and knowledge-gaps highlighted. Current slacklining models predominantly derive from human quiet-standing and frontal plane movement on stable surfaces. These provide a multi-tiered context of the unique and complex neuro-motoric requirements for slacklining's multiple applications, but are not sufficiently comprehensive. This consequently leaves an incomplete understanding of how slacklining is achieved, in relation to multi-directional instability and complex multi-dimensional human movement and behavior. This paper highlights the knowledge-gaps and sets a foundation for the required explanatory control mechanisms that evolve and expand a more detailed model of multi-dimensional slacklining and human functional movement. Such a model facilitates a more complete understanding of existing performance and rehabilitation applications that opens the potential for future

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applications into broader areas of movement in diverse fields including prostheses, automation and machine-learning related to movement phenotypes.

Key Words: Slacklining; Neuromechanics; Human movement; Model; Balance; Rehabilitation

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Core Tip: Slacklining is an ancient activity; however, modern scientific literature is very recent and limited. This paper explores slacklining's origins to provide background on its evolution and incorporation into prehabilitation and rehabilitation. Existing mechanical models and neurophysiological explanations are considered, summarised, and their applications and knowledge-gaps highlighted. Consequently, the need for improved understanding and descriptive and mathematical models are highlighted to ensure a multi-tiered understanding of slacklining's unique and complex neuro-motoric requirements for its multiple applications, including human functional movement. With understanding slacklining's history and fundamentals comes the potential for future broader applications for functional movement, prosthesis, automation, and machine-learning.

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INTRODUCTION

Slacklining is defined as a complex neuromechanical task involving achievement of functional independence while maintaining dynamic stability through balance retention. This occurs from the interactions of the individual's whole-body where internal dynamics drive the response to external environmental changes, while treading on an unstable, three-dimensional moveable, tightened, webbing-band fixed at each end[1,2]. The concepts explored in this paper consider and address what slacklining is, and its historical origins, in order to provide essential background understanding of the activity and its evolution, recognition and progressive incorporation into prehabilitation and rehabilitation. With this background knowledge, the existing explanatory models can be considered, how they apply to an individual's capacity to achieve stability, and whether they provide a complete recognition and understanding of the explanatory control mechanisms for multi-directional instability and complex multi-dimensional movement. As such, they should be able to explain slacklining as a harmonious functional movement (HFM), namely the integrated interrelation of neural and muscular components to facilitate and enable a stable harmonized full-body functional movement[3]. Examining these current models enables the determination and recognition that there are knowledge-gaps, which indicates that existing models must be evolved and expanded in order to encompass the broad conceptual circumstances that achieve slacklining stability.

THE ORIGINS AND ACTIONS OF SLACKLINING

As a trend-sport, modern slacklining is an adaptation of the ancient performing art of traditional rope-walking. Modern slacklining was initially started by climbers and outdoor enthusiasts in the 1960s and 1970s in the European Alps of Switzerland, France and Austria as well as in Yosemite National Park in the United States of America, where ropes and cables were replaced with adapted lightweight webbing and ratchet technology that incorporated an easier, safer and more elastic line[4,5]. Slacklining was originally termed "line-walking" or "funambulaire" (the precursor term to slacklining) in Latin European regions and "Jultagi" or "Eoreum" in Korea as a representation of Central Asia[5,6]. Slacklining has very ancient, established history

and cultural traditions. The earliest records are insinuated as being possible from approximately 40000 years Before Christ (BC) when man first invented ropes[7]. Consequently, the necessity and challenge arose to walk along these ropes to enable the completion of normal tasks in construction, movement along and between habitation sites such as cliffs and trees[8], for communication and social interaction such as crossing gorges as continues in the Russian Dagestan region, on the ropes of early Phoenician sailing vessels in ancient Crete around 1000 BC, and eventually for entertainment[4,9]. More direct inference is made at approximately 20000 BC where, "line-walking" or "funambulaire" was an established societal activity in pre-ancient Greece, China and the Korean Peninsula[4,6,10]. The earliest documentation appears to be in pottery and figurines of Cycladic acrobats from around 3000 BC[11]; and as a performance component of the ancient Greek Olympics from 776 BC and earlier Greek Games where the "Thaumatron" was awarded to those who performed a marvelous act or spectacle[6].

However, historical writings suggest the ancient Olympics were an extension of games from earlier periods, particularly the bronze age of Anatolia (3000-2500 BC), Crete (3000-1100 BC) and Mycenae (1600-1100), with some archaeological data suggesting games dated back to the 10th century BC[12]. Funambulaire was an integral social performing art from at least 3000 BC[4,6]; and demonstrated in the fresco paintings of Selini funambulist rope-walkers from the Villa of Cicero in Pompeii's ash covered ruins estimated as approximately 100-50 BC[13]. The natural progression from ropes and cables to ratchets and webbing reflects human evolutionary capacity found in multiple incorporations and replacements of traditional and established items into modern product developments and activities[8]. The graded incorporation into rehabilitation could have been initiated at any time, but medical literary writings insinuate at least around 150 Anno Domini (AD) during the period of Imperial Roman (31BC-AD476)[10,14], while the first published papers were in European sports science literature around 2009[15,16] (Figure 1).

SLACKLINING: EXERCISE, REHABILITATION AND THERAPY

Slacklining in exercise and rehabilitation

The incorporation of such a fundamental yet physically complex recreational or cultural activity into the fields of therapy and rehabilitation is another evolutionary reflection. Slacklining, as therapy, has only been formally investigated and documented in the published scientific literature over the last decade[15-17]. There is anecdotal evidence of slacklining's therapeutic use since the 1970's and 1980's as both prehabilitation and rehabilitation for Alpine sports and athletes. This includes Ingemar Stenmark for downhill slalom ski[15], within Australia's competitive surfing community and elite training programs that led to the high performance center at Casuarina on the Australian East Coast[2], and for rock-climbing[17,18]. However, its first recorded application may be inferred from the Greek-Roman physician Galen-of-Pergamon from 150-200 AD. Galen is recognized as the father of "Exercise in Medicine"[10,19] with over 500 medical Treatises[20] that provide potential documentation for the use of rope walking for rehabilitation and prehabilitation purposes. The texts considered[21-23] do not mention rope walking specifically as an activity, but such an activity or exercise is highly likely to have been used and can be insinuated from the following knowledge: rope walking was, as mentioned, an accepted and integral activity within Imperial Roman Society[4,6]; Galen is considered the "father of rehabilitation" who advocated the importance of exercise, his texts and teaching were the recognized authority for almost 1600 years[24], particularly for exercise and health [22,25]. Galen wrote extensively on knee injuries including loss of function and balance in athletes and Gladiators, noting that knee muscle control required considerable time to regain due to loss of muscle activation, with "wasting in the absence of local muscle or nerve damage"[24], a reference to arthrogenic muscle inhibition (AMI)[6,11,14,18]. Galen prescribed exercise for rehabilitation and prehabilitation as essential for "… health and good condition"[26], and "… strength for function"[19,22]. Consequently, though not specific in detail, slacklining could have occurred through the informal or guided inclusion of an existing, recognized and challenging balance activity. Consequently, the incorporation of slacklining into rehabilitation may not be "that" recent, but actually date back some 2000 years.

Slacklining and arthrogenic muscle inhibition

The discussion of AMI is an important consideration as slacklining appears to negate

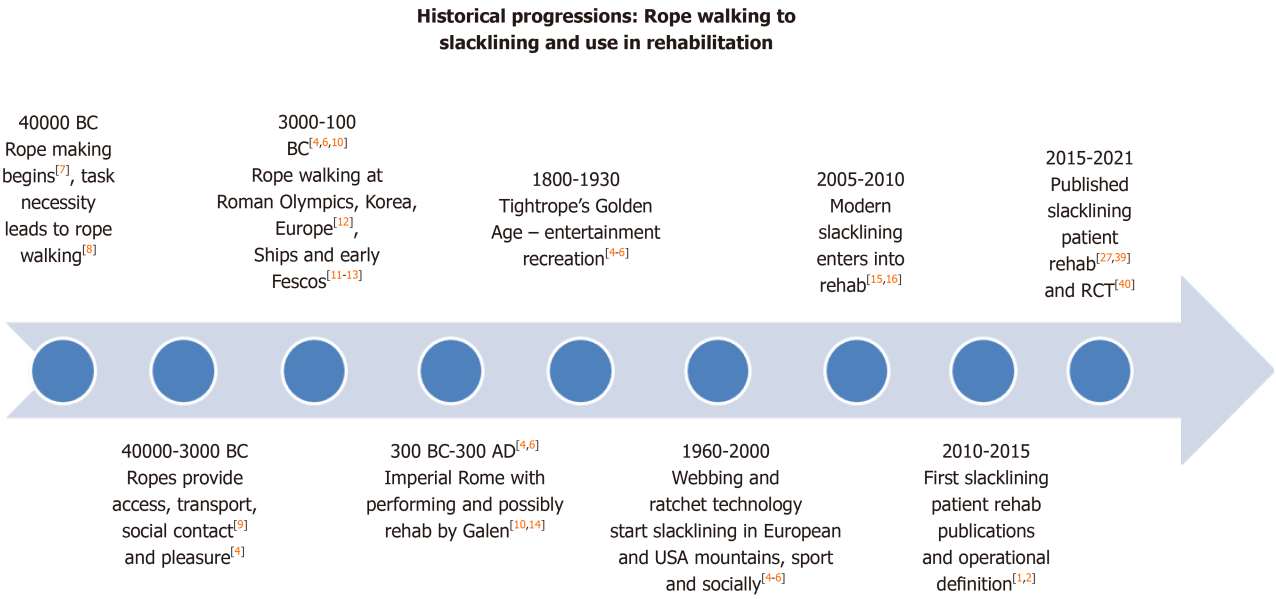


Figure 1 Historical progressions: Rope walking to slacklining and use in rehabilitation. BC: Before Christ; AD: Anno Domini.

the local muscular inhibitory action, particularly in the knee quadriceps[2] and potentially in the spinal lumbar multifidi[27]. AMI is defined as muscular activation failure, about a damaged or distended joint, due to ongoing neural activation deficit [28,29]. AMI has been well recognised since at least the 19th century as having a central-neural basis[30], being a consequence of articular sensory receptor discharge from joint afferents[31] due to swelling, inflammation, joint laxity[32] and tissue damage. The presence of AMI is consistent across different joints and joint pathologies, particularly the knee[29,30,32,33], hip[34], elbow[35], shoulder[31] ankle[36] and intersegmental spinal muscles[37]. Evidence indicates that with AMI, supra-spinal pathways potentially play a significant role through inhibitory down regulation that affects central nervous system (CNS) neural inhibition, that in-turn prevents full muscle activation. This is in conjunction with spinal reflex contributions through the Group-I non-reciprocal inhibitory pathway reflexes including the flexion and Gamma (γ)-loop[28]. Today, the full understanding of AMI remains incomplete and is the subject of significant investigative research[38]. However, slacklining's recognized effect in over-riding this down regulation, in the lumbo-pelvic[27] and lower limb regions[2,18] is gradually being recognized and is a significant advancement in anatomical and condition specific regional rehabilitation[39,40].

Slacklining as therapy

The therapeutic direction of slacklining has evolved over the past decade to become an adjunct in both injury prevention, such as falls in the elderly[41], and specific sports including judo[42], basketball[43], badminton[44], handball[45], and football/soccer [46]; as well as in rehabilitation[2], including orthopedics[2,27], neuro-logy[27,39,40], sports training[47], general physical training[46] perfor-mance[43], and recreation[5]. This inclusion of slacklining with other prevention and rehabilitation themes derives from the triad of sensory system contributors of proprioception, vision, and vestibular somatosensory inputs[48]. This is a consequence of the unique properties of slack-lining[2] due to its distinct action from other conventional balance activities[49] and apparatus[41,43] as a composite-chain activity, *i.e.* there is a weak link in the kinetic chain resulting in abnormal motor synergy patterns due to the contact surface of the loaded limbs having free, partially supported but unstable movement on a recoil resistance surface[50]. The coupling of these qualities and the CNS contributors results in slacklining having four integrated qualities[2]: Balance - the equilibrium control regulating the body's segmental dynamic movement and center-of-mass (CoM) within the base of support[51]; postural control - the body's positional control in space[52]; muscle strength - the muscular generated forces[43,53]; and neuromechanical demand - the integration of neurobiology and biomechanics[1].

MATHEMATICAL AND GENERAL MODELS THAT EXPLAIN SLACKLINING

Manifold models

It is recognised that the neuromechanical control strategies employed during slacklining are not fully understood[54]. Several detailed proposed models seek to explain slacklining and predominantly utilise a conceptual "manifold model". However, the term manifold has two denotations: firstly, within a general context as a "conceptual dimension inside a general discussion"; and secondly, within a mathematical context as a "mathematical subset with lower dimension inside a mathematical model"[55]. The latter context is a defined shaped space where all activity and analysis occurs[56], which for slacklining likely simulates a saddle-shape within ordinary task space[57]. This saddle-manifold is shaped concave in the dimensions of the direction of the slackline (X) and convex in the direction of its lateral shift (Y) and the dimension of gravity or sag (Z)[58,59].

Scientifically and mathematically a "manifold" has the same or lower dimensionality as the underlying mathematical model, though mathematically the number of dimensions possible is arbitrary. Each point within the manifold has its own "homeomorphic" space. Consequently, a "bi-continuous function" exists between all points being on both a continuum in a given direction, while concurrently having an opposing continuous inverse function[60]. The manifold model concept was initially proposed within robotics as the "self-motion manifold"[61], and, subsequently applied to human movement and functional tasks as the "un-controlled manifold" (UCM) model[62]. Such a model suitably explains quiet-standing[58,59] and simple functional frontal plane movements *e.g.,* walking and postural sway[57,63], but was not proposed for complicated tasks involving dynamic contact, *e.g.,* slacklining[1,54].

The UCM may still, however, provide a potential solution as it proposes a motor control strategy for redundant systems by using the abundant solutions inherent to them[62]. This postulates that the task redundant space of the effector is not homogeneous, but structured according to task requirements[61,64]. Consequently, the UCM model may be expanded to accommodate slacklining as the increased variability and redundancy found in such challenging actions can be redistributed, allowing acceptable levels of task variability to be maintained[56,65].

In human quiet-standing and frontal plane movement on stable surfaces, the Newtonian equations in classical mechanics of an inverted pendulum are generally considered acceptable mechanical models for self-balancing[51,59,66]. These considerations are critical in acknowledging "how" the body estimates its current orientation in space, in order to, subsequently, generate the corrective stabilizing actions required to maintain what is a mechanically unstable upright stance. However, for slacklining, this model is not suitable. The base is not fixed: Consequently, body neuromechanical dynamics are coupled with the slackline's external dynamics, and the natural actions and subsequent responses of body-sway[1,54,67].

Application of the manifold model to slacklining

To consider these attributes within a global encompassing model to describe slacklining as a dynamic and changing series of quantitative factors, Paoletti *et al*[1] proposed that "an optimal strategy is achieved" for self-balance. This is through the consideration of a nonlinear model that accounts for potential parameter coupling and overall CNS performance delays that occur on multiple time scales. These can be visualized as a system with passive coupled dynamics working in unison with sensory modalities, enabling orientation and activated motor coordination of the body to be self-directed or "inferred". In Serrien *et al*[68], where the balance strategy was examined within an "expanded manifold of a higher dimension" that the subjects must remain within, this approach in turn enabled the model to account for coordination from the perspective of "self-organizing maps"[68]. This model-modification allowed an entire kinematic chain response where equilibrium is achieved as an integrated CNS solution to the presented task-environment-subject dependent situation and allows for a large set of degrees of freedom (DoF) that facilitate understanding of postural control within the human motor system[69]. Additional perspectives from Vallery *et al*[53] clarify that these neuromuscular actions involve a decoupling of the stance leg/s, and its produced vector forces from the residual body, through muscular co-contraction at the hip. This is augmented by arm movement and bimanual arm coordination[70] that act as the primary initial compensatory reaction to CoM displacement[47], and in turn the arms concurrently provide angular momentum influences[54].

BALANCE AND HARMONIOUS FUNCTIONAL MOVEMENT

In the balance model for achieving slackline independence through human HFM, the manifold's defined space contains variables with a significant set of DoF that contribute to particular movements or functions[69], some of which provide the amalgamation of stability and mobility[3] through CNS control[56]. Consequently, the model's manifold contains both stable controlled variables and unstable un-controlled variables, where no action control is required as a task-variable's position is not affected[62]. Any given set of CNS controlled DoF that provide stability, consequently, have variables separated into two orthogonal/opposing-directional subspaces: one with actions that have no effect (on the controlled variables); the other with orthogonal-subspace actions that do[62]. If variability in the controlled subspace is smaller than that of the opposing orthogonal-subspace, then the CNS, and, consequently, stability control, is unaffected[56]. These manifold models simplify reality[1] and enable a mathematical representation and analysis. They also provide insight into what CNS control aspects are present when postural balance strategies are implemented[71,72], and that all responses occur within physically defined boundary limitations[47].

SUMMARY

The outlined existing hypothetical models of slacklining describe the neuromechanical control strategies that achieve this activity, predominantly through use of a conceptual "manifold" that simulates a "saddle-shaped" task space[58,59]. Through the use of classic mechanics this is envisaged as a self-balancing mechanical model of an inverted pendulum[51,66]. These concepts critically acknowledge spatial orientation and subsequently corrective stabilization actions. However, this is generally hypothesized around a stable or fixed base which is inadequate for a body dynamically coupled with external changes and response actions[1,54,67]. Consequently, there is a knowledge-gap and a required evolution and expansion of these ideas, not only from the perspective of mechanics[1,51,54], but also from that of the neurological[73] and biopsychosocial[74] constraints of the individual.

PHYSICAL FORCES AND ORDINARY SPACE

Existing models of harmonious functional movement

Models of human HFM and self-balancing generally consider two concurrent spheres of input: firstly, mathematical mechanical precision models bound by classical mechanics equations and; secondly, supplementary sensory and motoric neural control[47,67]. The mechanical models were initiated over the last 600 years, most likely from Da Vinci's documented model proposition: "motion is created by the destruction of balance, that is, of equality of weight, for nothing can move by itself which does not leave its state of balance, and that thing moves most rapidly which is furthest from its balance"[75]. In contrast, the importance and relevance of the control aspects of a neural source were not proposed till the mid to late 1800's, when the understanding of sensory input and neural latency were detailed in seminal German publications.

The initial aspects of sensory control include the perspective of frames of reference as used by the nervous system, and the kinematic constraints that these place upon any control aspect. Initially, this came from the role of vision and was established from Donders[75]' Law, namely "that there is a unique orientation of the eye when looking in any specific direction"[76]. This was supplemented by Listing's law which "… specifies what this orientation is"[77,78], being a principle that governs eye movements through the three dimensional (3D) planes of horizontal, vertical, and torsional, and is actively implemented by a neural mechanism[79]. Fick[79] proposed that Listing's law enhanced motor efficiency by "minimizing the rotational eccentricity of the eye"[80]. This sensory-motoric control system was quantified by von Helmholtz [80] who measured the time delay that occurs due to the finite speed of neural signal transmission, where response time is dependent on the input-output delays of single neurons and neural chains. Donders[81] furthered these control phenomena in his work related to "The speed of mental processing", which determined a relationship was present between an individual's "choice-response" and the number of stimuli

present[82]. This was, subsequently, supported and progressed by Merkel[82] who defined that "the response time is longer when a stimulus belongs to a larger set of stimuli". This eventually led to Hick's Law[83], or the Hick-Hyman Law almost 100 years later that proposed "…information is intimately concerned with reaction time" and describes "… the rate of gain of information", and assesses the involvement of "cognitive capacity"[84].

The Hick-Hyman Law denotes that the time an individual requires for decision-making results from the choices available, and will increase logarithmically with the number of choices. In slacklining, these choices increase dramatically compared to simple frontal plane movements[54,57,63]. Consequently, transmission rates vary significantly between cell types and transmission mediums being affected by neuron size, the presence of axon myelination and its composition[85], sheath number, length, thickness and distribution[86], the size and distance between nodes of Ranvier, types of intervening synapses and how many occur between the CNS and peripheral receptors, and the stimuli strength, and quality[85,87]. The sphere of task control and the time-delay present is due to the sensory and motoric neural pathways necessary signaling processes, such that delay increases as the system and its requirements become more complicated[58,73]. This accounts for the balance organ with the integrated labyrinthine and vision systems that are adapted to account for these time delays[67], and ensure the essential limitations necessary for the human body to remain stable[64].

This is particularly relevant for more complex movements, such as those that occur on unstable surfaces, at higher speeds and require greater skill, with slacklining being such an example. Accordingly, in human movement, the more complex the task and the more stimuli present, the slower the action[17,88] or the greater the response time, Fitts's[88] Law (Table 1), and the higher the neuronal firing rate[1]. Further considerations are the large variation in effects of normal and pathological ageing[85] on human mechanical structures[67,86], neural system time delays[64]; and that injured tissue and individuals at the global level (such as neurological conditions) will not be able to achieve the required levels of adaptation, and, consequently, the individual will exhibit postural deficiency or balance loss[53,89,90]. The overall consequence is a simplified large-scale time-delayed model that provides insight from classical mechanics into the integrated functioning of the body systems and organs that support the theories and hypotheses of "integrated control"[48,67].

The subsequent progressions in the mathematical mechanical human movement and self-balancing models came at the start of last century when Graham-Brown[90] reported on "dynamic principles involved in progression". He stated that: "The cycle of progression may be supposed to commence at a point at which one of the limbs is perpendicular to the ground. The "initial velocity" then carries the body past this point, and it then falls forwards along the circumference of a circle the radius of which is the limb in contact with the ground". Over the last half century there has been further evolution and progression with Bresler *et al*[91] who remarked that the "Dynamic balance of the "head, arms and trunk" about the supporting hip is dependent upon the control of pelvic motion by the hip musculature"; while Saunders *et al*[92] recognised the significance of "Pelvic lateral tilt (being) identified as one of the primary determinants of gait".

In 1971, Adams[93] proposed the Classical model of "…a closed-loop theory for learning simple movements", that incorporated feedback, error detection and error correction as key elements. This model required that the output of the system had feedback, and compared the reference for error detection and, if necessary corrected for this to provide the resulting movement, such that it was "… self-regulating by compensating for deviating from the reference". More recently, MacKinnon *et al*[50] described "Control of whole body balance in the frontal plane during human walking" through the model of the "inverted pendulum" which relies on the principles of equations from classical mechanics. This model was progressed through a series of evolving modifications to account for the influence of both random disturbance and control torque. This neurologically controlled delay is effectively present at the ankle joint due to the concurrent relationship between: the passive stiffness from the visco-elastic nature of the muscle-tendon-ligament complex; and the active modulating influence of regional muscles[73]. This is supplemented by the triceps surae muscles that maintains balance by "predictively controlling the proximal offset of the spring-like element in a ballistic-like manner"[94,95].

Within the mechanical model it is also critical to consider that the inherently unstable upright position, where the smallest deviation eliminates equilibrium, is retained through uniformity between retarding and controlling forces[67,96]. These provide contributing components that can be low-level, such as passive ankle stiffness,

Table 1 Glossary of definitions and explanation of scientific terms

Scientific Term	Explanation/definition
Fitts Law	Time to accomplish movement linearly increases with the logarithm of the index of the task difficulty
Hopf bifurcation point	A critical point where a system's stability switches and a periodic solution arises
Two-thirds Power Law	Expresses the robust local relationship between the geometrical and temporal aspects of human movement
Elliptic geometry	Non-Euclidean (or non-ordinary) geometry stating that there are no lines parallel to any given line, this is an example of Riemannian geometry
Affine Transformations	A transformation that preserves lines and parallelism
Equi-affine Transformations	a transformation that preserves areas, in addition to lines and parallelism
Temporal Segmentation	The central or brain action of breaking down motion sequences into different actions
Isochrony Principle	The duration of voluntary movement remains approximately constant across a range of movement distances; that is, movement duration is independent of movement extent
Kinematic redundancy	Kinematic redundancy occurs when a manipulator has more degrees of freedom than those strictly required to execute a given task. Additional active joints and interlinked segments improve both mobility and the available degrees of freedom
Inter-segmental law of coordination	A kinematic law that describes the coordination patterns among the elevation angles of the lower limb segments during locomotion (Borghese). It is reliant on accurate progressive timing of muscular contractions in adjacent segments and appendages

vs high level, such as the growth-rate of the gravitational toppling torque[58,95]. Together these forces are considered a simple closed-loop control model[48] as a progression of Adams "closed loop" model[94]. A further mechanical model input consideration integrates neural sensory aspects, where feedback mechanisms are based predominantly on body-sway motion[63] from balance perturbations[97]. These evoke "sensory weights", a form of neural control representing comparative contributions of each sensory systems and integrated as a "package"[48]. This provides an internal estimate of orientation[71], where the assessed and adjusted responses are determined by how these inputs contribute to the total balance system as a single component[1]. Consequently, this "package" is itself dynamic and varies sufficiently to ensure equilibrium and prevent instability from corrective actions being either over- or under-produced[48]. The inputs themselves therefore exhibit bi-fold competing variations, due to the quality of the sensory information received. This is a consequence of changes in: (1) The external environmental conditions; and (2) The internal conditions affected by injury, neurologic disorders[90,98], or other psychosocial factors[65,74]. In the presence of a moving platform, as with slacklining, the vestibular and somatic sensory feedback is more highly weighted; while in quiet-standing the proprioceptive and visual systems are dominant[71]. Further, during afferent motor control the CNS creates "muscle synergies" where groups of muscles are combined as a common neural signal to control a range of movements which can be modulated differently by each individual, consequently demonstrating the neuromuscular capacity for adaptive strategies to facilitate stability while slacklining [99]. This reinforces the findings of neuroplastic change, automatic or "packaged" signals[48,71], engrams[100] and homunculus smudging[37], all of which occur as a response to complex, demanding, balance challenge activities[100], which will, consequently, include slacklining[2,101].

The consequential reactive motoric action that produces the stability, in the mechanical paradigm perspective, is achieved through the generation of joint torques that appropriately correct for any deviations from a desired orientation[48,72]. The original perturbation changes are detected primarily by inputs from the visual, proprioceptive, and vestibular sensory sub-systems[67,71], with the resultant reflex delay[1,72] enabling a "Hopf bifurcation point"[2] (Table 1). This achieves a temporary, though dynamic, "solution" for equilibrium and self-balance, with suitable active control strategies[58,67]. This "equilibrium solution" is explained by both the mechanical and sensory aspects within a "saddle-like" 3D phase-space that is characterized by geometrical properties and spatial relations of position and velocity[58]. It is achieved through the optimal parity between two competing manifolds: one which is stable along the saddle and provides slow convergent motion in a direction toward the equilibrium; and the other which is unstable and provides divergent spiral motions such as pitch, roll, and yaw[97] about the axis of the phase planes, which further increase the number of dimensions and DoF present, as these actions occur in

directions away from the equilibrium[58]. This "solution" is overseen by an intermittent "proportional and derivative" feedback system controller, that is characterized by the switching function at the "Hopf bifurcation point" in such a way that the proportional and derivative control is "off" when the net force is near the stable manifold of the saddle and is "on" in all other circumstances. This controller is able to use considerably smaller regional space and feedback parameters, which make it more robust[58] in the designated phase plane, as it exhibits the "two-thirds power law"[3] (Table 1) scaling regimes typically found in physiological sway movements in humans. Concurrently, the nominal equilibrium state is itself surrounded by a "dead zone" that reflects the time-delay from the sensory neural control inputs[72] that will allow a motoric reaction[64] that provides spontaneous movement patterns, like sway, to occur[95]. As a simple feedback loop system, this can provide an acceptable model for dynamic stability to ensue[52,58]. It also accounts for: Age-related differential findings due to physiological change - such as passive joint stiffness and damping from osseous degeneration, and proprioceptive delay, which affect center-of-pressure-based sway behaviors[57,66]; plus notably increased "noise" from larger amplitude, plus false and extraneous input signals[57,73] that can all be viewed from a "classical mechanics" influence perspective[67].

Any integrated mechanical and sensory model must also consider and discuss optimization approaches occurring, concurrently, within both aspects of the model, and that account for the "smoothness" or "flow" of HFM[3,102], *e.g.*, compare a curve joining multiple points to a series of straight lines. This smooth, HFM is a consequence of the process of "speed-curvature coupling"[103] which is optimized by the coordinated brain action of sensory and motoric control under the influence of pre-planning and "temporal segmentation", the process that "…identifies motion breakpoints and separates the different constituent phases"[104]. These sensory considerations are based on the mechanical assumptions of Riemannian or elliptic geometry[4,103] (Table 1). There is also a need to consider geometrical transformations that are both "affine"[5] (Table 1) and "equi-affine"[6] (Table 1), particularly in unstable settings, such as on a slackline, where the involved rotation, translation and shearing actions are both achieved and minimized in order to provide constant speed [102], such as occurs in the jerk response or Hoffman reflex[105].

This is of significant importance in relation to sensory input, particularly visual processing, as it confirms that "temporal segmentation"[7] (Table 1) of movement control complies with "equi-affine geometry"[103]. This geometrical transformation consequently accounts for the "two-thirds power law", which governs the relationship between the geometrical and temporal parameters of human movement. This is centrally represented in "motion-planning"[61] and "human vision processing" and ensures that the "Isochrony principle"[8] (Table 1) is upheld[103]. This, consequently, allows for the application of differentiable manifolds of higher dimensions, an important consideration for complex activities on unstable mobile surfaces, such as slacklining. The consideration of these additional aspects within a mechanical model clarifies that human locomotion complies with the principles of "Kinematic redundancy"[9] (Table 1); and the "Inter-segmental law of coordination"[10,103] (Table 1).

Together, these multiple aspects and considerations form the sensory and motoric neural control sphere, as noted previously from 18th Century German scientists, concepts that were, subsequently, integrated with the mechanical sphere. In unison they explain functional independence and balance control as the aforementioned closed-loop feedback system[94], with parity between the different integrated sensory orientation source information on one hand, and system feedback control constraints on the other[48]. However, such a conceptual model and presentation of balance, functional independence, and postural control, is only truly valid on stable surfaces [58]. When unstable surfaces, such as a slackline, are considered in such models, then further descriptive initiates, progressions, and evolutions are required[1,54] to account for the dynamic changing postures and positions[2,27,106]. This has led to the concept of "dimensionally-bound" manifold models, which require that the size-volume of the manifold is expanded. This accounts for the patterns of movement, control and balance-retention, that require higher levels of complexity within the significant DoF available for human motor system postural control[54].

THE CURRENT DESCRIPTIVE MODEL OF SLACKLINING

The concept of functional independence and self-balance being explained by

dimensionally bound models, with expanded size-volume, takes into account activities such as slacklining that are significant progressions from those found in quiet-standing and simple frontal plane walking. This complexity occurs through the forces being produced more rapidly with the requirement for greater control occurring through smaller, more precise action-reaction dissipation[68]. There is a simultaneous reduction in both frequency and velocity in most available DoF, coupled with increased control of range of motion (RoM)[69]. This expanded manifold model allows greater distance in the Y and Z dimensions for any given X dimension position, but is limited by the physical constraints of the given slackline length (X dimension), its width and how far it can be moved laterally (Y Dimension) and the elastic-stretch that enables an optimal sag (Z Dimension). Consequently, a minimal effort or energy expenditure must be achieved and utilized to maintain stability in the presence of any perturbation[47]. This is consistent with the strategies of quiet-standing and stable surface walking[70]. However, any perturbation must be limited within the Y Axis, or lateral component of movement, to a distance in the order of 10 cm, for novices to moderate skilled slackliners, if control and balance on the line is to be retained[47]. Expert slackliners appear to exhibit greater lateral movement limitations within an expanded manifold[69].

This 3D model form has been envisaged and detailed with mathematical equations to validate positions[1,58]. However, to compound the descriptive difficulty of the model, it must be recognized that the optimal adopted strategy is individually selected. It can only be one of two methods prior to the introduction of any perturbation: (1) Two feet on the slackline, including use of an unloaded limb to touch and stabilize the line; or (2) One foot[2,5], with the other not touching but as a counter-balance that indirectly affects the manifold of the contacted and weight bearing foot [47]. In recognition of this deficiency the model was subsequently modified[54] through introducing a regional decoupling at the hips of the arms and trunk from the legs. This then accounted for the discrepancy that action-reaction forces generated by the arms, trunk, or free leg, could influence the point of contact, without moving the foot or changing the anterior-posterior direction by virtue of sheer forces, and ensures the principle of "energy optimization" was maintained[54]. This then allowed for individual joint torque and segmental interplay, where there is task distribution between the legs as the ultimate dissipater of the force vectors *via* the CoP dynamics at the foot/feet, but decoupled at the hips from the trunk and arms that influence, but do not control, angular momentum[47].

This 3D model then has the context that simulates the following example: an inverted pendulum[51] (the person), mounted on a cart (the slackline), that is moving on a circular or elliptical track[1] (the physical finite 3D ordinary space limitations of possible slackline movement), to a maximal distance from the slackline contact point [47] during instantaneous stability. Concurrently, the segments of the arms and trunk facilitate angular momentum control, and are decoupled by muscular co-contraction at the hips from the stance leg/s, that dynamically direct the vector forces[54].

The acquired movement control to achieve balance on a slackline is a set of self-learned patterns[96]. These form an instantaneous but fluid and interactive dynamic saddle-shaped manifold[58] that the individual must remain within to ensure stability [69] through balance control[66]. Stability is retained by the production of forces that are pro-active and re-active to those of the slackline's 3D reciprocal forces at and through a point/s of fixed contact with the body *via* the foot[47] or feet[47]. Consequently, the slackline's reactionary forces line of action always passes through the subject's contact foot/feet and cannot be influenced without a dissipated moment from the force vector. This force, *via* the foot to the leg, is in the X-dimension or anterior-posterior direction[54], the Y-dimension of lateral deviation within the physical limit of the slackline's topographical space[47], and the Z-dimension of available sag or reactionary bounce[107]. These forces form within the "high-dimensional manifold" "… in which the subjects have to stay in order to maintain balance"[68].

The expansion of this manifold can be learnt, with the improved balance then interpreted as enabling an increased RoM before the manifold edges are reached and balance is lost. Because the expanded manifold's edge is now further, the frequency of movement change is lower, as the need to adapt or change is less, which in-turn leads to a reduced velocity of motion and less kinetic energy being required when reaching the manifold's edge. Consequently, maintaining balance is easier and the energy used to counter the perturbation is dissipated in a stepwise manner[47,97].

FACTORS THAT NECESSITATE CHANGES TO THE CLASSICAL MECHANICS MANIFOLD MODEL

Currently, the models of HFM and self-balance are limited to those described above. They can account for all available DoFs as found with dynamic unpredictable movement on unstable surfaces that consider and account for kinematic redundancy in consort with inter-segmental coordination.

This can be summarised as follows: An integrated mathematical mechanical precision model, bound by classical mechanics equations in parity with sensory and motoric neural controls that approximates a dynamic "saddle-like" phase-space, high-dimensional manifold characterized by two internal competing manifolds of convergent and divergent motion.

This hypothetical model facilitates understanding the mechanisms for independent HFM and balance. These mechanical and neural components increase their complexity when considering the influence of "qualitative-implicit-knowledge", such as the physics of gravity[108]. Generally, the brain hypothetically uses a qualitative internal model that incorporates classical mechanics-based equations from its existing knowledge of gravity and time as a multi-faceted perspective that include a quantified unit and both a spatial and cortical experience, even if this knowledge is quantitatively based[108]. This supplements sensory information when estimating more complex activities that involve external components, and not simply a body activity in isolation, including interceptive actions like hitting or catching[109]. However, when performing a "catch" in zero-gravity, movement is initiated earlier[109] as "qualitative-implicit-knowledge" is relied upon to pre-empt and approximate interceptive timing through pre-information that compensates for "no-gravity"[108]. This is analogous to core muscle pre-activation when using a limb. Further, "qualitative-implicit-knowledge" is influenced by the individual's psychological state, motivation level, past activity-specific experience, the social context where the activity is performed and the presence of positive support or negative perceived social pressure to participate or "perform" [53,74]. Current movement models do not accommodate or acknowledge these additional aspects. By considering a highly skilled complex activity, such as slacklining as opposed to quiet standing, the intent is to consequently, recognize the areas of knowledge-gap so an evolved and expanded hypothetical model and paradigm can be proposed.

CONCLUSION

The successful achievement strategy that enables an individual to balance and remain on a slackline is currently explained as: A saddle shaped manifold model, where a moving inverted pendulum is subjected to self-generated and environmental forces within a defined 3D space, where the arm and trunk segments provide dynamic force influences but are decoupled from the hips and legs. This model integrates with gravity and the slackline's elastic reactive properties being governed by classical mechanics. However, there remains a knowledge-gap as this dynamic stability is transitory, momentary, and acquired through the integration of additional dimensions not hereto considered. Consequently, within the context of historical and contemporary slacklining, the existing models are insufficient for the required explanatory control mechanisms that can accommodate multi-directional instability and complex multi-dimensional human HFM. This knowledge-gap requires an evolved and expanded model in order to provide an explanation for the control mechanisms in place. This evolved model will represent multiple, integrated dimensions that will facilitate the understanding of existing performance and incorporate general and rehabilitation activity. With such a model these applications can be applied more broadly in the future to movement in diverse fields that would potentially include prostheses, mechanized automation, altered gravity, robotics, mechatronics, artificial-intelligence-driven movement and machine-learning related to movement phenotypes.

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MINIREVIEWS

Off-the-shelf 3D printed titanium cups in primary total hip arthroplasty

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Abstract

Three-dimensional (3D)-printed titanium cups used in primary total hip arthroplasty (THA) were developed to combine the benefits of a low elastic modulus with a highly porous surface. The aim was to improve local vascularization and bony ingrowth, and at the same time to reduce periprosthetic stress shielding. Additive manufacturing, starting with a titanium alloy powder, allows serial production of devices with large interconnected pores (trabecular titanium), overcoming the drawbacks of tantalum and conventional manufacturing techniques. To date, 3D-printed cups have achieved dependable clinical and radiological outcomes with results not inferior to conventional sockets and with good rates of osseointegration. No mechanical failures and no abnormal ion release and biocompatibility warnings have been reported. In this review, we focused on the manufacturing technique, cup features, clinical outcomes, open questions and future developments of off-the-shelf 3D-printed titanium shells in THA.

Key Words: Socket; Highly porous; Additive manufacturing; Ultraporous; Trabecular; Beam melting

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Core Tip: Three-dimensional printed titanium cups theoretically provide a porous, rough surface that improves local vascularization and osseointegration, while avoiding stress shielding because of the low elastic modulus. We herein discuss the manufacturing, main features, and clinical results obtained with 3D-printed titanium cups, with a focus on the open questions and possible future developments to improve this newborn device and technology.

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INTRODUCTION

Acetabular component loosening is one of the most frequent reasons for revision in primary total hip arthroplasty (THA)[1]. Uncemented third-generation sockets were designed to improve local vascularization and the subsequent bony ingrowth promoted by the porosity of the cup surface and the biocompatibility of the metal alloy coating[2,3]. The long-term clinical and radiological performance and reliable safety profile of third-generation tantalum cups in primary THA is outstanding, even if some sporadic concerns have arisen after consulting registry data[4]. Highly porous titanium implants were developed based on the previous solid experience with third-generation, highly porous tantalum cups. The aim was to overcome drawbacks related to the cost of tantalum, which is a rare metal. 3D printed cups are a specific stand-alone type of highly porous titanium cups[2]. While they share the material and porosity with other highly porous titanium cups, because of additive manufacturing, 3D printed cups have larger pore sizes and higher porosity, reproducing trabecular bone-like elastic modulus in unique monoblock implants with no coatings[2]. 3D-printed cups may exhibit differences in the surface and beyond the surface with different biological advantages than traditionally manufactured highly porous titanium cups, including improved osseointegration, reduced stress shielding, and have unique failure modalities like cracking and ion release[2,5].

MANUFACTURING TECHNIQUES

3D printed cups are produced using additive manufacturing, an industrial process that transforms 3D computer models into devices by layer-on-layer, titanium alloy powder-based fusion technology. This production method is very different from the manufacturing of traditional implants, usually by subtracting machinery and forming. Additive manufacturing is particularly suitable for custom made implants, complex geometries, and diverse surfaces, even with serial production. On the other side, conventional techniques are mainly limited to mass production and off-the shelf devices because of manufacturing constraints[5]. These features allow additive manufacturing devices to integrate surface porosity within a monoblock implant, which improves osseointegration and potentially reduces stress shielding by mimicking the stiffness of the periprosthetic bone (Figure 1). The additive manufacturing process is a powder bed fusion technology that adopts electron beam melting (EBM) and/or laser beam melting (SLM) energy sources for producing titanium alloy cups[6]. Both techniques start with a titanium alloy powder, whose chemical and physical properties are chosen as a function of the production technique and the powder bed fusion technology. The powder can be processed using a computer-aided design (CAD) model. The device is produced by a beam, with melting and bonding the powder layer after layer with precisely controlled cooling[5,6].

Some important differences exist between the two main additive manufacturing technologies. EBM technology is driven by a higher power source, requires a vacuum chamber at 600-1000°C, and is controlled by electromagnetic lenses that focus the beam, which is regulated by a deflection coil. A preheating scan is required, however,

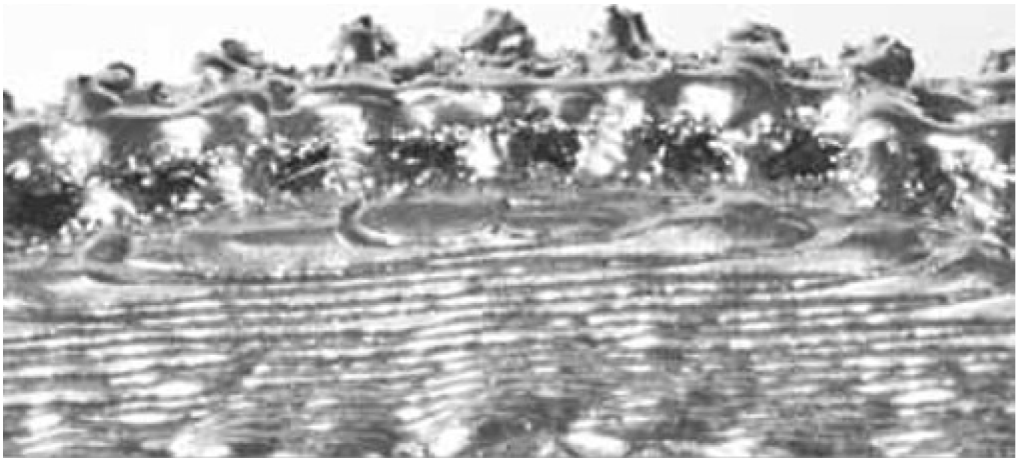


Figure 1 Layer-by-layer additive manufacturing was used to produce a monoblock cup with an ultraporous surface (Ti-Por, Adler Ortho). Courtesy of Adler Ortho.

the support during manufacturing is scarce because of the high speed and the vacuum environment. On the other hand, SLM is characterized by a much lower power source, is performed in a purified inert gas atmosphere at 200°C, and is controlled by a CAD mechanical mirror system. Preheating is not required, and the support during manufacturing is more intense. A most striking difference between EBM and SLM is the powder that is used. EBM used larger particles (45-150 μm *vs* 20-100 μm) and thicker powder layers (50-200 μm *vs* 20-100 μm)[5-7]. Post processing steps include cleaning (removal of excess powder), surface finishing, and thermal treatment, particularly for SLM.

The manufacturing technology has a noticeable impact on the final qualities of the device. The surface is rougher and the CAD design is more accurately reproduced after EBM manufacturing. Moreover, the mechanical properties of EBM devices are good because there are residual tensile stresses. The superior mechanical properties mean that heat treatment is not required, which reduces the manufacturing costs and makes EBM faster and more cost-effective than SLM[8]. The biocompatibility of the devices produced with the two different technologies is dependable, and neither dermal irritation nor delayed hypersensitivity were demonstrated in animals[6,9]. A comparative study cell reported that adhesion, proliferation, and activity were more pronounced in the SLM cohort[10].

CUP FEATURES

A complete list of off-the-shelf 3D printed titanium cups is shown in Table 1. Nearly all the 3D printed cups have similar features, which include a porous surface structure of interconnected pores larger than 200 μm with a porosity higher than 50% (Figure 2). The elastic modulus and coefficient of friction were rarely provided by the manufacturers. Many cups had multihole designs with even augments, making the devices adaptable for massive bone stock loss and cup revision settings.

PRECLINICAL STUDIES

Few preclinical studies of 3D printed titanium cups are available. Jahnke *et al*[11] compared the micromotion of 3D printed cups (EPore) and conventional sockets in sawbone models. The 3D printed cups had acceptable micromotion, lower than of conventional cups with low wall thickness. The investigators reported that the wall thickness, together with the highly porous surface, contributed to 3D cup stability, allowing peripheral micromotion of the sockets, and at the same time, provided rigidity with the thicker walls[11]. Dall'Ava *et al*[12] evaluated the outer surfaces of three off-the -shelf 3D printed titanium cups (Delta TT, Trident II Tritanium, and Mpact 3D Metal). The three cups have differences as wall thickness, pore size, porosity, and metallic structure. Some molten beads were present, with differences of size and density related to the production technology[12]. Dall'Ava *et al*[13] compared

Table 1 Off-the-shelf 3D printed titanium cups that are commercially available

Cup	Manufacturer	Pore size (μm)	Porosity (%)	Design	Modularity	Notes	Available clinical studies
Fixa Ti-Por	Adler Ortho, Milan, Italy	700	70	Hemispherical	Yes		Yes
Agilis Ti-Por	Adler Ortho, Milan, Italy	700	70	Hemispherical	No, Delta ceramic	Large ceramic-on-ceramic heads	No
Polymax Ti-Por	Adler Ortho, Milan, Italy	700	70	Hemispherical	No, XLPE		Yes
Omnia Ti-Por	Adler Ortho, Milan, Italy	700	70	Hemispherical	Yes	Multihole, Ti augments	No
Delta TT	Lima Corporate, San Daniele, Italy	640	65	Hemispherical	Yes	Elastic modulus: 1.12 GPa	Yes
Delta One TT	Lima Corporate, San Daniele, Italy	640	65	Hemispherical	Yes	Multihole, Ti augments	Yes
Delta Revision TT	Lima Corporate, San Daniele, Italy	640	65	Hemispherical, triflanged	Yes	Commercially pure Ti, multihole, Ti augments	Yes
SQRUM TT	Kyocera, Kyoto, Japan	640	60	Hemispherical	Yes	Coefficient of friction: 1.09	Yes
Mpact 3D Metal	Medacta, Castel San Pietro, Switzerland	600-800	75	Hemispherical	Yes	Multihole, Ti augments	No
Trinity Plus	Corin, Cirencester, United Kingdom	300-900	50-90	Hemispherical	Yes	Even multihole	No
Ecofit Epore	Implatcast, Buxtehude, Germany	100-500	60	Hemispherical	Yes	Multihole	No
Redapt	Smith and Nephew, Menphis, United States	202-934	60-80	Hemispherical	Yes	Multihole	No
Trident II Tritanium	Stryker, Mahwah, United States	100-700	55-65	Hemispherical	Yes	Laser rapid melting technology	Yes
G7	Zimmer, Warsaw, United States	475	70	Hemispherical	Yes	Even multihole shells	Yes
3D ACT	ITI Medical Equipment, Changzhou City, China	600-800	80		Yes	Coefficient of friction: 1.08	Yes

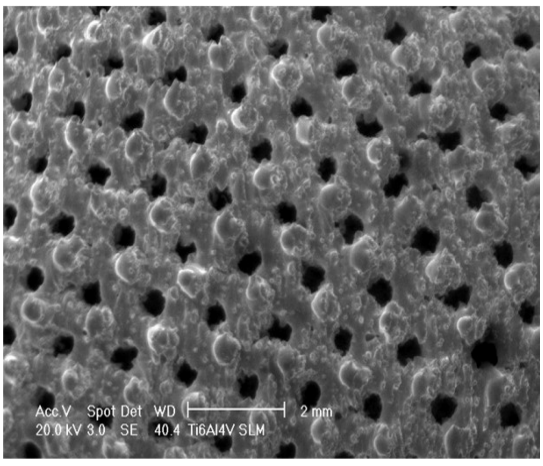


Figure 2 The highly porous surface structure has a large number of deep, interconnected pores (Ti-Por, Adler Ortho). Courtesy of Adler Ortho.

3D printed cups (Delta TT) with conventional cups (Pinnacle Porocoat, DePuy, United States). Pore size, porosity, and the mechanical features of the pores of the 3D printed caps and the conventional cups were significantly different. A visual assessment revealed higher percentages of bony attachment and tissue ingrowth for the 3D printed cups, but the differences comparison with the conventional sockets were not significant[13]. Hothi *et al*[14] compared three 3D printed cups with conventional

sockets. Two of the 3D-printed acetabular shells were produced by EBM (Delta TT and Mpact 3D) and one by laser rapid melting (Trident II Tritanium). Structural cavities were evident in all the 3D-printed cups and in none of the conventional sockets, with a significantly higher density, but no difference in cavity size, in the laser rapid melting socket. The presence of cavities was attributed to suboptimal manufacturing parameters, gas entrapment, or gaps in the starting powder beads[14].

CLINICAL AND RADIOLOGICAL OUTCOMES

A systematic review of the outcomes and survivorship of 3D printed titanium cups in THA was conducted following retrieval of published studies indexed in the PubMed/MEDLINE database. {query box: ["highly" (All Fields) AND "porous" (All Fields)]} OR ["trabecular" (All Fields) OR "trabecularization" (All Fields) OR "trabecularized" (All Fields)] OR "pore" (All Fields) OR {"3D" (All Fields) AND ["printed" (All Fields) OR "printing" (MeSH Terms) OR "printing" (All Fields) OR "print" (All Fields) OR "printings" (All Fields) OR "prints" (All Fields)]} OR ["printed" (All Fields) OR "printing" (MeSH Terms) OR "printing" (All Fields) OR "print" (All Fields) OR "printings" (All Fields) OR "prints" (All Fields)] OR "3D printed" (All Fields) OR {["porosity"(MeSH Terms) OR "porosity" (All Fields) OR "porosities" (All Fields)] OR ["addit manuf" (Journal) OR ["additive" (All Fields) AND "manufacturing" (All Fields)] OR "additive manufacturing" (All Fields)]} AND "cup" (All Fields) AND ["hip" (MeSH Terms) OR "hip" (All Fields)] AND ["arthroplasty" (MeSH Terms) OR "arthroplasty" (All Fields) OR "arthroplasties" (All Fields)]; double check for 3D printed titanium cup brands, as listed in the paper by Dall'Ava: Ti-Por, Delta TT, Trinity, EcoFit, C-Fit, Mpact, Redapt, Trident, G7 {query box: Cup brand AND "cup" (All Fields) AND ["hip" (MeSH Terms) OR "hip" (All Fields)]}.

Ten papers were included. The two largest studies were registry reports, one from Registro dell'Implantologia Protesica Ortopedica (RIPO) and the other from the New Zealand arthroplasty registry. The RIPO registry study investigated the mid-term outcomes of 9864 Ti-Por cups, compared with other cementless cups (Figure 3). The non-stratified survival rates showed that the 3D printed cups had a significantly higher survival rate (98.7% *vs* 97.9%) at 7 years. The survival rates with cup aseptic loosening as the study end point showed that Ti-Por cups performed better than the other cementless cups (99.9% *vs* 99.5%). With similar articulation surfaces, Ti-Por cups achieved survival rates comparable to those of the control group[15].

The New Zealand registry compared 2192 3D-printed cups (1397 Delta TT cups, 640 Ti-Por, and 155 Polymax cups) and other cementless sockets (Pinnacle, Trident, and RM). The outcomes were similar in both cohorts with no differences in the revision rates and functional scores (P = 0.058, hazard ratio: 1.29) while additive manufactured sockets were more frequently implanted in younger patients; the rates of aseptic cup loosening and deep infections were similar in both cohorts. Polymax cups achieved the lowest rates among the 3D cups[16].

Perticarini *et al*[17] published the first clinical and radiographic description of a 3D printed cup (Delta TT) cohort with a follow-up of 72 months. The clinical and radiographic outcomes of 134 THAs were satisfying, with 99.3% of the sockets radiographically stable at final follow-up. Only one case of aseptic cup loosening was reported. It occurred in a high-grade dysplastic patient, and was caused by the high dislodging forces of the lengthened abductor muscles (no femoral shortening was performed). The cup was successfully revised with another Delta TT device. The survival rate at mid-term was 99.3%[17].

Berend *et al*[18] evaluated 400 hips with G7 cups at a minimum follow-up of 1 year. Clinical and radiographic outcomes were satisfactory, with no radiolucent lines; two cup failures occurred because of impaired bony ingrowth[18].

Berend *et al*[19] updated the results of the previous case series at a minimum follow-up of 3 years in 152 implants. The clinical outcomes significantly improved, and the radiographic findings showed no radiolucent lines. The overall survival rate at 3.4 years was 99.5%, one case required cup revision because of failed bony ingrowth[19].

Massari *et al*[20] reported dual-energy x-ray absorptiometry outcomes of 3D printed cups (Delta TT): They found a reduction of bone mass density at 6 months, with slight recovery and stabilizing by 24 months. The bone mass variation was dependent on the body mass index. They reported also a significant clinical improvement with respect to the pre-operative status and no cases of failed cups[20].

Imai *et al*[21] compared the hip replacement outcomes of 101 3D printed cups (SQRUM TT) and 35 hydroxyapatite-coated sockets (SQRUM HA) in low-grade

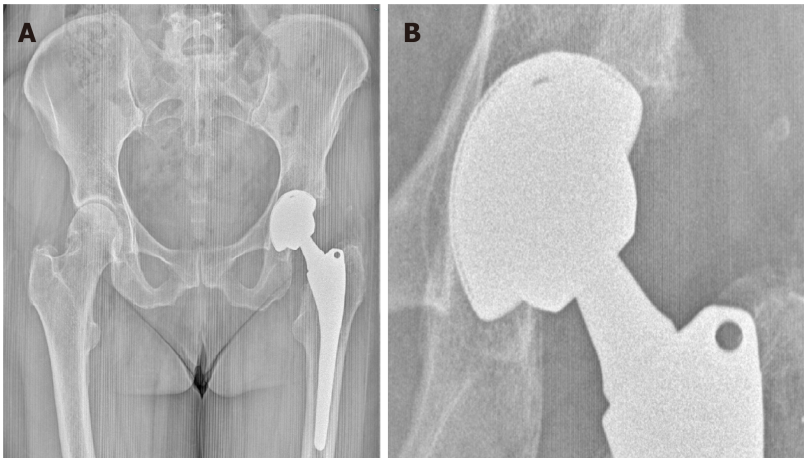


Figure 3 A Ti-Por cup was implanted in a 59-year-old woman with primary osteoarthritis The socket has an hemispheric design with a rough surface with multiple spikes. A: Primary osteoarthritis; B: The socket has a hemispherical design.

dysplastic patients receiving the same stems and the same bearings. The short-term clinical outcomes significantly improved in both the cohorts, achieving similar results. The radiographic 2-year outcomes showed that the 3D printed cups had a higher rate of radiolucent lines and fibrous ingrowth than the conventional hydroxyapatite sockets[21].

Bistolfi *et al*[22] evaluated the metal ion levels in the blood and urine in a cohort of 19 patients with conventional cups (Delta PF) and 19 with 3D printed cups (Delta TT). At 24 months, differences in the blood and urine levels of titanium, aluminum, and vanadium ions in of the two cohorts were not significant. A trend of decreasing ion levels was evident in both cohorts[22].

Castagnini *et al*[23] published a retrospective comparison of 24 metachronous bilateral THAs, a Ti-Por cup on one side and a hydroxyapatite-coated socket on the other side (Figure 4). The mid-term clinical outcomes showed comparable rates of cup loosening and radiographic osseointegration in both cohorts. The Ti-Por group had more evident medial stress shielding, but the difference was not significant (P = 0.067). Neither was the decrease in acetabular radiographic density in the DeLee and Charnley Zone II[23,24].

Alamanda *et al*[25] used multiacquisition variable-resonance image combination magnetic resonance imaging to assess the radiological osseointegration of 3D printed cups, evaluating 19 Trident II Tritanium shells and 20 Trident sockets as a control group. The 3D cup cohort achieved significantly better outcomes in terms of bony ingrowth (P = 0.009) with good osseointegration in 99.4% of the cases compared with 91.6% for the conventional cups. Only 0.6% of the bone-cup interface, measured in nine acetabular zones, were fibrotic compared with 8.3% of the conventional cups, mainly involving the central posterior zone[25].

The outcomes of 3D printed ACT sockets were retrospectively assessed in 108 hips by Geng *et al*[26] at an average follow-up of 48 months. A significant clinical improvement was observed, with 106 of 108 (91.3%) patients satisfied with the outcome. No acetabular cup failed: some transient radiolucent lines completely disappeared after 6 months. Radiographic signs of osseointegration were evident in all the cups. The overall survival rate was 99.1% at 72 months, with cup survival rate achieving 100%[26].

In summary, the clinical and radiological outcomes of 3D-printed titanium cups were dependable at mid-term, with large sized studies providing data not inferior to conventional cups. No mechanical failures were recorded and the metal ion release was reassuring. Some radiological findings of fibrotic ingrowth and radiolucent lines were also reported, making longer follow-up and more preclinical studies of 3D printed cups desirable.

OPEN QUESTIONS AND FUTURE DEVELOPMENTS

The first open question about 3D-printed cups is about manufacturing. The layer-over-layer production and the highly porous structure may predispose to delamination and

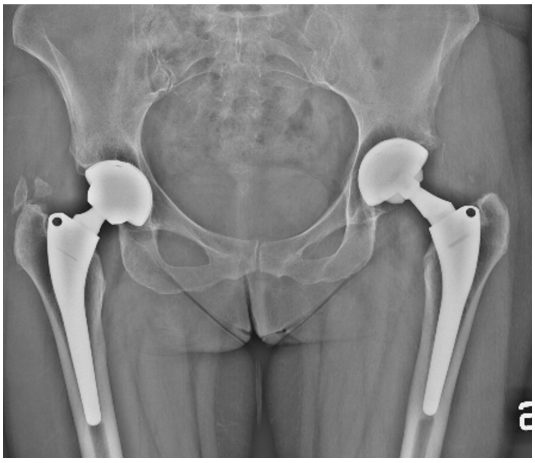


Figure 4 A bilateral total hip arthroplasty, with a Ti-Por cup on the right and a hydroxyapatite-coated socket on the left. The different surface roughness is evident. Both the cups had good radiographic osseointegration at 3 years.

fatigue fracture, and the findings about cavities are not reassuring[14]. Another concern is related to the balling effect of metallic droplets on the molten surfaces, potentially causing cracking and undesired roughness on the inner surface that compromises the locking mechanism and the liner seating, wear, and hardness. While some concerns of fatigue fractures and liner failures may be raised, to date no mechanical failures of 3D-printed cups have been reported, only a case of hemispherical modulus failure in a hip revision[27,28]. Similarly, no cases of delamination failure or mechanical problems related to the liner could be found.

The stress shielding and the fibrous membrane interface issues in the medial zone may be reasons of concern in 3D printed cups. It is likely that these findings are mainly related to the different stress distribution around the periprosthetic acetabular bone and the improved circumferential grip of the highly porous sockets. Thus, it can be hypothesized that a device with nonuniform porosity may reduce medial stress shielding and improve long-term osseointegration. However, in mechanical testing, Le Cann *et al*[28] demonstrated that the opposite condition (micro-roughness around the peripheral rim and macro-roughness on the rest of the cup) promoted better primary stability by reducing the damage of the supportive circumferential bone[28]. To date, many doubts exist about the optimal pore size, porosity, and porous surface extension of titanium devices although fundamental investigations addressing this topic were carried out in the 1980s for tantalum metal blocks[29-32]. Some investigators have reported that the use of pores that were too large could be detrimental for osseointegration by promoting fibrous tissue growth, at least for a short time[33]. Some data on ultraporous titanium cups are available from laboratory and clinical cohort studies, but no definitive conclusions can be drawn, as long-term follow-up is lacking and the tested populations are small.

Another aspect to be developed is related to the cup stabilization provided by high friction coefficients in highly porous devices. Theoretically, the high friction coefficient and the better initial scratch fit would improve primary stability, possibly enhancing the secondary bony ingrowth. Some investigators have found improvements with some less porous cups (plasma-sprayed devices)[34]**.** Unfortunately, there have been no supporting studies with definitive results comparing ultraporous cups and more recent surface textures, as described by Goldman *et al*[35]. In that study, ultraporous DePuy Gription cups did not provide better resistance to bending loads in comparison to standard DePuy Porocoat titanium bead sockets following implantation in seven cadaver models.

3D-printed cups have a good biosafety profile, that needs to be confirmed in large clinical studies[6,22]. More *in vivo* and long-term studies are needed to evaluate and compare the biocompatibility of 3D-printed medical devices, considering the possibility of immunological rejection and inflammatory reactions that can account for the failure of metallic implants.

To date, the optimal 3D printing technique is still unknown. The 3D printed cups that have been evaluated in preclinical studies differ in pore size, porosity and structure, and some features that are dependent on the manufacturing method[12]. Moreover, while additive manufacturing is a highly efficient method with up to a 50% reduction of production costs and up to a 75% reduction of raw material use, the fine

balance between efficiency and quality is yet to be determined[8,9,36]. More studies of the optimization of the energy requirements and scanning speed and their influence on the product quality and the subsequent need for post processing stages would be welcomed.

The possibility of achieving a good elastic modulus and a very highly porous surface makes 3D-printed cups particularly appealing for revision procedures when the bone stock is severely compromised. To date, short-term data on the use of 3D-printed cups are available in the literature; long-term data are lacking[37]. The preliminary short-to-midterm outcomes indicate that off-the-shelf 3D-printed titanium cups are dependable. Castagnini *et al*[38] reported no loosening of Ti-Por devices at a minimum follow-up of 5 years. Gallart *et al*[39] described two cases of Delta TT loosening out of 72 implants with augments, prevalently for revision hips, after more than 2 years. Steno *et al*[27] reported no re-revisions for loosening of Delta TT devices more than 3 years after implantation[27,38-40].

CONCLUSION

In summary, 3D printed cups produced using additive manufacturing demonstrated reliable clinical and radiographic mid-term outcomes, even in large patient series. These implants also had a reliable safety profile. The metal ion levels and rates of deep infection were comparable to control groups, and no cases of mechanical failure were reported. Nonetheless, to date no clinical studies have demonstrated significantly better outcomes when compared with conventional cups with the same bearing forces. Clinical trials and registry studies with longer follow-up are required to confirm the theoretical benefits of 3D-printed cups in terms of osseointegration and a decreased rate of aseptic loosening.

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ORIGINAL ARTICLE

Case Control Study

Evidence-based approach to providing informed consent for hip fracture surgery during the COVID-19 era

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Author contributions: Cuthbert R designed the research study, performed data acquisition, and wrote the manuscript; Ferguson D and Kayani B designed the research study and performed data acquisition; Haque S and Ali A performed data acquisition; Parkar A, Bates P and Vemulapalli K contributed towards conception of the study and final editing; all authors revised the article critically for important intellectual content, and provided final approval for the paper to be published.

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Informed consent statement: Informed consent was not required for the above study as data was collected retrospectively and

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Abstract

BACKGROUND

Hip fractures are the most common reason for inpatient orthopaedic trauma admission. Urgent surgical intervention for hip fractures has remained a clinical priority throughout the coronavirus disease 2019 (COVID-19) pandemic. Despite this, there is a paucity of clinical guidance addressing the informed consent process for hip fracture surgery in COVID-19 positive patients. This is of paramount medicolegal importance in a high-risk patient population.

AIM

To quantify the additional perioperative risks for COVID-19 positive patients undergoing hip fracture surgery and provide clinicians with an evidence-based framework to establish an informed consent process.

METHODS

Two hundred and fifty nine consecutive patients undergoing surgical intervention for hip fractures in four hospitals in the United Kingdom were recruited. 51 patients were confirmed positive for COVID-19. Predefined outcomes were analyzed over a 30-d postoperative period. COVID-19 positive and COVID-19 negative patients were compared after adjustment for confounding factors.

RESULTS

COVID-19 positive patients had more intensive care admissions (27% *vs* 5%, $P < 0.001$), longer inpatient stays (median 23 d *vs* 9 d, $P < 0.001$) and a higher 30-d mortality (29% *vs* 10%, $P = 0.001$) than COVID-19 negative patients. Postoperative complications were evident in 74.5% of COVID-19 positive patients. 35.3% of

COVID-19 positive patients suffered postoperative lower respiratory tract infections with 13.7% developing acute respiratory distress syndrome (ARDS) and 9.8% experiencing symptomatic thromboembolic events.

CONCLUSION

The COVID-19 pandemic has created uncertainty in the medical community worldwide and poses unique challenges in providing informed consent for surgery. COVID-19 positive patients undergoing hip fracture surgery should be consented for the additional risk of postoperative complications (including lower respiratory tract infection, ARDS, deep vein thrombosis and pulmonary embolism), increased requirement for intensive care admission, longer inpatient stay and higher risk of mortality. Further, clinicians must be transparent about the potential for unknown risks as research into the long-term surgical outcomes of COVID-19 positive patients continues to evolve.

Key Words: COVID-19; Hip fractures; Mortality; Morbidity; Outcome assessment; Informed consent

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Core Tip: Coronavirus disease 2019 positive patients undergoing hip fracture surgery should be consented for the increased risk of postoperative complications (including lower respiratory tract infection, acute respiratory distress syndrome, deep vein thrombosis and pulmonary embolism), increased requirement for intensive care admission, longer inpatient stay and a higher risk of mortality. It is medicolegally imperative that these risks are addressed as part of an informed consent process.

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INTRODUCTION

Hip fractures are the most common reason for inpatient orthopaedic trauma admission, with an estimated 1.6 million cases globally *per* year[1]. Incidence has remained stable during the coronavirus disease 2019 (COVID-19) pandemic[2], and the British Orthopaedic Association continues to advocate urgent surgical intervention[3]. Patients are usually elderly with multiple comorbidities and poor physiological reserves[4]. Therefore, it is medicolegally imperative that the material risks inherent in hip fracture surgery for COVID-19 positive patients are addressed and quantified to facilitate an informed consent process.

A multi-center study from our institution reviewed outcomes in 422 hip fracture patients in the Greater London area and found postoperative 30-d mortality in COVID-19 positive patients was 30.5% compared to 10.3% in COVID-19 negative patients ($P < 0.001$). COVID-19 positive patients were also associated with increased perioperative morbidity, more admissions to the intensive care unit, and increased length of hospital stay compared to COVID-19 negative patients. However, there remains a paucity of focussed clinical guidance for providing informed consent for hip fracture surgery in COVID-19 positive patients. Davies reports that only one in 46 patients undergoing orthopaedic surgery was consented for the risk of complications secondary to COVID-19 infection[5]. This underscores the importance of establishing COVID-19 related perioperative risks in hip fracture surgery and providing clinicians with a clear structure to facilitate informed consent.

This study includes an additional 110 patients who were not included in the original multi-center review, and addresses the following objectives: Firstly we seek to quantify the additional perioperative risks for COVID-19 positive patients undergoing hip fracture surgery and secondly we develop an evidence-based framework for

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providing informed consent for hip fracture surgery during the COVID-19 pandemic.

MATERIALS AND METHODS

Study design

This retrospective cohort study included all patients undergoing surgical treatment for hip fractures at four National Health Service (NHS) hospitals between February 1–May 21, 2020. All adult patients undergoing operative treatment for a closed intracapsular, intertrochanteric or subtrochanteric hip fracture were included. Paediatric patients, open hip fractures, femoral shaft fractures (defined as 5 cm distal to the lesser trochanter) and periprosthetic femoral fractures were excluded. Research approval was obtained from respective departmental leads, and the NHS Research Ethics Committee decision tool excluded need for ethical review.

Patients

Of 259 patients were recruited. 51 patients were COVID-19 positive and 146 patients were COVID-19 negative. 62 patients were excluded as they were not tested for COVID-19. Patients were classified COVID-19 positive in the presence of clinical symptoms and a positive throat and nose swab assay using reverse transcriptase-polymerase chain reaction (RT-PCR) for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Patients were classified COVID-19 negative in the absence of clinical symptoms and a negative throat and nose swab assay using RT-PCR for SARS-CoV-2. Repeat swabs were performed if patients exhibited new or persistent symptoms.

Data collection

The following predefined study outcomes were recorded by orthopaedic registrars using a standardized collection proforma: Patient demographics and baseline characteristics [age, gender, ethnicity, American Society of Anaesthesiologists (ASA) grade, comorbidities, dementia status, mobility]; preoperative factors (admission haemoglobin, admission leukocytes, RT-PCR SARS-CoV-2 swab results, associated injuries, systemic symptoms on admission, medical treatment on admission); operative factors (time from injury to surgery, type of anaesthesia, surgical procedure, grade of operating surgeon, operative time, intra-operative complications); postoperative outcomes (location of postoperative treatment, outcome at 30-d post-surgery and time from surgery to hospital discharge or mortality); and postoperative complications (COVID-19 positive patients). Outcomes were sourced from electronic medical records.

Statistical analysis

Analyses of the demographics and baseline characteristics of COVID-19 positive and COVID-19 negative patients were performed using the unpaired *t*-test for continuous variables following normal distributions, and the Mann-Whitney U test for continuous variables not following normal distributions. Categorical variables were compared using the Chi-squared test except for variables with small sample sizes where Fisher's exact test was preferred.

Outcomes in COVID-19 positive and COVID-19 negative patients were compared statistically before and after adjustment for confounding factors exhibiting a difference between cohorts in the initial analyses ($P < 0.2$). Logistic regression was performed to analyze binary outcomes. Survival analysis was performed using Cox regression to compare length of inpatient stay. Patients who were still in the hospital and not ready for discharge when the data was finalized were censored. Patients who died were censored at the time of death.

Odds ratios were used to quantify the size of the association between each variable and outcome. The *P* value for statistical significance was set at < 0.05. The statistical analysis was performed using Stata version 15.1 (Stata Corp LLC, College Station, Texas).

RESULTS

Baseline characteristics and operative factors

There was no significant difference between COVID-19 positive and COVID-19 negative patients for age, gender, ASA grade, comorbidities, dementia, mobility or admission leukocyte levels. Admission haemoglobin levels were significantly reduced in COVID-19 positive patients (108 g/L *vs* 116 g/L, $P = 0.02$) (Table 1).

There was no significant difference between COVID-19 positive and COVID-19 negative patients for choice of anaesthesia, surgical procedure or grade of operating surgeon. COVID-19 positive patients had an increased waiting time from admission to surgery (3 d *vs* 2 d, $P = 0.03$) and reduced operative time (71 min *vs* 80 min, $P = 0.008$) comparative to COVID-19 negative patients (Table 1).

The effects of COVID-19 on study outcomes

COVID-19 positive patients had more intensive care admissions (27% *vs* 5%, $P < 0.001$), longer inpatient stays (median 23 d *vs* 9 d, $P < 0.001$) and a higher 30-d mortality (29% *vs* 10%, $P = 0.001$) than COVID-19 negative patients (Table 2).

After adjusting for potentially confounding variables, odds of intensive care admission were 4.64 times higher (95%CI: 1.59-13.50, $P = 0.005$), and odds of 30-d mortality were 3 times higher (95%CI: 1.22-7.40, $P = 0.02$) in the COVID-19 positive cohort (Table 2).

Postoperative complications were evident in 74.5% of COVID-19 positive patients. 35.3% of COVID-19 positive patients suffered postoperative lower respiratory tract infections (LRTI) with 13.7% developing acute respiratory distress syndrome (ARDS). 9.8% of COVID-19 positive patients experienced symptomatic thromboembolic events with a 3.9% incidence of deep vein thrombosis (DVT) and a 3.9% incidence of pulmonary emboli (PE) (Table 3).

DISCUSSION

Informed consent is grounded in the assumption that we as clinicians know the risks of a surgical procedure with a reasonable degree of accuracy, and are able to convey these risks to patients in order to facilitate a balanced decision on whether to proceed with surgical intervention. The COVID-19 pandemic has created uncertainty in the medical community worldwide and poses unique challenges in providing informed consent for surgery.

A hip fracture in the elderly population is a life-threatening injury. Despite advancement in prosthesis design, antibiotic prophylaxis and focussed rehabilitation, mortality following hip fracture surgery remains 7.9%-9.6% at 30 d and 22.8%-27.0% at one year[6,7]. Operative intervention is recommended to enable early mobilisation, provide effective pain relief and reduce mortality from complications secondary to prolonged bedrest[8].

COVID-19 positive patients had a higher 30-d mortality (29% *vs* 10%, $P = 0.001$) than COVID-19 negative patients. These findings echo other studies in Europe and America: Results from the Spanish Hip-COVID Observational Study illustrated a 14-d mortality of 30.4% in COVID-19 positive patients[9], while the 30-d mortality for COVID-19 positive patients following hip fracture surgery in New York was 52.9% [10]. It is therefore clear that a full and frank discussion about the increased risk of post-operative mortality must form an integral aspect of the informed consent process for COVID-19 positive patients undergoing hip fracture surgery.

Informed consent mandates exploration of alternative treatment options. Non-operative management of hip fractures typically requires a prolonged period of bedrest or traction. This may condemn patients to weeks of pain; the National Institute for Health and Care Excellence guidelines advocate even if a hip fracture complicates or precipitates a terminal illness, surgery should still be considered as part of a palliative care approach[8]. Prolonged bedrest increases the risk of complications such as pneumonia, urinary tract infection and pressure sores[11]. In studies prior to the pandemic, hip fracture mortality following non-operative management with bedrest was 63.6%-73.0% at 30 d and 84.4% at one year[12,13]. In patients managed non-operatively in the Spanish Hip-Covid Observational Study, the 14-d mortality was 67%[9]. These mortality rates are significantly higher than 30-d mortality rates reported in COVID-19 positive patients following hip fracture surgery. Therefore, COVID-19 positive patients who are medically fit for hip fracture surgery should be advised that existing literature does not support deviation from surgical intervention

Table 1 Patient demographics and baseline characteristics

Variable	Category	COVID-19 negative (*n* = 146)	COVID-19 positive (*n* = 51)	*P* value[1]
Age	-	77.3 ± 12.8	79.3 ± 11.0	0.31
Gender, *n* (%)	Female	92 (63)	28 (49)	0.08
	Male	54 (37)	26 (51)	
ASA grade, *n* (%)	1 or 2	46 (32)	15 (29)	0.64
	3	64 (44)	20 (39)	
	4	36 (25)	16 (31)	
Number of comorbidities	-	3.0 ± 1.5	3.3 ± 1.7	0.23
Dementia, *n* (%)	No	93 (64)	36 (71)	0.37
	Yes	53 (36)	15 (29)	
Mobility, *n* (%)	Independent	65 (47)	18 (36)	0.14
	Stick	48 (35)	16 (32)	
	Frame	26 (19)	16 (32)	
Admission haemoglobin (g/L)	-	116 ± 19	108 ± 18	0.02
Admission leucocytes ($\times 10^9$/L)	-	1.1 [0.8, 1.3]	1.1 [0.7, 1.3]	0.50
Procedure, *n* (%)	Cannulated screw	16 (11)	4 (8)	0.28
	Dynamic hip screw	29 (20)	14 (28)	
	Intramedullary nail	34 (23)	11 (22)	
	Hemiarthroplasty	56 (39)	21 (42)	
	Total hip replacement	10 (7)	0 (0)	
Operative time	-	80 [65, 102]	71 [58, 83]	0.008
Surgeon level, *n* (%)	Senior house officer	4 (3)	0 (0)	0.48
	Registrar	102 (70)	32 (64)	
	Associate specialist	11 (8)	5 (10)	
	Consultant	28 (19)	26 (13)	
Admission to surgery (d)	-	2 [1, 3]	3 [2, 5]	0.03
Anaesthesia, *n* (%)	General	80 (55)	30 (61)	0.46
	Spinal	65 (45)	19 (39)	

Summary statistics are: mean ± SD, median [inter-quartile range] or number (percentage).
[1]*P* values indicating the significance of the difference between coronavirus disease 2019 (COVID-19) positive and COVID-19 negative cohorts. COVID-19: Coronavirus disease 2019; ASA: American Society of Anaesthesiologists.

as the optimum standard of care.

COVID-19 positive patients had more intensive care admissions (27% *vs* 5%, $P < 0.001$) and longer inpatient stays (median 23 d *vs* 9 d, $P < 0.001$) than COVID-19 negative patients. Although often overlooked and not technically a prerequisite of the informed consent process, preoperative discussion regarding location of postoperative care and anticipated length of inpatient stay are invaluable in ensuring patients develop realistic expectations for their recovery. Further, providing a pragmatic estimation for duration of inpatient stay enables patients to prepare in advance for the logistical complexities of mandatory self-isolation post hospital discharge for COVID-19 positive patients. This is especially important when care arrangements need to be made for other vulnerable persons living at the same address as the patient.

Postoperative complications were evident in 74.5% of COVID-19 positive patients. 35.3% of COVID-19 positive patients suffered postoperative LRTI with 13.7% developing ARDS (Table 3). This reflects results from the CovidSurg collaborative which analyzed 835 COVID-19 positive patients undergoing emergency surgery and identified post-operative LRTI in 40% of patients with 14.3% developing ARDS[14].

Table 2 Comparison of outcomes between coronavirus disease 2019 positive and coronavirus disease 2019 negative cohorts

Outcome	Analysis	Negative (*n* = 146), *n* (%)	Positive (*n* = 51), *n* (%)	Odds ratio[2] (95%CI)	*P* value
Intensive care	Unadjusted	8 (5)	14 (27)	6.53 (2.55, 16.7)	< 0.001
Admission	Adjusted[1]	-	-	4.64 (1.59, 13.5)	0.005
30-d mortality	Unadjusted	14 (10)	15 (29)	3.93 (1.74, 8.89)	0.001
	Adjusted[1]	-	-	3.00 (1.22, 7.40)	0.02
		Negative (*n* = 146), Med [IQR]	Positive (*n* = 51), Med [IQR]	Hazard ratio[2] (95%CI)	
Length of stay	Unadjusted	9 [7, 13]	23 [19, 31]	0.28 (0.18, 0.42)	< 0.001
(d)	Adjusted[1]	-	-	0.26 (0.17, 0.42)	< 0.001

[1]Adjusted for: gender, mobility, admission haemoglobin, operative time and time from admission to surgery.
[2]Expressed as outcome in the coronavirus disease 2019 (COVID-19) positive group relative to the outcome in the COVID-19 negative group.

Table 3 Postoperative complications in coronavirus disease 2019 positive patients

Complication	*n* (%)
Lower respiratory tract infection	18 (35.29)
Acute respiratory distress syndrome	7 (13.73)
Sepsis	7 (13.73)
Thromboembolic event	5 (9.80)
Acute kidney injury	5 (9.80)
Anaemia	4 (7.84)
Myocardial infarction	2 (3.92)
Urinary tract infection	2 (3.92)
Cellulitis/wound infection	2 (3.92)
Upper gastrointestinal bleed	1 (1.96)
None	13 (25.49)

Prior to the pandemic, the rate of LRTI post hip fracture surgery was estimated to be 4.9%-7.0% with the combined incidence of atelectasis, respiratory failure, pulmonary embolism and ARDS at 4%[15,16]. It is theorised that fracture and surgical intervention may trigger an oxidative stress response promoting excessive inflammation and decreasing patients' immunity–increasing the likelihood of respiratory complications secondary to COVID-19 infection[17]. Therefore, COVID-19 positive patients undergoing hip fracture surgery must be consented for the increased risk of postoperative LRTI and development of ARDS.

The British Orthopaedic Association's blue book for the care of patients with fragility fractures reports a 3% incidence of symptomatic DVT and a 1% incidence of pulmonary embolism following hip fracture surgery[18]. In our study, 9.8% of COVID-19 positive patients experienced a symptomatic thromboembolic event with a 3.9% incidence of DVT, a 3.9% incidence of PE and a 1.96% incidence of cerebrovascular infarction. This corroborates findings from the CovidSurg collaborative where 2.2% of COVID-19 patients undergoing emergency surgery developed postoperative PEs[14]. In critically unwell COVID-19 positive patients, rates of thromboembolic events are even higher–with 25% patients admitted to an intensive care unit in Holland developing a DVT after 21 d[19].

Patients with hip fractures and COVID-19 infection automatically fulfil two of the three criteria in Virchow's triad for thrombus formation: Venous stasis due to immobility and hypercoagulability secondary to an inflammatory state[20]. Evidence suggests COVID-19 may also cause the third criteria: endothelial injury. It is proposed that serum levels of angiotensin 2 are elevated in COVID-19 positive patients stimulating production of reactive oxygen species responsible for the breakdown of nitric oxide which leads to endothelial dysfunction[21]. In the context of these studies,

it is prudent to consent COVID-19 positive patients undergoing hip fracture surgery for the increased risk of postoperative thromboembolic events, and to reiterate the importance of compliance with venous thromboembolism protocols.

In summary, COVID-19 positive patients undergoing hip fracture surgery should be consented for the increased risk of postoperative complications (including LRTI, ARDS, DVT and PE), increased requirement for intensive care admission, longer inpatient stay and a higher risk of mortality. Further, COVID-19 has enforced an additional requirement for the informed consent process: Transparency about the potential for unknown long-term risks and an honest admission of how little we currently understand as research into the long-term surgical outcomes of COVID-19 positive patients continues to evolve.

The principle strengths of this study are that a robust and comprehensive range of predefined study outcomes were recorded using a standardized collection proforma; the study collected data over a four month period from four NHS hospitals at the epicentre of the United Kingdom's COVID-19 outbreak providing a large sample size; only those patients with confirmed COVID-19 positive or COVID-19 negative swab assays were included rather than reliance on interpretation of vague and variable symptomatology; and the study included a control group of COVID-19 negative patients undergoing operative intervention in the same time period with outcome analysis including adjustment for confounding variables between cohorts.

This study has limitations which must be considered when interpreting findings. Diagnosis of COVID-19 was reliant on a positive throat and nose swab assay with a systematic review of the accuracy of COVID-19 tests establishing false negative rates between 2% and 29%[22]. Further, our study focussed exclusively on patients undergoing hip fracture surgery. This minimized demographic and surgical confounders, but makes the generalisability of our findings to other trauma or elective orthopaedic procedures unclear.

CONCLUSION

COVID-19 positive patients undergoing hip fracture surgery should be consented for the increased risk of postoperative complications (including lower respiratory tract infection, ARDS, DVT and pulmonary embolism), increased requirement for intensive care admission, longer inpatient stay and a higher risk of mortality. Both clinicians and patients must acknowledge these risks as part of a detailed informed consent process.

ARTICLE HIGHLIGHTS

Research background

The incidence of hip fractures has remained stable throughout the coronavirus disease 2019 (COVID-19) pandemic, and urgent surgical intervention continues to be prioritized. However, there remains a persistent lack of clinical guidance addressing the subject of informed consent for COVID-19 positive patients undergoing hip fracture surgery. This is of paramount medicolegal importance in a high-risk patient cohort.

Research motivation

The COVID-19 pandemic has created novel challenges and uncertainties in providing informed consent for surgery throughout the medical community. Hip fractures are the most common reason for inpatient orthopaedic trauma admission, with an estimated 1.6 million cases globally *per* year. Therefore, an evidence-based framework for facilitating an informed consent process for hip fracture surgery would provide clinicians with valuable support and clarity worldwide.

Research objectives

This study had two primary objectives. Firstly, we aimed to quantify the additional perioperative risks for COVID-19 positive patients undergoing hip fracture surgery. Secondly, we sought to provide clinicians with an evidence-based framework for facilitating informed consent in COVID-19 positive patients undergoing hip fracture surgery.

Research methods

Two hundred and fifty nine consecutive patients undergoing hip fracture surgical intervention in four hospitals in the United Kingdom were recruited. 51 patients were confirmed positive for COVID-19. Predefined study outcomes were recorded over a 30-d period using a standardized collection proforma. COVID-19 positive and COVID-19 negative patients were compared statistically before and after adjustment for confounding factors. Logistic regression was performed to analyze binary outcomes. Survival analysis was performed using Cox regression to compare length of inpatient stay.

Research results

After adjusting for potentially confounding variables, in COVID-19 positive patients the odds of intensive care admission were 4.64 times higher (95%CI: 1.59-13.50, P = 0.005) and the odds of 30-d mortality were 3 times higher (95%CI: 1.22-7.40, P = 0.02). 75% of COVID-19 positive patients suffered post-operative complications. 35.3% experienced postoperative lower respiratory tract infections, 14.3% developed acute respiratory distress syndrome (ARDS) and symptomatic thromboembolic events were evident in 9.8%.

Research conclusions

We conclude that the informed consent process for COVID-19 positive patients undergoing hip fracture surgery should discuss the additional risk of postoperative complications (particularly lower respiratory tract infection, ARDS, deep vein thrombosis and pulmonary embolism), increased requirement for intensive care admission, longer inpatient stay and higher risk of mortality.

Research perspectives

This study contributes to the body of literature reporting short-term surgical outcomes in COVID-19 positive patients. Future research in this field should analyze long-term surgical outcomes in COVID-19 positive patients. In the interim, it is integral that clinicians are transparent with patients that long-term risks of surgery in COVID-19 positive patients remain unknown.

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Retrospective Cohort Study

Dermatomyositis and polymyositis in total hip arthroplasty

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Abstract

BACKGROUND

Idiopathic inflammatory myopathies (IIM) are systemic autoimmune disorders such as dermatomyositis (DM), polymyositis (PM), inclusion body myopathy, and autoimmune necrotizing myopathy that, similar to osteoarthritis, affect quality of life and activities of daily living. Moreover, these patients are often burdened with chronic pain and disability; however, the outcomes and risk of total hip arthroplasty (THA) in this patient population remain unclear.

AIM

To evaluate 90-d complications and costs in patients with these conditions.

METHODS

A retrospective case control study was designed by accessing data from the Medicare dataset available on the PearlDiver server. Patients with IIM, here, those with DM and PM were matched based on possible confounding variables to a cohort without these diseases and with the same 10-year risk of mortality as defined by the Charlson Comorbidity Index Score (CCI). Univariate and multivariate analysis were performed to evaluate complications and t-tests to evaluate 90-d Medicare reimbursements as markers of costs after THA.

RESULTS

The total sample was 1090 patients with each cohort comprised of 545. Females were 74.9% of the population. The mean CCI was 5.89 (SD 2.11). Those with IIM had increased rates of pneumonia [odds ratio (OR) 1.45, $P < 0.001$] and pulmonary embolism (OR 1.46, $P = 0.035$) and decreased hematoma risks (OR 0.58, $P = 0.00$). 90-d costs were on average $1411 greater for those with IIM yet not significantly different ($P = 0.034$).

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CONCLUSION

Patients with IIM have an increased 90-d rate of pneumonia and pulmonary embolism concomitant with a decreased hematoma rate consistent with their pro-coagulatory state. Further attention to increased resource utilization in these patients is also warranted.

Key Words: Dermatomyositis; Arthroplasty; Polymyositis; Outcomes; Charges; Reimbursement

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Core Tip: Patients with dermatomyositis have an increased 90-d rates of pneumonia and pulmonary embolisms. The increased rates of these complications is concordant with a decreased hematoma rates consistent with the prothrombotic state of these patients. Surgeons should remember the implications of dermatomyositis when patients are undergoing total hip arthroplasty, and further discuss deep vein thrombosis prophylaxis.

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INTRODUCTION

Preoperative patient expectations are an important factor in a patient's decision to undergo arthroplasty[1-3]. Such expectations are intimately related to, among other factors, the likely risks and benefits for an individual patient[1-3]. As a result, there is burgeoning interest in all surgical specialties towards quantifying the expected risks and benefits associated with a given procedure[4].

One particular population that has not been widely studied with respect to arthroplasty are patients with idiopathic inflammatory myopathies (IIM), a group of four rare, systemic autoimmune disorders [dermatomyositis (DM), polymyositis (PM), inclusion body myopathy, and autoimmune necrotizing myopathy] that share a number of clinical characteristics[5-7]. IIM patients have baseline increased risk of deep vein thromboses and death[5-9].

Degenerative joint disease is observed in up to 53% of patients with IIM[10]. It is unclear whether IIM directly contributes to joint degeneration[6,7]. High-dose corticosteroids are also often necessary to control major manifestations of IIM, which may result in osteonecrosis and eventual collapse and destruction of joints[9].

Despite the proven success of total hip arthroplasty (THA) in the general population, patients with IIM are amongst the most complex patients who undergo this procedure and there is a paucity in the evidence-based literature with regards to whether these patients experience a higher rate of complications, higher costs, or poorer outcomes following surgery[9,11,12].

The purpose of this study was to evaluate ninety-day complications and costs in patients with IIM, specifically DM or PM, undergoing primary THA for end-stage hip arthritis. The study hypothesized that patients with IIM would experience a higher rate of complications and higher costs following THA compared with the general population.

MATERIALS AND METHODS

Given the low prevalence of IIM, a retrospective review was performed using a national database of surgeries and outcomes. A subset of the United States Medicare patient population was evaluated by way of the Medicare Standard Analytical Files. This dataset is available on the PearlDiver server (PearlDiver Inc., Colorado Springs,

CO, United States), a health insurance portability and accountability act-compliant and commercially-available software that allows for scrutiny of large number of records through International Classification of Disease, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) codes. This server contains over 50 million patient records and has been used extensively by various groups around the country to study a variety of conditions and diseases. No Institutional Review Board approval was required for this study, given the de-identified dataset.

Adult patients with a diagnosis of IIM were identified through ICD-9 710.3 (DM) and 710.4 (PM). These two specific conditions were used as a surrogate for IIM as a whole, given that the available IIM literature–particularly with respect to morbidity and mortality–tends to focus primarily on these two conditions. Cases of THA were identified through ICD-9 81.51 and CPT 27130. Hemiarthroplasty and revision procedures were excluded from the study. Included patients with IIM who underwent primary THA were then matched with controls at a one-to-one ratio through a well-established, comprehensive set of variables. These included age distribution, sex and Charlson Comorbidity Index (CCI). The CCI is a validated predictor of 10-year mortality and has been widely used across multiple medical specialties. Following the matching process, patient groups were compared with respect to age distribution, sex, geographic region where the procedure was performed, and specific comorbidities.

The outcomes assessed in this study included postoperative complications and costs. Diagnosis codes used to identify and compare complications in the postoperative period were similar to those used in previous studies and are reported in Supplementary material[13]. Reimbursement data for day-of-surgery and the ninety-day postoperative period were collected as a surrogate for costs[14]. The ninety-day timeframe was chosen as it is the most common time frame involved in bundled payment programs.

Statistical analysis

All statistical analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria). Chi-square tests with Fischer corrections were used for dichotomous variables and paired *t*-tests were used for cost data after it was determined that the data was parametric through the Kolmogorov-Smirnov test. Multivariate regressions including age, gender, CCI and the presence *vs* absence of IIM were performed for each of the outcomes of interest, yielding an adjusted odds ratio (OR) with corresponding 95% confidence interval (CI). For all statistical analyses, the threshold for significance was established at $P \leq 0.05$. Unless noted otherwise, numerical values given were mean ± SD.

RESULTS

Initial query of the database identified 78005 patients with a diagnosis of IIM and 1145631 cases of THA. After inclusion, exclusion, and matching criteria were applied, 1090 patients were captured for a final total of 545 patients in each of the two groups from 2005 to 2014.

The majority of patients were aged 69 and younger, with no significant difference in age distribution between groups (Table 1).

Females comprised the majority of patients in both groups, with 408 (74.9%) in each ($P = 1.000$). There were no significant differences between groups with respect to the geographic distribution of patients by region ($P = 0.185$).

The mean CCI was identical for both groups (5.89 ± 2.11; $P = 1.000$). Compared with patients with IIM, a significantly higher proportion of patients in the control group had diabetes mellitus (59% *vs* 44%; $P < 0.0001$), pulmonary disease (56% *vs* 46%; $P = 0.001$), and peripheral vascular disease (31% *vs* 30%; $P = 0.008$). Table 2 presents the pre-operative comorbidity profiles of both cohorts. Groups were otherwise similar with respect to comorbidities.

Multivariate regression analysis demonstrated that, compared with controls, patients with IIM had a higher risk of developing pneumonia (OR = 1.456, 95%CI: 1.170-1.812; $P = 0.001$) and pulmonary embolism (OR = 1.460, 95%CI: 1.026-2.077; $P = 0.035$) following THA (Table 3). Further, regression analysis demonstrated that patients with IIM had a lower risk of hematoma formation that became clinically significant compared with controls (OR = 0.582, 95%CI: 0.406-0.833; $P = 0.003$). Groups were otherwise similar with respect to risk of complications following THA.

When evaluating mean day-of-surgery reimbursements, there were no significant differences identified between IIM patients ($12952 ± $4002 *per* patient) and controls

Table 1 Demographic factors for patients included in this study

	No. of IIM patients	No. of control patients	*P* value
Total number of patients	545	545	
Female patients	74.90%	74.90%	1.000
Age (yr)			
≤ 64	24.4%	23.6%	
65-69	25.0%	24.1%	
70-74	19.1%	19.7%	0.993
75-79	17.1%	18.1%	
80-84	11.4%	11.2%	
≥ 85	3.1%	3.4%	
Region			
Midwest	23.1%	26.8%	
Northeast	18.5%	21.5%	0.1851
South	41.3%	36.9%	
West	17.1%	14.9%	

Reported percentages reflect the proportion of total patients in each of the two sample populations (*e.g.*, patients with idiopathic inflammatory myopathies or controls). IIM: Idiopathic inflammatory myopathies.

Table 2 Additional comorbidities for patients included in this study

Comorbidity	Proportion of IIM patients without comorbidity	Proportion of control patients without comorbidity	*P* value
AIDS	0.59%	1.74%	0.479
Congestive heart failure	29.66%	30.68%	1.000
Depression	37.3%	40.52%	0.402
Diabetes mellitus[1]	44.35%	58.61%	0.000
SUD–Drugs	6.31%	7.96%	0.910
SUD–Alcohol	2.35%	4.2%	0.716
Hypertension	89.43%	92.19%	0.112
Hypothyroidism	42.44%	38.21%	0.059
Liver disease	12.92%	12.45%	0.355
Lymphoma	3.38%	4.63%	1.000
Metastatic cancer	5.14%	6.8%	0.901
Neurological disease	13.07%	13.6%	0.742
Pulmonary disease[1]	45.96%	55.86%	0.001
PVD[1]	30.1%	30.54%	0.008

[1]Denotes significance, $P < 0.05$. Reported percentages reflect the proportion of total patients in each of the two sample populations (*e.g.*, patients with idiopathic inflammatory myopathies or controls) with the listed comorbidity. AIDS: Acquired immunodeficiency syndrome; SUD: Substance use disorder; PVD: Peripheral vascular disease; IIM: Idiopathic inflammatory myopathies.

($12445 ± $3857 *per* patient; $P = 0.299$). Similarly, mean ninety-day reimbursements were comparable for patients with IIM ($15530 ± $4901 *per* patient) and controls ($14480 ± $4525 *per* patient; $P = 0.140$).

Table 3 Results of multivariate regression analysis to evaluate the relative risk of complications in patients with idiopathic inflammatory myopathies compared with controls following total hip arthroplasty

Complication		OR (95%CI)	*P* value
Acute kidney injury	0.034	1.035 (0.817-1.311)	0.778
Cardiac arrest	0.315	1.370 (0.712-2.636)	0.346
Deep vein thrombosis	0.423	1.526 (0.524-4.443)	0.438
Nerve injury	-0.966	0.381 (0.039-3.687)	0.405
Pneumonia[1]	0.376	1.456 (1.170-1.812)	0.001
Pulmonary embolism[1]	0.378	1.460 (1.026-2.077)	0.035
Urinary tract infection	0.123	1.131 (0.931-1.374)	0.215
Wound disruption	-0.249	0.780 (0.485-1.253)	0.304
Hematoma[1]	-0.542	0.582 (0.406-0.833)	0.003
Transfusion	0.060	1.062 (0.861-1.310)	0.573
Capsulitis	0.355	1.426 (0.952-2.137)	0.085
Infection	-0.342	0.71 (0.442-1.139)	0.156

[1]Denotes significance, $P < 0.05$. CI: Confidence interval; OR: Odds ratio.

DISCUSSION

The results of this study support the hypothesis that patients with IIM experience a higher rate of ninety-day complications, namely pneumonia and pulmonary embolism, following THA. However, the study results also contradict part of our hypothesis in that costs (as represented by ninety-day reimbursements) were similar between patients with IIM and controls. Interestingly, there was one complication (clinically diagnosed hematoma formation) we identified that occurred less frequently in patients with IIM, likely given the pro-thrombotic state of these inflammatory conditions as discussed below. To our knowledge, this is the first study to comprehensively analyze the specific complications and reimbursements associated with THA in patients with IIM compared with patients in the general population with a matched comorbidity profile.

There are a myriad of disease manifestations, comorbidities, and medication side-effects that patients with IIM are susceptible to, which may place them at a higher risk of complications following arthroplasty compared with the general popula-tion[5-9,12,15]. One of the most feared and potentially devastating complications in arthroplasty is venous thromboembolism (VTE)[9]. Depending on the diagnostic study used and the chosen endpoint (*e.g.*, asymptomatic, symptomatic, fatal, *etc.*), the risk of VTE following lower-extremity arthroplasty has been reported to be less than 1%-2% when chemoprophylaxis is used[9,16,17]. It is well-documented that IIM carries a heightened risk of thromboembolic events, with one study reporting that these patients have an eight-fold higher risk of developing VTE compared with the general population[8]. Our study identified that patients with IIM demonstrated a nearly 1.5-fold higher risk of pulmonary embolism compared with controls. The discrepancy in the observed increased risk of thromboembolic events between the two studies is likely due, in part, to the fact that our study used a comorbidity-matched control group, who themselves likely have an elevated risk of thromboembolic events above the general population. Moreover, our findings describe a nationwide cohort representative of the average IIM patient undergoing THA, whereas the study by Antovic *et al*[8] did not evaluate the rates of VTE in a surgical cohort and instead compared VTE incidences between IIM patients and the general population. Conversely, bleeding and hematoma formation are also potential complications, with 0.41% of patients who undergo THA requiring surgical evacuation of a hematoma[18]. Interestingly, this study found that patients with IIM had a 42% lower incidence of hematoma compared with controls, which is in concordance with the hypercoagulable state these patients are in at baseline.

Based on the results of this study and studies involving other high-risk groups undergoing arthroplasty, it may be prudent to use more aggressive postoperative chemoprophylaxis in IIM patients undergoing THA as part of a multimodal approach

to overall VTE prophylaxis. Further research is necessary to better characterize the elevated VTE risk and commensurate prophylaxis regimen for IIM patients undergoing THA.

Patients with IIM have an elevated baseline risk of developing pulmonary disease, including pneumonia[5-7,19]. The lungs are the most commonly involved extra-muscular organs in IIM. Infectious pulmonary complications occur in 26% of IIM patients, with *Pseudomonas* and *Staphylococcus* being the most common causative organisms for pneumonia in these patients[19]. In the present study, we found that IIM patients demonstrated a nearly 1.5-fold higher risk of pneumonia compared with controls. It is unclear which, if any, IIM-associated risk factors (*e.g.*, dysphagia, leukopenia, hypoproteinemia, myopathy of thoracic musculature, concurrent immunosuppressive treatment) contributed to the development of pneumonia in our study population or what subtype of pneumonia each patient developed (*e.g.*, community-acquired, hospital-acquired, *etc.*)[19]. Further studies are necessary to better characterize pneumonia in this population, including elucidating the most common mechanisms (*e.g.*, aspiration, poor hand or equipment hygiene of staff, *etc.*) and whether more intensive therapy or precautions (*e.g.*, pulmonary hygiene, topical decontamination, vaccination, *etc.*) may be warranted.

With total annual Medicare reimbursements of approximately $20 billion and growing for arthroplasty, considerable efforts have been undertaken to reduce costs and limit spending[20]. In this study, we observed similar ninety-day reimbursements between IIM patients ($15530) and controls ($14480). On the one hand, the similarity in reimbursement is commensurate with the matched comorbidity profile of the two groups. On the other hand, given the higher number of complications observed in patients with IIM, it was surprising that we did not observe a corresponding higher reimbursement. With complications comes increased healthcare utilization, leading to increased costs and ultimately increased insurance reimbursements[20-22]. The Center for Medicare and Medicaid Services' Comprehensive Care for Joint Replacement (CJR) bundled payments program penalizes hospitals with higher-than-average reimbursements and rewards hospitals with lower-than-average reimbursements[21]. As a result, there is debate as to whether such bundling programs may incentivize hospitals and providers to treat patients who are more profitable (*e.g.*, fewer comorbidities, lower costs) while creating barriers to treatment for higher-risk populations[21]. Currently, the CJR program risk-stratifies patients undergoing lower extremity arthroplasty based on diagnosis related group codes, geographic region, and presence of a fracture; there is currently minimal risk adjustment for comorbidities [21]. The specific complications quantified in this study contribute to an overall more robust risk stratification for IIM patients undergoing THA. This may have the added benefit of aiding bundled payment negotiations, providing more equitable reimbursement, and ultimately improving access for certain higher-risk patients.

There are a number of limitations with this retrospective data review that must be considered. As with any large, national database, there is the potential for errors, omissions, inconsistencies, and/or variability in the data. When statistical analysis is performed on a large dataset, the establishment of statistically significant differences is likely. Unfortunately, clinically important differences in rates of complications are seldom defined, as they are often subjective. Thus, clinically important differences in rates of complications were not established in our methodology. The database includes no specific operative details (*e.g.*, operative time, anesthesia, intraoperative findings, prosthesis used, antibiotics used, postoperative protocol, *etc.*). Patients were not stratified based on length-of-stay in the hospital after surgery. Due to the nature of the database query in this study, there is the potential for retrospective bias. Using reimbursement data as a surrogate for costs introduces limitations to our analysis, given the convoluted payment models currently in place in the healthcare industry. In addition, reimbursement values captured in this study were not adjusted for inflation. Notwithstanding, these values represent reimbursements from the biggest payer in the country (Medicare) and thus allow for comparisons between studies[4]. This study included a majority of female patients and did not evaluate hemiarthroplasty, revision procedures, or the two remaining IIM groups (inclusion body myopathy and autoimmune necrotizing myopathy), which may limit the generalizability of our results. Lastly, numerous studies have reported consistent validity of the CCI as a prognostic factor for mortality and health costs, the CCI includes only a limited number of fields for diagnosis entry and does not account for the clinical severity of most of the included diagnoses[21,23]. Consequently, CCI may potentially underestimate the number and/or extent of comorbidities, which may limit the external validity of our results. In addition, and despite an identical mean CCI for both groups, the control group had a higher frequency of comorbid diabetes, pulmonary disease,

and peripheral vascular disease, which may have had a confounding effect on postoperative complications and/or reimbursements. Future studies are needed to prospectively follow these patients and their complications, yet the low prevalence of IIM makes this a difficult feat.

CONCLUSION

Compared with patients in the general population with a matched comorbidity profile, patients with IIM who undergo primary THA are at an increased risk of potentially serious ninety-day complications (pneumonia and pulmonary embolism) and incur similar total costs following surgery. The results of this study may help improve patient selection for surgery and aid physicians in providing a more accurate, individualized risk-benefit assessment for IIM patients prior to surgery.

ARTICLE HIGHLIGHTS

Research background

There is a paucity of data evaluating patients with dermatomyositis (DM) and polymyositis (PM) undergoing total hip arthroplasty (THA).

Research motivation

To compare and contrast the outcomes of patients undergoing THA with DM and PM *vs* a matched control without inflammatory arthropathies.

Research objectives

To elucidate whether patients with DM and PM have increased risk of complications and greater 90-d costs when undergoing THA compared to controls.

Research methods

A retrospective case control was performed based on the medicare data.

Research results

Patients with DM and PM had increased rates of pneumonia [odds ratio (OR) 1.45, $P < 0.001$] and pulmonary embolism (OR 1.46, $P = 0.035$) and decreased hematoma risks (OR 0.58, $P = 0.00$). 90-d costs were on average $1411 greater for those with idiopathic inflammatory myopathies (IIM) yet not significantly different ($P = 0.034$).

Research conclusions

Patients with IIM have an increased 90-d rate of pneumonia and pulmonary embolism concomitant with a decreased hematoma rate consistent with their pro-coagulatory state.

Research perspectives

It is important to evaluate deep vein thrombose prophylaxis and respiratory status in those undergoing THA with DM or PM.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Outcome and revision rate of uncemented humeral head resurfacing: Mid-term follow-up study

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Abstract

BACKGROUND

Glenohumeral osteoarthritis (OA) is a common cause of pain and disability affecting nearly a third of the world's population over 60 years of age. As in other joints, shoulder arthroplasty appears to be the most effective treatment. The implant design has evolved during time transitioning to shorter humeral stem lengths or even stemless components.

AIM

To evaluate the medium-term outcome and survival of a cementless humeral head resurfacing (HHR) in a group of patients affected with OA or avascular necrosis.

METHODS

This is a retrospective study of prospectively collected data using HHR in 23 patients (15 female and 8 male) after a 7.4 year follow-up. The collected data included clinical and radiographical evaluation. The Constant score, the visual analogue scale, and a clinical evaluation of range of motion were registered pre- and postoperatively. Fifteen patients affected with OA (2 cases of mild, 6 moderate, and 7 severe) and 10 with avascular necrosis (stage III according to Cruess classification) were enrolled. X-rays were evaluated to detect loosening signs, degenerative changes, and superior humeral head migration. Magnetic resonance preoperatively was also performed to assess the rotator cuff status. Tendon integrity was mandatory to implant the HHR.

RESULTS

In total, 19 patients (21 shoulders) completed the follow-up. Data on 4 shoulders,

Data sharing statement: Patients were not required to give informed consent to the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

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in 4 patients, were lost because of prosthesis failure. The global revision rate was 16%. A statistically significant improvement in the mean Constant score, visual analogue scale, and range of motion have been reported. No signs of loosening were registered, while in 12 cases a glenoid erosion was found. The osteophytes appeared 7 times on the humeral side and 12 on the glenoid. Superior humeral migration was recorded in only 1 case.

CONCLUSION

HHR remains a reasonable option in patients with an intact rotator cuff for the treatment of OA and avascular necrosis.

Key Words: Shoulder; Arthroplasty; Humeral head; Resurfacing; Glenoid erosion; Prosthesis failure

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Core Tip: Shoulder arthroplasty is the most effective treatment of glenohumeral osteoarthritis. The medium-term outcome and survival of a cementless humeral head resurfacing was retrospectively evaluated in 23 patients affected with osteoarthritis or avascular necrosis after a 7.4 year follow-up. The global revision rate was 16%. A statistically significant improvement in the mean Constant score, visual analogue scale, and range of motion have been reported. No signs of loosening were registered, while in 12 cases a glenoid erosion was found. Humeral head resurfacing remains a reasonable option in patients with an intact rotator cuff for the treatment of osteoarthritis and avascular necrosis.

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INTRODUCTION

Glenohumeral osteoarthritis (OA) is a common cause of pain and physical limitation, with an estimated prevalence between 4% and 26%[1], affecting nearly a third of the world's population over 60 years of age[2]. The choice of treatment of shoulder OA is often controversial, and it is related to the surgeon and based on the patient's age, severity of symptoms, level of activity, radiographic findings, and medical comorbidities[3]. Activity modification, physical therapy, and anti-inflammatory drugs are the major nonoperative treatment options. In case of failure (nonresponding) of this therapeutic approach and when the patients may not wish to progress directly to surgery, intra-articular injection with either corticosteroid or hyaluronic acid or platelet-reach plasma[4] represents a valid alternative. Finally, surgery may be considered. As in other joints affected by severe OA, different surgical procedures are available, being joint arthroplasty the most effective treatment[3].

Shoulder arthroplasty was introduced by Neer *et al*[5]; from that date prosthesis design has evolved during time to better reproduce and accommodate the individual shoulder anatomy and variability[3,6]. During this evolution, implants have transitioned to shorter humeral stem lengths or even stemless components. The latter has been introduced in 2004 by Copeland, who designed a cementless humeral head resurfacing (HHR) prosthesis for the treatment of glenohumeral OA[7], providing good clinical results[8]. Over time, the indications to implant a cementless HHR changed and extended to other shoulder pathologies, such as humeral head avascular necrosis (AVN), instability arthropathy, rheumatoid arthritis, post-traumatic arthropathy, and cuff tear arthropathy, with good functional results[8,9]. The rationale to implant a cementless HHR is to restore the patient's individual humeral head anatomy, characterized by articular retroversion, neck shaft angle, lateral offset, and center of rotation, and it is easier to remove, preserving the bone stock for a possible

future revision[8,10].

The main criticism referred to HHR is usually related to the incorrect sizing and orientation of the prosthesis, resulting in an oversizing of the joint. A deviation of the center of rotation higher than 5 mm has been shown to correlate to clinical failure of the implant[10]. HHR failure rate is among 6% and 37%[9,11,12]. A direct correlation between overstuffing and glenoid wear has been demonstrated, leading to prosthesis failure[13]. Moreover, an operative change of the lateral glenohumeral offset as a predictive factor for implant failure has been reported[14]. Among other causes for prosthesis failure, rotator cuff tear, painful stiffness without glenoid erosion, or infections were reported[14].

The aim of the present study was to evaluate the medium-term outcomes and survival of a specific cementless HHR in a group of patients operated by a single surgeon in a single center.

MATERIALS AND METHODS

This is a report of prospectively collected data of 23 patients who have undergone cementless Aequalis HHR (Tornier, Warsaw, IN, United States) with a mean follow-up of 89 mo (range 44-131 mo).

All procedures involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with 1964 Helsinki Declaration and its later amendments. This study was reviewed and approved by the Ethics Committee/Scientific Council of the Istituto Chirurgico Ortopedico Traumatologico of Latina, Italy.

All participants gave informed written consent.

Subjects

Between February 2009 and May 2014, 25 shoulders in 23 patients (15 females and 8 males; mean age: 67.2 years, min/max: 39-83 years) were surgically treated with the same type of cementless HHR performed by the same surgeon (CC) in a single center. The indications for surface replacement were primary OA (15 shoulders) and humeral head AVN (10 shoulders). The exclusion criteria were the presence of rotator cuff tears (partial or complete) and a damaged glenoid (evaluated with magnetic resonance).

Surgical technique

All patients were operated under general anesthesia in the beach-chair position, by using the delto-pectoral approach. An L-shaped tenotomy of the subscapularis tendon was performed, followed by a capsular release for soft tissue balancing. The glenoid surface status was then assessed by retracting the humeral head. Once the humeral head was exposed, all osteophytes were carefully circumferentially removed. This step is critical because head sizing and head orientation are based off the anatomic neck. If the actual humeral head appeared to be in between sizes, the smaller size was selected. The humeral head was then reamed down to restore the original head height. The uncemented press-fit technique was the method of choice for fixing the resurfacing implant (Aequalis RH Tornier, Warsaw, IN, United States). Primary stability was achieved in all cases thanks to the presence of a tapered press-fit, tri-fin antirotational stem and a diamond-shaped macrotexture. In addition, all bone contacting surfaces were hydroxyapatite-coated.

In all cases, the long head biceps tenotomy was performed close to its glenoid attachment, followed by tenodesis in the bicipital groove. After implant reduction, the subscapularis was repaired in a tendon-to-tendon fashion using three to five nonabsorbable sutures. In no cases drains were placed in the shoulder.

The patient's arm was placed in a shoulder abduction pillow for 4 wk. Passive rehabilitation was started from day 2 with external rotation restricted to 0°. Patients were asked to support these movements actively. Free range of motion was allowed 6 wk after surgery.

Clinical study

Clinical evaluation included pre- and postoperative administration of the Constant scale and the visual analogue scale. The active range of motion was evaluated in pre- and postoperative time, with particular attention to the forward elevation, abduction, and external rotation with the arm at the side.

Radiological study

Pre- and postoperative radiographs were performed in two projections: A true antero-posterior view in neutral rotation and an axillary view. All radiographs were digitalized and scaled on the same size thanks to the software of Picture Archiving and Communication System monitor (General Electric, Chicago, IL, United States), available in the radiology department of our institute.

In the preoperative, the glenohumeral OA and humeral head AVN were radiologically classified according to Samilson and Prieto (mild: inferior humeral and/or glenoid exostosis < 3 mm in height; moderate: inferior humeral and/or glenoid exostosis measuring 3 mm to 7 mm, slight glenohumeral irregularity; severe: inferior humeral and/or glenoid exostosis measuring > 7 mm, glenohumeral joint narrowing and sclerosis) and Cruess (stage I: normal X-ray, changes on magnetic resonance; stage II: sclerosis, osteopenia; stage III: crescent sign indicating a subchondral fracture; stage IV: flattening and collapse; stage V: degenerative changes extend to glenoid).

Preoperative X-ray images revealed OA in 15 shoulders (2 cases of mild, 6 moderate, and 7 severe) and 10 shoulders affected by humeral head AVN (10 cases stage III).

During follow-up, the radiographic evaluation was useful to check signs of: (1) Loosening around the peg and in the eighth humeral zone. Probably loosening is intended as a radiolucent 2 mm wide line or greater around the implant without any change in position of the implant. Definite loosening was defined as a change in position of the implant over time; (2) Degenerative changes (*i.e.* glenoid erosion, humeral head or glenoidal osteophytes); and (3) Vertical humeral migration of the head intended as a superior migration of the prosthesis outside the center of the glenoid.

Statistical analysis

The paired t-test was used to determine whether there was a significant difference between preoperative and postoperative Constant score, visual analogue scale, and range of motion obtained at the latest check-up at 7.4 years. A P value of < 0.05 was considered to be statistically significant.

RESULTS

In total, 19 patients (21 shoulders) completed the follow-up.

Data on 4 shoulders in 4 patients were lost because of prosthesis failure due to a rotator cuff tear after a traumatic accident (1 case) (Figure 1) and glenoid erosion (3 cases) (Figure 2) that required a revision surgery (Table 1). In all the revised cases the implant was removed without complications, leaving a sufficient bone stock for reimplantation (Figure 3)

The Constant score improved from the preoperative mean value of 31.1 (range 16-57) to the postoperative mean value of 74.9 (range 57-100) (P < 0.001). In detail, an improvement of all the sections of the Constant score was registered from the preoperative to the postoperative latest evaluation and was statistically significant (P < 0.001) except for the recovery of the strength (P = 0.3).

The pretreatment visual analogue scale grading scale was 7.8 (range 5-10), while at the final follow-up decreased to 2.1 (range 0-5) (P < 0.001).

An improvement in the clinical evaluation of the active range of motion was also registered. The mean flexion forward changed from 75° (range 30°-120°) in the preoperative to 111° (range 60°-160°) in the postoperative (P = 0.06). The pre- and postoperative mean value of abduction were respectively 68° (range 30°-120°) and 104° (range 60°-160°) (P < 0.001), while the mean external rotation value pre- and postoperative were respectively 30° (range 10°-50°) and 54° (range 30°-75°) (P < 0.001) (Table 2).

No signs of loosening around the peg and in the eighth humeral zone[15] were detected at the latest follow-up. In 11 cases, a glenoidal erosion has been reported. In 3 patients, this condition was symptomatic, while in the remaining 8 it was not. In 12 cases the presence of inferior glenoidal osteophytes was registered, and in 7 cases humeral head osteophytes were registered. Only 1 case of superior humeral migration had been reported due to the traumatic rotator cuff tear (Figure 1).

The global revision rate was 16% at a mean follow-up of 7.4 years, and the survival rate was 84% (Figure 4).

Table 1 Demographic data of patients who required revision

Patient	Sex	Age	Indication	Lifespan of the prosthesis	Failure cause	Revision
1	Male	66	Right OA	65 mo (5.41 yr)	Glenoiditis	rTSA
2	Female	78	Right AVN	44 mo (3.66 yr)	Traumatic RCT	rTSA
3	Female	75	Right AVN	50 mo (4.16 yr)	Glenoiditis	rTSA
4	Male	48	Left AVN	66 mo (5.50 yr)	Glenoiditis	TSA

AVN: Avascular necrosis; OA: Osteoarthritis; RCT: Rotator cuff tear; rTSA: Reverse total shoulder arthroplasty.

Table 2 Preoperative and 7.4 yr postoperative clinical finding

	Preoperative value (min-max)	Postoperative value (min-max)	*P* value
Pain	3.20 (0-5)	12.38 (10-15)	< 0.001
Daily activity level	7.96 (6-11)	16.66 (12-20)	< 0.001
ROM	10.48 (2-17)	35.47 (28-40)	< 0.001
Strength	9.44 (3-25)	10.42 (4-25)	0.3
Constant score	31.08 (16-57)	74.95 (57-100)	< 0.001
VAS	2.88 (1-4)	7.76 (5-10)	< 0.001
Flexion forward	74.80° (30°-120°)	111.42° (60°-160°)	0.06
Abduction	68.00° (30°-120°)	104.28° (60°-160°)	< 0.001
External rotation	30.40° (10°-50°)	54.04° (30°-75°)	< 0.001

ROM: Range of motion; VAS: Visual analog scale.



Figure 1 Patient 2. X-ray of a right shoulder anteroposterior view. Note the superior humeral head migration caused by a traumatic rotator cuff tear 3, 6 yr after surgery.

DISCUSSION

Even if during the years the indications to implant a cementless HHR changed and extended from OA to numerous shoulder pathologies[8,9], the authors' rationale to implant a cementless HHR was to restore the patient's individual humeral head anatomy, and two major aspects were considered crucial: (1) The integrity of the rotator cuff; and (2) A good bone stock to fix the implant.

The latter aspect may be a problem in AVN. This condition in fact is characterized by the death of cellular components of bone secondary to an interruption of the subchondral blood supply determining a deep bone distortion with abnormal

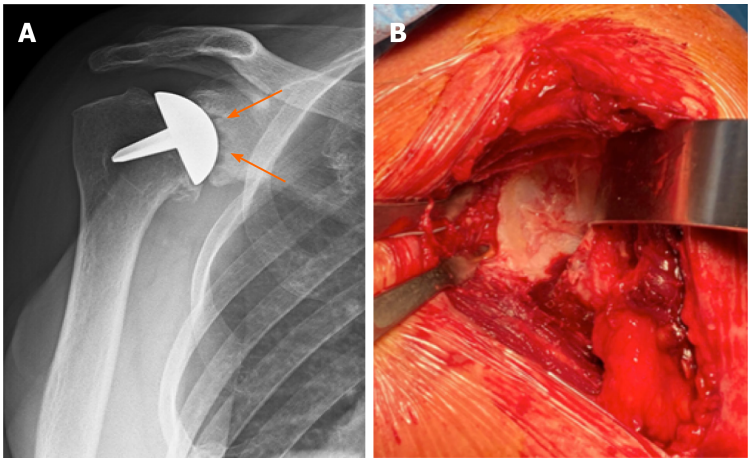


Figure 2 Patient 3. A: X-ray of the right shoulder. Anteroposterior view. An evident glenoid erosion (arrows) is detectable 5.5 yr after humeral head resurfacing; B: Revision surgery. Deltopectoral approach. After removal of the implant the glenoid surface damage was assessed by retracting the humerus.

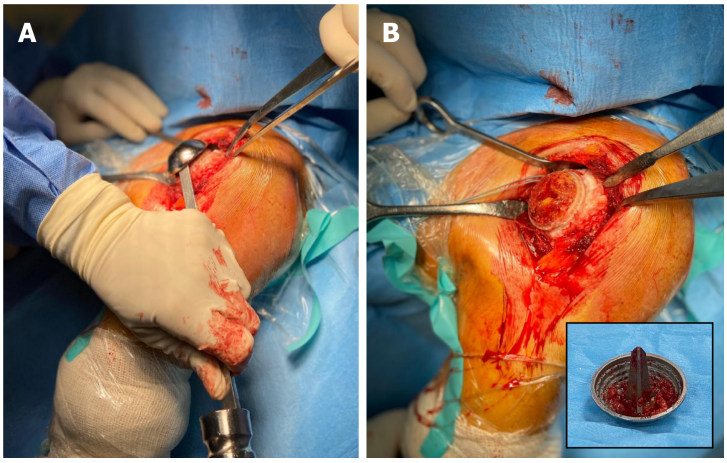


Figure 3 Patient 4. Revision surgery, deltopectoral approach. A: The removal of the implant; B: The humeral bone stock appears maintained after prosthesis removal (square).

architecture and for this reason may be considered not an absolute indication to implant a cementless HHR, especially in its late stages (IV and V according to Cruess).

According to the findings of the present study, the clinical and radiological results were good in a mean term follow-up of more than 7 years using the Aequalis HHR in the treatment of glenohumeral OA and humeral head AVN compared to similar data reported in the literature[9,11,14,16-19] (Figure 5).

In contrast, to our knowledge there exists only one paper reporting no failure at a long-term follow-up[20]. In that paper, the study population consisted of 14 young patients (aged 19-49 years) affected by juvenile idiopathic arthritis and treated with HHR with a 10.4 year follow-up period. The authors reported that only two shoulders required early arthroscopic subacromial decompression. This interesting study may have a limitation/bias in the age of its population because it was limited to young patients.

As underlined above, the use of HHR as the primary implant presents numerous advantages in all ages, but especially in younger patients. The cementless implant may preserve the bone stock, and this aspect could be useful during a future revision[7]. Moreover, HHR may be considered a valid alternative in the post-traumatic arthropathy to restore shoulder anatomy[7,14].

As already underlined in the literature and confirmed by this study, glenoid erosion is considered as the most important reported cause of prosthesis failure[14,16,17]. This complication could be caused by an incorrect assessment of the humeral head size and orientation, producing an overstuffing of the joint[10,21].

In the past, different attempts were suggested to limit glenoid erosion, and particular interest was given to the procedure employing a biological glenoid

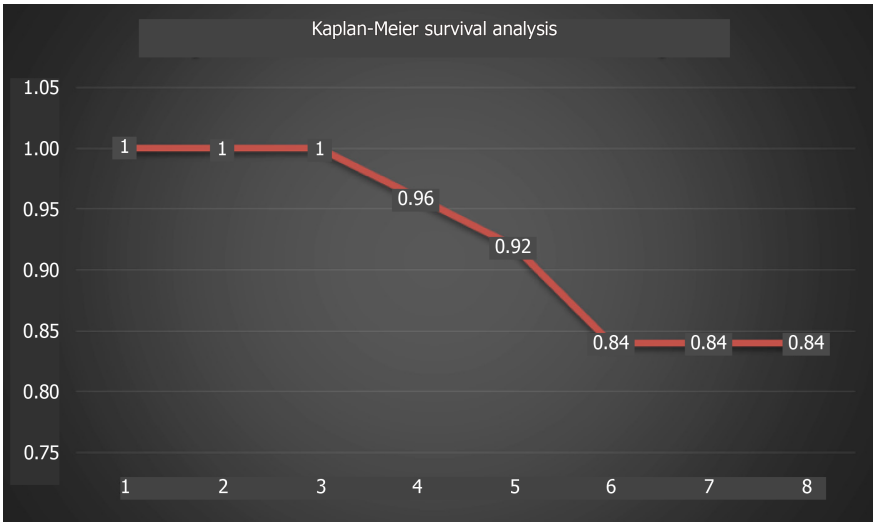


Figure 4 Kaplan-Meier survival analysis.

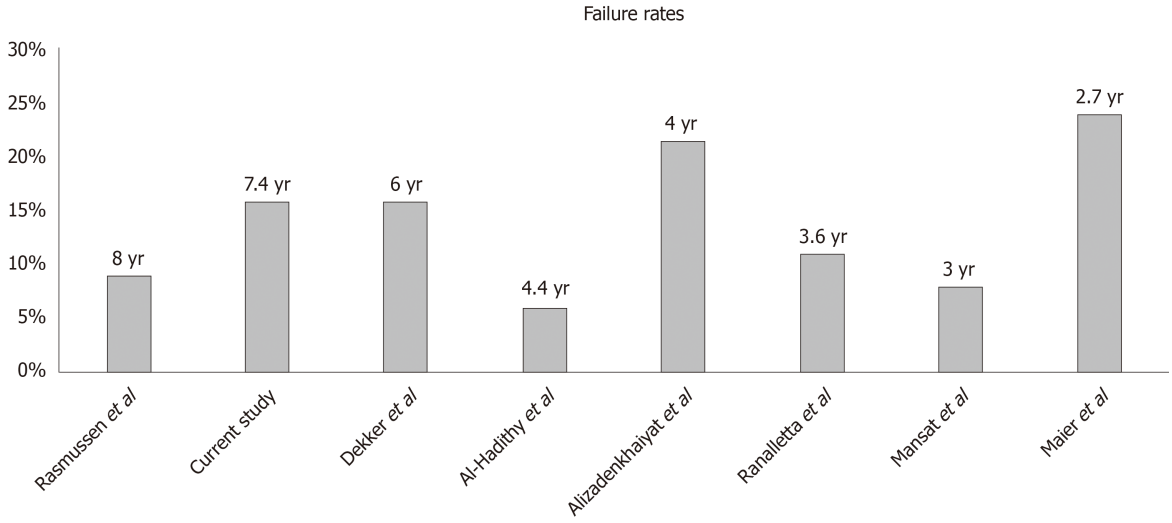


Figure 5 Reported incidence of humeral head resurfacing failure rates in the literature compared with the current study.

resurfacing[22-24]. After promising early results, all these attempts have failed. The reported long-term failure rate of the biological glenoid resurfacing was 56% using the anterior shoulder capsule even though the authors registered good clinical results after 5 years[22].

Also, the use of autograft Achilles tendon or allograft fascia lata for biological glenoid resurfacing was inconsistent. Elhassan *et al*[23] registered 10 cases of erosion in 13 patients (failure rate > 70%), so they do not recommend this kind of treatment. The same conclusion was drawn by Lollino *et al*[24] who proposed to resurface glenoid with the lateral meniscus. After a 2 year follow-up period, the authors reported a narrowing of the articular space, probably related to the meniscal reabsorption.

Taking into consideration the overall results of HHR, the weak part is to date the glenoid. This conclusion is apparently similar to the results of the traditional anatomical shoulder arthroplasty[25]. In fact, many studies have reported that the glenoid component loosening, and failure represented the most common long-term complication of total shoulder arthroplasty. This accounted for approximately 24% of all total shoulder arthroplasty complications[26], so that we have to conclude that the result of a shoulder replacement highly depends on the status of the glenoid, be it native or implanted. Unfortunately, this remains still true although glenoid component design, material, and surgical technique of implant including cement use have been rapidly changed and evolved during the last decades[25].

CONCLUSION

HHR can be considered a good treatment option in OA and humeral head AVN in patients with an intact rotator cuff. This paper, even though is based on a small cohort of patients, shows a good outcome with a failure rate of 16% in a 7.4 year follow-up. No loosening or infection issues were encountered. The main problem of this prosthesis is the higher revision rate due to glenoid erosion, which is comparable to reported rates on total shoulder arthroplasty. Its advantage is bone preservation in the proximal humerus.

ARTICLE HIGHLIGHTS

Research background

Glenohumeral osteoarthritis and avascular necrosis are causes of shoulder pain and disability. Shoulder arthroplasty is the most effective treatment. The implant design has evolved during time transitioning to shorter humeral stem lengths or even stemless components.

Research motivation

The rationale to implant a cementless humeral head resurfacing (HHR) is to restore the patient's individual humeral head anatomy, characterized by articular retroversion, neck shaft angle, lateral offset, and center of rotation, and it is easier to remove, preserving the bone stock for a possible future revision. The reported revision rate at a mid-term follow-up is not so high, so this could be an alternative to a total shoulder arthroplasty.

Research objectives

Our aim is to evaluate the medium-term outcome and survival of a cementless HHR in a group of patients affected with osteoarthritis or avascular necrosis.

Research methods

This is a report of prospectively collected data using HHR in 23 patients (15 female and 8 male) after a 7.4 year follow-up.

Research results

The global revision rate was 16%. Data on 4 shoulders in 4 patients were lost because of prosthesis failure. Nineteen patients (21 shoulders) completed the follow-up. No signs of loosening were registered, while in 12 cases a glenoid erosion was found. The osteophytes appeared 7 times on the humeral side and 12 on the glenoid. Superior humeral migration was recorded in only one case.

Research conclusions

The use of a cementless HHR in the treatment of osteoarthritis and early stage avascular necrosis could nowadays be consider a valid therapeutic option.

Research perspectives

Further research based on well-designed studies with longer follow-up examination and with a bigger patient population need to be performed in order to elucidate the efficacy of cementless HHR.

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ORIGINAL ARTICLE

Retrospective Study

Trends in leadership at orthopaedic surgery sports medicine fellowships

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Abstract

BACKGROUND

Fellowship directors (FDs) in sports medicine influence the future of trainees in the field of orthopaedics. Understanding the characteristics these leaders share must be brought into focus. For all current sports medicine FDs, our group analyzed their demographic background, institutional training, and academic experience.

AIM

To serve as a framework for those aspiring to achieve this position in orthopaedics and also identify opportunities to improve the position.

METHODS

Fellowship programs were identified using both the American Orthopaedic Society for Sports Medicine and the Arthroscopy Association of North America Sports Medicine Fellowship Directories. The demographic and educational background data for each FD was gathered *via* author review of current curriculum vitae (CVs). Any information that was unavailable on CV review was gathered from institutional biographies, Scopus Web of Science, and emailed questionnaires. To ensure the collection of as many data points as possible, fellowship program coordinators, orthopaedic department offices and FDs were directly contacted *via* phone if there was no response *via* email. Demographic information of interest included: Age, gender, ethnicity, residency/fellowship training, residency/fellowship graduation year, year hired by current institution,

time since training completion until FD appointment, length in FD role, status as a team physician and H-index.

RESULTS

Information was gathered for 82 FDs. Of these, 97.5% (n = 80) of the leadership were male; 84.15% (n = 69) were Caucasian, 7.32% (n = 6) were Asian-American, 2.44% (n = 2) were Hispanic and 2.44% (n = 2) were African American, and 3.66% (n = 3) were of another race or ethnicity. The mean age of current FDs was 56 years old (± 9.00 years), and the mean Scopus H-index was 23.49 (± 16.57). The mean calendar years for completion of residency and fellowship training were 1996 (± 15 years) and 1997 (± 9.51 years), respectively. The time since fellowship training completion until FD appointment was 9.77 years. 17.07% (n = 14) of FDs currently work at the same institution where they completed residency training; 21.95% (n = 18) of FDs work at the same institution where they completed fellowship training; and 6.10% (n = 5) work at the same institution where they completed both residency and fellowship training. Additionally, 69.5% (n = 57) are also team physicians at the professional and/or collegiate level. Of those that were found to currently serve as team physicians, 56.14% (n = 32) of them worked with professional sports teams, 29.82% (n = 17) with collegiate sports teams, and 14.04% (n = 8) with both professional and collegiate sports teams. Seven residency programs produced the greatest number of future FDs, included programs produced at least three future FDs. Seven fellowship programs produced the greatest number of future FDs, included programs produced at least four future FDs. Eight FDs (9.75%) completed two fellowships and three FDs (3.66%) finished three fellowships. Three FDs (3.66%) did not graduate from any fellowship training program. The Scopus H-indices for FDs are displayed as ranges that include 1 to 15 (31.71%, n = 26), 15 to 30 (34.15%, n = 28), 30 to 45 (20.73%, n = 17), 45 to 60 (6.10%, n = 5) and 60 to 80 (3.66%, n = 3). Specifically, the most impactful FD in research currently has a Scopus H-index value of 79. By comparison, the tenth most impactful FD in research had a Scopus H-index value of 43 (accessed December 1, 2019).

CONCLUSION

This study provides an overview of current sports medicine FDs within the United States and functions as a guide to direct initiatives to achieve diversity equality.

Key Words: Sports medicine fellowship; Medical education; Orthopaedic surgery; Orthopaedic fellowship; Orthopaedic leadership

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Core Tip: This retrospective study provides an overview of current fellowship directors (FDs) within sports medicine in the United States. Currently, orthopaedics has lower percentages of females and minorities in leadership roles than many other specialties. Gender and racial diversity of these specialties should be a continued focus for improvement. Overall, the trends identified in this study serve as objective data on current FDs within sports medicine. These trends could function as a guide for individuals who strive to become academic leaders in sports medicine orthopaedics as well as direct initiatives to achieve diversity equality.

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INTRODUCTION

In medicine, those in leadership roles share certain characteristics that are gained from their formal training and mentors. Specifically, the fellowship director (FD) is one that will be a significant influence on many aspiring leaders. Potential factors that help physicians reach leadership positions are the ability to influence peers, develop research and educate the next generation of physicians. Through academic training, societal and community involvement, and clinical experience, such individuals decisively develop a set of leadership skills. However, the objective standards that serve as a foundation for these leaders, and sets them apart from others, remains unclear. Furthermore, it seems that developing orthopaedic surgeons pursuing these leadership positions lack objective directions on how to achieve them.

Within orthopaedics, sports medicine FDs oversee decisions that have an effect on current and future trainees. An assessment of the shared attributes associated with these individuals that achieve professional accomplishment to this extent needs to be developed. This review evaluated objective information on the traits and attributes of these leaders. Particularly, this review identifies and examines the demographics, academic experience, and institutional training backgrounds of current sports medicine FDs in the United States. Overall, this study may serve as a guide for aspiring leaders on how to achieve leadership positions in orthopaedic sports medicine and identify opportunities to improve the FD position, specifically with regards to diversifying leaders' racial, gender, training, and research backgrounds.

MATERIALS AND METHODS

Data collection

The American Orthopaedic Society for Sports Medicine (AOSSM) and the Arthroscopy Association of North America Sports Medicine Fellowship Directories for 2019-2020 were queried in order to locate all sports medicine orthopaedic surgery fellowships in the United States. For each program, all listed FDs were included. The demographic and educational background data for each FD was gathered *via* author review of current curriculum vitae (CVs). Any information that was unavailable on CV review was gathered from institutional biographies, Scopus Web of Science, and emailed questionnaires sent to fellowship administrators. To ensure the collection of as many data points as possible, fellowship program coordinators, orthopaedic department offices and FD were directly contacted *via* phone if there was no response *via* email. The demographic information of interest included: Age, gender, race/ethnicity, former residency and fellowship training location, the year of residency and fellowship graduation, year hired by current institution, time since residency and fellowship completion until FD appointment, length in FD role, each individual's H-index and status as a team physician at either the professional or collegiate level. Team physician roles included in the study were 'team physician', 'head team physician' or 'assistant team physician'.

To obtain the individual H-index for each FD, the Scopus database (Elsevier BV, Waltham, MA, United States) was queried to access their research specific information. This database has a search engine feature that operates through an extensive repository of peer-reviewed scientific literature with a citation tracking component. Scopus was employed to retrieve the H-index for every FD in the study.

Pearson correlation coefficients were determined *via* Statistical Analytics System (9.4) software. Data was interpreted according to Mukaka's guide for correlation coefficients[1]. Values under 0.3, 0.3 to 0.5, 0.5 to 0.7, 0.7 to 0.9 and greater than 0.90 are indicative of negligible, low, moderate, high, and very high positive correlation respectively.

RESULTS

Of 82 FDs were included in this study. The demographic information includes age, gender, race/ethnicity, and mean Scopus H-index. This information is summarized in Table 1.

Table 2 presents a detailed overview of educational, employment, and leadership progression of sports medicine FDs, including mean calendar years for completion of residency and fellowship training, mean duration from fellowship graduation until FD appointment, mean duration of employment for a FD at his/her current institution,

Table 1 Demographics of sports medicine fellowship directors

Demographics	
Male	80 (97.5%)
Female	2 (2.5%)
Race/ethnicity	
Caucasian	84.15% (n = 69)
Asian-Americans	7.32% (n = 6)
Hispanic/Latinos	2.44% (n = 2)
African American	2.44% (n = 2)
Other	3.66% (n = 3)
Mean age, yr	56 ± 9.00 (n = 76)
Mean FD Scopus H-index	23.49 ± 16.57 (n = 81)

FD: Fellowship director.

Table 2 Education, employment, and leadership progression of sports medicine fellowship directors

Education and employment progression	mean ± SD
Mean calendar year of residency graduation	1996 ± 15.00 (n = 73)
Mean calendar year of fellowship graduation	1997 ± 9.51 (n = 73)
Mean duration from fellowship graduation to earning position of FD	9.77 yr ± 7.33 (n = 57)
Mean duration of employment at current institution	18.20 yr ± 9.12 (n = 65)
Mean duration that FD has held position as FD	13.14 yr ± 9.54 (n = 59)
Mean time from year of hire by current institution to year promoted to FD	4.72 yr ± 7.93 (n = 64)
Institutional loyalty	***n* (%)**
FDs currently working at same institution as Residency training	14 (17.07)
FDs currently working at same institution as Fellowship training	18 (21.95)
FDs currently working at same institution as both Residency and Fellowship training	5 (6.10)
Correlation of research productivity	***r* (*P* value)**
Years as FD *vs* Scopus H-index	0.29 (0.02)
Age *vs* Scopus H-index	0.38 (0.001)[1]

[1]Correlation is significant. FD: Fellowship director.

mean duration that an FD has held his/her current position, and the average time from initial hire until FD appointment. Table 2 also details the percentages of FDs who, at the time of the study, were working at the same institution where he/she completed their residency training, fellowship training, or both residency and fellowship training. Correlation of research productivity, which was measured in the form of Scopus H-indices, is included in Table 2.

Table 3 demonstrates FD team physician status. Furthermore, team physician status is categorized into professional and collegiate team physicians, as well as sport specific involvement.

Figures 1 and 2 represent the most attended orthopaedic surgery residency and fellowship training programs, respectively. Figure 1 includes the orthopaedic surgery residency programs which trained at least 3 current FDs. Figure 2 includes the orthopaedic surgery fellowship programs which trained at least 4 current. Notably, 8 FDs (9.8%) completed two fellowships and 3 FDs (3.7%) finished three fellowships. Three FDs (3.7%) did not complete any formal orthopaedic surgery fellowship training.

Table 3 Additional team physician roles of sports medicine fellowship directors, *n* (%)

Team physician roles	
Fellowship directors' team physician status	***n* = 82**
Yes	57 (69.51)
No	25 (30.49)
Professional *vs* collegiate	***n* = 57**
Professional	32 (56.14)
Collegiate	17 (29.82)
Both	8 (14.04)
Sport	***n* = 103**
University-wide Athletics	26 (25.24)
Professional other	23 (22.33)
Professional baseball	20 (19.41)
Professional football	16 (15.53)
Professional hockey	8 (7.77)
Professional basketball	7 (6.80)
Professional soccer	3 (2.91)

FD: Fellowship director.

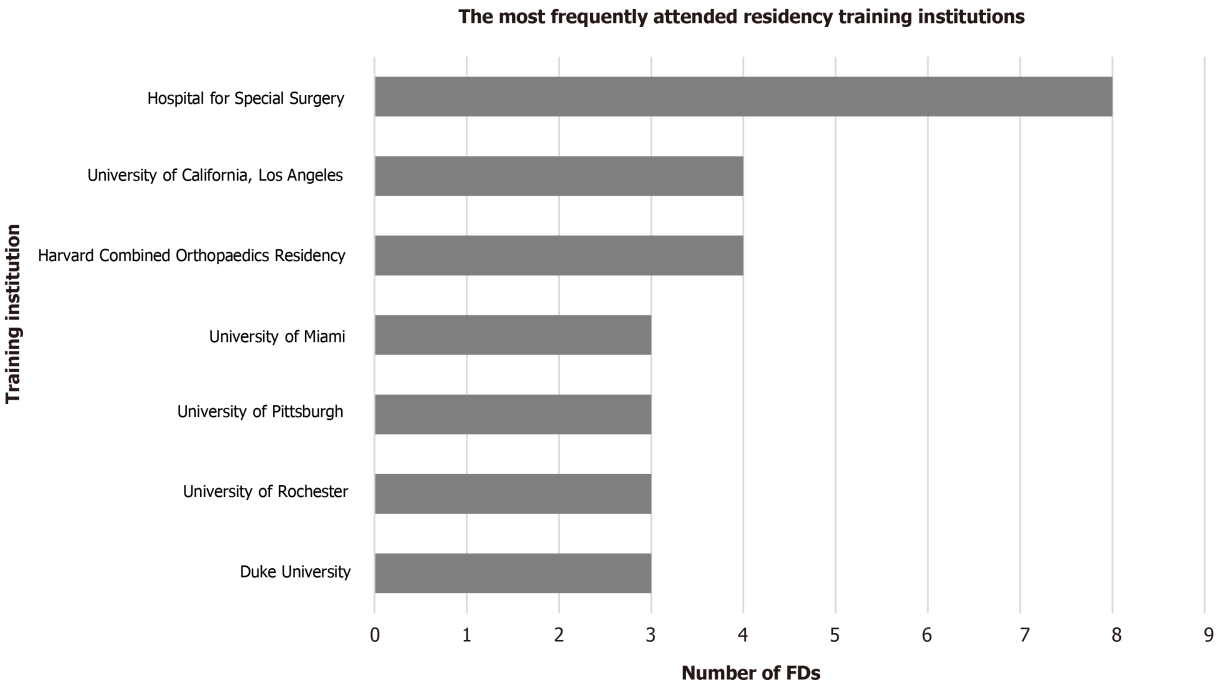


Figure 1 A summary of the most attended residency training programs among current sports medicine fellowship directors. Note: Residency programs at which at least 3 fellowship directors trained were included. FD: Fellowship director.

Figure 3 illustrates the distribution the Scopus H-indices for FDs in the form of ranges. In terms of Scopus H-indices, the ten most impactful sports medicine FDs in research had a Scopus H-index values between 43 and 79. (data retrieved December 1, 2019).

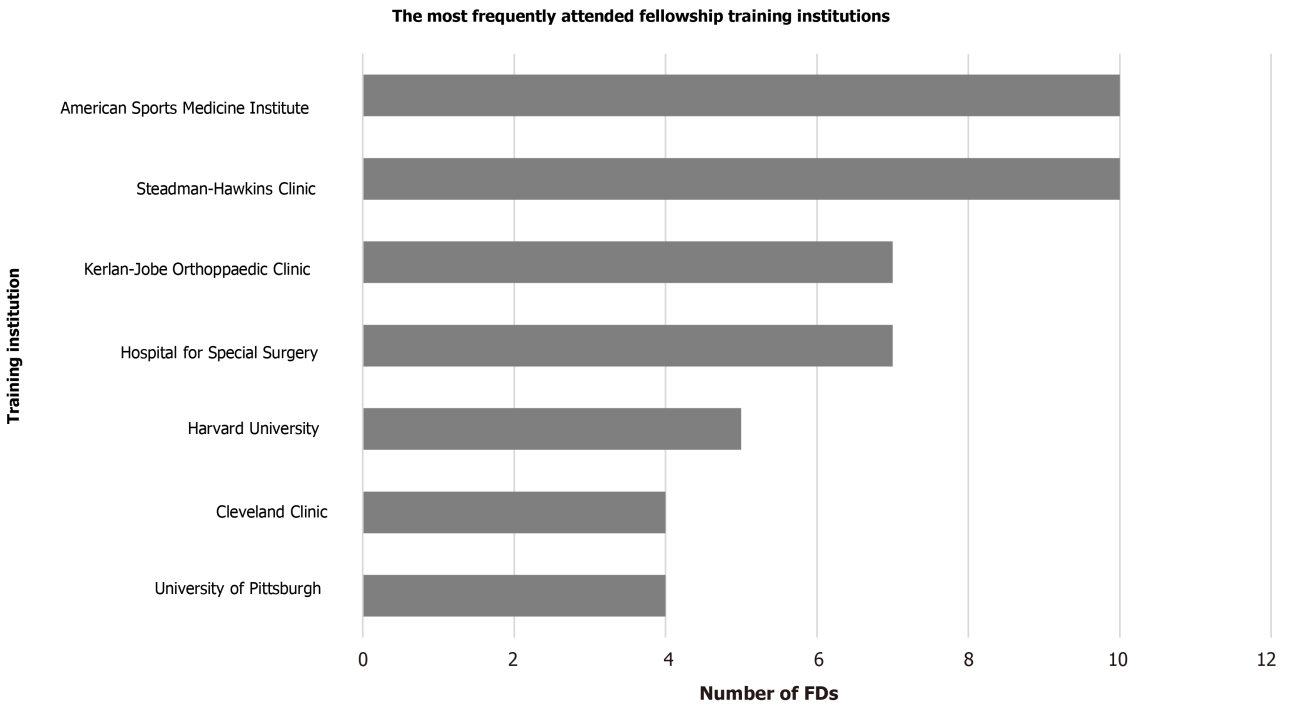


Figure 2 A summary of the most attended fellowship training programs among Current sports medicine fellowship directors. Note: Fellowship programs at which at least 4 fellowship directors trained were included. FD: Fellowship director.

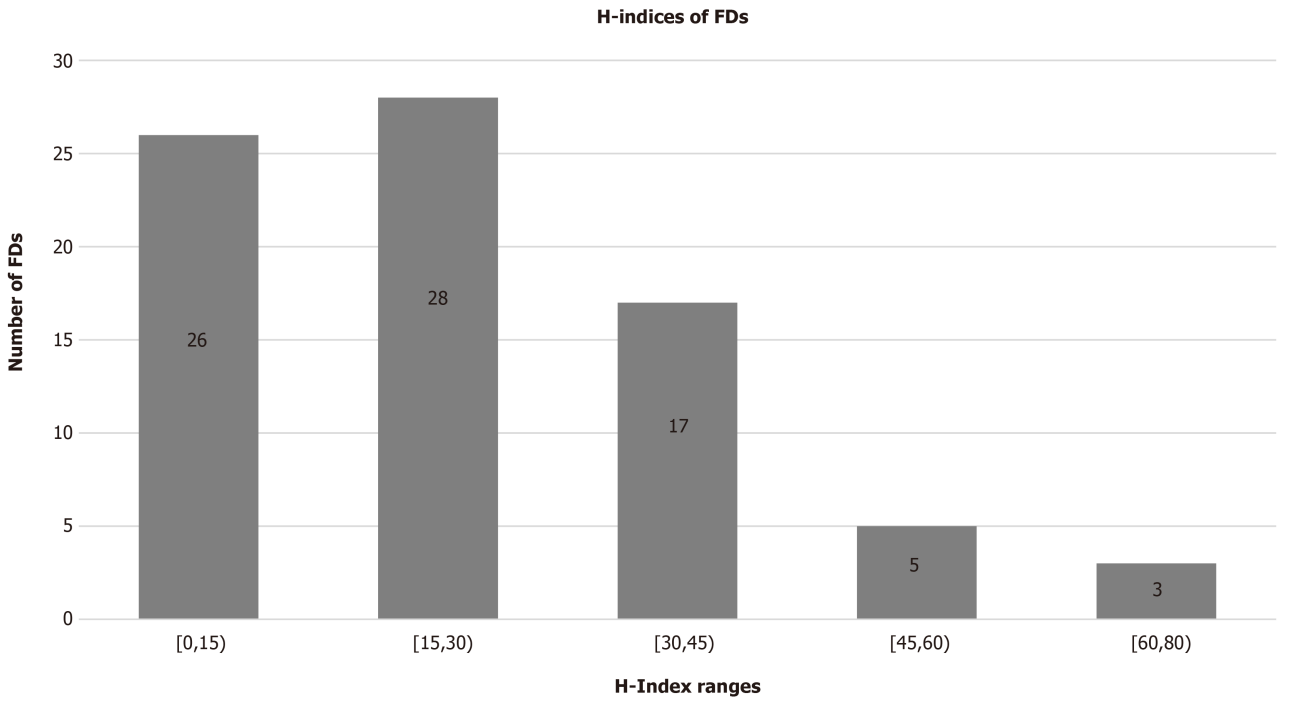


Figure 3 A representation of the Scopus H-indices of all sports medicine fellowship directors. Note: The Scopus H-index values are as of December 1, 2019. Interval notation is used. "[": Indicates that the range includes the adjacent numerical value; "(": Indicates that the range does not include the adjacent numerical value. FD: Fellowship director.

DISCUSSION

Currently, literature documenting the necessary training and skill development of physician leaders in other surgical specialties is limited[2-5]. One study in the field of general surgery, discussed the relationship between past residents' rank lists to future academic career path[6]. Plastic surgery is another subspecialized field that has also evaluated leadership roles and trends in characteristics[7,8]. Previous studies in

orthopaedics have considered the pertinent motivating factors impacting the applicant selection process of residency and FDs, as well as the selection process of medical students and residents when considering orthopaedic surgery as a specialty[9-15]. In discussions on appropriate or discrepant representation of gender and cultural diversity, the leadership within orthopaedics has come into focus[16-19]. Two other studies have described demographic characteristics for spine fellowship leaders and adult reconstruction FDs which similarly noted FDs are more likely to have graduated from certain residency and fellowship programs[7,20]. As in this sports medicine cohort, the spine and adult reconstruction cohorts might attract applicants with a predilection to later seek academic leadership roles post-training[7,19,20].

Academic careers within medicine are founded upon clinical service, teaching, and research. Involvement and, naturally, productivity in research is a significant metric among those who achieve academic leadership positions. One study, by Cvetanovich *et al*[21] concluded that a higher cumulative h index correlated with higher academic rank among AOSSM sports medicine fellowship faculty[21]. Our analysis reveals a mean Scopus H-index of 23.49 (± 16.57) for sports medicine FDs which is considered high. Paralleled to these findings in research productivity, our results indicated that clinical experience is a crucial factor to sports medicine leadership appointment as the mean duration from fellowship graduation to FD appointment was 9.77 years (± 7.33 years). This data is similar to the results in the other orthopaedics FD demographic studies. Spine FDs' mean duration from fellowship graduation to FD appointment was 8.59 years, while, adult reconstruction FD's had a mean duration 9.55 years[7,20]. The average age of sports medicine FDs was 56 years-old. Compared to an average age 52.85 years and 52.60 years for spine and adult reconstruction FDs, respectively[7,20].

Based on our data, a select group of residency and fellowship training programs have a predilection for producing future sports medicine FDs. The residency program most commonly attended by current sports medicine FDs produced 8 current directors, while six other residency programs produced between 3 and 4 current FDs each. Interestingly, 8 FDs (9.75%) graduated from two fellowships and 3 FDs (3.66%) graduated from three fellowships. Unusually, 3 FDs (3.66%) did not undergo any post-residency training most likely because they completed their training before the 1990s.

In our study, we noted that 91.5% (n = 76) of FDs were AOSSM members. While subspeciality society membership is not a requirement to be in an academic leadership role, the benefits of such societies can give orthopaedic surgeons more access to collaborative research, networking opportunities, team physician skills as well as committee leadership positions. These early leadership roles can develop the necessary skillset required to transition into a FD role later in one's career. AOSSM is a society with a mission to foster the development and growth of all those affiliated in the care of athletes, and through this affords an aspiring FD access to the annual meeting, scholarships, faculty resources, online education and recertification aid. These many facets of the society all likely contribute to the growth of these surgeons into academic leaders. Specifically, words from the presidential address at 43rd annual AOSSM meeting highlight these concepts well "AOSSM inspires all of us to participate in the organization, strive for excellence in the care of our patients, produce outstanding research, and share knowledge and educate ourselves."[22]

Among fellowship programs attended, two programs each produced 10 current sports medicine FDs, while the next five programs produced between 4 and 7 FDs each. Overall, the top seven fellowship programs produced 57.32% (n = 47) of all the current sports medicine FDs. Interestingly, there was significant overlap in the training sites for both the sports and spine leadership training and show some overlap between sports and adult reconstruction[7,20]. This may indicate that attending specific fellowship training programs may correlate with future academic leadership possibilities. These programs potentially offer specific training curricula that foster the development of vital skills that translate well into leadership roles, perhaps through mentor style training between residents of different training levels and attendings alike. It is also likely that these institutions provide increased access to scholarly activity and have more research staff. This is supported by a study that included all faculty at United States adult reconstruction fellowship programs that indicated that most of the literature in adult reconstruction is generated from a small subset of academic institutions[23]. Thus, orthopaedic surgeons in-training interested in pursuing academic leadership positions may be more incentivized to select programs that promote orthopaedic surgery research. Program reputation and professional networks might serve as additional factors that could potentially play a role in the association of these specific programs with current FDs. These are just some possible explanations for our findings, however this is likely multifactorial. Nonetheless, our analysis supports the correlation that attending and graduating from specific training

programs has a predilection to produce future program directors.

Of the major professional sports in America, sports FDs most commonly served as team physicians in baseball, then football, followed by hockey, basketball and soccer. It was also more likely that FDs also served as team physicians for university-wide athletics and provide care for all affiliated sports teams. This is likely due to the collaborative care philosophy amongst the various team physicians part of an academic institution or because part of being the FD for an academic institution includes the responsibilities of treating all types of athletes in all types of sports.

While literature exists regarding the legality, responsibilities, ethics and financial aspects of being a team physician, currently, there is no literature describing how an orthopaedic surgeon becomes a team physician and if leadership within the field tends to influence team physician status[24-28]. Our results showed that 69.51% (n = 57) of current sports medicine FDs also served as team physicians at the professional or collegiate level or both. It is possible that the percentage of FDs as team physicians is likely not the same as non-FD sports medicine surgeons. While having a leadership position, such as FD, potentially opens more opportunities for sports medicine physicians, it may also give them increased options to be involved as a team physician. This may be due to the similar leadership skills that are required as a FD and team physician. Alternatively, it may be that athletic teams, particularly at the more elite levels, desire to have surgeons with leadership roles caring for their organizations. Aspiring sports medicine physicians, therefore, may find that being a FD might possibly enhance their chances of becoming a team physician or vice versa. Therefore, a better understanding of these objective leadership qualities may enhance the likelihood of a sports medicine surgeon achieving either/both of those roles.

Our study indicates that there is a significant gender disparity in the FD role, as females were notably under-represented at only 2.5% (n = 2) of all the current sports medicine FDs. This is actually a better representation that what was observed among adult reconstruction FDs, where no females were in an FD position at the time of the study[20]. As the healthcare profession advances, there has been a focus on the importance of overall diversity. Specifically, gender diversity has been addressed in several healthcare specialties with a broad range of findings[17,29]. Currently, orthopaedic surgery has one of the poorest ratios of female to male residents as compared to other specialties in medicine[17,29]. Although the total amount of orthopaedic surgery female residents has increased over the past 10 years, the corresponding percentage change is not as significant as other historically male-dominated specialties[29]. Moreover, certain orthopaedic subspecialties, such as sports medicine, continue to have decreased female involvement[29]. This may represent the inappropriate but historically prevalent perspective of the physicality of orthopaedics and sports medicine specifically. In addition, because of historical restrictions on females in male locker rooms, particularly at the most elite levels, gender inequality has existed in the team physician role. Most recently, the current leadership of the American Academy of Orthopaedic Surgeons, and more specifically the AOSSM, have identified this issue and have focused on achieving gender equality. This is evidenced by the recent female presidents of both of these organizations, the establishment of Diversity Committees within each societies' infrastructure and the creation of educational programs in their regional, national and international meetings focused on diversity equality. In a study by Ence *et al*[30] it was specifically reported that a lower median H-index was observed when comparing female orthopaedic surgeons to their male colleagues[30]. And yet, most certainly some of the most impactful and important research is created by female investigators. This could be a critical issue as our study shows research productivity is a key feature to achieving leadership roles. Furthermore, the previous gender barriers in the team physician role are being removed as all types and levels of sports teams have enlisted females as team physicians [31]. As gender disparity continues to be addressed in medicine, and more specifically orthopaedics, this study could be used to support those initiatives that seek to enlist female members, to provide female access to both mentorship and research, and to encourage female participation in all leadership roles.

Our study also considered racial and ethnic diversity, demonstrating that sports medicine leadership at the FD level also lacks underrepresented minorities. Among the sports medicine FDs in the study, only 7.32% (n = 6) were Asian-Americans, 2.44% (n = 2) were Hispanic/Latino, 2.44% (n = 2) were African American and 3.66% (n = 3) were of another race or ethnicity. One study from 1999[32] and another from 2004[33], reviewed the disparities in underrepresented minorities within the field of orthopaedics, and may have played a part in progressive changes that followed. Okike *et al*[34] described that total minority representation in orthopaedic surgery averaged 20.2% from the years 2001 to 2008, this included 11.7% Asians or Asian-Americans,

4.0% African Americans, and 3.8% Hispanics. Upon reviewing their data, the authors believed that this was an improvement compared to years prior with regards to representation of minorities among orthopaedic residents[34]. Adelani *et al*[35] subsequently illustrated a regression in minority representation. The number of programs *per* year with more than one underrepresented minority resident fell from 61 programs in 2002 to 53 programs in 2016 and reached as low as 31 programs in 2010. Likewise, the number of programs *per* year without a single underrepresented minority resident rose from 40 programs in 2002 to 60 programs in 2016 and reached 76 programs in 2011. In the end, the study called for a more detailed evaluation of program-level diversity and its impact on the recruitment of underrepresented minorities to orthopaedic surgery[35]. Our data identified a similar trend to those previously reported. As the orthopaedic community continues to adapt, a focus on diversity will remain pivotal to the advancement of any healthcare system that desires to appropriately represent the population it serves. Focusing on increasing the number of underrepresented minorities in leadership positions may be one way to begin to address these disparities.

This study does have several limitations. One limitation was the use of CV for data collection. Given that CV's are usually self-reported, there is an inherent potential bias with the possibility of reporting errors including duplication of events, failure to list appropriate research or leadership activities, and outdated information. Furthermore, this cross-sectional study design only provides information on sports FDs at a single point in time. Future studies may opt to complete a year-by-year comparison to understand the changes in the leadership over time. Lastly, a subset of sports medicine trained orthopaedic surgeons may have selected specific programs with academic career aspirations in mind with the understanding that certain training institutions tend to produce future FDs and leaders.

CONCLUSION

This study provides an assessment of current FDs within sports medicine in the United States. Currently, the field of orthopaedics has lower percentages of females and minorities in leadership roles. Gender and racial diversity of these specialties should be a continued focus. Overall, the trends identified in this study serve as objective data on current FDs within sports medicine. These trends could function as a guide for individuals who strive to become academic leaders in sports medicine orthopaedics as well as direct initiatives to achieve diversity equality.

ARTICLE HIGHLIGHTS

Research background

Fellowship directors (FDs) in sports medicine influence the future of trainees in the field of orthopaedics. Understanding the characteristics these leaders share must be brought into focus. Currently, there is little research regarding the demographic landscape of these leaders.

Research motivation

The current literature highlighted a lack of research specifically using objective data analyze sports medicine FDs. By adding to this gap in the literature, this study may promote future research towards understanding further the requirements and qualifications needed to hold a leadership position in orthopedic surgery.

Research objectives

This study aimed to analyze the demographic background, institutional training, and academic experience for all current sports medicine FDs.

Research methods

A national orthopedic surgery sports medicine fellowship program directory was used to incorporate all United States fellowships and their respective FDs. Demographic information of interest included: Age, gender, ethnicity, residency/fellowship training, residency/fellowship graduation year, year hired by current institution, time since training completion until FD appointment, length in FD role, status as a team

physician and H-index. This information was collected *via* online resources, emailed questionnaires, phone call and current curriculum vitae. Data was then complied and reviewed to evaluate for trends among sports medicine FDs. This is a novel research method for analyzing the current cohort of sports medicine FDs.

Research results

Of 82 FDs were incorporated into the study, 97.5% of which were male. 84.15% identified as Caucasian, 7.32% as Asian-American, 2.44% as African American, and 2.44% as Hispanic, and 3.66% were of another race or ethnicity. The mean age of current FDs was 56 years old, and the mean Scopus H-index was 23.49. 45.12% completed their residency training, fellowship training or both at the same institution where they currently work. Additionally, 69.5% are also team physicians at the professional and/or collegiate level. Seven residency programs least three future FDs. While seven fellowship programs produced at least four future FDs. 9.75% of FDs completed two fellowships and 3.66% of FDs completed three fellowships. 3.66% of FDs did not graduate from any fellowship training program.

Research conclusions

This study provides an overview of current sports medicine FDs within the United States and functions as a guide to direct initiatives to achieve diversity equality. This study may be referenced to help dictate efforts to address disparities in gender and racial equality in orthopedic surgery.

Research perspectives

The direction of future research should focus on the progression of leaders in orthopedic surgery, evaluating the changes in demographic and academic backgrounds of leaders in subsequent years. Applying this methodology longitudinally may prove paramount in reaching the goals the field of orthopedic surgery aims to achieve.

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ORIGINAL ARTICLE

Prospective Study

Has platelet-rich plasma any role in partial tears of the anterior cruciate ligament? Prospective comparative study

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Abstract

BACKGROUND

Partial tears of the anterior cruciate ligament (ACL) are frequent, and there is still considerable controversy surrounding their diagnosis, natural history and treatment.

AIM

To examine patient-reported outcomes, physical examination and magnetic resonance imaging (MRI) findings of partial ACL tears treated with an intraarticular injection of platelet-rich plasma (PRP) compared to a control group.

METHODS

From January 2015 to November 2017, consecutive patients from a single institution with partial ACL tears treated nonoperatively were prospectively evaluated. Partial tears were defined as a positive Lachman test with a clear endpoint, a negative pivot-shift and less than 3 mm of side-to-side difference using the KT1000 arthrometer. Patients in group 1 were treated with one intraarticular injection of PRP and specific physical therapy protocol. Control group consisted of patients treated only with physical therapy. Prospective analyzed data included physical examination, Tegner activity level and Lysholm and International Knee Documentation Committee scores. Baseline MRI findings and at 6 mo follow-up were reviewed. Failure was defined as those patients with clinical instability at follow-up that required a subsequent ACL reconstruction.

RESULTS

A total of 40 patients where included, 21 treated with PRP injection with a mean follow-up of 25 mo [standard deviation (SD): 3.6] and 19 in the control group with a mean follow-up of 25 mo (SD: 5.68). Overall failure rate was 32.0% (n = 13). No significant differences were observed between groups regarding subjective outcomes, return to sport and failure rate. MRI findings revealed an improvement in the ACL signal in half of the patients of both groups. However, we did not find

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a significant relationship between MRI findings and clinical outcomes.

CONCLUSION

Overall, 95.0% of patients returned to sports at a mean follow-up of 25 mo. Mean time to return to sports was 4 mo. Out of these patients, almost 30.0% in each group had a new episode of instability and required surgery at a median time of 5 mo in group 1 and 8 mo in group 2. The addition of PRP alone was not sufficient to enhance any of the outcome measures evaluated, including MRI images, clinical evaluation and failure rate.

Key Words: Anterior cruciate ligament; Partial tears; Platelet-rich plasma; Non-operative treatment

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Core Tip: This was a prospective comparative study with 40 patients seeking to evaluate the effect of platelet-rich plasma on partial tears of the anterior cruciate ligament. Prospective analyzed data included physical examination, Tegner activity level and Lysholm and International Knee Documentation Committee scores. Baseline magnetic resonance imaging findings and at 6 mo follow-up were also reviewed.

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INTRODUCTION

Partial tears account for 10% to 30% of all anterior cruciate ligament (ACL) tears[1,2]. There is still considerable controversy surrounding the diagnosis, natural history and treatment of this type of lesion[3,4]. Diverse criteria are often used to define a partial ACL tear. Magnetic resonance imaging (MRI) features include the estimation of the percentage of torn fibers, specific affected bundle (anteromedial or posterolateral) and location of the tear (proximal, middle third or distal). The physical examination is decisive in this type of lesion[1]. Finally, arthroscopy remains the gold standard for the diagnosis of macroscopic integrity of the intact bundle. Intraoperative findings of intact remnant ACL fibers from femur to tibia insertion points confirm the diagnosis[5-7].

Regarding natural history, complete ACL tears have low intrinsic healing capacity, which prevent restoring anatomy and function. However, there has been some disagreement concerning whether partial ACL tears could heal. Though favorable results have been reported with either nonoperative or surgical treatment (such as repair or augmentation) as well as with biological approaches, some authors reported progression to complete deficiency of the ACL and symptomatic knee laxity with conservative treatment[4,7-10].

Platelet-rich plasma (PRP) has received much attention in the last years as a biologic alternative for the treatment of sports-related injuries. Various growth factors and bioactive proteins from the a-granules contained in platelets can potentially enhance tissue healing[11-14]. PRP utilization in ligament injuries has grown remarkably[15-17]. Regarding specifically to ACL injuries, the focus has been mostly on biologic augmentation to improve graft healing after a reconstruction, and only a few studies aimed to improve healing of the native injured ACL[18-22].

The purpose of this study was to examine patient-reported outcomes, physical examination and MRI findings of partial ACL tears treated with an intraarticular injection of PRP compared to a control group.

MATERIALS AND METHODS

Patient population

Following Institutional Review Board approval, all patients who were diagnosed with a partial ACL tear and treated nonoperatively between January 2015 and November 2017 were retrospectively selected from a database of prospectively collected data. Figure 1 shows the algorithm used for the diagnosis and treatment of partial ACL tears. It consists of an adaptation of a previously published algorithm by Sonnery-Cottet *et al*[1]. We included patients with a positive Lachman's test with a firm endpoint, negative pivot shift, a side-to-side differential laxity less than 3 mm measured by arthrometer (KT-1000 knee arthrometer, MEDmetric Corp.) and MRI signs of partial ACL tear. Patients with a differential laxity between 3 and 5 mm without meniscal lesions and/or participation in high-risk sports were also included.

The exclusion criteria were as follows: patients younger than 18-years-old, patients with less than 6 mo follow-up, patients diagnosed after 1 mo of injury, previous ipsilateral ACL tear or reconstruction, confirmed or suspected contralateral ACL injury, diagnosis of concomitant ipsilateral posterior cruciate ligament, posterolateral corner or grade 3 medial collateral ligament injury and arthritis (International Knee Documentation Committee C or higher).

Nonoperative treatment consisted of one intra-articular injection of leukocyte reduced PRP during the first 4 wk after injury (within the inflammatory phase) and specific physical therapy protocol (group 1). However, not all patients were able to receive the PRP injection, mostly because medical insurance coverage or refusal from the patient to do so. These patients were considered the control group (group 2).

Data collection and definitions

All medical care interventions are centrally registered in a computerized data repository, with only one electronic health record per person. After initial consultation and treatment, patients underwent clinical follow-up at 1, 3, 6 and 12 mo by the same observer. Variables analyzed included patient gender, age, Tegner activity Score both at time of injury and at time of final follow-up, return to sports (RTS) rate, time to RTS and subsequent surgeries. Subjective assessment included Lysholm and International Knee Documentation Committee scores.

Objective stability was tested at the time of injury and at 6 mo follow-up with a knee arthrometer test (KT-1000 knee arthrometer, MEDmetric Corp.), and the manual maximum difference between knees (in mm) was used for analysis of reported mean side-to-side differences. All patients were evaluated by a single orthopedic observer (JPZ-staff member/knee surgeon).

Baseline MRI findings and at 6 mo follow-up were reviewed. Images were analyzed according to a classification published by van Meer *et al*[23]. Nine features are used to assess the ACL on MRI: fiber continuity, signal intensity, slope of ACL with respect to the Blumensaat line, distance between the Blumensaat line and ACL, tension, thickness, clear boundaries, assessment of original insertions and assessment of intercondylar notch. A total score is determined by summing scores for these 9 features. A score of 10 is maximally abnormal for all features, whereas a score of 0 is normal for all features. Lesion localization was also determined (proximal, middle third and distal). All images were evaluated by a single orthopedic observer (JPZ) who was blinded to the treatment group.

Failure was defined as those patients with clinical instability at follow-up that required a subsequent ACL reconstruction.

PRP preparation

On the basis of previously published reports on criteria that influence the composition or biological effect of PRP[24], we included the following information regarding PRP preparation. After harvesting 150 mL of blood, the extracted unit was doubled centrifuged in a Thermo Scientific Sorvall BP-16 Refrigerated Blood Bank Centrifuge. First, a light centrifugation for 4 min at 1400 rpm to separate the PRP from the globular mass was performed. The product obtained was separated into satellite bags without opening the circuit, guaranteeing the sterility of the process. Next, the PRP was centrifuged for 6 min at 3000 rpm to achieve a higher concentration of the product. At the end of the process, quality control was carried out on the product through an XT ROCHE hematological counter. It consists of volume, platelet count, white blood cell count and calculation of product concentration.

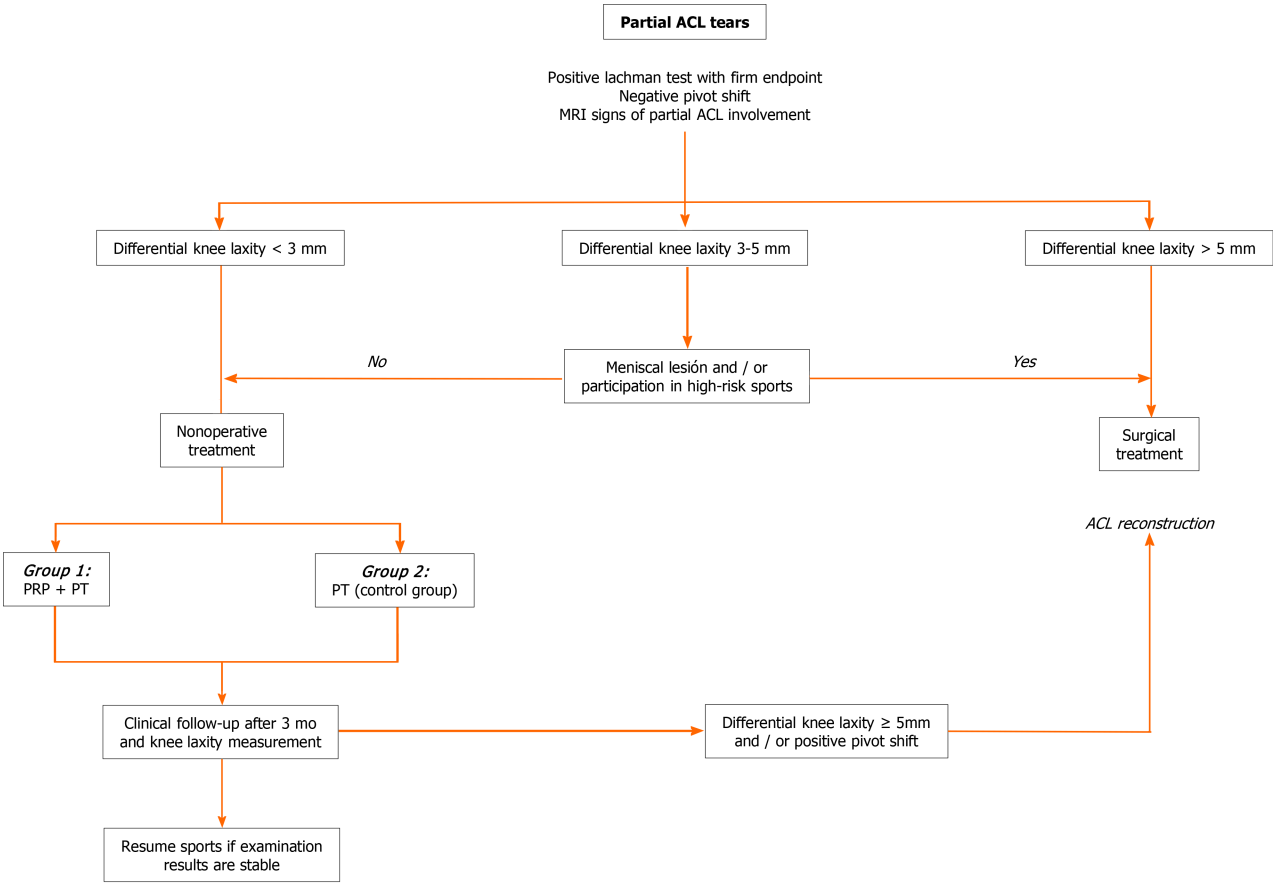


Figure 1 Flow chart for partial anterior cruciate ligament tears. Management algorithm used to select treatment for partial anterior cruciate ligament tears. ACL: Anterior cruciate ligament; MRI: Magnetic resonance imaging; PRP: Platelet-rich plasma; PT: Physical therapy.

Injection protocol

Group 1 (PRP group) received a single intra-articular injection of PRP. A median of 8 mL (6-10) was injected. All injections were performed by one of the authors (Zicaro JP). Intra-articular injection aiming at the ACL was performed as a standard sterile procedure. A 25-gauge 3.0-inch needle was inserted through the skin in a similar localization as a medial portal, towards the ACL femoral insertion. No imaging was used as guidance. The median concentrations of platelets and white cells of the product are detailed in Table 1. After the procedure, full weight bearing, cryotherapy and daily life activities was allowed as tolerated. No post treatment bracing was administered. Physical therapy protocol began after 72 h of the injection.

Physical therapy protocol

Even though not all patients performed the rehabilitation at the same center, both groups received the same rehabilitation protocol. The goals of the first 4 wk were to recover range of motion, prevent quadriceps inhibition and normalize proximal muscle strength. Nonimpact exercises such as bicycle or swimming were allowed during the first week. Linear impact and strengthening exercises began 6 wk after injection, with progression to multiplanar exercises between 8 to 10 wk. The goal was to return to their previous sport not before 3 to 4 mo after injection.

Statistical analyses

Descriptive statistics including means, standard deviations (SDs), medians and quartile ranges were applied as appropriate to assess the available demographic, surgical, physical examination and patient-reported outcome data. Statistical hypothesis testing was performed using the Fisher exact test and Wilcoxon rank-sum test. Categorical data was performed using Chi square test. Analysis was performed with 95% confidence interval, and P values < 0.05 were considered statistically significant. All statistical analyses were performed using STATA version 13.

Table 1 Details of the baseline and platelet rich plasma platelets and white cells concentrations

	Initial platelet concentration	PRP	%
Platelets, median (IQR)	264500 (247000-278000)	1125500 (1088000-1340500)	444 (407-519)
WC, median (IQR)	5200 (4790-6480)	600 (220-810)	10 (3-15)

IQR: Interquartile range; PRP: Platelet rich plasma; WC: White cells.

RESULTS

A total of 40 patients where included. In total, 21 treated with PRP injection (group 1) with a mean follow-up of 25 mo (SD: 3.60) and 19 in the control group (group 2) with a mean follow-up of 25 mo (SD: 5.68). The overall median age was 26.0-years-old (IQR 22.5-35.0). Demographic data is shown in Table 2. The only statistically significant difference between groups was gender; no females were included in the control group ($P = 0.021$).

Results at final follow-up are shown in Table 3. One patient in each group (5.0%) was unable to RTS due to subjective instability. The other 95.0% in each group were able to return to their previous sports level. Overall mean RTS time was 4 mo (SD: 1.06), without significant differences between groups. We found no significant differences for subjective outcomes between groups.

Regarding objective stability, at 6 mo follow-up in group 1, 13 presented a decrease in the side-to-side difference, 7 remained with the same difference, and 1 had 2 mm more. In group 2, 9 had a decrease in the side-to-side difference, 9 remained with the same difference, and 1 had 1 mm more. None of the patients had a positive pivot shift at final follow-up.

According to van Meer *et al*[23], MRI classification for partial ACL tears at baseline for most patients were classified between 4 and 10 in both groups (Table 4). At 6 mo follow-up, more than 50.0% of patients in both groups where classified as 0 and 3, showing an improvement in the ACL MRI signal (Figure 2).

Overall failure rate was 32.0% ($n = 13$) with no significant differences between groups (Table 3). Five failures in group 1 where Tegner 7, one Tegner 8 and one Tegner 5. In group 2, four failures where Tegner 7 and two Tegner 6. We found no significant differences when analyzing the location of the lesion and failure in both groups. Two proximal (2/10) and five mid-substance (5/11) tears failed in group 1 ($P = 0.21$). Four proximal (4/12) and two mid-substance (2/7) tears failed in group 2 ($P = 0.83$).

DISCUSSION

The present study evaluated the results of a series of patients with partial ACL tears treated nonoperatively. No significant differences were identified between patients treated or not with a single intraarticular injection of PRP. Overall, 32.0% failures were observed in both groups at a mean follow-up of 25 mo. The remaining 67.0% of patients were able to RTS in a mean of 4 mo.

A key factor in the treatment of partial ACL tears is a correct diagnosis. There has been some disagreement with regard to the definition of this lesion, and most of them are underdiagnosed. Some authors agree that physical examination cannot differentiate a partial ACL tear from an intact ACL[25,26]. On the other hand, MRI has a low level of accuracy for the diagnosis of partial ACL tears (25.0%-50.0%), mainly because of the significant overlap of the imaging findings between partial and complete tears, mucoid degeneration of the ACL and the initial post-traumatic hematoma[27]. Therefore, many surgeons rely on arthroscopy to define the extent of injury. A recently published study analyzed the correlation between preoperative clinical assessment and the arthroscopic examination in patients with ACL tears[26]. While evaluation under anesthesia demonstrated a high sensitivity for the detection of partial tears (100%), it was not necessarily specific (65.5%) and resulted in a high number of false positive partial tears. MRI, on the other hand, demonstrated a relatively high sensitivity (90.9%) and specificity (85.7%). The accuracy of MRI (86.3%) was also greater than that of evaluation under anesthesia (69.5%). These results suggested that MRI is 1.24 times more likely to result in correctly diagnosing a partial tear, which was a statistically significant finding.

Table 2 Demographic data

	Group 1, *n* = 21	Group 2, *n* = 19	*P* value
Age in yr, median (IQR)	25 (22-39)	31 (26-34)	0.54
Male, *n* (%)	15 (71.4)	19 (100)	0.02
FU in mo, median (IQR)	25 (18-36)	25 (18-30)	0.86
MRI tear location:			
Proximal, *n* (%)	10 (48)	12 (63)	
Mid-substance, *n* (%)	11 (52)	7 (27)	

FU: Follow-up; IQR: Inter quartile range; MRI: Magnetic resonance imaging; TAL: Tegner activity level.

Table 3 Results at final follow-up

Baseline	Group 1, *n* = 21	Group 2, *n* = 19	*P* value
Lysholm score, median (IQR)	69.5 (43.0-85.0)	54.0 (41.0-77.0)	0.41
IKDC score, median (IQR)	58.5 (44.0-60.0)	58.0 (44.0-60.0)	0.84
TAL, mean ± SD	6.90 ± 1.07	6.70 ± 1.18	0.65
At final follow-up			
Lysholm score, median (IQR)	80 (75-90)	80 (73-86)	0.53
IKDC score, median (IQR)	77 (71-89)	71 (70-79)	0.33
TAL, mean ± SD	6.70 ± 1.52	6.50 ± 1.61	0.7
RTS rate, *n* (%)	20 (95)	18 (95)	0.9
Time to RTS in mo, mean ± SD	3.8 ± 0.8	4.3 ± 1.2	0.09
Failure rate, *n* (%)	7 (33)	6 (31)	0.9

IKDC: International Knee Documentation Committee; IQR: inter quartile range; RTS: return to sports; SD: Standard deviation; TAL: Tegner activity level.

Table 4 Magnetic resonance image Van Meer classification at baseline and at 6 mo

	MRI Van Meer classification		
	Group 1	Group 2	*P* value
Baseline MRI, mean ± SD	6.1 ± 1.7	6.2 ± 2.4	0.97
MRI at 6 mo follow-up, mean ± SD	3.4 ± 2.9	3.6 ± 2.5	0.82

MRI: Magnetic resonance image; SD: Standard deviation.

Regarding nonsurgical management of partial ACL tears, Pujol *et al*[8] performed a systematic review and analyzed 12 articles where diagnosis was confirmed on arthroscopy, without ACL surgery. A total of 436 patients were followed up over the period 1976-1997 with a mean follow-up of 5.2 years (range 1.0-15.0). They found good short- and mid-term functional results, especially when patients limited their sports activities. The mean rate of revision ACL was 8.1% (0%-21.0%). RTS rate was 52.0% (21.0%-60.0%), lower than our findings, with 95.0% of patients returning to the same level. Noyes *et al*[7] reported a 38.0% progression to a complete rupture in a prospective evaluation of 32 patients with a partial ACL tear. Lehnert *et al*[28] reviewed a series of 39 partial ACL tears 5 years after injury and found that 56.0% had progressed to ACL deficiency. Finally, Fritschy *et al*[9] reported a rate of 42.0% in 43 patients. and Fruensgaard *et al*[29] reported 51.0% in a series of 41 patients. Although these results may be comparable to our overall 32.0% failure, these findings are to be viewed in the light of the indications for ACL surgery in vogue 30 years ago. It is

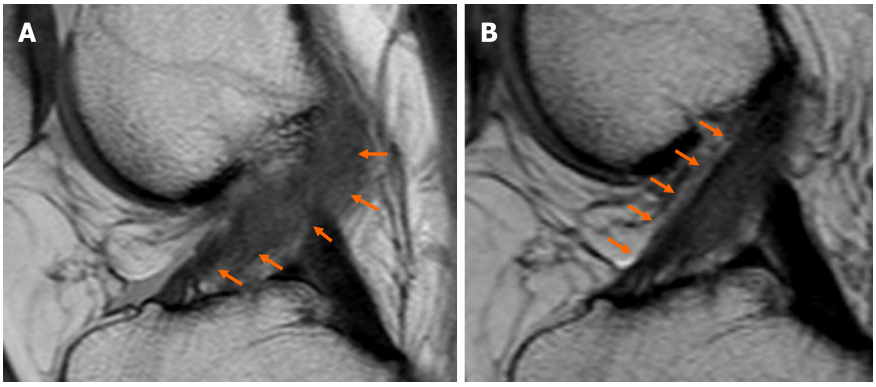


Figure 2 Magnetic resonance images. A: Baseline magnetic resonance imaging (MRI) showed widening of anterior cruciate ligament (ACL) fibers with continuity of fibers (orange arrows). Total score of 4 points according to Van Meer's classification; B: Six months after platelet-rich plasma injection, MRI showed an improvement in the signal intensity as well as tension of ACL fibers (orange arrows). Total score of 0 points according to Van Meer's classification (MRI sequence: sagittal proton density weighted turbo spin echo).

important to highlight that in some cases, side-to-side difference in KT-1000 arthrometric evaluation was greater, probably due to a lack of healing of ACL fibers, particularly cases when the anteromedial bundle was affected. Nevertheless, most of these patients were active in their sports practice.

The use of biologic agents, including growth factors, PRP, stem cells and biological scaffolds, has been the focus of current research in ACL repair and healing[3]. In a systematic review analyzing biologic agents for ACL healing, the large majority of articles (21 out of 23) were focused on their application during ACL reconstructive surgery, whereas only two trials, both case series, investigated their potential in partial ACL tears[19]. Centeno *et al*[30] published a prospective case series of 10 patients treated with percutaneous injection of autologous bone narrow nucleated cells, using fluoroscopic guidance. Patients were included if they had a grade 1, 2 or 3 ACL tear without greater than 1 cm retraction. Treatment protocol consisted of a preinjection of a hypertonic dextrose solution into the ACL followed by a reinjection of 2-3 mL of bone marrow cells, PRP and platelets 2-5 d after, using the same procedure. Seven of ten patients demonstrated improvement in MRI measures of ACL integrity at a mean follow-up of 3 mo. The lack of a control group and the multiple component of the protocol are the main shortcomings of their methods. On the other hand, Seijas *et al*[20] published a retrospective case series of 19 football players (Tegner 9-10) with a partial ACL tear treated with an arthroscopic intraligamentary application of PRP (leukocyte poor). All cases presented a complete rupture of the anteromedial bundle with an intact posterolateral bundle. RTS rate was 84%. Average RTS in 15 patients Tegner 9 was 16 wk and in 2 patients Tegner 10 was 12 wk. In our study, mean time to return to sport was 4 mo.

Regarding the use of MRI in partial ACL tears, we consider there is an important role in the diagnosis and follow-up. However, these results must not be considered in isolation. Although we thoroughly analyzed nine different imaging parameters, no significant correlation was found between laxity and MRI images. Neither association was identified between lesion localization and treatment failure. These findings might be due to the low number of patients.

The lack of standardization of PRP protocols has been published recently[24]. Chahla *et al*[24] analyzed 105 studies finding high inconsistences in the way PRP preparation was reported. The majority of studies did not provide sufficient information to allow the protocol to be reproduced, which also prevents comparison of the PRP products. Based on this review and following the proposed guidelines, we included in our study data regarding PRP preparation and composition of the PRP delivered.

It is plausible that a number of limitations may have influenced the results obtained. First, the sample size might be considered to be low. However, a sample size estimation was not possible due to the lack of studies published with the same treatment. Although a control group was established, this group was not randomized, which may raise the possibility of a selection bias. Another possible source of error related to the procedure. The injections were not guided by imaging, and patients underwent only one injection. Nevertheless, there is no standardization in terms of how much and how many PRP injections are required for better results.

CONCLUSION

Our research provided further evidence about natural history of nonoperative management of partial ACL tears. Overall, 67% of patients with this type of lesion RTS in a mean of 4 mo without clinical instability either with or without an intra-articular PRP injection. The addition of PRP alone was not sufficient to enhance any of the outcome measures evaluated, including MRI images and clinical evaluation.

ARTICLE HIGHLIGHTS

Research background

Platelet-rich plasma (PRP) is being widely used in many orthopedic areas. The use of PRP has for "healing" purposes is still controversial in the field of partial ligamentous lesions.

Research motivation

To our knowledge, there are no comparative series reported in the literature regarding the use of PRP for partial anterior cruciate ligament (ACL) tears.

Research objectives

The aim was to prospectively compare the patient-reported outcomes, rerupture rate and magnetic resonance (MR) findings in patients with partial ACL tears treated with a single PRP intra-articular injection compared to a control group.

Research methods

Patients who met the inclusion criteria for stable partial ACL tears were divided into two groups. One group received a single intra-articular leukocyte-poor PRP injection within the first 4 wk after the lesion. Both groups received the same rehabilitation protocol. Clinical objective outcomes (KT1000 arthrometric evaluation), subjective outcomes, time to return to sports, rerupture rate and MR findings were evaluated. PRP preparation data was detailed.

Research results

Forty patients where included, 21 treated with PRP injection (group 1) (mean follow-up of 25 mo) and 19 in the control group (group 2) (mean follow-up of 25 mo). Overall, 95% of patients in each group returned to their previous sport at a mean time of 4 mo. After 6 mo follow-up, more than 50% of patients improved the ACL signal intensity in the MR. Overall failure rate was 32% (n = 13) with no significant differences between groups.

Research conclusions

A single PRP intra-articular injection was not sufficient to enhance any of the outcome measures evaluated, including MR images and clinical evaluation. Overall, 67% of patients returned to sports in a mean of 4 mo without clinical instability either with or without an intra-articular PRP injection.

Research perspectives

Further rigorous and objective studies including more patients and different PRP preparations, such as less platelet concentrations or leukocyte-rich preparations, would be useful to determine the true efficacy of PRP for enhancing healing properties of partial ACL lesions.

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SYSTEMATIC REVIEWS

Arthroereisis in juvenile flexible flatfoot: Which device should we implant? A systematic review of literature published in the last 5 years

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Abstract

BACKGROUND

Flexible flatfoot (FFF) is a very common condition in children, characterized by the loss of the medial arch and by an increase in the support base with valgus of the hindfoot. Arthroereisis (AR) procedures are widely performed corrective surgeries and are classified as subtalar AR and calcaneo-stop (CS).

AIM

We investigated the literature published in the last 5 years with the aim of providing an update on the evidence related to AR treatment in FFF patients. We report the principal findings of subtalar AR and CS procedures concerning clinical and radiological outcomes and complication rates in the general population, young athletes, and obese people according to material device.

METHODS

Following the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses, a systematic review of studies published in the past 5 years and included the PubMed and Science Direct databases was performed on May 6, 2020. The research string used was (pediatric OR children OR Juvenile NOT adult) AND (flexible NOT rigid) AND (flat foot OR pes planus) AND (calcaneo-Stop OR arthroereisis OR subtalar extra-articular screw OR SESA OR subtalar arthroereisis OR endosinotarsal). The risk of bias assessment was performed using the Dutch checklist form for prognosis.

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RESULTS

A total of 47 articles were found. Ultimately, after reading the full text and checking reference lists, we selected 17 articles that met the inclusion and exclusion criteria. A total of 1864 FFFs were identified. Eight studies concerned the subtalar AR (47.1%) and nine concerning CS (52.9%). The average age of patients at start of treatment was 11.8 years, the average follow-up of the studies was 71.9 mo (range 29.1-130). Globally, complications occurred in 153 of the 1864 FFF treated, with a rate of 8.2%.

CONCLUSION

Both AR procedures are valid surgical techniques for treating FFF. Surgeon experience, implant cost, and cosmetic correction are the most common considerations included in the orthopedic device decision-making process. In obese patients, the subtalar AR is not recommended. In adolescents who need to improve sports performance, the CS screw had better results compared with other implants.

Key Words: Pes planus; Arthroereisis; Treatment; Calcaneo-stop; Subtalar arthroereisis; Complication

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Core Tip: Arthroereisis (AR) procedures are widely performed corrective surgeries for juvenile flexible flatfoot. The AR procedures include impact blocking devices and self-locking implants. Impact blocking devices include subtalar extra-articular calcaneo-stop (CS) screws that have a stem and a head and interfere with the talus. Self-locking implants (subtalar AR) are inserted in the sinus tarsi along its main axis. Surgeon experience, implant cost, and, cosmetic correction are the most common criteria included in the orthopedic decision-making process. Both AR procedures improved clinical and radiological parameters. Considering the complications, calcaneo-stop screws had a slightly better rate than subtalar AR.

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INTRODUCTION

Flexible flatfoot (FFF) is a very common condition in children[1] characterized by loss of the medial arch and increases of both heel valgus and plantar pressure[1]. FFF is typically an asymptomatic condition, but pain may occur in the lower leg or medial level of the foot at the insertion point of the posterior tibial on the scaphoid, especially after intense exercise or long walks[2]. In some cases, early and easy fatigue can occur and are consider important symptoms[3]. Surgical treatment is indicated in symptomatic children over 8 years of age or not responsive to conservative treatment. Arthroereisis (AR) procedures are common corrective surgeries that are widely performed. AR was first introduced in 1946 by Chambers[4], who described the "abduction block," as a wedge-shaped bone block aimed to impact the anterior border of the posterior facet of the calcaneus and to limit excessive anterior displacement of the talus on the calcaneus and correct the deformity.

The first author to introduce the term "arthroereisis" was Lelièvre[5] in the early 70s to illustrate a temporary staple across the subtalar joint. In 1979, the Buruturan[6] impact blocking screw, which was inserted into the calcaneus using the sinus tarsi as the entry point, is the first description of a calcaneo-stop (CS) procedure. In 1992, Viladot[7] reported the success rate achieved by the first non-osseous sinus tarsi implant. The aim of implants is to correct the FFF deformity with preservation of foot function and limitation of excessive anterior displacement of the talus upon the

calcaneus[8]. Moreover, some authors[9,10] have hypothesized that CS could play a role in the activation of mechanoreceptors in the sinus tarsi, although it has not yet been supported by experimental evidence. Subtalar implants are classified by type as impact blocking devices, which include subtalar AR; and self-locking implants, which include CS screws[11]. Impact blocking devices have a stem that is fixed in the sinus tarsi vertically just anteriorly to the posterior subtalar surface and a head, that interferes with the talar lateral process, limiting its internal rotation. Self-locking implants are inserted in the sinus tarsi along its main axis, supporting the talar neck, avoiding contact between talar lateral process and sinus tarsi floor, and reducing talar adduction and plantar flexion.

The aim of the study was to review the literature of the last 5 years regarding the surgical treatment of juvenile FFF with a focus on the AR procedures and to report the principal subtalar AR and CS procedure findings concerning clinical and radiological outcomes and complication rate in general population, young athletes and obese population according to the device.

MATERIALS AND METHODS

Study design

A systematic review of studies published in the last 5 years. Clinical outcomes and radiological measurements, Athletes and Obese cohorts' outcomes, Complications, Materials of subtalar AR and CS were recorded.

Search strategy

A systematic review of studies published in the last 5 years and indexed in PubMed and Science Direct was performed by an author (Vescio A) on May 6, 2020. The research string used was "(pediatric OR children OR Juvenile NOT adult) AND (flexible NOT rigid) AND (flat foot OR pes planus) AND (calcaneo-stop OR arthroereisis OR SESA OR subtalar arthroereisis OR s OR subtalar extra-articular screw)".

Study selection and inclusion criteria

Eligible studies for this systematic review included FFF treatment and AR. The titles and abstracts were screened, using the following inclusion criteria: treatment consisted of AR with or without additional soft tissue procedures, operative treatment, or cast application, and a minimum average follow-up of 6 mo in patients between 7 and 17 years of age. Studies of patients with secondary, including syndromic and neurological FFF, nonoperative treatment or lateral column lengthening (LCL), or medializing calcaneal osteotomy duplicate publications, articles dealing with other topics, those with poor scientific methodology or without an accessible abstract were excluded. Reference lists were also hand-searched for further relevant studies. Systematic reviews, Meta-analyses, abstracts, case reports, conference presentations, editorials, and expert opinions were excluded.

Data extraction and quality assessment

Two subtalar implant types were considered, impact blocking devices and self-locking implants[13]. The risk of bias assessment was performed independently by two authors (Vescio A and Amico M) using the Dutch checklist form for prognosis recommended by the Cochrane Collaboration[13]. Conflicts about data were resolved by consultation with a senior surgeon (Pavone V). Table 1 presents a risk of bias summary including checklist items with low risk (+), high risk (-), or unclear risk (?). The forms were compared and discussed for final consensus (Table 2).

Evidence synthesis

For each included article, a standard data entry form was used to extract the number of patients, number of feet treated, affected side, sex, patient age when treated, type of procedure with or without additional surgeries, number of successes and failures, period of the study, and implant materials. We considered improvement of the medial arch, hindfoot valgus, radiological evaluation, pedobarographic measurements, and functional outcome as indicators of treatment success. The assessment included: (1) The American Orthopedic Foot and Ankle Society (AOFAS) Ankle–Hindfoot score; (2) The Oxford Ankle Foot Questionnaire for Children; (3) The Foot and Ankle Disability Index (FADI); (4) FADI Sport scores; (5) The Foot Function Index Questionnaire; (6) The self-reported Foot and Ankle Score; and (7) Visual Analogue Score. Major and

Table 1 Study results

Ref.	Patients (mean age)	AR type	Assessment	Results	Complications	Limits
Ruiz-Picazo *et al*[8], 2019	16 (32 FFF), 9 yr (range: 7-11 yr).	Subtalar device. Titanium self-locking device.	OxAFQ-C pre- and postoperatively.	Postoperative results were positive, with statistical significance for the "school and play", "emotional", and "footwear" domains of the OxAFQ-C scale ($P < 0.05$) and no differences in the "physical" domain.	4 (25%). 2 extrusion of the implant and 2 overcorrections.	Retrospective nature, no control group, sample size. lack of objectively measurable parameters.
Pavone *et al* [16], 2019	105 (174 FFF) (12.6 ± 1.3 yr), mean follow-up 67.5 ± 16.4 mo.	Calcaneo-stop.	BMI-for-age AOFAS, FADI, FADI Sport, and SF-36 at 1 and 3 yr. Variation of the angles measured on X-ray images.	AOFAS, FADI, FADI Sport, and SF-36 scores and radiological assessments improved significantly postoperatively ($P = 0.001$) and remained stable over time (1 yr: $P < 0.001$; 5 yr: $P < 0.001$) in all groups of patients. An increased persistence of pain and/or discomfort in obese patients than in normal weight patients ($P = 0.02$).	20 (11.5%) patients. 1 screw loosening (0.6%); 14 transient pain and discomfort at the level of the surgical incision (8%), 2 contractures of the lateral peroneal muscles (1.15%); 3 superficial infections (1.7%).	Retrospective nature, no control group, sample size. lack of objectively measurable parameters.
Pavone *et al* [1], 2018	68 (136 FFF) 12.7 yr (9-15 yr), mean follow-up 57.6 mo.	Calcaneo-stop.	AOFAS, Yoo Score, FADI, FADI Sport, OxAFQ-C scores at 1 and 3 yr. variation of the angles measured on X-ray images.	AOFAS (F 2, 201 = 287.51; $P < 0.0001$), Yoo Score (F 2, 201= 2627.00; $P < 0.0001$), OxAFQ-C (F2201 = 210.60; $P < 0.0001$), FADI (F 2, 201 = 372.62; $P < 0.0001$) and FADI Sport (F 2, 201= 189.32; $P < 0.0001$). Radiological assessments improved ($P < 0.0001$).	17 (12.5%); 5 pain at surgical scar (3.7%), 4 local symptoms at the incision (2.9%), 3 screw loosening (1.2%) and 4 superficial Infections (2.9%); 1 screw breakage (0.73).	Retrospective study. No control group. Mid-term follow-up. Lack of objectively measurable parameters.
Memeo *et al* [26], 2019	202 FFF, 13.6 yr (8-16 yr). Median follow-up was 130 mo (35-150 mo).	Calcaneo-stop.	Clinical evaluation, pain, and variation of the angles measured on X-ray images.	92% Percutaneous lengthening of the Achilles tendon. Improvement of clinical outcome, restoration of the medial arch and the hind foot valgus in orthostasis.	32 (15.8%): 23 (11.4%) incomplete correction; 9 (4.5%) screw breakages.	Retrospective study. No control group. Short-term follow-up. Lack of objectively measurable parameters.
Memeo *et al* [26], 2019	200 FFF, 12.8 yr (8 to 16 yr). Median follow-up 130 mo (35-150 mo).	Subtalar AR bioabsorbable device.	Clinical evaluation, pain, and variation of the angles measured on X-ray images.	71% Percutaneous lengthening of the Achilles tendon. Improvement of clinical outcome, restoration of the medial arch and the hind foot valgus in orthostasis.	25 (12.5%): 20 (10%) inflammatory process involving soft tissues around tarsal sinus; 5 (2.5%) device. removals and substitutes.	Retrospective study. No control group. Mid-term follow-up. Lack of objectively measurable parameters.
Megremis *et al*[18], 2019	14 (28 FFF), 10.71 ± 1.58 yr (range 8-14 yr). Mean follow-up duration of 35.14 ± 9.82 mo (19-60 mo).	Subtalar AR.	AOFAS pre- and postoperatively.	The mean postoperative AOFAS score was 88.851 (range 83-97) points ($P < 0.0001$).	No complication.	Retrospective study. No control group. Short-term follow-up. Lack of objectively measurable parameters.
Martinelli *et al*[14], 2018	49 (98 FFF) 10.7 yr (7-14 yr), mean follow-up 4.9 yr.	Subtalar AR.	CHQCF; OxAFQ pre- and postoperatively. Number of sessions per week.	The mean OxAFQ scores within the 'Emotional' ($P < 0.05$) and 'footwear' item ($P < 0.05$) (children), and in the 'school and play' ($P < 0.05$) and 'footwear' item for the parent scale. 44 (89%) parents were satisfied with the surgical procedure.	Three residual pain; 1 residual deformity, and one sport limitation. 3 subtalar implants removed because of pain at the sinus tarsi.	Retrospective nature; as some of the anthropological measures were not obtained before surgery.
Kubo *et al* [20], 2020	Group A (5-8 yr): 6 (11 FFF) MA 7.4 ± 1.2 yr; Group B (9-12 yr): 33 (63 FFF) MA: 11.2 ± 1.0 yr; Group C (13-15 yr): 11 (21 FFF). MA 13.6 ± 0.7 yr.	Calcaneo-stop.	CP; lat. TCA; a.p. TCA, kite angle; NCI; Meary angle. Bony maturation.	Improvement of radiological assessment in each group ($P < 0.05$). Best deformity correction when surgery was conducted between 9 and 12 yr, with significant improvement in all measured parameters without secondary deterioration during FU.	No complications.	Retrospective study; no clinical scores.

Indino *et al* [28], 2020	56 (112 FFF), 9-14 yr (MA 15.5 ± 1.2 yr), mean follow-up 40.1 ± 23.6 mo.	Subtalar AR.	AOFAS, SEFAS, SF-12.	AOFAS 97.3 ± 4.5, SEFAS 47.2 ± 1.5, SF-12.MCS 51.1 ± 8.8, SF-12.PCS 55.6 ± 9.1, Clinical scores were not correlated with the foot radiographic parameters at follow-up period.	No complications.	No preoperative clinical or functional scores.
Hsieh *et al* [15], 2019	102 (204 FFF) MA 9.1 ± 0.2 yr).	Subtalar AR.	CP; lat. TCA; a.p. TCA, kite angle; NCI; Meary angle.	22 cases of bilateral extrusion in the overweight group (39%) *vs* 13 cases bilateral extrusion in the low body weight group (23%) (P = 0.0004). The inter-observer correlation was 0.95. Improvement of radiological assessment at 3 mo postoperative follow-up (P < 0.05).	19%.	Retrospective nature, no control group, sample size. lack of objectively measurable parameters. No BMI loss evaluation surgical outcomes.
Hagen *et al* [32], 2019	7 (13 FFF), MA 12.43 ± 1.27 yr.	Calcaneo-stop.	Pedobarographic measurements before surgery, 3, 14, 28 d after.	The ground force increased significantly in lateral foot areas (P < 0.001) and decreased in medial areas (P < 0.001).	1 minor soreness.	Sample size, short follow-up.
Hagen *et al* [31], 2020	14 (27 FFF), MA 12.4 ± 1.4 yr.	Calcaneo-stop.	Heel angle, rearfoot angle, leg axis angle, step length, and walking speed, pre- and postoperatively.	Heel valgus (F 1, 24 = 110.465, P < 0.001); Dynamic heel angles *vs* static heel angles (F 1, 24 = 38.498, P < 0.001). Correlation between heel angle and rearfoot angle (static: r = 0.647, P < 0.001; dynamic: r = 0.640, P = 0.001). Dynamic rearfoot angle *vs* static rearfoot angle (F 1, 24 = 166.55, P < 0.001).	No complications.	Small size. No clinical assessment.
Giannini *et al*[21], 2017	44 (88 FFF). MA 11.7 yr (8-14 yr).	Bioabsorbable Calcaneo-stop.	Patient satisfaction; Meary angle; talocalcaneal angle.	33 excellent, 9 good outcome, and 2 poor clinical. Meary's, talocalcaneal angle had improved (P < 0.001).	2 breakages.	Retrospective nature, no control group, sample size. lack of objectively measurable parameters.
Faldini *et al* [24], 2018	173 (283 FFF), MA 11.2 yr. MF 49.5 mo.	Bioabsorbable Calcaneo-stop.	FFI, SEFAS.	FFI score 4; SEFAS score 47.2, well into the normal range. No statistically significant differences between males and females (P value > 0.05).	3 implant breakages, 1 persistent pain secondary to a local inflammatory response.	No radiological assessment. No control group.
Caravaggi *et al*[33], 2018	13 (26 FFF), MA 11.3 ± 1.6 yr, MF 1 yr (12.5 ± 3.7 mo).	Endo-orthotic implant and Calcaneo-stop.	A 10-point VAS, Kinematic and kinetic analysis during normal walking, radiological parameters.	All radiological parameters and VAS were significantly improved at 1-yr follow-up (P < 0.001). No significant differences were detected in spatiotemporal and ground-reaction-force parameters between pre-op evaluation and control in either implant groups.	No complications.	Multisegment foot protocol. Small size. No clinical assessment.
Bernasconi *et al*[27], 2020	31 (62 FFF), MA 10.5 ± 1.6 yr, MF 62 ± 15 mo.	Subtalar AR.	ROM; AOFAS; VAS-FA, radiological parameters.	Improvement clinical score and radiological parameters except talonavicular coverage angle (P = 0.49) and calcaneo-fifth metatarsal angle (P = 0.53). Improvement of dorso-plantar view. No loss of correction was found after removal of the implant.	17 (24%) sinus tarsi syndromes.	Retrospective nature, no control group, sample size. lack of objectively measurable parameters.
Elmarghany *et al*[38], 2020	42 (84 FFF); MA 9.92 ± 2.2 yr; range (7-15 yr). MF 29.1 mo.	Calcaneo-stop.	AOFAS; radiological parameters.	Improvement clinical score and radiological parameters (P value < 0.000).	3 minor complications, 1 (0.02%) under correction. 1 sunken screw. 1 synovits around screw.	Retrospective nature, No control group, sample size. lack of objectively measurable parameters.

AOFAS: American Orthopedic Foot and Ankle Society; AR: Arthroereisis; FADI: Foot and Ankle Disability Index; FFF: Flexible flatfoot; FFI: Foot Function Index Questionnaire; MA: Mean age; MF: Mean follow-up; OxAFQ-C: Oxford Ankle Foot Questionnaire for Children; ROM: Range of motion; SEFAS: Self-

reported Foot and Ankle Score; VAS: Visual Analogue score.

minor complications included screw device loosening, transient pain and discomfort at the level of the surgical incision, contracture of the lateral peroneal muscles, and superficial infection.

RESULTS

Study selection

A total of 47 articles were retrieved, 34 duplicate publications were excluded, and after the first screening following the previously described selection criteria, 22 were eligible for full-text evaluation. After full-text evaluation, and reference list checking, we selected 17 articles for inclusion (Table 1). The Preferred Reporting Items for Systematic Reviews and Meta-Anal (PRISMA)[12] flowchart of selection and screening is shown in Figure 1. A total of 1864 FFFs were treated In the 17 studies. Eight (762 FFFs) evaluated subtalar AR (47.1%) and nine (1102 FFFs) evaluated CS devices (52.9%). At start of treatment, the average age of patients was 11.8 years, the average follow-up was 71.9 mo (range 29.1-130), and complications occurred in 153 of the 1864 FFF treated, a rate of 8.2% (Table 1).

Clinical outcomes and radiological measurements

Eight studies evaluated subtalar AR in a total of 762 FFFs. The average age of patients at the start of treatment was 11.6 years (range 7 to 16 years) and the average follow-up of the studies was 68.9 mo. Every study reported statistically significant differences between pre- and postoperative assessments of pain, clinical scores, or parent and patient satisfaction (P values of 0.001 to 0.05). Radiological measurements showed improvement in every trial (P values of 0.001 to 0.05).

Nine articles evaluated CS in a total of 1102 FFFs. The average age of patients at the start of treatment was 12.0 years (range 7 to 17 years) and the average follow-up of the studies was 70.9 mo. As with subtalar AR Every study reported statistically significant differences between pre- and postoperative assessments of pain, clinical scores, or parent and patient satisfaction (P values of 0.001 to 0.05). Radiological measurements showed improvement in every trial (P values of 0.001 to 0.05). The clinical and radiological characteristics are summarized in Table 1.

Athlete and obese patient outcomes

Two articles investigated sport activities in FFF patients. In Martinelli *et al*[14]'s, 49 patients (98 FFFs) underwent to clinical and radiological evaluation after subtalar AR implant. Despite improvements in the emotional, school and play, and footwear ($P < 0.05$) items of the OxAFQ, the authors did not find any increase sport ability ($P > 0.05$). On the other hand, Pavone *et al*[1]. evaluated 68 CS-treated FFFs and reported improvement of sport activity levels, with patients recovering sports activity within 3 mo of surgery and without limitation in the execution of preferred activities (FADI Sport pre- *vs* postoperative scores $P < 0.005$).

Two studies included obese patients. Hsieh *et al*[15] evaluated 102 (204 FFFs) subtalar AR-treated patients. The study outcome was radiological assessment at 3 mo postoperative follow-up. Significatively differences in implant bilateral extrusion (39% *vs* 23%) were seen in overweight and normal weight patients, respectively, $P = 0.0004$). Obese patients treated with CS procedure reported a persistence of foot pain (AOFAS pain domain $P < 0.05$) at 1 year after the surgery compared with normal weight and overweight subjects[16].

Complications

Complications occurred in 74 of the 762 FFFs treated with subtalar AR 9.7% and 79 of 1102 FFFs treated with CS (7.2%). The complications in subtalar AR patients included tarsi pain in 40 patients, and under- or overcorrection in four patients. The complications in CS patients included incomplete correction of the deformity in 24 and transient pain or discomfort at the incision site in 20 patients.

Materials

Fourteen studies evaluated nonabsorbable implants, seven were CS studies, and seven

Table 2 Risk of bias of the included studies

Ref.	Dutch checklist form for prognosis				
	No participant selection took place	Groups are comparable regarding age	Validated measuring system used	Independent (blind) determination of outcomes	Clear description of groups available
Ruiz-Picazo *et al* [8], 2019	+	-	+	?	+
Pavone *et al*[16], 2019	+	+	+	-	+
Pavone *et al*[1], 2018	+	+	+	-	+
Memeo *et al*[26], 2019	+	+	+	?	+
Megremis *et al* [18], 2019	+	-	+	-	+
Martinelli *et al* [14], 2018	+	?	+	?	+
Kubo *et al*[20], 2020	+	+	+	?	+
Indino *et al*[28], 2020	+	-	+	?	+
Hsieh *et al*[15], 2019	+	+	+	-	+
Hagen *et al*[32], 2019	+	+	+	?	+
Hagen *et al*[31], 2020	+	+	+	?	+
Giannini *et al* [21], 2017	+	+	+	?	+
Faldini *et al*[24], 2018	+	+	+	-	+
Caravaggi *et al* [33], 2018	+	+	+	-	+
Bernasconi *et al* [27], 2020	+	+	+	?	+
Elmarghany *et al* [38], 2020	+	+	+	-	+

+: Low risk; -: High risk; ?: Unclear.

were subtalar AR studies. Four investigated bioabsorbable implants, three CS screws and one subtalar AR).

DISCUSSION

AR procedures were found to simple, reliable, and minimally invasive interventions for the treatment of pediatric FFF, allowing the alignment of the talus and calcaneus and restoring a proper foot arch. Both implants improved clinical and radiological outcomes. Despite pain persistence for 1 year following CS treatment, subtalar self-locking is not recommended for obese patients. At the same time, an increase of sport activities was reported after CS implants but no differences were noted after subtalar implant procedures. Complications were reported in 153 of the 1864 FFFs that were treated. To the best of our knowledge, this is the first article investigating the outcomes of AR-treated patients reported in the past 5 years and analyzing CS procedures for impact blocking devices and subtalar AR self-locking implant results separately, including the technique-associated complications in specific populations.

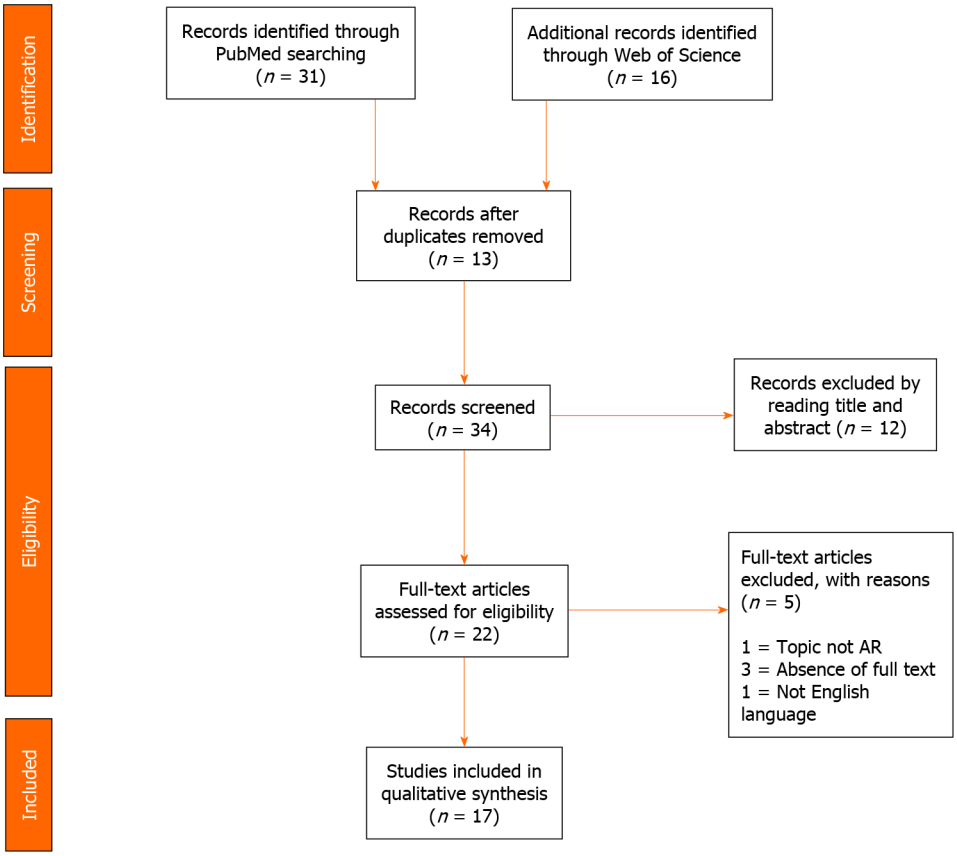


Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart of the systematic literature review. AR: Arthroereisis.

The juvenile and adult surgical indications were not completely defined, and a common consensus was not present among orthopedic surgeons. The principal intervention parameters were age, symptoms including pain while walking or standing, postural fatigue, or cramping sensation in the foot or arch. Night cramps, lower back or knee pain, or sedentary preference may also be reasons for patients to seek medical intervention[16-28]. In juvenile FFFs the most median age at treatment is 8 to 14 years of age, but only when the pain is persistent after conservative treatment[19]. Kubo *et al*[20], considering bone maturation stage, found that the best deformity correction was achieved when surgically was performed between 9 and 12 years of age, without secondary deterioration during follow-up.

Every study included in this systematic review reported significative improvements of clinical and radiological assessments. Unfortunately, few articles[24,29,30], comparing the self-locking and impact blocking devices, were published in the last 5 years. The articles did not clearly report the exact indication for the implant choice or if the procedures were all performed by the same surgeon. Nevertheless, subtalar AR and CS techniques were found to be similar. Hagen *et al*[31,32] described an increased ground force in lateral foot areas, a decrease in medial areas, and a correlation between heel angle and rearfoot angle. On the other hand, in Caravaggi *et al*[33] did not find significant differences in spatiotemporal and ground-reaction-force between preoperative evaluation and postoperative control achieved in either implant group.

The findings related to the return to sport activities after AR implant differed. Patients who underwent CS had improved levels of sport activities without any notable limitation in physical activity[16]. No enhancement of sport activities was found in a subtalar AR study[14]. Pavone *et al*[16] hypothesized better body awareness, removal of the impact of minor deformity on function, less FFF-related embarrassment, and the possibility of socializing through sport could have influenced the emotional involvement of CS-treated patients in social interactions. Emotional status was improved in patients with subtalar self-locking devices, but improvement of sport activities was not seen.

Obesity has long been considered a contraindication to AR implant because of excessive stress on the implant[20]. Two studies aimed to investigate the functional and radiological outcomes in overweight and obese patients. Pavone *et al*[16] reported

improvement of clinical and radiological assessments following treatment with CS procedures, even in heavy subjects, despite the persistence of pain for 1 year, compared to nonobese children. The discomfort could be related to the overload of foot structures[16], increased foot pressure with higher peak pressure, and peak force under the midfoot and metatarsal regions[25] during walking and inactivity, which delay the resolution of symptoms in obese children. On the other hand, Hsieh *et al*[15] noted that subtalar self-blocking implants in overweight patients had an increased possibility of implant extrusion, especially while walking.

Furthermore, a high percentage of satisfaction (78.5% *vs* 96.4%)[34] with AR procedures, lower risk and complication rates were reported when compared with other procedures. Suh *et al*[34] reported complication rates of 3.5% to 45% of minor complications in more than 50% of LCL studies. They also reported a 30% rate difference in complications between silicone, polyethylene, staple, titanium, bioresorbable, and stainless steel "old-type" AR implants (45%) and "recent-type" implants (15.4%). In this review, the overall complication rate was 8.2%; 7.2% with CS devices and 9.7% with subtalar AR. Differences in the potential for complications are related to the CS technique or subtalar self-locking devices[35].

As sinus tarsi pain is the most common complication (54.0%) associated with subtalar self-locking devices[35], with a total of 40 cases (5.2%). It has hypothesized that extrusion and over- or under correction occur because of the difficulty of finding the correct dimension of the implant. Under correction can result from a small device that cannot fully correct excessive subtalar joint eversion, and allow a few degrees of remaining eversion. On the other hand, if the chosen implant size is too large, the subtalar joint motion could be limited, thus resulting in pain or extrusion caused by weight bearing activities. The most frequent complication of CS procedures was the incomplete correction of the deformity (24 cases, 2.2%), transient pain, or discomfort at the incision site (20 patients, 1.8%).

Regarding surgery, no consensus is present about the indications for bioabsorbable, nonabsorbable, or a combination of implant materials[17]. Fourteen studies evaluated nonabsorbable implants (seven CS and 7 subtalar AR studies) and four (three CS[20,24,25], and one subtalar AR[26]) evaluated bioabsorbable implants. Both AR categories were found to result in improvement of clinical and radiological outcome measurements. Major advantages of the use of bioabsorbable implants include decreased interference during magnetic resonance imaging and avoidance of a second surgical procedure for hardware removal. Disadvantages and possible complications include screw breakage, inflammatory and foreign body reactions, cyst formation, and local bone lysis[29]. In the bioabsorbable implants studies, below-knee boot and crutch gait assistance were needed immediately after surgery for weight bearing or partial weight bearing to prevent implant breakage. Aggressive walking or athletic activities were not allowed. Fourteen of the 419 implanted bioabsorbable devices (3.3%) were broken compared with the only CS screw breakage in 683 nonabsorbable implanted devices. Polymer chemical structure, processing conditions and storage history, implant molecular weight, crystallinity, and size are common reasons of premature poly-(L-lactide) degradation. Cellular responses may include mild and temporary inflammatory reactions[23]. Despite implant rupture, the patients had good self-reported results, comparable to the other patients, even after having the implant removed[24,25]. A few months were not considered sufficient to promote complete correction of the deformity[9]. On the other hand, a second surgery was often necessary to remove nonabsorbable implants. In the AOFAS 2015 web-based survey[30], one-third of the participants who performed subtalar AR had decided to abandon the procedure because of the failure rate and the need for implant removal. Many participants who were dissatisfied by the AR practiced in the United States. Some authors believe that abandonment might be related to problems with health insurance payments[11].

Surgeon experience, implant costs, and cosmetic correction are the most common considerations in the orthopedic decision-making process. The CS procedure is less expensive surgery, compared with any of the other implants[16,17]. Moreover, Ortiz *et al*[19] noted that, in selected patients, tarsal canal implants produced better cosmetic corrections compared with the CS technique.

Few high-quality studies AR studies have been published. To the best of our knowledge, two systematic reviews and one meta-analysis were previously published. Baryeh *et al*[36] reported partially conclusive data supporting the subtalar AR as an adjunct treatment, but the analysis was limited to adult acquired flatfoot. Suh *et al*[34] performed a comparison between AR and the LCL procedures and concluded that LCL achieved more radiographic corrections and more improvements in the AOFAS score than the AR. Complications were more common in the LCL group than in the AR group, and the reoperation rates in the two groups were similar. As reported in a

recent European Pediatric Orthopedic Society flatfoot survey[3], the procedure indications are different. At the same time, the survey included dated findings regarding AR complications and first AR devices. A meta-analysis by Hsieh *et al*[37] in 2020 did not find a superiority between subtalar AR and CS procedures according to the clinical score, but endosinotarsal devices showed a better improvement in Meary's angle than exosinotarsal screws. Despite the remarkable conclusion, some concerns were present, for example, the authors chose the AOFAS score for the clinical assessment and Meary's angle for the radiological evaluation. Neither measurement is specific for juvenile FFF, moreover in the few studies included in the meta-analysis, the assessments were not the primary study outcomes and were supplemented with other measurements. In addition differences in study design made group comparability difficult in some cases.

The strength of this study is the reporting of the most important evidence published in the last 5 years. Major limitations include great heterogeneity of the outcome assessments and the lack of high-profile studies. We extensively searched and identified all relevant investigations of FFF treated with AR devices. Therefore, risk of bias assessment had moderate overall risk of influencing our analysis. Statistical analysis was not performed. Variations in clinical and radiological scores were reported in the selected studies. Often more than one measurement was performed in order to evaluate different disease features. Moreover, no FFF-specific scores or X-ray lines were developed, and randomized clinical trials are missing and few were case-control studies. In our opinion, the analysis of partial or not high-quality study data could be misleading.

CONCLUSION

In conclusion, despite both AR procedures being valid surgical techniques for the treatment of FFF, surgeon experience, implant cost, and cosmetic correction are the most common considerations in the orthopedic decision-making process and AR choice. In obese patients, subtalar ARs are not recommended. In adolescents who need to improve sports performance, CS screws had a slightly lower rate of complications than subtalar self-locking implants.

ARTICLE HIGHLIGHTS

Research background

Flexible flatfoot (FFF) is a common disorder during childhood. When symptoms of early and easy fatigue during walking or pain are present, treatment is mandatory. Arthoereisis (AR) is frequently used for surgical management. Two device types were described, subtalar AR and calcaneo-stop (CS).

Research motivation

No common consensus or AR among orthopedic surgeons is present.

Research objectives

The aim of the study was to report the clinical and radiological outcomes after subtalar AR and CS procedures, including the results in obese and athlete populations, and the technique-related complications. Moreover, the intent was to include the more recent findings of the material devices.

Research methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used to perform a systematic review of English-language articles published of the last 5 years.

Research results

Seventeen articles were included in the study after the initial screening and the risk of bias assessment. A total of 1864 FFFs were identified. Eight studies evaluated subtalar AR and nine evaluated CS (52.9%). At the start of treatment, the average age of patients was 11.8 years and the average study follow-up was 71.9 mo.

Research conclusions

Both AR procedures are valid surgical techniques for FFF treatment, surgeon experience, implant cost, and cosmetic correction were the most common considerations in the orthopedic decision-making process and AR choice. In obese patients, the subtalar AR is not recommended. In adolescents who need to improve sports performance, the CS screw had better results compared with other implants. In adolescents who need to improve sports performance, CS screws had a slightly lower rate of complications than subtalar self-locking implants.

Research perspectives

High-quality randomized clinical trials are needed.

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CASE REPORT

Nuances of oblique lumbar interbody fusion at L5-S1: Three case reports

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Abstract

BACKGROUND

Oblique lumbar interbody fusion is a mini-open retroperitoneal approach that uses a wide corridor between the left psoas muscle and the aorta above L5. This approach avoids the limitations of lateral lumbar interbody fusion, is considered less invasive than anterior lumbar interbody fusion, and is similarly effective for indirect decompression and improving lordosis while maintaining a low complication profile. Including L5-S1, when required, adds to these advantages, as this allows single-position surgery. However, variations in vascular anatomy can affect the ease of access to the L5-S1 disc. The nuances of three different oblique anterolateral techniques to access L5-S1 for interbody fusion, namely, left-sided intra-bifurcation, left-sided pre-psoas, and right-sided pre-psoas approaches, are illustrated using three representative case studies.

CASE SUMMARY

Cases of three patients who underwent multilevel oblique lumbar interbody fusion including L5-S1, using one of the three different techniques, are described. All patients presented with symptomatic degenerative lumbar pathology and failed conservative management prior to surgery. The anatomical considerations that affected the decisions to utilize each approach are discussed. The pros and cons of each approach are also discussed. A parasagittal *facet line* objectively assesses the relationship between the left common iliac vein and the L5-S1 disc and assists in choosing the approach to L5-S1.

CONCLUSION

Oblique retroperitoneal access to L5-S1 in the lateral decubitus position is possible through three different approaches. The choice of approach to L5-S1 may be individualized based on a patient's vascular anatomy using preoperative imaging. While most surgeons will rely on their experience and comfort level in choosing the approach, this article elucidates the nuances of each technique.

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Core Tip: Oblique lumbar interbody fusion (OLIF) provides safe retroperitoneal access to nearly all lumbar levels, including L5-S1, thus, allowing single-position surgery. L5-S1 OLIF access may be attempted through three alternative approaches — left intra-bifurcation, left pre-psoas and right pre-psoas approaches — the choice of which can be customized according to the patient's vascular anatomy.

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INTRODUCTION

Oblique pre-psoas retroperitoneal access to the lumbar spine through a mini-open technique has recently gained popularity. The oblique trajectory avoids the iliac crest and lower ribs, which are impediments to lateral lumbar interbody fusion (LLIF)[1]. Staying outside the psoas reduces the risk of lumbar plexus injuries[2,3], and allows complete muscle relaxation as neuromonitoring is not considered essential for this approach[4,5]. Moreover, a wide anatomic corridor between the left psoas and aorta allows easy access to all lumbar spinal levels above L5[6], often without the need for any vascular retraction or ligation[7].

Isolated L5-S1 pathologies can be approached through the anterior lumbar interbody fusion (ALIF) technique in the supine position, taking advantage of the wide corridor between the bifurcated common iliac vessels. However, the ALIF approach requires ligation of the left iliolumbar vein (ILV) and transposition of the great vessels to reach the levels above L5[8]. In contrast, oblique lumbar interbody fusion (OLIF), or anterior to psoas (ATP) approach, performed with the patient in the lateral decubitus position, can address multiple lumbar levels, including L5-S1, with a relatively favorable complication profile[4,9]. The lateral decubitus position takes advantage of gravity-assisted retraction of the peritoneal sac, theoretically reducing the risk of postoperative ileus[10]. OLIF/ATP involves a mini-open muscle-splitting approach through the abdominal oblique and transverse muscles[11], which may be less traumatic than a midline ALIF approach through the anterior rectus muscle-sheath complex[12].

Oblique access to L5-S1 is not as straightforward as that for levels above L5. Variations in vascular anatomy create unique situations for which approaches may need to be customized. Oblique anterolateral approaches to L5-S1 have been described in previous studies as staying lateral to[4,13], or approaching between the bifurcated common iliac vessels[7] (Figure 1A and B). These variations of technique have been found to be safe and feasible in individual studies. However, these studies have not provided adequate guidance regarding the choice of approach. Careful assessment of the vascular anatomy is critical as vascular injuries range from 0.3%-4.3%, especially when L5-S1 is included[4,7,12]. Three representative case studies are presented to describe how the three previously described variations of approaches can be potentially customized based on a patient's anatomy.

All patients in the case studies were operated on in a single institution by a single spine surgeon with assistance from an access surgeon. Imaging and chart review were retrospectively performed. All patients presented with degenerative lumbar pathology and underwent nonsurgical treatment for a minimum of 6-12 wk before being considered for surgical intervention. After careful consideration, each patient elected to proceed with surgery and provided written informed consent.

In the preoperative magnetic resonance imaging (MRI), the location of the left common iliac vein (CIV) in relation to the L5-S1 disc was carefully assessed. We have previously described an imaginary parasagittal line drawn from the medial border of

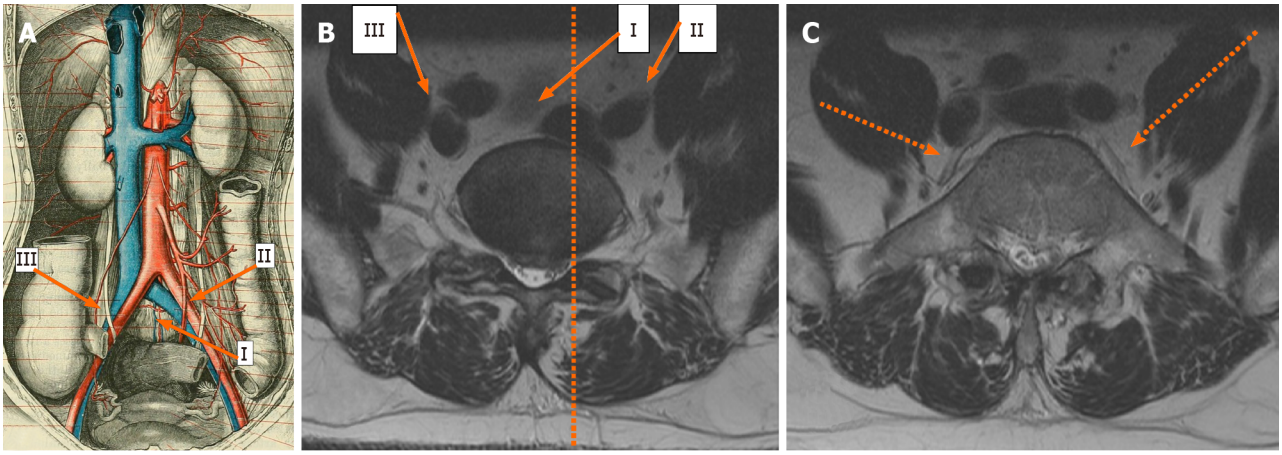


Figure 1 Vascular anatomy as depicted through an illustration showing the frontal aspect (A), and that depicted through magnetic resonance imaging axial sections (B, C). Image B shows magnetic resonance imaging (MRI) axial section through the L5-S1 disc, and the *facet line* (dotted line) running anteroposteriorly through the medial border of the left L5-S1 facet joint cutting through the left common iliac vein. The three oblique approaches to L5-S1; namely the left intra-bifurcation (i), the left pre-psoas (ii), and the right pre-psoas (iii) are shown in A and B. Image C shows an MRI axial section through mid-L5 vertebral body and shows the left and right ilio-lumbar veins (dotted arrows).

the left L5-S1 facet joint on the MRI axial section through the L5-S1 disc (the *facet line*) [13] and traced anteriorly to assess its relationship with the left CIV (Figure 1B). MRI axial images through the L5 vertebral body were also carefully evaluated to identify L5 segmental veins or ILV on either side[4] (Figure 1C). Computed tomography was not routinely performed to assess fusion.

Surgical techniques

Left intra-bifurcation approach: The left intra-bifurcation approach has been described by Woods *et al*[7] and others[1,13-15] and is a modification of the supine ALIF technique. This is performed with the patient in the right lateral decubitus position. Lateral fluoroscopy is performed to mark all target spinal levels on the skin (Figure 2). An oblique 5-6 cm incision in the left lower quadrant of the abdomen is marked 2 fingerbreadths anterior to the anterior iliac crest and extending inferior enough to reach the plane of the sacral slope.

A muscle-splitting approach through the external oblique, internal oblique, and transversus abdominis muscles is performed, and the retroperitoneal space is entered. Blunt dissection is performed to reach the left psoas muscle. The peritoneal sac is then retracted further medially and inferiorly to reach the medial aspect of the left common iliac vessels. Careful blunt dissection is performed to identify the anterior annulus of the L5-S1 disc, which is confirmed with fluoroscopy. The median sacral vessels are identified and ligated (Figure 3A). Blunt dissection may be required to mildly elevate and retract the left CIV laterally to further widen the *intra-bifurcation interval*. Discectomy and endplate preparation is then performed at L5-S1. Double-bent curettes may be needed to adequately reach the posterior portion of the L5 inferior endplate (Figure 3B). An ALIF cage (width: 32-40 mm; height: 12-20 mm; depth: 24-32 mm; lordosis: 14-20°) packed with bone graft is inserted through an oblique inserter under image guidance. The anteroposterior (AP) fluoroscopy confirms the midline position of the cage. A screw with a washer or a plate is usually placed to cover the cage to prevent dislodgement.

Left pre-psoas approach: The left pre-psoas approach has been described by Tannoury *et al*[4] and others[13,16,17], and is an inferior continuation of the pre-psoas OLIF approach to levels above L5. As above, the patient is positioned in the right lateral decubitus position and spinal levels marked on the skin. A 4-5 cm incision is marked along the skin lines about 2 fingerbreadths anterior to the iliac crest, approximately mid-way between the target levels (Figure 2). A muscle-splitting approach through all abdominal wall layers is then performed to reach the retroperitoneal space. The left psoas muscle is identified and the pre-psoas interval is developed and extended inferiorly. The left CIV is identified. The left ILV is often identified inferior to the L4-5 disc, with psoas retraction (Figure 3A). Ligation of this left ILV may be required to allow anteromedial mobilization of the left CIV. This exposes the lateral annulus of the L5-S1 disc. Discectomy and endplate preparation is then performed using specialized

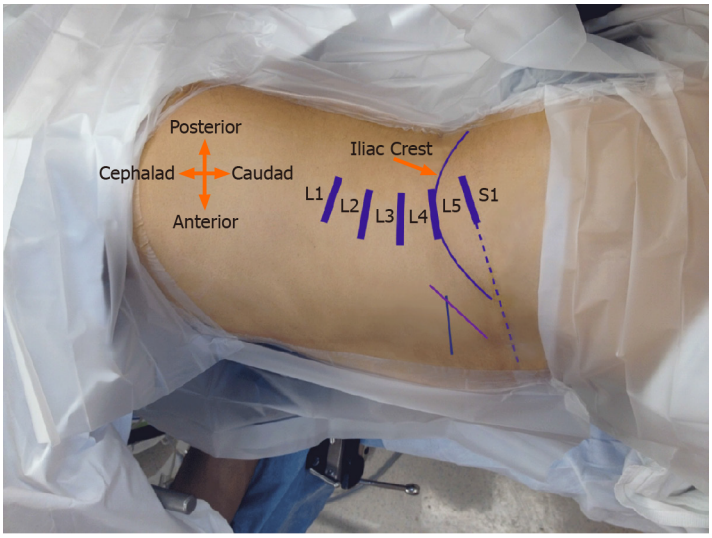


Figure 2 Clinical photograph of a patient in the right lateral decubitus position with superimposed skin markings. Disc levels from L1 to S1 are marked. L5-S1 disc marking is extended anteriorly (dotted line) to guide the incision. A longer oblique line (purple) somewhat parallel to the anterior iliac crest marks the suggested incision for a left intra-bifurcation approach for L3-S1 oblique lumbar interbody fusion (OLIF). The shorter transverse line (green) is the suggested incision (along skin lines) for a left pre-psoas approach for L3-S1 OLIF.

instruments that are bent in two planes (Figure 3C and D). An LLIF cage (width: 45-55 mm; height: 10-16 mm; depth: 18-22 mm; lordosis: 6-18°) packed with bone graft is inserted through a lateral inserter under image guidance. Fluoroscopy confirms the coronal position of the cage.

Right pre-psoas approach: The right pre-psoas approach is performed from the right side with the patient in the left lateral decubitus position and has been described by Tannoury *et al*[4] and others[13]. A transverse incision along the skin lines is made, as above. The procedure is similar to the aforementioned left pre-psoas approach in terms of muscle splitting, entering the retroperitoneal space, and retracting the peritoneal sac anteromedially. The right psoas and IVC are identified, and an interval is created between them. This interval is then traced inferiorly along the right CIV. The right L5 segmental vein, when present, is identified, ligated, and divided (Figure 4A). Next, the right CIV is carefully retracted anteromedially to expose the lateral annulus of the L5-S1 disc. Discectomy, endplate preparation, and placement of an LLIF cage is then performed using bent instruments (Figure 4B), similar to the left pre-psoas approach. While this approach has been found to be safe and feasible by previous studies[4,13], extensive experience and comfort level is required to work alongside the IVC.

CASE PRESENTATION

Chief complaints

Low back pain.

History of present illness

Case 1: A 58-year-old man [body mass index (BMI): 34 kg/m^2] presented with longstanding back and leg pain refractory to conservative treatment.

Case 2: A 69-year-old man (BMI: 31 kg/m^2) presented with longstanding back and leg pain refractory to conservative treatment.

Case 3: A 72-year-old man (BMI: 23 kg/m^2) presented with longstanding back and leg pain refractory to conservative treatment.

History of past illness

Case 1 had undergone prior laminotomy surgery. Case 2 and Case 3 did not have any relevant past illness.

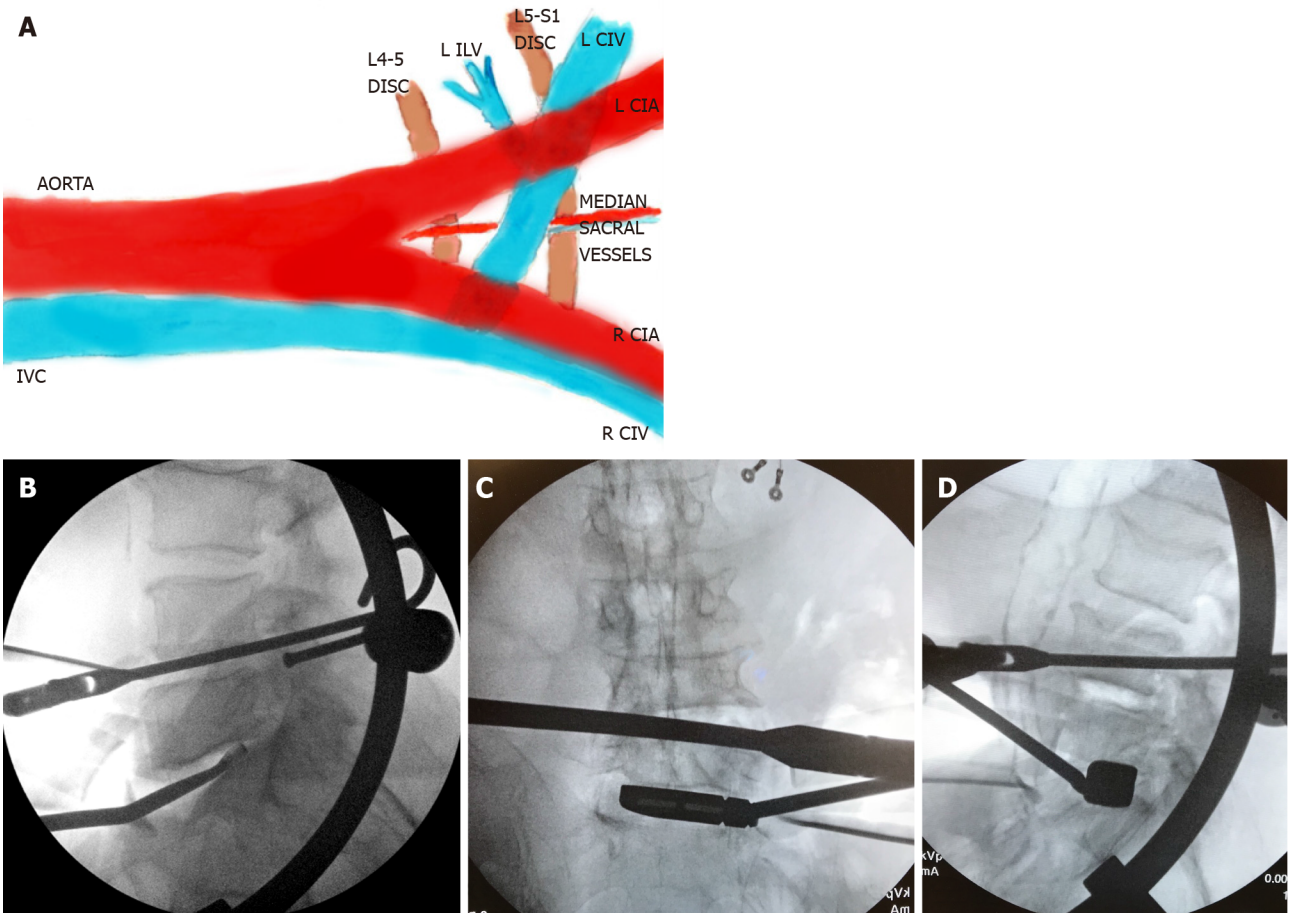


Figure 3 Illustration showing left-sided oblique anterolateral approaches (A), and intraoperative fluoroscopy images (B-D). Image A shows the median sacral vessels that are often encountered in the left intra-bifurcation approach, and the left ilio-lumbar vein (ILV), which may need ligation in a left pre-psoas approach. Image B shows a lateral fluoroscopy image with a double-bent curette which may be helpful in preparing the portions of the L5 inferior endplate that may not be under direct visualization. Images C and D show intraoperative anteroposterior and lateral fluoroscopy images during a left pre-psoas approach with specialized trial instrument bent in two planes. IVC: Inferior vena cava; CIV: Common iliac vein; CIA: Common iliac artery; ILV: Ilio-lumbar vein; R: Right; L: Left.

Personal and family history

None of the 3 patients had any relevant positive personal and family history.

Physical examination

All 3 patients had examination findings consistent with Lumbar degenerative disc disease and stenosis. No neurologic deficit was noted. Case 2, in addition, showed findings consistent with a severe lumbar dextroscoliosis.

Laboratory examinations

None of the 3 patients had any significant laboratory examination findings.

Imaging examinations

Case 1: He was found to have L3-S1 degenerative disc disease and stenosis (Figure 5). A careful review of all the available imaging revealed a wide intra-bifurcation interval between the left and right common iliac vessels in the axial section through the L5-S1 disc. There was an identifiable fat plane between the left CIV and the L5-S1 disc. The medial edge of the left CIV was lateral to the *facet line* (Figure 5B).

Case 2: He was found to have severe lumbar dextroscoliosis, sagittal imbalance, and multilevel stenosis (Figure 6). An MRI axial cut at the L5-S1 disc showed the left CIV in the midline with no obvious fat plane underneath it (Figure 6D).

Case 3: He was found to have L3-S1 degenerative disc disease with central & foraminal stenosis. L3-S1 OLIF with posterior PPSI was recommended. A thorough evaluation of preoperative imaging was performed (Figure 7). As seen on the L5-S1 disc axial MRI cut, the medial wall of the left CIV was medial to the *facet line*

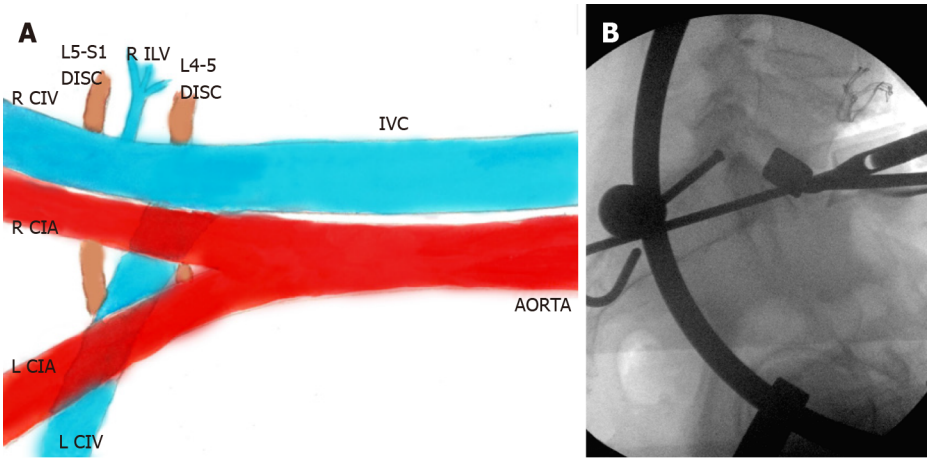


Figure 4 Illustration showing right-sided oblique anterolateral approach (A), and a lateral fluoroscopy image (B) during a right pre-psoas approach. The right ilio-lumbar vein (ILV) is longer in length and smaller in caliber (A) when compared to the left ILV (Figure 3A). Also note that the right common iliac vein (CIV) is visible throughout in the right pre-psoas approach, unlike the left CIV, which for the most part, is covered by the accompanying left common iliac artery. Image B again identifies specialized trial instrument bent in two planes (similar to Figure 3C and D). IVC: Inferior vena cava; CIV: Common iliac vein; CIA: Common iliac artery; ILV: Ilio-lumbar vein; R: Right; L: Left.

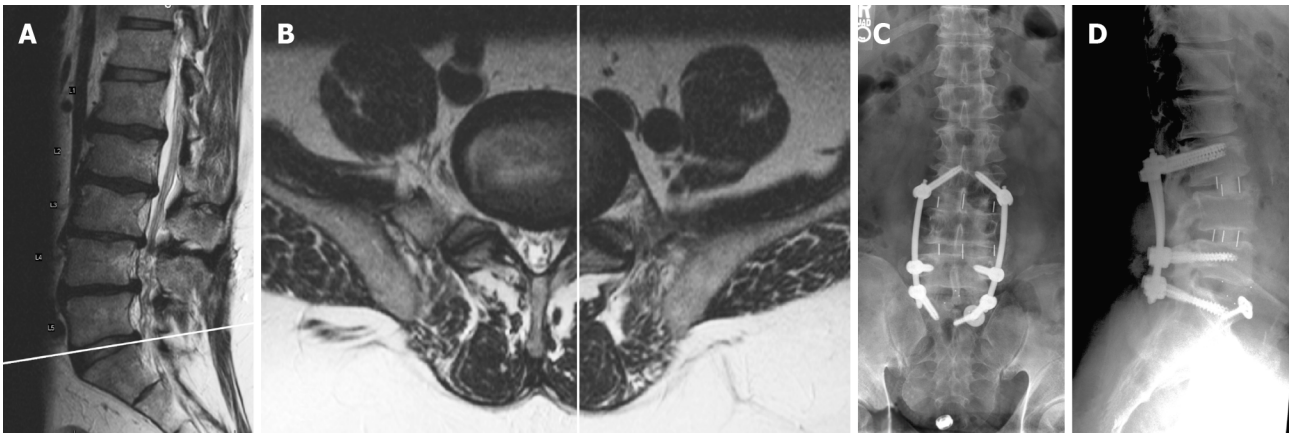


Figure 5 Preoperative magnetic resonance imaging sagittal (A) and axial (B) images and postoperative anteroposterior (C) and lateral (D) upright radiographs for Case 1. Image A shows the scout line corresponding to the axial image B. The anteroposterior *facet line* through the medial border of the left L5-S1 facet joint runs medial to the medial border of the left CIV (B). CIV: Common iliac vein.

(Figure 7B). The fat plane was not well-visualized between the left CIV and L5-S1 disc, but a small fat plane was identifiable between the right CIV and L5-S1 disc.

FINAL DIAGNOSIS

Case 1: L3-S1 degenerative disc disease and stenosis.

Case 2: Severe lumbar dextroscoliosis, sagittal imbalance, and multilevel stenosis.

Case 3: L3-S1 degenerative disc disease and stenosis.

TREATMENT

Case 1: L3-S1 OLIF with posterior percutaneous pedicle screw instrumentation (PPSI) was recommended. L5-S1 was approached through the left intra-bifurcation approach, and L3-4 and L4-5 through the left pre-psoas interval, all through the same incision. Minimal retraction and careful protection of the left common iliac vessels was required. Median sacral vessels were ligated. Posterior percutaneous pedicle screw

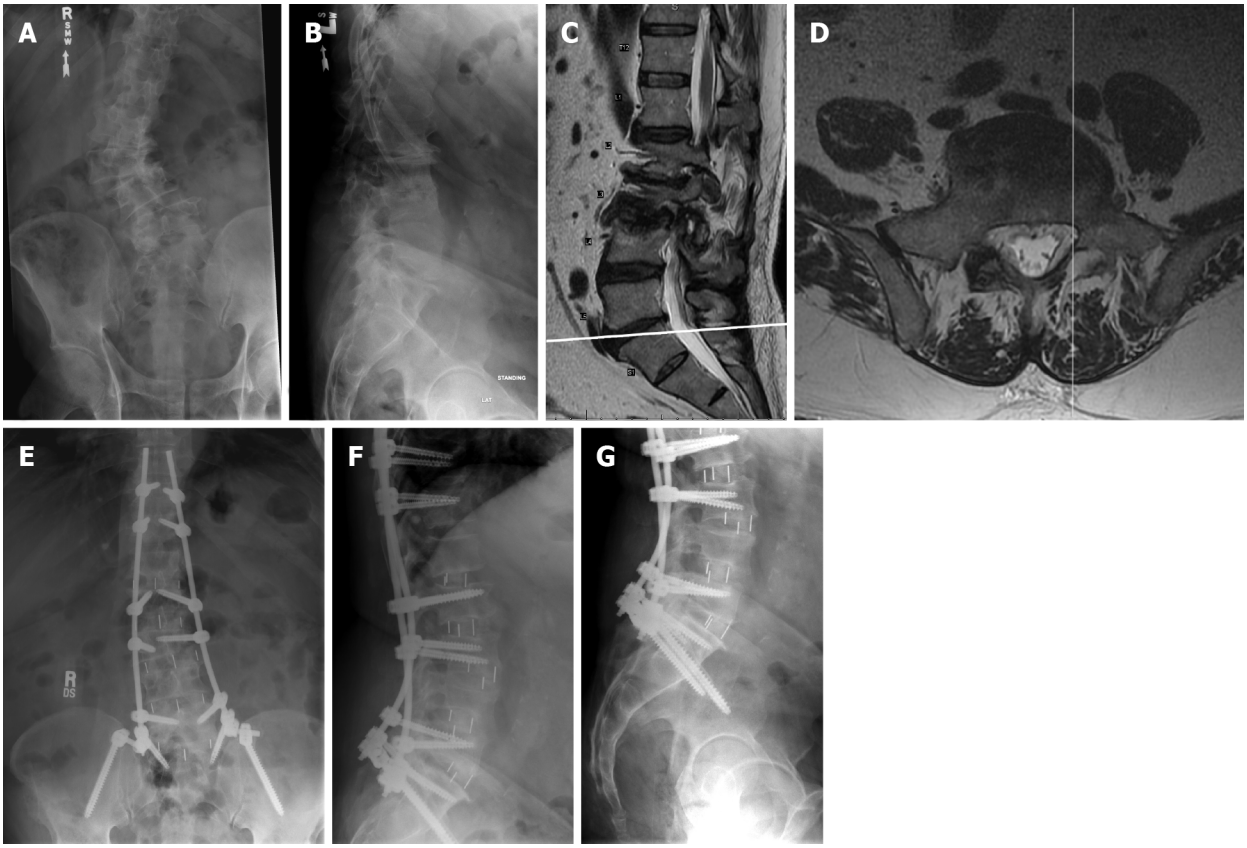


Figure 6 Preoperative upright anteroposterior (A) and lateral (B) radiographs, preoperative magnetic resonance imaging sagittal (C) and axial (D) images, and postoperative anteroposterior (E) and lateral (F, G) upright radiographs for Case 2. Image C shows the scout line corresponding to the axial image D. The left common iliac vein is in the midline medial to the anteroposterior *facet line* (D). CIV: Common iliac vein.

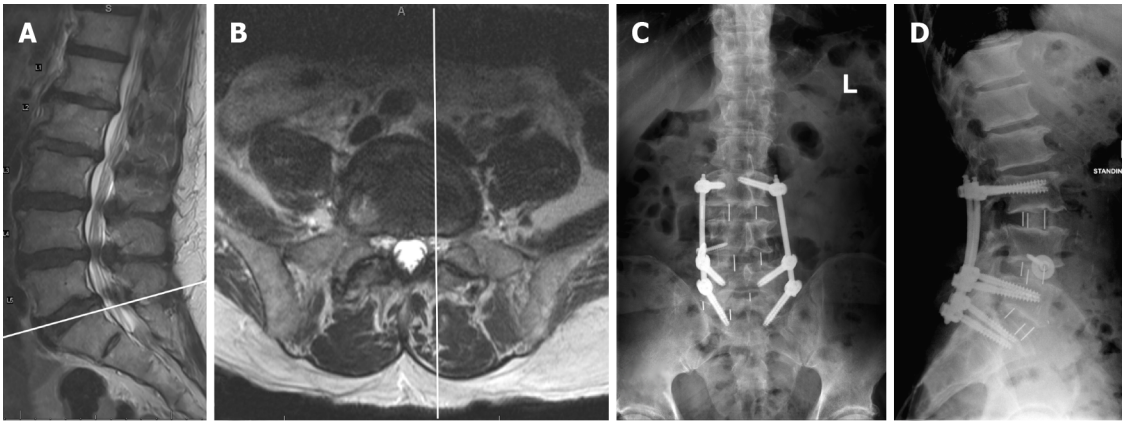


Figure 7 Preoperative magnetic resonance imaging sagittal (A) and axial (B) images and postoperative (C) anteroposterior and (D) lateral upright radiographs for Case 3. Image A shows the scout line corresponding to the axial image B. The anteroposterior *facet line* through the medial border of the left L5-S1 facet joint runs lateral to the medial border of the left common iliac vein (CIV) (B). The fat plane is better visualized under the right CIV than under the left CIV (B). CIV: Common iliac vein.

instrumentation was performed in the prone position in the same operative setting. Neuromonitoring was not utilized. Operative time was 358 minutes, and intraoperative blood loss was 100 mL. No vascular injuries and no perioperative blood transfusions were required.

Case 2: Staged L1-S1 OLIF followed by posterior T11-S1 PPSI and iliac fixation on the next day was recommended. A left-sided pre-psoas approach was performed. During the exposure of L5-S1, minimal retraction of the left common iliac artery and no retraction of the CIV were required. The left ILV was not identified and did not interfere with exposure. A single skin incision provided access to 5 spinal segments

from L1-S1, taking advantage of the scoliotic concavity on the left side. The patient underwent posterior instrumentation the next day, as planned. Neuromonitoring was used during the second stage only. Operative times for the two stages was 262 min and 294 min, and intra-operative blood loss was 500 mL and 250 mL, respectively. A minor vascular injury in the form of segmental bleed was encountered while exposing the L2-3 disc anterolaterally, which was controlled with ligation. No perioperative blood transfusions were required.

Case 3: L3-S1 OLIF with posterior PPSI was recommended. A right-sided pre-psoas approach was performed with the patient in the left lateral decubitus position. While accessing L5-S1, an L5 segmental vein was encountered, which was ligated with vascular clips and divided. Posterior PPSI was performed with the patient in the prone position at L3-S1 in the same operative setting. Neuromonitoring was not used. Operative time was 278 min, and intra-operative blood loss was 100 mL.

OUTCOME AND FOLLOW-UP

Case 1: The patient recovered well and was discharged home on postoperative day 2. Transient left groin pain was reported but resolved by the 2-wk follow-up. No other approach-related complications were observed. The patient reported excellent clinical improvement at his one year follow up visit. No subsidence or pseudarthrosis was seen.

Case 2: Excellent recovery was seen postoperatively, and the patient was discharged to a rehabilitation facility on day 6. He showed no approach-related complications. The patient reported excellent clinical improvement and radiographic maintenance of alignment at his two year follow up visit. No subsidence, pseudarthrosis, hardware failure, or proximal junctional issues were seen.

Case 3: The patient recovered well and was discharged home on postoperative day 2. There were no approach-related complications reported. The patient reported excellent clinical improvement at his one year follow up visit. No subsidence or pseudarthrosis was seen.

DISCUSSION

Lumbar interbody fusion techniques *via* anterior approaches (ALIF, OLIF, and LLIF) provide opportunities for indirect decompression[18] and better correction of lordosis than posterior techniques[19]. Among these approaches, OLIF/ATP shows the greatest versatility, allowing exposure of nearly all lumbar levels from T12-S1[4], and provides distinct advantages over other anterior and posterior approaches with favorable complication profiles[9,10]. Neuromonitoring is not considered essential[4,5,18] as the psoas muscle cushions the lumbar plexus during retraction. Intraoperative muscle relaxation can be employed with favorable effects on abdominal wall musculature compliance, psoas retractability[20], and intra-abdominal pressure.

Potential complications

Complication rates in OLIF/ATP approaches have been reported between 7.2% and 48.3% in different studies[4,21-23]. The incidence of certain complications may be higher when L5-S1 is included in the OLIF/ATP procedure[7,13,23]. This is especially true for vascular injuries, which can be catastrophic and potentially fatal. In a series of 940 patients, Tannoury *et al*[4] found vascular injuries in 0.3%. They approached L5-S1 *via* the left or right pre-psoas approaches. Woods *et al*[7] reported a 2.9% incidence of vascular injuries in their series of 137 patients. This incidence went up to 4.3% when L5-S1 was included in the approach. They used the intra-bifurcation approach to L5-S1. Our previously published series did not show any differences in incidence of vascular injuries between the three approaches to L5-S1[13]. Approach-related complications like ileus, ipsilateral groin pain, anterior thigh numbness or pain, incisional hernia, or pseudohernia have also been reported with the OLIF/ATP approach[4,7,12,23]. Subsidence may be seen more often with the OLIF approach compared to other anterior approaches for interbody fusion, according to Woods *et al* [7].

Pros and cons of each approach

The intra-bifurcation left-sided approach is a modification of an ALIF approach to L5-S1, which most spine surgeons are accustomed to. It utilizes an oblique trajectory through an anterolaterally placed incision with the insertion of an ALIF cage. This approach allows broad access to the anterior aspect of L5-S1, which permits near-complete resection of the anterior longitudinal ligament (ALL). Thus, better correction of lordosis can be achieved by utilizing a hyper-lordotic cage. This extensive ALL release may prompt the surgeon to place a plate or washer that covers the cage, to prevent the cage from dislodging anteriorly.

The intra-bifurcation approach may require careful retraction and mobilization of a flat left CIV that may be covering the left half of the L5-S1 disc[24] (Figure 3A). While this approach is similar to the supine ALIF approach, there is a higher likelihood of needing retraction or mobilization of the left CIV than the latter due to the left-sided oblique trajectory. This increases the risk of vascular injury as the medial aspect of the left CIV is often flat and stretched over the anterior osteophytes of the L5-S1 disc[13]. Additionally, in patients with a large sacral slope, a longer oblique incision extending far inferiorly may be required to align with the plane of the L5-S1 disc (Figure 2). In such instances, preparation of the L5 inferior endplate may be blind, requiring extensive help from fluoroscopy[15] (Figure 3B). Such blind endplate preparations might be common to all oblique approaches to L5-S1 and may be a reason for subsidence seen in some patients. Furthermore, due to the lower incision for L5-S1, separate incisions may be required to reach upper lumbar levels in multilevel surgeries. Midline orientation may also be challenging in the initial cases[7], because of the oblique trajectory of this approach. Lastly, the superior hypogastric sympathetic plexus, which lies anterior to the L5-S1 disc may still be at risk of injury with this approach.

The left and right pre-psoas approaches are an inferior continuation of the pre-psoas approach for levels above L5. Although the common iliac vessels are especially close to the psoas at L5-S1, this interval may be widened by retraction of the psoas and careful mobilization of the CIV, as needed. Being able to put a laterally-placed LLIF cage at L5-S1 reduces the need for longer skin incisions to align with the L5-S1 plane.

The left and right prepsoas approaches may be challenging in patients with large bulky psoas muscles. These approaches require specialized bent intruments and preparation of the L5 inferior endplate is often blind (Figure 3C, D and 4B). A blunt release of the contralateral annulus, which is common for OLIF or LLIF techniques at levels above L5, may not be advisable for the L5-S1 Level because of more laterally located contralateral common iliac vessels that may inadvertently get injured. ALL release is often not possible, however, a blunt ALL rupture may be achievable.

The right prepsoas approach may be useful in patients that may have a favorable indication to approach multiple levels from the right side; for example, in patients with a scoliotic concavity to the right, in those with prior left-sided abdominal surgeries with anticipated scarring, or in those with vascular anomalies[25]. This approach may also be used if the access surgeon believes that L5-S1 can be reached with greater safety than the other approaches[4]. However, this approach needs significant experience as the IVC and right CIV are approached head-on, and the prepsoas interval is much narrower at all levels on the right side.

How to choose the approach

Most patients could possibly undergo L5-S1 OLIF through more than one of the approaches described above. The choice should depend on the access surgeon's comfort level and experience. However, the anatomic relationship of the left CIV to the L5-S1 disc may also be an important consideration. A wide anterior interval between the left and right CIVs, and a more lateral position of the left CIV (Patient 1) may favor an intra-bifurcation approach[13,26]. Although other methods of assessing the relative position of the left CIV to the L5-S1 disc are available[26], the *facet line* may be an easy, quick method[13]. If the medial border of the left CIV is medial to this *facet line* without a distinct fat plane underneath, the intra-bifurcation approach may be challenging, and a pre-psoas approach may be considered (Cases 2, 3). In such cases, the authors personally prefer a right-sided pre-psoas approach for the following reasons. The right CIV is somewhat vertical and is visible throughout its course in a right-sided approach, while the left CIV takes a more horizontal oblique course and is often hidden underneath its accompanying artery in left-sided approaches[24] (Figure 3A and 4A). In the authors' experience, the more vertical right CIV is far more predictable in its course and easier to retract medially due to its rounded lateral edge, unlike the oblique and flat left CIV (Figure 7B). Moreover, according to Tannoury *et al*

[4], the right ILV tends to be longer in length and smaller in caliber than the left ILV. The right ILV is hence easier to ligate and divide. Careful assessment of MRI axial images through the L5 vertebral body, may help identify L5 segmental veins or ILV on either side[4] (Figure 1C).

The left pre-psoas approach may be beneficial in anatomy as in Patient 2, where the bifurcation is at a relatively lower vertebral level, such that the left CIV may not need any retraction or mobilization. The left pre-psoas approach can also be potentially used as an intraoperative bailout when an intra-bifurcation approach is unsuccessful due to difficulty retracting the left CIV laterally[13]. However, the right prepsoas approach has to be chosen prior to surgery and cannot be used as an intraoperative bailout.

CONCLUSION

Altogether, L5-S1 can be exposed *via* an oblique approach using three different techniques, the choice of which may be customized according to a patient's anatomy. A significant learning curve may be involved, and experience with identifying and ligating venous structures through mini-open exposures is required to safely perform these procedures. The availability of an experienced access surgeon is critical and may be essential for such exposures. While the right-sided pre-psoas approach has been shown to be safe and feasible in some studies, we strongly recommend gaining adequate experience before adopting this technique. In early cases and in patients with challenging vascular anatomy, posterior alternatives may be considered.

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EDITORIAL

Optimization of transdisciplinary management of elderly with femur proximal extremity fracture: A patient-tailored plan from orthopaedics to rehabilitation

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Abstract

Fractures of femur proximal extremity (FFPE) are the most common fragility fractures requiring hospitalization, with a high risk of mortality, low independence in the activities of daily living and severe consequences on health-related quality of life. Timing for surgery has a key role in the management of elderly patients with FFPE as recommended by the Australian and New Zealand guidelines and the National Institute for Health and Care Excellence guidelines. Early surgery (within 48 h from hospital admission) allows significant benefits in terms of lower rates of postoperative complications and risk of death and can provide better functional outcomes. Therefore, time for surgery could be considered as a comorbidity marker. The choice between conservative or surgical approach surprisingly seems to be still not strongly supported by available literature, but it seems that both 30 d and 1 year risk of mortality is higher with the conservative treatment rather than with surgery. In light of these considerations, the optimization of FFPE management care is mandatory to improve functional outcomes and to reduce sanitary costs. Albeit it is widely accepted that transdisciplinary approach to patients suffering from FFPE is mandatory to optimize both short-term and long-term outcomes, the feasibility of a comprehensive approach in clinical practice is still a challenge. In particular, the large

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variability of figures involved could be considered both a resource and an additional disadvantage taking into account the difficulty to coordinate multidisciplinary approach covering care in all settings. Therefore, the aim of the present article was to summarize current evidence supporting transdisciplinary management of patients with FFPE, highlighting the benefits, feasibility and limitations of this approach.

Key Words: Transdisciplinary management; Elderly; Femur fracture; Hip fracture; Rehabilitation; Pathway

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Core Tip: Optimization of fractures of femur proximal extremity management care is mandatory in order to improve functional outcomes and reduce sanitary costs. Albeit it is widely accepted that the transdisciplinary approach to patients suffering from fractures of femur proximal extremity is mandatory to optimize both short-term and long-term outcomes, the feasibility of a comprehensive approach in practice is still a challenge. Therefore, by the present study, we portray the potential benefits of transdisciplinary management of patients with fractures of femur proximal extremity, highlighting feasibility and limitations of this approach.

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INTRODUCTION

Fractures of femur proximal extremity (FFPE) are the most common fragility fractures requiring hospitalization[1], with a high risk of mortality[2], low independence in the activities of daily living[3] and severe consequences on health-related quality of life[4].

FPE fracture patients are expected to increase worldwide due to the aging population and increasing average life expectancy[5,6], reaching 4.5 million by the year 2050, with detrimental issues on the health care system and sanitary costs[7]. Kanis *et al*[8] recently reported a high variability in the incidence rate based on different countries, ranging from 439/100000 to 55/100000. According to the International Osteoporosis Foundation, women are mostly affected with a prevalence of 18% of hip fractures rather than 6% in men[9].

Aging is considered an independent, non-modifiable risk factor for fragility fracture, with over 90% of FFPE occurring in patients aged more than 65 years suffering from pre-existing medical comorbidities[10]. Disability related to hip fractures is responsible for major health care expenditures resulting from both medical care and assistance that should be associated with the sanitary costs due to surgical procedures and hospitalization[11-13]. Furthermore, a recent systematic review by Downey *et al*[14] reported that hospitalization costs for hip fracture patients during the first year might be estimated as £14000 (€15900/$18750) per patient.

Taken together, all these findings highlight that the optimization of hip fracture management care is mandatory in order to improve functional outcomes and to reduce sanitary costs. To date, it is widely accepted that the transdisciplinary approach to patients suffering from hip fractures is mandatory in the correct management of this condition to optimize both short-term and long-term outcomes[15]. More in detail, the Australian and New Zealand Guidelines[16] and the National Institute for Health and Care Excellence (NICE) guidelines[17] support a coordinated multidisciplinary approach covering care in all settings, from the ambulance to the discharge destination. Cornerstones of this approach were: Orthogeriatric assessment, optimi-zation of fitness for surgery, identification of rehabilitative goals, integration with related services including bone health and an adequate clinical and service governance

responsibility for all stages of the pathway of care and rehabilitation.

Therefore, an adequate coordination of different figures including orthopaedic surgeons, physical and rehabilitation physicians, geriatric physicians, physical therapists and caregivers should be planned for hip fracture patients.

The aim of the present article was to summarize current evidence supporting transdisciplinary management of patients with fracture of the proximal extremity of femur, highlighting the benefits, feasibility and limitations of this approach.

ORTHOPAEDIC SURGERY TIMING

It is widely accepted that timing for surgery has a key role in FFPE management[18-20], as also affirmed by the NICE guidelines[17] that recommended that an early surgery (within the first day or next day from the admission) improved functional outcomes in older patients with FFPE.

In this scenario, a recent meta-analysis performed by Simunovic *et al*[21] assessed the effects of surgery performed within the 72 h controlling for comorbidities, reporting significant benefits in terms of risk of death and lower rates of postoperative complications. Despite previous large studies suggesting that time for surgery could be considered as a comorbidity marker[22,23], higher rate of mortality and complication were recorded in patients with surgical delay over 24 h[24]. In contrast, a randomized controlled trial did not find significant differences between surgery performed within the first 6 h rather than within the first 24 h[25].

Albeit the early surgical approach is supported by high level of evidence according to both Australian and New Zealand[16] and NICE guidelines[17], the choice between conservative or surgical approach surprisingly seems to not be strongly supported by available literature. In particular, a Cochrane systematic review by Handoll *et al*[26] reported several biases in studies supporting surgical management, and the limited available evidence did not show significant differences between conservative and surgical management.

A recent systematic review and meta-analysis[27] assessed randomized controlled trials comparing conservative and surgical treatment. The authors included seven observational studies with a total of 1189 patients reporting that both 30 d and 1 year mortalities were higher in the conservative group rather than the surgical group (odds ratio (OR): 3.95, 95% confidence interval (CI): 1.43-10.96; OR: 3.84, 95%CI: 1.57- 9.41). Unfortunately, functional outcomes and health-related quality of life were not assessed by these studies.

Altogether, these findings suggest that early surgical approach should be considered in elderly patients suffering from FFPE, taking into account the need for a transdisciplinary integrated management of these patients.

TRANSDISCIPLINARY MANAGEMENT OF PATIENTS WITH FEMUR PROXIMAL EXTREMITY FRACTURE

A transdisciplinary management of FFPE patients started from a model of a "fracture liaison service" that might reduce the osteoporosis treatment gap, improving functional outcomes in these patients[28-30]. Figure 1 describes a model of a transdisciplinary management of patients with FFPE.

Lin *et al*[31] recently performed a meta-analysis assessing the effects of comprehensive geriatric care. They reported a consistent decrease of overall mortality (OR: 0.71; 95%CI: 0.53-0.95), whereas independence in activities of daily living significantly improved (standardized mean difference: 0.29; 95%CI: 0.12-0.47). Despite reports that hospital-based transdisciplinary rehabilitation could be more expensive than usual care, the sanitary costs may be offset by the benefits in terms of reduced length of stay and independence at discharge[32].

Furthermore, interdisciplinary management might play a key role also in the screening for common co-occurring conditions, such as delirium or pain[33]. In particular, delirium is very common after hip fractures, with a prevalence between 13.5% to 33.0%[34] and was shown to negatively affect clinical and functional outcomes[35,36]. Unfortunately, the clinical manifestations are heterogeneous, ranging from a hyperactive delirium, characterized by irritability, pressured speech and uneasiness to a hypoactive delirium, characterized by quiet mobility reduction, special-temporal disorientation, carelessness and trouble to answer simple questions

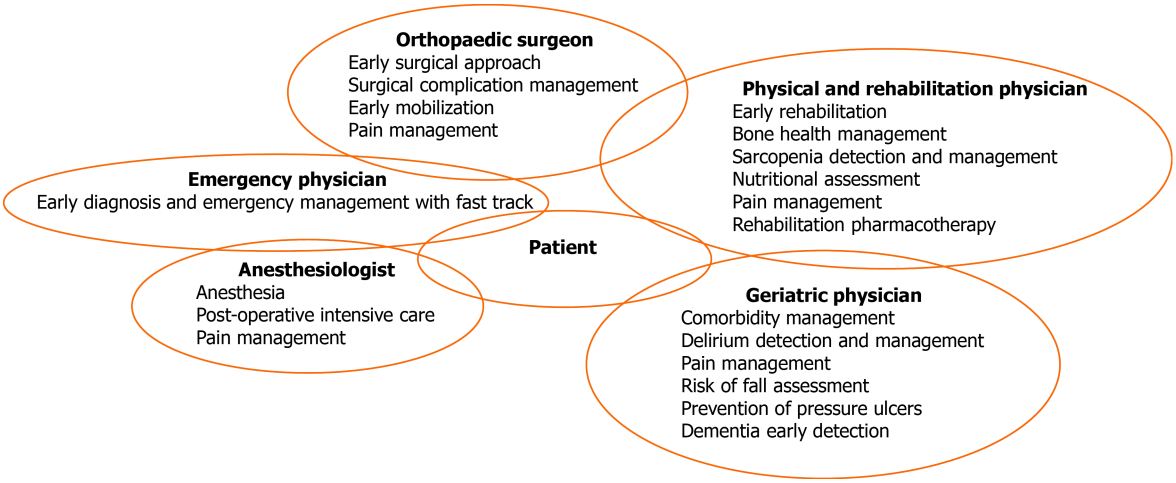


Figure 1 Model of a transdisciplinary management of patients with femur proximal extremity fracture.

[37]. A transdisciplinary screening for delirium should be provided across the FFPE management to avoid detrimental consequences on functional outcomes, complications and even mortality[10]. Unfortunately, routine assessment remains uncommon with approximately 39% of hip fracture patients suffering from delirium at discharge and 32% at 1 mo after fracture[36].

Taking into account that pain is a major risk factor for delirium, adequate management is mandatory to reduce delirium onset[10,38]. NICE guidelines[17] recommend analgesia administration within the first 30 min from hospital admission. Paracetamol should be considered as first-line in the management of the elderly with FFPE. However, frequent analgesia targets were not reached by paracetamol administration only. Therefore, oral opioids should be considered even if intravenous opioids provide faster relief[39]. Recently, peripheral nerve blocks have been introduced in managing pain and minimizing the side effects and sedation related to opioid drugs [40,41]. In addition, continuous blocks can be included after surgical intervention for postoperative analgesia, with potentially positive effects in terms of pain, confusional state and probably in time to the first mobilization[42].

In this context, an early rehabilitation might reduce pain in FFPE patients and should be adequately planned particularly in elderly patients.

REHABILITATION AND MANAGEMENT OF OSTEOSARCOPENIA

Rehabilitation is recommended by the main Osteoporosis Guidelines available in the literature in patients with osteoporotic FFPE[43]. The main goals of the rehabilitation management are reducing pain, improving physical function, independence in activities of daily living and health-related quality of life[44]. Oldmeadow *et al*[45] reported potential benefits of walking 24 h or 48 h from surgery compared to delayed assisted ambulation after 3 d or 4 d from surgery. Moreover, a higher rate of discharge to home (26.3%) was recorded compared to the delayed ambulation group (2.4%). In a single-blinded cohort study, Overgaard *et al*[46] assessed progressive strength training shortly (17.5 ± 5.7 d) after FFPE surgery in outpatients, with positive effects in terms of pain and functional outcome measurements.

In this context, rehabilitation plays a key role in the comprehensive management of FFPE patients, taking into account the positive effects of exercise in the recovery of functional status[47] and for balance and prevention of risk of falling, which is a major determinant of refracture occurrence[48].

During the transdisciplinary management of FFPE patients, caregivers should be included across the whole pathway[49,50]. As a matter of fact, functional impairment resulting from FFPE in elderly patients require long-term care in different settings. Albeit the transition from hospital to home should be conducted by health professionals[51], in outpatient settings, caregivers should be informed and trained with health education programs in order to optimize patient management at home[52-54].

In this scenario, long-term management of FFPE patients should include osteoporosis and sarcopenia screening[17]. In light of this consideration, dual-energy x-ray absorptiometry should be performed to provide data of the baseline condition

and treatment monitoring, whereas bone densitometry exams are not mandatory to start anabolic/antiresorptive treatment. However, promising studies showed that ultrasound assessment might be used for osteoporosis diagnosis[55,56].

Despite bone health playing a key role in patients suffering from FFPE, the optimal management of patients with fragility fractures is still evolving, with new pharmacological therapeutic strategies including sequential therapies aimed at optimizing bone formation or inhibit bone resorption[57].

Bisphosphonates are still the osteoporosis drug most commonly prescribed, characterized by antiresorptive action induced by osteoclast function inhibition[57,58]. However, denosumab, a fully human IgG2 monoclonal antibody preventing the development of osteoclasts by RANK inhibition, has been introduced as effective therapy for osteoporosis in the last decade[58,59]. In contrast, an anabolic drug such as teriparatide might stimulate bone formation and could be used in FFPE patients for a limited period of time (anabolic window)[60].

Several exercise modalities have been proposed as nonpharmacological treatments to prevent bone loss, increase bone mineral density and reduce fall risk[61]. In particular, balance training, weight-bearing, strength training, progressive resistance exercise and Tai Chi seem to be effective in both osteoporosis prevention and treatment. Moreover, these exercise trainings were encouraged by national and international recommendations[62]. Exercise therapy should be tailored to patients' characteristics, focusing on back extensors and hip muscles due to the widely noted osteogenic effects of physical exercise and the improvement in terms of balance control [63,64].

Moreover, besides osteoporosis management, physicians should focus on sarcopenia, taking into account the strict relation among muscle strength, function impairment and risk of fall. More in detail, sarcopenia is considered a multifactorial common condition sharing several pathophysiological mechanisms with osteoporotic hip fracture patients[47].

A recent meta-analysis including more than 10000 older patients reported that sarcopenic patients have a higher risk of falls compared to non-sarcopenic ones (pooled OR: 1.52, 95%CI: 1.32-1.77, I^2 = 39.1%)[65]. However, risk of fall is not the only mechanism linking sarcopenia and FFPE. Indeed, sarcopenia and osteoporosis share several underlying pathogenic factors, including cellular biomolecular pathways involving muscle-derived cytokines (myokines) influencing bone density, growth and repair[66].

Moreover, albeit aging is the most common risk factor for sarcopenia, malnutrition has been widely recognised to be strictly related to sarcopenia onset. In this context, previous studies reported a malnutrition prevalence in hip fracture patients ranging from 40% to 80% of hospitalized patients[67,68]. Furthermore, it has been reported that malnutrition may be considered a risk factor for FFPE, and it is a strong predictor of poor functional recovery[10,67]. In this scenario, oral nutrition supplementation has been proposed to reduce minor postoperative complications after FFPE, with promising results even in overall length of stay[69-71]. Nevertheless, a recent systematic review reported several methodological flaws on trials supporting oral supplementation, underlining that nutritional interventions were supported by only weak evidence[69]. In addition, nutrient supplementation without exercise seems ineffective in muscle strength improvement or physical frailty[72,73].

On the other hand, it has been reported that micronutrients might play a key role in the musculoskeletal system, promoting muscle anabolism and functioning in older people[74,75]. Therefore, combined nutrition and physical exercise might be crucial to treat complex and multifactorial conditions affecting the musculoskeletal system, including sarcopenia in hip fracture patients[76,77].

Taking into account these findings, our group has recently performed a pilot randomized controlled trial[47] to assess the effects of a transdisciplinary rehabilitative and nutritional approach, showing promising results in terms of strength and physical function in sarcopenic hip fracture patients. Moreover, a further analysis in a subgroup of this population suggested that serum myostatin levels might be considered as promising biomarkers of sarcopenia in hip fracture patients undergoing rehabilitation after orthopaedic surgery[78].

In this scenario, the "rehabilitation pharmacotherapy" has been recently introduced to characterize medical management based on optimization of functional outcomes and minimization of adverse effects on nutritional status[79].

Thus, these findings suggested that a comprehensive long-term patient-tailored rehabilitative approach should be planned for the elderly with FFPE to optimize physical exercise, nutritional intake, bone health and medical drugs to promote complete functional recovery of frail patients.

However, despite the large amount of literature supporting a transdisciplinary approach in the elderly suffering from FFPE, the feasibility in most hospital settings still remains difficult. We retain that this approach might optimize the integration among hospital care management, rehabilitative outcomes and ensure continuity of care at discharge[80,81].

DEMENTIA IN HIP FRACTURE PATIENTS

Dementia is a cognitive disorder characterized by intellectual function impairment affecting both function and social performance[82,83]. Recent studies[84,85] reported that approximately 19% of patients with FFPE meet diagnostic criteria for dementia. In addition, considering that age represents one of the most common risk factors for dementia, the number of hip fracture patients with dementia is expected to increase worldwide. To date, previous evidence showed that FFPE older patients with dementia were admitted to long-term care more frequently, and the mortality rate was significantly higher in these patients[86]. In this scenario, targeted interventions are needed to optimize a multidisciplinary management of hip fracture patients with dementia. In particular, structured and familiarised routines, orientation to environment and cues were proposed to enhance care pathway and their rehabilitation plan [87].

Despite physical and cognitive rehabilitation were considered as effective therapies to improve functional and performance outcomes in elderly, a gap in the current literature in terms of effectiveness in patients with dementia has been shown[88]. Similarly, a recent Cochrane systematic review[89] reported very low-quality evidence supporting geriatrician-led recovery and enhanced rehabilitation strategies in the functional recovery of elderly patients with dementia after FFPE surgery.

Therefore, the optimization of rehabilitative pathways in these particular patients might be considered a challenge. However, multidisciplinary management should be tailored to the patients in order to overpass cognitive impairment limitations to optimize functional outcomes of patients with dementia. Unfortunately, albeit the optimal rehabilitation and care model is still uncertain, an early detention in addition to dementia-focused treatment might be considered in the future, taking into account the potential role of assistive technologies and caregivers in the recovery pathway of these patients.

Furthermore, in light of these considerations, fragility fracture prevention should be emphasized to improve long-term management of patients with dementia. In contrast, it has been reported that dementia could be strictly linked to osteoporosis[90]. However, bone health management could be frequently underestimated in the elderly with cognitive impairment due to the short life expectancy of these patients[91]. On the other hand, a growing number of papers underlined poor compliance with osteoporosis drugs, especially in patients with dementia or elderly with polypharmacotherapy[92].

Therefore, given the high sanitary burden and the social consequences of fragility fracture recurrence, osteoporosis management should be emphasized considering subcutaneous denosumab or annual zoledronic acid infusions characterized by a lower discontinuation rate and earlier onset of efficacy in fracture reduction[93], with possible implications in long-term outcomes of patients after fragility fractures with dementia.

STUDY LIMITATIONS

Albeit the aim of the present article was to underline the key role of transdisciplinary management of patients with FFPE, some limitations should be taken into account before drawing conclusions.

First, in the clinical scenario, FFPEs are composed by a wide variability of anatomic presentations including head fractures, femur neck fractures, intertrochanteric fractures, subtrochanteric fractures and proximal femur shaft fractures. In the era of precision medicine, we are aware that a specific stratification should be provided to clearly present data of FFPE, given the strict linking among anatomic presentation, surgical intervention, bone health and rehabilitation. Unfortunately, the present editorial did not distinguish FFPEs; however, this intrinsic limitation reflects the high number of studies in the literature considering FFPE as a single pathology, resulting in a wrong generalization of study results probably affected by the type of fracture, with

crucial implication in terms of evidence supporting a patient-tailored therapeutic plan.

Furthermore, it should be noticed that the high heterogeneity of key topics discussed in the present study did not allow a systematic review to be performed. In light of these considerations, a narrative analytical technique has been performed to highlight the gaps in the current literature and to guide future research and clinicians in a tailored transdisciplinary management of FFPE.

CONCLUSIONS

Taken together, the optimization of FFPE patient management should be considered as crucial to avoid the detrimental consequences on functional outcomes and the assistance and healthcare burden related to fragility fractures. Albeit the current literature supports a transdisciplinary care of elderly patients suffering from FFPE, global challenges still exist to implement these findings in the common clinical practice. The main limitation in terms of generalization of organization models might be found in the large heterogeneity of settings, healthcare models, community opportunities and specializations involved in the complex management of these patients. It would be optimal to be able to organize the care of these patients in multidisciplinary hospital wards of orthogeriatrics. However, this editorial was meant to describe the need to define a tailored transdisciplinary management that could be performed in the common clinical practice to reduce functional and social consequences of patients with FFPE. Further studies are warranted to define feasible organization models supported by clear evidence to manage FFPE patients across the whole health care pathway, in both inpatient and outpatient settings.

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REVIEW

Technological advancements in the analysis of human motion and posture management through digital devices

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Abstract

Technological development of motion and posture analyses is rapidly progressing, especially in rehabilitation settings and sport biomechanics. Consequently, clear discrimination among different measurement systems is required to diversify their use as needed. This review aims to resume the currently used motion and posture analysis systems, clarify and suggest the appropriate approaches suitable for specific cases or contexts. The currently gold standard systems of motion analysis, widely used in clinical settings, present several limitations related to marker placement or long procedure time. Fully automated and markerless systems are overcoming these drawbacks for conducting biomechanical studies, especially outside laboratories. Similarly, new posture analysis techniques are emerging, often driven by the need for fast and non-invasive methods to obtain high-precision results. These new technologies have also become effective for children or adolescents with non-specific back pain and postural insufficiencies. The evolutions of these methods aim to standardize measurements and provide manageable tools in clinical practice for the early diagnosis of musculoskeletal pathologies and to monitor daily improvements of each patient. Herein, these devices and their uses are described, providing researchers, clinicians, orthopedics, physical therapists, and sports coaches an effective guide to use new technologies in their practice as instruments of

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Core Tip: Movement, gait, and posture analysis are increasingly crucial in the clinical setting and everyday life. Researchers have different tools at their disposal, such as markerless systems or lightweight wearable devices that allow human movement to be analyzed in biomechanical laboratories and sports fields. This review aims to compare the most sophisticated analysis systems with the most current digital devices to highlight specific characteristics and suggest their applications in the fields of surgery, rehabilitation, posture, and sport.

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INTRODUCTION

Over the last decades, human movement research has made significant progress in responding to the growing medicine and sport demand for precise and accurate methods to capture human movement[1] and refine data collection[2]. Motion and posture analyses are effective tools used in diagnosis, therapy, and prevention of musculoskeletal disorders. Notably, human motion assessment during functional activities also plays a crucial role in rehabilitative medicine and sports. Nevertheless, there is a solid need to diversify the use of each system in relation to specific contexts. In some instances, 2D biomechanical analysis can offer a quick and effective method of evaluation. Movements, such as walking or running, do not require sophisticated approaches, since they are easily analyzed in the sagittal plane. Otherwise, if the movement needs to be studied on multiple planes or forces investigation is required, it is more appropriate to use a 3D system, which requires in-depth expertise. Biomechanical researchers aim to standardize human movement parameters that can be understandable, comparable, and shareable with the entire scientific community. Quantitative analysis of human movements and posture is an effective tool used to analyze the correct movement execution, identify injury risk factors[3], help clinicians make the best decision to reduce patients' recovery time, and suggest a proper treatment plan[4].

Assessing walking speed through wearable systems could be a valuable indicator of adults' health and functional status[5,6]. For example, low physical activity levels are associated with muscle weakness, decreased mobility function, and widespread pains [7]. Fast return to play sports and exercise could trigger joint pains and musculoskeletal alterations; therefore, an accurate motion and posture analysis could help planning the right approach to resume physical activity.

Hence, technological devices can broadly be used to diagnose musculoskeletal disorders and plan a preventive strategy for returning to the sport practice. Similar advice is suggested for those who return to physical activity after surgery. Long periods of inactivity caused by surgery inevitably lead to loss of muscle mass and reduction of movements fluidity; therefore, movement analysis in the return-to-daily-activities phase can be performed to detect dysfunctions and re-educate the patients.

Although marker-based and non-invasive systems are more commonly used to evaluate pathological patients, *e.g.*, subjects with spinal cord damage, amputees, strokes and cerebral palsy, scoliosis…, instrumental biomechanics have the potential for reaching every subject, from the one who suffers from musculoskeletal pathologies to the one who reports only mild pain. Therefore, it is encouraged to use these devices to study every and unexplored aspect of movement science. This review aims to

highlight the importance of new technologies in human movement and posture analysis, suggesting how they can strengthen orthopedics, rehabilitation, health prevention, sports science and guide the clinicians towards a personalized diagnostic process and treatment plan based on the patient's characteristics.

FROM MARKER-BASED TO MARKERLESS MOTION ANALYSIS SYSTEMS

The optoelectronic stereophotogrammetric multi-camera capturing system is the gold standard for motion analysis, tracking reflective markers placed on the body[8,9]. One of the most known, the Vicon system (Vicon Motion Systems, Oxford, United Kingdom), consists of multiple infrared cameras for kinetic, kinematic, and spatiotemporal movement analysis. The markers, positioned on anatomical landmarks in correspondence with the joints involved in the analysis, allow tracking all the human motion features with high accuracy[10,11]. This system precisely evaluates each joint's movements in the space at any time, and it can define the level of functional limitation and disability resulting from the evolution of a disorder, including post-traumatic or surgical alterations. Vicon is commonly used in clinical gait analysis, amputee rehabilitation, lower limb movement studies, cerebral palsy research, motor control, and neurosciences. The company produced a platform for the life sciences community called Nexus, a powerful, all-inclusive modeling and processing tool for movement analysis. Operators can reduce the time spent processing the data by creating their workflow templates; the system automatically loads the data and produces the report in the simplest or most detailed way required. However, marker-based systems show several limitations, including long preparation times, soft tissue artifacts, or unfeasibility of specific movements due to the presence of the markers, which can hinder the correct execution of the movement[12]. These systems are expensive and require a large setting in order to place all the cameras needed for the analysis. The placement of the markers on anatomical landmarks can be challenging since it depends on the clinician's ability to locate them correctly and, therefore, human error could incur. Particularly for transverse plane movements, there is an inevitable variability in the marker positioning between different days or different clinicians' hands, reducing the measurements' reliability[13]. In the literature, several protocols can be found for locating joint centers or defining segment pose, as shown in Figure 1A; however, these different protocols produce variable results, especially for the sagittal plane, compared to the same gait cycles[13]. These drawbacks can limit the use of marker-based systems within certain areas of motion analysis. For these reasons, nowadays, markerless systems are offering new opportunities to obtain similar results.

The markerless motion analysis system presents a fast, fully automatic, and non-invasive approach that can significantly improve research and practice within sports biomechanics and rehabilitation. For instance, motion can be analyzed during normal training in a common laboratory, without the long preparation times due to the markers placement and the laborious manual work. Furthermore, it can provide a reasonable solution for a common dilemma faced in biomechanics laboratories, *i.e.*, the constant search for balance between accuracy and reproduction of motion without artifacts. Several researchers investigated the most common movements studied in biomechanics laboratories, *e.g.*, walking, jumping, and jogging, by analyzing the accuracy of markerless systems compared to marker-based techniques[14-16]. Therefore, a potential application of markerless systems in gait analysis in clinics is suggested, even though an experienced clinician should validate the results to ensure their reliability. The most popular markerless system, the Microsoft Kinect v1, is the first 3D camera whose affordable price made it accessible to almost all consumers. One of its innovations was that the sensor was suitable for gait assessment outside the laboratory, becoming a portable device[17-19]. Soon after, Microsoft launched the Kinect v2 with improved hardware and skeleton tracking system; its software, Kinect for Windows SDK 2.0, allows tracking the 3D positions and orientations of 25 joints, up to 6 users simultaneously[20]. This camera can track the skeleton through artificial intelligence (AI). Briefly, this feature allows recognizing joint centres and segment orientation, providing the ability to calculate joint kinematics and spatiotemporal aspects of the movement. The Microsoft Research team produced a specific algorithm to identify the anatomical landmarks, created by training a randomized decision forest algorithm using a subset of 100000 depth scans of a variety of movements, including running, dancing, driving, kicking[21].

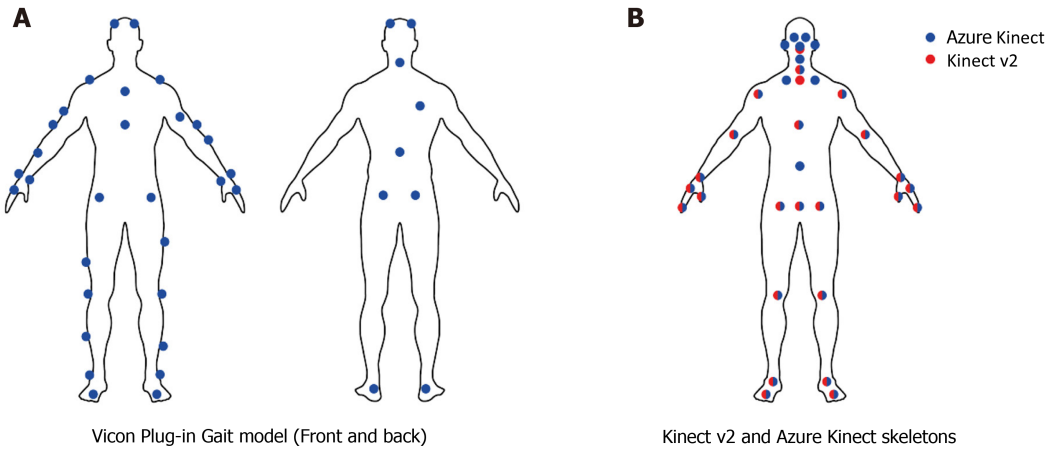


Figure 1 Markers setup for Vicon and markerless caption for Kinect cameras[28]. A: Markers setup for Vicon; B: Markerless caption for Kinect cameras.

In recent years, several studies investigated the reliability of Kinect v1 and v2 to evaluate if these devices could be used as an alternative to the multi-camera motion capturing systems. Several contexts were examined, such as walking on a treadmill or performing physical exercises at a static location[22]. Wang *et al*[23] examined the differences in human pose assessment between Kinect v1 and Kinect v2 in relation to twelve different rehabilitation exercises. The authors reported that Kinect v2 has overall better accuracy in joint estimation and body rotation detection than Kinect v1. Capecci *et al*[24] investigated the accuracy of Kinect v2, in terms of joint positions and angles, during dynamic postures used in low back pain rehabilitation, reporting that this system can measure timing characteristic of physical exercises and reproduce dynamic features similar to a stereophotogrammetric system[25,26]. Microsoft ended the production of the Kinect v2[27] in favor of new technology, the Azure Kinect DK. The latter offers significantly higher accuracy than other commercially available cameras[28]. Unlike the Kinect v2, the Azure Kinect employs a Body Tracking SDK to track multiple users up to 32 joints, as shown in Figure 1B; it includes more joints, *i.e.*, anatomical landmarks, in the face area, such as ears and eyes. Albert *et al*[28] collected data from Microsoft Kinect v2 and Azure Kinect in gait analysis and compared them to the Vicon system. The results showed high accuracy of both cameras, Microsoft Kinect v2 and Azure Kinect, but the latter showed better accuracy for spatial gait parameters. Figure 2 shows spatial agreement of Microsoft Kinect and Azure Kinect cameras with respect to the Vicon system. Walker View (Tecnobody®-Dalmine, Italy) is a treadmill whose base includes eight load cells that allow the system to detect the user's spatiotemporal parameters. The presence of a Microsoft Kinect 2 camera automatically identifies anatomical landmarks using AI. The system is connected to a 49" LCD Monitor for the biofeedback and the virtual reality. Its advantage is the fully automatic and non-invasive approach, which is also an improvement in sport and rehabilitation research and practice. During the testing phase the patient/athlete can auto select the preferred walking speed or choose the Speed Control feature that adapts the treadmill speed to user's step velocity. In addition to the gait analysis, the Walker View can also perform run analysis, an especially useful evaluation for athletes. Regarding the training area, the patient can perform the Gait Trainer program where the software, through visive and acoustic feedback, helps him to improve his walking. Furthermore, the Walker View, thanks to the Smart Gravity system, can be used for patients with severe walking deficits unable to stand on their own. This system consists of a mechanical support to which a sling worn by the patient is connected. It can simulate a walk in the pool by selecting the appropriate weight reduction as if it were hydrokinesitherapy.

Miniaturized inertial measurement units (IMUs) are a new generation of lightweight, small, and inexpensive systems embedding 3D accelerometers, gyroscopes, and magnetometers, which may offer other opportunities for the biomechanical assessment of motor functions. IMUs can track the trajectory of anatomical segments in real-time and estimate the kinematic parameters of the gait cycle[29]. Although evaluation protocols are not homogeneous, several studies estimated the possibility of assessing the gait analysis through IMUs[30-34], as reported in Table 1. Fusca *et al*[35] recruited ten volunteers on which they placed markers for motion capture using Elite

Table 1 Studies investigating the reliability of inertial measurement unit sensors

Ref.	Sensor/position	Comparison system	Results	Outcomes
Qiu *et al* [29], 2016	3 magnetic angular rate and gravity/thigh, shank, and foot	Vicon	Position accuracy of 0.3%, the ΔXY radial distance error of 0.82% and the distance error of 0.27%, position error of 0.4%	The combination of distributed wearable sensors with the Denavit–Hartenberg convention resulted in a promising tool for tracking lower limb movements
Sprager *et al* [30], 2015	1 multi-sensor platform integrated into a smart garment/knee	NP	Good activity discrimination can be achieved based RMSE and SD from flexible sensor, acceleration and gyroscope data	Preliminary results show that walking, running, stairs climbing can be discriminated based on the data collected
Cresswell *et al*[33], 2017	4 Shimmer3 sensor nodes/all sides of the shank	NP	The results of the fixed effects models highlighted the discrepancies between front–back mounting versus inner–outer mounting	For y-axis gyroscope data, the variation is mostly influenced by mounting location. Mounting location should not vary but if it has to vary, it is better for it to vary between inner and outer leg mounting locations
Fusca *et al* [35], 2018	1 IMU/posterior CoM	Elite (BTS)	Mean absolute percentage error of: Stride time is 5.7%; Cadence is 4.9%; Step's length is 5.6%; Step's speed is 13.5%	The use of IMU at CoM presents a good reliability for carrying out ambulatory, long-term, and ecologic kinematic of gait analysis
Saggio *et al* [36], 2020	7 IMU/pelvis, thighs, shanks and feet	Vicon	Joints ROMs RMSE and ICC PCC > 0.75, Reliability all the ICC > 0.975	IMUs sensors showed a high reliability on joints' movement and walking test

IMU: Inertial measurement unit; ICC: Intra-class correlation coefficients; RMSE: Root mean square error.

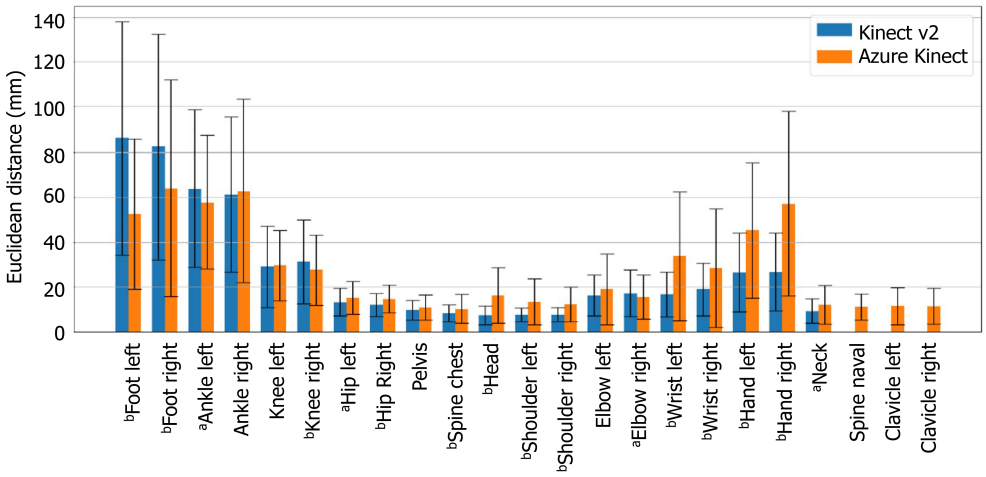
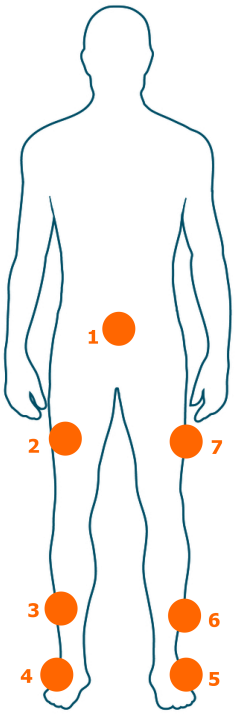


Figure 2 Spatial agreement of Microsoft Kinect and Azure Kinect cameras with respect to the Vicon system. Errors are represented as means ± SD of the 3D Euclidean distances between according joints. $^{a}P < 0.05$, $^{b}P < 0.01$[28].

(BTS) System, and IMU sensor placed anteriorly and close to the body's center of mass. The authors stated that it is preferable to place the IMU sensor posteriorly between the superior anterior iliac spines since abdominal breathing could lead to artifacts. Four walking trials were simultaneously recorded at a self-selected speed by blindly comparing the two systems. The stride time and the cadence had a mean absolute percentage error of 5.7% and 4.9%, respectively, for IMU. The mean absolute percentage errors were 5.6% and 13.5% in the step length and step speed measurement, respectively. Therefore, results confirmed that the IMU is effective for a reliable assessment of human gait spatiotemporal parameters. The Italian Company Captiks Srl developed a novel inertial-sensor based system, Movit System[36], which allows measuring gait parameters by positioning the IMUs through elastic bands on the pelvis (between iliac crests), thighs, shanks, and feet, as shown in Figure 3. The company compared the results obtained from Movit System and Vicon optoelectronic system. According to the statistical analysis of the data on joint ROM reported by Cuesta-Vargas *et al*[37] and Poitras *et al*[38], the authors agreed on the excellent accuracy and test-retest reliability of IMUs on joint movement and walking tests. IMUs can encounter some drawbacks: these devices are placed on the human body through



Sensor	Anatomical landmarks
1	Pelvis L5 level
2	Right thigh at mid-height of the femur
3	Right shank over the malleolus
4	Right foot in the dorsalis pedis
5	Left thigh at mid-height of the femur
6	Left shank over the malleolus
7	Left foot in the dorsalis pedis

Figure 3 Body position of the seven inertial measurement units of Movit System.

elastic bands, but unpredictable vibration artifacts can occur if the wearables are not firmly and adequately fixed. This represents an important issue since the artifacts are in the signal's frequency band, so not removable by filtering. Besides, misplacement of the sensors and movements that could cause the sensors to slip can lead to wrong measurements and make the analysis inconclusive[35]. The main differences between the mentioned motion analysis systems can be found in Table 2.

Considering that three-dimensional motion capture systems are rather expensive, different low-cost methods have been developed during recent years. For instance, Kinovea is a free 2D motion analysis software for computers that can measure kinematic parameters. This software allows analyzing video without markers, although its reliability may improve with marker positioning[39]. Several studies tested Kinovea software[40-43] in different environments with good results: Damsted *et al*[39] investigated its ability to detect hip and knee joint positions in the initial contact phase during running; Elwardany *et al*[44] analyzed the range of movement of the cervical spine in the sagittal plane while Mathew *et al*[45] used this software to study the ankle, knee, and hip joints at different gait cycle phases. Kinovea only needs a camera and eventually some markers, although it requires an experienced clinician to use it. Once the movement is recorded, the clinician, in post-production, places the virtual anatomical landmarks over the joint centers or the markers physically positioned on the user. Unlike Microsoft Kinect, Kinovea does not have the appropriate software for the skeleton tracking system, so accurate marker placement or precise location of virtual anatomical landmarks is required to evaluate the movement correctly, otherwise, the results may not be valid. As a matter of fact, the main limitations uncovered by the literature concern the lack of a standard video analysis protocol and the marker placement[44,45]. The study conducted by González *et al*[42] evaluated the inter- and intra-rater reliability of Kinovea and the agreement with a three-dimensional motion system (Vicon) to detect the lower limb's joint angles during walking. The results showed significant differences in the hip, knee and ankle angles reporting a ± 5° difference for the hip and ankle angles, ± 2.5° for knee angles. According to McGinley *et al*[46], an error of 2° or less is considered acceptable in clinical evaluation. Errors between 2° and 5° are also reasonable, although the data should be interpreted cautiously. Errors over 5° could mislead the interpretation. To conclude, as reported by Littrell *et al*[47], the use of Kinovea could lead to high error for the pelvis and the foot during the stance period of the gait cycle. However, the software is reliable when analyzing other phases of walking and other kinematic parameters such as joint angles[48], especially for sports environments or dynamic conditions where sophisticated systems could be impossible to be used.

Table 2 Main features of motion analysis systems

Motion analysis systems	Capture system	Anatomical landmark	Recording system
Optoeletronic measurement system	Stereoscopic 3D	Passive or active markers placed	Multi-IR cameras with stroboscopic LED
Microsoft Kinect	ToF method	Markeless	1 RGB - IR Camera
IMU	9 DOF	Sensor placed with elastic band	Microprocessor processing raw data

LED: Light-emitting diode; DOF: Degree of freedom; ToF: Time of flight; IMU: Inertial measurement unit; RGB: Red, green, blue.

Recently, the use of smartphone applications (app) to measure gait parameters increased. Clinicians, researchers, and coaches can use these applications to analyze joint angles immediately. Unlike the previously mentioned systems, mobile applications are less expensive, portable, and easy to use. Although there is a lack of scientific studies investigating their reliability, the possibility of quickly measuring posture and joint angles in ordinary circumstances makes these applications compelling. Coach's Eye (TechSmith Corp) is a 2D motion analysis mobile app able to evaluate gait analysis in patients and healthy individuals[49], although it was specifically designed for coaches and trainers to assess athletic performance. The app computes joint angles and their variations by a digitized goniometer without applying any marker on the body. The videos can be recorded on frontal and sagittal planes and analyzed, frame by frame, going forward or backward. An online video database allows comparing the recorded videos with those of other athletes. However, only a few studies compared the app's data with the 3D motion analysis systems during sports tasks. Mousavi *et al*[50] investigated the validity and reliability of Coach's Eye app for selected lower-limb kinematics during treadmill running by comparing the results with those deriving from a traditional 3D motion analysis system (Vicon). The authors recruited 20 healthy female recreational runners who wore 16 reflective markers for the 3D comparison. The subjects were asked to run on a treadmill at a self-selected speed. Concerning the validity, Coach's Eye showed only 1-2 degrees of difference compared to Vicon in kinematic measurements for the sagittal plane hip angles at touchdown and toe-off, knee angle at touchdown, ankle angle at toe-off, and rearfoot angles at touchdown and toe-off. Measures of ankle angle at touchdown and knee angle at toe-off were not as accurate, reporting a bias ranging from 4 to 20 degrees. Furthermore, Coach's Eye demonstrated excellent test-retest reliability for all joint kinematic measures, in agreement with Krause *et al*[51] who reported high reliability of the application during the squat execution.

The authors recommended the use of Coach's Eye to record and assess sagittal plane lower-limb joint kinematics and rearfoot in/eversion at touchdown, hip, ankle, and rearfoot eversion at toe-off, but not for hip and ankle at touchdown or knee at toe-off. Nevertheless, given its ease of use and low cost, it would represent a manageable tool for sports coaches who frequently evaluate athletes.

Electromagnetic motion acquisition systems consist of a series of receivers that measure their position in space and transmit it to a nearby receiver. They are based on the electromagnetism principle: the emission source produces an electromagnetic field, and the sensors send the signal *via* cable to the processing unit, then the computerized system calculates sensors' position and direction in space based on these signals. For example, Polhemus and Ascension are two of the most popular companies producing electromagnetic motion systems[52,53]. This system finds application in analyzing a single fine movement, such as taking an object with the hand, which has high accuracy and a low margin of error compared to camera-based systems[54]. However, complex movement analysis, such as walking, could be challenging. For this reason, the application is less suitable for clinical and sports movement analysis, such as gait analysis or technical sports gestures. Conversely, the entertainment industry exploits its high accuracy to reproduce the movement executed by a performer over a digital character[55]. Recently, Polhemus enabled localization of medical instruments through the trackers, especially for image-guided therapy[56]. The application of electromagnetic systems can be notably valid to enhance the medical students' skills, such as the use of endoscope and surgical instruments, tissue manipulation, use of precision tools, and other procedural skills before operating on patients.

In summary, the optoelectronic system is undoubtedly the gold standard for motion analysis, although modern markerless options might overcome some disadvantages and offer a valid alternative for outdoor examination. The strength of markerless systems relies on testing more users in shorter times and less equipment than the

marker-based system. The markerless approach is more suitable for sport and rehabilitation purposes rather than diagnostics. Another way to capture human motion is by IMUs, lightweight devices easy and comfortable to be used almost everywhere. Finally, software or mobile application is applied, especially in athletic contexts where sophisticated tools collide with sport practice.

GAIT ANALYSIS IN PREVENTION AND HEALTH PROMOTION

Gait analysis is recognized as a useful assessment tool in the field of human movement research, commonly used in biomechanical laboratories to assess walking ability in patients with specific motor disabilities[57-60], often due to conditions as severe developmental motor impairments[61], spinal cord damage[62], amputees[63], orthopedic surgery[64], strokes[65] and cerebral palsy[66]. Specifically, clinical gait analysis can be classified into two levels of examination: a first level which deals with the clinical evaluation of the lower limb impairments by collecting data from spatiotemporal parameters, kinematics, and kinetics of locomotion; a second level which involves the use of dynamic electromyography, during gait, to evaluate the neuromuscular activity[67]. For the purely medical use, the SIAMOC (Italian Society of Clinical Movement Analysis) proposes these guidelines: (1) in cerebral palsy, the use of gait analysis, combined with an expert clinical evaluation, can influence the planning of functional surgery; (2) in adult brain injuries, the use of gait analysis can influence the orthopaedic surgery, neuromuscular blocks or rehabilitation programs; and (3) in patients wearing lower limb prostheses, gait analysis might be useful for choices regarding the construction of the prosthesis and the planning of general models of rehabilitation[68]. Information deriving from this evaluation allows to increase diagnostic accuracy, differentiate diagnosis and severity, and help in decision-making about the treatments. Evidence demonstrates the efficacy of 3D gait analysis in defining gait problems, their causes, and the appropriate treatments (*e.g.*, surgery against non-surgical treatment or type of surgery). However, gait analysis continues to be a helpful tool partially exploited. The literature is not yet robust regarding using this system even outside clinical contests. Therefore, human motion analysis is limited to clinical examination, *i.e.*, orthopaedic, neurological, or surgical, not considering the possibilities deriving from daily life evaluation. Prevention and health promotion science could exploit gait analysis to avoid that a simple dysfunction develops into an actual disease. What would happen if orthopaedic patients performed gait analysis as a routine examination rather than in sight of surgery? For instance, according to Meireles *et al*[69], the early stages of knee osteoarthritis are challenging to detect, but it is known that biomechanical factors may contribute to its onset[70-73]. This study calculated knee contact forces and their relations with external knee adduction and flexion moments and reported that mechanical loading was not significantly higher in early osteoarthritis subjects. These results highlight the possibility that other causes (*e.g.*, spatiotemporal parameters, hip or ankle kinematics) might occur to develop osteoarthritis and therefore, gait analysis might be considered in disease management since current treatments offer limited benefits[74]. Several contests can benefit from an accurate gait analysis guiding clinicians towards the best decision based on patients' needs. Pathologies involving walking abnormalities that afflict the central nervous systems are highly variable, and several different motor patterns can be altered. In cerebral palsy subjects, gait analysis investigated the common altered gait patterns, including jump knee gait, toe-toe gait, crouch knee gait, stiff knee gait, and rotational abnormalities. However, each subject presents a unique combination of impairment and compensatory movements so, gait analysis can help clinicians recognizing the primary deformities and how they affect the musculoskeletal[75]. While the use of this approach in cerebral palsy has been widely investigated, there is less evidence in other neurological conditions. Gait analysis among spinal cord-damaged populations can help establish individualized interventions to enhance walking, improving muscle strength, coordination, proprioception, and postural control. Specifically, Murphy *et al* [62] highlighted how gait analysis could provide specific information to clinicians to deal with spasticity management, *i.e.*, botulinum toxin-a injection; best orthotic selection, *i.e.*, hinged or rigid; surgery, *i.e.*, joint fusion; or establish the well-suited rehabilitation program[76]. In orthopedic contests, gait analysis can enhance understanding the subject's functional capacity reduction before surgery and, in the same way, indicate the elements that need to be improved following the surgery[77]. The fear of moving after surgery is often present in patients[78]; digital support, in this case, can help the patient understanding that within a specific range of movement,

e.g., walking for 500 m or walking at speed 2 km/h, will not suffer further pain and will not negatively affect recovery.

The use of gait analysis in the early stages of many pathologies could suggest re-educational intervention to reduce surgery later. Therefore, patients should be first examined through markerless systems and proceed to in-depth marker-based analysis when necessary, as reported in Figure 4, with improved time and cost-efficiency.

COMPUTERIZED ANALYSIS OF THE SPINE

Rasterstereography is a non-invasive method used to measure 3D spine deformities by analyzing the back's surface topography on triangulation principles[79,80]. It was developed by Drerup and Hierholzer[81-83] in the 1980s as a valid alternative to radiography, and over the years, it has shown its high reliability in various studies[84-86], Table 3 shows the main differences among these studies. The system generates a 3D model of the spine by calculating specific deformities thanks to the precise convex shape of the spinous process of the vertebra prominence and the concavity of the lumbar dimples as fixed points. The rasterstereography is commonly used to assess the presence of scoliosis, but it can efficiently evaluate other parameters as pelvic obliquity, thoracic kyphosis and lumbar lordosis angles[87,88]. Since this system is a non-invasive method, it can perform several analysis repeated over time with high reliability, which can minimize the use of X-rays[79]. Krott *et al*[89] provided a meta-analysis of 19 eligible studies evaluating the reliability and validity of static rasterstereographic measurements in healthy subjects and patients with different spinal pathologies. The authors compared the results with the gold standard of radiological imaging techniques, reporting high validity levels in assessing patients' thoracic kyphosis angle, lumbar lordosis angle, and scoliosis angle. The easiest accessibility of rasterstereography can spread through evaluating common health problems among children, adolescents[90], and adults, such as non-specific back pain and postural insufficiencies[91-94]. Several studies proved the validity and reliability during static upright standing in children and healthy adults, while recently, it was investigated the use of rasterstereography from static to a dynamic system. Michalik *et al*[86] evaluated the spinal posture and pelvic position under dynamic conditions, *i.e.*, walking, and compared it to static measurements of the spine using a dynamic rasterstereographic system. Significant differences were found between static and dynamic conditions about the trunk inclination ($P < 0.001$), kyphotic angle at 2 km/h ($P = 0.003$), lordotic angles ($P < 0.001$) and lordotic angles with increasing walking velocities ($P < 0.001$). No differences were found between static and dynamic measurements for the surface rotation. März *et al*[95] used rasterstereography to determine the instantaneous influence of different occlusal positions on spine and body posture. After comparing ten spinal and body posture parameters (*i.e.*, trunk inclination, pelvic tilt, kyphotic and lordotic angles), in six different occlusal positions, only three parameters were found to differ. The authors concluded that a plausible explanation could be represented by neuromuscular compensation for body balance and posture on trigeminal proprioception[96]. For instance, postural alterations provoked by changes in dental occlusion and masticatory muscle function suggest a neurophysiological link between the stomatognathic system and other body muscles[97,98]. The rasterstereography field of application involves: screening programs, *e.g.*, early diagnosis and monitoring of scoliotic and scoliosis attitudes, lumbar hyperlordosis, dorsal hyperkyphosis, and all pathological conditions of the back; postural evaluation and musculoskeletal problems; design and verification of ergonomic and orthopaedic devices (ergonomic insoles, bites, prostheses, orthoses); support to therapeutic programs and postural re-education. Formetric (DIERS Medical Systems, Chicago, IL, United States) is a rasterstereographic technology for analyzing the spine and posture that does not present any contraindications or side effects. It emits parallel lines of light across the posterior trunk surface and, based on the distortion of those lines, reconstructs a digital image of the back's surface and produces a digital model of the spine. The optical scan detects the anatomical landmarks (C7 or prominent cervical vertebra, sacrum, lumbar dimples), the symmetry of the spine and the rotation of each segment. Three different versions are currently available on the market: Formetric Basic, Formetric Basic 4D, and Formetric Basic 4D Motion. Formetric Basic produces a 3D analysis of the spine and posture, but it does not allow to perform a dynamic analysis. Formetric 4D can acquire image sequences, automatically processing average values, with a duration of the detection sequences even greater than 1 minute and the possibility to acquire up to 10 images per second. The newest version of this system is

Table 3 Studies investigating the reliability of rasterstereography to evaluate the spine

Ref.	Aim	Coort	Results	Conclusion
Mohokum *et al*[84], 2010	To determine reproducibility of rasterstereography for kyphotic and lordotic angles, trunk length, and trunk inclination	51 healthy volunteers	Cronbach-α for the intratester-reliability of the kyphotic angle ICT-ITL (max.) between 0.921 and 0.992. The intertester-reliability for the same parameter is 0.979 (95%CI)	The reliability revealed good results, both for intratester and for intertester reliability of rasterstereography in kyphotic and lordotic parameters trunk length and trunk inclination
Guidetti *et al*[85], 2013	To determine intra- and interday reliability of spine rasterstereographic system Formetric 4D with and without reflective markers.	26 healthy volunteers with markers (M), 26 healthy volunteers without markers (NM)	In M group, for intra- and interday reliability coefficients were 0.971, 0.963, and 0.958 (ICC) and 0.987, 0.983, and 0.985 (Cα) for trunk length, kyphotic angle, and lordotic apex, respectively. In NM group, they were 0.978, 0.982, and 0.972 and 0.989, 0.991, and 0.991 for trunk length	The presence of the markers is not necessary for the intraday evaluations and can play a disturbing role for the interday evaluations, because of the repositioning process
Michalik *et al*[86], 2020	To study the spinal and pelvic position under dynamic conditions and compare it to static measurements using a rasterstereographic system.	121 healthy volunteers (56 females; 65 males)	Trunk inclination (5.31° *vs* 6.74°), vertebral kyphotic angle (42.53° *vs* 39.59°), and surface rotation (3.35° *vs* 3.81°) increase under dynamic conditions ($P < 0.001$). Trunk shows significant changes during walking compared to static conditions ($P < 0.001$)	The spinal posture differs between females and males during standing and during walking. Rasterstereography is a valuable tool for the dynamic evaluation of spinal posture and pelvic position
Albertsen *et al*[91], 2018	To investigate whether the clinical Matthiass test can be objectified by means ofdynamic rasterstereography in children.	101 healthy children	Cluster analysis identified two groups with different postural performance levels during the modified Matthiass Test. Low performers showed a higher increase in backward lean, kyphosis and lordosis (4°–5°, respectively) compared to high performers	Modified Matthiass Test applied with Rasterstereography can discriminate between low and high posture profile among children

the Formetric 4D Motion, which can accomplish a dynamic analysis of the whole body and the skeletal system during a step execution or treadmill walking, due to the possibility to acquire up to 24 images per second. The high sampling rate allows excluding effects due to spontaneous postural oscillations or breathing. Once the exam has been performed, the system produces a report about physiological alterations of the spine both in the frontal and in the sagittal plane, degrees of vertebral rotation, pelvic tilt and antero-retroversion.

MOBILE APPLICATION AND WEARABLE DEVICES FOR POSTURE MANAGEMENT

PostureScreen Mobile (PSM) (Trinity, FL, United States) is an app that guides clinicians in rapidly identifying anatomical landmarks and posture assessment. Without the use of reflective markers, the app calculates posture variables using digitized anatomical landmarks. The device camera is used within the app to take pictures of subjects from frontal and sagittal planes. Once the picture is taken, the clinician place digital anatomical landmarks on the picture to produce an evaluation of the misalignment of the landmarks on the coronal and sagittal planes, as reported in Figure 5. Therefore, the app provides a file report that indicates possible posture misalignments. In the frontal plane, it analyzes head, shoulders, hips tilt, and horizontal translation; in the sagittal plane, it analyzes the shift forward or rearward of the head, shoulders, hips and knees. Szucs *et al*[99] tested the app in healthy young adults. Based on the results, the PSM app has been a reliable method for assessing posture within and across raters when using defined procedures and markers. For intra-rater reliability, most posture variables showed good to excellent reliability (> 0.75). Angulation variables showed moderate to good reliability range (0.50-0.75). In contrast with the previous study, Hopkins *et al*[100] analyzed the intraclass correlation coefficient of postural analysis between PSM app and Vicon 3D analysis. The results showed a significant bias in postural measurements in the frontal and sagittal with the PSM app, while the intraclass correlations were similar in most of the measurements between the two systems. These data suggest caution using the PSM app when highly accurate postural assessments are necessary. Instead, innovative use of this technology is proposed by Iacob *et al*[101], which tested the PSM app to evaluate dental occlusion anomalies. Both static and dynamic occlusion were evaluated. In the first part of the study, the subjects were divided according to normal or abnormal occlusion; statist-

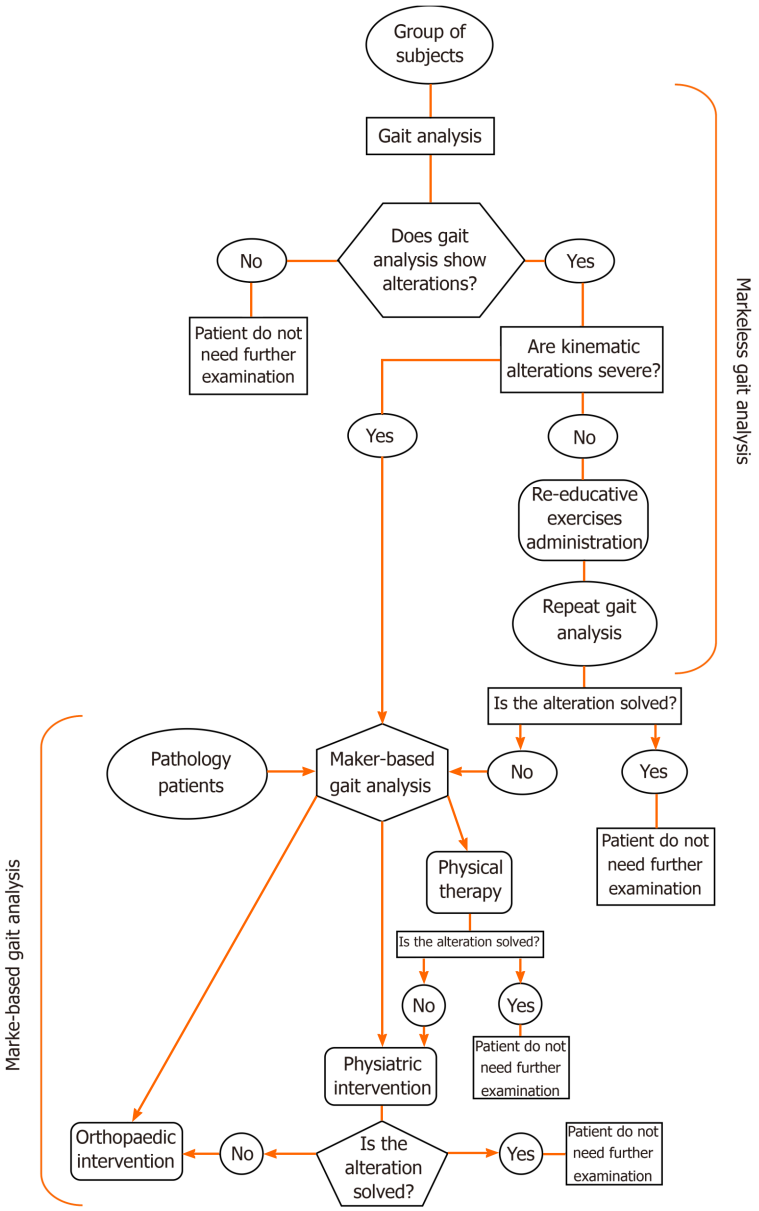


Figure 4 Flow chart of the gait analysis approach levels. A guide explaining when it is enough a markerless gait analysis and when it is needed a marker based gait analysis.

ically significant differences ($P < 0.05$) were obtained for only the head deviation angle. In the second part of the study, after examining the dental occlusion in each type of movement, subjects were grouped according to the presence or absence of premature contacts or interferences. Statistically significant differences regarding head deviation angle between the groups normal/abnormal occlusion were found, confirming a possible correlation between static occlusion and posture. Therefore, the PSM app is suggested to assess the impact of pathological dental conditions on posture. Furthermore, depending on the degree of postural deterioration, the clinician can direct the patient toward correction therapy before the postural abnormalities become definitive and harm the musculoskeletal system[101].

Among innovative technologies, the growing reliability of wearable devices is noteworthy. Wearable devices have been welcomed into the daily lives of healthy individuals, older adults, and those with chronic illnesses[102,103]. These devices represent an opportunity to quantify the movement patterns of all types of individuals in real-world settings. It is expected that the applicability of wearable devices to different populations will contribute to relevant advancements in understanding the daily gait patterns of walkers and runners[104]. The use of wearables is constantly expanding, especially in the field of gait analysis[105], post-operative rehabilitation [106,107], diagnosis and treatment of musculoskeletal disorders (*e.g.*, scoliosis,

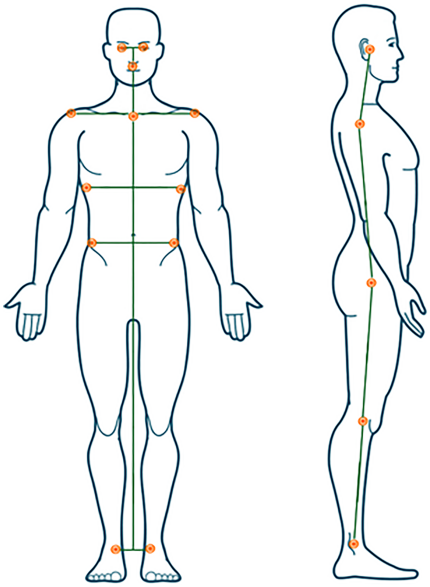


Figure 5 Body position of the digital landmarks of PostureScreen Mobile app. Frontal and side view.

kyphosis, lordosis)[108,109], and posture management in the workplace[110]. In the context of posture analysis, wearables offer a low-cost and easy-to-use tool that provides real-time feedback for correcting workers' posture and reducing postural pain onset. Poor posture can lead to musculoskeletal disorders or spinal complications. It is well established that long sitting hours in front of computers cause pain, usually at the back. Abyarjoo *et al*[111] proposed a wearable system for office workers that alarms the subject when he assumes a wrong posture. The Upright Go 2, following the success of its previous release (Upright Go), is a wearable device whose goal is to manage posture daily by promoting self-correction[112]. The device is about 48mm large, lightweight, and with a battery that lasts up to 35 h. It can be applied to the back using hypoallergenic adhesives or worn with a unique necklace that ensures that the device stays on the back. It is equipped with multiple sensors that perceived if the subject slouches, and in this case, it will emit vibrations that stimulate the subject to regain a correct posture. The Upright Go 2 provides an app to monitor the progress over time, suggesting workouts to maintain the correct posture. Future studies about whether the subject would maintain a correct posture even after the device is no longer used would be an interesting prospect.

OVERALL CONSIDERATIONS

In recent years, a wide variety of technologies to study human movement has emerged, ranging from 3D visual software to wearable devices with almost imperceptible weight. The increase of technological devices has made it possible to expand the field of biomechanical assessment not only to the clinical environment but also to re-educational, sports and everyday life contexts. However, rapid technological development risks providing tools that are often not sufficiently validated. For example, the study conducted by Yoong *et al*[113], published just in November 2019, reports wearables that are no longer in production. For a device to be considered valid in the scientific field, it must comply with some strict parameters, and above all, it must maintain the reliability of its measurements constant. The evaluation of posture, movement, and gait and their deviations from physiological conditions are increasingly helpful in the clinical setting to diagnose musculoskeletal pathologies and in daily life to reduce the incidence of pain and disorders. As reported in Figure 4, this approach involves subdivisions based on the patient's criticality levels. Concerning gait analysis, a markerless system is a valuable tool for first-level screening as fully automatic and non-invasive, allowing to quickly analyze a large number of patients without stressing them with lengthy procedures. This first step streamlines the use of a marker-based system, making it available to more complex cases.

Table 4 Application outline of each mentioned system

		Vicon	Microsoft Kinect	IMU	Electromagnetic	Rasterstereography	Kinovea	PostureScreen	Coach's Eye
Field of application	Clinical	High	Medium	Low	Medium	High	Low	NA	NA
	Sport	High	High	Medium	Low	NA	High	NA	Medium
	Posture	High	High	Low	Medium	High	High	Medium	Low
	Surgery	High	NA	NA	NA	Medium	NA	NA	NA
System potential	Accuracy	High	High	Medium	High	Medium	Medium	Medium/Low	Medium/Low
	Reliability	High	High/Medium	Medium	High	High	Medium	Medium/Low	Medium/Low
	Validity	High	High/Medium	Medium	Medium	High	Medium	Low	Low
	Reproducibility	Low	High	Low	Medium	High	Medium	Low	Low
Other characteristics	Outdoor	NA	Available	Available	NA	NA	Available	Available	Available
	Markers/Sensors	Required	NR	Required	Required	NR	NR	NR	NR
	Time required	High	Low	Medium	Medium	Low	Low	Low	Low
	Cost	High	Medium	Low	High	Medium	Low	Low	Low

NA: Not available; NR: Not required.

Similarly, the rasterstereography system, intended as a first-level approach, allows analyzing the back's topography leaving the second-level approach to radiographs, minimizing the need for repeat X-rays. In clinical practice, these approaches help in planning treatment, personalized rehabilitation programs, and surgical solutions. In everyday life, they give the possibility to remotely follow the patients, monitor progresses, and collect data on a large scale of users. As reported in Table 4, different systems serve different purposes, suggesting the need for a general scheme to direct the operator towards the most suitable analysis system to prefer.

CONCLUSION

This review highlighted the main applications of novel electronic devices in motion and posture analysis, describing their strengths and weaknesses. From the comparison of these systems, it is clear that some of the mentioned devices have the potential to be used in clinical practice, sports, and healthcare prevention. Therefore, it is suggested that the scientific community might embrace an improved biomechanical approach through these new currently available tools for a tailored evaluation of patient's characteristics. The future of biomechanical research is a fast, fully automatic, non-invasive, and repeatable approach further away from human-dependent errors.

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MINIREVIEWS

Arthrodesis of the first metatarsophalangeal joint: The "when and how"

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Abstract

Arthrodesis of the first metatarsophalangeal (MTP) joint has been established as the "gold standard" for the treatment of several first ray disorders, due to its perceived efficacy and the consistently reported good results in the literature. Arthrodesis is a commonly performed procedure for the treatment of end stage arthritis, rheumatoid arthritis with severe deformity, selected cases of severe hallux valgus (with or without signs of degenerative joint disease), as well as a salvage procedure after failed previous operation of the first ray. The goals of a successful 1st MTP arthrodesis are pain alleviation and deformity correction in order to restore a comfortable gait pattern and to improve shoe wear. Several techniques have been reported with several proposals regarding the preparation of the articular surfaces and the method of definitive fixation. As with any given surgical procedure, various complications may occur after arthrodesis of the 1st MTP joint, namely delayed union, nonunion, malunion, irritating hardware, *etc.*

Key Words: First metatarsophalangeal joint arthrodesis; Indications; Surgical techniques; Complications

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Core Tip: Disorders of the first ray are quite common in foot and ankle surgery, as multiple pathologies can lead to degeneration and may cause stiffness to the first metatarsophalangeal (MTP) joint. If non-operative treatment fails, arthrodesis of the first MTP joint is a well-established surgical option which has demonstrated very satisfactory results. Herein, we examine the various indications for this procedure, and

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the different surgical techniques, regarding joint preparation and fixation constructs, that we have at our disposal in order to obtain optimum results.

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INTRODUCTION

The first metatarsophalangeal (MTP) joint consists of the convex articular surface of the first metatarsal head, articulating with the corresponding elliptic, swallow, and concave base of the proximal phalanx of the first toe. The plantar articular surface of the first metatarsal head is unique, as it bears two well defined facets which are separated by an anteroposteriorly oriented central crest. The facets accommodate the tibial and fibular sesamoid bones, encased in each tendon of the flexor hallucis brevis. The joint is enclosed by a fibrous capsule that attaches close to the articular margins and extends more proximally at the plantar surface. The ligamentous complex which stabilizes the joint is composed by a collateral ligament on each side of the metatarsal, and a plantar and deep transverse transmetatarsal ligament. Blood supply comes from the first dorsal and plantar arteries of the medial digital branches, while innervation is from the medial plantar nerve, the medial dorsal cutaneous nerve and the terminal branch of the deep peroneal nerve[1].

The first MTP joint allows for flexion – extension, limited abduction and adduction and some degree of longitudinal rotation. Based on the literature, the joint has a total passive range of motion (ROM) of approximately 110°, which is the sum of 35° of plantar flexion and 75° of dorsiflexion[2,3]. However, the active ROM, even in healthy individuals, is reduced. During ambulation the first MTP joint is slightly dorsiflexed in most of the stance phase, whereas in late stance phase the joint reaches a peak of 50° to 60° of dorsiflexion and remains at a range of 30° to 40° of dorsiflexion during swing phase[4]. In various pathology, such as hallux rigidus, significant kinematic changes are noticed as a result of uncoupling of the normal center of rotation between the proximal phalanx and the metatarsal head[5].

INDICATIONS

Arthrodesis of the first MTP joint is a commonly performed procedure for the treatment of end stage arthritis (Hallux rigidus stage III and IV). Surgical treatment is usually indicated in symptomatic patients with arthritis who have failed to respond to conservative management including activity modifications, over the counter medication, intra-articular corticosteroid injections, accommodative footwear, special orthotics and other symptomatic measures. Other proposed treatments for treating severe hallux rigidus include total joint replacement, hemi arthroplasty, resection arthroplasty and interposition arthroplasty. All these interventions though, have not yield the same high efficacy and functional results which have established arthrodesis as the gold standard in the treatment of this pathology. Arthrodesis demonstrates significantly better outcomes in terms of pain alleviation and functional satisfaction, as well as lower revision rates, lower complication rates and faster return to normal activity[6].

First MTP joint arthrodesis should also be considered as the treatment of choice in other severe pathology affecting the Hallux such as rheumatoid arthritis (RA), gout and post traumatic arthritis[7]. It is further considered in selected cases of severe hallux valgus (with or without signs of degenerative joint disease), with rather increased intermetatarsal and hallux valgus angle, concomitant medial column instability, transfer metatarsalgia or in elderly[8].

Arthrodesis of the 1st MTP joint has also been widely proposed as a salvage procedure after failed procedures of the first ray, including failed previous osteotomies for hallux valgus correction resulting in recurrent deformity, iatrogenic hallux varus or avascular necrosis, as well as salvage after failed resectional and replacement

arthroplasties or failed cheilectomy[9-12]. First MTP arthrodesis is also indicated in hallux valgus secondary to neuromuscular disorders, in primary hallux varus, in arthritis secondary to infection and in rigid plantarflexion deformities[13-15].

Relative contraindications regarding the use of arthrodesis of the first MTP joint include the early stages of hallux rigidus (stages I and II), where joint-preserving osteotomies are preferable. Absolute contraindications are the presence of compromised soft tissues, infection, rigid scar tissue formation with direct adhesion of the skin to the bone or the presence of chronic ulcers, where the other alternatives including amputation of the great toe should be considered as a preferable treatment option.

EPIDEMIOLOGY, SYMPTOMS, CLINICAL AND RADIOLOGIC EVALUATION

The first MTP joint is considered the most common arthritic site in the foot. This condition affects nearly 10% of adults; however, radiographic evidence of arthritic changes may be present in 20% to 48% of adults older than 40 years old[16,17]. Hallux rigidus is frequently bilateral, and more than half of the patients report a family history of this specific pathology[18]. Symptomatic arthritis of the first MTP joint is characterized by debilitating pain, reduced range of motion, especially dorsiflexion, and disability to perform activities such as running, stairs climbing, and push-ups. The gait mechanics is altered, as the patients attempt to offload the hallux overloading the lateral column. Compression neuritis of the dorsomedial cutaneous nerve and discomfort with certain types of shoe wear are common problems due to the presence of prominent dorsomedial osteophytes[19].

Several inflammatory joint diseases such as RA, widely affect the forefoot. Pain caused by synovitis or arthritis of the first MTP joint is often the initial symptom and it has been reported that within the first 3 years of the onset of rheumatoid arthritis, approximately 65% of the patients have some degree of MTP joint involvement. It is estimated that more than 60% of the patients with chronic involvement will develop a severe hallux valgus deformity and/or subluxation and dislocation of the lesser MTP joints. Therefore, 5%-22% of these patients will require some type of surgical treatment [20-22].

The foot must be evaluated in both seated and standing positions. The seated position facilitates ROM assessment, while the standing position provides more information regarding the dynamic alignment and function of the hallux. In the presence of arthritis, the joint is tender dorsally, with often present palpable osteophytes, limited ROM with less than 10° of dorsiflexion in severe cases, while pain is elicited even in midrange of passive motion.

Radiographic evaluation of hallux rigidus requiring arthrodesis (grade 3 and 4) consists of standard standing anteroposterior, and lateral foot radiographs. Substantial joint space narrowing, flattening and widening of the metatarsal head, formation of periarticular dorsal, lateral and even medial osteophytes both proximally and distally at the joint, irregular or enlarged sesamoids and subchondral sclerosis are the most common and significant findings[18].

Hallux valgus deformity requiring a first MTP arthrodesis is usually characterized by severe HV and IM angle (more than 40 and 20 degrees, respectively) and secondary degenerative changes of the first MTP joint[8,23].

SURGICAL TECHNIQUES

The goals of a successful first MTP arthrodesis are pain alleviation and deformity correction in order to restore a comfortable gait pattern and to improve shoe wear. Several techniques have been reported in the literature with several proposals regarding the preparation of the articular surfaces and the method of definitive fixation.

The most commonly used surgical incision is the dorsal longitudinal which is centered over the first MTP joint, but a medial incision has also been utilized as a safe alternative in the presence of severe scarring in the dorsal aspect of the Hallux. This later approach has the disadvantage of not facilitating supplementary dorsal plating, but the surgeon should wisely balance the strength of fixation and the maximum potential of soft tissue healing. Dissection should always be meticulous, taking care to elevate full thickness flaps with adequate mobilization of the extensor hallucis longus (EHL) tendon and protection of the neurovascular bundles[24].

There are a few recent reports of endoscopic lateral release of the first MTP joint and subsequent arthroscopic arthrodesis in selected groups of patients. The selection criteria reported in those studies were severe hallux valgus deformity, degenerative and rheumatoid arthritis, adequate bone quality and no signs of transfer metatarsalgia. Lateral release of the adductor hallucis tendon and the lateral capsule-ligamentous complex of the 1st MTP joint are performed through a toe web and a plantar portal in order to convert the deformity into a more flexible one. Adequate release facilitates the arthroscopic removal of the cartilage, the microfractures to the fusion surfaces and the definitive fixation with 2 crossed cannulated screws[25,26].

Spherical cup-and-cone articular surface preparation techniques are currently the most widely used, whereas peg and socket techniques as well as utilization of planar cuts have also been thoroughly reported in the literature. Cup and cone techniques utilizing cannulated reamers are relatively easy by a technical point of view and rather reproducible. Such techniques provide a significant surface contact area thus enhancing the potential for bone healing by means of fusion and allow for easy intraoperative positioning in all planes. Finally, they offer greater stability, minimizing the potential bone loss and the potential shortening, which are commonly encountered in other preparation techniques, and have been shown to be biomechanically superior when fixation is applied in comparison to the other preparation techniques[27]. Peg and socket techniques have the advantage of providing inherent stability, but they may cause shortening, significant bone loss and are technically demanding[28,29]. Planar cuts have the advantage of being quick and technically easy, but they may also lead to significant shortening and bone loss, mainly in cases where repositioning is required[30].

Stable internal fixation with compression across the fusion site has been established as the standard of care regarding the most preferable fixation technique. Several reports have proposed the sole use of plates, single or two lag screw constructs with variations of either cannulated or solid as well as crossed or parallel, and more often a combination of plates and screws. More recently, the use of memory compression or pure titanium staples has also been described[31-35]. Biomechanical studies comparing several fixation techniques have demonstrated that a dorsal plate in combination with a lag screw across the fusion site have been proven to provide the most stable fixation constructs comparing to those provided with a single plate, sole lag screws, staples or (K)-wire fixation[36,37].

For the last 20 years, the authors routinely utilize a dorsal midline approach (Figure 1A), in order to gain adequate access to the joint and ease the positioning of the arthrodesis as well as the placement of the implants. The joint capsule is divided longitudinally just medial to the EHL; the tendon is then retracted laterally and the collateral ligaments and the capsule are reflected from the 1st metatarsal head (Figure 1B). The joint surfaces are being prepared in a standard fashion. Initially, all dorsal osteophytes as well as a part of the medial eminence are removed, and a minimal flat cut is made to the head of the 1st metatarsal with the use of an oscillating saw (Figure 1C). This preliminary partial cartilage or sclerotic subchondral bone removal facilitates subsequent reaming over a guidewire which is inserted to the center of the 1st metatarsal head (Figure 1D). Hemispherical cup and cone reamers are used in order to remove the articular surfaces and create concentric concave and convex surfaces of bleeding subchondral bone (Figure 1E and F). Reaming should be done on full speed in a gentle, concentric tapping motion to avoid excessive bony resection and metatarsal shortening. The prepared surfaces are then perforated multiple times with a K-wire in order to promote fusion (Figure 1G). These two surfaces are then provisionally reduced and fixed with two K-wires in the considered optimum position (Figure 1H). The sagittal alignment is being checked intraoperatively both by C-ARM guidance and by using a flat tray simulating weight bearing. Therefore, the 1st MTP joint is positioned in a way that allows the pulp of the great toe to rest 5-10 mm above the flat surface with simulated weight bearing (Figure 1I). Valgus alignment is set to 10 degrees, rotation is kept to neutral and final checks are made to ensure that the dorsiflexion angle is within the range of 15 to 20 degrees. Any remaining dorsal prominences are then removed to allow proper seating of the plate. A pre-contoured titanium low profile neutralization plate is applied dorsally (Figure 1J), with at least four locking titanium screws and the fixation is additionally secured with an interfragmentary compression screw placed in a distal-inferomedial to proximal-superolateral direction to achieve compression across the MTP joint. The provisional K wires are removed and the position of the hallux is again checked both fluoroscopically and clinically. Any minor local defects are filled with bone graft taken from the reamers and the wound is closed in layers. Gauges and compression bandage is applied. The patients are allowed to fully weight bear immediately in a heel wedged

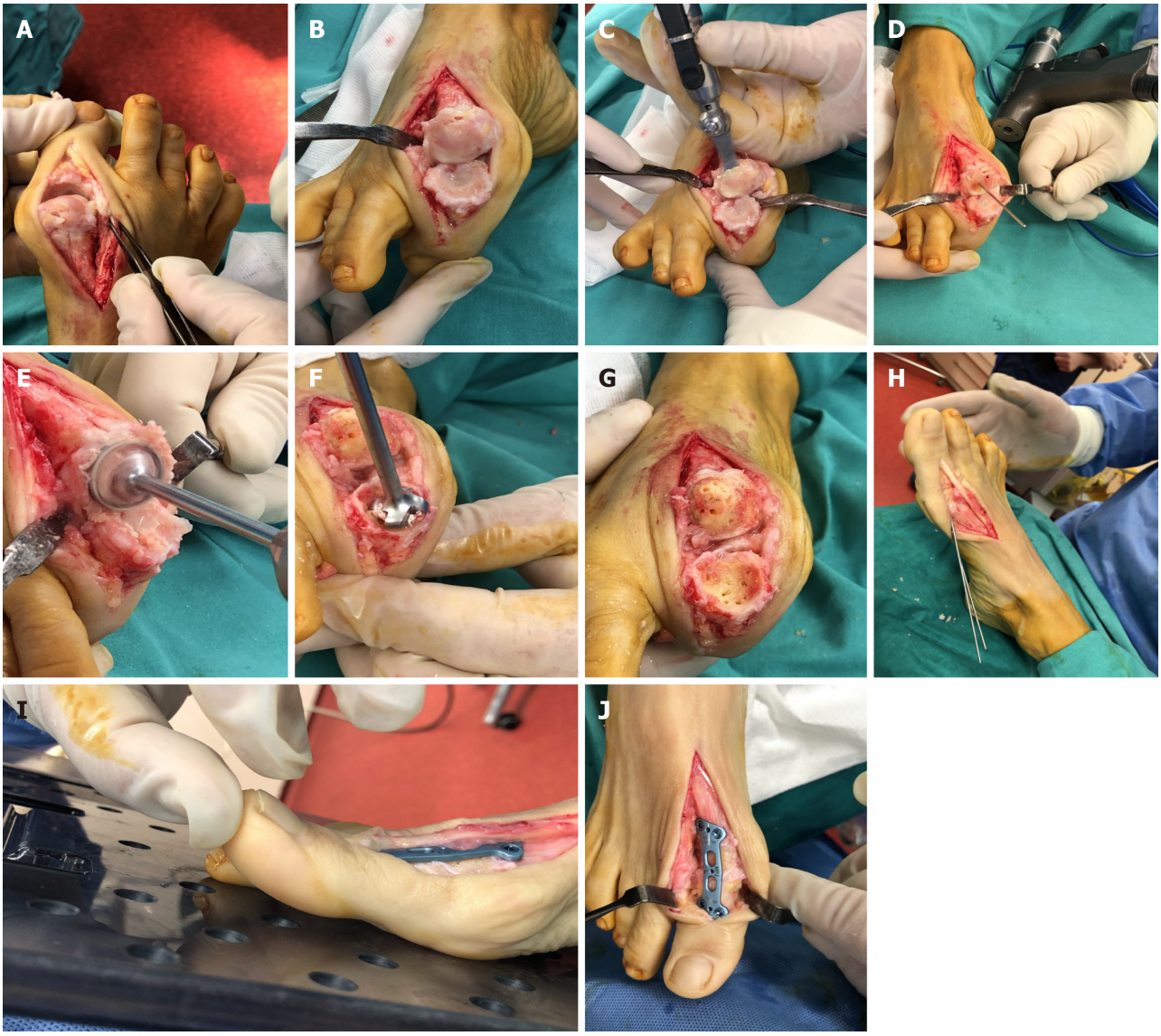


Figure 1 Surgical technique. A: A dorsal midline approach provides adequate access to the joint; B: Extensor hallucis longus tendon is laterally retracted and adequate collateral ligament and capsule reflection provides excellent working space; C: A minimal flat cut is made to the head of the 1st metatarsal utilizing an oscillating saw; D: A guidewire is inserted to the center of the 1st metatarsal head; E and F: Hemispherical cup and cone reamers are used in order to remove the articular surfaces; G: Concave and convex surfaces of bleeding subchondral bone have been prepared with multiple perforations; H: Provisional fixation with two K-wires in the considered optimum position; I: The sagittal alignment is being checked intraoperatively using a flat tray simulating weight bearing. The 1st metatarsophalangeal joint is positioned in a way that allows the pulp of the great toe to rest 5-10 mm above the flat surface; J: Final position of the plate.

velcro shoe for six to eight weeks.

In the setting of severe osseous defects, commonly encountered after failed previous hallux surgery, the main goal is to restore the normal length of the first ray, thus avoiding the overload of the lesser metatarsal heads which could lead to transfer metatarsalgia. Therefore, any remaining defects are filled with either autologous bone graft or bone substitutes. In cases of minor defects, these may be filled with cancellous bone taken from either the calcaneus, or the distal/proximal tibial metaphysis. Larger defects are usually filled with structural corticocancellous grafts taken from the anterior iliac crest.

COMPLICATIONS

As with any given surgical procedure, various complications may occur from a first MTP arthrodesis, namely delayed union, nonunion, malunion, wound dehiscence, seroma, infection, osteomyelitis, hallux ischemia, nerve damage, hematoma, failed or prominent and irritating hardware, and hallux interphalangeal joint arthritis[38-40].

In an effort to investigate the incidence of these complications, Roukis *et al*[40] performed a retrospective review of 2818 feet from 37 studies and reported an average nonunion rate of 5.4%, regardless of the reported fixation technique with just 32.7% of them being symptomatic. Average malunion rate was found to be 6.1%, while the incidence of symptomatic hardware necessitating removal was 8.5%, regardless the type of fixation being used[40]. These figures roughly represent 50% of those that had been previously reported in the literature, regarding the incidence of malunion, nonunion and hardware removal after arthrodesis of the first MTP joint[30,39,41].

A rather common metabolic pathology that may complicate the outcome is diabetes mellitus. Anderson *et al*[42] reported that although first MTP arthrodesis is overall an effective and beneficial procedure in patients with diabetes mellitus, those with peripheral neuropathy have an increased risk for mild and moderate complications. 35.5% of the study's diabetic patients had one or more mild to moderate complications but only a small number of those required revision surgery. 68% of the study's diabetic patients with peripheral neuropathy had one or more mild to moderate complications (wound dehiscence, infection, delayed or no bone healing). This is significantly higher than the results of non-diabetic patients who had approximately 10% of complications [42].

The most commonly reported complications, namely malunion and nonunion, usually occur due to inadequate surgical technique and/or poor patient's compliance. Positioning of the hallux is of paramount importance in order to obtain proper foot function and optimal shoe fit. Malunion can occur in one or more of the sagittal, frontal, and transverse planes. Sagittal plane malposition, especially excessive dorsiflexion is poorly tolerated by the patient due to increased plantar pressure at the 1st MTP joint and concomitant abutment of the hallux against the shoe wear, whereas excessive plantarflexion significantly increases pressure on the big toe during heel off. Malrotation may also represent a problem as it causes painful callosities as well as painful nail deformities. Finally, malunion in the transverse plane, namely varus malposition, usually causes painful abutment of the medial aspect of the hallux against the shoe.

The main three factors leading to nonunion are: inadequate joint preparation, mechanical failure of the fixation construct being used and lack of patient's compliance. Risk factors leading to nonunion break down into 2 categories, the surgeon-dependent and patient-dependent. Thus, it is of paramount importance to the surgeon to select the preparation technique and fixation method which is familiar with, as well as to select those patients with factors predisposing for a successful outcome.

DISCUSSION

Arthrodesis of the first MTP joint has been established as the "gold standard" for the treatment of several first ray disorders, due to its perceived efficacy along with the consistently reported good results in the literature. Several studies (Level II evidence) have compared arthrodesis with hemiarthroplasty and Keller resection arthroplasty of the first MTP joint. Arthrodesis consistently demonstrated equivalent or superior results with lower complication rate. The procedure alleviates pain, and maintains stability and alignment of the first ray, thus providing better functional outcomes, lower revision rates, reduced hospital stay, as well as faster return to normal activity [43,44].

Despite the fact that first MTP joint arthrodesis has been established as a reliable treatment option for several disorders of the first ray, there is no evidence based documentation of its potential superiority, comparing to other interventions, when it is applied to any given pathological entity. Desmarchelier *et al*[45] compared the functional outcomes and the complications rate in two groups of patients who had been treated for hallux valgus deformity with either a Scarf osteotomy or a first MTP joint arthrodesis. The authors reported that there was no statistically significant difference in the complications rate and the postoperative pain level (AOFAS score: 35.6 ± 6.5 in the Scarf group and 34.5 ± 5.9 in the MTP arthrodesis group) between the two groups. The overall satisfaction rate was similar to the Scarf and the MTP arthrodesis groups, with 91.4% *vs* 90% of very satisfied or satisfied patients respectively, but when the authors utilized more function specific evaluation tools such as SF 36-a general quality of life score-, the Foot Function Index, and the Foot and Ankle Ability Measure[42], they found a statistically significant difference favoring MTP arthrodesis[45]. The issues arising from the later report are those of a study that was solely based on a postoperative questionnaire with no pre-operative scores

available, as well as that the leading pathologies in the two groups were not completely similar.

Hyer *et al*[46] investigated the fusion rate and time interval to fusion in two groups of patients with either hallux rigidus or rheumatoid arthritis who received a first MTP joint arthrodesis as a definitive procedure. In a total of 155 first MTP fusions, 116 (74.83%) had been performed for the treatment of hallux rigidus and 39 (25.16%) for rheumatoid arthritis. The overall fusion rate was 89% in the hallux rigidus group and 94% in the rheumatoid arthritis group, but the difference was not statistically significant different. There was also no statistically significant difference in the clinical outcome. Finally, the time interval to fusion was statistically significantly shorter in the rheumatoid arthritis group comparing to the hallux rigidus group (93 and 113 d, respectively)[46]. It should be noted though, that a number of intraoperative technical variables such as the method of joint preparation, the use of autologous bone marrow aspiration, as well as the use of any concomitant surgery were not taken into account.

First MTP joint arthrodesis has been established as an open procedure, but there are recent proposals of percutaneous as well as arthroscopic approaches. The increased interest in arthroscopy along with the evolution of modern techniques and instrumentation have led a few surgeons to perform an arthroscopically assisted arthrodesis of the 1st MTP joint for the treatment of hallux rigidus and other pathology of the first MTP joint. Although the later approach is often proposed during the last decade it is rarely performed, thus there is a lack of adequate evidence demonstrating its efficacy. The reason for the lack of increased number of reports is clearly the technical complexity and the steep learning curve of such a procedure, requiring additional training and more refined instrumentation. The most common complication encountered with this technique is failure to achieve fusion[26,47,48]. The recent invasion of minimally invasive surgery (MIS) techniques, with small incisions and reduced soft tissue dissection compared to open surgery, rely on the theoretical advantages of reduced wound healing complications, smaller scars, faster recovery and reduced infection rate. The current literature reporting on the safety and effectiveness of minimally invasive arthrodesis remains scarce and its potential advantages over open surgery are still a matter of debate. Therefore, more prospective studies are required providing adequate level of evidence of any potential benefit of MIS comparing to standard 1st MTP arthrodesis[49,50].

A literature review of the several proposed joint preparation methods, demonstrates that the use of cup and cone technique provides biomechanically superior results comparing to those obtained by other techniques. Curtis *et al*[27] in a biomechanical study, reported that the cup and cone joint preparation provided statistically significant greater stiffness than planar cuts excision. The authors also noticed that the method of fixation was less important than the joint preparation technique[27]. Flavin *et al*[34] concluded that the combination of the cup and cone joint preparation technique with the use of a dorsal contoured plate provided the best operative results with lower complications rate. Brodsky *et al*[51] in a prospective gait analysis study, reported that there was statistically significant increased stability on the involved foot, better weight bearing function and increased ankle push-off power when arthrodesis had been achieved with cup and cone reamers. Singh *et al*[52] conducted a cadaveric study in an effort to evaluate the incidence of transfer metatarsalgia related to the amount of bone shortening after various joint preparation techniques. The authors reported that, despite the presumed superiority of the cup and cone technique, the post-procedure length of the first ray was similar in both cup and cone as well as flat cut techniques. The issue arising from this study is that there was no consistent method of measurement of the exact amount of cartilage and subchondral bone removed utilizing each technique, thus the results might not be completely accurate [52].

There are multiple reports of first MTP joint arthrodesis with a variety of fixation techniques. A significant number of retrospective clinical as well as biomechanical studies favor the use of a dorsal precontoured plate in combination with an interfragmentary lag screw over the other reported methods of fixation. This later type of fixation has been proved to be an efficient and reproducible method to achieve proper alignment of the Hallux, high fusion rate as well as safer postoperative mobilization. Politi *et al*[37] performed a biomechanical study comparing the strength of fixation of five commonly utilized techniques in first MTP joint arthrodesis. They used saw bone models applying dorsiflexion force across the fused joint thus simulating the forces produced during the gait cycle. According to their results the combination of a dorsal plate with an oblique lag screw provided the best results followed by a sole lag screw fixation while the use of a single dorsal plate or Kirschner wire fixation, provided the weakest constructs[37]. The use of 2 crossed screws, although a commonly reported

method of fixation, was not assessed in this study. This later method was tested in a different biomechanical study, which demonstrated that a single intramedullary screw fixation was stronger and stiffer thus biomechanically superior comparing to two crossed screws fixation[36]. In a cadaveric study, constructs provided by either a small six hole plate with an interfragmentary screw or by two crossed lag screws were stressed to failure by using a computer-integrated materials tester. The plate and lag screw fixation construct provided statistically significant greater stiffness and ultimate load to failure[53]. Despite the aforementioned results, the fixation methods of either a single lag screw, 2 crossed cannulated screws or titanium staples are still in use, as there are several studies demonstrating similar rates and time to fusion comparing to those with the plate and lag screw construct. Moreover, the use of these two fixation methods are regarded to be significantly more cost effective in achieving fusion of the first MTP joint, with a lower rate of additional surgery for hardware removal[31,32,35].

CONCLUSION

First MTP joint arthrodesis is a very useful and a highly effective procedure for a variety of disorders of the first ray, with a relative low rate of complications. An ideal arthrodesis should be properly positioned, easily reproduced and demonstrate an excellent functional outcome. Factors affecting the success of this type of surgery include careful selection of patients relying on individuals' profile, meticulous surgical technique, and adequate postoperative rehabilitation regime.

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ORIGINAL ARTICLE

Retrospective Study

Strategies and outcomes in severe open tibial shaft fractures at a major trauma center: A large retrospective case-series

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Abstract

BACKGROUND

Severe open tibia fractures are challenging to treat with a lack of published clear management strategies. Our aim was to provide an overview of the largest single-center experience in the literature, with minimum 1-year follow-up, of adult type 3 open tibial shaft fractures at Cambridge University Hospitals (a United Kingdom major trauma center). We sought to define patient characteristics and our main outcome measures were infection, union and re-fracture.

AIM

To retrospectively define patient and injury characteristics, present our surgical methods and analyze our outcomes–namely infection, union and re-fracture rates.

METHODS

Consecutive series of 74 patients with 75 open tibial fractures treated between 2014 and 2020 (26 classified as Gustilo-Anderson 3A, 47 were 3B and two were 3C). Nine patients underwent intramedullary nailing (IMN), 61 underwent Taylor spatial frame (TSF) fixation and 5 were treated with Masquelet technique (IMN and subsequent bone grafting).

RESULTS

Mean follow-up was 16 mo (IMN) and 25 mo (TSF). We had an infection rate of 6.7% (5), non-union rate of 4% (3) and re-fracture rate of 2.7% (2). Average time to union was 22 wk for IMN and 38.6 wk for TSF. Thirty-three cases had a bone defect with a mean of 5.4 cm (2-11). Patient age, sex, diabetes, smoking status or injury severity did not have a significant effect on union time with either fixation method. Our limb salvage rate was 98.7%.

CONCLUSION

Grade 1 to 3A injuries can effectively be treated with reamed or unreamed IMN. Grade 3B/C injuries are best treated by circular external fixators as they provide

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good, reproducible outcomes and allow large bone defects to be addressed *via* distraction osteogenesis.

Key Words: Tibia; Open fracture; Taylor spatial frame; Intramedullary nailing; Bone defect

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Core Tip: Our aim was to provide an overview of the largest single-center experience in the literature, with minimum 1-year follow-up, of adult type 3 open tibial shaft fractures at Cambridge University Hospitals (a United Kingdom major trauma center). Meticulous and aggressive debridement of GA type 3 open tibia wounds by experienced orthopaedic and plastic surgeons is paramount. Grade 1 to 3A injuries can effectively be treated with reamed or unreamed intramedullary nailing. Grade 3B/C injuries are best treated by circular external fixators as they provide good if not superior outcomes to other limb salvage techniques and allow large bone defects to be addressed *via* distraction osteogenesis. In addition, Taylor spatial frame offers the advantages of postoperative adjustability.

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INTRODUCTION

Severe open tibia fractures remain challenging to treat with long-term social, physical and financial implications. They are the most common long bone fractures, with a higher incidence in working-age males and are often associated with polytrauma[1]. These high-energy fractures are often mutlifragmentary with extensive soft tissue disruption and require a multidisciplinary ortho-plastics approach. The publication of British Orthopaedic Association Standards for Trauma (BOAST 4) in 2009 and the introduction of the Major Trauma Network in 2010 have unquestionably improved outcomes in open tibia fractures[2].

Circular external fixators (CEF) such as the Taylor spatial frame (TSF) (Smith & nephew, Memphis, TN, United States), a multiplanar computer-assisted hexapod system, have been shown to result in good functional and radiological outcomes following severe open tibia fractures[3]. Alternatively, both reamed and unreamed intramedullary nailing (IMN) are established treatment options with comparable surgical outcomes in experienced hands[4]. More complex injury patterns, such as segmental fractures or where critical post-traumatic bone defects are present, provide their own challenges. In these cases, special techniques must be considered; for example, the induced membrane Masquelet technique[5].

Several crucial aspects in the surgical management of these patients remain equivocal with no clear guidelines and therefore, proceeding with evidence-based interventions is essential. We sought to retrospectively define patient and injury characteristics, present our surgical methods and analyze our outcomes–namely infection, union and re-fracture rates. To the best of our knowledge, we present the largest single-center experience of type 3 open tibial shaft fractures, with 1-year minimum follow-up, in the literature.

MATERIALS AND METHODS

Using our local electronic database, we retrospectively identified 74 adult patients with 75 GA type 3 open tibial shaft fractures who underwent treatment between October 2014 and February 2020 at Cambridge University Hospitals NHS Trust, a large level 1 trauma center. We recorded patient demographics, fracture type, mechanism of injury, timing and number of operations, time to union, infection, re-

fracture and complications. The influence of patient characteristics on healing was also analyzed. There were 54 males and 24 females with a mean age of 43.1 (18-83). The fractures were classified according to the Gustilo-Anderson and Orthopaedic trauma association (OTA) grading systems. All intra-articular fractures were excluded with the majority of fractures diaphyseal (58, 77%), although metaphyseal fractures around the knee (3, 4%) and ankle (14, 19%) were included. Patients who required primary amputation due to injury severity (2 patients) or had less than 12 mo follow-up were excluded.

All patients received intravenous antibiotics in the Emergency Department and 68 patients (91.9%) initially underwent damage control procedures with debridement, lavage and skeletal stabilisation within 24 h of presentation. The remaining six underwent IMN as their primary procedure. Definitive surgery was performed at a mean of 22 d (0-45) from admission with timing dependent on patient physiology and soft tissue condition. All patients were treated by a single surgeon specializing in trauma and limb reconstruction with access to a dedicated team of nurses and physiotherapists. Plastic surgeons were involved on admission and soft tissue coverage was performed at a mean of 9.3 d (1-41) from injury on a combined ortho-plastics list. Soft tissue coverage comprised a free flap in 60 cases (80%; gracilis, latissimus dorsi or anterolateral thigh), local flap in 10 (10.7%) and split skin graft in 5 cases (6.7%). Two patients had injury to the posterior tibial artery which required urgent bypass grafting by the vascular surgeons.

Definitive surgery was either with TSF or IMN depending on patient factors (*e.g.*, compliance, age), fracture pattern and soft tissue condition (GA severity). Weight-bearing was commenced where possible depending on fracture configuration and other injuries. Patients with reduced mobility were given venous thromboembolism prophylaxis. Where required, a low-energy corticotomy was performed at the time of TSF application with bone transport starting on day 8 post-op. Fracture malalignment was corrected during outpatient clinics and regular pin-site care was adhered to. Twelve patients required further TSF adjustment in the operating theatre. Five patients with bone defects were treated using the described induced membrane Masquelet technique with aggressive debridement, use of the reamer/irrigator/aspirator (RIA, DePuy Synthes, West Chester, PA, United States) for bone graft harvesting, antibiotic-loaded cement and calcium sulphate beads[6]. The mean interval between 1st and 2nd stages was 16.8 wk (9-27).

Fracture union was defined as evidence of bridging trabeculae seen on three cortices on plain radiographs or computed tomography (CT). The absence of pain following frame dynamization was also considered indicative of union. In those who underwent bone transport, regenerate of sufficient quality on radiographs was also required prior to frame removal. Infection was defined as the identification of organisms on two or more tissue samples. Antibiotic treatment was led by a microbiologist.

Statistical analysis was carried out using GraphPad (GraphPad Software Inc, San Diego, CA, United States). Descriptive statistics for means, ranges and frequency are provided. Analysis of categorical data was performed using the Mann-Whitney *U* test and continuous variables using Spearman's correlation coefficient. A P value < 0.05 (two-tailed) was considered significant.

RESULTS

Patient demographics are presented in Table 1. Of the 75 fractures, 26 were classified as GA 3A, 47 were 3B and two were 3C. OTA classification was also recorded (Table 2). 61 fractures were treated with TSFs, 9 were treated with IMN and 5 were treated using the Masquelet technique with IMN and subsequent bone grafting. 72 fractures went on to union after primary surgery. Average time to union was 22 wk for IMN (excluding those who underwent the Masquelet technique) and 38.6 wk for TSF (Table 3).

We treated 11 segmental fractures (3 with IMN and 8 with TSF) with a mean union time of 48.9 wk. The mean number of operations prior to IMN and TSF was 0.5 (0-1) and 2.2 (1-5) respectively. Thirty-three cases had a bone defect with a mean of 5.4 cm (2-11). Mean follow-up was 16 mo (13-26) for IMN and 25 mo (15-38) for TSF.

Two of the 5 fractures treated with the Masquelet technique developed infections which required revision procedures (both TSFs) (Table 4). A total of 5 patients, all of whom had GA 3B fractures, developed post-operative infections (Table 5). Three patients (all of whom were treated with TSFs) developed non-unions. All progressed to union following revision procedures (Table 6). Two patients treated with TSFs went

Table 1 Summary of cases

	n (%)
Demographics	
Mean age (43.1 yr)	
Males	20 (27)
Females	54 (73)
Relevant comorbidities	
Smoker	13 (18)
Diabetes mellitus	4 (6)
Alcohol excess	3 (4)
Dementia	1 (1)
Mechanism of injury	
Road traffic accident	44 (59.5)
Fall from height	17 (23.0)
Cycling	4 (5.3)
Horse riding	2 (2.7)
Other	7 (9.5)
Injury	
Associated polytrauma	25 (33)
Vascular injury	2 (3)
Fasciotomy	6 (8)
Treatment	
TSF	61 (81)
IMN	9 (12)
IMN & Masquelet	5 (7)
Complications	
Major	
Deep infection	5 (7)
Re-fracture	2 (3)
Non-union	3 (4)
Minor	
Pin-site infection	15 (25)
Equinus ankle stiffness	12 (16)
Mean follow-up (mo)	
TSF	25
IMN	16

IMN: Intramedullary nail; TSF: Taylor spatial frame.

on to re-fracture at the docking site, following removal of frame (Table 7). Both re-fractures occurred despite CT evidence of bony union and one had previously been treated for an infected non-union. Patient age, sex, diabetes, smoking status or injury severity (based on GA classification) did not have a significant effect on time to union with either fixation method. One patient, following fracture union with TSF, underwent amputation at another hospital due to chronic intractable pain.

Table 2 Fracture classification and treatment

	IMN, *n* (%)	TSF, *n* (%)
OTA classification		
41A3	0	3
42A1	4	0
42A2	5	0
42B3	0	8
42C2	3 (Masquelet)	11
42C3	2 (Masquelet)	25
43A1	0	4
43A2	0	8
43A3	0	2
Gustilo-Anderson classification		
3A	10	16
3B	3	44
3C	1	1

OTA: Orthopaedic trauma association; IMN: Intramedullary nail; TSF: Taylor spatial frame.

Table 3 Time to union based on fixation method and fracture type

	Time to union (wk)
Fixation method	
IMN	22
IMN/Masquelet	27.9
TSF	38.6
Gustilo-Anderson classification	
3A (IMN)	25.9
3A (TSF)	41.1
3B (IMN)	42
3C (IMN)	68
3C (TSF)	44

IMN: Intramedullary nail; TSF: Taylor spatial frame.

DISCUSSION

Severe open tibial shaft fractures are often associated with high-energy polytrauma and consequently are managed according to Advanced Trauma Life Support guidelines. Several studies have shown these fractures to be associated with rates of chronic infection and non-union as high as 38% and 50% respectively[7,8]. Our study shows that it is possible to achieve good results with a timely multi-disciplinary approach and careful soft tissue management, as evidenced by our deep infection rate of 6.7%, non-union rate of 4% and re-fracture rate of 2.7%.

Although the timing of initial debridement is controversial[9], we believe aggressive soft tissue debridement by an experienced surgeon and damage control with temporary external skeletal stabilisation within 24 h of injury is critical. The BOAST 4 standards of care recommend definitive soft tissue closure or cover within 72 h, however, 90.1% of our patients waited longer than this. This was because a significant

Table 4 Summary of patients treated with Masquelet technique

Cases	Stage 1	Stage 2	Time to 2nd stage (wk)	Further procedures	Bone defect (cm)	Gustilo-Anderson classification
Patient 1	IMN & cement spacer	Spacer removal and bone graft	27	None	5	3A
Patient 2	IMN & cement spacer	Spacer removal and bone graft	23	None	3	3C
Patient 3	IMN & cement spacer	Spacer removal and bone graft	10	TSF (infection)	10	3B
Patient 4	IMN & cement spacer	TSF	9	None	6	3B
Patient 5	IMN & cement spacer	Exchange nailing, cement removal and bone graft	15	TSF (infection)	11	3B

IMN: Intramedullary nail; TSF: Taylor spatial frame.

Table 5 Treatment of infected cases

Cases	Organism	Treatment	Gustilo-Anderson classification
Patient 1 (M 62)	Staphylococcus, Clostridium	IMN converted to TSF after positive samples	3B
Patient 2 (F 72)	Staphylococcus	TSF	3B
Patient 3 (F 62)	Staphylococcus	TSF	3B
Patient 4 (F 22)	Staphylococcus	IMN (2nd stage Masquelet converted to TSF after positive microbiology samples)	3B
Patient 5 (M 32)	Staphylococcus	IMN (2nd stage Masquelet converted to TSF after positive microbiology samples)	3B

M: Male; F: Female; IMN: Intramedullary nail; TSF: Taylor spatial frame.

Table 6 Treatment of non-union following Taylor spatial frame application

Cases	Smoking status	Site of re-fracture	Treatment of non-union	Bone graft	Outcome
Patient 1 (M 31)	Smoker	Fracture	IMN	Yes	Bony union
Patient 2 (F 19)	Non-smoker	Fracture	Revision TSF (5 cm devitalised bone excised)	Yes	Bony union
Patient 3 (M 25)	Smoker	Fracture	IMN (fracture site opened)	Yes	Bony union

M: Male; F: Female; IMN: Intramedullary nail; TSF: Taylor spatial frame.

proportion of our patients required prolonged intensive care admission which inevitably delayed surgery. Our use of negative-pressure wound therapy (VACâ) in open fractures until definitive soft tissue closure is well supported in the literature [10]. Early prophylactic antibiotic therapy in patients with open fractures results in a relative risk reduction of 59% for acute infection and consequently all our patients received 1.2 g intravenous co-amoxiclav (or clindamycin if penicillin allergic) as early as possible after injury and until definitive soft tissue closure[11,12]. We recommend the use of antibiotic-impregnated calcium sulphate beads (Stimulanâ, Biocomposites Inc, Wilmington, NC, United States) in type 3 open fractures where there is a bone defect as this has shown to reduce infection rate (6.5% *vs* 20.6%, $P < 0.001$)[13]. We found that age, smoking, diabetes and GA severity had no significant effect on infection rate and this has been reflected in other studies[3]. Wordsworth *et al*[2] reported a deep infection rate of 1.6%, however, two of our patients who developed

Table 7 Re-fracture following Taylor spatial frame removal

Cases	Time from frame removal (wk)	Site of re-fracture	Union prior to removal	Treatment of re-fracture	Infection
Patient 1 (M 49)	12	Docking site	Non-union	Revision TSF with bone graft	No
Patient 2 (M 62)	3	Docking site	CT-confirmed union	IMN with bone graft	Yes

M: Male; IMN: Intramedullary nail; TSF: Taylor spatial frame; CT: Computed tomography.

deep infection were treated with the induced membrane technique for bone transport which we have found to have an unacceptably high failure rate as previously described[2,6]. Adjusting for this, our infection rate would be in line with most other studies.

In our study, the majority of patients who underwent IMN fixation had GA type 3A fractures (71.4%). Several studies have shown IMN fixation to be associated with high union, low infection and low re-operation rates in GA type 1 to 3A tibial shaft fractures [14,15]. Inan *et al*[16] reported a significantly shorter time to union (19 wk *vs* 21 wk, P = 0.04) with IMN compared to Ilizarov fixation in GA type 3A fractures although there was no difference in deep infection[16]. Our results show that IMN fixation leads to a faster union time than TSF in GA type 3A fractures (25.9 wk *vs* 41.1 wk), however, comparison is difficult as fractures treated with TSF tended to be more complex. All patients who were treated with temporizing external fixation prior to IMN fixation were converted within 14 d as this has been shown to be important in the prevention of deep infection[17]. We prefer reamed IMN although there is no clear evidence showing this to be superior to unreamed IMN in open tibia fractures[18].

Studies that have shown higher rates of non-union and infection with external fixation compared to IMN have only included monolateral external fixators which are biomechanically inferior to CEF[19]. A meta-analysis of five randomized controlled trials concluded that IMN was the more effective treatment for GA type 3 fractures due to the lower incidence of infections. In that study however, monolateral external fixators and CEF were grouped together and fracture classifications were not consistently specified[20]. Our mean TSF union time of 38.6 wk is longer than that reported in other studies (25-26 wk)[3,21]. This is explained by the fact that 28 cases (45.9%) had significant bone loss requiring distraction osteogenesis. Furthermore, 25 patients (33.8%) presented with polytrauma which prolonged post-operative rehabilitation and consequently, union time. Of 61 patients treated with TSF, 3 developed aseptic non-union (4.9%), which is comparable to other studies[21,22]. Two of these, both smokers, underwent exchange nailing and the third, re-application of TSF. All went on to unite. Assessing functional outcome was beyond the scope of our study, however, the literature suggests that CEF yields good functional outcomes in the majority of cases in GA type 3 fractures[23].

In the presence of critical bone loss, we found that treatment with TSF provides a safe and reliable method of regenerating significant quantities of bone *via* distraction osteogenesis following an osteotomy at a site away from the fracture. Our bone healing index (time to bony union divided by length of bony defect) was 56 d/cm. This did not necessarily correlate with when bone regenerate was considered strong enough for frame removal. Other authors have reported similar results[24]. We therefore advocate early resection of devitalized bone, as this reduces the risk of infection whilst still achieving good results with long transport distances. In selected cases of large bone loss, a protocol of debridement/PMMA spacer, soft tissue coverage, circular frame application, removal of spacer/corticotomy and distraction osteogenesis published by Hohmann *et al*[25] reported good outcomes[25]. Open segmental diaphyseal fractures present their own challenges and, as reflected in our study, often result in longer times to union. A systematic review by McMahon *et al*[26] concluded that CEF provides the most satisfactory outcomes in this group of patients [26].

In our study, two patients sustained atraumatic re-fracture at the docking site following removal of TSF. In addition to autologous bone graft, one patient was treated with IMN and the other with re-application of TSF. A successful outcome was achieved in both patients. There is very little in the literature regarding re-fracture as a complication of CEF[27].

Our limb salvage rate was 98.7% which is consistent with other studies. Superficial pin site infection requiring oral antibiotics (20%) and ankle equinus (16%) were the most common complications with TSF treatment and both are well recognised[28].

Importantly, pin site infection does not appear to translate into deep infection. We had no cases of symptomatic malunion and there were no further interventions required to correct malalignment.

Retrospective case-series have their limitations and despite being the largest single-center study of GA type 3 open tibia fractures, the study is not powered to promote one treatment over another with any certainty. Variations in fracture pattern, degree of bone loss and soft tissue management make comparison difficult. We look forward to the results of the FIXIT study, a prospective multicenter RCT comparing 1-year outcomes after treatment of severe open tibial shaft fractures with modern CEF *vs* internal fixation in adults[29]. Further study should include patient-reported outcome measures when comparing treatments.

CONCLUSION

Meticulous and aggressive debridement of GA type 3 open tibia wounds by experienced orthopaedic and plastic surgeons is paramount. Grade 1 to 3A injuries can effectively be treated with reamed or unreamed IMN. Grade 3B/C injuries are best treated by CEF as they provide good if not superior outcomes to other limb salvage techniques and allow large bone defects to be addressed *via* distraction osteogenesis. In addition, TSF offers the advantages of postoperative adjustability.

ARTICLE HIGHLIGHTS

Research background

Open tibial fractures are a challenging injury to treat. They are often associated with high energy trauma and multiply injured patients. There is also a spectrum of severity of injury which makes it a challenge to establish clear treatment guidelines.

Research motivation

The motivation for this study was to assess the outcomes of a single surgeon treating open fractures in a level one trauma center. These injuries remain a challenge to manage and various treatment options are available and indeed used over the period studies.

Research objectives

We aimed to review the results of the treatment of these severe injuries. We chose infection, union and re-fracture rates as our primary outcome measures. We also sought to compare the outcomes of intramedullary nailing (IMN), Taylor spatial frame (TSF) and the Masquelet technique.

Research methods

This was a case series of 75 open tibial fractures in 74 patients treated over the course of six years by a single trauma surgeon in level one trauma center. We reviewed fracture type, mechanism of injury, timing and number of operations, time to union, infection, re-fracture and complication rates. Mann-Whitney *U* test and Spearman's correlation coefficients were used for statistical analysis. Follow up time was 16 mo for intramedullary nails and 25 mo for TSF.

Research results

Of 26 injuries were classified as Gustilo-Anderson 3A, 47 were 3B and two were 3C. Nine patients underwent IMN, 61 underwent TSF fixation and 5 were treated with Masquelet technique. Infection rate was 6.7%, non-union rate was 4% and re-fracture rate was 2.7%. Average time to union was 22 wk for IMN and 38.6 wk for TSF fixation. Limb salvage rate was 98.7%

Research conclusions

Meticulous and aggressive debridement of Gustilo-Anderson type 3 fractures by experienced orthopaedic and plastic surgeons is paramount. Grade 1 to 3A injuries can effectively be treated with reamed or unreamed IMN. Grade 3B/C injuries are best treated using circular external fixation as this provide good if not superior outcomes to other limb salvage techniques and allows large bone defects to be addressed *via*

distraction osteogenesis. In addition, this approach offers the advantages of postoperative adjustability.

Research perspectives

Further studies should be prospective, and ideally include patient recorded outcome measures, particularly if comparing the results of different treatments available for the fixation of open tibial fractures.

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ORIGINAL ARTICLE

Observational Study

Arthroscopic removal as an effective treatment option for intra-articular osteoid osteoma of the knee

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Abstract

BACKGROUND

Intra-articular osteoid osteoma (iaOO) can be found in 5.2% up to 10% of cases. They may cause non-specific symptoms, mimicking degenerative or traumatic pathologies. If iaOO is left untreated, it may lead to severe muscle atrophy, tenderness, swelling, and limited range of motion. Therefore, surgical treatment is recommended. The main goal of surgical treatment is complete removal or destruction of iaOO.

AIM

To evaluate the efficiency of arthroscopic removal of iaOO of the knee in our cases and cases available in the literature.

METHODS

Analysis of available hospital records of four patients with iaOO of the knee treated by arthroscopic removal from August 2005 to December 2015 at our Department was performed. All patients had a diagnosis of iaOO confirmed by histopathologic analysis. Additional literature review of cases of iaOO of the knee available on PubMed and Google Scholar was made. All cases of iaOO of the knee treated by arthroscopic or arthroscopically assisted removal were reviewed in order to further evaluate the efficiency of the method.

RESULTS

The average age of patients included in our study was 23.2 (range 16-37) years. The average duration of the symptoms prior to surgery was 14.2 (range 6-24) months. All of the patients had persistent knee pain. Three patients reported worsening of pain during the night, while two reported worsening of pain during activity. Three patients reported alleviation of pain on non-steroidal anti-inflammatory drugs (NSAIDs), while one patient reported partial alleviation of pain on

checklist of items, and the manuscript was prepared and revised according to the STROBE Statement-checklist of items.

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NSAIDs. No intraoperative complications were noted, and the postoperative period was uneventful in all patients. The patients reported immediate pain relief in the postoperative period. No recurrence of the disease was noted in any of the patients during the follow-up period of at least 24 mo. The literature review revealed 14 cases with an average age of 27.6 (range 16-48) years and onset of symptoms 27.7 (range 6-108) months prior to surgery, with recurrence of the disease noted in a single case.

CONCLUSION
Arthroscopic removal is an efficient treatment method that allows excision of iaOO that is neither insufficient nor excessive, thus avoiding disease recurrence while obtaining adequate material for histopathologic analysis.

Key Words: Osteoid osteoma; Knee; Arthroscopy; Bone diseases; Surgical procedures; Operative; Pathology; Surgical

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Core Tip: Advantages of the arthroscopic or arthroscopic assisted removal of the intra-articular osteoid osteoma of the knee are the ability to obtain adequate material for histopathologic analysis and to perform neither excessive nor insufficient excision, thus avoiding disease recurrence, as well as chondral lesions and bone necrosis.

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INTRODUCTION

Osteoid osteoma (OO) is a third most common benign lesion of the bone, commonly localized in the diaphysis of long bones of the lower extremity[1]. Studies report that intra-articular OO (iaOO) can be found in 5.2% up to 10% of cases, with the knee being the third most common localization, after the hip and ankle[1,2]. In 1986, Heuijerjans *et al*[3] reported on a first successful arthroscopic removal of iaOO. Since then, arthroscopic removal of iaOO was frequently used in various joints, with a high success rate and a low recurrence rate[4-7]. However, despite the first-ever reported arthroscopic removal of iaOO was in the knee, only case reports can be found on this topic in the literature.

The aim of this study was to present the first case series of patients treated with arthroscopic removal of iaOO of the knee and to give a literature overview of arthroscopic and arthroscopically assisted removal of such lesions.

MATERIALS AND METHODS

Case series collection

This research has been approved by the Institutional Ethics Committee of the authors' affiliated institutions. A retrospective analysis of available hospital records revealed four consecutive patients diagnosed with OO of the knee confirmed by histopathologic analysis that were treated by arthroscopic removal from August 2005 to December 2015 at our Department. All of the patients have agreed to participate in the study. Available hospital records were reviewed in December 2020 by an independent examiner who was not involved in the treatment process. Demographic information, including age and gender, as well as clinical characteristics, such as symptoms, effects of non-steroidal anti-inflammatory drugs (NSAIDs) on pain relief, duration of the symptoms until the accurate diagnosis, history of trauma, diagnostic imaging utilized

preoperatively, intraoperative findings, results of histopathological analysis, follow-up duration and recurrence of the disease were analyzed.

Surgical technique

The senior author performed arthroscopic removal of iaOO of the knee in all patients (Table 1). Patients were in a supine position, under spinal anesthesia, with the affected knee placed in a leg holder. A tourniquet was applied in all of the procedures. Knee arthroscopy was performed with a 4.0 mm arthroscope angled at 30°. Standard anteromedial and anterolateral portals were used in all of the procedures, while in some, due to OO's localization, additional portals were utilized (Figures 1 and 2)[8,9]. After a thorough examination of the knee, a cherry-red, elevated lesion was localized, consistent with the typical appearance of the nidus. An arthroscopic curette was used to remove the nidus, and an arthroscopic grasper was used to remove the tissue, obtaining a suitable specimen for histopathologic analysis. An arthroscopic burr and curette were used to remove the remaining part of the lesion and surrounding bone sclerosis until visualizing healthy trabecular bone. Afterward, lavage of the knee was performed. Insertion of a drain through the anterolateral portal and closure of the skin at the arthroscopic portals followed.

Postoperative management

All patients followed the same postoperative regimen. On the first postoperative day, the drain was removed, and the patients started active and passive range of motion exercises. Partial weight-bearing as tolerated with crutches was advised for the first two weeks, with full weight-bearing advised afterward. During the first postoperative month, they underwent a course of physiotherapy, consisting of range of motion and strengthening exercises. The patients underwent monthly follow-up examinations for the first three postoperative months. After that, the follow-up visits were scheduled at six, twelve, and 24 mo postoperatively.

Literature review

A literature review of cases with iaOO of the knee available on PubMed and Google Scholar was made. Search strategy for PubMed included two search queries: (1) Osteoma, Osteoid[MeSH] AND Knee[MeSH]; and (2) osteoid osteoma AND knee. Search strategy for Google Scholar included one search query: osteoid osteoma AND knee. The search was performed on December 29, 2020. All results available on PubMed and the first 1000 results on Google Scholar were screened. Only cases of iaOO of the knee treated by arthroscopic or arthroscopically assisted removal were included and further reviewed in order to evaluate the efficiency of the method.

Data interpretation

Statistical analyses were performed using SPSS (version 21). Continuous variables were described as average (range minimum-maximum). The normality of distribution was tested using the Shapiro-Wilks test.

RESULTS

Demographic information, clinical presentation, preoperative and postoperative features of the patients treated by arthroscopic removal of iaOO of the knee are presented in Table 1. The average patient age was 23.2 (range 16-37) years. The average duration of the symptoms prior to surgery was 14.2 (range 6-24) months. Symptoms occurred in one patient after suffering a first-time lateral patellar dislocation, which became recurrent over time. One of the patients underwent an open biopsy performed by another physician ten months before he was referred to the senior author for re-evaluation. The biopsy was performed in an incorrect location of the bone due to an extensive bone marrow edema found on magnetic resonance imaging (MRI) in the medial femoral condyle. The result of the biopsy was negative, and patient's symptoms persisted. A detailed analysis of symptoms showed the patient had worsening of pain at night and after activity, which partially alleviated on NSAIDs. As the senior author suspected of iaOO of the knee, a bone scan and a follow-up MRI were performed that confirmed the diagnosis of iaOO. Computerized tomography (CT) was performed in other patients to better localize the lesion, thus allowing efficient preoperative planning.

Table 1 Demographic information, clinical presentation, preoperative and postoperative features of the patients treated by arthroscopic removal of intra-articular osteoid osteoma of the knee

Age (yr)/gender	Side	Symptoms	Pain alleviating on NSAIDs	Duration of symptoms until the accurate diagnosis (mo)	Trauma history	Location	Diagnostic imaging	Arthroscopic portals	HPA confirmed osteoid osteoma	Follow-up (mo)	Recurrence
16/F	L	Persistent knee pain worsening at night	Yes	15	Yes	Anterolateral part of the femur above the cartilage border of the trochlea	CT, bone scan	AM, AL, SL	Yes	171	No
23/M	L	Persistent knee pain worsening in activity and at night	Partially	24	No	Anteromedial part of the femur on the cartilage border of the trochlea	MRI (2)[1], bone scan	AM, AL	Yes	24	No
17/F	L	Persistent knee pain worsening in activity and at night	Yes	6	No	Anterolateral part of the femur above the cartilage border of the trochlea	MRI, CT	AM, AL, SL	Yes	55	No
37/F	R	Persistent knee pain and swelling	Yes	12	No	Posterior aspect of the lateral femoral condyle	MRI, CT, bone scan	AM, AL, PM, PL	Yes	24	No

[1]Patient had a first magnetic resonance imaging (MRI) performed, after which another physician performed an open biopsy at our department. As the symptoms persisted over the course of 10 mo, the patient was referred to the senior author to re-evaluate the case. After detailed analysis, the senior author suspected of intra-articular osteoid osteoma (iaOO) of the knee and issued a bone scan and a follow-up MRI, which confirmed the diagnosis of iaOO of the knee. NSAIDs: Non-steroidal anti-inflammatory drugs; HPA: Histopathologic analysis; F: Female; M: Male; CT: Computerized tomography; MRI: Magnetic resonance imaging; AM: Anteromedial; AL: Anterolateral; SL: Superolateral; PM: Posteromedial; PL: Posterolateral.

No intraoperative complications were noted, and the postoperative period was uneventful in all patients. The patients reported immediate pain relief in the postoperative period. No recurrence of the disease was noted in any of the patients during the follow-up period of at least 24 mo.

The literature review revealed 14 cases of iaOO of the knee treated by arthroscopic or arthroscopically assisted removal, which are presented in Table 2[1,3,10-20]. The average age of those patients was 27.6 (range 16-48) years, the average onset of symptoms was 27.7 (range 6-108) mo prior to surgery, and recurrence of the disease was noted in a single case.

DISCUSSION

This article reports on a successful treatment of iaOO of the knee using arthroscopy. Patients suffering from iaOO usually have non-specific and variable symptoms, different from the classic night pain relieved by NSAIDs found in extra-articular OOs [21]. Such clinical presentation may mislead the clinician to suspect other more common knee pathologies such as meniscal or chondral lesions[15]. A study of patients with OO that presented with knee pain showed that in 60% of them, OO was located adjacent to the hip or in the middle femoral shaft instead of the knee[22]. Moreover, some authors suggest that the worsening of pain during the night in iaOO is not typical as for extra-articular OOs[21,23,24]. However, in more than 80% of reviewed cases and three of our cases, patients complained of worsening pain during the night. Furthermore, Spiker *et al*[7] reviewed cases of iaOO of the hip and showed that in cases that recorded the presence of pain during the night, 83.3% reported

Table 2 Literature review of cases with intra-articular osteoid osteoma of the knee treated by arthroscopic or arthroscopically assisted removal

Ref.	Age (yr) /gender	Side	Symptoms	Pain alleviating on NSAIDs	Duration of symptoms until the accurate diagnosis (mo)	Trauma history	Location	Diagnostic imaging	Surgery	HPA confirmed osteoid osteoma	Follow-up (mo)	Recurrence
Heuijerjans *et al*[3], 1986	29/F	NR	Knee pain, limited ROM	NR	108	NR	Lateral tibial plateau	NR	Arthroscopic removal	Yes	18	No
Franceschi *et al*[13], 2005	28/M	NR	Light knee pain worsening at night, swelling, limited ROM	Yes	12	NR	Lateral tibial plateau	MRI, CT	Arthroscopically assisted removal – percutaneous K wire insertion to the tumor under CT, arthroscopic visualization of the knee, tumor removal by a core reamer and curettage, bone defect filled with autologous bone graft from proximal tibia	Yes	24	No
Franceschi *et al*[14], 2008	16/F	L	Light knee pain worsening at night, swelling, limited ROM	Yes	NR	NR	Central region of the patella	MRI, CT, bone scan	Arthroscopically assisted removal – percutaneous K wire insertion to the tumor under CT, arthroscopic visualization of the knee, tumor removal by a hollow drill and curettage, bone defect filled with autologous bone graft from proximal tibia	Yes	36	No
Abnousi *et al* [15], 2008	35/M	L	Diffuse dull knee pain worsening on activity, limited ROM, swelling	Partially	24	No	Medial femoral condyle	MRI, CT	Arthroscopically assisted removal – arthroscopic visualization of the tumor and *en-bloc* resection *via* miniature arthrotomy	Yes	22	No
Gunes *et al* [16], 2008	18/M	R	Knee pain worsening at night	Yes	6	NR	Medial femoral condyle	MRI, CT	Arthroscopic removal	Yes	15	No
Furukawa *et al*[17], 2011	23/F	L	Persistent knee painworsening at night, swelling	Partially	24	NR	Lateral femoral condyle	MRI, CT, bone scan	Arthroscopic removal	Yes	24	No
Saeed *et al* [18], 2011	38/M	L	Mild knee pain worsening at night	Yes	26	NR	Lateral tibial plateau	MRI, CT, bone scan	Arthroscopic removal	Yes	72	Yes[1]
Adachi *et al* [19], 2014	32/M	L	Severe knee pain, worsening at night, limited ROM	Partially	NR	No	Lateral tibial plateau	MRI	Arthroscopically assisted removal – arthroscopic visualization of the tumor, insertion of a K wire in the tumor under fluoroscopy and removal with core reamer, bone defect filled with artificial bone	Yes	18	No
Kang *et al* [20], 2016	20/F	R	Mild knee pain worsening at night	No	12	No	Lateral femoral condyle	MRI, CT, bone scan	Arthroscopic removal	Yes	24	No
Rolvien *et al* [1], 2016	26/M	NR	Knee pain worsening at night	Yes	24	No	Lateral tibial plateau	MRI, CT	Arthroscopic removal	Yes	3	No
Krause *et al* [10], 2016	26/M	NR	Knee pain worsening at night	Partially	19	NR	Lateral tibial plateau	MRI, CT	Arthroscopic removal	Yes	3	No
Rolvien *et al*	48/M	R	Persistent knee pain	Yes	24	NR	Lateral	MRI, CT	Arthroscopic removal	Yes	NR	NR

[11], 2019							femoral condyle					
Monroe *et al* [12], 2019	20/M	R	Knee pain worsening in activity	No	18	No	Medial femoral trochlea	MRI, CT	Arthroscopic removal – bone defect filled with allograft	Yes	84	No
	28/M	R	Persistent knee pain	Partially	36	NR	Medial femoral condyle	MRI, CT	Arthroscopically assisted removal – arthroscopic visualization of the tumor and removal *via* small arthrotomy, bone defect filled with allograft	Yes	6	No

[1]Six years following the arthroscopic removal, the patient had similar symptoms, and the follow-up imaging revealed recurrence of the osteoid osteoma at the same location. Another arthroscopic removal could cause extensive damage of the lateral tibial plateau, and to avoid such complication, the authors decided to perform an unicondylar knee arthroplasty. HPA: histopathologic analysis, NSAIDs: Non-steroidal anti-inflammatory drugs; NR: Not reported; F: Female; M: Male; MRI: Magnetic resonance imaging; CT: Computerized tomography; K: Kirschner; ROM: Range of motion.

positive. Also, Allen *et al*[23] report that iaOOs are less responsive to NSAIDs than extra-articular OO. Spiker *et al*[7] report that in iaOO of the hip in cases which recorded the effect of NSAIDs on pain, 69.7% reported alleviation of pain on NSAIDs. From cases of iaOO of the knee that recorded the effect of NSAIDs, 84.6% reported on either partial or complete alleviation of pain on NSAIDs[1,3,10-20].

Szendroi *et al*[2] state that plain radiographs were sufficient for diagnosis of iaOO prior to surgery in 36.8%, compared to 73.3% for diagnosis of extra-articular OOs. Furthermore, Papagrigorakis *et al*[25] state that when the first symptoms occur in iaOO patients, over 80% of patients have no visible nidus or sclerosis on plain radiographs. Therefore, further diagnostic imaging is often needed. As clinicians commonly suspect other more common knee pathologies, MRI is usually issued as a diagnostic procedure after obtaining plain radiographs. MRI may be useful in obtaining a correct diagnosis. However, joint effusion, bone edema, and soft tissue edema are frequently present and may mask the nidus[17,26]. Furthermore, Allen *et al*[23] note that the nidus is either not visible or poorly visible in 50% of iaOOs on MRI. Moreover, Bhure *et al*[27] reported that MRI may lead to misdiagnosis in up to 35% of cases if used as a solitary diagnostic procedure. Therefore, MRI findings combined with non-specific symptoms may mimic conditions such as osteomyelitis or malignant bone tumors[28]. Such a case occurred in one of our patients, who underwent an open biopsy performed in the incorrect location on the bone, resulting in persistence of symptoms and delay in diagnosis.

If MRI does not confirm iaOO, further diagnostic imaging is issued. A bone scan proved to be useful in diagnosing iaOO. It lacks the usual "double-density" sign seen in extra-articular OOs, but it presents with increased focal uptake matching with the localization of the nidus[23]. When the localization is found, a CT scan may be performed. Assoun *et al*[26] report that CT scan proved to be more accurate than MRI in detection of the nidus in 63% of cases. Also, CT scans proved to be a valuable tool in preoperative planning of the surgery[29]. Therefore, we have performed a CT scan in three of our patients.

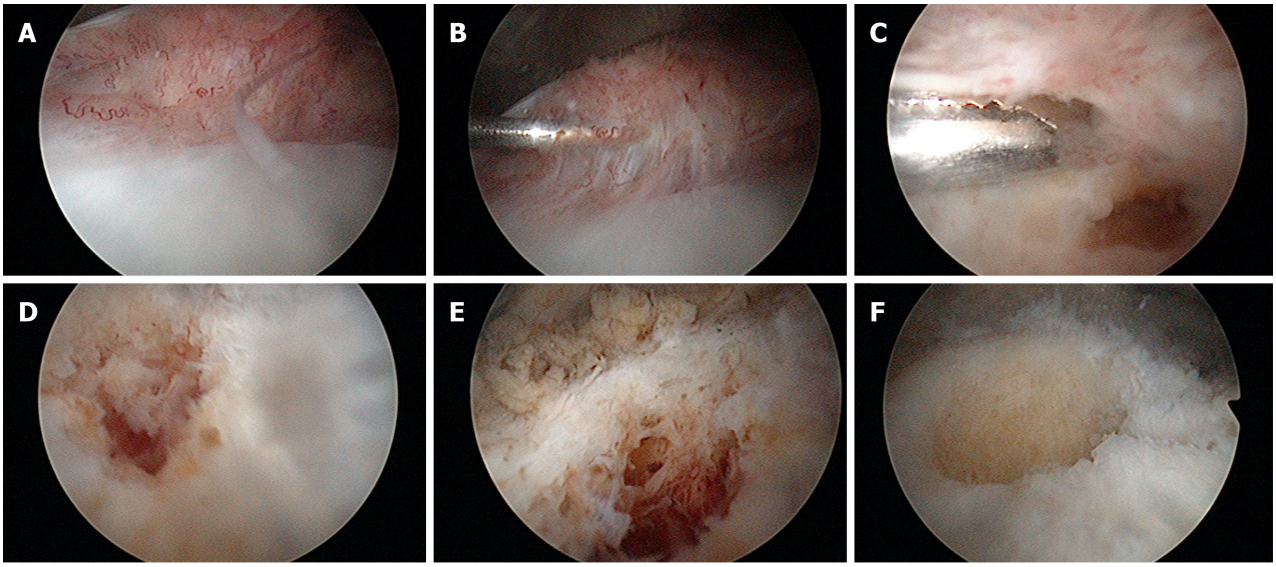


Figure 1 Sequential arthroscopic views of the anteromedial part of the femur above the cartilage with the arthroscope in the anterolateral portal. A: synovial hyperplasia; B: Palpation of the elevated synovial tissue with a probe; C: Removal of the synovial tissue reveals the altered tissue; D and E: After partial removal, the extensiveness of the altered tissue is revealed; F: The remaining crater after complete removal of the lesion.

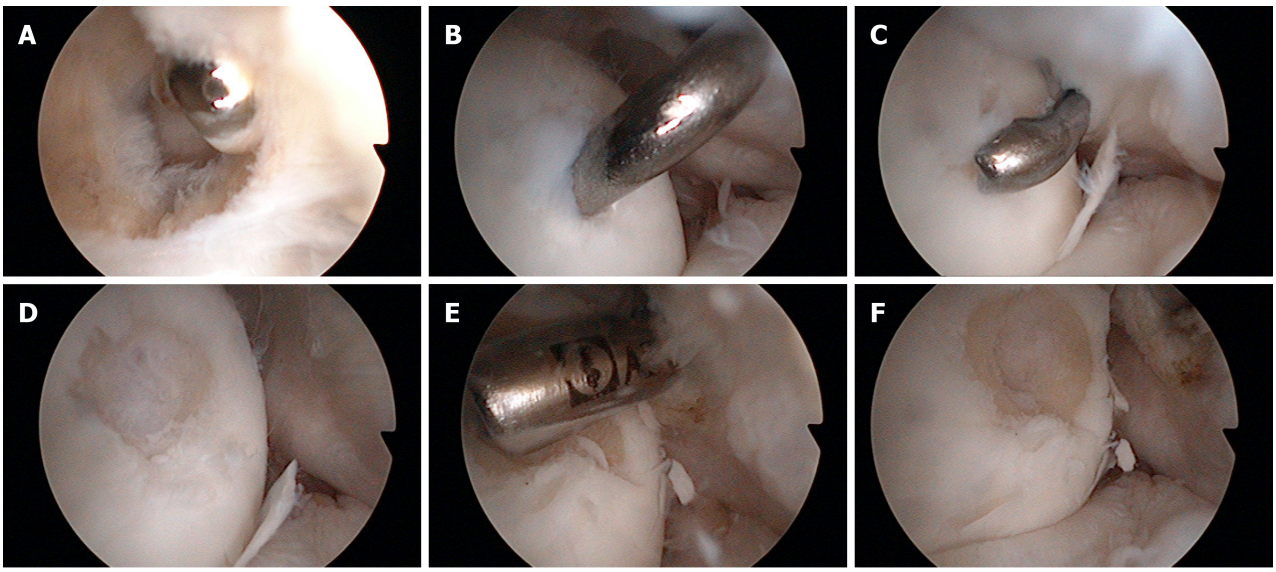


Figure 2 Sequential arthroscopic views of posterior part of lateral femoral condyle with the arthroscope positioned in the posteromedial portal. A: Trans-septal approach; B: Palpation of the altered tissue with a probe from the posterolateral portal; C: Removal of the altered tissue with a cochlea; D: Visualization of the sclerotic bone after removal of altered tissue; E: Removal of the nidus and surrounding sclerosis with a motorized instrument; F: The remaining crater after complete removal of the lesion.

Peculiarities of the clinical presentation and diagnostic imaging of iaOOs lead to a significant delay in diagnosis in comparison to extra-articular OOs. Rolvien *et al*[1] report that the mean time for a correct diagnosis of iaOO was 20.7 mo, while Szendroi *et al*[2] state that the mean time for diagnosing extra-articular OO was 8.5 mo in comparison to 26.6 mo for iaOO. When considering the duration of symptoms of iaOO of the knee, the average duration until obtaining a diagnosis in our patients was 14.2 mo (range 6-24), while of those we have analyzed from the literature was 27.7 mo (range 6-108)[1,3,10-20]. The symptoms duration in our patients is somewhat shorter than reported in the literature. However, due to the small number of cases we report, we consider that the actual delay in diagnosis is usually closer to the average expressed from the analyzed literature.

Nowadays, the treatment of choice for extra-articular OOs is the CT-guided radiofrequency ablation (RFA), with a success rate of up to 97%[10]. However, the treatment of iaOO with RFA requires certain precautions, as this method may cause a

cortical and bone marrow necrosis of up to 1.3 cm in diameter[30]. As iaOO may be located close to the cartilage and other joint tissues, this may be the limiting factor for the use of RFA. Another minimally invasive method that proved to be efficient is the CT-guided percutaneous resection[14]. However, percutaneous resection may result in cutaneous necrosis, neurapraxia, osteomyelitis, and fractures[14]. Furthermore, these methods are often unable to provide a sufficient sample for the histopathologic analysis[17].

The most significant concerns of arthroscopic removal of iaOO are the difficulty of localization of the lesion intraoperatively and the possibility of recurrence due to incomplete excision. However, with adequate preoperative planning, the advantage of great visualization allowed by 30° and 70° arthroscopes, and possible intraoperative fluoroscopic assessment, we believe no difficulties in localizing iaOO should occur. So far, for only one arthroscopically treated case of iaOO of the knee recurrence of the disease was reported, meaning the success rate of this method is 94.4%[1,3,10-20]. The success rate of arthroscopic removal of iaOO in the ankle is 96%, in the upper extremity is 93.8%, while in the hip is 100%[4-7]. Advantages of the arthroscopic removal are the ability to obtain adequate material for histopathologic analysis and to perform an excision of iaOO that would neither be insufficient nor excessive, thus avoiding both recurrence of the disease, as well as chondral lesions and bone necrosis. As Furukawa *et al*[17] note, arthroscopic removal is at least as effective as CT-guided methods for both localizing and removal of the lesion.

Localization of iaOO in our case series was on the femur exclusively, with 3 cases proximal to the superior cartilage border of the trochlea and one case in the posterior part of the lateral femoral condyle (Table 1). On the contrary, seven cases from the literature report that iaOO was localized on the femoral side, six were on the tibial side, and one was in the patella (Table 2)[1,3,10-20]. However, due to the relatively small number of cases, it is difficult to pinpoint the typical localization of the iaOO in the knee.

This study has shown the efficiency of arthroscopic removal of iaOO of the knee. However, its retrospective nature presents a limitation. Furthermore, we have not compared our results with open surgical treatment or removal of OO in other locations, as these also represent the limitations of this study. Due to a small number of cases in our study, as well as limited availability of more valued study designs in the literature, we did not find it justified to compare our results with arthroscopic treatment of iaOO in other locations, which have much larger case series. This suggests that only uncommon and novel cases of iaOO of the knee have been published, and further research will additionally clarify peculiarities of this pathology. Moreover, a possible limitation to the study is that no follow-up diagnostic imaging was performed. However, it is suggested that follow-up diagnostic imaging should be performed only in patients with a thorough suspicion of a recurrence of OO. Therefore, as our patients were all symptom-free during follow-up, we believed no diagnostic imaging is needed.

CONCLUSION

Our case series, as well as the literature review, suggest that arthroscopic removal is an efficient and safe method of treatment in patients with intra-articular osteoid osteoma of the knee. It enables excision of the tumor that is neither insufficient nor excessive, thus avoiding both recurrence of the disease, as well as chondral lesions and bone necrosis, while obtaining adequate material for histopathologic analysis. Therefore, arthroscopic removal should be considered as a treatment option when dealing with this rare entity.

ARTICLE HIGHLIGHTS

Research background

Intra-articular osteoid osteoma of the knee is a rare entity that may present with non-specific symptoms and may lead to severe disability if left untreated. There are several treatment options, one of which is arthroscopic removal.

Research motivation

As there is a low number of reported cases of intra-articular osteoid osteoma of the

knee, our goal was to report our results and further elaborate on the results available in the literature.

Research objectives

To analyze whether arthroscopic removal is an effective treatment option for intra-articular osteoid osteoma of the knee.

Research methods

A first case series ever of such patients was reported, as well as the review of all available cases in the literature that report on the same pathology and treatment options.

Research results

Both the case series and cases from the literature report that arthroscopic removal of intra-articular osteoid osteoma is an effective treatment option with a low chance for recurrence of the disease.

Research conclusions

Arthroscopic removal of intra-articular osteoid osteoma enables excision that is neither insufficient nor excessive, thus avoiding both recurrence of the disease, as well as chondral lesions and bone necrosis, while obtaining adequate material for histopathologic analysis. Therefore, it should be considered as a treatment option if physicians come across such a case.

Research perspectives

Future research will additionally clarify the efficiency of arthroscopic removal of intra-articular osteoid osteoma, possibly on a larger case series than reported in this article and in the literature so far.

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REVIEW

International recognition of the Ilizarov bone reconstruction techniques: Current practice and research (dedicated to 100th birthday of G. A. Ilizarov)

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Abstract

The Ilizarov method is one of the current methods used in bone reconstruction. It originated in the middle of the past century and comprises a number of bone reconstruction techniques executed with a ring external fixator developed by Ilizarov GA. Its main merits are viable new bone formation through distraction osteogenesis, high union rates and functional use of the limb throughout the course of treatment. The study of the phenomenon of distraction osteogenesis induced by tension stress with the Ilizarov apparatus was the impetus for advancement in bone reconstruction surgery. Since then, the original method has been used along with a number of its modifications developed due to emergence of new fixation devices and techniques of their application such as hexapod external fixators and motorized intramedullary lengthening nails. They gave rise to a relatively new orthopedic subspecialty termed "limb lengthening and reconstruction surgery". Based on a comprehensive literature search, we summarized the recent clinical practice and research in bone reconstruction by the Ilizarov method with a special focus on its modification and recognition by the world orthopedic community. The international influence of the Ilizarov method was reviewed in regard to the origin country of the authors and journal's rating. The Ilizarov method and other techniques based on distraction osteogenesis have been used in many countries and on all populated continents. It proves its international significance and confirms the greatest contribution of Ilizarov GA to bone reconstruction surgery.

Key Words: Ilizarov method; Ilizarov apparatus; Distraction osteogenesis; Bone lengthening; Bone defect; Bone transport; Arthrodesis

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Core Tip: The Ilizarov method of bone reconstruction involves bone repair and new bone formation. It is based on the biological phenomenon of distraction osteogenesis that is used for bone lengthening and deformity correction. The Ilizarov bone transport is a salvage procedure for a number of conditions, including large bone defects and infection. The method gave an impetus to new developments in bone reconstruction surgery based on the regeneration potential of bone tissue. Acceleration of distraction regenerate consolidation is one of the objectives of the current research in new bone formation.

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INTRODUCTION

Reconstructive surgery is performed to recover body parts that are affected aesthetically or functionally in congenital defects, developmental abnormalities or trauma. Bone reconstruction is the procedure of repair, rebuilding, and reshaping of skeleton bones. The goal of bone reconstruction surgery is reparation and creation of vital bone tissue with a variety of treatment methods available. It involves the management of bone injuries and their sequelae such as nonunion, post-traumatic bone defects and bone infection as well as bone deformities and shortening of the extremities due to acquired conditions or congenital malformations. It aims to correct bone loss, length and axis, reshape a limb segment and change its malposition so that to restore or improve its anatomy and functions.

The Ilizarov method is one of the current methods used in bone reconstruction. It originated in the middle of the past century and comprises a number of bone reconstruction techniques performed with a ring external fixator developed by Ilizarov GA (1921-1992) in 1951 in the former Soviet Union[1]. Professor Ilizarov GA (Figure 1) and his team were searching for solutions to develop external fixation (EF) techniques to treat the pathology of long and short bones of both upper and lower limbs, cancellous bones of the skull, pelvis and spine, and joint disorders at one of the largest orthopedic centers for limb reconstruction founded in Kurgan (Russia) in 1971[1-4]. Bone repair and reconstruction with this method are realized by means of applying compression or distraction forces to bone fragments for bone consolidation, axial alignment or new bone formation through the phenomenon of distraction osteogenesis induced by tension stress with the Ilizarov apparatus based on external supports and transosseously drilled wires that, driven with threaded units, are able to produce multiplanar actions on bone fragments. The scientific activity of the Kurgan institute for traumatology and orthopedics promoted basic research on the investigation of bone and soft-tissue regeneration[1-4]. The fundamental and clinical studies on the principles of bone regeneration and reconstruction using the Ilizarov tension-stress effect were disclosed in the author's monograph and several publications that appeared in the English language at the end of the last century[2-4]. They have been considered as major publications of the author and still are his most read works that have been cited more than 1500 times. The Ilizarov bone compression-distraction method, implemented with the author's apparatus, has been called the classical Ilizarov method[1].

The Ilizarov method techniques became known to the world orthopedic community and started to be used in several European countries in the 1980s. Since then, the original method has been used along with a number of its modifications and developments due to emergence of new fixation devices and techniques of their application[1,5,6]. The geography of their application has expanded much while the advancements in bone reconstruction that followed are of international significance and gave rise to a relatively new orthopedic subspecialty which has been termed limb lengthening and reconstruction surgery (LLRS)[7,8]. The purpose of this update was to



Figure 1 Ilizarov GA at the beginning of his career in Kurgan (1960). Photo courtesy of the Ilizarov Center Museum.

summarize the clinical practice and research in bone reconstruction with the Ilizarov and LLRS techniques published in the last 5 years with a special focus on their modification, advance, and recognition by the world orthopedic community.

BONE FIXATION DEVICES

Internal or external bone fixators are mechanical means in bone reconstruction ensuring the stability of a fractured or osteotomized bone, bone compression or distraction, and guided fragment transport. The Ilizarov system that comprises circular external fixator modules and techniques of their application for specific clinical situations[4] has experienced many modifications over the last 50 years[9,10]. Development and progress in bone fixation devices have been greatly influenced by the Ilizarov's "revolutionary entrance" to the world of orthopedics and aimed at constant improvement of clinical outcomes and patients' comfort. External fixators (the Ilizarov apparatus, hybrid and hexapod external fixators, the Orthofix limb reconstruction system, the Taylor Spatial Frame) are the main devices in bone reconstruction surgery that involves new bone formation and correction[5,6,10]. The conventional circular external fixator has been enhanced with innovative configurations, pin and ring modifications, wire and half-pin coatings that can potentially decrease infection rates in thick soft-tissue limb segments while parts fabricated from carbon fibers make the whole circular frame weight lower[5,9]. Monolateral rail external systems have been used for a better comfort of patients undergoing a bone lengthening procedure in the femur[6]. Computerized circular fixators and motorized intramedullary lengthening nails which ensure distraction osteogenesis have been called the major orthopedic advances in the techniques of limb lengthening[5]. However, they are either dependent on specialized computer software and computed tomography (CT) data or costly for the health systems and therefore cannot be used on a large scale. New systems have been designed based on a commercially available motorized lengthening nail for an all-internal segmental bone transport and optional lengthening but their application has been still under investigation[11]. Motorized internal lengthening plates for lengthening in the situations in which intramedullary nailing is contraindicated have been recently under development and might be a major advancement in the field of limb lengthening[12].

Nevertheless, despite the emergence of innovative devices, the Ilizarov-type external fixators remain affordable and preferred devices for management of a great variety of orthopedic conditions due to good clinical results achieved by their application, fast bone tissue formation during callus distraction, much less shear forces compared to unilateral external or hexapod fixators, versatility and lower costs[6]. Moreover, their manufacture has been organized by international and national companies in many countries of the world.

CURRENT CLINICAL PRACTICE AND RESEARCH IN THE ILIZAROV TECHNIQUES OF BONE RECONSTRUCTION

Our review is based on a comprehensive literature search for clinical studies and research on the current use of the Ilizarov techniques for bone reconstruction or their modifications in PubMed, Scopus and Web of Science databases written in the English language and published in the period from 2016 to 2020 with a special emphasis on the international representation of their authors and journals of their publication. The studies available from the journals included into the international indexing systems above mentioned were grouped according to their targeted applications, as described by Ilizarov GA[1,4]. The international influence of the Ilizarov method on the current state of bone reconstruction was reviewed in regard to the origin country of the authors and the impact factor that measures journal's citations, and therefore shows journal's significance for the world orthopedic audience.

Fracture repair

The use of EF in the management of fractures is an old concept. Ilizarov GA and his Kurgan team attempted to design a set of the external apparatus parts that could be assembled into frames for definitive treatment of bone injuries and on any bone segment, including hand and foot bones[4]. However, the evolution of fixation means and of the Ilizarov techniques over the years has specified the fracture types for which the Ilizarov external frames are more efficient. First of all, those are complex open and closed comminuted fractures which are not amenable to open reduction and internal fixation or cast immobilization[13,14]. Indications include pediatric juxta-articular distal radial, distal femoral, distal humeral and distal tibial fractures that are comminuted, complicated, and/or open[15]. The basic principles of the Ilizarov fixation for fracture repair in children avoid additional injury to the growth plate with K-wires, enable careful and accurate reduction without interfragmentary compression, ensure anatomic alignment and fracture stability, preserve periosteal blood supply and allow for joint motion and early weight-bearing. Management of complex pediatric tibial fractures (open injuries, with bone loss or soft-tissue compromise) with the Ilizarov fixator was found safe, effective and reliable with good functional results and health-related quality of life during treatment[16]. Numerous published reports regarding complex trauma reflect the utilization of the Ilizarov techniques in adults, especially for para-articular injuries[17-24]. The Ilizarov bone transport for isolated and *comminuted tibial* fractures with bone defects or tibial deformities was found effective after studying its long-term outcomes and complications at one center for more than 30 years[25]. The Ilizarov ring fixator was recommended as an effective treatment modality for open comminuted distal femur fractures and resulted in high union rate, adequate alignment and satisfactory functional outcomes[17]. It can be reliably used and showed good clinical and quality-of-life results in adult trauma for tibia plateau and pilon fractures[18-22]. Clinical and radiographic outcomes of the Ilizarov technique for high-energy pilon and severe tibial plateau fractures (Schatzker IV-VI) were accompanied by minimal complications or impaired functions. Definitive fixation with circular external fixator in the patients with multiple traumatic injuries was effective in a comparative study evaluating its outcomes *vs* plating for complex Schatzker VI tibial plateau fractures with better union rates, lower infection and compromised soft tissues problems despite some walking impairments detected[18]. There was no difference regarding the rate of deep infection, reoperations, range of knee motion and concerns about physical satisfaction between the two groups treated for proximal tibial fractures with the Ilizarov frame or locking plates[22]. Neglected tibial pilon fractures treated with the Ilizarov frame healed without deep infection and ankle arthrodesis was avoided in most cases[21]. The use of EF for treating displaced intra-articular calcaneal fractures was an alternative to plating and screw fixation with good results achieved by clinicians in most cases due to early mobilization of the peritalar joints and early post-operative loading[23,24]. Long-term functional outcomes of definitive treatment utilizing bone transport for exposed comminuted tibial fractures with bone defects were in line with the literature[25].

The Ilizarov fixator was used in elderly patients for tibia plateau fractures, pilon fractures, ankle fusions, non-unions, deformity correction and miscellaneous trauma [26]. It was concluded that there was no difference between the subgroups of diseases concerning the physical and mental health. First reports on Ilizarov EF for periprosthetic femur and tibial fractures after total knee arthroplasty (TKA) have appeared and have been judged as a feasible and low invasive treatment option providing stable fixation, early post-operative mobilization and no major complications what is

especially important in elderly individuals after TKA[27]. Microvascular fibular grafting was combined with the Ilizarov circular fixation for large acute bone defects in severe trauma with acute bone loss[28]. And finally, placement of the Ilizarov external frame has been much used as a temporary bone fixation means in polytrauma cases and acute compartment syndrome due to high-energy trauma in the lower limbs [29]. The authors of the studies point to the advantages of the Ilizarov fracture stabilization such as maintaining the frame till union, early mobilization, restoration of the normal lower extremity alignment, versatility, and improved union rate in patients with multiple traumatic injuries, including exposed fractures associated with soft tissue trauma.

Long-bone nonunion and defects, including infected ones

The management of bone defects and nonunion continues to be a subject of great interest in the international orthopedic literature[30,31]. A contemporary surgeon has a number of options with proven clinical evidence for management of bone defects and nonunion. Depending on the anatomical location and the size of the defect, current treatment techniques range from acute shortening to vascularized bone grafts, the Ilizarov bone transport and the Masquelet induced membrane technique[31-33]. As shown by several comparative studies, these treatment options have their advantages and limitations. However, the Ilizarov bone transport has been the most frequent practice in nonunion and defect management, especially in infected tibia[34,35]. Current clinical investigations focus on the need for complete eradication of infection through radical debridement[34-39]. Deep femoral infection resulting from intramedullary fixation of closed femoral fractures was resolved with staged treatment that included radical debridement and continuous canal irrigation, followed by monolateral bifocal bone transport[36]. The technique of an L-shaped partial corticotomy with preservation of intact and uninvolved posterior tibial bone was proposed that reduced circular fixator duration in the cases of focal tibial osteomyelitis and bone deficit of 8 cm after debridement[37]. Extensive debridement of all the devitalized tissues and bone transport was a reliable solution in the treatment of gunshot bone defects of the tibia[38]. On the contrary, limited debridement was enough to control infection and achieve good results without radical resection in managing chronic osteomyelitis in pediatric cases[40]. Both bone transport and soft-tissue flaps were used concurrently for management of post-traumatic composite bone and soft tissue defects[41]. EF techniques were found to play a key role in the management of nonunion after Monteggia injuries[42,43]. Lengthening using external fixators was possible in bone resection defects due to tumors[44,45].

Much research has been done in finding solutions for filling critical-sized bone defects in order to promote faster new bone formation utilizing distraction osteogenesis[30,31]. There is a variety of more or less biologic alternatives for the reconstruction of defects, but still distraction osteogenesis undoubtedly has the highest potential for remodeling[31]. One of them is trifocal treatment (two lengthening sites) that shortens EF duration[38]. It was associated with better results compared with bifocal treatment (one lengthening site) for defects of > 8 cm, despite a longer operative time in the trifocal group. Several mechanical solutions utilizing compression and distraction were proposed for failed distraction osteogenesis in large bone defects[46]. One more technique is ipsilateral fibula expansion that is an option of radial instead of longitudinal distraction osteogenesis. Gradual fibular transfer with the Ilizarov external fixator was used in post-traumatic and post-infection large tibial bone defects[47,48]. Although the induced membrane technique has gained much popularity in bone defect treatment, the Ilizarov bone transport remains the main tool in the situations with bone deformity and limb length discrepancy[31]. Its main merits are viable new bone formation to bridge the defect, high union rates and functional use of the limb throughout the course of its many-months treatment, preventing disuse osteoporosis[33-35,49].

Long-bone lengthening and deformity correction

Most modifications of the classical Ilizarov method refer to limb lengthening and deformity correction. First, it was the Taylor Spatial frame supplied with computer guidance for long-bone lengthening and deformity correction[5,6,50]. Then, EF was supplemented by internal fixation with a nail. The combined modifications used currently are lengthening over nail and lengthening and then nailing techniques[6]. One more combined technology is the use of flexible intramedullary HA-coated wires along with the Ilizarov apparatus[51]. These techniques apply external fixators in the lengthening procedure and intramedullary nails in the regenerate consolidation phase to protect the regenerate. However, the comparative studies evaluating the efficacy of

bone formation and prevalence of complications show that they are superior to the conventional method only in regard to the EF index and decrease in the total time of being with the external fixator on[52]. The most recent developments are motorized implantable lengthening nails that provide reasonable lengthening magnitudes[6,53-55]. Despite the complications reported in small series of patients, the new technology of motorized intramedullary nails (MIMN) has simplified upper limb lengthening surgery and made lower limb lengthening more comfortable for patients[53]. Monolateral EF lengthening was compared with MIMN lengthening in children with congenital femoral deficiency and similar lengthening parameters[54]. The MIMN group had lower complication rates and better range of motion at the end of distraction and at consolidation. MIMN technology yields better results for range of motion, which is one of the benefits to patient's quality of life. Improved patient comfort and psychological tolerance, faster recovery of activities, low infection rates and absence of fractures in the regenerated bone are the merits of MIMN against the limitations, such as maximum distraction of 5 cm and the fact that it cannot be used if the growth plates are still open. The PRECICE nail was found to carefully manage the rate of distraction to prevent complications in bone consolidation but the remote controller and the cost were found its weak points[6,55]. Moreover, it was reported that reamed intramedullary nailing showed an adverse effect on bone regeneration during the distraction phase in tibial lengthening[56].

Limb deformity and shortening remains a main issue of bone reconstruction in pediatric orthopedics and its correction is a necessity for a variety of rare congenital conditions[57-61]. EF systems are preferred by the surgeons in pediatric cases[57-59]. Ilizarov two-ring tibial lengthening was found effective in maintaining segmental alignment, efficient in callus production and relatively comfortable for pediatric patients with few significant complications[58]. Monolateral external systems for femoral lengthening were used children and adolescents[59]. Despite the popularity of guided growth systems, the EF role in pediatric deformity correction is significant and can be played by different external devices that allow multiplanar corrections[62]. Nevertheless, Ollier's disease, fibrous dysplasia, osteogenesis imperfecta and other metabolic diseases are still great challenges for orthopedic surgeons[63-66]. Titanium or hydroxyapatite-coated elastic nails in combination with an external fixator may be a way out in limb lengthening and deformity correction of abnormal bone in children [61,65]. These thin HA-coated implants show osteoactive properties and do not migrate as reported by long-term follow-ups. Upon external frame removal after completion of correction, they remain in situ for reinforcement of the abnormal bone in patients with metabolic bone disorders and skeletal dysplasia. Correction through combined bony realignment and lateral collateral ligament tightening in achondroplasia was reported with good or excellent subjective outcomes[66].

Very good results were achieved in humeral lengthening with the Ilizarov techniques. Although the motorized nails were also attempted for this purpose, more magnitude was achieved with EF[67-69]. A series of extensive lengthening in patients with achondroplasia and hypochondroplasia was compared showing complications by bone segment, and between the techniques of simultaneous bilateral lengthening and crossed lengthening[70]. Humeral lengthening in that series was associated with significantly fewer complications and quicker healing than lower-extremity lengthening. The crossed lengthening technique in the lower extremity had a greater incidence of malalignment and leg-length discrepancy compared with the transverse technique. This experience may be useful for limb lengthening done for esthetic purposes[6,71,72]. Recently, limb lengthening for esthetic purposes in patients with constitutional short stature performed either with the Ilizarov-type fixator in the tibia or MIMN in the tibia and femur has become very popular. It was shown to be safe and was judged beneficial to the patients in regard to their social capabilities and self-confidence. Yet, patients should be well informed about the complications and risks of the esthetic lengthening surgery[72].

The basic osteotomy techniques were discussed in regard to bone formation and the study stressed the importance of the procedure for qualitative distraction osteogenesis [73]. The regular 1-mm rate of daily lengthening, confirmed in the historical experiments by the Ilizarov's team[4], should be followed with any fixator or adjusted down if problems appear in order to have stable bone regeneration[48]. The regenerate condition and consolidation is of primary concern to allow full weight-bearing[74]. Current research in limb lengthening has been based on the experiments which are aimed at distraction osteogenesis acceleration and faster regenerate maturation that take many months to complete efficient bone formation. The protocol of injecting bone marrow aspirate concentrate in multiple areas of poor regenerate was used to correct delayed union in achondroplasia during distraction osteogenesis, but the study evokes

concerns of bias in confirming its role for faster healing[75]. Several studies used pharmacological agents to improve regenerate formation. Teriparatide, the bioactive component of parathyroid hormone, was delivered by daily subcutaneous injections after bone-transport docking[76,77]. It was stated that teriparatide treatment during the consolidation phase of distraction osteogenesis doubled the mineralization rate of the regenerate when compared to no treatment. The experiment on a canine model attempted automated high-frequency distraction with a daily 3-mm rate and confirmed that the bone had the potential for regeneration under the conditions described but there were concerns about the response of soft tissues and joints[78]. Histological differences were observed in bone and muscle tissue when Ilizarov fixation was supplemented by intramedullary HA-coated thin nails compared with no intramedullary stabilization in that experiment. Only few recent studies were found on the effect of mechanical forces and some agents to accelerate or improve bone regeneration[76-79]. Thus, the problem still remains on the agenda of future research. There has been an increasing interest in technologically based surgical strategies for limb deformity correction and lengthening[80]. Nevertheless, the recent advances in an increased use of computers and mobile devices along with the application of dynamic hexapod EFs and MIMN are still based on the principles described by Ilizarov GA and Paley D.

Rare conditions

Although there is a lot of investigation on the management of congenital pseudarthrosis of the tibia (CPT) and an extreme interest to the Masquelet technique attempted recently for this rare pathology, the appropriate solutions have not been found yet[81-86]. Latest reports support a combined basis in CPT management for both the biological and mechanical components of the conditions, utilizing the Ilizarov EF and intramedullary rod stabilization along with a corticocancellous bone autograft. It could ensure a statistically significant reduction in the number of refractures compared with standalone fixation methods. A multicenter study of the influencing factors in the management of Crawford-type IV CPT with follow-ups till skeletal maturity showed that the use of the Ilizarov technique, transfixing the ankle and subtalar joints, use of a cortical graft and not operating on the fibula were associated with better outcomes than combining intramedullary nailing with the Ilizarov technique and the use of bone morphogenetic protein[85]. The induced membrane technique combined with the Ilizarov bone transport has been tried to improve the outcomes of CPT management and demonstrated promising results in regard to avoid refractures[86]. It also included morphological investigation of the human induced membrane and its potential for osteogenesis. Injections of bone marrow aspirate concentrate in the pseudarthrosis site after focus removal in combination with circular EF achieved faster bone healing compared with EF only, and the lower refracture rate but a longer follow-up would be required to determine if the results of this adjuvant therapy will hold up over time[87]. It was revealed that additive rhBMP-2 might shorten the time to initial healing of pseudarthroses but not guarantee bony union[81]. Severe cases of proximal tibial dysplasia associated with CPT were treated using lengthening either with a transphyseal distraction or an osteotomy directly next to the physis[88]. It found that lengthening through the physis had a lower healing index (faster healing) than after metaphyseal corticotomy but should be best done near maturity. Reconstruction with several procedures along with EF ended in limb salvage in tibial hemimelia[89,90]. Lengthening and deformity correction with the Ilizarov principles were reported for multiple hereditary exostoses of the forearm, radial deformity, radial clubhand, ulnar longitudinal deficiency[91-94]. A large series of children with hereditary exostoses was reported who were treated by either unilateral or circular EF for lengthening[91]. A technique of bifocal distal radial osteotomy for acute angular correction distally and lengthening with EF more proximally was described for patients with distal radial deformity and concurrent shortening[92].

Foot bone malformation and deformities

The Ilizarov techniques of gradual correction in multicomponent foot deformities and gradual soft tissue distraction with open releases and/or bony procedures can achieve a pain-free and plantigrade foot[95-99]. Placement of the Ilizarov-type frame on the foot and its adjustments require both an experienced surgeon and a motivated patient but the techniques achieve the goals both in bone reconstruction and functionality of the foot. In complex cases, distraction osteogenesis should be reserved as a salvage solution and should be performed at specialized centers. The techniques for foot pathology are implemented with a number of frame modifications, including hexapod external fixators[99]. The techniques may be regarded as salvage procedures in

neglected adult clubfoot, challenging ulcerations, ankle joint arthrodesis for treating Charcot neuroarthropathy despite the complications[96,100-103]. Thus, a hybrid technique of circular EF and an intramedullary nail coated with antibiotic cement salvaged lower limbs in most patients and achieved a functional and clinically stable foot in infected neuropathic ankles[104]. Infected ankles were also salvaged with the Ilizarov method[104-106]. Reconstruction of the hind foot and ankle with concurrent lengthening through a distal tibial corticotomy utilizing the Ilizarov frame was found comparable to other treatment alternatives[107]. Modifications were proposed for rare congenital malformations of the foot, including brachymetatarsia and cleft foot[108-110]. Different foot and ankle frame assemblies were grouped into a few standard hexapod configurations and foot treatment strategies were demonstrated[111].

Hand malformation and deformities

The Ilizarov-type external mini-fixator and some other small external fixators were specially developed for hand bone injuries, lengthening, congenital malformation and deformities[112-115]. They confirm the success of the ideas of Ilizarov GA in utilizing distraction osteogenesis and soft tissue traction in the management of hand pathology [4].

Joint disorders

Ilizarov's ideas also contributed to joint reconstruction surgery[4,116]. Reconstruction techniques continue to find applications in the management of complex pediatric hip pathology. Recently, good results have been reported using EF systems for correction of proximal femoral deformities secondary to slipped capital femoral epiphysis, Perthes' disease in children, coxa vara, sequelae of pediatric hip septic coxitis, and ischemic deformities of the hip[116-121]. A safe and effective technique of a low-profile Ilizarov external fixator was applied for developmental coxa vara following an acute, opened wedge subtrochanteric valgus-flexion-derotation femoral osteotomy using a percutaneous multiple hole drilling for treating multiplanar proximal femoral deformities in children[117]. Proximal femoral and triple pelvic osteotomies and the Ilizarov frame module were successfully used for treatment of adolescent developmental hip dysplasia[119]. Pertrochanteric osteotomy and femoral neck lengthening by distraction were efficient in treatment of proximal hip ischemic deformities in children [120]. Management of a chronic, traumatic posterior hip dislocation in an 8-year-old boy by open reduction, grafting, femoral shortening, and stabilization with articulated iliofemoral EF was described[121].

Joint distraction with EF frames is not a frequent procedure but the published studies report on clinical improvements in adult patients with knee osteoarthritis [122]. Despite the short follow-ups, small sample sizes and high frequency of pin tract infection reported which is of concern, since most patients will further require joint replacement, the technique might allow delaying joint replacement surgery for several years[123]. Ankle arthrodiastasis was also shown as an option for patients with end-stage primary or post-traumatic ankle osteoarthritis[124]. The authors believe that distraction within the joint optimizes the intraarticular environment for equilibration of hydrostatic pressure, promoting subchondral morphoangiogenesis, and decreases subchondral sclerosis, thereby mitigating pain. The process allows for joint salvage as an alternative to arthrodesis or ankle implant arthroplasty. The authors see joint distraction to be a useful approach to the management of ankle pain secondary to loss of functional joint surface.

Unfortunately, arthrodesis is still a salvage surgical procedure for knee and ankle joints in cases of infected total arthroplasty, tumor, failed arthroplasty or posttraumatic complication. Arthrodesis of the knee with the Ilizarov external fixator has been found successful in achieving quality of fusion and recovery of the limb supporting function [125,126]. Effective ankle arthrodesis using either external or internal fixation was reported but better outcomes were achieved in the EF group[127]. The technique of tibiotalocalcaneal arthrodesis in patients with and without diabetes, closed arthrodesis in infected neuropathic ankles and infected ankle fractures with segmental bone-loss using Ilizarov concepts were assessed as salvage procedures[107,128,129]. An interesting study on the use of shoulder arthrodesis for septic arthritis of the shoulder due to proximal humerus osteomyelitis was presented[130].

Other pathology

We should finally mention flat bone reconstruction based on the Ilizarov principles. The apparatus for transpedicular EF in spinal pathology was first experimented on animals under the supervision of Ilizarov GA and later developed by his followers at the Ilizarov Center in Kurgan[131]. It could provide gradual controlled correction for

high-grade kyphoscoliosis in adolescents and transition to internal fixation following its removal with preserved correction at long term. The Ilizarov's experimental team also investigated gradual expansion of skull bones and surrounding soft tissues. It was applied for traumatic skull defects and brain vascularity stimulation after brain stroke but the techniques remained on the stage of uncompleted clinical trials. On the contrary, the role and significance of craniomaxillofacial distraction procedures have been much discussed in the specialized literature and has been found applicable in craniofacial deficiency or dentofacial anomalies that are corrected with distraction procedures and special devices[132,133]. Another Ilizarov's idea of stimulating the vascularity in chronic ischemic diseases in the lower extremities has been revived and its modification has been called tibial transverse distraction[134,135].

THE INTERNATIONAL IMPACT OF THE ILIZAROV METHOD ON THE EVOLUTION OF BONE RECONSTRUCTION SURGERY

The laws of compression-distraction osteogenesis due to tension-stress effect were discovered by Professor Ilizarov GA and his team of scientists more than 60 years ago and the techniques were termed "transosseous osteosynthesis"[1-4]. Our literature review shows that they have been still largely implemented with the external apparatus that bears his name. The versatility of the assemblies constructed from the Ilizarov apparatus set of parts resulted in a great variety of possible applications in bone reconstruction surgery that are fracture repair, bone nonunion, mal-union, bone defects, limb length discrepancy, long-bone deformity, hip disorders, knee arthrodesis, ankle arthrodesis, foot deformities, foot bone lengthening, anomalies and fractures of the hand. It is the main tool in the management of complex intraarticular fractures, bone transport and bone infection in the tibia, foot deformities and ankle arthrodesis. No other system of external bone fixation is able to produce so many options and variants used for bone recovery. The biological phenomenon of distraction osteogenesis developed by Ilizarov GA may be considered one of the greatest achievements in bone reconstruction surgery.

Our goal was to present to your attention the studies on the current international practice and research in bone reconstruction that have been based on the Ilizarov's ideas. The search for literature in the international databases has revealed a huge amount of practical studies that encapsulate a broad spectrum of pathologies treated with interventions or devices developed within the LLRS subspecialty due to the impact of the Ilizarov method. The original Ilizarov techniques of bone reconstruction and their modifications or innovations have been investigated at a variety of institutions across the world but the main centers of clinical research and practice are located in the United States, United Kingdom, China, Russia, Italy, Egypt, and India [136,137]. It is well seen from Table 1 that presents the number of authors per country that published their studies in the period under investigation (data from PubMed platform of the National Library of Medicine, United States) (Table 1).

The impact of the Ilizarov method on bone reconstruction surgery is of great international value. Interestingly, but the shortcomings of the Ilizarov method which are mainly related the ring fixator such as transfixation of muscles and other soft tissues with wires and half-pins, pain, pin-tract infection, and psychosocial limitations imposed on the patient due to prolonged use of the Ilizarov circular fixator have led to vigorous research and development of new devices able to decrease or avoid them. However, the principles of new bone tissue formation discovered by Ilizarov GA have been recognized as universal. Ilizarov-minded surgeons continue to use this method due to its efficacy proven by more than a half-century practice. LLRS has been regarded as an orthopedic subspecialty that emerged due to the advancements in bone reconstruction after the introduction of the Ilizarov method[138]. National limb lengthening and reconstruction societies, though under various names, have been active worldwide. The first one was the Association for the Study and Application of the Ilizarov Methods (ASAMI) that appeared in Italy and was the one that played the major role in the popularization of the Ilizarov techniques. Its activities were broadened by the International ASAMI and the International LLRS which hold biannual meetings around the world. Such meetings and courses were held in Milan, Baltimore, Cairo, Lima, St. Petersburg, Barcelona, Bombay, San Paolo, Miami, Liverpool, Dhaka, Sydney, and other cities. The nearest meeting has been scheduled to be held in Mexico in 2022. There is a LLRS specialty day at the annual meeting of the American Academy of Orthopaedic Surgeons at which bone reconstruction surgeons from around the world present their studies and hold workshops. The *Journal of Bone*

Table 1 Number of authors per country that published their studies on bone reconstruction with the Ilizarov techniques or their modifications (PubMed search results for 2016-2020)

#	Country	Number of authors	%	#	Country	Number of authors	%
1	China	105	19.1	26	Spain	4	0.7
2	Russian Federation	52	9.5	27	Nigeria	4	0.7
3	United States	43	7.8	28	Belgium	3	0.5
4	United Kingdom	40	7.3	29	Canada	3	0.5
5	India	39	7.1	30	Indonesia	3	0.5
6	Egypt	39	7.1	31	Serbia	3	0.5
7	Japan	22	4.0	32	Singapore	3	0.5
8	Poland	21	3.8	33	Cameroon	3	0.5
9	Pakistan	18	3.3	34	Iran	2	0.4
10	Turkey	16	2.9	35	Netherlands	2	0.4
11	Italy	15	2.7	36	Finland	1	0.2
12	Germany	12	2.2	37	Iraq	1	0.2
13	Bangladesh	10	1.8	38	Ireland	1	0.2
14	Switzerland	9	1.6	39	Israel	1	0.2
15	Thailand	8	1.5	40	Kuwait	1	0.2
16	Australia	7	1.3	41	Mexico	1	0.2
17	Greece	7	1.3	42	Morocco	1	0.2
18	Tunisia	7	1.3	43	Philippines	1	0.2
19	France	6	1.1	44	Puerto Rico	1	0.2
20	South Korea	6	1.1	45	Saudi Arabia	1	0.2
21	Austria	5	0.9	46	Sudan	1	0.2
22	Brazil	5	0.9	47	Portugal	1	0.2
23	Denmark	5	0.9	48	Argentina	1	0.2
24	Malaysia	5	0.9	49	Lebanon	1	0.2
25	South Africa	4	0.7		Total of authors	550	100

and Joint Surgery of the Association of Bone and Joint Surgeons publishes annual guest editorials on the topic of new studies in limb lengthening and deformity correction [136].

Our survey which is based on the data from the international databases for the latest 5-year period has revealed that more than 150 journals dedicated their space to the topic under our discussion. These journals published more than 750 articles on the Ilizarov techniques of bone reconstruction and their modifications submitted by the authors from 50 countries. SCImago metrics on ratings of the journals in the field of Orthopedics&Sports Medicine based on Scopus® database shows that numerous studies have been published in the journals of high citation level and international value (Table 2). The high-rated journals, popular among orthopedic surgeons, such as *Injury*, *Bone and Joint Journal*, *Journal of Paediatric Orthopaedics*, *International Orthopaedics*, *Journal of Foot and Ankle Surgery* have published the biggest number of the articles (Table 2). Table 2 also lists the countries of the authors that published their clinical and basic research on the Ilizarov techniques, their modifications and related fields of study. The most read and cited orthopedic journals also appear to have a wide authors' representation from around the world.

Authors from the countries with large population such as China, the United States, India and Russia came first in the line. China was formally introduced with the Ilizarov method in 1990 but has become the leader in the last 10 years. The interest to the original method evoked new ideas and applications, including continuous basic research on the biological mechanisms of distraction osteogenesis and its translation to

Table 2 Publication of studies on the Ilizarov techniques or their modifications in the international journals of high scientific impact and specialized limb lengthening and reconstruction surgery journals in 2016-2020 (SCImago metrics and Scopus database)

#	Journal title	Society, institution or publishing company	SJR 2019	Number of articles	Origin country of the authors of the studies
Quartile Q1					
1	*Injury*	British Trauma Society, Australasian Trauma Society, Saudi Orthopaedic Association in Trauma	0.904	40	Australia, Austria, China, Egypt, Germany, India, Italy, Japan, Malaysia, Poland, French Republic, Serbia, South Africa, Spain, Switzerland, Turkey, United Kingdom, United States
2	*Bone and Joint Journal*	British Editorial Society of Bone and Joint Surgery, United Kingdom	2.375	14	Australia, Austria, China, Egypt, Germany, India, Italy, Kuwait, Pakistan, Russia, South Korea, Switzerland, United Kingdom
3	*International Orthopaedics*	International Society of Orthopaedic Surgery and Traumatology (SICOT)	1.533	14	Austria, China, Egypt, Ireland, Japan, Russia
4	*Journal of Orthopaedic Trauma*	Orthopaedic Trauma Association, AO Trauma North America, Belgian Orthopaedic Trauma Association, *etc.*	1.023	9	Egypt, Japan, Switzerland, United Kingdom, United States
5	*Archives of Orthopaedic and Trauma Surgery*	Springer Verlag, Germany	1.152	8	Belgium, Egypt, Italy, Netherlands, Poland, Russia, Serbia, South Africa, Switzerland, United Kingdom
6	*Journal of Pediatric Orthopaedics*	Pediatric Orthopaedic Society of North America (POSNA)	1.19	7	Egypt, India, Iran, Republic of Korea, United Kingdom, United States
7	*Clinical Orthopaedics and Related Research*	Association of Bone and Joint Surgeons	1.487	5	Australia, China, United Kingdom
8	*Knee*	British Association for Surgery of the Knee, the Australian Knee Society, and the German Knee Society	1.083	4	China, Greece, Italy, Turkey
9	*Scientific reports*	Universities and research institutions, United Kingdom	1.341	4	China, Poland
10	*HSS Journal*	Hospital for Special Surgery, United States	0.76	3	Israel, Italy, Russia, United States
11	*Orthopaedics and Traumatology: Surgery and Research*	French Society for Orthopaedic Surgery and Traumatology (SoFCOT)	0.949	3	Egypt, France, United Kingdom
Quartile Q2					
12	*Journal of Orthopaedic Translation*	Chinese Speaking Orthopaedic Society (CSOS) and the International Chinese Musculoskeletal Research Society (ICMRS)	0.73	16	China, Hong Kong, United Kingdom
13	*BMC Musculoskeletal Disorders*	BioMedCentral, part of Springer Nature	0.76	12	China, Japan, Mexico, Poland
14	*Journal of Pediatric Orthopaedics Part B*	International Federation of Paediatric Orthopaedic Societies (IFPOS)	0.411	12	China, Egypt, India, Poland, French Republic, Spain, United Kingdom, United States
15	*Journal of Foot and Ankle Surgery*	American College of Foot and Ankle Surgeons	0.619	11	China, Egypt, Greece, Japan, French Republic, United Kingdom, United States
16	*Medicine (United States)*	Medicine®, universities and research institutions in the United States	0.639	8	China, Japan, Poland, United States
17	*Journal of Orthopaedic Surgery and Research*	BioMedCentral, part of Springer Nature	0.669	7	China, Denmark, Germany, Poland, United Kingdom, United States
18	*Journal of Orthopaedic Science*	Japanese Orthopaedic Association	0.56	6	China, Japan, South Korea, United Kingdom
19	*Journal of Children's Orthopaedics*	European Paediatric Orthopaedic Society (EPOS)	0.597	5	Egypt, France, Italy, Russia, Switzerland
20	*Acta Orthopaedica et Traumatologica Turcica*	Turk Ortopedi ve Travmatoloji Dernegi	0.442	4	China, Russia, Turkey
21	*European Journal of Orthopaedic Surgery and Traumatology*	Springer-Verlag France SAS, part of Springer Nature	0.681	4	Egypt, Greece, Italy, Serbia, United Kingdom, United States
22	*Orthopaedic Surgery*	Chinese Orthopaedic Association and John Wiley and Sons Australia, Ltd.	0.618	4	China, Thailand

23	*World Journal of Orthopaedics*	Baishideng Publishing Group	0.798	4	Egypt, Russia
24	*Foot and Ankle Surgery*	European Foot and Ankle Society	0.716	3	China, Egypt
Quartile Q3					
25	[1]*Strategies in Trauma and Limb Reconstruction*	British Limb Reconstruction Society	0.481	30	Australia, Denmark , Egypt, India, Italy, Pakistan, Russia, Singapore, Turkey, United Kingdom, United States
26	*Indian Journal of Orthopaedics*	Indian Orthopaedic Association (IOA)	0.39	10	Greece, India, Italy, Russia
27	*Journal of Clinical Orthopaedics and Trauma*	Delhi Orthopaedic Association	0.469	10	India, Italy, Russia, Thailand
28	*Journal of Orthopaedics*	Prof. PK Surendran Memorial Educational Foundation and Indo Korean Orthopaedic Foundation	0.2	10	China, India, Indonesia, Japan, Russia, Turkey, United Kingdom, United States
29	*Ortopedia Traumatologia Rehabilitacja*	Foundation of Medical Education, Poland	0.195	6	India, Italy, Poland
30	*Revista Brasileira de Ortopedia*	Brazilian Society of Orthopedics and Traumatology	0.437	6	Brazil, China, India, Russia
31	*Chinese Journal of Traumatology*	Daping Hospital and the Research Institute of Surgery of the Third Military Medical University	0.385	5	Brazil, India, Russia, Singapore
32	*Clinics in Podiatric Medicine and Surgery*	Clinics series, ELSEVIER	0.326	5	United States
33	*Acta Orthopaedica Belgica*	The Belgian Orthopaedic Trauma Association	0.31	4	Egypt, India, Russia, United States
34	*Malaysian Orthopaedic Journal*	Malaysian Orthopaedic Association and ASEAN Orthopaedic Association	0.25	4	India, Pakistan
Quartile Q4					
35	[1]*Genij Ortopedii*	Association of Study and Application of Methods of Ilizarov (Russia)	0.151	109	Bangladesh, France, India, Russia, Switzerland, United States, Uzbekistan
36	*Trauma Case Reports*	Affiliated to *Injury* Journal	0.15	4	Japan
37	*Mymensingh Medical Journal*	Bangladesh Academy of Sciences	0.159	3	Bangladesh
38	[2]*Journal of Limb Lengthening and Reconstruction*	Association of Study and Application of Methods of Ilizarov and the International Limb Lengthening and Reconstruction Society	-	80	India, United States, United Kingdom, Portugal, Brazil, Japan, Egypt, Canada, South Africa, Saudi Arabia, Malaysia, Russia, Italy, Germany, Lebanon, Greece, Israel, Argentina, Australia

[1]Specialized limb lengthening and reconstruction surgery (LLRS) journals.
[2]Specialized LLRS journals not included in Scopus. SJR: Scientific Journal Ranking (SCImago Journal and Country Rank).

the clinical practice[137]. One of the newest editions is the *Journal of Orthopaedic Translation* of the Chinese Speaking Orthopaedic Society (CSOS) and the International Chinese Musculoskeletal Research Society (ICMRS) which main goal is to publish papers that "identify and fill scientific knowledge gaps at the junction of basic research and clinical application (from bench to bedside) or community application (from bench to community)". It published 16 articles on the application of the techniques based on the Ilizarov method and basic research in a special issue (November 2020), titled *Ilizarov Techniques in China for 30 years: From Research to Clinical Translation* that focuses on shortening of treatment duration by stimulating distraction histogenesis [135,137].

There are three specialized journals that are meant by their founders to be dedicated to LLRS. *Strategies in Trauma and Limb Reconstruction* of the British Limb Reconstruction Society has been adopted as the English language journal on this subspecialty by several ASAMI and LLRS societies (Brazil, Egypt, Japan, LLRS North America, LLRS South Africa, LLRS Nordic, ASAMI Philippines, Pakistan, Malaysia, South Korea, CEFM China)[1,66,73]. *Journal of Limb Lengthening & Reconstruction*, the official publication for the International ASAMI and ILLRS, is a platform for exchanging the opinions on the topics of bone and joint reconstruction that has issued six volumes since its initiation but unfortunately still lacks indexing by the interna-

tional databases of Scopus, Web of Science and the PubMed platform[8,74]. The *Genius of Orthopaedics (Genij Ortopedii)* issued at the Ilizarov National Medical Research Center for Traumatology and Orthopedics (former Russian Ilizarov Scientific Center for Restorative Traumatology and Orthopedics) by ASAMI Russia has been included in the Scopus database and provides a free on-line access to its volumes both in Russian and English[86]. These journals show the evolution and the main tendencies in LLSR in the post-Ilizarov era reflected in clinical and basic research.

It is no doubt that the use of the Ilizarov method has been discussed in general medical and orthopedic journals that are issued in national languages or are read at national level. Those journals may not be included into the famous databases and are not so much known to the international orthopedic community but could testify on the geography of the Ilizarov method distribution across the continents[139]. The studies written by the authors from Cameroon and Nigeria on Ilizarov limb reconstruction in Africa conclude that the use of the Ilizarov method has been sparsely reported on the continent but should be "popularized in the countries with limited resources because it would be an attractive alternative to the amputations that are sometimes performed" [140,141].

Although the Ilizarov method requires a lot of training and expertise to perform it successfully, a great number of surgeons throughout the world have mastered its principles and basic techniques to improve or save their patients' lives. The three databases that we have reviewed include the studies of the authors practicing in 50 developed and developing nations from all the populated continents. We have undertaken a lot of effort to fulfill the noble goal of this investigation but acknowledge that our data are far from complete but they prove that the Ilizarov's ideas of bone reconstruction have been shared in clinical practice and followed across the world.

CONCLUSION

The Ilizarov's principles of bone reconstruction have stood the test of time and have been internationally recognized. It has been confirmed by numerous studies published in honored international and national journals. The Ilizarov method and other techniques based on distraction osteogenesis have been used in a great number of countries and all continents. These facts prove its international significance and confirm the greatest contribution of Ilizarov GA to bone reconstruction surgery. Undoubtedly, the great heritage he has left to the world should be emphasized once again in 2021, the year when his 100th birthday is marked.

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MINIREVIEWS

Calcar-guided short-stem total hip arthroplasty: Will it be the future standard? Review and perspectives

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Abstract

Short stems in total hip arthroplasty (THA) are becoming increasingly popular. In Germany, already 10.4% of all primary THAs are performed using a cementless short stem. The concept of modern, calcar-guided, short stems aims for an individualized reconstruction of the hip anatomy by following the calcar of the femoral neck, a bone- and soft-tissue-sparing implantation technique, and physiological loading. The stem design uses either metaphyseal fixation alone or additional diaphyseal anchoring, depending on the stem alignment and indication. These individualized anchorage types increase the potential indications for the safe use of a short stem. The design features may account for potential advantages of current short stem implants compared with earlier short-stem designs, particularly in cases of reduced bone quality or osteonecrosis of the femoral head and femoral neck fractures. The implantation technique, however, requires distinct knowledge regarding the characteristics of varus and valgus positioning, with the potential for clinical consequences. A learning curve for surgeons new to this technique must be taken into account. Cortical contact with the distal lateral cortex appears to be crucial to provide sufficient primary stability, and the use of intraoperative imaging to identify "undersizing" is highly recommended. Current results of several national registries indicate that calcar-guided short stems are among the most successful implants in terms of mid-term survivorship. However, long-term data remain scarce. This review introduces the characteristics of calcar-guided short-stem THA and summarizes the current evidence.

Key Words: Total hip arthroplasty; Short stem; Calcar-guided; Classification; Indications;

Grade A (Excellent): A
Grade B (Very good): 0
Grade C (Good): 0
Grade D (Fair): 0
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Core Tip: Modern calcar-guided short stems offer numerous advantages compared with conventional total hip arthroplasty (THA). The broad potential to reconstruct the individual hip geometry, the reduced proximal bone remodeling, and the simplified soft-tissue-sparing implantation represent true accomplishments in THA. Mid-term data indicates encouraging outcomes and excellent implant survival. If long-term data confirm these promising results, chances are good that calcar-guided short stems will become the future standard in THA.

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INTRODUCTION

Total hip arthroplasty (THA) is considered one of the most successful procedures developed during the last century, with excellent long-term results. Worldwide, increasingly younger and more active patients with osteoarthritis are being treated, demanding increasing levels of postoperative clinical function and the ability to engage in physical activity[1]. In Europe, over 20% of all patients treated with THA are under the age of 60 years[2]. The demand for surgical procedures and implants that allow for an active, high-quality, daily life continues to grow. Minimally invasive techniques are on the rise, allowing for the performance of muscle- and soft-tissue-sparing implantations. In contemporary THA, in addition to choosing the right approach, the choice of implant can potentially determine the postoperative outcome. Selecting an adequate femoral implant strongly contributes to the optimal use of minimally invasive techniques[3].

To date, four types of femoral implants are available for THA: hip resurfacing, conventional straight stems, anatomical shortened conventional stems, and short stems.

Hip resurfacing has been introduced as a bone-sparing alternative to conventional THA, associated with a reduced risk of dislocation, easy replication of hip biomechanics, and easier revision, if necessary[4]. However, problems with femoral head necrosis and osteolysis caused by wear and metallosis caused by metal-on-metal bearing couples have resulted in a strong decline in the implantation numbers. The unrestricted use of this technique cannot currently be recommended[5].

Although excellent long-term survival rates have been reported with the use of conventional femoral stems in THA, proximal stress shielding and thigh pain often occur after THA[6-8]. In younger patients, who will likely require eventual revision surgery, the conservation of proximal bone mass and extended service life are preferable for femoral implants. Additionally, minimally invasive techniques may be adversely affected using conventional stems[3].

Short stems have become increasingly popular in recent years. Short-stem THA aims to preserve bone, prevent stress shielding, and provide favorable conditions for revision without altering the basic concepts of conventional THA. Most short-stem designs focus on metaphyseal fixation. Short femoral stems were previously developed decades ago to ensure a bone- and soft-tissue-sparing implantation approach; however, in recent years, numerous innovations and modifications have emerged on the market[9]. However, some short-stem designs have already been withdrawn from the market for a variety of reasons. In Europe, the concept of short-stem THA has become increasingly important, and implantation numbers increase yearly. For example, in Germany, 10.4% of all primary THA procedures are performed using a cementless short stem[10]. However, a large variety of short stem models are available, which differ in both design and function[11].

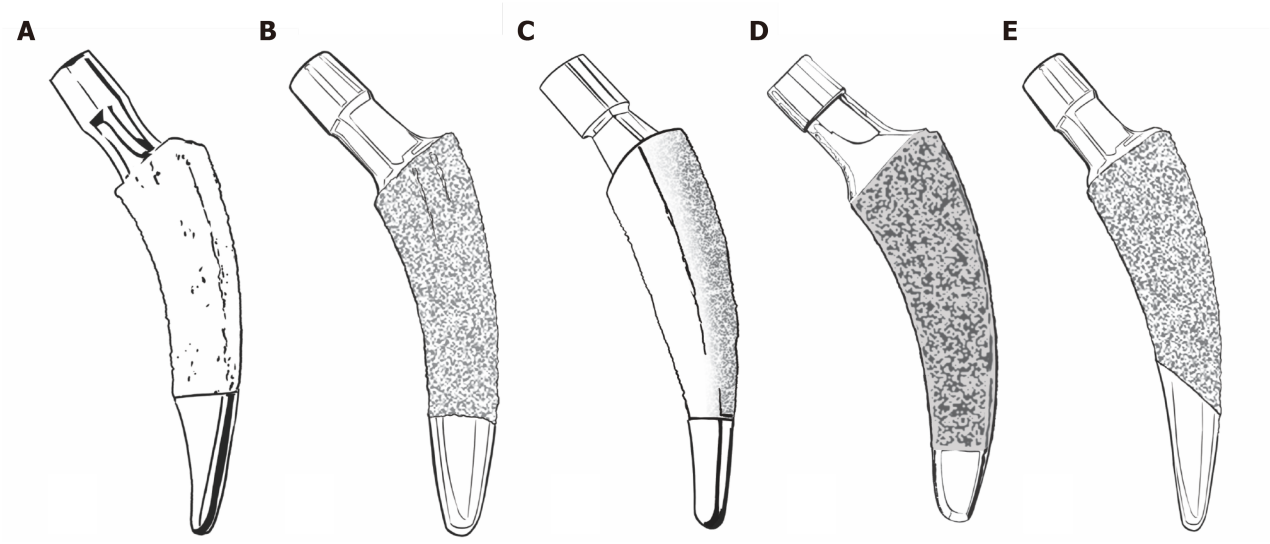


Figure 1 Common new-generation calcar-guided short stems. A: Nanos stem (Smith&Nephew, Marl, Germany; on the market since 2004); B: MiniHip stem (Corin, Cirencester, UK; on the market since 2007); C: ColloMIS stem (Lima Corporate, Villanova di San Daniele del Friuli, Italy; on the market since 2009); D: optimys stem (Mathys Ltd., Bettlach, Switzerland; on the market since 2013); E: A2 stem (Artiqo, Luedinghausen, Germany; on the market since 2016).

For most new-generation short-stem designs, short- and mid-term results have been reported[12-15]. At present, however, little data is available regarding long-term outcomes[16]. A major concern in reducing length and diaphyseal fixation of the femoral component is the concomitant reduction of implant stability and the increase of interface micromotion. By interfering with osteointegration, the long-term risk of implant loosening might increase as well[17,18]. Also, positive effects on bone remodeling and stress shielding in the long term have yet to be demonstrated for many short-stem designs[19].

The concept of modern calcar-guided short stems in THA aims for the precise reconstruction of the individual, anatomic hip geometry, using a bone- and soft-tissue sparing implantation technique associated with a physiological loading in the meta-diaphysis to conserve proximal bone stock over the long term. This new-generation short stem design allows for the reconstruction of the individual patient's anatomy by following the calcar of the femoral neck[20]. Meta-diaphyseal anchoring is applied, consisting of either pronounced metaphyseal anchorage alone or with additional diaphyseal anchorage, depending on the stem alignment and indication[15,21]. The classification of this stem design therefore is challenging; however, in Europe, the term "calcar-guided" has become established in recent years[22] (Figure 1).

CLASSIFICATION

An early classification system for short stems in THA was proposed by Jerosch[23] and adjusted by Falez *et al*[11]. This system is based on the corresponding level of the femoral neck resection, differentiating between neck-retaining, partially neck-retaining, and neck-resecting short stems. Distinctions in terms of biomechanics and implantation techniques are also considered. Another recent classification system, described by Khanuja *et al*[24], was introduced in 2014. This system categorizes all short-stem designs into four groups, in addition to subgroups. The group of partially neck-retaining stems defined by Jerosch comprises the group of calcar-loading stems defined by Khanuja *et al*[24] (Group 2). A subclassification method was added, dividing calcar-loading stems into trapezoidal, rounded, threaded, and thrust-plate designs. Modern calcar-guided short stems are almost exclusively classified as trapezoidal, rounded, calcar-loading stems according to the system defined by Khanuja *et al*[24] (Groups 2A and B). The newest generation of contemporary short stems consists almost exclusively of calcar-guided and calcar-loading short stems, such as the Nanos stem (Smith&Nephew, Marl, Germany), the MiniHip stem (Corin, Cirencester, UK), the ColloMIS stem (Lima Corporate, Villanova di San Daniele del Friuli, Italy), the optimys stem (Mathys Ltd., Bettlach, Switzerland), and the A2 stem (Artiqo, Luedinghausen, Germany) (Figure 1). All of these stem designs can be anchored either by metaphyseal anchorage alone or with the addition of diaphyseal

anchorage, depending on an individualized positioning. Thus, classification depends not only on the design features but also on the positioning.

To account for differences in the individualized positioning and anchorage of calcar-guided short stems, a second subclassification method is suggested, distinguishing metaphyseal anchorage [for example Group 2B(M)] from meta-diaphyseal anchorage [Group 2B(MD)], for all stems summarized in Group 2B (Figure 2A and B).

RECONSTRUCTION OF THE ANATOMY

The design of modern calcar-guided short stems features a characteristically rounded shape that can be adapted to the medial anatomical calcar curve (Figure 3). The positioning is performed according to the individual anatomy along the calcar curve [20]. It is dependent on the resection level of the femoral neck. This feature differentiates this design from other conventional stems and many other short-stem designs. Calcar-guided short stems can follow a valgus anatomy into a valgus position or a varus anatomy into a varus position. The positioning must be accomplished by the surgeon, through the intraoperative selection of an individualized, adjusted level of resection, according to the preoperative plan (Figure 4A and B). A high resection of the femoral neck leads to a varus position, with a corresponding high offset, whereas a low resection results in a valgus alignment and a corresponding low offset[20]. It has been demonstrated that the individual anatomy of the proximal femur can, therefore, be reconstructed across a broad bandwidth and offset, allowing leg length to be restored[25-27]. Kutzner *et al*[21] introduced a classification divided into Groups A–E, in which Groups A and B represented varus anatomies, Groups C represented a neutral hip, and Groups D and E represented valgus anatomies, based on the caput collum diaphysis (CCD) angle. A stem design with an anatomical calcar fit has been reported to be advantageous for preventing unwanted valgization[28]. Additionally, in the second plane, the natural anterior tilt of the femoral neck can only be preserved by a short femoral implant, without needing the application of high antetorsion, facilitating the restoration of both lateral and anterior offset[29] (Figure 5).

SPARING THE BONE AND SOFT TISSUE

Due to the short and rounded design, the insertion of the instruments and the implantation itself is performed using a 'round-the-corner' technique, which spares the greater trochanter region[30]. This conveniently avoids the potential fracturing of the trochanter and also reduces the damage to muscle and soft tissues that insert at the piriformis fossa and the greater trochanter, such as the crucial gluteal muscles. Compared with the implantation of conventional implant designs, more proximal femur bone mass can be preserved during short stem implantation surgery[31]. Minimally invasive approaches, without transection or damage to the muscles, are clearly facilitated by the use of this technique (Figure 6). Recent studies have indicated that calcar-guided short stems are advantageous compared with conventional stem designs in terms of intraoperative blood loss and the rates of blood transfusion[32]. In general, the design features of calcar-guided short stems are particularly suitable for minimally invasive approaches[30].

ANCHORAGE

The primary concept of short stems focuses on anchoring in the metaphysis. Most short-stem designs use three-point anchoring to achieve a stable primary fixation (Figure 7A–C). The first short-stem design to pursue this philosophy was the Mayo stem (Zimmer Biomet, Warsaw, Indiana, USA), which was introduced in 1985 and is no longer available on the market (Figure 7A). The pronounced metaphyseal anchorage aimed to achieve the physiological loading of the proximal femoral bone. The minimization of stress shielding is preferable[21,33]. The preservation of bone stock is considered to be beneficial in case future revision surgery is necessary[31]. A popular and widespread representative of the metaphyseal anchoring philosophy is the Metha stem (Aesculap, Tuttlingen, Germany) (Figure 7B). The design features of this stem in the distal part do not easily accommodate an additional diaphyseal anchorage, which is almost impossible to attain during surgery, even in neutral or

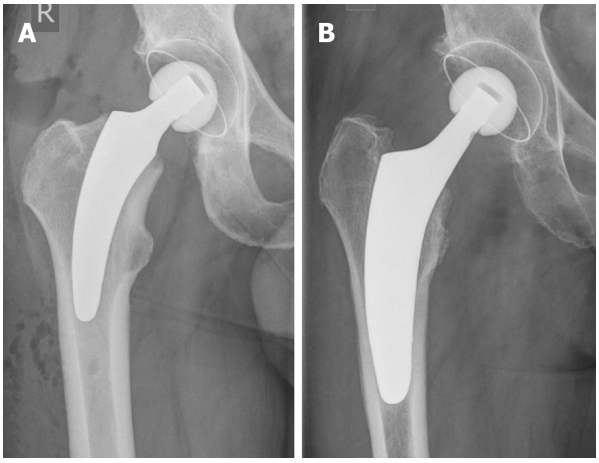


Figure 2 Introduction of a subclassification to account for the individualized positioning of group 2A and 2B stems, according to Khanuja *et al*[24]. A: Metaphyseal anchorage [for example group 2B(M)]; classical three-point anchoring; B: Meta-diaphyseal anchorage [group 2B(MD)]; additional fit-and-fill in the proximal diaphysis. Citation: Khanuja HS, Banerjee S, Jain D, Pivec R, Mont MA. Short bone-conserving stems in cementless hip arthroplasty. *J Bone Joint Surg Am* 2014; 96: 1742-1752.

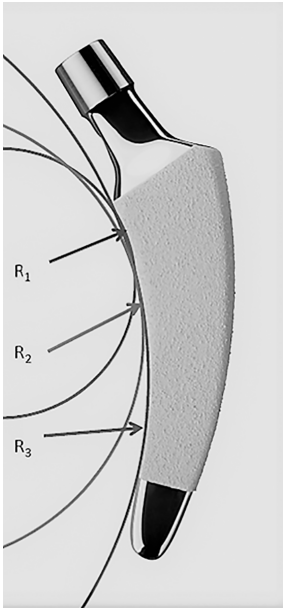


Figure 3 The design of modern calcar-guided short stems, with a rounded shape, is adapted to the medial anatomical calcar curve. In the case of the optimys stem (Mathys Ltd., Bettlach, Switzerland), three different radii were used to design the curve (R1-3). (Copyright Mathys Ltd., Bettlach, Switzerland).

valgus anatomies (Figure 8A). Therefore, a strictly non-compromised proximal bone stock and sufficient bone quality are mandatory prerequisites for the safe implantation of this stem[14]. Similarly, the Nanos stem, an early representative of calcar-guided short stems, features narrowing in the distal section of the stem, primarily intended to allow proximal fixation, at the same time limiting the option of additional diaphyseal anchorage (Figure 8B).

In new-generation, calcar-guided, short-stem THA, in addition to individualized positioning, the anchoring type can be individualized. When using the optimys stem in a varus position, a classical three-point anchoring approach should be attempted (Figure 2A). In the neutral and valgus position, an additional diaphyseal anchorage is possible (Figure 2B). In varus hips, the high level of the osteotomy proximal wedging combined with the three-point anchoring approach is typically sufficient, whereas in valgus hips, due to the low resection level, the stems may require an additional diaphyseal anchorage to achieve primary stability[34] (Figure 8C). Changing the type of anchorage through the addition of a diaphyseal anchorage will potentially result in negative effects on proximal bone remodeling and stress shielding compared with

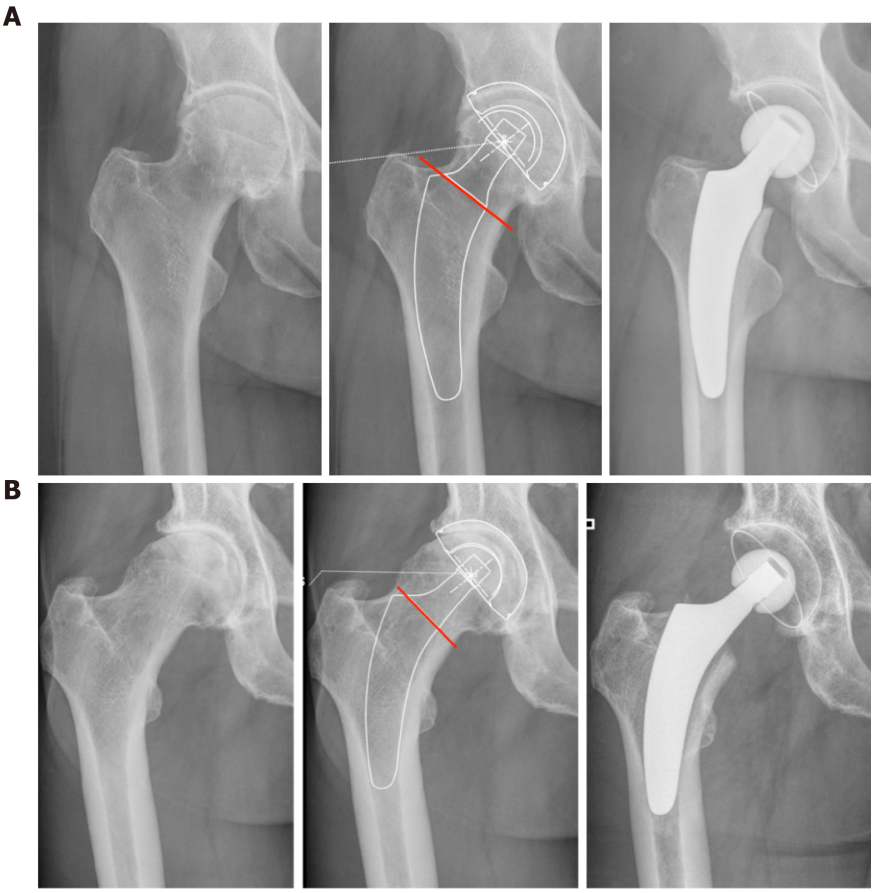


Figure 4 Individualized levels of resection, according to preoperative planning. A: Valgus anatomy; B: Varus anatomy.

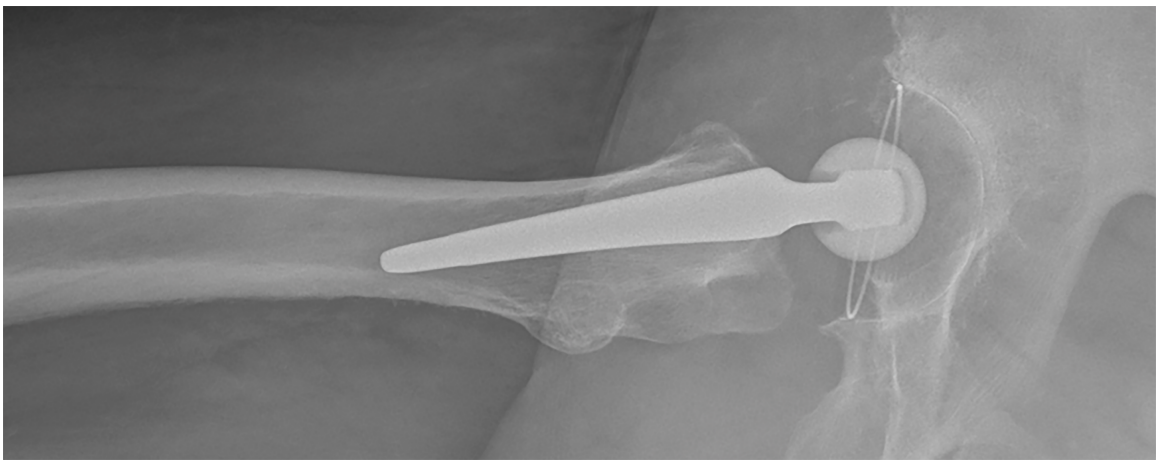


Figure 5 The natural anterior tilt of the femoral neck (in the second plane) can only be reconstructed using a short stem.

metaphyseal anchorage alone[21,34]. However, the option of additional individualized anchorage types increases the potential indications for the safe use of a short stem. The design features of calcar-guided short stems, including the ability to apply individualized meta-diaphyseal anchorages, may account for advantages of this stem type compared with earlier short-stem designs in terms of indications for use, including reduced quality of bone, osteonecrosis of the femoral head (ONFH), and femoral neck fractures[35-37].

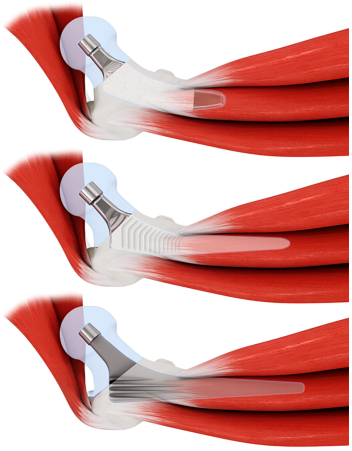


Figure 6 Using rounded short stems (top), minimally invasive approaches, without requiring transection or damage to the muscles, are facilitated compared with conventional stems (middle and bottom). Copyright Mathys Ltd., Bettlach, Switzerland.

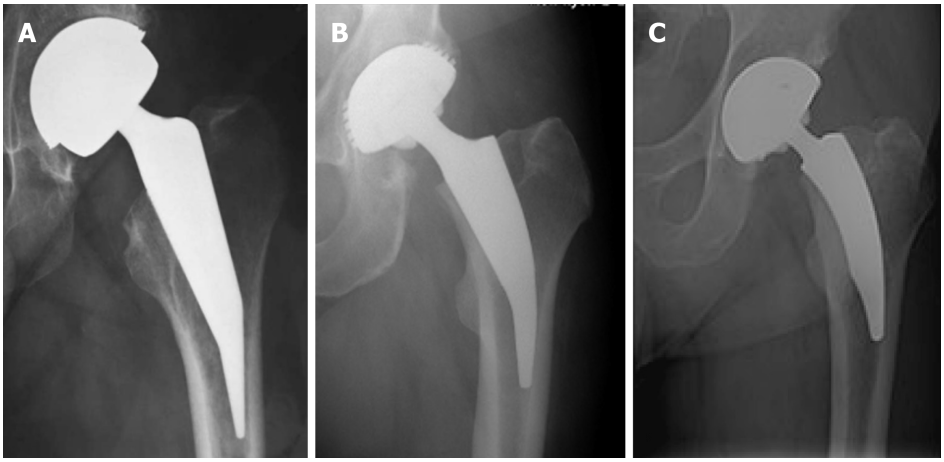


Figure 7 Metaphyseal anchoring using three-point fixation. A: Mayo stem (Zimmer Biomet, Warsaw, Indiana, USA); B: Metha stem (Aesculap, Tuttlingen, Germany); C: Nanos stem (Smith&Nephew, Marl, Germany).

BONE REMODELING

Due to distinct differences in the manifestation of bone remodeling, Yan *et al*[19] concluded in a recent review analysis that short stems should not be treated as one single implant group because periprosthetic bone loss is highly dependent on each particular stem design. The Metha stem has been associated with bone loss in the calcar region, whereas the Nanos stem presented bone resorption primarily in the greater trochanteric region, and these differences may be due to differences in the stem designs. Compared with conventional stems, such as the CLS stem (Zimmer Biomet, Warsaw, Indiana, USA) and the Bicontact stem (Aesculap, Tuttlingen, Germany), the study by Yan *et al*[19] also indicated that most short stems were associated with an overall lower rate of bone remodeling. A recent dual-energy X-ray absorptiometry study reported by Hochreiter *et al*[38] evaluated bone remodeling around the calcar-guided optimys stem. Bone mineral density increased primarily in the lateral region (Gruen zones 2 and 3) and the distal-medial region (Gruen zone 5), suggesting lateral loading. Thus, stress-shielding was limited, and periprosthetic bone loss was minimized when using this stem design.

Typical signs of diaphyseal stress, such as cortical hypertrophy, are commonly observed during the use of several conventional stem designs, frequently resulting in thigh pain. Cortical hypertrophy was commonly observed with the Fitmore stem (Zimmer Biomet, Warsaw, Indiana, USA)[39], whereas a low rate of distal bone remodeling associated with cortical hypertrophy has been reported for the calcar-guided optimys stem[33]. Almost all new-generation short stems present with a polished tip to reduce peak stresses and to prevent distal ingrowth (Figure 1).

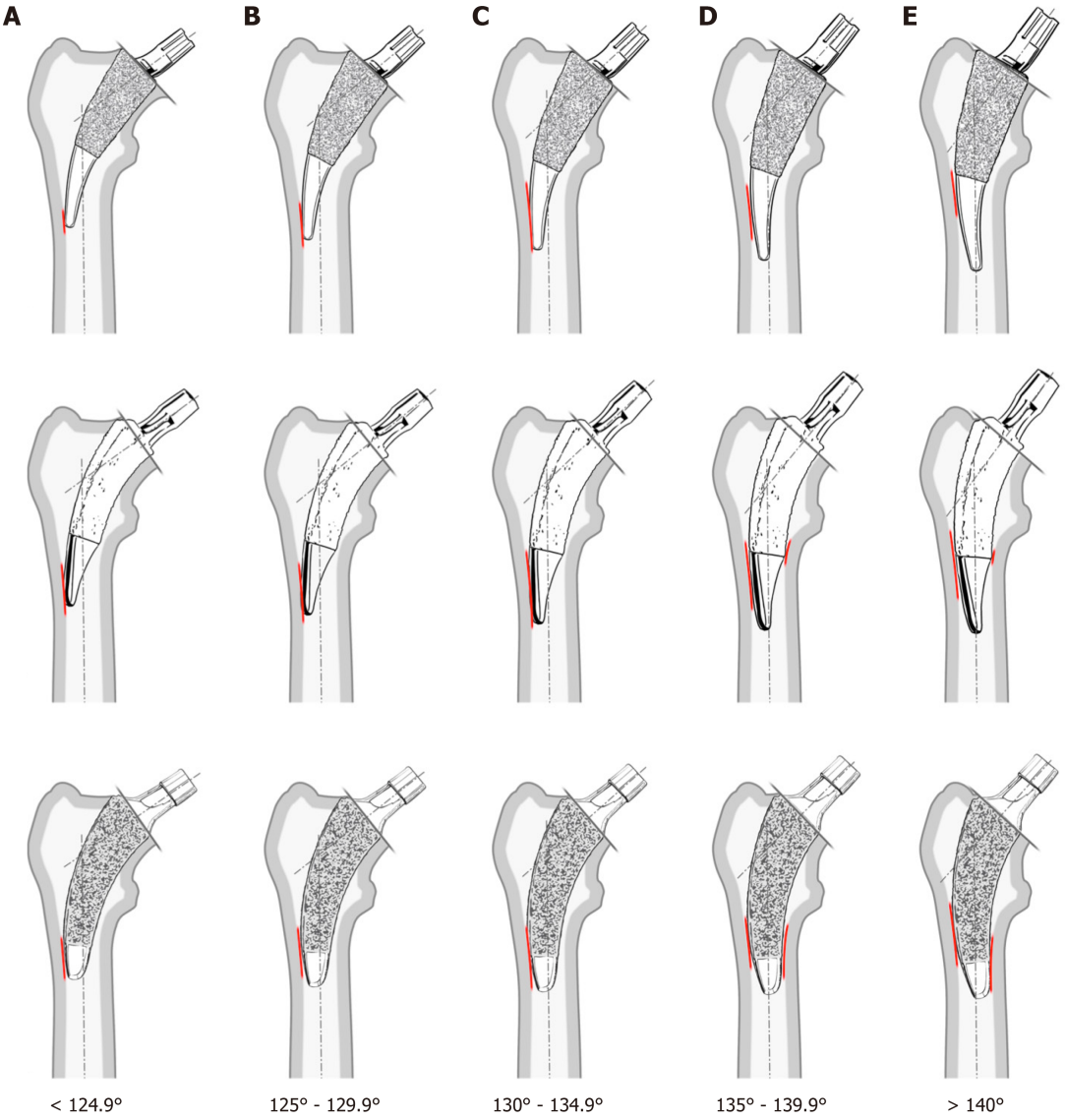


Figure 8 Characteristics of various short stem designs at different CCD angles, according to the classification of Groups A–E established by Kutzner *et al*[22,35]. A: Metha stem (Aesculap, Tuttlingen, Germany); additional diaphyseal anchorage is almost impossible to attain; B: Nanos stem (Smith&Nephew, Marl, Germany); narrowing in the distal part limits the option of additional diaphyseal anchorage; C: Optimys stem (Mathys Ltd., Bettlach, Switzerland); in neutral and valgus positions, an additional diaphyseal anchorage is possible, when intended. (Copyright Mathys Ltd., Bettlach, Switzerland).

MIGRATION AND SECONDARY STABILITY

The reduction in the length and diaphyseal fixation of the femoral component in short-stem THA may cause some concerns. A concomitant reduction of implant stability and an increase in interface micromotion might interfere with osteointegration, increasing the risk of aseptic loosening[17], which is likely to have crucial effects on long-term outcomes and revision rates. Whether this new group of stems will perform as well as conventional stems, which have a 25-year survival rate of 60%, cannot yet be predicted [40]. Studies investigating the migration patterns of modern short stems using EBRA-FCA (Ein-Bild-Roentgen-Analyse; femoral component analysis) have suggested an initial, pronounced settlement into the metaphyseal bone upon the initiation of full weight-bearing, followed by a subsequent stabilization[41-46]. In a recent investigation, most of the investigated stems showed delayed settlement during the first 2 years after surgery, suggesting that these new-generation stems are likely to display different migration patterns from conventional stems[34]. Male patients and heavy-weight patients have been shown to be at higher risk of subsidence, as are stems with valgus alignment[41]. Recent studies using radiostereometric analyses (RSA) have confirmed these findings. De Waard *et al*[47] reported the occurrence of secondary stabilization after initial migration using the optimys stem, suggesting a low risk of long-term aseptic loosening. Similarly, the mid-term results reported by the

prospective RSA study performed by Floerkemeier *et al*[48] using the Metha stem showed no correlation between a greater initial migration and inferior clinical outcomes and no increased risk of aseptic loosening.

A securely achieved cortical contact with the distal lateral cortex appears to be crucial to provide sufficient primary stability[49] (Figure 8). A missing cortical contact has previously been defined as "undersizing"[49]. The use of intraoperative imaging to identify the potential "undersizing" of calcar-guided short stems is highly recommended, especially with regard to individualized positioning[20,50]. If the cortical contact is not securely achieved with the trial components, the stem should be upsized. At the mid-term, no clinically negative consequences were obvious in terms of implant survival[15,34]. Long-term results should, however, be obtained to further determine the impacts of early migration on secondary stability and short stem survival.

INDICATIONS

Short stems have been developed for use in young and active patients. To date, this group of patients continues to be primarily treated with short-stem THA. The most frequent indications for short-term THA are primary and secondary osteoarthritis; however, indications have constantly been expanded during recent years. To date, little clear evidence is available regarding the indications and contraindications of short stem use due to the limited availability of data.

Several short stems have been reported to be suitable for use in patients with developmental dysplasia of the hip joint[15,51-53]. While investigating the calcar-guided short stem MiniHip, Buttaro *et al*[54] found a survival rate of 100% at 5 years, using revision for aseptic loosening as the end point. They concluded that this stem design was well suitable for patients with hip dysplasia, producing only a few intraoperative technical problems.

Undoubtedly, the quality of the femoral bone stock plays a crucial role in the safe use of calcar-guided short stems. A recent multicenter investigation found a significantly increased periprosthetic fracture rate in patients with Dorr type C femora compared with those with Dorr type A and B femora[35]. Thus, the indication for use should be limited to Dorr type A and B. However, as the rates of stem revision did not differ significantly between younger and older patients; therefore, advanced age alone is not necessarily a contraindication for the use of calcar-guided short-stem THA, although longer follow-up has yet to be obtained[35].

The opportunity to intentionally choose an additional fit-and-fill in the proximal diaphysis associated with some calcar-guided short-stem designs potentially accounts for advantages compared with other short stems, particularly in terms of the broad range of indications associated with the use of these short stems. In addition to the classical short-stem philosophy of metaphyseal anchorage (Figure 9A), the same patient can also be treated by adding a fit-and-fill in the proximal diaphysis, if desired, such as in cases of reduced bone quality (Figure 9B). Generally, in these cases, the stem requires some degree of upsizing.

The indication of ONFH in short-stem THA is controversial. The potentially reduced bone quality and the osteonecrotic area beyond the femoral head may also affect the femoral neck and the metaphyseal bone, and metaphyseal anchoring designs may be associated with poor primary stability and impaired osteointegration, which can jeopardize implant survival. For example, Schnurr *et al*[55] compared the use of the Metha stem in patients with ONFH with its use in patients with primary osteoarthritis over a 10-year period. They found that the aseptic loosening rate was significantly elevated among patients with ONFH. Recently, Afghanyar *et al*[36] reported a survival rate of 100% at the mid-term for the calcar-guided optimys stem in patients with ONFH. The findings strongly support the safe use of calcar-guided short stems for the treatment of patients with ONFH (Figure 10), providing sufficient primary stability and successful osteointegration. Further data on different calcar-guided short stems have confirmed these findings[56,57].

To date, little evidence regarding the use of short cementless femoral components in cases of femoral neck fractures is available. However, Schneider *et al*[37] reported promising results using a calcar-guided short stem in patients with a femoral neck fracture who were active, characterized by Dorr type A or B femora, and provide an intact cortical ring of the femoral neck (Figure 11). A total of 16% of patients who required treatment due to femoral neck fracture were found to be eligible for this stem design, and a low complication rate was reported. However, the study has not come to

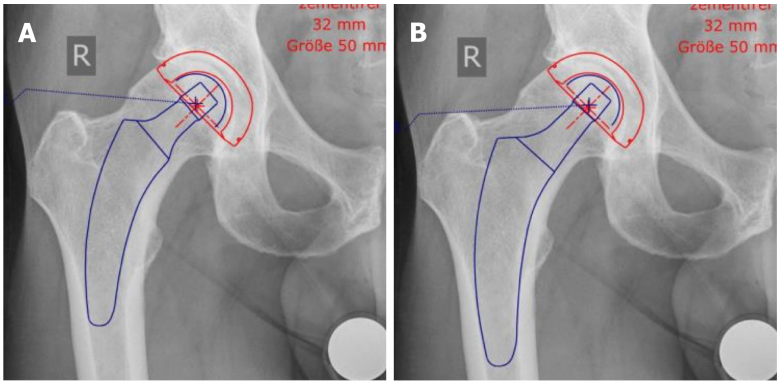


Figure 9 The same patient can be planned and treated by the application of metaphyseal anchorage or the addition of a fit-and-fill in the proximal diaphysis by valgization and upsizing, depending on the indication and bone quality. A: Metaphyseal anchorage; B: Additional fit-and-fill in the proximal diaphysis.

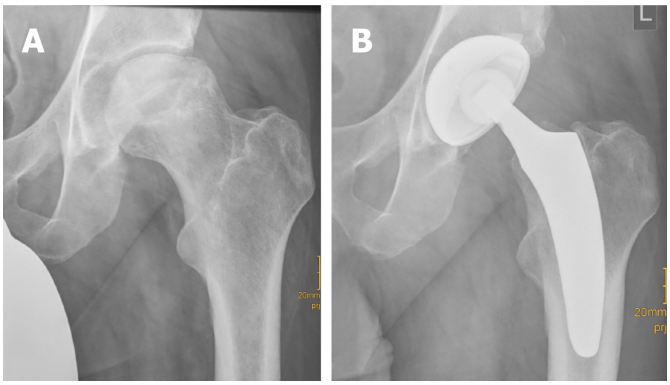


Figure 10 Calcar-guided short stem total hip arthroplasty in a case of osteonecrosis of the femoral head. A: Preoperative; B: Postoperative.

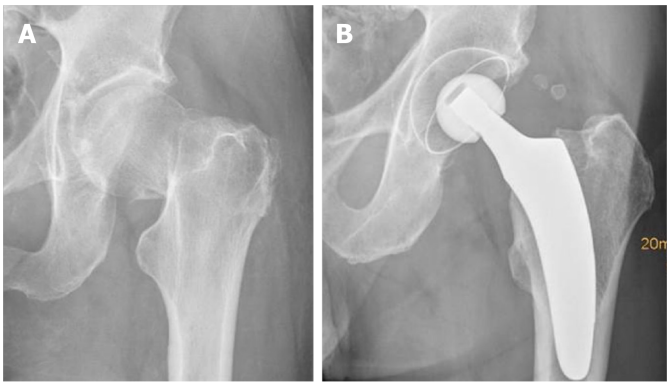


Figure 11 Calcar-guided short stem total hip arthroplasty in a case of a femoral neck fracture. A: Preoperative; B: Postoperative.

an end yet. Two additional studies are available in the literature that investigated shorter stem designs in patients with femoral neck fractures, which reported encouraging outcomes; however, both stem designs were classified as shortened conventional stems (Group 4) based on the system established by Khanuja *et al*[58,59].

Cemented short-stem THA may represent a potential alternative for patients with poor bone quality and osteoporosis, such as Dorr type C femora. To date, however, no new-generation short stem THA with cemented fixation are available on the market. Using prototypes of the optimys stem fabricated using polished steel (Figure 12), a recent *in vitro* biomechanical study demonstrated that the concept of a line-to-line cementation technique could be further pursued for the development of a cemented short stem in THA[60]. This finding was confirmed in a validated, computed tomography-based, finite element analysis performed by Azari *et al*[61] that quantified



Figure 12 Prototype of a cemented calcar-guided short stem made out of polished steel (optimys stem, Mathys Ltd., Bettlach, Switzerland). Copyright Mathys Ltd., Bettlach, Switzerland.

the mechanical performance of this short stem design. The results suggested that cemented short stems are a promising alternative for use in osteoporotic bone and may, therefore, further expand the range of indications in the future.

REGISTRY DATA

In recent years, short stems have increasingly been involved in national arthroplasty registries. The results of several national registries indicate that calcar-guided short stems are among the most successful implants in terms of early-stage survivorship. For example, in the German national joint registry, calcar-guided short stems, such as the optimys stem, the Nanos stem, the A2 stem, and the MiniHip stem, have been associated with excellent implant survival[10]. These results are strongly supported by findings from the Australian and the Swiss national registries, which provided similar results for these implant designs[62,63]. However, only mid-term registry data are currently available.

CONCLUSION

Modern calcar-guided short-stem THA offers numerous advantages compared with conventional THA. The broad potential to reconstruct the individual anatomical hip geometry, the reduction in proximal bone remodeling, and the simplified soft-tissue-sparing implantation represent true accomplishments. In Europe and globally, this group of implants is likely to become increasingly popular. Although this group of implants is still young, a large body of evidence has been obtained. The short- and mid-term outcomes are encouraging, although long-term results remain scarce.

If the long-term results confirm the promising early data, the option to anchor the femoral implant individually and the associated broad range of indications are likely to strongly favor calcar-guided stem designs as the future standard in THA. However, standard procedures, in general, should be easy to implement, reproducible, and practicable for every surgeon, regardless of technical expertise or surgical experience. The individualized implantation technique, however, requires distinct knowledge of the characteristics associated with varus and valgus positioning and the consequences of different types of anchoring, resulting in a significant learning curve for surgeons new to this technique, which must be considered. Contraindications to the use of these implants should be respected. Thus, improving education and collecting further clinical evidence will be crucial determinants of the future of calcar-guided short-stem THA.

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ORIGINAL ARTICLE

Basic Study

Fibula pro-tibia *vs* standard locking plate fixation in an ankle fracture saw bone model

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Author contributions: Okoro T contributed study design, performance of biomechanical testing, analysis of results, drafting and proof reading of manuscript; Teoh KH contributed study design, analysis of results, drafting and proof-reading of manuscript; Tanaka H contributed study design, supervision of study, analysis of results, drafting and proof reading of manuscript.

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Abstract

BACKGROUND

Locking plate fixation in osteoporotic ankle fractures may fail due to cut-out or metalwork failure. Fibula pro-tibia fixation was a technique prior to the advent of locking plates that was used to enhance stability in ankle fractures by achieving tri or tetra-cortical fixation. With locking plates, the strength of this fixation construct can be further enhanced. There is lack of evidence currently on the merits of tibia-pro-fibula augmented locking plate fixation of unstable ankle fractures.

AIM

To assess if there is increased strength to failure, in an ankle fracture saw bone model, with a fibula pro-tibia construct when compared with standard locking plate fixation.

METHODS

Ten osteoporotic saw bones with simulated supination external rotation injuries were used. Five saw bones were fixed with standard locking plates whilst the other 5 saw bones were fixed with locking plates in a fibula pro-tibia construct. The fibula pro-tibia construct involved fixation with 3 consecutive locking screws applied across 3 cortices proximally from the level of the syndesmosis. All fixations were tested in axial external rotation to failure on an electromagnetic test frame (MTS 858 Mini-Bionix test machine, MTS Corp, Eden Praire, MN, United States). Torque at 30 degrees external rotation, failure torque, and external rotation angle at failure were compared between both groups and statistically analyzed.

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RESULTS

The fibula pro-tibia construct demonstrated a statistically higher torque at 30 degrees external rotation (4.421 ± 0.796 N/m *vs* 1.451 ± 0.467 N/m; *t*-test P = 0.000), as well as maximum torque at failure (5.079 ± 0.694N/m *vs* 2.299 ± 0.931 N/m; *t*-test P = 0.001) compared to the standard locking plate construct. The fibula pro-tibia construct also had a lower external rotation angle at failure (54.7 ± 14.5 *vs* 67.7 ± 22.9).

CONCLUSION

The fibula pro-tibia locking plate construct demonstrates biomechanical superiority to standard locking plates in fixation of unstable ankle fractures in this saw bone model. There is merit in the use of this construct in patients with unstable osteoporotic ankle fractures as it may aid improved clinical outcomes.

Key Words: Unstable ankle fractures; Pro-tibia fixation; Improved stability; Simulated biomechanical analysis; Osteoporotic fractures; Ankle injuries

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Core Tip: Locking plate fixation in osteoporotic ankle fractures may fail due to cut-out or metalwork failure. This study compared a fibula pro-tibia construct to standard locking plate fixation in an ankle fracture saw bone model. The fibula pro-tibia construct demonstrated biomechanical superiority and there is merit to consideration of its use in patients with unstable osteoporotic ankle fractures.

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INTRODUCTION

In osteoporotic bone, there is unsatisfactory fixation strength with uni-cortical cancellous fixation for distal fibula fractures[1,2], which can lead to loss of fixation as well as delayed or non-union[3]. The ways to try to obviate these risks include the use of locking, posterior plating, or non-locking constructs with adjunct fixation. One such example of the latter is the use of tri- or tetra-cortical fixation with fibula pro-tibia (syndesmotic) screws[1]. In comparison to the same construct without additional screws, fibula pro-tibia fixation has demonstrated a 9% increase in torque to failure, 24% increase ability to withstand external rotation, and a 34% increase in energy before failure of the construct[4]. This technique adds little operative time, is inexpensive, and is a technically straightforward method to increase the stability of the construct[4].

In unstable bi-malleolar ankle fractures, the talus remains attached to the lateral malleous[5]. Reducing the medial malleolus alone may prevent anatomical repositioning of the talus, as in some cases the lateral malleolus cannot be accurately reduced when it impinges on the proximal fibular fragment. Repositioning of the talus can be achieved by forcibly internally rotating the ankle in such cases, but this stretches the fibular collateral ligament. When external immobilization is discontinued, the lateral ligaments remain in a stretched position and slight to moderate talar instability, which predisposes to development of late degenerative arthritis, may be the result[5].

The lateral malleolus appears therefore to be the key to the anatomical reduction of displaced bi-malleolar fractures, and restoring the integrity of the lateral malleolus restores the integrity of the ankle[5].

Being able to maintain the integrity of the lateral malleolar fixation in osteoporotic bone in therefore important. This study aims to biomechanically assess whether there is an increased strength to failure with a fibula pro-tibia construct when compared with standard locking plate fixation for ankle fractures in an ankle fracture saw bone model.

MATERIALS AND METHODS

Materials

Ten osteoporotic saw bones (Pacific Research Laboratories Inc., Vashon, WA, United States) with simulated supination external rotation injuries were used in this study.

Fracture simulation

A lateral malleolar ankle fracture was simulated with an osteotomy at the lateral malleolus (oblique orientation, starting medially at the level of the tibial plafond), and extending distally and laterally at a 45° angle[4]. Figure 1 illustrates the simulated lateral malleolar fracture.

Fracture fixation

Five of the lateral malleolar osteotomies were fixed in a standard fashion using a fibular locking plate (Stryker Variax locking plate; Stryker, Mahwah, NJ, United States; Figure 2A) whilst fibula pro-tibia fixation was utilized in the other 5 models [fibular locking plate (Stryker Variax locking plate; Mahwah, NJ, United States)] with tri-cortical fixation. Tri-cortical fibula pro-tibia fixation entailed the use of 3 consecutive fully threaded cortical 3.5mm locking screws placed proximal to the lateral malleolar osteotomy at the level of the tibio-fibular syndesmosis (Figure 2B).

Biomechanical testing

Each model was then subjected to biomechanical analysis after being mounted on a resin and tested on an electromagnetic test frame (MTS 858 Mini-Bionix test machine, MTS Corp, Eden Praire, MN, United States), Figure 3, with measurement of torque (N/m) at 30 degrees external rotation, maximum failure torque (N/m) and external rotation angle (°) at failure.

Statistical analysis

The student's *t*-test was used to analyze differences between both groups with a P value < 0.05 taken as statistically significant.

RESULTS

Fibula pro-tibia vs standard locking plates (torque assessment)

The mean torque for the fibula pro-tibia constructs at 30° external rotation was 4.421 ± 0.796 N/m, which was significantly higher than that obtained for the standard locking plate fixation constructs 1.451 ± 0.467 N/m (*t* test $P = 0.000$). This difference was also noted in the maximum torque to failure (tibia-pro-fibula 5.079 ± 0.694 N/m *vs* standard locking plate fixation 2.298 ± 0.931 N/m; *t* test $P = 0.001$).

The torque values of each construct for the above parameters are detailed in Tables 1 and 2.

Fibula pro-tibia vs standard locking plates (angle to failure)

There was a lower mean external rotation angle to failure for the fibula pro-tibia construct (54.7° ± 14.5°) compared to standard locking plate fixation 67.7° ± 22.9°, but this was not statistically significant; *t* test $P = 0.313$.

DISCUSSION

Open reduction and internal fixation for an unstable ankle fracture in young patients is relatively predictable with excellent outcomes[6]. However the management of ankle fractures in the elderly remains less predictable, secondary to the various comorbidities associated with elderly patients such as osteoporosis, diabetes, cardiovascular, and peripheral vascular disease[3].

A recent trial demonstrated superiority of tibio-talo-calcaneal (TTC) nailing over standard locking plate fixation in the elderly in terms of having a low risk of complications, an earlier return to previous level of mobility, and the allowance of an immediate return to full weight bearing[6]. A limitation to the use of the TTC nail in routine practice is the risk of proximal peri-prosthetic fractures, as well as the need for the availability of a senior trauma surgeon or foot and ankle specialist to obtain

Table 1 Torque (N/m) recorded for fibula pro-tibia and standard locking plate constructs (torque at 30 degrees external rotation)

Construct	Fixation type	Torque (N/m)
1	Fibula pro-tibia	3.723
2	Fibula pro-tibia	5.692
3	Fibula pro-tibia	4.695
4	Fibula pro-tibia	4.043
5	Fibula pro-tibia	3.954
6	Standard locking plate	0.829
7	Standard locking plate	1.709
8	Standard locking plate	1.539
9	Standard locking plate	1.155
10	Standard locking plate	2.022

Table 2 Torque (N/m) recorded for fibula pro-tibia and standard locking plate constructs (maximum torque at failure)

Construct	Fixation type	Maximum torque at failure (N/m)
1	Fibula pro-tibia	4.270
2	Fibula pro-tibia	5.970
3	Fibula pro-tibia	5.176
4	Fibula pro-tibia	5.468
5	Fibula pro-tibia	4.513
6	Standard locking plate	1.187
7	Standard locking plate	2.869
8	Standard locking plate	1.519
9	Standard locking plate	2.497
10	Standard locking plate	3.422



Figure 1 Simulated lateral malleolar sawbone ankle fracture.

optimal outcomes[7].

This study demonstrates that the fibula pro-tibia locking plate construct has biomechanical superiority to standard locking plates in a saw-bone model. There is increased torque at 30 degrees external rotation as well as a higher torque at maximum failure of the construct. The reduced maximal external rotation angle at failure of the

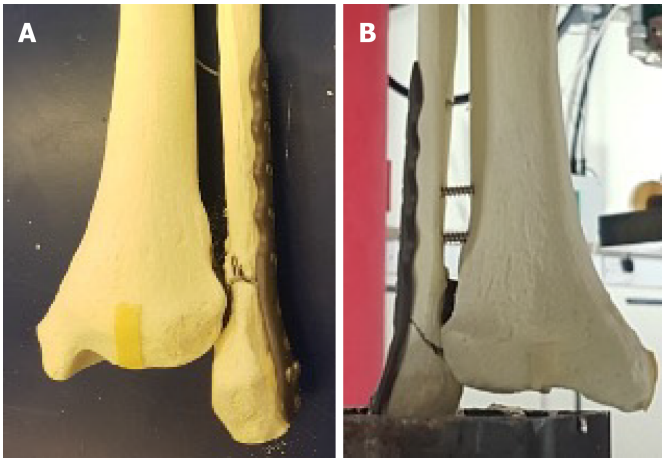


Figure 2 Sawbone lateral malleolar fixation construct. A: Sawbone lateral malleolar fracture treated with standard locking plate; B: Sawbone lateral malleolar fracture treated with locking plate in fibula pro-tibia configuration.

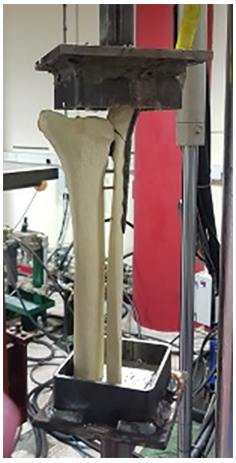


Figure 3 Fibula pro-tibia construct of ankle fracture sawbone model mounted on the electromagnetic test frame (MTS 858 Mini-Bionix test machine, MTS Corp, Eden Praire, MN, United States).

construct is most likely due to the increased rigidity of the fixation, which is potentially beneficial for osteoporotic bone.

A limitation of this study is that it was performed on sawbones not cadaveric bone. Such data may therefore not be readily transferable to a clinical scenario, as we have performed an isolated analysis of a lateral malleolar fracture. The data we have shown however gives an objective assessment of the difference in biomechanical properties between the two constructs. Another limitation of the study is that we have not used a model that accounts for a bi-malleolar fracture pattern. The lateral malleolus is key to the anatomical reduction of displaced bi-malleolar fractures, and restoring the integrity of the lateral malleolus restores the integrity of the ankle[5]. The use of fibula pro-tibia fixation in this study demonstrates that there is up to approximately 3 times the level of torque achieved at 30 degrees external rotation and twice the failure torque in comparison to standard locking plate fixation. Initiating use of the adjunctive technique whilst performing such fixation is inexpensive, adds little operative time, and is not technically demanding. We propose the 3, 3, 3 rule for use of this adjunctive technique; Fixation with 3 screws across 3 cortices starting 3 cm above the tibial plafond.

The fibula pro-tibia construct utilizes the combined pull-out strength of locking screws to ensure a more biomechanical stronger construct. By using a tricortical fixation, it also ensures that the fixation is not as rigid as non-locking tetracortical fixation and provides some syndesmosis micro movement. There is therefore not a need for removal before weight bearing of the patient.

The increased biomechanical strength of the fibula pro-tibia construct demonstrates that there is merit to its use in patients with unstable osteoporotic ankle fractures.

Future research is required to evaluate if its use would aid improved clinical outcomes in this important group of patients.

CONCLUSION

This study compared a fibula pro-tibia construct to standard locking plate fixation in an ankle fracture saw bone model. The fibula pro-tibia construct demonstrated biomechanical superiority and there is merit to consideration of its use in patients with unstable osteoporotic ankle fractures.

ARTICLE HIGHLIGHTS

Research background

The lateral malleolus is key to the anatomical reduction of displaced bi-malleolar fractures, and restoring its structural integrity restores the integrity of the ankle. Various fixation techniques have been utilized in osteoporotic bone to ensure lateral malleolar integrity.

Research motivation

Biomechanical assessment of whether there is an increased strength to failure with a fibula pro-tibia construct when compared with standard locking plate fixation for ankle fractures in an ankle fracture saw bone model.

Research objectives

To compare a fibula pro-tibia construct to standard locking plate fixation in a saw bone model using biomechanical parameters.

Research methods

After simulation of supination/external rotation injuries in a series of n = 10 sawbones, n = 5 were fixed with the fibula pro-tibia construct and n = 5 were fixed with the standard locking plate. Biomechanical analysis was performed to assess torque (N/m) at 30 degrees external rotation, maximum failure torque (N/m) and external rotation angle (°) at failure. Students t test was used for comparison of both groups.

Research results

The fibula pro-tibia construct was biomechanically superior to the standard locking plate in torque at 30 degrees external rotation, and maximum failure torque. There was no statistically significant difference in the external rotation angle at failure.

Research conclusions

There is merit to considering the use of the fibula pro-tibia construct in fixation of bimalleolar ankle fractures in view of its biomechanical superiority over standard locking plates.

Research perspectives

Future research should evaluate the clinical significance of these findings.

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ORIGINAL ARTICLE

Observational Study

Thromboelastography in elective total hip arthroplasty

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Abstract

BACKGROUND

Hypercoagulability plays an important role in predisposing patients to venous thromboembolism (VTE) after total hip arthroplasty (THA). We used thromboelastography (TEG) to examine the coagulation status of patients undergoing THA.

AIM

To examine coagulation as measured by TEG in patients undergoing THA who received standard VTE chemoprophylaxis with enoxaparin.

METHODS

After ethical approval, we performed a retrospective analysis of data collected in patients undergoing primary elective THA. We analyzed TEG data on samples performed before skin incision, intraoperatively and for 5 d postoperatively. Conventional coagulation tests were performed preoperatively and on postoperative day 5.

RESULTS

Twenty patients undergoing general anesthesia and 32 patients undergoing spinal anesthesia (SA) were included. TEG demonstrated a progressively hypercoagulable state postoperatively, characterized by elevated maximum amplitude. TEG also demonstrated transient intraoperative hypercoagulability in patients receiving SA. In contrast, conventional coagulation tests were normal in all patients, pre- and postoperatively, except for an increase in plasma fibrinogen day 5 postoperatively.

CONCLUSION

Despite VTE prophylaxis, patients following total hip replacement remain in a

available from the corresponding author on reasonable request. Original data is contained on old Minitab (.mtw) files that have compatibility issues with recent versions.

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hypercoagulable state as measured by both TEG and conventional tests. This group may benefit from more optimal anticoagulation and/or additional perioperative hemostatic monitoring, *via* TEG or otherwise.

Key Words: Surgery; Orthopedic; Anesthesia; Hip arthroplasty; Hypercoagulability; Thrombelastography

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Core Tip: Patients undergoing total hip arthroplasty are a high-risk cohort for venous thromboembolism postoperatively. Thromboelastography (TEG) is a modality for investigating global coagulation status. There is limited evidence surrounding the use of TEG in this patient group. Our observational study revealed this patient cohort exhibits a progressively hypercoagulable state postoperatively, characterized primarily by elevated TEG maximum amplitude. The clinical significance of this hypercoagulability is yet to be fully elucidated, however suggests further outcome-based studies exploring anti-coagulation therapy in this cohort may be beneficial.

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INTRODUCTION

Patients undergoing total hip replacement are at high risk of developing venous thromboembolism (VTE), with Australian incidence of postoperative deep vein thrombosis (DVT) approximately 9% in this group despite VTE prophylaxis[1]. An intrinsic hypercoagulable state is thought to be a major contributor to the development of DVT in this group, as well as postoperative stasis[2-6]. Despite routine postoperative prophylaxis, VTE remains a clinically important complication of joint arthroplasty, resulting in an incidence of pulmonary embolism of 0.14%-0.27% and associated mortality rate of 19.49%[7,8]. Recent major reviews on thromboembolism in this population have demonstrated that enoxaparin is effective in reducing DVT incidence [9]. The effect of enoxaparin on the overall global coagulation picture in this group remains limited, with our data augmenting evidence provided by other small observational studies in this cohort[10].

Thromboelastography (TEG) measures whole blood coagulation and fibrinolysis. Whilst neuraxial anesthesia techniques have been reported to diminish intra- and postoperative hypercoagulability by providing improved analgesia, the incidence of VTE after total hip arthroplasty (THA) appears to be similar in patients undergoing general anesthesia (GA)[11-14]. This study aims to describe the coagulation pattern observed by TEG in patients undergoing THA, and also to determine the impact of anesthetic technique on coagulation status.

MATERIALS AND METHODS

This study is a retrospective, observational study, using data from an electronic TEG database collected between 2000-2015 at a single tertiary center. The data was originally collected as part of routine clinical care, investigating the effect of routine enoxaparin administration on postoperative coagulation in THA patients, as measured by TEG. Our primary objective was to assess coagulation status in this group as measured by TEG, comparing baseline maximum amplitude (MA) to postoperative days 1, 2 and 5. Secondary outcomes were to: (1) Assess perioperative changes in other TEG parameters; (2) Compare perioperative TEG parameter changes based on the type of anesthetic used [either GA or spinal anesthesia (SA)]; and (3) Assess perioperative changes in conventional coagulation tests (international normalized ratio, activated partial thromboplastin time and fibrinogen). This study was not designed to investi-

gate clinical outcomes or incidence of VTE.

Participants

The Austin Health Research and Ethics Committee approved a retrospective analysis of historical data. The original data was collected using TEG as routine care (approval number: LNR/19/Austin/21). The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000315112).

Original participants were recruited from perioperative anesthesia and orthopedic clinics at the Austin Hospital, Melbourne, Australia. Inclusion criteria included adult patients (> 18 years) undergoing primary, elective THA with American Society of Anesthesiologists (ASA) Grade 3 or lower. Exclusion criteria included patients with significant atherosclerotic disease, known coagulopathy or thrombophilia, abnormal liver function tests, impaired renal function (estimated glomerular filtration rate < 60 mL/min/1.73m^2, KDIGO stage 3A or greater) and use (< 10 d pre-operatively) of any of the following medications: Warfarin, heparin (high or low molecular weight), adenosine diphosphate receptor inhibitors, glycoprotein IIB/IIIA inhibitors, adenosine re-uptake inhibitors or thromboxane inhibitors. Patients were assessed for baseline comorbidities including ischemic heart disease, cerebrovascular disease, diabetes mellitus, smoking status and hypertension.

Standardization of setting

Anesthesia was managed by a group of anesthesiologists using a standardized care protocol. All patients scheduled for surgery underwent routine pre-operative investigations in a dedicated pre-operative anesthesiology clinic. This included a multidisciplinary review by an anesthesiologist, pharmacist, peri-operative nurse and orthopedic medical officer. Investigations included electrocardiogram (EKG), Chest X-ray and pathology testing including full blood count, urea and electrolytes and coagulation studies. Comorbidities were optimized which included smoking cessation counselling, optimization of cardiovascular risk factors and perioperative anemia and glycemic control. These were managed in accordance with National Australian Guidelines. Patients were provided with full informed consent in the pre-operative anesthesiology clinic and counselled regarding anesthetic technique. Anesthesia preference was for SA unless contraindicated (previous spinal surgery, aortic stenosis, patient refusal). Routine intraoperative anesthesia monitoring included continuous EKG and pulse oximetry as well as non-invasive blood pressure monitoring, with continuous blood pressure monitoring *via* an arterial line used in select patients (*i.e.* those with cardiorespiratory comorbidities). The threshold for blood transfusion was a hemoglobin less than 8 g/dL. No patient received intraoperative fibrinolytic therapy (*e.g.* tranexamic acid). All patients received non-pharmacologic methods of VTE prophylaxis. VTE chemoprophylaxis included enoxaparin (40 mg) administered immediately prior to skin closure, continued daily until hospital discharge. Patient charts were reviewed to ascertain the incidence of postoperative VTE.

Blood sampling and processing

Blood samples for TEG measurement were taken at 6 intervals: Immediately pre-operatively (baseline), midpoint intraoperatively (mid-point of surgery), immediately prior to skin closure (end of surgery), and on postoperative days 1, 2 and 5. Blood samples for conventional laboratory coagulation tests were pre-operatively (baseline) and postoperatively on day 5. All samples were collected using a single peripheral aseptic venepuncture. Viscoelasticity was measured on a TEG5000 system (Haemonetics®, United States) performed by a technician, expert in TEG, blinded to the choice of anesthesia technique. TEG was performed within 4 min of sampling, complying with our institution's standard technique at time of collection, which has been previously reported[15,16]. TEG variables measured were reaction time (R, min), coagulation time (K, min), clot formation angle (degree), MA (mm) and fibrinolytic index (LY60%).

Postoperatively, blood for TEG and conventional laboratory coagulation assays were sampled approximately 1 h before administration of daily VTE chemoprophylaxis using standard techniques (Supplementary Appendix 1).

No patients were eliminated from this study secondary to a lack of availability of TEG.

Statistical analysis

Non-parametric statistical analysis (Friedman's test) followed by the Wilcoxon signed rank test with Bonferroni correction was used to evaluate changes in TEG over time in

each group.

The Mann-Whitney *U* test was used to compare data between patients having GA and SA. Data are presented as medians with quartiles. A $P < 0.05$ was considered statistically significant.

RESULTS

A total of 52 patients were enrolled. Indications for THA were osteoarthritis ($n = 50$) and avascular necrosis of the femoral head ($n = 2$). Thirty patients were ASA 2 and 22 patients were ASA 3. Twenty patients received GA and 32 received SA. Patients receiving GA were younger than patients receiving SA [61 years (IQR: 56-70) *vs* 74 years (IQR: 66-79), $P < 0.01$]. There were no differences in patient weight (70 kg, IQR: 65-88 *vs* 70 kg; IQR: 62–74, $P = 0.67$), sex distribution (male/female: 7/13 *vs* 14/18, $P = 0.23$), ASA class ($P = 0.56$) or incidence of cardiovascular comorbidities ($P > 0.99$) based on type of anesthetic used (Table 1). Examining the primary end-point, baseline TEG MA was within normal limits with no differences based on anesthetic technique [GA: 62 mm (IQR: 56–68), SA: 61 mm (54–65)]. MA remained within normal limits without significant difference from baseline, and without difference between anesthetic groups throughout surgery. By days 2 and 5 post operatively, MA became significantly elevated *vs* baseline, and exceeding normal limits, in both anesthetic groups (Table 2). Regarding secondary aims, we observed decreased R time, decreased K time and increased alpha angle intraoperatively *vs* baseline (Table 2). This resolved postoperatively days 1 to 5. Fibrinogen levels were elevated *vs* baseline and exceeding normal limits in both anesthetic groups postoperatively [GA pre: 3.1 (IQR: 2.9–3.3), GA post: 4.6 (4.1–5.3), SA pre: 3.1 (2.9–3.6), SA post: 4.5 (4–4.9)] (Table 3). No changes were demonstrated in other conventional coagulation tests. There were zero cases of clinically significant VTE detected within five days postoperatively. Notably one patient in the spinal cohort complained of dyspnea and chest pain three days postoperative but returned a negative Computed Tomography Pulmonary Angiography (CTPA), while one patient in the GA cohort developed unilateral calf swelling five days postoperatively before returning a negative lower limb doppler ultrasound.

DISCUSSION

Key findings

We observed that TEG findings in the THA population demonstrated a hypercoagulable state postoperatively, characterized by a steady increase in MA regardless of anesthetic technique used. Other TEG parameters demonstrated a transient, intraoperative hypercoagulability using SA, with these parameters returning to baseline by day 5 postoperatively. Fibrinogen levels were significantly elevated postoperatively, in both anesthetic groups. No difference was demonstrated in any other conventional coagulation tests compared to baseline.

Relationship with previous studies

Our findings agree with and add to previously published research. A 2013 study examining 61 patients undergoing primary, elective THA found MA increased throughout postoperative day 1, peaked by day 7, and remained elevated until day 14 [17]. Like our study, this population all received routine enoxaparin prophylaxis. This study demonstrated a decline in platelet level postoperative day 1, increase after day 3, and peak between days 7-14, and again demonstrated elevated fibrinogen level postoperative day 3 to day 14. This study examined coagulation tests on differing days to our study, measuring TEG and conventional tests immediately postoperatively, day 1, 3, 7 and 14 postoperatively[17]. Similarly, a 2014 study examining 42 patients undergoing THA, also found an increasingly hypercoagulable picture postoperatively [10]. Unlike our data, which demonstrated no difference in any TEG parameter except MA *vs* baseline, this study demonstrated the hypercoagulable picture of this patient group was mostly attributed to a mixed enzymatic and platelet contribution. Importantly however, this study examined patients on days 1, 4 and 9 postoperatively, compared to days 1, 2 and 5 postoperatively for our study. This study also used a different form of low molecular weight heparin (fraxiparine) and did not report any conventional coagulation tests, as well as enrolling fewer patients. Our findings support other small, observational study data, wherein TEG demonstrates increase in

Table 1 Baseline patient comorbidities according to anesthetic technique

	Spinal (*n* = 32)	GA (*n* = 20)	*P* value
Median age	74	61	< 0.01
Median weight (kg)	70	70	0.67
Sex (male)	14	7	0.23
ASA class 2	17	13	0.56
ASA class 3	15	7	
Ischemic heart disease	1	0	> 0.99
Cerebrovascular disease	0	0	
Diabetes	3	1	
Hypertension	6	4	
Smoking history	4	4	

GA: General anesthesia; ASA: American society of anesthesiologists.

Table 2 Perioperative thromboelastography findings in patients undergoing total hip arthroplasty

TEG parameter	Type	Baseline	Mid-point of surgery	End of surgery	Post-op day 1	Post-op day 2	Post-op day 5
Reaction time (R time, min)	GA	3.0 (2.6-3.6)	2.4 (1.8-3.1)	2.2 (1.8-2.4)	2.9 (2.1-3.8)	3.1 (2.3-5.0)	4.0 (2.4-5.2)
	SA	3.0 (2.7-3.8)	2.5 (1.3-3.0)[a]	2.2 (1.4-2.4)[b]	2.9 (2.3-41)	2.8 (2.3-3.7)	3.8 (2.7-5.7)
Clot kinetics time (K time, min)	GA	4.2 (3.6-5.1)	3.3 (2.5-4.1)	3.0 (2.8-3.4)	3.9 (2.6-5.6)	3.7 (2.7-6.4)	5.3 (3.3-7.1)
	SA	4.4 (3.8-5.1)	3.2 (2.0-4.1)[a]	2.8 (2.3-3.3)[b]	4.2 (3.2-5.8)	3.7 (2.9-5.0)	5.4 (3.9-8.0)
Clot formation angle (degrees)	GA	36 (30-43)	50 (39-58)	43 (34-53)	44 (33-54)	46 (31-58)	41 (33-50)
	SA	35 (29-40)	47 (36-57)[b]	45 (40-57)[b]	43 (28-49)	49 (37-57)[b]	36 (25-47)
Maximum amplitude (mm)	GA	62 (56-68)	68 (63-71)	65 (54-71)	71 (66-76)[a]	77 (70-81)[b]	77 (74-81)[b]
	SA	61 (54-65)	64 (59-69)	63 (58-68)	69 (66-75)[b]	74 (70-81)[b]	78 (72-82)[b]
Clot lysis (LY60%)	GA	5 (3-6)	4 (3-7)	4 (2-7)	6 (2-7)	5 (3-6)	3 (1-4)
	SA	4 (4-6)	4 (2-5)	4 (2-4)	7 (5-10)[a]	5 (4-9)	3 (2-7)

All results are presented as median with interquartile range.

[a]$P < 0.05$.

[b]$P < 0.01$ compared to baseline in each group.

GA: General anesthesia; SA: Spinal anesthesia; TEG: Thromboelastography; LY60%: Fibrinolysis index. (Normal reference ranges: R time: 4-9 min, K time: 1-3 min. Angle: 59-74 degrees, Maximum amplitude: 55-70 millimeters, LY60: 0%-8%)

MA post THA[18]. Intraoperative hypercoagulable states detected by TEG have been reported in previous studies and attributed to either surgical trauma or acute blood loss and hemodilution[2,3,19]. The location of hip arthroplasty surgery makes it appropriate for neuraxial anesthesia techniques (epidural and SA). It has been demonstrated neuraxial techniques may attenuate the stress response and improve local blood flow, and have been associated with direct and indirect effects on the hemostatic system[11]. A previous study reported that epidural anesthesia and analgesia attenuated postoperative hypercoagulability as measured by TEG and reduced thromboembolic sequelae post major vascular surgery[20]. However, these findings have not been reproduced[21,22]. We failed to detect an association between coagulation state and anesthetic technique used for THA. Our findings are congruent with existing evidence, which demonstrate perioperative activation of the coagulation

Table 3 Perioperative conventional coagulation test findings in patients undergoing total hip arthroplasty

Conventional coagulation test	Anesthetic type	Baseline	Post-op day 5
Prothrombin time (min)	GA	12 (12-12)	12 (11-12)
	SA	12 (12-13)	12 (12-13)
INR	GA	0.9 (0.9-1.0)	0.9 (0.9-1.0)
	SA	1.0 (0.9-1.0)	1.0 (0.9-1.0)
aPTT (sec)	GA	32 (30-35)	32 (29-35)
	SA	32 (30-34)	32 (29-34)
Fibrinogen level (g/dL)	GA	3.1 (2.9-3.3)	4.6 (4.1-5.3)[b]
	SA	3.1 (2.9-3.6)	4.5 (4.0-4.9)[b]

All results are presented as median with interquartile range.

[b]$P < 0.01$ compared to baseline in each group.

GA: General anesthesia; SA: Spinal anesthesia; INR: International normalized ratio; aPTT: Activated partial thromboplastin time.

and fibrinolysis systems are similar regardless of anesthetic technique used, resulting in SA having no benefit in reducing hypercoagulability in this group[23-28]. The utility of TEG at predicting thromboembolic events in this patient population remains unknown. A comprehensive 2018 meta-analysis of 41 studies found the sensitivity and specificity of TEG at predicting thromboembolic events was 56% (95%CI: 44-67) and 76% (95%CI: 67-83), respectively[29]. This meta-analysis included data from over 10000 individuals from a heterogenous population. A prospective 2016 study focusing on the diagnostic predictive value of TEG in orthopedic patients revealed a sensitivity of 14% and specificity of 62%[30]. However, this study only performed pre-operative TEG, with several variables changing between pre-operative TEG sampling and the development of post-operative VTE limiting the interpretation of these results. To our knowledge, no evidence is currently available which examines the diagnostic predictive value of post-operative TEG at predicting VTE events in orthopedic patients. We believe our unique, novel findings add to the available evidence in this area and could help guide future outcome-based studies in this group.

Limitations

This study carried several significant limitations. It used data collected several years ago, however we feel that as anesthesia, chemoprophylaxis and surgical principles have not varied significantly *vs* when data was collected that our study results remain valid, and an important contribution to existing evidence. TEG was collected days 1, 2 and 5, compared to a single day 5 postoperative laboratory test. This was in keeping with the practice at our institution at the time of data collection. Importantly, no platelet counts were recorded for any patient during original data collection. We acknowledge that this is a major weakness in the original study design, given platelet contribution to thrombus formation, and subsequently the observed MA, and possibly the overall hypercoagulable state we observed. This is a single center, small observational study, which may limit the external validity of our findings. However, our hospital is representative of many tertiary institutions with patient outcomes equivalent to those of other tertiary hospitals in Australia[31]. The study was also observational and descriptive only and inadequately powered to assess clinical outcomes, including incidence of VTE or VTE associated complications, such as pulmonary embolism and overall morbidity/mortality. Patients were not actively investigated for venous thromboembolic complications including either the routine use of lower limb ultrasound or CTPA. However, this was never the intention of this research, and we seek to make valid data available to the broader scientific community. Ideally, further research conducted in this area would involve paired TEG and conventional coagulation tests sampling at dedicated, simultaneous time-points perioperatively, including platelet count (and ideally, platelet function).

Implications of study findings

Our findings imply that despite routine VTE chemoprophylaxis, patients undergoing THA remain in a hypercoagulable state as measured by both TEG and conventional tests. Going further, as TEG MA is a measure of thrombus size, it is influenced by both

fibrinogen and platelet number and function[32]. These are in turn both influenced by postoperative inflammatory mediators[33]. This leads us to question whether this patient group optimally anticoagulated. Existing evidence suggests solely targeting thrombin production (through administering low molecular weight heparin) may not provide sufficient protection against platelet activation, hence a hypercoagulable state may persist[34,35]. Increased TEG MA suggests that routine VTE chemoprophylaxis cannot prevent the development of platelet-dependent hypercoagulability after THA and that additional antiplatelet drugs may have a role[36,37]. A recent major review of thromboprophylaxis in major orthopedic surgery concluded that aspirin alone for VTE chemoprophylaxis is not recommended, however it's value as an adjunct remains unknown[9].

CONCLUSION

In conclusion, using TEG, we examined the coagulation status of over 50 patients undergoing elective, primary THA and found that in this patient group, TEG demonstrated a progressively hypercoagulable state postoperatively, characterized primarily by elevated MA. Hypercoagulability was also demonstrated by elevated conventional fibrinogen levels day 5 post-operatively. Our findings suggest that despite VTE prophylaxis, patients following total hip replacement remain in a hypercoagulable state as measured by both TEG and conventional tests. This group may benefit from further outcome-based studies to determine if additional perioperative hemostatic monitoring and/or anticoagulation is beneficial.

ARTICLE HIGHLIGHTS

Research background

Patients undergoing total hip arthroplasty (THA) are known to be at high risk of developing venous thromboembolism (VTE), causing significant morbidity and mortality. Thromboelastography (TEG) offers real-time information regarding the global coagulation state of a patient. This technology may be useful in investigating the coagulation of this high-risk population.

Research motivation

Available evidence surrounding the use of TEG in this patient cohort is limited, including both observational data, describing the coagulation status in these patients, and interventional data, guiding anticoagulant therapy. Our motivation for this study was to investigate the coagulation state observed in this patient group as assessed by TEG, and examine how these observations change according to time course post-operatively, and anesthetic technique, in order to ultimately improve perioperative care of these high-risk patients.

Research objectives

We aim primarily to demonstrate the coagulation profile of patients undergoing elective THA, using TEG. We secondarily aim to describe how this coagulation pattern varies according to anesthetic technique chosen [spinal neuraxial *vs* general anesthesia (GA)] and how TEG findings compare to traditional coagulation tests.

Research methods

We performed a retrospective, observational study, examining archived data of elective THA patients. Patients were selected from a dedicated orthopedic preadmission clinic, meeting strict inclusion criteria, and all received enoxaparin as routine post-operatively. We analyzed baseline TEG maximum amplitude (MA), compared to intraoperative and postoperative days 1, 2 and 5. We then compared observations based on anesthetic technique received (GA *vs* spinal) and those described by conventional coagulation tests.

Research results

We studied a total of 52 patients. We found that MA remained within normal limits, without significant difference from baseline, throughout surgery. We observed elevated MA postoperatively on days 1 and 2, before resolving day 5. This was

consistent regardless of anesthetic technique used. All patients had elevated fibrinogen levels day 5 post-operatively, with no other abnormalities detected by conventional coagulation tests.

Research conclusions

Patients undergoing elective THA demonstrate postoperative hypercoagulability when assessed by TEG (characterized by elevated TEG MA), despite routine VTE prophylaxis. Anesthetic technique (spinal *vs* GA) had no influence on the postoperative coagulation profile observed in these patients, as assessed by TEG.

Research perspectives

Our study findings imply that routine VTE prophylaxis in patients undergoing elective THA does not ablate the postoperative hypercoagulable state, according to TEG. These findings suggest that further research comparing TEG with both conventional coagulation tests, (including platelet count) and platelet function testing may be useful.

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ORIGINAL ARTICLE

Prospective Study

Performance of alpha-defensin lateral flow test after synovial fluid centrifugation for diagnosis of periprosthetic knee infection

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Abstract

BACKGROUND

The quantitative alpha-defensin enzyme-linked immunosorbent assay (ELISA) demands a prior synovial fluid centrifugation, whereas this processing is not routinely required prior to the alpha-defensin lateral flow test.

AIM

To evaluate whether a prior synovial fluid centrifugation could lead the lateral flow performance to achieve comparable results to ELISA during periprosthetic joint infection (PJI) diagnosis.

METHODS

Fifty-three cases were included in this study: 22 classified as PJI and 31 classified as aseptic cases, according to Musculoskeletal Infection Society 2013 criteria. Synovial fluid samples were submitted to centrifugation, and the supernatant was evaluated by ELISA and lateral flow tests. The sensitivity (SE), specificity (SP) and accuracy of each method were calculated as well as the agreement between those two methods.

RESULTS

In all of the 31 samples from aseptic patients, alpha-defensin ELISA and lateral flow tests showed negative results for infection. Regarding the 22 infected patients, the lateral flow test was positive in 19 cases (86.4%) and the ELISA was positive in 21 (95.5%). Sensibility, SP and accuracy were, respectively, 86.4%

Amparo à Pesquisa do Estado de São Paulo.

Institutional review board statement: The study was approved by the local Institutional Review Board (2179456).

Informed consent statement: All study participants, or their legal guardian, provided written consent prior to study enrollment.

Conflict-of-interest statement: The authors declare that there are no any conflicts of interest.

Data sharing statement: There is no additional data available.

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(95%CI: 65.1%-97.1%), 100% (95%CI: 88.8%-100%) and 93.2% (95%CI: 82.8%-98.3%) for the lateral flow test and 95.5% (95%CI: 77.2%-99.9%), 100% (95%CI: 88.8%-100%) and 98.1% (95%CI: 89.9%-100%) for ELISA. An agreement of 96.2% between those methods were observed. No statistical difference was found between them (P = 0.48).

CONCLUSION

Alpha-defensin lateral flow test showed high SE, SP and accuracy after a prior synovial fluid centrifugation, achieving comparable results to ELISA. Considering the lower complexity of the lateral flow and its equivalent performance obtained in this condition, a prior centrifugation might be added as a valuable step to enhance the PJI diagnosis.

Key Words: Alpha-defensin; Alpha-defensin lateral flow; Periprosthetic joint infection

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Core Tip: This was a prospective study seeking to evaluate whether the synovial fluid centrifugation prior to the alpha-defensin lateral flow test leads to comparable results in relation to the alpha-defensin enzyme-linked immunosorbent assay (ELISA) during periprosthetic joint infection of the knee. Prior centrifugation of the synovial fluid showed to achieve high sensitivity, specificity and accuracy for the lateral flow test during periprosthetic joint infection diagnosis, leading to similar results in comparison to alpha-defensin ELISA.

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INTRODUCTION

Total knee arthroplasty (TKA) is one of the most successful orthopedic procedures, providing excellent improvement in knee pain, function and quality of life[1]. With the population ageing and the growth incidence of symptomatic osteoarthritis, an increased number of TKA has been observed over the years[2,3]. Despite the most satisfactory results, several complications can occur after TKA, such as long-term pain, periprosthetic fractures, and joint infection[4]. Periprosthetic joint infection (PJI) after TKA is a catastrophic postoperative complication, that ranges from 0.5% to 3% of cases [5-7]. PJI can lead to serious consequences, including death[8], and accounts for a quarter of TKA revision surgeries[6], leading to a substantial economic impact on the healthcare system[9].

Although timing and precision of PJI diagnosis is critical for the patient's evolution, there is no one-hundred percent exam to provide its confirmation. For that reason, the Musculoskeletal Infection Society (MSIS) has developed a score for unifying PJI definition[10,11]. Considering the most updated criteria, alpha-defensin has been included as a new biomarker during the investigation of PJI[10].

Alpha-defensin is a neutrophil-released antimicrobial peptide[12] that increases in response to pathogens[13]. Nowadays, both the synovial alpha-defensin tests available [the quantitative enzyme-linked immunosorbent assay (ELISA) and the qualitative lateral flow test] provide important information during the investigation of PJI[14]. However, given the higher performance of ELISA, this test has a slight advantage[15, 16]. The lateral flow test, despite the inferior performance, offers benefits regarding the ease of use, time-efficiency and cost[14]. One potential reason that could reduce the measurement of the lateral flow test is regarding the differences between fluid processing. While the synovial fluid sample has to be centrifuged preceding ELISA measurement, the same processing is not routinely performed before the lateral flow,

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according to the manufacturer's instructions. Thus, the maintenance of cellular debris and other particles within the synovial fluid could interfere in the results.

Here, we aimed to evaluate the performance of the alpha-defensin lateral flow test post synovial fluid centrifugation, and compare these results with the synovial alpha-defensin ELISA. Our hypothesis was that a prior centrifugation of the synovial fluid would achieve high sensitivity and specificity to predict knee PJI, leading to equivalent performance as alpha-defensin ELISA.

MATERIALS AND METHODS

The study was approved by the local Institutional Review Board (2179456). Written informed consent was obtained from each patient prior to participation.

We conducted a prospective, cross-sectional diagnostic study to assess the performance of the alpha defensin lateral flow measured after synovial fluid centrifugation in patients under investigation of chronic knee PJI. Inclusion and exclusion criteria are displayed in Table 1.

The primary outcome was to evaluate the sensitivity, specificity and accuracy of the lateral flow test post fluid centrifugation. Secondarily, we assessed the performance of the alpha-defensin ELISA in the same population of study, and compared the results between both modalities.

Initially, 59 patients were selected. Of these, three patients had insufficient joint fluid aspirate for analysis, and three patients were using antibiotics, being excluded from the study. A total of 53 patients were included. Figure 1 represents the flowchart of enrolled patients. The recruitment was performed between August 2016 and July 2019.

Among those 53 patients, 22 were diagnosed as infected, and 31 as aseptic. The revised MSIS 2013 criteria were used for the diagnosis of knee PJI[11].

Intervention

Demographic data was recorded. Clinical examination and laboratory evaluations, including serum C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) were collected on the same day as joint aspiration. Knee aspiration was conducted using the superolateral approach, with a 21-gauge needle and a 20-mL syringe. The possible maximum volume of synovial liquid was collected. In this study, at least 3 mL of joint fluid was required for proper analysis. All aspiration procedures were performed by the same author (RCTA).

After that, the synovial fluid samples were referred to the laboratory within 2 h. Part of the fluid from each sample was sent to analysis for cell count, percentage of polymorphonuclear leukocytes and cultures from aerobic, anaerobic and fungi. The remaining fluid was centrifuged for 10 minutes at 2700 rpm to separate all cell debris and particles. The supernatant was collected and divided into two aliquots, as following: approximately 1 mL of synovial fluid was referred to the qualitative alpha-defensin lateral flow test; the rest of the fluid was stored at -80° C until further immunoassay analyses. To quantify synovial alpha-defensin using ELISA, approximately 1.5 to 2 mL of synovial fluid was needed.

Qualitative alpha-defensin analysis

For the qualitative measurement, a lateral flow test (Synovasure® Zimmer-Biomet, Warsaw, IN, United States) was used according to the manufacturer's label. The centrifuged synovial fluid sample was diluted in the dilution buffer supplied by the kit, and deposited on the Synovasure® device. The qualitative result was read after 10 min. The result was considered positive for PJI if two lines appeared in the reading panel, regardless of its intensity.

Quantitative alpha-defensins analysis

For the quantitative alpha-defensin test, the commercial alpha-defensin (HNP1-3) ELISA kit (Hycult Biotech®, Uden, Netherlands) was employed. This ELISA kit is used to determine human HNP1-3. All assays were optimized and performed in duplicate by an experienced laboratory technician. The dilution optimization of the synovial fluid at 1:5000 was performed to decrease the effects of the fluid viscosity on the assay. Results were generated in optical density units (OD) using a spectrophotometer. The results in OD were plotted on the vertical axis with the corresponding concentration values on the horizontal axis (logarithmic scale). The concentration and the dilution factor were multiplied to reach alpha-defensin values in mg/L. The assay was

Table 1 Inclusion and exclusion criteria of the study

Inclusion criteria	Exclusion criteria
Any of the following suspicious signs or symptoms of chronic knee PJI (more than 90 d), as following:	Acute signs or symptoms of knee infection (less than 90 d)
Persistent knee pain (more than 3 mo), without other apparent cause	
Persistent joint effusion (more than 3 mo)	
Persistent local heat (more than 3 mo)	
Presence of draining sinus	
Early failure of the prosthesis (less than 5 yr)	
Radiographic findings suggesting infection[33]	
Have not used antibiotics for at least 4 wk before the evaluation	Insufficient synovial fluid volume during knee aspiration
	Insufficient data for fulfilling the periprosthesis infection criteria[11]

PJI: Periprosthetic joint infection.

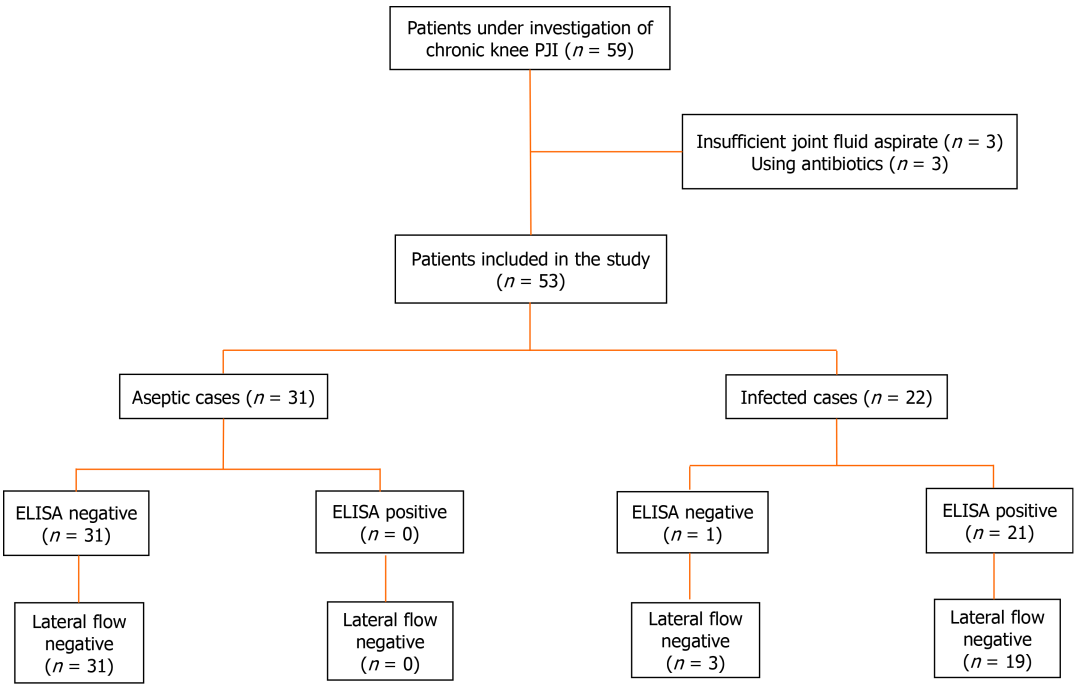


Figure 1 Flowchart of the patients included in the study.

optimized to operate at a cutoff value of 5.2 mg/L, based on previous studies[17,18].

Statistical analysis

Shapiro-Wilk test was applied to assess normality. Continuous variables were expressed as descriptive analysis, and categorical variables were expressed as proportions. To compare continuous variables, unpaired *t*-test or Mann-Whitney test were used, as appropriate. Fisher's exact test was applied to compare categorical variables. The cutoff value was obtained using the Receiver Operator Curve (ROC) through the SPSS software® (version 25.0 for Mac; SPSS, Chicago, IL), giving the results as a semiquantitative signal-to-cutoff ratio (S/CO) of 1.0. Sensitivity, specificity and accuracy (and 95%CI) of each method were calculated using the MSIS 2013 criteria as standard. The agreement between ELISA and lateral flow test was evaluated based on the percentage of concordant results, and McNemar's test was performed to calculate the statistical difference between those two alpha-defensin tests. Statistical significance was set at $P < 0.05$.

To further investigate whether draining sinus has influenced the tests results, we also calculated sensitivity, specificity and accuracy of each method excluding patients with fistulization.

RESULTS

Of the 53 patients included in the study, 31 were considered without infection (aseptic cases) and 22 were classified as infected. Table 2 shows the patient demographics.

In relation to the aseptic cases, all lateral flow tests showed negative results for infection. Likewise, alpha-defensin ELISA showed a mean S/CO of 0.28 ± 0.13, which was considered negative for all cases.

Regarding the infected patients, lateral flow showed positive results in 19 cases (86.4%). The 3 false negatives occurred in patients with sinus tract. The ELISA presented 21 positive (95.5%) (mean S/CO-4.93 ± 2.28) and one negative result (S/CO-0.24). Similarly, this false negative case referred to a patient with draining sinus.

Lateral flow test showed a sensitivity of 86.4% (95%CI: 65.1%-97.1%), a specificity of 100% (95%CI: 88.8%-100%) and an accuracy of 93.2% (95%CI: 82.8%-98.3%). Alpha-defensin ELISA presented a sensitivity of 95.5% (95%CI: 77.2%-99.9%), a specificity of 100% (95%CI: 88.8%-100%) and an accuracy of 98.1% (95%CI: 89.9%-100%). Table 3 summarizes those findings.

In terms of ROC analysis, area under curve was 93.2% (95%CI: 84.6%-100%) for the lateral flow test and 97.9% (95%CI: 93.6%-100%) for ELISA. The agreement between lateral flow and ELISA was observed in 51 cases (96.2%; 95%CI: 87.0%-99.5%). The two disagreement cases were false negatives for the lateral flow. No statistical difference between those two tests were found (P = 0.48).

Given that all false positive results occurred in patients with sinus tract, we performed an exploratory analysis to evaluate whether the lateral flow and the ELISA would change after excluding those selected patients (4 patients with sinus tract). In this situation, a sensitivity of 100% (95%CI: 81.5%-100%), specificity of 100% (95%CI: 88.8%-100%), accuracy of 100% (95%CI: 92.8%-100%) and agreement of 100% (95%CI: 92.9%-100%) were found for both tests (Table 4).

DISCUSSION

The findings of this study reinforce our hypothesis that a prior synovial fluid centrifugation before the lateral flow measurement provides high sensitivity, specificity and accuracy, leading to comparable performance of the alpha-defensin ELISA, so far the best method to measure synovial alpha-defensin[15]. This preliminary finding may bring a novel concept to the major topic of PJI.

Diagnosis of PJI is frequently defiant, particularly in chronic infections in which the clinical symptoms might be subtle and inflammatory markers might be normal[19]. In this regard, a great need for new diagnostic tests is observed[20]. Alpha-defensin is a small antimicrobial peptide that acts as part of the host's innate immune response against pathogens[12]. After the pathogen insult, the release of alpha-defensin increases, and a rapid interaction of this peptide with the pathogen's membrane occurs. As a consequence, the membrane depolarizes, and the pathogen is killed[21]. Under a knee infection, the concentration of alpha-defensin elevates into the joint. Indeed, this synovial fluid biomarker has been studied for PJI diagnosis, providing exciting findings in terms of sensitivity and specificity[14,22]. It has been demonstrated that, even in the presence of inflammatory disease or antibiotic use, the results are similar[17]. Here, we opted to exclude patients using antibiotics to avoid potential bias. However, we did include patients with inflammatory diseases, which in fact did not influence those tests' performance. Due to its relevance and applicability, alpha-defensin has been included as a diagnostic criterion in the updated consensus of PJI[10].

Currently, there are two commercially available methods for the determination of synovial alpha-defensin. The quantitative laboratory-based ELISA, that requires a centrifuged synovial fluid to assess the concentration of alpha-defensin[17], and the qualitative lateral flow test. As mentioned, both tests have shown to be successful for the investigation of PJI, with ELISA presenting the best performance[17,18,23,24]. However, alpha-defensin ELISA is much more complex, requiring a laboratory structure and an experienced professional to be performed. Conversely, the lateral flow test can be done by the physician at any location, and the result is rapidly

Table 2 Patient demographics

	Total	Aseptic cases	Infected cases	*P* value
n	53	31	22	
Sex				0.22[1]
Male	14 (26.4)	6 (19.4)	8 (36.4)	
Female	39 (73.6)	25 (80.6)	14 (63.6)	
Age (range)	68 (47-85)	67 (47-85)	70 (52-85)	0.30[2]
Laterality				> 0.99[1]
Right knee	28 (52.8)	16 (51.6)	12 (54.5)	
Left knee	25 (47.2)	15 (48.4)	10 (45.5)	
Inflammatory disease	12 (22.6)	7 (22.6)	5 (22.7)	> 0.99[1]
RA	10 (18.9)	7 (22.6)	3 (13.6)	
Gout	2 (3.8)	0	2 (9.1)	
Sinus tract	4 (7.5)	0	4 (18.2)	
Alpha-defensin S/CO	2.21 ± 2.73	0.28 ± 0.13	4.93 ± 2.28	< 0.01[3]

[1]Fisher's exact test.
[2]Unpaired *t* test.
[3]Mann-Whitney test. Values expressed in number (percentage). Age in years is presented as mean (range) and alpha-defensin S/CO in mean (standard deviation). RA: Rheumatoid arthritis.

Table 3 Statistical results of enzyme-linked immunosorbent assay and lateral flow test for all patients

	Aseptic	Infected	Sensitivity (95%CI)	Specificity (95%CI)	Accuracy (95%CI)
ELISA			95.5% (77.2%-99.9%)	100% (88.8%-100%)	98.1% (89.9%-100%)
Negative	31	1			
Positive	0	21			
Lateral flow			86.4% (65.1%-97.1%)	100% (88.8%-100%)	93.2% (82.8%-98.3%)
Negative	31	3			
Positive	0	19			

ELISA: Enzyme-linked immunosorbent assay.

expressed within 10 minutes.

As suggested by our team, one potential reason for the inferior results regarding the lateral flow test is that, during its execution, fluid centrifugation is not performed (in accordance with the manufacturer's instruction). Consequently, some particles and cellular debris could lead to false results. Although some evidence shows that blood contamination does not influence the lateral flow reading[19], the sample processing is not equivalent between ELISA and lateral flow test, which may interfere in the device reading[15,16]. In this study, we indirectly suggest this plausible issue, since a favorable performance of the lateral flow test was reached after centrifugation. Here, we obtained a sensitivity of 86.4%, a specificity of 100% and an accuracy of 93.2%, superior values than the ones observed in some previous non-centrifuged studies. Indeed, sensitivity of approximately 67%-69%, specificity of 93%-94%, and accuracy of 85% were previously reported for the lateral flow test[25,26]. It is noteworthy to mention that, although some recent systematic reviews and meta-analyses present higher pooled values for the lateral flow, the moderate-to-high heterogeneity among the included studies compels careful interpretation. Even so, the 83% sensitivity and 94% specificity found in these studies are still slightly lower than the achieved here[14,27]. In our series, the centrifuged lateral flow performed similarly to ELISA, which also demonstrated excellent results in concordance to the literature[16,27].

Table 4 Statistical results of enzyme-linked immunosorbent assay and lateral flow test for patients without sinus tract

	Aseptic	Infected	Sensitivity (95%CI)	Specificity (95%CI)	Accuracy (95%CI)
ELISA			100% (81.5%-100%)	100% (88.8%-100%)	100% (92.8%-100%)
Negative	31	0			
Positive	0	18			
Lateral flow			100% (81.5%-100%)	100% (88.8%-100%)	100% (92.8%-100%)
Negative	31	0			
Positive	0	18			

ELISA: Enzyme-linked immunosorbent assay.

Some authors have described false positive results using the lateral flow test in cases of metallosis[23,25] and crystal deposition disease[28,29]. This current study did not find any false positive case, despite the presence of four patients with gout. Once again, the centrifugation might improve the measurement by removing these particles. On the other hand, one false negative (by ELISA) and three false negatives (by the lateral flow test) were observed. All of those occurred in patients with sinus tract, as previously shown[30,31]. Although it was not directly investigated here, we speculate that the fistulization tends to drain the synovial fluid, avoiding the accumulation of pathogen and alpha-defensin within the knee. Considering the presence of draining sinus as a confirmation of PJI diagnosis, additional investigation would not be required. In this regard, excluding these specific patients, a sensitivity, specificity, accuracy and agreement of 100% were obtained for both tests.

The study has several limitations. First, we did not perform a direct comparison between centrifuged and non-centrifuged samples for the lateral flow test. Due to the high cost of lateral flow test in our region when this preliminary study was designed, we decided to compare these initial findings with the literature. As we know, there are several studies presenting remarkable data[14,25,26,32]. Further comparative trials are necessary and might add stronger conclusions. In addition, understanding the reason for false positive cases in patients with crystal arthropathy or metallosis, and the beneficial effects of synovial fluid centrifugation in these contexts may be valuable for its proper management. Moreover, despite the prospective design, the study was not randomized. Given the rarity of the cases that fit in our study, a randomization is impracticable. Therefore, we provide interesting data showing that a prior centrifugation may improve the lateral flow test performance. Considering the ease of execution and interpretation of the lateral flow, the addition of this prior step deserves further investigation and, potentially, a place in the PJI diagnosis.

CONCLUSION

In conclusion, we have identified that an extra step of synovial fluid centrifugation prior to the alpha-defensin lateral flow test achieved high sensitivity, specificity and accuracy. The results obtained using this methodology were comparable to those obtained with the alpha-defensin ELISA. Furthermore, centrifuged lateral flow demonstrated performance values slightly higher than the previously reported in the literature. Therefore, the use of the alpha-defensin lateral flow post synovial fluid centrifugation may represent a novel and interesting strategy during the PJI investigation given its lower complexity and equivalent performance in comparison to ELISA.

ARTICLE HIGHLIGHTS

Research background

Periprosthetic joint infection (PJI) is a serious postoperative complication that leads to severe morbidity as well as substantial financial burden to the healthcare system. Currently, two synovial alpha-defensin tests [the quantitative enzyme-linked

immunosorbent assay (ELISA) and the qualitative lateral flow test] are available and provide important information during PJI investigation, with the ELISA presenting slightly superior performance. However, the lateral flow test offers benefits in terms of the ease of use, time-efficiency and cost.

Research motivation

While the synovial fluid sample has to be centrifuged preceding ELISA, prior centrifugation is not routinely performed to the lateral flow test. The maintenance of synovial fluid debris could potentially interfere in the lateral flow results.

Research objectives

This study aimed to evaluate the performance of the alpha-defensin lateral flow test with prior synovial fluid centrifugation and compare the results with the synovial alpha-defensin ELISA.

Research methods

In this prospective study, 53 cases of total knee arthroplasty were evaluated: 22 classified as PJI and 31 classified as aseptic knees. Synovial fluid samples were collected and submitted to centrifugation, and the supernatant was evaluated by lateral flow test and ELISA. Sensitivity, specificity, and accuracy of each method as well as the agreement between those two methods were calculated.

Research results

Alpha-defensin ELISA and lateral flow tests showed negative results for infection in all 31 aseptic patient samples. In regard to the 22 infected cases, the lateral flow test showed positive results in 19 cases (86.4%) whereas the ELISA was positive in 21 cases (95.5%). Sensibility, specificity, and accuracy were 86.4% (95%CI: 65.1%-97.1%), 100% (95%CI: 88.8%-100%) and 93.2% (95%CI: 82.8%-98.3%), respectively, for the lateral flow test and 95.5% (95%CI: 77.2%-99.9%), 100% (95%CI: 88.8%-100%) and 98.1% (95%CI: 89.9%-100%) for ELISA. Agreement of 96.2% between these two methods were found, without statistical difference between them (P = 0.48).

Research conclusions

Alpha-defensin lateral flow test with prior synovial fluid centrifugation showed high sensitivity, specificity, and accuracy, achieving comparable results to ELISA. Given the lower complexity of the lateral flow test, a prior centrifugation might be a valuable strategy to enhance its performance.

Research perspectives

Prior synovial fluid centrifugation may be a novel and interesting strategy to improve the lateral flow performance during the PJI diagnosis. Further investigation is required to clarify its actual benefit.

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SYSTEMATIC REVIEWS

Limb lengthening with PRECICE magnetic nail in pediatric patients: A systematic review

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Abstract

BACKGROUND

Limb lengthening techniques play an increasingly important role in the pediatric orthopedic field. The principles of the osteogenesis distraction bonded traditionally with external fixators; however, the recent deployment of fully implantable systems has been able to overcome severities related to external fixators. The PRECICE® is an implantable limb lengthening intramedullary nail system that is remotely controlled and magnetically driven.

AIM

To review the current literature available on this matter in order to assess the PRECICE clinical and radiological outcomes and its possible complications in a population of pediatric patients undergoing limb lengthening.

METHODS

Only five studies met the inclusion criteria and were consequently included in the review for a total of 131 patients and 135 femurs. The clinical and radiological outcomes of interest were: the main lengthening obtained, the distraction rate, the period of time to full weight bearing, the consolidation index, and the Association for the Study and Application of Methods of Ilizarov score.

RESULTS

In conclusion, data collected from the articles under investigation were comparable with the exception of the consolidation index. Unfortunately, the study population was too small and the patients' follow-up was too short to make definitive conclusions.

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CONCLUSION
This review shows that the PRECICE Nail System is still a therapeutic challenge in limb lengthening for pediatric orthopedic surgeons; however, careful preoperative planning and an accurate surgical technique could allow the correction of more complex deformities with a low rate of complications.

Key Words: Limbs lengthening; PRECICE; Nail; Pediatric; Dysmetria; Deformities

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Core Tip: Limb lengthening techniques play an increasingly important role in the pediatric orthopedic field. The PRECICE® is an implantable limb lengthening intramedullary nail system that is remotely controlled and magnetically driven. The aim of our study was to review the current literature in order to assess the clinical and radiological outcomes and possible complications in a population of pediatric patients undergoing limb lengthening. This review shows that the PRECICE allows correction of the more complex deformities with a low rate of complications.

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INTRODUCTION

Limb lengthening techniques play an increasingly important role in the field of pediatrics orthopedics with regard to length discrepancy, angular deformities (referable either to fractures sequelae or congenital malformations), and short stature correction[1-4]. The osteogenesis distraction is a reparative process involving not only the bone but also the soft tissues including the muscles, nerves, and skin. Therefore, accurate distraction control is required since too rapid correction could lead to nonunion, nerve damage, and joint contractures, while on the other hand a process that is too slow could result in premature consolidation[5].

The principles of the osteogenesis distraction bonded traditionally with the external fixators, considering both monolateral and circular fixators[6,7]. More recently, the deployment of fully implantable systems for limb lengthening has allowed overcoming external fixator-related severities such as pin-site infections, soft tissue tethering, and patient device intolerance during treatment, to name a few[8-10]. Intramedullary nails were initially used in conjunction with external fixation in hybrid techniques such as lengthening over nail or lengthening and then nailing[11,12], in order to reduce fixator time and prevent secondary deformities. However, these techniques are not free from external fixator-related complications. Over the past couple of decades, internal bone lengthening devices have been developed to obviate the need for external fixators. They seem to decrease patients' pain and discomfort and facilitate a more rapid and effective rehabilitation compared with external fixation[13].

At present, three types of telescopic nails are mainly used: mechanically activated nails, motorized nails, and magnetically driven nails[14-16]. The PRECICE® Intramedullary Limb Lengthening System (NuVasive Specialized Orthopedics, San Diego, CA, United States) is a remotely controlled, magnetically driven, implantable limb lengthening intramedullary nail system first used in Europe in 2012[17-19]. The PRECICE nail is a magnet-operated telescopic internal lengthening device with an ERC that contains two rotating magnets[20]. When placed by the patient on the skin, above the magnet which is within the nail, it causes this internal magnet to rotate, which translates to the thinner nail element telescoping out of the thicker surrounding nail; the nail can be both extended and retracted by altering the settings on the ERC as well as accurately setting the rate of distraction. A distance of 1 mm requires the ERC to be placed over the magnet within the nail for 7 min[21].

The PRECICE represents a safe and accurate technique able to correct both deformity and limb-length discrepancy, lengthening but also shortening (unlike other lengthening nails[22]) with reduced side effects . Among the advantages of opting for this implant, there is the ability to maintain the knee range of motion during the lengthening process and also the rapid bone healing allows a relatively early return to weight bearing[23,24].

The aim of our study was to review the current literature available on this matter in order to assess the PRECICE clinical and radiological outcomes and its possible complications in a population of pediatric patients undergoing limb lengthening.

MATERIALS AND METHODS

A systematic review of the literature indexed in PubMed MEDLINE and Cochrane Library databases using the search key word "PRECICE" was carried out. To minimize the number of missed studies, no filters were applied to the search strategy. The bibliography of the selected studies was accurately searched by hand, in order to identify further studies not found during our electronic search. No restrictions on the date of publication or language were applied. The title of the journal, name of authors, or supporting institutions were not masked at any stage. No attempt to contact authors in order to obtain individual patient data was made. The Preferred Reporting Items for Systematically Reviews and Meta-Analyses (PRISMA) was followed as reported in Figure 1. In order to be considered for this review, the articles needed to comply with the following inclusion criteria: use of the PRECICE® Intramedullary Limb Lengthening System (NuVasive Specialized Orthopedics) for femur lengthening and patient age under 18 years. No restrictions for surgical approach to nailing were applied. Abstracts and full texts were independently screened by two authors (Vitiello R and Maccauro G), and any discordance was solved by consensus with a third author (Palmacci O). The methodological quality of the studies was assessed using the modified Coleman Methodology Score (mCMS)[25]. Each article was evaluated by two independent investigators (Vitiello R and Bocchi MB); in cases with more than a five-point difference between their rating, the discrepancy was solved by consensus with a third author (Palmacci O). The mCMS ranges from 0 to 100 points, representing a well-designed study with no bias or confounding factors.

RESULTS

The electronic search resulted in 60 hits. Following the PRISMA flow chart[26], only five studies met the inclusion criteria and were taken into consideration in the review [27-31]. Eight papers partially followed the inclusion criteria; these studies included a non-specific pediatric population. An extra analysis was performed for these latter papers. All of the selected studies were retrospectively analyzed. The target population consisted of 131 patients for a total of 135 femurs. According to the mCMS evaluation, the mean score of the studies reached was 47 points (25-57 points) showing a poor-mediocre result. The papers we took into consideration had several methodological issues, particularly when considering the procedure in assessing the outcomes. Moreover, the study population was too small and the patient's follow-up was too short. However, all of the papers accurately reported the indications for surgical intervention and the surgical technique (respectively 5 points each). Studies by Szymczuk *et al*[30] and Hammouda *et al*[32] compared the PRECICE intramedullary nailing with external fixation, but in our analysis, we only took into account the PRECICE nailing results. In studies by Nasto *et al*[27] and Iliadis *et al*[29], both retrograde and antegrade approaches were used, and some tibia nailing was included. Other studies preferred the antegrade approach to the femur.

DISCUSSION

Demographic data and etiology

We reached a population of 131 male and female patients for a total of 135 femurs. Males and females numbered 69 and 62, respectively. The mean age was 14.8 years old, ranged between 7 and 18 years old[31]. All of the studies reported pre-operative discrepancy except one[31], with a mean value of 5.2 cm (range, 4.9 to 6.3). The mean

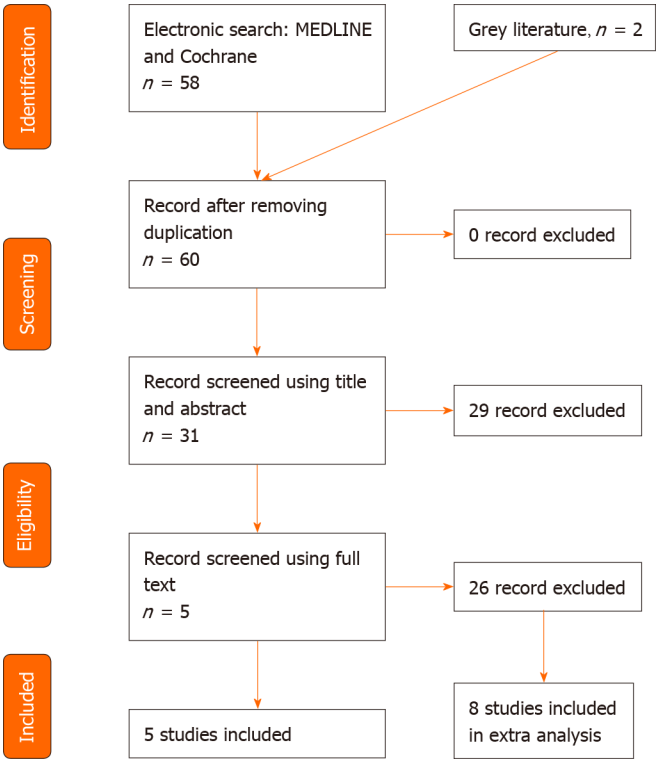


Figure 1 PRISMA flowchart.

follow-up was 1.7 years when reported (Table 1). Concerning surgical indications, one study only focused on a single pathology; in particular, Szymczuk *et al*[30] focused on congenital femoral deficiency treatment for a total of 30 femurs (Table 2). Among other papers, the principal surgical indication was congenital femoral deficiency (19 femurs), and yet post-traumatic malformations (18 femurs), achondroplasia (8 femurs), hemihypertrophy (8 femurs) and Ollier disease (6 femurs). Nevertheless, the main indication remained "miscellaneous" (46 femurs).

Clinical and radiological outcomes

Regarding the PRECICE system results, the studies examined focused on the following issues: The main lengthening obtained with particular reference to accuracy and reliability, the distraction rate, the period to reach full weight bearing, the consolidation index, and the Association for the Study and Application of Method of Ilizarov (ASAMI) score (Table 3 and Table 4). Nail accuracy is defined as the ratio between the lengthening obtained and the planned length, while nail reliability is the ratio between the number of implanted lengthening devices and the number of successfully ended lengthening treatments. Analyzing the main lengthening obtained, the results were similar across all studies. In particular, Hammouda *et al*[31] reported a mean lengthening of 5.6 (3-6.7), with no reference to accuracy and reliability. It is relevant to notice that the authors performed intramedullary nailing using the trochanteric entry. During the follow-up time no patients showed radiographic nor clinical signs of femoral head necrosis. The average lengthening achieved reported by Nasto *et al*[27] was 4.4 ± 1.2, with a nail accuracy and reliability of 91% and 88% respectively. Iliadis *et al*[29] reported a nail accuracy of 96% and a nail reliability of 98%, due to a single case where a nail was implanted without lengthening because of the patient's mental health issues.

The distraction index (DI), defined as the ratio between the number of days of distraction and the achieved length (days/cm), was reported in all of the studies analyzed, except for Hammouda *et al*[31]. Among the articles, the results were almost comparable. Szymczuk *et al*[30] described a DI of 0.7 ± 0.18, while Iliadis *et al*[29] reported a DI of 0.92 (0.67-1). Furthermore, this latter retrospective review was the only one considering the days to full weight bearing from lengthening accomplishment with a mean of 45 days. All patients in fact gradually obtained full weight bearing over a 4-wk period after the planned length achievement. The consolidation index (CI) is defined as the ratio between the total duration required to achieve bone healing and the achieved length (day/cm). The data collected in the articles under

Table 1 Demographic data

Ref.	Number of patients	Gender	Tibia nailing	Age (yr)	Discrepancy (cm)	Follow-up (yr)	mCMS
Hammouda *et al*[32]	28 patients; 31 femurs	17 males; 11 females	-	12.9	-	1.9	49
Szymczuk *et al*[30]	30	14 males; 16 females	-	15.4	4.9	1.9	51
Iliadis *et al*[29]	42 patients; 43 femurs	20 males; 22 females	7	15	4.9	-	54
Nasto *et al*[27]	26	15 males; 11 females	5	14.7	4.9	1.4	57
Tomaszewski *et al*[28]	5	3 males; 2 females	-	16.3	6.3	-	27

In brackets measurement unit; Data are reported as absolute value. mCMS: Modified Coleman Methodology Score.

Table 2 Etiology

Ref.	Congenital femoral deficiency	Achondroplasia	Post-traumatic	Hemihypertrophy	Ollier disease	Miscellaneous
Hammouda *et al*[32]	10	6	5	3	2	5
Szymczuk *et al*[30]	30	-	-	-	-	-
Iliadis *et al*[29]	5	2	7	5	1	23
Nasto *et al*[27]	4	-	4	-	3	15
Tomaszewski *et al*[28]	-	-	2	-	-	3

In brackets measurement unit; Data are reported as absolute values.

Table 3 Result

Ref.	Mean lengthening (cm)	Accuracy	Reliability	Distraction rate (mm/d)	Day to full weight bearing	Consolidation index (d/cm)	ASAMI functional score	ASAMI bone score
Hammouda *et al*[32]	5.6 (3-6.7)	-	-	-	-	-	-	-
Szymczuk *et al*[30]	4.75 ± 1.43	95%	-	0.7 ± 0.18	-	34.7 ± 11.2	-	-
Iliadis *et al*[29]	-	96%	98%	0.92 (0.67-1)	45 (21-132)	28 (18-43)	35 excellent; 11 good; 3 fairs; 1 poor	41 excellent; 8 good; 1 fair
Nasto *et al*[27]	4.4 ± 1.2	91%	88%	0.9 ± 0.1	-	11.9 ± 2.1	22 excellent; 3 good; 1 fair	24 excellent; 1 fair; 1 poor
Tomaszewski *et al*[28]	4.9 (4-5.8)	-	-	0.8 (0.8-1)	-	29.3 (21-33)	-	-

In brackets measurement unit; Data are reported as absolute values.

investigation were different. Nasto *et al*[27] in particular obtained a CI of 11.9 ± 2.1, while Szymczuk *et al*[30] obtained a CI of 34.7 ± 11.2. Nasto *et al*[27] and Iliadis *et al*[29] reported the modified ASAMI score, which is a scoring system that classifies clinical results into excellent, good, fair, and poor based on four different parameters. The data we collected were similar and encouraging, supporting the efficacy of this device. In the paper by Iliadis *et al*[29], patients reported a low pain score throughout the lengthening and consolidation period. No significant impact on daily living activities was reported by 66% of patients, to the extent that 92% of patients were satisfied with the surgical treatment results and felt that they had achieved their goals.

Complications

Adverse events were divided into problems, obstacles, and complications in accordance with the data previously described by Paley[17]. Problems were defined as

Table 4 Complication

Ref.	Number of patients	Problem	Obstacle	Complication
Hammouda *et al*[32]	28 patients; 31 femurs	-	-	2
Szymczuk *et al*[30]	30	8	19	4
Iliadis *et al*[29]	42 patients; 43 femurs	7	4	4
Nasto *et al*[27]	26	5	1	3
Tomaszewski *et al*[28]	5	1	-	-

In brackets measurement unit; Data are reported as absolute values. Problems are post-operative difficulties that resolved completely with non-operative intervention; obstacles were difficulties that needed an operative intervention, resolved completely after surgery; complications consisted of all intra- and post-operative complications that remained unresolved even after treatment was completed.

difficulties after the surgical procedure resolved with conservative treatment, obstacles were difficulties that required surgical treatment, and complications were true intra or post-operative complications that persisted after the treatment. Hammouda *et al*[31] reported no problems or obstacles in 28 patients and two complications. Among them, 1 patient developed hip subluxation and delayed union of the regenerate, which was treated surgically. In addition, the nail was exchanged 6 mo after surgery. Iliadis *et al*[29] reported instead seven problems, four obstacles, and four complications. In 7 cases, they reported joint stiffness during the lengthening period, which was resolved with physiotherapy and by slowing down the distraction. Two femoral nails required the locking bolts removal as they were causing discomfort after consolidation. One patient with fibrous dysplasia, who previously underwent proximal femoral osteotomy with locking plate fixation, had a periprosthetic fracture so the PRECICE was exchanged with a trauma nail, but with loss of about 30 mm of lengthening.

Tomaszewski *et al*[28] reported no inflammatory complications, but in 1 case, after a lengthening of more than 45 mm, they noted a knee flexion contracture of about 10° despite the physiotherapy. Moreover, they had to stop the lengthening treatment in 1 case due to the pain and femoral nerve paresthesia. In the retrospective multi-center study conducted by Nasto *et al*[27], a total of five problems (joint contractures), one obstacle (femur fracture), and three complications (hip subluxation, 1 deep infection and 1 nail running back) were encountered. No bone healing complications were reported. Considering the patient who developed deep infection, the treatment was suspended and the nail removed. Regarding the case of hip subluxation, we would like to note that the patient had a developmental hip dysplasia history treated with proximal femur varus derotation osteotomy (VDRO) and Dega osteotomy. This complication was surgically treated with periacetabular osteotomy and VDRO; at the latest follow-up, the patient was asymptomatic and pain free during walking.

Non-specific pediatric population

Analyzing the entire population, a great heterogeneity has emerged in terms of age (7-72), male/female ratio, surgical access and surgical site[18,19,21,32-36]. The rise in the average population age has led to an increase of post-traumatic etiology[32], although the congenital and syndromic causes are still well represented[18,32,36]. All of the reviewed articles analyzed both femoral and tibial lengthening nails outcomes, except one[32]. In a retrospective review by Wagner *et al*[18], both PRECICE nail accuracy and precision reached 97.3% and 92.4%, respectively, with a total of nine complications (28%), all of which were successfully resolved without any long-term sequelae. In his 24-nail series, Kirane *et al*[21] revealed an accuracy of 96% and a precision of 86% with only one (4%) implant-related failure caused by a non-functional distractor mechanism and 6 (24%) non-implant-related obstacles; the minimum follow-up was 3 wk (mean 14 wk). In a different 9 case series by Wiebking *et al*[34], there were significant differences regarding the lengthening goal achievement and thus also the full weight bearing among patients. Consequently, the accuracy and the precision rate were 78% *vs* 61%, respectively. Despite the complications, patient satisfaction was generally positive.

A slight improvement in the quality of life was shown in preoperative and 12-mo postoperative Enneking scores; no differences were revealed in the physical and mental SF-12 score[18].

Concerning complications, a low complication rate was demonstrated in a series of 17 post-traumatic femoral lengthening nails with 2.2-year follow-up[32]. Hammouda *et al*[32] reported 3 patients (18%) with non-implant related complications that all resolved without permanent sequelae. Similar outcomes were reported by Horn *et al* [35] who described 8 of 50 complications, which were treated by surgery without sequelae and therefore were graded as obstacles. However, in this study, 16 nails were not PRECICE[35].

CONCLUSION

This review shows that the PRECICE Nail System is still a therapeutic challenge in limb lengthening for pediatric orthopedic surgeons. In the literature, only few studies have been published; nevertheless, the outcome demonstrates excellent clinical results and patient satisfaction. Careful pre-operative planning and an accurate surgical technique could allow correction of the more complex deformities with a low rate of complications.

ARTICLE HIGHLIGHTS

Research background

Limb lengthening devices have evolved in the last century to correct limb length discrepancies, congenital short statures, and limb deformities. The unilateral external fixator has been the standard method of fixation for a long time; however, the method of fixation has rapidly evolved from unilateral external fixator to the ring fixator, to the computer-assisted fixator, and finally to the lengthening of intramedullary nails.

Research motivation

The large number of complications related to the use of external fixation has led to the development of alternatives. The PRECICE represents an innovative and less invasive option to external fixation with regard to limb lengthening, allowing a controlled lengthening phase with the ability to shorten and regulate the device if necessary.

Research objectives

To review the current literature available on the specific matter in order to assess the PRECICE clinical and radiological outcomes and its possible complications in a population of pediatric patients undergoing femur lengthening.

Research methods

The current study is the result of a systematic review of the available literature using a single search term "PRECICE". The articles were sorted according to both pre-determined inclusion and exclusion criteria. PRISMA was followed.

Research results

Five studies met the inclusion criteria for a total of 131 patients. The studies examined focused on the following issues: the main lengthening obtained, the distraction rate, the number of days necessary to reach full weight bearing, the consolidation index and the ASAMI score. Among the articles all the results were almost comparable with the only exception of the consolidation index. Adverse events that emerged in a low percentage were divided into problems, obstacles, and complications.

Research conclusions

Although the PRECICE nail system is still a therapeutic challenge, the results have shown excellent clinical results and patient satisfaction with a low rate of complications. Therefore this approach could represent a valid alternative to the traditional limb lengthening systems.

Research perspectives

Future studies on larger and more homogeneous samples are needed to validate the use of PRECICE.

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SYSTEMATIC REVIEWS

Complications in growth-friendly spinal surgeries for early-onset scoliosis: Literature review

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Abstract

BACKGROUND

The treatments for early-onset scoliosis (EOS), defined as curvature of the spine with onset before 10 years of age, continue to pose a great challenge for pediatric orthopedics. The treatment goals for EOS include minimizing spinal deformity while maximizing thoracic volume and pulmonary function. Different surgical techniques have different advantages and drawbacks; however, the two major concerns in the management of EOS are repeated surgeries and complications.

AIM

To review the current literature to assess the safety of EOS surgical treatment in terms of the rate of complications and unplanned surgeries.

METHODS

In January 2021 two independent reviewers systematically searched three electronic medical databases (PubMed, the Cochrane Library, and Embase) for relevant articles. Every step of the review was done according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Due to the heterogeneity of articles and topics after data analysis, a descriptive (synthetic) analysis was performed.

RESULTS

A total of 2136 articles were found. Forty articles were included in this systematic review, after applying our inclusion and exclusion criteria. EOS surgery has a varying but high rate of complications. The most frequent complications were categorized as implant (54%), general (17%), wound (15%) and alignment (12%).

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The rate of complications might have been even higher than reported, as some authors do not report all types of complications. About 54% of patients required unplanned surgeries due to complications, which comprised 15% of all surgeries.

CONCLUSION

The literature concerning the definitions, collection, and interpretation of data regarding EOS surgery complications is often difficult to interpret. This creates problems in the comparison, analysis, and improvement of spine surgery practice. Additionally, this observation indicates that data on the incidence of complications can be underestimated, and should be interpreted with caution. Awareness of the high rate of complications of EOS surgery is crucial, and an optimal strategy for prevention should become a priority.

Key Words: Scoliosis; Spine; Growth-friendly implant; Surgery; Complications; Treatment

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Core Tip: Early-onset scoliosis (EOS) is defined as curvature of the spine ≥ 10° with onset before 10 years of age, regardless of etiology. The treatment for EOS is still a great challenge for pediatric orthopedics, and surgery is often necessary. Repeated surgeries and complications are two major concerns in EOS management. The literature on the definitions, collection, and interpretation of data regarding EOS surgery complications is often difficult to interpret. This creates problems in the comparison, analysis, and improvement of spine surgery practice. Data on the incidence of complications can be underestimated, and should be interpreted with caution.

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INTRODUCTION

Early-onset scoliosis (EOS) is defined as curvature of the spine ≥ 10° in the frontal plane with onset before 10 years of age[1]. EOS is not a diagnosis, but can rather be defined as the age of onset of a coronal plane spinal deformity. As such, EOS includes spinal deformities resulting from congenital malformations, neuromuscular conditions, inherited bone dysplasias and syndromes, and, in idiopathic cases, with no underlying disorder. As EOS has such a wide variety of etiologies, its natural history varies widely, and in many cases is established at the time of the child's diagnosis which reveals the spinal deformity[2]. The natural history of untreated progressive EOS was reported on by Scott and Morgan in 1955[3]. They documented the progression of curves from 30 to 100 degrees. Moreover, 4 patients out of 28 died before the age of 20 years, of cardiorespiratory disease. Relentless curve progression, in the absence of treatment, results in increasing chest wall deformity. Rib rotation and curve progression produce restrictive pulmonary disease, with worsening pulmonary function, as documented by diminishing forced vital capacity and total lung volume. If left untreated, the spinal deformity produces chest wall rotation, which obliterates the space available for the lungs[4]. The treatment for EOS remains a great challenge for pediatric orthopedics. The treatment goals for EOS, regardless of the diagnosis, are the same: minimizing spinal deformity while maximizing thoracic volume and pulmonary function[5]. When conservative treatment is ineffective, the option is surgery[6]. Different techniques have different advantages and drawbacks. Those most often used are traditional growing rods (TGR), vertical expandable prosthetic titanium ribs (VEPTR), magnetically controlled growing rods (MCGR), and the Shilla growth guidance system (SGGS). Repeated surgeries and complications are two major concerns in EOS management. The aim of the study was to review the current

literature to assess the safety of EOS surgical treatment in terms of the rate of complications and unplanned surgeries.

MATERIALS AND METHODS

Literature search strategy

The systematic review was conducted according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[7] (Figure 1). In January 2021, a search of three electronic medical databases (PubMed, the Cochrane Library, and Embase) was performed by three independent authors. We combined the terms: "early-onset scoliosis" OR "eos" OR "juvenile scoliosis" OR "infantile scoliosis" OR "tgr" OR "veptr" OR "MCGR" OR "Shilla" OR "growth-friendly" AND "complication". The reference lists of all retrieved articles were reviewed for the further identification of potentially relevant studies, and assessed using the inclusion and exclusion criteria.

Selection criteria

The eligible studies for the reference review included those dealing with complications in the operative treatment of EOS. The initial screening of titles and abstracts was made using the following inclusion criteria: studies of any level of evidence, reporting clinical results, published in peer review journals, and dealing with complications in operative EOS treatment. Exclusion criteria were: studies with complications in the non-operative treatment of EOS, in vitro, or animal model studies. We also excluded all the remaining duplicates, articles dealing with other topics, and those with poor scientific methodology, or without an accessible abstract. Reference lists were also manually searched for further relevant studies. Reviews, abstracts, case reports, conference presentations, and expert opinions, were excluded.

All papers were tagged: (1) according to the system used: TGR, VEPTR, MCGR, Shilla (guided growth); (2) the number of cases as a "big group" – more than 30 cases, "medium group" – 10-29 cases, and "small group" – less than 10 cases; and (3) the time of follow-up – "short" – less than 2 years, "minimum" – more than 2 years, and "optimum" – more than 5 years. The final inclusion criteria were primarily limited to "big group" and "optimum follow-up". During the paper extraction, no papers with VEPTR, and only one with Shilla and MCGR, were found, so that the groups' extracted papers had to be extended with "medium group" and "minimum" follow-up.

Data extraction and criteria appraisal

Three investigators independently reviewed each article. Discrepancies between the reviewers were resolved by discussion and consensus. All data were extracted from article texts, tables, and figures, and put into tables in an Excel sheet.

Complications were categorized as wound-related, implant-related, alignment-related, and general (surgical or medical). Surgical procedures were classified as planned [implantations, lengthenings, final fusions (FF)], and unplanned (revisions). Implantation procedures were included as equal to the number of patients. Not-given information was calculated using specific formulas based on the known data, *i.e.,* the mean number of operations per patient, the number of patients, and the number of operations. Some data – especially in TGR-group patients - like the number of lengthenings and derived information – were estimated based on the mean duration between lengthenings, using formulas, *i.e.,* the mean duration between lengthenings, and follow-up, *i.e.* the number of lengthenings. The mean durations between lengthenings, if not specified, were taken as the mean value of durations between lengthenings specified in other papers. These data were marked in the table with the symbol "1". In some papers the number of unplanned surgeries was not provided. In those cases, such complications as deep infections and implant fractures were estimated as an indication of at least one revision/unplanned surgery. Some fields were left empty when there were not enough data to estimate the value. When the data in the main text and the tables did not match, the higher value was taken.

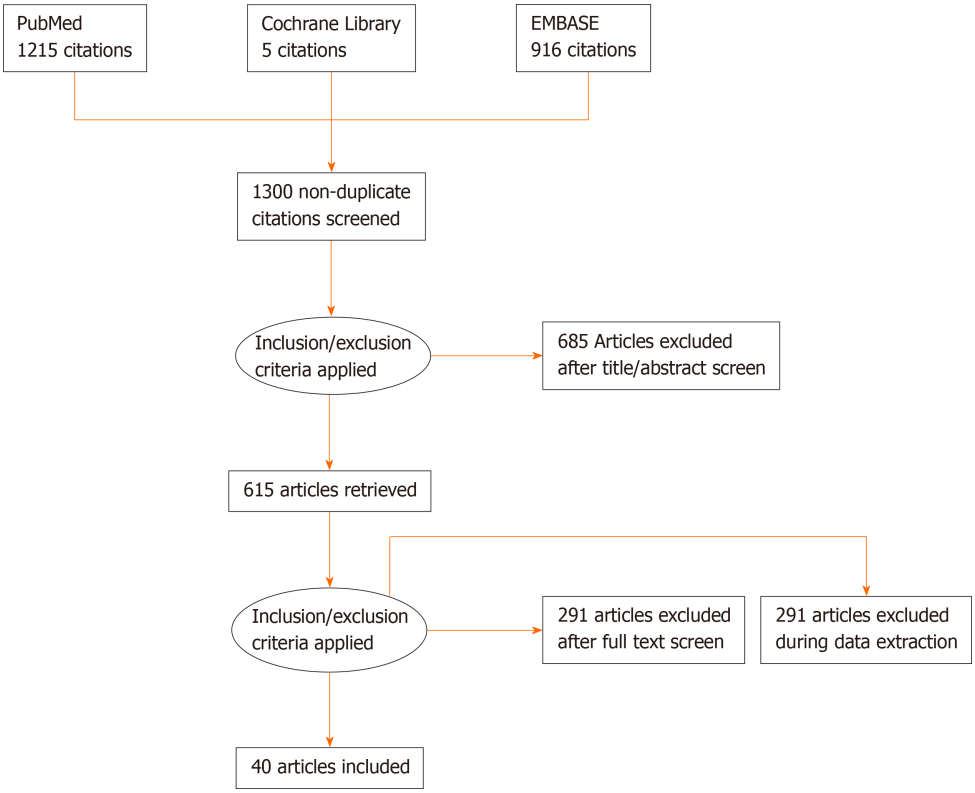


Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart of the method of selection and screening.

RESULTS

Included studies

A total of 2136 articles were found. After the exclusion of duplicates, 1300 articles were selected. At the end of the first screening, following the previously described selection criteria, we selected 615 articles eligible for full-text reading. Ultimately, after full-text reading and reference-list checks, we selected n = 40 articles, following previously adopted criteria. A PRISMA flowchart of the method of selection and screening is presented in Figure 1. The included articles focus on complications in the most commonly used systems – TGR (17 papers), VEPTR (13 papers), MCGR (8 papers), and Shilla (guided growth) (7 papers). Data extracted from these papers were assigned to the appropriate system. Harris *et al*[8], 2020, in their paper analyzed the impact of patient and surgical factors on the proximal complications and revision rates of early-onset scoliosis patients using a multicenter database. Total 353 patients met the inclusion criteria: growing rods = 318 and VEPTR = 35. Helenius *et al*[9], 2018, analyzed the outcomes of surgeries using growing rods in patients with severe *vs* moderate early-onset scoliosis. From the group of 214 patients, 198 were treated with TGR and 14 with MCGR. As in the main texts, the data were not separated out, so we included them in the TGR group, as the vast majority were treated with this system. Papers by Akbarnia *et al*[10], Bachabi *et al*[11], Haapala *et al*[12], Andras *et al*[13], and Luhmann *et al*[14], dealt with comparisons between TGR and MCGR, TGR, and VEPTR, Shilla and MCGR, and TGR and Shilla, respectively, so they appear in the table for the applicable system. The demographic findings of the included articles are summarized in Table 1.

Tables 2-5 present the number of surgical procedures (planned and unplanned). The number of patients is re-listed for easier reference to the remaining data. As the quantitative data depends on the number of analyzed patients, the second part of the table presents the percentage data. It shows the percentage of unplanned surgeries, the percentage of unplanned surgeries to all surgeries, the percentage of unplanned surgeries to patients with at least one complication, and the ratio of planned to unplanned surgeries. Eight papers were excluded from these tables, as there were no data on unplanned surgeries. Some fields were left empty if there were insufficient data. From the 40 analyzed papers 12 described all 4 complications (wound and implant-related, alignment, and medical/surgical). These data are marked in the table with the symbol "2". In the others, some of these complications were not described. It

Table 1 Demographic data from the reviewed articles

	Ref.	Construct	Subject	Sex (male/female)	Age at IP	Follow up	Diagnosis	No of patient with final spinal fusion	Comments, kind of complication analyzed
1	Bess *et al*[15], 2010	TGR	140	71/59	6	5.0	Neuromuscular (*n* = 52), idiopathic (*n* = 40), congenital (*n* = 24), and other (*n* = 24)	50	W, I, A, M
2	Du *et al*[16], 2020		167	69/98	7,2	10.7	Idiopathic (*n* = 45), neuromuscular (*n* = 56), syndromic (*n* = 43), congenital (*n* = 21), other (*n* = 2)	167	Analyzed patients who had undergone a FF after growing-rod treatment, W, I, A, M
3	Andras *et al* [13], 2015		36	nd	6.1	4.3	Syndromal (*n* = 10), idiopathic (*n* = 11), congenital (*n* = 2), neuromuscular (*n* = 13)	nd	I, M
4	Myung *et al* [17], 2014		159	nd	5	4.7	Neuromuscular (*n* = 46), congenital (*n* = 42), idiopathic (*n* = 37), syndromal (*n* = 34)	nd	I
5	Arandi *et al* [18], 2014		175	78/97	5.9	5.2	Idiopathic (*n* = 69), syndromal (*n* = 62), neuromuscular (*n* = 44)	nd	I
6	Liang *et al* [19], 2015		55	16/39	6.8	38.4	Congenital (*n* = 28), idiopathic (*n* = 6), syndromal (*n* = 8), neuromuscular (*n* = 6) and miscellaneous disorders (*n* = 7)	10	W, I, A, M
7	Ramirez *et al* [20], 2020		67	32/35	6	4.1	Only non-ambulatory neuromuscular early-onset scoliosis	nd	W, I, M
8	Yamaguchi *et al*[21], 2014		176	nd	nd	4.7	Congenital (*n* = 48), neuromuscular (*n* = 42), syndromal (*n* = 37), idiopathic scoliosis (*n* = 32) and miscellaneous (*n* = 17)	nd	I
9	Poe-Kochert *et al*[22], 2016		100	42/58	7	4.3	Neuromuscular (*n* = 38), syndromic (*n* = 31), idiopathic (*n* = 22), congenital (*n* = 9)	100	Analyzed patients who had undergone a FF after growing-rod treatment; W, I
10	Kabirian *et al* [23], 2014		379	177/202	6.3	5.3	nd	nd	Only deep infection analyzed
11	Hosseini *et al* [24], 2018		274	114/160	6.7	6.3	Neuromuscular (*n* = 84), congenital (*n* = 43), syndromic (*n* = 89), idiopathic (*n* = 58)	nd	I
12	Johnston *et al* [25], 2013		27	nd	5.3	4.5	Neuromuscular (*n* = 6), idiopathic (*n* = 11), syndromic (*n* = 10)	6	Comparing with cast treatment, complications in total
13	Bachabi *et al* [11], 2020		50	nd	5.5	8.3	nd	nd	W, I, A, M
14	Luhmann *et al* [14], 2017		18	18	7.7	7.4	Idiopathic (*n* = 9), neuromuscular (*n* = 7), syndromic (*n* = 1), congenital (*n* = 1)	17	W, I, M
15	Akbarnia *et al* [10], 2014		12	5	6.5	4.1	Not given	nd	W, I, M
16	Harris *et al*[8], 2020		353	nd	6	6.0	Not given	nd	I, TGR -318 cases, 35 - VEPTR cases
17	Helenius *et al* [9], 2018		214	94/120	5.6	6.0	Neuromuscular (*n* = 68), congenital (*n* = 28), syndromic (*n* = 74), idiopathic (*n* = 44)	49	W, I, M TGR cases 198) MCGR cases 16
18	Gadepalli *et al* [26], 2011	VEPTR	26	16/10	7.58	7.0	Congenital or infantile scoliosis (*n* = 12), neuromuscular scoliosis (*n* = 5), unspecified structural thoracic disorder (*n* = 7), Jeune syndrome (*n* = 2)	nd	W, I, M
19	Bachabi *et al*		22	nd	4.3	7.7	nd	nd	W, I, M

	[11], 2020								
20	Crews *et al* [27], 2018		151	16/6	7.1	3+	nd	nd	Only SSIs following VEPTR implant or revision surgeries were identified
21	Murphy *et al* [28], 2016		25	12/13	5.7	4.5	Congenital (*n* = 25)	nd	W, I, M
22	Berger-Groch *et al*[29], 2020		13	7/6	2.2	7.6	Congenital (*n* = 13)	nd	W, I, M
23	Hasler *et al* [30], 2010		23	8/15	6.5	3.6	Early onset idiopathic scoliosis (*n* = 1), neuromuscular (*n* = 11), post-thoracotomy scoliosis (*n* = 2), Sprengel deformity (*n* = 1), hyperkyphosis (*n* = 2), myopathy (*n* = 1), syndromic (*n* = 5)	nd	W, I, A, M
24	Latalski *et al* [31], 2011		12	nd	5.25	2.5	Congenital (*n* = 3), neuromuscular (*n* = 9)	0	W, I, A, M
25	Hell *et al*[32], 2005		15	8/7	6	nd	Congenital (*n* = 9), neuromuscular (*n* = 6)	0	W, I, M
26	Garg *et al*[33], 2014		103	57/46	5.3		Neuromuscular (*n* = 30), congenital (*n* = 44), syndromic (*n* = 18), idiopathic (*n* = 11)		Only wound complications following VEPTR implant or revision surgeries were identified
27	Waldhausen *et al*[34], 2016		65	nd	6.9	6.9	Congenital (*n* = 23), neuromuscular (*n* = 12), syndromic (*n* = 14), idiopathic (*n* = 2), other (*n* = 14)	28	W, I, M
28	Striano *et al* [35], 2019		166		6.81		Neuromuscular (*n* = 61), syndromic (*n* = 38), congenital (*n* = 64), idiopathic (*n* = 3)	nd	Only wound complications following VEPTR implant or revision surgeries were identified
29	Lucas *et al* [36], 2013		54	21/33	7	2.0	Neuromuscular (*n* = 19), congenital (*n* = 30), syndromic (*n* = 7), idiopathic (*n* = 3)	nd	W, I, A, M
30	Garg *et al*[37], 2016		38	22/16	5.51	4.1	Neuromuscular (*n* = 18), congenital (*n* = 13), syndromic (*n* = 5), idiopathic (*n* = 2)	nd	Only wound complications following VEPTR implant or revision surgeries were identified
31	Subramanian *et al*[38], 2018	MCGR	31	15/16	7.7	3.9	Neuromuscular (*n* = 4), syndromic (*n* = 19), idiopathic (*n* = 6), congenital (*n* = 2)	nd	W, I, A, M
32	Urbański *et al* [39], 2020		47	14/18	8.8	1-2.5	Neuromuscular (*n* = 10), syndromic (*n* = 11), idiopathic (*n* = 20), congenital (*n* = 6)	0	W, I, A, M
33	Akbarnia *et al* [10], 2014		12	5/7	6.8	2.5	Neuromuscular (*n* = 4), syndromic (*n* = 4), idiopathic (*n* = 3), congenital (*n* = 1)	nd	I, M
34	Studer *et al* [40], 2019		30	10/20	9.4	2.1	Congenital (*n* = 11), neuromuscular (*n* = 10), syndromic (*n* = 4), idiopathic (*n* = 5)	nd	W, I, A
35	Kwan *et al* [41], 2017		30	11/19	7.3	3.0	Syndromal (*n* = 8), idiopathic (*n* = 8), congenital (*n* = 6), neuromuscular (*n* = 8)	5	W, I, A,
36	Obid *et al*[42], 2020		22	4/18	9.5	4.0	Idiopathic (*n* = 14), neurofbromatosis (*n* = 2), neuromuscular and syndromic (*n* = 6)	9	W, I, A, M
37	Lampe *et al* [43], 2019		24	7/17	10.5	3.5	Syndromal (*n* = 4), idiopathic (*n* = 9), congenital (*n* = 1), neuromuscular (*n* = 10)	nd	W, I, A, M

38	Haapala *et al* [12], 2020		18	11/7	6.8	3.2	Neuromuscular (*n* = 12) II, syndromic (*n* = 8) EOS two NFI (*n* = 2)	5	I, A, M
39	Haapala *et al* [12], 2020	Shilla	13	8/5	6	4.0	Neuromuscular (*n* = 11), syndromic (*n* = 2)	4	W, I, M
40	Andras *et al* [13], 2015	Shilla	36	nd	6.1	4.6	Syndromal (*n* = 10), idiopathic (*n* = 11), congenital (*n* = 2), neuromuscular (*n* = 13)	nd	I, M
41	Nazareth *et al* [44], 2020	Shilla	20	10/10	5.7	5.2	Syndromic (*n* = 9), neuromuscular (*n* = 5), idiopathic (*n* = 3), congenital (*n* = 3).	7	W, I, M
42	Miękisiak *et al* [45], 2019	GGS	57	13/44	9.8	2+	Not given	nd	GGS – the same principle as Shilla. System made of Ti. W, I, A, M
43	McCarthy *et al* [46], 2014	Shilla	10	2/8	7.5	2.0	Idiopathic (*n* = 3), congenital scoliosis (*n* = 1), syndromic (*n* = 2), neuromuscular scoliosis (*n* = 4)	nd	W, I
44	Luhmann *et al* [14], 2017	Shilla	18	nd	7.9	6.1	Idiopathic (*n* = 8), neuromuscular (*n* = 7), syndromic (*n* = 3)	15 and 3 implant removals	W, I, M
45	McCarthy *et al* [47], 2015	Shilla	40	17/23	6.11	5.0	Idiopathic (*n* = 9), congenital (*n* = 1), neuromuscular (*n* = 16), syndromic (*n* = 14)	15 and 3 Implant removals	W, I, A

Type of complications: Wound (W), implant-related (I), alignment (A), and medical/surgical complications (M). FF: Final fusions; GGS: Growth guidance system; VEPTR: Vertical expandable prosthetic titanium ribs; TGR: Traditional growing rods; MCGR: Magnetically controlled growing rods.

probably means that the number of unplanned surgeries was understated.

Excluded from these tables were papers in which the number of unplanned surgeries was not specified, and were not calculated; some cases referred to final fusion, but it was not specified when, so the total number based on the duration between lengthenings was not possible to estimate.

Unplanned surgeries are due to complications which cannot be resolved conservatively. The total number of complications is much higher. Table 6 presents the total number of complications, the number of patients with a minimum of one complication, the percentage of complications in all patients, the percentage of patients with a minimum of one complication, the number of complications in complicated patients, the complication rate per surgical procedure in percentage terms, and the percentage complications requiring surgical procedures. Some cells in the table are empty because of insufficient data in the corresponding papers.

In Table 7 the total number of complications are divided into wound-related, implant-related, alignment, and surgical/medical-related. Only 12 out of 40 papers include analyses of all these types. The paper by Johnston *et al*[25], 2013, did not differentiate the types of complications, so this reference was excluded from Table 7.

Smith *et al*[48] published in 2015 a New Classification System to Report Complications in Growing Spine Surgery, and only 4 out of 23 papers published in 2016 used this system (Table 8).

DISCUSSION

Currently there is great interest in the concept of the continued growth of the spine and chest while treating spinal deformity in EOS patients. The risk of complications is inherent in correction surgeries, regardless of etiology. Many studies agree that in the case of neuromuscular scoliosis the probability of a complication is 35%, while for EOS the probability increases to 48%[49]. Watanabe *et al*[50] identified risk factors for complications in the treatment of early-onset scoliosis using the dual growing rod technique. Postoperative complications occurred after 119 out of 538 procedures (22%) and affected 50 patients (57%). Complications mostly included implant-related failures (72%), and infections (16%). The authors suggested that independent risk factors for postoperative complications included an increase of every 20° in the proximal thoracic Cobb angle, an increase of every 20° in the thoracic kyphosis angle, and 6 or more rod-

Table 2 The number of planned and unplanned surgical procedures in the traditional growing rods group

Ref.	Subject	Surgical procedures (*n*)	Planned surgical procedures (*n*)	Unplanned surgical procedure		% unplanned surgeries to all surgeries	% unplanned surgery to patients with at least one complication	Ratio of planned to unplanned surgery
				n	%			
Bess *et al* [15], 2010	140	897	823	74	52.9[2]	8.2[2]	91.4[2]	11.12
Du *et al*[16], 2020	167	199	167	32	19.2[3]	16.1[3]	100.0[3]	5.22
Andras *et al* [13], 2015	36	288	259	29	80.6	10.1	100.0	8.9
Myung *et al* [17], 2014	159	1081[1]	1050[1]	31[1]	19.5	2.9	83.8	33.87
Arandi *et al* [18], 2014	175	1247[1]	1190	57[1]	32.6	4.6	71.3	20.88
Liang *et al* [19], 2015	55	272	263	23[1]	41.8[2]	8.5[2]	100.0[2]	11.43
Ramirez *et al* [20], 2020	67	463[1]	396[1]	67	100	14.5	163.4	5.91
Poe-Kochert *et al*[22], 2016	100	157[1]	100[1]	57	57[3]	36.3[3]	285.0[3]	1.75
Kabirian e *et al*[23], 2014	379	2344	2274[1]	70	18.5	3.0	166.7	32.49
Luhmann *et al*[14], 2017	18	167	141	26	144.4	15.6		5.42
Akbarnia *et al*[10], 2014	12	73	68	5	41.7	6.8	45.5	13.6
Harris *et al* [8], 2020	353	3141[1]	2895[1]	246	69.7	7.8	174.5	11.77
Helenius *et al* [9], 2018	214	1971	1836	133	62.1	6.7	137.1	13.8

[1]Data estimated based on the mean values of duration between lengthenings.
[2]The values of the % of unplanned surgeries in which all four complications were analyzed in the paper.
[3]Corresponds to the papers in which all the patients were after the final fusion.

lengthening procedures. According to Bess *et al*[15], the patients' early age when carrying out the index surgery influenced the incidence of complications, but Watanabe did not confirm this. He believed that a patient's being young at the time of the index surgery significantly reduced the risk of the child's developing a significant deformity, the degree of which at the start of the treatment significantly affects the risk of its course. However, one should be aware of the inverse relationship between the age of the index surgery and the number of lengthenings in distraction-based methods [4].

Bess, and the Growing Spine Study Group, stated in publications that there was a 24% complication rate each time a growing-rod construct was surgically lengthened, and a 13% decrease in complications for each additional year of age at the time of the initial growing rod implantation[15]. Rod implantation below age 7 years, increasing kyphosis, and more severe major curve magnitude, have been shown to correlate with a higher rate of complications overall[51].

Surgical difficulties, as well as the potentially harmful effect of repeated anesthesia, have led to the adoption of magnetically controlled growing rods, and guided growth systems like Shilla. However, problems with the loss of fixation and failure of the implants in some cases persist[10,47]. Some authors have pointed out an additional problem connected with metal debris which appears in the serum and surrounding tissues[52]. Although it does not directly affect the outcome of the treatment, it is worth considering this occurrence as undesirable/a complication.

The most important issue is that authors define complications in different ways. In Andras *et al*[13], major complications are defined as any neurological injury and any

Table 3 The number of planned and unplanned surgical procedures in the vertical expandable prosthetic titanium ribs group

Ref.	Subject	Surgical procedures (*n*)	Planned surgical procedures (*n*)	Unplanned surgical procedure		% unplanned surgeries to all surgeries	% unplanned surgery to patients with at least one complication	Ratio of planned to unplanned surgery
				n	%			
Murphy *et al* [28], 2016	25	232	188	40	160	17.2	266.7	4.69
Gadepalli *et al*[26], 2011	26	100	86	14	53.8	14.0		6.14
Berger-Groch *et al*[29], 2020	13	182	178	5	38.5	2.7		35.6
Hasler *et al* [30], 2010	23	187	172	15	65.2[2]	8.0[2]	166.7[2]	11.47
Latalski *et al* [31], 2011	12	44	38	6	50[2]	13.6[2]	75.0[2]	6.33
Striano *et al* [35], 2019	166	670	560	110	66.3	16.4	275.0	5.09
Lucas *et al* [36], 2013	54	184	152	30	55.6[2]	16.3[2]	83.3[2]	5.07
Garg *et al* [37], 2016	38	410	350[1]	60[1]	157.9	14.6		5.83

[1]Data estimated based on the mean values of duration between lengthenings.
[2]The values of the % of unplanned surgeries in which all four complications were analyzed in the paper.

Table 4 The number of planned and unplanned surgical procedures in the magnetically controlled growing rods group

Ref.	Subject	Surgical procedures (*n*)	Planned surgical procedures (*n*)	Unplanned surgical procedure		% unplanned surgeries to all surgeries	% unplanned surgery to patients with at least one complication	Ratio of planned to unplanned surgery
				n	%			
Subramanian *et al*[38], 2018	31	53	31	22	71[2]	41.5[2]	104.8	1.41
Urbański *et al* [39], 2020	47	60	47	13	27.7[2]	21.7[2]	81.3	3.62
Akbarnia *et al* [10], 2014	12	16	12	4	33.3	25.0	100.0	3
Studer *et al*[40], 2019	30	43	30	13	43.3	30.2	118.2	2.31
Kwan *et al*[41], 2017	30	44	30	14	46.7	31.8	100.0	2.14
Obid *et al*[42], 2020	22	46	19	5	22.7[2]	10.9[2]	41.7[2]	3.8
Lampe *et al*[43], 2019	24	43	24	19	79.2[2]	44.2[2]	172.7[2]	1.26

[2]The values of the % of unplanned surgeries in which all four complications were analyzed in the paper.

issue requiring surgery for implant revision or infection. In Ramirez *et al*[20], complications are defined as any change from the normal postoperative course which occurred from the time of the surgery until the most recent follow-up visit. In McCarthy *et al*[47], 2015, complications are defined as any problem requiring a return to the operating room, so all returns to the operating room were considered unanticipated. Some authors report major complications and some report the whole range of general complications.

Table 5 The number of planned and unplanned surgical procedures in guided growth group – the Shilla and growth guidance system groups

Ref.	Subject	Surgical procedures (*n*)	Planned surgical procedures (*n*)	Unplanned surgical procedure		% unplanned surgeries to all surgeries	% unplanned surgeries to patients with at least one complication	Ratio of planned to unplanned surgery
				n	%			
Haapala *et al* [12], 2020	13	19	17	2	15.4	10.5	40.0	8.5
Andras *et al* [13], 2015	36	101	36	65	180.6	64.4	224.1	0.55
Nazareth *et al*[44], 2020	20	41	20	21	105	51.2	140.0	0.95
Miękisiak *et al*[45], 2019	57	82	57	25	43.9[2]	30.5[2]		2.28
McCarthy *et al*[46], 2014	10	15	10	5	50	33.3	100.0	2
Luhmann *et al*[14], 2017	18	56	36	20	111.1			1.8
McCarthy *et al*[47], 2015	40	109	58	51	127.5			1.14

[2]The values of the % of unplanned surgeries in which all four complications were analyzed in the paper.

For this study, complications were categorized as wound, implant, alignment, or general [surgical or medical]. Wound problems were classified as either superficial or deep infections, and other wound-related problems, such as painful scars. Implant complications included rod breakage, failure of foundation fixation such as hook or screw pullout, and implant prominence. Alignment complications included junctional kyphosis (proximal or distal), curve progression above or below the instrumented levels, and curve progression after definitive fusion. General complications included, but were not limited to, dural tears, hematomas, and postoperative cardiopulmonary and gastrointestinal complications. Unfortunately, not all authors evaluated all these kinds of complications together – 4 out of 17 in TGR, 3 out of 13 in VEPTR, 4 out of 8 in MCGR, and 1 out of 7 in Shilla. Only 16 out of 44 papers (36%) referred to alignment complication in the evaluation – mostly in MCGR (88%), and conversely to VEPTR (23%). Five papers (11%) (TGR) described only implant-related complications, and 5 only wound-related (4 VEPTR and 1 TGR). The most frequently evaluated set of complications were wound, implant, and medical-related – 13 papers (30% of the papers). The original idea of the paper was to evaluate the number of procedures used to treat complications categorized as either planned or unplanned. Planned procedures were defined as procedures which were scheduled as part of the routine growing-rod-treatment protocol. Unplanned procedures were defined as unscheduled surgical procedures performed to manage a complication. Unfortunately, there was no division into such treatments, so the data were simplified and surgical procedures were classified as planned (implantations, lengthenings, final fusions) and unplanned (revisions). In that case, the number of complications requiring surgical treatment could have been greater, as some of them could have been repaired during the planned lengthening procedure. Only 10 papers (23%) (2 TGR, 3 VEPTR, 4 MAGEC, 1 Shilla) included data with unplanned surgeries, and all described complications concurrently. FF significantly influenced the number of surgeries. Despite the number of patients with FFs being known, there were no data about the time of the FFs – so estimated data based on the mean follow-up times and durations between lengthening procedures were understated. Deleting these references from the statements in question leaves 6 papers with no TGR patients. Adding Smith's classification for evaluation as a criterion further reduces the number of papers to only one. That is why the analysis had to be simplified.

TGRs constitute the most commonly applied technique, and are considered the gold standard for EOS with long curves[53]. In the reviewed papers, the complication rate per patient of the growing rod technique was very high and ranged from 19% to 208% (median 84%). Interestingly, Akbarnia *et al*[10], presented a complication rate of 208%

Table 6 Number of complications analyzed in extracted papers

Ref.	Subject	Total No. of complications	No. of patients with a minimum of one complication	% of complications in all patients	% of patients with a minimum one complication	No. of complications in complicated patients	Complication rate per surgical procedure (%)	% complications requiring surgical procedures
TGR								
Bess *et al*[15], 2010	140	171	81	122.1[2]	57.9[2]	2.1[2]	19.1[2]	43.3[2]
Du *et al*[16], 2020	167	49	32	29.3[2,3]	19.2[3]	1.5[3]	nd	nd
Andras *et al* [13], 2015	36	47	29	130.6	80.6	1.6	16.3	61.7
Myung *et al* [17], 2014	159	64	37	40.3	23.3	1.7	5.9	48.4
Arandi *et al* [18], 2014	175	146	80	83.4	45.7	1.8	11.7	39.0
Liang *et al* [19], 2015	55	42	23	76.4[2]	41.8[2]	1.8[2]	15.4[2]	54.8[2]
Ramirez *et al* [20], 2020	67	92	41	137.3	61.2	2.2	19.9	72.8
Yamaguchi *et al*[21], 2014	176	44	26	25.0	14.8	1.7		
Poe-Kochert *et al*[22], 2016	100	30	20	30.0[3]	20.0[3]	1.5[3]	19.1[3]	190.0
Kabirian *et al* [23], 2014	379	70	42	18.5	11.1	1.7	3.0	
Johnston *et al* [25], 2013	27	23	12	85.2	44.4	1.9	12.8	
Bachabi *et al* [11], 2020	50	45	33	90.0[2]	66.0[2]	1.4[2]	9.4[2]	
Luhmann *et al*[14], 2017	18	26		144.4	nd		15.6	
Akbarnia *et al* [10], 2014	12	25	11	208.3	91.7	2.3	34.2	
Harris *et al* [8], 2020	353	264	141	74.8	39.9	1.9	nd	93.2
Helenius *et al* [9], 2018	214	216	97	100.9	45.3	2.2	11.0	61.6
VEPTR								
Bachabi *et al* [11], 2020	22	26	18	118.2	81.8	1.4	7.9	
Crews *et al* [27], 2018	151	26	22	17.2	14.6	1.2	8.0	
Murphy *et al* [28], 2016	25	41	15	164.0	60.0	2.7	17.7	97.6
Gadepalli *et al*[26], 2011	26	36	nd	138.5	nd	nd		38.9
Berger-Groch *et al*[29], 2020	13	21	nd	161.5	nd	nd	11.5	23.8
Hasler *et al* [30], 2010	23	31	9	134.8[2]	39.1[2]	3.4	16.6[2]	48.4
Latalski *et al* [31], 2011	12	15	8	125.0[2]	66.7[2]	1.9	34.1[2]	40.0
Hell, *et al*	15	3	3	20.0	20.0	1.0	10.7	

[32]. 2005								
Garg *et al* [33], 2014	103	33	25	32.0	24.3	1.3	nd	
Waldhausen *et al*[34], 2016	65	37	22	56.9	33.8	1.7		
Striano *et al* [35], 2019	166	47	40	28.3	24.1	1.2	7.0	234.0
Lucas *et al* [36], 2013	54	74	36	137.0[2]	66.7[2]	2.1[2]	40.2[2]	40.5
Garg *et al* [37], 2016	38	86		226.3	nd			69.8
MCGR								
Subramanian *et al*[38], 2018	31	25	21	80.6[2]	67.7[2]	1.2[2]	47.2[2]	88.0
Urbański *et al* [39], 2020	47	17	16	36.2[2]	34.0[2]	1.1[2]	28.3[2]	76.5
Akbarnia *et al* [10], 2014	12	12	4	100.0	33.3	3.0	75.0	33.3
Studer *et al* [40], 2019	30	12	11	40.0	36.7	1.1	27.9	108.3
Kwan *et al* [41], 2017	30	15	14	50.0	46.7	1.1	34.1	93.3
Obid *et al* [42], 2020	22	12	12	54.5[2]	54.5[2]	1.0[2]	26.1[2]	41.7
Lampe *et al* [43], 2019	24	20	11	83.3[2]	45.8	1.8	46.5	95.0
Haapala *et al* [12], 2020	18	10	6	55.6	33.3	1.7	20.0	
Shilla								
Haapala *et al* [12], 2020	13	5	5	38.5	38.5	1.0	26.3	
Andras *et al* [13], 2015	36	69	29	191.7	80.6	2.4	68.3	
Nazareth *et al* [44], 2020	20	31	15	155.0	75.0	2.1	75.6	
Miękisiak *et al*[45], 2019	57	57		100.0[2]	0.0		69.5	
McCarthy *et al*[46], 2014	10	5	5	50.0	50.0	1.0	33.3	
Luhmann *et al*[14], 2017	18	20		111.1	0.0		35.7	
McCarthy *et al*[47], 2015	40	59	38	147.5	95.0	1.6	54.1	

[2]The values of the % of unplanned surgeries in which all four complications were analyzed in the paper.

[3]Corresponds to the papers in which all patients were after final fusion.

TGR: Traditional growing rods; VEPTR: Vertical expandable prosthetic titanium ribs; MCGR: Magnetically controlled growing rods.

(wound, implant-related and medical) in only 12 patients, whereas the rate for deep infections was 19% in 379 cases[23]. Comparing only implant-related complications, this parameter varied from 25%[21] to 40%[17], to 83%[18] – the authors analyzed a similar group of approximately 160 patients. The complication rate per surgical procedure varied from 3% to 34% (median 15%). There were two complications in complication-affected patients. In the analyzed papers, an average of 946 surgical procedures were performed. The incidence of unplanned surgeries in all patients varied from 19% to 144% (median 53%). The percentage of unplanned surgeries for all surgeries was 8% (3%-36%). The ratio of planned to unplanned surgeries was 11.6% (1.8%-33.9%). The most frequent complications were implant-related (61%) and

Table 7 Total number of complications divided into wound-related, implant-related, alignment and surgical/medical related

Ref.	Total No. of complications	Wound complications total/infection		Implant complications mechanical complication		Alignment complications		Surgical or medical complications	
		n	%	*n*	%	*n*	%	*n*	%
TGR									
Bess *et al*[15], 2010	171	34	20	105	61	10	6	22	13
Du *et al*[16], 2020	49	19	39	13	27	9	18	8	16
Andras *et al*[13], 2015	32			24	75			8	25
Myung *et al*[17], 2014	64			64	100				
Arandi *et al*[18], 2014	146			146	100				
Liang *et al*[19], 2015	42	5	12	25	60	4	10	8	19
Ramirez *et al*[20], 2020	92	49	53	30	33			13	14
Yamaguchi *et al* [21], 2014	44			44	100				
Poe-Kochert *et al* [22], 2016	29	16	55	13	45				
Kabirian *et al*[23], 2014	70	70	100						
Hosseini *et al*[24], 2018	134			134	100				
Bachabi *et al*[11], 2020	45	7	16	28	62	2	4	8	18
Luhmann *et al*[14], 2017	26	9	35	11	42			6	23
Akbarnia *et al*[10], 2014	25	4	16	13	52			8	32
Harris *et al*[8], 2020	264			264	100				
Helenius *et al*[9], 2018	216	40	19	127	59			49	23
VEPTR									
Bachabi *et al*[11], 2020	26	9	35	15	58			2	8
Crews *et al*[27], 2018	26	26	100						
Murphy *et al*[28], 2016	57	16	28	28	49			13	23
Gadepalli *et al*[26], 2011	25	6	24	3	12			16	64
Berger-Groch *et al* [29], 2020	24	1	4			2	8	21	88
Hasler *et al*[30], 2010	31	16	52	7	23	7	23	1	3
Latalski *et al*[31], 2011	15	1	7	7	47	1	7	6	40
Hell, *et al*[32], 2005	3	1	33	1	33			1	33
Garg *et al*[33], 2014	34	34	100						
Waldhausen *et al* [34], 2016	37	12	32	21	57			4	11
Striano *et al*[35],	47	47	100						

2019									
Lucas *et al*[36], 2013	49	11	22	28	57	7	14	3	6
Garg *et al*[37], 2016	86	86	100						
MCGR									
Subramanian *et al*[38], 2018	24	6	25	16	67	1	4	1	4
Urbański *et al*[39], 2020	16	2	13	8	50	1	6	5	31
Akbarnia *et al*[10], 2014	12			8	67			4	33
Studer *et al*[40], 2019	12	3	25	6	50	3	25		
Kwan *et al*[41], 2017	15	2	13	12	80	1	7		
Obid *et al*[42], 2020	12	1	8	3	25	7	58	1	8
Lampe *et al*[43], 2019	20	3	15	7	35	6	30	4	20
Haapala *et al*[12], 2020	10			6	60	1	10	3	30
Shilla									
Haapala *et al*[12], 2020	5	1	20	3	60			1	20
Andras *et al*[13], 2015	56			55	98			1	2
Nazareth *et al*[44], 2020	31	4	13	26	84			1	3
Miękisiak *et al*[45], 2019	57	3	5	34	60	10	18	10	18
McCarthy *et al*[46], 2014	5	2	40	3	60				
Luhmann *et al*[14], 2017	20	6	30	13	65			1	5
McCarthy *et al*[47], 2015	59	6	10	42	71	11	19		

TGR: Traditional growing rods; VEPTR: Vertical expandable prosthetic titanium ribs; MCGR: Magnetically controlled growing rods.

wound-related (27%), while medical complications and alignments accounted for 19% and 8%, respectively. The most concerning problem related to TGRs is the high complication rate. The risks for implant failure, infections, and wound healing problems are significantly increased as a consequence of the repeated lengthening procedures and an unfused spine. If rod breakage or screw displacement occurs, revision surgeries are indicated to change the rod or extend the instrumented segments. Additionally, repeated general anesthesia can pose a threat to mental health. Adequate informed consent and close follow-ups are necessary.

VEPTR was developed for patients with thoracic insufficiency syndrome (TIS), but it is sometimes indicated for individuals with EOS who are at risk of secondary TIS[54, 55]. The complication rate per patient was as high as 125% (17%-226%) with a 9% rate per surgical procedure (7%-18%). Such a discrepancy is very confusing. Garg *et al*[37] identified only wound complications following VEPTR implant or revision surgeries. If so, adding implant, alignment, and medical-related complications, the final percentage of complications should be expected at a much higher level. On the other hand, Crews *et al*[27] analyzed wound, implant, and general complications at the level of 17%. The most frequent complications were implant-related 48%, and wound-related 33%, while medical complications and alignments accounted for 23% and 11%. respectively. which limits their applications. In the analyzed papers, an average of 251 surgical procedures were performed. The percentage of unplanned surgeries in all patients varied from 39% to 160% (median 60%). The percentage of unplanned

Table 8 Complication grades according to Smith

Ref.	Total No. of complications	Related to disease				Related to device				
		Complication grade I	Complication grade II	Complication grade III	Complication grade IV	Complication grade I	Complication grade IIA	Complication grade IIB	Complication grade III	Complication grade IV
Ramirez *et al* [20], 2020	92					8	8	17	4	4
Murphy *et al* [28], 2016	57	5	6	2	1	13	8	3	4	
Studer *et al*[40], 2019	12					2	7			
Miękisiak *et al* [45], 2019	57	32	17	8	0					

surgeries to all surgeries was 14% (3%-17%). The proportion of planned to unplanned surgeries was 6% (4.7%-35.6%).

MCGRs were introduced by Takaso *et al*[56] in 1998 as remote-controlled growing-rod spinal instrumentation. The system did not require open lengthening as TGRs did, and the effect could instead be achieved by external remote control without repeated anesthesia. The complication rate of the magnetically controlled growing rod technique per patient varied from 36% to 100% (median 55%). In this group of patients, the distribution of complications is fairly homogeneous. Only Akbarnia *et al* [10] described such a high level of complications while omitting wound-related and alignment problems. The complication rate per surgical procedure varied from 20% to 75% (median 31%). In the analyzed papers, an average of 44 surgical procedures were performed. The percentage of unplanned surgeries in all patients varied from 23% to 79% (median 43%). The percentage of unplanned surgeries in all surgeries was 30% (11%-34%). The ratio of planned to unplanned surgeries was 2.3 (1.3-3.8). The most frequently occurring complication was implant-related – 55%, then general (25%), wound (14%), and alignment (10%). La Rosa *et al*[57] stated that MCGRs can prevent surgical scarring, surgical site infections, and psychological distress, which occur in patients with TGRs and VEPTR due to the multiple surgeries. The decreased rate of infections and wound healing problems in patients who received MCGRs is of great benefit to patients. However, Aslan *et al*[58] used psychosocial tools to compare the mental state of patients receiving MCGRs and TGRs. He affirmed that if the patient noticed benefit from the growing rods, and did not experience major complications, the non-invasiveness of the lengthening procedures did not show an advantage on the patients' psychosocial state. Besides, although MCGRs were associated with a lower rate of infections [both deep and superficial], they were associated with a significantly increased risk of metalwork problems and unplanned revisions[59].

The Shilla technique guides spinal growth towards a normal alignment[60]. The technique first corrects the apical deformity towards a neutral alignment. Then the upper and lower growth guidance portions extend into the distal and proximal areas of the curve, using special screws and caps, allowing the rod to slide with growth in a longitudinal direction. Multiple open lengthening surgeries are avoided, as in MCGRs. The complication rate was as high as 111% of the patients (39%-192%), and the complication rate per surgical procedure was 54%. Haapala *et al*[12] showed the fewest complications – 39%. The remaining authors assessed the number of complications at a similar level. The most frequently appearing complications were implant-related (65%). Wound-related and alignment problems were 16% and 18%, respectively. General complications were only 5%. The percentage of unplanned surgeries in all patients varied from 15% to 181% (median 105%). The percentage of unplanned surgeries to all surgeries was 33% (11%-64%). The ratio of planned to unplanned surgeries was 1.8 (0.6-8.5). Luhmann *et al*[14] found that the Shilla growth guidance system compared favorably with TGRs in terms of the degree of correction of the major curve, spinal length, and growth, and the maintenance of the sagittal alignment. Looking at these data the benefits are not so obvious. Similar to MCGR and TGR, the SGGS is associated with a very high rate of implant-related complications, which usually results in revision surgery. Additionally, for patients with great growth potential, the distal and proximal screws can slide off the rod, requiring the rods to be changed.

EOS surgery has a varying but high rate of complications. Based on this review of 40 papers, 3249 cases, and 15037 surgical procedures, the most-frequent implant complications (total 54%), the general, wound, and alignment were 17%, 15%, and 12%, respectively. These data are simplified and certainly underestimated, because of the reasons described earlier. The rate of complications might have been higher than reported, as some authors did not report every type of complication. Due to complications, 54% of the patients required unplanned surgeries, which equated to 15% of all surgeries.

The long-term risks of EOS surgery have not yet been reported on in research. There is a lack of papers with homogenous cases, long-term follow-up, all revision surgeries, and complication data.

One would expect that successful treatment which encourages the growth of the spine and chest would lead to favorable outcomes in patients with early-onset idiopathic scoliosis. But it is not unambiguous with patients with, *e.g.*, progressive neuromuscular conditions such as congenital muscular dystrophies and spinal muscular atrophy. Surgery can effect spinal growth with expandable instrumentation, but worsening muscle weakness can negate the positive effects of growth-friendly procedures[2]. Tsirikos *et al*[61] showed that the life expectancy of patients with cerebral palsy and other neurogenic deformities subjected to deformation correction does not change, but only an additional source of data such as the number of days in the intensive care unit after surgery, and the presence of severe preoperative thoracic hyperkyphosis, were the only factors affecting survival rates.

As highlighted by Hawes[62], the complexity of spinal surgery is reflected in the diversity of complications which might occur months or even years later. Given the time delay and difficulty in diagnosis, it is likely that some of the events are not recognized as surgical complications. Therefore, clear uniformity of definitions and the carefulness of the surgeon are important in assessing patient follow-up and treatment outcomes.

CONCLUSION

The literature concerning the definitions, collection, and interpretation of data regarding EOS surgery complications is often difficult to interpret. This causes problems in the comparison, analysis, and improvement of spine surgery practice. Additionally, this observation indicates that data on the incidence of complications can be underestimated and should be interpreted with caution. Awareness of the high rate of complications of EOS surgery is crucial, and an optimal strategy for prevention should become a priority.

ARTICLE HIGHLIGHTS

Research background

The treatment for early-onset scoliosis (EOS) remains a great challenge for pediatric orthopedics. The treatment goals for EOS, regardless of the diagnosis, are the same: minimizing spinal deformity while maximizing thoracic volume and pulmonary function. When conservative treatment is ineffective, the option is surgery.

Research motivation

Different surgical techniques have different advantages and drawbacks. Those most often used are traditional growing rods (TGR), vertical expandable prosthetic titanium ribs (VEPTR), magnetically controlled growing rods (MCGR), and the Shilla growth guidance system (SGGS). Repeated surgeries and complications are two major concerns in EOS management.

Research objectives

The aim of the study was to review the current literature to assess the safety of EOS surgical treatment in terms of the rate of complications and unplanned surgeries.

Research methods

The systematic review was conducted according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses. In January 2021, a search of three electronic medical databases (PubMed, the Cochrane Library, and Embase) was performed by three independent authors. We combined the terms: "early-onset scoliosis" OR "eos" OR "juvenile scoliosis" OR "infantile scoliosis" OR "tgr" OR "veptr" OR "MCGR" OR "Shilla" OR "growth-friendly" AND "complication".

Research results

EOS surgery has a varying but high rate of complications. The most frequent complications were categorized as implant, general, wound and alignment. The rate of complications might have been even higher than reported, as some authors do not report all types of complications.

Research conclusions

The literature concerning the definitions, collection, and interpretation of data regarding EOS surgery complications is often difficult to interpret. This creates problems in the comparison, analysis, and improvement of spine surgery practice. Awareness of the high rate of complications of EOS surgery is crucial, and an optimal strategy for prevention should become a priority.

Research perspectives

This observation indicates that data on the incidence of complications can be underestimated, and should be interpreted with caution. Further studies are needed to confirm the study results, especially concerning longitudinal data.

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SYSTEMATIC REVIEWS

Safety and efficacy of surgical hip dislocation in managing femoral head fractures: A systematic review and meta-analysis

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Abstract

BACKGROUND

Femoral head fractures (FHFs) are considered relatively uncommon injuries; however, open reduction and internal fixation is preferred for most displaced fractures. Several surgical approaches had been utilized with controversial results; surgical hip dislocation (SHD) is among these approaches, with the reputation of being demanding and leading to higher complication rates.

AIM

To determine the efficacy and safety of SHD in managing FHFs by reviewing the results reported in the literature.

METHODS

Major databases including PubMed, Embase, Web of Science, and Cochrane Central Register of Controlled Trials were searched to identify studies reporting on outcomes of SHD utilized as an approach in treating FHFs. We extracted basic studies data, surgery-related data, functional outcomes, radiological outcomes, and postoperative complications. We calculated the mean differences for continuous data with 95% confidence intervals for each outcome and the odds ratio with 95% confidence intervals for binary outcomes. $P < 0.05$ was considered significant.

RESULTS

Our search retrieved nine studies meeting our inclusion criteria, with a total of 129 FHFs. The results of our analysis revealed that the average operation time was 123.74 min, while the average blood loss was 491.89 mL. After an average follow-up of 38.4 mo, a satisfactory clinical outcome was achieved in 85% of patients,

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with 74% obtained anatomical fracture reduction. Overall complication rate ranged from 30% to 86%, with avascular necrosis, heterotopic ossification, and osteoarthritis being the most common complications occurring at an incidence of 12%, 25%, and 16%, respectively. Trochanteric flip osteotomy nonunion and trochanteric bursitis as a unique complication of SHD occurred at an incidence of 3.4% and 3.8%, respectively.

CONCLUSION

The integration of SHD approach for dealing with FHFs offered acceptable functional and radiological outcomes with a wide range of safety in regards to the hip joint vascularity and the development of avascular necrosis, the formation of heterotopic ossification, and the development of posttraumatic osteoarthritis; however, it still carries its unique risk of trochanteric flip osteotomy nonunion and persistent lateral thigh pain.

Key Words: Femoral head; Pipkin fracture; Surgical hip dislocation; Ganz; Systematic review; Meta-analysis

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Core Tip: In the past few years, surgical hip dislocation had been adopted by many trauma surgeons as an approach for femoral head fractures management. The current systematic review and metanalysis collected data from the most recent literature showed the efficacy of this approach in regards to obtaining acceptable functional and radiological outcomes as well as resulting in relatively low complication rates when compared with other approaches reported in the literature. However, it carries some unique complications such as trochanteric bursitis and trochanteric flip osteotomy nonunion.

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INTRODUCTION

Femoral head fractures (FHFs) are considered rare injuries resulting from high energy trauma, which is usually associated with posterior hip dislocation and rarely anterior subluxation [1,2]. The rarity of this injury makes it difficult to report on large numbers of patients, and the performance of high quality prospective randomized studies is even more challenging [1,3].

The commonly used classification system for this injury is the Pipkin classification, where four types were identified according to the fracture location and the presence of associated injuries (Type I where the fracture fragment is distal to the fovea, Type II where the fracture fragment including or above the fovea, Type III if the fracture is associated with a femoral neck fracture, and Type IV if it was associated with acetabular wall fractures)[4].

The management of FHFs follows a broad spectrum of options (primarily based on its Pipkin type), where conservative management is kept for the minimally displaced Pipkin I fracture, and at the end of the spectrum, total hip arthroplasty could be offered for older patients with highly comminuted fractures[5].

The basic principles of intraarticular fracture management still apply to FHFs, where obtaining anatomical reduction and stable fixation [achieved by open reduction and internal fixation (ORIF)] is mandatory for good long-term results. The controversy exists regarding the optimum approach that should be used safely for ORIF[2,3,6], either anterior, lateral, or posterior based approaches including the use of safe surgical hip dislocation (SHD), which was initially described by Ganz *et al*[7] as a safe approach for management of different intraarticular hip pathologies with no or few complic-

ations especially those related to femoral head vascularity[3,7].

One of the significant complications occurring either due to the trauma itself or as a consequence of surgical management is avascular necrosis (AVN) of the femoral head [2,3]. After Ganz popularized the safety of SHD in regard to hip vascularity preservation[7], this encouraged more trauma surgeons to introduce this approach in the armamentarium of approaches in the management of FHFs[2,3,6,8].

As a trial to collect large data on these injuries, a systematic review was performed by Giannoudis *et al*[2] in 2009, pooling the data from 29 studies that constituted a total of 453 FHFs treated through different approaches, where they evaluated various aspects related to management; however, one drawback of this review was the heterogenicity of the reported studies, and the inclusion of relatively few numbers of patients (36 FHFs) treated through SHD[2].

Recently, more studies with a larger number of patients reported the utilization of SHD in the management of FHFs; this encouraged us to carry out this systematic review and metanalysis to update the knowledge regarding the clinical and radiological outcomes as well as the safety (by reporting the incidence of complications) of using SHD in the management of FHFs.

MATERIALS AND METHODS

Search protocol and information sources

We conducted a systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist[9]. PubMed, Embase, Web of Science, and Cochrane Central Register of Controlled Trials databases were searched for the last 20 years (until January 2021) using a combination of the following search terms: Femoral head fracture, Pipkin fracture, surgical hip dislocation, Ganz.

Eligibility criteria, study selection, and data items

Retrieved results were imported into Endnote X9 software (Thomson Reuters, New York, NY, United States), where a check for duplicates was conducted. The titles and abstracts of the remaining articles were then screened, and the selection was based on the following exclusion criteria: (1) Articles published in languages other than English; (2) Reviews, guidelines, or classifications; (3) Letters to the editor, case reports, or conference papers; (4) *In vitro* and animal experiment studies; and (5) Irrelevant studies.

Subsequently, full-text articles of potentially relevant studies were obtained and assessed for eligibility. We included studies that met the following inclusion criteria: (1) Prospective or retrospective cohorts or case series investigating SHD *via* a trochanteric flip osteotomy (TFO) (as described initially by Ganz *et al*[7]) as an approach to treat FHFs in adult populations or studies from which data could be extracted independently; (2) A minimum sample size of 5 patients; and (3) The ability to extract data related to the outcomes of interest (data should be genuine and not reported in another study).

Data collection process

Two independent reviewers reviewed the list of potentially eligible articles (they also performed data extraction), and a third reviewer was consulted, when necessary, to decide any uncertainties regarding eligibility. The following information was extracted from studies that met the inclusion criteria: The name of the first author, year of publication, study design, number of cases, patients age and gender, classification of the fracture according to Pipkin classification system, the strategy of management (ORIF or fragment excision), type of the implant used for fixation, operation time, blood loss, length of follow-up time, and outcomes of interest including functional outcome, radiological outcome, complication rate, and reoperation or revision surgery details.

Summary measures, synthesis of results, and risk of bias across studies

When mean or standard deviation values were not available in the publications, we used statistical methods described in previous literature to derive the needed numerical values[10]. We performed all data analyses using Review Manager version 5.4.1. (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). We calculated the odds ratio with a 95% confidence interval (CI) for binary outcomes, while the mean difference with 95%CI for continuous outcomes was calculated. To

calculate the overall effect estimate with 95%CI, we used a fixed-effect model with the method of Mantel-Haenszel when there was no evidence of heterogeneity between studies. Otherwise, a random-effects model with the method of DerSiomonian and Laird was chosen. Heterogeneity between studies was evaluated using the Q statistic and I^2 test, which describes the percentage of variability in the effect estimates. A P value of < 0.05 was considered significant.

RESULTS

Study selection

The electronic search yielded 1002 references from the four databases. After excluding 192 duplicates, 810 records remained for a title and abstract screening. We had 18 relevant articles for full-text screening: Eight fulfilled the inclusion criteria, and ten were excluded (one article not in English, six articles were case reports or included less than five cases, two articles the data of interest could not be extracted, and in one article the same data was reported in one of the included articles). The manual search of the included articles references imported one additional article. Nine studies[11-19] were ultimately included in the qualitative and quantitative analyses. The flow diagram of the study selection process is shown in Figure 1.

Study characteristics

Nine studies included a total of 129 FHFs from which basic demographic data were extracted (the data on outcomes were extracted from 127 FHFs, as in one study[15], the authors reported missing the assessment of two patients in their results section). Two studies[15,16] were prospective, while seven[11-14,17-19] were retrospective. Across studies, the mean age was 38.2 years (range from 17 to 64). The average follow-up period was 38.4 mo (ranged from 10.8 to 77.0). The majority of participants were males (76.4%). In one study[18], the fracture classification was not reported, while in the remaining eight studies, the fracture classification according to Pipkin was as follows, 77 (62.6%) type I and II, while 46 (37.4%) were type IV, and none (0%) were Pipkin type III. All patients underwent fixation (96.9%) except four (3.1%) patients who underwent fragment excision; no patient underwent total hip arthroplasty as the primary management. Details for included studies are summarized in (Table 1).

Surgical data

Associated intraarticular injuries: Regarding the intraarticular associated injuries (other than the primary fractures either in the femoral head or the acetabulum), in four studies[12,14,15,19], the authors reported intraoperative diagnosis of Labral injuries at an incidence of 41.3% (33 out of 80 hips). Head impaction injury was reported in three studies[14,15,19], which occurred at an incidence of 23.5% (16 out of 68 hips).

Operation time: It was reported in five studies[12-14,16,18]. However, we were able to pool the results of four studies[12-14,16] due to incomplete data from the fifth study. No significant heterogeneity was detected (I^2 = 41.33%, P = 0.164) using the fixed-effect model for analysis. The mean operation time ranged from 120.0 to 155.2 min, with the pooled estimate being 123.7 (95%CI: 116.58–130.89). The result was statistically significant (Z = 33.91, P = 0.000). Details of operation time in included studies are shown in (Table 2).

Blood loss: It was reported in six studies[12-14,16-18]. However, we were able to pool the results of five studies[12-14,16,17] due to incomplete data from the sixth study. We used the random effect model for analysis as significant heterogeneity was detected (I^2 = 91.52%, P = 0.000). The mean amount of blood loss ranged from 283.0 to 1436.9 mL, with the pooled estimate being 491.9 (95%CI: 347.01–636.77). The result was statistically significant (Z = 6.66, P = 0.000). Details of blood loss in included studies are shown in (Table 2).

Functional outcomes

Functional outcomes (Figure 2) of the hip were reported in eight studies[11-16,18,19], but the assessment methods used were different. The Harris Hip Score (HHS) was used in three studies[14,18,19], in six studies[11-13,15,16,19] Merle d'Aubigne-Postel score was used, Thompson–Epstein scale was used in three studies[11-13], and the Oxford Hip Score was used in one study[15]. In the current meta-analysis, a satisfactory functional outcome was defined as HHS or Merle d'Aubigne-Postel score

Table 1 Baseline characteristics of included studies

Ref.	Study design	Sample size	Age[1], yr	Sex		Pipkin classification (I/II/III/IV)	Management		Implant	Follow up[1], mo
				M	F		Fixation	Excision		
Henle *et al* [11], 2007	Retrospective	12	39.8 (26-71)	10	2	1/3/0/8	12	0	Mini or small fragment cortical screws (2.0-2.7 mm) or Herbert screws or absorbable pins	31.1 (3-96)
Solberg *et al* [12], 2009	Retrospective	12	-	10	2	0/0/0/12	11	1	Headless variable-pitch screws or Herbert screws	47 (24-71)
Mostafa *et al* [13], 2014	Retrospective	12	-	-	-	12/0/0	12	0	Partially threaded cancellous screws or Herbert headless screws	31 (24-84)
Massè*et al* [14], 2015	Retrospective	13	34 (22-54)	11	2	5/2/0/6	13	0	2.7 mm nonabsorbable screws	77 (26-122)
Gavaskar *et al*[15], 2015	Prospective	28	-	-	-	6/22/0/0	26	2	2.4 mm headless screws (Synthes-India).	36 (25-46)
Wang *et al* [16], 2019	Prospective	12	39.9 ± 12.2	8	4	4/3/0/5	12	0	3.2 mm Herbert screws or partially threaded screws	35 (25-48)
Engel *et al* [17], 2020	Retrospective	7	39.57 (17-64)	4	3	0/0/0/7	6	1	Buried headless screw	29.8 (11.6-67.2)
Rana *et al* [18], 2020	Retrospective	6	42 (32-54)	4	2	-	6	0	Herbert (headless) screw	10.8 (8-18)
Khalifa *et al* [19], 2020	Retrospective	27	33.8 (18-45)	21	6	6/13/0/8	27	0	4 mm partially threaded cancellous screws or Herbert headless screws	48 (24-72)

[1]Data are presented as mean ± SD or mean (range). M: Male; F: Female.

Table 2 Operation time and blood loss (six studies)

Ref.	Operation time	Blood loss
Solberg *et al*[12], 2009	121.0 ± 28.3 (102-215)	350.00 ± 125.00 (250-750)
Mostafa *et al*[13], 2014	120.0 ± 19.7	283.00 ± 124.90
Massè*et al*[14], 2015	155.2 ± 53.1	1436.90 ± 663.80
Wang *et al*[16], 2019	124.2 ± 22.1	437.50 ± 113.10
Engel *et al*[17], 2020	NR	503.00 ± 181.25
Rana *et al*[18], 2020	90.0	450.00

NR: Not reported.

graded as excellent or good. No significant heterogeneity was detected (I^2 = 0%, P = 0.893) using the fixed-effect model for analysis. The event rates of satisfactory outcome ranged from 0.62 to 0.98, with the pooled estimate being 0.85 (95%CI: 0.77-0.91). The result was statistically significant (Z = 6.55, P = 0.000). According to individual assessment score or scale, excellent or good results were obtained in 87.9% (29 of 33 hips), 87.1% (88 of 101 hips), and 83.3% (30 of 36 hips) according to HHS, Merle d'Aubigne-Postel score, and Thompson–Epstein scale, respectively.

Radiological outcome

Four studies[14-16,19] reported radiological outcomes in terms of obtaining fracture anatomical reduction. No significant heterogeneity was detected (I^2 = 49.66%, P = 0.114) using the fixed-effect model for analysis. The overall incidence of anatomic reduction ranged from 0.30 to 0.86, with the pooled estimate being 0.74 (95%CI: 0.61–0.83). The result was statistically significant (Z = 3.37, P = 0.001, Figure 3).

Complication rate

All nine studies[11-19] reported on the postoperative complications, namely AVN of

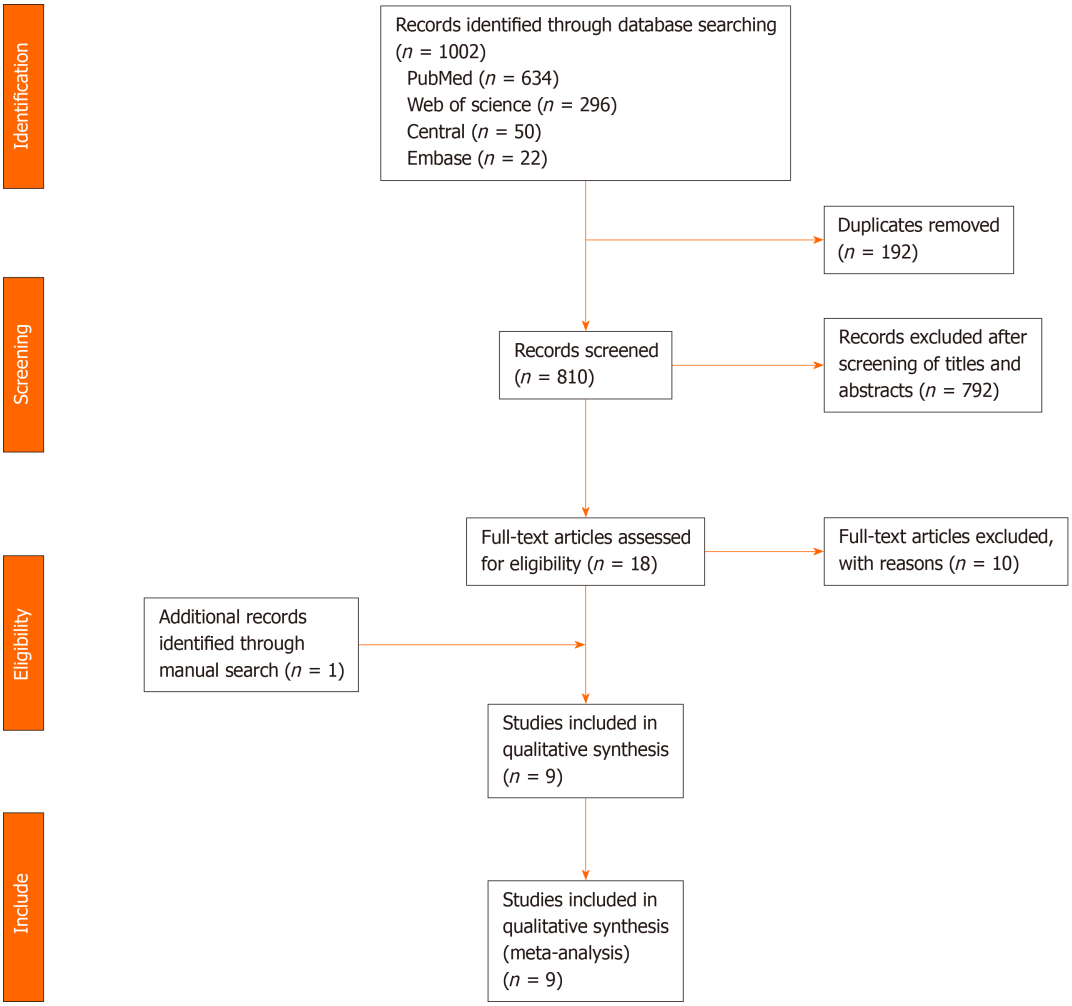


Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of search results, studies' screening, and selection.

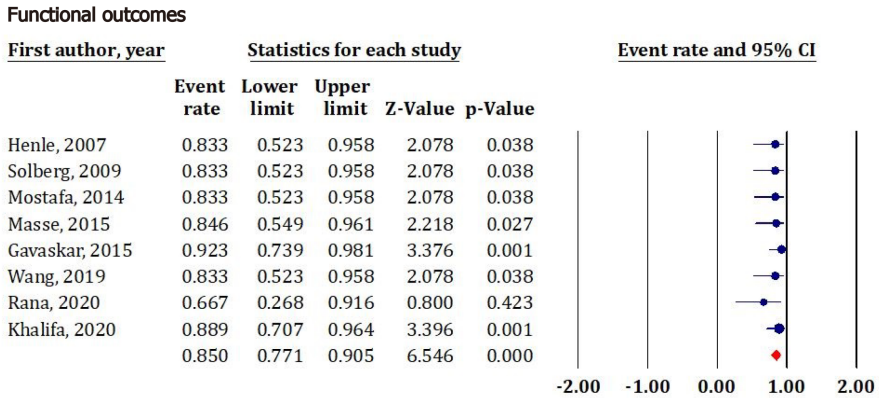


Figure 2 Forest plot diagram shows postoperative functional outcomes. CI: Confidence interval.

the femoral head, heterotopic ossification (HO) formation, posttraumatic osteoarthritis (OA), deep infection, trochanteric bursitis, and nonunion of the TFO. No significant heterogeneity was detected (I^2 = 11.18%, P = 0.342) using the fixed-effect model for analysis. The overall incidence of postoperative complications ranged from 0.30 to 0.86, with the pooled estimate being 0.44 (95%CI: 0.35–0.53). The result was statistically insignificant (Z = -1.27, P = 0.205) (Figure 4A).

AVN of the femoral head: AVN was reported in all nine studies[11-19]. No significant heterogeneity was detected (I^2 = 0%, P = 0.509) using the fixed-effect model for

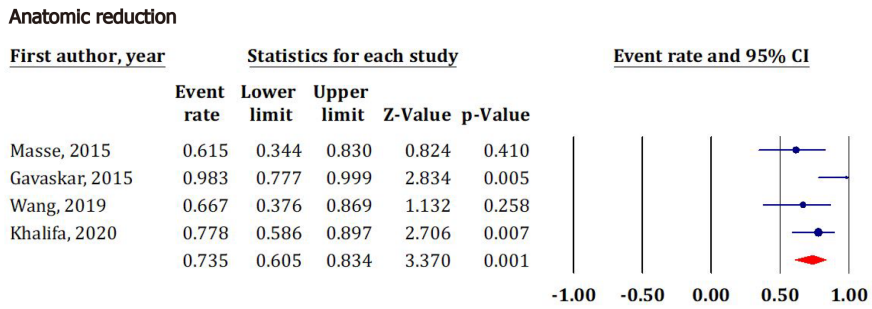


Figure 3 Forest plot diagram shows postoperative anatomical reduction as a representative of radiological outcomes. CI: Confidence interval.

analysis. The incidence of AVN ranged from 0.02 to 0.33, with the pooled estimate being 0.12 (95%CI: 0.07–0.21). The result was statistically significant (Z = -6.32, *P* = 0.000) (Figure 4B).

HO formation: HO was reported in eight studies[11-17,19]. No significant heterogeneity was detected (I^2 = 0%, *P* = 0.798) using the fixed-effect model for analysis. The incidence of HO ranged from 0.14 to 0.33, with the pooled estimate being 0.25 (95%CI: 0.18–0.34). The result was statistically significant (Z = -5.12, *P* = 0.000) (Figure 4C). According to the Brooker classification system[20], there was grade I in ten (33.3%) patients, grade II in 13 (43.3%), grade III in six (20%), and grade IV in one (3.4%). Excision was required in three (10%) patients.

Posttraumatic OA: OA was reported in five studies[11,15,17,19]. We used the random effect model for analysis as significant heterogeneity was detected (I^2 = 71.82%, *P* = 6.696). The incidence of OA ranged from 0.04 to 0.86, with the pooled estimate being 0.16 (95%CI: 0.04–0.47). The result was statistically significant (Z = -2.12, *P* = 0.034) (Figure 4D).

Other complications: Further complications that were not included in the meta-analysis were presented as follows. Nonunion of the TFO was reported in five studies [11,13-16,19] and occurred at an incidence of 3.4% (3 out of 89 hips). Presence of infection was reported in six studies[13-17,19] and occurred at an incidence of 2.1% (2 out of 97 hips). Trochanteric bursitis was reported in one study[15], which occurred at an incidence of 3.8% (1 out of 26 hips).

Reoperation rate

Reoperation rate was reported in eight studies[11-17,19]. No significant heterogeneity was detected (I^2 = 36.16%, *P* = 0.140) using the fixed effect model for analysis. The event rate for reoperation ranged from 0.08 to 0.57, with the pooled estimate being 0.20 (95%CI: 0.13–0.29) (Figure 5). The result was statistically significant (Z = -5.53, *P* = 0.000). Details of the reoperations required are in Table 3.

DISCUSSION

FHFs possess a challenge to the trauma surgeon, owing to the lack of a standard protocol for management and the various controversial issues around the best management option. The surgeon has to choose between conservative and surgical management. If the latter was chosen, then the surgeon must decide whether will it be excision or ORIF and through which approach it would be carried out[16,21,22]. Various surgical approaches have been utilized, including medial (Ludloff), anterior Smith-Petersen (S-P), posterior Kocher-Langenbeck (K-L), and anterolateral (Watson-Jones) approaches. Even hip arthroscopy was reported to be a way of management; SHD has emerged in the past few years and gained popularity as an option to approach and treat FHFs[2,3,6,23].

The most important findings in the current systematic review and metanalysis are that a large percentage of patients with FHFs obtained proper postoperative hip joint function after being managed through SHD; this approach enabled the surgeon to achieve anatomical fracture reduction and an acceptable rate of postoperative complic-

Table 3 Details of reoperation (eight studies)

Ref.	Indication of reoperation	Intervention
Henle *et al*[11], 2007	2 AVN	THA
	2 HO	Excision
Solberg *et al*[12], 2009	1 AVN	THA
Mostafa *et al*[13], 2014	1 AVN	THA
	1 TFO Nonunion	Revision of fixation
Massè*et al*[14], 2015	1 AVN	THA
	1 OA	THA
Gavaskar *et al*[15], 2015	1 Infection	Debridement
	1 Bursitis	Screw removal
Wang *et al*[16], 2019	1 AVN	THA
	1 HO	Excision
	1 TFO Nonunion	Revision of fixation
Engel *et al*[17], 2020	2 OA/ AVN	THA
	1 OA/HO	THA
	1 OA/Metal failure/Infection	Revision/Girdlestone/THA
Khalifa *et al*[19], 2020	2 AVN	THA
	1 OA	THA

AVN: Avascular necrosis; HO: Heterotopic ossification; THA: Total hip arthroplasty; OA: Osteoarthritis; TFO: Trochanteric flip osteotomy.

ations, mainly femoral head AVN, HO formation, and posttraumatic OA development.

In the systematic review by Giannoudis *et al*[2], the data regarding the surgical approaches were collected from 14 articles forming 177 surgical cases and was distributed as follows: The K-L was the most commonly used in 72 (40.7%) cases, followed by the S-P in 44 (24.9%), in third place was the SHD through TFO, which was used in 36 (20.3%). The remaining were other approaches reported in fewer numbers (lateral, anterolateral, medial, and dual approach). Thirty-six FHFs were treated through SHD, which was driven from four studies[2], while in the current systematic review, we included data of 129 FHFs from nine studies, meaning that in the past 10 years, the cases treated through SHD nearly tripled, indicating that this approach is gaining popularity among trauma surgeons.

Surgical data

In the current systematic review, the reported average operative time was 123.7 minutes, which is considered to be shorter than the operative time reported with the K-L approach but longer than the S-P. In a study by Wang *et al*[24], the authors compared managing Pipkin type I and II FHFs (21 through S-P and 18 through K-L). The average operative time for the S-P approach group was 96.9 ± 14.8 min, which was significantly shorter than the K-L approach group where the average operative time was 131.8 ± 21.2 min ($P < 0.001$)[24]. Many factors could affect the operative time, such as the presence of a concomitant injury that needed further management, such as an acetabular fracture (which was present in the current systematic review in 37.4% of the patients) or the presence of intra-articular injuries, mainly labral and head impaction injuries that were reported in the current systematic review in 41.3% and 23.5% of patients, respectively. Another factor that might play a role is the surgical skill and familiarity of the surgeon with the SHD approach and the learning curve needed to master managing such injuries through SHD, which we were unable to assess.

The relatively prolonged operative time and the presence of associated injuries led to an increase in the blood loss, as the reported average blood loss in the current systematic review was 491.9 mL, with a maximum blood loss of 1436.9 mL as reported in one study[14]. In Wang *et al*[24] study, the average blood loss was lower in both

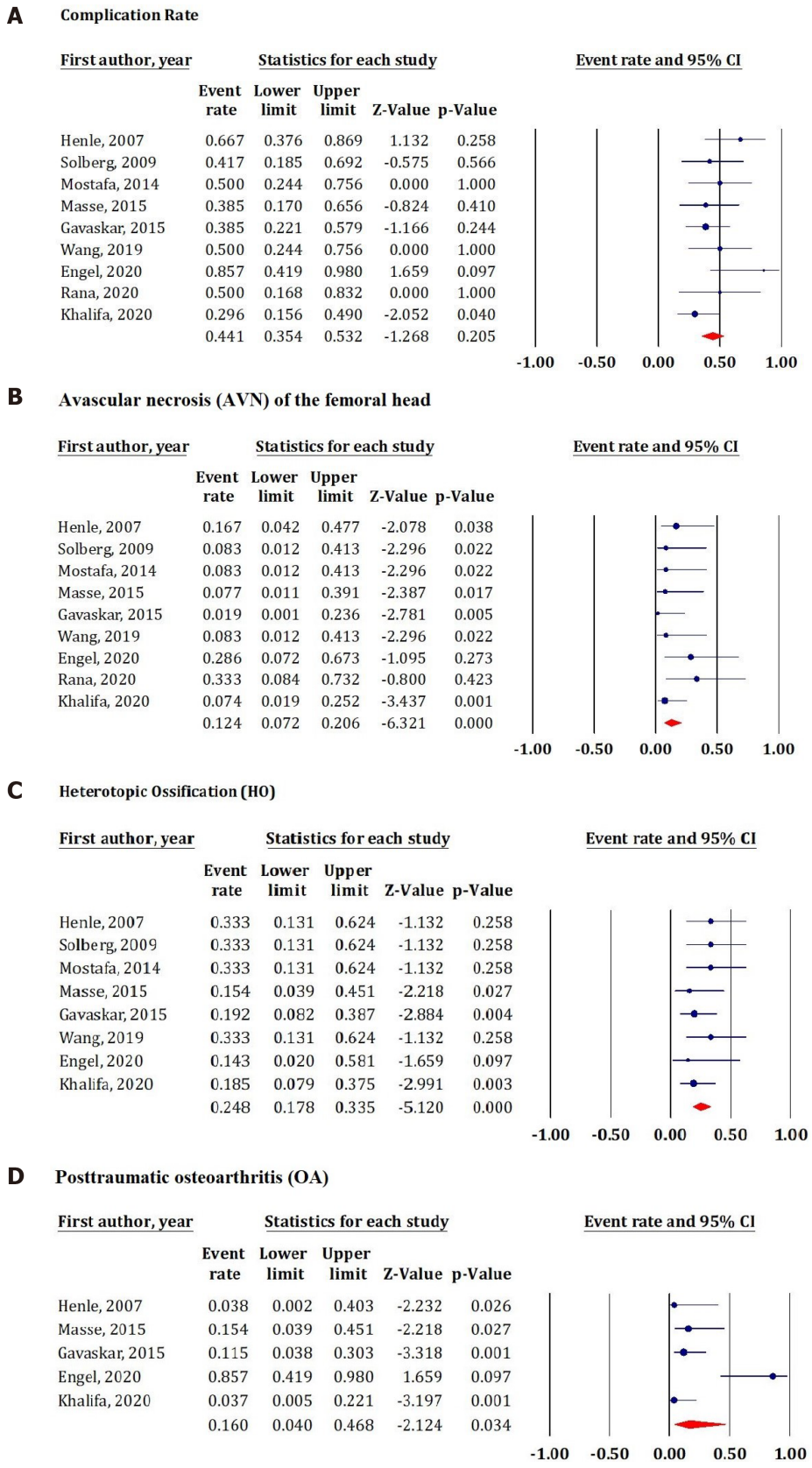


Figure 4 Forest plot diagram shows postoperative complications. A: Overall complications incidence; B: Avascular necrosis of the femoral head; C: Heterotopic ossification formation; D: Posttraumatic osteoarthritis. AVN: Avascular necrosis; CI: Confidence interval; HO: Heterotopic ossification; OA: Osteoarthritis.

approaches than what was reported with SHD in the current review, and the S-P approach group was even significantly lower than the K-L group, 103.3 ± 28.5 *vs* 334.5 ± 58.9, respectively ($P < 0.001$).

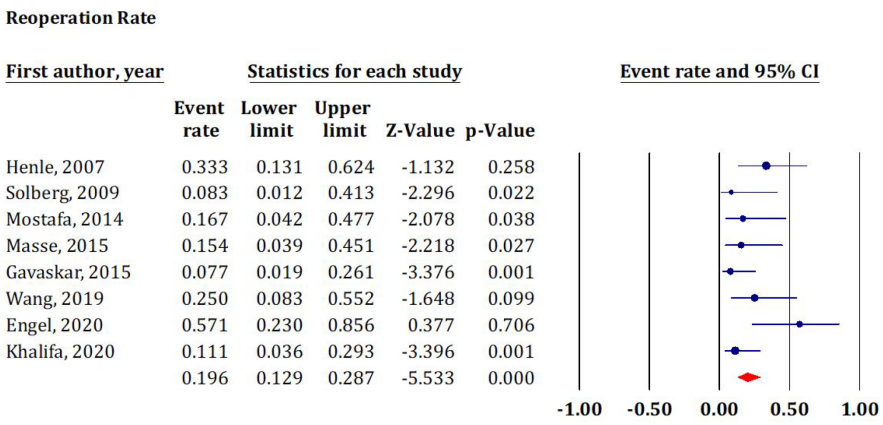


Figure 5 Forest plot diagram shows postoperative reoperation rate. CI: Confidence interval.

Many fixation devices could be used when ORIF is decided, such as headless subchondral screws, countersinking lag screws, bioabsorbable pins or screws, and suture fixation[15,25-27]. The same diversity was reported in the current systematic review, as various implants were used for fracture fixation, as reported in (Table 1). Some of the fixation devices had been criticized for causing foreign body reactions such as biodegradable screws or pins[26]; metal implants may lead to stress shielding besides causing an allergic reaction in susceptible patients[28].

Functional outcomes

Although there was diversity in reporting the functional outcomes among the studies included in this meta-analysis owing to implementing different assessment scales and scores, an overall satisfactory functional outcome (defined as excellent or good according to HHS or Merle d'Aubigne-Postel) was reported in 85% of the patients. Giannoudis *et al*[2] studied the relation between the functional outcomes and the utilized approach in 119 cases from nine studies. Excellent and good results according to the Thompson–Epstein scale was reported in 83.4% of patients treated through SHD compared to 65.4% and 49% in patients who received S-P or K-L approaches, respectively. In the current systematic review, we found nearly the same result as 83.3% of the patients where the Thompson–Epstein scale was used for functional assessment reported being excellent or good. However, the functional results obtained in patients treated through SHD were better than what was reported in other studies using the K-L or S-P approaches. In a study by Del Core *et al*[29], they retrospectively reviewed the results of 22 patient managed for FHFs (five Pipkin I, three Pipkin II, 0 Pipkin III, and 14 Pipkin IV). Surgical intervention was needed in 18 (82%) patients: S-P approach was used in 5 (28%) patients, and K-L approach in 13 (72%). Overall functional results (regardless of the approach used) according to the Thompson and Epstein scale were excellent and good in 12 (54%) patients, fair and poor in 10 (46%) [29]. In a systematic review and meta-analysis carried out by Wang *et al*[21] comparing the S-P *vs* K-L approaches for managing Pipkin type I and II fractures, five case-control trials were evaluated, including data of 68 patients (34 in each approach). An acceptable hip function (excellent or good) according to Thompson and Epstein scale was achieved in 67.6% (23/34) treated through the S-P approach, and this was not different from the K-L approach (P = 0.82)[21].

Radiological outcomes

There is no agreement on a scale or specific criteria to assess the quality of FHF reduction (as what is to be considered as non-anatomical or mal-reduction) in the postoperative period and follow-up radiographs, which makes comparison across studies difficult. However, Massè *et al*[14] was the first to describe using the Matta criteria[30] (originally described for acetabular fracture quality of reduction assessment) and applied it to the FHFs. In the current systematic review, a postoperative anatomic reduction was reported in about 74% of the patients reported from four studies. Three of them[14,16,19] reported using the Matta criteria, while in the fourth study[15], the authors did not report a specific method of assessment. As the SHD allows for 360 degrees of head exposure, it is postulated that it will allow a better anatomical reduction of the fracture compared with the limited visualization offered by other approaches[7].

Complications

The three major reported complications after FHF management had been alternating between AVN of the femoral head, HO formation, and posttraumatic OA as reported in many studies regardless of the approach used for surgery[1-3,25]. Controversy exists as to whether the trauma incident itself or the surgical intervention (including the surgical approach) is the cause leading to these complications; for example, the timing of reduction (if the patient presented with a dislocated hip) could affect the complication incidence[8,11,31], and disruption of the femoral head vascularity (leading to AVN) can occur at the time of trauma rather than being a consequence of surgical intervention[32].

The overall incidence of postoperative complications in the current systematic review was 44%; however, only half of those patients needed further intervention. This incidence was higher than what was reported in the initial series by Ganz *et al*[7] (treating non-traumatic conditions), where they reported a major complication rate of 3.3% in 213 patients. However, the incidence was lower than the overall complications reported in the Giannoudis *et al*[2] systematic review, where the major three complications were reported to occur at an incidence of 68%, which reached 84.4% when cases treated through SHD were excluded.

AVN of the femoral head

Ganz *et al*[7] reported 0% of AVN in their study; however, the cases they reported were non-traumatic conditions. The authors proved the safety of SHD in regard to hip vascularity preservation. In the systematic review by Giannoudis *et al*[2], after a mean follow-up of 59.7 mo, AVN was reported in 2 (5.3%) out of 38 patients treated through the S-P approach, 3 (8.3%) out of 36 patients treated through SHD, and 11 (16.9%) patients out of 65 treated through the K-L approach. The authors reported that the chance of a patient to develop AVN when treated through a K-L approach was 3.67 and 2.24 times higher compared to S-P or SHD approach, respectively ($P > 0.05$)[2]. In the current systematic review, we reported an incidence of AVN of 12%, which was better than the K-L approach and higher than the S-P approach, as reported in the previous study.

The same previous finding was confirmed in further studies as follows. In a study by Scolaro *et al*[1] on 147 FHFs classified according to Pipkin classification into type I (27%), II (42%), III (4.7%), IV (15%), and as others which included impaction injuries (10%). ORIF was performed in 78 (53.1%) fractures; 97% of these were approached through the S–P approach. After a mean follow-up of 12.4 months, 6 (8.7%) patients developed AVN, mostly all Pipkin III fractures ($n = 5$) had AVN[1]. In a study by Stannard *et al*[33] where they surgically treated 17 patients diagnosed with FHFs, in 6 patients (35%) the S-P approach was used, 10 (59%) underwent the K-L approach, and 1 (6%) underwent dual anterior and posterior approaches. The authors reported that 4 of the 5 patients who had AVN were managed through the K-L approach. They reported that the odds ratio was 3.2 times higher for AVN when the K-L approach was used compared to the S-P approach[33].

In a retrospective analysis by Swiontkowski *et al*[34] of 24 patients presented with Pipkin types I and II (12 patients were treated through the K-L approach and 12 through the S-P approach), the authors reported an incidence of AVN of 16.7% with the K-L approach compared to 0% when the surgery was performed through the S-P approach[34]. In the systematic review by Guo *et al*[35], they included studies from 1980 to April 2009 to evaluate the relation of the surgical approach to the development of AVN; ten studies were eligible to be included with a total of 176 cases. The incidence of AVN was more with the K-L approach (16.9%) than the S-P (7.9%); however, the difference was not significant[35].

HO formation

It is not clearly defined if HO formation relates to the surgical approach or the traumatic muscle injury[25]. The exact pathogenesis is still unclear, but other factors rather than the type of the approach have been accused such as being a polytrauma patient, concomitant craniocerebral or thoracoabdominal trauma, male sex, the time to hip reduction (if dislocated), delay to surgery, and associated fractures as in type III and IV injuries[36-38]. In the current systematic review, SHD was associated with HO formation at an incidence of 25%; surprisingly, this incidence was lower than the incidence reported with treating non-traumatic conditions as Ganz *et al*[7] reported 37% of their patients having HO formation.

In another study by Kargin *et al*[39] where they evaluated 44 patients who underwent SHD for non-traumatic causes with a mean follow up of 66 mo, they

reported an incidence of HO formation of 36.5%. The incidence reported in the current systematic review was lower than what was reported by Giannoudis *et al*[2], as they noted that HO of any grade occurred in 44.7% of patients treated with the S-P approach and in 32.3% of patients treated through the K-L approach. However, the difference between approaches was not significant ($P > 0.05$). The authors reported an incidence of 47.2% in the patients treated through SHD included in their review (which was nearly double the incidence in the current review). They estimated a 1.87 times higher rate of HO following SHD; however, they noted that this higher incidence did not affect the functional outcomes[2].

In the systematic review by Guo *et al*[35], HO formation was lower in the SHD group (33.3%) compared to the S-P or K-L approaches (42.1% and 36.9%), although the difference was not statistically significant. In a study by Peng *et al*[40] reporting their results of treating FHFs at an average follow up of 3.3 years, 18 patients treated through the S-P approach, and 6 through the K-L approach, the overall incidence of HO was 43%. No surgical intervention was needed.

In the current systematic review, lower grades of HO (Brooker I and II) occurred in 76.5 % of the patients, while higher grades (III and IV) occurred in 23.4 %. This was nearly similar to the results obtained from the study by Scolaro *et al*[1] where low-grade HO developed in 74% of the patients, while higher grades developed in 24%. However, they had a lower incidence of surgical intervention for HO in only 2.9% of patients who required surgical excision compared to 10% of the patients in the current systematic review. The lower incidence of HO formation in the current systematic review compared to the previous reports may be attributed to the advancement in HO prophylaxis techniques, more orientation about the problem, which was gained from previous studies, and to increasing experience of surgeons with the SHD technique paying more respect to soft tissues.

Posttraumatic OA

This complication could develop due to improper fracture reduction or as a consequence of AVN, as in some studies the authors reported AVN and OA as a single entity[1]. In the current systematic review, we reported an incidence of posttraumatic OA of 16% after SHD, which is considered higher than the incidence reported with cases managed through SHD in the Giannoudis *et al*[2] systematic review, where the authors reported 0% incidence. However, the incidence reported with SHD was still lower than other approaches, as Giannoudis *et al*[2] reported an incidence of 21.0% and 29.2% in patients treated through the S-P and K-L approaches, respectively. They estimated a 20.3 ($P = 0.04$) and 30.6 ($P = 0.018$) times higher incidence of posttraumatic OA development when the S-P or K-L approach was used, respectively, compared to SHD[2]. An increased incidence with other approaches was reported in other studies, as in the study by Wang *et al*[24] the authors reported a posttraumatic OA incidence of 14.3% and 16.7% with the S-P and K-L approaches, respectively. The difference was insignificant ($P = 1.000$). Del Core *et al*[29] reported an overall incidence of 23% in their patients. In the current systematic review, the increased incidence of OA development could be attributed to the fact that 6 of the 12 patients who developed posttraumatic OA were reported from Engel *et al*[17] study, where all the included cases were Pipkin type IV with an incidence of OA of 85.7% (6 out of 7 patients), owing to the severity and complexity of this type of injury.

Infection

This was the lowest reported complication in the current systematic review, which occurred at an incidence of 2.1%. Only 2 patients required further surgical intervention; this was in accordance with previous studies, as in the systematic review by Giannoudis *et al*[2] the incidence of infection was 3.2%. In the study by Del Core *et al*[29], 1 patient (5%) developed a postoperative infection. In a study by Peng *et al*[40], no deep infection was reported.

SHD unique complications

The possibility of TFO nonunion and the development of trochanteric bursitis with lateral thigh pain secondary to irritation by the screws used to fix the TFO are unique complications to the SHD approach[7,13,41,42]. An incidence of TFO nonunion was reported in five studies in the current review giving an incidence of 3.4%, and two patients required refixation. The incidence was even lower in the studies reported on non-traumatic conditions, as in a multicentre study by Sink *et al*[43]. They evaluated 334 hips from eight different North American centres with a minimum of 12 months follow-up. TFO nonunion was reported in six hips (1.8%), all united after revision of

the internal fixation. Ganz *et al*[7] reported three (1.4%) cases with TFO nonunion. In the current systematic review, we reported an incidence of trochanteric bursitis with lateral thigh pain in 1 (3.8%) patient out of 26 hips, which required screw removal. In the study by Kargin *et al*[39], lateral thigh pain was reported to occur in 28.8% of their patients.

Advantages of the SHD approach

Trauma surgeons were encouraged to incorporate SHD in the management of FHFs as it offered many advantages. Firstly, the wide exposure (360 degrees) of both the femoral head and the acetabulum makes it possible to treat both pathologies if present (as in Pipkin Type 4) at the same time. Secondly, it enables the detection and dealing with other intraarticular injuries such as labrum injury or head impaction injuries, which may be difficult to diagnose in preoperative imaging studies[44-46]. Thirdly, the ability of the approach allows the surgeon to perform better reduction and fixation of the fractured fragments. Lastly, it enables the ability to check the vascularity of the femoral head intraoperatively by using the drill test [7,8].

Limitations of the current systematic review

First, we did not compare the results obtained from SHD with other approaches, which might be due to the lack of comparative studies in this field. Second, one crucial point that was not assessed is the experience of the surgeon with this approach. Some authors reported having no familiarity with this approach[40]. On the other hand, in two studies[14,19] included in the meta-analysis, the authors reported having previous experience with the SHD approach; however, we found it unmeasurable and challenging to state the learning curve needed to master this technique. Lastly, limiting the article search to the past 20 years might lead to missing some earlier articles; however, we aimed at presenting as updated data as possible.

CONCLUSION

Incorporating SHD as an optional approach in the armamentarium of approaches in dealing with FHFs enables trauma surgeons to properly manage these intraarticular fractures and detect and deal with additional intraarticular injuries. It offered acceptable functional and radiological outcomes with a wide range of safety in regards to the hip joint vascularity and the development of AVN, the formation of HO, and the development of posttraumatic OA; however, it still carries its unique risk of complications such as TFO nonunion and persistent lateral thigh pain.

ARTICLE HIGHLIGHTS

Research background

Surgical hip dislocation (SHD) was introduced as a safe approach for managing various hip pathologies. It gained popularity among trauma surgeons as a new approach for the management of femoral head fractures (FHFs). Several studies were published on this subject. However, no systematic reviews were carried pooling these data together to generate stronger evidence of this approach utility.

Research motivation

FHFs are considered as intraarticular fractures. Anatomical reduction and preservation of its vascularity are two mandatory perquisites for obtaining optimum outcomes; SHD was introduced for the management of these fractures with the advantage of preserving femoral head vascularity and providing 360 degree visualization of the femoral head.

Research objectives

We carried out this systematic review and meta-analysis to evaluate the efficacy (functional and radiological outcomes) as well as the safety (complications incidence) of using the SHD approach for management of FHFs, which could help encourage more surgeons to widely adopting this approach in their practice.

Research methods

Four major databases were searched (PubMed, Embase, Web of Science, and Cochrane Central Register of Controlled Trials) to collect eligible studies reporting on various outcomes (functional, radiological, and complications) after utilizing SHD as described by Ganz in the management of FHFs. Articles basic, surgical, functional, radiographic, and complications data were collected from the included articles.

Research results

Nine studies were eligible and included in the analysis, forming a total of 129 FHFs with an average follow up of 38.4 mo. The average operative time and blood loss were 123.74 min and 491.89 mL, respectively. Excellent and good functional outcomes were obtained in 85% of the patients, while anatomical fracture reduction could be obtained in 74%. The overall complication rate was 44%; the main reported complications were femoral head avascular necrosis, heterotopic ossification, and osteoarthritis, which occurred at an incidence of 12%, 25%, and 16%, respectively. A unique complication to SHD was trochanteric flip osteotomy nonunion and trochanteric bursitis, which occurred at an incidence of 3.4% and 3.8%, respectively. The issue of surgeon experience and its relation to the results and utilization of this approach is still to be studied.

Research conclusions

We believe that this was the most recent systematic review collecting and reporting the data regarding the efficacy and safety of SHD as an approach for management of FHFs; the results of this systematic review suggest the high safety profile of this approach with acceptable functional outcomes.

Research perspectives

We believe that there is a need for further studies and systematic reviews comparing the SHD approach to conventional approaches (anterior and posterior) in the management of FHFs to prove its safety and efficacy.

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MINIREVIEWS

Coronaviruses: An overview with special emphasis on COVID-19 outbreak with musculoskeletal manifestations

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Abstract

An acute respiratory illness caused by a novel coronavirus, namely, severe acute respiratory syndrome coronavirus 2, the virus that causes coro-navirus disease 2019 (COVID-19), began spreading across China in late December 2019. The disease gained global attention as it spread worldwide. Since the COVID-19 pandemic began, many studies have focused on the impact of the disease on conditions such as diabetes, cardiovascular disease, pulmonary disorders, and renal malfunction. However, few studies have focused on musculoskeletal disorders related to COVID-19 infection. In this review, we update the current knowledge on the coronavirus with special reference to its effects during and after the pandemic on musculoskeletal aliments, which may inform clinical practice.

Key Words: Coronaviruses; COVID-19; Musculoskeletal; Infection; Pandemic; Orthopaedics

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Core Tip: Severe acute respiratory syndrome coronavirus 2, the virus that causes coronavirus disease 2019 (COVID-19), began spreading across China in late December 2019 and became a pandemic. This review focuses on musculoskeletal signs and symptoms of COVID-19 infection. Furthermore, a hypothetical pathway showing factor-induced hypoxic conditions and their downflow changes in the musculoskeletal system during severe COVID-19 infection are discussed.

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INTRODUCTION

Coronaviruses, RNA-positive sensory viruses, are 60–140 nm diameter spheres with spiked projections that make them appear crown-like under an electron microscope [1]. Subsequent to β-coronavirus and pneumonia outbreaks occurring in 2019 in Wuhan, China, the World Health Organization (WHO) named the novel coronavirus 2019-nCoV on January 12, 2020. The WHO formally identified coronavirus disease 2019 as COVID-19, and the Coronaviridae Study Group of the International Committee on Taxonomy of Viruses designated the severe acute respiratory syndrome coronavirus as SARS-CoV-2 on February 11, 2020[2]. The WHO declared that the COVID-19 outbreak was a global pandemic on March 11, 2020.

In more than 210 countries and territories, the virus spread within a brief period. Almost 58699047 cases of COVID-19 have been reported to date, of which 40639477 people have recovered and 1389562 people have died. The numbers are increasing, so these figures are changing every day[3].

The enormous potential of infection and low-to-moderate death rates due to COVID-19 have presented a significant challenge to health care systems worldwide. Furthermore, according to the current information, the novel coronavirus is predominately transmitted through aerosols and direct contact with infected surfaces. Therefore, for any specific prophylactic measures, both of these types of transmission need to be considered.

In this pandemic situation, it is a misconception that COVID-19 affects only specific health care specialties/systems. In fact, all body systems are affected by COVID-19. It has been observed that most developed countries, even those with well-established health care systems, have suffered greatly due to COVID-19. Therefore, it is not difficult to understand the disastrous effect of COVID-19 in low-resource countries with very limited health care . In the present review, we provide information about coronavirus with special reference to musculoskeletal aliments that have been found in COVID-19 patients during the pandemic and may continue to appear after the pandemic is over, thereby affecting clinical practice.

CORONAVIRUSES

Severe acute respiratory syndrome coronavirus (SARS-CoV) first appeared in 2003, and later, in 2012, the Middle East Respiratory Syndrome coronavirus (MERS-CoV) emerged, although the first coronavirus was reported even earlier, in 1965[4]. The diverse family of viruses infects mammalian and avian hosts' respiratory and gastrointestinal tracts, and the bat is a natural reservoir for these viruses[5]. The virus belongs to the *Nidovirales* order, which includes four families: *Coronaviridae, Arteriviridae, Roniviridae* and *Mesoniviridae,* in which *Coronaviridae* consists of a vast genome size of 26–32 kb; again, it has a subfamily, *coronavirinae* and *toronavirinae* with four genera, α, β, γ and Δ coronavirus[6].

SARS-CoV-2 is the causative agent of the novel COVID-19 and belongs to the β-genera coronavirus family. The virus consists of positive single-stranded RNA with a single linear RNA fragment[7]. Under an electron microscope, it appears crown-shaped, circular or oval with a diameter of 60–140 nm, and the length of the genome is 30 kb[8].

Types of coronaviruses

According to the U.S. Centers for Disease Control, there are seven varieties of coronaviruses: 229E, NL63 (α coronaviruses), OC43, and HKU1 are beta coronaviruses, MERS-CoV (β coronavirus), SARS-CoV (β coronaviruses), and COVID-19 (SARS-CoV-2)[9].

Differential molecular structure of COVID-19

A study on protein sequences found that there is 94.6% similarity among all seven nonstructural proteins and amino acids as well as the genomes of both COVID-19 and

SARS-CoV. The spikes on the viruses consist of two linked parts; when those halves divide, the spike activates, and only then does the virus reach the host cell. This division happens in SARS-CoV with some difficulty. Nevertheless, in SARS-CoV-2, the bridge that links the two halves can be quickly broken by an enzyme named furin produced by human cells and crucially in several tissues[8]. COVID-19 shares a 79.5% identical genomic structure with SARS CoV[9].

Key virulent factor of COVID-19

According to a report by Wu *et al*[10], nonstructural protein 1 (Nsp1), Nsp3c, and open reading frame 7a (ORF7a) are the three main coronavirus virulence factors that interfere with the host's innate immunity and assist in coronavirus immune escape. Nsp1 interacts with the host's 40S ribosomal subunit, which directly causes mRNA degradation in the host and inhibits interferon development. Nsp3c has the potential to bind ADP ribose from the host to allow coronavirus escape of innate immunity. In addition, bone marrow matrix antigen 2 (BST2) may prevent host cells from releasing newly assembled coronavirus. SARS-CoV ORF7a binds directly to BST2 and inhibits its activity by preventing BST2 glycosylation[10].

What is COVID-19?

COVID-19 is an infectious disease caused by a novel coronavirus that may induce flu-like symptoms, such as fever and dry cough (the two most frequent symptoms), weakness, nausea, and nasal congestion. As the pandemic progresses globally, certain new signs have arisen, such as loss of smell and taste. COVID-19 has a fatality risk of 4.4%, which is significantly lower than that of SARS (10%) and MERS-CoV (approximately 30%). However, the potency of infection with COVID-19 is much greater than that of either SARS or MERS-CoV. In addition, it is crucially undetectable, even asymptomatic patients or patients with minor symptoms are able to transmit the infection[11].

Why is COVID-19 the most virulent form?

A study showed that the virus uses the human angiotensin-converting enzyme-2 (ACE-2) receptor and recognizes it with comparable affinity to SARS-CoV isolates, which indicates that it can spread effectively in humans[12]. Researchers also found that the RBD spike protein of COVID-19 binds with human ACE-2. This is why the COVID-19 spike protein with high affinity (10–20 times) to human ACE-2 is the most contagious and virulent form (Figure 1)[13,14].

IMPACT OF RISK FACTORS AND COMORBIDITIES ON THE CLINICAL OUTCOME OF COVID-19-INFECTED PATIENTS

Previous studies[15-29] have indicated and correlated the risk and severity of COVID-19 illness in patients with comorbidities and compared these patients to those without comorbidities. Therefore, triage is carried out by carefully reviewing the medical history of COVID-19 patients, as this will help to distinguish patients according to their prognoses. Patients with COVID-19 who have any associated comorbidities are at high risk and should be treated with extra caution in an intensive care unit (ICU) facility if needed.

There is an urgent need to consider severe clinical comorbidities to improve risk stratification and strategic planning for COVID-19 patients. Based on the knowledge and clinical experience currently available, older people and people of all ages with severe underlying medical conditions, such as diabetes, cardiovascular disease, pulmonary disorders, and renal malfunction, could be at higher risk of acute disease following COVID-19[15].

In a retrospective study, Zhou *et al*[16] found that advanced age, higher rates of sepsis-related organ failure assessment score, and high d-dimer at enrolment were risk factors for the deaths of COVID-19 adult patients[16]. In the sex-based comparison, there were more male than female patients. This inequality indicates that women have more robust innate and adaptive immune responses[17,18]. However, this observation may also be due to occupational risk factors for men in Huanan's wet market[19].

According to some studies[20-23], the most prominent comorbidity with COVID-19 infections was hypertension (14%-30%) and diabetes (6%-19%), followed by cardiovascular diseases such as acute cardiac injury or failure (4%-8%) and respiratory system diseases such as pulmonary hypertension and chronic obstructive pulmonary

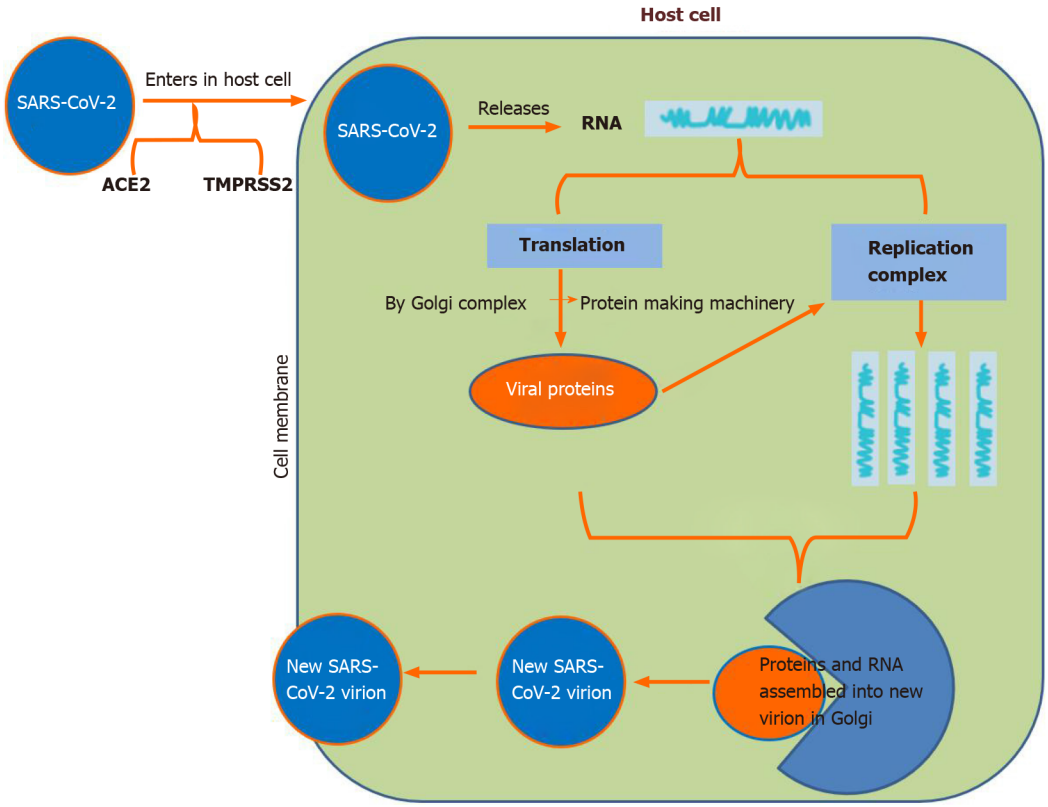


Figure 1 Spike protein on the virion binds to angiotensin-converting enzyme-2 (cell surface protein), transmembrane protease serine-2, an enzyme that helps the virion enter and release virion RNA. Some RNA is translated into proteins by the cell machinery; some of these proteins form replication complexes to make more RNA. The proteins and RNA assemble into a new virion in the Golgi and are finally released. ACE-2: Angiotensin-converting enzyme-2; SARS-CoV-2: Severe acute respiratory syndrome coronavirus-2; TMPRSS-2: Transmembrane protease serine-2.

disease (COPD) (1%-3%)[20-23]. Among these comorbidities, hypertension is associated with an almost 2.5-fold higher risk of severe illness or death with SARS-CoV-2 infections. According to Schiffrin *et al*[24], there is no evidence to date that hypertension is related to COVID-19 outcomes. In COVID-19 patients, people with diabetes present poor outcomes; however, the susceptibility to COVID-19 infection in diabetic patients may not be more significant[25]. Because of a lack of clinical evidence, current guidelines from the European Cardiology Society also strongly recommend that patients use their typical diabetic/antihypertensive medications as usual in the COVID-19 pandemic situation[26]. In a comprehensive meta-analysis, Lippi and Henry[27] showed that COPD is associated with more than a fivefold elevated risk and severity of COVID-19 infection; thus, patients with COPD must be advised to take more effective measures to prevent from becoming infected with COVID-19. Patients with chronic cardiovascular disease are among the individuals at highest risk for severe COVID-19 disease and death from acute cardiac injury or failure[20]. According to Li *et al*[28], patients with prior cardiovascular and metabolic disorders may face a higher risk of COVID-19 infection with a poor prognosis due to sudden morphological and hemodynamic damage to heart tissues.

Similarly, patients with chronic musculoskeletal disorders may also be at high risk of COVID-19 infection. This might be due to impaired immunity because of prolonged use of corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs) in daily life.

However, the main limitation to properly assessing the comorbid risk with COVID-19 is self-reporting on admission, mainly due to lack of awareness. Moreover, underreporting of comorbidities might be a significant confounding factor affecting the strength of association with poor prognoses. Thus, more controlled and well-designed studies with large sample sizes are needed to explore their associations in a more reliable way.

MUSCULOSKELETAL ANOMALY DURING SEVERE COVID-19 INFECTION

The number of COVID-19 patients is increasing dramatically worldwide. It is necessary to discriminate between patients with mild and severe cases of COVID-19 to prevent overburdening the ICU and to timely triage severely ill patients. In severely ill patients with COVID-19, due to prolonged pulmonary malfunction, chronic hypoxic conditions develop.

Compared to other body organs, the musculoskeletal system is more adaptive to hypoxic situations due to special muscle fibers (intermediate muscle fibers). However, the WHO recently declared that some musculoskeletal-associated symptoms (14.8%) are related to severe COVID-19 infection, including myalgia or arthralgia[29]. Hypoxia-inducible factor (HIF) studies in skeletal muscles are complicated due to various energy metabolism mechanisms, including various O_2 supplies and homeostasis and varying proportions of oxidative, glycolytic and intermediate fibers [30]. This section discusses the downflow changes of severe COVID-19-infected patients with the initiation of musculoskeletal-associated symptoms.

In severe COVID-19 patients, the low oxygen level in skeletal muscles may lead to the formation of excess lactic acid because of muscle pain (myalgia), a low pH level (cramps) or other related complications. Furthermore, in chronic hypoxic conditions, muscle tissue shows a significant alteration in gene regulation[29]. The HIF family plays a crucial role in the hypoxic response of the musculoskeletal system, similar to other tissues[29]. HIFs are heterodimeric transcriptional regulatory factors comprised of unstable HIF-α and HIF-β subunits. HIF signaling contributes to an adaptive pathway to minimize the oxygen requirement and increase the oxygen supply to achieve a new equilibrium. The cellular level of HIF-α is oxygen-dependent and conditionally balanced by proteasomal degradation (normoxia)[31-34].

As seen in severe COVID-19 patients in chronic hypoxic conditions, the low oxygen level inactivates the prolyl hydroxylase action and constrains HIF-α hydroxylation. Subsequently, stabilized HIF-α binds with HIF-β to form a stable dimer. This dimer enters the nucleus and transactivates target genes by directly stimulating the expression of fibrogenic factors. It affects signaling pathways, including the transforming growth factor-β/Smad, Notch, phosphoinositide 3-kinase/Akt, and nuclear factor kappa B pathways, to further affect various biological and pathological processes, ranging from fibrosis and skeletal muscle wasting angiogenesis, erythropoiesis, cell proliferation, inflammation, and apoptosis[30,32-38]. These hypoxic conditions induce altered gene regulation that may lead to more pronounced initial musculoskeletal symptoms, such as myalgia (which may be due to excess lactic acid production), arthralgia (which may be due to inflammation), and other musculoskeletal abnormalities (such as lower back pain and cervical pain), that ultimately indicate the severity of COVID-19 in patients (Figure 2). Apart from associated symptoms and inadequate peripheral oxygen saturation levels, several laboratory parameters such as low lymphocyte count and elevated C-reactive protein, D-dimers, interleukin 6, ferritin and cardiac troponin may also indicate the severity or poor prognosis of COVID-19 patients. The clinician should consider these parameters in prioritizing risk stratification and admittance to the ICUs of COVID-19 patients[38]. Additionally, these alterations in blood parameters might directly or indirectly affect musculoskeletal physiology. However, further research needs to delineate the possible musculoskeletal pathophysiology mechanism.

COVID-19 IN MUSCULOSKELETAL MANIFESTATIONS

As already discussed, the effect of comorbidities on the outcome of COVID-19 is well observed, but information that highlights the chronic musculoskeletal comorbid condition is not currently available. Many questions remain, such as "Do musculoskeletal comorbidities worsen the prognosis of COVID-19 patients?" Whether these comorbidities are a prominent risk factor for COVID-19 infections remains a dilemma to date. This may alter the natural course of the disease.

It is also a matter of concern that most musculoskeletal patients are either middle-aged or elderly persons with a history of taking corticosteroids or NSAIDs for a long time to control pain and relieve localized inflammation[39]. A long-term history of taking these medications may result in a weaker immune system and make these individuals more susceptible to any infection , including COVID-19 infections. Thus, corticosteroids or NSAIDs may alter the clinical picture of these patients. The use of methylprednisolone causes delayed viral shedding in SARS-CoV2 and MERS-CoV and

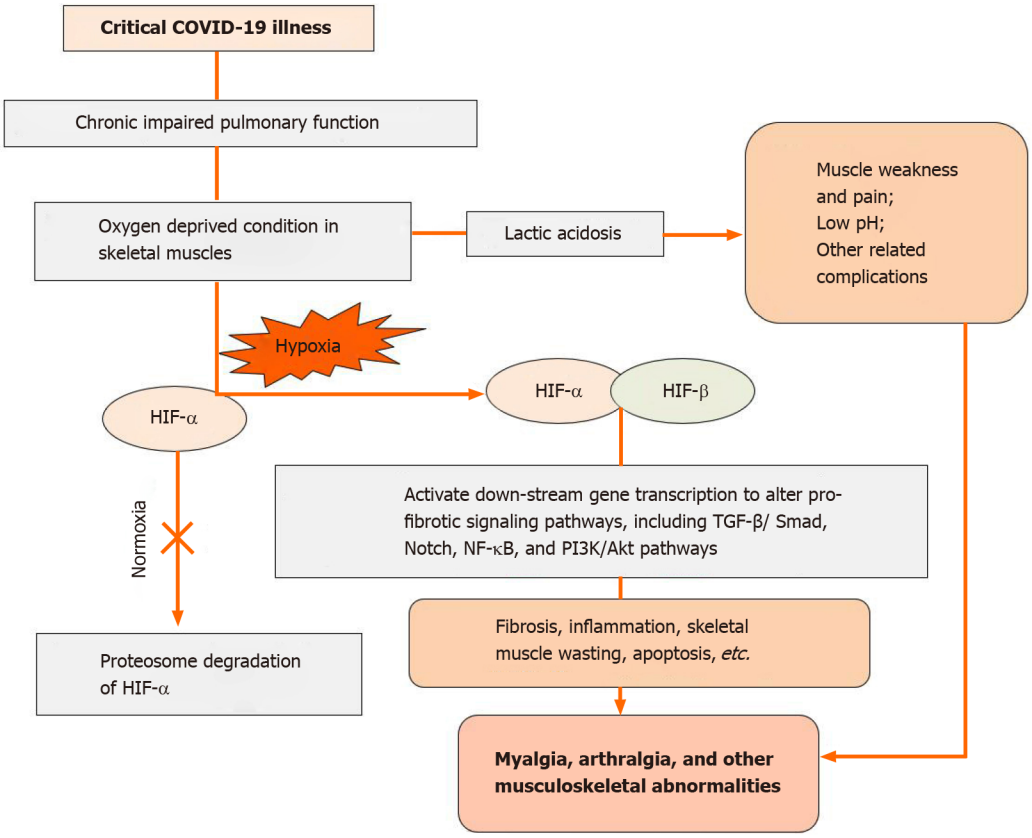


Figure 2 Tentative representation of musculoskeletal anomalies during severe coronavirus disease 2019 infection. COVID-19: Coronavirus disease 2019; HIF: Hypoxia-inducible factors; NF-κβ: Nuclear factor-kappa beta; PI3K: Phosphoinositide 3-kinase; TGF-β: Transforming growth factor β.

avascular necrosis and psychosis related to SARS-CoV. It was also observed that using methylprednisolone can increase mortality in influenza infections[40]. Thus, the WHO currently does not advise the use of any corticosteroids during COVID-19 infection unless they are associated with acute respiratory distress[41]. A previous human study showed that intraarticular steroid application significantly diminished the effectiveness of the influenza vaccine, and patients became more susceptible to viral streaming[42]. However, to date, no research paper explicitly focusing on intraarticular steroid administration in the COVID-19 pandemic situation is available, but the WHO advises not using steroids/NSAIDs unless the patient is in acute respiratory distress syndrome[29].

The current advice is to use mild analgesics and antipyretics such as paracetamol to treat symptoms such as fever and pain[43]. Corticosteroids or NSAIDs may cause significant release of specific cytokines, termed "cytokine storms," and could lead to multiple organ failure. Taking these drugs at the initial stages of COVID-19 may lead to more severe respiratory or cardiac complications with altered disease outcomes.

Again, the problem is not limited to the current COVID-19 pandemic. It is assumed that musculoskeletal disorders will worsen during the post-pandemic situation. According to the WHO[30], musculoskeletal disorders are the world's most significant contributor to disabilities, with low back pain being the single most significant global cause of disabilities. Severe COVID-19 infection affects muscle tissue (proposed pathway given in the previous section), leading to pain, muscle weakness, myalgia, arthralgia and other musculoskeletal issues. In recovered COVID-19 patients, these musculoskeletal disorders may persist for a longer duration and significantly affect their mental health and socioeconomic loss, as well as place an extra burden on treatment centers. The altered musculoskeletal physiology induced due to severe COVID-19 infection may also increase the chance of many bony pathologies or fractures. Therefore, it is clear that in post-pandemic circumstances, apart from patients with regular musculoskeletal disorders, recovered COVID-19 patients with musculoskeletal anomalies will dramatically increase.

CONCLUSION

This COVID-19 outbreak has challenged the health care infrastructure and socio-economic balance worldwide. In addition, it was assumed that the severity of COVID-19 infection significantly affects many associated musculoskeletal disorders. Therefore, it is necessary to improve the overall health care system and revise related comprehensive guidelines for every specialty to better prepare providers, especially those in orthopedics, to cope with the effects of post-pandemic COVID-19 and future pandemics.

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MINIREVIEWS

Hip prosthetic loosening: A very personal review

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Abstract

Hip prosthetic loosening is often difficult to detect at an early stage, and there has been uncertainty for a long time as to when the loosening occurs and thus to the basic causes. By comparing different diagnostic methods, we found that loosening is best defined as prosthetic migration and measured by radiostereometric analysis. Convincing evidence indicates that poor interlock, poor bone quality, and resorption of a necrotic bone bed may initiate loosening during or shortly after surgery; this forms the basis of the theory of early loosening. Biomechanical factors do affect the subsequent progression of loosening, which may increase subclinically during a long period of time. Eventually, the loosening may be detected on standard radiographs and may be interpreted as late loosening but should to be interpreted as late detection of loosening. The theory of early loosening explains the rapid early migration, the development of periprosthetic osteolysis and granulomas, the causality between wear and loosening, and largely the epidemiology of clinical failure of hip prostheses. Aspects discussed are definition of loosening, the pattern of early migration, the choice of migration threshold, the current understanding of loosening, a less exothermic bone cement, cemented taper-slip stems, a new exciting computed tomography-based technique for simpler implant migration studies, and research suggestions.

Key Words: Hip prosthesis; Prosthesis failure; Radiostereometric analysis; Bone resorption; Bone cements; Radionuclide imaging

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Core Tip: Much evidence indicates that prosthetic loosening is initiated during or shortly after surgery. The prosthetic micromovements may increase subclinically during a long period of time. Eventually, the loosening may be detected on standard radiographs and may be interpreted as late loosening but should to be interpreted as late detection of loosening. The discussion includes the definition of loosening, the pattern of early migration, the choice of migration threshold, the current understanding of loosening, a less exothermic bone cement, cemented taper-slip stems, a new exciting

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INTRODUCTION

Hip arthroplasty is one of the most successful of all orthopedic operations, but the results do deteriorate with time because of loosening. Radiographic changes indicating loosening are often difficult to detect at an early stage, and there has been uncertainty for a long time as to when the loosening occurs and thus to the basic causes. Confusion also arose because some hips with obviously loose prosthetic components are not painful[1-3]. To solve these issues, a few steps are required. First, the definition of loosening must be clarified. Second, the loosening must be carefully followed from its earliest detection. Third, the most important triggering factors must be identified, as well as other factors that affect the subsequent progression of loosening. Then the simplest scientific explanation that fits the evidence should be chosen.

DEFINITION OF LOOSENING

When I, as a newly graduated orthopedic surgeon in the early 1980s, started studying hip prosthetic loosening in Lund (in Southern Sweden), the diagnosis of loosening was based on insensitive radiographic criteria (periprosthetic radiolucent lines wider than 2 mm, prosthetic migration exceeding 4 mm, cement fracture, *etc*.). Several poorly defined terms were used, such as allergic loosening, aseptic loosening, mechanical loosening, progressive loosening, and reactive loosening – all without clear distinctions between each other.

Radiostereometric analysis (RSA) was introduced in Lund in 1974 by Göran Selvik (1938–1990). It is a technique for obtaining reliable three-dimensional measurements from radiographs and is based on implantation of tantalum bone markers, roentgen calibration equipment, and rigid-body kinematic analysis[4,5]. RSA was mainly used for studies of various bone growth disorders but was also found feasible for the study of hip prostheses[6,7].

My tutor, Lars Ingvar Hansson (1937–1987), advised me to use RSA to look for any pattern in loosening. We used analog films measured with a photogrammetric instrument and assessed (by double examinations) the limit for significant migration along the longitudinal axis to be 0.2 mm. However, later RSA studies have reached a detection limit of 0.08 mm when using fully digital technology[8,9]. By comparing contrast arthrography[10,11], radionuclide arthrography[12,13], bone scintigraphy (^{99m}Tc-MDP)[14,15], and RSA (comprising both instability under load and migration with time) in 14 painful hip arthroplasties, we found that loosening is best defined as migration[16]: All prosthetic components unstable by RSA, or with abnormal arthrogram, or with increased bone scintigraphic activity, or loose at revision were migrating, but no non-migrating components demonstrated any of these signs of loosening. Interestingly, increased activity at the tip of the femoral component by bone scintigraphy (Figure 1) had high sensitivity and specificity in detecting loosening, which was also pointed out earlier[14,15].

PATTERN OF EARLY MIGRATION

To study early prosthetic migration, RSA was performed prospectively on cemented primary hip arthroplasties in two series followed for 2–3 years after surgery[17,18]. Taking these two studies together, we found that 19 of the 36 acetabular components migrated cranially and seven of the 34 femoral components migrated distally during



Figure 1 Focally increased activity at the tip of a migrating femoral component at ^{99m}Tc-MDP scan. From Mjöberg *et al*[16] with permission.

the observation period (two femoral components in the latter series[18] were excluded due to insufficient tantalum bone markers); and that in all the cases, but three (two acetabular and one femoral), migration was detected within 4 mo after surgery (Figure 2). We also did not find any correlation between wear and early migration of either prosthetic component[19]. We concluded: (1) That RSA may distinguish between a migrating and a non-migrating prosthetic component within 4 mo after surgery; (2) That the initial migration may be caused by insufficient initial fixation or by resorption of a necrotic bone bed formed due to the heat from curing cement but not by wear products; and (3) That "late loosening" may be the result of late detection rather than of genuine late onset of loosening.

HIGH OR LOW MIGRATION THRESHOLD?

Many RSA studies of hip prostheses have now shown that early migration poses a risk of future failure[9,20-24]. This does not mean that all early migrating components will fail in the foreseeable future. Indeed, certain early migrating uncemented femoral components appear to achieve stability during the healing period[25-27], but it does mean that the failing prosthetic components are recruited from the group of early migrating components.

Some authors have determined a high migration threshold to predict an unacceptably high risk of future clinical failure, *e.g.*, 1.2 mm and 2.6 mm distal migration after 2 years for cemented composite-beam femoral components to predict a revision rate exceeding of 50% and 95%, respectively, within 7 years[20]. As far as I know, no migration threshold values have yet been published for either cemented taper-slip or uncemented femoral components[23].

Others have determined a low migration threshold below which an early migration poses no or almost no risk of future failure, *e.g.*, 0.2 mm cranial migration after 2 years for acetabular components[22] and 0.15 mm distal migration after 2 years for cemented composite-beam femoral components[23] to predict a revision rate of less than 5% within 10 years. Between these extremes (2.6 mm and 0.15 mm), of course, there is a large gray zone. The choice of migration threshold depends on the purpose. In my opinion, a high probability of permanent prosthetic fixation is a more advantageous prediction.

CURRENT UNDERSTANDING OF LOOSENING

Inadequate preparation and cementing technique were probably the main causes of loosening during the pioneering years and greatly reduced rates of loosening were demonstrated after improved technique[3,28-30]. Convincing evidence from both clinical and experimental research indicates that the initial fixation may be insufficient

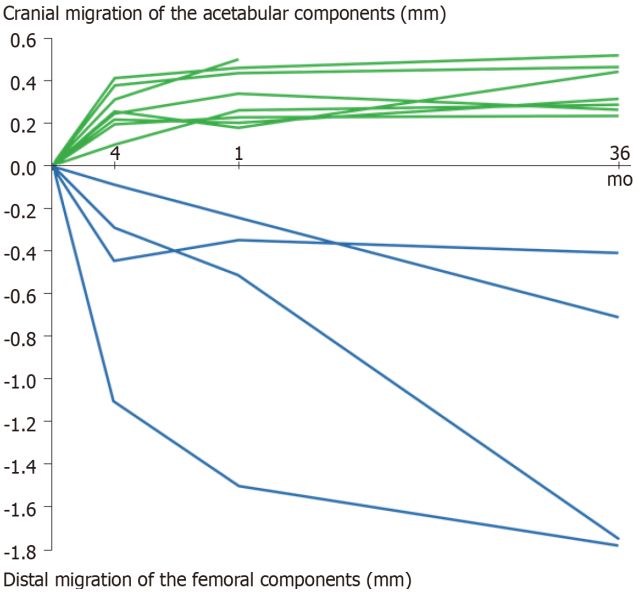


Figure 2 Prosthetic migration along the longitudinal axis. Migration of the migrating eight acetabular (green) and four femoral components (blue) in the series followed by radiostereometric analysis for 3 years [eight acetabular and ten femoral components did not pass the limit (0.2 mm) for significant migration]. From Mjöberg *et al*[18] with permission.

due to poor interlock (inadequate cement filling, interposition of tissue debris, *etc.*)[31-34] or because of poor bone quality (osteoporosis, rheumatoid arthritis, *etc.*)[35-38]. Adequate initial fixation does, however, not eliminate the risk of loosening; resorption of a layer of a necrotic bone bed may result in early loss of otherwise optimal fixation [39,40].

The theory of early loosening[41,42] postulates (the hypothetico-deductive method) that loosening is initiated during or shortly after surgery by these factors alone: Insufficient initial fixation (poor interlock or poor bone quality) or early loss of fixation (resorption of a layer of a necrotic bone). Interestingly, the resorption of necrotic bone can be inhibited with a bisphosphonate during the healing period, which reduces early migration[43] and consequently increases the mean prosthetic survival time[44].

If initiated, the progression of loosening is affected by the degree of early instability, the bone quality, and by the magnitude of the mechanical stresses to which the prosthetic components are exposed during normal daily activity. Thus, femoral components with a high offset[24] or in a varus position[3,34] can be expected to be over-represented among prosthetic failures due to faster increase in the micro-movements of the components in which loosening has been initiated. Similarly, acetabular components that are eccentric (due to design[45] or wear[46]) or have high frictional torque (*e.g.*, metal-on-polyacetal[46] or metal-on-metal articulations[47,48]) can for purely biomechanical reasons be expected to be overrepresented among prosthetic failures. However, such individual components (*e.g.*, femoral components with a high offset or in a varus position) can, if loosening has not been initiated, be well-fixed[3].

The micromovements of a loosened prosthetic component may cause devitalizing spikes of high fluid pressure in the periprosthetic interstice, which can induce osteolysis[49-51] by a complex series of inflammatory responses to the damage-associated molecular patterns of the generated necrotic cells and cell fragments[52]. The periprosthetic fluid may be forced further into the bone (Figure 3), devitalizing the bone tissue that is resorbed, and form a focal osteolysis that is invaded by granulation tissue[54]. The prosthetic micromovements and the subsequent periprosthetic osteolysis may increase subclinically during a long period of time.

The theory of early loosening explains the rapid early migration (Figure 2), the development of periprosthetic osteolysis and granulomas (Figure 3), the bone loss commonly seen in the proximal femur of distally apparently well-fixed stems, the causality between wear and loosening, and largely the epidemiology of clinical failure of hip prostheses[41,42]. But as always, if new data emerge that contradicts the predictions of the theory, the theory must be supplemented or replaced with a more complete theory.

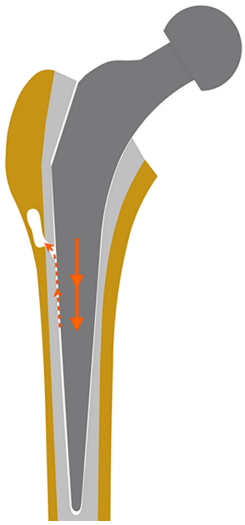


Figure 3 Graph shows how prosthetic micromovements cause a focal osteolysis. The prosthetic micromovements (orange arrows) pump joint fluid under high pressure (orange dashed arrows) from the gap between the stem and the cement through a defect in the cement mantle. The pressure waves may devitalize the adjacent bone tissue, which is resorbed, thus causing a focal osteolysis. From Mjöberg[53] with permission.

THE COOLFIX CEMENT

The specific heat production is directly proportional to the amount of monomer in the cement dough: 556 J/g monomer[55]. A low-monomer bone cement, Coolfix, was developed in the mid-1980s that produced less heat and less evaporating toxic monomer during the polymerization. The basic idea was to minimize the interspaces between the powder beads (which are filled with the liquid monomer) by a *bimodal particle size distribution*: 20 mL of liquid monomer was mixed with 70 g of Coolfix powder (instead of just about 40 g of a conventional bone cement powder). The temperature rise of Coolfix was (as expected) two-thirds of that of a conventional bone cement. The compressive strength was about 85% compared to Palacos R, probably due to the fact that the cement was made too dry (*i.e.* unsaturated) in the ambition to reduce the amount of liquid monomer. Therefore, this prototype Coolfix cement had a high viscosity and was more difficult to handle, especially in the acetabulum. The initial migration of the components in 24 hip prostheses was studied using RSA following randomized use of Coolfix and Palacos R[56]. After 1 year, five of the 12 acetabular components with Palacos R had migrated 0.4–0.7 mm, while all 11 acetabular components with Coolfix (one acetabular component with Coolfix was excluded due to insufficient tantalum bone markers) had migrated less than 0.3 mm (Figure 4). Only one femoral component (with Palacos R) had migrated significantly by then (0.4 mm distally).

An improved composition of Coolfix (the PMMA powders were purchased from Röhm GmbH, Darmstadt, Germany) was developed (Table 1), which had several attractive properties in addition to being less exothermic than a conventional bone cement: The improved cement was easily modeled and non-sticky, had a short mixing time, and smelled less. Unfortunately, the leadership of the Department of Orthopedics, Lund University Hospital, suddenly did not allow further clinical trials unless highly extended preclinical tests after vacuum mixing of the cement were performed; in practice, the project was stopped, and shortly afterwards I left Lund (but after my retirement and after a new department leadership had taken office in Lund, I became affiliated with the Department of Orthopedics, Lund University, once again). The improved Coolfix cement was never clinically tested.

Later, another low-monomer cement (Cemex Rx) was marketed, where, unlike Coolfix, the smallest particles in the powder had been removed. However, compared to Palacos R, no significant difference was achieved in either curing temperature[57] or prosthetic migration[57,58].

CEMENTED TAPER-SLIP STEMS

The continuous migration of taper-slip stems has been reported to be consistent with

Table 1 Coolfix powder composition 70 g

Plexidon M489 (300–500 μm)	32.0 g
Plexidon M527 (30–60 μm)	22.3 g
Plexigum M914	6.3 g
Benzoyl peroxide	0.6 g
Zirconium dioxide	8.8 g

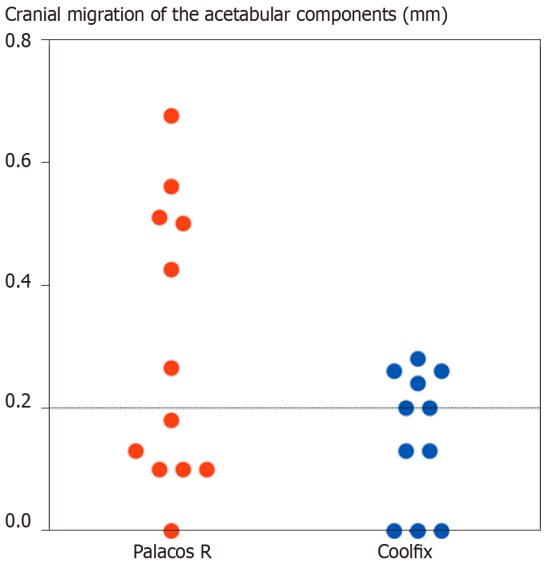


Figure 4 Cranial migration of the acetabular components after 1 year. By then, six of the 12 with Palacos R and four of the 11 with Coolfix had passed the limit (0.2 mm) for significant migration. However, five acetabular components with Palacos R had migrated 0.4–0.7 mm, while all 11 with Coolfix had migrated less than 0.3 mm ($P < 0.04$, Student's *t*-test, one-tailed).

good long-term clinical results[59-62] and has even been considered beneficial by contributing to secure fixation[59,61]. But does continuous migration really contribute to secure fixation? Or otherwise expressed: How much can a stem migrate distally without failing[63]?

The Exeter THA has, according to *the Nordic Arthroplasty Register Association database* (consisting of 100000 s hip arthroplasties)[64], a survivorship fairly on par with the Lubinus THA of up to about 10 years, but afterwards, its failure rate increases faster (Figure 5).

A plausible explanation is as follows: In cases of considerable subsidence, the self-locking effect of a cemented tapered stem declines because the stem and cement mantle no longer fit well together. A play space arises around the stem, and the micromovements of the loosened stem induces periprosthetic osteolysis (due to inflammatory responses to the damage-associated molecular patterns of the necrotic cells and cell fragments generated by devitalizing spikes of high periprosthetic fluid pressure from the unstable stem). When the cement is no longer sufficiently supported by the surrounding bone, the cement mantle will crack and the stem instability will increase, resulting in a rapid subsidence[60] and ultimately a fracture of the stem[65] or a fracture of the proximal femur[66,67].

No significant prosthetic migration is safer in the long run than good 10-year clinical results!

EXCITING NEW TECHNIQUE AND RESEARCH SUGGESTIONS

The recently developed low-dose computed tomography-based implant motion analysis has been shown to have an accuracy and a precision on par with RSA; this measuring method (without the need for bone or implant markers and specialized RSA equipment) "opens up the possibility for simpler implant migration studies"[68-70]. Very exciting technique! Maybe this is a future golden standard for implant

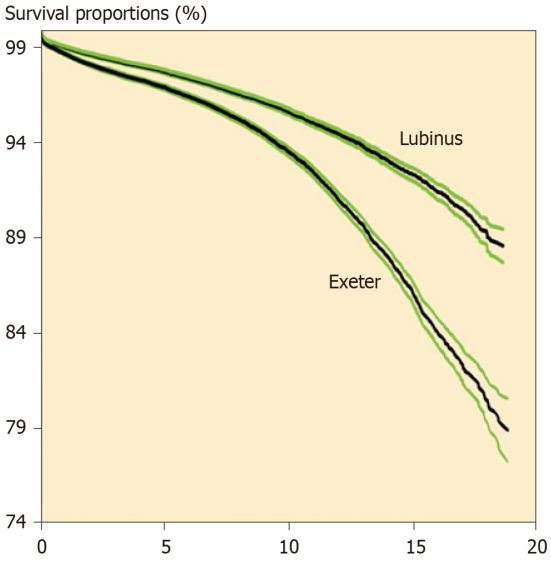


Figure 5 Kaplan-Meier implant survival of cemented total hip devices. Calculated from the Nordic Arthroplasty Register Association database. Green lines are upper and lower 95% confidence limits. Compiled from Junnila *et al*[64] with permission.

motion analysis?

The less heat production and less evaporating toxic monomer during the polymerization, the more the risk of superficial bone necrosis adjacent to the Coolfix cement is reduced. A locally applied bisphosphonate inhibits the resorption of necrotic bone during the healing period[41]. The synergistic effect of this combination (the Coolfix cement and a locally applied bisphosphonate) should increase the probability of permanent prosthetic fixation. Although the improved Coolfix cement, unlike a chemically modified bone cement, after curing is chemically equivalent to conventional bone cements and should have similar mechanical properties, a preclinical characterization is required prior to a clinical trial.

Bone scintigraphy (^{99m}Tc-MDP) is extremely sensitive but generally non-specific for diagnosing loosening[71]. The scan is usually normalized within 6–9 mo after surgery [14], indicating that the healing period is over and that the prosthesis has become osseointegrated. Persistent uptake beyond 1 year represents increased bone turnover and bone perfusion – and probably continuous prosthetic migration. However, no prospective RSA study has been combined with scintigraphy, which would be interesting from both a pathophysiological and diagnostic point of view.

In contrast to the many RSA studies of hip prostheses that have shown that early migration poses a risk of future failure (the larger the early migration, the greater the risk of future failure)[9,20-24], some RSA studies indicate (as mentioned earlier) that certain uncemented femoral components appear to achieve stability during the healing period despite significant early migration[25-27]. However, do these femoral components, as suggested in these studies, really become osseointegrated or do some of them continue to migrate very slowly? Bone scintigraphy could probably tell.

CONCLUSION

Hip prosthetic loosening is often difficult to detect at an early stage. When loosening is eventually detected on standard radiographs it may be interpreted as late loosening but should be interpreted as late detection of loosening, initiated during or shortly after surgery by insufficient initial fixation or by early loss of fixation.

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MINIREVIEWS

Jones type fifth metatarsal fracture fixation in athletes: A review and current concept

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Abstract

Jones type fifth metatarsal fracture is a common occurrence among athletes at all levels. These fractures may occur due to several mechanisms, but inversions and twisting injuries are considered some of the leading causes in sports. However, while Jones fracture incidences are frequent in the sporting world, there is still a lack of consensus on how such fractures should be effectively managed. There are numerous treatment options for patients with fifth metatarsal Jones fractures. The role of nonoperative treatment remains controversial, with concerns about delayed union and nonunion. Surgical stabilization of metatarsal Jones fractures is therefore often recommended for athletes, as it is often associated with a low number of complications and a higher rate of union than nonoperative management. This review will focus on literature regarding the prevalence of Jones type fifth metatarsal fracture, alongside the efficacy of both conservative and surgical treatment within this population.

Key Words: Athletes; Surgery; Fifth Metatarsal; Jones fracture; Rehabilitation; Fracture

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Core Tip: Jones type fifth metatarsal fractures are a common injury among athletes. However, there remains a lack of consensus on the effective management of such fractures, especially in a demanding population group where time is often of the essence. Treatment recommendations often depend on the location and understanding of the fracture in addition to the patient's underlying state of health and other factors

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that influence surgical risk and outcome. The role of nonoperative treatment is still controversial, but surgical stabilization of metatarsal Jones fractures is often recommended for athletes and other high-demand population groups.

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INTRODUCTION

Jones type fifth metatarsal fractures are a common occurrence among athletes at all levels. These fractures may occur due to several movement mechanisms, but inversions and twisting injuries are considered some of the leading causes in sports. However, while this fracture type occurs frequently in the sporting world, there is still a lack of consensus on how such fractures should be effectively managed, especially in an industry where time is often of the essence. Treatment recommendations often depend on the location and understanding of the fracture anatomy in addition to the patient's underlying health. Several research studies have demonstrated that nonoperative treatment pathways can be used successfully in these types of fractures, although concern exists about delayed and nonunion fractures. This remains a controversial area. Surgical treatment is often recommended for athletes, as it is often associated with a low number of complications and a higher rate of union than nonoperative treatment. This review focuses on defining this fracture subtype and the efficacy of both operative and nonoperative treatment options. Operative intervention is further evaluated primarily with respect to screw *vs* plate fixation techniques.

OVERVIEW OF THE TYPES OF FIFTH METATARSAL JONES FRACTURES

Jones fracture was first described in 1902 by Sir Robert Jones as a unique type of fracture of the base of the fifth metatarsal; he described this fracture as being 1/3 inch from the base[1]. Statistically, metatarsal fractures account for a significant proportion of foot injuries, comprising 35% of fractures within the foot region and approximately 5%-6% of all skeletal injuries, with an estimated incidence of 6.7 per 10000 individuals [2]. In the normal adult population, females tend to sustain the injury more than males at a ratio of 2:1; however, in sports, which are primarily dominated by males, these injuries are more common among males[3-5]. In their review of foot injuries among athletes, Boutefnouchet *et al*[3] noted that these fractures are 10 times more likely to occur in males, with a mean age of 26 years. In this case, the high prevalence of these injuries in the sporting world was attributed to the strenuous nature of activities, resulting in the application of specific stresses within this region, such as during jumping, running, and tackling.

Anatomically, fifth metatarsal fractures are classified into two groups. According to Sarpong *et al*[2], the two groups to which these fractures belong are proximal and distal fractures. This classification is based on the fractures' healing potential as dictated by the blood supply to the affected zones. The blood supply to the proximal fifth metatarsal was first investigated by Bowes and Buckley[6], using a cadaver model for the study. Their findings discovered that blood supply within this region emanates from three possible sources: the nutrient artery, metaphyseal perforators, and periosteal arteries.

Expansion of the classification system by Torg *et al*[7] resulted in the simplification of how proximal fifth metatarsal fractures are classified. Bowes and Buckley noted that this simplification resulted in the proximal diaphysis distal classification as tuberosity, which made it part of the Jones fracture[6]. Under this system, three categories of Jones fractures emerge: Type I (acute proximal metatarsal fracture), Type II (delayed union proximal metatarsal fracture), and Type III (nonunion proximal metatarsal fracture).

Type I (acute proximal metatarsal fracture)

Type I fractures feature a fracture line and lacks intramedullary sclerosis differentiation. According to many researchers[8-11], the history of injuries in this group should include no history of a previous fracture. However, in some cases, patients may report the existence of previous pain. In other words, at the location of previous pain, the fracture is often presumed to be Type I, and due to the pain being on the lateral cortex, patients often experience limited movement.

Type II (delayed union) proximal metatarsal fracture

As noted by Do *et al*[8], Cheung and Lui[9], Saluta *et al*[12], Type II fractures are different from Type I due to the presence of an earlier injury that is characterized by a widened fracture line and the presence of intramedullary sclerosis.

Type III (non-union proximal metatarsal fracture)

Type III fractures' distinguishing features include a "complete obliteration of the medullary canal by sclerotic bone with a history of repetitive trauma and recurrent symptoms"[6]. In other words, this type of fracture contains a complete disconnection of the adjacent bones, and the treatment of this type of fracture often requires corrective surgery (Table 1).

ANATOMY AND PATHOPHYSIOLOGY OF FIFTH METATARSAL FRACTURES

Understanding foot anatomy is crucial in evaluating an effective treatment plan for athletes with Jones fractures. The fifth metatarsal is distinguished from other lesser metatarsals by the presence of a tendon insertion at the base comprising the peroneus brevis, which inserts dorsally on the proximal tubercle, and the peroneus tertius, which dorsally inserts the diaphyseal junction[2]. In addition, the plantar fascia is attached to the tubercle.

The pathophysiology of fifth metatarsal fractures is mainly represented by acute trauma. According to studies by Do *et al*[8], the mechanism of pain in patients (athletes) with Zone 1 fractures is often experienced during supination with plantar flexion (rolling motion of the outside edge of the foot during a step), such as during pitching in baseball. This type of movement often results in a pull of the plantar fascia lateral band, which results in pain. In Zone 2, injuries often emanate from plantar flexing of the forefoot. In contrast, in Zone 3 injuries, the pain usually originates from repetitive trauma. In the case of athletes, it could be due to continuous pressure when a player jumps, runs, or tackles an opponent. Notably, according to a recent study by Benjamin *et al*[13], athletes with cavovarus feet are prone to repetitive trauma, which results in Zone 3 injuries. This study proposes the theory that the physical structure of an athlete's foot could be one of the significant determinants of Jones-type fracture prevalence.

Similarly, according to other studies, there is a relationship between cavovarus feet and the development of both Jones fractures and stress fractures in the fifth metatarsal. For instance, in their study, "The Cavovarus Foot and Its Association with Fractures of the Fifth Metatarsal," Fuchs *et al*[14] noted that patients with acute Jones fractures presented with radiographic hindfoot varus. Some studies have suggested that since Zone 2 and Zone 3 may exhibit similar characteristics, it is not necessary to differentiate between them. For instance, Sarpong *et al*[2] provides an example of distal diaphyseal fractures, which occur when excessive force is applied within a position of plantar flexion, and an inversion injury occurs. In athletes, such as sprinters or volleyball players, such an injury could occur during jumping, in which toes are used, or an inversion injury is sustained with the ankle in a fully plantar flexed position. In summary, these injuries among athletes are common, as most field actions involve a broad utilization of foot movements, resulting in stress to the fifth metatarsal.

TREATMENT

Treatment options for Jones type fifth metatarsal fracture are based on the zone of the injury, comorbidities of the injured patient, and — if a sub-acute presentation — radiographic signs of healing. Acute Zone 1 injuries are mostly treated conservatively with protected weight-bearing medical boots, such as the air cast variety, hard-soled

Table 1 Summary of fifth metatarsal fractures

Class	Description
Zone 1	(1) Proximal tubercle avulsion; (2) Long plantar ligament leads to a lateral band of the plantar fascia or the peroneus Brevis's contraction; (3) May extend into the Cubo-metatarsal joint; and (4) Nonunion is uncommon
Zone 2 (Jones fracture)	(1) Metaphyseal-diaphyseal junction; (2) Involves the fourth and fifth metatarsal articulation; (3) Vascular watershed area; (4) Acute injury; and (5) Increased risk of nonunion
Zone 3	(1) Proximal diaphyseal fracture; (2) Distal to the fourth and fifth metatarsal articulation; (3) Stress fracture in athletes; (4) Associated with cavovarus foot deformities. or sensory neuropathies; and (5) Increased risk of nonunion

shoes, or casts. These devices are designed primarily for a patient's comfort rather than fracture stability, and can therefore be discontinued when the patient feels the pain has subsided. Operative treatment modalities are not first-line pathways for patients with a Zone 1 injury. In contrast, the level of severity in Zone 2 and Zone 3 fractures tends to be higher than that in Zone 1 fractures and may have better outcomes with surgical management.

Compared with the general population, athletes often require different treatment types due to their specific injury patterns and higher demands. According to a study conducted by Japjec *et al*[15] on how athletes require different treatments of injuries to the fifth metatarsal, it was suggested that on average, nonoperative treatment pathways took as long as 20 wk to heal completely, which was not a feasible amount of time for both the players and their teams[15]. In their analysis, the researchers proposed a new classification of these injuries, which included metaphyseal (Zone 1 and the majority of Zone 2) and metadiaphyseal fractures (remnants of Zone 2 and Zone 3) (see Table 2). However, the exact anatomical boundaries within this classification are not clearly defined and need further research. Nonetheless, the study successfully demonstrated that given the frequency of fractures in athletes, surgical treatment plans are efficient in treating zone 2 and 3 fifth metatarsal Jones fractures.

An analysis of the efficacy of nonsurgical and surgical treatment plants was recently conducted in a virtual study by Mirza *et al*[16]. They aimed to analyze the outcomes within the different treatment pathways of patients with basal fifth metatarsal fractures[16]. Out of the 270 study participants, 73.6% had Zone 1 fractures, 22.2% had Zone 2 fractures, and 4.2% had Zone 3 fractures. The researchers concluded that conventional treatment methods for Zones 1 and 2 took longer to cure patients (12 wk) than surgical procedures (Zone 3), which reduced the healing time by 50%. These findings support following a surgical pathway from the outset in the treatment of athletes with fifth metatarsal Jones fractures.

SURGICAL TECHNIQUES

There are several operative techniques described in the literature for fifth metatarsal Jones fractures. The choice of technique utilized is primarily dependent on the characteristics of the fracture(s). The techniques described include intramedullary screws, closed reduction, and cross-pinning with K-wire (Kirschner-wire) fixation, bone grafting, and internal fixation with a mini fragment plate and screws[6,17,18]. We focus on comparing outcomes between fixation techniques that primarily utilize screws or plates.

Surgical techniques using screws

Surgical techniques are common among athletes due to the short time it takes to heal these fractures and the lower possibility of nonunion. Studies by Watson *et al*[19], Lareau *et al*[20], Willegger *et al*[21], and D'Hooghe *et al*[22] assert that intramedullary screws and aggressive rehabilitation protocols have become popular among professional athletes seeking to return to the field after experiencing Zone 2-3 fifth metatarsal Jones fractures[23,24]. According to these studies, this technique's main advantage is that it is minimally invasive in addition to the short healing time needed and the accelerated mobility. DeLee, Evans, and Julian were the first to demonstrate the efficacy of percutaneous intramedullary screw fixation in a 1983 study titled "Stress Fracture of the Fifth Metatarsal"[6,25,26]. The study focused on utilizing 4.5-mm malleolar screws in diaphyseal stress fracture fixation in 10 athletes in which they reported an average healing time of 7.5 wk. This healing time allowed for adequate time for rehabilitation and return to sporting activities.

Table 2 Stewart classification of Jones fracture[16]

Stewart classification	
Type 1	Extra-articular fracture between the metatarsal base and diaphysis
Type 2	Intra-articular fracture of the metatarsal base
Type 3	Avulsion fracture
Type 4	Comminuted fractures with intra-articular extension
Type 5	Partial avulsion of the metatarsal base with or without a fracture

There are currently various types of intramedullary screws in use by surgeons in the fixation of fifth metatarsal Jones fractures. Among the significant options of this technique include solid and cannulated screws, whose individual performance has been studied. For instance, Bowes and Buckey noted that cannulated screws offer better precision and ease of use when placed over a guidewire[6]. However, some studies have argued that cannulated screws present an increased risk of refracture.

Studies have also evaluated the subsequent failure of cannulated screws in delayed unions, nonunion, and acute Jones fractures. For instance, Bowes and Buckley noted that intramedullary screw fixation using 4.5-mm malleolar screws resulted in re-fracture and may cause delayed union or non-union in Jones fractures[6]. However, in a round table discussion by Carpenter *et al*[27] and recent studies by Bryant *et al*[28], O'Malley *et al*[29] and Tan *et al*[30], this method offers a higher rate of healing among athletes, with lower re-occurrence of fractures. Thus, based on this argument, it could be concluded that the utilization of larger diameters during surgery may help to prevent future fracture.

Surgical techniques using plates (plantar plate fixation)

An alternative to intramedullary screws in fixing Jones fractures is the plantar plate fixation surgical technique. Plantar plate fixation, as reported by Duplantier *et al*[31], Mitchell *et al*[32], Young *et al*[33], and Miller *et al*[34], describes the procedure of plantar plate fixation. Researchers note that the process involves the positioning of a contoured plate[19] across the fracture site, such that the locking holes are aligned on the proximal side (the oblong). In contrast, the remaining locking holes are aligned with the distal side of the injury. One of the noted advantages of the plantar plate fixation method in treating Jones fractures is that it offers stability to the broken bones, accelerating healing. In addition, the procedure provides one of the fastest ways of managing this type of fracture among athletes.

However, several studies on the advantages and disadvantages of plantar plate fixation techniques have indicated that the method presents some risks regarding nonunion and the possibility of injuries reoccurring in the same location. According to Bernstein *et al*[35] and Haslan *et al*[36], with tension-side plating, there have been cases of pain and persistent fracture nonunion, especially in the treatment of stress fractures among athletes. Furthermore, studies indicate that the procedure requires the addition of calcaneus autografts to optimize the healing process. According to Mitchell *et al*[32], previously reported risks associated with percutaneous calcaneal autograft harvesting are currently low. This finding has improved the performance of plantar plating fixation in the treatment of fifth metatarsal Jones fractures. In addition to the issues with biomechanical principles, the literature also suggests that plantar plating is associated with hardware prominence. According to Mitchell *et al*[32], hardware prominence typically occurs due to the surgeon's failure to confirm that the plate used is adequately aligned against the cortex of the bone. Failure to position the plate properly could also result in nonunion, irritation, and an increased risk of refracture. These risks for plantar plate fixation can be reduced by using low-profile screws and plates that are accurately contoured to the cortex. This ensures that the tension side of the fracture is stabilized[37]. Adoption of these techniques allows for plantar plating to be used with good outcomes in high-demand patients, such as athletes.

POST-OPERATION MANAGEMENT PROTOCOL

As mentioned above, surgical procedures might offer faster recovery among athletes who have suffered fifth metatarsal Jones fractures. Recovery takes an average of 3-4

wk, depending on the postoperative procedures[38]. To facilitate healing, specific protocols need to be followed. Watson *et al*[38] stated that postoperative rehabilitation can be divided into five phases, as illustrated in Table 3 and Figure 1.

POSTOPERATIVE COMPLICATIONS

Postoperative complications are common, and some are higher within the athlete population. The risk of injury to the sural nerve and its branches during procedures, such as intramedullary screw fixation, is well recognized. However, historically, injury to the sural nerve or any of its branches has not been reported as a significant postoperative complication arising from the fixation of Jones fractures[9]. Nonetheless, despite the lack of reporting, several studies have indicated the occurrence of unexplained postoperative pain and paraesthesia over the lateral aspect of the foot, which fails to subside even after the removal of the screw or the plate. In such cases, researchers have often concluded that the occurrence of such pain is a result of nerve damage from surgical intervention.

Failure to note the natural curvature of the bone during surgery has been considered a major cause of nerve injury after surgical treatment. As noted by Aynardi *et al*[39], despite the success of intramedullary screw fixation of the fifth metatarsal for metaphyseal-diaphyseal and diaphyseal fractures, the size, shape, and quality of the bone cortices are crucial in preventing surgical injuries to the lateral dorsal cutaneous nerve. According to the researchers, failure to consider the natural curvature of the fifth metatarsal bone during surgery could impede the placement of a guidewire, which can lead to intraoperative complications, such as nerve damage. Therefore, to reduce the risk of nerve injury, surgeons should ensure the proper entry point of the guidewire and screw with a correct trajectory within the medullary canal. This is best achieved by a proper understanding of the patients' specific bony anatomy.

Both delayed and nonunion are commonly attributed to the use of smaller screws in surgery. Watson *et al*[38] noted that delayed unions in Zone 2 and 3 fractures are often a result of choosing screws that are smaller than 4.5 mm in diameter. In the case of athletes, according to Wukich *et al*[40], it is advisable to use larger solid screws as a way of countering the higher amount of torsional stress directed towards the fracture site. Similarly, in the case of nonunion and refractures in Zones 2 and 3, Cheung and Lui[9] recommend treatment with medullary curettage and intramedullary screw fixation or inlay grafting. However, in this case, revision of the previous screw fixation that resulted in complications should be performed with larger diameter screws in addition to reaming of the medullary canal.

Other possible postoperative complications include wound infection, impingement by a prominent screw head, rupture of the peroneus brevis tendon, metatarsalgia, iatrogenic fracture of the metatarsal bone, and the screw missing the medullary canal. Cheung and Lui[9] summarized specific methods of avoiding and managing these complications. First, wound infection and tendon nerve injury can be avoided by careful soft tissue handling during surgery using implants with low profiles. Second, impingement by the screw head can be avoided by adequate countersinking of the cortex before the insertion of the screw and be further addressed by athletes using larger and spacious shoes. Third, screws missing the medullary canal can be avoided through the use of proper surgical techniques, choosing the correct implant, and having a proper understanding of the patients' bony anatomy. Last, the major cause of postoperative metatarsalgia is fibrosis of the joints and tendons adjacent to the site of the operation.

NON-SURGICAL TREATMENT

There are several nonsurgical treatment plans used for fifth metatarsal Jones fractures. These modalities vary by anatomical region of the fracture, patient history, and radiological findings[41-43]. Evidence-based medicine has assisted in the tailoring of individual treatment of metatarsal fractures. For example, as highlighted by several studies, some cases of nondisplaced and neck fractures of the fifth metatarsal are often treated nonoperatively. The preference to treat these injuries using nonsurgical options indicates that their level of severity is low. Examples of nonsurgical treatment options include walking casts, elastic dressings, rigid shoes, hard plastic cast shoes with weight-bearing, and posterior splints[44,45]. The effectiveness of these options depends on both the nature of the treatment option and the type of patient.

Table 3 Postoperative rehabilitation protocol for athletes

Phases of postoperative rehabilitation for fifth metatarsal Jones fractures	
Phase I	After surgery, the patient can toe-touch using weight-bearing medical aids, such as walking boots or crutches. Discontinuation of use of these aids depends on how fast an individual heals or when they can tolerate body weight. Patients are required to use bone simulators at least twice a day and perform four-way ankle-resisted exercises two times a day. These exercises include plantar flexion, dorsiflexion, inversion, and eversion[18]
Phase II	In this phase, the patient can tolerate his or her full weight and can now use a walking boot. Bone simulators and ankle exercises are limited to twice a day. Furthermore, the patient participates in training using underwater treadmills with sessions lasting approximately 20 min at a speed of between 2.5 and 3.0 mph. These parameters are adjusted per the ability of the patient to tolerate an increase. "By the end of Phase II rehabilitation, the patient should be able to do interval training for 20 min in waist-deep water. An example of an interval training protocol is as follows: 60 seconds at a 5-6 mph pace followed by a 90-s run at 7-8 mph with jet resistance at approximately 45%-60% weight bearing"[19,38]
Phase III	At this stage, walking boots are replaced with cross-training shoes with rigid or orthotic inserts. Patients are gradually introduced to single-calf exercises in combination with dorsiflexion stretching and single-leg proprioception training. Progression to full weight bearing is continued and managed using limited change of direction and position exercises. For at least two times a day, the patient is involved in bone stimulation and resistance ankle routines
Phase IV	Patients can use professional sporting shoes such as cleats or boots with rigid or orthotic inserts. Full-weight running is combined with drill works that feature a position-specific change of direction. Single-leg plyometric exercises are included. Additionally, the athlete is required to continue using "bone stimulator, resisted ankle exercises, single-leg calf raises, dorsiflexion stretching exercises, and single-leg plyometric exercises"[19,38]. This phase aims to facilitate a limited return to regular training
Phase V	The patient can now participate in full training. The bone simulator is used twice a day combined with a regular training routine until the patient is fully recovered

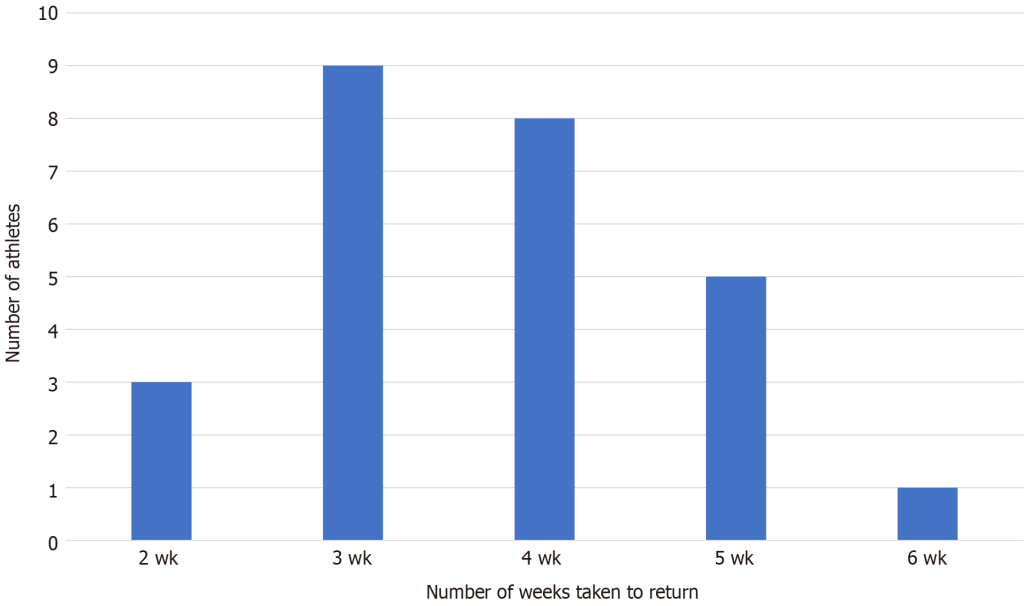


Figure 1 Number of athletes returning to play *vs* weeks in rehabilitation[38].

Recently, various studies have attempted to statistically analyze patients' satisfaction with nonoperative treatment pathways in treating acute Jones fractures. For instance, in studies undertaken by Sesti *et al*[46], it was established that on average, 60% to 70% of patients with acute Jones fracture were very satisfied with nonoperative procedures, 28% were satisfied, 8% reasonably satisfied, and 4% were dissatisfied (see Figure 2). These findings indicate that the choice for nonsurgical treatment is often based on perception, and, in some cases, is at the discretion of the patient.

The literature suggests that there is a significant variation in the effectiveness of conservative treatment within different fracture subtypes. Nondisplaced Zone 1 fractures at the fifth metatarsal base are often treated using protected weight-bearing methods, such as leg casts, that offer low nonunion rates of between 0.5% and 2.1% [47]. In other studies, it has been illustrated that nonoperative procedures for acute Zone 2 and 3 fractures result in longer recuperation times and a higher risk of refracturing. As highlighted in Figure 3, the average times to union for "tuberosity fractures, Jones, stress, segmental shaft, and oblique distal shaft/neck fractures were 3.7, 3.5, 4.8, 3.6 and 3.4 mo, respectively"[6]. Thus, compared with the surgical method, nonoperative techniques are not feasible for professional athletes due to their inability to achieve union in Zone 2 and 3 fractures within acceptable timeframes.

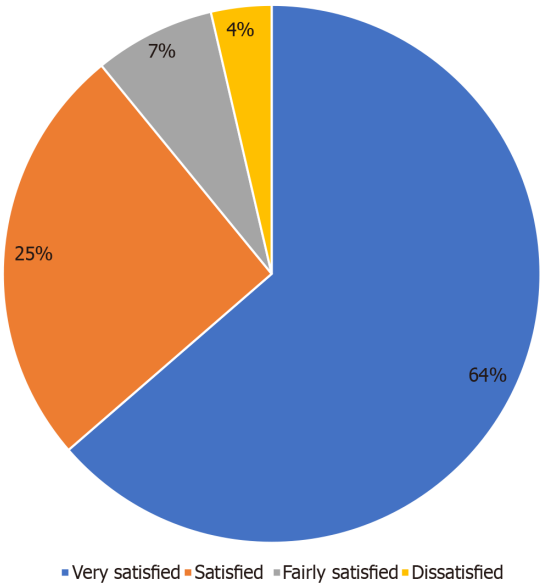


Figure 2 Patient Satisfaction with non-operative treatment of fifth metatarsal Jones fractures.

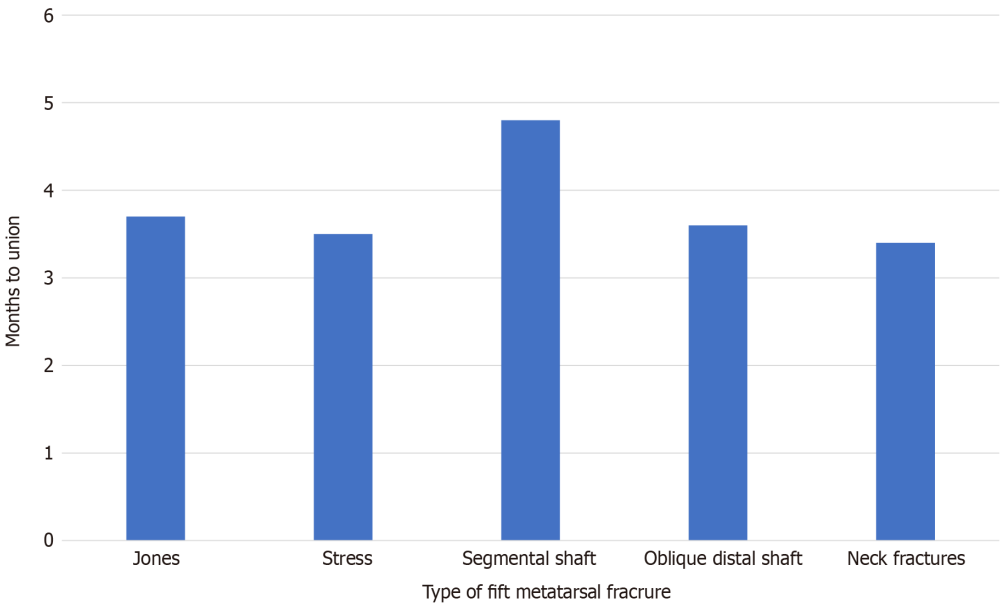


Figure 3 Average number of months to fracture union.

REHABILITATION

Several studies have described and issued recommendations on specific rehabilitation protocols to be followed during the recuperation period. In their research, Marecek *et al*[48] detailed their preferred rehabilitation protocol based on clinical data on patients with acute Jones fractures[48]. The authors note that for patients with Zone 1 fractures, non-weight-bearing options could be used in the first 3 wk after the injury. Similarly, Rhim and Hunt[49], along with Slater *et al*[50] and Qi *et al*[51], suggest the placement of the affected foot in a cast or boot for 2-3 wk. Once a union is observed, the patient can be transitioned to physical therapy, with a focus on regaining strength through eccentric and concentric open-chain exercises or muscle-specific workouts. Non-impact activities, such as elliptical trainers or static bicycles and deep-water running activities, are useful for athletes recovering from acute Jones fractures.

CONCLUSION

As discussed, there are numerous treatment options for patients with fifth metatarsal Jones fractures. For the general population, non-time-sensitive approaches, such as using a short leg cast with immobilization, could be used for treatment. However, for active individuals, such as athletes in competitive sports, the need to quickly return to play often calls for more aggressive treatment plans. Owing to various reports of faster healing and return to play, treatment options among athletes with Jones fractures have significantly shifted from nonoperative procedures to surgical options that include intramedullary screw fixation and plantar plate fixations. These procedures offer predictable union rates in addition to minimum periods of immobilization, which makes them ideal techniques for managing fifth metatarsal Jones fractures in the sporting world.

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MINIREVIEWS

Effects of sclerostin antibody on bone healing

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Abstract

Promoting bone healing after a fracture has been a frequent subject of research. Recently, sclerostin antibody (Scl-Ab) has been introduced as a new anabolic agent for the treatment of osteoporosis. Scl-Ab activates the canonical Wnt (cWnt)-β-catenin pathway, leading to an increase in bone formation and decrease in bone resorption. Because of its rich osteogenic effects, preclinically, Scl-Ab has shown positive effects on bone healing in rodent models; researchers have reported an increase in bone mass, mechanical strength, histological bone formation, total mineralized callus volume, bone mineral density, neovascularization, proliferating cell nuclear antigen score, and bone morphogenic protein expression at the fracture site after Scl-Ab administration. In addition, in a rat critical-size femoral-defect model, the Scl-Ab-treated group demonstrated a higher bone healing rate. On the other hand, two clinical reports have researched Scl-Ab in bone healing and failed to show positive effects in the femur and tibia. This review discusses why Scl-Ab appears to be effective in animal models of fracture healing and not in clinical cases.

Key Words: Canonical Wnt-β-catenin pathway; Fracture healing; Osteoporosis; Romosozumab; Sclerostin antibody

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Core Tip: Sclerostin antibody (Scl-Ab) has been recently introduced for the treatment of osteoporosis. Several researchers have reported on the effects of Scl-Ab in bone fracture healing because of its rich osteogenic potential. In this review, we describe the latest reports of preclinical and clinical studies on the bone-healing effects of Scl-Ab.

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INTRODUCTION

Achieving robust bone healing is the ultimate goal in the treatment of bone fractures. The development of methods to promote fracture healing has been a frequent subject of research. Recently, the safety of several osteoporosis drugs has been established in large-scale clinical trials, and it is expected that these drugs could be converted to fracture treatment. In experimental studies, some agents used to treat osteoporosis have had a positive effect on the promotion of bone healing, including parathyroid hormone (PTH), bisphosphonates, and sclerostin antibody (Scl-Ab).

Romosozumab, an Scl-Ab for humans, which recently has been developed for the treatment of osteoporosis, is an anabolic agent that stimulates bone formation. The difference between Scl-Ab and PTH_{1-34} (teriparatide), a former anabolic agent, is that teriparatide increases both bone formation and resorption *via* PTH-PTH receptor signaling, whereas Scl-Ab increases bone formation and simultaneously decreases bone resorption *via* canonical Wnt (cWnt)-β-catenin signaling[1]. This difference shows that the bone formation by PTH_{1-34} is primarily "remodeling-based" and that by Scl-Ab is primarily "modeling-based"[2,3].

In this review, we describe how Scl-Ab effects the cWnt-β-catenin pathway to stimulate bone formation and then discuss the current experimental and clinical evidence in bone healing.

SCLEROSTIN AND THE CANONICAL WNT/BETA-CATENIN PATHWAY IN BONE METABOLISM

The cWnt-β-catenin pathway plays an important role in bone metabolism, including skeletal development and homeostasis and bone remodeling[4]. The pathway is activated by the binding of Wnt proteins to receptor complexes composed of frizzled receptors and co-receptors of the low-density lipoprotein receptor-related protein (LRP) family, LRP5 and LRP6. This event increases the level of β-catenin and induces its translocation to the nucleus and activates the transcription of gene; it further accelerates the differentiation of osteoblast precursors and promotes the maturation of osteoblast and their survival, leading to osteogenesis by the increased and activated osteoblasts. On the other hand, the increased level of β-catenin results in an increased expression of osteoprotegerin, which binds to RANKL as a decoy receptor, preventing the binding of RANKL and RANK. Osteoclast activation and differentiation, which lead to bone resorption, occurs in the presence of RANKL-to-RANK binding. Thus, the activation of this pathway leads to increased bone formation by the increased and activated osteoblasts and to decreased bone resorption due to the disturbed binding of RANKL to RANK[5-7].

In the regulation of the cWnt-β-catenin pathway, osteocytes play an important role as producers and targets of Wnt ligands and as secretors of molecules that regulate Wnt action[8]. One regulation mechanism is the secretion of sclerostin, a potent antagonist of Wnt signaling. Sclerostin is a protein encoded by the *SOST* gene primarily expressed by mature osteocytes, but not by early osteocytes or osteoblasts [9]. Sclerostin binds to the Wnt co-receptors LRP5/LRP6, antagonizing downstream signaling in the cWnt-β-catenin pathway[10]. Thus, when the stoichiometry levels of sclerostin overwhelms the levels of the Wnt ligands, the signals will not be activated, leading to β-catenin degradation, lower bone formation, and higher bone resorption. On the other hand, when the stoichiometry levels favor in Wnt ligands than sclerostin, Wnt-β-catenin signaling will be activated, leading to stabilized β-catenin for translocation to the nucleus and the activation of target genes to increase bone formation and decrease bone resorption[2]. In addition, not only LRP 5 and 6, but also LRP4 was associated with bone homeostasis by interacting with sclerostin; mutation of LRP4, impairing interaction with sclerostin was found in patients suffering from bone overgrowth[11]. Thus, sclerostin is established as a bone formation inhibitor, though the molecular mechanisms are not fully understood.

In humans, the absence of sclerostin expression or secretion causes an abnormally high bone mass. These conditions have been seen in the rare hereditary diseases sclerosteosis and van Buchem disease. Sclerosteosis was first described by Truswell as osteopetrosis with syndactyly and is mostly seen in patients in South Africa; van Buchem disease was described by van Buchem as hyperostosis corticalis generalisata familiaris and is mostly found in patients in the Netherlands[12,13]. In both diseases, the *SOST* gene encoding sclerostin was identified as the gene responsible; a loss-of-function mutation occurs in sclerosteosis, and the downregulation of the expression of the *SOST* gene occurs in van Buchem disease[14]. Bone mineral density (BMD) and bone strength are significantly higher in patients with these diseases than those in the general population[15,16]. In experimental reports using mice, genetic deletion of the *SOST* gene or neutralizing antibodies for sclerostin duplicated the high bone mass found in humans lacking sclerostin[17-19]. Conversely, sclerostin overexpression leads to a decrease in bone mass[20-22].

SCLEROSTIN ANTIBODY THERAPY AND OSTEOPOROSIS

As the mechanisms of sclerostin and the cWnt-β-catenin pathway were elucidated, improvement in bone mass became the expected outcome of inhibiting the action of sclerostin. In a study using a model of ovariectomized rats with postmenopausal osteoporosis treated with Scl-Ab, researchers found a significant increase in bone formation on the trabecular, periosteal, endocortical, and intracortical surfaces. Furthermore, osteoblast and mineralizing surfaces increased, while the osteoclast surface decreased. These results suggest that the use of Scl-Ab increased bone formation and decreased bone resorption for osteoporosis[23]. In another study evaluating the effects of the osteoblast lineage in young rats with Scl-Ab and PTH_{1-34}, the osteoblastic surface and estimated total number of osteoblasts increased to similar levels in both the Scl-Ab and PTH_{1-34} groups at week 4. However, both parameters decreased in the Scl-Ab group while maintaining in the PTH_{1-34} group at week 26. Similarly, the osteoprogenitors increased to similar levels in both groups at week 4, and only those in the Scl-Ab group decreased at week 26. Interestingly, the percentage of labeled perimeter of the periosteal surface of the femur diaphysis was higher in the Scl-Ab group at both weeks 4 and 26, and the percentage of labeled perimeter of the endocortical surface was at the same level at week 4 and was higher in the Scl-Ab group at week 26. These results suggest that Scl-Ab strongly increases the differentiation induction of osteoprogenitors to osteoblasts, while increase of osteoprogenitors are only seen in the early stages of administration. While, PTH_{1-34} increases both the differentiation induction of osteoprogenitors to osteoblasts and the number of osteoprogenitors at similar levels throughout the administration period, although the level of bone formation was similar or even higher in Scl-Ab than in PTH_{1-34}[24].

In cynomolgus monkeys, treatment with Scl-Ab led to increase in BMD and bone strength just like in the rats. No increase in bone resorption markers was noted, while a significant increase in bone formation markers was demonstrated, also suggesting the distinct effects of modeling-based bone formation associated with Scl-Ab, differing from remodeling-based bone formation by PTH_{1-34} in which osteoblast-mediated bone formation follows osteoclast-mediated bone resorption[25]. Summarizing the difference between Scl-Ab and PTH, with Scl-Ab, bone formation is seen with no increase or even some decrease of bone resorption. The effect of bone formation is stronger in the early stages of administration and decreases with longer administration due to lack of osteoprogenitors after the strongly accelerated differentiation to osteoblasts. With PTH, bone formation is also seen with increase of bone resorption (relatively higher formation than resorption). Bone formation is similar in any stage of administration due to increase in both number of osteoprogenitors and differentiation to osteoblasts.

Romosozumab, a Scl-Ab agent for humans, has recently become commercially available for clinical use. A phase III clinical trial has shown that romosozumab strengthened osteoporotic bone by increasing BMD and decreased the incidence of new fractures. The Fracture Study in Postmenopausal Women with Osteoporosis trial evaluated the 12-month efficacy of romosozumab as compared with the placebo. The risk of vertebral fracture was reduced by 73% at 12 mo (incidence, 0.5% in the romosozumab group *vs* 1.8% in the placebo group, $P < 0.001$), and the risk of clinical fracture was reduced by 36% at 12 mo (incidence, 1.6% in the romosozumab group *vs* 2.5% in the placebo group, $P = 0.008$). The percentage of change in BMD from baseline was 13.3% greater in the lumbar spine, 6.9% greater in the total hip, and 5.9% greater

in the femoral neck in the romosozumab group than in the placebo group. An increase in the bone formation marker P1NP was seen in the romosozumab group, and a decrease in the bone resorption marker β-CTX was seen early in treatment, suggesting modeling-based bone formation[26]. Similar results of increased bone formation and strength, decreased fracture risk, and increased levels of bone formation markers with decreased levels of bone resorption markers have been shown in other phase III trials (ARCH trial, romosozumab *vs* alendronate; STRUCTURE trial, romosozumab *vs* teriparatide)[1,27].

SCLEROSTIN ANTIBODY THERAPY AND BONE HEALING

Preclinical evidence

Bone healing is a complex process controlled by numerous cellular signaling pathways regulated by factors expressed in a time and concentration-dependent manner. The cWnt-β-catenin pathway is one of the most critical signaling pathways involved in bone healing[28-30]. The peak of upregulation was from 7 to 14 d in rat models[31,32]. Upregulating and/or controlling the cWnt pathway along with the levels of β-catenin have the potential of accelerating bone healing. Bone healing occurs in two different mechanisms; intramembranous or endochondral bone formation. Marsell *et al*[33] reported Wnt-responsive cells were not observed near the marrow cavity but seen over the periosteal callus, presuming that the cWnt-β-catenin pathway associates with endochondral bone formation rather than intramembranous bone formation. Liedert *et al*[34] suggested that Wnt inhibitors play a role in delayed union and Montjovent *et al* [35] demonstrated non-rigid fixation of femoral defects caused increase levels of inhibitors of Wnt proteins. In non-rigid fixation, endochondral bone formation becomes the main healing process. Inhibiting the inhibitors of Wnt proteins and activating the cWnt-β-catenin pathway may help bone healing in such fractures.

The efficacy of Scl-Ab for bone healing has been demonstrated in several reports with animal models (Table 1). In a mouse tibial-shaft osteotomy model, both the sclerostin knockout and wild-type groups showed an increase in bone mass at the osteotomy site when Scl-Ab was administered[36]. Ominsky *et al*[37] observed in a rat femur fracture model that an increase in bone mass and mechanical strength at the fracture site occurred after 7 wk in the Scl-Ab group. The other researchers also reported similar positive effects of Scl-Ab for a rat femur fracture or osteotomy model [38,39]. Virdi *et al*[40] also observed that in a rat femoral bone ablation model with intramedullary fixation, there was a 1.9-fold increase in fixation strength at week 4 and a 2.2-fold increase at week 8 in the Scl-Ab group compared to the vehicle group. Furthermore, Yee *et al*[41] reported in a type 1 diabetes mellitus (T1DM) mouse model, administration of Scl-Ab mitigates inhibition of osteoblast differentiation caused by the diabetic state. They found a significant benefit in callus bone volume, increase in callus size and a reverse of lower mineralization seen in T1DM mouse model. Studying the mechanisms for the fracture healing effect of Scl-Ab, Feng *et al* reported an increase in the proliferating cell nuclear antigen score and bone morphogenetic protein (BMP)-2 expression at weeks 1 and 2 in a femur osteotomy model in young rats. Furthermore, cartilage decreased and BMD and the mechanical strength of the callus associated with accelerated fracture healing increased at weeks 4 and 6[42].

As an evaluation outside the long tubular bone fracture model, Agholme *et al*[43] inserted screws into the proximal tibia of young rats and measured the pull-out strength; the Scl-Ab-treated group showed a 50% increase after 2 and 4 wk compared with the saline-treated group. They conducted the same experiment comparing with PTH, and the PTH group showed significant higher pull-out strength in the metaphyseal, while Scl-Ab significantly increased femoral cortical and vertebral strength[44]. In a rat model of distraction osteogenesis, no difference occurred in the rate of bone union between the Scl-Ab and control groups, but mechanical strength and bone mass increased in the Scl-Ab group, suggesting that the optimal effect of Scl-Ab treatment is achieved in the later stages of distraction osteogenesis[45]. In addition, in a rat critical-size femoral-defect model with a 6-mm femoral defect, 24% of the Scl-Ab-treated group had healed after 12 wk compared with no cases of healing in the control group[46]. Furthermore, in the treated group, systemic Scl-Ab administration plus local BMP-2 administration resulted in significantly more robust healing of critical-size femoral defects than did BMP-2 alone[47].

On the other hand, Kruck *et al*[48] negatively reported on the effects of Scl-Ab on bone healing. The author created rigid and semirigid fixation models for femoral osteotomy in rats. All groups showed an increase in bone mass, but no difference in

Table 1 The efficacy of sclerostin antibody for bone healing has been demonstrated in several reports with animal models

Animal model	Bone	Bone injury model	Dosage, frequency	Major findings	Ref.
Mouse	Tibia	Osteotomy	100 mg/kg, 1/wk	BV/TV↑, strength↑	[36]
Rat	Femur	Fracture	25 mg/kg, 2/wk	Callus↑, BMC↑, BV/TV↑, strength↑	[37]
Cynomolgus monkey	Fibula	Osteotomy	30 mg/kg, 1/2 wk	Callus↑, BMC↑, strength↑	[37]
Rat	Femur	Ablation	25 mg/kg, 2/wk	Fixation strength↑, cortical thickness↑, BV/TV↑	[40]
Rat	Femur	Fracture	25 mg/kg, 2/wk	BMD↑, BV/TV↑, strength↑, MS/BS↑, BFR/BS↑	[38]
Rat	Femur	Osteotomy	25 mg/kg, 2/wk	Callus↑, BMD↑, BV/TV↑, strength↑, bone area↑, cartilage↓	[39]
Mouse	Femur	Fracture	25 mg/kg, 2/wk	BV/TV↑, BMC↑	[41]
T1DM mouse	Femur	Fracture	25 mg/kg, 2/wk	BV/TV↑, BMC↑	[41]
Rat	Femur	Osteotomy	25 mg/kg, 2/wk	Mature callus↑, BMC↑, BMD↑, strength↑	[42]
Rat	Tibia	Metaphyseal screw	25 mg/kg, 2/wk	Pull-out strength↑, bone volume surrounding screw↑	[43]
Rat	Femur	Distraction osteogenesis	25 mg/kg, 2/wk	Union rate→, (united bones) strength↑, bone volume↑	[45]
Rat	Femur	Critical defect	25 mg/kg, 2/wk	Union rate↑, bone formation markers↑	[46]
Mouse	Femur	Osteotomy rigid fix	25 mg/kg, 2/wk	Periosteal and/or intracortical bridging→, endosteal bridging↑	[48]
Mouse	Femur	Osteotomy semi-rigid fix	25 mg/kg, 2/wk	Periosteal and/or intracortical bridging→, endosteal bridging↑	[48]

T1DM: Type 1 diabetes mellitus; BV/TV: Bone volume to total bone volume ratio; BMC: Bone mineral content; BMD: Bone mineral density; MS/BS: Mineralizing surface rate; BFR/BS: Bone formation rate.

delayed healing occurred with semirigid fixation between the Scl-Ab and control groups. In rigid fixation, Scl-Ab had more bridging of the endosteum, which adversely affected late healing, suggesting delayed callus remodeling and marrow reconstitution at the time of fracture. These results suggest that Scl-Ab promotes bone formation in the early stages of healing, but not in the advanced stages of fracture callus remodeling [48].

Clinical evidence

Two phase II clinical trials have reported the efficacy of romosozumab in adult fresh fractures. Bhandari *et al*[49] reported the efficacy of romosozumab in 402 patients with fresh unilateral tibial diaphyseal fractures (median age, 40 years; range, 18−82 years) who underwent fracture fixation with intramedullary nails. Patients were randomized to a placebo (n = 103) or one of nine different romosozumab groups (n = 299), with three different doses and frequencies of administration (doses: 70 mg, 140 mg, and 210 mg; administration: twice, postoperative day 1 and week 2; three times, postoperative days 1 and 2 and week 6; and four times, postoperative days 1 and 2 and weeks 6 and 12). The percentage of patients with a radiological cure, defined as the bridging of three of the four cortices as shown on the radiographs, which ranged from 63.2% to 84.7% at week 24 and from 83.4% to 96.7% at week 52 in the romosozumab group and from 76.1% at week 24 and 87.1% at week 52 in the placebo group. The estimated median time to radiological cure ranged from 14.4 to 18.6 wk in the romosozumab group and 16.4 wk in the placebo group. Thus, no significant difference occurred between both groups. In addition, no significant difference occurred in the time to clinical healing (defined as the ability to bear weight without pain at the fracture site) between the groups. Furthermore, the authors found no treatment effects of romosozumab on the incidence of unplanned revision surgery, physical function scores, or adverse events. The study concluded that romosozumab did not promote the healing of tibial fractures in this patient population.

Schemitsch *et al*[50] reported on a trial of romosozumab for the treatment of hip fractures in 332 patients (median age, 78 years; range 55−94 years). Patients were randomized to groups receiving a placebo (n = 89) or romosozumab at three different doses (70 mg, 140 mg, and 210 mg). Patients received subcutaneous romosozumab

injections on postoperative days 1, 2, 6, and 12, and the percentage of patients with radiographic evidence of healing ranged from 66.2% to 78.6% at week 24 and from 89.1% to 93.2% at week 52, with no significant difference between the treatment groups. In addition, no significant difference occurred in the estimated median time to radiographic evidence of healing neither between the groups nor in functional mobility assessment, radiographic fracture healing assessment, and hip pain scores. Similar to the results with patients with tibial fractures, romosozumab did not improve fracture healing in patients with hip fractures.

It is unclear why bone healing was not accelerated in humans. In both studies, romosozumab was administered starting on postoperative day 1. Since romosozumab promotes the differentiation of osteoblasts from osteoprogenitors with little increase in osteoprogenitors[24], it is possible that administering romosozumab early in the fracture healing process period is not ideally timed. Yukata *et al*[51] reported that *SOST* gene expression were more abundant in the hard callus in the later stages of bone repair than in the soft callus in the early stages in a mouse tibia fracture model, and PTH administration upregulated *SOST* expression as the hard callus increased. These suggest the need to change the starting point of administration and to consider the combination of romosozumab and PTH, which has the effect of increasing immature cells. Additionally, in both studies the patients were treated at sites for high surgical standards of care and they received rigid fixation. The quality of the surgery and care may out-weighed the effects of romosozumab on fracture healing[49,50]. Future studies may focus on healing of serious fractures, which could only accomplish relatively un-rigid fixation.

CONCLUSION

Despite the preclinical success of Scl-Ab in promoting fracture healing in animals, currently, no clinical evidence exists for the positive effects of Scl-Ab for bone healing in humans. As an osteogenic agent in osteoporosis, Scl-Ab offers promising effects supported by reliable evidence. Although the drug targets the same bone tissue, further research is needed on the differences in the pathogenesis of osteoporosis and fracture, spatio-temporal expression pattern of *SOST* according to bone healing process, and corresponding timing and interval of drug administration.

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MINIREVIEWS

Current concepts in the management of bisphosphonate associated atypical femoral fractures

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Abstract

Bisphosphonates are a class of drugs used as the mainstay of treatment for osteoporosis. Bisphosphonates function by binding to hydroxyapatite, and subsequently targeting osteoclasts by altering their ability to resorb and remodel bone. Whilst aiming to reduce the risk of fragility fractures, bisphosphonates have been associated with atypical insufficiency fractures, specifically in the femur. Atypical femoral fractures occur distal to the lesser trochanter, until the supracondylar flare. There are a number of the differing clinical and radiological features between atypical femoral fractures and osteoporotic femoral fractures, indicating that there is a distinct difference in the respective underlying pathophysiology. At the point of presentation of an atypical femoral fracture, bisphosphonate should be discontinued. This is due to the proposed inhibition of osteoclasts and apoptosis, resulting in impaired callus healing. Conservative management consists primarily of cessation of bisphosphonate therapy and partial weightbearing activity. Nutritional deficiencies should be investigated and appro-priately corrected, most notably dietary calcium and vitamin D. Currently there is no established treatment guidelines for either complete or incomplete fractures. There is agreement in the literature that nonoperative management of bisphosphonate-associated femoral fractures conveys poor outcomes. Currently, the favoured methods of surgical fixation are cephalomedullary nailing and plate fixation. Newer techniques advocate the use of both modalities as it gives the plate advantage of best reducing the fracture and compressing the lateral cortex, with the support of the intramedullary nail to stabilise an atypical fracture with

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increased ability to load-share, and a reduced bending moment across the fracture site. The evidence suggests that cephalomedullary nailing of the fracture has lower revision rates. However, it is important to appreciate that the anatomical location and patient factors may not always allow for this. Although causation between bisphosphonates and atypical fractures is yet to be demonstrated, there is a growing evidence base to suggest a higher incidence to atypical femoral fractures in patients who take bisphosphonates. As we encounter a growing co-morbid elderly population, the prevalence of this fracture-type will likely increase. Therefore, it is imperative clinicians continue to be attentive of atypical femoral fractures and treat them effectively.

Key Words: Bisphosphonates; Atypical fracture; Surgical fixation; Atypical femoral fracture; Osteoporosis

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Core Tip: Bisphosphates are a class of drugs used as the mainstay of treatment for osteoporosis. A number of the clinical and radiological features of atypical femoral fractures and osteoporotic femoral fractures are different, indicating that there is a distinct difference in the respective underlying pathophysiology. At the point of presentation of an atypical femoral fracture, bisphosphonate should be discontinued. Currently there is no established treatment guidelines for either complete or incomplete fractures. The evidence suggests that cephalomedullary nailing of the fracture has lower revision rates.

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INTRODUCTION

Bisphosphonates are a class of drugs used as the mainstay of treatment for osteoporosis, as well as other metabolic bone diseases worldwide. Osteoporosis is a systemic disease resulting primarily in a low bone mineral density. It is defined by the World Health Organisation as a T score < -2.5 SD below the mean[1]. It is characterised by a deterioration in bone micro-architecture, and subsequent increased susceptibility to fracture[2]. This results in a significant health, social and economic burden to society [3].

Whilst aiming to reduce the risk of fragility fractures, bisphosphonates have been associated with atypical insufficiency fractures, specifically in the femur. These atypical fractures account for 1.1% of all femoral fractures[4]. This paper aims to review the mechanism of action of these drugs, their risks, benefits and in particular how associated fractures should be managed. It should aid clinicians in their understanding of this counterintuitive sequela of bisphosphonate use and ensure patients are counselled appropriately when considering commencement of bisphosphonate treatment.

BISPHOSPHONATES

Bisphosphonates function by binding to the inorganic components of bone, namely hydroxyapatite, and subsequently targeting osteoclasts by altering their ability to resorb and remodel bone. All drugs in this class have a chemical structure consisting of two phosphonic acids attached to a carbon atom with two side chains (R1 and R2), which are short and long respectively[5,6]. The chemical structure of the side chains influences the properties of the drug with the short side primarily influencing the

pharmokinetics while the long influencing the mode of action and potency. Bisphosphonates with higher binding affinity spread through bone slower than their lower affinity counterparts, however, if treatment is stopped, they remain in the bone for longer. The drug is absorbed in its active form with no systemic metabolism required. 50% of the absorbed drug binds to bone surfaces, most avidly at sites of remodelling, whilst the rest is rapidly excreted by the kidneys.

First generation or more commonly "non-nitrogen-containing bisphosphonates" such as etidronate had a very close structural similarity to inorganic pyrophosphate and were incorporated into newly formed adenosine triphosphate (ATP) molecules and absorbed by the osteoclasts. These toxic ATP molecules accumulated inside the cell and resulted in apoptosis. Second and 3rd generation or more commonly "nitrogenous" bisphosphonates such as alendronate, risedronate, ibandronate, pamidronate and zoledronic acid, have nitrogen containing R2 side chains which when absorbed by the osteoclast bind to and inhibit the activity of farnesyl pyrophosphate synthase, a key regulatory enzyme in the mevalonic acid pathway ultimately resulting in impaired formation of the ruffled border and bone resorption [5].

Currently the National Institute of Clinical Excellence[7] recommends bisphosphonates for any adult who has been identified as being high risk for osteoporotic fragility fracture as per standard risk assessment tools. This is achieved through the use of the fracture risk assessment tool[8]. It must be noted that consideration of individual circumstances and risks/benefit profiles should be considered within the assessment. This ensures a patient led approach to prevention of osteoporosis. The first line option is oral Alendronic acid, which in a 2008 Cochrane systematic review demonstrated a significant reduction in osteoporotic fractures in post menopausal women. Similarly a significant reduction in osteoporotic vertebral fractures was noted when used in primary prevention[9].

Recognised side effects of bisphosphonate use include gastrointestinal irritation, musculoskeletal pain, osteonecrosis of the jaw, and more recently recognised, atypical femoral fractures[6]. Oral preparations are now able to be given once weekly making the gastrointestinal (GI) side effects much more tolerable. Unfortunately they are still poorly absorbed, even under ideal condition such as being taken sitting up, after a prolonged fast. IV preparations such as pamidronate and zolendronic acid require even less frequent dosing and do not cause the same GI side effects however are subject to acute phase reactions characterised by flu like symptoms[10].

ATYPICAL FEMORAL FRACTURES

Atypical femoral fractures are insufficiency fractures that can be related to bisphosphonate use and are identified by major and minor criteria[11] (Table 1). Atypical femoral fractures occur distal to the lesser trochanter, until the supracondylar flare. In general, subtrochanteric and diaphyseal femoral fractures account for 5%-10% of all hip and femoral fractures. A small subset of these fractures (17-29[11,12]) are classified as atypical. Currently, evidence of association between atypical femoral fractures and bisphosphonate use is based upon observational studies. There is growing concern that the long-term effects of bisphosphonates on bone remodelling could cause a shift in the classical pattern of hip and femoral fractures towards this atypical configuration [13]. A Swedish study based upon their national registry (1521131 women over 55 years old with a 5% bisphosphonate use) found 46 atypical fractures in the 83311 bisphosphonate users over the 3 year period examined, and estimated a crude incidence of 5.5 atypical fractures per 10000 patient years[14]. This compared to 13 atypical fractures seen in the 1437820 non-bisphosphonate users in the same 3-year period. This equates to an estimated incidence of 0.09. Although this study demonstrated a high prevalence of bisphosphonate use in patients with atypical fractures, the absolute risk of this was very small. The authors concluded that with an appropriate indication, the benefits of fracture prevention with bisphosphonate use greatly outweigh the risk of atypical femoral fracture. A similar conclusion was drawn from a study reviewing 10 years of data, indicating risk of atypical femoral fracture increased with longer duration of bisphosphonate use, but that the absolute risk remained low compared with the reduction in risk of other osteoporotic fractures[15].

Table 1 Atypical femoral fractures are insufficiency fractures that can be related to bisphosphonate use and are identified by major and minor criteria

Major criteria (all must be met)	Minor criteria (none required)
Fracture line located anywhere between the distal border of the lesser trochanter of the femur to the proximal edge of the supracondylar flare	Localised periosteal reaction at lateral cortex – beaking, flaring
Lateral cortex must be involved (incomplete or complete – normally with medial cortical spike)	Generalised, diaphyseal cortical thickening
Transverse or short oblique fracture line No comminution	Prodromal groin/thigh pain
No or minimal precipitating trauma	Bilateral fracture and symptoms
	Delayed healing
	Co-morbidities (rheumatoid arthritis, vitamin and mineral deficiencies)
	Concomitant use of pharmacological agents (BP, corticosteroids, proton pump inhibitors)
Exclusions	
Neck of femur fractures, fractures relating to primary or secondary bone tumours and peri-prosthetic fractures[11].	

RISK FACTORS OF ATYPICAL FEMORAL FRACTURES

Despite the common use of bisphosphonates for the treatment of osteoporosis, atypical femoral fractures remain rare. The majority of patients who are treated with bisphosphonates will not sustain a clinical change in their femur. However, the consequence of an atypical femoral fracture can have significant impact of mortality and morbidity. Therefore, it is imperative that risk factors are identified and screened accordingly.

A number of the clinical and radiological features of atypical femoral fractures and osteoporotic femoral fractures are different, indicating that there is a distinct difference in the respective underlying pathophysiology. These features are similar to those found in stress fractures, with radiological evidence of a transverse fracture, lack of comminution, and localised cortical thickening at the fracture site (Figure 1)[11,16]. Clinically, patients may experience prodromal pain, as well as bilateral pathology[17].

Biological and biochemical

Bisphosphonate therapy has been shown in randomised controlled trials to increase bone density and reduce the risk of fracture in patients diagnosed with osteoporosis [18,19]. However, there is an association with atypical femoral fractures. Although causation between bisphosphonates and atypical femoral fractures is yet to be demonstrated, several properties of bisphosphonates and their effect on bone physiology are considered to play a role in the development of these fractures[11]. The first is the profound effect that bisphosphonates have on bone turnover[20]. This is achieved through suppression of osteoclast activity[21]. Histologically, this results in reduced resorption depth and a decreased activation frequency of new remodelling units[22], the consequence of which is a reduction in the rate of bone formation. This in turn impairs the ability to repair accumulated microdamage that occurs secondary to usual physiological stresses, leading to a two to seven-fold increase after management with bisphosphonates[23,24]. As well as microdamage accumulation, long-term over suppression of bone turnover results in secondary mineralisation of bone[25]. This hyper-mineralised bone may be more susceptible to fracture due to its brittle properties[26]. This remodelling and hyper-mineralisation results in a 20% decrease in bone toughness without a simultaneous reduction in bone mass[27]. The net effect could be explained by an increase in the young's modulus of the bone, with reduced ultimate tensile strength resulting in a smaller area under the stress-strain curve.

Genetics

While the aforementioned properties and resultant effects of bisphosphonates on normal physiology are associated with atypical femoral fractures, it remains unclear as to why these effects are not universal. More recently, genetic mutations have been found to influence susceptibility to atypical femoral fractures following bisphosphonate therapy, most notably GGPS1[28]. Other variants have been identified to predispose individuals to atypical fractures, irrespective of pharmacological therapy



Figure 1 Plain radiographs before and after atypical bisphosphonate associated femoral fracture fixation. A: Before atypical bisphosphonate associated femoral fracture fixation; B: After atypical bisphosphonate associated femoral fracture fixation.

[29]. A study has highlighted four uncommon polymorphisms associated with atypical femoral fractures, but no common genetic mutations[30]. The presence of a genetic metabolic bone disorder may be another important risk factor in the development of atypical femoral fractures.

Due to the increase in prevalence of bisphosphonate therapy and incidence of atypical femoral fractures, further research will determine the role of molecular genetics in relation to atypical fractures.

Biomechanical

Extrinsic bone strength depends on a combination of structural and material properties of the bone itself. The previously mentioned pathological fracture site is the lateral cortex of the femur; the location of maximal tensile stress[31]. The biomechanical alignment of the hip and femur determines the stresses placed upon the lateral cortex[32]. It has been shown that the lateral femoral bowing angle is the main determinant for location of atypical femoral fracture, with a higher lateral femoral bowing angle predisposing to diaphyseal fracture[31]. For this reason, an argument has been made that individuals of Asian descent are at a higher risk of atypical femoral fracture due to a greater natural bowing to the femoral shaft[33]. There is conflicting evidence regarding the effect of bisphosphonates on the extrinsic bone strength[34], warranting further investigation in this field.

SCREENING

A transverse line on plain radiographs has become pathognomonic of atypical femoral fractures[35]. Whilst this makes a diagnosis of a complete fracture more obvious, it is essential that incomplete or impending fractures are not missed. When patients present with the aforementioned clinical features of an atypical femoral fracture, in particular those who are recipients of bisphosphonate therapy, a high index of suspicion and close attention to detail with regards to any imaging should be maintained. Close examination for fracture lines in the lateral cortex and localised periosteal thickening is warranted, as the sensitivity and specificity of these signs has been shown to be high[36].

More recently, the role of computed tomography (CT) in the diagnosis and evaluation of atypical femoral fractures has been inspected. It has been shown that patients with atypical femoral fractures have had pre-fracture imaging showing a thicker lateral cortex at the site of the injury compared with that of bisphosphonate users who did not go on to develop a fracture[37]. Another study revealed that 34% of asymptomatic individuals with atypical femoral fractures displayed evidence of radiologic progression, with a mean time to progression of 25.6 mo[38]. Therefore, in the detection of future atypical femoral fractures, computed tomography and magnetic resonance imaging may provide valuable diagnostic information regarding the water and mineral content of bone[39-42]. Dual-energy X-ray absorptiometry (DEXA) combined with further image analysis techniques may further permit the discovery of abnormalities associated with atypical femoral fractures, providing a window of

opportunity for early intervention[41]. Bone scintigraphy provides clinicians with another imaging adjunct to ensure early detection[43]. At present, there are no high quality studies which consider bone scintigraphy compared to magnetic resonance imaging (MRI) for identification of occult fractures in bisphosphonate related atypical femoral fractures. However, a recent meta-analysis on the use of advanced imaging in occult hip fractures of the elderly suggests that CT and bone scan (sensitivity, 79% and 87% respectively) are less sensitive for occult hip fractures compared with MRI[44].

Serum markers provide a clinical value for initiation and monitoring bisphosphonate use. The present definition for osteoporosis is based on the value of bone mineral density (BMD) measured by DEXA or occurrence of fragility fracture. BMD response to bisphosphonate use is slow, which makes monitoring bone turnover difficult. Bone turnover markers (BTM) provide a more real time reflection of bone formation and bone resorption through the monitoring of serum and urine. A comprehensive review by Vasikaran *et al*[45] demonstrated that high level of BTMs may predict fracture risk independently to BMD for post-menopausal women. Despite the ability of BTM to monitor the pharmacologic effects of osteoporosis, the inconsistency in metrics of measurement and unsuitable trials on the BTM levels with treatment compared to controls limits its use.

MANAGEMENT OF ATYPICAL FEMORAL FRACTURES

Medical management and considerations

At the point of presentation of an atypical femoral fracture, bisphosphonate or any antiresorptive agent should be discontinued. This is due to the proposed inhibition of osteoclasts and apoptosis, resulting in impaired callus healing. Animal studies suggest that there is larger formation of fracture callus, with resultant increase in bone volume and mineral content, but has delayed hard callus remodeling during endochondral fracture repair[46,47]. In contrast, *in vivo* human studies of human trabecular bone demonstrated bisphosphonates induced osteoclastic proliferation and maturation, with upregulation of type 1 collagen and osteocalcin[48]. It is still unclear whether these medications should be withheld indefinitely or resumed after a certain time period thereby giving the patient a "bisphosphonate holiday"[49,50]. It is important to appreciate that bisphosphonates have different binding and anti-resporptive properties, thus providing a "holiday" from bisphsphonates may have an impact on femoral fractures[51]. Discontinuing bisphosphonates will possibly reverse bone modelling suppression and promote fracture healing. Data from the Kaiser data base suggests that if bisphosphonates are stopped soon after an atypical fracture, then 20% will fracture the contralateral leg, compared to 50% if continued for 3 years after the primary atypical femoral fracture[52]. It must be noted that alternative therapies should be considered if bisphosphonates are discontinued.

Conservative management consists primarily of cessation of bisphosphonate therapy and partial weightbearing activity, and has been proven to be effective in some cohorts[53]. Any nutritional deficiencies should be investigated and appropriately corrected, most notably dietary calcium and vitamin D[11]. More recently, there has been some conflicting evidence surrounding the use of teriparatide in patients with bisphosphonate-associated atypical femoral fractures[54]. It is a recombinant form of parathyroid hormone, and is thought to selectively target bone turnover suppression that occurs as a result of prolonged bisphosphonate use. Whilst some of the evidence is promising, there are also case reports suggesting an absence of this desired effect[55]. Therefore, further investigation is warranted prior to the routine prescription of teriparatide.

Operative fixation

Due to the paucity of evidence for the management of atypical femoral fractures, currently there is no established treatment guidelines for either complete or incomplete fractures. There is agreement in the literature that nonoperative management of bisphosphonate-associated femoral fractures conveys poor outcomes [56,57]. Therefore, it is generally accepted that the current preferred method for first-line management of complete atypical femoral fractures is surgical fixation with a device(s) that can withstand full body loading for a prolonged period to allow bony union. Cephalomedullary nailing, biomechanically gives the most favourable loading properties with on-axis fixation and co-linear strain (Figure 2)[58,59]. Other methods such as plate fixation have been used, usually due to the anatomical location of the fracture but suffer from off–axis fixation and differing strains patterns which can lead



Figure 2 Plain radiograph illustrating fixation of an atypical bisphosphonate associated fracture and beaking on the contralateral limb at the same level.

to failure. There is evidence that fractures managed with plate fixation are at greater risk of requiring revision compared with cephalomedullary nailing (31.3% *vs* 12.9% respectively)[57]. Newer techniques advocate the use of both modalities as it gives the plate advantage of best reducing the fracture and compressing the lateral cortex which has failed in tension with the support of the intramedullary nail to stabilise an atypical fracture with increased ability to load-share, and a reduced bending moment across the fracture site[58,60] (Figure 3). With either fixation technique, however, it is important to avoid fixing the fracture in varus and the operating surgeon should consider creating a small osteotomy along the lateral cortex to remove the pathological bone and best restore the anatomical alignment[50,61].

The evidence base for the management of incomplete atypical femoral fractures is unclear. It has been shown that up to 28.3% of these develop into complete fractures within six months of their detection[62]. Concerning signs include functional pain and a visible transverse fracture line on plain radiographs extending > 50% of the lateral cortex. The rationale behind performing a prophylactic operation on an incomplete atypical femoral fracture is two-fold: progression to complete fracture is prevented and hospital stay is reduced[63]. In addition, the success rate of operative management of complete atypical femoral fractures is reduced by almost 50% when compared with that of incomplete fractures[64]. However, the authors of this study advocate that surgical management for patients presenting with incomplete bisphosphonate-related atypical femoral fractures should be reserved for patients with persistent pain, refractory to nonoperative management or progressive radiographic lesions. There is also recent evidence that prophylactic repair of the contralateral limb may be cost-effective in the treatment of patients presenting with atypical femoral fractures[65].

The literature suggests that operative management of atypical fractures is more challenging than that of typical femoral fractures, necessitating a greater level of surgical expertise and technique[61]. Atypical femoral fracture repair has also been found to have an increased incidence of iatrogenic intraoperative fractures, as well as a higher implant failure rate[66]. The general consensus in the literature is that further large-scale prospective studies are required to evaluate both the outcomes of surgical and conservative management of bisphosphonate-related atypical femoral fractures, as well as trials comparing outcomes from cephalomedullary nailing and other methods of fracture repair in this cohort.

Fracture healing using bone graft in this complex group of patients is an area of consideration to the surgeon. Pathologic by nature, bisphosphonate related atypical femoral fractures are due to chronic osteoclast inhibition, resulting in a site on the femur of reduced remodelling and sclerosis. Autologous bone grafting or bone marrow aspirate may restore the normal bone homeostasis. Currently, the literature is limited in regards to the theoretical benefits. A report by the American Society for Bone and Mineral research found limited evidence to suggest the chronic suppression

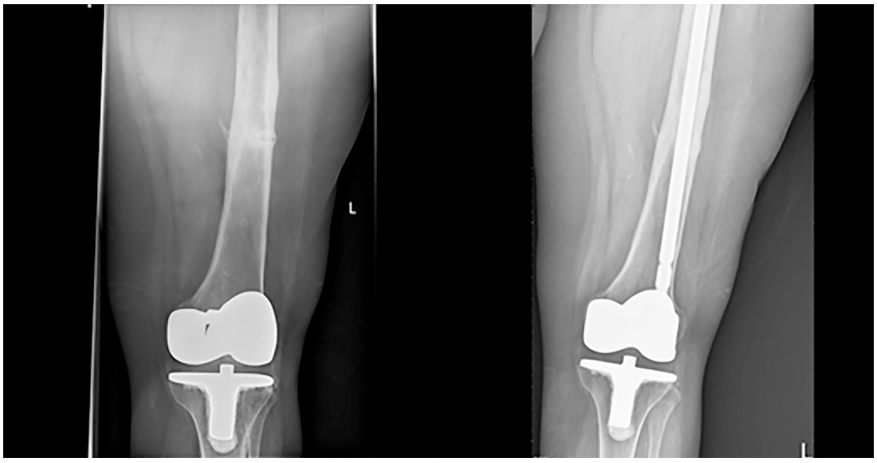


Figure 3 Plain radiographs of the "dreaded lucent line" and distal unlocked intramedullary stabilisation to minimise the stress riser around a knee replacement.

of osteoclasts may affect the efficacy of bone grafting at the fracture site[11]. Conversely, a study showed no decrease in bone formation after transiliac crest grafting in a similar patient population[67]. This shows that further research is required regarding femoral fractures improving time to fracture union.

Complications and considerations specific to atypical femoral fractures

Some of the literature reveals favourable outcomes following surgical repair of the atypical femoral fractures, with a reported 95.7% successfully healing without the need of a further operation[37]. However, a multicentre review with a greater study population found that 12.6% of atypical femoral fracture repair required revision surgery[57]. This is higher than the revision rate for typical femoral fracture repair, which is reported in the literature as 4.7%[68]. However, it must be noted that the median ages in these two patient populations vary widely, as patients receiving bisphosphonate therapy skew the median age in this cohort upwards. There are numerous proposed mechanisms for the difference in rates of revision surgery between atypical and typical femoral fracture repair. The primary explanation is that of delayed healing following operative management of an atypical femoral fracture. The mean time to heal following primary repair of atypical fracture by means of cephalomedullary nailing was 10.7 mo[69]. This may be related to impaired bone remodelling as a result of bisphosphonate use[11]. Although, interestingly, in a review where data regarding preoperative bisphosphonate use was readily available, there was no difference in time to healing when comparing those who had prior treatment with bisphosphonate use for greater than five years and those who had not ($P > 0.05$)[57].

A consideration unique to atypical femoral fractures is the incidence of contralateral pathology in those who present after bisphosphonate therapy. There is variation in the reported incidence of contralateral pathology in this population, ranging from approximately 22%[70] to 62.9%[71]. Regardless, there is evidence enough to suggest routine imaging of the contralateral side in the presence of prodromal pain.

CONCLUSION

Bisphosphonates are integral to the treatment of osteoporosis, although there is a particular association with atypical femoral fractures. Although causation between bisphosphonates and atypical fractures is yet to be demonstrated, there is a growing evidence base to suggest a higher predilection of atypical femoral fractures in patients who take bisphosphonates[14]. As we encounter a growing co-morbid elderly population, the prevalence of this fracture type will likely increase. Therefore, it is imperative clinicians continue to be attentive of atypical femoral fractures. This can, in part, be done by screening and requesting plain film radiographs, CT scans and DEXA imaging modalities for identification of incomplete or impending fractures. The evidence for the management of complete atypical femoral fractures suggests cephalomedullary nailing to be a favourable compared to plate fixation, in regards to

likelihood for revision[58,60]. However, it is important to appreciate that the anatomical location and patient factors may not always allow for this. A common subset of atypical femoral fractures are incomplete. Within this population, there is evidence to suggest a significant proportion go on to suffer complete fractures[62]. Therefore, prophylactic cephalomedullary nailing has been suggested in clinically symptomatic patients and visible transverse fracture lines on plain radiographs extending > 50% of the lateral cortex. This has been shown to be a cost effective means of reducing the burden of complete fractures on hospitals. However, surgical fixation in this population does not come without risk and meaningful dialogue with the patients is suggested to individualise treatment decisions in each case.

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MINIREVIEWS

Virtual orthopedic assessment: Main principles and specific regions

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Abstract

Telemedicine was originally created as a way to treat patients who were located in remote places far away from local health facilities or in areas with shortages of medical professionals. Telemedicine is still used today to address those problems, and is increasingly becoming a tool for convenient medical care. With the emergence of pandemics, telemedicine became almost a mandatory and valuable option for continuing to provide medical care in various specialties. As the threat of pandemic progress has continued for months and may continue for years, it is essential to validate existing tools to maintain clinical assessment and patient treatment to avoid negative consequences of the lack of medical follow-up. Therefore, the establishment of a virtual assessment technique that can be conducted effectively is of outmost importance as a way of adapting to the current situation. This study evaluated the role of telemedicine in the assessment of various orthopedic pathologies by means of a systematic virtual evaluation.

Key Words: Telemedicine; Virtual assessment; Orthopedics; Epidemic diseases

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Core Tip: Telemedicine can be used to diagnose many orthopedic disorders and can be used for follow-up care after medical and surgical treatment. Its importance has

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increased dramatically with the emergence of epidemic diseases. However, an initial face-to-face assessment is recommended, especially in complicated cases where the diagnosis is uncertain. In this article, describe the role of telemedicine in the assessment of various orthopedic pathologies by systematic virtual evaluation.

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INTRODUCTION

Telemedicine uses technology for distant communication for health care purposes. With the emergence of epidemic diseases and need for social distance, telemedicine has become a valuable, almost a mandatory option for maintaining medical care provided in various medical specialties. Orthopedic surgery is one of the medical fields to which telemedicine can provide a good channel for continuous follow-up of patients, diagnosing, and managing many diseases during the awful worldwide situation[1].

Virtual assessment and management of orthopedic patients can bypass geographical and time boundaries, improve patient comfort, increase data transmission security, reduce costs, digitize healthcare systems, and facilitate the establishment of medical databases with potential research and audit benefits. On the other hand, its implementation is impeded by the fact that certain steps in the clinical examination cannot be performed without face-to-face interactions are vital for making the diagnosis[2].

Virtual orthopedic assessment depends on three items. The first is history taking, which has a very high impact in telemedicine to guide the physician throughout the entire assessment session. Examination is the next step of the assessment, and it must be adjusted to match the virtual setting of examining the patient without touch. After obtaining the data, physician orders the required laboratory or radiological investigations needed to reach the final diagnosis[3]. In this study, we evaluated the role of telemedicine in the assessment of various orthopedic pathologies through a systematic virtual assessment. Noted that in case of emergencies and inability to reach a definite diagnosis a consultation with an actual visit to a physician cannot be replaced.

INFRASTRUCTURE AND TECHNICAL REQUIREMENTS

The infrastructure and technical requirements needed for telemedicine assessment of orthopedic patients are easily available. Hardware devices include computers, cell phones, or tablets. Cameras and microphones are needed, and a wireless network connection, cable internet connection, or cellular network should be available. Many video platforms can be used during video conference consultations, such as Skype, Zoom, and Google Duo, *etc.*[4]. Specialized orthopedic software such as goniometer applications are useful for both initial consultations and in follow-up assessments of treatment efficacy. They can be also used for X-ray measurements (*e.g.*, to determine the degree of scoliosis). Gait analysis software can be used as it is an important clinical tool to assess gait deviations[5,6].

HISTORY

For reaching an appropriate diagnosis of a patient problem by telemedicine, the surgeon should take a full patient history, with more time for history taking and patient inspection as he cannot assess the patient by touch, but only by visual inspection and by listening to the patient history to gather information that he can interpret before ordering specific investigations needed to confirm his suspected

diagnosis. A full, accurate personal history, patient complaints, history of trauma if it occurred, medical, surgical, and family history, can raise the surgeon's suspicion of a specific cause of the patient problem that can be confirmed by examination and investigation. The personal history, including age, sex, occupation, residence, special habits like smoking, sports, and marital status, is important, as many diseases or fracture types are more likely in specific age groups have a sex difference. For example Freiber's disease is common in female patients 13-18 years of age[7].

Pain is the commonest patient complaint. Surgeon should fully analyze the pain to determine if it is localized or generalized, and the type of pain, what increases the pain, and to what extent it affects the activity of patient. For example how many kilometers can the patient walk or if the pain awakes the patient from sleep. During sleep, muscle spasms, which are a protective mechanism, do not occur, and movement can cause severe pain. Generalized pain usually associated with degenerative changes, complex regional pain syndrome or nerve injury. Localized pain that can be pointed to with a finger may be caused by a fracture, ligament injury, or tendinitis[7,8].

Early morning stiffness or stiffness after rest complain is usually an indicator of arthritis, as rheumatoid arthritis or osteoarthritis. Another cause of stiffness is post traumatic fracture malunion. It should be determined whether swelling is generalized or localized. Generalized swelling has many causes such as rheumatoid, septic, or osteoarthritis, severe soft tissue injury, or systemic diseases affecting the heart, like heart failure. Localized swelling has many causes, like bone fracture or ligament injury. If there is history of trauma, the mode should be determined, as the specific mode of trauma causes specific problems[7,9].

SHOULDER VIRTUAL ASSESSMENT

Shoulder pain is a common reason for seeking medical advice. Localized anterolateral shoulder pain in the "Codman zone" associated with night pain is a clue of some degenerative shoulder pathology, either impingement or rotator cuff tear. Posterior shoulder pain usually occurs with scapular dyskinesia as well as cervical muscle spasm. Shoulder stiffness is a complaint usually associated with pain that may occur because of impingement, rotator cuff tear, arthritis, or frozen shoulder "adhesive capsulitis". Instability and recurrent shoulder dislocation complains are often seen in athletes and in young age groups[10,11].

Inspection should be done for swelling, muscle wasting, or scars of previous operations. Inspection from the front is done to see whether there is a prominent sternoclavicular joint (subluxation) or clavicle deformity (old fracture), prominent acromioclavicular joint (subluxation or osteoarthritis), or deltoid wasting (disuse or axillary nerve palsy). Assessment done from side and behind is done to see whether the scapulae is normally shaped and situated, or small and high, as in Sprengel's shoulder or Klippel–Feil syndrome, or if there is winging of the scapula owing to paralysis of the serratus anterior[11].

An active range of motion (ROM) evaluation is done by instructing the patient to perform movements shown by physician, with assessment of obvious limitation if present and asking the patient which movement is painful, which most often is shoulder abduction. Ask the patient to perform external rotation with adduction and with abduction, if limited in comparison to other side it may indicate a frozen shoulder [10,11].

Special shoulder examination tests include an impingement assessment done by asking the patient to perform forward flexion of the shoulder with 90 degrees of elbow flexion and then shoulder internal rotation. Ask the patient whether it is painful or not and where exactly he feels the pain. If it is "mostly in the lateral and anterolateral shoulder region", then it indicates the presence of impingement. The resisted abduction test requires equipment, any item that weighs 2 kg, and is done by asking the patient to do a shoulder abduction while lifting the 2 kg object with internal rotation of the shoulder. The test simulates the empty can test for rotator cuff tear (Figure 1). Testing for slap lesion is done by resisted shoulder flexion with the forearm pronated and asking the patient resist the movement with his other hand over the forearm. The test is positive with a slap lesion and it simulates the speed test. An abduction external rotation test is performed by asking the patient to perform external rotation with abduction of the shoulder and ask if he/she feels afraid of dislocation. The test simulates the apprehension test for anterior shoulder instability. Scapular dyskinesia is tested by asking the patient to perform forward flexion of the shoulder while inspecting his back to follow scapular motion and monitor the symmetry of



Figure 1 Modified empty can test.

scapular motion during the movement. Scapular winging is tested by instructing the patient to lean with both hands against a wall. Watch the inferior angle of the scapula. Any tendency of winging of the scapula immediately becomes apparent[12].

ELBOW VIRUAL ASSESSMENT

A patient complaint of localized pain related to the lateral epicondyle is specific for tennis elbow, radial tunnel syndrome, or osteochondritis of the capitellum. Localized pain over the medial epicondyle is specific for golfer's elbow, cubital tunnel syndrome, and ulnar collateral ligament injury. Aching pain usually caused by arthritic changes. Pain with activity is usually caused by tendinosis or instability[13]. Virtual elbow assessment should include inspection of the elbow from all sides in flexion and extension, looking for any swelling, muscle wasting, scars of previous operations, and any deformity. The elbow should be inspected in extension with the arm by the side and the forearm supinated for determining carrying angle. It is increased (cubitus valgus) in cases of lateral condyle fracture nonunion and premature lateral epiphysis closure, and decreased (cubitus varus) in supracondylar humerus fracture[13].

Active ROM is tested by a flexion and extension test done with the patient's shoulder abducted 90 degrees. Normal flexion is to 140 degrees and extension to −10 degrees. Pronation and supination ROM are tested after instructing the patient to place the elbow flexed 90 degrees by his side. Normal pronation is from 0 to 70 degrees and supination is from 0 to 85 degrees (Figure 2). Limited range is usually found in patients with old fractures and arthritis. Both sides should be compared[14,15].

Special tests, such as Thomsen's test, specific for tennis elbow is done by asking the patient to clench his fist, extend his elbow and dorsiflex his wrist against resistance. Patients with tennis elbow will experience pain over lateral epicondyle[7]. For Tinel's test, which is specific for ulnar nerve entrapment and neuropathy, the patient should be asked to flex his elbow to 20 degrees and a healthcare giver is asked to tap gently between the olecranon and medial epicondyle over the ulnar groove. The test is positive for ulnar neuropathy if the patient has a tingling sensation down the forearm until the ulnar part of hand. For a specific test of golfer's elbow, the patient is asked to flex his elbow and then supinate the forearm. A healthcare giver is asked to extend the elbow against resistance. If positive, the patient will have pain over the medial epicondyle. The chair pushup test is for assessment of posterolateral rotator instability in cases of injury to the lateral collateral ligament complex. It is done with the patient in a seated position with the hands grasping the arms of the chair. The elbows, in about 90° of flexion, are supinated and the arms abducted. The patient attempts to rise from the chair by pushing down. A positive result is pain as the elbow slowly extends while the patient rises[14,15].

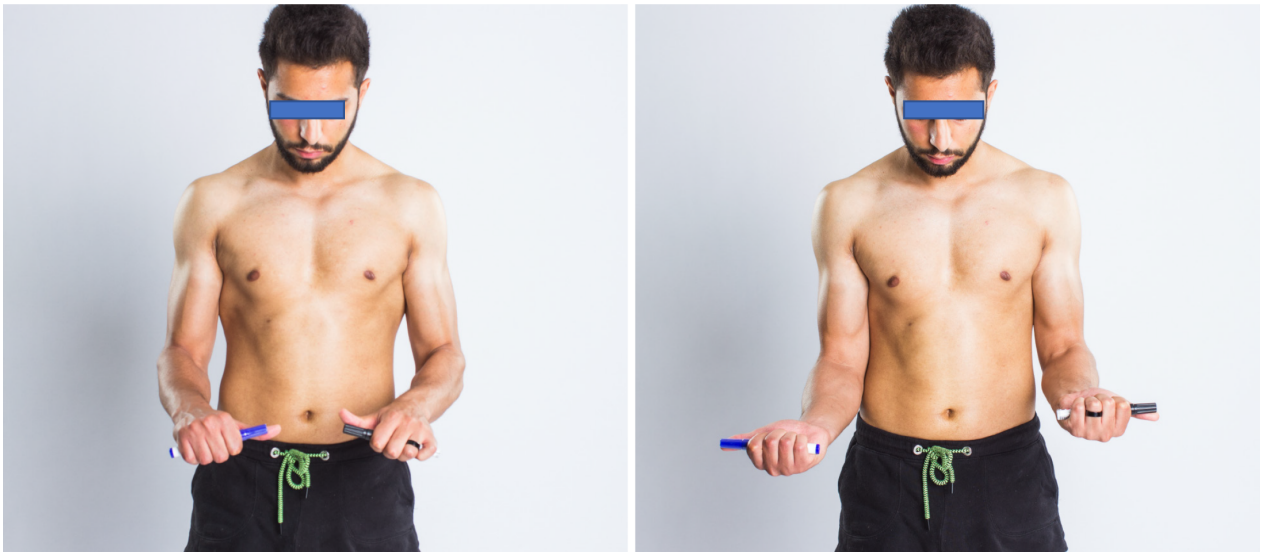


Figure 2 Assessing the active pronation and supination range of the elbow.

HAND VIRTUAL ASSESSMENT

Specific patients complaints are very important for making a specific diagnosis. Localized ulnar-side wrist pain may indicate conditions including a triangular fibrocartilage complex tear, or distal radioulnar joint instability/arthritis. Radial-side wrist pain suggests De Quervain's tendinitis, scaphoid fractures, *etc.*[16]. Wrist drop suggests radial nerve injury, while partial claw hand suggests ulnar nerve involvement[16,17]. A painless, slowly growing swelling at the dorsum of the hand just distal to the lister tubercle is suggestive of ganglion. Complaints of clicking and locking suggest Trigger finger, especially in the presence of a nodule on the corresponding metacarpophalangeal (MP) joint[18].

Hand inspection should be from the shoulders to the hands from all sides, with comparison between both sides. We inspect the hand to detect any deformity of alignment, scars, swelling, color changes, callosities, and ulcerations. Deformities such as short stumpy fingers seen in achondroplasia, as swan neck deformity, mallet finger, Boutonniere deformity, Z deformity of the thumb, and Dupuytren's contracture deformities should be inspected. Muscle wasting should also be noted as it suggests a root, plexus, or nerve lesion. A wasted Theaner eminence is associated with median nerve injury, wasted hypotheanar and interossei with ulnar nerve injury, and wasted anatomical snuff box with radial nerve injury[19].

Active movement of the finger joints is tested individually. Each finger is flexed maximally, while other fingers are extended and clearly seen, and then extended maximally. The normal active ROM is 0 to 90 degrees for the metacarpophalangeal (MP) joint, 0-100° for the proximal interphalangeal (IP) joint, 0 to 80 degrees for the distal IP joint, −20 to 15 degrees for thumb carpometacarpal joint, −5 to 55 degrees for thumb MP joint, and −20 to 80 degrees for the thumb IP joint. Similar assessments of thumb adduction, abduction, and apposition, wrist flexion and extension, ulnar and radial deviation can be made. The patient abducts and adducts the fingers as possible, with thumb adduction, radial abduction, and apposition[17].

Neurological sensory assessment can be assessed by asking a care giver to touch specific sites with cotton while comparing both sides with the patient's eyes closed. The sites are the tip of index finger (for median nerve injury), tip of little finger (for ulnar nerve injury), and the snuff box region (for radial nerve injury)[20,21]. Neurological motor assessments are done by asking the patient to make an "OK" sign by touching tip of thumb and the index finger to assess injury of the anterior interosseous nerve. With injury of the posterior interosseous nerve, the patient will have weak wrist extension with radial deviation. Loss of wrist extension is seen with radial nerve injury[20]. The ulnar nerve is assessed with Froment's test by asking the patient to grasp a piece of paper in the first web space on both sides while a caregiver holds the other side. Failure to adduct the thumb, and flexing it instead, indicates a positive test, with ulnar nerve injury[22]. For assessment of carpel tunnel syndrome Phalen's test (Figure 3) can be done by asking the patient to place the wrists in a maximal flexion position, which will reproduce the symptoms, if positive[23].



Figure 3 Phalen test.

HIP VIRTUAL ASSESSMENT

Hip pain is a common complaint of those seeking medical advice. Patients with hip problems also complain of limping, mechanical symptoms such as, clicking, snapping, catching, popping, and locking. The patient should be asked about a history of constitutional symptoms as fever, sweating, and nocturnal pain. The medical history should also address avascular necrosis of hip, usually seen in patients with systemic lupus and immune system disorders. Hip function can be objectively assessed with validated hip scores that can be assessed in the initial and in follow-up visits, especially after treatment. The Harris Scoring System and Western Ontario and McMaster Universities Arthritis Index hip scores are commonly used[3,10].

For inspection of the hip, undressing to underwear, if possible, is required to inspect the whole lower limb. Inspect from the front, sides, and back for skin scars, sinuses, discoloration, swellings, and muscle weakness or wasting (*e.g.*, Trendelenburg test). Inspect for any deformities in the sagittal plane and in the coronal view. Observe the gait, positive or negative limb length discrepancy from the front, sides and behind. Try to assess stride length, its components, and possible associated stiffness, shortening, pain and gluteal insufficiency[10].

Active ROM can be performed *via* telemedicine. For flexion, ask the patient to lie supine then flex each hip one time as possible. For extension, ask the patient to lie supine at the edge of a couch, then ask him/her to lie down one limb a time. For abduction and adduction, the camera should be at a level high enough to have a top view. Ask the patient to lie supine and then move the thighs away from each other far as possible and then back to the other side, crossing over as far as possible. For internal and external rotation, ask the patient to sit on the edge of the couch, and then move the legs away from each other as far as possible and then back toward the other side, crossing over as far as possible[10].

Fixed flexion deformities also can be assessed. An alternative to the Thomas test that can be conducted *via* telemedicine is to ask the patient to lie supine. Then starting in the knee-to-chest position and ask to actively extend each limb. Limb length assessment for discrepancy is done with the Geleazzi test (Figure 4), which can be effectively conducted *via* telemedicine. Ask the patient to lie supine and then flex both knees and hips 45 degrees. A static shot is taken from the top and the side views. Another way to determine limb length discrepancy is that in a normal patient the heels should be level with each other and the plane of the anterior superior iliac spines at right angles to the edge of the couch. If there is significant, true shortening the heels will not be level and the discrepancy is a guide to the amount of shortening. The pelvis will not be tilted[10].

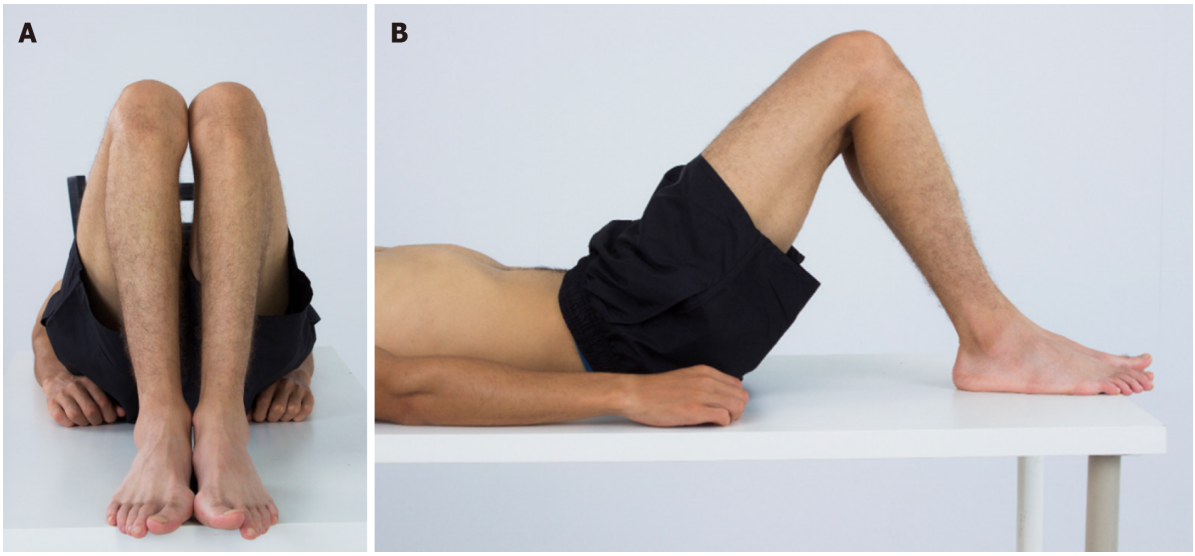


Figure 4 Geleazzi test to assess limb length discrepancy. A: Top view; B: Side view.

KNEE EXAMINATION

Specific complaints reveal the most common symptoms of patients with knee instability. Accurate assessment of the symptoms tells the physician a lot about the exact diagnosis[10,24]. Inspection should be done with bilateral knee exposure after instructing the patient to wear short swimwear. Look for genu recurvatum, genuvalgum, and genuvarum while patient is standing and for the position of the patella relative to the femoral condyles. The position of the patella should also be examined with knee flexion to assess the lateral position in case of lateral patellar dislocation. Then ask the patient to extend the knees, and look for any gross disturbance of patellar tracking. It should move smoothly in the patellar groove. Quadriceps wasting is assessed by asking the patient to put a towel underneath the popliteal fossa and push against it[24].

Active ROM done by instructing the patient to flex and extend the knees, assess if there is any limitation of movement, and ask the patient if the movement is painful or not. If the patient cannot fully extend the knee actively, extension lag and knee flexion deformity are differentiated by asking the patient to put his other leg beside the examined leg and try to complete the range of extension. If the examined leg is extended more, the reason is extension lag, and if it is not extended more, then it is knee flexion deformity[10,24].

Rupture of the posterior cruciate ligament may permit the tibia to sublux backwards. The knee should be flexed to 20°, with a sandbag under the thigh. The patient should be asked to lift the heel from the couch while observing the knee from the lateral aspect. Any posterior subluxation should normally correct during extension of the knee, confirming the diagnosis[10,24].

The Thessaly test (Figure 5) is done to examine for meniscal injury. It is performed at 5° and 10° of flexion. The patient can use a front wall as a support during a single leg squat to maintain balance the knee is flexed to the required amount. With the other lifted clear, the patient twists slowly from side to side. The result is positive if the patient experiences joint-line pain or sensations of locking or catching within the knee [10,24]. Common peroneal nerve testing is done easily by assessing the patient's ability to do ankle and big toe dorsiflexion[24].

ANKLE AND FOOT VIRTUAL EXAMINATION

Ankle joint assessment should be done with ipsilateral foot and knee assessment. For full inspection of ankle and foot, the patient should be asked to remove the shoes and socks with exposure to at least above the knee. Inspection should be from all sides, the anterior, posterior, lateral, medial, dorsal, and plantar surfaces of foot, and while standing and sitting. The surgeon should inspect the gait of the patient and also inspect the other side. We inspect the ankle and foot to detect any alignment



Figure 5 Thessaly test. Patient stands on one leg at a time, then rotates slowly from side to side. The maneuver should be performed three times, and the test is considered positive if the patient experiences pain, locking, or catching.

deformity, scars, swelling, color change, callosities, and ulcerations[25]. While the patient is standing in an anterior view, the surgeon should note whether the external rotation of the foot in the sagittal plane is within the normal range of 5-18 degrees. Causes of toe-out or toe-in signs should be investigated if noticed[25,26]. The big toe should be evaluated for abnormalities such as hallux valgus or hallux varus. Alignment of the lesser toes should be inspected to detect any abnormal alignment, such as hammertoe[25]. From the medial aspect with the patient standing, the surgeon should note whether the medial longitudinal arch of foot if normal or shows a deformity such as pescavus or pesplanus[7,25]. From the posterior with the patient standing, hindfoot alignment is evaluated by the angle between an imaginary line bisecting heel and another line bisecting the calf, which is normally in valgus about 5-10 degrees[25]. The importance of palpation of the foot is to determine the point of maximum tenderness, which is easily done in the ankle and foot by asking the patient to use the index finger to palpate all over the sides and surfaces of ankle and foot and asking which is the point of maximum tenderness.

Active ROM done by instructing the patient to do the same movements as the surgeon or as shown in a figure, with assessment of any obvious limitations. The patient should be asked which movement is painful and to compare both ankles. Active ROM is tested by asking the patient to stand on tiptoes to assess active plantar-flexion and to stand over the heels to assess active dorsiflexion. Active inversion and eversion are tested by asking the patient to stand over the inner and outer borders of the foot. Ankle passive dorsiflexion and planter flexion are done with the help of caregiver by holding the patient's heel neutral with one hand, inverting the midfoot with the other hand, and dorsiflex the ankle with the knee extended and then with the knee flexed at 90 degrees. Flexion is limited in case of stiffness, ankle fracture, or posterior structure. If the angle of dorsiflexion is same with knee flexion or extension, then the cause is the soleus muscle. If dorsiflexion is greater with the flexed knee, then the cause is gastrocnemius contracture[26].

Thompson's test is used to test the integrity of the tendon Achilles. The patient is asked to take the prone position with the feet off the end of table. A caregiver is asked to squeeze the calf on the normal and on the affected side. If the planter flexion movement is lost on the affected side, then a tear in the Achilles tendon is indicated [25]. The Coleman Block Test (Figure 6) is performed by placing the patient's foot on wooden block, 2.5-4 cm thick, with the heel and lateral border of foot on the block and bearing full weight while the first, second, and third metatarsals are allowed to hang freely. The test is used to assess the flexibility of hindfoot deformity in cases of cavovarus foot[27]. The tiptoe test is used to differentiate between flexible and rigid pesplanus deformity. In flexible flatfoot, the foot arch forms again when standing tiptoe[27,28].



Figure 6 Block test for assessment of hindfoot flexibility in cavovarus foot deformity.

SPINE VIRTUAL ASSESSMENT

Deformity with a progressive course in adolescence suggests scoliosis, while in old age and obesity back pain radiating to the extremity can suggest spondylosis. Ambulation or inadequate upper or lower limb function may indicate myelopathy or signify the degree of compression and possible need of surgical intervention. Bowel/bladder and sexual symptoms must to be evaluated to exclude the possible development of cauda equina syndrome[29,30]. The proper inspection of the entire spine is done by asking the patient to undress to underwear as possible. Normal sagittal curvature has cervical lordosis, thoracic kyphosis, and lumbar lordosis. Lost lumbar lordosis may indicate a protective spasm or posterior pelvic tilt, while exaggerated lumbar lordosis may suggest spondylolisthesis. Coronal alignment assessment should be done in a systematic descending manner, looking from head to heels. Gait should be inspected. Abnormal gaits related to spine disorders include a short step gait for back muscle spasm, an unsteady gait for myelopathy, and a sciatica gait for nerve root tension and lumbar disc prolapse. Heel to toe walking helps to approximately assess the motor power of the L4 and S1 nerve roots[31,32].

Start with cervical ROM assessment by asking the patient to point the camera sagittal to the of neck. Then ask the patient to move the chin to the chest and measure the distance between them (flexion) using a virtual ruler. Extension is determined with the patient looking at the ceiling and measuring the angle between the face and a horizontal line using goniometer-based software if available. Lateral bending is determined with the camera pointed at the front of the neck. Ask the patient to touch the ear to the shoulder and measure the distance between them using a virtual ruler. Rotation can then be determined by asking the patient to turn the chin to the shoulder. The same concepts are followed in thoracolumbar ROM assessment. Ask the patient to lean forward with extended knees and measure the degrees of flexion, Extension is the determined by extending the back as much as possible and measuring the degrees of extension as the angle between the back and a vertical line. Coronally, lateral bending is determined by asking the patient to lean laterally and advance the fingers down the legs with extended knees and measuring the degree of bending by finger to floor distance. Then, for thoracic rotation, with the patient sitting on a chair and the camera at a higher level, ask him/her to rotate the trunk, and measure the angle between shoulder and the coronal planes.

Sensory assessment can be done with a chart of the upper and lower limbs that shows the dermatomes at clear, easily located points. A caregiver can help by using cotton and the chart to compare both sides, with the patient's eyes closed. Motor assessment can be performed using simple measures to exclude weakness. If the patient can perform the movement against resistance, then the muscle grading is three or more. If any degree of resistance is offered, the grade is four or five. For cervical nerve root motor assessment, ask the patient to flex the elbow (C5), to extend the

elbow (C7), to extend the wrist (C6), to flex the fingers (C8), and to abduct them (T1). Similarly, lumbar nerve root assessment can be conducted by asking the patient to sit and then elevate the hip maximally (L1, 2), to lie supine with knees flexed 30 degrees into a triangle. Ask the patient to extend completely (L3), then to lie on the side and ask him/her to elevate the limb with the knee extended (L5). In all the previous motions, a caregiver is asked to provide resistance. We can rely on slump test to diagnose lumbar nerve root stretch *via* telemedicine instead of the straight leg test. Ask the patient to sit on the edge of the couch, lean the trunk forward while the neck extended to maintain a forward gaze, and then extend the knee as actively as possible. Ask for presence of pain and its location to confirm the diagnosis (Figure 7). The Valsalva maneuver with the knee is extended can confirm nerve stretch by pain accentuation[31,33].

PEDIATRIC ASSESSMENT

The age of the child is crucial for developing a differential diagnosis, for example, hip symptoms in a 7-year-old boy with delayed bone age can suggest Perthes disease[34,35]. Birth history is an important consideration especially when neuromuscular conditions such as cerebral palsy are suspected. Birth history can be divided into prenatal, natal, and postnatal periods. In the prenatal period, any history of maternal infection in the first trimester or vaginal bleeding may provide a clue for possible brain injury that could lead to cerebral palsy. Important factors to consider in the natal period include birth weight, type of presentation, mode of delivery, home or hospital delivery, any birth injuries, and whether the child was delivered full-term or preterm. Postnatally, any neonatal jaundice necessitating UV light intervention, need for neonatal intensive care unit, incidence of hypoxia or cyanosis, and Apgar score should be noted[36,37]. A family history can be important for detecting diseases such as neurofibromatosis. A nutritional history is important to consider as well, especially in the pediatric patient, and may help identify nutritional rickets as the underlying etiology for deformities in toddlers. Finally, a developmental history with both physical and mental milestones can be useful, particularly in suspected cases of neurodevelopmental disorders[38].

General examination should include facial abnormalities that may occur in Down syndrome, blue sclera that can suggest osteogenesis imperfecta, and abnormalities in height and proportions that suggest dysplasia, and café au lait spots that are characteristic of neurofibromatosis[39]. The evaluation should include observation of joint alignment to determine whether the patient has a symmetrical shoulder level, symmetrical scapulae, and a level pelvis. Search for any possible coronal knee deformities, and document intermalleolar and intercondylar distance. Observe for other potential knee deformities, including squinting patellae caused by excessive femoral anteversion, ankle deformities, and deformities of the forefoot, midfoot, and hindfoot. A similar systematic sequence can be applied to the upper limb[39].

Gait assessment should be done from coronal and sagittal views while observing the appearance of the hip, knee, and foot. Inspect for any possible anterior or posterior pelvic tilt, scissoring of the thighs, any coronal knee deformities, squinting patellae, any flexed knee gait, pes planovalgus or pes cavovarus, forefoot abduction, big toe deformities, and coronal ankle deformities. Observe for general patterns of gait deformities such as jumping, crouch, equine, ataxic, and circumduction gaits. Trendelenburg gait may occur in the setting of hip diseases like developmental dysplasia of the hip or coxa vara, short limb gait in a limb length discrepancy, out-toeing gait which may be seen in slipped capital femoral epiphysis (SCFE), and high stepping gait that often occurs in knee flexion deformities[34,35,39]. The Geleazzi test for limb length measurement can be effectively translated to telemedicine. Ask the patient to lie supine and then flex both knees and hips to 45 degrees from the top and the side views, which can then be used to interpret the cause of limb length discrepancy[39].

INVESTIGATION

Plain X-rays are usually needed for evaluation of fractures, loose bodies, and the presence of arthritis. Anteroposterior and lateral views are standard and are usually required. Special views such as foot obliques or mortise view of the ankle are useful for assessment of syndesmosis, scaphoid view for scaphoid fracture diagnosis, stress

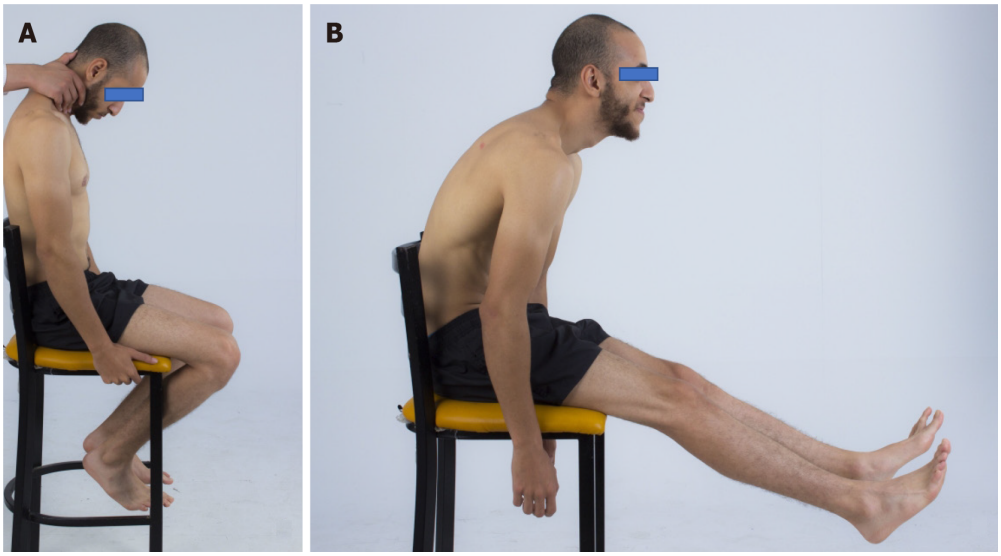


Figure 7 Special tests. A: Lhermitte test; B: Slump test.

views, such as clenched fist, for carpal instability, Other plain X-ray views are useful. The Zanca view may help visualize acromioclavicular joint pathologies, The Stryker notch view can show a Hill-Sachs lesion[40-42]. Computed tomography is used to show details, configuration of fractures as evaluation of intra-articular extension as in pilon fracture, or evaluation of osteochondral lesions and arthritis. Magnetic resonance imaging is used to assess the integrity of soft tissues, ligaments, tendons, occult fracture, vascular status of bone, and is also useful to detect disc herniation and nerve root compression. Nerve conduction tests are used for evaluation of nerve entrapments. Scanograms can be used to measure limb length discrepancy and the site and degree of discrepancy[41,43,44].

Laboratory studies like complete blood count, erythrocyte sedimentation rate, and C-reactive protein can be useful for detecting the presence of infection. A metabolic profile and vitamin D assay can be useful for the evaluation of nutritional rickets and SCFE. Renal function tests should be ordered if renal osteodystrophy is suspected. Finally, a serum creatin kinase-MB test should be ordered if muscle dystrophy is suspected.

CONCLUSION

Virtual assessment and management of orthopedic patients can cross geographical and temporal boundaries, improve patient comfort, increase data transmission security, reduce cost, digitize healthcare system data, and facilitate the establishment of medical databases, with potential research and audit benefits, which confirm its efficacy during health crises and epidemic diseases.

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MINIREVIEWS

Machine learning in orthopaedic surgery

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Abstract

Artificial intelligence and machine learning in orthopaedic surgery has gained mass interest over the last decade or so. In prior studies, researchers have demonstrated that machine learning in orthopaedics can be used for different applications such as fracture detection, bone tumor diagnosis, detecting hip implant mechanical loosening, and grading osteoarthritis. As time goes on, the utility of artificial intelligence and machine learning algorithms, such as deep learning, continues to grow and expand in orthopaedic surgery. The purpose of this review is to provide an understanding of the concepts of machine learning and a background of current and future orthopaedic applications of machine learning in risk assessment, outcomes assessment, imaging, and basic science fields. In most cases, machine learning has proven to be just as effective, if not more effective, than prior methods such as logistic regression in assessment and prediction. With the help of deep learning algorithms, such as artificial neural networks and convolutional neural networks, artificial intelligence in orthopaedics has been able to improve diagnostic accuracy and speed, flag the most critical and urgent patients for immediate attention, reduce the amount of human error, reduce the strain on medical professionals, and improve care. Because machine learning has shown diagnostic and prognostic uses in orthopaedic surgery, physicians should continue to research these techniques and be trained to use these methods effectively in order to improve orthopaedic treatment.

Key Words: Artificial intelligence; Machine learning; Supervised learning; Unsupervised learning; Deep learning; Orthopaedic surgery

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Core Tip: With the mass interest artificial intelligence and machine learning have garnered in orthopaedic surgery, a literature review of recent studies is necessary. By demonstrating the utility of various machine learning algorithms across various subspecialties of orthopaedic surgery, researchers should encourage physicians to understand the benefits of machine learning techniques and learn how to effectively incorporate these elements into their own practice to improve patient care. This clinical review outlines the concepts of machine learning and summarizes current and future orthopaedic applications of machine learning in risk assessment, outcomes assessment, imaging, and basic science fields.

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INTRODUCTION

The application of artificial intelligence (AI) has taken our world by storm. AI has been used in many aspects of modern life such as recommendation systems used by Netflix, YouTube, and Spotify, search engines like Google, and social-media feeds like Facebook and Twitter[1]. Additionally, AI has entered the realm of medicine. For example, there is substantial evidence that AI performs on par or better than humans in various tasks such as analyzing medical images as well as correlating symptoms and biomarkers from electronic medical records with the characterization and prognosis of disease[2]. Specifically in orthopaedic surgery, certain subfields of AI have been successfully implemented to improve clinical decision making and patient care[3].

To better understand the utility of AI in orthopaedic surgery, some terms must first be defined. AI started as a theory that computers could eventually learn to perform tasks through pattern recognition with minimal to no human involvement[1,4]. Today, the definition has been adapted to include the application of algorithms that provide machines the ability to solve problems that traditionally required human intelligence [1,5]. AI, which is often used as an umbrella term, encompasses subfields such as machine learning (ML), which is defined as a series of mathematical algorithms that enable the machine to "learn" the relationship between the input and output data without being explicitly told how to do so[3]. Furthermore, machine learning contains the subfield of deep learning (DL) which can be used to find correlations without labelling, that are too complex to render using previous machine learning algorithms, by processing input data through artificial neural networks[6,7].

In the field of orthopaedic surgery, ML has been used for different applications such as fracture detection, bone tumor diagnosis, detecting hip implant mechanical loosening, and grading osteoarthritis (OA)[3]. As time goes on, the utility of AI and ML in orthopaedic surgery continues to grow and expand. The purpose of this review is to provide an understanding of the concepts of ML and a background of current and future orthopaedic applications of ML in risk assessment, outcomes assessment, imaging, and basic science fields.

WHAT IS ML?

ML focuses on developing automated computer systems that predict outputs through algorithms and mathematics[8,9]. Classic or conventional ML algorithms that are meant to extract knowledge from more tabulated data sets include decision trees, random forests, nearest neighbors, linear regression, support vector machine (SVM), and k-means clustering[3,10]. On the other hand, more recently developed DL algorithms and artificial neural networks (ANN) are used to extract knowledge from imaging data sets. Regardless of which algorithms are used, ML requires software to "learn" patterns or relationships from sets of empirical data. This "learning" can be achieved through three different means: supervised learning, unsupervised learning,

and reinforcement learning[11-13].

Types of ML

Supervised learning, also termed inductive learning, is the most prevalent type of ML and occurs when data is labeled to tell the machine exactly what patterns it should look for[14]. For example, if an ML algorithm is used to detect arthritis on a knee radiograph, the arthritic features must be manually identified and labeled by a human along with the label of whether the radiograph is an example of an arthritic or normal knee[1]. On the other hand, unsupervised learning, also termed deductive or analytic learning, occurs when the data is not labeled and the machine looks for patterns[14] (Figure 1). In continuing with the last example, the arthritic features in unsupervised learning would not be labeled and therefore the algorithm relies on self-organization [1]. Lastly, reinforcement learning acts more like a reward or punishment system. Unlike supervised learning which makes data available at the beginning of the task, reinforcement learning uses feedback about the correctness after the task has been completed[15]. Usually, supervised learning is used because it requires the least amount of data and thus the least amount of time to learn.

DL and ANN

DL is modeled after the human brain's neural connections *via* complex and layered algorithms termed ANN[1,14]. The complex layering allows the algorithm to learn more complex and subtle patterns compared to more simple one or two layer networks[5,16,17]. Two known models of deep learning within the ANN include convolutional neural network (CNN) and recurrent neural network. The main type, CNN, has two main functions: (1) to extract features from imaging; and (2) classification[3]. The CNN extraction feature relies on the idea that filters learned on a small subset of a larger image to detect certain features can also be applied to other parts of the larger image in order to detect the same feature at different locations[3]. The CNN starts by searching for simple features in an image and then pools these simple features together to extract more complicated high-level features[3,18] (Figure 2). For the classification feature, the CNN acts as a classic neural network that combines all the high-level feature maps (generated from the aforementioned filters) from the deepest convolution layer and uses them to output a classification score[3]. During training, the CNN is presented with a series of images that have known classifications; the CNN must make a classification decision for each image and then calculate the classification error by comparing its classification decision with the known classification of the image. Through this training process, the CNN is able to update its learnable parameters and make classification decisions on images never before seen[3].

DL algorithms have been successfully applied to complex problems to improve diagnostic accuracy and speed, flag the most critical and urgent patients for immediate attention, reduce the amount of human error, reduce the strain on medical professionals, and improve orthopaedic care[3]. Specifically in orthopaedic surgery, the greatest application of DL is in image classification.

RISK ASSESSMENT

While ML has traditionally been used in medicine for rule-based approaches such as safe drug prescription, recent use of ML and DL in orthopaedic surgery has focused on clinical decision support such as risk assessment[14,19]. Currently, logistic regression is one of the most commonly used methods for identifying risk factors predictive of developing complications; however, in comparison, ANN allows for the identification of nonlinear patterns that make predictions more accurate[20-22].

Throughout orthopaedic literature, the application of ML and DL in risk assessment for various complications has been studied extensively (Table 1). For example, in Kim *et al*[23], ML models were used to predict mortality, venous thromboembolism, cardiac complications, and wound complications following posterior lumbar fusion. The ML models outperformed the American Society of Anesthesiologists (ASA) scores proving that ML can be more effective at predicting complications. Similarly, in Harris *et al* [24], ML was used to predict 30 day mortality and morbidity after total joint arthroplasty. While the ML model was found to be more accurate than standard models for cardiac complications and mortality, it was less effective for rarer complications such as re-operation and deep infection. More recently, Gowd *et al*[25] used supervised ML models to predict postoperative outcomes following total shoulder arthroplasty. ML algorithms outperformed the standard model for predicting adverse events,

Table 1 Summary of machine learning for orthopaedic surgery risk assessment

Ref.	Conclusion
Bevevino *et al* [26]	ANN capable of accurately estimating the likelihood of amputation
Gowd *et al*[25]	Supervised ML outperformed ASA classification models in predicting adverse events, transfusion, extended length of stay, surgical site infection, return to operating room, and readmission
Harris *et al*[24]	ML was moderately accurate in predicting 30-d mortality and cardiac complications after elective primary TJA
Kim *et al*[23]	ANN more accurate than ASA in predicting mortality, VTE, cardiac and wound complications following posterior lumbar spine fusion

ML: Machine learning; ANN: Artificial neural network; ASA: American Society of Anesthesiologists; TJA: Total joint arthroplasty; VTE: Venous thromboembolism.

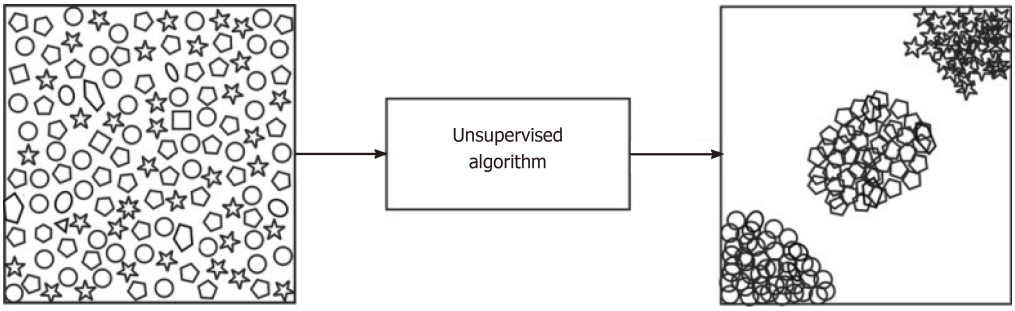


Figure 1 A visual illustration of an unsupervised algorithm[11]. Reused with permission. Citation: Sidey-Gibbons JAM, Sidey-Gibbons CJ. Machine learning in medicine: a practical introduction. *BMC Med Res Methodol* 2019; **19**: 64.

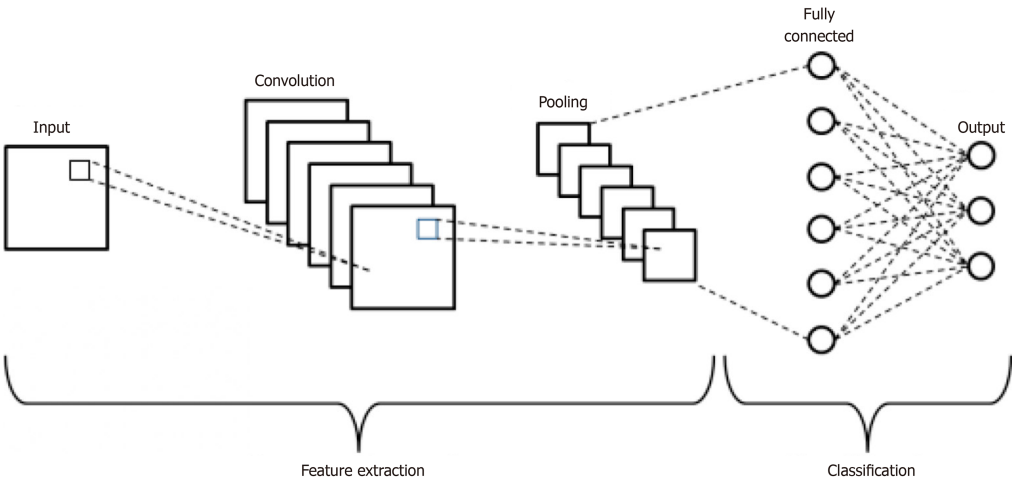


Figure 2 Schematic diagram of a basic convolutional neural network architecture[18]. Reused with permission. Citation: Phung VH, Rhee EJ. A High-Accuracy Model Average Ensemble of Convolutional Neural Networks for Classification of Cloud Image Patches on Small Datasets. *App Sci* 2019; 9: 4500.

transfusion, extended length of stay, surgical site infection, return to the operating room, and readmission. Furthermore, in risk assessment related to orthopaedic trauma, Bevevino *et al*[26] used a DL model to predict the likelihood of amputation based on 155 combat-related open calcaneal fractures and compared it to a standard logistical regression model. Twenty-six features with a proven or theoretical association with successful or unsuccessful limb salvage were analyzed; some of the features included were various patient demographics, mechanism of injury, wound size and location, and fracture type. Once again, the DL method was 30% more accurate and better suited to clinical use than the standard logistical regression model.

The orthopaedic literature shows that ML continuously outperforms more traditional legacy risk-stratification measures such as ASA classification, Charlson Comorbidity Index, and modified 5-item frailty index, in predicting complications

following a variety of orthopaedic procedures as well as identifying safe candidates for specific orthopaedic procedures like anterior cervical fusion and discectomy[25,27-29]. In all of the studies outlined above, the ML and DL algorithms outperformed the standard models indicating a higher level of accuracy for risk assessment[23-26]. Furthermore, comorbidity indices have previously been used to gauge perioperative risk, evaluate the need for postoperative admission, and determine prophylactic treatments[30-32]. With continued validation, ML algorithms may replace this paradigm. Whereas logistical regression models have typically been used for many years to predict risk, survival, mortality, and morbidity, the application of ML and DL, particularly in predicting the risk of complications following spine surgeries, joint surgeries, and orthopaedic trauma, shows much promise[14].

OUTCOMES ASSESSMENT

Over the last twenty years or so, the ability to predict outcomes has positively impacted medicine and patient care. From risk scores that guide anticoagulation (CHADS2) to the use of cholesterol medications (ASCVD), data-driven clinical predictions have become routine in medical practice[33]. Because ML has the ability to analyze large data sets, the accuracy of prediction significantly improves[33]. Specifically in orthopaedic surgery, recent literature has shown the utility of ML algorithms in outcomes assessment for orthopaedic oncology survival, patient-reported outcome measures (PROMs), hospital length of stay, and cost (Table 2).

When compared to ML algorithms, current prognostication models for survival following metastatic spinal disease are not built for estimation of short-term survival (30 to 90 d) and some studies even suggest a lack of accuracy in classic models[34-37]. In Janssen *et al*[38], authors compared a boosting ML algorithm to a classic scoring system and nomogram at 30 d, 90 d, and 1 year to study survival estimates in patients with long bone metastases. In all training data sets, the boosting ML algorithm was found to be far superior at each time point[38]. Paulino Pereira *et al*[37] conducted a similar study where they compared the boosting ML algorithm, nomogram, and the classic scoring system to predict survival in metastatic spine disease. In this study, the boosting ML algorithm was comparable to nomogram in its predictive ability for testing data sets. Thio *et al*[39] and Bongers *et al*[40] used ML methods on patient demographics, tumor characteristics, treatment, and outcome data to create an ML algorithm that could predict 5 year survival rate in patients with chondrosarcoma[39,40]. In the latter study, the authors found that the ML algorithm overestimated the survival rate in their data set, but when applied to a smaller data set, it overestimated survival to a lesser extent.

Within the last ten years, the concept of PROMs has gained rapid support in orthopaedic surgery as a way to measure healthcare quality and value[41]. The minimally clinically important difference (MCID) or the minimum change in PROM scores that patients perceive as clinically meaningful offers a threshold of score that portends clinical relevance[41-43]. Using predictive models to identify patients at risk of not achieving MCID is important for resource allocation as well as better monitoring especially for presurgical decision support[41]. Fontana *et al*[41] used three ML models to predict which patients would not achieve a MCID in four PROMs two years following total joint arthroplasty (TJA). When applied to presurgical registry data, the three ML models predicted 2-year postsurgical MCIDs with fair-to-good ability showing that ML has good predictive power in MCID following TJA. In another study, Menendez *et al*[44] used ML to understand sentiment by exploring the content of negative patient-experience comments after total shoulder arthroplasty (TSA). Through a ML based approach, they found that patient satisfaction was highly correlated to hospital environment, nontechnical skills, and delays. Menendez *et al*[44] showed the potential utility of AI and ML models to analyze post-surgical PROM surveys to determine quality and satisfaction after TSA.

A newer trend in orthopaedic surgery is using ML concepts to predict hospital length of stay as well as cost[45-47]. Today, ML models can be used to predict how long or how much a patient's surgery will cost prior to the elective procedure[48,49]. Ramkumar *et al*[45,47] and Navarro *et al*[46] used ML techniques on preoperative big data to predict length of stay and patient-specific payments following total hip arthroplasty (THA) and total knee arthroplasty (TKA), respectively[45-47]. In both studies, the ML techniques showed excellent predictability in length of stay. As complexity of the case increased, accuracy for predicting payment decreased proportionately in THA. On the other hand, as complexity of the case increased in TKA, accuracy for

Table 2 Summary of machine learning for orthopaedic surgery outcomes assessment

Ref.	Conclusion
Bongers *et al*[40]	ML algorithm overestimated ability to predict 5-year survival in patients with chondrosarcoma
Fontana *et al*[41]	Used ML to demonstrate fair-to-good ability in predicting 2-year postsurgical MCID following TJA
Greenstein *et al*[51]	Used EMR-integrated ANN to predict discharge disposition after TJA on small data set
Janssen *et al*[38]	Boosting ML algorithm far superior in training data sets to classic scoring system and nomogram in predicting survival in patients with long bone metastases at 30 days, 90 days, and 1 year
Karnuta *et al*[50]	Bayes ML algorithm demonstrated excellent accuracy in prediction of length of stay and cost of an episode of care for hip fracture
Menendez *et al*[44]	Used ML on patient-narrative analysis to show patient satisfaction after TSA is linked to hospital environment, nontechnical skills, and delays
Navarro *et al*[46]	Created a valid ML algorithm that predicted length of stay and costs before primary TKA
Pereira *et al*[55]	Boosting ML algorithm comparable to nomogram in its ability to predict survival in metastatic spine disease with testing data sets
Ramkumar *et al*[45]	Created a valid and reliable ML algorithm that predicted length of stay and payment prior to primary THA
Ramkumar *et al*[47]	Developed several ML based models for primary LEA that preoperatively predict cost, length of stay, and discharge disposition
Thio *et al*[39]	Created a high performing ML algorithm that could predict 5-year survival in patients with chondrosarcoma

ML: Machine learning; MCID: Minimally clinically important difference; TJA: Total joint arthroplasty; EMR: Electronic medical record; ANN: Artificial neural network; TSA: Total shoulder arthroplasty; TKA: Total knee arthroplasty; THA: Total hip arthroplasty; LEA: Lower extremity arthroplasty.

predicting costs increased by 3%, 10%, and 15% for moderate, severe, and extreme risk populations[46]. Similarly, Karnuta *et al*[50] used an ML algorithm on preoperative patient data to predict length of stay and cost after hip fracture; they found their ML algorithm to be 76.5% accurate for predicting length of stay and 79% accurate for predicting cost. Furthermore, Greenstein *et al*[51] used ML to preoperatively predict the likelihood a patient will be discharged to a skilled nursing facility after TJA. This study served as proof of concept that ML could be used as a prediction tool not only for big data sets, but also for small data sets. Using ML techniques to predict length of stay and cost has led to monumental improvements in establishing value-based care in orthopaedic surgery.

In orthopaedic surgery, AI and ML based techniques have demonstrated utility in predicting outcomes related to orthopaedic oncology, PROMs, length of stay, and cost. While ML techniques for survival in orthopaedic oncology have not yet been perfected, ML has proven to be effective with PROMs as well as predicting length of stay and cost. By using ML methods to make better outcome predictions, orthopaedic surgeons can improve their decision-making ability, which not only leads to better patient care, but also more efficient utilization of healthcare resources[52].

IMAGING

Since orthopaedic surgery diagnosis and treatment heavily rely on radiologic modalities [*e.g.*, computed tomography (CT), magnetic resonance imaging (MRI), and conventional radiographs], the vast majority of AI and ML based research has been applied to imaging. Recent advances in AI and ML have shown remarkable results with a few studies showing computers surpassing human test subjects at certain image interpretation tasks[53,54]. Within musculoskeletal medicine, DL has been shown to be useful for both text and image analysis[55-57]. ML and DL based techniques have the potential to assess earlier disease status and are currently the focus of significant orthopaedic research, particularly in the following subspecialties: Spine, joints/arthritis, trauma, and oncology (Table 3).

Spine

In spine surgery, technology has risen with the use of computer assisted navigation, robotic surgery, and augmented reality, all of which require reconstructions of the spinal column from CT or MRI scans[58-61]. This can only be achieved *via* ANNs and

Table 3 Summary of machine learning for orthopaedic surgery imaging applications

Ref.	Subspecialty	Conclusion
Al-Helo *et al*[66]	Spine	Neural network (93.2% accurate) and k-means approach (98% accurate) used on CT scans for segmentation and prediction of lumbar wedge fractures
Forsberg *et al*[62]	Spine	Annotated MRIs with information labels for each spine vertebrae used to accurately detect (99.8%) and label (97%) cervical and lumbar vertebrae
Hetherington *et al*[64]	Spine	CNN successfully identified lumbar vertebral levels on ultrasound images of the sacrum
Jamaludin *et al*[65]	Spine	CNN model achieved 95.6% accuracy comparable to experienced radiologists in disc detection and labeling of T2 weighted sagittal lumbar MRIs
Pesteie *et al*[63]	Spine	Used ML system to detect laminae and facet joints in ultrasound images to assist in epidural steroid injection and facet joint injection administration
Ashinsky *et al*[71]	Joints/arthritis	ML algorithm predicted clinically symptomatic OA on T2 weighted maps of central medial femoral condyle with 75% accuracy
Liu *et al*[72]	Joints/arthritis	CNN performed rapid and accurate cartilage and bone segmentation within the knee joint
Shah *et al*[73]	Joints/arthritis	CNN used to automate the segmentation and measurement of cartilage thickness based on MRIs of healthy knees
Xue *et al*[70]	Joints/arthritis	CNN model trained to diagnose hip OA comparable to an attending physician with 10 years of experience in diagnosing hip OA
Kruse *et al*[75]	Trauma	ML improved hip fracture detection beyond logistic regression using dual x-ray absorptiometry
Olczak *et al*[74]	Trauma	DL networks identified fracture, laterality, body part, and exam view on orthopaedic trauma radiographs of the hand, wrist, and ankle
Oh *et al*[78]	Oncology	ML showed superior predictive accuracy in predicting pathological femoral fractures in metastatic lung cancer

ML: Machine learning; CNN: Convolutional neural network; OA: Osteoarthritis.

DL through automated segmentation and detection of vertebrae. Numerous studies in the orthopaedic spine literature have analyzed the accuracy of DL techniques, especially for labeling and detection. For example, in Forsberg *et al*[62], annotated MRIs with information labels for each spine vertebrae were used to detect and label cervical and lumbar vertebrae. The highest performance showed an accuracy of 99.8% for detection and 97% for labeling. Furthermore, Pesteie *et al*[63] and Hetherington *et al*[64] used ANNs trained with ultrasound images to automatically detect optimal vertebra level and injection plane for percutaneous spinal needle injections; Pesteie *et al*[63] showed highest accuracy to be 95% and maximum precision to be 97%. ML and DL techniques have been shown to be useful in diagnosis as well. Jamaludin *et al*[65] used DL techniques to read T2 weighted sagittal lumbar MRI images, automate the identification of disc spaces, grade the degenerative changes such as spondylolisthesis and central canal stenosis, and compare them to what experienced radiologists would do (Figure 3). The DL model performed almost as well as experienced radiologists on test data with a best accuracy rate of 95% for the prediction of spondylolisthesis. Because this model did not require labeling and feature description, authors believe the model will gain more accuracy and reliability with the addition of coronal and axial views. Al-Helo *et al*[66] used ML techniques, specifically neural network and k-means approach, to learn lumbar wedge fracture diagnoses from CT image labeling for segmentation and prediction. The neural network showed an accuracy of 93.2% for lumbar fracture detection, while the k-means clustering approach attained an accuracy of 98%. These studies prove that the automation of radiologic grading is now on par with human performance; this can be incredibly beneficial in aiding clinical diagnoses in terms of grading and speed of analysis.

Joints/arthritis

OA, a highly prevalent disease associated with articular cartilage degeneration, can be effectively diagnosed in a cost-effective manner with X-ray imaging and in a more sensitive manner with MRI which can detect subtle morphologic changes in articular cartilage[67-69]. Throughout orthopaedic literature, DL has been used for hip and knee diagnostic purposes based on medical images. For the hip, Xue *et al*[70] trained a CNN with 420 hip X-ray images to highlight saliency regions. These saliency regions allow the deep learning model to extract the necessary information in order to diagnose hip OA (Figure 4). The CNN model was able to achieve an accuracy of 92.8%, comparable

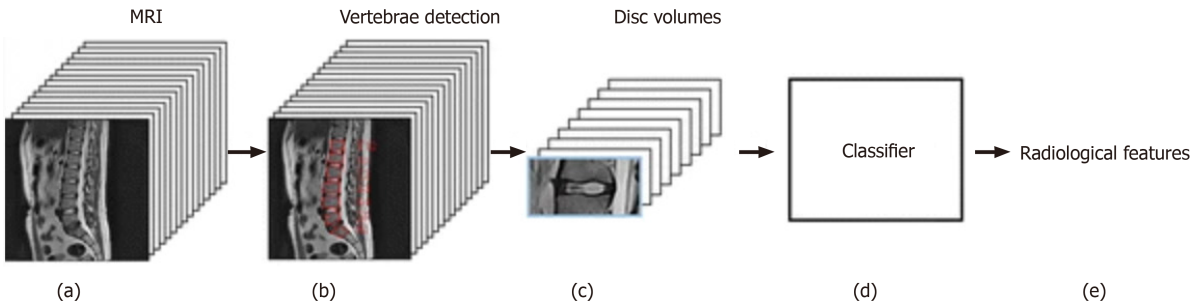


Figure 3 Input processing pipeline of T2 sagittal magnetic resonance imaging and output predictions of radiological features[65]. Reused with permission. Citation: Jamaludin A, Lootus M, Kadir T, Zisserman A, Urban J, Battié MC, Fairbank J, McCall I; Genodisc Consortium. ISSLS PRIZE IN BIOENGINEERING SCIENCE 2017: Automation of reading of radiological features from magnetic resonance images (MRIs) of the lumbar spine without human intervention is comparable with an expert radiologist. *Eur Spine J* 2017; 26: 1374-1383.

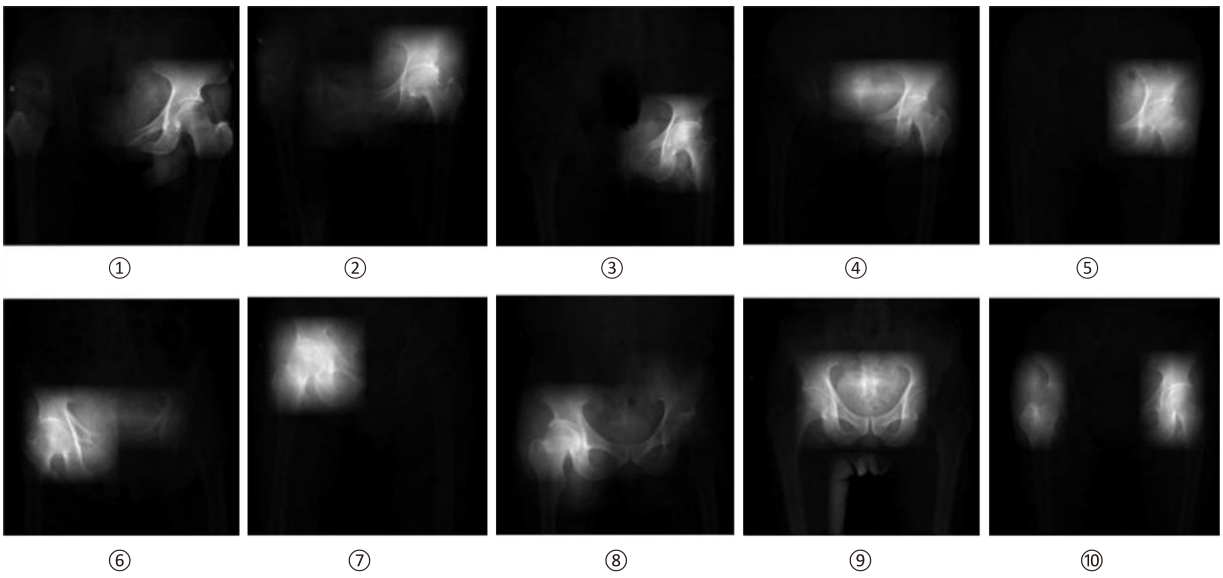


Figure 4 Saliency images from left hip joint (1-5), right hip joint (6-8), and both hip joints (9,10)[70]. Reused with permission. Citation: Xue Y, Zhang R, Deng Y, Chen K, Jiang T. A preliminary examination of the diagnostic value of deep learning in hip osteoarthritis. *PLoS One* 2017; 12: e0178992.

to an attending physician with ten years of experience in diagnosing hip OA. For the knee, Ashinsky *et al*[71] used a ML algorithm on T2 weighted maps of the central medial femoral condyle in order to predict progression to clinically symptomatic OA; the ML algorithm was able to predict the onset of OA with 75% accuracy. Liu *et al*[72] applied a CNN to a knee image data set for bone and cartilage segmentation and labeling (Figure 5). Authors reported a performance accuracy of 75.3% for femoral cartilage labeling and 78.1% for patellar cartilage labeling. Similar to Liu *et al*[72], Shah *et al*[73] used a CNN to successfully automate cartilage segmentation methods and measurement of articular cartilage thickness. This study showed that ML can be used to analyze cartilage thickness in an automated and efficient manner. The results of the studies summarized above indicate that DL has promising potential in the field of intelligent medical image diagnosis practice, especially for hip and knee OA.

Trauma

For orthopaedic trauma, ML derived tools can be used on imaging techniques to assist in diagnostic ability, particularly for detection of fractures. Olczak *et al*[74] applied ML to 256000 orthopaedic trauma radiographs with good results compared to radiologists. In this study, a database of hand, wrist, and ankle radiographs were used and four outcomes - laterality, exam view, fracture, and body part - were identified (Figure 6). Five DL networks were used and reached 99% accuracy when identifying body part, 90% on laterality, 95% on exam view, and 83% on detecting fractures[74]. Furthermore, Kruse *et al*[75] used ML to predict hip fractures from dual x-ray absorptiometry; they found that ML could improve hip fracture prediction beyond logistic regression. In

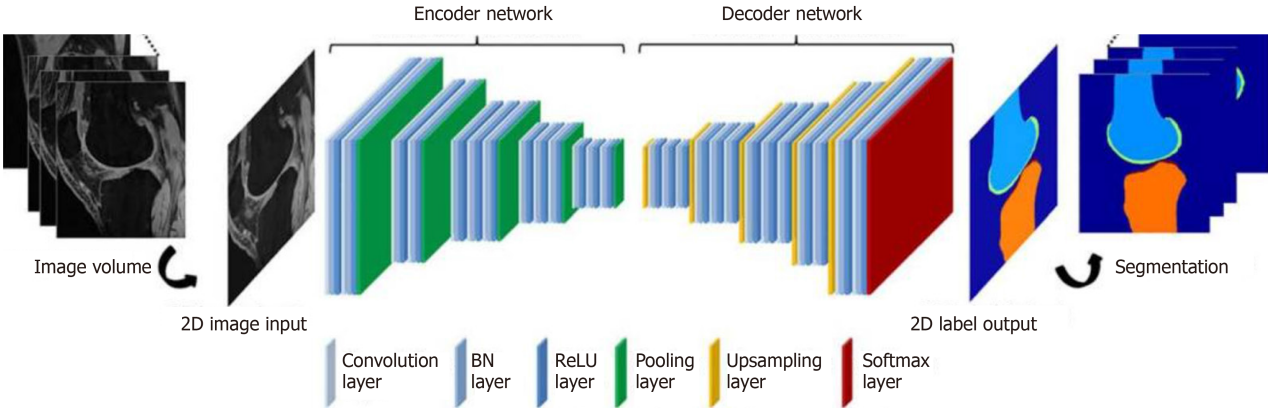


Figure 5 Convolutional neural network depiction of a knee image data set for bone and cartilage segmentation and labeling[72]. Reused with permission. Citation: Liu F, Zhou Z, Jang H, Samsonov A, Zhao G, Kijowski R. Deep convolutional neural network and 3D deformable approach for tissue segmentation in musculoskeletal magnetic resonance imaging. *Magn Reson Med* 2018; 79: 2379-2391.

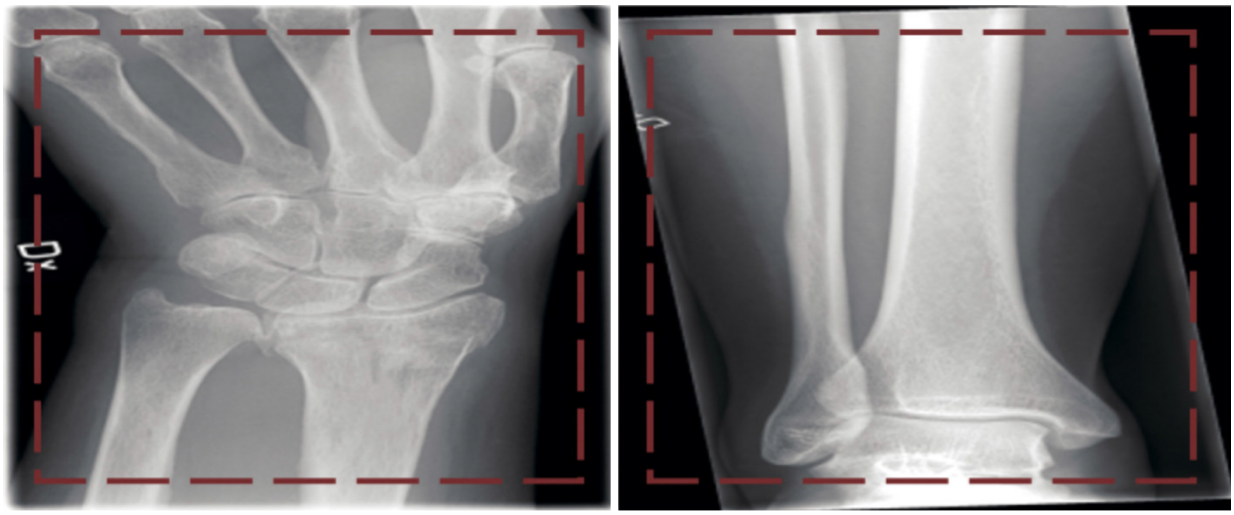


Figure 6 Two images (left, wrist fracture; right, no fracture) from the dataset presented to the network[74]. Reused with permission. Citation: Olczak J, Fahlberg N, Maki A, Razavian AS, Jilert A, Stark A, Sköldenberg O, Gordon M. Artificial intelligence for analyzing orthopedic trauma radiographs. *Acta Orthop* 2017; 88: 581-586.

orthopaedic trauma, ML based techniques have immense utility in predicting fractures. AI and ML based methods could be beneficial in the future of orthopaedic trauma as they may enhance workflow in the emergency department[76].

Oncology

In orthopaedic oncology, management of metastatic bone disease is a major focus, especially with respect to fracture and impending fracture care[77]. Oh *et al*[78] used ML on CT imaging and clinical features to extract radiologic features and derive predictions for pathological femoral fractures in metastatic lung cancer and compared the ML model with one that used CT features alone. The ML model, which included clinical features, showed superior predictive accuracy compared to the model that used CT features alone. By using AI and ML to accurately predict impending skeletal-related events, such as pathologic fracture, orthopaedic surgeons can prophylactically treat patients and thus improve patient outcomes[77].

BASIC SCIENCE APPLICATIONS

In the past, ML has been applied to basic science topics in medicine to predict chemical properties of drugs and proteins, predict vaccine immunogenicity, and identify promising drug targets[79-82]. In orthopaedic surgery, AI and ML has been applied to

Table 4 Summary of machine learning for orthopaedic surgery basic science applications

Ref.	Application	Conclusion
Begg *et al*[83]	Gait analysis	Used SVM to automate recognition of gait changes due to aging
Joyseeree *et al*[84]	Gait analysis	Used random forest, boosting, and SVM to identify disease on gait analysis data
Sikka *et al*[85]	Wearable technology	Utilized ML analytics *via* wearable technology to improve sports performance and identify risk factors for injury in sports
Cilla *et al*[86]	Implant design	ML techniques used to optimize short stem hip prosthesis to reduce stress shielding effects and achieve better short-stemmed implant performance

ML: Machine learning; SVM: Support vector machine.

more translational basic science concepts such as kinetics and gait analysis, wearable technology, and implant design[83-86] (Table 4).

It is well established in orthopaedic literature that aging influences various gait measures, such as gait velocity, stride length, and stance and swing phase times[87]. By applying ML to automate recognition of gait pattern changes, researchers can identify key variables of gait degeneration that might be predictors of falling behavior. Begg *et al*[83] used SVM, a specific ML approach, to automate recognition of gait changes due to aging using three types of gait measures: basic temporal/spatial, kinetic, and kinematic. When comparing gaits of twelve young participants to twelve elderly participants, the ML technique showed an overall accuracy of 91.7%. Furthermore, gait recognition improved when features were selected from different gait data types with an effective potential of 100% accuracy. Similarly, Joyseeree *et al*[84] applied ML algorithms, specifically random forest, boosting, and SVM, to gait analysis data for disease identification. Following a training and testing period, random forest and SVM had an accuracy of 100%, while boosting had an accuracy of 96.4%.

Another basic science application where ML has shown great promise is wearable technology. With the increase in wearable and portable technology, the general public as well as professional athletes have the power to monitor basic human physical and physiologic function that can combine with health records for analysis. *Sikka et al* used ML analytics *via* wearable technology such as camera-based monitoring systems, heart rate monitoring devices, radio-frequency identification tracking systems, and accelerometers, to improve sports performance[85]. Additionally, the data collected can be used to identify risk factors for injury in sports and therefore can proactively prevent injuries and direct injury prevention programs[85]. In the future, healthcare providers could utilize this information not only to develop optimal training programs for elite athletes while minimizing risk of injury and loss of play time, but also to create more cost-efficient care that is individually tailored for the average patient.

While shape optimization algorithms, which are different from ML, have previously been used to assess stem performance, the potential to further optimize short stem implants using ML has only recently been addressed[88-91]. For example, Cilla *et al*[86] used ANNs and SVMs to analyze four parameters with the end goal being to optimize short stem implant design, specifically for THA, to produce optimal performance, lack of bone resorption, and reduced stress shielding (Figure 7). They found that implants should be designed with a small stem length and a reduced length of the surface in contact with the bone to reduce stress shielding. The optimization approach using ML techniques can offer new and innovative possibilities in the design of hip implants and more. These analyses can be used to design new prostheses as well as aid orthopaedic surgeons in decision-making when choosing the most adequate implant.

CONCLUSION

In recent years, ML has garnered interest across various medical specialties and has proven its utility in orthopaedic surgery. Some studies even show that developed and validated ML models are capable of outperforming human specialists. Similarly, in orthopaedic surgery, ML has been incredibly useful in spine pathology detection, prosthesis control, gait classification, OA detection, and fracture detection. These

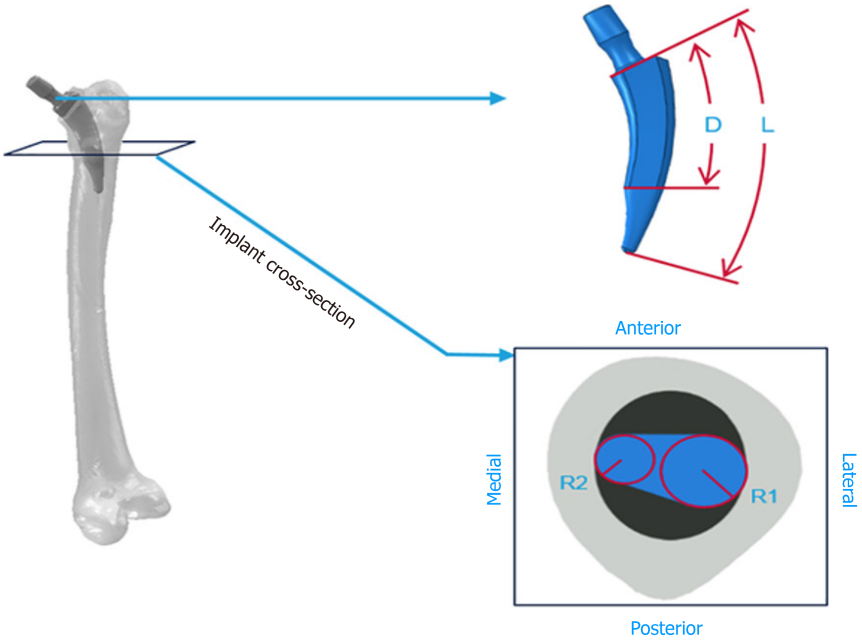


Figure 7 Graphic representation of the four parameters (*L*, total stem length; *R1*, radial circumference in the lateral side; *R2*, radial circumference in the medial; *D*, distance between the implant neck and the central stem surface)[86]. Reused with permission. Citation: Cilla M, Borgiani E, Martínez J, Duda GN, Checa S. Machine learning techniques for the optimization of joint replacements: Application to a short-stem hip implant. *PLoS One* 2017; 12: e0183755.

results corroborate the information that computers can outperform physicians in numerous tasks, even in orthopaedics. By and large, ML has diagnostic and prognostic uses that with continued research can offer more implications regarding orthopaedic treatment. With its surging trend of interest, AI and ML is expected to see an increase in use with risk assessment, outcomes assessment, imaging, and basic science applications in orthopaedics. Furthermore, because ML provides physicians the unique opportunity to understand their patients better, physicians should be trained to use these methods effectively in order to improve orthopaedic patient care.

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ORIGINAL ARTICLE

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Trends and risk factors for opioid administration for non-emergent lower back pain

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Abstract

BACKGROUND

Non-emergent low-back pain (LBP) is one of the most prevalent presenting complaints to the emergency department (ED) and has been shown to contribute to overcrowding in the ED as well as diverting attention away from more serious complaints. There has been an increasing focus in current literature regarding ED admission and opioid prescriptions for general complaints of pain, however, there is limited data concerning the trends over the last decade in ED admissions for non-emergent LBP as well as any subsequent opioid prescriptions by the ED for this complaint.

AIM

To determine trends in non-emergent ED visits for back pain; annual trends in opioid administration for patients presenting to the ED for back pain; and factors associated with receiving an opioid-based medication for non-emergent LBP in the ED

METHODS

Patients presenting to the ED for non-emergent LBP from 2010 to 2017 were retrospectively identified from the National Hospital Ambulatory Medical Care Survey database. The "year" variable was transformed to two-year intervals, and a weighted survey analysis was conducted utilizing the weighted variables to generate incidence estimates. Bivariate statistics were used to assess differences in count data, and logistic regression was performed to identify factors associated

with patients being discharged from the ED with narcotics. Statistical significance was set to a *P* value of 0.05.

RESULTS

Out of a total of 41658475 total ED visits, 3.8% (7726) met our inclusion and exclusion criteria. There was a decrease in the rates of non-emergent back pain to the ED from 4.05% of all cases during 2010 and 2011 to 3.56% during 2016 and 2017. The most common opioids prescribed over the period included hydrocodone-based medications (49.1%) and tramadol-based medications (16.9), with the combination of all other opioid types contributing to 35.7% of total opioids prescribed. Factors significantly associated with being prescribed narcotics included age over 43.84-years-old, higher income, private insurance, the obtainment of radiographic imaging in the ED, and region of the United States (all, $P < 0.05$). Emergency departments located in the Midwest [odds ratio (OR): 2.42, $P < 0.001$], South (OR: 2.35, < 0.001), and West (OR: 2.57, $P < 0.001$) were more likely to prescribe opioid-based medications for non-emergent LBP compared to EDs in the Northeast.

CONCLUSION

From 2010 to 2017, there was a significant decrease in the number of non-emergent LBP ED visits, as well as a decrease in opioids prescribed at these visits. These findings may be attributed to the increased focus and regulatory guidelines on opioid prescription practices at both the federal and state levels. Since non-emergent LBP is still a highly common ED presentation, conclusions drawn from opioid prescription practices within this cohort is necessary for limiting unnecessary ED opioid prescriptions.

Key Words: Opioids; Low back pain; Emergency Department; Spine; Complications; Trends

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Core Tip: A trend of diminishing opioid prescription for low back pain in the emergency department can be appreciated over a span of eight years. Such a trend may be a reflection of policies and guidelines aiming at opioid regulation. Factors that may increase the likelihood of opioid prescription for low back pain include age over 43.84-years-old, higher income, private insurance, the obtainment of radiographic imaging in the emergency department, and presenting within the Midwest/South/West regions of the United States. Providers should be cognizant of such risk factors given the burden imposed by opioid prescriptions on the healthcare system.

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INTRODUCTION

Low back pain (LBP) is one of the most common healthcare complaints and musculoskeletal disorders seen in the emergency department (ED)[1,2]. The prevalence of LBP ranges from 49% to greater than 80% in the United States[3]. While non-emergent LBP can be treated by primary care physicians, studies suggest that patients will visit the ED for evaluation of symptoms, potentially leading to overcrowding and distracting from other serious health complaints[4,5]. Patients presenting to the ED for non-emergent LBP have been found to receive unnecessary imaging with excess radiation, be admitted to the hospital for pain control, or be given prescriptions of opioid pain medication[6-8].

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Studies have shown inconclusive results in the efficacy using opioids to treating patients for LBP, with worse outcomes at 6-month follow-up. Furthermore, studies have shown similar efficacy of opioids compared to non-opioid medications in the treatment of both acute and chronic LBP[9-12]. Within the past decade, opioid prescribing for non-cancer pain has increased dramatically, along with an increase in opioid abuse and resulting deaths[13-16]. Davies *et al*[16] analyzed opioid prescribing rates from January 2005 to December 2015, stratifying patients by age. Their findings revealed that opioid prescriptions in patients older than the age of 85 increased nearly 2-fold. The American College of Emergency Physicians recommends utilizing opioids in the ED only when pain is severe, debilitating, or refractory to other treatments[17]. Further guidelines were mandated by the American Academy of Emergency Medicine, recommending opioids as a second-line treatment[18]. Despite the calls for regulation, evidence of deviation from guideline recommendations persists. Indeed, Hayden *et al*[19] reported 5% of previously opioid-naïve patients who present to the emergency department for low back pain become prolonged opioid users.

Temporal trends of ED visits for LBP, opioid prescription patterns for non-emergent LBP, and patient factors associated with receiving an opioid prescription have not been well documented but are necessary to combat the continuing opioid epidemic in the United States. Therefore, the purpose of this study was to determine trends in non-emergent ED visits for back pain; annual trends in opioid prescriptions for patients presenting to the ED for back pain; and factors associated with receiving an opioid based prescription for non-emergent LBP in the ED

MATERIALS AND METHODS

Database and Patient Selection

This was a retrospective study. The National Hospital Ambulatory Medical Care Survey (NHAMCS) was reviewed between the years 2010 and 2017. The NHAMCS is publicly available and is designed to collect data on the utilization and provision of ambulatory care services in hospital, emergency, and ambulatory care departments. Data is obtained from a sample of visits to non-federally employed office physicians. Prior to 2012, NHAMCS relied on paper instruments; the survey switched to computerized data collection in 2012. Each physician is randomly assigned to a one-week reporting period. During this period, data for a systematic random sample of visits are recorded by United States Census interviewers using a computerized Patient Record form. The survey uses a four-stage probability design with samples of primary sampling units (PSUs), hospitals within PSUs, clinics and emergency service areas within hospitals, and patient visits within clinics and emergency service areas. More details on NHAMCS can be found at cdc.gov.

Patients were included if they presented to one of the aforementioned ambulatory care settings captured by the NHAMCS with a complain of back pain. Patients with back pain were identified using the following string codes as a chief complaint: (1) "Back symptoms"; (2) "Back pain, ache, soreness, discomfort"; (3) "Back cramps, contractures, spasms"; (4) "Low back pain, ache, soreness, discomfort"; and (5) "Low back cramps, contractures, spasms". Patients were excluded if they were under the age of 18 or were admitted for inpatient hospital stay.

Statistical analysis

A weighted survey analysis was conducted utilizing the weighted variables to generate incidence estimates. A chi-square analysis was performed to assess differences in count data. The "year" variable was transformed to two-year intervals as per the recommendations by the Center for Disease Prevention and Control[20]. Logistic regression analysis was conducted to identify factors associated with patients being discharged from the ED with narcotics. Group variables entered into our logistic regression model were removed if all group level's *P*-value exceeded 0.1. Presenting pain was discretized to the following categories: "Low" = 0 to 3; "moderate" = 4 to 6; and "severe" = 7 or more. A *P* value of 0.05 was set as the threshold for statistical significance. All statistical analysis was conducted using R statistical software (Vienna, Austria). The 'survey' package was utilized to analyze survey data.

RESULTS

Trends in presentation to the ED for non-emergent back pain

After implementation of inclusion and exclusion criteria, the study group included 7726 cases, which was 3.8% of the 41658475 total ED visits [95% confidence interval (CI): 34317928 to 48999021] (95%CI: 3.65% to 3.99%). There was a decrease in the rates of non-emergent back pain to the ED from 4.05% of all cases (95%CI: 3.81 to 4.31) during 2010 and 2011 to 3.56% (95%CI: 3.21 to 3.91) during 2016 and 2017 (Figure 1).

Incidence of opioid prescription at discharge for non-emergent LBP

Fifty-two percent of all cases that presented to the ED for non-emergent LBP were prescribed an opioid-based medication between 2010 and 2017 (95%CI: 49.9% to 54.0%). However, the rates of opioid-based prescriptions decreased between the period of 2010 and 2011 (55.9%; 95%CI: 52.9% to 58.9%) and the period of 2016 and 2017 (45.0%; 95%CI: 39.86% to 50.22%) (Figure 2). The most common opioids prescribed included hydrocodone-based medications (49.1% of all opioids prescribed; 95%CI: 46.3% to 52.0%) and tramadol-based medications (16.9% of all opioids prescribed; 95%CI: 14.8% to 19.0%), with the combination of all other opioid types contributing to 35.7% (95%CI: 32.6% to 39.0%) of total opioids prescribed.

Trend analysis revealed a decrease in the prescriptions of hydrocodone-based medications for non-emergent LBP patients presenting to the ED between the period of 2010 and 2011 (28.0%; 95%CI: 25.3% to 30.7%) to the period of 2016 and 2017 (19.3%; 95%CI: 15.6% to 23.1%). However, there was no notable change in the rates of non-emergent LBP patients that received tramadol or other opioid types (Figure 3).

Factors associated with opioid prescriptions

Estimated household income was associated with receiving an opioid base narcotic. When compared to patients coming from the lowest income quartile (below 32793 dollars annually), patients belonging to the third income quartile (40627 dollars to 52387 dollars annually) had higher odds of receiving an opioid based medication [odds ratio (OR): 1.35; 95%CI: 1.13 to 1.61; $P \leq 0.001$] (Table 1). Patients who were privately insured (OR: 1.29; 95%CI: 1.04 to 1.58; $P = 0.018$) or were self-payers (OR: 1.25; 95%CI: 1.00 to 1.56; $P = 0.048$) had higher odds of receiving an opioid based medication when compared to Medicaid patients. Other factors associated with being discharged with opioid based medications included if radiographic images were obtained (OR: 1.47; 95%CI: 1.30 to 1.66; $P < 0.001$), age greater than 43.94-years (OR: 1.01; 95%CI: 1.00 to 1.01; $P = 0.001$), and if patients reported having severe back pain (OR: 2.14; 95%CI: 1.63 to 2.81; $P < 0.001$). ED location was also significantly associated with opioid prescription for back pain. Emergency departments located in the Midwest (OR: 2.42; 95%CI: 1.94 to 3.01; $P < 0.001$), South (OR: 2.35; 95%CI: 1.91 to 2.88; $P < 0.001$), and West (OR: 2.57; 95%CI: 1.94 to 3.42; $P < 0.001$) all yielded greater odds of prescribing opioid-based medications for non-emergent LBP when compared to EDs in the Northeast region.

DISCUSSION

While it has been shown that the overall prescription rates of opioids within the United States are gradually decreasing over the past five years, there is a paucity of literature evaluating trends in opioid prescriptions specifically in patients presenting to the ED with non-emergent LBP[21]. Overall, our study reports a significant decrease in the number of non-emergent LBP ED visits from 2010 to 2017, as well as a decrease in opioids prescribed at these visits. Furthermore, we noted several independent risk factors for increased opioid prescription following non-emergent LBP, including age over 43.84-years-old, higher income, private insurance, the obtainment of radiographic imaging in the ED, and region of the United States.

Our findings are consistent with previous literature demonstrating an overall decrease in ED opioid prescriptions[22-25]. Marra *et al*[22] analyzed NHAMCS information from 2005 to 2015 for patients presenting to the ED with pain of all causes, finding that prescribing rates at discharge decreased significantly by 32% during the study duration[22]. Since pain is one of the most common reasons for ED visits, a major limitation of Marra *et al*[22] study was grouping pain causes into a single cohort. The decrease in opioid prescriptions for non-emergent LBP found in our study was representative of the overall decrease in ED opioid prescriptions for general pain over a similar time interval as established by Marra *et al*[22]. As such, our findings provide

Table 1 Risk factors associated with emergency department opioid-based medication prescription for non-emergent low back pain

	Odds ratio	Lower 95%CI	Upper 95%CI	*P* value
Home income [quartile 1 (below 32793 dollars)]	Reference			
Home income [quartile 2 (32794-40626 dollars)]	1.17	0.98	1.40	0.078
Home income [quartile 3 (40627-52387 dollars)]	1.35	1.13	1.61	0.001
Home income [quartile 4 (52388 dollars or more)]	1.11	0.91	1.34	0.318
Insurance				
Medicaid	Reference			
Medicare	1.03	0.84	1.28	0.753
Other	1.38	0.71	2.67	0.337
Private insurance	1.29	1.04	1.58	0.018
Self-pay	1.25	1.00	1.56	0.048
Workers compensation	1.10	0.72	1.70	0.660
Images obtained	1.47	1.30	1.66	< 0.001
Mean centered age	1.01	1.00	1.01	0.001
Pain-low	Reference			
Pain-moderate	1.28	0.96	1.71	0.093
Pain-severe	2.14	1.63	2.81	< 0.001
Seen in ED within the last 72 hr	0.77	0.56	1.06	0.106
United States Census Region				
Northeast	Reference			
Midwest	2.42	1.94	3.01	< 0.001
South	2.35	1.91	2.88	< 0.001
West	2.57	1.94	3.42	< 0.001

ED: Emergency department; CI: Confidence interval.

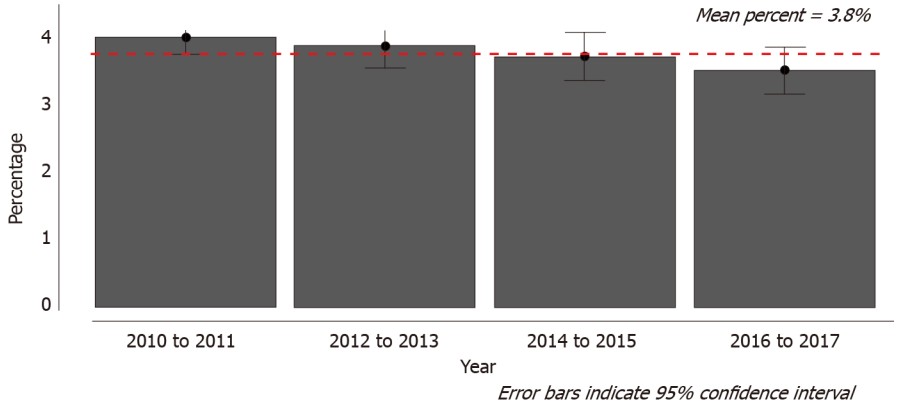


Figure 1 Incidences of non-emergent lower back pain that present to the emergency department between 2010 and 2017.

needed granularity in terms of specifically the non-emergent LBP population presenting to the ED

In elderly individuals, non-emergent LBP has been shown to have a prevalence ranging from 21.7% to 75%, with a direct correlation between age and LBP[26]. Our findings suggest that older age is an independent risk factor for increasing opioid prescriptions following ED admission for LBP, which may perhaps be due to older individuals presenting with increased severity of back pain. Severity of non-emergent

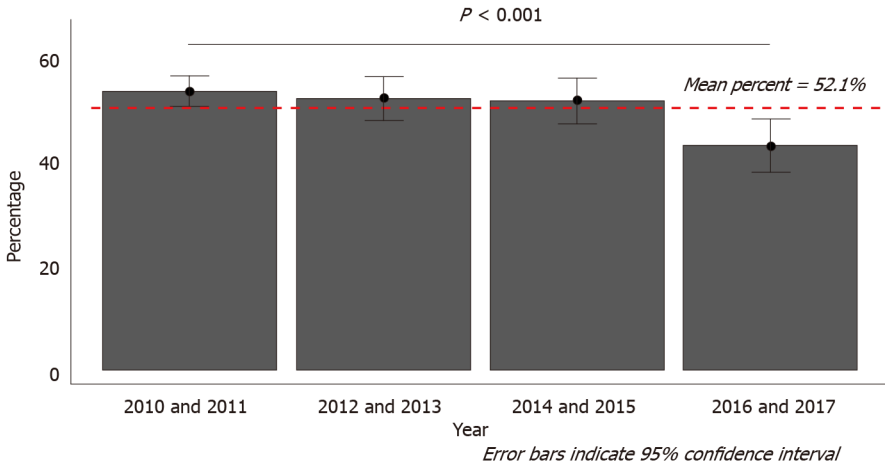


Figure 2 Percent of cases who presented to the emergency department with non-emergent back pain, that were prescribed opioid based medications upon discharge between 2010 and 2017.

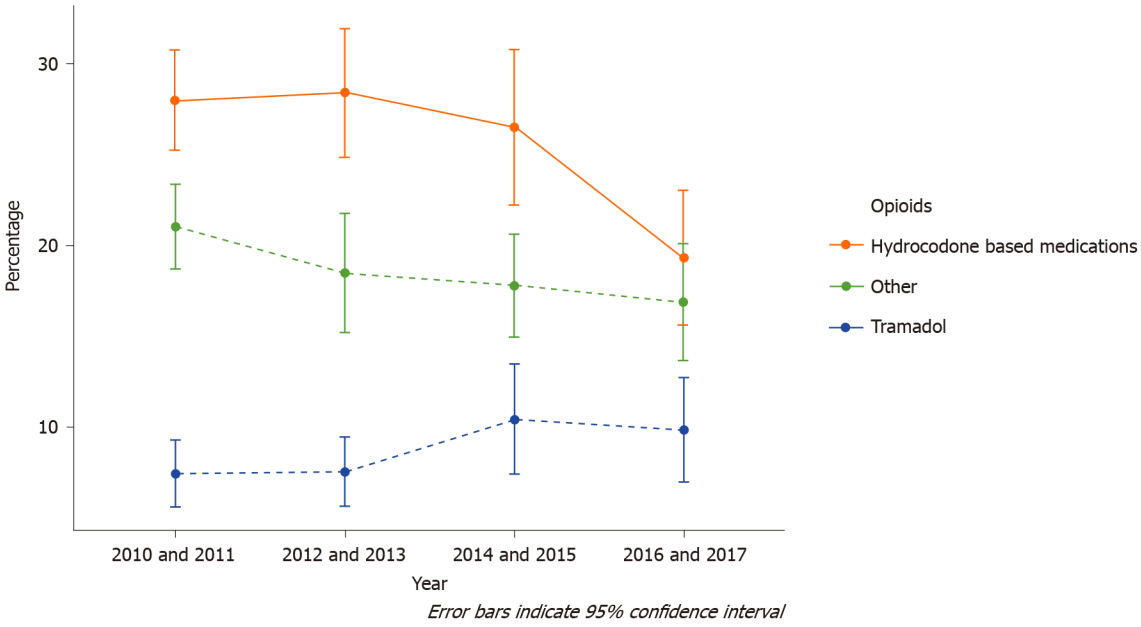


Figure 3 Types of opioids prescribed for non-emergent back pain that presented to the emergency department.

LBP is known to be highly correlated with increasing age, particularly relative to other common causes of opioid prescriptions following ED admission such as pain secondary to trauma[27,28]. This increased LBP severity in older patients likely contributed to the increased opioid prescriptions in older patients shown in our analysis.

In particular, our study found age over 43.84-years to be an independent risk factor for opioid pres-criptions in non-emergent LBP patients. However, the direct relationship between age and ED opioid prescriptions found in our study has not been demonstrated for all chief complaints presenting to the ED For instance, Ward *et al*[24] utilized the Data to Intelligence database aggregating electronic health record data from EDs within the United States from January 1, 2014 to May 31, 2014, and found no direct relationship between increasing age and opioid prescription. In their study, patients between the ages of 18 to 27 had the highest adjusted odds ratio (OR: 1.09) of being discharged with an opioid prescription, followed by patients between the ages of 40 to 54 (OR: 1.08), and lastly between the ages of 28 to 39 (OR: 1.02)[24]. Ward *et al* [24] studied all ED admissions, not limited to back pain, and attempted to account for variations in chief complaints utilization a categorization approach, however, the authors acknowledged remaining heterogeneity in terms of the chief complaints in their dataset. In comparison, our study only included patients presenting with non-

emergent LBP, such that the chief complaints were entirely homogenous, which contributed to the direct correlation we found between age and ED opioid prescriptions in non-emergent LBP patients.

With respect to insurance status, Ali *et al*[29] reported that 8% of patients with private insurance had potentially problematic opioid prescriptions, compared to 14% of patients with Medicaid. Problematic opioid prescription was defined in their study as opioid prescriptions which did not match the indication severity based on protocol established in previous literature[29]. Although our study did not address problematic opioid prescriptions, we did find that patients with private insurance or who were self-payers were more likely to be prescribed an opioid for non-emergent LBP compared to Medicaid patients.

In terms, of the Medicaid population specifically, Janakiram *et al*[25] performed a multistate analysis utilizing the Truven Marketscan Database from 2013 to 2015 and found Medicaid patients were more likely to receive prescriptions from an ED provider compared to a general practitioner, with back pain (14%) being the third leading cause for receiving an opioid prescription. Implementation of prior authorization plans within Medicaid plans has shown to not only minimize opioid-related morbidity within this cohort, but also discourage the initiation of long-acting opioid therapy[30,31]. Interestingly, studies have shown patients who present to the ED could be more appropriately managed by their primary care physician, which would potentially driving down ED visits. These studies demonstrate that adequate care reduces annual ED visits and decreases healthcare expenditure[32-34], therefore, lack of access to primary care may be the driving force of increasing patient visits to the ED especially for non-emergent indications such as LBP[35-37]. In other words, limited access to various primary care is likely associated with increased ED visits in patients with underlying mental and physical comorbid conditions.

Extended access primary care services have also been shown to decreased the amount of ED visits as well as pain prescriptions for non-emergent presentations[33]. Extended access primary care services offer patients the ability to book appointments outside of core contractual hours, either in the early morning, evening or at weekends. Whittaker *et al*[33] measured the impact of extended access in 56 primary care practices by offering seven-day extended access through providing care during the evenings and weekends, compared to 469 primary care practices with routine working hours. Implementing this extended access of care demonstrated a reduction in both the frequency and cost of patient-initiated ED visits for "minor" problems[33]. The majority of non-emergent LBP fits within this categorization of "minor" problems, so it is possible that more widespread extended access primary care services have the potential to reduce ED admissions and opioid prescriptions.

LBP has also been shown to be more prevalent and severe in older men compared to older women. Interestingly, our study found no difference in opioid prescriptions between men and women presenting to the ED with non-emergent LBP[38].

Finally, numeric pain scores have been implicated in contributing to the prescribed opioid epidemic, with opioids being administered to those who report higher pain scores[39]. In a recent cross-sectional study, Monitto *et al*[40] explored the association of patient factors with opioid dispensing, consumption, and medication remaining on completion of therapy after hospital discharge. Their findings suggest higher discharge pain scores can predict higher opioid dispensing and consumption. This is consistent with our findings as increasing pain scales was significantly associated with discharge from the ED with an opioid prescription. With further validation, these pain scales can be potentially utilized to predict and ultimately standardize the number of opioids patients presenting to the ED with non-emergent LBP should be prescribed.

This study has a few limitations which must be considered when interpreting our results, most of which are inherent to the use of an administrative database. First, recent studies have addressed concern regarding the validity of the NHAMCS database due to slight variability in documentation across the years[41]. Our study limited this potential issue by purposely utilizing variables that were collected in a consistent fashion over the years studied. Second, since information from the database is ascertained from individual ED visits, the study did not allow for longitudinal information on these patients or allowing us to determine the appropriateness of therapy[22]. For example, we were unable to identify patients with a history of substance abuse. However, this limitation does not preclude the validity of our findings as our study methodology included only cases of non-emergent back pain that presented to the ED and did not warrant admission. Finally, our study assessed data from 2010 to 2017, as this was the only time interval available from NHAMCS. Despite these limitations, the study provides valuable information regarding annual trends in ED visits for back pain, prescribing patterns, and patient risk factors for

being discharged with an opioid prescription.

CONCLUSION

Despite legislative efforts to improve access to care, ED continue to be burdened by non-emergent maladies such as LBP. Our study demonstrated a significant decrease in number of patients presenting to the ED with non-emergent LBP between 2010 and 2017, as well as a significant decrease in opioids prescribed in the ED for this indication of the same time period. Regression analysis identified age over 43.84-years-old, higher income, private insurance, the obtainment of radiographic imaging in the ED, and region of the United States as independent risk factors for being discharged with prescription narcotics after presenting to the ED for LBP. Emergency departments located in the Northeast region were the least likely to discharge patients with narcotics. Ultimately, physician-directed patient education is necessary to minimize ED burden by non-emergent LBP, and a heightened awareness of previous narcotic prescribing practices is needed to mitigate narcotic prescriptions for patients presenting to the ED with non-emergent LBP. Future prospective studies are necessary to determine the impact of state and federal legislative mandates on the influence of opioid prescriptions given at discharge.

ARTICLE HIGHLIGHTS

Research background

Low back pain a major cause of emergency department (ED) visits and ranges in incidence between 49% and 80% in the United States. Patients presenting to the ED for non-emergent LBP often receive unnecessary prescriptions of opioid pain medication.

Research motivation

Several guidelines have been implemented to mitigate opioid prescription for low-back pain. However, the impact of such guidelines is yet to be ascertained.

Research objectives

This study aimed to outline the trends of annual opioid prescriptions for patients presenting to the ED with non-emergent back pain; and risk factors associated with being prescribed an opioid based prescription for non-emergent LBP in the ED.

Research methods

We reviewed the National Hospital Ambulatory Medical Care Survey for all patients who presented to the ED with low back pain. Patients over 18 years of age who were not subsequently admitted were included. The primary outcome was opioid-based medication prescription. Trends and factors of opioid-based medication prescription were evaluated to identify chronological and patient-specific risk factors.

Research results

We reviewed the National Hospital Ambulatory Medical Care Survey for all patients who presented to the ED with low back pain. Patients over 18 years of age who were not subsequently admitted were included. The primary outcome was opioid-based medication prescription. Trends and factors of opioid-based medication prescription were evaluated to identify chronological and patient-specific risk factors.

Research conclusions

Overall opioid prescription demonstrated a mild decrease over the past decade; however, a pattern of diminished hydrocodone-based medications is associated with a mild increase in tramadol-based medication prescription. This pattern may be due to recent legislative guidelines.

Research perspectives

Further research is required to identify future trends that may be a more veritable reflection of more recent policies regulating opioid prescription for low back pain – particularly tramadol based medications.

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ORIGINAL ARTICLE

Retrospective Study

Correlation of stress radiographs to injuries associated with lateral ankle instability

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Abstract

BACKGROUND

Stress radiographs have demonstrated superior efficacy in the evaluation of ankle instability.

AIM

To determine if there is a degree of instability evidenced by stress radiographs that is associated with pathology concomitant with ankle ligamentous instability.

METHODS

A retrospective review of 87 consecutive patients aged 18-74 who had stress radiographs performed at a single institution between 2014 and 2020 was performed. These manual radiographic stress views were then correlated with magnetic resonance imaging and operative findings.

RESULTS

A statistically significant association was determined for the mean and median stress radiographic values and the presence of peroneal pathology (P = 0.008 for tendonitis and P = 0.020 for peroneal tendon tears). A significant inverse relationship was found between the presence of an osteochondral defect and increasing degrees of instability (P = 0.043).

CONCLUSION

Although valuable in the clinical evaluation of ankle instability, stress radiographs are not an independent predictor of conditions associated with ankle in-stability.

Key Words: Ankle stress radiographs; Lateral ankle instability; Osteochondral defect;

Data sharing statement: Please contact the corresponding author if access to the de-identified data is requested.

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Core Tip: Ankle Stress Radiographs were predictive of intraoperative findings. Specifically, they may assist the surgeon in clinical decision making regarding osteochondral lesions of the talus and peroneal tendon pathology.

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INTRODUCTION

Ankle instability is one of the most common sports related injuries with an incidence of 7 per 1000 persons per year[1]. Close to 40% of patients who sustain an inversion injury to their ankle report residual symptoms long after they have recovered from the injury to their lateral ligaments. This residual pain may be secondary to associated conditions that occur at the time of the injury or as a result of chronic instability[2]. The differential diagnosis for associated injuries or causes of residual symptoms is large and includes: occult fractures of the ankle, fractures of the metatarsals, peroneal tendon tears, osteochondral lesions of the talus (OLT), tarsal coalitions, neurogenic injuries, radicular pain, autonomic dysreflexia, impingement, syndesmotic injuries, and subtalar instability. Determining which symptoms are related to ligamentous injury and which symptoms are related to associated conditions can be a diagnostic dilemma. Clinicians use multiple resources to determine which patients have symptoms secondary to ligamentous instability at the tibiotalar joint *vs* symptoms related to other causes. Plain radiographs are often the first modality utilized and radiographs of the ankle and foot can rule out fractures. Unless there is frank instability, a superior retinaculum avulsion, or a large osteochondral fracture, static radiographs do not provide much information on the integrity of the lateral ligaments or associated conditions. Stress radiographs can provide information on the dynamic stability of the tibiotalar joint are often obtained in the evaluation of ankle instability. Previous studies have demonstrated that stress radiographs are more specific than magnetic resonance imaging (MRI) in the evaluation of ligamentous instability[3]. Ultrasound and MRI have a role in evaluating for associated injuries such as chondral injuries and tendon pathology. While being a highly sensitive modalities, MRI has also been shown to miss 20%-80% of associated injuries[4,5]. It would be ideal to have one imaging study that could assist the surgeon in making the diagnosis of instability and at the same time rule out or rule in associated pathology. Since stress radiographs have demonstrated superior efficacy in the evaluation of ankle instability, the purpose of this study is to determine if there is a degree of instability evidenced by stress radiographs that is associated with OLTs and peroneal pathology concomitant with ankle ligamentous instability.

MATERIALS AND METHODS

A retrospective review of consecutive patients aged 18-74 who had stress radiographs performed at a single institution between 2014 and 2020 was performed. Once the patients with documented stress radiographs were identified, the electronic medical record was utilized to collect the following information: degree of widening on the talar tilt stress radiograph, millimeters of anterior translation on the anterior drawer stress radiograph, presence of an OLT on MRI or noted in the operation report if an operation was performed, presence of a peroneal tendon tear or tendonitis noted on the MRI or in the operation report, and documentation of operative management of an OLT or peroneal tendon. All patients who had a stress radiograph performed were

included in the study. The presence of operative instability was not an inclusion or exclusion criteria.

Stress radiographs were performed manually. Although various providers performed the radiographs, the technique was standardized. An example of a stress radiograph is seen in Figure 1. An initial mortise film was obtained prior to the talar tilt stress view. Once the mortise was aligned, the tibia was held to maintain the mortise while an inversion force was applied to the ankle. Verification of an appropriate mortise view was obtained. The anterior drawer was obtained by first verifying that a perfect lateral of the talus was visible on digital radiography. The tibia was then held in the same alignment and an anterior force was applied to the calcaneus. Verification of the lateral was obtained. All stress radiographs were routinely measured by a board-certified radiologist unaffiliated with the study. An example of the technique utilized to measure the stress radiographs is demonstrated in Figure 2.

The associated findings to include OLTs and peroneal pathology were determined from the MRI reports and operative reports. All MRI reports were read by board certified radiologists unaffiliated with the study. Operative findings were obtained from the dictated operation reports. Because continuous data were not normally distributed, statistical analysis was performed with a nonparametric Wilcoxon Rank Sum Test to assess differences in median levels of anterior drawer and talar tilt angel between patients with and without selected outcomes. All analyses were conducted using SAS statistical software version 9.4 (SAS Institute Inc., Cary, NC, United States).

RESULTS

There were 87 patients meeting inclusion criteria including 14 females and 73 males. The mean talar tilt was 8.6° (range 0-25). The mean anterior drawer was 4.6 mm (range 0-9.9 mm). Peroneal tendonitis was documented in 22 patients (25%). Peroneal tendon tears were documented in 6 patients (7%). An OLT of any size was documented in 42 patients (48%). An OLT greater than 1 cm in its largest diameter was documented in 16 patients (18%). Operative management of an OLT to include microfracture or chondroplasty was performed in 35 patients (40%). Cartilage restoration with Biocartilage or DeNovo NT allograft was performed in 7 patients (8%). An operative exploration of the peroneal tendons was performed in 19 patients (22%). A peroneal tendon repair was required in 2 patients (2%). A lateral ligament repair or modified Broström procedure was performed in 64 patients (74%).

In order to evaluate the relationship between associated findings and stress view values, unpaired *t*-tests were utilized to evaluate mean differences in anterior drawer and talar tilt between patients with and without selected outcomes. There were no statistical associations based upon the anterior drawer as depicted in Table 1. By contrast, the talar tilt angle was associated with several outcomes. Patients with the diagnosis of peroneal tendonitis had a larger talar tilt on average than patients without peroneal tendonitis (mean = 11.8° *vs* 7.5°, $P = 0.004$). Similarly, patients with peroneal tears also had larger tilt angles on average than those without tears (mean = 13.8° *vs* 8.2°, $P = 0.026$). The remainder of associations are depicted in Table 2.

Tables 3 and 4 summarize results of nonparametric analyses to assess differences in median levels of anterior drawer and talar tilt, respectively, between patients with and without selected reasons for surgery. For anterior drawer, the evaluation shows an inverse relationship found between the degree of instability as measured on the anterior drawer image and the presence of an OLT. Patients who had an OLT had a median anterior drawer of 4.1°, while patients without an OLT had an anterior drawer measurement of 5.1°, $P = 0.035$.

For talar tilt, several significant findings are noted. Larger degrees of tilt were seen in patients who had peroneal tendonitis or peroneal tendon tears, and an inverse relationship was found between the degree of instability and the presence of an OLT. Patients with an OLT had a median talar tilt of 6° while patients without an OLT had a median talar tilt of 9°, $P = 0.039$. Large OLTs were evaluated separately from all OLTs and patients who had a large OLT of greater than 1 cm in diameter were found to have a talar tilt median of 3° while patients who did not have a large OLT were found to have a talar tilt of 8°, $P = 0.025$. As the senior surgeon utilized 9° of instability as an operative indication for a lateral ligament repair or Broström procedure, the data set confirms that selection criteria when utilizing both the mean and median values.

For each area of pathology that had a significant difference found for the mean or median values on stress radiographs, predictive statistics were performed to include

Table 1 Anterior drawer (mean ± SD)

Outcome	Outcome = No			Outcome = Yes			*P* value
	n	mean	SD	*n*	mean	SD	
Peroneal tendonitis	65	4.5	2.7	22	4.9	3.2	0.533
Peroneal tear	81	4.7	2.7	6	3.4	4.0	0.251
MRI OLT	45	5.0	3.0	42	4.2	2.5	0.206
MRI OLT < 1 cm	61	4.9	2.9	26	3.9	2.4	0.107
MRI > 1 cm	71	4.6	2.9	16	4.8	2.6	0.791
Broström	23	4.7	2.2	64	4.6	3.0	0.805
Operative peroneal exploration	68	4.7	2.8	19	4.4	2.8	0.675
Operative peroneal repair	85	4.6	2.8	2	5.8	1.7	0.548
Operative OLT microfracture/chondroplasty	52	5.1	2.8	35	3.9	2.7	0.066
Operative OLT restoration/repair	80	4.6	2.9	7	4.9	1.8	0.753

MRI: Magnetic resonance imaging; OLT: Osteochondral lesions of the talus.

Table 2 Tilt angle (mean ± SD)

Outcome	Outcome = No			Outcome = Yes			*P* value
	n	mean	SD	*n*	mean	SD	
Peroneal tendonitis	65	7.5	5.4	22	11.8	6.7	0.004
Peroneal tear	81	8.2	6.0	6	13.8	4.4	0.026
MRI OLT	45	9.8	6.0	42	7.3	5.8	0.051
MRI OLT < 1 cm	61	8.8	6.3	26	8.1	5.4	0.610
MRI > 1 cm	71	9.2	5.8	16	6.0	6.4	0.057
Broström	23	3.3	3.3	64	10.5	5.6	< 0.001
Operative peroneal exploration	68	8.3	6.0	19	9.7	6.0	0.372
Operative peroneal repair	85	8.6	6.0	2	10.0	8.5	0.739
Operative OLT microfracture/chondroplasty	52	9.1	6.2	35	7.8	5.8	0.339
Operative OLT restoration/repair	80	9.0	6.0	7	4.4	4.9	0.057

MRI: Magnetic resonance imaging; OLT: Osteochondral lesions of the talus.

sensitivity (Sn), specificity (Sp), positive predictive value (PPV), and negative predictive value (NPV). The results of this analysis are listed in Tables 5 and 6. Initial analysis of the talar tilt was performed using 10° as the threshold value as seen in Table 5. Given the significant inverted association demonstrated for OLTs and the anterior drawer stress radiograph, predictive analysis was performed for the anterior drawer test utilizing 5° as the threshold as seen in Table 6. Predictive statistics were not performed for the Broström procedure as the surgical candidates were selected largely based upon the stress radiographic results which resulted in the significant association between the Broström procedure and larger values on stress radiographs. In addition, predictive statistics were not performed for OLTs as a significant inverse relationship was demonstrated.

DISCUSSION

The lateral ligaments of the tibiotalar joint do not provide stability to the joint in isolation. The bony architecture of the tibiotalar joint contributes to its stability with

Table 3 Anterior drawer median and inter quartile range

Outcome	Outcome = No			Outcome = Yes			*P* value
	n	Median	IQR	*n*	Median	IQR	
Peroneal tendonitis	65	4.5	3.0-6.6	22	4.8	4.0-7.0	0.487
Peroneal tear	81	4.6	3.3-7.0	6	2.1	0.0-7.0	0.318
MRI OLT	45	5.2	2.7-7.5	42	4.3	3.0-5.6	0.110
MRI OLT < 1 cm	61	5.1	3.3-7.1	26	4.2	3.0-5.0	0.062
MRI > 1 cm	71	4.6	2.7-7.0	16	4.7	3.7-6.9	0.891
Broström	23	4.7	4.0-6.9	64	4.5	2.4-7.1	0.870
Operative peroneal exploration	68	4.9	3.3-6.9	19	4.3	2.7-7.0	0.550
Operative peroneal repair	85	4.5	3.0-7.0	2	5.8	4.6-7.0	0.514
Operative OLT microfracture/chondroplasty	52	5.1	3.7-7.2	35	4.1	2.7-5.6	0.035
Operative OLT restoration/repair	80	4.5	2.9-7.0	7	4.8	4.0-6.9	0.827

MRI: Magnetic resonance imaging; OLT: Osteochondral lesions of the talus; IQR: Inter quartile range.

Table 4 Tilt angle median and inter quartile range

Outcome	Outcome = No			Outcome = Yes			*P* value
	n	Median	IQR	*n*	Median	IQR	
Peroneal tendonitis	65	7	3-12	22	12	6-18	0.008[1]
Peroneal tear	81	8	3-12	6	15	10-16	0.020[1]
MRI OLT	45	9	5-14	42	6	2-13	0.043[1]
MRI OLT < 1 cm	61	8	3-14	26	8	3-13	0.763
MRI > 1 cm	71	8	4-13	16	3	1-10.5	0.025[1]
Broström	23	3	1-4	64	10	6.5-14	< 0.001[1]
Operative peroneal exploration	68	8	3-12	19	11	4-15	0.318
Operative peroneal repair	85	8	3-13	2	10	4-16	0.670
Operative OLT microfracture/chondroplasty	52	8	4-13	35	7	3-13	0.360
Operative OLT restoration/repair	80	8	3.5-13	7	3	1-6	0.039[1]

[1]Significant difference. MRI: Magnetic resonance imaging; OLT: Osteochondral lesions of the talus; IQR: Inter quartile range.

the talus widest anteriorly making the joint most stable in dorsiflexion[6]. In plantarflexion, the fibula internally rotates and moves inferiorly to maintain the stability of the mortise[7]. In addition to the syndesmotic ligaments, the tibiotalar joint is constrained medially by the deltoid ligamentous complex and laterally through the collateral ligament complex. Dynamic stability of the tibiotalar joint is provided by the surrounding extrinsic musculature. The tibialis anterior, extensor hallucis longus, extensor digitorum longus, and peroneal tertius contribute to dorsiflexion in the anterior compartment. Within the compartment, the tibialis anterior and extensor hallucis longus also contribute to inversion. This is balanced by the peroneal tertius which provides eversion in addition to dorsiflexion. In the lateral compartment, the peroneal longus and brevis both contribute to eversion which helps to mitigate inversion stresses across the ankle. Posteriorly, the tibialis posterior, flexor digitorum longus, and flexor hallucis longus all help to produce ankle inversion in conjunction with plantar flexion due to the oblique rotational axis of the tibiotalar joint[6].

Given that the lateral ligaments do not provide stability to the ankle in isolation, it follows that the lateral ligaments are not injured in isolation. Clinical studies have demonstrated that that ankle instability occurs with associated pathology such as

Table 5 Initial analysis of the talar tilt

	Talar tilt ≥ 10°	Talar tilt < 10°	Sn (%)	Sp (%)	PPV (%)	NPV (%)
Peroneal tendonitis	13/35	9/52	59	66	37	83
Peroneal tear	5/35	1/52	83	63	14	98
Any peroneal pathology	14/35	10/52	58	67	40	81
Any OLT	15/35	27/52	36	56	43	48

The sensitivity, specificity, positive predictive value, and negative predictive value are documented for the presence or absence of peroneal pathology in relationship to the talar tilt stress radiograph. Note that given the significant inverse relationship found between osteochondral lesions of the talus and stress radiographs, the predictive statistics were inverted as well utilizing a positive test as being a talar tilt < 10°. Sn: Sensitivity; Sp: Specificity; PPV: Positive predictive value; NPV: Negative predictive value; OLT: Osteochondral lesions of the talus.

Table 6 The anterior drawer test

	Anterior drawer < 5 mm	Anterior drawer ≥ 5 mm	Sn (%)	Sp (%)	PPV (%)	NPV (%)
OLT	30	13	70	57	64	68

The sensitivity, specificity, positive predictive value, and negative predictive value are documented for the presence or absence of peroneal pathology in relationship to the anterior drawer stress radiograph. Note that given the significant inverse relationship found between osteochondral lesions of the talus and stress radiographs, the predictive statistics were inverted as well utilizing a positive test as being an anterior drawer < 5 mm. Sn: Sensitivity; Sp: Specificity; PPV: Positive predictive value; NPV: Negative predictive value; OLT: Osteochondral lesions of the talus.

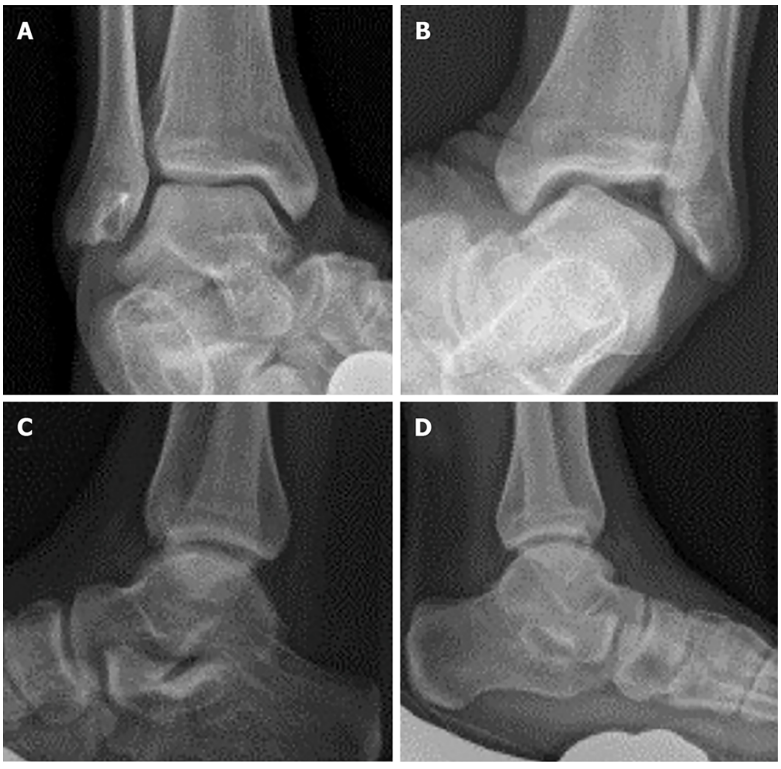


Figure 1 Stress radiographs. A: An example of a stable ankle which has previously undergone a modified Broström procedure is depicted; B: The contralateral ankle demonstrating instability on the talar tilt examination is depicted; C and D: The corresponding anterior drawer stress radiographs.

peroneal tendinopathy in up to 28% of cases[8]. Peroneal tendinopathy is considered to be an overuse injury related to inflammatory and degenerative changes[9]. In theory, chronic lateral ligament insufficiency may lead to overuse of the peroneal tendons as the peroneal longus and brevis provide dynamic support to the ankle. Our findings were consistent with this as we found a significant increase in peroneal

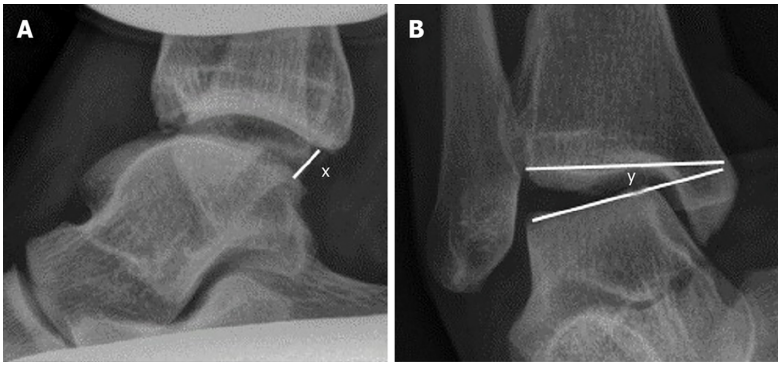


Figure 2 The measurements for stress radiographs are depicted here. A: The anterior drawer distance is obtained by drawing a line from the most posterior aspect of the distal tibial plafond to a point on the talus that is perpendicular to the articular surface of the talus. The distance 'x' is measured in millimeters; B: The anterior drawer is depicted. In order to measure the anterior drawer one line is drawn along the distal articular surface of the tibia and a second line is drawn along the proximal articular surface of the talus. The angle 'y' formed by the intersection of these two lines is the talar tilt angle and is measured in degrees.

tendonitis in patients who had a talar tilt of 11.8° when compared to patients who had a mean talar tilt of 7.5°.

Split tears of the peroneal brevis tendon are relatively common. A cadaveric study without clinical correlation found a prevalence of split tears in 37.5% of the 112 ankles evaluated[10]. Peroneal muscles are the first muscles to respond and contract in response to ankle inversion[11]. In theory, increasing inversion of an ankle secondary to ligamentous instability could place an increasing strain upon the peroneal tendons. In a review of 180 open ankle lateral ligament repair procedures, Strauss *et al*[8] found 51 (28%) ankles with a peroneal tendon injury. The authors did not further break down the type of injuries found or the treatment provided. Our study found that peroneal tendon tears occurred in patients with a mean talar tilt of 13.8° and was not seen in patients with a mean talar tilt of 8.2°. This data would suggest that increasing degrees of instability may be associated with an increasing incidence of peroneal tendon tears.

Classic imaging studies of peroneal pathology can include plain radiographs, ultrasound, computed tomography (CT), and MRI. Data from plain radiographs is limited in regard to peroneal pathology unless a 'fleck' sign is visualized which is pathognomonic for a superior peroneal retinaculum avulsion. Aside from evaluating associated osseous pathology, CT scan has a limited role in the evaluation of peroneal tendons. Ultrasound is provider dependent but has been shown to accurately predict peroneal tendon tears in 90% of cases[12]. MRI is commonly utilized and can document peroneal tendosynovitis or tears. The artifact that occurs as the tendons curve around the lateral malleolus, however, can decreased the sensitivity to 80% and the specificity to 75%[13].

Although we were able to find an association between larger degrees of instability and the presence of peroneal pathology, we were not able to find a degree of instability that was predictive of instability. Threshold values of 10 mm on the anterior drawer test or 10° on the talar tilt test have been found to correlate with clinical instability[14]. We evaluated the statistical performance of stress radiographs in terms of peroneal pathology. Since the mean talar tilt associated with peroneal tendonitis was 11.8°, and the mean talar tilt associated with a peroneal tendon tear was 13.8°, we evaluated the Sn, Sp, PPV, and NPV of the talar tilt utilizing 10° as the threshold for a positive test for peroneal pathology. We considered a value of 85% to be clinically meaningful given the significant association determined between the mean and medians for each pathology studied. A talar tilt test of < 10° had a NPV of 98% when evaluating the presence of a peroneal tendon tear in our analysis. The remainder of the values were not found to be clinically meaningful as demonstrated in Table 5.

We also looked at the relationship between OLTs and instability. The tibiotalar joint has a high level of congruency. In plantarflexion and dorsiflexion, the contact surface area of the ankle is decreased and the contact pressures increased[15,16]. Multiple previous studies have suggested an association between increased instability and OLTs. In a study of 148 patients with ankle instability who underwent operative management, Hintermann *et al*[17] found 26 patients (18%) with full thickness cartilaginous lesions of the talus. In a similar study of 65 patients undergoing operative management for lateral ankle instability by Cha *et al*[18], the authors found OLTs in 33 patients (51%). In this study, 22 of these lesions were classified as softening

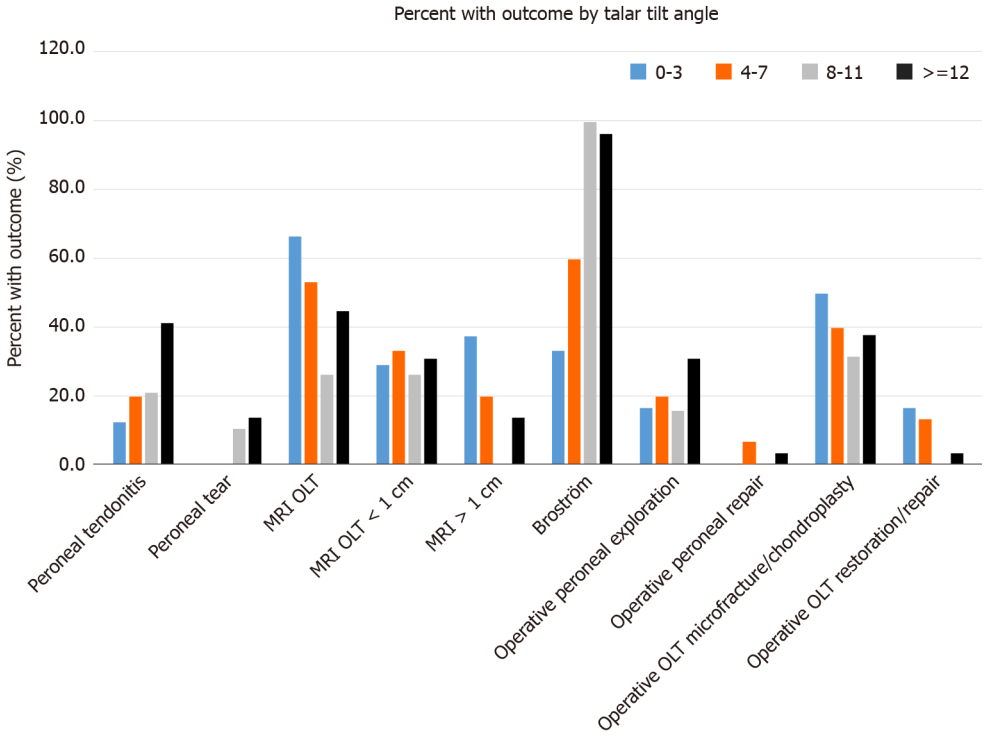


Figure 3 The presence of an associated condition is listed next to the number of ankles that have that condition when organized according to the degree of instability as measured on the talar tilt image. MRI: Magnetic resonance imaging; OLT: Osteochondral lesions of the talus.

or superficial fissuring with 20 (18%) being classified as deep fissures or exposed bone [18]. It is unclear as to how many of these lesions required surgical management. In a study of 283 patients requiring surgery for ankle fractures, OLTs were found in 61 patients (73%) during operative arthroscopy. More severe fracture patterns were associated with an increased incidence of OLTs[19]. The association of ankle instability with OLTs, however, has not been consistent in every study. In a recent study, Park *et al*[20] evaluated 195 patients with a history of an inversion injury who were evaluated with both MRI and stress radiographs. The authors defined radiographic instability as having a talar tilt of greater than or equal to 10°. An increased talar tilt was associated with a lower incidence of OLT and the presence of an OLT was associated with a decreased tibiotalar tilt. We found similar findings in our study group. Ankles that did not have an OLT had a mean talar tilt of 9.8° while patients who did have an OLT had a mean talar tilt of 7.3°. When we evaluated our data utilizing the median values rather than the mean to account for outliers, we found a very similar inverse relationship between the presence of an OLT and the degree of instability. We found that the 42 patients who had an OLT had a median talar tilt of 9° while the median talar tilt for the 45 patients who did have an OLT was 6°. As seen in Table 4, this inverse relationship remained significant for larger OLTs and for OLTs that underwent operative management. The inverse relationship in our data set is best depicted in Figure 3. We were not able to find a clinically meaningful value on the anterior drawer test or the talar tilt test in terms of sensitivity, specificity, the positive predictive value, or the negative predictive value. As seen in Table 5, we utilized 10° as the threshold for the talar tilt test. Given the inverse relationship noted for OLTs and instability, a positive test was described as a test having a value of less than 10°. Although a threshold of 10mm has been described for a positive anterior drawer test when evaluating for instability, we utilized a threshold of 5 mm based upon our evaluation of the medians with those patients with an OLT having a median anterior drawer of 3 mm *vs* 8 mm for patients without an OLT. Similar to the talar tilt results, a value of less than 5 mm on the anterior drawer was not predictive of an OLT in our analysis as demonstrated in Table 6.

This study has strengths and weaknesses. We evaluated not just the presence of associated conditions but also documented which conditions were treated surgically. With that said, the presence of conditions on imaging studies or documented during surgery is objective data, while the decision to perform a repair could be subject to bias. The relationship between stress radiographs and functional instability has not been clearly defined. For this reason, we did not evaluate the prevalence of associated

conditions based upon a defined degree of instability but rather evaluated the mean and median instability measured when associated conditions were present. The data confirms the relationship between instability and peroneal pathology demonstrating that patients with peroneal pathology had a significantly higher mean and median talar tilt measurement. In addition, we documented a significant inverse relationship between radiographic instability and the presence of an OLT. This is the second study to evaluate the inverse relationship seen between instability and OLTs.

CONCLUSION

In evaluating stress radiographs as they relate to associated conditions, we found several areas of significance. Increasing instability was associated with a statistically significant higher prevalence of peroneal tendinopathy and peroneal tendon tears. We also demonstrated an inverse relationship between the presence of OLTs and higher degrees of instability. The broad application of these findings to clinical practice is limited as demonstrated with low sensitivity, specificity, and predictive values for the thresholds measured. Ankle instability remains a complex diagnosis with known associated conditions. While stress radiographs may assist the surgeon in defining mechanical instability, this imaging study alone cannot be utilized to rule out or rule in concomitant pathology that is associated with ankle instability.

ARTICLE HIGHLIGHTS

Research background

Once patients were diagnosed with instability based upon stress radiographs, the surgical procedure was delayed due to the need to obtain a magnetic resonance imaging in order to define which patients had associated conditions. Prior to this study, the surgeons involved felt that higher degrees on instability were associated with the incidence of associated conditions that could result from instability.

Research motivation

In general, we hoped to avoid a delay in treatment due to the need to obtain advanced imaging. We assumed that patients with higher degrees of instability would have osteochondral lesions or peroneal pathology and would require diagnostic arthroscopy or peroneal exploration while patients with a lesser degree of instability could be addressed with a limited surgical procedure focused on the lateral ligaments.

Research objectives

We aimed to determine a degree of instability that could predict the incidence of peroneal pathology or osteochondral defects.

Research methods

A retrospective analysis of patients who had previously been diagnosed with ankle instability was performed. We stratified the patients based upon their degree of instability as defined by stress radiographs and evaluated the incidence of peroneal pathology and osteochondral defects as related to the varying degrees of instability.

Research results

Increasing degrees of instability was associated with a statistically significant increased prevalence of peroneal pathology. An inverse relationship was found between increasing degrees of instability and the presence of osteochondral defects. While we did confirm the association of ligamentous instability to peroneal pathology and the inverse relationship found between osteochondral defects and instability, we did not find a degree of instability that was predictive of peroneal pathology or osteochondral defects.

Research conclusions

Stress radiographs were not found to be predictive of peroneal tendon pathology or osteochondral defects of the talus.

Research perspectives

This is only the second study to demonstrate an inverse relationship between ankle instability and osteochondral defects of the talus. This is a novel discovery, but the injury mechanism that leads to ligamentous instability without chondral injury is unclear. Potentially axial load injuries are more likely to result in chondral injuries as opposed to rotational injuries that may lead to ankle instability. Further work is required to better understand this injury pattern.

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CASE REPORT

Atypical osteochondroma of the lumbar spine associated with suprasellar pineal germinoma: A case report

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Informed consent statement: Informed consent was obtained, and the study was approved by the institutional review board.

Conflict-of-interest statement: Heffernan MJ reports personal fees from Zimmer Biomet, Inc. Barnett SA, Suwak P, and Song BM have nothing to disclose.

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Abstract

BACKGROUND

Osteochondromas are the most common benign bone tumor, accounting for 36% of benign bone tumors. Often found within the appendicular skeleton, osteochondromas of the spine are rare, comprising 4% to 7% of primary benign spinal tumors.

CASE SUMMARY

We report a case of a solitary lumbar osteochondroma in an 18-year-old male with a history of a suprasellar pineal germinoma treated with combined chemotherapy and radiation. He underwent mass excision and partial laminectomy with the ultrasonic bone scalpel (Misonix, Farmingdale, NY, United States) at the L5 Level without the use of adjuvants. The patient returned to work and full activities without back pain at 3 mo postoperatively.

CONCLUSION

Osteochondromas are common tumors of the appendicular skeleton but rarely occur within the spine. This case discussion supplements current osteochondroma literature by describing an unusual presentation of this tumor.

Key Words: Spine osteochondroma; Lumbar osteochondroma; Laminectomy; Radiation-induced osteochondroma; Spine surgery; Case report

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Core Tip: Osteochondromas of the spine are a rare but treatable condition. For symptomatic lesions, complete resection is largely curative without adjuvant therapy. The patient in this case report was pain free at his post-operative visits without signs or symptoms of recurrence or complication. He returned to work as a manual laborer at 3 mo. Further reports of patients diagnosed with osteochondromas and a history of childhood radiation will enable better understanding of radiation-induced osteochondromas and the rates and locations at which they occur.

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INTRODUCTION

Osteochondromas are the most common benign bone tumor, accounting for 36% of benign bone tumors[1]. Often found within the appendicular skeleton, osteochondromas of the spine are rare, comprising 4% to 7% of primary benign spinal tumors[2,3]. Spine osteochondromas typically originate in the posterior elements as opposed to the vertebral bodies. The cervical spine is most affected (50%), followed by the thoracic and lumbar regions[4]. Characterized as outgrowths of bone covered with a cartilaginous cap, these lesions are considered aberrations of normal growth. Perichondral ring disruption at an active physis leads to cartilage herniation through the periosteal layer. Over time, the cartilaginous fragments undergo ossification and expand[5]. Their expansile nature may cause compression of surrounding structures resulting in pain and neurologic symptoms[4,6,7].

Radiation-induced osteochondroma is a known phenomenon that occurs in patients with a childhood history of radiation therapy[8]. Compared to spontaneous solitary osteochondromas and hereditary multiple exostosis, radiation-induced lesions are radiologically and pathologically identical[8,9]. The presence of a radiation-induced osteochondroma in the lumbar spine is extremely unusual, as in our presented case. A review of literature reveals only two cases of radiation induced osteochondroma occurring in the lumbar spine (one occurring in the L1 body of a 29-year-old female and the L3 spinous process of a 15-year-old female[10-12]. The case of the 15-year-old female appeared in a larger childhood post-radiative tumor study and was not formally presented. Difficulty in diagnosis stems from inconsistent visualization on plain radiographs. Computed tomography (CT) and magnetic resonance imaging (MRI) are the gold standard in the evaluation of spinal osteochondromas, especially in the setting of spinal cord compressive symptoms[13,14].

We present an atypical, symptomatic lumbar spine osteochondroma in an 18-year-old male with a history of chemotherapy and radiation. This case report received institutional review board approval.

CASE PRESENTATION

Chief complaints

An 18-year-old-male presented to the pediatric orthopaedic clinic with the complaint of a posterior midline protuberance at the level of the lumbar spine.

History of present illness

Per the patient, the mass had been present for one year and was gradually enlarging. He noted pain with prolonged sitting and while lying supine.

History of past illness

There was no history of prior trauma or activity-related injury to his low back, however the patient worked as a manual laborer. The patient denied constitutional or neurologic symptoms. His history was significant for a suprasellar pineal germinoma

successfully treated with chemotherapy and radiation at 9-years of age.

Personal and family history

No family history of hereditary multiple exostosis was reported.

Physical examination

On physical examination, there was a palpable osseous protuberance approximately 5 cm in width along the posterior midline at the level of the lumbar spine. The mass was fixed and exquisitely tender to palpation. Further examination of the body and extremities revealed no other masses. Neurologic testing was benign with normal sensorimotor response in all extremities, symmetric reflexes, no upper motor neuron or radicular signs, and no balance or gait abnormalities.

Laboratory examinations

No laboratory examinations were performed.

Imaging examinations

Initial radiographic evaluation demonstrated a large osteochondroma arising from the right spinous process/Lamina junction at the level of the L5 vertebral body (Figure 1). Subsequent CT and MRI imaging confirmed the radiographic findings without evidence of intraspinal abnormality or encroachment on the vertebral canal (Figures 2 and 3). Given the symptomatic nature and location of the mass, the patient was offered surgical treatment in the form of mass excision.

FINAL DIAGNOSIS

A diagnosis of an osteochondroma arising from the right spinous process/Lamina junction at the level of the L5 vertebral body was made, and this was later confirmed with surgical pathology.

TREATMENT

Intraoperatively, mass excision with partial laminectomy was performed through a posterior midline incision. Careful paramedian dissection was performed in order to free the soft tissues surrounding the mass without destabilization of the interspinous ligaments or the right L5-S1 facet joint. Once isolated, the mass was excised *en bloc* with use of a harmonic bone scalpel. A Woodson elevator was utilized under the lamina to gauge depth and ensure that the ventral surface of the lamina remained intact. After excision, a paraspinal muscular flap closure was performed to minimize the potential space created by the mass. Gross surgical pathology revealed a large bony mass measuring 3.8 cm × 3.5 cm × 2.5 cm that included a 1 cm thick sessile cartilaginous cap. Surgical margins were noted to be smooth (Figure 4). Microscopic examination demonstrated mature hyaline cartilage, fibrous perichondrium, and trabecular bone without cellular atypia or malignant features. Enchondral ossification was present within the sample without marrow elements identifiable within the trabecular bone. Pathology was consistent with benign osteochondroma (Figure 5).

OUTCOME AND FOLLOW-UP

Post-operatively, the patient was discharged on postoperative day 1 following removal of his drain. His post-operative course was uncomplicated. He returned to his work as a manual labor without pain or limitation at three months following surgery.

DISCUSSION

Osteochondromas are benign osteocartilaginous proliferations at a growth plate that typically stop increasing in size at skeletal maturity[5,15]. They infrequently occur in the spine (1% to 4% of osteochondromas) with the majority localized to the cervical spine[4]. Cases of lumbar osteochondromas, like the case presented, are scarce.

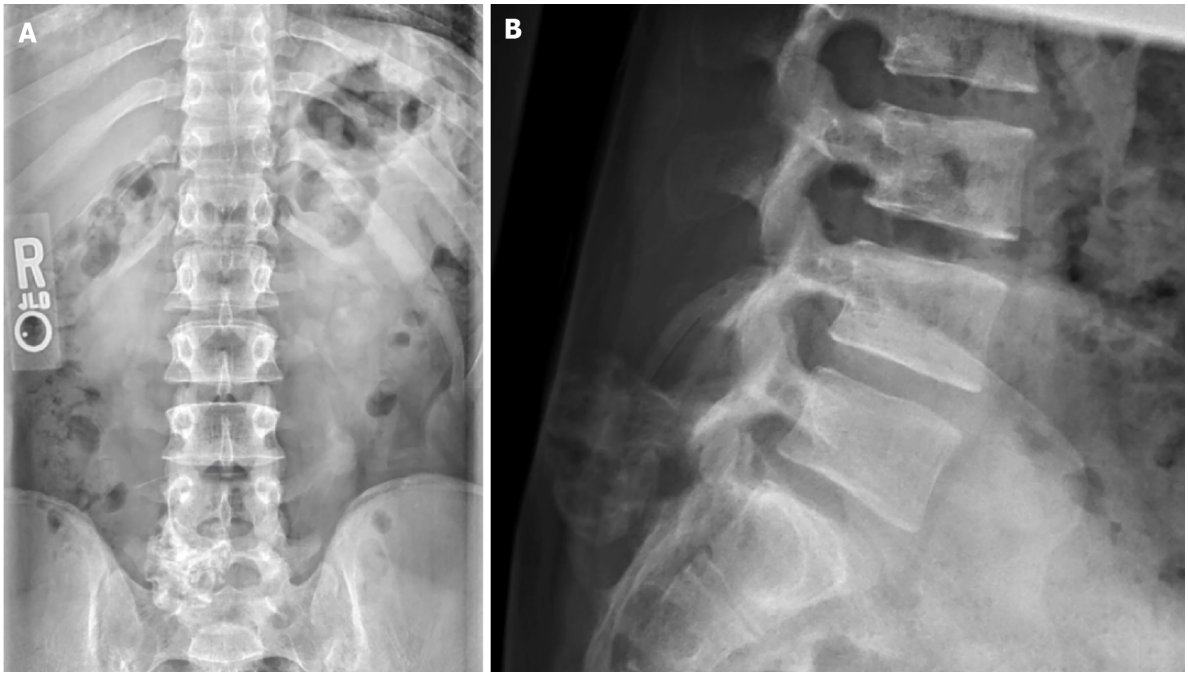


Figure 1 Anterior to posterior and lateral radiographs demonstrating calcified, pedunculated mass protruding from the posterior elements of the L5-S1 vertebral interval. A: Anterior to posterior radiograph; B: Lateral radiograph.

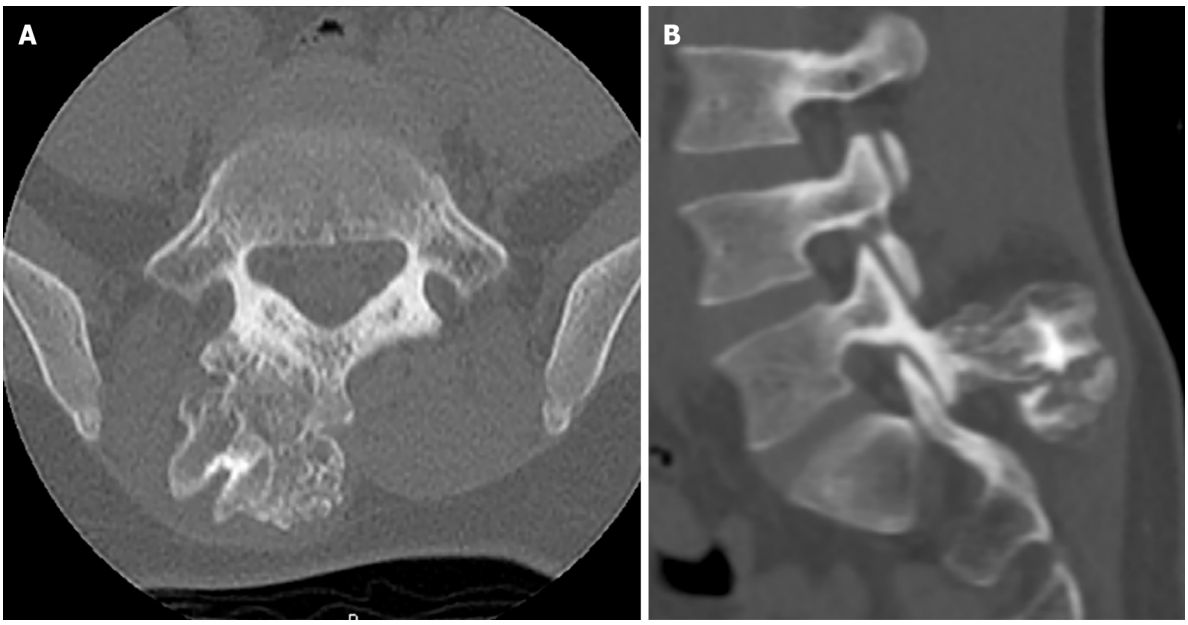


Figure 2 Computed tomography imagines. A: Axial computed tomography imaging demonstrating osteochondroma protruding from right spinous process/Lamina junction; B: Sagittal computed tomography imaging at the level of the L5/S1 facet joint depicts mass involvement of the right inferior articular process of L5. An ultrasonic bone scalpel was used to remove the mass *en bloc* from the articular process without disrupting the facet capsule.

Patients typically present with axial pain which may be exacerbated with certain positions or activity like the patient in this study. Neurological manifestations from cord compression are rare but have previously been reported[16]. Initial radiographic evaluation may reveal a spinal lesion composed of a cortical protuberance in continuity with the medullary canal. Advanced imaging is recommended to aid in diagnosis. CT imaging provides detail of the osseous and cartilaginous margins whereas MRI can provide the thickness and architecture of the cartilaginous cap. A cartilage cap > 3 cm thickness can indicate malignant transformation[1,4].

Lumbar involvement of these exostoses is rare, perhaps due to increased stiffness of the lumbar spine when compared to the cervical spine and therefore less microtrauma to the epiphyseal cartilage. Osteochondromas occur within the posterior elements of

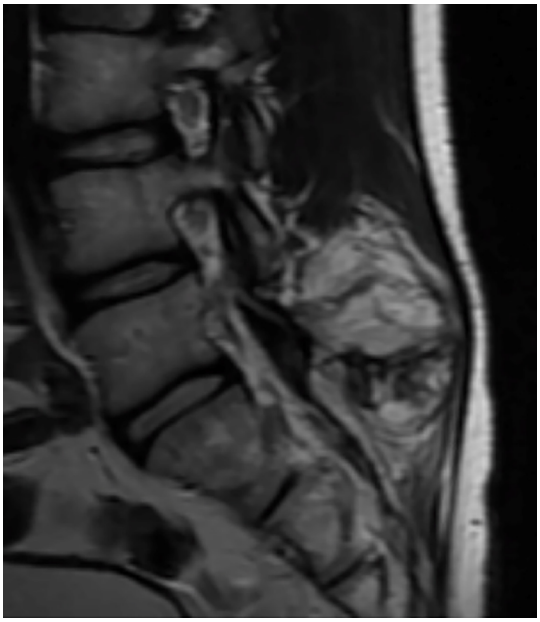


Figure 3 Sagittal T2 magnetic resonance image demonstrating the well-defined 1.5 cm cartilaginous cap of the lumbar osteochondroma extending into the right paraspinal musculature.

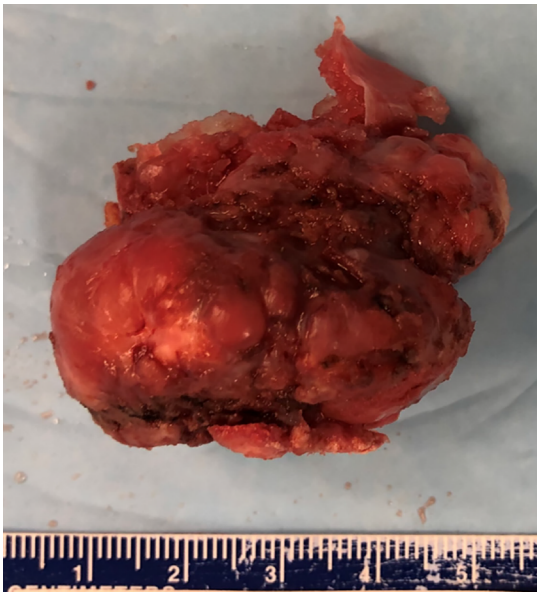


Figure 4 Gross specimen of excised lumbar mass measuring 3.8 cm × 3.5 cm × 2.5 cm with cartilaginous cap and smooth muscle margin.

the spine and may become symptomatic with growth into the paraspinal musculature [17]. A review of lumbosacral osteochondromas performed by Kuraishi *et al*[16] noted radicular symptoms in 4 out of 5 cases. In that series, involvement of the L4 inferior articular processes resulted in an L5 radiculopathy whereas involvement of the superior articular process of S1 corresponded with an L5 radiculopathy.

Given our patient's history of a suprasellar pineal germinoma requiring chemotherapy and radiation, the spinal lesion was potentially radiation-induced. Pediatric oncology literature describes osteochondroma growth as a complication of both localized radiation therapy as well as total body irradiation[18]. The proposed pathogenesis is radiative damage to the epiphyseal plate resulting in immature cartilage fragment migration to the epiphysis and periosteal layers. These cartilage fragments expand during subsequent maturation and ossification. Radiation-induced osteochondromas have been reported in the ulna, tibia, and hands[18-20]. To our knowledge, this is the first detailed case report of a spinal osteochondroma in a

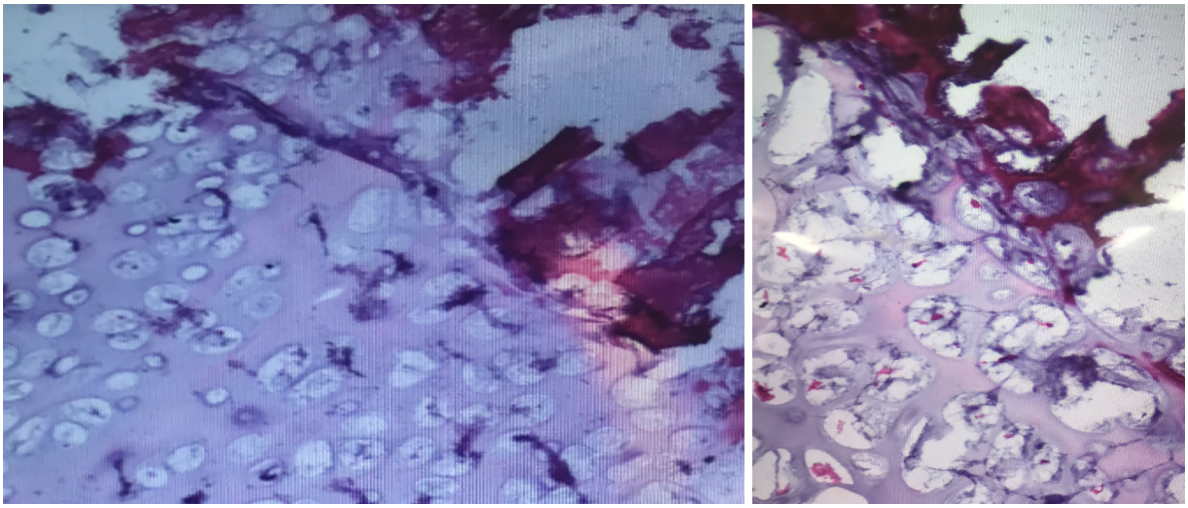


Figure 5 Histology of excised mass demonstrating mature cartilage, fibrous perichondrium, and trabecular bone without evidence of cellular atypia or malignant transformation; consistent with osteochondroma.

pediatric patient with previous radiation treatment.

Painful lesions or those causing neurologic deficit require surgical intervention. If resection entails destabilizing the spine, instrumentation and arthrodesis should be considered. The goal of surgery should be complete resection of the lesion[21]. Surgical nuance of our lumbar osteochondroma excision was the use of an ultrasonic bone scalpel. The ultrasonic bone scalpel amplifies electrical signals that oscillate a blunt blade, allowing for targeted resection of cortical bone without violation of soft tissues [22]. Given the location of our patients osteochondroma with abutment of the right L5 interspinous ligament and right L5-S1 facet capsule, excision of the mass without violating the soft tissues prevented posterior spinal destabilization requiring subsequent instrumentation and fusion.

CONCLUSION

Osteochondromas of the spine are a rare but treatable condition. For symptomatic lesions, complete resection is largely curative without adjuvant therapy. The patient in this case report was pain free at his post-operative visits without signs or symptoms of recurrence or complication. He returned to work as a manual laborer at 3 mo. Further reports of patients diagnosed with osteochondromas and a history of childhood radiation will enable better understanding of radiation-induced osteochondromas and the rates and locations at which they occur.

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EDITORIAL

Mixed reality for visualization of orthopedic surgical anatomy

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Abstract

In the modern era, preoperative planning is substantially facilitated by artificial reality technologies, which permit a better understanding of patient anatomy, thus increasing the safety and accuracy of surgical interventions. In the field of orthopedic surgery, the increase in safety and accuracy improves treatment quality and orthopedic patient outcomes. Artificial reality technologies, which include virtual reality (VR), augmented reality (AR), and mixed reality (MR), use digital images obtained from computed tomography or magnetic resonance imaging. VR replaces the user's physical environment with one that is computer generated. AR and MR have been defined as technologies that permit the fusing of the physical with the virtual environment, enabling the user to interact with both physical and virtual objects. MR has been defined as a technology that, in contrast to AR, enables users to visualize the depth and perspective of the virtual models. We aimed to shed light on the role that MR can play in the visualization of orthopedic surgical anatomy. The literature suggests that MR could be a valuable tool in orthopedic surgeon's hands for visualization of the anatomy. However, we remark that confusion exists in the literature concerning the characteristics of MR. Thus, a more clear description of MR is needed in orthopedic research, so that the potential of this technology can be more deeply understood.

Key Words: Orthopedic surgery; Mixed reality; Anatomy; Augmented reality; Three-dimensional visualization technologies; Artificial reality technologies

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Core Tip: Mixed reality could be a valuable tool in orthopedic surgeon's hands for visualization of anatomy, but a more clear description of this technology is needed in

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INTRODUCTION

In the modern era, surgical planning is substantially facilitated by artificial reality technologies, which permit a better understanding of patient anatomy, thus increasing safety and accuracy[1]. Among artificial reality technologies, virtual reality (VR) has been defined as a technology that completely replaces the user's physical environment with one that is computer generated[2]. Augmented reality (AR) enables specific devices, to fuse digital models with physical objects and allow for interaction with both[3]. MR, like AR, permits fusing of physical with virtual environment, but in contrast to AR, enables users to visualize depth and perspective in the virtual models [2,4]. The models are derived from preoperative images, obtained by computed tomography (CT) or magnetic resonance imaging[5]. Of these technologies, VR and AR allow for adequate visualization of orthopedic surgical anatomy, thus facilitating the performance of several types of orthopedic interventions[5]. The technologies provide surgeons with the ability to visualize patient data in real time, improve preoperative planning, and offer accuracy in performance of interventions, thus leading to upgrades of treatment quality and orthopedic patient outcomes[5]. We aimed to shed light on the role that MR can play in the perception of orthopedic surgical anatomy. We consider that, in contrast with VR and AR, the confusion that exists in the literature impedes the understanding of the value of this technology for the visualization of anatomy in orthopedic surgical procedures.

MIXED REALITY AND VISUALIZATION OF ORTHOPEDIC SURGICAL ANATOMY

In a review of the literature on the implementation of VR, AR, and MR in orthopedics Verhey *et al*[5] stated that similar to AR, an MR system produces stereoscopic images formed by combining the real world with three-dimensional (3D) virtual models[5]. It was also stated that in MR systems, virtual objects are not simply projected on real ones, as in AR, but the user can interact with both the real and digital objects. The definition, provided by Verhey *et al*[5], is different from that provided by Moro *et al* [3], according to which, AR does allow for interaction. Also, Verhey *et al*[5] argued that both MR systems and AR, produce stereoscopic images. Stereoscopic visualization has been defined as the combined view of two digital images seen separately by each eye, using special devices[6]. In contrast, monoscopic visualization comprises digital objects that can be three-dimensionally rotated but are projected on a two-dimensional screen[6]. According to the aforementioned definitions of stereoscopic visualization and AR, it can be noted that stereopsis is not an essential characteristic of AR, thus there is a disagreement with Verhey *et al*[5].

Condino *et al*[7] described an MR-based orthopedic surgery simulator for which hip arthroplasty was chosen as a benchmark for evaluation. The authors performed quantitative tests to "estimate the accuracy of the system by evaluating the perceived position of AR targets". According to Condino *et al*[7], the results of their study supported the use of MR to develop a simulator for orthopedic surgery. However, as can be concluded by the aforementioned purpose of the study, Condino *et al*[7] did not distinguish MR from AR.

Gregory *et al*[8] reported a case of a patient who underwent reverse shoulder arthroplasty performed with the aid of an MR headset. The authors noted that the system enabled accurate visualization of the patient's anatomy, which was beneficial for the safety of the procedure. A postoperative CT scan confirmed the satisfactory position of the prosthesis, and the patient experienced no peri- or postoperative complications

(Table 1). Nevertheless, in the introduction of their article, the authors stated that AR is commonly referred to as MR, thus they did not differentiate the two technologies.

Wu *et al*[9] reported a case of a patient with traumatic high paraplegia who underwent a complicated cervical spine fracture procedure with the use of MR technology. The authors noted that the MR system enabled the surgeon to clearly visualize the anatomy in the operative field, and that CT with 3D reconstruction could not adequately depict neuronal and vascular components around the fracture. However, in the introduction, the authors defined MR as "the merging of the real world and the virtual world," and did not explain the difference between MR and AR.

Wei *et al*[10] evaluated the clinical outcome of MR-assisted percutaneous kyphoplasty to treat an osteoporotic vertebral compression fracture with intravertebral vacuum cleft. It was concluded that percutaneous kyphoplasty assisted by MR provided the surgeon with accurate guidance to the intravertebral vacuum cleft area during the operation. A group of patients who underwent MR-assisted percutaneous kyphoplasty to treat an osteoporotic vertebral compression fracture with intravertebral vacuum cleft was compared with a group who underwent the same procedure with traditional C-arm fluoroscopy instead of MR. Vertebral height improvement, cement diffusion, and pain relief were significantly improved by MR assistance (Table 1). The authors stated that MR is a combination of AR and VR and that it permits accurate combination of virtual objects with the real world, without further explanation.

Wu *et al*[11] assessed the safety and accuracy of pedicle-screw placement in a 3D printed model of an upper cervical spine fracture under MR-based navigation. The authors noted that MR could effectively help surgeons visualize intraoperative anatomy, especially in complex cases involving the upper cervical spine. The authors highlighted the advantages of MR, which "generates computer graphics onto the holographic display of real scenes", and cited a study by Volonté *et al*[12]. However, Volonté *et al*[12] dealt with AR and not MR technology.

A study by Gu *et al*[13] included patients who were randomly divided in two groups. The first with MR-based lumbar pedicle-screw placement and the second with traditional screw placement. The implantation accuracy was significantly better in the first group than in the second one. Also, there was significantly less bleeding, shorter operative time, and faster recovery in the first group. One month postoperatively, the pain scores were significantly better in the first than in the second group (Table 1). The authors defined MR as a technology that combines virtual with physical objects, without further clarification.

Lei *et al*[14] performed a complicated total hip arthroplasty combining 3D printing technology with MR. It was noted that the virtual bone and other anatomical structures were accurately superimposed on the patient's body. Postoperatively, the range of motion for the hip joint was within the normal range, the patient's recovery was reported to be good, and he was discharged without obvious surgical complications (Table 1). The authors stated that "the unsatisfied accuracy of registration in MR technology is an urgent problem yet to be resolved" and cited an article by Fida *et al*[15]. However, Fida *et al*[15] reviewed the use of AR in open surgery, and both Lei *et al*[14] and Fida *et al*[15] used the terms "AR" and "MR" interchangeably.

CONCLUSION

According to the literature, MR can be a valuable tool in the orthopedic surgeon's hands for visualization of anatomy. Although the two technologies are distinct, the interchangeable use of the terms "AR" and "MR" in the orthopedic surgery literature does not permit researchers and surgeons to extract safe conclusions about the possible superiority of AR or MR. Because MR has been defined as a technology that provides depth and perspective in the virtual environment, in contrast to AR[2,4], it seems that the two technologies may have different values in perceiving orthopedic surgical anatomy. The literature suggests that the two technologies may have different anatomy teaching potential[16]. Currently, there is a lack of research to permit comparison between AR and MR in terms of their value in orthopedic surgical practice. The possible difference between the value of two technologies needs further investigation, which should proceed with a clear description of the technology under investigation and with differentiation between AR and MR.

Table 1 Studies of implementation of mixed reality for visualization of orthopedic surgical anatomy, with patient outcomes

Ref.	Operation	Effects of MR on visualization of orthopedic surgical anatomy	Patient outcomes
Gregory *et al*[8]	Reverse shoulder arthroplasty	Accurate visualization of the patient's anatomy	A postoperative CT scan confirmed the adequate position of the prosthesis, while the patient experienced no peri- or postoperative complications
Wei *et al* [10]	Percutaneous kyphoplasty to treat an osteoporotic vertebral compression fracture with intravertebral vacuum cleft	The surgeon could obtain accurate guidance to the intravertebral vacuum cleft area during the operation	Vertebral height improvement, cement diffusion and pain relief were significantly better in the MR group in comparison with the traditional C-arm fluoroscopy group
Gu *et al* [13]	Lumbar pedicle-screw placement	The implantation accuracy with the use of MR was significantly higher in comparison with traditional screw placement	Significantly less bleeding and operative time, faster recovery, significantly better pain scores at 1 month postoperatively with MR, in comparison with traditional screw placement
Lei *et al* [14]	Total hip arthroplasty	The patient's virtual bone, as well as the other anatomical structures, were accurately superimposed on the patient's body	The range of motion for the hip joint was within the normal range, while the patient's recovery was reported to be good and he was discharged without obvious surgical complications

CT: Computed tomography; MR: Mixed reality.

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Bicruciate-retaining total knee arthroplasty: What's new?

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Abstract

Primary total knee arthroplasty (TKA) is a widespread procedure to address end stage osteoarthritis with good results, clinical outcomes, and long-term survivorship. Although it is frequently performed in elderly, an increased demand in young and active people is expected in the next years. However, a considerable dissatisfaction rate has been reported by highly demanding patients due to the intrinsic limitations provided by the TKA. Bicruciate-retaining (BCR) TKA was developed to mimic knee biomechanics, through anterior cruciate ligament preservation. First-generation BCR TKA has not gained popularity due to its being a challenging technique and having poor survival outcomes. Thanks to implant design improvement and surgeon-friendly instrumentation, second-generation BCR TKA has seen renewed interest. This review will focus on surgical indications, kinematical basis, clinical results and latest developments of second-generation BCR TKA.

Key Words: Total knee arthroplasty; Anterior cruciate ligament; Bicruciate retaining; Knee kinematics; Second generation design; Knee osteoarthritis treatment

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Core Tip: Second-generation bicruciate-retaining total knee arthroplasty (BCR TKA) is designed to overcome the historical durability issues of this implant. Recent kinematics studies point out the advantage of this design in mimicking normal knee motion.

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Second-generation BCR TKA is generally associated with a more restrictive indication range in terms of coronal alignment, anterior cruciate ligament integrity, and preoperative range of motion. Available clinical results demonstrate variable outcomes with short-term follow-up.

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INTRODUCTION

Primary total knee arthroplasty (TKA) is a widespread surgery, capable of recovering articular function and relieving pain in end-stage osteoarthritis (OA) of the knee[1]. Once considered a procedure for the elderly, primary TKA is nowadays performed frequently in younger and high-demanding patients. Specifically, in the next years, side by side with an overall consistent increase for this procedure demand, the amount of TKA implanted before 65-years-old will exceed 55% of the total procedures[2]. Moreover, along with those demographic variations, despite technical advancement and a 20-year survival rate exceeding 90%, approximately 20%[3] of patients nowadays remain unsatisfied after surgery[4]. Those results are strictly related to the post-operative ability to perform activities of daily life[5]. Clement *et al*[6] have pointed out that those activities are frequently limited by having a TKA, causing a high dissatisfaction rate (25%) mostly in highly demanding patients that consequently see their expectation not fulfilled[7].

This dissatisfaction may potentially be overcome, improving the abnormal kinematics and proprioceptive instability reported by sacrificing the anterior cruciate ligament (ACL) in posterior stabilized (PS) and cruciate-retaining (CR) design[8,9]. Several reports of studies, in fact, mention the role of the ACL in joint kinematics[10], and the paradoxical anterior femoral motion in contemporary design with cruciate sacrifice as cause of dissatisfaction[8,11]. Thus, bicruciate-retaining (BCR) TKA may represent an effective solution to overcome biomechanical concerns and patients' dissatisfaction reported after implant without ACL.

Over the years, previous BCR TKA generations have not gained widespread popularity because of its being a challenging technique and the tension of retained ligaments, the risk for potential instability from ligament failure or tibial island fracture, and inability to correct major deformities of the knee[12]. Moreover, the U-shaped tibial component may lead to component breakage or mobilization because of reduced tibial coverage area and the thin anterior tibial bar[13]. The latest BCR TKA design was developed to overcome those problems. The aim of the literature review performed for this study focuses on surgical indications, results and latest developments about second-generation BCR TKA.

HISTORICAL NOTES

The first example of cruciate-sparing prosthesis was developed by Gunston[14] in 1960: the "Polycentric Knee". This implant was composed by two semi-circular cemented femoral sliding tracks with two distinct cemented fixed tibial components. Subsequently, the Mayo clinic team created the "Geometric" knee prosthesis, to retain both cruciate, composed of two femoral components linked with a cross-bar and unique polyethylene with a bridge anteriorly to the tibial island[15]. Thanks to Townley[16] in 1972, an anatomic cemented ACL-retaining TKA was created, made of thin, bilobed, horseshoe-shaped femoral components able to limit bone resection and ligaments resection. In 1975, Cloutier *et al*[17,18] developed an anatomic prosthesis with chromium-cobalt femoral component and a U-shaped tibial baseplate with two separated tibial bearing surfaces. The major failure rate on BCR models due to tibial loosening in the early implants, the demanding technique itself and improved clinical outcome of cruciate sacrifice models reduced the interest in development of innovative

design[19]. However, recent studies highlighted the proprioceptive role of the cruciate ligaments, renewing attention in their preservation during knee arthroplasty[20].

In the last years, thanks to advances in technology, saw the introduction of two models of BCR TKA [Vanguard XP Total Knee System (Zimmer Biomet, Warsaw, IN, United States) and Journey II XR (Smith and Nephew plc, Watford, United Kingdom)].

INDICATIONS

There is a growing interest in performing BCR TKA. As reported by De Faoite *et al*[21] from an international survey, 65% of the interviewed surgeons would consider implanting BCR TKA. Despite this, there is a significant lack of knowledge around patient segmentation for this surgery. Available literature on BCR TKA frequently do not specify indications in a precise manner; moreover, there is a significant overlap between recent unicompartmental (UKA) and bicompartmental knee replacement indications that may be confusing (Table 1). BCR TKA may, in fact, ideally combine the expected advantage of UKA in terms of restoring natural knee kinematics and TKA long-term survival rates. Despite this, the available data make it seem reasonable to choose UKA in case of limited unicompartmental knee OA, in contrast to when at least two compartments are involved in the degenerative process, when the choice between bicompartmental knee replacement and BCR TKA is still unclear. Moreover, age is not a barrier to BCR TKA *per se*[22], but the surgeon should preoperatively and/or intraoperatively evaluate the ACL integrity, the coronal alignment and range of motion (ROM) limitations to decide if this implant is the best choice.

Coronal alignment

Management of knee malalignment may be challenging in BCR TKA. A preoperative lower-limb alignment evaluation through long-leg radiographs to evaluate the source of deformity is mandatory. Despite this, the literature is unclear and there is considerable debate regarding the influence of preoperative deformity on BCR TKA outcomes[9]. Second-generation BCR TKA is generally associated with a more restrictive indication range[20,23-25]. Bauman *et al*[20], in his comparative study with UKA, excluded varus–valgus deformity of more than 10°, Christensen *et al*[24] included patients with a "minimal coronal deformity", while Pelt *et al*[25], in his retrospective review of a consecutive series of 175 knees, excluded patients with more than 15° of coronal malalignment. The latter postulate as a possible cause of the low survivorship rate of the BCR TKA reviewed or the pathological variation in knee kinematics that can be introduced with an implant designed to be placed with a traditional mechanical alignment technique within a soft tissue envelope that may not perfectly match after deformity correction. Therefore, exclusion of severe (> 15°) malalignment seems appropriate, but a greater consideration for patient to patient coronal alignment variability and restoration may, with future specifically-designed implants, lead to easier balancing of the ligaments and reduce the tibial component failure rate[26].

ACL integrity

Integrity assessment of both cruciate ligaments is crucial when a BCR TKA is performed. As recently reported by Ishii *et al*[27], from their retrospective evaluation of 247 TKA, 94% (233/247) of the evaluated knees had a visually intact ACL (normal or moderately damaged) at time of surgery. However, the ACL integrity in terms of strength and proprioception may be questionable in cases of end-stage OA, even though a visually intact ACL is present. Specifically, Mont *et al*[28] evaluated the histological properties of the ACL during TKA in 173 osteoarthritic knees. They reported mucoid degeneration in 85% of patients, even in visually intact ligaments. The authors linked older age, higher body mass index, and greater osteoarthritic changes to the degree of histological changes.

Moreover, as reported by Kawaguchi *et al*[29], this degeneration may extend to both cruciate ligaments, even when the PCL is intact on preoperative evaluation. Therefore, the author suggests to consider posterior stabilized (PS) TKA in case of ACL mucoid degeneration.

In addition, inflammatory arthritis was not considered as exclusion criteria in several clinical studies[13,18,30,31]. This is of special interest because inflammatory arthritis can impact the ACL integrity. More research is required to improve the understanding of inflammatory arthritis and mucoid degeneration role on ACL preserving arthroplasty. Clinical studies, to define ACL integrity, generally rely on

Table 1 Indications and relative contraindications summary

Indications	Relative contraindication
High-demand patients	Low-demand patients
End-stage bi- or tricompartmental knee OA	Severe coronal malalignment (> 15°)
Coronal malalignment < 15°	Inflammatory arthritis
ACL integrity:	ACL mucoid degeneration/absence
Clinical assessment (Lachman, anterior drawer test, pivot shift test)	Relevant preoperative reduction of ROM (> 10°)
Intraoperative assessment	
Minimal ROM reduction (< 5/10°)	

ACL: Anterior cruciate ligament; OA: Osteoarthritis; ROM: Range of motion.

visual evaluation[13,18,24,25,31] and/or clinical tests, like Lachmann test, the pivot shift test and anterior drawer test[13,18,25,31-34], while very few use radiological assessment in association. Kono *et al*[35] used a pre-operative magnetic resonance imaging (MRI) to determine the integrity of the ACL, while Pelt *et al*[25] used X-ray signs to indirectly assess the ACL status. In order to understand whether radiology may help in ACL status definition, we may refer to Johnson *et al*[36], who used the Lachman test alone, performed under anaesthesia. The investigators reported the test as ineffective in ACL functional integrity evaluation (33% sensitivity), while combination of the Lachman test with MRI scans brought the sensitivity and specificity of the combined tests to 93.3% and 99% respectively. Despite this, the lines of evidence about the role of MRI imaging or X-ray signs as an indicator of ACL insufficiency are limited. Future research should focus on ACL evaluation to select optimal candidates for this surgery.

Preoperative ROM

Restoration of a full ROM from a severe preoperative flexion contracture or a limited extension may be challenging in BCR TKA because of the cruciate ligament integrity and consequent confined surgical space, difficult ligament balancing, and soft tissue release.

There is no consensus in the available literature about acceptable preoperative ROM [9]. Christensen *et al*[24] limited their study to "minimal" contracture BCR indication; Pritchett[37] excluded patients with flexion of less than 90° and a flexion contracture of 20° or greater, while Pelt *et al*[25] included patients with less than 15° of flexion contracture.

Lavoie *et al*[34] conducted a retrospective comparative cohort study of 100 BCR TKAs and 100 PS TKAs, focusing on the influence of the preoperative to the postoperative ROM in the two-implant design. They found that BCR TKA with a preoperative flexion contracture equal or superior to 5° were almost 5-times more likely than PS implant to have a flexion contracture post-surgery and 10-times more likely to have a postoperative flexion contracture when the preoperative flexion contracture was equal or greater than 10°. Therefore, despite no systematic analysis being available with regard to the clinical outcomes in literature for second-generation implants, it seems appropriate to initially limit BCR TKA indications to patients with minimal reduction (< 10°) in ROM because preoperative motion issues are more likely to persist after TKA if both the cruciate ligaments are preserved.

TECHNICAL FEATURES

BCR TKA implies major technical challenges and specific complications resulting from ACL retention and difficult tissue balancing. Moreover, this surgery entails specific design-related issues, such as tibial baseplate stability in absence of a large tibial keel for fixation and reduced tibial coverage.

Second-generation implants are designed to overcome those durability issues; this is obtained through tibia component that comes with an asymmetric perimeter shape, a continuous keel and optimized anterior bridge to provide strength, and reduces historical design concerns related to anterior implant fractures to improve tibial

coverage. Furthermore, because some recent studies[24] found that second-generation BCR TKA with a symmetric, non-anatomical design were associated with an higher complication and revision rate. Newer implants are developed with a dedicated anatomical design that approximates physiological joint geometries to better replicate normal knee motion, allowing more mobility in the lateral compartment, as happens in the screw home mechanism, driven by cruciate ligaments. This is obtained through the tibia component, that includes a metal tibia tray with two independent and differently designed medial and lateral inserts with different radius of curvature of the surface and possibility to set different slope in association with an anatomical femoral component with asymmetrical condylar shape.

This new course adopted finds confirmation in the study conducted by Watanabe *et al*[26]. They investigated the effects of several alignment techniques on BCR TKA biomechanics. The most important finding of this study was that a symmetric BCR model implanted with a mechanical alignment demonstrated non-physiological knee biomechanics resulting from over-tensioning of the joint ligaments, especially the PCL and LCL. The rotational alignment of a symmetric femoral component with mechanical alignment (MA) is, in fact, essentially aligned to the epicondylar axis, and consequently the posterior femoral condyle is often larger than that of the preoperative knee and might excessively compress the lateral tibial plateau, resulting in reduced posterior translation of the lateral femoral condyle due to LCL and PCL tightness during knee flexion. Moreover, although the evaluation of a non-anatomical BCR TKA implanted with a kinematic alignment technique demonstrated a significantly reduced ligamentous tension and sensible improvements in joint kinematic, PCL and LCL tensions were still higher when compared to the normal knee. In view of those findings, they concluded that the non-anatomical shape of the evaluated implant contributed to the abnormal kinematic found and considered as a possible solution to those issues related to the introduction of an anatomical BCR TKA.

Therefore, especially in in the BCR implant, position of the components must be extremely precise to reach proper ligamentous balancing, avoid femoral component impingement on the central bone island, and restore joint line height and slope to obtain optimal ACL and PCL functionality and knee kinematics.

Despite so, as reported by Peng *et al*[38] in his 3D component orientations analysis relevant variations in component position were observed, especially for the tibial component, using standard instrumentation. Moreover, those variations, especially regarding tibial slope, where related to the 1-year clinical outcomes obtained. Because of this, they concluded that since the BCR TKA design aims to preserve both ACL and PCL it requires a higher level of attention to obtain an accurate and precise component orientation in order to restore the native knee biomechanics. This accuracy may ideally be provided by the use of additional surgical navigation guides/robotic assistance. Despite this, to our knowledge, there are no studies that have investigated the possible advantage of navigation guide or robotic assistance on BCR outcomes.

KINEMATIC STUDIES

Physiological knee kinematics are the result of a harmonic relationship between the articular surface, cruciate and collateral ligaments as well as the surrounding soft tissue. Theoretically, retaining both anterior and posterior cruciate ligament in TKA could contribute to restoration of nearly-normal knee kinematics, maintaining the posterior femoral rollback, reproducing medial pivot rotation and preserving proprioception. However, another aspect to consider that could influence kinematics is the implant design, which has been significantly improved with the last anatomic models. Several *ex vivo* studies demonstrated that BCR implants could preserve the screw-home mechanism, maintaining a more anterior femorotibial contact point, increasing the axial rotation and the posterior displacement through flexion in contrast to the ACL-sacrificing design and similar to a native knee[39-42]. However, in addition to ACL preservation, some authors have highlighted the importance of tibial geometry in the restoration of the physiological knee kinematics[41,43].

In their cadaver kinematic study, Hamada *et al*[43] found that normal rotational kinematics were not reproduced using a second-generation BCR TKA (Vanguard XP Total Knee System (Zimmer Biomet, Warsaw, IN, United States). In the same study, the authors showed that the screw-home mechanism was maintained after meniscectomy and femoral replacement but lost after tibial replacement, emphasizing the role of tibial geometry in implant kinematics[43]. Similarly, Wada *et al*[41], in their kinematic analysis of BCR TKA (Vanguard XP Total Knee System (Zimmer Biomet),

demonstrated that the amount of tibial internal rotation throughout knee flexion was greater, and more similar to the native knee, if a medial constrained insert was used compared to a flat insert. *Ex vivo* investigations on BCR TKA kinematics are partially confirmed by several clinical studies focused on daily activities[44-47]. Arauz *et al*[47] analysed the treadmill walking pattern in 29 patients with unilateral BCR TKA (Vanguard XP Total Knee System (Zimmer Biomet) compared to the non-operated contralateral side, using a combination of computed tomography scan and dual fluoroscopic imaging system[47]. The authors found an asymmetrical gait pattern in their unilateral BCR TKA patients: during the stance phase of gait cycle, a higher flexion and internal tibial rotation were observed in the operated knee; moreover, less anterior/posterior and medial/lateral translation were noticed on the TKA side. Nevertheless, the implanted and non-implanted knee had no significant difference in flexion/extension and axial rotation range of motion. They concluded that knee motion symmetry was not completely restored in patients with unilateral BCR TKA [47].

Hennessy *et al*[45] observed that sex could be an influential factor on knee kinematics in BCR TKA during gait. In their kinematic study, the authors found more antero-posterior interlimb asymmetry (BCR TKA *vs* healthy knee) in female patients (2.8 mm *vs* 1.6 mm) than in male patients (2.3 mm *vs* 1.8 mm) and this finding displayed increased posterior femoral translation throughout most of the stance phases of the gait cycle in female patients[45]. In another study, Arauz *et al*[46] investigated the *in vivo* knee kinematics of unilateral BCR TKA, compared to the healthy side, during daily activities, including sit-to-stand, single-leg deep lunge, and steps-up. Performing flexion activities, the BCR TKA side displayed a less posterior contact point on the lateral femoral condyle (from 6° to 100° of flexion). However, the magnitude of the lateral excursion was similar to the non-operated knee, except for the early degree of flexion (0° to 7°). Differently, on the medial side, the extent of femoral translation during knee flexion was inferior and the contact point more variable in BCR TKA compared to the healthy side. In addition, during all the activities, less femoral external rotation during mid-to high flexion was found in the BCR TKA side. The authors concluded that knee kinematics and the screw-home mechanism were only partially replicated with BCR TKA, emphasizing the importance of the implant articular geometry and components positioning[46]. Similar results were obtained in another kinematic study by the same group of authors when investigating strenuous flexion activities in unilateral BCR TKA patients[44].

An interesting *in vivo* biomechanics analysis on cruciate ligament preservation and femoral geometry was provided by Smith *et al*[48]. The authors performed a kinematic evaluation on 50 TKAs with same anatomical femoral geometry (40 Posterior Cruciate Retaining (PCR) – Journey II PCR; 10 BCR TKA – Journey II XR, Smith and Nephew plc, Watford, United Kingdom), during deep knee bending under fluoroscopic surveillance, in comparison to the normal knees (10 subjects). During early flexion, a better restoration of knee kinematics was achieved in BCR TKA subjects compared to PCR TKA, including a more anterior position of both femoral condyles in full extension and more magnitude of posterior-femoral roll back (PFR) in early flexion. However, normal knees showed a more anterior position of the lateral femoral condyle in full extension and more axial rotation compared to both TKA groups. The more posterior contact point of the femoral condyle combined with lesser external rotation shown in BCR TKA was attributed to the differences in femoral geometry between the implant and the native knee. In mid to late flexion, the influence of ACL decreases in favour to PCL, so the differences in kinematics between TKAs become poorer. Nevertheless, the BCR displayed less translational motion compared to PCR, reflecting the importance of balance within ACL and PCL. However, normal knees experienced a continued lateral PFR during flexion, that was only partially achieved in the BCR TKA group[48]. Despite the technical improvement of the second-generation BCR implants, other studies are needed to investigate the biomechanical implications between components design and kinematics.

CLINICAL RESULT

In the literature there are several long-term studies on first-generation BCR TKA, focused on clinical results; all studies have shown a significant improvement in the evaluated scores while ROM assessment indicates varied results (Table 2). Pritchett[31] conducted a longer retrospective study on BCR first-generation implant (Townley Anatomic; Biopro Inc, Port Huron, MI, United States) and reported a significant

Table 2 Second-generation bicruciate-retaining total knee arthroplasty clinical results

Ref.	Follow up in mo	BCR model (*n*)	Pre-op ROM flex, mean	Post-op ROM flex, mean	Pre-op KSS, mean	Post-op KSS, mean	FJS	WOMAC
Alnachoukati *et al* [23]	12	Vanguard XP (146)	116°	121°	48	96		
Biazzo *et al*[49]	33.82	Vanguard XP (24)						8.68 (BCR) *vs* 12.81 (CR)
Baumann *et al*[20]	18	Vanguard XP (34)					53.4 ± 26.4	
Hennessy *et al*[45]	12.7	Vanguard XP (29)			58.1 ± 11.8	86.6 ± 16.7		
Kono *et al*[35]	7.7	Journey II XR	128.7 ± 6.1					
Kalaai *et al*[33]	3.6	Vanguard XP (61)			36.2 ± 8.1	22 ± 10.1	58.4 ± 33.7	
Peng *et al*[38]	12.7	Vanguard XP (29)			58.1 ± 11.8	87.9 ± 16.7		
Pelt *et al*[25]	36	Vanguard XP (141)	121	123				
Tsai *et al*[32]	12.9	Vanguard XP (30)			58.5	86.6		

BCR: Bicruciate retaining; CR: Cruciate-retaining; FJS: Forgotten joint score; KSS: Knee Society score; ROM: Range of motion; WOMAC: Western Ontario and McMaster Osteoarthritis index

improvement in knee flexion, from a mean pre-operative value of 104° to 117° (P = 0.001) and Knee Society Score (KSS) from pre-op mean of 42 to 91 (P = 0.001). The same group collected the patients' preferences in bilateral two-stage TKA; four prosthetic design were implanted (bicruciate retaining, posterior cruciate-retaining, medial pivot, and posterior cruciate-substituting). The mean KSS of BCR implants at 8 years follow-up was 92.6, while the mean ROM was 119°. The conclusion of that study was that, despite the mean ROM, neither the pain score, KSS score nor functional score varied significantly between type of knee prosthesis used; patients with bilateral procedures were more likely to prefer retention of their ACL and PCL or substitution with the medial or lateral pivot prosthesis[37]. Lavoie *et al*[34] conducted a retrospective study, in which 100 BCR TKA (Hermes™ 2C ACR) were compared to 100 PS TKA (Hermes PS). They showed a lower post-op KSS in the BCR TKA cohort compared with the PS design (83.9 *vs* 89.2); moreover, the investigators documented post-operative stiffness at last follow-up in the BCR TKA group (1.5° *vs* 0.7°, P = 0.034). The most important result of the study was the lower maximum passive knee flexion in BCR knees relative to PS knees at every postoperative point, when preoperative flexion was less than 130°.

On the other hand, long-term and comparative studies on second-generation BCR TKA are still not available due to the recent market introduction and few models' availability. Alnachoukati *et al*[23] reported a mean postoperative increase in flexion values (116° preoperative to 121° postoperative) and a mean improvement in terms of KSS (48 to 96). Biazzo *et al*[49] compared functional outcomes between 24 BCR TKA knees [Vanguard XP Total Knee System (Zimmer Biomet)] and 24 CR TKA knees [Vanguard ID Total Knee System (Zimmer Biomet)] in short-term follow up; at the last follow-up, they showed a higher mean Western Ontario and McMaster Osteoarthritis index (WOMAC) score for the BCR group (8.68) than for the CR group (12.81) but no statistically significant difference between the groups (P = 0.33). Baumann *et al*[20] demonstrated the superior proprioceptive function of a bicruciate-retaining implant [Vanguard XP Total Knee System (Zimmer Biomet)] compared to unicondylar knee arthroplasty (UKA) and posterior-stabilized TKA (Genesis II Total Knee Replacement System; Smith and Nephew plc, Watford, United Kingdom) at mean follow-up of 18 mo. The BCR group showed no difference in the Forgotten Joint Score (FJS) relative to the UKA group (53.6 ± 22.2 *vs* 53.4 ± 26.4, P = 0.999). The PS TKA group revealed lower mean score value in the FJS compared to the BCR group (38.9 ± 22.3 *vs* 53.6 ± 22.2, P = 0.035) and UKA group (P = 0.031).

Hennessy *et al*[45] analysed kinematic gait in females and males (15/14) after BCR TKA implantation [Vanguard XP Total Knee System (Zimmer Biomet)]. The authors

demonstrated significant increases in KSS (58.1 ± 11.8 preoperative to 86.6 ± 16.7 postoperative, $P < 0.001$). Kalaai *et al*[33] designed a retrospective study in which 61 BCR TKA were compared to 61 CR TKA; the authors observed no statistical differences in FJS score between BCR TKA and CR TKA but a significant improvement ($P = 0.017$) in the EuroQol (EQ-5D) at 3-year follow-up in BCR TKA group. Kono *et al*[35] matched kinematic data from BCR TKA [Journey II XR (Smith and Nephew plc)], UKA and healthy controls during squatting motion, under fluoroscopic surveillance. There was a lower extension angle of UKA knees than healthy and BCR TKA knees ($P < 0.01$), lower flexion angle of BCR TKA knees than healthy and UKA knees ($P < 0.01$), and lower flexion angle of UKA knees than healthy knees ($P < 0.01$). Peng *et al*[38] examined the relation between component alignment and patient reported outcome measures (PROMs) in 29 BCR TKA implants [Vanguard XP Total Knee System (Zimmer Biomet)]. At 1-year follow-up, they verified a significant overall post-operative improvement in KSS (8.1 ± 11.8 preoperative to 87.9 ± 16.7 postoperative, $P < 0.001$). In that study, the regression analysis demonstrated that the postoperative KSS was negatively associated with a greater posterior tibial slope. Pelt *et al*[25] showed that knee flexion ROM improved from a preoperative mean of 121° to a postoperative mean of 123° after BCR TKA implant. Eventually, Tsai *et al*[32] reported significant improvement from a mean preoperative KSS of 58.5 to a 6-mo postoperative value of 86.6.

COMPLICATIONS AND REVISION RATES

First-generation implants

Pritchett[31] presented the largest and longest-term series on first-generation BCR TKA; the author reported on implant of 214 prosthesis (Townley Anatomic) in 160 patients and the clinical outcomes at a minimum follow-up of 20 years. The Kaplan–Meier survivorship was 89% [95% confidence interval (CI): 82%-93%], with revision for any reason as an endpoint. Twenty-two knees in 21 patients (5.6%) were revised and the most common causes where polyethylene wear, aseptic loosening of the femoral or tibial component (seven revisions) and infection (four revisions)[31]. Ries *et al*[50] showed mechanical failure in 20 first-generation BCR TKAs that required revision; the authors retrieved 16 porous coated cementless Ti-6Al-4V tibial trays (BioPro, Port Huron, MI, United States), 2 cast CoCr tibial trays (BioPro) , and two all polyethylene tibial implants (Geomedic; Howmedica, Rutherford, NJ, United States). Four failure implant ways were identified, namely fracture of the anterior tibial tray or bridge (fatigue fracture), insert dissociation, UHMWPE wear, and tibial component loosening[21].

Second-generation implants

Alnachoukati *et al*[23] reported in a short-term review of 146 BCR TKA implantations [Vanguard XP Total Knee System (Zimmer Biomet)], two revisions (1.4% revision rate) due to anterior arthrofibrosis and tibial component subsidence, and 1 reoperation (0.7% reoperation rate) with manipulation under anaesthesia. Nine out of one hundred and forty-six (6.2%) knees had an intraoperative fracture of the tibial island, which occurred in the beginning of the series, fixated with cancellous screw (Table 3).

A match-paired study with a mean follow-up of 33.82 mo carried out by Biazzo *et al*[49] reported two major and two minor complications after implant of 24 BCR TKA [Vanguard XP Total Knee System (Zimmer Biomet)]. There were two aseptic loosening cases with revisions of the tibial component, on periprosthetic joint infection treated conservatively, and one intraoperative fracture of the intercondylar tibial eminence fixed by cortical screw. That study pointed out the increased surgical time in the BCR design [92.19 min standard deviation (SD) 8.56] when compared to the CR design (76.67 min SD 19.91). Early learning curve experiences may explain the longer operative times and the higher complication rate. A case-control study designed by Kalaai *et al*[33] displayed a survival rate of 98.4% for both the CR and BCR TKA groups; one revision in the BCR group was caused by valgus thrust. Klaassen *et al*[51] presented 2 cases (3 knees) of cyclops lesions after BCR TKA with limited knee extension; these were treated by arthroscopic debridement. Therefore, the knee surgeons should suspect this lesion after BCR TKA implantation if full knee extension is not achieved.

Pelt *et al*[25] in their retrospective study on second-generation BCR implants [Vanguard XP Total Knee System (Zimmer Biomet)] revealed a revision-free survival of 88% at mean 3 years follow-up. The main causes of revision were isolated tibial

Table 3 Second-generation bicruciate-retaining total knee arthroplasty complications

Ref.	Year	BCR model (*n*)	Complication	Follow-up time in mo, mean
Alnachoukati *et al* [23]	2018	Vanguard XP (146)	9 intraoperative tibial island fracture; 1 cyclops lesion; 1 aseptic loosening of tibial component	12
Biazzo *et al*[49]	2020	Vanguard XP (24)	2 Aseptic loosening; 1 periprosthetic infection; 1 intraoperative tibial island fracture	33.82
Kalaai *et al*[33]	2019	Vanguard XP (61)	1 valgus thrust	3.6
Klaassen *et al*[51]	2017	Vanguard XP (3)	2 cyclops lesion (3 knees)	
Pelt *et al*[25]	2019	Vanguard XP (141)	2 Intraoperative tibial island fracture; 11 arthrofibrosis; 1 hematoma; 1 chronic pain	36

BCR: Bicruciate-retaining.

loosening (5/19), ACL impingement (3/19), chronic pain (3/19), unknown reasons (3/19), femoral and tibial loosening (2/19), metal allergy with chronic pain (1/19), ACL deficiency (1/19), and arthrofibrosis (1/19). There were two intraoperative tibial island fractures that were fixed with a screw[17].

CONCLUSION

The renewed interest in BCR TKA, as things currently stand, is mainly rooted on component design improvement and biomechanical and kinematical studies that corroborate the possible significant advantage that retention of cruciate ligaments can offer rather than high-quality long-term clinical trials. The literature on first-generation design has showed good long-term survival rates with satisfying clinical outcomes, while the second-generation-based studies have reported heterogeneous results in short to mid-term follow-ups. Anatomical BCR TKA associated with improved patient selection criteria definition for this surgery and greater consideration for patient-to-patient coronal alignment variability and restoration may improve the results obtained thus far. Further high- quality research will be necessary to investigate those hypotheses, evaluate the long-term clinical results, and define the ideal patient for BCR TKA.

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MINIREVIEWS

Surgical treatment of metastatic bone disease of the distal extremities

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Abstract

Metastatic bone disease of the distal extremities, also known as acrometastasis, is very rare. Thus, there is very limited information regarding the clinical manifestations and methods of surgical treatment. The current available literature shows that acrometastases are often encountered in the context of advanced disease and are thus associated with poor patient survival. As metastatic bone disease is generally uncurable, the goal of surgical treatment is to provide the patient with good function with as few complications as possible. In this article, we discuss the clinical manifestation of acrometastases, the methods of surgical intervention, and the expected clinical outcome. Non-surgically managed pathological fractures generally remain ununited; therefore, conservative treatment is reserved for patients with poor general condition or dismal prognosis. The current evidence suggests that in lesions of the lower arm and leg, osteosynthesis (plate and screw fixation or intramedullary nail) is the most common method of reconstruction, whereas local excision or amputation are more commonly used in cases of more distal lesions (such as ankle, foot and hand). Following surgery most patients receive adjuvant radiotherapy, even though its role is poorly documented. Close collaboration between orthopedic surgeons and medical oncologists is necessary to improve patient care and treatment outcome. Further studies are needed in order to provide stronger clinical evidence and improve decision-making, in an effort to optimize the patients' quality of life and avoid the need for revision surgery.

Key Words: Metastatic bone disease; Surgery; Radiotherapy; Pathological fractures; Distal

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Core Tip: Metastatic bone disease distal to the elbow and knee is rare, often encountered in patients with spread cancer. Limb-preserving surgery is often possible in the lower arm and leg, and osteosynthesis with plate and screws or intramedullary nails are the most common surgical methods. In the lesions of the ankle, hand and foot, amputation is often utilized.

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INTRODUCTION

Bone is one of the most common organs affected by cancer metastases[1]. Metastatic bone disease (MBD) can be caused by different primary tumors, with the highest prevalence being from breast and prostate cancer[2]. It has been described that the incidence of bone metastases depends on the origin of the primary tumor, although it increases primarily with more advanced disease, regardless of the tumor origin[3,4]. MBD causes a disruption of the bone's normal metabolism and physiology, which eventually could lead to hypercalcemia and bone pain[1,2]. Moreover, the disruption of bone architecture can lead to reduced bearing capacity and microfractures. In turn, this can cause a total loss of the bony integrity and result in bone fractures[1]. The skeleton is not equally affected by MBD, which is more common with metastases in bones consisting of a larger amount red marrow and trabecular bone. Metastatic tumors are also more abundant in the axial skeleton[2]. The most frequently affected long bone is femur, followed by humerus[5].

Diagnosis and treatment of MBD

It is important to diagnose MBD in its early stages so that mortality and morbiditiy can be reduced[6]. Generally, the diagnosis of MBD often starts with conventional radiography (X-ray) or computed tomography (CT), magnetic resonance imaging (MRI) and/or bone scans, depending on the clinical suspicion and origin of the metastasis. Conventional plain radiographs can detect and localize bone lesions, their frequency and size, the occurrence of pathological fractures, and potential soft tissue involvement. Moreover, X-rays can determine whether the bone lesions are sclerotic or lytic. CT scans could be helpful in situations when there is cortical destruction and mineralization[7], and they support the diagnosis process by differentiating benign and malignant tumors[6]. Moreover, CT scanning with 2D frontal-sagittal reconstructions has been proposed as a method for improving the performance of fracture prediction in impending fractures[8]. Although CT scans are proposed as the second step in the diagnosis process, they are most often the primary technique for detecting MBD, as they are part of the routine staging protocol when diagnosing all kinds of cancer[6]. MRIs have an extremely high sensitivity and specificity for assessing tumor spread in soft tissue and the surrounding structures, such as joints and skin. Moreover, MRI has the potential to detect bone marrow engagement even if it is diffuse[6,9]. Although MRI is the gold standard[9], it is inferior to CT scans in cases of small bones, such as the ones in hands, feet and skull[6].

Isotope bone scans are another method that is helpful in the diagnosis of MBD. These scans are useful when detecting obscured bone lesions and mapping tissue characterization. Positron emission tomography (PET) scans are superior to all other imaging techniques in cases of detecting primary lesion sites in the earlier stages of disease. PET scans are highly accurate and can also detect lesions in the distal extremities[10]. Moreover, fine needle aspiration cytology or core-needle biopsy is necessary and should take place in tissue diagnosis[9].

MBD is associated with poor survival, which is mainly due to the primary tumors' type and origin[10]. Generally, MBD is incurable and the treatment options aim to reduce symptoms[11]. Currently, the common treatments include osteoclast inhibition, chemotherapy, radiotherapy, and surgery[11]. Bisphosphonates and denosumab aim to inhibit bone resorption and thereby bone destruction[12-14], while radiation and chemotherapy help to ease pain and control tumor growth. Surgical treatment is needed when the MBD results in impending or pathological fractures[3,11]. However, surgery does not have a cancer-reducing effect nor improve survival[15,16]. Instead, it is the treatment of choice when it comes to stabilizing the bone structure and reducing pain[15].

Pathological fractures managed non-surgically will generally remain ununited[1,17,18]. Therefore, conservative treatment is an option only when the patient is inoperable [18]. Most patients receive radiation therapy following surgery[3], due to its counteractive effects towards pain, local recurrence, and tumor growth[3,19]. However, adjuvant radiotherapy could potentially cause surgical failures when some surgical techniques are used, such as osteosynthesis and un-cemented implants, and lead to wound healing problems and infection[20,21]. Generally, the role of adjuvant radiotherapy is poorly documented[19,22].

GENERAL PRINCIPLES OF ACROMETASTASES

As previously mentioned, the most frequently affected long bone is femur, followed by humerus. Other long bones, such as the ones in hands and feet, rarely harbor metastases[5]. The term acrometastases is used inconsistently[23]; sometimes, it is defined as metastatic lesions distal to the elbow and knee[16] and, other times as lesions distal to the ankle and wrist[23]. Acrometastases are a rare occurrence and the incidence is reported as 7%[17]. Approximately 0.1% of all acrometastases are located distal to the ankle and wrist[16]. The hands are more often affected by osseous metastases compared to the feet[9], with a ratio of 3:1[24]. Significant delay of the diagnosis is common[23], due to its rarity in combination with unspecific symptoms [16]. Associated signs and symptoms are, in general, soft tissue swelling, pain and functional impairment, steering the clinicians' ideas towards more benign conditions, such as gout, ligamentous sprains, osteoarthritis and more[16,25]. In addition, the common practice of metastatic skeletal surveys where whole body CT is used is to exclude the distal extremities, leading to possible under-reporting of these cases[26]. Considering metastatic disease as a differential diagnosis can therefore prevent late diagnosis and delayed treatment. For acrometastases in general, histological examinations have shown that the main tumor type is lung cancer, followed by gastrointestinal tract and genitourinary tract tumors[9].

Complete staging must be performed in order to determine the primary lesion, extension and metastatic count. This information is necessary in order to evaluate prognosis and provide input in determination of the treatment approach[16]. Staging often includes radiology of the lesion, preferably MRI, CT of the chest and abdomen, and bone scans. Tissue diagnosis is of importance. Some authors have recommended fine needle aspiration over incisional biopsies because of the risk of making the lesion extracompartmental[9,27]. When staging has been performed and the patients' prognosis and overall functional status is assessed as sufficient, surgical treatment can be considered[16].

Important elements exist that should be taken into consideration in the surgical planning and reconstruction decision-making. For example, renal metastases are relatively resistant to photon beam radiation therapy, explaining why total resection is recommended. This is in comparison to radiosensitive tumors for which intralesional curettage and stabilization is fitting[28]. Studies have also shown that certain tumor types, such as metastases from renal and thyroid origin, have the best prognosis when totally resected, when local recurrence and disease-free survival are the primary outcome measurements[29]. Nonetheless, prognosis of patients with acrometastatic cancer is poor[30], since most have widespread disease, and their mean survival time has been reported to be less than 6 mo[31].

ACROMETASTASES OF UPPER EXTREMITY

Hand

Acrometastases in the hands are mostly originated from lung cancer[9,32]. The phalanges are the most commonly affected location[10,33], followed by the metacarpal bones[33]. The mean survival for patients suffering from hand metastases have been reported to range from 5 mo to over 1 year[10,24,33]. Although there is no standardized treatment for hand metastases, a variety of treatment options, including radiotherapy, curettage, resection, radical disarticulation of the ray and amputation is available[9,16,33,34]. Most commonly limb salvage surgery is used, including resection and curettage[32]. As the prognosis of acrometastases depends on the characteristics of the primary tumor[10], the approach differs. In cases with poor response to cancer treatments, including radiation and chemotherapy, amputation is a more appropriate method[35]. Moreover, surgical methods, such as local excisions and curettage, could be hard to conduct due to the limited amount of soft tissue in the hands[16,35].

Lower arm (radius and ulna)

MBD in the lower arm is extremely rare. The incidence of metastases involving ulna has been reported as low as 1%[36]. In another small cohort study, the incidence of lower arm metastases was reported as 2 out of 34 fractures (6%)[37]. Because of the rare occurrence of MBD in the lower arm, the literature is sparse regarding these locations. To our knowledge, metastatic bone lesions in ulna and radius are very rarely described in the literature. Our experience is that most lesions can be managed with local excision and osteosynthesis with plate and screws (Figure 1).

ACROMETASTASES OF LOWER EXTREMITY

Foot

Studies suggest that less than 50% of acrometastases involve the feet[38,39]. MBD of the foot occurs in the context of widespread dissemination, which is the main reason why it has a poor prognosis[24]. Lung cancer is the most common primary tumor, followed by breast, kidney and colon/rectum, respectively. The hindfoot (calcaneus and talus) is the most common site, followed by the forefoot (metatarsal bones and phalanxes) and mid foot (cuniforme-, navicular- and cuboid bones)[16]. An average survival of 15 mo for patients with acrometastases of the foot has been reported[30].

Treatments of MBD of the foot vary from simple palliative care or pharmacological treatment, radiation therapy, chemotherapy, and surgery[30,35]. No standard treatment protocols exist because of the rarity of the condition and therefore are often approached on a case-by-case basis. The main goal however should be focused on palliation and improving quality of life[35]. Amputation and local curettage is common practice for these cases, with the former being the most frequent surgical option[16,35]. Midfoot or, more commonly, transtibial amputation can be performed depending on the location and spread of the tumor. If amputation is not acceptable curettage can be an alternative[24]. However, the recurrence rate after curettage has been reported to be approximately 20%[9]. Adjuvant radiation therapy or marginal excision are other options[24].

Lower leg (tibia and fibula)

MBD of the tibia has been reported to account for 3%-4% of MBD, thus being more frequent than metastases in the foot[17,40]. Fibular metastases are very rare and the representation in the literature mainly consists of case reports[41-43]. Due to its rarity, published cohorts of cases are small[17,44]. The somewhat higher occurrence of MBD involving the tibia has resulted in better data. The primary tumors giving rise to bone metastases in the tibia are breast and prostate cancer in women and men respectively, with lung, kidney and colorectal cancers also being represented independent of sex[8, 23,45]. The most common site of metastases in the tibia is the proximal metaphyseal region, followed by the diaphysis[21,23].

Surgery is the primary treatment choice, since the tibia is a major weight-bearing bone. The loading forces affecting the knee and ankle are mainly compressive, and the tensile forces are lower than in the proximal femur, hence decreasing the risk of mechanical failure[20]. The three main surgical management principles for MBD in the lower leg are stabilization after curettage with or without cement or bone graft, endoprosthetic reconstruction after complete resection, and amputation[28]. For



Figure 1 Metastatic bone disease in the lower arm. A: Osteolytic metastasis caused by lung adenocarcinoma in an elderly female patient; B: Treatment with curettage, bone cement and osteosynthesis with plate and screws.

reconstruction, intramedullary (IM) nails, plate and screws with or without cement, and endoprostheses are suitable options[28]. In the cases of proximally located tumors, especially the tibial metaphysis, curettage followed by cementation and stabilization with plate and screws is a good alternative. However, if the lesion is highly destructive and affecting the joint, endoprosthetic reconstruction with a medial gastrocnemius flap can be considered in patients with good prognosis[28]. Closed IM nailing, sometimes with the addition of curettage, and generally followed by radiation therapy, is the preferred method of choice when metastases are located in the diaphysis[8]. IM nail devices typically allow immediate weight bearing, and postoperative radiation therapy is not contraindicated, which is of great importance to the patient (Figure 2).

Metastatic lesions in the distal parts of the tibia are rare[21]. If reconstruction is an alternative, plate and screw fixation could be implemented with or without curettage and bone cement. Since there are no suitable prosthetic devices available after resection of the distal tibia, in cases of large destruction a retrograde IM nail through the calcaneus and talus into the tibia is the main option. Postoperative radiation therapy jeopardizes the fusion of the arthrodesis in these cases[20]. However, due to the poor functional performance of limb-sparing surgery, below knee amputation is a good alternative[28]. This procedure is also suitable in cases in which tumor growth is not controllable by adjuvant therapy, if soft-tissue quality is poor, or if previous surgery or reconstructions have failed[45].

As for the even rarer occurrence of fibular metastases, resection without reconstruction is the most reported procedure in the literature by far[20,28,44]. The fibula, as well as the ribs and clavicle, is an expandable bone, and resection can be performed without any functional impairment[20].

CONCLUSION

MBD in the distal extremities (acrometastases) is a rare condition and very poorly investigated in the medical literature. Patients with acrometastases generally have advanced disease and poor survival. Choosing the proper surgical treatment is important in order to improve the patient's quality of life and avoid implant failure and the need for revision surgery. Osteosynthesis is the most common treatment method in proximal acrometastases (lower arm and leg), with amputation being more common for distal lesions.

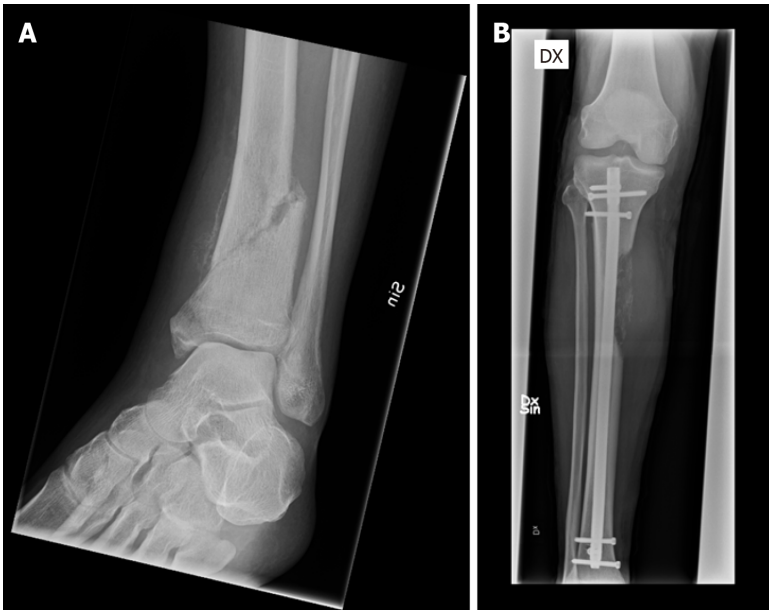


Figure 2 Metastatic bone disease in the lower leg. A: Well-defined osteolytic lesion of the proximal tibia diaphysis in a patient with renal cancer; B: Treatment with intramedullary nailing without any tumor removal.

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ORIGINAL ARTICLE

Case Control Study

SARS-CoV-2 outbreak impact on a trauma unit

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Abstract

BACKGROUND

From February 2020 onwards, our country has been hit by the coronavirus severe acute respiratory syndrome-2 (SARS-CoV-2) infection. At a glance, hospitals became overrun and had to reformulate all the assistance guidelines, focusing on the coronavirus disease 2019. One year after the start of the pandemic, we present the results of a morbimortality study.

AIM

To analyze how our department was affected by the outbreak in terms of morbimortality, and to analyze demographic data, admission to hospital-related data, and subgroups analyses for patients with hip fractures and polytrauma.

METHODS

We designed a study comparing data from patients who were admitted to our unit due to a lower limb fracture or a high energy trauma during the pandemic (from March to April 2020) to those admitted during the same period in 2019 before the pandemic. during the pandemic situation. Both cohorts completed a minimum of 6 mo of follow-up.

RESULTS

The number of patients admitted to hospital in 2020 was nearly half of those in 2019. Hip fractures in the elderly represented 52 out of 73 of the admitted patients. Twenty patients had a positive test result for SARS-CoV-2 infection. Patients with

SARS-CoV-2 infection were admitted to the hospital for a longer time than the non-infected ($P < 0.001$), and had a higher mortality rate during hospitalization and follow-up ($P = 0.02$). Patients with a hip fracture associated with a severe respiratory syndrome were mostly selected for conservative treatment ($P = 0.03$).

CONCLUSION

Mortality and readmission rates were higher in the 2020 cohort and during follow-up, in comparison with the cohort in 2019.

Key Words: Trauma department; COVID-19 pandemic; SARS-CoV-2 outbreak; Hip fractures; Morbimortality; Polytraumatic patients

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Core Tip: Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection was not a criterion for choosing conservative treatment, unless those patients infected with the virus had a poor general condition that made surgery unadvisable. We did not find a relationship between the employment of anticoagulant therapy and the severity of coronavirus disease 2019 (COVID-19) infection or a different mortality rate. Patients who died during hospitalization due to COVID-19 had higher C-reactive protein levels ($P < 0.001$) and higher urea levels ($P = 0.006$). The mortality rate in 2020 was 13.7% during hospitalization; 19% during the first month after discharge, and 24.6% in the 3 mo after discharge. The mortality rate in the COVID-19 positive patient subgroup was 38.9% after 6 mo of follow-up. Non-operative treatment in hip fractures was related to SARS-CoV-2 infection ($P = 0.03$) and with AO 31.B fractures. Polytrauma patients and high energy fractures were more common in 2019 (24%) than in 2020 (11.5%). The main difference between both periods was the injury mechanism.

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INTRODUCTION

A cluster of atypical pneumonia was identified in Wuhan, China, in December 2019, affecting China first, and rapidly spreading all over the world, starting a pandemic[1]. By the end of February 2020, the first case of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection was reported in our community (Madrid, Spain). As a consequence of the outbreak, elective surgeries were suspended. Some of the surgeons were assigned to interdisciplinary teams headed by Internal Medicine, aiding the fight against coronavirus disease 2019 (COVID-19). Surgeries and outpatient appointments were minimized to provide only essential services: emergencies, fractures, some surgical complications, and a few bone or soft tissue tumors.

This study aims to analyze the effect that the SARS-CoV-2 pandemic had on our Orthopedic and Trauma Department. We wanted to evaluate if COVID-19 influenced the decision-making with those patients admitted during the first wave of the SARS-CoV-2 outbreak and if conservative treatment was more frequently chosen. As we noticed that the number of patients admitted and their characteristics varied markedly, we decided to compare the 2020 results with a cohort of patients admitted to our hospital during the same period in 2019, using the same inclusion criteria for both groups.

the manuscript was prepared and revised according to the STROBE Statement—checklist of items.

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MATERIALS AND METHODS

This study consists of a prospective single-center observational study. We selected a cohort of patients under the following inclusion criteria: Patients that came to the Emergency Room (ER) after a traumatic injury, requiring hospitalization because of a lower limb fracture, or polytrauma patients from March 11th, 2020 (date of admission of the first positive case amongst our patients) to April 30th, 2020. Patients presenting a surgical complication were not included if they underwent surgery before the pandemic period. Tumors, upper limb, and spine fractures were omitted (unless polytraumas were presented with them), following the common criteria for admission in our Unit. A minimum of 6 mo of follow-up was required for inclusion in this analysis.

Patients were tested when they arrived in the ER: blood tests, chest AP radiographs and nasopharyngeal swabs. In some cases, if the complementary tests were highly suggestive of SARS-CoV-2 infection but the polymerase chain reaction (PCR) test was negative, a chest computed tomography scan was also performed. Patients with severe acute respiratory insufficiency and bilateral pneumonia were assumed as positives even if the PCR was negative.

Depending on those test results, patients were admitted to the hospital in different areas and operated on in different operating rooms. Postoperatively, we tried to reduce to the maximum the time spent in the hospital, at all times prioritizing clinical status, to avoid nosocomial transmission.

We collected demographic data, lesion mechanism and characteristics, previous functional status, different parameters obtained from chest AP view radiographs, blood tests, or SARS-CoV-2 tests. Time to surgery and average in-hospital stay were recorded. Complications were recorded, as well as readmissions to the hospital due to surgical or medical problems.

Another cohort, with the same characteristics and inclusion criteria, was obtained in the same period in 2019, to compare differences in our unit between a normal period and the pandemic period, the aim being that the only difference between them was the presence of SARS-CoV-2.

Selected data were collected in an electronic database [Microsoft® Excel for Windows® (Microsoft Corp, Redmond, WA, United States)], kept under restricted access in accordance with data protection legislation. All statistical analyses were performed by the Biostatistics Unit at our center. The level of significance was established at $P < 0.05$. The present study was approved by our Hospital's Ethics Committee.

RESULTS

Cohort of patients in 2020

During a period of 50 d, from March 11th, 2020 (date of admission of the first positive case among our patients) to April 30th, 2020 (last day of severe restrictions at the hospital), 73 patients fulfilled inclusion criteria and were included in this study. The most representative descriptive analysis results from the demographic data of the cohort of patients in 2020 are shown in Table 1. The age range was from 17-years-old to 97-years-old. The vast majority of the patients (71%) had a hip fracture, the mean age in this subgroup being 87-years-old (61-97-years-old). Except for those patients classified as polytraumas (11.5%), all patients suffered a fracture due to a low energy traumatism. In this cohort, 14 patients were under anticoagulant therapy and 7 under antiplatelet therapy. The use of these drugs had no relation to COVID-19 development nor the mortality rate. Patients who used them had a longer time to surgery ($P < 0.001$). While admitted to hospital, 3 patients developed a pulmonary embolism despite adequate treatment with low molecular weight heparin; all cases were related to COVID-19. During follow-up, no patients developed complications related to thromboembolic disease (deep vein thrombosis nor pulmonary embolisms).

Wide blood tests were performed systematically on all the patients when they arrived in the ER as part of a protocol to study COVID-19 patients. We noticed that COVID-19 positive patients presented higher values of C-reactive protein ($P < 0.001$). Patients who died during hospitalization had higher C-reactive protein levels ($P < 0.001$) and higher urea levels ($P = 0.006$). Nasopharyngeal swabs were performed systematically when patients arrived in the ER from March 24th onwards, following center protocols; previously it was ordered only in suspected cases. When swabs were not still mandatory, a lower time to surgery was observed ($P = 0.01$).

Table 1 Demographic data of the cohort of patients from 2020

	Minimum	Maximum	Mean	SD
Age (yr)	17	97	76.99	20.25
FAC	0	5	3.11	1.257
Barthel Index	0	100	71.82	29.649
Pfeiffer mental status	0	10	2.89	3.46
Charlson Comorbidity Index	4	11	6.66	1.75
Body temperature (°C)	35	37.4	36.1	0.5
Blood oxygen saturation (%)	82	100	94.7	3.37
Urea blood levels (mg/dL)	12	219	57.94	37.5
D-dimer (ng/mL)	2010	123070	23939.68	29893.51
Lactate dehydrogenase (UI/L)	152	851	307.66	125.75
C-reactive protein (mg/dL)	0	248	40.7	60.5

FAC: Functional Ambulation Classification; SD: Standard deviation.

Twenty patients obtained a positive test result for SARS-CoV-2 infection. Patients with SARS-CoV-2 infection were hospitalized for a longer time than non-infected ones ($P < 0.001$) and also had a higher mortality rate during hospitalization and follow-up ($P = 0.02$). Of those patients diagnosed with COVID-19 infection, 80% were operated on. The SARS-CoV-2 disease was not a criterion for not performing surgery, although severe respiratory syndrome was ($P = 0.03$).

The in-hospital stay was 11 d (0-61 d). Logically, COVID-19 had an influence on these data: this number varied from 8 d (0-43 d) for the group of negative patients to 18 d (4-61 d) for the group of positive patients ($P < 0.05$). Analyzing the group of patients with hip fractures, COVID-19 positive patients stayed a mean of 17 d (4-61 d) *vs* a mean of 8 d (1-43 d) for negative patients ($P < 0.05$). On the other hand, a longer time to surgery is related to a longer time to discharge ($P < 0.001$). A relationship between a longer time to surgery and the risk of nosocomial SARS-CoV-2 transmission or death could not be demonstrated. Clinical complications during the 3 mo after discharge were more common amongst COVID-19 positive patients (83.3%) than in those without SARS-CoV-2 infection (32.4%) ($P < 0.05$).

The mortality rate in 2020 was 13.7% during hospitalization, 19% during the first month after discharge, and 24.6% in the 3 mo after discharge. Those rates are high and are related to COVID-19. The mortality rate in the COVID-19 positive patient subgroup was 38.9% after a minimum of 6 mo of follow-up.

Hip fractures and SARS-CoV-2

During the period studied in 2020, 52 patients were admitted to the hospital due to a hip fracture, out of 73 patients. We did some analyses in this subgroup, including Functional Ambulation Classification, Barthel Index Score, Pfeiffer Short Portable Mental Status, and Charlson Comorbidity Index. Scores in these scales had no relation to the place where patients lived (home/nursing home) before the fracture, with COVID-19 infection, time of hospitalization, or death ($P > 0.05$). However, patients coming from a nursing home presented a higher rate of SARS-CoV-2 infection ($P = 0.03$), without any relationship between nursing homes and risk of death ($P = 0.1$).

Regarding the type of fracture (classified following AO criteria), we found a correlation with readmission to the hospital ($P = 0.001$), because all the patients who had a 31.A3 or bifocal femoral fractures were readmitted to the hospital due to medical complications.

In our cohort of 52 patients with hip fractures, 7 patients were treated non-operatively and 5 of them developed a severe respiratory insufficiency due to COVID-19. Non-operative treatment in hip fractures was related to SARS-CoV-2 infection ($P = 0.03$) and with AO 31.B fractures (intracapsular fractures) ($P < 0.001$), corresponding to 6 out of the 7 patients treated non-operatively.

Polytrauma patients

The cohort from 2020 includes 5 patients who suffered a high energy traumatism and were defined as polytraumas. The age range was 20-57-years-old with a mean age of 38-years-old. Three of them presented with open fractures. Two of them died during hospitalization due to respiratory failure, but none of them due to COVID-19.

Other fractures

Lower limb fractures, other than hip fractures in the elderly and fracture patients not considered polytrauma, showed a sharp decrease due to the lockdown.

Comparison to a similar cohort in 2019

In the same period of 50 d in 2019, 143 patients were admitted to the hospital and included in analyses following the same inclusion criteria. During the SARS-CoV-2 outbreak, the number of patients admitted to our unit decreased by 49% in comparison with the same period in 2019.

No statistical differences were found between both cohorts (2019 and 2020) regarding demographic data.

The number of patients that were not suitable for surgery was very similar in both periods, 11.5% in 2020 and 12.6% in 2019. In-hospital stay varied from 1 to 32 d (mean 8 d) in 2019, and from 1 to 61 d (mean 11 d) in 2020 ($P < 0.02$). Readmissions to the hospital in the 3 mo after discharge were higher in 2020 (10.8%) than in 2019 (5%) and more frequently due to a medical complication (71.4%). The mortality rate during hospitalization was 2% during the period in 2019, *vs* 13.7% in 2020. Mortality after 6 mo of follow-up was also higher in 2020 (24.6%) than in 2019 (2.8%), ($P < 0.001$).

Hip fractures 2019 vs 2020

The most common type of fracture was pertrochanteric (31.A) both in 2019 and 2020. Despite the sharp decrease in the admissions, the number of patients with a hip fracture increased, compared to 2019, when they represented 53% of the admissions. According to the AO Trauma classification, 31.A2 and 31.A3 fractures were more frequent in 2020 than in 2019, and this could contribute to the higher rate of complications and mortality during hospitalization in addition to SARS-CoV-2 infection (Table 2). Medical complications appeared in 50% of patients in 2020 (52% of them related to COVID-19), and over 20% of patients in 2019 ($P < 0.001$). The surgical complications rate was very similar in both periods (3.8% in 2020 and 5.6% in 2019), and no statistical differences were found.

Polytrauma patients

Polytrauma patients and high energy fractures were more common in 2019 (24%) than in 2020 (11.5%), due to lockdown measures implemented by the National Government. The main difference between both periods was the injury mechanism. In 2019, we recorded traffic accidents and suicide attempts as the most common mechanisms. Polytrauma injuries after car crashes or motorcycle accidents were less frequent in the studied period of 2020. After a few days, lockdown measures were modified and construction work was permitted again. Accidents at work then became one of the main causes of injury, with similar numbers of suicide attempts after falls from height.

Other fractures

The most relevant drop-in was observed in ankle fractures, with 6 cases who needed surgery in 2020 *vs* 26 surgical cases in the same period in 2019 ($P < 0.05$).

DISCUSSION

Continuing to provide health care to fracture patients became a challenge during the SARS-CoV-2 outbreak. As is widely known, hospitals were organized following internal protocols to maximize security and minimize the risk of nosocomial infection [2].

We wanted to study if all those changes had an impact on the results obtained by our patients after hospitalization and surgery, which is why we compared the 2020 results with a similar cohort in 2019, the aim being that the only difference was COVID-19 and its implications.

We observed that patients affected by SARS-CoV-2 infection were older than the non-infected ones ($P = 0.004$), even though age is not a risk factor for acquiring the

Table 2 Incidence of different hip fractures in 2019 *vs* 2020 according to AO trauma classification

	2019	2020
31.A1	18.2%	21.6%
31.A2	33.8%	40.5%
31.A3	6.5%	13.5%
31.B	41.6%	24.3%

infection; some colleagues found similar results[3], and age is a factor to take into consideration during surgery planning.

COVID-19 often presents thrombotic complications[4], which is a reason why some colleagues had hypothesized that patients under anticoagulant or antiplatelet therapy could develop fewer complications or less severe manifestations of COVID-19. We did not find a relationship between the use of these drugs and the severity of COVID-19 infection or a different mortality rate. No patients developed these types of complications during follow-up.

According to this early analysis, our management strategies allowed us to operate on patients safely and early, and in-hospital stay was similar to previous data in our center; except for those patients affected by COVID-19. These results are very similar to others previously published[5].

Sadly, the mortality rate was higher than in other periods and this was associated with SARS-CoV-2 infection, as was the readmission rate in the first 30 and 90 d of follow-up. Mortality rates continued to rise during follow-up, similar to results found by our Italian colleagues[6]; and as many others described, an increase in mortality rate was foreseeable in this group of patients[7].

Hip fractures and SARS-CoV-2

In some cases, COVID-19 pneumonia conditioned the surgeon's attitude. Some colleagues published that surgery could help patients with COVID-19 by stabilizing their respiratory parameters[8]. In our cohort of hip fractures, 7 out of 73 patients were treated non-operatively, patients with an intracapsular femoral fracture and/or SARS-CoV-2 infection were more frequently managed non-operatively ($P < 0.001$ and $P = 0.03$ respectively).

We tend to consider non-operative management as an option for intracapsular fractures when the patient has some comorbidities or a poor ability to perform everyday activities, as it has been demonstrated that they have a higher risk of complications[9]; however during the pandemic, conservative treatment has also been an option for intertrochanteric fractures in some centers[10]. We did not accept conservative treatment as an option for an intertrochanteric fracture except for those patients that were not suitable for surgery due to their medical condition. In our cohort, just one patient with an intertrochanteric fracture was managed under conservative measures, due to a severe respiratory syndrome-related to COVID-19, who in the end died.

Comparing the data from both groups, the number of patients selected for conservative treatment was very similar in both periods, 11.5% in 2020 and 12.6% in 2019 ($P = 1$). We can summarize that COVID-19 did not condition us towards conservative treatment, and this was only chosen when the patient was not suitable for surgery.

While most lower limb fractures decreased in frequency during this period due to lockdown, the number of hip fractures in the elderly rose even more than the normal annual increase, and we would like to emphasize the importance of this public health issue[11] and highlight the need for preventing the apparition of these fractures[12,13].

Polytrauma patients

After reviewing our data, we can conclude that the incidence of polytrauma did not vary drastically during the COVID-19 outbreak, although the incidence of these injuries decreased due to lockdown measures, compared to data from 2019. As other colleagues have described, what varied was the mechanism of injury, and a noticeable increase in work-related accidents was observed[14].

Other fractures

Conservative therapeutic approach had been an accepted alternative during the spread of COVID-19[15]. In our cohort we recorded a large decrease in surgical

treatment for certain types of fractures, particularly ankle fractures; however, their total incidence also fell, so clear conclusions cannot be drawn. Similar results were published by Park *et al*[16].

Our study has important limitations. Firstly, the short follow-up period is limited, and stronger conclusions could be made once the follow-up period is enlarged. Secondly, patients with fractures located in the upper extremities and spine were excluded, as well as surgical complications and tumoral lesions. This is due to an intention to enter into a criteria agreement, as we are a group of surgeons belonging to an Orthopedic Department, made up of a unit that works together, and kept working together during the outbreak. As a team, we all share the same principles of treatment and clinical management.

CONCLUSION

Notwithstanding the difficulties, we consider that protocols established in our center provided satisfactory results according to short times to surgery and in-hospital stay. The number of patients that were not suitable for surgery was very similar in both periods, 11.5% in 2020 and 12.6% in 2019, so we conclude that SARS-CoV-2 infection was not a criterion for choosing conservative treatment, unless those patients infected with the virus had a poor general condition that made surgery unadvisable as we do with any other health condition. The mortality rate during hospitalization and follow-up was higher than the previous year, but this was related to COVID-19. Complications during follow-up were also increased, the vast majority of which were also related to COVID-19. No differences were found in surgical complications between the different periods.

ARTICLE HIGHLIGHTS

Research background

From February 2020 onwards our country has been hit by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. At a glance, hospitals became overrun and had to reformulate all the assistance guidelines, focusing on the coronavirus disease 2019.

Research motivation

One year after the start of the pandemic, we present the results of a morbimortality study.

Research objectives

The main objective of this study is to analyze how our department was affected by the outbreak, in terms of morbimortality. As secondary objectives, we analyzed demographic data, admission to hospital-related data, and subgroups analyses for patients with hip fractures and polytrauma.

Research methods

We designed a study based on two sections in our tertiary hospital. The first is a cohort prospective study based on data collected on patients admitted to our unit during the pandemic (from March to April 2020, due to a lower limb fracture or a high energy trauma during the pandemic situation). This cohort completed a minimum of 6 mo of follow-up. The second part consists of the study of another cohort of patients, with the same inclusion criteria but selected in 2019, the only difference between them being the presence of SARS-CoV-2 in 2020 and its implications.

Research results

The number of patients admitted to hospital in 2020 was nearly half of those in 2019. Hip fractures in the elderly represented the vast majority of fractures during the outbreak. The incidence of polytrauma did not vary substantively, although the mechanism of injury did. Patients with a hip fracture associated with a severe respiratory syndrome were mostly selected for conservative treatment. Mortality and readmission rates were higher in the 2020 cohort and during follow-up in comparison with the cohort in 2019. Patients with SARS-CoV-2 infection were admitted to the

hospital for a longer time than the non-infected, and also had a higher mortality rate during hospitalization and follow-up.

Research conclusions

The SARS-CoV-2 disease is not a criterion for not performing surgery. Mortality and readmission rates were higher in the 2020 cohort and during follow-up, in comparison with the cohort in 2019. Hip fractures in the elderly represented the vast majority of fractures during the outbreak. The incidence of polytrauma did not vary substantively although the mechanism of injury did.

Research perspectives

The SARS-CoV-2 disease is not a criterion for not performing surgery.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Clinical outcome after surgery on schwannomas in the extremities

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Abstract

BACKGROUND

Schwannoma is a benign, encapsulated and slowly growing tumor originating from Schwann cells and is rarely seen in the peripheral nerve system. Typical symptoms are soreness, radiating pain and sensory loss combined with a soft tissue mass.

AIM

To evaluate pre- and postoperative symptoms in patients operated for schwannomas in the extremities and investigate the rate of malignant transformation.

METHODS

In this single center retrospective study design, all patients who had surgery for a benign schwannoma in the extremities from May 1997 to January 2018 were included. The location of the tumor in the extremities was divided into five groups; forearm, arm, shoulder, thigh and leg including foot. The locations of the tumor in the nerves were also categorized as either; proximal, distal, minor or major nerve. During the pre- and postoperative clinical evaluation, symptoms were classified as paresthesia, local pain, radiating pain, swelling, impairment of mobility/strength and asymptomatic tumors that were found incidentally (with magnetic resonance imaging). The patients were evaluated after surgery using the following categories: Asymptomatic or symptomatic patients (radiating and/or

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local pain) and those with complications. The follow up period was from the time of surgery until last examination of the particular physician. Multivariate logistic regression analysis was performed to identify independent prognostic factors for postoperative significant symptoms at follow-up.

RESULTS

We identified 858 cases from the institutional pathology register. We excluded cases with duplicate diagnoses (n = 407), pathology not including schwannomas (n = 157), lesions involving the torso, spine and neck (n = 150) leaving 144 patients for further analysis. In this group 99 patients underwent surgery and there were five complications recorded: 2 infections (treated with antibiotics) and 3 nerve palsies (2 involving the radial nerve and one involving the median nerve) that recovered spontaneously. At the end of follow-up, 1.4 mo (range 0.5-76) postoperatively, we recorded a post-operative decrease in clinical symptoms: Local pain 76% (6/25), radiating pain 97% (2/45), swelling 20% (8/10). Symptoms of paresthesia increased by 2.8% (37/36) and there was no change in motor weakness before and after surgery 1% (1/1). Multivariate analysis showed that tumors located within minor nerves had a significantly higher prevalence of postoperative symptoms compared with tumors in major nerves (odds ratio: 2.63; confidence intervals: 1.22-6.42, P = 0.029). One patient with schwannoma diagnosed by needle biopsy was diagnosed to have malignant transformation diagnosed in the surgically removed tumor. No local recurrences were reported.

CONCLUSION

Surgery of schwannomas can be conducted with low risk of postoperative complications, acceptable decrease in clinical symptoms and risk of malignant transformation is low.

Key Words: Schwannoma; Extremities; Surgery; Removal; Symptoms; Outcome

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Core Tip: Schwannoma is a benign slowly growing tumor which is most common in the central nerve system. Peripheral schwannomas can give symptoms as numbness, local- and radiating pain. Recent studies proves surgical excision can be made with low expectations for complications and a high rate of remission. Never the less, some patients show up with consisting and significant symptoms after surgery. Our study showed that location of tumor on the nerve is of importance when evaluating patients' clinical symptoms post-operatively.

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INTRODUCTION

Schwannomas are one of the most common benign tumors in the peripheral nervous system. They originate from Schwann cells and account for about 5% of all tumors in the upper extremity. The most common presentation of a schwannoma is as a slowly growing, non-invasive single mass with a diameter ranging from 10–250 mm[1]. Patients present most commonly in their third to fifth decades of life with no racial and gender difference[2-5]. Symptoms described in the literature are mainly sensory as radiating pain, local irritation and sensation of a heavy mass. Primary motor involvement has also been described leading to paresis and eventually paralysis[6].

Schwannomas is commonly diagnosed using magnetic resonance imaging (MRI) but ultrasound and clinical examination is also well described[7,8].

Malignant peripheral nerve sheath tumors are rarely reported to have arisen from a primary schwannomas but when this occurs the reason ought to be malignant transformation of Schwann cells[9]. There are few studies documenting the malignant transformation of schwannomas[10,11]. The aim of our study was to describe the pre- and postoperative symptoms in patients treated surgically for benign schwannomas and examine whether tumor size, anatomical location or specific nerve location had an impact on the clinical symptoms prior to and after surgery. We also investigated the rate of malignant transformation.

MATERIALS AND METHODS

In this single center retrospective study design, all patients who had surgery due to benign schwannoma from May 1997 to January 2018 were included in the study. Patient data were collected both from our institutional pathology database and patient files.

To make sure no schwannomas were missed in the patients' data files for the study, we conducted a search in the pathology register that included all nerve sheath tumors. We found 858 cases including schwannoma, neurofibroma, neuroma and malignant schwannoma (ICD Codes D36.10; D36.11; D36.17; C47).

We excluded the following: Duplications of patients (n = 407), pathology other than solitary schwannoma (Schwannomatosis, Neuromas and Neurofibromas) (n = 157), surgery performed in the torso, spine, neck, pelvis and retroperitoneum (n = 150) and conservatively treated schwannomas (n = 45) thus leaving 99 patients treated surgically for further analyses (Figure 1).

By using data from patient files, we analyzed age, sex, data on nerve involvement including site and branch involved, pre- and postoperative symptoms and complications. We measured the size of the tumor by examining the patient's pre-operative MRI. Post-operative symptoms and objective findings were recovered from patient records. Patients were not followed up further if they were symptom free at the first postoperative examination at two weeks. Symptoms were classified as either paresthesia, local pain, radiating pain, swelling, motor involvement and no symptoms (incidental MRI-finding).

The patients who were symptomatic at end of follow-up were followed up with a custom-made questionnaire January 2018 investigating symptoms before and after surgery.

Those patients who reported new symptoms, recurrence of a mass or unsatisfactory results were offered an MRI-scanning and a follow-up to rule out a recurrence or malign transformation of the schwannoma.

The location of the tumor in the extremities was divided into five groups; forearm, upper arm, shoulder, thigh and leg (including foot). The location of the tumor in the nerve was categorized as either proximal, distal, minor nerve or major nerve. Proximal locations were defined as upper arm, thigh and shoulder and distal locations as leg and forearm. Nerve branches were classified as follows: Minor nerve was defined as schwannoma on muscular or terminal branch and major nerve as tumors located on either ischial-, femoral-, peroneal- or tibia nerves in the lower limb and axillary-, radial, ulnar- or median nerves in the upper limb.

Surgical complications were categorized as infection (superficial or deep), transient paresis and reoperation (all causes). Symptoms categorized as significant were motor paresis and pain (both local and radiating).

The study was cleared by the National Patient Safety Authority (Case numbers 3-3013-1550/1 and 3-3013-1550/2) and by the Data Protection Agency of the Capital Region of Denmark (number: RH-2016-144, I-Suite number.: 04677).

Surgical procedure

A preoperative MRI was used to plan excision and surgical approach. The affected nerve was exposed visualizing the tumor in the center with the proximal and distal healthy nerve ends. By using loupe magnification, nerve fascicles passing outside the tumor were identified and tested with a nerve stimulator and protected. The capsule of the tumor was incised away from nerve tissue. With a blunt dissector the tumor was loosened and removed when possible. If the tumor was attached to nerve tissue a swab was used to loosen the tumor under testing with the nerve stimulator. After removal, the tumor was sent to pathological examination. Hemostasis was secured and the wound closed with vicryl suture in fascia and subcutaneous layers and skin (intracutaneous). All patients were mobilized immediately and discharged from the

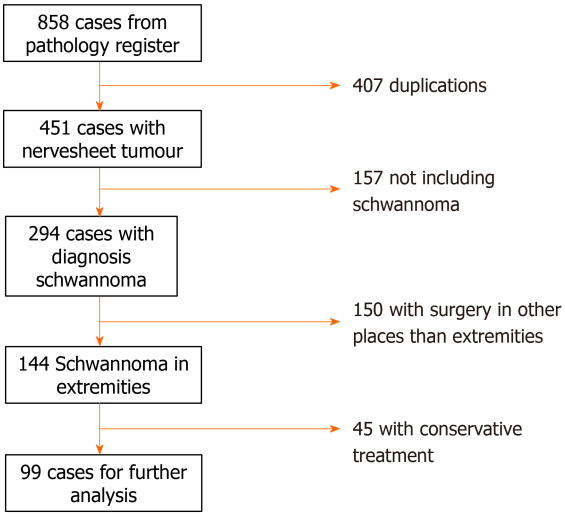


Figure 1 Flow chart for exclusion.

hospital within 24 h.

Statistics

All data are presented as median values together with total range.

Univariate logistic regression analysis was carried out in order to identify predictable factors for significant symptoms at follow-up. Patients with significant symptoms at follow up were compared with those without symptoms. Median values were defined as cut off for both size (24 mm) and age (53 years). The parameters compared were anatomical location and location on a minor or major nerve. A multivariate analysis was performed to identify independent prognostic factors for significant postoperative symptoms. In multivariate analysis no elimination of parameters was performed.

We assumed variables mentioned above were normally distributed. No substitution was made for missing data points. The results of the logistic regression analyses were presented as the odds ratio (OR) together with the 95% confidence intervals (CI) and *P* values below 0.05 are considered significant.

RESULTS

We included 99 patients with the baseline characteristics shown in Table 1. There were 51 men and 49 women. Median age was 53 (17-89) years and median postoperative follow-up was 0.5 (0.5-76) mo.

Preoperative symptoms were observed in 86% (85/99) of the operated patients, the remaining tumors were found incidentally on an unrelated MRI.

We recorded 5 complications: 1 superficial infection (treated with oral antibiotics), 1 reoperation (attempted arthroscopic excision was unsuccessful), and 3 transient nerve palsies (two involving radial and one involving median nerve).

At the end of follow-up, we registered a post-operative decrease in symptoms: local pain 76% (6/25), radiating pain 97% (2/45), swelling 20% (8/10). Symptoms of paresthesia increased by 3% (37/36) and there was no change in motor weakness before and after surgery 1% (1/1). One patient with schwannoma diagnosed by needle biopsy had malignant transformation to Neurofibrosarcoma verified after final surgery (Figure 2). No local recurrences were reported.

Univariate analysis showed a tendency (OR: 2.19; 95%CI: 0.97-5.09; $P = 0.063$) towards a higher degree of significant postoperative symptoms if a minor rather than a major nerve was involved. Multivariate analysis showed that tumor location on a minor nerve had a statistically significant higher risk of having significant symptoms after surgery (OR: 2.63; 95%CI: 1.22-6.42; $P = 0.029$) (Table 2).

Tumor location (proximal or distal), size (24 mm cut off) and age (53 years cut off) had no influence on the surgical outcomes.

Our letter with the questionnaire was sent out to 98% (97/99) of the patients and in total 44% (44/99) replied. Out of these 18 got a second MRI and one patient had an

Table 1 Baseline characteristics (*n* = 99)

Category	
Age, median (range)	53 (17–89)
Male, *n* (%)	51
Tumor size (range) (mm)	24 (5–175)
Preoperative symptoms	Local pain 25%
	Radiating pain 45%
	Swelling 10%
	Motor weakness 1%
	Paresthesia 36%
Nerve branch	Major 51 %
Anatomical localization of tumor	Distal 44%

Table 2 Predictive factors for consisting symptoms after surgical removal of schwannomas

	Univariate		Multivariate		Reference
	OR (CI)	*P* value	OR (CI)	*P* value	
Localization	1.48 (0.65-3.40)	0.354	1.61 (0.69-3.85)	0.276	Proximal
Nerve	2.19 (0.97-5.09)	0.063	2.63 (1.22-6.42)	0.029	Minor
Size	0.84 (0.37-1.90)	0.680	0.91 (0.39-2.13)	0.828	< 24 mm
Age	0.65 (0.29-1.46)	0.301	0.57 (0.23-1.35)	0.205	< 53 yr

OR: Odds ratio; CI: Confidence interval.

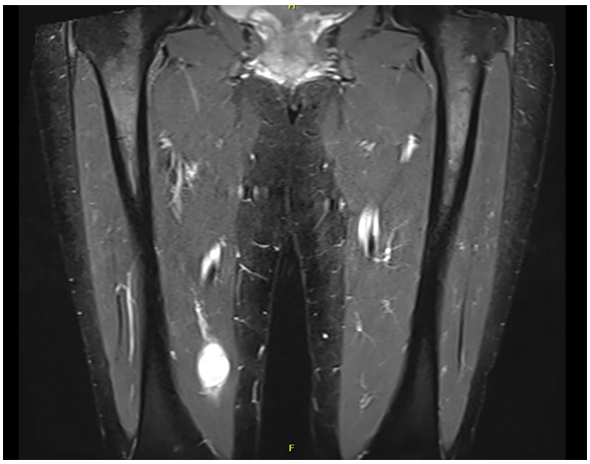


Figure 2 Patient with needle biopsy first diagnosed with schwannoma and after final biopsy showed to have a neurofibrosarcoma.

ultrasound examination as she had contraindication against MRI (because of an ICD-unit). None of the patients who had a second scan had local recurrence or malignant transformation. All the patients whom reported symptoms had scar tissue and adherence mass around the operative field on MR scanning.

DISCUSSION

Our report investigated symptoms and remission rate after surgical removal of peripheral benign schwannomas in the extremities. The most significant finding was

that surgical removal of tumors involving terminal nerve branches showed an increased risk of getting significant symptoms (local or radiating pain) compared to tumors originating from major nerve branches.

We decided to exclude those who had more than one schwannoma and Schwannomatosis as these patients often have many operations, larger operation area, multiple affected nerves and clinical results regarding symptoms after operation can be difficult to categorize. Gosk *et al*[12] included patients with more than one schwannoma[12]. Four of their patients had a total of 14 tumors removed and due to the reasons mentioned above, we believe this complicates analysis of the clinical outcome and could contribute to bias regarding the post-surgical evaluation.

Other articles have investigated complications after surgery of schwannomas and have reported numbers as high as 76.6%[13] and 42.7%[14] where they define loss of sensibility immediately after operation as a complication, even though it is often just transient.

We choose not to include loss of sensibility after surgery as a complication, as we do not consider it to be an adverse effect when studies showed that loss of sensibility had a remission rate of 73%-100%[6,13,15,16]. This difference in the definition made our rate of complications remarkably lower.

Several studies have shown an incidence of neurological deficits after surgery ranging between 1.5% and 80%[6,13,15,17-20]. One reason for this may be the vast variation in follow-up periods. Another contributing factor could be the differences in the definition of neurological deficits. We did not define neurological deficits as a combined group but instead divided it into either local pain, radiating pain, paresis and/or paresthesia. The first two subgroups (local pain and radiating pain) showed a decrease in symptoms with time but the last group (paresthesia) actually showed an increase after surgery. This highlights the importance of recording different components of preoperative deficits before comparing this to changes of neurological status after surgery. Combining sensory and motor deficits could compromise evaluation of outcomes.

Previous reports have shown that the incidence of postoperative complications was significantly higher in patients with larger tumors, tumors on the upper extremities[6,13,15], younger age[6] and tumors originating from the ulnar nerve[21], but these features were not found to be risk factors in our study.

Other studies report that surgery for schwannomas originating from unidentified terminal branches in the muscle or in the skin does not cause postoperative neurological symptoms[22]. Our study proved that this might not be the case as many of our patients who had excisions of tumors involving terminal nerve branches had significant postoperative symptoms.

One possible reason for our finding of higher risk of symptoms after surgery in terminal branches, may be due to the lower soft tissue coverage distally than proximally. Adani *et al*[17] described this phenomenon but found that tumors lying distally and in the upper limb gave more symptoms after surgery, something we could not conclude in our report.

The limitations of our study are inherent in its retrospective design. Also data files show a vast number of surgeons operating schwannoma, and also a great discrepancy in the charts describing clinical symptoms at final exam. The follow-up period was varying among patients and most were relatively short.

CONCLUSION

The authors of this study found evidence for reduction of pre-operative symptoms especially regarding local pain and radiating pain after surgical excision of solitary schwannomas of the extremities and opine that this balances the risks of operative treatment.

ARTICLE HIGHLIGHTS

Research background

Schwannomas are one of the most common benign tumors in the peripheral nervous system and symptoms described in the literature are mainly sensory as radiating pain, local irritation, and sensation of a heavy mass, while primary motor involvement leading to paresis is uncommon.

Research motivation

Surgical removal of schwannomas in the peripheral nervous system is by many surgeons considered a high risk procedure with surgery directly on peripheral nerves and since the literature regarding the clinical results that can be expected after this procedure is relatively sparse, we found it of interest to examine the postoperative results after this procedure.

Research objectives

To evaluate the pre- and postoperative symptoms in patients treated surgically for benign schwannomas and examine whether tumor size, anatomical location or specific nerve location had an impact on the clinical symptoms prior to and after surgery. Finally, we also aimed to investigate the rate of malignant transformation.

Research methods

All patients who had surgery due to benign schwannomas from May 1997 to January 2018 at our institution were identified and included in the study. We registered preoperative baseline data and postoperative symptoms and objective findings were recovered from patient records and a questionnaire. Patients that reported new symptoms, recurrence of a mass, or unsatisfactory results were offered an magnetic resonance imaging-scanning and a follow-up to rule out a recurrence or malignant transformation of the tumor.

Research results

At the end of follow-up we recorded a significant post-operative decrease in clinical symptoms such as local pain and radiating pain. Multivariate analysis showed that tumors located within minor nerves had a significantly higher prevalence of postoperative symptoms compared with tumors in major nerves. One patient with schwannoma diagnosed initially by needle biopsy was diagnosed to have malignant transformation diagnosed in the surgically removed tumor. No local recurrences were reported.

Research conclusions

Surgery of schwannomas can be conducted with low risk of postoperative complications, acceptable decrease in clinical symptoms and risk of local recurrence and malignant transformation is low.

Research perspectives

Future studies should provide prospective data and especially give more detailed information for those few patients who got worsening of their pre-operative symptoms and give further information about the specific characteristics of the patient and the tumor that may affect the outcome of the surgical tumor removal.

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ORIGINAL ARTICLE

Retrospective Study

Osteolysis in total hip arthroplasty in relation to metal ion release: Comparison between monolithic prostheses and different modularities

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Abstract

BACKGROUND

Among the various complications associated with total hip arthroplasty (THA) periprosthetic osteolysis and wear phenomena due to the release of metal particles, are two of the most common and have been reported to be correlated because of inflammatory responses directed towards released particles that generally activate macrophagic osteolytic effects. Therein, new masses known as pseudotumors can appear in soft tissues around a prosthetic implant. To date, there is paucity of reliable data from studies investigating for any association between the above mentioned adverse events.

AIM

To investigate for the existence of any association between serum and urine concentrations of metal-ions released in THA and periprosthetic osteolysis for modular neck and monolithic implants.

METHODS

Overall, 76 patients were divided into three groups according to the type of hip prosthesis implants: Monoblock, modular with metal head and modular with ceramic head. With an average f-up of 4 years, we conducted a radiological

appendix, statistical code, and dataset available from the corresponding author at francesco.manfreda@libero.it. Participants gave informed consent for data sharing.

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evaluation in order to detect any area of osteolysis around the prosthesis of both the femur and the acetabulum. Moreover, serum and urinary tests were performed to assess the values of Chromium and Cobalt released. Statistical analysis was performed to determine any association between the ion release and osteolysis.

RESULTS
For the 3 study groups, the monolithic, modular ceramic-headed and modular metal-headed implants had different incidences of osteolysis events, which were higher for the modular implants. Furthermore, the most serious of these (grade 3) were detected almost exclusively for the modular implants with metal heads. A mapping of the affected areas was performed revealing that the highest incidences of osteolysis were evidenced in the pertrochanteric region at the femur level, and in the supero-external region at the acetabular level. Regarding the evaluation of the release of metals-ions from wear processes, serum and urinary chromium and cobalt values were found to be higher in cases of modularity, and even more so for those with metal head. Statistical linear correlation test results suggested positive correlations between increasing metal concentrations and incidences areas of osteolysis. However, no cases of pseudo-tumor were detected.

CONCLUSION
Future studies are needed to identify risk factors that increase peri-prosthetic metal ion levels and whether these factors might be implicated in the triggering of local events, including osteolysis and aseptic loosening.

Key Words: Total hip arthroplasty; Peri-prosthetic osteolysis; Metal-ions; Monolithic total hip arthroplasty; Modular ceramic headed total hip arthroplasty; Modular metallic headed total hip arthroplasty

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Core Tip: In this study a rigorous and statistically proven correlation was made between the release of periprosthetic metal ions in hip arthroplasty and the phenomenon of osteolysis, for severity and localization. A novel aspect of this study was that these evaluations were classified according to the types of prostheses: Monolithic, modular with ceramic head and modular with metal head. This was done so to conduct a contextual comparison between them. In fact, the results appeared quite clear, although further randomized trials and studies of higher scientific evidence will be needed.

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INTRODUCTION

The introduction of total hip arthroplasty (THA) was one of the most important achievements in medical landscape over the last century. It led to an improvement in the quality of life of patients by reducing pain and improving hip functionality. Additionally, surgeons and engineers sought to improve upon the surgical technique and the design of the prostheses, with the aim of reproducing the natural biomechanics of the hip, to improve functionality and longevity of the implant. Likewise, as the technology improved the lifespan of the implants, issues with debris from joint surfaces were encountered.

The advent of modularity in THA brought to orthopedic surgery a great potential gain for restoring biomechanical parameters. In fact, the use of the modular neck prosthesis has the advantage of restoring the offset, the length of the limbs and the neck version, compared to a mono-block prosthesis[1]. The major disadvantages

associated with the modular neck prothesis have been reported to be corrosion, adverse reactions of tissue spaces and increased blood metal ions release[1,2], often leading to mechanical failure of the implant and a possible systemic toxicity. In addition, these adverse events derive from the higher contact-surfaces of implants. In fact, a larger number of elements in a modular system correspond to a larger amount of stress-forces of the implant surfaces.

The active corrosion process of metallic surfaces and the particles released due to wear are a source of soluble metal ions[3] As stated above, orthopaedic implants generate ions and metal particles, most of them of Cobalt and Chrome (CoCr), predominantly of nanometric dimensions[4]. CoCr particles are generally smaller than 50 nm[5], while larger particles can be formed from the smaller size particles agglomeration[6]. Within periprosthetic tissues, particles larger than 0.1 μm are degraded by macrophages, where they are subsequently eliminated from the joint[6]. However, nanometric particles are not able to stimulate phagocytosis by macrophages[7,8]. Ultra-fine particles are generally more inflammatory than fine particles of the same material[9]. The precise mechanism underlying this increased activity is currently unknown. However, it is thought to be the result of a complex series of biological reactions, which depend on particle size, shape, and chemistry and surface properties. Generally, the inflammatory response to the accumulation of particles and ions within periprosthetic tissues is considered one of the major causes of aseptic mobilization and implant failure[10]. In many cases, a thin fibrous membrane develops at the interface between the implant and the bone. This measures 0.1-0.3 mm in width at the femoral component, increasing with implant survival, and > 0.1 mm at the acetabular component. This may be considered a normal response to a foreign body and does not necessarily indicate a damaging inflammatory reaction. However, whenever excess debris is produced and/or macrophages are unable to phagocytize it all, there is a dramatic increase in particles in the periprosthetic tissue[7]. The accumulation of these debris particles tends to increase the infiltration of inflammatory cells (macrophages and mononuclear giant cells) into the tissue. These cells drive the subsequent inflammatory reaction by creating fibrin deposits at the interface. Activation of macrophages leads to the release of inflammatory mediators such as interleukin-6 and tumor necrosis factor-α. In some cases this histiocytic reaction may cause a progressive destruction of the surrounding bone, known as osteolysis, which is mediated by a complex series of biological interactions between activated macrophages, osteoclasts and osteoblasts[8,11]. Osteolysis may depend on the composition and shape of the debris particles. Experimental evidence suggests that osteolysis, that is caused by CoCr particles, may be due to a direct action of inflammatory cytokines, in contrast to osteolysis caused by titanium and polyethylene[12]. With regard to periprosthetic tissues, a significant amount of macrophage cells and a dramatic perivascular accumulation of T-cells and/or B-cells as well as plasma cells were found[13-16].

In addition, a relation between the phenomenon of osteolysis and a pseudotumor has been well described in literature.

It would be worthwhile to investigate for an association among the amount of metal-ion release, the potential consequent osteolysis as a direct response, and the presence of pseudotumors.

To date, few studies have compared modular and monoblock implants clinically, radiographically and tribologically. In this paper, we sought to investigate for the presence of any association between serum and urine concentrations of metal-ions released in THA and periprosthetic osteolysis for modular neck and monolithic implants

MATERIALS AND METHODS

Type of study: Comparative retrospective. Level III Evidence.

The inclusion and exclusion criteria we chose were the following.

Inclusion criteria: (1) Diagnosis: Primary hip OA; (2) Age under 86 years old; (3) First implant prostheses; (4) Use of implants: ABG II Stryker® Modular Neck metal or ceramic ones, and ABG II Stryker® with metal head; and (5) Polyethylene head-acetabulum interface

Exclusion criteria: (1) Patients not present at 2-year follow-up; (2) Septic loosening; (3) Contralateral hip or other prosthetic implants; and (4) Occupational Hazard for metals (Metallic industries; chemical/pharmaceutical industries; textile industries; glass processing; paint processing; photographic processing).

Because of the severe criteria, we could enroll only 81 patients, of which 5 were lost over follow-up (76): 23 monoblock prostheses with metal heads (Group A, Table 1), 21 modular prostheses with ceramic heads (Group B, Table 2), 32 modular prostheses with metal heads (Group C, Table 3). The hip surgical approach adopted was the same for all the patients: Kocher-Langebeck posterior approach. The mean age for Group A was 71.08 years, for Group B it was 71.2 years, and for Group C it was 70.9 years. The mean follow-up period for Group A was 46.10 mo; for Group B it was 39.19 mo; for Group C it was 47.05 mo.

Although we did not conduct any invasive procedures, all patients included in the study signed an informed consensus.

For each patient, we conducted anterior-posterior weight-bearing and axial radiographs on the operated hip. Both of the x-ray-projections were evaluated by the Authors, who looked for possible osteolytic processes and periprosthetic aseptic detachment, and whenever localized, both the site and degree of osteolysis were recorded. The assessment of osteolysis was conducted by revealing the presence of radiolucent areas or lines around the implant in all the zones described by Gruen for the femur and DeLee for the acetabulum[17] (Figures 1 and 2).

As suggested in literature, we quantified grades of osteolysis by measuring radiolucent signs in mm with the software for viewing the radiographs (Figure 3).

The degree of osteolysis was established as follows: Grade 0 no osteolysis; grade 1 osteolysis of 1-2 mm; grade 2 osteolysis between 2.1-3 mm; grade 3 osteolysis > 3 mm [17].

We also measured serum and urinary levels of Cr and Co for each patient, as shown in Tables 1-3. Patients underwent blood and urinary analyses for the study of Cr and Co values at the laboratory of Occupational Diseases of the University Clinic of Perugia. Presently, normal ranges in serum for Cr and Co are defined as 0.1-0.5 μg/L and 0.05-0.1 μg/L, respectively. While normal ranges in urine for Cr and Co are 0.05-0.35 μg/L and 0.1-1.5 μg/L[18].

We investigated for graphical and statistical correlations between levels of Cr and Co in blood and urinary exams, in order to estimate the hypothetical direct effect of higher metallic levels on the processes of osteolysis. For this, we used the statistical test of linear regression.

Finally, in all the cases of either high levels of metallic ions or painful-symptomatic, we recommended an magnetic resonance imaging (MRI), so to exclude for the presence of a pseudo-tumor around the prosthesis or other tissues-lesions.

RESULTS

As stated above, in the radiological evaluations we determined the site and grade of the osteolysis, finding that only Group C presented a grade 3 osteolysis (Figure 4) while grade 2 was prevalent in THAs with a modular neck (16 cases), compared to monoblock THAs (2 cases).

In Figure 4, we present the final report on the observed processes of osteolysis for each group, while in Table 4 we report the localizations of the osteolysis in the peri-prosthetic field along with relative severity (Figure 4 and Table 4).

We calculated the mean values for each group: Serum Cr was 0. 54 (SD 0.56) μg/L (normal range 0. 1-0.2 μg/L) for Group A, 0.67 (SD 0.60) μg/L for Group B and 0.91 (SD 0.69) μg/L for Group C; the mean value of serum Co was 3.59 (SD 3.46) μg/L (normal range 0.05-0.3 μg/L) for Group A, 3.05 (SD 1.76) μg/L for Group B and 5.29 (3.46) μg/L for group C; the mean value of urine Cr was 1.41 (1.33) μg/L (normal range 0.05-0.35 μg/L) for Group A, 2.34 (SD 1.66) μg/L for Group B and. 95 (SD 1.75) μg/L for Group C; the mean value of urine Co was 10.06 μg/L (SD 10.19) (normal range 0.1-1.5 μg/L) for Group A, 14.42 (SD 9.18) μg/L for Group B and 21.73 (SD 12.64) μg/L for Group C (Tables 1-3).

We observed that in the modular THAs groups (B and C) there were higher serum and urinary Cr and Co levels and higher prevalence of osteolysis.

Table 5 reports on the correspondence between mean values of metal-concentration and cases of osteolysis.

Linear regressions conducted in order to quantify a direct relation between ion-release and osteolysis revealed a positive result (where positivity corresponds to $P > 0$ at linear regression) for every test; though there were varying degrees of significance for each test.

Cr levels from blood exams showed a coefficient of linear regression equal to 0. 048 for grade 2 of osteolysis and 0.101 for grade 3 osteolysis.

Table 1 Patients with monolithic total hip arthroplasty

Group A					
Patient	**Age**	**Cr serum (μg/L)**	**Cr urine (μg/L)**	**Co serum (μg/L)**	**Co urine (μg/L)**
1	58	0.53	0.69	3.9	6
2	63	0.14	0	0	0.76
3	69	0.92	2.71	3.22	14.53
4	76	0.8	2.14	11.1	34.9
5	77	0.07	0.11	0.1	0.1
6	65	no	1.48	5.03	14.9
7	71	0.1	0.4	0.82	0.2
8	74	0.08	0.61	0.73	2.1
9	75	0.5	1.13	4.3	9.6
10	78	0.77	2.94	10.65	27.5
11	79	2.05	4.36	7.92	17.4
12	75	0.7	1.7	4.6	9.4
13	65	0.37	2.3	7.84	26
14	75	1.14	3.86	6.38	24.2
15	70	0.1	0.1	0.1	0.1
16	69	0.3	1.25	1.77	7.1
17	72	0.34	0.04	0.1	0
18	71	0.76	1.07	2.06	9.3
19	74	0.1	0.09	0.67	0.1
20	65	0.1	0.22	1.34	3.9
21	64	0.1	0.52	0.34	0.2
22	72	1.87	3.69	7.25	12.38
23	78	0.1	1.02	2.41	10.7
Mean	71.08	0.54	1.41	3.59	10.06
ST.DEV		0.56	1.33	3.46	10.19

Coefficients for Cr in urine resulted being 0.21 for grade 2 osteolysis and 0.37 for grade 3; resulting in a stronger correlation, compared to the Cr in the blood.

Coefficients for Co in the blood resulted being 0.17 for grade 2 of osteolysis and 0.66 for grade 3 (both stronger than Cr). Whereas, coefficients for Co in the urine resulted being 1.51 for grade 2 of osteolysis and 3.16 for grade 3.

Graphs below (Dispersion graphs) show that, although there having been a variability in coefficients of linear regression for the different exams, every test result exhibited a regular tract of linear correlation, except for the serum cobalt values (Figure 5).

As for pseudotumors, of the few MRI tests we were able to carry out, there were no diagnosed cases. Additionally, all patients with loosening of the THA met exclusion criteria, so we could not conduct a correlation between the levels of metals and loosening of THA.

DISCUSSION

Corrosion at the stem-neck junction was first described in 1980[19]. Neck-to-stem wear is more significant than the head-to-neck junction, due to the higher mechanical stresses and an increased lever arm in the former[20].

Table 2 Patients with modular/ceramic head total hip harthroplasty

Group B					
Patient	**Age**	**Cr serum (μg/L)**	**Cr urine (μg/L)**	**Co serum (μg/L)**	**Co urine (μg/L)**
24	68	1.56	3.9	4.19	19.2
25	71	0.1	2.34	2.09	21.15
26	69	0.38	1.59	2.3	15.2
27	70	0.67	1.91	0.61	0.2
28	71	2.25	7.52	5.6	17.7
29	75	0.77	2.36	6.33	19.5
30	55	0.44	1.55	3.76	19.9
31	74	0.53	1.9	3.4	23.9
32	76	0.55	1.94	2.95	29.4
33	74	0.18	0.24	1.83	4.7
34	69	0.11	1.54	0.85	0.2
35	81	0.2	1.28	1.79	2.1
36	78	0.5	0.49	3.93	12.5
37	65	0.38	3.89	1.44	12.4
38	74	1.03	2.59	6.28	26.4
39	79	0.73	3.19	2.55	4.7
40	72	0.35	1.57	1.93	16
41	73	0.24	0.78	2.19	5.3
42	55	1.13	1.97	1.93	7.2
43	71	0.1	1.41	0.46	27.2
44	77	1.96	3.48	3.63	24.4
Mean	71.28	0.67	2.34	3.05	14.42
ST.DEV		0.60	1.66	1.76	9.18

Our study suggester this condition, highlighting a greater degree of osteolysis for the proximal portion of the femur (zones 1 and 7).

The choice of materials have been reported to affect the durability and survival of the implant. In current-day hip prostheses, the physical properties of CoCr provide an ideal surface for supporting the load and movement with minimal degradation over a long period. The CoCr Mo neck has increased rigidity and wear resistance compared to Ti6Al4V[21]. One possible cause of corrosion is the failure of the stem, due to a loss of tension of soft tissues, that creates micromovements of the neck; also inappropriate neck orientation on the stem creates a stress concentration on the neckline; impingement between the femoral neck and the acetabular cup, osteolysis and fretting are other possible causes of dissociation[21,22]. In addition, the formation of pseudotumors is a known complication of modular neck prostheses, even though there is no widely held consensus regarding a possible correlation with urinary and blood metal ions levels[23]. The pathophysiology of these lesions is not known, although it is assumed to be a consequence of local chronic inflammation, due to the release of metal particles causing necrosis and cell cytotoxicity[22-26]. Some authors have reported that patients with pseudotumors have higher chromium and cobalt serum levels, compared to patients without pseudotumors[27]. Furthermore, over the last decade, physicians have described additional adverse effects beyond osteolysis, including pseudotumors and loosening caused by metallosis. In fact, several studies have described how Metal-on–Metal prostheses may be a potential cause of ALVAL lesions[28]. ALVAL is short for "Aseptic Lymphocyte-Dominant Vasculitis-Associated Lesions" a histological entity denoting a chronic inflammatory response to metal particles, as a T-lymphocyte-mediated type IV hypersensitivity reaction. Specifically, the particles activate cytotoxic T-lymphocytes and macrophages, which in turn leads

Table 3 Patients with modular/metallic head total hip arthroplasty

Group C					
Patient	**Age**	**Cr serum (μg/L)**	**Cr urine (μg/L)**	**Co serum (μg/L)**	**Co urine (μg/L)**
45	84	1.78	4	7.02	27.7
46	73	0.9	4.89	9.8	28.9
47	67	2.19	8.4	5.1	19.1
48	73	0.27	2.56	4.43	24.9
49	69	1.26	5.04	8.56	40.1
50	68	0.26	0.8	3.01	15
51	73	0.32	3.18	3.2	18.2
52	74	0.1	1.96	2.7	3.5
53	62	0.84	2.96	3.5	12.3
54	79	0.81	3.27	4.45	19.7
55	71	0.55	2.72	3.86	18.6
56	78	2.5	1.9	5.22	14.8
57	73	0.84	1.99	0.46	7.5
58	59	1.31	3.8	4.77	25.3
59	75	0.19	2.99	4.03	22.5
60	59	0.39	0.88	0.76	7.89
61	74	0.9	3.5	4.56	24.7
62	52	0.55	0.98	5.55	19.8
63	64	0.7	2.21	4	14.5
64	85	0.59	7.19	5.72	41.6
65	72	1.94	4.69	7.14	41.9
66	77	0.15	1.94	2.17	16.1
67	71	0.1	1.58	1.33	7.9
68	72	1.4	3.57	8.84	35.4
69	85	1.24	2.07	13.78	60.2
70	32	2.65	1.77	7.03	16.7
71	79	1.27	3.28	2.09	18.2
72	79	0.84	1.7	4.52	17
73	74	0.96	3.89	15.47	36.8
74	60	0.14	1.05	4.94	11.16
75	79	0.49	2.41	1	6
76	78	0.75	1.5	7.22	18
Mean	70.93	0.91	2.95	5.29	21.73
ST.DEV		0.69	1.75	3.41	12.64

to tissue damage[29].

Joint prostheses in CoCr are not subject to standard biological monitoring and the acceptable levels of CoCr in the blood and urine have yet to be established. To date, it is uncommon practice to measure CoCr serum and urinary levels in patients who had undergone prosthetic implant surgery. There is no standardized assessment for maximum levels, either for either blood or urine levels, which might assist surgeons in patient management; instead surgeons can rely upon only clinical symptoms and/or adverse reactions. Therefore, although there is no currently held agreement on what

Table 4 Localization of osteolysis in peri-prosthetic field

	Group A	Group B	Group C
Site of osteolysis			
Gruen zone 7	2	2	4
Gruen zone 1	2	6	12
DeLee zone 1 and 2	5	3	3

Table 5 For every group mean values of blood and urinal concentration of Chrom and Cobalt are related to cases of osteolysis

	Cr Serum (μg/L)	Cr urine (μg/L)	Co serum (μg/L)	Co urine (μg/L)	Cases of Gr. 2 osteolysis	Cases of Gr. 3 osteolysis
Group 1	0.54	1.41	3.59	10.06	2	0
Group 2	0.67	2.24	3.05	14.42	7	0
Group 3	0.91	2.95	5.29	21.73	9	3

Cr: Chrom; Co: Cobalt.

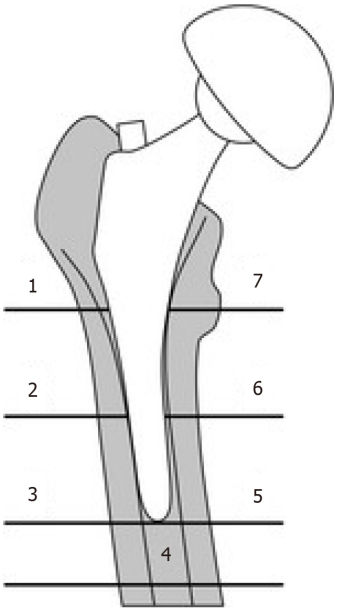


Figure 1 Gruen's classification for femural osteolysis.

the possible decision limits could be for increases in blood and urine metal levels, any elevation should always be considered relevant and worthy of attention.

While there have been studies that have analyzed these events from a pathophysiological perspective, it is evident that in literature there have been few studies that have been designed with a clinical, radiological and tribological approach for patients with modular and monoblock prostheses, regardless of the coupling of metals and non-metallic material (ceramic, polyethylene) used in their modularity.

For the most part, most studies have statistically evaluated ion elevations relating to the type of prostheses, whereas few have correlated osteolytic events and/or conducted clinical follow-up. Another limitation of past studies concerns their short follow-ups, with only a few studies planning periods longer than 40 mo.

In 2007, Daniel *et al*[30] conducted a four-year follow-up after THAs in young and active patients. Like in our study, the authors reported significant increases in the levels of metal ions at 1-year follow-up, compared to pre-operative times. At 4-year follow-up, the same Authors observed a progressive reduction in these levels; statistically significant for Cr but not for Co[30].

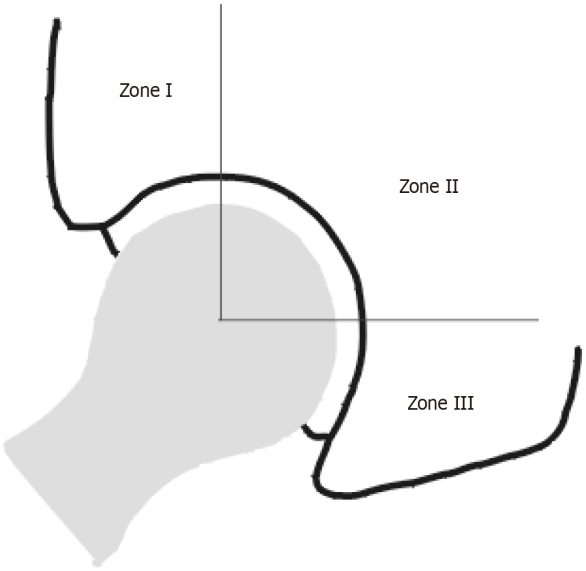


Figure 2 DeLee-Charney's classification for acetabular osteolysis.

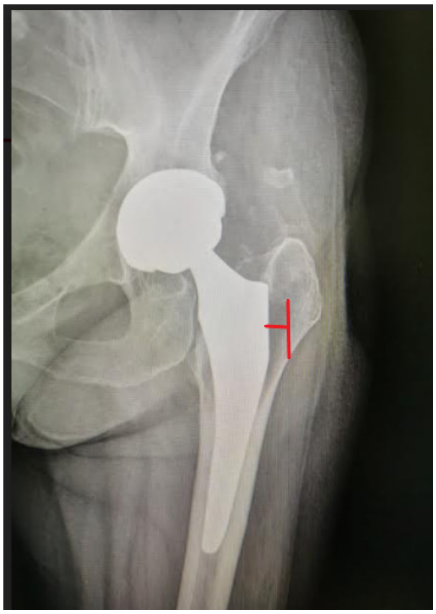


Figure 3 Measurement of grades of osteolysis.

In 2020, Pozzuoli *et al*[31], were able to perform a 7-year follow-up, from which they reported a revision-rate for MOM prostheses where they conducted clinical and radiographic evaluations in relation to metal-ion release[31].

For our study results, we saw how the release of metal ions could, either directly or indirectly, set off the activity of the osteoclasts, and might, therefore, have been responsible for periprosthetic bone resorption, and in some cases for aseptic loosening of the implant itself. From our radiogram findings, it is evident (Graph I) that the cases of marked osteolysis were only in Group C, which was also the group with the most cases of grade-two osteolysis. We can therefore affirm that, in our study, a greater release of metal ions corresponded to a greater number of osteolysis cases.

The statistical tests of the linear regression used, generally showed positive correlations between detected increases in the values of metal ions and the severity of osteolysis.

However, these results need to be challenged by further investigations. Our sample of patients underwent investigations that could not be complete, including biomechanical tests and/or longer follow-up. Unfortunately, MRI was not performed on all the patients in this series, and when done so, it could not be performed in a standardized

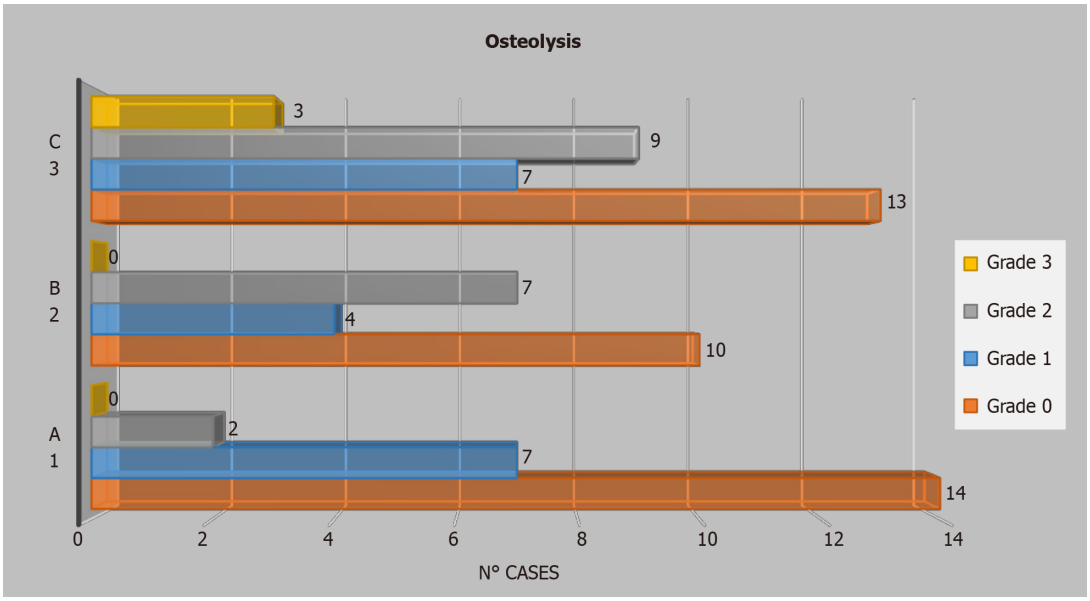


Figure 4 Cases of osteolysis and relative severity for every group.

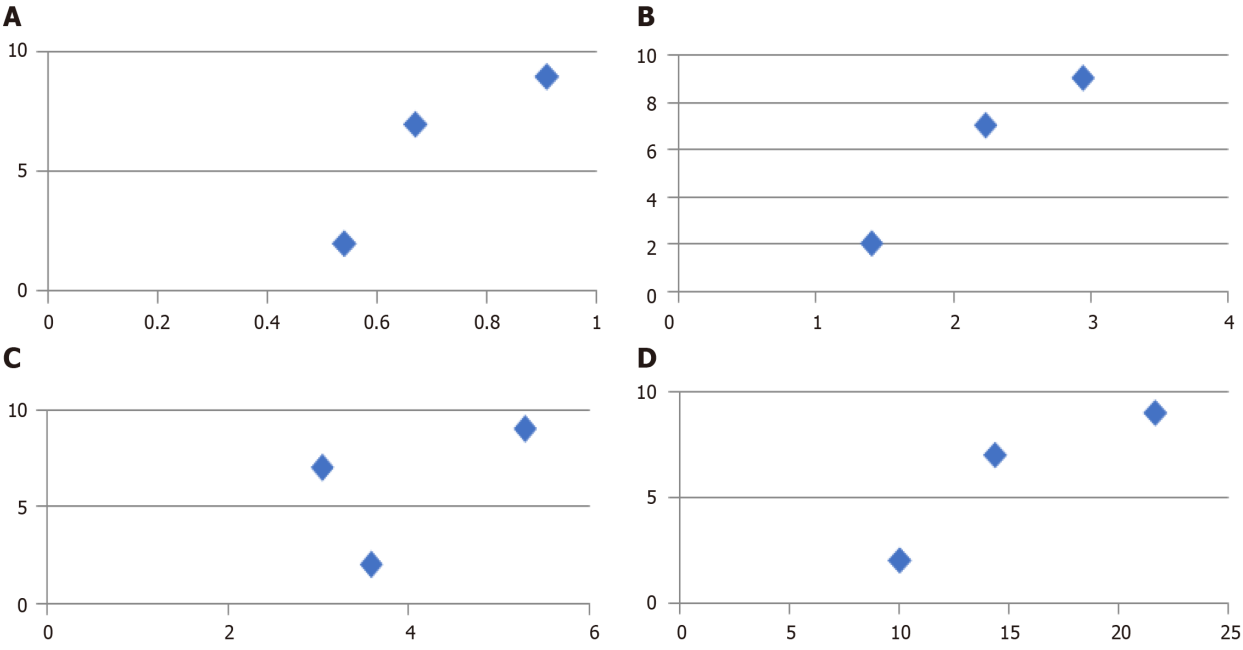


Figure 5 Relation between serum chrome, urine chrome, serum cobalt, urine cobalt and osteolysis. A: Serum chrome and osteolysis; B: Urine chrome and osteolysis; C: Serum cobalt and osteolysis; D: Urine cobalt and osteolysis.

manner. This made those few examinations, neither clinically nor statistically comparable. So, it was not possible to hypothesize on a relationship between either the phenomenon of inflammatory lesions and the degree of metal release or the severity of periprosthetic osteolysis.

CONCLUSION

Periprosthetic osteolysis in total hip replacement is one of the most significant mid- and long-term adverse events that has been described over the years. The cause of this event has been widely debated, with a wide consensus on a macrophage inflammatory response due to the presence of metal ions released from the implants caused by wear mechanisms. Our study results indicate a direct quantitative, as well as qualitative relationship, between the release of the most common periprosthetic metal ions in

THAs (Cr and Co) and the presence of periprosthetic osteolysis. Furthermore, our results showed how modularity in THAs has irrefutable biomechanical advantages but is, however, associated with both a higher degree of metal ion release and greater prevalence of osteolysis events. These increases were even greater when metals rather than ceramic components were detected in the modularity.

To obtain a robust level of evidence, future randomized and controlled trials should be designed to identify further risk factors that could affect the levels of metal ions, which could also be associated either systemic adverse effects or local events, such as osteolysis, aseptic loosening and/or tissues-lesions.

ARTICLE HIGHLIGHTS

Research background

Osteolysis is one of the most common and important adverse reactions to total hip arthroplasty (THA). Therefore it's important to define if there are conditions that facilitate its occurrence.

Research motivation

There is a lack of works studying the correlation between metal ions levels and osteolysis and its different prevalence between modular THA and monolithic prostheses.

Research objectives

Studies analyzing these topics would help the surgeons in the choice of the implants and in the in a correct patients' follow-up. So that we designed this work aiming to have a comprehensive vision of a complication, such as the osteolysis, in THA.

Research methods

We enrolled 76 patients who underwent an operation of first implant of THA, with no other prosthesis and no Cobalt and Chrome (CoCr) work exposure. We divided them in three groups: Patients with monoblock prosthesis with metal head (Group A,), patients with modular prosthesis with ceramic head (Group B), patients with modular prosthesis with metal head (Group C). We analyzed the presence, if any, of osteolysis, its localization and the serum and urinary metal ions levels (Cr and Co).

Research results

We found out a direct correlation between the release of periprosthetic metal ions and osteolysis, also this study highlights that modularity is related to a higher metal ion release and osteolysis events.

Research conclusions

Our study reveals that there is a correlation between metal ions levels and presence and severity of osteolysis and that this is more evident in modular THA, due to higher corrosion.

Research perspectives

Obviously there is a need for more studies to obtain a good level of evidence and confirm these findings.

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ORIGINAL ARTICLE

Clinical Trials Study

Short-term effectiveness of high- and low-intensity percutaneous electrolysis in patients with patellofemoral pain syndrome: A pilot study

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Abstract

BACKGROUND

Unilateral patellofemoral pain syndrome (PFPS) is the most frequently diagnosed knee condition in populations aged < 50 years old. Although the treatment of myofascial trigger points (MTrPs) is a common and effective tool for reducing pain, previous studies showed no additional benefits compared with placebo in populations with PFPS. Percutaneous electrolysis is a minimally invasive approach frequently used in musculotendinous pathologies which consists of the application of a galvanic current through dry needling (DN).

AIM

To evaluate changes in sensitivity, knee pain perception and perceived pain during the application of these three invasive techniques.

METHODS

A triple-blinded, pilot randomized controlled trial was conducted on fifteen patients with unilateral PFPS who were randomized to the high-intensity percutaneous electrolysis (HIPE) experimental group, low-intensity percutaneous electrolysis (LIPE) experimental group or DN active control group. All interventions were conducted in the most active MTrP, in the rectus femoris muscle. The HIPE group received a 660 mA galvanic current for 10 s, the LIPE group 220 mA × 30 s and the DN group received no galvanic current. The MTrP and patellar tendon pain pressure thresholds (PPTs) and subjective anterior knee pain perception (SAKPP) were assessed before, after and 7 d after the single intervention. In addition, perceived pain during the intervention was also assessed.

conflicts of interest.

Data sharing statement: The data that support the findings of this study are available from the corresponding author (JA Valera-Calero), upon reasonable request.

CONSORT 2010 statement: This clinical trial followed the CONSORT for pragmatic clinical trials.

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RESULTS

Both groups were comparable at baseline as no significant differences were found for age, height, weight, body mass index, PPTs or SAKPP. No adverse events were reported during or after the interventions. A significant decrease in SAKPP (both HIPE and LIPE, $P < 0.01$) and increased patellar tendon PPT (all, $P < 0.001$) were found, with no differences between the groups (VAS: $F = 0.30$; $\eta^2 = 0.05$; $P > 0.05$; tendon PPT immediate effects: $F = 0.15$; $\eta^2 = 0.02$; $P > 0.05$ and tendon PPT 7-d effects: $F = 0.67$; $\eta^2 = 0.10$; $P > 0.05$). A significant PPT increase in rectus femoris MTrP was found at follow-up in both the HIPE and LIPE groups (both, $P < 0.001$) with no differences between the groups (immediate effects: $F = 1.55$; $\eta^2 = 0.20$; $P > 0.05$ and 7-d effects: $F = 0.71$; $\eta^2 = 0.10$; $P > 0.05$). Both HIPE and LIPE interventions were considered less painful compared with DN ($F = 8.52$; $\eta^2 = 0.587$; $P < 0.01$).

CONCLUSION

HIPE and LIPE induce PPT changes in MTrPs and patellar tendon and improvements in SAKPP, and seem to produce less pain during the intervention compared with DN.

Key Words: Patellofemoral pain syndrome; Electrolysis; Myofascial pain syndromes; Dry needling; Clinical trial

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Core Tip: Percutaneous electrolysis is a minimally invasive approach frequently used in lower limb musculotendinous pathologies which consists of the application of a galvanic current through a dry needling (DN) or acupuncture needle which acts as a negative electrode, increasing the pH and cellular necrosis by a local electrochemical reaction. However, the current evidence regarding its application in myofascial trigger points (MTrPs) is limited. Therefore, the aim of this study was to assess the efficacy of percutaneous electrolysis compared with DN in patients with unilateral patellofemoral pain syndrome to improve rectus femoris MTrP and patellar tendon pain pressure thresholds, subjective anterior knee pain perception and induced pain during interventions.

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INTRODUCTION

In patients with knee complaints younger than 50 years, patellofemoral pain syndrome (PFPS) is the most frequently diagnosed condition[1] and is characterized by the high rates of recurrence and chronicity (up to the 90%)[2]. The current evidence suggests a multifactorial etiology[3]. Although the incidence is still unknown and sociodemographic features [*e.g.*, height, weight, body mass index (BMI), and age] are not clearly identified as risk factors, women are more likely to develop PFPS (Odds ratio: 2.23)[4]. In addition, psychological conditions, physical conditioning, larger medial tibial intercondylar distance, vertical ground reaction force, plantar pressure features, onset timing of vastus medialis and lateralis, muscle flexibility (*e.g.*, hamstring, quadriceps and gastrocnemius) and general joint laxity are clinical risk factors for developing PFPS[1].

With regard to PFPS management, although a systematic review and meta-analysis considered that trigger point dry needling (DN) is a common and (in general) effective technique in clinical practice[5] for reducing pain, the evidence shows no additional improvements compared with placebo in patients with PFPS[6]. DN consists of inserting a solid and thin needle into a myofascial trigger point (MTrP) to reduce the muscle stiffness, relieve pain and improve muscle function[7]. MTrPs are located in

taut bands of skeletal muscles and course with pain and motor and neurovegetative dysfunctions[8]. At least one part of the MTrP nociceptive input is derived from blood capillary compression by these taut bands, inducing ischemia and hypoxia in the MTrP area[9]. Reduced levels of oxygen result in decreased pH (to 4.5), activation of acid-sensing ion channels, inhibition of acetylcholinesterase, and liberation of ATP, bradykinins, tumor necrosis factor-alpha, interleukins, serotonin, noradrenaline, substance P and calcitonin gene-related peptide[10-13].

Percutaneous electrolysis is a minimally invasive approach frequently used in lower limb musculotendinous pathologies[14] as preliminary evidence has suggested that it is more effectiveness when compared with DN[15], which consists of the application of a galvanic current through a DN or acupuncture needle which acts as a negative electrode, increasing the pH and cellular necrosis by a local electrochemical reaction [16]. Although the application of this procedure in a MTrP is limited, a previous clinical trial demonstrated greater improvements in pain and function compared with DN in patients with temporomandibular disorders[17].

As a previous study proposed that treatment of MTrP may be an effective way to diminish the pain associated with PFPS[6,18], the aim of this study was to assess the efficacy of percutaneous electrolysis compared with DN in patients with unilateral PFPS for improving rectus femoris MTrP and patellar tendon pain pressure thresholds (PPTs), subjective anterior knee pain perception (SAKPP) and perceived pain during interventions.

MATERIALS AND METHODS

Study design

A parallel-group, controlled, triple-blinded, randomized pilot clinical trial comparing the effects of a single session of high-intensity percutaneous electrolysis (HIPE), low-intensity percutaneous electrolysis (LIPE) and DN applied to the rectus femoris most active MTrP in patients with unilateral PFPS was conducted. This clinical trial followed the Consolidated Standards of Reporting Trials for pragmatic clinical trials [19]. This study was conducted according to the Declaration of Helsinki and approved by the Institutional Ethics Committee of Clinical Research of Alfonso X el Sabio University (UAX 26-02-2020). All participants signed a written informed consent prior to their participation in this study.

Participants

A consecutive sample of patients with unilateral PFPS was screened for eligibility criteria from September 2020 to December 2020 from a private university located in Spain (Camilo José Cela University). To be eligible, participants had to report anterior knee pain of at least 6 mo duration, unilateral pain location, aged 18 to 50 years, with at least one active MTrP present in the rectus femoris muscle. Exclusion criteria included being under pharmacological (*e.g.*, analgesics) or physiotherapy treatment 7 d prior to their participation or during the study, needle fear, prior lower extremity or spine surgery, absence of pain, any musculoskeletal or neuropathic conditions (*e.g.*, peripheral compressive neuropathy, radiculopathy, sarcopenia, fiber ruptures…), traumatic injuries (*e.g.*, fractures or fissures), or any medical condition or contraindication for needling treatment (*e.g.*, anticoagulants).

Randomization and masking

Participants were randomly assigned to the HIPE experimental group, the LIPE experimental group or the DN active control group. Concealed allocation was conducted using a random-number generator (Research Randomizer Vr.4.0). Individual and sequentially numbered cards with the random assignment were folded in sealed opaque envelopes. One external researcher selected the envelope and proceeded with appropriate allocation. Then, the participants' allocation was revealed after baseline data collection. Participants, examiner and rater were blinded to the allocation group.

Interventions

All interventions were performed by an experienced assessor (more than 10 years of experience) in invasive physiotherapy procedures and MTrP management.

As MTrP diagnosis is most commonly conducted by manual palpation, active MTrPs were located following the instructions provided by Fernández-de-las-Peñas

and Dommerholt[20]. Palpation evaluation can be used for the clinical diagnosis of MTrPs in this specific location as it shows acceptable reliability if experienced examiners are involved[21]. All participants were placed in the supine position with their knee passively flexed at 30º. The single intervention was conducted on the most painful active MTrP of the rectus femoris ipsilateral to the affected area. This MTrP was marked with a grid of 2 perpendicular lines and considered to be the one that elicited the highest recognized pain sensation under the same palpation pressure[22] (Figure 1A).

The same procedure was conducted for all groups as follows: After cleaning the skin with chlorhexidine (Lainco® 2%), a DN 0.30 × 40 needle (Agupunt, Barcelona, Spain) was inserted using an in-plane approach with a 70-80º angle to the skin surface until it produced the first local twitch response following a multiple rapid insertion technique, pain response and recognized MTrP referred pain pattern. The needle was statically placed in this location for 30 s in all groups. After placement, the needle was connected to a modified electrosurgical scalpel from an EPTE device (Ionclinics, Valencia, Spain) which acted as a cathode while a surface anode was placed 10 cm proximal to the location of the MTrP (Figure 1B).

For both HIPE and LIPE groups, a Q = 0.0066 coulombs (C) current was set. From the total 30 s intervention time in all groups: (1) The HIPE group received a galvanic current of 660 mA × 10 s and 20 s with no current; (2) The LIPE group received 220 mA × 30 s; and (3) The DN group, although the needle was connected to the device, received no current during the 30 s. Finally, hemostasis using a cotton swab was performed for 1 min in order to avoid post-needling soreness[20].

To ensure participants, examiner and rater blindness, one external assessor set the device settings according with the group allocation (660 mA × 10 s; 220 mA× 30 s; or none) and the same sounds were emitted for all groups at the start of the intervention and after 30 s.

Outcomes

Outcomes were evaluated before, immediately after and 7 d after the single intervention by an assessor blinded to the subject allocation group.

The primary outcome measure was the PPT of the most active MTrP. In addition, patellar tendon PPT, SAKPP and perceived pain during the intervention were the secondary outcomes.

As patients with PFPS showed lower PPTs compared with controls, PPTs were considered a pain sensitivity indicator[24]. First, PPTs were assessed using the analogic algometer Fischer FPN100. Two locations were unilaterally examined by the same rater: (1) MTrP; and (2) Patellar tendon (at the midpoint between the lower edge of the patella and tibial tuberosity)[25]. We performed three evaluations at each point with a 30 s rest, increasing the pressure at a rate of 1 kg/s and the average (kg/cm^2) was recorded for analysis. Prior to the evaluation, the patients received standardized instructions to signal the first change from pressure to pain[26].

Second, SAKPP was assessed as an indicator of subjective pain perception using a Visual Analogue Scale (VAS). Patients were asked to identify their level of pain in a 100 mm VAS, where 0 was "no pain" and 100 was the worst imaginable pain[27]. The mean of 3 scores was calculated: The maximum pain perceived during the last 7 d, the minimum pain perceived during the last 7 d, and the current pain[28].

Finally, to assess the tolerability of all the techniques, the pain perceived during intervention was assessed using a VAS. Participants were asked to identify their mean level of pain during the 30 s interventions in a 100 mm VAS.

Treatment side effects

Participants were asked to report any adverse events experienced during or after the interventions (up to the 1-mo duration of this study). Adverse events were defined as sequelae of short-medium term symptoms perceived as unacceptable to the patient and required further treatment using a self-reported document provided to the participants and informed to an external clinician during the study[29].

Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics Version 22 (IBM Corporation, Armonk, NY, United States), with a significance level of $P < 0.05$. After verifying the normal distribution of the data, descriptive statistics were used to summarize the sociodemographic and clinical variables. Normal-distributed data were described by means, SD, and 95%CI.

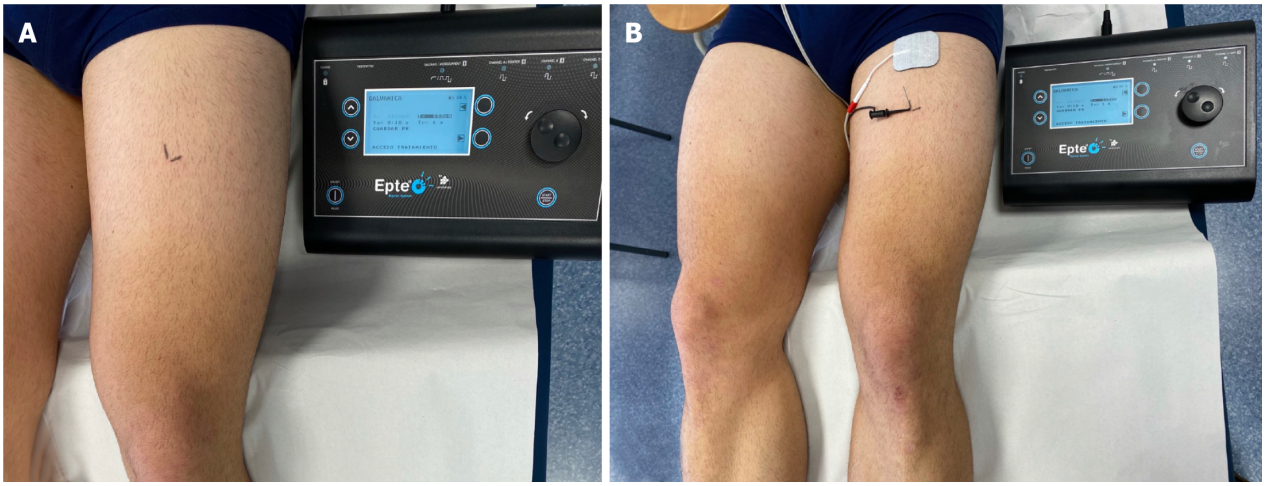


Figure 1 Rectus femoris myofascial trigger point location and needle insertion for all three procedures. A: Rectus femoris myofascial trigger point location; B: Needle insertion for all three procedures.

Comparability of groups at baseline was assessed using a one-way analysis of variance (ANOVA) test (Bonferroni *post-hoc* correction). To assess the effects of the three types of treatment on the primary and secondary outcomes, between-group differences in response to the interventions (HIPE, LIPE or DN) were analyzed using AN(C)OVA repeated measurement (groups *vs* time). For SAKPP, within-groups differences were assessed with the Student *t*-test. The effect size was estimated using η2 when significant. An effect size of 0.01 was considered small, 0.06 medium and 0.14 large. *P* values were assumed to be significant only at < 0.017 (Bonferroni correction: 0.05/3) level[30].

RESULTS

Twenty-one patients with PFPS were initially recruited in September 2020. Six participants were excluded for the following reasons: Fear of needles (n = 2), bilateral PFPS (n = 3), and refused to participate for personal reasons (n = 1). Fifteen patients with unilateral PFPS were finally included and randomized into one of three groups: HIPE (n = 5), LIPE (n = 5) or DN (n = 5). None of the participants in these groups were lost at 7 d follow-up (Figure 2). None of the participants reported adverse effects during the study. Both groups were comparable at baseline as no significant differences in the variables assessed were observed (Table 1).

The mixed-model ANCOVA revealed no significant group * time interactions for the outcomes assessed in this study (all, P > 0.05). Post hoc analyses revealed significant improvements in both MTrP (HIPE and LIPE, P < 0.001) and patellar tendon (all groups, P < 0.001) PPTs and SAKPP (HIPE and LIPE, P < 0.05) at follow-up with no significant within-group immediate changes (P > 0.05) (Tables 2 and 3).

Finally, participants who received the HIPE and LIPE interventions experienced less pain during the intervention compared with the DN group (HIPE *vs* DN and LIPE *vs* DN, P < 0.01) (Table 4).

DISCUSSION

Findings

The aim of this study was to assess the efficacy of two different protocols of percutaneous electrolysis at different intensities and time periods (applying the same electric charge in both groups) compared with DN to improve subjective pain and PPTs at the 7 d follow-up after a single intervention. In addition, perceived pain during the intervention was also assessed. Local twitch responses were found in all the participants during the interventions.

Several findings in this pilot clinical trial were observed. First, the results showed similar improvements in patellar tendon PPTs in all the groups at the 7 d follow up. Second, significant changes in the active rectus femoris MTrP after both electrolysis

Table 1 Sociodemographic features of the total sample and by group

	Subjects, *n* (%)	Age (yr)	Height (m)	Weight (kg)	BMI (kg/m^2)
Sample	15 (100)	25.6 ± 1.9	1.73 ± 0.05	73.5 ± 6.7	24.4 ± 1.6
Intervention group					
HIPE	5 (33.3)	25.4 ± 2.3	1.71 ± 0.05	72.0 ± 7.7	24.5 ± 2.1
LIPE	5 (33.3)	26.8 ± 1.4	1.75 ± 0.04	75.9 ± 6.1	24.6 ± 1.4
DN	5 (33.3)	24.8 ± 1.8	1.73 ± 0.05	72.8 ± 6.9	24.1 ± 1.6

HIPE: High-intensity percutaneous electrolysis; LIPE: Low-intensity percutaneous electrolysis; DN: Dry needling; BMI: Body mass index.

Table 2 Pain pressure thresholds

Variable	Time of measurement	HIPE	LIPE	DN	Mean difference	ANOVA interaction effect	Bonferroni *post-hoc* analysis	
MTrP (kg/cm^2)	Pre	4.20 ± 0.57	4.10 ± 0.54	3.80 ± 0.67	0.10 (-0.95-1.15)[1]; 0.40 (-0.65-1.45)[2]; 0.30 (-0.75-1.35)[1]	$F = 0.65$; $P = 0.562$; $\eta^2 = 0.09$	Group	NA
	Post	3.50 ± 0.61	3.60 ± 0.41	4.00 ± 0.35	0.10 (-0.73-0.93)[1]; 0.50 (-0.33-1.33)[2]; 0.40 (-0.43-1.23)[3]	$F = 1.55$; $P = 0.251$; $\eta^2 = 0.20$	Time	
	7 d follow-up	5.00 ± 1.00	5.00 ± 0.50	4.50 ± 0.70	0.00 (-1.34-1.34)[1]; 0.50 (-0.84-1.84)[2]; 0.50 (-0.84-1.84)[3]	$F = 0.71$; $P = 0.509$; $\eta^2 = 0.10$		Follow up > post, $P < 0.001$[4,5]
Patellar tendon (kg/cm^2)	Pre	5.20 ± 0.83	5.30 ± 0.27	5.20 ± 0.83	0.10 (-1.13-1.33)[1]; 0.00 (-1.23-1.23)[2]; 0.10 (-1.13-1.33)[3]	$F = 0.03$; $P = 0.967$; $\eta^2 = 0.00$	Group	NA
	Post	4.90 ± 1.19	4.70 ± 0.44	5.00 ± 0.79	0.20 (-1.32-1.72)[1]; 0.10 (-1.42-1.62)[2]; 0.30 (-1.22-1.82)[3]	$F = 0.15$; $P = 0.858$; $\eta^2 = 0.02$	Time	Follow-up > pre, $P < 0.001$[4,5,6]
	7 d follow-up	9.10 ± 0.82	9.50 ± 0.35	9.00 ± 0.86	0.40 (-1.66-0.86)[1]; 0.10 (-1.16-1.36)[2]; 0.50 (-0.76-1.76)[3]	$F = 0.67$; $P = 0.526$; $\eta^2 = 0.10$		Follow-up > post, $P < 0.001$[4,5,6]

[1]High-intensity percutaneous electrolysis (HIPE) *vs* low-intensity percutaneous electrolysis (LIPE).
[2]HIPE *vs* dry needling (DN).
[3]LIPE *vs* DN.
[4]Simple within-group effects in the HIPE group.
[5]Simple within-group effects in the LIPE group.
[6]Simple within-group effects in the DN group.
MTrP: Myofascial trigger point; HIPE: High-intensity percutaneous electrolysis; LIPE: Low-intensity percutaneous electrolysis; DN: Dry needling; ANOVA: One-way analysis of variance.

procedures were observed at the 7 d follow-up, but no changes were found after DN. Third, both electrolysis procedures showed lower SAKPP compared with DN. Fourth, surprisingly, both percutaneous electrolysis procedures were perceived as "less painful" when compared with DN. Finally, several statistical estimates for sample size calculation are reported to develop further research with proper statistical power.

Current evidence recommends a multidisciplinary therapeutic approach, including MTrP management to reduce exacerbated mechano-sensitivity and SAKPP and improve knee function[6,18]. Although several invasive procedures have been compared (*e.g.*, DN with MTrP infiltration (with no significant differences between the methods)[31], and superficial *vs* deep DN)[32], the available evidence comparing DN with percutaneous electrolysis applied to MTrPs is limited. To our knowledge, only one clinical trial has compared percutaneous electrolysis and DN in patients with temporomandibular disorders[17]. Although this study reported greater improvements in pain reduction and function recovery, these results cannot be extrapolated (as just one pathology was assessed). In addition, as only one electrolysis procedure was assessed, studies evaluating the same electric charges with different application intensity and time or different electric charges are needed.

Available evidence on the efficacy of DN in pain and disability management of patients with PFPS is also limited with controversial findings[33,34]. The use of DN on quadriceps active MTrPs showed no additional pain or function improvements compared with placebo in a single session[6]. However, although VAS and PFPS disability questionnaires were assessed, it should be noted that PPTs were not

Table 3 Subjective anterior knee pain perception

Variable	Time of measurement	HIPE	LIPE	DN	Mean difference	ANOVA interaction effect	Group: Bonferroni *post-hoc* analysis; time: Student *t*-test	
VAS (0-10)	Pre	4.2 ± 0.5	4.5 ± 1.0	4.6 ± 1.3	0.3 (-1.6-2.1)[1]; 0.3 (-1.5-2.2)[2]; 0.1 (-1.8-1.9)[3]	F = 0.14; *P* = 0.868; η^2 = 0.02	Group	NA
	7 d follow-up	2.9 ± 0.9	2.8 ± 0.7	3.2 ± 0.9	0.1 (-1.5-1.6)[1]; 0.3 (-1.2-1.9)[2]; 0.4 (-1.1-1.9)[3]	F = 0.30; *P* = 0.741; η^2 = 0.05	Time	Follow up < pre, *P* < 0.05[4,5]

[1]High-intensity percutaneous electrolysis (HIPE) *vs* low-intensity percutaneous electrolysis (LIPE).
[2]HIPE *vs* dry needling (DN).
[3]LIPE *vs* DN.
[4]Simple within-group effects in the HIPE group.
[5]Simple within-group effects in the LIPE group.
VAS: Visual Analogue Scale; HIPE: High-intensity percutaneous electrolysis; LIPE: Low-intensity percutaneous electrolysis; DN: Dry needling; ANOVA: One-way analysis of variance.

Table 4 Pain induced during the interventions

Variable	HIPE (*n* = 5)	LIPE (*n* = 5)	DN (*n* = 5)	Mean difference (95%CI)	ANOVA interaction effect	Bonferroni *post-hoc* analysis	
VAS (0-10)	3.2 ± 0.8	3.2 ± 0.8	5.0 ± 1.1	0.0 (-1.4-1.4)[1]1.80 ± (-3.2--0.4)[2]1.80 (-3.2--0.4)[3]	F = 8.52; *P* = 0.005; η^2 = 0.587	Group	*P* < 0.01[4,5]

[1]High-intensity percutaneous electrolysis (HIPE) *vs* low-intensity percutaneous electrolysis (LIPE).
[2]HIPE *vs* dry needling (DN).
[3]LIPE *vs* DN.
[4]Simple between-group effects between HIPE and DN.
[5]Simple between-group effects between LIPE and DN.
VAS: Visual Analogue Scale; HIPE: High-intensity percutaneous electrolysis; LIPE: Low-intensity percutaneous electrolysis; DN: Dry needling; ANOVA: One-way analysis of variance.

included and samples sizes are not representative.

One possible explanation for our results regarding better PPT improvements in the active MTrP following HIPE or LIPE compared with DN could be the combined effect of both mechanic (twitch response) and electric stimuli (electrolysis)[14-16]. Further research is needed to analyze the association between clinical improvements and pH-induced changes.

Limitations

This study had several limitations. First, this was a pilot study. Therefore, our results should be carefully interpreted as the sample size was small and type II errors should be considered. This pilot study was designed to calculate the effect size and provide the sample size needed to obtain appropriate power. Considering the PPT as our primary outcome and setting the effect size f to 0.314 (since eta-squared = 0.09); a = 0.05; 3 groups; and 3 measurements and correlation among repeated measures = 0.3 in the G*Power software V.3.1 for Mac OS, a sample size of 39 subjects is needed to obtain > 0.90 of power. Second, we applied a single session with a limited follow-up. Further research with a larger sample size, number of interventions and longer follow-up is needed to confirm the clinical significance of these study findings.

CONCLUSION

This triple-blinded, randomized clinical pilot study suggests that a single session of high- or low-intensity percutaneous electrolysis, if the same electric charge is applied, induced similar SAKPP and PPTs improvements in patients with unilateral PFPS. Furthermore, both HIPE and LIPE interventions seemed to be better tolerated compared with DN. However, no differences between-groups were found for SAKPP or PPTs. Further research including larger sample sizes, number of sessions and longer follow-up are needed to confirm these findings.

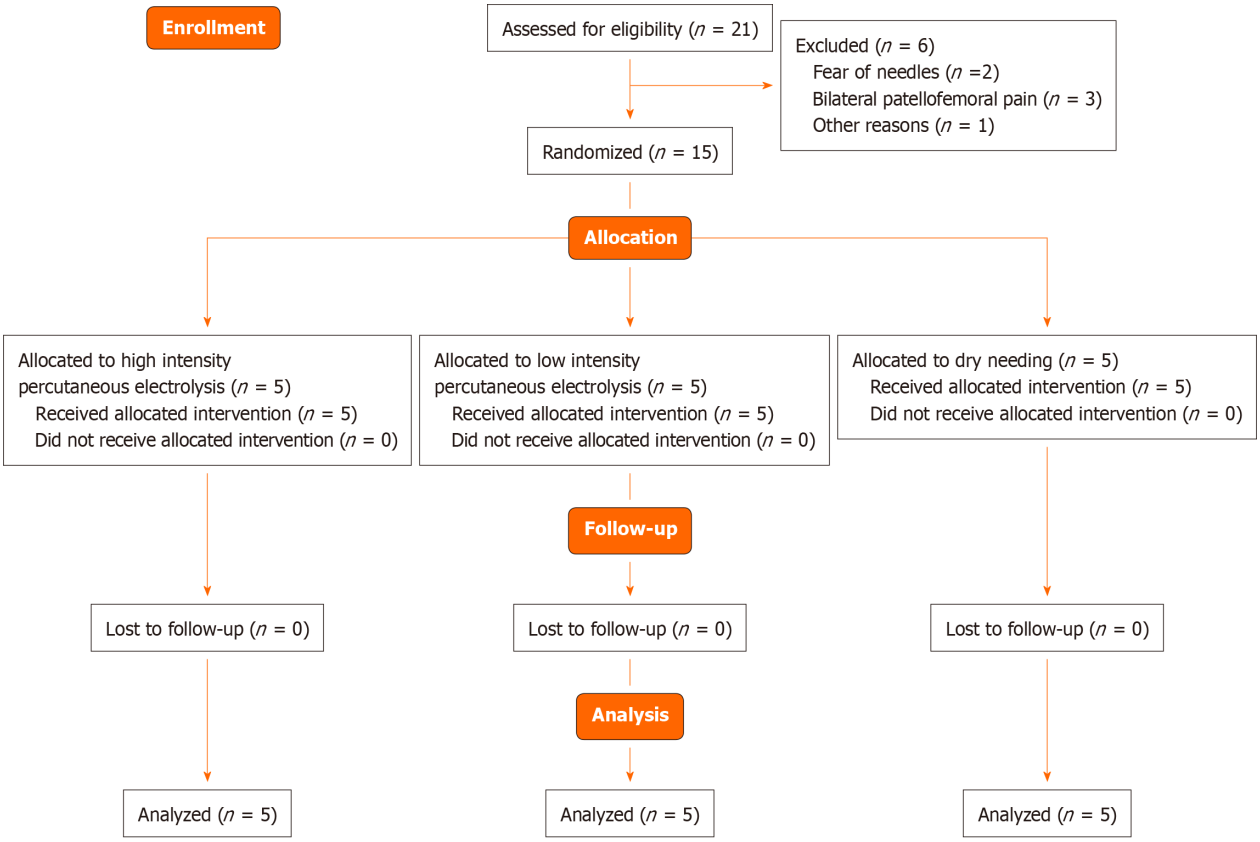


Figure 2 Participants Consolidated Standards of Reporting Trials 2010 flow diagram.

ARTICLE HIGHLIGHTS

Research background

Dry needling (DN) has shown no additional improvements compared with placebo in patients with patellofemoral pain syndrome (PFPS).

Research motivation

Previous evidence suggested that percutaneous electrolysis could be more effective than DN for managing musculoskeletal pain. However, evidence is limited regarding its efficacy in different conditions and locations.

Research objectives

The efficacy of percutaneous electrolysis compared with DN in patients with unilateral PFPS for improving pain pressure thresholds, subjective anterior knee pain perception and perceived pain during interventions were assessed.

Research methods

A parallel-group, controlled, triple-blinded, randomized pilot clinical trial was conducted to compare high-intensity percutaneous electrolysis, low-intensity percutaneous electrolysis and DN applied to the most active myofascial trigger points located in the rectus femoris.

Research results

Both percutaneous electrolysis modalities induced similar short-term effects on pain perception and sensitivity in patients with unilateral patellofemoral pain syndrome. However, percutaneous electrolysis was better tolerated compared with DN.

Research conclusions

Percutaneous electrolysis could be a potential less-painful alternative to DN for reducing pain in patients with unilateral PFPS.

Research perspectives

Further research including larger sample sizes, number of sessions and longer follow-up is needed.

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SYSTEMATIC REVIEWS

Alignment of the hindfoot following total knee arthroplasty: A systematic review

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Abstract

BACKGROUND

There appears to be a close relationship between deformities at the knee joint and at the hindfoot in patients with knee osteoarthritis (OA). Despite this intrinsic link, there is a dearth of studies investigating alterations in hindfoot alignment following total knee arthroplasty (TKA) in patients with knee OA.

AIM

To evaluate changes in alignment of the hindfoot following TKA, foot and ankle clinical outcomes in terms of subjective clinical scoring tools following surgical intervention, and to analyse the level of evidence (LOE) and quality of evidence (QOE) of the included studies.

METHODS

MEDLINE, EMBASE and Cochrane Library databases were systematically reviewed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Studies reporting changes in the postoperative alignment of the hindfoot following TKA were included. The level and QOE were recorded and assessed.

RESULTS

Eleven studies with a total of 1142 patients (1358 knees) met the inclusion/exclusion criteria. Six studies were of LOE II and 5 studies were of LOE III. Patients with preoperative varus knee deformity and valgus hindfoot deformity demonstrated improvement in hindfoot alignment post TKA. Patients with preoperative varus knee deformity and varus hindfoot deformity demonstrated no improvement in hindfoot alignment following TKA. Twelve different radiographic parameters were used to measure the alignment of the hindfoot across the included studies, with the tibio-calcaneal angle most frequently utilised

Checklist.

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(27.3%).

CONCLUSION

This systematic review demonstrated that the hindfoot may display compensatory changes in alignment following TKA in patients with knee OA. However, the marked heterogeneity between the included studies and poor QOE limits any meaningful cross sectional comparisons between studies. Further, well designed studies are necessary to determine the changes and outcomes of hindfoot alignment following TKA.

Key Words: Total knee arthroplasty; Hindfoot alignment; Hindfoot; Knee osteoarthritis; Varus knee deformity; Valgus hindfoot deformity

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Core Tip: This current systematic review has found that correction of deformities at the knee joint following total knee arthroplasty typically resulted in improved changes in the alignment of the hindfoot. However, the poor quality of evidence together with the marked heterogeneity between the included studies, underscores the need for further higher quality studies.

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INTRODUCTION

Osteoarthritis (OA) of the knee is one of the leading causes of pain in the older population, affecting 30% of adults over the age of 60 years old[1]. Although the etiology and pathogenesis of knee OA remains unclear, knee malalignment is a significant risk factor for knee OA. Even minor changes in knee alignment can lead to abnormal load distribution across the articular surface of the knee joint, leading to degeneration of the joint capsule and further progression of OA[2,3]. Replacement procedures, such as total knee arthroplasty (TKA), aim to restore neutral mechanical alignment of the lower extremity.

The alignment of the lower extremity is frequently evaluated by extrapolating the femoral-tibial angle (FTA) and the mechanical axis from standing, full-length, plain radiographs[4,5]. However, the FTA and mechanical axis provide an incomplete picture of the alignment of the lower limb as they exclude assessment of the hindfoot axis. There are a variety of reports demonstrating a relationship between varus or valgus deformities at the knee joint and hindfoot malalignment in patients with knee OA[6-16]. In fact, hindfoot malalignment has been shown to improve following TKA in patients with knee OA[6-10,12-16]. This suggests that knee OA leads to compensatory changes in the hindfoot or, hindfoot deformities may predispose the knee to osteoarthritic change. As a result, pre and post-operative radiological imaging of the hindfoot, *via* Cobey views or otherwise, is crucial in the management of knee OA[17].

Despite the intrinsic link between deformities at the knee joint and the hindfoot in knee OA, there appears to be scant literature extensively investigating the relationship between these 2 pathologies. There also seems to be no consensus regarding the optimal imaging method for hindfoot alignment. The purpose of this systematic review was to evaluate changes in hindfoot alignment and foot and ankle clinical outcomes in terms of subjective clinical scoring tools following TKA.

MATERIALS AND METHODS

Search strategy

During October 2019, a systematic review of the MEDLINE, EMBASE and Cochrane Library databases was performed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Figure 1) guidelines. The following search terms were used: [(Hindfoot OR foot OR ankle) AND (alignment OR malalignment OR misalignment OR position OR kinematics OR axis OR anatomy) AND (knee replacement OR TKR OR knee arthroplasty OR TKA)]. The inclusion and exclusion criteria are shown in Table 1. Following retrieval of the data, the titles, abstracts and full text articles were screened by two independent reviewers of all searched studies by applying the aforementioned criteria. A senior author was consulted to arbitrate any disagreements that arose.

Assessment of level of evidence and methodological quality

The level of evidence (LOE) was assessed using the criteria published by the Journal of Bone & Joint Surgery. The methodological quality of evidence (QOE) was assessed using the Modified Coleman Methodology Score (MCMS)[18]. Two independent reviewers determined the MCMS for each study. If any discrepancy existed, the senior author evaluated the available data and a consensus was reached. Excellent studies had a score between 85 to 100 points, good studies scored between 70 to 84 points, fair studies had a score between 55 to 69 points and poor studies scored less than 55 points.

Data extraction and evaluation

Two independent reviewers independently extracted and assessed the data from each study. Patient demographic data and postoperative follow up times were gathered. Radiographic parameters used to evaluate the alignment of the hindfoot, lower extremity and ankle joint were also collected. Data on postoperative clinical outcomes in terms of subjective clinical scoring tools were evaluated.

Statistical analysis

All other statistical analyses were performed using SAS software version 9.3 (SAS Institute, Inc., Cary, NC, United States). Descriptive statistics were calculated for all continuous and categorical variables. Continuous variables were reported as weighted mean and estimated standard deviation, whereas categorical variables were reported as frequencies with percentages. A value of $P < 0.05$ was considered statistically significant.

RESULTS

The search generated 2606 studies. Of these, 11 met the inclusion and exclusion criteria of this systematic review (Table 1). The studies were published between 2004 and 2019.

Patient demographics

From the 11 studies, 1142 patients (1358 knees) with a weighted mean age of 69.1 ± 3.6 years (range, 63.4-74.7), had radiographic imaging of the hindfoot following TKA. The weighted mean postoperative follow-up time was 10.9 ± 9.4 mo (range, 0.75–31.3) (Table 2).

LOE and QOE

Six studies were LOE II and 5 studies were LOE III. The mean MCMS of all included studies was 53.5 ± 8.5 of 100 points. No studies were classified as excellent quality using the MCMS. There was 1 study of good quality, 3 studies of fair quality and 7 studies of poor quality. 8 studies had a large patient cohort ($n > 60$).

Radiologic assessment

The radiologic assessment data are listed in Table 3. Twelve different radiographic parameters were used to evaluate the alignment of the hindfoot. The most commonly utilised radiographic tool was the tibio-calcaneal angle (TCA) in 3 studies (27.3%)[6,7,13]. Other radiographic parameters utilised included the varus-valgus angle (VVA) in 2 studies (18.2%)[8,16], hindfoot alignment view angle (HAVA) in 1 study[10], calcaneal pitch and naviculocuboid overlap in 1 study (9.1%)[14], tibia-hindfoot angle

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Clinical studies related to changes in the hindfoot following TKA	Less than 10 patients
Published in a peer review journal	Case reports
Written in English	Cadaveric studies
Full text version available	Animal studies
	Review articles
	In vivo studies

TKA: Total knee arthroplasty.

Table 2 Study characteristics and patient demographics

Ref.	LOE	Patients, *n* (%)	Knees, *n* (%)	Age (yr)	Sex (M/F)	Follow-up (mo)	MCMS
Chandler and Moskal[6], 2004	2	86	86	N/R	N/R	3	48
Cho *et al*[7], 2017	2	117	195	69.1	8/187	24	66
Hara *et al*[8], 2015	3	100	100	74.3	14/86	0.75	48
Jeong *et al*[9], 2018	2	331	375	68.3	23/308	6	60
Kim *et al*[10], 2018	3	55	65	69.3	N/R	31.3	71
Levinger *et al*[11], 2012	2	19	26	67.5	13/6	12	46
Mansur *et al*[12], 2019	2	72	72	N/R	23/49	3	44
Mullaji and Shetty[13], 2011	2	125	165	66.1	24/101	12	51
Okamoto *et al*[14], 2017	3	75	80	72.5	8/67	24	48
Palanisami *et al*[15], 2020	3	91	121	63.4	29/62	12	58
Takenaka *et al*[16], 2016	3	71	73	74.7	17/56	12	48

LOE: Level of evidence; M/F: Male/female; MCMS: Modified Coleman methodological score.

and varus-valgus index (VVI) in 1 study (9.1%)[15], foot posture index in 1 study (9.1%)[11], the hindfoot alignment angle (HA), hindfoot alignment ratio (HR) and hindfoot alignment distance (HD) in 1 study (9.1%)[9], and the intersection of the load axis of the leg and the calcaneus axis in 1 study (9.1%)[12].

Six radiographic parameters were used to measure the alignment of the lower extremity, the most common of which was the FTA in 4 studies (36.4%)[6,8,11,12]. Other radiographic tools used included mechanical axis in 2 studies (18.2%)[9,14], mechanical axis deviation angle in 1 study (9.1%)[10], mechanical alignment angle in 1 study (9.1%)[7], conventional mechanical axis deviation in 1 study (9.1%)[13], femorotibial mechanical angle in 1 study (9.1%)[15].

Only 3 studies (27.3%) recorded the alignment of the ankle joint, with the talar tilt (TT) utilised in 3 studies (27.3%)[9,10,14], the tibial anterior surface angle (TAS) used in 2 studies (18.2%)[9,10], the ground talar dome angle of foot (GD) and lateral surface angle of distal tibia used in 1 study each (9.1%)[9], the TAS, distal medial clear space (DMCS), and medial tibiotalar joint space (MTTJS) and frontal tibial ground angle (FTGA) were utilised in 1 study each (9.1%)[10].

Changes in hindfoot alignment following TKA

Ten studies evaluated changes in hindfoot alignment following TKA for patients with varus deformity of the knee joint[7-16]. Nine of these studies demonstrated improvement of hindfoot valgus alignment following TKA[7-10,12-16]. Chandler and Moskal[6], Cho *et al*[7] and Mullaji and Shetty[13] showed a mean postoperative improvement in TCA of 3.1°, 3.1° and 2.0° respectively. Hara *et al*[8] and Takenaka *et al*[16] highlighted a mean postoperative improvement in VVA of 3.1° and 3.4° respectively. Jeong *et al*[9] demonstrated a mean postoperative improvement in HA,

Table 3 Summary of outcomes

Ref.	Patients, *n* (%)	Knees, *n* (%)	Knee deformity	Radiographic Assessment			AOFAS		Postoperative outcomes
				Hindfoot	Ankle	Lower limb alignment	Pre-op	Post-op	
Chandler and Moskal [6], 2004	86	86	Both valgus and varus	TCA: Pre-op = 0.4°; Post-op = -0.1°		FTA: Pre-op = 3.6°; Post-op = 6.6°			Both valgus and varus hindfoot alignment improved post TKA Valgus hindfoot alignment remained in valgus alignment post TKA Varus hindfoot alignment remained in varus alignment post TKA
Cho *et al* [7], 2017	117	195	Varus only	TCA: Pre-op = 5.2° valgus; Post-op = 2.1° valgus		Mechanical alignment angle: Pre-op = 10.8° varus; Post-op = 1.8° varus			Valgus hindfoot alignment improved post TKA Severe varus knee deformities had best improvement in hindfoot alignment post TKA
Hara *et al* [8], 2015	100	100	Varus only	VVA: Pre-op = 78.8°; Post-op = 76.7°		FTA: Pre-op = 186.7°; Post-op = 174.4°			Varus hindfoot alignment with varus knee deformity remained in varus alignment post TKA Valgus hindfoot alignment with varus knee deformity improved post TKA
Jeong *et al* [9], 2018	331	375	Varus only	HA: Pre-op = 13.5°; Post-op = 5.8°. HR: Pre-op = 0.2°; Post-op = 0.3°. HD: Pre-op = 11.0°; Post-op = 5.2°	TT: Pre-op = 0.4°; Post-op = 0.1°. GD: Pre-op = 6.5°; Post-op = 0.2°. TAS: Pre-op = 92.0°; Post-op = 92.0°. TLS: Pre-op = 81.8°; Post-op = 81.3°	Mechanical axis: Pre-op = 11.1° varus; Post-op = 0.3° varus			Valgus hindfoot alignment improved post TKA Subtalar joint became more varus post TKA
Kim *et al* [10], 2018	55	65	Varus only	HAVA: Pre-op = 6.1°; Post-op = 5.7°	TT: Pre-op = 1.9°; Post-op = 1.7°. TAS: Pre-op = 85.9°; Post-op = 84.9°. MCS: Pre-op = 2.4 mm; Post-op = 2.6 mm. MTTJS: Pre-op = 2.8°; Post-op = 2.3°. FTGA: Pre-op = 85.6°; Post-op = 86.5°	Mechanical axis deviation angle: Pre-op = 10.0°; Post-op = 1.9°	95.2	91.5	Valgus hindfoot alignment slightly improved post TKA Newly developed ankle pain post TKA was associated with larger degrees of residual varus knee deformity
Levinger *et al*[11], 2012	19	26	Varus only	FPI: Pre-op = 2.9°; Post-op = 2.7°		FTA: Pre-op = -1.2°; Post-op = 4.9°			Increased range of motion of the rearfoot in the frontal plane post TKA No change in static foot pressure post TKA
Mansur *et al* [12], 2019	72	72	Both varus and valgus	Intersection of the load axis of the leg and the calcaneus axis: Pre-op = -3.8°; Post-op = -4.4°		FTA: Pre-op = ?	74.3	89.4	Varus hindfoot alignment with varus knee deformity remained in varus alignment post TKA Varus hindfoot alignment with valgus knee deformity, valgus hindfoot alignment with valgus knee deformity and valgus hindfoot alignment with varus knee deformity all improved post TKA
Mullaji and Shetty[13],	125	165	Both varus and valgus	TCA: Pre-op = 188°; Post-op = 185.5°		CMAD: Pre-op = 34.3 mm;			Valgus hindfoot alignment with varus knee deformity

2011						Post-op = 0.0 mm. GMAD: Pre-op = 31.0 mm; Post-op = -6.0 mm			improved post TKA 87% of patients had persistent valgus hindfoot alignment post TKA
Okamoto *et al*[14], 2017	75	80	Varus only	Calcaneal pitch: Pre-op = 14.9°. Naviculocuboid overlap: Pre-op = 84.7°; Post-op = 65.7°	TT: Pre-op = 13.1°; Post-op = 4.4°. TI: Pre-op = 9.9°; Post-op = 0.8°	Mechanical axis: Pre-op = 5.0°; Post-op = 0.7°	46.6	60.2	Valgus hindfoot alignment with severe varus knee deformity did not improve post TKA Valgus hindfoot alignment with moderate varus knee deformity improved post TKA
Palanisami *et al*[15], 2020	91	121	Varus only	TH: Pre-op = 9.9°; Post-op = 4.7°. VVI: Pre-op = -0.29; Post-op = -0.04		FTMA: Pre-op = 162.0°; Post-op = 178.8°	59.2	88.7	Valgus hindfoot alignment with varus knee deformity improved post TKA TKA restores foot loading pattern medially
Takenaka *et al*[16], 2016	71	73	Varus only	VVA: Preop = 78.2; Post-op = 76.0		FTA: Pre-op = 184.8; Post-op = 173.9			Valgus hindfoot alignment with varus knee deformity improved post TKA Varus hindfoot alignment with varus knee deformity did not improve post TKA

TKA: Total knee arthroplasty; FTA: Femoral-tibial angle; VVA: Varus valgus angle; TH: Tibial hindfoot; VVI: Varus-valgus index; FTMA: Femorotibial mechanical angle; AOFAS: American Orthopaedic Foot and Ankle Society; TCA: Tibio-calcaneal angle; FPI: Foot posture index; MTTJS: Medial tibiotalar joint space; FTGA: Frontal tibial ground angle; HA: Hindfoot alignment; CMAD: Conventional mechanical axis deviation.

HR and HD of 7.7°, 0.1° and 5.8° respectively. Kim *et al*[10] illustrated a mean postoperative improvement in HAVA of 1.4°. Mansur *et al*[12] demonstrated a mean postoperative improvement of hindfoot alignment of 3.6. Okamoto *et al*[14] illustrated a mean postoperative improvement in naviculocuboid overlap of 19.0°. Palanisami *et al*[15] highlighted a mean postoperative improvement in VVI of 0.25.

Okamoto *et al*[14] noted that a cohort of patients with severe varus knee deformity did not show correction of hindfoot malalignment following TKA[14]. Conversely, Cho *et al*[7] showed that patients with severe varus knee deformity had the greatest overall improvement in hindfoot alignment. Patients with a severe varus knee deformity displayed a mean change in HA of 4.0° ± 3.0° in contrast to patients with a less severe varus knee deformity who displayed a mean change in HA of 1.8° ± 2.5°[7].

Three studies highlighted that patients with preoperative hindfoot varus malalignment with varus deformity at the knee joint retained varus hindfoot alignment post TKA[8,12,16].

Two studies investigated alterations in hindfoot alignment following TKA in patients with valgus deformity at the knee joint[12,13]. Both studies recorded improvements in postoperative hindfoot varus alignment. Mansur *et al*[12] reported an increase in mean hindfoot alignment axis of 7.5, while Mullaji and Shetty[13] recorded a mean decrease in TCA of 1.5°. Also, Mullaji and Shetty[13] reported an improvement in postoperative hindfoot valgus alignment, as evident by a decrease in mean hindfoot alignment axis of 3.3.

Changes in ankle joint alignment following TKA

Three studies reported changes in ankle joint alignment following TKA for knee OA[9,10,14]. There was a decrease in the TT postoperatively in 2 studies, indicating a varus shift in the TT[9,14], with no significant change reported in 1 study[14]. The GD shifted towards a valgus alignment in 1 study[9]. The TLS changed significantly in 1 study[9]. The TAS, DMCS, MTTJS and FTGA showed no statistically significant change following TKA.

Subjective clinical outcomes

Clinical outcomes were evaluated using the American Orthopaedic Foot and Ankle Society (AOFAS) score in 4 studies[10,12,14,15]. The weighted mean preoperative AOFAS score improved from 66.1 ± 18.1 to 82.0 ± 12.9 postoperatively at a mean of 17.6 mo of follow-up. One study reported that patients with newly developed ankle

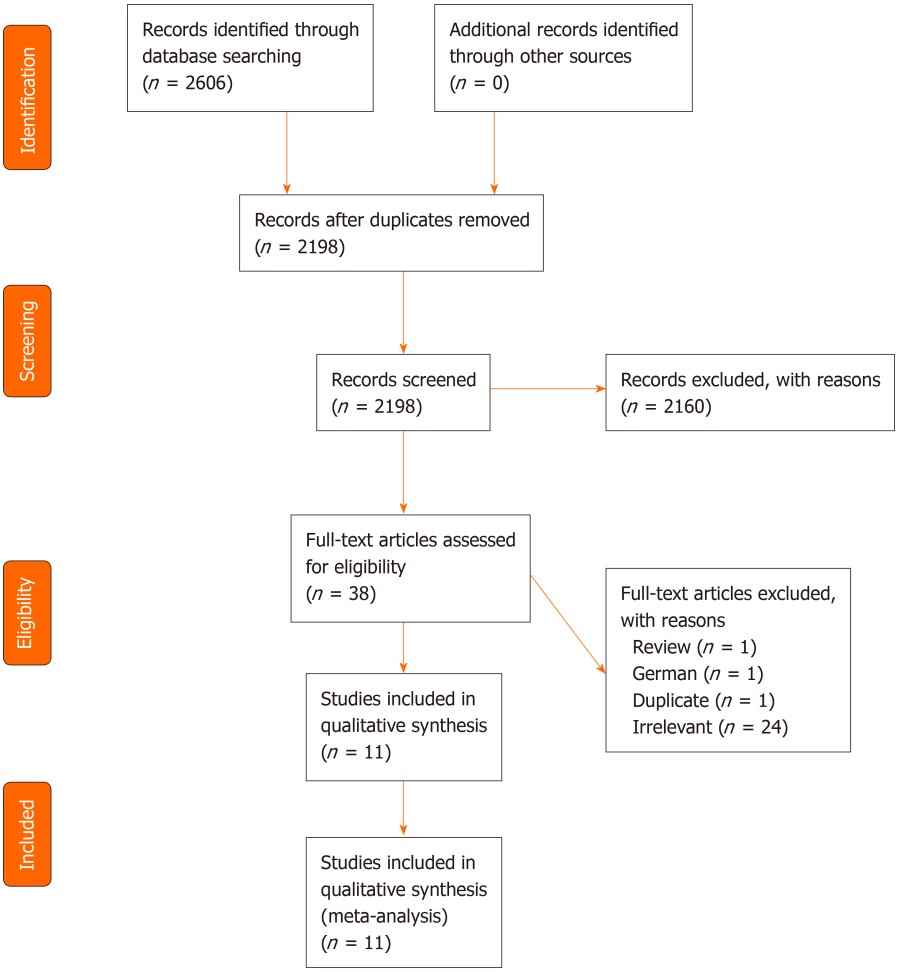


Figure 1 A systematic review of the MEDLINE, EMBASE and Cochrane Library databases was performed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

pain or who experienced an aggravation of existing pain after TKA had significantly larger degrees of residual varus knee than patients without ankle pain before and after TKA or those with ankle pain before surgery that did not change during the follow-up period[10]. One study demonstrated that patients with severe preoperative varus deformity at the knee had no statistically significant improvement in AOFAS score following TKA

DISCUSSION

This current systematic review has found that correction of deformities at the knee joint following TKA typically resulted in improved changes in the alignment of the hindfoot. However, the poor QOE together with the marked heterogeneity between the included studies, underscores the need for further higher quality studies.

All studies reported that preoperative varus or valgus knee deformity was associated with malalignment of the hindfoot. Typically varus knee OA was accompanied by a valgus hindfoot deformity. Furthermore, the findings of this current review highlights that patients who undergo TKA for a varus osteoarthritic knee with pre-existing valgus hindfoot deformity may display improvements in hindfoot alignment postoperatively. This suggests that these patients may have a residual capacity to compensate for the corrected lower limb malalignment. Interestingly, Cho *et al*[7] reported improvement in hindfoot alignment at 6 wk post TKA but little to no improvement at 2 years postoperatively, suggesting that compensatory changes in hindfoot alignment predominantly occur during the early postoperative period. This lack of improvement in hindfoot alignment at the 2 year follow up point may indicate that following the early postoperative period, there may be no further hindfoot alignment compensation as the knee joint alignment has now been corrected following

TKA. However, Takenaka *et al*[16] recorded improvement in hindfoot alignment at 3 wk post TKA with further improvement noted 1 year post TKA. The discrepancy between these 2 studies highlights that further research is warranted to understand the complex lower limb biomechanical alterations that occur in sequential postoperative time points following TKA.

This current study demonstrated that patients with co-existing varus knee deformities and varus hindfoot malalignment showed no improvement in hindfoot alignment post TKA[8,12,16]. There are several reasons that could explain this resistance to change in varus hindfoot deformity. Firstly, varus feet cause nonparallel alignment of the midtarsal axes, which in turn leads to the foot displaying rigid stability so as to support the body's weight[8]. This may reduce the ability of the preoperative varus hindfoot to change alignment following TKA of a varus osteoarthritic knee. Varus hindfoot is often associated with a rigid or non-correctible hindfoot alignment, either from increase calcaneal pitch or mechanical changes from neuromuscular changes that are not reversible. Charcot Marie Tooth is commonly associated with a varus hindfoot but this is typically not compensated for by knee realignment. In contrast, many valgus hindfoot alignments are correctible and flexible adapting to better alignment in the femoral tibia joint by re-establishing improved hindfoot alignment.

The ability to achieve a neutral alignment is essential if knee re-alignment is to have any measurable impact on hindfoot alignment. Tarsal coalition in valgus hindfeet and CMT and other neurological conditions associated with varus hindfeet will prevent re-establishing normal hindfoot alignment. In addition, advanced post-traumatic osteoarthritis (PTOA) of the ankle or subtalar joint will also prevent neutral alignment of the hindfoot[9]. The ability to change alignment of the hindfoot is critical in survivorship of the knee implant as persistent varus hindfoot deformity post TKA may lead to asymmetric wear, osteolysis and failure of the implant[19].

There were conflicting reports regarding the severity of knee joint deformity and postoperative outcomes. Okamoto *et al*[14] demonstrated that patients with severe varus knee deformity presented with postoperative hindfoot pain and valgus alignment[14]. This may in part be explained by the advanced stage of PTOA in the hindfoot and the advanced stage of knee varus malalignment from delayed operative intervention. Restriction in motion preventing restoration of neutral hindfoot alignment would be expected in the advanced stages of PTOA where peri articular osteophytes and soft tissue cicatrization would prevent choparts and ankle joint motion. In contrast, Cho *et al*[7] showed that patients who underwent surgical intervention for severe varus knee deformity had the best postoperative outcomes but his cohort was younger and had less advanced ankle arthritic change[7]. Further studies are required to determine the correlation between severity of knee deformity and post TKA outcomes, but it does seem that earlier intervention in knee OA is helpful in addressing knee pain but also has downstream effects on hindfoot biomechanical alignment and consequent health of the ankle joint.

This current systematic review has demonstrated that there is marked heterogeneity in the assessment of the alignment of the hindfoot. Twelve different radiographic parameters were utilised across the 11 studies, with the TCA being the most commonly utilised metric in 3 studies[6,7,13]. The lack of consensus regarding what radiographic parameter to utilise to evaluate the alignment of the hindfoot underpins the need for a standardised imaging protocol of the limb following knee arthroplasty. In addition, only 2 studies reported radiographic data at 2 or more sequential operative time points[7,16]. Assessing the alignment of the hindfoot at regular intervals postoperatively may be necessary to determine the time at which correction of hindfoot malalignment occurs and could possibly predict the time at which a surgical realignment of the hindfoot is required to protect the longevity of the knee implant (Table 4).

This current systematic review found that only 4 studies reported pre and postoperative clinical scoring systems, with the AOFAS score utilised in all 4 studies [10,12,14,15]. AOFAS scores tended to increase post TKA, suggesting that correction of lower limb malalignment resulted in improved functional and pain outcomes in the foot and ankle. Interestingly, 1 study demonstrated that patients presenting with new or aggravated pre-existing foot and ankle pain following TKA had a residual varus deformity at the knee joint[10]. Furthermore, Okamoto *et al*[14] reported that patients with severe varus deformity at the knee joint had no statistically significant improvement in AOFAS score, possibly due to loss of residual capacity for compensation in the hindfoot[14]. However, these outcomes should be assessed with caution due to a lack of a validated scoring tool for the foot and ankle following TKA.

Table 4 Hindfoot radiographic parameters

Hindfoot radiographic parameters	Studies, *n* (%)
TCA	3 (27.3)
VVA	2 (18.2)
HAVA	1 (9.1)
Intersection of the load axis of the leg and the calcaneus axis	1 (9.1)
TH	1 (9.1)
Calcaneal pitch	1 (9.1)
Naviculocuboid overlap	1 (9.1)
FPI	1 (9.1)
HA	1 (9.1)
HR	1 (9.1)
HD	1 (9.1)

TCA: Tibiocalcaneal angle; VVA: Varus valgus angle; HAVA: Hindfoot alignment view angle; TH: Tibial hindfoot angle; FPI: Foot posture index; HA: Hindfoot alignment angle; HR: Hindfoot alignment ratio; HD: Hindfoot alignment diameter.

This systematic review has several inherent limitations and/or potential biases. The criterion was limited to MEDLINE, EMBASE and Cochrane Library Database articles published exclusively in English. A further limitation was the marked heterogeneity between studies, in terms of both patient selection and pre and post-operative radiographic assessment. As a result, cross-sectional comparison amongst studies could not be analysed. Another limitation with this review is the poor QOE of the included studies. Lastly, the data was not extracted blindly, but was extracted by two independent reviewers and later confirmed by the lead author.

CONCLUSION

In conclusion, this systematic review demonstrated that the hindfoot typically displays compensatory changes in alignment following TKA in patients with knee osteoarthritis. However, the marked heterogeneity between the included studies and poor QOE limits any meaningful cross sectional comparisons between studies. Further, well designed studies, are necessary to determine the changes and outcomes of hindfoot alignment following TKA.

ARTICLE HIGHLIGHTS

Research background

There are a variety of reports demonstrating a relationship between deformities at the knee joint and hindfoot malalignment in patients with knee osteoarthritis (OA).

Research motivation

The relationship between knee joint deformities and alterations in hindfoot alignment following total knee arthroplasty (TKA) has not been fully investigated to date.

Research objectives

To evaluate changes in alignment of the hindfoot following TKA and foot and ankle clinical outcomes in terms of subjective clinical scoring tools following surgical intervention.

Research methods

MEDLINE, EMBASE and Cochrane Library databases were systematically reviewed. Studies reporting changes in the postoperative alignment of the hindfoot following

TKA were included.

Research results

Eleven studies with a total of 1142 patients (1358 knees) were included. Patients with preoperative varus knee deformity and valgus hindfoot deformity demonstrated improvement in hindfoot alignment post TKA. Patients with preoperative varus knee deformity and varus hindfoot deformity demonstrated no improvement in hindfoot alignment following TKA. Twelve different radiographic parameters were used to measure the alignment of the hindfoot, with the tibio-calcaneal angle most frequently utilised (27.3%).

Research conclusions

The hindfoot may display compensatory changes in alignment following TKA in patients with knee OA. However, the marked heterogeneity between the included studies and poor quality of evidence confounds the generation of robust conclusions from this review.

Research perspectives

Further, higher quality studies are required to determine the changes and outcomes of hindfoot alignment following TKA.

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CASE REPORT

Simultaneous repair of bilateral pectoralis major tendons: A case report

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Author contributions: Okoroha KR, Shah S, Buckley P, and Abbas MJ were members of the patients care team and reviewed the literature and contributed to manuscript writing; Okoroha KR and Shah S were the orthopaedic surgeons who managed the patient operatively; Buckley P and Abbas MJ recorded the operative technique and captured images of the patients in the perioperative setting; all authors contributed to revisions of the manuscript and issued approval on the draft submitted.

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Abstract

BACKGROUND

Injuries to the pectoralis major are infrequent, with only a few hundred cases currently recorded in the literature.

CASE SUMMARY

We report a case of a patient who sustained bilateral pectoralis major tendon ruptures. While other cases of bilateral pectoralis major tears have been reported in the literature, the operative management in this report differs. Due to delayed presentation of the patient right and left pectoralis major repairs were performed simultaneously.

CONCLUSION

Patients with delayed presentation of bilateral pectoralis major tendon ruptures can undergo simultaneous repair of both tendon with a good postoperative outcome and high patient satisfaction.

Key Words: Bilateral repair; Pectoralis major; Tendon rupture; Simultaneous repair; Case report

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Core Tip: Patients with delayed presentation of bilateral pectoralis major tendon ruptures can undergo simultaneous repair of both tendon with a good postoperative outcome and high patient satisfaction.

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INTRODUCTION

Injuries to the pectoralis major are infrequent, with only a few hundred cases currently recorded in the literature[1,2]. Yet, pectoralis major tears are occurring at an increasing rate over the past few decades, including over half all reported cases occurring in the past decade[1,3-6]. Over 80% of pectoralis major injuries result from indirect trauma and up to half occur during weight training, especially during the eccentric part of a bench press[1-3,7,8]. We report a case of a patient who sustained bilateral pectoralis major tendon ruptures. While other cases of bilateral pectoralis major tears have been reported in the literature, the operative management in this report differs by providing clinical outcomes for simultaneous repair of both tendons[9-12].

CASE PRESENTATION

Chief complaints

A thirty-nine-year-old man presented to our ambulatory sports medicine clinic with complaints of painful range motion in the upper extremities, as well as localized swelling and ecchymosis over bilateral pectoralis major and arms.

History of present illness

Four weeks ago, the patient was performing a flat bench pressing with 405 Lbs. On the sixth repetition of his second set, the patient described feeling a tearing sensation and hearing loud pop emanating from both axillae before re-racking the weight (Video 1). Patient reports the immediate onset of a dull and aching pain and swelling following the incident, as well as reduced strength in internal rotation and adduction of the bilateral upper extremities. In the subsequent morning the patient described significant ecchymosis and swelling in the axillae and anterior surface of the arms bilaterally. Upon assessment of medications, patient denied the use of anabolic steroids and fluoroquinolones. Due to issues with insurance, the patient delayed seeking care. The patient provided informed consent for all imaging, reports, and publications regarding his injury.

History of past illness

The patient has no known surgical history and a past medical history of a transient ischemic attack, myalgia and Wilson's disease.

Physical examination

During a focused physical exam, our patient presented with a loss of the anterior axillary contour bilaterally (Figure 1), as well as retraction of the pectoralis major muscles medially when performing an isometric contraction in the prayer position (Figure 2). On clinical strength testing, the patient's internal rotation was 4- of 5 bilaterally and adduction was of 4- of 5 bilaterally.

Imaging examinations

Magnetic resonance imaging (MRI) confirmed the diagnosis of bilateral pectoralis major tendon ruptures and demonstrated tears with approximately 7 cm of retraction on the right and 5cm of retraction on the left (Figure 3).

FINAL DIAGNOSIS

The final diagnosis of was bilateral pectoralis major tendon ruptures.



Figure 1 Photographs of patient four weeks since initial injury, demonstrating loss of axillary fold on the right side and on the left side. A: Right side; B: Left side.



Figure 2 Photograph of patient four weeks since initial injury, demonstrating medial retraction of pectoralis major muscle while isometrically contracting in the prayer position.

TREATMENT

Due to delayed presentation of the patient and his desire to return to maximal strength, right and left pectoralis major repairs were performed simultaneously using all suture anchors. The patient was placed in beach chair position and both upper extremities were draped simultaneously (Figure 4). The bed was placed in a slight Trendelenburg and a deltopectoral approach was used (Figure 5). Fascia distal to the clavicular head of the pectoralis major was opened and hematoma was evacuated before identifying the retracted ruptured pectoralis major tendon. A tag stitch was then placed through the tendon to facilitate mobilization (Figure 6). The pectoralis major insertion site was then identified lateral to the long head of the biceps tendon and a burr was used to create a bleeding bony bed (Figure 7). Following the preparation of the insertion site three 2.8 Q fix all suture anchors (Smith & Nephew, Waterford, England, UK) were place with one proximally, one in the middle, and one distally (Figure 8). One set of sutures from each anchor pair was passed through the tendon in a horizontal mattress fashion and the second suture set was passed medially to act as a rip stop (Figure 9). All sutures were sequentially tied from proximal to distal. Range of motion was then examined, and wound was closed and dressed in standard fashion. Postoperatively both shoulders were immobilized for 6 wks. in adduction and internal rotation with a Shoulder Immobilizer.

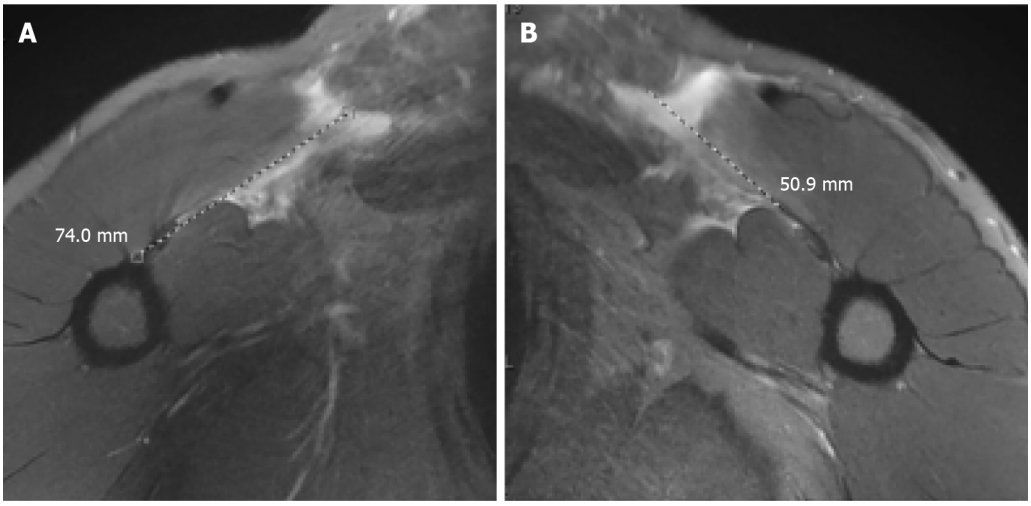


Figure 3 Magnetic resonance imaging of pectoralis major tear. A: 7 cm of retraction on the right pectoralis major tendon; B: 5 cm of retraction on the left pectoralis major tendon.



Figure 4 Photograph demonstrating patient in the beach chair position with both upper extremities draped.

OUTCOME AND FOLLOW-UP

During the first post-operative visit at 10 d following surgery the patient reported PROMIS interference scores for upper extremity, physical function, pain, and depression of 21.2, 26.1, 68.1, and 34.2 respectively. Patient visual analog pain score (VAS) was 7. Rehabilitation started at 2 wks. post-operatively with Cuff isometrics and passive shoulder ROM. After 6 wks. postoperatively the sling was discontinued, and the patient began active shoulder motion, rotator cuff and scapular stabilizer strengthening, and restoration of full passive shoulder range of motion (ROM).

At three-months postoperatively the patient presented with strength of 5- of 5 on clinical evaluation of internal rotation and adduction of the arms bilaterally. The patient had full ROM in forward flexion, abduction, internal rotation and external rotation bilaterally. PROMIS interference scores for upper extremity, physical function, pain, and depression were recorded as 54.2, 56.1, 58.1, and 54.2 respectively. VAS score was reported as 2. In physical therapy the patient continued to progress with strengthening and was permitted to start performing a light bench press. The patient has reported no discomfort with resistance training.

During the patients most recent follow-up, six-months postoperatively, the patient reported PROMIS interference scores for upper extremity, physical function, pain, and depression of 51.4, 56.1, 38.7, and 34.2 respectively. The patient reported a VAS score of 1 and demonstrated full range of motion in forward flexion, abduction, internal

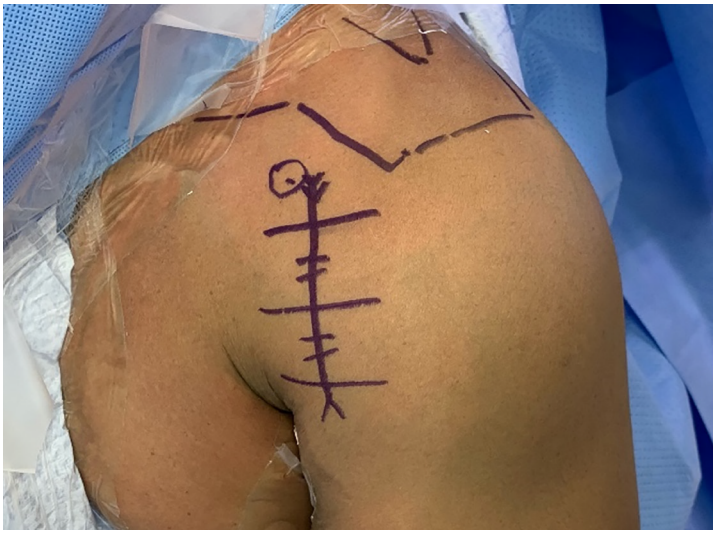


Figure 5 Photograph of anatomical landmarks used to perform a deltopectoral approach

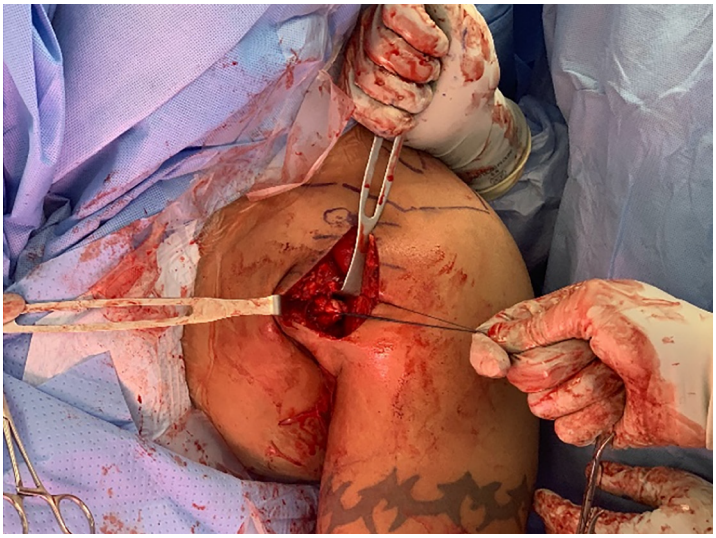


Figure 6 Photograph of a tag stitch that was place through the pectoralis major tendon.

rotation and external rotation bilaterally (Figure 10). Patient has completed physical therapy and was cleared to resume full strengthening activities.

DISCUSSION

Complete tear of the pectoralis major is increasing in frequency over the past few decades. Between the first case recorded in 1822[13] and 1990, fewer than 90 cases were documented in the literature. As of 2010 there have been 365 recorded cases in the literature[1]. According to a recent meta-analysis performed by Bodendorfer *et al* [3], there are currently 693 cases reported in the literature. The authors described that 63.2% of pectoralis major tears occur due to weight training, including 39.5% of all documented tears resulting from a bench press. Eighty-seven percent (n = 603) of all tears underwent surgical management either acutely or chronically. Bodendorfer *et al* [3]'s results were consistent with previous studies which concluded operative treatment is superior to non-operative treatment in both the acute and chronic setting [1,14,15]. When compared to patients managed non-operatively, surgical intervention yielded greater functional improvement according to Bak criteria[2] (scored 1-4; P = 0.027), increased likelihood to regain full isometric strength (P < 0.001), better iso-kinetic strength as measured against the contralateral side (P < 0.001), decreased chance of a resting deformity (P = 0.037), and increased cosmetic satisfaction (P <

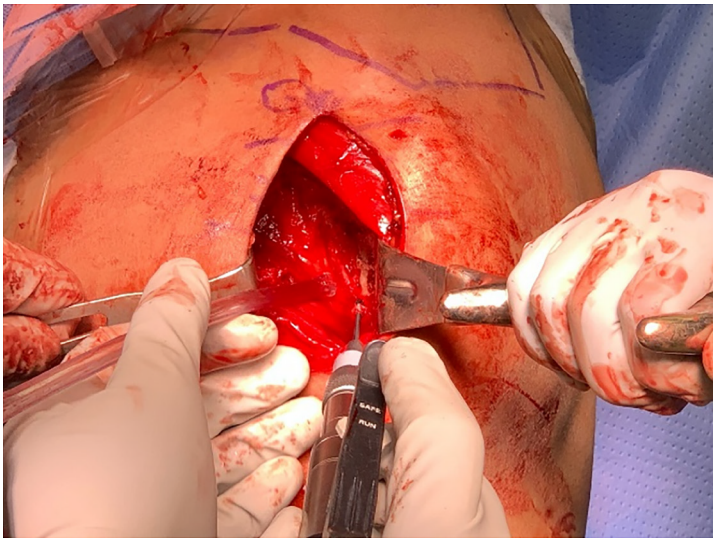


Figure 7 Photograph of the pectoralis major insertion was site with the burr that was used to debride the site and create a bleeding bony bed.

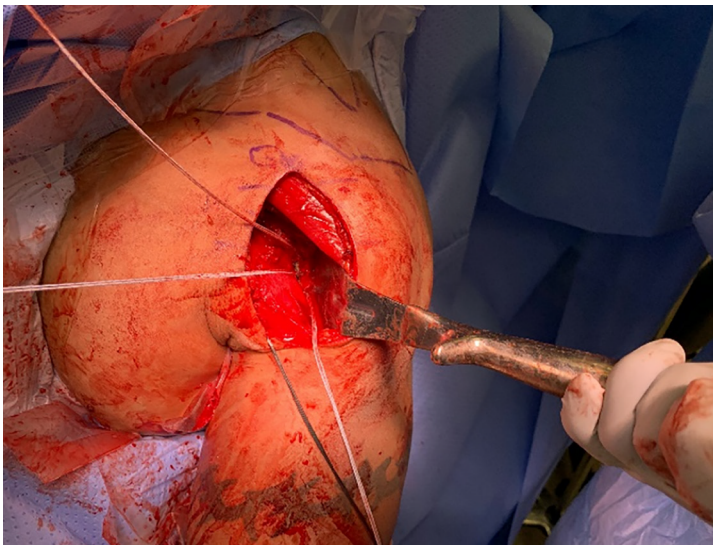


Figure 8 Photograph of the three 2.8 Q fix all suture anchors that were place with one proximally, one in the middle, and one distally.

0.001).

Our patient's bilateral tears occurred during a bench press, the most common mechanism by which pectoralis major tears occur[1-3,7,8]. Additionally, as a thirty-nine year old male, our patient matches the demographic most often affected by pectoralis major tears: males in their third or fourth decade[1-3,5]. MRI was performed (Figure 3) to confirm the diagnosis, determine the severity and location of the tear, and better create a preoperative plan as described by Kadu *et al*[16].

Our patient presented to our clinic 29 d out from injury; if the patient had appeared closer to the date of injury, staggering the surgeries between sides would have been contemplated. This would have allowed for use of the contralateral arm while the surgical arm was placed in a sling. It has been demonstrated that patients who underwent surgery within 6 wks. of injury have better outcomes compared to those who delay surgery beyond 6 wks.[14,15]. Furthermore, the findings from Ritsch's[17] prospective study of 25 patients with chronic pectoralis major tears demonstrated even when post-operative clinical outcomes are adequate, as defined by the Bak criteria, there is a higher risk of complications (24%). Considering all factors along with confirmation from our patient there was someone to help with activities of daily living when both arms would be in a sling post-operatively, we decided to proceed with simultaneous, bilateral pectoralis major repairs. Extra considerations must be made

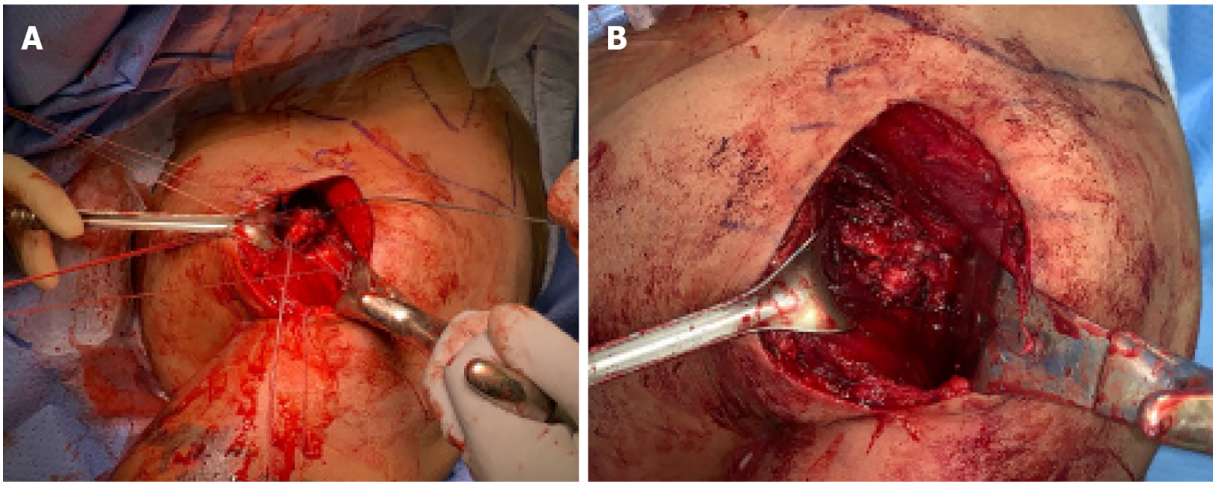


Figure 9 Photograph of sutures being passed through the tendon and all sutures being tied from proximal to distal. A: Sutures being passed through the tendon; B: All sutures being tied from proximal to distal.



Figure 10 Photograph of patient at 6 months post-operatively in abduction internal rotation of shoulder, abduction external rotation of the shoulder, forward flexion of the shoulder, and abduction of the shoulder. A: Abduction internal rotation of shoulder; B: Abduction external rotation of the shoulder; C: Forward flexion of the shoulder; D: Abduction of the shoulder.

when opting to perform simultaneous bilateral surgical repairs. Patient selection is critical particularly in patients with significant comorbidities as there could be potential for increased perioperative complications. Additionally, it is essential that patients understand their limited function in the immediate postoperative period and have a dependable support system to aid in the recovery process. Operative time is also a consideration as performing bilateral simultaneous repairs will lead to increased anesthesia, higher risk for clotting, and increased blood loss than a one sided procedure.

According to the systematic review performed by Gupton *et al*[18], there are currently three main surgical techniques used to repair a pectoralis major tear:

Transosseus suture *via* drill holes, suture anchor, and unicortical or bicortical button. Compared to the button technique, both the transosseus suture (OR = 6.28, 95%CI: 1.37-28.75; P = 0.02) and suture anchor (OR = 3.40; 95%CI: 1.06-10.85; P = 0.04) techniques demonstrated better clinical outcomes according to the Bak criteria. There was no significant difference between the suture anchor and transosseus techniques (OR = 1.85; 95%CI: 0.33-10.45; P = 0.49). The benefits to the suture anchor technique include decreased operative time, less operative insult to the cortical humerus, excellent approximation of the tendon to its anatomic insertion, and reliable fixation [14,18-21]. All-suture anchors confer the benefit of decreased bone loss and smaller anchor footprint has been demonstrated compared to traditional anchors[22-24]. Only a handful of cases regarding bilateral rupture of the pectoralis major tendon have been recorded in the literature demonstrating staggered repair of each tendon[9-12]; however, this case represents a simultaneous repair for bilateral rupture of the pectoralis major tendons.

CONCLUSION

Patients with delayed presentation of bilateral pectoralis major tendon ruptures can undergo simultaneous repair of both tendon with a good postoperative outcome and high patient satisfaction.

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OPINION REVIEW

Revisiting Pauwels' classification of femoral neck fractures

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Author contributions: Nandi S reviewed the existing literature, performed the data analysis, and wrote the manuscript; He has approved the final manuscript

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Abstract

Pauwels' femoral neck fracture classification is based on the biomechanical principle that shear stress and varus force increase along more vertically oriented fractures, resulting in higher risk of fracture displacement and ultimately nonunion. This principle continues to guide construct selection for femoral neck fracture internal fixation and is the foundation for treating non-union with valgus osteotomy. However, with poor inter- and intra-rater reliability, dated treatment recommendations, and unreliable prognostic value, the Pauwels classification cannot be directly applied in its entirety to the management of femoral neck fractures in modern practice.

Key Words: Pauwels; Fracture; Femoral neck; Internal fixation; Arthroplasty

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Core Tip: Pauwels' classification of femoral neck fractures continues to guide construct selection for femoral neck fracture internal fixation and is the foundation for treating non-union with valgus osteotomy. However, with poor inter- and intra-rater reliability, dated treatment recommendations, and unreliable prognostic value, the Pauwels classification cannot be directly applied in its entirety to the management of femoral neck fractures in modern practice.

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INTRODUCTION

Femoral neck fractures are common, with an overall incidence of 146 per 100000 adults in 2013[1]. The increasing incidence with age is demonstrated by the occurrence of more than 800000 femoral neck fractures in patients older than 65 in the United States alone from 2003 to 2013[1]. The vast majority of femoral neck fractures are treated operatively, so there is morbidity and mortality associated with both the injury and its treatment[2]. Femoral neck fractures are costly not only to patients, but also the healthcare system at an estimated 17 to 20 billion dollars per year[3,4].

The first femoral neck fracture classification was described by Cooper[5] in 1823, who categorized these fractures by location into extracapsular or intracapsular variants. Later, in 1935, Pauwels[6] published his femoral neck fracture classification based on biomechanical principles. Fractures were categorized by orientation of the fracture line, across which compressive and shearing forces vary. Errors in interpretation of Pauwels' original manuscript, written in German, have caused confusion surrounding the fracture types in his classification system[7]. Meticulous analysis by several groups, as well as an English-language supplement published by Pauwels in 1976, provided subsequent clarification[7-9].

Pauwels devised his femoral neck fracture classification to: (1) Predict propensity for healing based on forces acting to displace the fracture; and (2) Identify the optimal treatment modality that neutralizes these forces. To achieve the above aims, Pauwels classified femoral neck fracture patterns as observed on anteroposterior (AP) plain films. The Pauwels classification predates modern hip fracture fixation devices and arthroplasty, which are understandably absent from the treatments recommended in the original manuscript. Both of these factors are barriers to the Pauwels classification fulfilling its purpose in current practice, as further discussed below.

CLASSIFICATION

Pauwels classified femoral neck fractures according to the degree of inclination of the fracture line measured from the horizontal on an AP radiograph (Table 1)[6-8]. The three types of femoral neck fractures according to Pauwels are: Type I, with fracture line inclination from 0° to 30°; Type II, with inclination of 30° to 50°; and Type III, with inclination of 50° and greater. Compressive forces predominate across horizontally oriented fractures with a low degree of inclination. Shear stresses and varus forces increase along more vertically oriented fractures with a high degree of inclination. As the distance between the fracture line and the center of the femoral head increases, so do these forces across the fracture.

The treatment and prognosis of femoral neck fractures according to Pauwels is determined by the biomechanical favorability at the fracture site for healing[6-8]. With low fracture line inclination there is compression at the fracture site, which promotes union. For this reason, Pauwels believed fractures with inclination angles less than 30° could be treated nonoperatively. Increasing fracture line inclination, accompanied by greater shear stress and varus force, results in higher risk of fracture displacement and ultimately nonunion. As a result, Pauwels recommended internal fixation for fractures with inclination angles of 30° to 50° and valgus osteotomy for fractures with inclination angles greater than 50°. These measures counteract and reverse, respectively, forces across steeply oriented fractures.

VALIDITY

Existing literature questions the validity of Pauwels' classification with regard to the description, treatment, and prognosis of femoral neck fractures. Several studies have found inter- and intra-observer reliability of the Pauwels classification to be worse than that of both AO and Garden classifications[10-12].

Nearly all femoral neck fractures, except for stress fractures involving the compression side, are currently treated operatively to allow early mobilization, improve healing, and prevent displacement[2]. Internal fixation or arthroplasty are the mainstays of treatment depending on patient age and physical demands[2,13]. However, Pauwels advised nonoperative management of Type I fractures in his classification scheme. Type III fractures are rarely treated with an acute valgus osteotomy as recommended by Pauwels. This procedure is now reserved for femoral neck fracture nonunion[14].

Table 1 Pauwels' classification of femoral neck fractures

	Inclination of fracture line from horizontal	Predominant force at fracture site	Treatment (original classification)	Treatment (modern)	Risk of nonunion
Type I	0-30	Compressive force	Nonoperative	Internal fixation *vs* arthroplasty	Low
Type II	30-50	Shearing stress	Internal fixation	Internal fixation *vs* arthroplasty	Medium
Type III	> 50	Significant shearing stress and varus force	Valgus osteotomy	Internal fixation *vs* arthroplasty	High

Pauwels believed that risk of displacement, and thus non-union, increased with femoral neck fracture line inclination. However, Parker and Dynan[15] found no relationship between Pauwels fracture type and rate of non-union. Calandruccio and Anderson[16] did not observe a higher rate of avascular necrosis with increasing Pauwels inclination angle. These findings are contrary to Pauwels' notion of more unfavorable biomechanics and healing potential at fracture sites with steeper inclination angles.

The failure to observe differences in union rate and avascular necrosis across Pauwels fracture types may be due to surgeon customization of fixation construct according to femoral neck fracture line inclination. In achieving desired union rates by appropriately counteracting fracture site shear stresses and varus forces, Pauwels' principles are validated. Multiple studies have highlighted the need for more robust fixation constructs to address the unfavorable biomechanics of Pauwels Type III fractures[13,17-20].

DISCUSSION

There are several factors that limit the applicability of the Pauwels classification. First, it may be difficult to accurately determine femoral neck fracture line inclination on immediate post-injury radiographs in which the lower extremity is often rotated, abducted, or adducted. In addition, the use of lateral radiographs for further fracture pattern evaluation is not described in Pauwels' classification. It has been suggested that inclination angle be measured on intraoperative post-reduction fluoroscopic imaging, but this diminishes the opportunity to utilize Pauwels' classification for preoperative planning[11]. Nonetheless, there are ways to consistently apply Pauwels' principles to fracture management. Femoral neck fracture line inclination can be determined using preoperative computed tomography images, ubiquitous in the workup of high energy trauma patients though not a part of Pauwels' original classification scheme.

Per Pauwels, a reference horizontal must be reliably established to measure fracture inclination but can only be arbitrarily assigned on potentially suboptimal radiographs. For this reason, Wang *et al*[21] proposed using the line perpendicular to the anatomic axis of the femur as an objective reference horizontal when measuring Pauwels' inclination angle.

Advances in fracture fixation and arthroplasty following publication of Pauwels' classification have rendered its treatment recommendations less applicable in certain circumstances. Pauwels suggested Type I fractures be treated nonoperatively, but it has since been established that nonoperative treatment of femoral neck fractures is associated with an unacceptably high mortality rate[22]. Valgus osteotomy is currently reserved for some femoral neck fracture non-unions, not Pauwels Type III fractures as originally described[13,14]. Pauwels' classification predates the advent of modern arthroplasty, so his treatment rubric does not address this modality. In older patients with displaced femoral neck fractures, fracture line inclination is less relevant as all such fractures are treated with arthroplasty[2,23]. However, the presence of a Pauwels Type III fracture in an older patient may have implications on femoral stem selection, specifically the need for a calcar replacing, fully porous coated, or distally fixed stem, if there is involvement of the lesser trochanter.

CONCLUSION

The Pauwels classification of femoral neck fractures is novel in its biomechanical basis. As a result, Pauwels contributed significantly to the evolution of our understanding and treatment of femoral neck fractures. The principles he described continue to guide construct selection for femoral neck fracture internal fixation and are the foundation for treating femoral neck fracture non-union with valgus osteotomy. However, with poor inter- and intra-rater reliability, dated treatment recommendations, and unreliable prognostic value, the Pauwels classification cannot be directly applied in its entirety to the management of femoral neck fractures in modern practice.

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ORIGINAL ARTICLE

Case Control Study

Paraspinal strength and electromyographic fatigue in patients with sub-acute back pain and controls: Reliability, clinical applicability and between-group differences

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Abstract

BACKGROUND

Paraspinal muscle strength and fatigue are considered important in low back pain (LBP) prevention and rehabilitation. High reliability of paraspinal strength and electromyographic (EMG)-fatigue parameters has not been universally reported. Moreover, the discriminative validity of these parameters requires further exploration, under the threat of potentially poor reliability of the methods examined.

AIM

To investigate the reliability and discriminative validity of paraspinal strength and EMG-related fatigue in subjects with recurrent LBP and healthy participants.

METHODS

Test-retest measurements were performed in 26 healthy and 66 LBP volunteers, for reliability. Paraspinal isometric maximal and mean strength were determined with a maximum voluntary isometric contraction (MVIC) protocol, performed in a custom-made device. For the fatigue test, participants performed a 60% MIVC level continuous isometric contraction of the paraspinals, in conjunction with EMG analysis from 4 muscle sites of the lumbar spine. Initial median frequency (IMF), the median frequency slope (MFslope), as well as the root mean square (RMS) slope EMG parameters were used as fatigue measures. Data were analysed with repeated measures ANOVA for test-retest differences. For reliability, the intraclass correlation coefficient ($ICC_{3,1}$), standard error of the measurement (SEM) and the smallest detectable difference (SDD) were reported. Group-related

differences for fatigue measures were analysed with a Multivariate Analysis of Covariance, with age, weight and strength as covariates.

RESULTS

Isometric strength presented statistically significant between-day differences ($P < 0.01$), however these did not exceed 10% (healthy: 7.2%/LBP-patients: 9.7%) and ICC reliability values were excellent, yet test-retest error was increased for the patient group (healthy: $ICC_{3,1}$: 0.92-0.96, SEM: 5.72-5.94 Hz, SDD: 18.51%-18.57%/LBP-patients: $ICC_{3,1}$: 0.91-0.96, SEM: 6.49-6.96, SDD: 30.75%-31.61%). For the frequency data, IMF reliability was excellent (healthy: $ICC_{3,1}$: 0.91-0.94, SEM: 3.45-7.27 Hz, SDD: 9.56%-20.14%/patients: $ICC_{3,1}$: 0.90-0.94, SEM: 6.41-7.59 Hz, SDD: 17.75%-21.02%) and of MF raw and normalised slopes was good (healthy: $ICC_{3,1}$: 0.78-0.82, SEM: 4.93-6.02 Hz, SDD: 13.66-16.67%/LBP-patients: $ICC_{3,1}$: 0.83-0.85, SEM: 6.75-7.47 Hz, SDD: 18.69%-20.69%). However, the reliability for RMS data presented unacceptably high SDD values and were not considered further. For discriminative validity, less MVIC and less steep MFslopes were registered for the patient group ($P < 0.01$).

CONCLUSION

Reliability and discriminative ability of paraspinal strength and EMG-related frequency parameters were demonstrated in healthy participants and patients with LBP.

Key Words: Low back pain; Power spectral analysis; Surface electromyography; Multifidus; Reliability

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Core Tip: Patients with low back pain (LBP) frequently exhibit muscle strength and fatigue impairments. Sixty-six patients with sub-acute recurrent LBP, able to perform a short duration isometric maximal strength evaluation, followed by a brief submaximal endurance performance test of the paraspinals, demonstrated strength deficits, as well as electromyographic (EMG)-fatigue differences in relation to a group of healthy participants. Test-retest reliability examining the level of accuracy of strength and EMG-fatigue measures, and the discriminative validity of frequency data were also reported. There were no adverse effects of the methodology followed. Paraspinal muscle re-training to improve the identified deficits should be emphasised.

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INTRODUCTION

Low back pain (LBP) is drawing a lot of research effort worldwide, due to the disability and work loss associated with this health care condition[1]. For approximately 80% of LBP cases labeled as non-specific LBP a precise diagnosis cannot be established and only 15% of cases can be attributed to a specific pathology[1]. The "non-specific" category is the one that presents the greatest challenge, as it forms the largest group but also as there seems to be no apparent etiologic link between pain and structure[2].

Due to the episodic nature of LBP, the condition has been labelled as recurrent, if present on less than half the days (< 6 mo) in a 12-month period, occurring in multiple episodes over the year[3]. Around 2/3 of people who ever had back pain will have some recurrence each year[4]. The causes of recurrence are not clear and may vary for different populations, however both biomechanical and psychosocial factors have been proposed as contributors to LBP disability[1,5], with alterations in muscle structure

prior to study inclusion.

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and function being more evident in chronic LBP (CLBP) than in recurrent LBP (RLBP) [6,7].

The trunk muscle activity functional alterations already evident in people with RLBP even during periods of remission of symptoms compared to healthy controls, have been recently summarized as greater co-contraction, different redistribution of muscle activity, and delayed postural control of deeper trunk muscles[8]. Redistribution of the pattern of activity between different parts of the paraspinal muscles, synergistically contracting in response to the functional demands of spinal movement and stability, has also been described to vary between the upper and lower spinal segments in CLBP and healthy controls, rendering the lower spinal segments of patients with CLBP relatively unprotected upon sustained contractions, registering in parallel deficits in timed endurance[9]. Additionally, patients with RLBP compared to those with CLBP demonstrated a generalised lack of activation ability of the paraspinals while performing a low-load lumbar extension task, corresponding to a lower metabolic activity at both the erector spinae and multifidus and combined with less perceived exertion following completion of the task, possibly due to the lower activation levels of those muscles[6].

Considering the anti-gravity functional role of the paraspinals muscles, good paraspinal muscle endurance (fatigue-resistance), assessed with an isometric time to complete exhaustion test was found to prevent first-time occurrence of back pain in men only[10] and in both men and women, however only for subjects in the lowest performance tertile[11]. Measuring paraspinal fatigue to complete exhaustion possesses inherent limitations, as measurements can be affected by patients' psychology[12,13], depending on their willingness to perform a test that is physically demanding and potentially having a pain-provocation effect during its execution and afterwards.

Given the significant role of paraspinal muscle fatigue in LBP progression[14,15], alternative fatigue assessment techniques were required, to overcome validity issues in the determination of paraspinal endurance with the classic Sorensen test performed to complete exhaustion, especially in pain populations[16]. Significant metabolic processes within the muscle, associated with a decreasing pattern of motor unit firing frequencies can be detected with electromyographic (EMG) monitoring from the beginning of a contraction, much earlier than the time of mechanical inability to sustain the contraction, with accurate methods required to assess the pattern of these processes[17]. Therefore, brief paraspinal muscle testing, performed at set percentages of a maximum voluntary isometric contraction (MVIC), estimating the fatigue characteristics of contracting muscles from EMG-related parameters have been developed [18]. Indeed, EMG-fatigue data were more reliable under a task performed at a set percentage of an MVIC than a modified Sorensen test of 1 min duration, when directly compared in healthy participants[19].

Besides the brevity of the contractions required and the non-invasive nature of the surface EMG methods involved, it is of high importance to ascertain the reliability and validity level of the EMG-related spectrum and amplitude parameters of the paraspinal muscles, therefore providing an accessible monitoring method for clinicians [17]. However, the random nature of the EMG signal in general, as well as the EMG activity redistribution differences between healthy controls and patients with LBP[9], render these measurement properties difficult to achieve[20-22]. Additionally, the safety of paraspinal muscle maximal strength assessment in healthy and patient populations is important, due to the intense contractions involved. Due to the different physiological and structural changes identified between patients with recurrent and CLBP[6], between patients and healthy controls[9,23] and a possible role of paraspinal EMG-determined fatigue in the prediction of LBP development[15], the measurement of EMG-fatigue parameters of these muscles in different LBP patient subgroups and subjects without LBP requires systematic study.

The aims of this study were to investigate the reliability and discriminative validity of paraspinal strength and EMG-related endurance spectrum and amplitude parameters in subjects with RLBP at the sub-acute stage of symptoms in relation to healthy participants.

MATERIALS AND METHODS

Subjects

Adult subjects (> 18 years), without LBP (n = 26) and patients with LBP (n = 66), participated in this study, between January-September 2000. Subjects without LBP

were either students or University employees. Patients were recruited from the orthopaedic clinic of a local hospital and several local general practices. Patients were eligible for the study if they had a history of RLBP (repeated episodes of pain in past year collectively lasting for less than 6 mo)[24] of a nonspecific nature, defined as back pain complaints occurring without identifiable specific anatomical or neurophysiological causative factors[2]. To establish this, all patients included had a prior clinical examination by their physician, including a radiograph or a magnetic resonance imaging scan. Patients with previous spinal surgery, "red flags" (*i.e.*, serious spinal pathology or nerve root pain signs), signs and symptoms of instability (radiological diagnosis of spondylolysis or spondylolisthesis corresponding to a symptomatic spinal level; "catching," "locking," "giving way," or "a feeling of instability" in one or multiple directions of spinal movement)[25] were excluded. It was ensured that patients' symptoms were at a subacute stage, to avoid pain interference with testing. The anthropometric data of patients and healthy participants are presented in Table 1. Additionally, patients had to be medically fit (no cardiovascular, neurological or musculoskeletal inflammatory conditions), no pregnancy for female participants and willing to participate in the experimental procedures and be able to travel independently to the hospital. All subjects were employed at the time of study and were not involved in any current workers' compensation or litigation procedures.

The local National Health Service (NHS) Trust and University Ethical Committees granted ethical approval for all experiments. All research assessments were conducted in a local research centre. All subjects gave informed consent prior to their participation. All rights of participants were protected at all times, according to the declaration of Helsinki.

Apparatus and procedures for paraspinal strength measurement

Muscle strength was assessed in a custom-made isomyometer designed and manufactured by the Medical Physics Department (St Mary's Hospital, Central Manchester Healthcare Trust-CMHT). Its design was based on a very similar type of myometer developed in the Boston Neuromuscular Research Centre, the "Back Analysis System"[18,26]. Subjects were put in a standing position in the myometer, with appropriate stabilisation of the lower limbs. Subjects had to pull maximally backwards performing an isometric contraction of their paraspinal muscles and force was registered on an S-type load cell (250-kg Tedea Huntleigh, United Kingdom), positioned directly in front of their chest. A special built-in calibration system of the back myometer was also employed, in order to regularly test the transducer's linear response between 0-200 kg, with known weights (Medical Physics Dept). An inextensible strap made of nylon linked the transducer to the subjects. The strap was securely fixed on the subjects' back around the T6-T7 level, through a chest harness (Figure 1). In order to be able to comfortably generate paraspinal muscle strength, the hip, knees and ankle joints were placed in mid-range functional positions. The force transducer was interfaced to a computer and by means of a graphical programming analysis system (LabVIEW 5.0™, National Instruments, Texas, United States), its output was online displayed on a flat-screen computer monitor placed at participants eye-level for visual feedback purposes.

Paraspinal muscle MVIC was determined in the upright position, in the following manner: three or more MVIC attempts were requested until the efforts were within 5-10% of each other. The best effort was taken as the MVC. Contraction duration was kept as short as possible (3-5 s), to minimise any reduced motivation or pain arising from prolonged contractions. Rest intervals between repeat MVICs were set at 60-s[27,28].

Apparatus and procedures for EMG

A four-channel EMG recorder (MP100 WSW, BIOPAC Systems), was used to collect EMG signals from 2 different back muscles bilaterally, the erector spinae (L2/3) and multifidus (L4/5). EMG signals were high-pass and low-pass filtered at 8 and 500 Hz respectively, amplified (× 10, CMRR: 110 dB min, SNR: 65 dB min) and analogue-to-digital converted at a sampling rate of 1024 Hz. An additional sharp 50 Hz notch filter was applied for DC noise removal. The waveforms collected were online analysed by a graphical programming analysis system (LabVIEW™ 5.0) in order to continuously derive the median frequency (MF) of the power density spectrum every second, using a Fast Fourier Transform algorithm. Also, the root mean square (RMS) was calculated every second. A linear regression line was fitted through the MF and RMS 60-s history, to obtain a measure of the rate of MF decrease (Figure 2) and RMS increase.

Table 1 Anthropometric measures (mean ± SD) of participants

	Age (yr)	Height (cm)	Body mass (kg)	BMI (kg/m^2)
Healthy				
Male (n = 13)	27.0 ± 6.8[a]	178.4 ± 5.5	78.9 ± 8.7	24.7 ± 2.3
Female (n = 13)	24.6 ± 5.3[b]	163.0 ± 8.0	56.8 ± 5.7[b]	21.5 ± 3.5[b]
Total (n = 26)	25.8 ± 6.1[b]	170.7 ± 10.4	67.8 ± 13.4[b]	23.1 ± 3.3[b]
Patients				
Male (n = 34)	35.7 ± 10.2	177.5 ± 6.4	81.1 ± 10.6	25.7 ± 2.6
Female (n = 32)	39.2 ± 10.9	166.2 ± 5.8	74.5 ± 13.6	26.9 ± 4.4
Total (n = 66)	37.4 ± 10.6	172.1 ± 8.4	77.9 ± 12.5	26.3 ± 3.6

Significantly different to patients' corresponding data:
[a]P = 0.01.
[b]P < 0.01.
BMI: Body mass index.

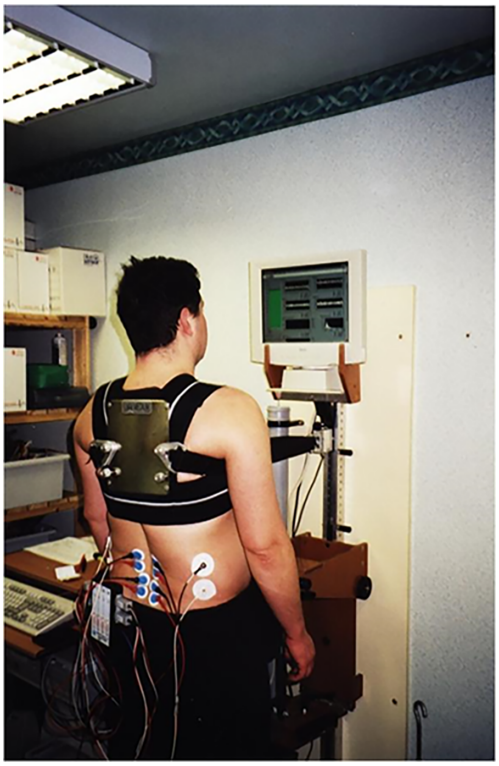


Figure 1 Performance of the 60-s isometric endurance test.

The bipolar electrode technique was utilised for the acquisition of the EMG signal. Appropriate skin preparation methods were used (light abrasion with fine sandpaper and wiping contact areas with cotton-wool soaked with surgical spirit) to reduce skin resistance to acceptable levels for recording, below 10 KOhms[19]. Four pairs of disposable pregelled surface electrodes (Ag/AgCl, Blue Sensor M-00-S, Medicotest, Ltd.) were applied in the direction of the muscle fibres, according to previous anatomic specifications[27,29]. As no significant differences have been identified between male and female subjects in the fibre orientation of both muscles[30], a uniform procedure was followed for electrode placement in both genders. The reference electrodes for each of the channels were placed on the skin surface, overlying an electrically unrelated tissue to the one the bipolar configuration was recording from [19]. Inter-electrode distance for the recording electrodes was set at 20 mm. The electrode location was reproduced in follow-up assessments by tracing their initial

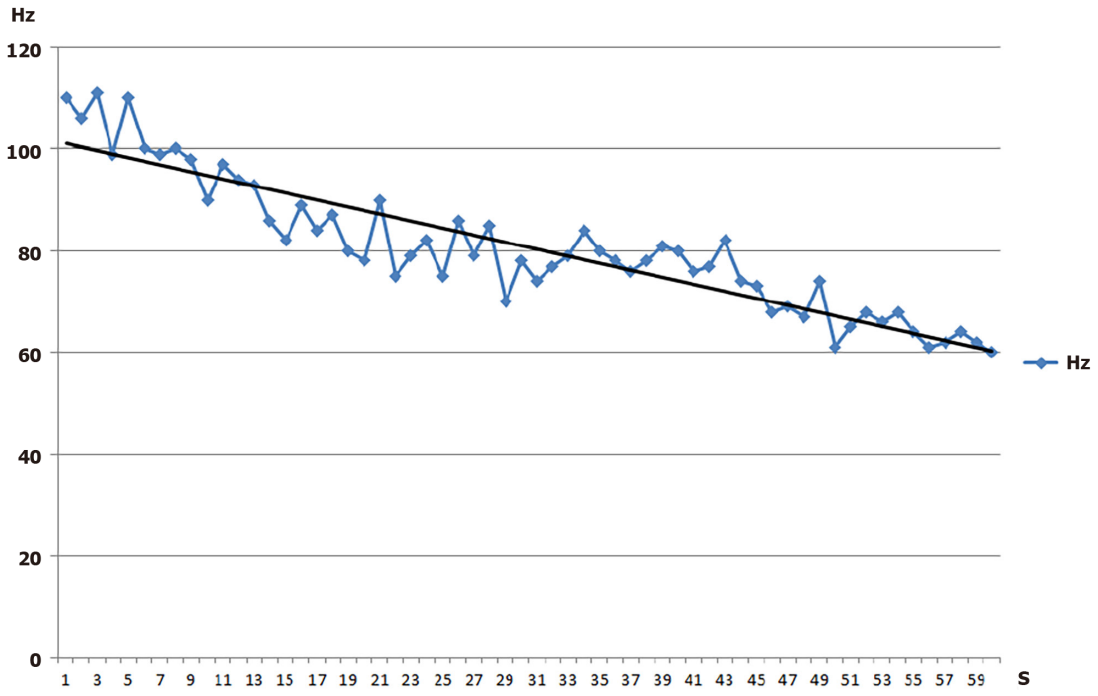


Figure 2 Schematic representation of the median frequency decrease with time. Hz: Hertz.

location onto a transparent A4 sheet, along with natural skin blemishes and distinctive marks, at the first assessment[19]. Skin impedance was checked right after the application of electrodes and was generally kept below 10 KOhms. In very few occasions appropriate skin impedance was not achieved and those electrodes had to be replaced and the skin preparation technique to be repeated.

Testing protocol and experimental design

The principal investigator conducted all experiments (test-retest reliability) in healthy participants and patients with LBP, to minimise any between-rater variance. Participants' paraspinal muscle strength and fatigue performance were assessed on two separate occasions, with a week's interval between measurements for normal subjects and a 3-5 d interval for patients. During the time interval between the 2 measurements, subjects were asked to maintain normal activities.

Muscle fatigue measurements followed the strength measurements on each of the 2 testing days. All subjects performed a 60% MVIC back muscle contraction in the isomyometer for 60 s, while EMG signal was acquired and online transformed to collect all EMG-fatigue related measurements for subsequent analysis.

Statistical analysis

Sample size was based on an a priori power calculation, estimating that at least 26 participants per group would be required to detect a 6.6%/min between-group difference in normalized MF slopes (MFslopes), at 80% power and a significance level of a = 0.05 (nQuery Advisor, v.3.0, Statistical Solutions, Saugus, MA, United States)[27].

The normality of distribution of all continuous variables was examined with the Kolmogorov-Smirnov test. Demographics were compared between-groups (independent samples *t*-test), to identify possible significant differences in factors known to affect the EMG-fatigue measures. Significant systematic between-sides differences were examined for the EMG-fatigue parameters (paired samples *t*-test).

For the reliability study, repeated measures ANOVA analysis was performed to detect any significant between-day systematic differences for each population separately. Test-retest reliability was established with 3 different measures, one of relative reliability, the intraclass correlation coefficient ($ICC_{3,1}$)[31] and two of absolute reliability, the standard error of measurement (SEM)[32,33] derived from the ANOVA error components and the smallest detectable difference (SDD)[33], to determine the magnitude of change that exceeds the threshold of measurement error at the 95% confidence level and is not to be attributed to test-retest error. The $ICC_{3,1}$ was chosen, as only one rater was involved in all measurements[31]. ICC values less than 0.50

indicate poor reliability, between 0.50 and 0.75 moderate, between 0.75 and 0.90 good and values greater than 0.90 excellent reliability[31]. The SEM is based only on the within-subject error/variability, it is a measure of the "precision" of measurement, expressed in the same units as the original measurement and can be directly compared against subjects' values. SDD is considered a "clinical applicability" index, derived from the SEM (SDD = 1.96√2SEM), expressed either in raw terms (actual units of measurement) or as a percentage of the parameter's grand mean. It is a useful index for diagnostic tests, indicating the level of change in a parameter attributed with 95% certainty to a true change in a subject's condition, instead of being caused by test-retest errors. A small SDD associated with repeated test application renders a measurement more responsive to change.

For paraspinal strength, two force variables were derived: mean strength (the mean of 3 MVICs within 5%-10% of each other) and maximum strength (the highest of the 3 MVICs) to establish whether any of the two presented an advantage over the other. If EMG-fatigue reliability indices were of good-excellent level, measures were averaged across bilateral muscles within a session, as this practice has been previously reported to increase the reliability of these measures further[34].

For discriminative validity, preliminary analysis was conducted (independent samples *t*-tests), to determine which of those EMG-fatigue variables that displayed good-excellent reliability also presented significant between-group differences. Subsequently, a one-way Multivariate Analysis of Covariance (MANCOVA) was conducted to determine whether the initially detected statistically significant between-group differences in EMG-fatigue parameters would remain significant, after controlling for factors that could have influenced in parallel the EMG-fatigue parameters. Such factors, according to previous studies, were age[35-38], participants' body mass[37] and the MVIC levels used for EMG-fatigue testing, with higher force levels resulting in higher fatigue rates[26] and were introduced as covariates. The assumptions required for conducting ANCOVA analysis were checked with relevant statistical procedures[39]. The statistical review of the study was performed by a biomedical statistician.

RESULTS

All data satisfied the normality of distribution criterion and were therefore summarised as means ± SD and analyzed with parametric statistics. The demographic characteristics of each group are presented in Table 1. Significant between-group differences were identified for age ($P < 0.001$), weight ($P = 0.002$) and body mass index ($P = 0.001$). Male and female participants were equally distributed in both groups, thus the effect of gender on EMG parameters was controlled.

Raw data from the two testing occasions are presented in Tables 2 and 3. For strength, the repeated measures ANOVA revealed statistically significant between-day differences in both groups, due to generally better performance on day 2 (Table 2). In clinical terms though, the mean % increase detected was rather insignificant (6.5%-7.2% for healthy and 9.4%-9.7% for patients). Relative reliability ICC indices were excellent for both mean and maximum MVIC, however the SDD was around 18.5% for healthy and 31.0%-31.5% for patients with LBP (Table 4).

For the EMG-fatigue measures (Table 3), only the L2/3 MFslope on the right side (raw) in healthy and L4/5 MFslope on the L side (normalized) in patients were significantly steeper on the second day. Data between sides were pooled, as no apparent R/L differences were present in general. EMG-fatigue reliability was similar in both populations (Table 5). The ICCs for the initial MF (IMF) data from individual channels and for the merged R/L values were excellent and the SDDs were between 9.5%-20.0% for healthy and 17.7%-21.0% for LBP patients. The ICCs for the raw and normalised MFslopes were good and the SDDs were between 13.7%-16.7% for healthy and 18.7%-20.7% for LBP patients. All 3 reliability indices (ICC, SEM, SDD) generally improved for the pooled data. However, the ICCs for the amplitude data (RMSslopes) were poor-moderate and the SDDs were between 41.1%-67.0% for healthy and 30.0%-40.1% for LBP patients, deemed as unacceptably high for clinical applications.

For the discriminative validity, no significant differences were identified for the IMF, therefore this parameter was not tested further, while all MFslopes presented significant between-group differences ($P < 0.001$). A one-way MANCOVA analysis determined that there was a statistically significant difference between the 2 groups of participants on the combined dependent variables, after controlling for age, weight and MVIC, $F(4,84) = 3.95$, $P = 0.006$, Wilks' Lambda = 0.835, partial $\eta^2 = 0.165$. Follow

Table 2 Maximum strength (mean ± SD) values in controls and patients

	Non-LBP (*n* = 26)			LBP (*n* = 66)		
MVIC (kg)	**Day 1 (practice)**	**Day 2**	***P* value**	**Day 1 (practice)**	**Day 2**	***P* value**
Maximum	85.8 ± 23.7	91.4 ± 26.7	0.005[b]	58.7 ± 24.8	63.5 ± 26.5	0.0005[b]
		Mean increase: 6.5%			Mean increase: 9.4%	
Mean	82.6 ± 22.7	88.5 ± 25.5	0.002[b]	56.0 ± 24.1	61.1 ± 26.0	0.0005[b]
		Mean increase: 7.2%			Mean increase: 9.7%	

[b]$P < 0.01$.

MVIC: Maximum/mean voluntary isometric contraction.

up univariate tests revealed that differences between healthy and participants with RLBP were highly significant ($P < 0.009$) for all the EMG-frequency slope data (raw MFslopes and normalised MFslopes), when controlling for age, weight and MVIC (Table 6). Assumptions for running a one-way MANCOVA were systematically checked prior to its conduct. Linear relationships between pairs of dependent variables and between pairs of dependent variables and covariates within each group of the independent variables were examined with scatterplot matrices. Homogeneity of regression slopes and homogeneity of variances and covariances were equal in all groups of the independent variable (Box's M Test of equality of covariance matrices, $P = 0.06$). Homogeneity of error variances of the dependent variables within each group were also equal (Levene's test of equality of error variances, $P > 0.05$). No significant univariate outliers were detected in the groups of independent variables for each of the dependent variables, by inspection of the standardised residuals.

DISCUSSION

Back pain is a very prevalent musculoskeletal pathology of recurrent nature[4], and has been associated with a variety of possible causative factors[5]. 'Previous LBP' significantly contributes to the condition's recurrence, having an odds ratio between 1.5-4.5[5]. However, many of the remaining physical impairments from 'previous LBP' episodes that possibly contribute to symptoms' recurrence remain speculative, as in their majority these are not apparent with radiological methods or are masked during clinical assessment by co-existing pain, disability or psychological parameters[1]. Thus LBP is labelled in many instances as 'non-specific'[2].

Nearly all (14/15) clinical guidelines on the effective management of non-specific LBP in primary care recommend the use of exercise, among other treatment options [40]. The type of exercise should be adapted according to the specific requirements of each LBP stage, however endurance re-training of the trunk muscles is well-placed within the 'muscle re-education' algorithm proposed[41]. Periods of pain remission between recurrences should be viewed as opportune timeframes to assess and functionally re-train the neuromuscular and anatomical deficits of trunk muscles, than being periods of rest that progressively lead to deconditioning of the neuromuscular system[8].

Under this framework, the present study aimed to assess the reliability of MVIC and of EMG time-dependent frequency and amplitude parameters of the paraspinals during an isometric fatigue test at 60% MVIC level, in patients with RLBP and healthy controls. Group-related performance differences were also examined.

Paraspinal strength

Many factors need to be carefully considered in a maximal performance test such as the assessment of isometric strength. The upright position of the subjects was selected, as it has been successfully used before in multiple studies of different research centres [23,42,43], without any known contra-indications reported in the literature (safety of test ensured). Also, the intention was to avoid any lifting-type strength assessment activities where the trunk is in forward flexion[44]. Trunk forward flexion may have been the position that some of the LBP participants had "injured" themselves in the past and also it is not a comfortable position for many LBP patients[25], so on these grounds it was avoided. Additionally, no significant benefit over the upright position

Table 3 Mean ± SD values on 2 separate days for initial median frequency, median frequency-slope and root mean square for the isometric endurance test in both groups

	Healthy (*n* = 26)			LBP (*n* = 66)		
Parameter	**Day 1**	**Day 2**	***P* value**	**Day 1**	**Day 2**	***P* value**
IMF (Hz)						
L2/3 R	60.3 ± 10.9	61.0 ± 11.1	0.48	66.5 ± 17.6	66.1 ± 15.8	0.82
L2/3 L	58.2 ± 9.0	59.1 ± 12.3	0.52	63.5 ± 17.2	61.9 ± 13.2	0.18
L4/5 R	89.3 ± 20.3	91.0 ± 16.4	0.49	83.2 ± 24.3	83.0 ± 21.3	0.89
L4/5 L	90.9 ± 20.1	92.3 ± 17.3	0.59	82.7 ± 26.0	83.5 ± 20.8	0.59
L2/3	59.24 ± 9.7	60.1 ± 11.4	0.44	65.0 ± 16.4	64.0 ± 13.8	0.39
L4/5	90.1 ± 19.4	91.6 ± 15.9	0.49	82.9 ± 24.3	83.2 ± 20.0	0.83
MF slopes (raw, Hz/s)						
L2/3 R	-0.30 ± 0.14	-0.35 ± 0.12	0.02[a]	-0.12 ± 0.16	-0.12 ± 0.17	0.77
L2/3 L	-0.30 ± 0.11	-0.31 ± 0.10	0.52	-0.10 ± 0.18	-0.11 ± 0.14	0.41
L4/5 R	-0.48 ± 0.16	-0.54 ± 0.22	0.19	-0.23 ± 0.25	-0.22 ± 0.20	0.62
L4/5 L	-0.56 ± 0.21	-0.61 ± 0.19	0.19	-0.21 ± 0.25	-0.23 ± 0.25	0.53
L2/3	-0.30 ± 0.11	-0.33 ± 0.10	0.08	-0.11 ± 0.16	-0.11 ± 0.15	0.51
L4/5	-0.52 ± 0.17	-0.57 ± 0.19	0.13	-0.22 ± 0.23	-0.22 ± 0.20	0.84
MF slopes (normalised, %/min)						
L2/3 R	-28.8 ± 11.5	-31.5 ± 9.0	0.14	-9.0 ± 15.2	-9.9 ± 15.8	0.55
L2/3 L	-29.9 ± 9.3	-29.8 ± 8.4	0.95	-8.1 ± 15.9	-10.5 ± 14.8	0.11
L4/5 R	-34.0 ± 11.3	-34.2 ± 11.9	0.90	-15.0 ± 15.7	-15.0 ± 12.0	0.98
L4/5 L	-36.4 ± 10.7	-37.7 ± 10.4	0.58	-13.2 ± 14.0	-17.1 ± 13.3	0.01[a]
L2/3	-29.3 ± 9.8	-30.6 ± 7.9	0.39	-8.6 ± 14.8	-10.2 ± 14.5	0.21
L4/5	-35.2 ± 9.6	-36.0 ± 10.2	0.67	-14.1 ± 13.7	-16.1 ± 11.7	0.10
RMS slopes (normalised, %/min)						
L2/3 R	43.4 ± 45.0	37.4 ± 35.2	0.35	10.4 ± 21.4	11.3 ± 18.5	0.72
L2/3 L	27.4 ± 30.8	29.0 ± 28.3	0.73	11.3 ± 17.3	13.9 ± 22.8	0.17
L4-5 R	42.6 ± 35.9	32.7 ± 29.2	0.19	14.3 ± 21.2	12.6 ± 22.2	0.43
L4/5 L	37.1 ± 36.2	38.4 ± 34.1	0.85	10.3 ± 19.3	13.9 ± 21.2	0.07

[a]$P < 0.05$.

Hz: Hertz; IMF: Initial median frequency; MF: Median frequency; RMS: Root mean square.

in EMG-fatigue reliability has been demonstrated with the latter type of experiment [44]. Confirming previous observations, MVIC measurement with the methods used was not associated with any new low back injuries. Only slight discomfort was reported by some participants from the patient group during the performance of the MVICs and for a short period (around 10 min) afterwards.

Similar trends with other strength experiments[43] were observed for the non-LBP as well as the RLBP population used for the paraspinal strength repeated measures, reflecting a learning effect between the 2 measurement sessions. Both groups of participants generally demonstrated increased strength output on the second testing occasion. However, due to the standardised methodology employed[28], the average increase was kept below 10% (between 6.5%-9.7%), a value clinically rather insignificant. Indeed, a similar previous study that conducted 3 measurement sessions, reported no further improvement in isometric MVIC after the second session[34]. In view of this learning effect though, for the discriminative validity analysis, only data from the second testing occasion were utilised.

Table 4 Maximum strength reliability indices in controls and patients

	Controls (*n* = 26)			Patients (*n* = 66)		
Parameter	**$ICC_{3,1}$**	**SEM**	**SDD%**	**$ICC_{3,1}$**	**SEM**	**SDD%**
MVIC (kg)						
Maximum	0.92 (0.83-0.97)	5.94	18.57	0.91 (0.86-0.94)	6.96	31.61
Mean	0.96 (0.90-0.98)	5.72	18.51	0.96 (0.93-0.97)	6.49	30.75

ICC: Intraclass correlation coefficient; SEM: Standard error of the measurement; SDD: Smallest detectable difference; MVIC: Maximum/mean voluntary isometric contraction.

EMG-Fatigue: initial values and time dependent changes

This reliability study in the patient group was the largest so far in the literature[20]. Results clearly indicate that the technique employed for healthy participants and patients, considering the relative (ICCs) and absolute reliability indices (SEMs/SDDs) together[32,33], demonstrated good-excellent reliability for all the frequency-related parameters and that clinical differences can be reliably detected for values of EMG-fatigue MFslopes that exceed 18.7%-20.7%/min of initial values. Averaging data between sides, as previously suggested[34], increased reliability and decreased measurement error even further. The general trend in participants of this study was that no between-sides imbalances were present. It has to be emphasized, though, that the method of averaging data between-sides renders the technique insensitive in detecting between-sides differences present in some individuals.

Conversely, amplitude related RMS slopes presented with poor-moderate test-retest reliability and were not processed further. It might have been that these indices were either more sensitive to the differences in MVIC levels between-sessions or that they present more variability in day-to-day testing, due to load sharing phenomena present in sustained contractions[9]. However, as a general trend, it can be attested that RMS increases were lower in general for the patients with RLBP than the healthy participants (Table 3), denoting a lower activation of those muscles in RLBP, similar to other studies[6,41].

Similar findings for poor reliability in RMS amplitude slopes have been previously reported for isometric fatigue testing at 60% MVIC level[19,44], however for MFslopes variable reliability levels have been reported[20-22,34].

EMG-frequency parameters group-related performance differences

For discriminative validity, a one-way MANCOVA determined that there was a statistically significant difference between the 2 groups of participants regarding the EMG-frequency raw or normalised MFslopes from both upper and lower muscle sites, after controlling for age, weight and MVIC. Interestingly, while the EMG time-dependent frequency parameters presented highly significant differences between the two groups, less decline in MFslopes was demonstrated in patients with RLBP.

The rate of decrease in MF, as expressed by the least squares linear regression from the beginning to the end of a sustained contraction (MFslope) has been initially proposed to be mainly related to the endurance capacity of a muscle (Figure 2), with steeper slopes indicating greater muscle fatigue almost invariably present in patients with CLBP[18,45,46]. The rate of fatigue with this type of experiment depends on the level of sub-maximal contraction it is performed, in this instance at 60% MVIC level. Therefore, if patients under-perform during MVIC generation, they will be performing the fatigue test under a lower load level. Thus, in this study, the MVIC was introduced as a covariate in the ANCOVA analysis, to statistically control against this eventuality.

The paraspinals are a characteristic example of a multi-layer multiple muscle system, synergistically activated to perform a variety of tasks under different conditions[8,9] in combination with muscles from adjacent body parts[47]. The initial distribution of activation in their various parts and the progressive re-distribution of activation during sustained activities[6,9], is organised and continuously monitored by the central nervous system (CNS). However, various factors relative to cognitive[12,48] or physiologically-controlled peripheral requirements like inter-individual characteristics[37], task biomechanical demands[19,49], the presence of atrophy related mainly to ongoing disability[7] or pain frequency characteristics (recurrent or continuous)[6] can lead to either steeper MFslopes (in case of selective atrophy of type II fibres[50] or a 'confronter' type of patient with LBP[48]) or less steep MFslopes (due to generalised

Table 5 Reliability of initial median frequency, median frequency-slope and root mean square for the isometric endurance test in both groups

	Controls (n = 26)			Patients (n = 66)		
Parameter	**$ICC_{3,1}$**	**SEM**	**SDD**	**$ICC_{3,1}$**	**SEM**	**SDD**
IMF (Hz)						
L2/3 R	0.91 (0.80-0.96)	3.32	9.19	0.80 (0.69-0.87)	7.56	20.95
L2/3 L	0.82 (0.63-0.92)	4.57	12.66	0.80 (0.69-0.87)	6.88	19.06
L4/5 R	0.82 (0.61-0.92)	7.99	22.13	0.82 (0.73-0.89)	9.64	26.70
L4/5 L	0.81 (0.60-0.91)	8.31	23.02	0.86 (0.79-0.92)	8.61	23.85
L 2/3	0.94 (0.87-0.98)	3.45	9.56	0.90 (0.84-0.94)	6.41	17.75
L 4/5	0.91 (0.79-0.96)	7.27	20.14	0.94 (0.90-0.96)	7.59	21.02
MF slopes (raw, Hz/s)						
L2/3 R	0.61 (0.27-0.81)	0.07	0.19	0.75 (0.62-0.84)	0.08	0.22
L2/3 L	0.67 (0.36-0.85)	0.06	0.17	0.66 (0.50-0.78)	0.09	0.25
L4/5 R	0.52 (0.14-0.77)	0.13	0.36	0.73 (0.60-0.83)	0.12	0.33
L4/5 L	0.55 (0.18-0.78)	0.13	0.36	0.62 (0.45-0.75)	0.15	0.41
L 2/3	0.77 (0.46-0.90)	0.06	0.17	0.86 (0.77-0.91)	0.08	0.22
L 4/5	0.73 (0.35-0.89)	0.11	0.30	0.88 (0.80-0.92)	0.10	0.28
MF slopes (normalised, %/min)						
L2/3 R	0.67 (0.36-0.85)	5.79	16.03	0.69 (0.55-0.80)	8.59	23.79
L2/3 L	0.65 (0.33-0.84)	5.36	14.85	0.69 (0.54-0.80)	8.44	23.38
L4/5 R	0.64 (0.31-0.83)	7.11	19.69	0.62 (0.45-0.75)	8.59	23.79
L4/5 L	0.50 (0.11-0.75)	7.60	21.05	0.57 (0.38-0.71)	8.66	23.99
L 2/3	0.82 (0.57-0.92)	4.93	13.66	0.85 (0.75-0.91)	7.47	20.69
L 4/5	0.78 (0.49-0.91)	6.02	16.67	0.83 (0.73-0.90)	6.75	18.69
RMS slopes (normalised, %/min)						
L2/3 R	0.73 (0.46-0.88)	21.00	58.17	0.48 (0.27-0.65)	14.48	40.11
L2/3 L	0.76 (0.51-0.89)	14.83	41.08	0.71 (0.56-0.81)	10.83	30.00
L4/5 R	0.44 (0.04-0.72)	24.07	66.67	0.73 (0.60-0.83)	11.26	31.19
L4/5 L	0.54 (0.17-0.78)	24.20	67.03	0.61 (0.44-0.74)	12.44	34.46

Hz: Hertz; ICC: Intraclass correlation coefficient; SEM: Standard error of the measurement; SDD: Smallest detectable difference; IMF: Initial median frequency; MF: Median frequency; RMS: Root mean square.

inhibition[6,51], redistribution of muscle activity phenomena[23,28] or 'avoider' type of patient with LBP[48]), or even a mixed picture[38,42] compared to healthy participants.

EMG signal estimating the rate of muscle fatigue, through analysis of the frequency and time domain of the signal is rather complex, affected by the anatomical and physiological properties of muscles[6], the control scheme of the CNS[9] and the characteristics of the equipment used to collect the signal[26]. EMG fatigue measures, collected at a certain level of maintained contraction according to the methodology of the experiment conducted, are considered relatively independent of subjects' volitional effort, as the firing frequency of motor units cannot be perceived nor regulated[18].

However, it can also be logically derived that non-volitional alterations in the organization of the motor commands controlled by the CNS[52], can influence the manifestations of EMG-fatigue time-dependent indices[23,42]. A point to consider in the interpretation of paraspinal muscle behaviour under maximal (strength) or prolonged (fatigue-related) contractions is the present and past history of LBP episodes. If patients are in an acute or even at a sub-acute remission stage of symp-

Table 6 Adjusted between-group median frequency-slope differences in the isometric endurance test at 60% of maximum voluntary isometric contraction

	Healthy (*n* = 26)		LBP (*n* = 66)		Mean difference	*P* value
Parameter	Mean	SE	Mean	SE		
MF slopes (raw, Hz/s)						
L2/3	-0.25	0.03	-0.14	0.02	0.12	0.002[b]
L4/5	-0.44	0.05	-0.26	0.02	0.18	0.002[b]
MF slopes (normalised, %/min)						
L2/3	-22.4	2.9	-13.0	1.4	9.4	0.009[b]
L4/5	-29.4	2.5	-18.4	1.2	11.0	0.000[b]

[b]$P < 0.01$.

Hz: Hertz; LBP: Low back pain; MF: Median frequency.

toms, local muscle pain inhibition phenomena and redistribution of myoelectric activity are favoured[53]. Recent results show that paraspinal muscles in patients with recurrent or with non-continuous CLBP are not yet infiltrated by fat when compared to patients with continuous CLBP; however, patients with RLBP demonstrate lowered activation ability of the paraspinal muscles in general, compared to patients with CLBP[6]. Our results of decreased MVIC and less time-dependent MFslope decline in both muscle sites (corresponding to iliocostalis and multifidus) in patients with RLBP compared to healthy controls concur with this finding, although derived with different methodology (testing position) and outcomes (strength and EMG-fatigue measures). However, three studies with similar methodology to ours confirm our findings[23,42,54], another two studies that reported 'mixed' findings partly confirm our findings, as some participants demonstrated steeper and some less steep MFslopes in relation to healthy counterparts[48,55] and another one registered similar although not statistically significant trends[28]. Indeed, in one of the former three studies that clearly demonstrated between-group differences it was stated that "unexpectedly, healthy men showed higher fatigability than back pain patients", a result attributed to the smaller absolute load that patients performed the fatigue test[54]. However, the ANCOVA analysis has shown that the MFslope differences in the current study remained highly significant even after controlling for the MVIC values between-groups also, therefore the hypothesis of transient muscle inhibition is favoured. Indeed, given the recurrent nature of LBP in the patients recruited in this study, it is possible that the less steep slopes obtained both at higher (L2/3) and lower (L4/5) segments are due to generalised muscle decreased activation/partial inhibition of normal activity for a given level of contraction, rather than atrophy of type II fibers, more apparent in patients with non-specific CLBP[7].

Additionally, two studies on the redistribution of paraspinal muscle activity under sustained contractions offer complementary support to the findings of this study. The first showed that in healthy participants there was an increase in paraspinal level of contraction at lower spinal segments, whereas patients with CLBP did not demonstrate such shift[56]. In the second, patients with RLBP demonstrated a shift of activity from lower to higher spinal levels in relation to healthy controls and that the extent of this redistribution of activity correlated with lower endurance times[9]. The finding of redistribution of activity between upper and lower segments, at least between the ones (L2/3 *vs* L4/5) examined herein, is not supported by this study, as similarly less MFslope decline was demonstrated in higher and lower spinal segments. Possible differences in the task employed or as a large array of electrodes was not used in our study could have accounted for the differences between the results of our study and this latter study. The fact remains that in both of those studies a lower activation in lower spinal segments has been supported, a finding concordant with our study for the L4/5 spinal level. A previous study had even documented a shift of muscle activity towards the gluteals in relation to that of lower spinal segments in patients with CLBP relative to controls[47].

Another issue to consider is the direction of a 'desired improvement' in the patient group which is a debatable point, as the MFslopes in this group were significantly less steep than in the healthy participants ($P < 0.002$) across all muscle sites monitored, even after controlling for age, weight and different MVIC levels between the groups

(Table 6). Indeed, opposite changes in MF slopes post rehabilitation have been reported, possibly reflecting better activation of paraspinal muscles post-rehabilitation [51]. Pain-related muscle inhibition phenomena and different load-sharing patterns in the back muscles of patients, which may be a possible CNS strategy (non-volitional) to distribute the load "evenly" between all muscle groups involved in the contraction[23, 42,48,54,55] may potentially limit the applicability of the frequency spectrum EMG indices as endurance indicators. Alternatively, they may expand the definition of power spectrum frequency parameters, as indicators of neural motor control strategies [42].

Limitations-Future directions

A single rater experienced in the measurement methods employed was only involved in all measurements, to eliminate any between-rater error. Also, due to the variability of the EMG signal, only isometric examination methods of the paraspinal muscles were employed. However, the test-retest reliability, clinical applicability and discriminative validity of the methods involved was thoroughly examined in an adequate sample of healthy volunteers and in patients with recurrent non-specific LBP at a sub-acute stage of symptoms. An a priori sample size calculation was also performed to ensure sufficient power of the study based on expected between-group differences. Future studies could further examine the inter-rater reliability of the techniques already presented or expand the testing methods to either examine different exercise tasks (intermittent isometric contractions, different MVIC levels, dynamic contractions), including additional muscle groups (abdominals, gluteals) and patients with LBP with a range of neuromuscular deconditioning, disability and cognitive characteristics that affect functional performance.

CONCLUSION

Reliability, clinical applicability and discriminative ability of paraspinal strength and EMG-related frequency parameters were demonstrated in healthy participants and patients with non-specific recurrent sub-acute LBP. The EMG-related amplitude parameters did not present adequate reliability and the IMF parameter did not present significant differences between the groups examined. Further examination of those methods is endorsed.

ARTICLE HIGHLIGHTS

Research background

A significant predictor of low back pain (LBP) recurrence is 'previous LBP'. Partly, this may be due to persisting neuromuscular system activation deficits linked to strength deficits, as well as endurance deficits in patients with recurrent LBP (RLBP) even during periods of symptoms remission. LBP management clinical guidelines propose muscle re-conditioning as a prerequisite for successful management of recurrences.

Research motivation

Paraspinal muscle strength and endurance deficits require reliable monitoring. To overcome patient motivation or cognitive-related concerns affecting maximal strength testing, as well as endurance testing with prolonged contractions to complete exhaustion, alternative methods have been proposed in patients with RLBP, in order to establish the contribution of those parameters in neuromuscular deconditioning, to limit further recurrences.

Research objectives

As electromyographic (EMG)-based frequency and amplitude domain time dependent alterations, linked to the endurance characteristics of the muscles monitored have not been universally obtained for the paraspinals, a primary objective of this study was to determine the reliability of those measures. The reliability level of maximal paraspinal muscle strength performance was also examined. Furthermore, the discriminative validity of paraspinals muscle strength and time-dependent EMG frequency and amplitude domain alterations was tested.

Research methods

A custom-made isomyometer was utilised to initially assess the maximum voluntary isometric contraction (MVIC) of the paraspinals in the upright trunk position. Subsequently, short duration (60-s) isometric contractions at a submaximal level of contraction (60% of MVIC) were employed, to determine the EMG-time dependent frequency [initial median frequency (IMF) and median frequency (MF) slopes] and amplitude changes [root mean square (RMS) slopes] of the paraspinal muscles with recording electrodes placed at 4 muscle sites (L2/3 and L4/5, bilaterally). The most reliable parameters were used further to test the between populations discriminative ability of the method.

Research results

For both groups, MVIC presented excellent intraclass correlation coefficient (ICC) reliability values, although statistically significant between-day increases ($P < 0.01$) were recorded, within a margin of 10%; test-retest error was increased for patients compared to healthy participants. The EMG reliability of the frequency parameters was good (MF slopes) to excellent (IMF), however for the amplitude parameter (RMS slope) it was poor, for both groups. Statistically significant less MVIC and less steep MF slopes were registered for the patient group. These findings confirm previous research in the field, however in a larger population of participants with a history of RLBP and a sufficiently large comparison group of healthy participants.

Research conclusions

Although EMG time-dependent frequency parameters presented highly significant differences between the two groups, these were in the opposite than the expected direction. The validity of this finding is enhanced for two reasons; the between-group differences in MF slopes remained after statistically controlling for possible confounders and these differences were confirmed at all muscle sites monitored. Apparently, alterations in the organization of the motor commands in patients with RLBP can additionally influence the manifestations of EMG-related time-dependent indices. Therefore, the alterations in the EMG-frequency spectrum under sustained contractions cannot only be considered as indicators of peripheral fatigue or peripheral muscle atrophy.

Research perspectives

This methodology of EMG-related alterations followed in the current experiment is reliable. The validity of the between-group differences obtained between patients with RLBP and healthy participants requires further study. In order to explain the significance of the current findings, the history of LBP has to be taken into consideration. Therefore, results from patients with varying amounts of LBP-related disability and disease duration are required, in conjunction with detailed imaging methods of peripheral muscle state and recording of the different patterns of activation utilised under controlled experimental conditions or less controlled functional tasks. Furthermore, the effect of exercise on EMG-related frequency parameters and whether the alterations registered post-exercise in the frequency domain correspond to less LBP recurrences requires examination from a clinical viewpoint.

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ORIGINAL ARTICLE

Retrospective Cohort Study

Preseason elimination impact on anterior cruciate ligament injury in the National Football League

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Abstract

BACKGROUND

Anterior cruciate ligament (ACL) injuries represent detrimental injuries in the National Football League (NFL). A significant portion of these injuries often occur in preseason exhibitions. The Coronavirus disease 2019 pandemic presented a unique disruption to preseason NFL football with the cancelation of all preseason games.

AIM

To compare the incidence of ACL tears through the first eight weeks of the NFL season in 2020 to the mean incidence over the previous 5 seasons (2015-2019) and determine if there was any change in incidence with the elimination of the preseason.

METHODS

NFL players who suffered ACL tears during the preseason and first eight weeks of the NFL season from 2015-2020 were identified. The number of ACL injuries for the 2015-2019 seasons was compared to the 2020 season for four different timeframes. For each analysis, the cumulative number of ACL injuries to that time point was used to calculate the percent difference for descriptive analysis. Additionally, the number of teams with at least one player suffering an ACL tear were identified and compared using Chi-Squared testing. Finally, a cumulative relative risk was calculated for each week played.

RESULTS

There were 14 ACL tears through the first four games of the 2020 season, a 118.8% (14 *vs* 6.4) increase in comparison to the 5-year average over the first 4 regular season weeks of 2015-2019. However, when accounting for injuries occurring during the preseason from 2015-2019, there were 18.6% (14 *vs* 17.2) fewer total ACL injuries through regular season week 4 with no significant difference in

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percentage of teams impacted when these preseason injuries were accounted for P = 0.394. Results were similar (19 *vs* 17.2) over 8 total games played (whether regular season or preseason), and over 8 regular season games (P = 0.196, P = 0.600).

CONCLUSION
The elimination of the NFL preseason resulted in a higher rate of injuries during the first 4 games of the regular season. However, these increases are offset by the injuries typically sustained during the preseason. This suggests there may be front-loading of injuries over the course of an NFL season, such that players may be more prone to injury when the intensity of play suddenly increases, whether in the preseason or regular season.

Key Words: Anterior cruciate ligament; National football league; Player safety; Ligamentous injury; Preseason; COVID-19

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Core Tip: The coronavirus disease 2019 pandemic presented a unique disruption to preseason National Football League (NFL) football with the cancelation of all preseason games. This study compared the incidence of anterior cruciate ligament (ACL) tears through the first eight weeks of the NFL season in 2020 to the mean incidence over the previous 5 seasons and found that there was indeed an increase in ACL tears through the first four games of the 2020 season with no significant difference when accounting for the preseason. This suggests that there may be front-loading of injuries over the course of an NFL season. In summary, this study suggests that if preseason games are eliminated, players can expect similar rates of ACL tears overall when compared to conventional seasons, but with more ACL tears in the first four weeks of the regular season.

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INTRODUCTION

Anterior cruciate ligament (ACL) injuries are among the most common knee injuries in American football players, and their incidence increases with increased level of competition. In one survey, 14.2% of retired National Football League (NFL) players reported a history of ACL injury[1]. Because of the high incidence of ACL injuries and their potential to end players' seasons or careers, extensive research has been conducted to identify risk factors that may contribute to ACL injury and modifications to improve player safety. One of these modifiable risk factors may be preseason training.

Over the last decade, NFL and National Football League Players Association have disputed the importance and number of preseason games necessary before the NFL season. Since 1978, NFL teams participated in a 4-game stretch of weekly exhibition games to prepare for the upcoming season. However, in 2020 the coronavirus disease 2019 (COVID-19) pandemic presented a unique disruption to this sequence, with all preseason games cancelled prior to the beginning of the season.

ACL tears are catastrophic and common injuries in football, with athletes estimated to have a ten times higher risk of rupture in participation when compared to other sports[2]. A recent systematic review reported the overall return to play rate in NFL athletes after an ACL tear at only 67.2%, with significant variability depending on the position and experience of the athlete[3-5]. Additionally, of players able to return, the financial impact of these injuries on player earning potentials is well documented, with salary losses of roughly $2 million per year after injury[6].

The purpose of this study was to compare the incidence of ACL tears through the first eight games played of the NFL season in 2020 to the mean incidence over the previous 5 seasons (2015-2019) and determine if there was any change in incidence with the elimination of the preseason.

MATERIALS AND METHODS

NFL players who suffered ACL tears during preseason games and first eight regular season games played of the NFL season for the years 2015-2020 were identified and confirmed using reports from official NFL team websites. Only injuries occurring during regular and preseason games were included. Injuries occurring in organized team activities, practices, or individual training sessions were not included in the analysis, as regimens and activities of individual players and teams inherently vary considerably. The five-year total and yearly mean number of ACL injuries were calculated for the 2015-2019 seasons and compared to the 2020 season for four different timeframes.

First, the first four regular season games of the 2020 season were compared to the first four regular season games of 2015-2019 season, excluding any preseason injuries. Second, the first four regular season games for the 2020 season were compared to first four regular season games played of the 2015-2019 season, including injuries sustained in the four preseason games accrued in 2015-219. Third, the first 8 regular season games played for the 2020 season were compared to the first eighth regular season games played of the 2015-2019 season, including injuries sustained in the four preseason games. Lastly, the cumulative number of injuries through 8 wk of any gameplay were compared, and a relative risk was calculated for player injuries per game played by each week. In other words, the first 4 preseason games of 2015-2019 were analyzed in combination with the first 4 games of their respective regular seasons and compared to the first 8 regular season games of 2020.

For each analysis, the cumulative number of ACL injuries to that time point was used to calculate the percent difference for a descriptive analysis. Additionally, the number of teams with at least one player suffering an ACL tear were identified and compared using Chi-Squared testing. All collected data was then analyzed using IBM SPSS Statistics Version 25 (Armonk, NY, United States). P values < 0.05 were considered statistically significant.

RESULTS

Comparison of first four regular season games

There was a total of 14 ACL tears through the first four games of the 2020 season, a 118.8% increase in comparison to the 5-year average over the first 4 wk of the 2015-2019 seasons (Table 1 and Figure 1A). More teams (11) were impacted with an ACL tear in 2020 during the first 4 wk of the season than any season from 2015-2019. Chi squared testing demonstrated a significant difference in rates of teams impacted (Table 1; P = 0.039) in 2020 compared to 2015-2019.

Comparison through the first four regular season games, including preseason

When accounting for injuries occurring during the preseason from 2015-2019, there were 18.6% fewer total ACL injuries through regular season week 4 (Table 1 and Figure 1B). There was no significant difference in percentage of teams impacted when these preseason injuries were accounted for (Table 1; P = 0.394).

Comparison through the first eight regular season games, including preseason

Repeat analysis through 8 wk comparing the 2020 season to the 2015-2019 averages including the preseason demonstrated similar results to week 4 analysis, with overall tears down 16.7% with no significant difference in the number of teams affected (Table 1; P = 0.196).

Comparison of the first eight games played

When comparing an equivalent number of games, regardless of regular or preseason designation, there was a 10.5% increase in ACL tear occurrence in the 2020 season (Table 1 and Figure 1C), but no significant difference in the number of teams impacted (Table 1; P = 0.600), or injury rate at any timepoint through eight weeks (Table 2).

Table 1 Cumulative anterior cruciate ligament tear count

Season	Total ACL tears	Percent difference	Teams impacted	*P* value[1]
Through four regular season games, excluding preseason				
2020	14	+118.8%	**11**	**0.039**
2015-2019 average	6.4		**5.8**	
Through four regular season games, including preseason injuries				
2020	14	-18.6%	11	0.394
2015-2019 average	17.2		13.6	
Through eight regular season games, including preseason injuries				
2020	19	-16.7%	12	0.196
2015-2019 average	22.8		16.0	
Through eight games played, regular or preseason				
2020	19	+10.5%	12	0.600
2015-2019 average	17.2		13.6	

[1]*P* value calculated using Chi-squared analysis. Bold indicated statistical significance.
ACL: Anterior cruciate ligament.

Table 2 Week by week comparison of cumulative anterior cruciate ligament tear rate for the first 8 games played

	Year	Total injuries	Total games	Rate	RR	95%CI	*P* value
Game 1	2020	3	16	0.188	1.071	0.348-3.302	0.904
	2015-2019	14	80	0.175			
Game 2	2020	10	32	0.313	1.724	0.937-3.174	0.08
	2015-2019	29	160	0.181			
Game 3	2020	13	48	0.271	1.477	0.865-2.524	0.153
	2015-2019	44	240	0.183			
Game 4	2020	14	63	0.222	1.317	0.781-2.22	0.301
	2015-2019	54	320	0.169			
Game 5	2020	15	77	0.195	1.237	0.745-2.055	0.412
	2015-2019	63	400	0.158			
Game 6	2020	17	91	0.187	1.338	0.826-2.169	0.237
	2015-2019	67	480	0.140			
Game 7	2020	19	105	0.181	1.333	0.844-2.107	0.218
	2015-2019	76	560	0.136			
Game 8	2020	19	119	0.160	1.181	0.748-1.864	0.476
	2015-2019	86	636	0.135			

RR: Relative risk; CI: Confidence interval.

DISCUSSION

The results of this study demonstrate that without participation in preseason games, NFL players sustain ACL injuries at a higher rate during the early portion of the regular season. However, when accounting for injuries sustained in preseason, the differences quickly equilibrate and there is no difference in the total number of ACL injuries, or the ACL injuries per game played. Additionally, the injury rate per game

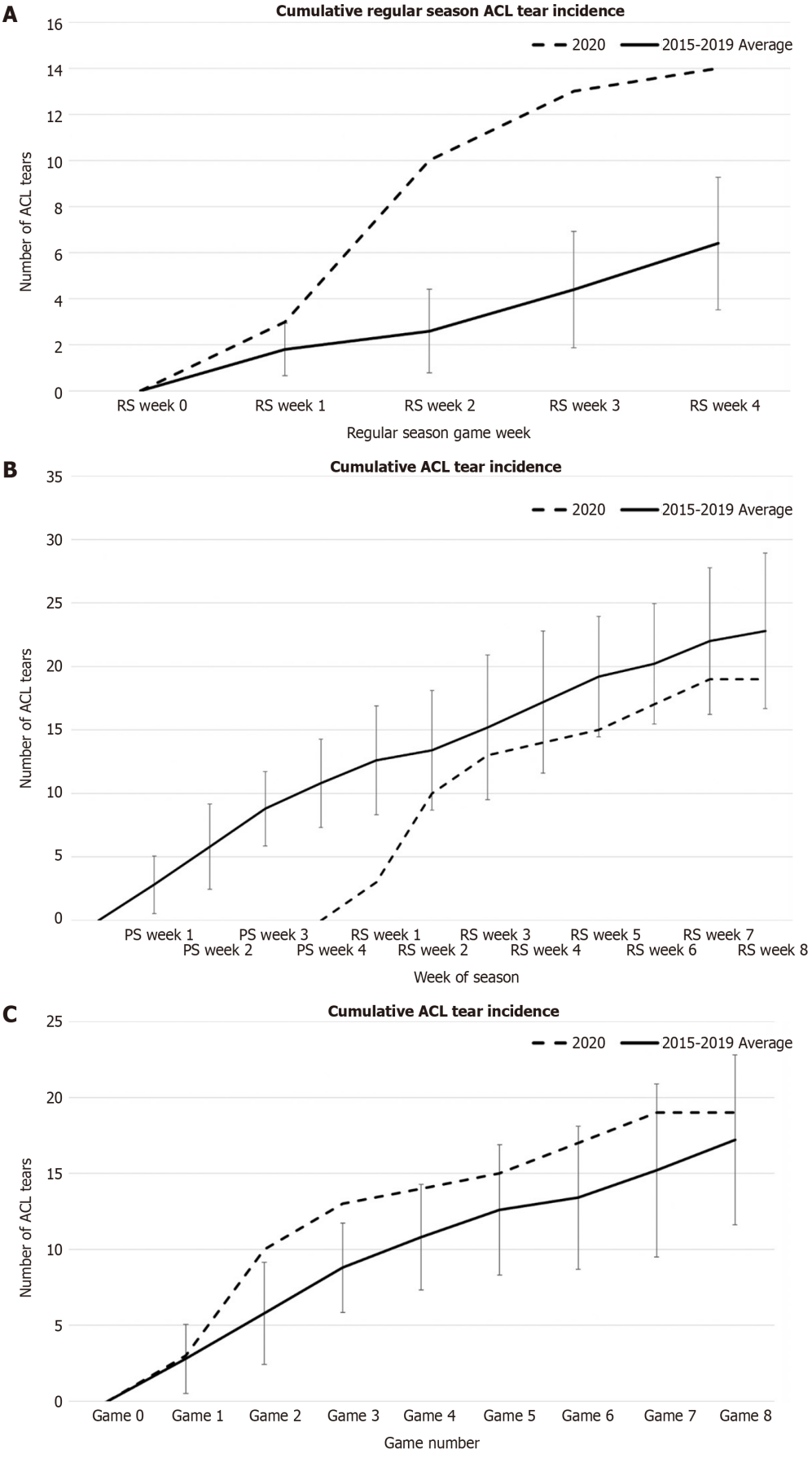


Figure 1 Cumulative plot comparing the number of anterior cruciate ligament tears. A: In the first four regular season (RS) games of the 2020 season to the 2015-2019 RS; B: In the 2020 season to the 2015-2019 average for the preseason (PS) and first 8 wk of the RS. C: In the 2020 season to the 2015-2019 average over the first 8 games played (PS or RS) in each group. Error bars designate the CI above and below the mean. ACL: Anterior cruciate ligament; RS:

Regular season; PS: Preseason.

played is not statistically different between seasons with and without a preseason.

Recent studies of rugby, Australian rules football, and European soccer teams showed that increased participation in preseason training sessions was associated with a lower in-season injury burden[7-9]. One study of European soccer teams found that every 10 additional preseason training sessions that team members participated in was associated with significantly fewer in-season layoff days due to injury and significantly fewer severe in-season injuries[9]. This highlights the potential benefits of increased preseason training in reducing in-season injury burden. With no preseason games in the 2020 season, NFL players participated in less preseason training. This was associated with an increased risk of injury during their early regular season games compared to a traditional year. However, when comparing the first games played of the 2020 season *vs* the preseason games in prior seasons, there is no significant difference in total number of injuries or injury rate.

The above information suggests that the elimination of preseason and pre-season training would increase the incidence of ACL injury, which is consistent with the results of our study. Additionally, some studies suggest that targeted training and warm-up exercises can reduce the incidence and risk of ACL injuries[10,11]. One study of American National Collegiate Athletic Association soccer by Silvers-Granelli *et al* [10] demonstrated that the FIFA 11+ injury prevention program, a 15-20 min dynamic warm-up program performed before training and games, resulted in a 4.25-fold reduction in the likelihood of ACL injury. This highlights the importance of warm-up training directly before vigorous training or exercise. Currently, the NFL does not have a standardized warm-up program, and there have been little to no studies on the impact of warm-up training in the NFL. Thus, the implementation of a similar program into NFL preseason training, regular season training, and NFL games should be explored in future studies, as it may help reduce the incidence of ACL injury.

Another study by Li *et al*[12] investigated the relationship between soft tissue injury and training load in American football. Player training load was measured using wearable global position system devices outfitted to record acceleration in various axes. They found that a sudden increase in training load was associated with more soft tissue injuries, including ankle ligamentous injury, knee ligamentous injury, hamstring strain and other muscle strain. They concluded that soft tissue injuries during the regular season occurred most often during weeks with increased training loads, as compared to the training load over the month prior to injury[12]. These findings are consistent with the results demonstrated in our study, as a large workload increase in 2020 relative to limited offseason participation may have predisposed NFL athletes to early-season injury. The results of our study show a significant increase in the number of teams with ACL tears in the first four weeks of the 2020 season, as compared to the average number of teams with ACL tears from the first four regular season weeks of the 2015 through 2019 seasons (Table 2). Seeing as regular season games are often played with greater intensity due to the increased level of competition[12], it is likely that NFL players in the first four weeks of the 2020 season experienced increased physical demands, or in the words of Li *et al*[12], "training loads", as compared to the weeks leading up to the regular season since there were no preseason games. This sudden increase in physical demand may contribute to the increased ACL tears in the first four weeks of the 2020 regular season in comparison to the recent historic average.

However, it is notable that when including ACL injuries from the preseason and the first four weeks of the regular season in 2015 to 2019 in comparison to injuries in the first four weeks of the 2020 season, there was no significant increase in teams impacted by ACL injury through the first four or eight regular season games of the season. Thus, this higher susceptibility to ACL injury due to increased training demand may simply occur in the preseason instead of the regular season historically. In fact, when including preseason games, descriptive reports in this study demonstrated an 18.6% decrease in ACL injuries in the first four weeks of the 2020 season in comparison to 2015-2019 and a 16.7% decrease through the first eight weeks. Results remained inconclusive when looking at injury incidence over an equivalent timespan, with a 10.5% increase in 2020 ACL tear frequency compared to the running average of the preceding 5 NFL seasons with no significant difference in the number of teams impacted. This highlights that there may be front-loading of injuries, such that players may be more prone to injury when the intensity of play suddenly increases, whether that is in the preseason or regular season. This is further supported in our chronologic analysis, which demonstrated no change in the relative risk at any timepoint in the

first 8 games of NFL play, regardless of if they were preseason or regular season games. Thus, players are likely at increased risk of injury when they engage in full contact play, whether it is in the preseason or regular season. Steiner *et al*[13] found that full contact preseason practice and scrimmages correlated with a significant increase in practice injuries among college football players, as compared to non-contact practice. This was true of in-season full contact practices and scrimmages as well. This is substantiated by the fact that the majority of ACL injuries in American football are from contact[1].

The major limitation of the current study is that it is observational and retrospective. While this data shows an interesting association between the number of ACL injuries, as well as number of teams with ACL injuries with and without a preseason, we cannot draw conclusions on the causative effect of a preseason since many factors affect a player's risk for ACL injury. These include external factors, such as playing surface and cleat design, as well as internal factors, such as previous injury, age, body composition, knee alignment, intercondylar notch width, muscle flexibility, foot biomechanics, and movement patterns[14-17]. This study also did not account for injuries that occurred during practices, off-season training, and organized team activities, though these occur at much lower rates than in-game injuries. Additionally, we only have one season of data in which no preseason games were played. Finally, there are additional variables that complicate the 2020 season, including multiple players opting out of the season entirely, other players missing time due to COVID-19 protocols, and game scheduling delays as a result of COVID-19.

CONCLUSION

While the COVID-19 pandemic is first and foremost a calamity, it has provided a unique opportunity to examine the rates of ACL injuries in the NFL with a complete elimination of the preseason. The results of this study suggest that if preseason games are eliminated, players can expect similar rates of ACL tears overall when compared to conventional seasons, but with more ACL tears in the first four weeks of the regular season.

ARTICLE HIGHLIGHTS

Research background

In 2020, the National Football League (NFL) preseason was eliminated due to the coronavirus disease 2019 pandemic. The purpose of this study was to determine if this unique elimination of the preseason resulted in a change in incidence of anterior cruciate ligament (ACL) tears.

Research motivation

Prior to the pandemic, there had been many discussions regarding the need of the NFL preseason, with the main concern being player safety. Our goal was to obtain relevant data on the impact of the preseason on ACL injuries that can be used for future discussions around that topic.

Research objectives

The main objective of this study was to compare the incidence of ACL tears through the first eight weeks of the 2020 NFL season to the mean incidence over the previous 5 seasons (2015-2019) and determine if there was any change in incidence in 2020. Though this objective was realized, this data can be strengthened if future studies are performed for a greater number of NFL seasons, as we were only able to obtain 5 years of data for this study.

Research methods

NFL players who sustained ACL tears during the preseason and first eight weeks of the NFL season from 2015-2020 were identified using online publicly available data. The number of ACL injuries for the 2015-2019 seasons was compared to the 2020 season.

Research results

A 118.8% increase in ACL tears was noted through the first four games of the 2020 season in comparison to the previous 5-year average over the first four regular season weeks of 2015-2019. However, when accounting for injuries occurring during the preseason from 2015-2019, there were 18.6% fewer ACL injuries through regular season week 4.

Research conclusions

There may be front-loading of injuries over the course of an NFL season, such that players may be more prone to injury when the intensity of play suddenly increases, whether in the preseason or regular season. This study also suggests that although the elimination of the preseason results in similar rates of ACL tears overall, it is correlated with increased ACL tears in the first four weeks of the regular season.

Research perspectives

Future research should be performed comparing the 2020 NFL season with a greater number of NFL seasons, as further data is needed to obtain more definitive results. Additionally, warm-up training has not been studied extensively in American football and is certainly a topic that should be studied for ACL injury prevention.

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ORIGINAL ARTICLE

Retrospective Study

Risk of methicillin-resistant staphylococcus aureus prosthetic joint infection in elective total hip and knee arthroplasty following eradication therapy

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Author contributions: Kapur BP, Tonge X and Kumar G contributed equally to this work.

Institutional review board statement: No ethics approval was required for this retrospective review. This study was registered with the hospitals audit department.

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Data sharing statement: Data is available if requested from the corresponding author at benjaminkapur@nhs.net.

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Abstract

BACKGROUND

Prosthetic joint infection (PJI) is a devastating complication requiring prolonged treatment and multiple operations, leading to significant morbidity for the patient. Patients are routinely tested for methicillin-resistant staphylococcus aureus (MRSA) colonisation. MRSA positive patients are given eradication therapy. We hypothesise that patients who are MRSA positive pre-operatively, have increased risk of developing PJI.

AIM

To identify deep wound infection (PJI) rates in patients who are colonised MRSA positive compared with those who are not colonised; and long term clinical and radiological outcomes.

METHODS

All patients who underwent total hip and knee replacements (THR/TKR) between December 2009 and December 2019 were identified. Patients who were also identified as being MRSA positive at pre-operative assessment were then selected. Confirmation of prescribing eradication treatment was recorded. Patient records, including consultation letters, operation notes and microbiology results were reviewed retrospectively. Comparison of outcomes for each MRSA positive patient was made with 2 MRSA negative patients undergoing the same operation of a similar age by the same consultant.

RESULTS

Screening identified 42 knee and 32 hip arthroplasty patients as MRSA positive, 84 MRSA negative knee and 64 hip patients were reviewed. Patients were matched with medical co-morbidities in each group. Mean follow up was 5 years. PJI was identified in 4/32 (12.5%) of THR MRSA positive and 3/42 (7%) of TKR

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patients. All patients had PJI within one year of surgery.

CONCLUSION

MRSA positive patients are given eradication therapy routinely. However, no confirmation of eradication is sought. Patients who have MRSA colonisation pre-operatively, in our study had a significantly increased risk of PJI, when compared to negative patients. We would recommend establishing true eradication after treatment prior to arthroplasty.

Key Words: Hip; Knee; Prosthetic joint infection

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Core Tip: Retesting to ascertain true eradication of methicillin-resistant staphylococcus aureus (MRSA) prior to arthroplasty is essential. Without this, eradication treatment success remains undetermined with the resultant increased incidence of MRSA prosthetic joint infection and associated morbidity and mortality with revision surgery.

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INTRODUCTION

Total joint arthroplasty (TJA) of the hip and knee are the two most commonly performed orthopaedic procedures. Due to an aging population, the numbers of patients undergoing TJA is increasing yearly as shown in the National Joint Registry reports[1]. Prosthetic joint infection (PJI) after TJA is reported in 1%-2% of patients[2]. Revision arthroplasty has significantly higher complication rates with infection rates reported over 20%. PJI has increased morbidity and mortality for patients and increased associated healthcare costs due to treatment, length of stay and readmission [2]. PJI was defined by adaptation of the Musculoskeletal Infection Society criteria a described by Parvizi *et al*[3] Major and minor criteria were used[3]. In our institution inflammatory markers are taken (C-reactive protein and erythrocyte sedimentation rate) and aspiration of the joint are routinely performed and observation for a sinus tract. We do not perform synovial tests or alpha-defensin.

Depending on microbial virulence, PJI can manifest either early (within the first few weeks after implantation) or with a delay (typically within 3 mo and 3 years). Early infections manifest with clear local and systemic signs of inflammation and are predominately high virulence organisms (*e.g.* Staphylococcus aureus, enterococcus and streptococcus). Delayed infections usually present insidiously with symptoms to suggest failing implants such as joint pain and loosening. Low virulence organisms often responsible such as coagulase negative staphylococci or cutibacterium species[4].

All prosthetic joints remain susceptible to haematogenous seeding from a distant primary focus during their entire indwelling time[2]. High vascularity of periprosthetic tissue exposes the prosthesis to the highest risk of haematogenous infection in the first years after implantation. Patients often present with acute onset of clinical symptoms after a painless post-operative period[5]. The risk after bacteraemia with S. aureus is reported up to 34%[6]. The most commonly isolated organism in PJI after TJA is staphylococcus aureus. Present in the anterior nares, 25%-30% of the population are colonized at any given time. Carriers are at higher risk for surgical site infection (SSI) after invasive medical or surgical procedures. It has been demonstrated in the literature that carriers are 2 to 9 times higher to have a SSI[7]. Strains of methicillin-resistant staphylococcus aureus (MRSA) are much lower, 1% of the population with a higher preponderance for the elderly, immune-compromised or those with multiple co-morbidities. It has been shown that 85% of SSIs can be traced to endogenous colonisation of the patient[7].

The centers of disease control recognised nasal colonisation as a risk factor for SSI [8]. As a result there has been a focus on pre-operative screening and decolonisation prior to the patient undergoing surgery. Most strategies to decrease the incidence of SSIs have focused on timely antibiotic administration, optimising patients co-morbidities and nutrition, minimising surgical wound contamination in the operating theatre by using isolation suits and reduced personnel in the theatre suite.

The purpose of this study are to (1) Identify deep wound infection (PJI) rates in patients who are colonised MRSA positive compared with those who are not colonised; and (2) Long term clinical and radiological outcomes.

Ethical approval was not required for this study.

MATERIALS AND METHODS

This study is a retrospective analysis of elective primary total hip and total knee arthroplasty procedures done at our institution from December 2009 to December 2019. Patients were identified from a prospectively collected database and cross-referenced with the hospital database using procedural codes. The policy at our institution is to screen for MRSA using (culture) swabs in surgical pre-operative assessment when the patient is listed for elective surgery. Those patients identified as colonised with MRSA are contacted and instructed to undergo self-administered standard protocol decolonisation eradication therapy. This consists of prontoderm® nasal spray (Braun) and octenisan® antimicrobial wash (Schulke) to be used 5 d prior to and finishing on the morning of surgery. The patients are not retested following treatment.

The microbiology data of all these patients was reviewed, which confirmed the preoperatively diagnosed MRSA colonised patients. Detailed review of the medical records of these patients was undertaken to determine risk factors, eradication prophylaxis and perioperative antibiotics and outcomes.

Indication for surgery, operating consultant, co-morbities, age and complications including infection and revision were recorded for all patients. A control group was generated using patients undergoing the same elective arthroplasty procedure by the same consultant, within a 6 mo time period. Patients were matched on a 2 to 1 basis of MRSA negative to positive by comparable age (within 5 years) and same co-morbidities to make the groups representative of each other rather than using all the arthroplasty patients. To reduce selection bias, patients in the non-MRSA cohort were selected by operative date closest to the operative date of the MRSA positive patient, surgeon and co-morbidities selected.

Antibiotic prophylaxis for primary arthroplasty patients is teicoplanin 1.2 g intravenous on induction if the patient had tested positive for MRSA colonisation. Standard protocol is a stat dose of cefuroxime 1.5 g intravenous on induction and no further antibiotics.

At pre-operative assessment patients have a health screen, observation parameters are taken and blood tests are performed to identify any abnormalities that require addressing prior to surgery and an electrocardiogram is performed. Patients provide a urine sample for analysis at pre-operative assessment and are treated if required.

Patient outcomes are recorded for SSI, organisms, complications, revision procedures undertaken and eventual outcome.

RESULTS

Between January 2009 and December 2019, 3166 total knee arthroplasty and 2738 hip athroplasty procedures were performed.

For the purpose of this study, we used matched analysis with a ratio of 2 MRSA negative patients to 1 colonised MRSA positive patient.

The total number of MRSA negative patients was 3124 total knee replacements (TKRs) and 2706 total hip replacements (THRs). Combining positive MRSA colonised and negative patients, MRSA colonisation was observed in 74 patients (32 hip, 42 knee) with a colonisation rate of 1.25%.

All 74 patients were issued with decolonisation treatment to be utilised for the 5 d prior to surgery; however, no patients were retested prior to their surgery.

There were 42 MRSA colonised positive TKR patients matched based on surgeon, age, co-morbidities with 84 MRSA negative patients. The average age was 69.3 years (range 54-83). The average follow up was 4.78 years (range 1-10). Table 1 outlines the

Table 1 Total knee replacement–demographics

	MRSA negative	MRSA positive
Mean age (yr)	70.2	69.3
Follow up (yr)	4.88	4.78
Total no. Patients	84	42
Male, *n* (%)	38	19
Female, *n* (%)	46	23

MRSA: Methicillin-resistant staphylococcus aureus.

demographics of this group.

Our cohort of colonised patients self-administered their decolonisation therapy and all lived at home. In the MRSA colonised positive TKR group, 7 patients were diabetic, 21 patients had pre-existing cardiac disease and were on anticoagulation, 12 patients had chronic respiratory conditions, 10 has inflammatory conditions (on steroids/methotrexate) and 2 patients had a malignancy.

Of 3 out of 42 TKR patients developed MRSA PJI requiring revision surgery within 1 year of their index procedure, giving an incidence of 7%. 2 out of 3 patients underwent two-stage revision and 1 patient underwent debridement, antibiotics and implant retention (DAIR). Mean follow up from revision surgery is 4 years and all patients are clinically and radiologically infection free. Patient one was diabetic and had renal disease, patient two was diabetic and had respiratory disease and malignancy and patient three was on steroid for inflammatory disease and had pre-existing ischaemic heart disease and used anticoagulation.

The MRSA negative TKR control group, which consisted of 84 patients, matched by surgeon and comorbidities as described above had an average age of 70.2 years (range 50-82). Follow up average 4.8 years (range 1-10). Of the 84 patients there was 1 patient with diagnosed with an e. coli PJI requiring a DAIR. This patient had chronic kidney disease. The patient is clinically and radiologically infection free at 6 years. The incidence of PJI was 1.2%.

There were 32 MRSA positive THR patients matched based on surgeon, age, co-morbidities with 64 MRSA negative patients. The average age was 67.6 (range 54-94). The average follow up was 5.1 years (range 1-10 years). Table 2 outlines the demographics of this group.

In the MRSA positive THR group, 4 patients were diabetic, 12 had cardiac conditions and were on anticoagulation, 7 had chronic respiratory conditions, 2 had inflammatory conditions (on steroids/methotrexate) and 4 had malignancy.

Out of the 32 patients, 4 developed MRSA PJI requiring revision surgery within 1 year of their index procedure giving an incidence of 12.5%. Three patients underwent two-stage revision and 1 underwent single stage with prolonged antibiotics. Patient one had diabetes and was on steroid, patient two had chronic kidney disease and ischemic heart disease and used anticoagulation, patient three had malignancy and was on steroid and patient four was diabetic with chronic renal disease and respiratory disease. Mean follow up from revision surgery is 5 years and all patients are infection free clinically and radiologically.

The MRSA negative THR control group, which consisted of 64 patients, matched by surgeon and co-morbidities as described above had an average age of 67.8 years (range 50-94). Follow up average 6 years (range 1-10 years). Of the 64 patients, there have been no incidences of PJI during this follow up period.

The results of the incidence of PJI are summarised in Table 3.

All PJI s were methicillin resistant, there were no methicillin sensitive staphylococcus organisms.

DISCUSSION

This study demonstrates a higher incidence of methicillin resistant staphylococcus aureus infection in patients who have been previously colonised in elective hip and knee arthroplasty. The results of this study show that at our institution there is a 1.25% MRSA colonisation rate in patients undergoing total hip and knee arthroplasty. This is

Table 2 Total hip replacement-demographics

	MRSA negative	MRSA positive
Mean age (yr)	67.8	67.7
Follow up (yr)	6	5.1
Total no. Patients	64	32
Male, *n* (%)	16	9
Female, *n* (%)	48	23

MRSA: Methicillin-resistant staphylococcus aureus.

Table 3 The results of the incidence of prosthetic joint infection

	MRSA negative	MRSA positive
Total knee replacement	1/84 (1.2%)	3/ 42 (7%)
Total hip replacement	0/64	4/32 (12.5%)

MRSA: Methicillin-resistant staphylococcus aureus.

comparable with studies in the literature demonstrating rates by Tandon *et al*[8] of 1.3%.

PJI after THR and TKR are associated with substantial patient morbidity and economic burden to the healthcare system. Many approaches and resources have focused on infection reduction methods. A targeted strategy is to identify patients who are MRSA positive and attempt to decolonise them, as MRSA is a risk factor for PJI. There are limited data on the success of decolonisation protocols and their subsequent effect on PJI. A 69% reduction in the prevalence of PJI has been demonstrated with screening and eradication[9,10].

Kim *et al*[11] include the single largest cohort of orthopaedic patients[11]. They found a decrease in surgical site and PJI in their treatment group with compared with historical controls and MRSA negative patients.

Literature has shown mixed results on the role of decolonisation of MRSA carriers and is effect on carrier rates and PJI in elective orthopaedic surgery. This in part depends on whether patients comply with treatment.

Shukla *et al*[12] identified 2.5 times higher risk than the normal population of developing postoperative MRSA SSI and PJI in carriers in an orthopaedic trauma unit [12].

In a prospective observational study of elective hip and knee replacements, One study showed no postoperative cases of staphylococcus aureus SSI at 1 year follow up in the group who had screening and successful decolonisation treatment. 3.5% infection rate was noted in the concurrent control group[12]. This is in keeping with the results we obtained suggesting retesting and further eradication treatment contributes towards the prevention of PJI.

A weakness of this study is that it is a retrospective analysis. A weakness of our protocol is that patients are issued the treatment and it is used up to and finishing on the day of surgery however, there is no assurance that the patients comply. There is no re-test to ensure eradication of MRSA and no opportunity for further eradication treatment if the patient is still positive.

Kim *et al*[11] have shown that there is 22% treatment failure rate with MRSA decolonisation nasal and soap treatment. They hypothesise that the factors associated with treatment failure are non-compliance and the presence of resistant organisms. This supports the need for screening post treatment to ensure eradication and address any modifiable risk factors for PJI. This also has an impact on consent and quantifying risk for patients.

The balance is in favour of screening, eradication therapy and re-screening to reduce the risk of PJI, which is a costly complication following elective surgery. The financial implications of treating MRSA PJI are immense. Current revision practice is changing in the United Kingdom[13]. Pathways for centralisation and regionalisation of revision services are being created. Nathwani[14] studied the impact on separate elements

–hospital, patient and society[14]. Bozic and Ries[15] showed that costs associated with revision arthroplasty due to infection are 2.8 times higher than aseptic revision and 4.8 times higher than primary arthroplasty[15]. Revisions due to infection were associated with 3 times the number of repeat hospitalisations and outpatient visits and nearly 4 times the number of operations with approximately 22 d in hospital when compared with aseptic revisions. Given the current protocol–12.5% of THR and 7% of TKRs becomes infected with MRSA, which generates complications and carries with it the financial implications.

Screening for MRSA is inexpensive (500 rupees for a screening test). Although this study did not investigate the cost analysis of MRSA PJI, VandenBergh *et al*[16] determined the cost-effectiveness of perioperative mupirocin (Bactroban; GlaxoSmithKline, Middlesex, United Kingdom) in cardiothoracic surgery[16]. They suggested that due to the immense cost of a PJI, an effective intervention with a relatively cheap agent like mupirocin is likely to be cost-effective as a risk reduction of 1% would be cost-effective already. Also the side effect profile of mupirocin is negligible. This has to be balanced with the risk of recurrence and resistance to standard treatment, which is a recognised complication[16,17]. Young and Winston[18] estimated the cost effectiveness of a screen and treat strategy. Based on a carriage rate of 31% and a risk reduction of 48%, a saving of approximately $1.5 million *per* 10000 patients screened was predicted. In the United States of America for example where 30 million surgical procedures are performed annually, extrapolation results in a saving of $4.5 billion (£3.5 billion). This would reduce the revision burden in the healthcare economy and also patient morbidity.

We acknowledge that this is a retrospective study and therefore has limitations however we aimed to reduce bias by using continuous patients in the non-MRSA group to match the MRSA positive patients by demographic and co-morbidities.

CONCLUSION

In conclusion, our retrospective study has demonstrated that there is a significantly higher risk of MRSA PJI in patients who have had MRSA colonisation undergoing total hip and knee replacements. We advocate rescreening of patients and further eradication treatment. If the patient fails to respond and remains MRSA positive then this can form the basis of discussion during the consent process for joint arthroplasty. Screening and treatment for MRSA is cheap and effective when used which in comparison to the morbidity and cost associated with MRSA PJI.

ARTICLE HIGHLIGHTS

Research background

Difference in screening between two hospital trust which were merging.

Research motivation

Developing a uniform policy for screening and managing methicillin-resistant staphylococcus aureus (MRSA) prosthetic joint infection (PJI).

Research objectives

Eradication therapy is not universally effective. The reasons for this are multifactorial including dose strength and compliance.

Research methods

All patients who underwent total hip and knee arthroplasty between December 2009 and December 2019 were identified. Patients who were also identified as positive for MRSA in the preoperative evaluation. After recording the confirmation of the eradication treatment prescription, all the processes were reviewed retrospectively. The results of each MRSA-positive patient were compared with the results of two MRSA-negative patients who had the same consultant, were of the same age, and had the same surgery.

Research results

Screening identified 42 knee and 32 hip arthroplasty patients as MRSA positive, 84

MRSA negative knee and 64 hip patients were reviewed. Patients were matched with medical co-morbidities in each group. Mean follow up was 5 years. PJI was identified in 4/32 (12.5%) of total hip replacements MRSA positive and 3/42 (7%) of total knee replacements patients. All patients had PJI within one year of surgery.

Research conclusions

MRSA positive patients are given eradication therapy routinely. However, no confirmation of eradication is sought. Patients who have MRSA colonisation pre-operatively, in our study had a significantly increased risk of PJI, when compared to negative patients. We would recommend establishing true eradication after treatment prior to arthroplasty.

Research perspectives

Further research needs to be performed into eradication therapy and strategy and also for those patients who do not respond to eradication therapy.

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ORIGINAL ARTICLE

Retrospective Study

Reliability of a simple fluoroscopic image to assess leg length discrepancy during direct anterior approach total hip arthroplasty

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Abstract

BACKGROUND

Direct anterior approach (DAA) total hip arthroplasty (THA) in a supine position provides a unique opportunity to assess leg length discrepancy (LLD) intra-operatively with fluoroscopy. Reported fluoroscopic techniques are useful but are generally complicated or costly. Despite the use of multiple techniques for leg length assessment, LLD continues to be a major post-operative source of patient dissatisfaction further emphasizing the importance of near-anatomic restoration. The utility of an alternative direct measurement of LLD on an intra-operative fluoroscopic pelvic image during DAA THA has not been reported.

AIM

To determine the reliability of a novel simple intra-operative measurement of LLD using a parallel line technique on a single fluoroscopic digital image of the pelvis.

METHODS

One hundred and seventy-one patients who underwent DAA THA were included for analysis. Intra-operative fluoroscopic and post-operative anterior-posterior radiographs were imported to TraumaCad and calibrated for LLD measurement. LLD was measured on each image using the right-left hip differences in lesser trochanter to pelvic reference line distances. Pelvic reference points included the teardrops and ischia. Fluoroscopic LLD was compared to the gold-standard measurement of LLD measured on a post-operative radiograph.

RESULTS

Mean absolute difference in teardrop referenced LLD between fluoroscopic and post-operative radiographs was 2.17 mm and based on the ischia mean absolute difference was 2.63 mm. Linear regression of fluoroscopic and post-operative

disclose.

Data sharing statement: No additional data are available.

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radiograph LLD based on teardrop and ischia LLD found r^2 values of 0.57 and 0.84, respectively. Mean absolute difference between fluoroscopic and post-operative x-ray LLD was within 5 mm in 95% of cases regardless of pelvic reference.

CONCLUSION

This study demonstrates that a single fluoroscopic view obtained during DAA THA for leg length assessment is clinically useful.

Key Words: Leg-length discrepancy; Total hip arthroplasty; Intra-operative fluoroscopy; Direct anterior approach; Limb asymmetry

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Core Tip: The direct anterior approach (DAA) for total hip arthroplasty (THA) has grown in popularity among Orthopaedic Surgeons in recent years. Despite the growth in this approach for THA, leg length discrepancy continues to be a major source of post-arthroplasty dissatisfaction in patients. Here we demonstrate that a single intra-operative fluoroscopic image for leg length assessment has clinical significance among patients undergoing DAA THA.

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INTRODUCTION

Leg length discrepancy (LLD) is a significant source of patient dissatisfaction after total hip arthroplasty (THA). An error in achieving acceptable leg length may manifest as discomfort, nerve palsy, pelvic obliquity, compensatory lumbar scoliosis, or result in need for revision surgery[1-4]. To minimize LLD after THA, multiple techniques have been developed for intra-operative assessment of leg length. In a survey conducted by the British Hip Society, surgeons reported utilizing a median of five techniques during THA to estimate LLD[5].

The direct anterior approach (DAA) for THA with a patient in a supine position has recently grown in popularity and presents an opportunity to use fluoroscopy intra-operatively to assess component position, size, femoral offset and LLD. Use of a specialized traction table facilitates this procedure but may also increase reliance on fluoroscopically based assessment of LLD[6,7]. Reported techniques to assess LLD intra-operatively with fluoroscopy during DAA THA include printed or virtual image overlays, concurrent imaging of a radio-opaque linear marker, and computer assisted image analysis techniques to correct for image distortion[5,8]. These previously reported fluoroscopic techniques can add time, complexity, radiation exposure, or significant cost to the procedure.

The aim of this study is to determine the reliability of an alternative novel simple intra-operative measurement of LLD using a parallel line technique on a single fluoroscopic digital image of the pelvis during DAA THA.

MATERIALS AND METHODS

Subjects

A retrospective study was performed of DAA THA's performed by two fellowship trained adult reconstruction surgeons between January 1, 2019 and December 31, 2019. Over this period, 182 patients were identified as eligible for inclusion in this study. Eligibility criteria included THA done by DAA on a Hana table, an adequate quality

appropriate intra-operative fluoroscopic image saved, and a standard post-operative pelvic radiograph available. The fluoroscopic image had to be a centered view of the pelvis such that both lesser trochanters were visible with all final THA components in place including the final femoral head. This study was approved by our institutional review board.

LLD Intra-operative measurement

During each DAA THA, LLD was assessed after trial components were in place using a single view of the pelvis obtained with an 18-inch OEC image intensifier (GE Healthcare). The image was typically performed with each leg externally rotated 20 degrees to display the profiles of the lesser trochanters. Once an adequately centered image of the pelvis was obtained, a line was drawn between the radiographic teardrops utilizing the OEC digital measurement tool. Then a second line was drawn through the prominence of the lesser trochanters. The two lines were then visually inspected to determine how near they were to parallel. Adjustments to trial components were made as necessary and fluoroscopic measurements repeated until satisfactory leg length was achieved. Other factors considered in determining leg length included soft tissue tension determined with a "shuck test" and correlation of intra-operative images with the pre-operative template. After the final components were placed, a centered fluoroscopic view of the pelvis was saved. This was the same view of the pelvis used to assess leg length during component trialing. Finally, after surgical closure, an anterior-posterior (AP) pelvis radiograph was obtained in the OR with the patient supine on a hospital bed.

LLD Measurement technique

Fluoroscopic and AP radiographs each with the final components in position were imported to TraumaCad for analysis by two independent observers (Nelms NJ and Caus S). Fluoroscopic and AP radiographs were calibrated manually to adjust for image magnification by matching the circular shape of the THA femoral head to the surgical component size in millimeters as recorded in the subject's operative note. The digital leg length comparison tool within TraumaCad was utilized to measure LLD based on teardrop and ischial pelvic reference lines (Figures 1 and 2). From each reference line a perpendicular distance was measured to the medial prominence of the right and left lesser trochanters. The left hip distance was subtracted from the right hip on both the fluoroscopic and x-ray images so that a positive or negative value represented which leg was longer. A positive value indicated a longer right leg, conversely a negative value indicated a shorter right leg. This was important to be able to define the relative LLD by side in case fluoroscopy and x-ray conflicted as to which leg was longer.

After all measurements were independently completed by two observers, cases with an inter-observer disagreement in LLD measurement of greater than 5 mm in either the intra-operative fluoroscopic images or anterior posterior radiographs were flagged for repeat measurement[8]. Repeat measurements were again performed independently to determine if the two observers could agree within 5 mm on LLD measurement. Of the initial 182 cases there were 25 cases for which two observers could not agree within 5 mm on LLD and a second independent measurement was completed. Of these 25 cases, the observers were unable to agree within 5 mm on the measured LLD in 11 cases. These 11 cases were removed from further analysis because the measurement inconsistency was attributed to poor image quality or difficult to define radiographic landmarks. This left a final count of 171 subjects for statistical analysis.

Statistical methods

The mean, standard deviation, and maximum LLD measured on x-ray and intra-operative fluoroscopy with teardrop and ischium references were calculated (n = 171). The difference in x-ray and fluoroscopic LLD was calculated by subtraction and the absolute value taken. The mean absolute difference in x-ray and fluoroscopic LLD measurements were compared between the teardrop and ischial reference points using a paired t-test. Linear regression was performed to determine the relationship between LLD measured with fluoroscopy *vs* x-ray for both teardrop and ischial references.

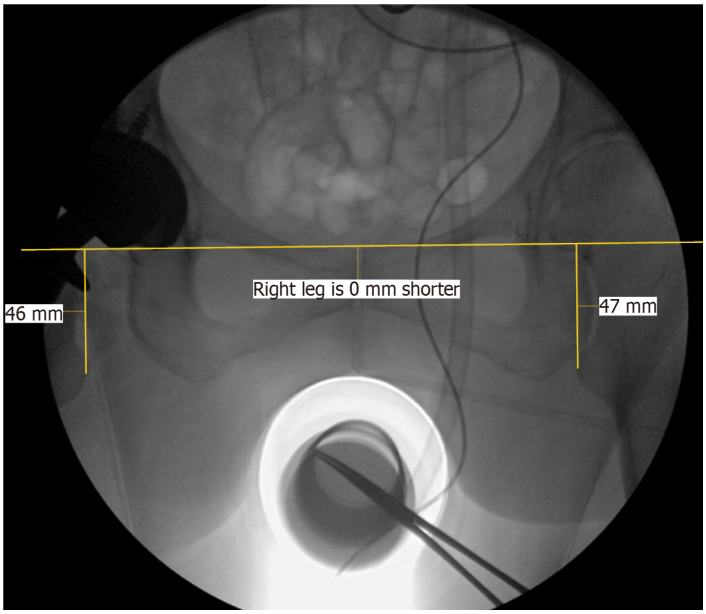


Figure 1 Intra-operative fluoroscopy image capture. Representative image of observer obtained leg length discrepancy measurements on a saved intra-operative fluoroscopic view of the pelvis. Image capture was performed by the OEC image intensifier intra-operatively as described. Shown is a line drawn through bilateral radiographic teardrops with perpendicular lines to the medial prominence of bilateral lesser trochanters.

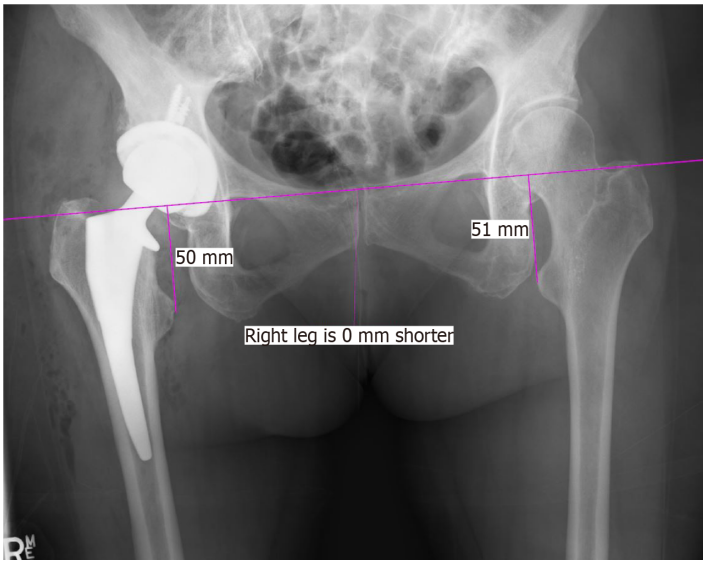


Figure 2 Post-operative x-ray image capture. Representative image of observer obtained leg length discrepancy measurements on a corresponding post-operative anterior-posterior x-ray of the pelvis. Single line drawn through bilateral radiographic teardrops with perpendicular lines to the medial prominence of bilateral lesser trochanters.

RESULTS

Overall mean LLD measured by the teardrops with fluoroscopy was 2.89 mm (SD = 2.07) and by x-ray 2.45 mm (SD = 2.11). Mean LLD measured by the ischia with fluoroscopy was 3.93 mm (SD = 2.95) and by x-ray 3.27 mm (SD = 3.01) (Table 1). Measurements with both teardrop and ischial landmarks demonstrated a statistically significant difference between the mean observed LLD with fluoroscopy compared with the gold standard x-ray (P = 0.007, P < 0.001). This difference included a bias toward overestimation of LLD by fluoroscopy especially when using an ischial pelvic reference.

Based on the teardrops, the mean absolute difference in LLD between fluoroscopic and x-ray was 2.17 mm (SD = 1.7). Referencing the ischia, the mean absolute difference in fluoroscopic and x-ray LLD was 2.63 mm (SD = 1.64) (Table 2). There was a statistically significant difference between the ischial and teardrop reference measurements

Table 1 Comparison of fluoroscopic and x-ray leg length discrepancy

	Fluoroscopic				X-ray				
	Mean	SD	Min	Max	Mean	SD	Min	Max	*P* value
LLD by Teardrops	2.89	2.07	0.0	11.0	2.45	2.11	0.0	12.5	0.007
LLD by Ischiums	3.93	2.95	0.0	16.0	3.27	3.01	0.0	15.5	< 0.001

Summary descriptive statistics including mean, SD, minimum and maximum values for leg length discrepancy as obtained by two independent observers. LLD: Leg length discrepancy.

Table 2 Absolute difference in leg length discrepancy

	Teardrop				Ischium				
	Mean	SD	Min	Max	Mean	SD	Min	Max	*P* value
Fluoro-x-ray difference	2.17	1.7	0.0	9.50	2.63	1.64	0.0	9.5	< 0.001

Absolute difference in mean leg length discrepancy between fluoroscopy and x-ray obtained measurements using radiographic teardrop or ischium reference points. All measurements were obtained by two independent observers.

of LLD, with a larger discrepancy between x-ray and fluoroscopic LLD observed using the ischial reference points ($P < 0.001$).

Linear regression of fluoroscopic and x-ray measurements based on the teardrops and ischia found r^2 values of 0.57 and 0.84, respectively (Figure 3). Despite the observed statistical differences, the absolute difference in LLD between fluoroscopic and x-ray measurements with either landmark was within 5 mm in 95% of cases. In only 1.8% of cases were both teardrop and ischial referenced fluoroscopic LLD measurements greater than 5 mm different from the gold standard x-ray LLD. Furthermore, we achieved a LLD of < 5 mm in 88.9% of patients and of < 10 mm in 98.8% of patients as assessed on a gold-standard post-operative x-ray of the pelvis.

DISCUSSION

Direct measurement of LLD on a single fluoroscopic view of the pelvis during DAA THA provided a clinically reasonable estimation of LLD in most of our cases. Using the teardrops for pelvic reference resulted in the closest association between intra-operative fluoroscopic and post-operative x-ray LLD. Although an ischial reference had a stronger linear correlation for LLD than the teardrops, there was a greater systematic overestimation of LLD when measuring from the ischia with fluoroscopy. Nonetheless, the difference between fluoroscopic and x-ray assessment of LLD using either teardrop or ischial landmarks was typically relatively small from a clinical standpoint. The fluoroscopic measurements with either pelvic landmark were in agreement with post-operative x-ray LLD measurements by a margin of 5 mm in 95% of cases. This degree of accuracy is useful because up to a 5 mm LLD is widely considered clinically insignificant and even up to and slightly beyond 10 mm may not be clinically meaningful[8-11]. For comparison, this simple technique appears more accurate than intra-operative x-ray assessment of LLD with patients in a lateral position. One study found that taking an x-ray with a patient in a lateral position resulted in 20% of cases displaying an intra-operative LLD measurement more than 5 mm different from that measured on a post-operative supine AP pelvis x-ray[12]. It also remains unclear as to the amount of post-operative LLD that can be tolerated without impacting patient function or satisfaction post-operatively[11,13]. Some studies have shown no clinically significant detrimental outcomes in LLDs approaching or even greater than 10 mm, while others have reported significantly worse OHS scores in patients able to perceive any LLD post-operatively[14,15]. Despite evidence that some LLD can be well tolerated after THA, restoration of near anatomic leg length is an important goal. Minimizing LLD after THA is critical because patient perceived post-operative LLD can result in post-operative joint pain, early revision arthroplasty or litigation[16].

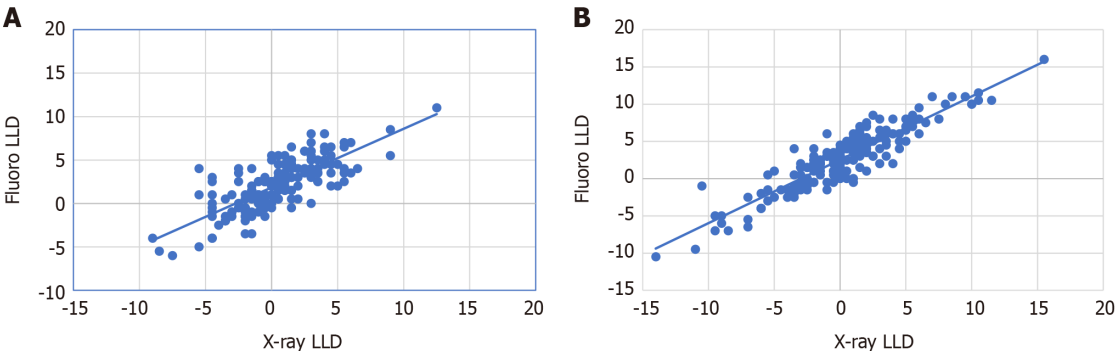


Figure 3 Measured leg length discrepancy. A: Measured leg length discrepancy based on teardrop reference point. Comparison showing mean x-ray leg length discrepancy (LLD) and fluoroscopic LLD using radiographic teardrop reference points as measured by two independent observers. Corresponding linear regression r^2 value of 0.56; B: Measured leg length discrepancy (LLD) based on ischium reference point. Comparison showing mean x-ray and fluoroscopic LLD using ischium references points as measured by two independent observers. Corresponding linear regression r^2 value of 0.87. LLD: Leg length discrepancy.

While there is growing clinical evidence in support of a DAA for THA, there is not a gold-standard technique for intra-operative LLD assessment[1,7,13,17]. Previously reported fluoroscopic techniques can add time, complexity, or cost[18-21]. One common technique is overlaying traced printed fluoroscopic images of the contralateral hip, or of the operative hip taken at the start of the procedure, with an image of the operative hip with trial implants in place. This relies heavily on accurate tracing and the surgeon may risk breaching sterility to draw on the images themselves. Also access to a fluoroscopic printer and the cost of printing supplies may prevent this from being universally available to surgeons. Another simple technique is to lay a transverse metal rod over the patient while images are taken until the rod is positioned in a way to estimate a relative LLD. Unfortunately, this usually requires multiple fluoroscopic images to achieve appropriate position of the rod. More specialized computer assisted techniques can partially automate LLD comparisons by allowing virtual image overlays, image stitching, and image correction for distortion. All of these commercial products based on advanced technology add cost.

The benefits of fluoroscopy during DAA THA are technique dependent, but fluoroscopy can provide an intra-operative assessment of leg length, offset, component size, and implant position[22-25]. Interestingly, Bingham *et al*[26] found no significant difference in post-operative LLD with or without use of intra-operative fluoroscopy when DAA THA was performed by very experienced surgeons with specific techniques which differ from ours. They achieved an impressive mean post-operative LLD of only 1.1 mm with fluoroscopy and 0.8 mm without. However, all DAA THA's performed in that study without fluoroscopy were performed on a standard operating table with both legs draped to allow direct visual comparison of LLD. Potential benefits of DAA THA on a specialized traction table include improved surgical exposure and access for intra-operative fluoroscopy. Fluoroscopic assessment of LLD is particularly helpful when a specialized traction table is used for DAA THA because the patient's feet are placed in traction boots which prevents direct clinical comparison of LLD. Even the two most commonly used intra-operative fluoroscopic measurement techniques to minimize image distortion may not result in anatomic leg length restoration. Austin *et al*[8] reported an average LLD measured on final post-operative x-rays relative to the teardrops of 4.8 mm using fluoroscopic tracing and 4.4 mm using a transverse metal rod technique[8]. These values are similar but surprisingly greater than our comparable average post-operative LLD of 2.45 mm LLD on post-operative x-rays. Austin *et al*[8] also reported that of the two fluoroscopic techniques, even the most accurate resulted in a final LLD of < 5 mm in only 59.6% of patients but of < 10 mm in 95.3%, which contrasts with our rates of 88.9% and 98.8%, respectively.

We found the assessment of LLD on a single fluoroscopic view of the pelvis to be a useful and simple technique of moderate accuracy. We suspect that by drawing lines through the teardrops or ischiums and comparing this to a line through the lesser trochanters is effective because image distortion is partially cancelled by such effects on both lines. In our clinical practice, we have achieved success by combining this parallel line fluoroscopic estimation of LLD with careful pre-operative templating and assessment of THA tension with a "shuck test" using a bone hook to feel the force necessary to distract the hip. We believe it is important to have more than one technique to estimate LLD intra-operatively. This study shows the clinical usefulness of fluoroscopy during THA on a traction table using a very simple technique.

Our study does have several limitations. In 6% of cases, our independent observers could not agree within 5 mm on the LLD measurements. This demonstrates some subjectivity in identifying radiographic landmarks despite efforts to establish consistency in these measurements between observers prior to beginning this study. We believe it was reasonable to exclude these cases so that the effects of subjective image interpretation can be diminished. We acknowledge that any measurement of LLD based on imaging of the pelvis alone may not represent discrepancy in overall leg lengths. True leg length comparison requires clinical evaluation or long leg x-rays, each of which also have their own intrinsic inaccuracies. Even so we demonstrate that combining this fluoroscopic technique with careful pre-operative templating and assessment of joint laxity resulted in minimal average post-operative LLD apparent on x-ray. And this demonstrates that the effects of intra-operative fluoroscopic image distortion do not preclude the clinical usefulness of this simple technique. Our findings are in contrast to the degree of fluoroscopic distortion observed by Carlson *et al*[27]. This could be because there was less electromagnetic interference in our operating suites or the use of a different model of C-arm.

CONCLUSION

An intra-operative estimation of LLD of moderate accuracy can be achieved during DAA THA by assessment of a simple AP fluoroscopic image. Assessment of LLD with this technique is achieved by comparing how parallel a digital line drawn through the radiographic teardrops is to a line drawn between corresponding points on the lesser trochanters.

ARTICLE HIGHLIGHTS

Research background

The direct anterior approach (DAA) in total hip arthroplasty (THA) with a patient in the supine position has gained popularity in recent years and provides an opportunity for intra-operative fluoroscopy for assessment of leg length discrepancy (LLD), as well as other intra-operative parameters of interest to Orthopaedic surgeons. LLD remains a significant source of patient dissatisfaction post-arthroplasty and we recognize an opportunity to evaluate the reliability of a novel simple parallel line technique on a single intra-operative fluoroscopic image.

Research motivation

The increase in popularity of the DAA THA combined with the opportunity to utilize intra-operative fluoroscopy has made surgeons wonder about the reliability of fluoroscopy in the clinical setting. We aimed to provide an assessment of this based on a simple parallel line technique on a single intra-operative fluoroscopic image of the pelvis once final arthroplasty components had been positioned.

Research objectives

The primary objective of this study was to understand the accuracy and reliability of a novel simple intra-operative fluoroscopy LLD assessment technique as compared to the standard post-operative x-ray.

Research methods

171 intra-operative fluoroscopic and anterior-posterior (AP) radiographs with final components in position were imported to TraumaCad for observer LLD analysis. LLD measurements were taken on each image utilizing right-left hip differences in lesser trochanters to two separate pelvic reference points. These were either the radiographic teardrops or ischia. Fluoroscopic LLD measurements were compared to the standard measurement of LLD on a post-operative AP radiograph.

Research results

Mean absolute difference between fluoroscopic and post-operative x-ray LLD was within 5 mm in 95% of cases regardless of pelvic reference point. Utilizing the simple parallel line technique on a single fluoroscopic image of the pelvis we achieved an LLD of < 5 mm in 88.9% of subjects and of < 10 mm in 98.8% of subjects as measured

on the gold-standard post-operative x-ray.

Research conclusions

We demonstrate moderate accuracy in estimation of LLD intra-operatively by assessment of a simple AP fluoroscopic image, specifically with a novel simple parallel line technique. This technique is performed by visually comparing how parallel a digital line drawn trough the radiographic teardrops is to a line drawn between corresponding points on the lesser trochanters. We acknowledge the importance of continuing to have more than one technique intra-operatively to most accurately estimate LLD.

Research perspectives

Our study adds to a body of research investigating the clinical usefulness of intra-operative fluoroscopy in the DAA THA, specifically we demonstrate that this technique has clinical benefit in our cohort of patients. Not only do we hope this adds to the body of research and clinical understanding of fluoroscopy, but also hope it can be utilized as an additional reliable technique for assessment of intra-operative LLD.

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ORIGINAL ARTICLE

Retrospective Study

Anthropometric method for estimating component sizes in total hip arthroplasty

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Abstract

BACKGROUND

Preoperative templating is essential in total hip arthroplasty (THA) as it not only helps to facilitate the correct implant type and size but also determines the post-operative biomechanics. Templating is also increasingly important from a medico-legal perspective and recommended in the British Orthopaedic Association Guide to Good Practice. Although templating has become increasingly digitised, there are no simple anthropometric models to predict implant sizes in the absence of digital methods.

AIM

To assess the accuracy of using an easily obtainable measurement (shoe size) to predict component sizes in THA compared with digital templating.

METHODS

Digital radiographs from a cohort of 102 patients (40 male, 62 female) who had undergone uncemented or hybrid THA at a single centre were retrospectively templated to desired cup and stem sizes using TraumaCad®. We compared the

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templated size to the actual size of the implant and assessed if there was any correlation with the patient's shoe size.

RESULTS

Statistically significant positive correlations were observed between: shoe size and templated cup size ($\rho = 0.92$, $P < 0.001$); shoe size with implanted cup size ($\rho = 0.71$, $P < 0.001$); shoe size and templated stem size ($\rho = 0.87$, $P < 0.001$); and shoe size with implanted stem size ($\rho = 0.57$, $P < 0.001$). Templated and implanted acetabular cup sizes were positively correlated ($\rho = 0.76$, $P < 0.001$) and were exact in 43.1% cases; 80.4% of implanted cup sizes were within 1 size (+/- 2 mm) of the template and 100% within 2 sizes (+/- 4 mm). Positive correlation was also demonstrated between templated and implanted femoral stem sizes ($\rho = 0.69$, $P < 0.001$) and were exact in 52.6% cases; 92.6% were within 1 size of the template and 98% within 2 sizes.

CONCLUSION

This study has shown there to be a significant positive correlation between shoe size and templated size. Anthropometric measurements are easily obtainable and can be used to predict uncemented component sizes in the absence of digital methods.

Key Words: Anthropometric; Digital templating; Hip; Preoperative planning; Total hip arthroplasty

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Core Tip: Templating for component size in total hip arthroplasty is becoming increasingly digitised, which can be limited by cost and availability of software. There are no anthropometric models to predict component sizes in the absence of digital methods. We demonstrated significant positive correlations between a patient's shoe size and both their templated and implanted component sizes. Shoe size can reliably predict implant sizes in uncemented hip arthroplasty. In addition to helping the surgeon make a rapid estimation of implant size; this simple system can also assist purchasing departments to plan preoperative stock requirements without specialised software.

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INTRODUCTION

Accurate preoperative templating is an essential step in total hip arthroplasty (THA) and is recommended by the British Orthopaedic Association's Best Practice for Hip Arthroplasty[1]. Templating has proven to be effective in selecting the correct implant size, optimisation of biomechanics such as leg length discrepancy, centre of rotation and alignment. Furthermore, preoperative planning has been well documented to improve component stability, reduce the operative time and minimise wear due to implant malposition[2].

Alongside the widespread introduction of digital radiography throughout the United Kingdom, preoperative templating of THA has become increasingly digitised with several software products currently on the market. However these software packages may not be universally available and are dependent on the user's training and level of surgical experience[3]. Digital templating and computer-navigated surgery have been used to improve the quality and outcomes of THA however these methods can be expensive and may not be a feasible option for some departments.

Preoperative estimations of implant sizes may be useful for resource-scarce departments as it allows for better organisation of hospital funds by reducing the number of excess implants "on the shelf"[4]. Shoe size is an easily obtainable and cost-free anthropomorphic measurement, which is a reliable reflection of foot length, overall longitudinal growth and stature[5,6]. We propose preoperative shoe size as a simple measurement tool for predicting component sizes for primary uncemented THA. The aim of this study is to determine the accuracy of using this measurement as an estimator for acetabular cup and femoral stem sizes when compared with digitally templated sizes for the same hip.

MATERIALS AND METHODS

Patients

A retrospective, single-centre cohort study was performed for patients who had received primary uncemented or hybrid THA for osteoarthritis between October 2015 and October 2016. Patients were excluded if they had a body mass index (BMI) greater than 35; had undergone previous foot and ankle surgery; diagnosed with foot or ankle disease; noted a change in shoe size during adulthood or if they required a complex primary arthroplasty. Cemented components of hybrid THA were also excluded. A total of 102 acetabular cups and 95 femoral stems from 102 consecutive patients were included in the final analysis, comprising of 40 men and 62 women. The mean age of the study group was 69.9 ± 10.9 years (range 33-90) and mean BMI 32 ± 3.6 (range 20.2-39.0). All THAs were performed by a single surgeon and using a posterior approach to the hip. The uncemented components implanted were the POLAR R3 cup and POLARSTEM stem (Smith & Nephew, Memphis, TN, United States). Implant sizes were recorded along with the corresponding patient's standard United Kingdom shoe size at the time of surgery. Shoe sizes ranged from 3 to 11. Institutional Review Board approval was not required in accordance with the United Kingdom National Research Ethics Service guidance on the use of anonymised data collected retrospectively as part of routine clinical care.

Radiographs and templating

Preoperative anteroposterior (AP) digital pelvic radiographs were obtained for all patients using a standard protocol (Figure 1) with the feet internally rotated at 15 and the X-ray beam centered on the superior margin of the symphysis pubis[7]. All patient identifiers were removed from radiographs and replaced by unique sequential numbers before being imported into TraumaCad® (Brainlab, United States) for calibration and templating. Each component was digitally templated to a desired size in a manner as described by Bono[8], by two orthopaedic surgeons who were familiar with the software (Figure 2). A third examiner (senior surgeon) reviewed all size discrepancies and a final decision was achieved by consensus. All examiners were blinded to the actual size of the implanted components.

Statistical analysis

The Spearman's rank correlation coefficient (ρ) was used to assess the correlation between the patient's shoe size with: (1) Templated component size; and (2) Implanted component size; and if there was any difference between templated and implanted sizes. A P value of < 0.05 was considered to be statistically significant. Statistical analysis was performed with SPSS v22.0 (IBM, Armonk, NY, United States). By analyzing any observed relationships we intended to produce a table for estimating the component size from the patient's shoe size.

RESULTS

Statistically significant positive correlations were observed between: shoe size and templated cup size ($\rho = 0.92$, $P < 0.001$); shoe size with implanted cup size ($\rho = 0.71$, $P < 0.001$); shoe size and templated stem size ($\rho = 0.87$, $P < 0.001$); and shoe size with implanted stem size ($\rho = 0.57$, $P < 0.001$). Correlation coefficients based on gender subgroups are presented in Table 1. Templated and implanted acetabular cup sizes were exact in 43.1% cases, 80.4% of implanted cup sizes were within 1 size (+/- 2 mm) of the template and 100% were within 2 sizes (+/- 4 mm). Templated and implanted femoral stem sizes were exact in 52.6% cases, 92.6% were within 1 size of the template

Table 1 Subgroup correlation coefficients (Spearman's rank)

	Overall	*P* value	Male	*P* value	Female	*P* value
Shoe/templated cup	0.923	< 0.001[a]	0.782	< 0.001[a]	0.828	< 0.001[a]
Shoe/implanted cup	0.712	< 0.001[a]	0.007	0.964	0.527	< 0.001[a]
Shoe/templated stem	0.872	< 0.001[a]	0.835	< 0.001[a]	0.786	< 0.001[a]
Shoe/implanted stem	0.570	< 0.001[a]	0.137	0.400	0.647	< 0.001[a]

[a]$P < 0.05$ was selected to indicate statistical significance.

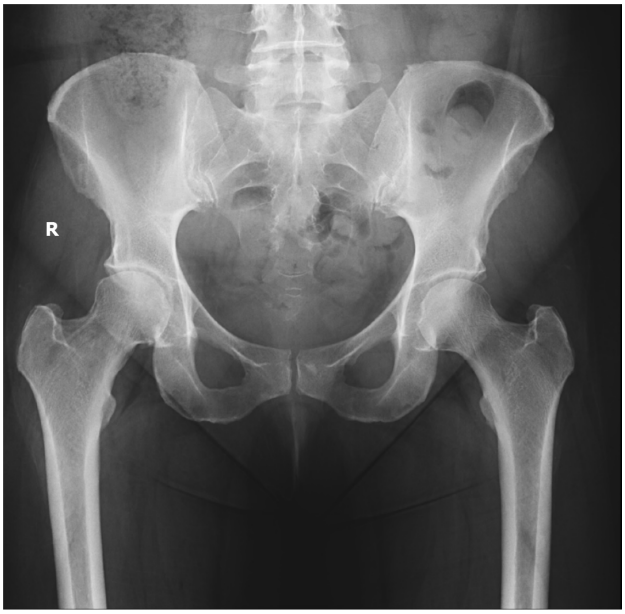


Figure 1 Standardised anteroposterior pelvic radiograph. A preoperative radiograph of a patient with a degenerative right hip was obtained in the standardised protocol with the feet internally rotated at 15 and with the X-ray beam centered on the superior margin of the symphysis pubis.

and 98% were within 2 sizes. Statistically significant positive correlations were observed between implanted cups ($\rho = 0.76$, $P < 0.001$) and stems ($\rho = 0.69$, $P < 0.001$) from their templated sizes. Predicted component sizes from shoe size, adjusted for sex, are presented in Table 2.

DISCUSSION

Templating is an important step prior to performing a total hip replacement, as there has shown to be a greater risk of prosthesis failure if components are inadequately sized[9]. Accurate templating should form part of the routine preoperative assessment and is not only recommended by the British Orthopaedic Association Guide to Best Practice[1] but is also associated with reduced operative time and fewer complications [10]. Preoperative planning encourages surgical precision by accounting for femoral offset restoration, leg length correction and implant alignment[2]. Analogue templating using manufacturer acetates has become incompatible since the widespread introduction of digital radiography throughout all acute hospitals in the United Kingdom. As a result templating has become digitised and allows the user to accurately calibrate the magnification and sizing of the radiograph. Predicting implant sizes can enable orthopaedic purchasing departments to procure accurate stock volumes. This is an important factor when considering the cost and shelf life of expensive implants.

Recent studies have proposed the use of 3D computed tomography (CT) and magnetic resonance imaging with reports of up to 100% predictive accuracy for templating cup size and orientation when compared with 2D templating from digital radiographs[11,12]. However, Westacott *et al*[13] further observed that CT scans are

Table 2 Quick reference table

United Kingdom shoe size: Male	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Predicted cup size	51	52	53	54	54	55	56
Predicted stem size	2	2 - 3	3	4	4	5	6
United Kingdom shoe size: Female	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Predicted cup size	46	48	49	50	51	52	53
Predicted stem size	0	0-1	1-2	2	2-3	3	3-4

Quick reference conversion table for predicted cup and stem sizes from United Kingdom shoe sizes by male and female subgroups.

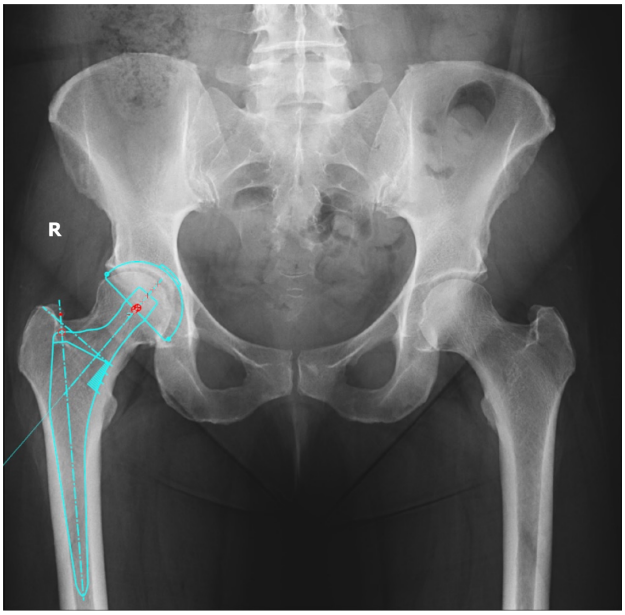


Figure 2 Digital templating using TraumaCAD®. Acetabular and femoral components of an uncemented total hip arthroplasty are digitally templated to a desired size from a standardised and calibrated pelvic radiograph.

performed with the subject supine and therefore do not represent the functional position of the pelvis when the subject is standing. Consequently the pelvic obliquity due to tilt and leg length discrepancy will change the abduction angle and version when standing and may not provide the optimum functional position of the implants. Nonetheless, templating software is expensive and may not be readily available in all orthopaedic departments due to local hardware, software and financial constraints. Surgeons may also wish to avoid the additional radiation risk and cost burden associated with routine preoperative CT scanning for all their patients.

The precision of digital templating is dependent on the quality, rotation and magnification of radiographs. Various methods have been developed, notably the KingMark®, in an effort to calibrate digital radiographs for accurate templating[14]. For patients with advanced degenerative arthritis it may not be possible to obtain a good quality radiograph. In such cases the templating can be performed on the contralateral hip though in patients with bilateral deformities, this process becomes less reliable. Templating relies on the subjective decision of the examiner and can be affected by their level of surgical experience and familiarity with templating software. As a result there are varying degrees of intraobserver reliability reported in the literature[11,15].

Similar to our study findings, the difference in sizes between predicted and implanted uncemented prostheses are well documented in THA, as these implants require an element of under-reaming for press-fit fixation[16]. Consequently, surgeons may opt for a smaller than templated prosthesis size to avoid intraoperative fracture if they feel that stability has been achieved. Furthermore, some hip systems such as the POLARSTEM are designed to be impacted into a compacted cancellous bone bed for fixation. As a result post-operative radiographs may reveal an approximately 1 mm

radiolucent line between the stem and the inner cortex, which represents this cancellous layer[17].

In this study we chose shoe size as a non-invasive, fast and harm-free measurement as a predictor for stature[6]. Recent studies have also demonstrated a significant positive correlation between shoe size and component size in total knee arthroplasty with up to 80% predictive accuracy[18,19]. To date, a similar correlation has not been described for THA in the current literature. Unlike height or weight, foot length does not change significantly during adulthood[20]. Collective evidence from forensic literature advocates that shoe size can reliably predict both skeletal foot size and the overall height of the individual[5,6]. The standard United Kingdom shoe size arises from the longitudinal length of the 'last', which is the physical template over which a shoe is manufactured[19]. As each person determines which shoe size provides the best fit it therefore follows that the individual knows his or her size accurately. In the outpatient setting shoe size is a readily obtainable value and doesn't require additional measurement aids such as for height or weight, which may not be easily available. We further propose a simple conversion table to enable the surgeon to make a quick estimation for the required component sizes from both male or female shoe sizes (Table 2).

We acknowledge several limitations in our study. Our modest sample size was comparable to those in mentioned in the literature though it was not large enough to calculate predictive rules pairing unique shoe sizes to their exact component sizes. This study investigated United Kingdom shoe sizes and therefore the relationships described may not translate to some countries. Patients with a history of foot and ankle surgery were excluded from this report as the dimensions of the foot may change in adulthood secondary to deformity such as hallux valgus. However, Sawalha *et al*[19], in their series of 93 knee replacements did not see any change in accuracy of predicting component size from shoe size when patients with foot pathology or history of foot surgery were included. This would indicate that shoe size is a reliable predictor of component size in all patients irrespective of foot pathology. Our sample size excluded cemented implants, which may limit the broader application of our reported results to cemented hip systems. Finally, the authors appreciate the increasing worldwide use of templating software and computer navigated arthroplasty surgery. However like many other departments, templating software licences are often limited to the operating theatre suites and may not readily be available in the outpatient setting when consulting patients. The proposed advantage of an anthropometric predictive model allows for easy, rapid component size estimation in the absence of computer software and may have a role in allowing purchasing departments to procure accurate stock levels well in advance of planned arthroplasty procedures.

CONCLUSION

In conclusion, our study shows there to be a strong positive correlation between shoe size and templated component sizes in primary uncemented THA. This relationship may allow surgeons to confidently predict component sizes in the absence of digital templating.

ARTICLE HIGHLIGHTS

Research background

Preoperative templating is an essential in total hip arthroplasty (THA) as the correct size and orientation of components play a key role in the success of the prosthesis. Templating is becoming digitised yet many orthopaedic departments lack access to software due to cost and resources.

Research motivation

Available evidence surrounding the correlation between a patient's shoe size and knee arthroplasty component sizes suggests reliable positive correlations. Our motivation for this study was to assess if there was a reliable anthropometric method to predict THA component sizes from shoe size in the absence of digital methods.

Research objectives

We aim to determine the accuracy of using an easily obtainable measurement (shoe

size) to predict component sizes in THA when compared with the digitally templated sizes of the same hip.

Research methods

We performed a retrospective review of 102 patients (40 male, 62 female) who had undergone elective uncemented or hybrid THA at our single centre. Standardised digital pelvic radiographs were retrospectively templated to desired cup and stem sizes using TraumaCad®. We then compared the templated size to the actual size of the implant that the patient received and assessed if there was any correlation with the patient's shoe size.

Research results

Statistically significant positive correlations were observed between patient shoe size: templated cup and implanted cup size; templated stem and implanted stem size. Positive correlations were also demonstrated between templated and implanted acetabular cup sizes, and templated and implanted stem sizes.

Research conclusions

Our study has shown there to be strong positive correlations between shoe size and templated component sizes in primary uncemented THA. Shoe size is an easily obtainable measurement and can allow surgeons to confidently predict component sizes in the absence of digital templating.

Research perspectives

Future research should evaluate the clinical significance of these findings with cemented hip systems.

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ORIGINAL ARTICLE

Retrospective Study

Treatment of knee osteochondritis dissecans with autologous tendon transplantation: Clinical and radiological results

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Institutional review board statement: This study was approved by the institutional review board of our hospital.

Informed consent statement: Patients were not required to give informed consent to the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

Conflict-of-interest statement: The authors declare that there are no conflicts of interest.

Data sharing statement: The participants gave informed consent

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Abstract

BACKGROUND

Defect treatment with tendon autograft in osteochondral lesions has been published in the literature with an experimental study in dogs. To demonstrate that it is possible to treat knee osteochondral lesions with the technique of autologous tendon transplantation.

AIM

To evaluate the clinical and radiological results of patients with knee osteochondral lesions who were treated with autologous tendon transplantation.

METHODS

Twenty patients (22 knees) with osteochondritis dissecans (OCD) lesions involving the knee were treated with autologous tendon transplantation between 2005-2018. All lesions were International Cartilage Repair Society grade IV. All patients were evaluated clinically at final follow-up with knee injury and osteoarthritis outcome score (KOOS); and radiologically with magnetic resonance observation and cartilage repair tissue (MOCART) and Kellgren-Lawrence (KL) classification.

for data sharing.

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RESULTS
A total of 20 patients (22 knees) with a mean age of 25.5± 6.8 years were included. The average defect size was 4.2 ± 2.1 cm^2, and the average defect depth was 0.9 ± 0.4 cm. Total KOOS score was preoperatively 29.4 ± 5.5 and was later found to be 81.5 ± 5.9 after an average of 68.7 ± 37.7 mo follow-up. The mean MOCART score was 56.2 ± 10.7. Preoperatively, all of the patients had KL grades of 0–1; during the follow-up period, 80% of the patients showed no radiological progress of osteoarthritis. Patients with less than 4 cm^2 lesion had statistically significantly better overall KOOS than patients whose more than 4 cm^2 lesion, particularly in sport and quality of life subscales.

CONCLUSION
The autologous tendon transplantation is a single-step, safe, simple, cost-effective method for the treatment of knee OCD with satisfactory clinical and radiological outcomes, particularly in patients with less than 4 cm^2 lesion.

Key Words: Osteochondritis dissecans; Knee; Tendon; Transplantation; Autologous; Peroneus

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Core Tip: Defect treatment with tendon autograft in osteochondral lesions has been published in the literature with an experimental study in dogs. However, to date, only one case in the capitellum of the elbow has been scientifically published in humans. This retrospective study shows that knee osteochondral lesions are possible with tendon autograft transplantation technique.

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INTRODUCTION

Knee osteochondritis dissecans (OCD) is a common pathology affecting the articular cartilage and resulting in the delamination of subchondral bone[1,2]. The exact causes are unknown, however, biological (ischemia, osteonecrosis) and mechanical factors (trauma, overuse) has been proposed[3,4]. The OCD can cause a very wide range of clinical presentation from completely asymptomatic to functional impairment. If left untreated, these lesions may lead to the development of osteoarthritis[5].

The management of OCD in young patients who may not be good candidates for arthroplasty remains a challenge for the knee surgeons. Many treatments have been proposed including fragment fixation, microfracture, osteochondral autograft /allograft transplantation, matrix-induced chondrogenesis, and autologous chondrocyte implantation, depending on the size and depth of lesion[6,7]. The purpose of any surgical interventions is to re-establish the joint surface, provide the joint congruency, relieve the symptoms and decrease the risk of degenerative osteoarthritis. The numerous number of treatment options reveals the challenge of the management of knee OCD. However, the real challenge being to choose the 'most rational' of several alternative options which potentially differing in their outcomes.

Osteochondral autograft transplantation and mosaicplasty are common surgical procedures for treating symptomatic International Cartilage Repair Society (ICRS) grade 3 or 4 defects smaller than 3 cm^2[8]. These techniques has several advanteges including resurface the defect with normal cartilage and replace concurrently the subchondral bone. But, the donor site morbidity is a major disadvantage. Furthermore, obtaining a congruent surface with donor grafts requires technically challenging skill [9]. To address these problems, we have proposed a new graft source, the peroneus longus tendon, hypotesizing that the tendon autograft with elastic structure can enable

easly joint congruence and with solid structure can provide early weight-bearing. Encouraged by the success of tendon autograft in a dog model[10], the technique was applied in a series of 20 patients with a OCD.

The purpose of this study is to retrospectively evaluate the clinical and radiological results of autologous tendon transplantation using the peroneus longus tendon in patients with ICRS grade 3 or 4 defects.

MATERIALS AND METHODS

This study was approved by the institutional review board of our hospital. Patients were retrospectively followed up for a minimum of 2 years and data were evaluated retrospectively. Twenty-two consecutive knees (20 patients, 2 bilateral) who underwent autologous tendon transplantation for knee OCD were enrolled from 2005 to 2018. The inclusion criteria for the treatment were (1) Patients with osteochondral defects graded IV on ICRS (International Cartilage Repair Society) classification; (2) Patients with a OCD lesions located at the femoral condyles, sized more than 2 cm^2, causing knee symptoms (pain, swelling or locking) and lesions were not suitable for fixation; and (3) Patients who failed a conservative treatment at least 6-mo period. The exclusion criteria were (1) Kellgren and Lawrence grade ≥ 2 osteoarthritis; (2) Osteonecrosis and infammatory arthropathy; (3) Meniscal deficiency or ligament instability; (4) Patients with other general medical conditions (*e.g.*, diabetes mellitus or rheumatoid arthritis); (5) Multiple and recent intra-articular injections with steroids; (6) Deformity or OA at ipsilateral and contralateral hip or ankle joints; and (7) Possible non-compliance to the proposed rehabilitation protocol.

Preoperatively, all patients underwent a thorough physical examination, including knee passive and active range of motion, ligamentous stability and knee specific tests. Standard radiography were acquired in every patient to evaluate the osteochondral lesions and knee osteoarthritis. The magnetic resonance images (MRI) were obtained routinely to evaluate the size and depth of the OCD lesion. Patients were assessed with Knee Injury and Osteoarthritis Outcome Score (KOOS) before the operation and at the final follow-up. The radiological outcomes were assessed with magnetic resonance observation of cartilage repair tissue (MOCART) score and with Kellgren-Lawrence (KL) classification.

The osteochondral defect repair was radiologically evaluated by MRI using the Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART). Images were evaluated according to defect filling, integration into the border region, surface of the repair tissue, structure of the repair tissue, signal intensity of the repair tissue, subchondral lamina status, integrity of the subchondral bone, and joint adhesion and infusion[11]. Integrity assessment of the subchondral bone could not be made because the defect area was restored with autologous tendon in the treatment procedure. Therefore, the score ranged from 0 (worst result) to 90 (best possible result).

MRI was performed on a 1.5 Tesla system (Avanto; Siemens Medical Solution, Erlangen, Germany) using ankle coil. The following sequences with axial, coronal and sagittal plains were used: T1-weighted turbo spin echo (T1W TSE) [TR/TE = 777/12 ms, matrix = 320 x 224, field of view (FOV) = 16 cm, excitations = 1, slice thickness = 3 mm, spacing = 0.6 mm], fat saturated proton density weighted turbo spin echo (PDW TSE FS) (TR/TE = 3330/47 ms, matrix = 320 x 224, FOV = 16 cm, excitations = 1, slice thickness = 4 mm, spacing = 1.2 mm), and fat saturated T2-weighted turbo spin echo (T2 TSE FS) (TR/TE = 5200/75 ms, matrix = 208 x 256, FOV = 16 cm, excitations = 1, slice thickness = 4 mm, spacing = 1.2 mm).

KOOS is a specific questionnaire form about the knee containing 42 questions in 5 individual subheadings. These 5 subgroups are: pain, symptoms, activities of daily living, sports and quality of life. KOOS is a recommended scoring system in cartilage repair patients and is a reliable test being used in patients after their surgical treatments of focal cartilage lesions in recent years[12].

Surgical technique

All procedures were performed in a supine position under general or spinal anesthesia and a thigh tourniquet was applied. A diagnostic arthroscopy was performed, intraarticular conditions were evaluated, associated meniscal injuries were treated and any loose bodies were removed. A mini-arthrotomy was used, depending on the size and site of the lesion. The osteochondral lesion was removed and debrided until viable bleeding bone was reached. The subchondral bone was drilled at 2-4 mm intervals with 1 mm thick K-wire. Following this, a longitudinal posterolateral mini-incision

was opened over the peroneus longus tendon, 10 cm proximal to the lateral malleolus on the ipsilateral side. A split portion of tendon was harvested from the peroneus longus. The graft was folded back on itself and held with absorbable suture, creating a "ball" and then fixed into the defect with suture anchor (Figure 1). The spherical congruency of the joint was checked. Finally, a cylindrical cast or orthosis was applied at 15 degrees of knee flexion.

Post-operative follow-up; Immediate isometric quadriceps exercise was started postoperatively. All patients were mobilized with weight-bearing on postoperative day 1. At the end of the 4th week, cylindrical cast was removed and active and passive knee joint movements were prescribed. All patients followed the same rehabilitation protocol for 6 mo, respectively, based on current knowledge of the graft healing biology: protect the transplant from excessive loads and shearing forces, gain full extension and gradual recovery of knee flexion, progressive recovery in daily functional activities, increase the strength of the quadriceps and hamstrings, recovery of full range of motion, further increase in strength of quadriceps and flexors muscles, further increase in functional activities level, prepare athlete for a return to team and competition with good recovery of the aerobic endurance, maintain a good quality of life, avoiding excess of body fat and preventing risk of reinjury.

All patients were followed up in the outpatient clinic at the 2nd week, 4th week, 8th week, 12th week, 6th month, at the end of 1 year and at the last clinical follow-up. Clinical follow-ups; It was performed together with a surgeon and a physiotherapist in the surgical team, and the data were documented at each clinical control.

All patients were evaluated radiologically with MRI at the end of the first year and at the last follow-up. Radiological evaluations were evaluated by 2 independent radiologists in consensus.

Statistical analysis

The statistical analysis was performed using SPSS Version 22.0 statistical analysis software. Percentage, rate, average and SD were used as descriptive statistics. The compliance of the quantitative data with normal distribution was evaluated using the Kolmogorov–Smirnov test. The parametric data were compared using the Student *t*-test and the nonparametric data were compared using the Mann-Whitney *U* test. *P* value less than 0.05 was considered to be statistically significant.

RESULTS

Twenty-two knees of 20 patients underwent autologous tendon transplantation who had knee OCD were included in the study. The mean patient age was 25.5 ± 6.8 years (range, 19-42 years) and the follow-up period was 68.7± 37.7 mo (range, 30-182 mo). Detailed patients demographics are shown in Table 1.

Preoperatively, the average KOOS score was 32.2 ± 5.8 for pain, 28.2 ± 6.4 for symotom, 44.5 ± 8.1 for activity of daily living, 22.4 ± 4.6 for sport, and 24.5 ± 5.8 for quality of life. Postoperatively, the average KOOS score was 91.3 ± 4.2 for pain, 89.1 ± 7.2 for symptom, 85.1 ± 6.8 for activity of daily living, 74.5 ± 7.2 for sport, and 72.4 ± 8.1 for quality of life. Preoperative total KOOS score was 29.4 ± 5.5 (range, 21.4-40.5). KOOS total score was found to be increased to 81.5 ± 5.9 (range, 74.2-92.7). All parameters of the KOOS score improved significantly ($P < 0.001$) (Table 2).

The mean MOCART score was found 56.2 ± 10.7 (range, 40-75) at last follow-up. There was no significant correlation between the total MOCART and KOOS scores. Preoperatively, all of the patients had Kellgren–Lawrence grades of 0–1; during the follow-up period, 80% ($n = 16$) of the patients no showed radiographical progression of osteoarthritis (Figure 2). Patients with less than 4 cm^2 lesion had statistically significantly better overall KOOS ($P < 0.01$) than patients whose more than 4 cm^2 lesion. In terms of the KOOS subscales, however, this was true only with sport ($P = 0.01$) and quality of life ($P = 0.02$). There were no statistically significant differences in the subscales pain, symptoms and activity of daily living (Figure 3).

Second-look arthroscopy was performed during contralateral knee operation to the patients who was operated from both knees at one year intervals. Second look arthroscopy view at 1-year follow-up of ICRS grade 4 of medial femoral condyle showing filling of the defect with a well-integrated, smooth surfaced and stable regenerated cartilage. The graft adaptation and incorporation were assessed to be excellent (Figure 4).

Peroneus longus tendons were used as autologous grafts in all patients. No complications developed in any patient regarding donor site. In the graft donor site, no patient

Table 1 Demographic characteristics of patients

Age at time of surgery, yr, mean ± SD (range)	25.5 ± 6.8 (19-42)
Sex, M/F, *n* (%)	15 (75%)/5 (25%)
BMI, kg/cm^2, mean ± SD (range)	27.1 ± 3.5 (21.6-32.4)
Side, R/L, *n* (%)	13 (59.9%)/9 (40.1%)
Location, MFC/LFC, *n* (%)	18 (81.8%)/4 (18.2%)
Size, cm^2, mean ± SD (range)	4.2 ± 2.1 (2.1-9.0)
Depth, cm, mean ± SD (range)	0.9 ± 0.4 (0.4-1.7)
Follow-up duration, mo, mean ± SD (range)	68.7 ± 37.7 (30-182)

BMI: Body mass index; F: Female; L: left; LFC: Lateral femoral condyle; M: Male; MFC: Medial femoral condyle; R: Right; SD: Standard deviation.

Table 2 Clinical and radiological results of patients

	Preoperative, mean ± SD (range)	At final follow-up, mean ± SD (range)	*P* value
Total KOOS score	29.4± 5.5 (21.4-40.5)	81.5 ± 5.9 (74.2-92.7)	< 0.01
Pain	32.2 ± 5.8	91.3 ± 4.2	< 0.01
Symptoms	28.2 ± 6.4	89.1 ± 7.2	< 0.01
ADL	44.5 ± 8.1	85.1 ± 6.8	< 0.01
Sport	22.4 ± 4.6	74.5 ± 7.2	< 0.01
QOL	24.5 ± 5.8	72.4 ± 8.1	< 0.01
MOCART score	NM	56.2 ± 10.7 (40-75)	NM
Kellgren-Lawrence grade	0.4 ± 0.1 (0-1)	0.6 ± 0.1 (0-1)	NS

ADL: Activity of daily living; QOL: Quality of life; KOOS: Knee injury and osteoarthritis outcome score; MOCART: Magnetic resonance observation of cartilage repair tissue score; NM: Not measured; NS: Not significant; SD: Standard deviation.

reported a neurological symptom. Hypertorphic scar tissue did not occur in any of the patients in the donor site. At the end of the 6th month, all patients returned to their daily work and daily activities without any restrictions.

DISCUSSION

The most important finding of the present study is that all of the patients treated with autologous tendon transplantation had "excellent and good" clinical and radiological outcomes with minimum 2 years follow-up. All parameters of the KOOS score improved significantly ($P < 0.001$). Patients with less than 4 cm^2 lesion had statistically significantly better overall KOOS ($P < 0.01$) than patients whose more than 4 cm^2 lesion.

The main aim in the treatment of osteochondral defect is to restore joint integrity by creating a tissue that is the same or similar to the biomechanical properties of the articular cartilage. This is the basic logic of this method. The reason we think of using tendons in the treatment of OCD is that the tendon has a viscoelastic and anisotropic structure that has main tasks of carrying energy from muscle to bone and storing energy with its highly organized hierarchy[13-15]. Tendons have been proven to increase their amounts of proteoglycan and glycosaminoglycan present in the matrix under compression conditions, and can resist compressive loads thanks to these two substances[13,15,16]. Another feature of the tendons is that they can change their structures and compositions in case of mechanical load changes. Cells in the tendon are responsible for adaptive changes and can alter gene expression, protein synthesis and cell phenotype against mechanical load. In addition, the extracellular matrix of the

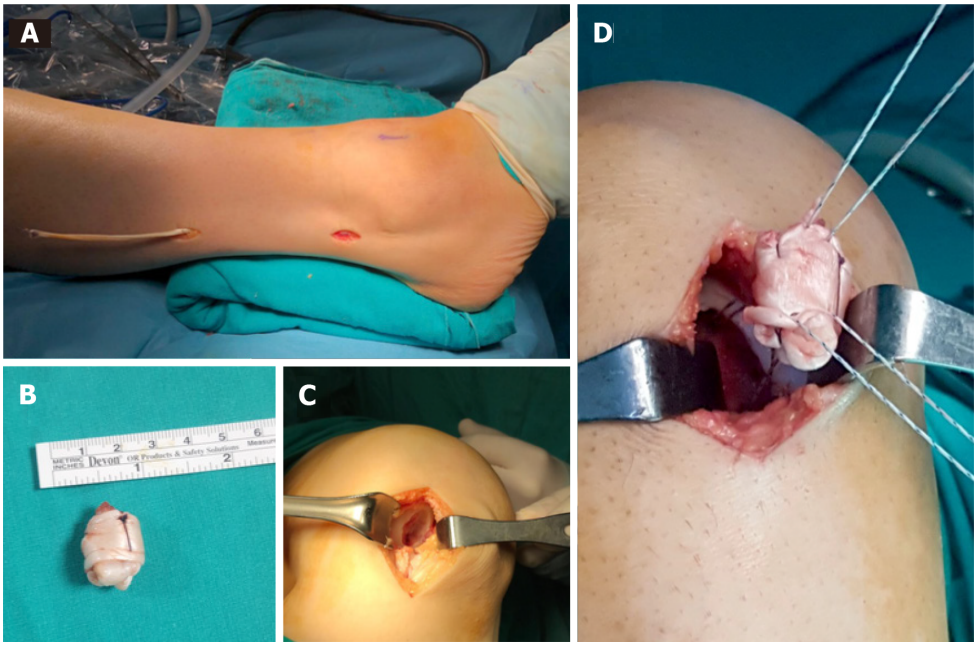


Figure 1 The technique of harvesting the autologous peroneal tendon from the donor area and placing it in the prepared osteochondral lesion area of the knee. A: Two mini incisions were made in the ipsilateal leg to harvest a split portion of the peroneus longus tendon; B: Intaoperative image showing the rolled peroneus longus tendon with absorbable suture; C: Osteochondral defect was prepared for transplantation; D: The rolled tendon autograft was transplanted into the osteochondral defect space and fixed with suture anchor.

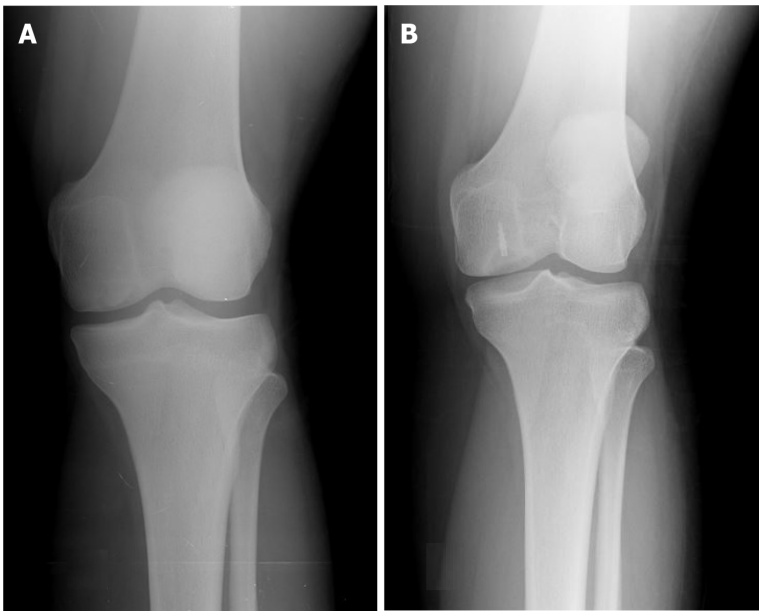


Figure 2 Radiographic images of a patient treated with the Autologous Tendon Transplantation technique. A: Anteroposterior radiograph of the knee of a 24-year old female with a symptomatic lesion of the medial femoral condyle (4.6 cm^2 size and 1.4 cm depth); B: Anteroposterior radiograph of the knee 6 years after autologous tendon transplantation with suture anchor show congruency of the articular surface of the medial femoral condyle. There are no arthritic changes. The patient is asymptomatic, free from pain and has no limitation of movement.

tendon acts as a scaffold, allowing cell adhesion, development, and differentiation[16, 17]. Joint compliance is easily provided by the elastic structure of the tendon, hence solid structure forms a load carrying surface; thus, the pain is eliminated, joint functions are preserved and degeneration is stopped. The results of this technique we have described show that we have achieved this.

The technique we have described is actually a tissue-based cartilage repair technique. Therefore, it can be compared with osteochondral autograft or allograft repair techniques, which are tissue-based repair techniques. The most important advantage of the osteochondral autograft technique is that the graft is autograft and it

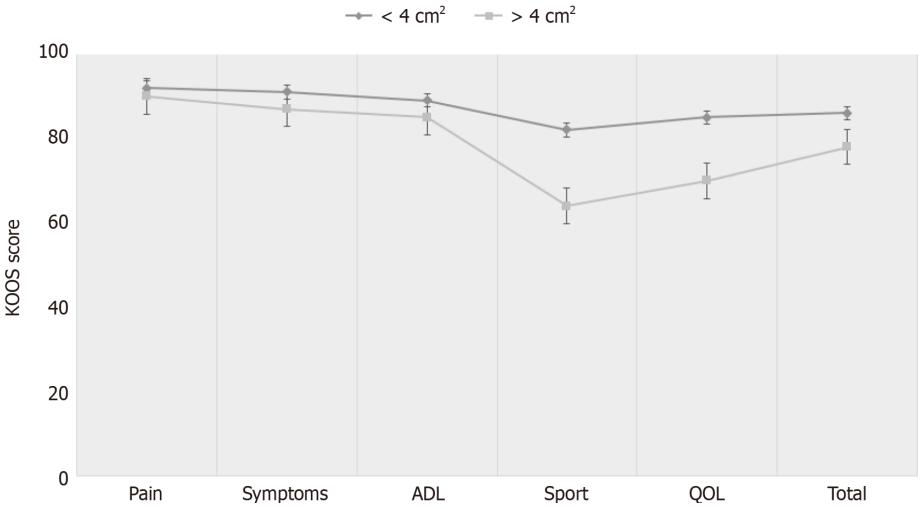


Figure 3 Knee injury and osteoarthritis outcome scores for different defect size. Patients with less than 4 cm^2 lesion had statistically significantly better overall knee injury and osteoarthritis outcome score than patients whose more than 4 cm^2 lesion, particularly in sport and quality of life subscales. KOOS: Knee injury and osteoarthritis outcome score; ADL: Activity of daily living; QOL: Quality of life.

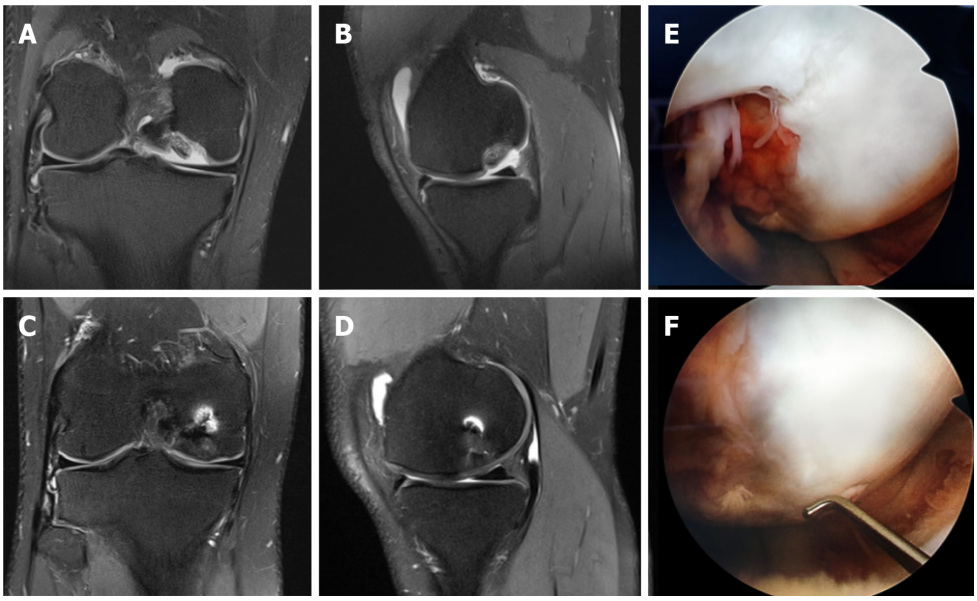


Figure 4 Magnetic resonance images and intraoperative images of a patient treated with the Autologous Tendon Transplantation technique. A, B: Coronal and Sagittal T2 section magnetic resonance images (MRI) of a grade 4 osteochondral lesion involving articular surface of medial femoral condyle (3.4 cm^2 size and 0.5 cm depth) in 24-year old male; C, D: 1-year follow-up coronal and sagittal T2 section MRI showing complete filling of the defect and establishment of smooth articular surface; E, F: Second look arthroscopy view at 1-year follow-up of grade 4 osteochondral lesion of medial femoral condyle showing filling of the defect with a well-integrated, smooth surfaced and stable regenerated cartilage.

enables the subchondral tissue to be restored[18]. But it has potential disadvantages such as donor site morbidity and poor joint compliance. In addition, the larger the defect area is, the higher the risk of complications are[19]. The osteochondral autograft technique may exhibit mismatch in connection geometry at the recipient site. In addition, the need for multiple grafts in large lesions complicates the provision of joint geometry and increases donor site morbidity. This can cause premature degeneration of the graft and joint, synovitis, and pain[20-23].

Another tissue-based cartilage repair technique is osteochondral allografts. These allografts have been used for many years in orthopedic surgery to reconstruct osteochondral defects[24]. It has also become an option in the treatment of cartilage abnormalities affecting subchondral bones, such as osteochondritis dissecans[25]. Osteochondral allograft is a highly beneficial procedure especially in the treatment of large lesions that are between the sizes 2-20 cm^2 and in the treatment of a failed OCD [26-29]. Even if successful results have been reported in previous studies, the most

important disadvantage of osteochondral allografts are their shorter storage life. Williams *et al*[30] in their study; reported that fresh human osteochondral allograft tissue that was kept for more than fourteen days, preserves its glycosaminoglycan content and biomechanical properties, yet it significantly loses its chondrocyte viability, viable cell density and metabolic activity. Other disadvantages of this method are the difficulty of accessibility to the graft, immunogenicity and graft rejection, the risk of disease transmission such as HIV and Hepatitis, disjointedness in joint geometry and collapse problems[25,31]. With the autograft we used, the disadvantages of osteochondral allografts are avoided.

The most important limitation of this study is the small number of patients. Even if we compare the study with previous studies, the absence of a control group is another limitation. Cartilage evaluation was evaluated with standart (1.5 Tesla system (Avanto; Siemens Medical Solution, Erlangen, Germany) MRI. Another shortcoming is that we did not perform imaging with gadolinium-enriched MRI.

CONCLUSION

This technique allows to avoid many of the disadvantages of other techniques. Important advantages; It is done in one step, it is an autograft, it does not require additional cost and it is easy to apply. Since it is an autograft, there is no risk of tissue rejection and contagious infection. Similar clinical and radiological results were obtained when compared to other treatment modalities. The autologous tendon transplantation is a single-step, safe, simple, cost-effective method for the treatment of knee OCD with satisfactory clinical and radiological outcomes, particularly in patients with less than 4 cm^2 lesion.

ARTICLE HIGHLIGHTS

Research background

This research was initiated by being inspired by the article titled "Treatment of osteochondral defects with tendon autografts in a dog knee model" made in 1999 and the articles titled "Tendon regeneration: an anatomical and histological study in sheep" published in 2004.

Research motivation

Our teacher Ahmet Uğur Turhan's interest in joint surgery and his publications in 1999-2004 inspired him.

Research objectives

In order to protect the knee joint, the authors share the new technique with the world, and share the results with the world and to inspire new publications.

Research methods

A report of multiple patients with the same treatment, but no control group or comparison group.

Research results

All parameters of the knee injury and osteoarthritis outcome score (KOOS) score improved significantly in all patients. Patients with lesions less than 4 cm^2 had a significantly better overall KOOS than patients with lesions greater than 4 cm^2.

Research conclusions

Autologous tendon transplantation has satisfactory clinical and radiological results in patients with osteochondral lesions of the knee.

Research perspectives

The autologous tendon transplantation is a single-step, safe, simple, cost-effective method for the treatment of knee osteochondritis dissecans with satisfactory.

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ORIGINAL ARTICLE

Clinical Trials Study

Direct anterior approach *vs* Hardinge in obese and nonobese osteoarthritic patients: A randomized controlled trial

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Author contributions: Macheras G, Stasi S, Sarantis M, Triantafyllou A, Tzefronis D and Papadakis S designed research; Stasi S, Tzefronis D, Sarantis M and Triantafyllou A performed literature research; Macheras G and Papadakis S were the two chief orthopedic surgeons; Tzefronis D and Sarantis M were the orthopedic surgeons' assistants; Stasi S performed the postoperative physiotherapy; Stasi S wrote the manuscript; Macheras G and Triantafyllou A edited the manuscript.

Institutional review board statement: The Scientific Research Council of the "KAT" General Hospital of Attica, Athens, Greece approved the study's protocol (ref: No8/19-03-2019).

Clinical trial registration statement: The study has been registered at www.isrctn.com following identification number:

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Abstract

BACKGROUND

The increased prevalence of obesity has resulted in orthopedic surgeons being likely to face many patients with a high body mass index (BMI) who warrant total hip arthroplasties (THAs) over the coming years. Studies' findings considered the postoperative clinical, and functional outcomes in these patients are controversial, and selecting the most appropriate surgical approach remains debatable.

AIM

To compare pain-levels, functionality, and quality-of-life in obese and nonobese osteoarthritic patients who have undergone primary total hip arthroplasty through either direct-anterior-approach (DAA) or Hardinge-approach.

METHODS

One hundred and twenty participants (> 50 years) were divided into four groups according to the surgical approach (DAA or Hardinge) and patients' BMI (nonobese < 30 kg/m^2 *vs* obese ≥ 30 kg/m^2). Outcomes were measured preoperatively and postoperatively (6th and 12th week). Pain was measured with Face Pain Scale-Revised (FPS-R). Functionality was measured with Timed Up & Go (TUG) test and Modified Harris Hip Score-Greek version (MHHS-Gr). Quality-of-life was evaluated with the 12-item-International Hip Outcome Tool-Greek version (iHOT12-Gr) (Clinical Trial Identifier: ISRCTN15066737).

ISRCTN15066737 https://doi.org/10.1186/ISRCTN15066737.

Informed consent statement: All study participants provided informed written consent prior to study enrolment.

Conflict-of-interest statement: The authors declare that they have no conflict of interest.

Data sharing statement: No additional data are available.

CONSORT 2010 statement: The authors have read the CONSORT 2010 statement, and the manuscript was prepared and revised according to the CONSORT 2010 statement.

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RESULTS

DAA *vs* Hardinge: (week 6) DAA-patients showed 12.2% less pain, more functionality (14.8% shorter TUG-performance time, 21.5% higher MHHS-Gr), and 38.16% better quality-of-life (iHOT12-Gr) compared to Hardinge-patients (all *P* values < 0.001). These differences were further increased on week 12 (all *P* values ≤ 0.05)]. DAA-obese *vs* Hardinge–obese: (week 6) DAA-obese patients had less pain, shorter TUG-performance time, better MHHS-Gr and iHOT12-Gr scores than Hardinge-obese (all *P* values < 0.01). (Week 12) Only the TUG-performance time of DAA-obese was significantly shortened (22.57%, *P* < 0.001). DAA-nonobese *vs* DAA-obese: no statistically significant differences were observed comparing the 6th and 12th weeks' outcomes.

CONCLUSION

DAA-groups reported less pain, more functionality and better quality-of-life, compared to the Hardinge-groups. The DAA benefited obese and nonobese patients, similarly yet faster, suggesting that it should be the more preferred choice for obese patients, instead of Hardinge. However, more comparative studies with more extended follow-up periods are needed to confirm our results and better evaluate all patients' long-term outcomes.

Key Words: Total hip arthroplasty; Osteoarthritis; Obesity; Pain; Functional ability; Quality-of-life

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Core Tip: The selection of the best total hip arthroplasties (THA)-surgical approach for obese hip osteoarthritis patients is a matter of debate. In the present study, both obese and nonobese patients of direct anterior approach (DAA) groups reached equivalent pain-levels, functionality, and quality-of-life. Moreover, the comparison between obese patients showed that DAA leads faster to better functional ability and quality-of-life than the Hardinge approach. These findings suggested that DAA is a better suited THA surgical approach than Hardinge for patients with increased body mass index.

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INTRODUCTION

In recent years, there has been a growing interest in minimally invasive surgical techniques that are used for the performance of total hip arthroplasty (THA). The advantages of these techniques include lesser soft tissue trauma, lesser amount of blood loss, minor postoperative pain, shorter hospital stay, better aesthetic appearance of the incision and a faster recovery time[1-3]. Over the past decade, the direct anterior approach (DAA) has sparked scientific interest due to its soft-tissue-preserving nature (intermuscular and internerval technique), coupled with the relatively lower risk of dislocation[4]. The DAA approach can be performed through a vertical or a horizontal (bikini) incision[5].

On the other hand, THA is an effective treatment for most patients who suffer from pain and decreased functionality due to end-stage symptomatic hip osteoarthritis (OA) [6]. Epidemiological studies report that hip OA occurs in 88 out of 100000 people, and the reported prevalence was 0.9 and 1.6 per 1000 yearly, in both men and women, respectively[7]. Within the Greek population, 0.9 per 1000 people develop osteoarthritis of the hip and the incidence of the disease is 1.5 per 1000 in women and 0.3 per 1000 in men[8]. The main risk factors for developing hip OA are advanced age, family history of OA, previous hip injury, hip dysplasia and obesity. Specifically, obesity is a high-ranking risk factor for osteoarthritis development, as its effect increases the joint

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reaction forces and alters gait biomechanics by creating abnormal loadings[9]. Additionally, the increased accumulation of body fat and adipokines contributes to low-grade systemic inflammation that adversely affects the cartilage's normal biology [10]. In the literature, it has been reported that obesity is significantly associated with a greater need for joint replacement and that compared to patients with normal body mass index (BMI), obese patients may require a THA up to ten years earlier[9].

Several studies have indicated that obesity is associated with both a higher complication rate after THA and poorer clinical functional outcomes[11-13]. Other studies have shown that obese patients do not differ from nonobese in terms of postoperative outcomes[14-16]. The data are considered controversial and further studies need to be performed on obese patients, especially comparative evaluations that compare minimally invasive techniques such as DAA with classical surgical techniques, such as the Hardinge approach (HA). The Hardinge was chosen because, compared to other classical surgical approaches used in obese patients, it offers better access to the hip joint and achieves a lower rate of dislocation by preserving the joint's posterior stabilizer muscles[17].

This trial aims to compare DAA and Hardinge in hip OA patients who have undergone primary THA, with regards to postoperative pain levels, functional status, and quality-of-life. In addition, it was investigated whether these parameters differ between obese and nonobese patients.

MATERIALS AND METHODS

Study design

The present study was a prospective, four-group randomised controlled trial (Clinical Trial Identifier: ISRCTN15066737) conducted according to the ethical principles stated in the Declaration of Helsinki and its later amendments[18]. The Scientific Research Council of the "KAT" General Hospital of Attica, Athens, Greece approved the study's protocol (ref: No8/19-03-2019). The study conformed to the "Consolidated Standards of Reporting Trials" (CONSORT) 2010 Statement checklist of information to include when reporting a randomised trial[19].

Sample size estimation

It was estimated that a sample size of 120 patients was required in order to have a 90% probability of demonstrating a –between surgical approaches- difference of 10% change from baseline to 6th week (DAA: -50% ± 12% *vs* Harginge: 40% ± 12%) in TUG test performance time, with a significance of < 5% (Two-tailed test).

Participants

Participants were selected from patients who have chosen to be operated by either of the two chief orthopedic surgeons/co-researchers of the present trial. One of the head-orthopedic surgeons (GM) performs primary THA using DAA technique -through a single vertical incision-[20], whilst the other (SP) prefers the Hardinge[21]. Surgical approach and BMI were used as factors in the randomisation process, while the randomisation list was formed on the basis of these factors. An independent clinician was responsible for the random allocation sequence and assigned participants to groups. Specifically, participants were divided into four groups (30 patients per group) according to both the surgical approach used and their body mass index (BMI), as follow: (1) DAA-nonobese group: patients with BMI ≥ 20 kg/m^2 and < 30 kg/m^2, who underwent THA through DAA; (2) DAA-obese group: Patients with BMI ≥ 30 kg/m^2, who underwent THA through DAA; (3) Harginge-nonobese group: patients with BMI ≥ 20 kg/m^2 and < 30 kg/m^2, who underwent THA through Harginge; and (4) Harginge-obese group: patients with BMI ≥ 30 kg/m^2, who underwent THA through Harginge.

To be eligible for randomization, patients had to meet the following inclusion criteria: Symptomatic hip OA, age > 50 years, and to be ambulatory before surgery. Patients were excluded if they had dementia, chronic respiratory disease, chronic renal failure, heart failure or neurological disorder. In addition, after discharge, patients would also be excluded if they discontinued the postoperative physiotherapy before the 6th week's measurement. No patient or clinician was blinded to the group allocation.

An uncemented prosthesis was used in all patients. Physiotherapy intervention was started on the first postoperative day and lasted for 6 wk, firstly on an in-patient basis, and following hospital discharge, home-based. One physiotherapist was responsible

for carrying out the physiotherapy during hospitalization and at home, evaluating the progress according to the protocol and ensuring the patient's compliance adherence to it, on all groups.

Procedures

Outcome measures were obtained at three different time points: prior to surgery (baseline), at the end of the 6th week, and at the end of the 12th week, postoperatively. Pain-levels were measured with the Face Pain Scale – Revised (FPS-R)[22,23]. Functional ability was evaluated with the objective physical performance measure Timed Up & Go (TUG) test[24], and with the reliable and validated Greek version of the Modified Harris Hip Score (MHHS-Gr)[25]. Quality-of-life was measured with the reliable and validated Greek version of the International Hip Outcome Tool -12 items (iHOT12-Gr)[26]. One examiner carried out the measurements of all outcomes, and he did not involve in any other part of the study.

Outcome Measures

FPS-R: The FPS-R is a patient-reported instrument frequently used to measure pain intensity. It includes six facial expressions covering the entire range of pain levels in an ascending -regarding discomfort levels- order[22]. Patients describe their pain according to one of the six facial expressions that correspond to their pain and enabling them to translate their subjective experience of pain into a quantitative, numeric measure[23].

TUG test: The TUG test was used to assess participants' functionality. This test was introduced in 1991 as a modification of the "Get-Up and Go" test[24]. It is a simple, easy, and thus widespread clinical tool for measuring the lower limbs' functionality and mobility[27]. The TUG test measures the time (in seconds) taken by a participant to stand up from an armed chair with a seat height of 46 cm, walk for 3 m, turn around a cone and return to sit on that very same chair. A shorter performance time represents better functionality[24,27]. Participants were asked to perform the test as quickly as they could while still feeling safe, and were allowed to use the walking aid on which they depended on at the time of measurement. The participants performed the test twice, with a 5-minute resting interval in between. The shorter of the two performance times was then recorded.

MHHS: The MHHS is a patient-reported questionnaire that includes assessments based on pain and on function[25]. One item evaluates the pain (0-44 points), while 7 items evaluate the patient's functionality (0-47 points). The total points form a scale from 0 to 91. A multiplier of 1.1 provides a total score of 100 (best possible outcome) [28].

iHOT12: The iHOT12 questionnaire includes 12 questions on the patient's symptoms, functional and sports limitations as well as social, emotional, and occupational limitations[26]. The patient is asked to consider the problems arising from their hip disorders and quantify their quality-of-life level on a 100 mm horizontal line (visual analogue scale) by marking it with a slash. Each question has equal value, giving a mean score from 0-100. A score of 100 indicates excellent quality-of-life (full function and no symptoms), whereas zero signifies the worst quality-of-life (maximum limitations and extreme symptoms)[29].

Statistical analysis

Data was expressed as mean ± SD or mean ± SE (for two way ANOVA analysis results) for continuous variables and as percentages for categorical data. The Kolmogorov—Smirnov test was utilized for normality analysis of the continuous variables.

The two-way ANOVA model was used to examine the interaction between the "Surgical Approach" factor (DAA & Hardinge) and "BMI" factor (< 30 kg/m^2 and ≥ 30 kg/m^2). In the case that there was no statistically significant interaction, we compared the factor "Surgical Approach" regardless of "BMI" factor and the factor "BMI" regardless of "Surgical Approach" factor.

Due to we have found significant interaction, we created a new factor categorising the combination of the existing categories of "Surgical Approach" with "BMI" factors (DAA-nonobese, DAA-obese, Hardinge-nonobese, Hardinge-obese). The analysis of variables was performed using the "One way ANOVA model". Pairwise comparisons were performed using the Bonferroni test.

All tests were two-sided and statistical significance was set at $P < 0.05$. All analyses were carried out using the statistical package SPSS v21.00 (IBM Corporation, Somers, NY, United States).

RESULTS

Descriptive and clinical data

Patient recruitment lasted from January 2018 to March 2020, by which time the required number of participants had been reached. The recruitment procedure is depicted in the flow diagram in Figure 1. Eight patients (one from DAA-nonobese group, two from DAA-obese group, two from Hardinge–nonobese group and four from Hardinge-obese group) were lost to follow up due to wound healing problems. Finally, data from 120 patients (30 patients per group) were analysed (Figure 1). There is homogeneity between compared groups for all demographic and clinical characteristics apart from weight ($P < 0.001$) and BMI ($P < 0.001$), as expected (Table 1). At baseline, there is a statistically significant difference between compared groups in relation of variables, FPS-R ($P = 0.045$), TUG ($P = 0.033$), MHSS-Gr ($P < 0.001$); except iHOT12-Gr ($P = 0.100$) (Table 1); hence, the percentage (%) of changes of all variables/outcome scores in between groups - from baseline to 6th and 12th week- were presented.

The comparison of all variables/outcomes' scores during the observation period per group, showed that its absolute values were statistically significant different ($P < 0.001$) (Table 2). Patients of all groups benefited from the THA regarding the pain's level, functionality and quality-of-life.

The exploration of interaction between "BMI" and "Surgical Approach" factors revealed statistically significant difference in pain-levels (FPS-R) at 12th week [$F(1.116) = 4.11$, $P = 0.045$] (Table 3). Exploring the data to illustrate the source of that interaction, we also compared the percentage of change of the other variables/outcome measures (TUG, MHHS-Gr, iHOT112-Gr) from baseline to 6th and 12th week: a) across the two surgical approaches by BMI-level, and b) across BMI-level per surgical approach, adjusting significance cut-off points for multiple comparison.

Comparative results

DAA *vs* Hardinge regardless of BMI: At the 6th postoperative week's measurements, DAA patients reported 12.2 % lesser pain (FPS-R), more functional ability (14.8% faster TUG test performance time and 21.5% higher MHHS-Gr score), and 38.2% better quality-of-life (iHOT12-Gr) compared to Hardinge patients, with statistically significant differences (all P values <0.001) (Table 4). At 12th postoperative week's measurements these differences of both DAA groups' outcomes were further increased [FPS-R: 9.9% ($P < 0.001$), TUG test: 21.2 % ($P < 0.001$), MHHS-Gr: 22.5% ($P = 0.05$), and iHOT12-Gr: 40.5% ($P < 0.001$)] (Table 4). The DAA resulted in less postoperative pain, and offered faster and increased functional ability and better quality-of-life compared to the Hardinge.

DAA-nonobese *vs* Hardinge-nonobese: At the measurement of the 6th postoperative week, the DAA-nonobese group had better % percentage of change in all outcomes: [FPS-R: 14.8% ($P < 0.001$), TUG test: 13.5 % ($P < 0.001$), MHHS-Gr: 16.5% ($P = 0.026$), and iHOT12-Gr: 44.9% ($P < 0.001$)] in comparison to the Hardinge –nonobese (Table 4). At the 12th postoperative week's measurements the DAA-nonobese FPS-R was lowered by 14.0% ($P < 0.001$), the TUG test performance time was shortened by 19.8 % ($P < 0.001$), and iHOT12-Gr got higher by 41.7% ($P = 0.048$), than Hardinge –nonobese. Although the DAA-nonobese group MHHS-Gr was higher by 11.5%, no statistically significant difference was revealed ($P = 0.777$) (Table 4). The DAA leads faster to better functional ability and quality-of-life compared to the Hardinge, in nonobese patients.

DAA-obese *vs* Hardinge-obese: At the 6th postoperative week's measurements DAA-obese patients had a greater % percentage of change of all outcomes [FPS-R: 9.7% ($P = 0.002$), TUG test performance time: 16.0% ($P < 0.001$), MHHS-Gr: 26.6% ($P = 0.012$), and iHOT12-Gr: 31.4% ($P = 0.031$) compared to Hardinge-obese patients (Table 4). At the 12th postoperative week's measurements, the only statistically significant difference was revealed at TUG test performance time of DAA-obese: 22.6% ($P < 0.001$), while the differences of the FPS-R, MHHS-Gr and iHOT-Gr were not statistically significant (Table 4). Regarding obese patients, DAA leads faster to better functional ability and quality-of-life compared to the Hardinge; at 12 wk the statistically significant

Table 1 Demographic characteristics and clinical measurements of the study sample (*n* = 120)

Characteristics and Clinical Measurements	DAA–nonobese (*n* = 30)	DAA–obese (*n* = 30)	Hardinge–nonobese (*n* = 30)	Hardinge–obese (*n* = 30)	*P* value
Age (yr)[1]	66.40 ± 7.31	63.73 ± 6.96	69.00 ± 9.00	63.73 ± 6.96	0.102
Height (m)[1]	1.65 ± 0.09	1.64 ± 0.10	1.62 ± 0.08	1.64 ± 0.09	0.442
Weight (kg)[1]	73.10 ± 10.95	92.63 ± 14.14[a,b]	66.30 ± 8.10	93.93 ± 16.09[a,b]	< 0.001
Body mass index (kg/m^2)[1]	26.61 ± 2.16	34.27 ± 4.12[a,b]	25.30 ± 2.03	34.73 ± 4.57[a,b]	< 0.001
Dominant lower limb, *n* (%)					
Right	24 (80.0)	25 (83.3)	27 (90.0)	25 (83.3)	0.756
Left	6 (20.0)	5 (16.7)	3 (10.0)	5 (16.7)	
Affected hip, *n* (%)					
Right	15 (50.0)	18 (60.0)	14 (46.7)	18 (60.0)	0.442
Left	15 (50.0)	12 (40.0)	16 (53.3)	12 (40.0)	
Walking aid, *n* (%)					
No	25 (83.3)	22 (73.3)	24 (80)	19 (63.3)	0.292
Yes	5 (16.7)	8 (26.7)	6 (20.0)	11 (36.7)	
Kellgren & Lawrence classification, *n* (%)					
Grade 3	21 (70.0)	19 (63.3)	20 (66.7)	19 (63.3)	0.939
Grade 4	9 (30.0)	11 (36.7)	10 (33.3)	11 (36.7)	
Face Pain Scale-Revised[1] (10 = worst pain)	6.47 ± 1.55[a]	6.87 ± 1.80	7.13 ± 1.36	7.60 ± 1.52	0.045
Timed Up and Go test (s)[1]	16.09 ± 3.07[a]	16.07 ± 5.56[a]	17.12 ± 5.22	19.32 ± 4.99	0.033
Modified Harris Hip Score – Greek version[1] (100 = max best score)	41.00 ± 6.55	33.94 ± 9.62[b]	38.53 ± 8.15	31.66 ± 11.14[b]	< 0.001
International Hip Outcome Tool (12 items) – Greek version[1] (100 = max best score)	31.43 ± 9.04	31.52 ± 8.26	28.28 ± 9.24	26.39 ± 10.00	0.100

[1]The values are expressed as mean ± SD.
[a]$P < 0.005$ *vs* DAA-nonodese.
[b]$P < 0.005$ *vs* Hardinge –nonobese. DAA: Direct anterior approach.

differences between groups were narrowed.

Nonobese *vs* obese regardless of surgical approach: At the 6th postoperative week's measurements obese patients reported higher MHHS-Gr (16.8%) with statistically significant difference ($P = 0.001$) than nonobese. No statistically significant differences were revealed regarding the other outcomes (Table 5). At the 12th postoperative week's measurements obese patients' MHHS-Gr score was further increased (37.5%, $P = 0.001$), but still no statistically significant differences were revealed regarding the other outcomes (Table 5). Overall, regardless of the surgical approach, the only statistically significant difference between obese and nonobese patients was revealed in the self-reported functional ability as expressed by the MHHS-Gr questionnaire.

DAA-nonobese *vs* DAA-obese: At the 6th postoperative weeks' measure-ments, no statistically significant differences were observed in the comparison of postoperative outcomes (Table 5). Likewise, no statistically significant differences were observed in comparing postoperative outcomes at the 12th postoperative weeks' measurements (Table 5). The DAA similarly benefited both obese and nonobese patients.

Hardinge-nonobese *vs* Hardinge-obese: At the 6th postoperative weeks' measure-ments, no statistically significant differences were observed between Hardinge-nonobese and Hardinge-obese groups (Table 5). At the 12th postoperative weeks' measurements, only the TUG test performance time of Hardinge-nonobese patients was significantly shorter (5.5%, $P = 0.001$) compared to Hardinge-obese patients (Table 5). Overall, Hardinge-nonobese reached in higher functionality, as expressed by

Table 2 Comparison of outcomes' scores during the observation period per group

Groups	Preoperative measurement	6th postoperative week	12th postoperative week	*P* value
Face Pain Scale-Revised (min 0 - max 10)				
DAA-nonobese	6.46 ± 1.55	1.97 ± 0.72	0.13 ± 0.35	F(2.58) = 563.8, $P < 0.001$
DAA-obese	6.87 ± 1.79	1.93 ± 0.69	0.30 ± 0.53	F(2.58) = 293.1, $P < 0.001$
Hardinge-nonobese	7.13 ± 1.36	3.20 ± 0.80	1.17 ± 0.70	F(2.58) = 830.9, $P < 0.001$
Hardinge-obese	7.60 ± 1.52	3.00 ± 0.69	1.00 ± 0.69	F(2.58) = 673.7, $P < 0.001$
Timed Up and Go Test (second)				
DAA-nonobese	16.09 ± 3.07	11.22 ± 2.29	7.81 ± 1.74	F(2.58) = 399.81, $P < 0.001$
DAA-obese	16.07 ± 5.56	10.95 ± 2.52	8.02 ± 2.32	F(2.58) = 89.55, $P < 0.001$
Hardinge-nonobese	17.12 ± 5.21	14.17 ± 3.69	11.62 ± 3.00	F(2.58) = 122.04, $P < 0.001$
Hardinge-obese	19.32 ± 5.00	16.60 ± 4.14	14.33 ± 3.84	F(2.58) = 289.56, $P < 0.001$
Modified Harris Hip Score – Greek version (min 0 – max 100)				
DAA-nonobese	41.00 ± 6.54	70.75 ± 8.20	92.41 ± 3.83	F(2.58) = 1148.1, $P < 0.001$
DAA-obese	33.94 ± 9.62	63.98 ± 10.86	87.83 ± 6.29	F(2.58) = 893.7, $p<0.001$
Hardinge-nonobese	38.53 ± 8.15	60.68 ± 10.68	82.17 ± 9.00	F(2.58) = 1291.8, $P < 0.001$
Hardinge-obese	32.07 ± 10.41	53.82 ± 15.00	74.38 ± 11.78	F(2.58) = 1066.6, $P < 0.001$
International Hip Outcome Tool (12 items) – Greek Version (min 0 – max 100)				
DAA-nonobese	31.43 ± 9.04	67.00 ± 10.05	86.18 ± 10.00	F(2.58) = 703.53, $P < 0.001$
DAA-obese	31.52 ± 8.25	66.06 ± 12.95	88.43 ± 7.77	F(2.58) = 740.71, $P < 0.001$
Hardinge-nonobese	28.28 ± 9.24	50.39 ± 15.72	67.96 ± 14.77	F(2.58) = 411.82, $P < 0.001$
Hardinge-obese	26.39 ± 10.00	47.21 ± 16.88	63.46 ± 16.21	F(2.58) = 351.81, $P < 0.001$

All values are presented as mean ± SD; All time points are statistically significant different between them, $P < 0.001$. DAA: Direct anterior approach.

Table 3 Interaction between "body mass index" and "surgical approach" factors

Outcomes/Variables	6th postoperative week	12th postoperative week
Face Pain Scale-Revised	F(1.116) = 1.96, $P = 0.164$	F(1.116) = 4.11, $P = 0.045$
Timed Up and Go Test	F(1.116) = 0.97, $P = 0.328$	F(1.116) = 0.79, $P = 0.376$
Modified Harris Hip Score – Greek version	F(1.116) = 1.01, $P = 0.316$	F(1.116) = 0.93, $P = 0.337$
International Hip Outcome Tool (12 items) – Greek Version	F(1.116) = 0.80, $P = 0.373$	F(1.116) = 0.11, $P = 0.917$

Significant $P < 0.05$.

TUG test, than Hardinge-obese patients.

DISCUSSION

In the present study, the effect of two different THA surgical approaches (DAA *vs* Hardinge) on postoperative pain levels, functionality and quality-of-life in both obese and nonobese hip OA patients was explored. Our results showed that the DAA resulted in less postoperative pain, and offered faster achieved and increased functional ability and better quality-of-life compared to the Hardinge. In addition, the measured outcomes of the aforementioned parameters did not differ between obese and nonobese DAA patients; DAA similarly benefited both obese and nonobese patients.

Table 4 The % percentage changes of outcome scores, between surgical approaches, according and regardless of body mass index, compared to corresponding baseline measurements

		Nonobese (BMI < 30 kg/m^2)			Obese (BMI ≥ 30 kg/m^2)			Comparison between surgical approaches regardless of BMI		
Outcomes/ variables	**Postope-rative measure-ments**	**DAA[1]**	**Hard-inge[1]**	***P* value[3]**	**DAA[1]**	**Hard-inge[1]**	***P* value[3]**	**DAA[2]**	**Hardinge[2]**	***P* value[3]**
Face Pain Scale - Revised (%)	6th week	-70.1 ± 6.7	-55.3 ± 7.3	< 0.001	-70.0 ± 15.8	-60.3 ± 6.9	0.002	-70.0 ± 1.3	-57.8 ± 1.3	< 0.001
	12th week	-98.4 ± 4.1	-84.4 ± 8.2	< 0.001	-93.3 ± 18.7	-87.5 ± 8.3	0.429	-95.8 ± 1.4	-86.0 ± 1.4	< 0.001
Timed Up and Go Test (%)	6th week	-30.1 ± 6.5	-16.5 ± 4.8	< 0.001	-29.9 ± 10.9	-13.9 ± 2.9	< 0.001	-30.0 ± 0.9	-15.2 ± 0.9	< 0.001
	12th week	-51.2 ± 6.4	-31.4 ± 5.9	< 0.001	-48.5 ± 14.4	-25.9 ± 3.9	< 0.001	-49.9 ± 1.1	-28.7 ± 1.1	< 0.001
Modified Harris Hip Score – Greek version (%)	6th week	76.2 ± 27.4	59.6 ± 13.9	0.026	97.9 ± 38.5	71.4 ± 23.6	0.012	87.0 ± 3.5	65.5 ± 3.5	< 0.001
	12th week	132.9 ± 50.4	121.4 ± 43.2	0.777	181.4 ± 89.6	147.8 ± 56.4	0.317	157.1 ± 8.1	134.6 ± 8.1	0.050
International Hip Outcome Tool (12 items) – Greek version (%)	6th week	124.4 ± 51.6	79.5 ± 22.9	< 0.001	115.7 ± 39.4	84.3 ± 46.0	0.031	120.1 ± 5.3	81.9 ± 5.3	< 0.001
	12th week	192.0 ± 76.1	150.3 ± 43.7	0.048	195.4 ± 64.2	156.1 ± 67.5	0.077	193.7 ± 8.3	153.2 ± 8.3	< 0.001

[1]The values are presented as mean ± SD.

[2]The values are presented as mean ± SE (%).

[3]*P* value$_{\text{Bonferroni correction}}$. BMI: Body mass index; DAA: Direct anterior approach.

The selection of the best surgical approach for THA remains a matter of debate. While Hardinge is widely used, mainly due to its reduced dislocation rate[17], DAA is gaining popularity as its intermuscular pathway preserves soft tissues, ensuring an excellent functional outcome and reduced postoperative pain[4]. Our results are in line with other studies which suggest that DAA is more beneficial to the patients in terms of postoperative pain relief and faster recovery, than Hardinge[30]. A recent meta-analysis has concluded that, in comparison to the lateral approach, the anterior approach is correlated with reduced pain at 6 wk postoperatively, increased walking velocity, stride length and step length, while no difference was found in the Harris Hip Score and the rate of complications[31]. In the present study, we found that DAA was associated with higher pain relief, enhanced functional outcomes and quality-of-life at the 6th week, while these outcomes increased even more at 12th week.

Several studies have shown that obese patients do not differ from the nonobese ones in terms of postoperative outcomes[14-16]. Similarly, in the present study, both obese and nonobese patients of DAA groups reached equivalent pain-levels, functionality and quality-of-life, suggesting that BMI is indeed not a factor that will influence the postoperative outcomes of DAA. However, this was not observed in Hardinge-groups. Although at 6th weeks' measurements, no statistically significant differences were observed between Hardinge-nonobese and Hardinge-obese groups, at 12th week, Hardinge-nonobese presented significantly improved TUG test performance time in comparison to Hardinge-obese patients. This could be explained by the fact that, preoperatively, Hardinge-nonobese had no-significant shorter TUG test performance time than Hardinge-obese (Table 1), which became significant after the THA.

The comparison between obese patients showed that, DAA leads faster to better functional ability and quality-of-life compared to the Hardinge. At 12th postoperative week's measurements, the only statistically significant difference was revealed at TUG test performance time of DAA-obese group. This is not surprising since it is well known that the hip abductor strength improved at 3 mo following THA performed by a conventional approach, such as Hardinge[32], while the hip abductor strength was linear associated with TUG test[33].

In the present study, most cases with wound healing problems were reported in Hardinge-obese patients (four out of 35 patients, 11.4%), as shown in our flow diagram. This rate was lower than the rates reported in the literature, for obese

Table 5 The % percentage changes of outcome scores, between body mass index groups, according and regardless of surgical approach, compared to corresponding baseline measurements

Outcomes/ variables	Postope-rative measure-ments	DAA			Hardinge approach			Comparison between BMI groups regardless of surgical approach		
		Nonobese	Obese[1]	*P* value[3]	Nono-bese[1]	Obese[1]	*P* value	Nono-bese[2]	Obese[1]	*P* value[3]
Face Pain Scale - Revised (%)	6th week	-70.1 ± 6.7	-70.0 ± 15.8	1.000	-55.3 ± 7.3	-60.3 ± 6.9	0.304	-62.7 ± 01.3	-65.1 ± 1.3	0.178
	12th week	-98.4 ± 4.1	-93.3 ± 18.7	0.468	-84.4 ± 8.2	-87.5 ± 8.3	0.451	-91.4 ± 1.4	-90.4 ± 1.4	0.631
Timed Up and Go Test (%)	6th week	-30.1 ± 6.5	-29.9 ± 10.9	1.000	-16.5 ± 4.8	-13.9 ± 2.9	0.102	-23.3 ± 0.9	-21.9 ± 0.9	0.278
	12th week	-51.2 ± 6.4	-48.5 ± 14.4	0.783	-31.4 ± 5.9	-25.9 ± 3.9	0.001	-41.3 ± 1.1	-37.2 ± 1.1	0.010
Modified Harris Hip Score – Greek version (%)	6th week	76.1 ± 27.4	97.9 ± 38.5	0.068	59.6 ± 13.9	71.4 ± 23.6	0.102	67.9 ± 3.5	84.6 ± 3.5	0.001
	12th week	132.9 ± 50.4	181.4 ± 89.6	0.061	121.4 ± 43.2	147.8 ± 56.4	0.186	127.1 ± 8.1	164.6 ± 8.1	0.001
International Hip Outcome Tool (12 items) – Greek version (%)	6th week	124.4 ± 51.6	115.7 ± 39.4	0.841	79.5 ± 22.9	84.3 ± 46.0	0.957	102.0 ± 5.3	100.0 ± 5.3	0.793
	12th week	192.0 ± 76.1	195.4 ± 64.2	1.000	150.3 ± 43.7	156.1 ± 67.5	1.000	171.1 ± 8.3	175.7 ± 8.3	0.697

[1]The values are presented as mean ± SD.
[2]The values are presented as mean ± SE (%).
[3]*P* value$_{\text{Bonferroni correction}}$. BMI: Body mass index; DAA: Direct anterior approach.

patients, on other classical surgical approaches, ranging from 14.5% to 22%[34,35]. Regarding DAA, one incidence in nonobese and two incidences in obese participants were found (3.5 % and 5.7%, respectively). The study's results are within the rates reported in the literature: for DAA-nonobese ranging between 0.8% and 3%, while for DAA-obese patients ranging from 4.46% to 10.0%[36-38]. It is worth to be noted that the horizontal (bikini) incision was shown to facilitate even more wound healing in obese patients. In the retrospective comparative study by Manrique *et al*[39], involving obese patients (BMI > 30 kg/m^2) it was reported that patients with horizontal incision had significant lower rates of wound healing problems compared to patients with vertical incision (0.00% *vs* 16.6%, $P = 0.04$)[39]. Nevertheless, the current evidence is limited, and further trials are warranted to identify differences between the two DAA skin incisions regarding wound healing in obese patients.

While the risks associated with THA in obese patients are well documented [11,34], the present study results show that DAA would be a preferable THA approach for obese patients. Since it is a minimally invasive surgical technique that provides the most direct access to the hip joint, DAA can be safely performed, by an experienced surgeon and under certain precautions, without an increased and adverse risk for obese patients[4,40].

Strengths and limitations

The present study was a four-group randomised controlled trial. All patients underwent uncemented THA, and the same physiotherapist was responsible for the physiotherapy intervention in all four groups. After discharge, the supervision and guidance from the physiotherapist, during in-home sessions, helped ensure patient adherence to protocol and thus, the study's dropout rate was minimal. Moreover, all measurements were made by the same examiner, who was not involved in any other part of the study. These factors added strength and statistical power to the results of this study.

On the other hand, there are important limitations that ought to be mentioned. Patients were followed up until the 12th postoperative week; it is, therefore, unclear whether the observed postoperative differences between DAA and Hardinge will be maintained over time, even though several studies consistently showed better outcomes with DAA during functional rehabilitation within one year of surgery[41-

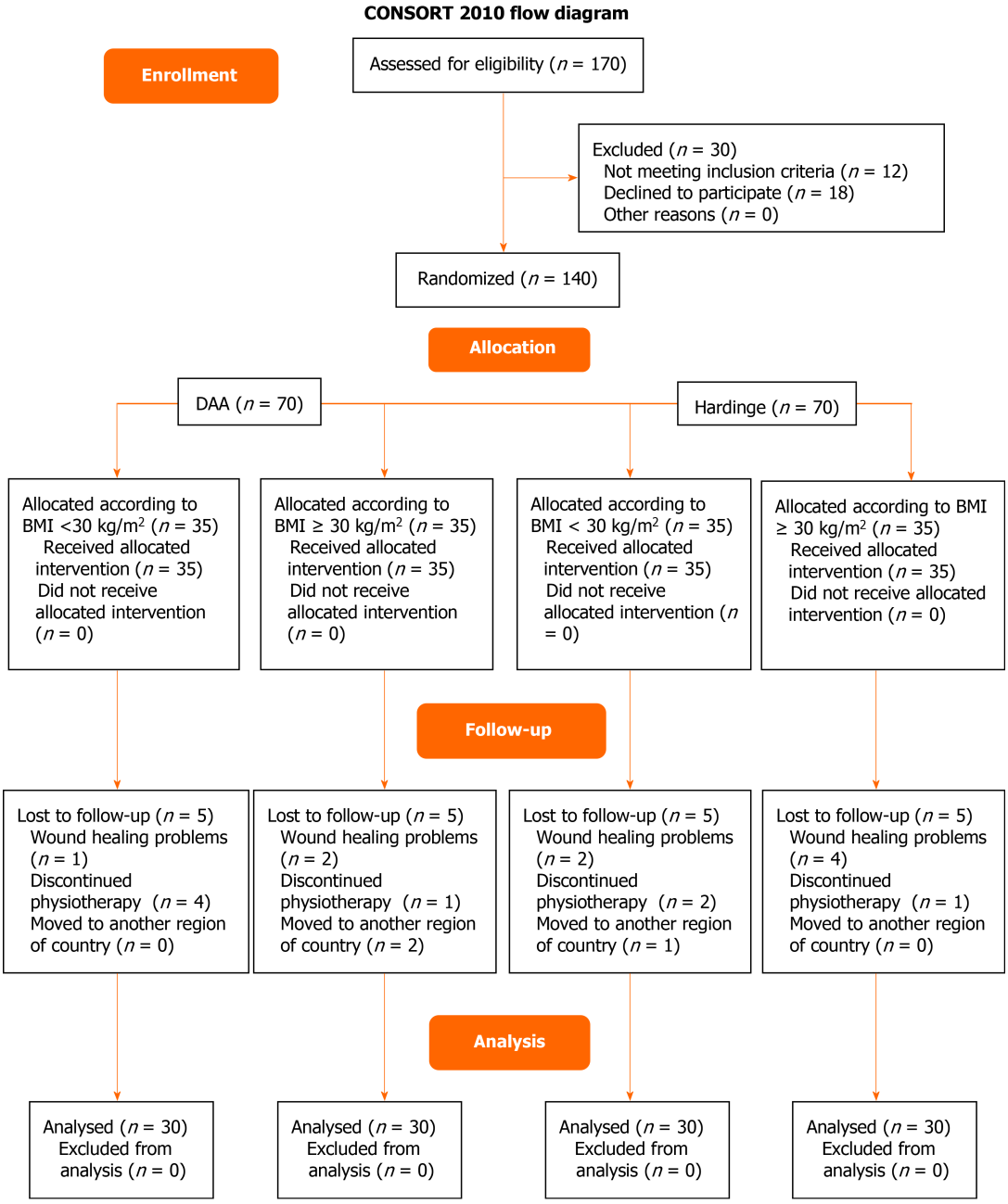


Figure 1 The flow diagram of the study. DAA: Direct anterior approach.

44]. However, the fact that DAA allowed our patients to achieve a more rapid recovery than Hardinge concluded to their postoperative rehabilitation being less costly, since their independency was faster obtained, regardless of BMI. Another limitation is that DAA and Hardinge were performed by two different orthopaedic surgeons, a fact that may predispose biased conclusions. Even though our results are indicative, further research is needed to produce safer results regarding the impact of obesity in pain, functional outcomes, and quality-of-life after THA in between different approaches, which is ultimately more appropriate for obese hip OA patients.

CONCLUSION

In conclusion, the patients of our study reported less pain, more functionality and quality-of-life improvements, more so after THA with DAA, compared to the Hardinge. Moreover, DAA exhibits equivalent postoperative outcomes in obese and nonobese patients, suggesting a better-suited THA surgical approach for patients with increased BMI. Understanding the postoperative changes in pain's level, functional

outcomes and quality-of-life in both obese and nonobese patients, as reported in the current study, will be helpful for both the patients and the surgeons regarding the decision-making process for the more appropriate THA surgical technique.

ARTICLE HIGHLIGHTS

Research background

Total hip arthroplasty (THA) is an effective treatment for most patients who suffer from pain and decreased functional ability due to hip osteoarthritis (OA). The main risk factors for developing hip OA are advanced age, family history of OA, previous hip injury, hip dysplasia, and obesity. The increased prevalence of obesity has resulted in orthopedic surgeons being likely to face many patients with a high body mass index (BMI) who warrant THAs over the coming years. On the other hand, there has been growing interest in the direct anterior approach (DAA) in recent years because of its soft-tissue–preserving nature. Total hip arthroplasty (THA) is an effective treatment for most patients who suffer from pain and decreased functional ability due to hip osteoarthritis (OA). The main risk factors for developing hip OA are advanced age, family history of OA, previous hip injury, hip dysplasia, and obesity. The increased prevalence of obesity has resulted in orthopedic surgeons being likely to face many patients with a high body mass index (BMI) who warrant THAs over the coming years. On the other hand, there has been growing interest in the direct anterior approach (DAA) in recent years because of its soft-tissue–preserving nature.

Research motivation

In the literature, it has been reported that obesity is significantly associated with a greater need for joint replacement and that compared to patients with normal body mass index (BMI), obese patients may require a THA up to ten years earlier. Some studies indicate that obesity is associated with poorer clinical, functional outcomes, while others have shown that obese patients do not differ from the nonobese in this respect. The data are considered controversial, and further studies need to be performed on obese patients, especially comparative evaluations that compare minimally invasive techniques such as DAA with classical surgical techniques, such as the Hardinge approach. Compared to other classical surgical approaches used in obese patients, the Hardinge was chosen because it offers better access to the hip joint and achieves a lower dislocation rate by preserving its posterior stabilizer muscles.

Research objectives

We aimed to compare DAA and Hardinge in hip OA patients who have undergone primary THA regarding postoperative pain levels, functional status, and quality-of-life. In addition, it was investigated whether these parameters differ between obese and nonobese patients.

Research methods

The present study was a prospective, four-group randomized controlled trial (Clinical Trial Identifier: ISRCTN15066737). One hundred twenty participants were divided into four groups (30 patients per group) according to both the surgical approach used and their body mass index (BMI) as follow: DAA-nonobese group (BMI < 30 kg/m^2), DAA-obese group (BMI ≥ 30 kg/m^2), Harginge-nonobese group (BMI < 30 kg/m^2) and Harginge-obese group (BMI ≥ 30 kg/m^2). Measurements were carried out prior to surgery (baseline) and postoperatively (at the end of the 6th week and 12th week). Pain levels were measured with the Face Pain Scale – Revised (FPS-R). Functional ability was evaluated with the Timed Up & Go (TUG) test and the Greek version of the Modified Harris Hip Score (MHHS-Gr). Quality-of-life was measured with the Greek version of the International Hip Outcome Tool -12 items (iHOT12-Gr).

Research results

DAA *vs* Hardinge regardless of BMI: The DAA resulted in less postoperative pain and offered faster and increased functional ability and better quality-of-life than the Hardinge. DAA-nonobese *vs* Hardinge-nonobese: The DAA leads faster to better functional ability and quality-of-life compared to the Hardinge in nonobese patients. DAA-obese *vs* Hardinge-obese: DAA leads faster to better functional ability and quality-of-life of obese patients than the Hardinge; at 12 wk, statistically significant differences between groups were narrowed. Nonobese *vs* obese regardless of surgical

approach: the only statistically significant difference between obese and nonobese patients was revealed in the self-reported functional ability. DAA-nonobese *vs* DAA-obese: no statistically significant differences were observed in comparing postoperative outcomes. The DAA similarly benefited both obese and nonobese patients. Hardinge-nonobese *vs* Hardinge-obese: Hardinge-nonobese reached higher functionality than Hardinge-obese patients.

Research conclusions

DAA patients reported less pain, more functionality, and quality-of-life improvements compared to the Hardinge. Moreover, DAA exhibits equivalent postoperative outcomes in obese and nonobese patients, suggesting a better-suited THA surgical approach for patients with increased BMI.

Research perspectives

Further research based on well-designed studies with longer follow-up and larger samples need to be performed to elucidate the efficacy of DAA on functionality and quality of life of hip OA obese patients.

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ORIGINAL ARTICLE

Observational Study

Work-related musculoskeletal injuries among upper extremity surgeons: A web-based survey

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Informed consent statement: This study didn't require consent forms from the participants and filling up the survey was considered a consent from the participating surgeons.

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Abstract

BACKGROUND

Work-related injuries have gained recent attention, especially in the orthopaedic literature. As upper extremity orthopaedic surgical tasks require repetitive and constant maneuvers, these surgeons can be at increased risk of acquiring work-related musculoskeletal (MSK) disorders during their years in practice.

AIM

To assess the prevalence, characteristics and impact of MSK disorders among upper extremity orthopaedic surgeons.

METHODS

A modified version of the physical discomfort survey was sent to surgeons who were members of the American Shoulder and Elbow Surgeons and the Canadian shoulder and elbow society *via* e-mail. The collected data were analyzed using descriptive statistics, one-way analysis of variance, and Fisher's exact test. *P* values of < 0.05 were considered statistically significant.

RESULTS

Of the 142 respondents, 90.8% were males and the majority were younger than 55 years old (65.5%). A work-related MSK injury was reported by 89.4% of respondents, of which the most common diagnoses were low back pain (26.1%) and lateral elbow epicondylitis (18.3%). Among those that reported an injury, 82.7% required treatment and 26% required time off work as a direct result of their injury. The need to undergo treatment due to the injury was associated with increased number of injuries ($P < 0.01$). Moreover, surgeons were more likely to require time off work when they had been in practice for > 21 years ($P < 0.05$).

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CONCLUSION

A high proportion of surgeons in our survey reported MSK injuries, with more than one quarter of surgeons reported requiring time off work due to an MSK injury. The high incidence of these disorders may place a financial and psychological burden on surgeons and affect their ability to provide patient care. Awareness of operative ergonomics, irrespective of surgical specialty may help to decrease or possibly prevent the occurrence of these disorders.

Key Words: Upper; Extremity; Surgeon; Prevalence; Musculoskeletal; Disorders

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Core Tip: A high proportion of surgeons in our survey reported MSK injuries, with more than one quarter of surgeons reported requiring time off work due to an MSK injury. Awareness of operative ergonomics, irrespective of surgical specialty may help to decrease or possibly prevent the occurrence of these disorders.

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INTRODUCTION

Healthcare professionals are exposed daily to occupational hazards in their work environment, which can be chemical, radiation, psychological or musculoskeletal (MSK)[1-3]. The latter has gained increased attention in the medical literature due to its high prevalence in physicians, especially surgeons, in addition to its significant impact both physically and psychologically on the physician and thus health care system in general[4-6].

While all surgeons have been found to have an increased risk of sustaining work related MSK disorders, recent studies have shown that the orthopaedic surgeon is at an even increased risk[2,6-8]. Repetitive and constantly forceful surgical tasks have been identified as the major contributing factor to their increased prevalence in orthopaedic surgeons. In addition, these MSK disorders can involve multiple regions, including the lower back and both upper and lower extremities.

Improving operative room setup and ergonomics, in addition to implementing safe workplace recommendations can lead to a decrease in the incidence of these injuries[9-11]. Multiple hurdles have been identified that prevent specific ergonomic setups or hinder executing work space recommendations, which may contribute to the lack of decline of these MSK disorders in the healthcare profession population[12-13].

We performed a study to investigate the prevalence and characteristics of MSK disorders among upper extremity orthopaedic surgeons. In addition, we assessed for any associated risk factors and explored the impact of these injuries on the upper extremity surgeon's practice.

MATERIALS AND METHODS

A modified version of the physical discomfort survey was sent to surgeons who were members of the American Shoulder and Elbow Surgeons and the Canadian shoulder and elbow society *via* e-mail. The initial email was sent in June 2016, followed by a reminder email in December 2016, and survey collection was ended in June 2017.

The survey contained questions related to the surgeons demographics (*e.g.*, age, gender, hand-dominance, type of practice, number of years in practice and annual caseload), which were divided into groups guided by previously published similar studies. Also, the survey contained questions exploring work related MSK injuries, these were divided into anatomical regions, including neck, shoulder, elbow/forearm,

Table 1 Demographics of surveyed upper extremity surgeons

	Number	Percentage (%)
Total respondents	142	100
Sex		
Male	129	90.8
Female	13	9.2
Hand dominance		
Right	122	85.9
Left	20	14.1

wrist/hand, hip, knee, foot and ankle, low back. In addition, participants were asked about both treatments required and time off work required due to the reported injuries, if any.

The collected data were analyzed using descriptive statistics, one-way analysis of variance, and Fisher's exact test. P values of < 0.05 were considered statistically significant.

RESULTS

One hundred and forty-two surgeons responded to the survey, with a respondent rate of 12.5%. Of the 142 respondents, 90.8% were males and 9.2% were females (Table 1). Hand dominance was right in 122 and left in 20 respondents (Table 1). More than 60% of the respondents were younger than 55 years old (Figure 1). The majority of responding surgeons were within their first 20 years of practice (Figure 2). We found that above half of the respondents were in academic practice, 23.2% in community practice, 18.3% in private practice.

Work-related MSK injuries were reported by 89.4% of respondents (Table 2), of which the most common diagnoses were low back pain (26%), lateral elbow epicondylitis (18%), and neck pain (15.5%) (Figure 3). We found no association between the number of work-related injuries incurred and age, type of practice nor years in practice.

Of the surgeons that reported an injury, 82.7% required treatment, with 65.7% requiring medical treatment, 20% requiring surgical treatment and 14.3% requiring both (Table 3). The need to undergo treatment due to the injury was associated with increased number of injuries ($P < 0.01$). Age and number of years in practice were not associated with the requirement of treatment for sustained injuries. More than a quarter of the surgeons required time off work as a direct result of their injury, which was associated with being in practice for > 21 years ($P < 0.05$), but not with the surgeon's age (Table 2).

DISCUSSION

A number of studies in the current literature have assessed the prevalence of work-related hazards, both on a general healthcare worker scale and specific medical and surgical specialties[1,2,14,15]. Our current study explored the prevalence of MSK injuries in the orthopaedic upper extremity surgeon population, who share with other orthopaedic surgeons' exposure to forceful and repetitive operative task that put this cohort at an increased risk for sustaining these injuries during their career.

More than 89% of our studied cohort reported a work related MSK injury at some time in their career, with spine and elbow injuries being the most common. This prevalence was found to be higher than the findings in previously published studies in other orthopaedic specialties, as in a study of 183 arthroplasty surgeons, 66% reported a work-related MSK injury[14]. Similarly, in the orthopaedic trauma surgeon and pediatric orthopaedic surgeon cohorts the prevalence was 66% and 67%, respectively [6,7]. Concerning the most commonly reported regions, cervical and lumbar spine disease and rotator cuff pathology were identified as the most common work-related musculoskeletal disorders in a recent meta-analysis of 5828 physicians[4]. In the

Table 2 Percentage of surveyed upper extremity surgeons with disorders and their requirement of time off work according to sex, age, hand dominance, type of practice, number of institutes, years in practice and annual caseload

	Number of respondents (%)	Number of respondents with injuries (%)	Number of injured requiring time off work (%)
Age (yr)			
≤ 45	38.7	81.8	14.5
46-55	26.8	92.1	34.2
56-65	26.1	70.3	29.7
> 65	8.4	91.7	8.3
Sex			
Male	90.8	92.2	24
Female	9.2	61.5	15.4
Hand dominance			
Right	85.9	88.5	26.2
Left	14.1	95	5
Type of practice			
Academic	50.7	88.9	23.6
Community	23.2	87.9	21.2
Private	18.3	88.5	26.9
Other	7.8	100	18.2
Number of institutes			
1	92.3	88.5	23.7
> 1	7.7	100	18.2
Year in practice			
≤ 10	26.7	78.9	15.8
11-20	35.2	90	26
21-30	21.2	100	30
> 30	16.9	91.7	20.8
Annual caseload			
≤ 250	15.5	90.9	18.2
251-500	64.1	87.9	22
501-750	16.9	91.7	33.3
> 750	3.5	100	20

orthopaedic literature, low back and elbow injuries (especially lateral epicondylitis) were the most common regions involved in the majority of these studies, similar to our findings[6,7]. This may be attributed to the sometime long operative procedures associated with a standing posture, in addition to the frequent pronation/supination movements required during these procedures.

Interestingly, we found no association between the age nor number of years in practice and the risk for sustaining a work-related MSK injury. This is in agreement with the study by Alqahtani *et al*[14] on 183 arthroplasty surgeons, that also found no association. In contrast, a study on the orthopaedic trauma surgeon population identified an association between the number of MSK disorders and the surgeons age and number of years in practice. Alzahrani *et al*[6,7]. also found the same association in a study of 402 pediatric orthopaedic surgeons, where increasing age, working in more than one institute and being in practice more than 21 years was associated with increased number of work-related MSK injuries.

Table 3 Percentage of surveyed upper extremity surgeons with diagnosed disorders per region and number of respondents requiring treatment, requiring surgical treatment and requiring time-off work due to their musculoskeletal disorders

Region	Percentage of respondents with injuries	Percentage of injured respondents requiring treatment	Percentage of treated respondents requiring surgical treatment	Percentage of treated respondents requiring time-off work
Neck	32.3	17.7	5.9	4.4
Shoulder	36.0	22.8	6.6	7.4
Elbow	27.2	14.0	2.2	1.5
Forearm, wrist and hand	32.3	13.2	4.4	3.7
Hip and thigh	6.8	3.0	3.0	2.3
Knee and lower leg	15.9	9.1	6.1	4.6
Foot and ankle	10.6	4.6	0	0
Lower back	43.9	26.5	3.0	5.3

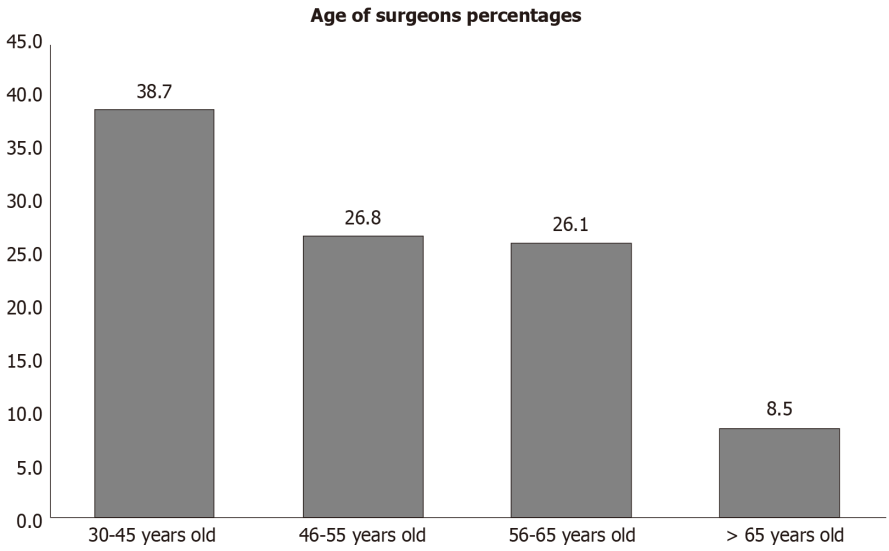


Figure 1 Surgeon age distribution.

Our current study and previously published literature indicate that the risk of work-related musculoskeletal disorders is high, especially in orthopaedic surgeons. Specific attention should be directed towards improving operative room ergonomics and surgeon education on the adequate and safe postures and movements while in the operating room[10,16]. In addition, utilizing instruments that decrease the requirement of repetitive forceful movements in the operating room (*e.g.*, power for inserting screws) may help protect these surgeons during their long career[13].

Our study has some limitations, including recall bias of these reported injuries. In addition, similar to previously used surveys which include self-reported measures, our current survey has not had its reliability and validity established. Also, due to the low response rate, selection bias may also be another limitation. But we believe that this sample size is truly representative of the population in study as the sample size is similar to a number of previously published similar studies.

CONCLUSION

MSK injuries were reported by a high proportion of our surveyed cohort of upper extremity surgeons, with more than a quarter of them requiring time off work. As these injuries may place a psychological burden on the surgeon and affect the

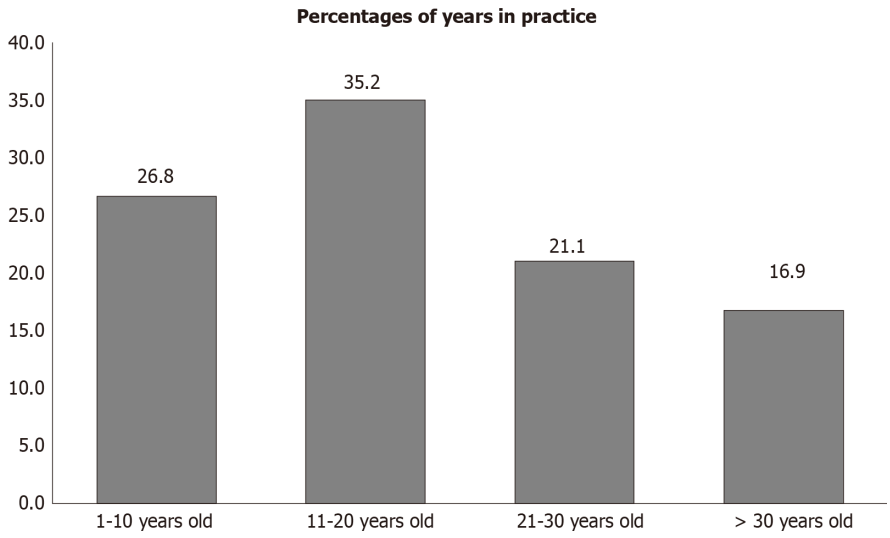


Figure 2 Surgeons years in practice among survey participants.

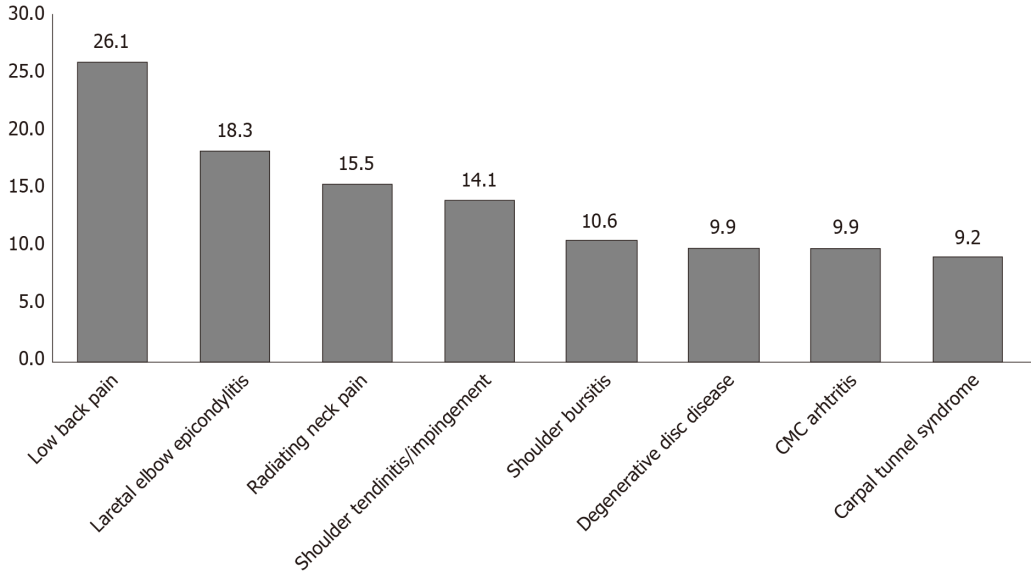


Figure 3 Musculoskeletal disorders and complaints among survey participants.

healthcare system, specific attention should be directed towards improving ergonomics and safety in the operative room to help decrease the high prevalence of these injuries in the future.

ARTICLE HIGHLIGHTS

Research background

Upper extremity orthopaedic surgical tasks require repetitive and constant maneuvers, which can put them at increased risk of acquiring work-related musculoskeletal disorders during their years in practice.

Research motivation

As these injuries may place a psychological burden on the surgeon and affect the healthcare system, attention should be directed at studying their prevalence and associated factors.

Research objectives
To assess the prevalence, characteristics and impact of musculoskeletal disorders among upper extremity orthopaedic surgeons.

Research methods
A modified version of the physical discomfort survey was sent to surgeons who were members of the American Shoulder and Elbow Surgeons and the Canadian shoulder and elbow society *via* e-mail. The collected data were analyzed using descriptive statistics, one-way analysis of variance, and Fisher's exact test. *P* values of <0.05 were considered statistically significant.

Research results
A work-related musculoskeletal injury was reported by 89.4% of respondents, of which the most common diagnoses were low back pain and lateral elbow epicondylitis.

Research conclusions
Musculoskeletal injuries were reported by a high proportion of our surveyed cohort of upper extremity surgeons, with more than a quarter of them requiring time off work.

Research perspectives
Specific attention should be directed towards improving ergonomics and safety in the operative room to help decrease the high prevalence of these injuries in the future.

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EVIDENCE-BASED MEDICINE

Implementation science for the adductor canal block: A new and adaptable methodology process

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Abstract

BACKGROUND

Following the successful Perioperative Surgical Home (PSH) practice for total knee arthroplasty (TKA) at our institution, the need for continuous improvement was realized, including the deimplementation of antiquated PSH elements and introduction of new practices.

AIM

To investigate the transition from femoral nerve blocks (FNB) to adductor canal nerve blocks (ACB) during TKA.

METHODS

Our 13-month study from June 2016 to 2017 was divided into four periods: a three-month baseline (103 patients), a one-month pilot (47 patients), a three-month implementation and hardwiring period (100 patients), and a six-month evaluation period (185 patients). In total, 435 subjects were reviewed. Data within 30 postoperative days were extracted from electronic medical records, such as physical therapy results and administration of oral morphine equivalents (OME).

RESULTS

Our institution reduced FNB application (64% to 3%) and increased ACB

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utilization (36% to 97%) at 10 mo. Patients in the ACB group were found to have increased ambulation on the day of surgery (4.1 *vs* 2.0 m) and lower incidence of falls (0 *vs* 1%) and buckling (5% *vs* 27%) compared with FNB patients ($P < 0.05$). While ACB patients (13.9) reported lower OME than FNB patients (15.9), the difference ($P = 0.087$) did not fall below our designated statistical threshold of P value < 0.05.

CONCLUSION
By demonstrating closure of the "knowledge to action gap" within 6 mo, our institution's findings demonstrate evidence in the value of implementation science. Physician education, technical support, and performance monitoring were deemed key facilitators of our program's success. Expanded patient populations and additional orthopedic procedures are recommended for future study.

Key Words: Total knee arthroplasty; Femoral nerve block; Adductor canal block; Physical therapy; Oral morphine equivalent; Action-related information gap

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Core Tip: This study showed improved immediate postoperative outcomes of total knee arthroplasty patients through effective anesthetic management, specifically in regard to increased mobility (4.1 *vs* 2.0 m) and decreased oral morphine equivalents (13.9 *vs* 15.9) by employing adductor canal block instead of femoral nerve block. Our data supports the value of implementation science to generate institutional change though the application of guidelines from the modified Consolidated Framework for Implementation Research. It is proposed that the key enablers of implementation success, and in our case achieved a "knowledge to action" gap closure in 6 mo, are physician education, technical support, and performance monitoring.

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INTRODUCTION

The "knowledge to action gap" is notoriously large in clinical medicine and translation implementation can take up to 17 years[1]. The apparent disconnect, deemed the "second translational gap," is one of the most daunting tasks facing the global healthcare system as declared by the World Health Organization (WHO)[2-3]. Although the Enhanced Recovery Program (ERP), Perioperative Surgical Home (PSH) and the WHO's Surgical Safety Checklist (SSC) program have achieved remarkable success in the perioperative setting, these programs have varied significantly in their clinical effectiveness at the institutional level, often due to the uneven implementation effectiveness.

Historically, there are delays in two factors which enable success: the foundation of strong clinical evidence and a sound implementation process. The latter is challenging to achieve with consistency at an institutional level. In 2016, we previously reported the success of PSH practice for ambulatory total knee arthroplasty (TKA) at our institution's pilot program[4]. Within approximately 24 mo, we spread the practice through our 21 hospitals and surgical centers guided by the Consolidated Framework for Implementation Research (CFIR)[5]. By employing CFIR principles, we achieved both clinical and implementation effectiveness in all our facilities, which led to significant reductions in length of stay (LOS) for all TKA patients regardless of where they received the care in our system.

The need for continuous improvement was made aware at our institution, including the removal of antiquated PSH elements and the introduction of new practices. Specifically, the substitution of the routine femoral nerve block (FNB) for the adductor canal block (ACB) was deemed important due to demonstrated improvements in postoperative quadriceps strength, patient mobility, and knee recovery in TKA patients[6]. While ACB practice was not novel, its strategy for effective and rapid implementation was of utmost interest, particularly to investigate how change management could be translated to other interventions.

The primary three goals of our study were to investigate the role of implementation guidelines adapted from the Consolidated Framework for Implementation Research (CFIR) to phase-out the routine FNB and phase-in the alternative ACB[7]. to assess our institution's implementation process measured through utilization rates by neuraxial anesthesia type; to compare perioperative outcomes between FNB and ACB patient. By using CFIR guidelines,[7]. we deimplemented the routine FNB and implemented the abductor ACB as the new standard at our institution. We report here the principle, process and effectiveness of such an implementation method.

MATERIALS AND METHODS

Objective

To evaluate the step-by-step implementation and deimplementation roadmap depicted in Figure 1. Specific implementation factors at our institution were part of an overall change management plan adopted from the Consolidated Framework for Implementation Research[7].

Setting, design and sample size

A baseline period (103 patients) was established from June to August 2016. Following a one-month pilot (47 patients) in September 2016 during which those trained in the ACB educated the providers in the team. Patients were informed of the change if they had received the FNB for their previous procedure. The dosage and technicality of the blocks were standardized and disseminated at the beginning of the pilot and reminders were given at each phase.

A three-month implementation and hardwiring period (100 patients) from October to December 2016 was executed for the replacement of FNB for ACB. From January to June 2017, there was a six-month evaluation period (185 patients). During the evaluation period, the dataset was analyzed to determine providers for whom there remained obstacles to implementation; these barriers were addressed biweekly and resolved. In total, 435 TKA patients were reviewed over 13 mo from June 2016 to June 2017.

Methods for data collection and distribution

Data on patient demographics (*e.g.*, sex, age, BMI, ASA status), anesthesia and analgesia (*e.g.*, OME), intraoperative data (*e.g.*, length of operation, estimated blood loss, site infection, transfusion), and perioperative outcomes (*e.g.*, pain scores, distance traveled, buckling, LOS, 30 d readmission, MI or stroke, UTI, and fall) were collected and reviewed. Data was collected prospectively; however, it was retrospectively analyzed as a cohort over time. Reports were generated to evaluate progress initially biweekly and then monthly and during each phase until full implementation. Oral morphine equivalents (OME) were determined based on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) equianalgesic calculator as an average over 24 h after surgery. Analysis was conducted in imperial units and then converted to International System of Units (SI) equivalents (*e.g.*, feet to meters).

Data Analysis

Statistical analysis was performed to compare between ACB and FNB groups using JMP® Pro, Version 13 (SAS Institute Inc., Cary, NC, 1989-2020) at a P value < 0.05. Continuous variables were summarized using descriptive statistics, such as mean, median, and range, and evaluated using two-tailed Student's t-test. Proportions were calculated for ordinal variables and compared using Pearson chi-squared test. Outliers were removed as defined as three times outside 10% tail quantile.

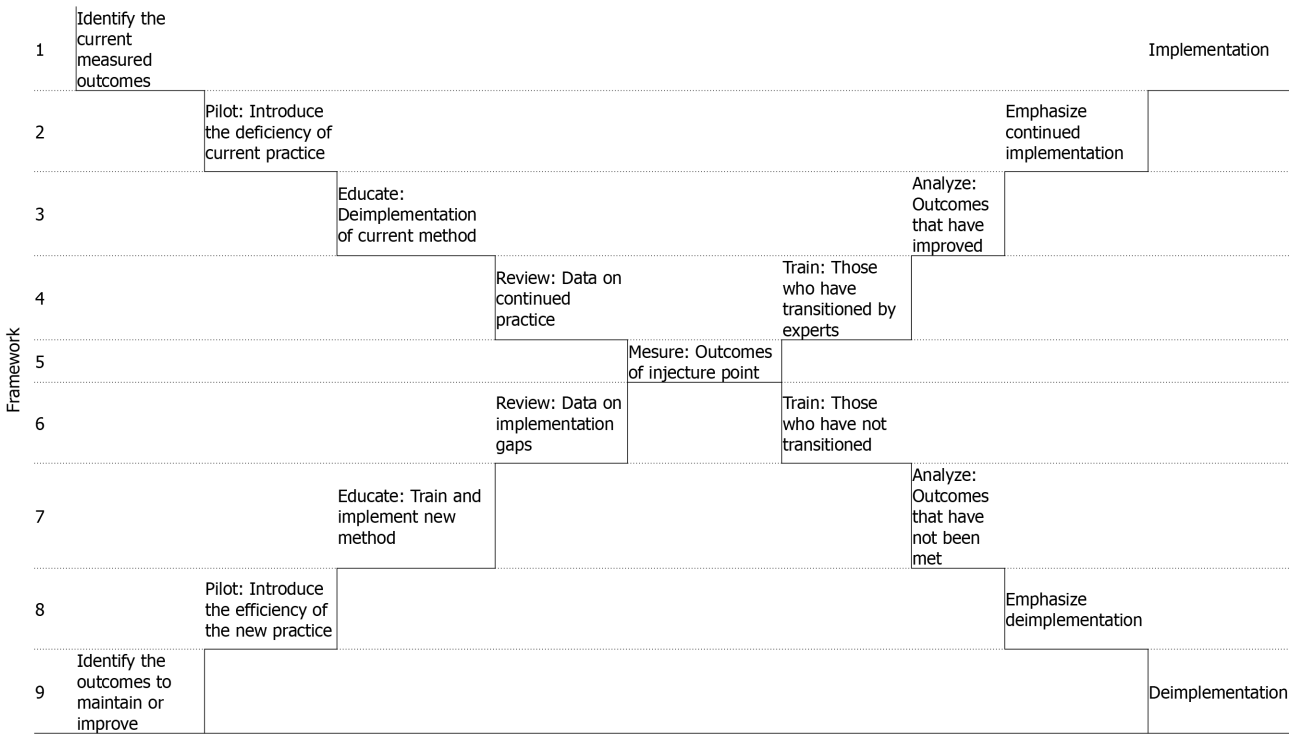


Figure 1 Nine steps involved in inverse pathways to implementation and deimplementation.

RESULTS

Overall, study population characteristics shown in Table 1 were similar to our reported baseline. Figure 2 illustrates the phase-out of the FNB and phase-in of the ACB over the 13-month study period. The preference for ACB *vs* FNB as peripheral nerve block improved after the pilot from October 2016 (36% *vs* 64%) to post-implementation in June 2017 (97% *vs* 3%).

Table 2 demonstrates a summary of patient outcomes between the two groups. While FNB cases utilized lower amounts of local anesthetic (mg), ACB cases were shown to have lower estimated blood loss (mL), fall rates, and incidence of buckling during physical therapy. While the ACB group (13.9) reported lower OME *vs* FNB group (15.9), the difference did not meet our statistical threshold of $P < 0.05$ ($P = 0.087$). On the day of surgery, ACB patients were observed to have an increased mean distance traveled during mobilization compared with FNB patients (4.1 *vs* 2.0 m) as demonstrated in Figure 3.

DISCUSSION

While the average duration to translate new practice into routine adoption is 17 years, only half of evidence-based changes end up reaching broad medical usage[8-9]. In 2012, the replacement of low-value care, defined as inefficient or unwarranted health care practices, received widespread recognition by the American Board of Internal Medicine Foundation through its Choosing Wisely (CW) initiative[10-13]. Although CW campaigns gained initial enthusiasm, promising recommendations often stood in isolation, which resulted in poor adoption rates and lacked the capacity for sustained change[14-17]. The reasons for delayed or missed uptake of evidence-based practices include inadequate resources for mobilizing change, competing demands of providers, and dissonance between operational and research priorities[18]. In addition, the context of current practices, including both the barriers and facilitators of change, is an overlooked, yet imperative, consideration for successful deimplementation[19]. Thus, there is the need to develop targeted strategies to increase the proliferation of evidence-based practices, chiefly by learning through case studies in hospital systems [20].

As of today, implementation science remains an overlooked opportunity for accelerating patient care and improving clinical outcomes. Annually, there are nearly

Table 1 Population description

Demographics	Results
Total, *n*	435
Anesthesia, *n* (%)	
Spinal	368 (85)
General	67 (15)
Spinal converted to General	8 (2)
Sex, *n* (%)	
Male	148 (34)
Female	287 (66)
Age, Mean, Median [Range]	72.3, 71 [65.0-91.0]
Age Group, *n* (%)	
65 to 75	329 (76)
76 to 85	93 (21)
86 to 91	13 (3)
ASA status, *n* (%)	
I or II	283 (65)
III, IV, or V	152 (35)

ASA status: American Society of Anesthesiologists Physical Status Classification System.

seven million complications and one million deaths shortly after surgery, despite the fact that the perioperative patient care accounts for more than 60% of hospital expenditure[2]. Moreover, it has been shown that roughly half of adverse outcomes are potentially avoidable[21]. In spite of many established clinical pathways and strategies that have been tailored to minimize negative impacts, the clinical outcomes have been staggering not due to lack of evidence and knowledge, but because of lack of implementation framework and strategies to sustain the effect of positive changes.

By applying the principle of implementation science, we replaced the femoral nerve block for TKA with the abductor canal block within 13 mo in our established PSH pathway. The learning for the new technique was rapid, the group adoption and transition of the practice was immediate, and consolidation of learning and practice was persistent. We found that ACB patients had increased ambulation and decreased falls and buckling compared with FNB patients, thereby validating an institutional practice change to enhance short-term patient outcomes after surgery. Our findings on improvement mobility are consistent with explanations that ACB may help assist in speedier knee recovery and maintenance of quadriceps strength[6]. We demonstrate that significant healthcare performance improvement can be achieved through the synergistic effect of evidence-based practice and evidence-based implementation science. Furthermore, successful implementation can be achieved through the simultaneous deimplementation of old practices within established PSH pathways.

Past research suggests that ERP initiatives are facilitated by successful pilot programs that generate preliminary evidence and demonstrate local effectiveness for further implementation[22-23]. As defined by Proctor et. al, our institution achieved high penetration, or diffusion rate of intervention, and sustainability, or continued use of intended practice, in the replacement of ACB for FNB during our 13-month study period[24]. Furthermore, it has been suggested that increasing ERP visibility, such as advertising pilot start dates, are beneficial to the implementation process[25,26]. In our case, much attention was focused around our program's launch, as evidenced by the spike in ACB uptake (72%) during the September 2016 pilot. Although there was a subsequent dip in the following two months (36% and 44%), the steady adoption and study's inverse relationship between ACB implementation and FNB deimplementation indicate strong adherence to our program's intended outcome.

Comprehensive transition packages are recommended for dissemination across other regions[13,27]. The Institute for Healthcare Improvement (IHI) advocates that

Table 2 Summary of patient outcomes

Variable	Adductor	Femoral	*P* value
Demographics			
Number of patients	289 (66%)	146 (34%)	-
Sex			0.57
Male	101 (35%)	47 (32%)	-
Female	188 (65%)	99 (68%)	-
Age	72.3, 71 [65-91]	72.3, 71 [65-91]	0.90
BMI in kg/m^2	31.2, 31.0 [19.3-50.0]	30.8, 29.8 [21.0-51.1]	0.55
ASA status			0.52
I or II	185 (64%)	98 (67%)	-
III, IV, or V	104 (36%)	48 (33%)	-
Intraoperative data			
Anesthesia			0.067
Spinal	246 (85%)	114 (78%)	-
General	38 (13%)	29 (20%)	-
Spinal converted to General	5 (2%)	3 (2%)	-
Length of operation in min	122.7, 118 [83-235]	121.7, 107 [83-199]	0.64
Estimated blood loss in mL	57.6, 45 [20-200]	68.2, 75 [20-200]	0.0031[b]
Local anesthetic in mg	94.2, 100 [11.3-225]	89.4, 93.8 [11.3-150]	0.036[a]
Site infection or redness	2 (1%)	1 (1%)	0.99
Transfusion	1 (0%)	1 (1%)	0.62
Day of surgery outcomes			
Pain score from 0 to 10	1.9, 1.7 [0-6.6]	2.0, 1.7 [0-6.1]	0.59
OME	13.9, 12.8 [0-66]	15.9, 15 [0-50]	0.087
Distance traveled in meters	4.1, 1.5 [0-45.7]	2.0, 0.3 [0-30.5]	0.0004[b]
Buckling	14 (5%)	40 (27%)	< 0.0001[b]
Physical therapy complication	7 (2%)	2 (1%)	0.47
Postoperative outcomes			
Length of stay in days	1.9, 1.4 [1.1-8.4]	2.1, 2.1 [1.1-6.2]	0.091
30 d readmission	8 (3%)	7 (5%)	0.27
MI and stroke	0 (0%)	0 (0%)	-
UTI	1 (0%)	1 (1%)	0.69
Fall	0 (0%)	2 (1%)	0.046[a]

[a]$P < 0.05$;
[b]$P < 0.01$. Continuous variables represented as mean, median [range] and evaluated using two-tailed Student's *t*-test. Ordinal variables represented as *n* (%) and evaluated using Pearson chi-squared test. Outliers for length of operation, estimated blood loss, OME, and distance traveled were removed as defined as three times the interquartile range outside 0.1 tail quantile. BMI: Body mass index; ASA status: American Society of Anesthesiologists Physical Status Classification System; OME: Oral morphine equivalents based on Hospital Consumer Assessment of Healthcare Providers and Systems equianalgesic calculator; MI: Myocardial infarction; UTI: Urinary tract infection.

"care bundles" provide solid evidence for change in practice, limited debate over efficacy, and robust acceptance[28]. Gilhooly *et al*[29] categorized compliance to practice changes into three levels: high (70%-100%), medium (40%-69%), and low (0%-39%). Specifically, while high and medium compliance groups leveraged interdisciplinary teams, champion networks, and structured audits and feedback loops, low compliance groups employed less interactive strategies, such as posters and screen

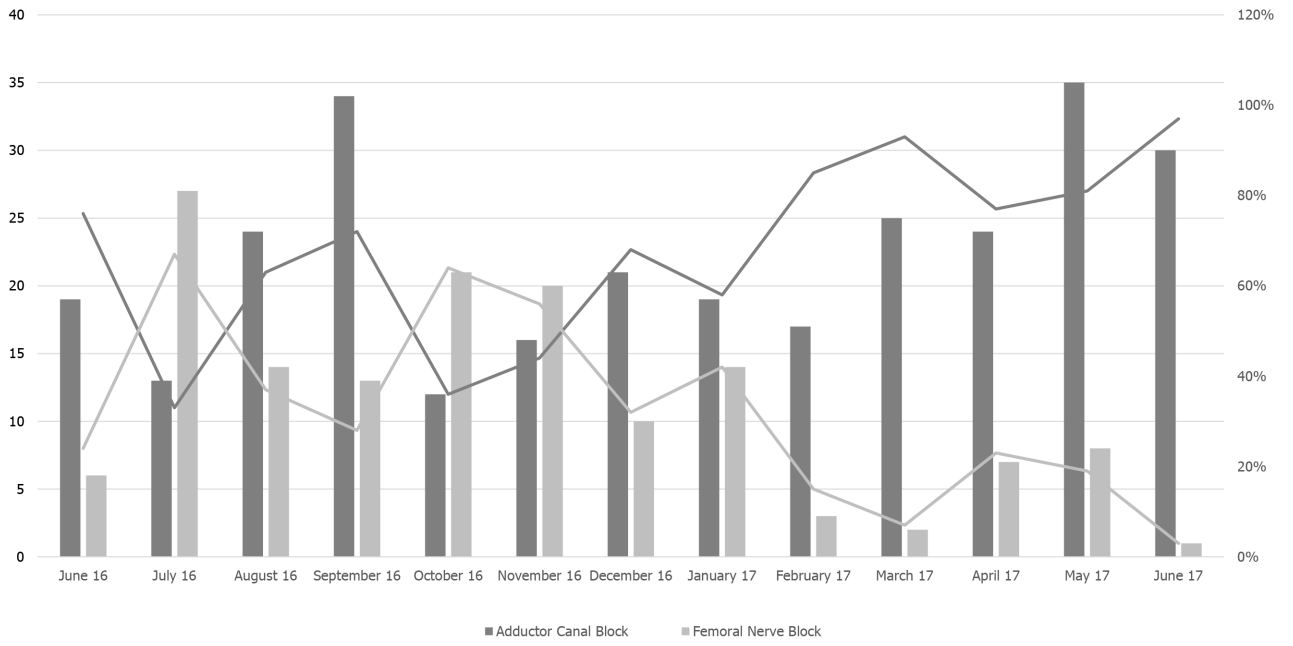


Figure 2 Utilization rates of adductor *vs* femoral canal block over our 13 mo study period demonstrate successful implementation and deimplementation adherence.

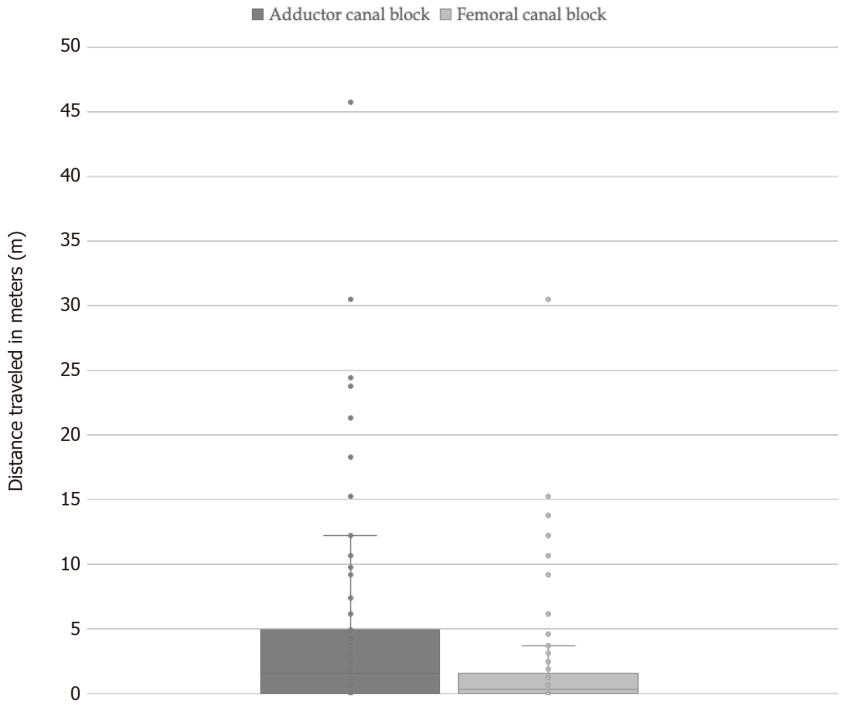


Figure 3 Patients receiving adductor canal block achieved a greater distance traveled in meters on postoperative day 0 compared to femoral canal block patients.

saver reminders[29]. Our institution serves as another case study of how high engagement strategies, including one-on-one coaching and timely program evaluations, helped a large provider team realize 97% ACB utilization rate by our study's endpoint.

It is often discussed that the primary end goal of implementation science is to achieve "sustainability", in which new knowledge and reformed practices are embedded in routine care[30]. As Rapport *et al*[30] propose in their "diffusion-dissemination-implementation" continuum, the concept of sustainability, along with adoption, is only one of five critical stages in the feedback loop that ensure sound

implementation. With the goal for implementation science to seek long-term impact, purposeful language (*i.e.*, terminology that can be refined and fit future needs) and shared agendas with the greater hospital organization help support sustainable change [30]. In our case, we ensured that our program's messaging mirrored our group's strategic initiatives, as well as the broader transformational goals of our hospital management organization. In building the case for practice change, it has been recommended that pre-implementation data includes, at a minimum, one year of prior data to support the endorsement of senior leaders and assignment of resources and capital[31]. While post-implementation cost savings analysis can facilitate future programs, there may be incalculable benefits, such as expanded experiential learning opportunities for residents and encouragement in critical thinking and evaluation of therapeutic interventions[31].

There are limitations to our study. By prescribing exclusion criteria to patients under 65 years old, our findings on ACB mobility benefits and lower incidence of falls and buckling may be narrowed to the older patient and more representative of the demographics of our specific medical center. In a previous analysis of data on 9580 total hip and knee patients across 11 of our region's medical centers, it was found that 40% of patients were under 65 years old[32]. Future studies should explore younger patient populations and various demographics. Furthermore, there was variability in how the estimated distance traveled during postoperative physical therapy was recorded. For example, while some providers noted mobility progress in imperial units (*e.g.*, "80 feet"), others included more qualitative measurements (*e.g.*, "2 sidesteps") which needed to be normalized in our database by adopting consistent assumptions (*i.e.*, 1 sidestep = 1 foot). There is an opportunity for standardization in approach for tracking key physical therapy metrics as we continue to build our dataset across our regional network. In the future, there is value for implementation strategies to include cost to benefit analyses on the allocated change management resources (*e.g.*, training, dedicated staff, campaign awareness) and perioperative patient outcomes to quantify the financial impact of such programs.

CONCLUSION

In this study, we closed the "knowledge to action gap" within 6 mo, proving the implementation effectiveness of the Consolidated Framework for Implementation Research and implementation science in our setting. The inverse relationship between the adoption of ACB utilization and phasing out of FCB suggests the benefits of implementation science guided by a roadmap of physician education, technical support, and performance monitoring. Moreover, our study demonstrates evidence that transition to ACB as the choice regional anesthesia technique during TKA may improve patient mobility and physical therapy outcomes following surgery. There is an opportunity to bridge our growing knowledge in improving perioperative techniques with an effective implementation framework. Next steps including expanded patient populations, additional medical centers, and other orthopedic procedures are warranted.

ARTICLE HIGHLIGHTS

Research background

In 2016, we employed Perioperative Surgical Home (PSH) practice change for ambulatory total knee arthroplasty (TKA) resulting in reduced length of stay in our system. Nevertheless, we acknowledged the need for continuous improvement and implementation of new practices to optimize short-term outcomes in our TKA patient population.

Research motivation

We employed a new look at implementation science to remove outdated PSH elements and adopt modified consolidated framework for implementation research (mCFIR) practices. Our motivation was to investigate the transition from femoral nerve blocks (FNB) to adductor canal nerve blocks (ACB) and how learnings on change management could be applied to other surgical areas.

Research objectives

To execute our institution's implementation process during the phase-out of FNB and phase-in of ACB during TKA. While the rationale for ACB practice was not novel, we focused on identifying the enablers of success practice change.

Research methods

We tracked our institution's implementation progress through utilization rates by neuraxial anesthesia type. Goals of enhancing patient care were validated through the comparison of perioperative outcomes between FNB and ACB patients.

Research results

Application of the mCFIR was shown to be successful in implementing institutional practice change for ACB during TKA within 6 mo. Increased patient mobility and improved physical therapy outcomes were demonstrated in ACB *vs* FNB patients.

Research conclusions

Our institution's successful phase-out of FNB and phase-in of ACB within 6 mo demonstrates the valuable role of implementation science. Effective physician education with technical support and metrics evaluation are critical methods to achieve swift practice change.

Research perspectives

Future research should be focused on younger patient populations and different orthopedic procedures.

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SYSTEMATIC REVIEWS

Femoral lengthening in young patients: An evidence-based comparison between motorized lengthening nails and external fixation

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Abstract

BACKGROUND

Femoral lengthening is a procedure of great importance in the treatment of congenital and acquired limb deficiencies. Technological advances have led to the latest designs of fully implantable motorized intramedullary lengthening nails. The use of these nails has increased over the last few years.

AIM

To review and critically appraise the literature comparing the outcome of femoral lengthening in children using intramedullary motorized lengthening nails to external fixation.

METHODS

Electronic databases (MEDLINE, CINAHL, EMBASE, Cochrane) were systematically searched in November 2019 for studies comparing the outcome of femoral lengthening in children using magnetic lengthening nails and external fixation. The outcomes included amount of gained length, healing index, complications and patient reported outcomes.

RESULTS

Checklist.

Of the 452 identified studies, only two (retrospective and non-randomized) met the inclusion criteria. A total of 91 femora were included. In both studies, the age of patients treated with nails ranged from 15 to 21 years compared to 9 to 15 years for patients in the external fixation group. Both devices achieved the target length. Prevalence of adverse events was less in the nail (60%-73%) than in the external fixation (81%-100%) group. None of the studies presented patient reported outcomes.

CONCLUSION

The clinical effectiveness of motorized nails is equivalent or superior to external fixation for femoral lengthening in young patients. The available literature is limited and does not provide evidence on patient quality of life or cost effectiveness of the interventions.

Key Words: Lengthening nails; Motorized nails; Distraction ostepgenesis; Lengthening

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Core Tip: Femoral lengthening in young patients using motorized lengthening nails has gained recent popularity. This study reviewed the literature comparing the outcomes of femoral lengthening using motorized lengthening nails and external fixators in this age group. The advantages and complications of each treatment option were discussed.

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INTRODUCTION

Limb length discrepancy (LLD) is a common finding in multiple congenital and acquired disorders. LLD may lead to significant consequences such as changes in gait biomechanics, back pain, lower limb osteoarthritis, psychological problems, and poor function and lifestyle. It is accepted that LLD below 2 cm can be treated with appropriate orthotics. LLD of 2 to 5 cm can be managed with growth modification (epiphysiodesis) of the longer side. For a LLD greater than 5 cm, limb lengthening is indicated[1].

Gavrill Ilizarov introduced the concept of distraction osteogenesis (DO) and circular external fixators for management of trauma and deformities[2]. For decades, the Ilizarov technique was the most effective method of limb lengthening. It is cheap, reproducible and allows correction of angular deformities and spanning of joints if required[3]. However, external fixation significantly limits the patient's activities and life style and has a high risk of complications[4]. The preference of external fixation for bone lengthening has started to decline since the introduction of motorized lengthening nails.

Lengthening nails are intramedullary telescopic devices that securely fix within the intramedullary canal and telescope to produce the desired length (Figure 1). The older designs of lengthening nails relied on a ratchet mechanism that was activated by rotating the leg to produce lengthening[2]. Recent designs of lengthening nails provide distraction by activation of a motor inside the nail with external remote control (ERC) applied externally to the limb. Motorized nails include the PRECICE nail (PRECICE lengthening nail: Nuvasive, CA, United States) and Fitbone nail [FITBONE Telescope Active Actuator (TAA) nail: Wittenstein Intens, Igersheim, Germany].

The initial designs of lengthening nails were associated with failure of the telescoping mechanism[5]. The newer generation of motorized lengthening nails have improved results[6-9]. Lengthening nails were reported to offer more active post-operative life styles, fewer post-operative infections and less metal work failures compared to earlier designs and external fixation[10]. Motorized lengthening nails

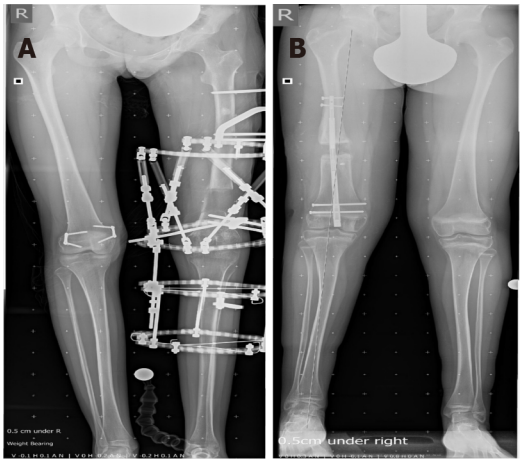


Figure 1 Left femoral lengthening with external fixation (A) and right femoral lengthening with magnetic lengthening nail (B).

have been used initially for femoral lengthening, however their applications have increased to include other long bones such as tibia[7] and humerus[11].

The average cost of the motorized nail implants is £12000-£13000 (€14000–€15000/$15000-$16000) while the average cost of external fixators varies from £3000 to £9000 (€3500–€10500/$3500-$11500)[12].

Within the limited resources available to the National Health Service (NHS) and the United Kingdom being a welfare state, increasing emphasis has been placed on cost-effectiveness. The assessment of health-related quality of life (HR-QoL) and cost utility analysis have become the foundation of economic evaluation of health technologies and gained importance in supporting the decision for allocation of NHS resources.

The recent shift to use motorized nails for bone lengthening in children despite the significant difference in implant costs compared to traditional treatment with external fixation necessitated this systematic review. This review is focused on femoral lengthening only because the initial lengthening nails were designed for femoral lengthening and the femur is the most frequently lengthened bone with motorized nails.

We present a systematic review of the studies comparing femoral lengthening in children using motorized nails to external fixation. We aimed to identify the most clinical and economic effective technique of femoral lengthening in children.

MATERIALS AND METHODS

Review question

Is the extra cost of the motorized intramedullary nails compared to external fixation in children justified?

This question can be divided to the following questions: (1) What is the clinical effectiveness of motorized lengthening nails in comparison to external fixation for femoral lengthening in children? (2) Is there a difference in the HR-QoL between the two techniques? and (3) What is the cost effectiveness of the two techniques?

Methods

Eligibility criteria: All studies, irrespective of design, that compared the outcomes of both techniques for femoral lengthening in children (less than 18 years old). All indications for femoral lengthening were included. Use of a motorized lengthening nail was the intervention and any type of external fixation was considered the comparator. The outcomes included clinical, radiological and HR-QoL.

Literature search strategy: Literature search on Healthcare Database Advanced Search (HDAS) was conducted on Medline and EMBASE databases. The HDAS search was supplemented with a complementary search on PubMed (NCBI) database. Medical subject heading (MeSH) was identified from the available studies and searched separately. References and citations from the identified studies were screened to identify further eligible papers. Terms "limb lengthening", "bone lengthening", "distraction osteogenesis', "external fixation", Ilizarov", intramedullary nails",

"lengthening nails", "magnetic nails", "quality of life", "cost-benefit analysis"," Health care cost" and "quality adjusted life years" were used for the HDAS search, A thesaurus was used to further identify the MeSH on different databases. Different results were combined with "and' or "or" where applicable. The reference lists of all relevant articles were screened to find other potentially relevant articles. Titles, abstracts and when relevant the full texts of the relevant studies were reviewed. Only studies published in English were retrieved. No time limit was selected.

Data extraction: Study design, methodology, country, number and age of participants, type of intervention and outcome of treatment (clinical, radiological, and quality of life) were recorded.

Quality assessment of eligible papers was performed using the Critical Appraisal Skills Program (CASP) checklist.

Data synthesis: Given the small number of papers retrieved, we provide a narrative summary of findings and a description of their strengths and limitations rather than calculating summary scores/statistical analysis.

RESULTS

A total of 452 studies were identified (Figure 2). After screening the titles and abstracts of these studies, 98 were considered potentially eligible for inclusion. Of these, 30 were excluded because the full texts were not available. Of the remaining 62, 60 were excluded, either because they were not comparative studies (58) or were not in children[2]. Therefore, there were only two studies which met our inclusion criteria.

Study design and patient population

Both were non-randomized retrospective studies. Szymczuk *et al*[13] compared the PRECICE nail in 30 femora to 32 cases of femoral lengthening using the LRS (Limb Reconstruction System Orthofix, McKinney, TX, United States) monolateral external fixator. The average ages were 15.4 and 9.4 years for the nail and external fixator groups respectively. Black *et al*[14] compared the outcome of femoral lengthening using the retrograde Fitbone nail in 15 femora with the outcome of lengthening using circular fixators in 14 femora. The average ages were 15 and 18 years for the nail and external fixator groups respectively.

Outcomes

Both studies evaluated the outcome based on average length achieved, and complications. Szymczuk *et al*[13] also reviewed range of movement (ROM) and healing index (HI). None of the studies reported children's quality of life or cost of treatment.

Gain in length and HI

Szymczuk *et al*[13] reported an average length gain of 4.8 cm (range 3.4 to 6.2 cm) with the PRECICE nail and 5.6 cm (range 3.9 to 7.3 cm) with the LRS external fixator. In their study, 26 patients (87%) in the nail and 28 patients (88%) in the fixator group achieved the target length of 4 cm. The healing index (HI) was 34.3 d/cm and 29.3 d/cm for nails and fixators respectively. Length of hospitalisation was not recorded.

Black *et al*[14] reported an average length gain of 4.8cm (range 1 to 7.4 cm) and 4.4 cm (range 1.5 to 7 cm) with the external fixator and motorized nails respectively. In Black's study, 10 patients (71%) in the external fixator group and 11 (73%) patients in the nail achieved the target length of 4 cm. There was no report on HI, however the time to full weight bearing was 7.7 mo with nails and 8.8 mo with external fixators. Length of hospitalisation was 7 and 9.5 d with nails and fixators respectively.

Complications

Szymczuk *et al*[13] reported complications in 18 (60%) of the nails compared to 26 (81%) in the fixator group ($P < 0.001$). The average complication per lengthening session was 1.0 with nails and 1.8 with external fixators.

By comparison, Black *et al*[14] reported complications in 10 (73%) of the nails compared to all 15 (100%) in the circular fixator group. Minor complications such as pin site infections and minimal joint contractures were seen in 5 (33%) of the nail group compared to 12 (79%) in the circular frame group. There was no statistical difference between the rate of types II and IIIA complications between the two groups.

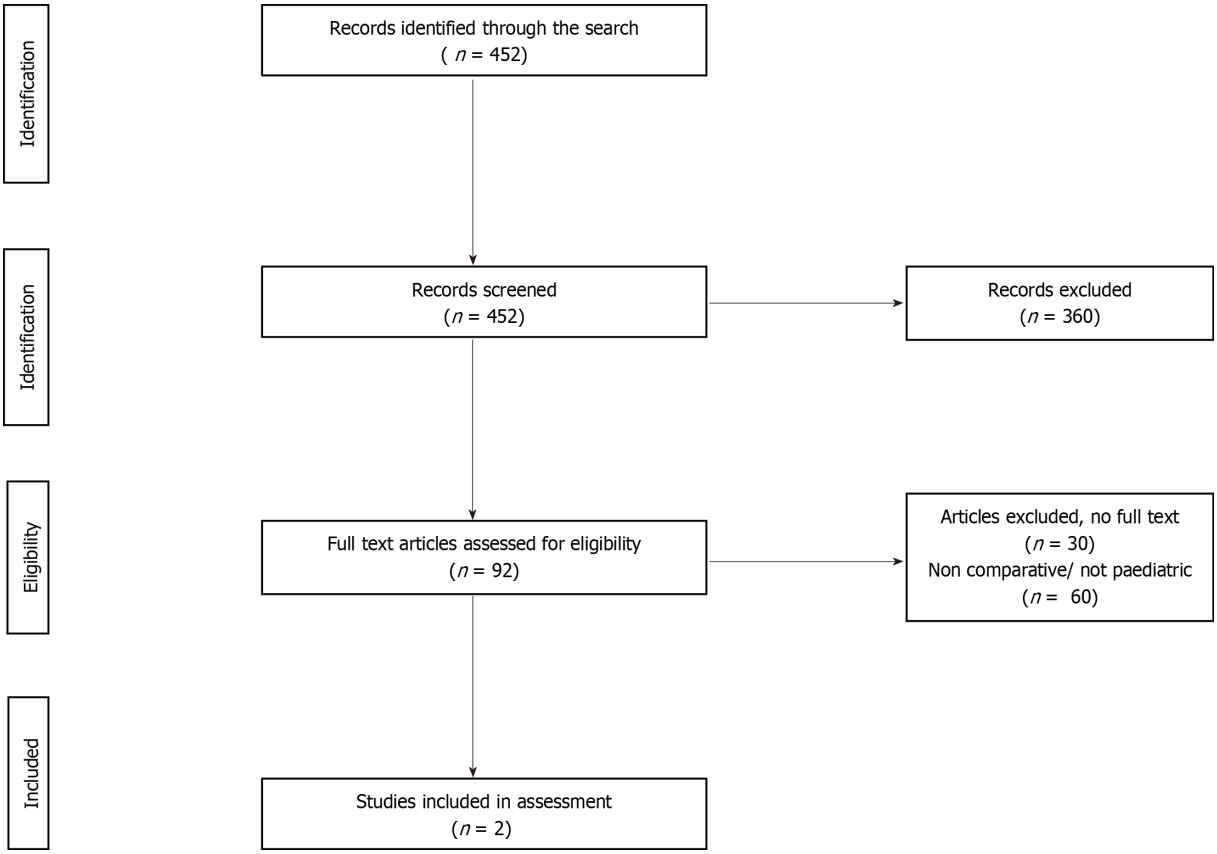


Figure 2 PRISMA flow diagram for the systematic review.

Serious complications such as joint dislocations were less common with the nails, 3 (20%) compared to 5 (36%). In the circular fixator group, there was no statistical difference between the two groups for moderate complications such as delayed union. The average complication per lengthening was 1.2 with nails and 2.6 with external fixators. Characteristics of the publications are summarized in Table 1. Results are summarized in Table 2.

Quality of papers: This is summarized in Table 3.

DISCUSSION

The presented literature review identified a lack of comparative studies in children. Two studies combined adults and children in the same group but did not present the data in such a way as to allow extraction of the pediatric data[15,16]. There is no evidence of QOL comparison between these interventions. No cost analysis was presented to support the use of lengthening nails. All these findings mandate further research to cover these points.

The current knowledge in respect to the research questions are summarized as follow: What is the clinical effectiveness of motorized lengthening nails in comparison with external fixation for femoral lengthening in children?

Both motorized nails and external fixators can effectively achieve the target femoral length. Range of motion of the knee was better preserved during the course of lengthening with nails, however there was no significant difference at the final follow up visit[13]. The overall gained length was greater with external fixators compared to motorized nails; 4.8 *vs* 4.4 cm[14] and 5.6 *vs* 4.8 cm[13] respectively. Black *et al*[14] reported a shorter time to union (by 1.1 mo) with motorized nails although Szymczuk *et al*[13] reported a shorter healing index (by 5 d/cm) with the LRS external fixator. Complication rates were lower with lengthening nails however knee subluxation was specifically reported with the nails due to the inability of the technology to span the knee. For this reason a recommendation to reconstruct knee ligaments at preparatory surgery prior to lengthening with nails was suggested[13]. However, the long-term outcome and cost effectiveness of ligament reconstructions prior to lengthening are

Table 1 Characteristics of the included publications

Ref.	Study design	Patient characteristics	Intervention	Comparator	Clinical outcomes
Black *et al* [14]	Comparative non-randomized retrospective	(1) Congenital short femur; (2) Skeletally mature children; (3) *n* = 29 (15 in FITBONE group and 14 in circular external fixation group); and (4) Age (mean): 18.2 yr in FITBONE and 15.8 yr in circular fixators	Motorized lengthening nails (FITBONE)	Circular external fixator	Length achieved, complications rates
Szymczuk *et al*[13]	Comparative non-randomized retrospective	(1) Congenital short femur; (2) *n* = 62 (30 in PRECICE group and 32 in LRS group); and (3) Age (mean): 15.4 yr in PRECICE and 9.4 yr in LRS	Magnetic lengthening nails (PRECICE)	LRS external fixator	ROM, length achieved HI and complication rates

not yet clear.

External fixation devices are very versatile, they can be applied in young children with short or deformed femora[2]. External fixators are relatively cheap compared to motorized intramedullary nails, however there were many reported adverse events related to external fixators. Pin site infection, pain, stiffness, fracture, injury to nerves or vessels and psychological problems were frequently reported with external fixation [17]. On the other hand, intramedullary nails can only be used in relatively longer femora with appropriate width of the medullary canal. The presence of an open distal femoral physis in skeletally immature children is generally a contraindication for retrograde nails however, if the femoral canal is wide enough and the femur had normal proximal anatomy a trochanteric entry nail can be used safely[18].

Laubscher *et al*[15], reported better clinical outcomes and less complications with magnetic nails compared to monolateral fixator for femoral lengthening. This study included paediatric and adult age groups. According to this study 100% of the nail and 68% of the fixator participants chose to have same treatment again. Horn *et al*[16], compared the outcome of femoral lengthening with motorized nails to external fixation in age and sex matched patients. The mean age of patients was 27 years. HI and knee ROM were better with lengthening nails, while complications were more frequent with external fixators. Morrison *et al*[19], compared the outcome of humeral lengthening with lengthening nails in 6 patients to external fixations in 7 patients. Lengthening nails patients had less complications compared to external fixators. Lengthening nails were reported to be safe, well tolerated, and effective for humeral lengthening[19].

Is there a difference in the HR-QoL between the two techniques?

We did not identify any studies which compared the quality of life of children treated with motorized lengthening nails and external fixators. However, HR-QoL was the outcome for two non-comparative studies. The authors concluded that patients have lower quality of life scores during the course of treatment[20]. One study[20] compared patient satisfaction following lengthening nails to a previous session of lengthening using external fixation in 13 patients. Patients reported less pain, more satisfaction, easier physiotherapy, and better cosmetic appearance following magnetic nails compared to previous lengthening using external fixators. It is worth mentioning that this study did not utilize a validated outcome questionnaire and there was high probability of recall bias since the QoL scores were recorded at the time of final interview[21]. The pediatric quality of live inventory (PedsQL) was used in studies for children treated with external fixation. The children and their parents reported significantly lower HR-QoL scores on all PedsQl domains compared with a normal healthy population.

The HR-QoL of motorized nails compared to external fixators for femoral lengthening in children is not known. It is clear that both techniques have a negative impact on HR-QoL. There is limited evidence suggesting that this negative impact is greater for external fixators than for motorized nails.

What is the cost effectiveness of the two techniques?

A cost comparison of the two techniques has not previously been reported. However Richardson *et al*[12] did estimate the cost of lengthening with the PRECICE nail to be approximately $44449 (£34650, €40110). This value was calculated after reviewing hospital costs and surgeon fees from the lengthening surgery up until the time of union in 39 femora. This study included adults and children, neither the surgical costs of nail removal nor the costs of loss of income, hospital visits and outpatient medications were included.

Table 2 Findings of the included publications

Black *et al*[14]					
Comparison of FITBONE and circular fixation with respect to several treatment outcomes					
Outcome	FITBONE		Circular fixator		*P* value
Length achieved (cm)	4.4		4.8		0.63
Time to full weight bearing (mo)	7.7		8.8		0.27
Length of F/U (yr)	3		3.6		0.6
Classification of complications according to the authors					
Grade	Definition		Example		
I	Minimal intervention required; goal still achieved		Pin site infection, mild joint contracture		
II	Change to treatment plan, goal still achieved		Unplanned return to theatre, delayed union requiring bone graft.		
IIIA	Fail to achieve plan, no new pathology		Premature union, inability to tolerate lengthening, fracture		
IIIB	Fail to achieve goal, new pathology/permanent complications		Dislocations, deformity, nerve injury, deep infection		
Comparison of FITBONE and circular fixation with respect to adverse events					
Complication	FITBONE		Circular fixator		*P* value
	No. of complications (*n* = 15)	*n* (%) of lengthening sessions affected by complications	No. of complication (*n* = 14)	*n* (%) of lengthening sessions affected by complications	
I	7	5 (33)	15	11 (79)	0.03
II	6	6 (40)	8	6 (43)	0.88
IIIA	4	3 (20)	4	4 (29)	0.68
IIIB	3	3 (20)	6	5 (36)	0.43
Any complication	20	11 (73)	33	14 (100)	0.10
Szymczuk *et al*[13]					
Comparison of PRECICE and LRS fixation with respect to ROM					
ROM	PRECICE		LRS fixator		*P* value
	Extension	Flexion	Extension	Flexion	
Preoperative	0.83	127.7	0.47	123.3	0.35
Post-distraction	0.93	96.3	-0.6	69.9	0.0007

Post-consolidation	-0.4	121.5	0.74	81.3	< 0.0001
Final follow up	-0.4	119.6	-0.7	120.2	0.9
Comparison of PRECICE and LRS fixation with respect to several treatment outcomes					
Outcome	PRECICE		LRS fixator		*P* value
Lengthening goal (cm)	4.97		5.58		0.15
Length achieved (cm)	4.75		5.55		0.052
Healing Index (d/cm)	34.77		29.33		0.08
Comparison of complication rates between PRECICE and LRS[22]					
Complication	PRECICE		LRS fixator		*P* value
	Total events	Affected segment	Total events	Affected segments	
Problems[1], *n* (%)	8 (25.8)	7(23.3)	32 (55)	20 (62.5)	< 0.001
Obstacle[1], *n* (%)	19 (61)	11 (36.7)	20 (34.5)	10 (31.3)	0.66
Complications[1], *n* (%)	4 (12.9)	4 (13.3)	6 (10.3)	5 (15.6)	0.99
Total, *n* (%)	31	18(60)	58	26 (81.3)	0.07

[1]Problems, obstacles, complications: A classification system of adverse events associated with limb lengthening.
Problems include incidents that do not need operative intervention. Obstacles were the incidents requiring operative but did not lead to permeant complications. Complications included intraoperative injuries and non- resolved problems before the end of treatment.

Table 3 Quality assessment of included publications

Strengths	Limitations
Black *et al*[14]	
(1) Clear methodology: Objective, design, inclusion / exclusion criteria, outcome, and results; (2) Age matched participants; (3) All participants had the same underlying diagnosis; and (4) Complications were described in detail	(1) Clinical and radiological outcome results were not declared due to compassionate use policy; (2) Selection bias; (3) All participants were skeletally mature (not fully representing the Paediatric population); (4) No validated scores were used; (5) No attempt was made to avoid observer bias; and (6) Sample size calculations were not undertaken
Szymczuk *et al*[13]	
(1) Clear methodology: Objective, design, inclusion/exclusion criteria, outcome, and results; (2) The study focused only on children; (3) All participants had the same underlying diagnosis; (4) Probability values (*P* values) were reported; and (5) Complications were described in detail	(1) Bias such as selection and follow up; (2) There is no mention of potential confounders or how they may have varied between groups; (3) No validated scores were used; (4) No attempt was made to avoid observer bias; (5) Nails were used only in older children, resulting in uneven distribution of the intervention especially in the higher-risk younger age group; and (6) Sample size calculations were not undertaken

The cost effectiveness of motorized nails compared to external fixators for femoral lengthening in children is not known.

Critical appraisal of the included publications

The objectives of and interventions used in both studies were clearly mentioned and inclusion and exclusion criteria were specified. The measured outcomes were mentioned clearly in the methods and in the results sections. Statistical analysis was clear with appropriate statistical test (*t*-test) in Szymczuk *et al*[13]. Authors of both studies classified the complications according to severity and reported the complications accurately.

Limitations were also identified in both studies. Both focused on one indication for femoral lengthening (congenital femoral deficiency), excluding all other causes of femoral shortening such as trauma and infection. There was a high possibility of selection bias in both studies, given their non-randomized retrospective designs. At the time of the study, the Fitbone nail did not have FDA (Food and Drug Administration agency) approval for use in the United States; therefore patients recruited to the study by Black *et al*[14] were treated on a compassionate-use basis. This suggests that the selection of patients was based on meeting the criteria for inclusion on a compassionate basis rather than matching the nails and external fixator groups. Szymczuk *et al*[13] did not specify their selection criteria. Neither study was blinded; this would have been difficult given the nature of the interventions being compared.

The age of patients both groups in the study by Szymczuk *et al*[13] were not matched. Nails were used for children over 9 years and fixators for children as young as 3 years. This policy might have affected the overall complication rates due to increased use of fixators in the higher risk group of younger children. Black *et al*[14] included patients of matched age groups, however all the patients who were treated with nails were skeletally mature and all of the nails were inserted retrograde sparing the trochanteric region. This might suggest that although the participants of this group were younger than 18 years, they had adult bones and the results might not be representative for children.

CONCLUSION

There is no literature comparing the cost effectiveness and patient satisfaction of femoral lengthening with motorized lengthening nails and external fixators in children. Further research is necessary in order to ascertain the efficacy of these treatment methods, to optimize patient outcomes and to ensure health care resources are spent appropriately.

ARTICLE HIGHLIGHTS

Research background

For decades external fixation was the only reliable, safe, and reproducible technique for bone lengthening. The use of external fixation declined recently due to the development of motorized lengthening nails. Lengthening nails are expensive.

Research motivation

Is the extra cost of the motorized intramedullary nails compared to external fixation in children justified?

Research objectives

The main objective was to review the literature to compare the clinical effectiveness of motorized lengthening nails to external fixation. Other objectives were to identify differences in the health-related quality of life between the two techniques in current literature.

Research methods

Electronic databases (MEDLINE, CINAHL, EMBASE, Cochrane) were searched, and all relevant studies were considered for analysis based on predetermined inclusion/exclusion criteria. The subject headings "distraction osteogenesis", "motorized nails", '' external fixation'' and their related key terms were used.

Research results

Only 2 studies out of 452 studies met the inclusion criteria. The ages of the patients ranged from 9 to 21 years. Lengthening nails were effective in achieving the target length with less prevalence of adverse events.

Research conclusions

The clinical effectiveness of lengthening nails was comparable to external fixation. No report on the quality-of-life difference between the 2 techniques during lengthening. No reports on the cost effectiveness of lengthening nails compared to external fixations.

Research perspectives

Further research is necessary in order to ascertain the efficacy of these treatment methods, to optimize patient outcomes and to ensure health care resources are spent appropriately.

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META-ANALYSIS

Role of coatings and materials of external fixation pins on the rates of pin tract infection: A systematic review and meta-analysis

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Abstract

BACKGROUND

Infection at the pin tract is a frequent and feared complication of external fixators (EF). The type of pin material and coatings have been regarded as possibly influencing infection rates. Over the last 20 years, few prospective clinical studies and systematic reviews addressed the role of coated pins on the rate of pin site infection in human clinical studies.

AIM

To assess the EF literature over the past 20 years on the clinical benefits of pins manufactured from varied materials and coating systems and their possible role in pin tract infection rates.

METHODS

We performed a systematic review according to the PRISMA and PICOS guidelines using four scientific platforms: PubMed, LiLacs, SciELO, and Cochrane. We searched the literature for related publications over the past 20 years.

RESULTS

A literature search yielded 29 articles, among which seven met the inclusion criteria. These studies compared stainless-steel pins and pins coated with

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hydroxyapatite (HA), titanium and silver. The pin tract infection definitions were arbitrary and not standardized among studies. Most studies included a low number of patients in the analysis and used a short follow-up time. Three meta-analyses were carried out, comparing stainless steel *vs* silver pins, stainless steel *vs* HA-coated pins, and titanium *vs* HA-coated pins. None of this analysis resulted in statistically significant differences in pin tract infection rates.

CONCLUSION
Currently, no clinical evidence supports the advantage of EF pins manufactured with materials other than stainless steel or coated over uncoated pins in reducing the rates of pin tract infections. A standardized definition of pin tract infection in external fixation is still lacking.

Key Words: External fixator; Pin tract infection; Stainless steel pin; Coated pin; Coating systems; Pin site infection

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Core Tip: There is no consensus in the literature that different materials or pin coatings of external fixators can interfere with the infection rates. This is the first manuscript that evaluates related publications over the last 20 years and develops a meta-analysis evaluating three different types of metallic coatings.

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INTRODUCTION

External fixators (EF) are used for bone stabilization using minimally invasive percutaneous insertion of pins, thin and olive wires, interconnected by threaded shafts, bars, and metal rings. These devices provide robust support in the management of fractures and cases of long bone nonunions, malunions, infections, and serious limb malalignment deformities[1]. At the same time, pins are a pathway of contact between the external environment and the skin, subcutaneous tissue, muscle, and bone. Consequently, infection is one of the main complications[1,2]. When infection is superficial, clinical treatment entails local measures and orally administered antibiotics for control. Cases where the infection progresses from the skin and soft tissues into bones and consequently results in pin loosening usually require pin removal or replacement and long-term intravenous antibiotic therapy for chronic osteomyelitis, increasing the cost and complexity of treatment[3].

Infections associated with implants are usually caused by microorganisms that grow in biofilms attached to the implant surface, which is also the case with pin tract infections. A biofilm is a well-controlled and protected environment favoring sessile microorganisms to develop a multi-factorial tolerance to antibiotics and host defenses. This tolerance has been attributed to restricted penetration of the antibiotics, restricted growth at low-oxygen tension, expression of biofilm-specific genes and the presence of non-dividing microorganisms[4]. The formation of biofilms is a major contributor to the clinical challenges encountered in treating pin tract infections.

Therefore, previous studies have assessed different measures to control infectious pin complications, from pin base local care protocols to nonmetallic (ceramic) manufactured pins and coating systems to avoid biofilm formation[5-8]. Clinical benefits regarding infection and loosening of coated vs. uncoated pins have yet to be well defined[9,10]. Indeed, many published articles failed to reach definitive conclusions regarding the impact of different pin materials and coatings on the reduction of pin tract infections[11]. In a 2005 clinical review on hydroxyapatite-coated pins, Moroni *et al*[12] concluded that this type of coating system could reduce the rate

of post-operative complications, including infections. Nevertheless, current research assessing the real clinical benefits of tapered pins coated with hydroxyapatite is still lacking. A 2010 systematic review by Saithna *et al*[11] that included only four randomized controlled trials failed to show a clear clinical benefit of using hydroxyapatite-coated pins to decrease pin loosening and pin tract infection rates.

A few types of pin materials have been assessed in previous published clinical studies, including ceramic and metallic (stainless steel and titanium), and also coatings such as hydroxyapatite (HA), HA plus fibroblast growth factor 2 (FGF-2), silver coating and iodine-coated systems[6,11,13-15]. Even though HA coating is one of the most studied coating systems, whether this and other products can effectively reduce the number of infections remains unclear[11,15-18]. Indeed, over the last 20 years, few prospective clinical studies and only two systematic reviews addressed the role of coated pins on the rate of pin site infection in human clinical studies. Moreover, only a hydroxyapatite coating system was assessed in these published reviews. Considering the advances in materials and surfaces in recent years, we aimed at assessing the clinical benefits and rates of infectious complications of EF pins manufactured from varied materials with different coating systems. This systematic review and meta-analysis compiled comparative data on superficial and deep infectious complications found in different types of external fixation pin materials and coatings in human clinical studies.

MATERIALS AND METHODS

Literature sources

A systematic review was carried out according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines in the following databases: PubMed, LiLacs, SciELO and Cochrane. The search period spanned from January 2000 to December 2020, encompassing all relevant articles published in the last 20 years. The search was performed using key words related to the subject: "External Fixators", "Fixation Devices, External", "Pin Site", "Pin Tract", "Coated Pin", "Hydroxyapatite Coated", "Stainless Steel Pin" and "Hydroxyapatite-coated". We used English terms when searching all databases and Spanish and Portuguese terms when searching the LiLacs and SciELO databases.

Study selection

In the search, the population subject of this review is defined as any human being, regardless of sex or age, who has undergone any type of external fixator device procedure for the treatment of any pathology. In these studies, an objective assessment of pin tract infection rates should be made. One or more types of pin materials and coatings may be studied besides steel pins. We included clinical studies with a level of evidence of 1-2. In vitro, basic science, animal studies and previous systematic reviews are exclusion criteria. Also, studies with a level of evidence of 3-5 are excluded. The main objective of this study is to assess whether different materials and coatings, in addition to stainless steel, play a role in reducing the infection rate of the pin site, using the body of available clinical literature and its level of evidence. The quality of published literature was assessed. Whenever possible, a meta-analysis was performed to assess the effectiveness of coating systems and materials at reducing the rates of pin infection.

Data extraction

Two reviewers (CS, MJCS) independently selected the relevant articles based on reading the abstracts. Articles containing only scientific information on different infection rates and comparisons of the different types of pin materials and coatings were selected. All relevant texts, tables and figures have been revised for data extraction. If additional information was needed, the corresponding authors of the articles would be contacted, but it was not necessary. Discrepancies between the two reviewers were resolved by consensus discussion.

Risk of bias

We used the Cochrane Risk of Bias Tool to calculate the risk of bias, as shown in Table 1. Among the 29 articles selected for the study, seven studies classified as clinical trials were selected for the article, all of these articles presented a low risk of bias for the randomization sequence generation category (Coester, 2006; Masse, 2000; Morone,

Table 1 Cochrane risk of bias tool - clinical trials

Study	Random sequence generation	Allocation concealment	Blinding of patients, personnel	Blinding of outcome assessor	Incomplete outcome data	Selective outcome reporting	Other
Coester, 2006	Low	Low	Unclear	Low	Low	Low	Low
Masse, 2000	Low	Unclear	Unclear	Unclear	Low	Low	Low
Morone, 2001	Low	Low	Unclear	Unclear	Low	Low	Low
Pieske, 2010	Low	Low	Low	Low	Low	Low	Low
Pieske, 2011	Low	Low	Low	Low	Low	Low	Low
Pizà, 2004	Low	Low	Unclear	Unclear	Low	Low	Low
Pommer, 2002	Low	Low	Unclear	Low	Low	Low	Low

2001; Pieske, 2010; Pieske, 2011; Pizà, 2004; Pommer, 2002). Five described how allocation secrecy was carried out to reduce the risk of bias (Morone, 2001; Pieske, 2010; Pieske, 2011; Pizà, 2004; Pommer, 2002). Only two studies blinded patients (Pieske, 2010; Pieske, 2011), and three articles blinded the evaluators (Pieske, 2010; Pieske, 2011; Pommer, 2002). All seven articles presented the follow-up losses of study participants and presented a low risk of bias for the selective outcome reporting category (Coester, 2006; Masse, 2000; Morone, 2001; Pieske, 2010; Pieske, 2011; Pizà, 2004; Pommer, 2002).

Statistical analysis

The meta-analysis was performed using the Mantel-Haenszel statistical method. The model used was of random effects and the measurement of the effect through the relative risk. An alpha value of 0.05 and a 95% confidence interval were considered statistically significant. The statistical heterogeneity of the treatment effects between the studies was assessed by the Cochran Q test. Inconsistency was assessed by the I2 test, in which values between 25% and 50% were considered to indicate moderate heterogeneity and high heterogeneity was shown by values greater than 50%. All analyses were performed using Review Manager software version 5.4 (Cochrane Collaboration).

RESULTS

Study selection

A total of 13951 articles were initially retrieved from different platforms. The abstracts of these articles were downloaded to the EndNote Clarivate™ analytics platform. After analyzing the abstracts of all 13951 articles retrieved from the search platform, both reviewers defined the same group of 29 articles for inclusion in the systematic review.

After the initial selection stage, further screening was carried out in which the 29 articles were read in full, and their contents discussed to reach a consensus on their inclusion in the final results of the study. The final group of articles comprised only clinical studies that focused on infection rates associated with the different external fixator pin materials and coatings in humans within the aforementioned inclusion criteria. Seven of the 29 articles contained data on infection rates involving the different pin materials and coatings in humans.

All stages of search, selection and exclusion of the articles listed in this study, as the 2009 PRISMA guide recommends, are shown as a diagram in Figure 1.

A total of seven scientific articles were selected as consistent scientific sources for inclusion in the systematic review. The selection results, showing the different types of materials and coatings studied and their results with respect to infection rates in the pin tract, are described below. It was possible to perform three meta-analyses

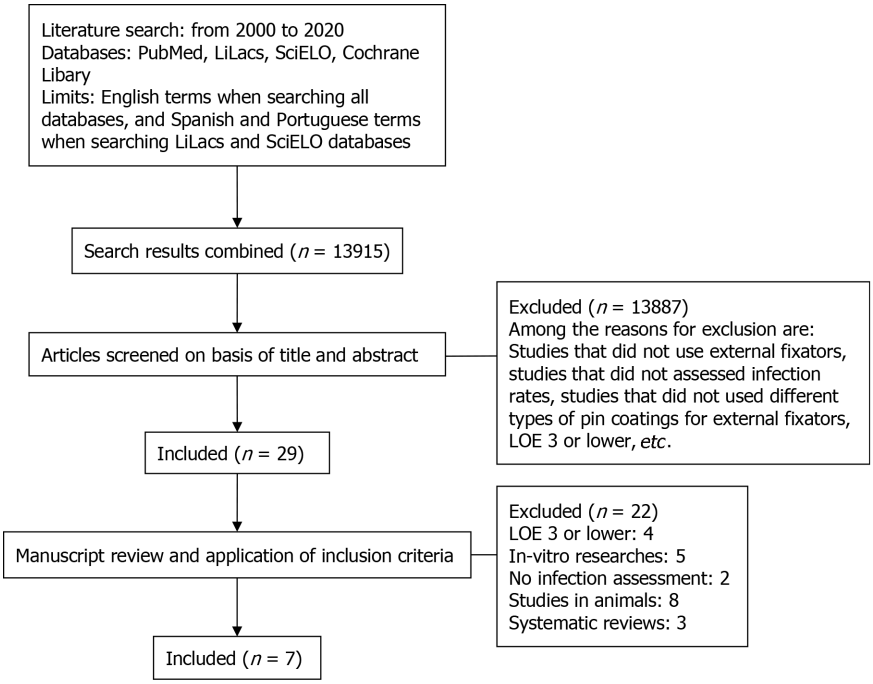


Figure 1 Preferred reporting items for systematic reviews and meta-analyses diagram flow diagram of search and selection strategy for systematic review.

comparing the following coatings: silver-steel, HA-titanium, and HA-steel.

Stainless steel vs hydroxyapatite

In 2001, Moroni *et al*[12] conducted a prospective randomized study comparing infection rates in 20 patients with wrist fractures treated with external fixators divided into two groups. One of the groups used steel pins, and the other one used pins coated with hydroxyapatite. The Checketts-Otterburn classification was used as a criterion for infection, and the patients were followed for 6 wk. There were no reports of infection in both groups[19].

In 2004, Pizà *et al*[14] conducted a prospective randomized clinical study, comparing infection rates between pins coated with hydroxyapatite and steel pins. Overall, 23 patients were evaluated in which 56 external fixators were used, with a follow-up of 530 d. Infection rates between pins were assessed using the Checketts-Otterburn classification and found to be similar, with 30.4% for hydroxyapatite pins and 30.7% for steel pins[14].

In 2010, Pieske *et al*[20] published a prospective randomized study comparing the clinical benefits of traditional stainless-steel pins to hydroxyapatite-coated pins for the treatment of wrist fractures with external fixators. The authors assessed rates of pin tract infection and loosening based on bespoke criteria defining infection. A short period of follow-up (6 wk) was used until EF removal in both groups. Overall, 40 patients were assessed and divided into two groups of 20 patients each. Hydroxyapatite-coated pins showed a tendency toward better clinical outcomes, but no statistical difference was found for pin tract infection or loosening between groups. The prevalence of infections requiring antibiotics was 2.6% for coated pins *vs* 5.3% for uncoated pins. The authors concluded that the superior pin-bone anchorage associated with hydroxyapatite-coated pins was clinically irrelevant, as was the infection rate[10].

Titanium vs hydroxyapatite

In 2002, Pommer *et al*[21] published a randomized clinical trial comparing pins coated with hydroxyapatite and titanium pins. In this study, 46 patients submitted to bone transport or tibial bone lengthening with external fixators were evaluated, divided into two groups according to the type of materials. The follow-up was 38 wk, and the infection criterion used was that of Mahan *et al*[22] (1991). The infection rates found were 0% in the group with pins coated with hydroxyapatite and 13% in the group with titanium pins, showing a statistically significant difference in infection rates[21].

In 2011, Pieske *et al*[20] published a prospective controlled cohort study comparing hydroxyapatite-coated pins with titanium alloy pins for the treatment of wrist

fractures using external fixators. As in their 2010 study described above, the authors assessed pin infection and loosening rates and employed bespoke criteria for defining pin tract infection. The follow-up time was 6 wk until the removal of fixators in both groups. They also assessed 40 patients divided into two groups, each comprising of 20 patients. The results proved comparable to those of the previous study by the same authors, revealing only a tendency of hydroxyapatite-coated pins to yield lower rates of loosening and infection, although this difference did not reach statistical significance[21].

Stainless steel vs silver

Two articles compared infection rates in silver pins with steel pins. In 2000, Masse published a prospective randomized study in which they evaluated 24 patients, comparing, among other variables, the infection rates between silver and steel pins. The infection criterion was based upon Mahan *et al*[22], and the follow-up for the silver and steel groups was 109 d and 113 d, respectively. The infection rate was 30% for silver pins and 42.9% for steel pins, but the difference was not statistically significant. In addition, they observed an increase in serum silver levels in some patients who received silver pins, and as a conclusion, they advised against the use of silver pins[23].

In 2006, Coester *et al*[24] carried out a randomized clinical trial comparing silver pins with steel pins. They evaluated 19 patients over an average period of 16.7 wk. As an infection criterion, they used a bespoke evaluation and found an infection rate of 30% in silver pins against 21% in steel pins, with no statistically significant difference between the two[24].

It is worth mentioning that all selected studies compared only two types of pin materials and coating systems. None included more than two different types of coating for comparison. Additionally, information such as the reasons for external fixator indications and classification for the severity of fractures or deformities were not necessarily mentioned in the studies. Nevertheless, the selected articles met the inclusion criteria and the desired literary quality.

The main characteristics of all selected studies are shown in Table 2.

RESULTS

Stainless steel vs silver

Two studies compared the infection rate between silver pins vs. steel pins[23,24]. The use of silver pins did not show any significant difference (0.92; 95%CI: 0.47 to 1.83; I^2 = 51%; P = 0.82) in the infection rate compared to steel pins, as shown in Figure 2. The meta-analysis showed high heterogeneity and can be explained by the methodological difference in assessing the infection rate, according to criteria described by different authors. Both articles showed good methodological quality.

Stainless steel vs hydroxyapatite

Three articles compared pin tract infection rates between HA-coated pins vs. stainless steel pins[10,14,19]. No statistically significant difference was found in the rate of infection when comparing HA-coated with stainless steel pins (0.88; 95%CI: 0.71 to 1.08; I^2 = 0%, P = 0, 23), as shown in Figure 3.

Titanium vs hydroxyapatite

Two studies compared the infection rate between HA-coated pins vs. titanium pins[20,21]. The use of HA-coated pins had no significant difference in the rate of infection compared to titanium pins (0.35; 95%CI: 0.00 to 79.17; I^2 = 86%, P = 0, 71), as shown in Figure 4. The heterogeneity of this meta-analysis is characterized as high, possibly because these articles evaluate the rates of infection using different scales. Both articles have good methodological quality.

DISCUSSION

The following coatings and materials were studied in addition to steel in the studies selected for analysis according to our inclusion criteria: (1) Silver: Known for its antimicrobial and bacteriostatic activity, is used in medical equipment such as special dressings and urinary catheters. Its potential antimicrobial mechanisms are the

Table 2 Characteristics of seven studies selected and included for analysis

Author	Year	Level of evidence	Number of patient (*n*)	Coatings	Follow-up	Infection criteria	Infection rate	Conclusion
Masse	2000	2	24	Silver *vs* Steel	109 d *vs* 113 d	Mahan *et al*[22] criteria	30% *vs* 42.9%	No statistical difference
Moroni	2001	1	20	Hydroxyapatite *vs* Steel	6 wk	Checketts-Otterburn	0	No statistical difference
Pommer	2002	1	16	Hydroxyapatite *vs* Titanium	38 wk	Mahan *et al*[22] criteria	0% *vs* 13%	Statistically significant
Pizá	2004	1	23	Hydroxyapatite *vs* Steel	530 d	Checketts-Otterburn	30.4% *vs* 30.7%	No statistical difference
Coaster	2006	1	19	Silver *vs* Steel	16,7 wk	Bespoke	30% *vs* 21%	No statistical difference
Pieske	2010	2	20 *vs* 20	Steel *vs* Hydroxyapatite	65 d	Bespoke	5.3% *vs* 2.6%	No statistical difference
Pieske	2011	2	20 *vs* 20	Titanium *vs* Hydroxyapatite	56 d	Bespoke	0% *vs* 10%	No statistical difference

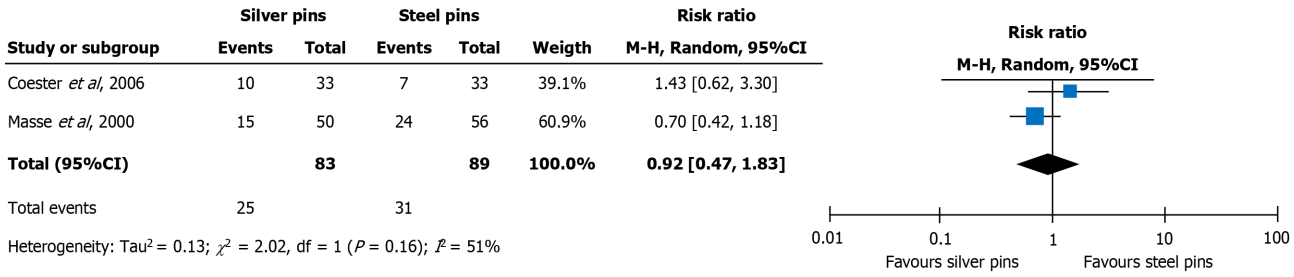


Figure 2 Stainless steel vs silver.



Figure 3 Stainless steel vs hydroxyapatite.

production of reactive oxygen species with direct effects on DNA and cell membranes. Bacterial resistance to silver is rare[25]; and (2) Hydroxyapatite: A molecule composed of calcium and phosphate, is the main mineral component of human bone and is used on a large scale in orthopedic surgery. It has osteoconductive properties and has been used in an attempt to decrease infection and loosening rates in the pins of external fixators[11,26].

Titanium has anti-corrosion and mechanical properties that favor its use in external fixators. With exposure to oxygen, a spontaneous stable oxide layer forms and leads to biocompatibility[27].

We also found studies evaluating other materials that did not meet the inclusion criteria: ceramic pins, pins with bisphosphonate coating, titanium pins with iodine coating, and pins with FGF-2-apatite coating.

Study or subgroup	Hydroxyapatite-coated pins Events	Total	Titanium alloy pins Events	Total	Weigth	Risk ratio M-H, Random, 95%CI
Pieske *et al*, 2011	2	76	0	80	49.4%	5.26 [0.26, 107.81]
Pommer; Murh; Dávid, 2002	0	165	20	169	50.6%	0.02 [0.00, 0.41]
Total (95%CI)		**241**		**249**	**100.0%**	**0.35 [0.00, 79.14]**
Total events	2		20			

Heterogeneity: Tau² = 13.07; χ^2 = 6.92, df = 1 (P = 0.009); I^2 = 86%

Test for overall effect: Z = 0.38 (P = 0.71)

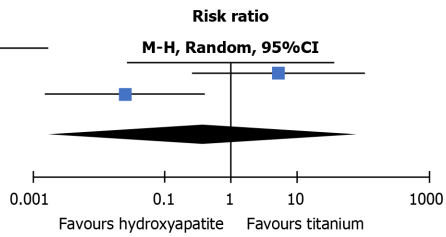


Figure 4 Titanium *vs* hydroxyapatite.

Ceramic pins produced low interference in the MRI signal, an advantage over metal pins in the event that CNS imaging assessment is required. However, rates of infection and aseptic loosening of ceramic pins were significantly higher than for titanium alloy pins. The infection rate in ceramic pins was 27.3% (12/44) *vs* 13.3% (35/263) in titanium pins (P = 0.031). Hence, the advantage of lesser interference in MRI for ceramic pins was outweighed by their higher complication rates. The study was not included due to its low level of evidence (LoE)[28].

Bisphosphonate-coated pins have been shown to increase adherence to bone in dental implants. In a randomized clinical trial published in 2013, the possibility of decreasing the rates of loosening of pins in human diaphyseal bone was evaluated. This study was not included because it did not aim to evaluate infection rates between different coatings[16].

Iodine-coated titanium pins were studied in a prospective cohort study published in 2014 that assessed the infection rates in iodine-coated titanium pins in 39 external fixators involving 38 patients. The infection rate was 3.6% (17/476 pins), and all cases were superficial. After comparing with other published studies, the authors concluded that coating titanium with iodine reduced infection rates in external fixator pins. The study was not included due to its low LoE[2].

FGF-2-apatite coating was evaluated in a prospective controlled study comparing titanium pins with and without FGF-2-apatite coating published in 2018. Overall, no significant difference between groups for pin tract infection or loosening was found. The study results concluded that pins coated with FGF-2-apatite were safe, and no severe pin tract infections were observed[29].

In addition to the materials and coatings discussed above, a review study published in 2013 by Jennison *et al*[30] commented on the possible effect of other materials and coatings such as copper, nitric oxide, chitosan and antibiotics, concluding that at that time, none of them had shown a reduction in infection rates in human clinical trials [30].

Only seven relevant publications with LoE 2 or more were available comparing different pin materials and coating systems with rates of infections in human clinical studies over the past 20 years. The main complications investigated were pin tract infections, torque force for pin removal and loosening rates. The results revealed a lack of standardized criteria established to define and classify pin tract infection. Overall, among the seven studies reviewed, only four systematically adopted a published pin infection classification system, such as the Checketts-Otterburn or the Mahan classification. The other three studies used the authors' own criteria to classify the degree of infection, potentially leading to disparities between evaluators[10,21,24]. The data retrieved from these studies warranted three meta-analyses, in which two studies compared silver with steel pins[23,24], three studies compared steel pins with HA-coated pins[10,14,19] and two studies compared titanium pins with HA-coated pins [20,21]. Interestingly, none showed a statistically significant impact on the outcome of pin tract infection, which corroborated and confirmed the information shown by other systematic reviews and studies previously carried out[11,12,30].

Despite the limited number of clinical studies addressing new materials and coated pins proposed to prevent infections, some modern strategies have been developed [31]. However, outcomes often depend on coating systems that use different antibiotic compounds, polymers or antibiotic film peptides, silver or nitric ions, nanoparticles or even antiseptics such as chlorhexidine or silver sulfadiazine[1,5,31]. Unfortunately, none of these materials have progressed to clinical trials.

CONCLUSION

In conclusion, a small number of clinical studies assessing the impact of different coatings and materials on the EF pin tract infection rates have been published over the last 20 years. Currently, there are no standardized methods of defining and classifying pin tract infections. The lack of a clear and universal definition renders existing studies difficult to evaluate and compare. We identified seven quality clinical trials, comparing three different types of coatings, that enabled us to carry out three meta-analyses. The meta-analysis showed high heterogeneity, and none of the coating systems and materials was superior at reducing the pin tract infection rates. Under these circumstances, no scientific evidence supports materials other than steel pins to control infection rates of EF pins. Prospective multicenter clinical trials involving modern pin materials and new coating systems are very much welcomed to find a way to reduce infection rates, which are considerable in the use of EF.

ARTICLE HIGHLIGHTS

Research background

Few clinical studies assessed the impact of pin materials and coating systems on infection rates over the last 20 years.

Research motivation

Few studies identified significant differences between pin materials in the rate of infection. There has been a lack of standardized criteria for defining and grading pin tract infection of external fixators.

Research objectives

Search the literature of the last 20 years for evidence on the influence of coating systems and different materials of external fixator pins on infection rates.

Research methods

A systematic review was carried out, over the last 20 years, according to the preferred reporting items for systematic reviews and meta-analyses guidelines in the following databases: PubMed, LiLacs, SciELO and Cochrane.

Research results

Seven studies met the inclusion criteria and allowed for three different meta-analyses between similar coating systems and materials used. Due to the heterogeneity of the studies, it was not possible to carry out a meta-analysis that encompassed all selected works.

Research conclusions

Currently, no significant clinical benefit to control infection rates has been achieved with our coating pins systems.

Research perspectives

Prospective multicenter clinical trials involving pin materials and new coating systems should be carried out.

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CASE REPORT

Allergic dermatitis after knee arthroscopy with repeated exposure to Dermabond Prineo™ in pediatric patients: Two case reports

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Abstract

BACKGROUND

Allergic contact dermatitis (ACD) secondary to Dermabond Prineo™ is rare, but documented. To our knowledge, there are no described reports of this ACD reaction within the pediatric population following arthroscopic surgery.

CASE SUMMARY

We report two cases of pediatric ACD upon second exposure to Dermabond Prineo™ after knee arthroscopy. Both cases presented within two weeks of the inciting second exposure. The cases resolved with differing described combinations of sterile cleaning, diphenhydramine, and antibiotic administration. No long-term sequelae were found.

CONCLUSION

This case report elucidates the rare complication of allergic dermatitis secondary to Dermabond Prineo™ repeat exposure use in pediatric arthroscopy.

Key Words: Dermabond; Prineo; Arthroscopy; Sports medicine; Contact dermatitis; Case report

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Core Tip: Dermabond Prineo™ has shown to be advantageous as a wound closure

prepared and revised in compliance with the CARE Checklist (2016).

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device with regards to operative efficiency, cosmetic results, and decreased postoperative restrictions. With the increased use of Prineo™ as a wound closure alternative, surgeons should be aware of potential risks, especially in cases with previous exposure to Dermabond™ or Prineo™. Both cases in this series resolved with differing described combinations of sterile cleaning, diphenhydramine, and antibiotic administration.

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INTRODUCTION

Efforts to decrease total operative time during a given surgical procedure are becoming more critical as both surgeons and administrators consider cost savings for hospital systems and surgical centers. It is estimated that one minute in the operating room can cost up to over $130 depending on the facility[1,2]. With the advent of rapid wound closure products such as Dermabond™ and Dermabond Prineo™ (Ethicon Endo-Surgery, Cincinnati, OH), operative times can be shortened, resources saved, and operative efficiency and post-operative patient comfort increased[3-5].

Prineo™ is a wound closure system that utilizes a self-adhering polyester-based mesh in combination with a monomeric 2-octyl cyanoacrylate formulation and the colorant D&C Violet No. 2. The wound closure system is intended to be used in conjunction with deep dermal stitches. Reported benefits of Prineo™ include a protective microbial barrier, greater skin holding strength when compared to skin staples or subcuticular sutures, more evenly distributed tension away from wound edges, easy removal, and reduction in overall wound closure time[3,6-8].

While there are reported cases of post-operative allergic contact dermatitis (ACD) with the use of Dermabond™, there are few reported cases of such dermatitis associated with the Prineo™ wound closure system, and even fewer associated with a pediatric age group[9-11]. This case report describes instances of ACD following exposure to Prineo™ in a pediatric age group.

CASE PRESENTATION

Chief complaints

Case 1: Six days after an arthroscopic left medial meniscus repair and bone marrow aspirate injection, a 15-year-old female reported increasing itching and a burning sensation around the incision sites that progressed to feeling like her left knee was "on fire."

Case 2: The second patient is a 12-year-old female who presented one week after her left medial meniscal allograft transplantation and reconstruction of anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), and medial collateral ligament (MCL) with complaints of two days of itching around her operative sites.

History of present illness

Case 1: The patient underwent an arthroscopic left medial meniscus repair and bone marrow aspirate injection in which the portal incision sites were closed with Prineo™. Thrombo-Embolus-Deterrent (TED) hose were applied after the surgical drapes were taken down. The procedure was uncomplicated. Upon the patient's return for her one-week postoperative follow up appointment, she was noted to have large blisters covering the anterior portal sites (Figure 1A). The Prineo™ mesh dressing was removed and it was noted that there were large blisters to the anterior left knee.

Case 2: The patient underwent a left meniscal allograft transplantation with reconstruction of the ACL, PCL, and MCL for congenital absence of these structures.

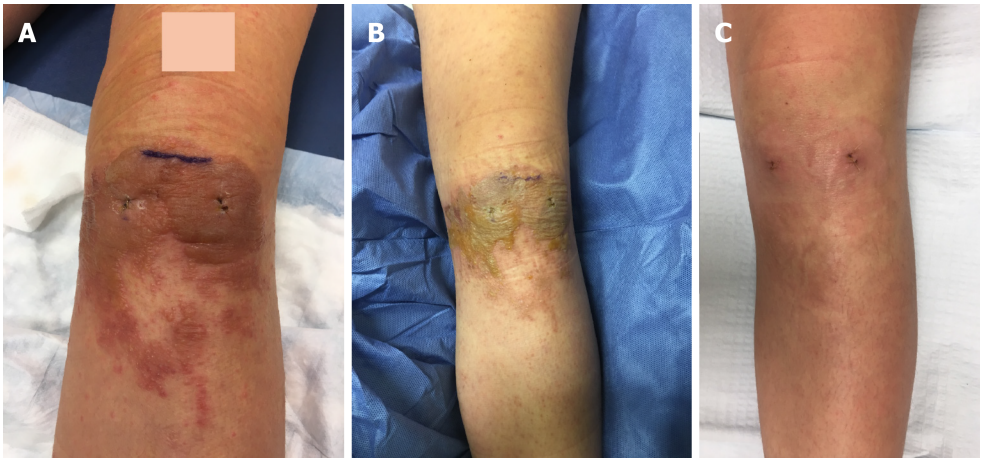


Figure 1 Patient 1. A: Left knee operative site, one week post-operation and use of Prineo™ for wound closure; B: Left knee operative site, two weeks post-operation; C: Left knee operative site, three weeks post-operation.

All incisions and portal sites were closed with Prineo™. Surgical drapes were taken down and TED hose were applied bilaterally. The procedure was uncomplicated. The patient then returned for her one-week postoperative follow-up appointment with a red papular rash surrounding the anterior knee and surgical sites. She complained of itching around these sites.

History of past illness

Case 1: This patient had a right knee ACL reconstruction two years prior in which the incisions were closed with Prineo™. There was no allergic reaction to the closure device at that time. She then sustained a left knee injury while playing softball. She was found to have a medial meniscus tear that was subsequently treated surgically as presented in this case.

Case 2: She had previously undergone a right medial meniscal allograft transplantation with ACL and MCL reconstruction a year and a half prior for congenital absence of these structures, performed by the senior author. Dermabond™ was used for wound closure during her first surgical procedure and Prineo™ was used in this case.

Personal and family history

Case 1: This patient had an unremarkable personal and family medical history.

Case 2: This patient had an unremarkable family medical history with a personal medical history of congenital absence of bilateral ACL, MCL and medial meniscus.

Physical examination

Case 1: The blisters were intact and raised. She also had pruritic scattered papules on the thigh and lower leg. She had a negative Homan sign and the remainder of her physical exam was unremarkable for her postoperative course.

Case 2: One week post-operatively, the dressings covering the operative knee were removed and she was noted to have significant skin inflammation with blisters and welts along the entirety of her surgical incisions (Figure 2A). She also had scattered papules from her groin to her left ankle that were erythematous but not draining nor pustular. The surgical incisions and portal sites were noted to be well approximated with no evidence of drainage.

FINAL DIAGNOSIS

The above cases demonstrate the occurrence of pediatric ACD upon second exposure to Prineo™. Both cases presented with this within one week of the surgical procedure.

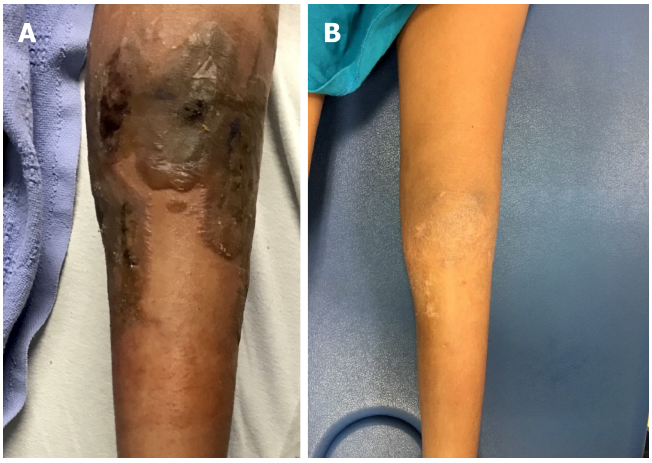


Figure 2 Patient 2. A: Left knee operative site, one week post-operation and use of Prineo™ for wound closure; B: Left knee operative site, six weeks post-operation.

TREATMENT

Case 1: She was prescribed diphenhydramine 25 mg twice daily and placed on doxycycline 100 mg daily for seven days for treatment of concurrent folliculitis. Her wounds were cleaned with sterile water and patted dry. They were then redressed with a nonadherent dressing over the blistering area followed by soft dressings over top. Her TED hose were discontinued until the blisters dried up.

Case 2: The patient's TED hose were discontinued on the operative side (left) and the skin was cleaned above and below the incisions. The incision sites were then redressed with a non-adhesive dressing followed by soft dressings. She was placed on diphenhydramine 25 mg twice daily which was increased to four times *per* day as needed for persistent itching. She underwent daily dressing changes through postoperative day nine when the blisters became flaccid.

OUTCOME AND FOLLOW-UP

Case 1: At her 2-wk post-operative visit, the raised plaques had flattened, the erythema had decreased, and her pruritis had resolved (Figure 1B). She was followed weekly and noted to have significant improvement of the contact dermatitis at her three-week postoperative visit. Her blisters had resolved and no active drainage was appreciated on exam (Figure 1C). The patient was followed two years postoperatively and had no recurrence of any skin reaction surrounding the surgical incisions or elsewhere on her body.

Case 2: On postoperative day fifteen, all blisters had drained and epithelialization of the underlying skin was appreciated. At the patient's three-week postoperative appointment, she was instructed to shower and refrain from using any lotions or creams as scabbing of the blisters was noted. At her six-week postoperative appointment, the allergic dermatitis was completely resolved (Figure 2B). The patient was followed regularly for two years postoperatively and had no recurrence of any skin reaction surrounding the surgical incisions or elsewhere on her body.

DISCUSSION

The occurrence of allergic reaction to Dermabond™ and Dermabond Prineo™ is rare and infrequently reported in the literature. Durando *et al*[12] reported an incidence rate of 1.7% (15 of 912 patients) over a two-year span involving 912 total knee arthroplasty (TKA) cases using Dermabond™. Of these 15 patients who developed a suspected ACD, three agreed to participate in patch testing to determine if they were allergic to Dermabond™ or 28 other possible allergens. Prineo™ was not used in these patient's cases and as such was not studied. Of the three who agreed to participate,

two of the three developed a positive reaction to Dermabond™[12].

Chan *et al*[13] reported 3 cases of allergic reaction to Prineo™ out of 366 patients (1.8%) that were managed by a single surgeon following TKA. Each of the cases presented within 4-9 d postoperatively and the reaction resolved between 4 wk to 12 wk postoperatively. Each patient was referred to a dermatologist and 2 of the 3 patients received a course of topical corticosteroids. Similar to our cases, no long-term sequelae, including recurrence or superficial or deep joint infection, occurred when followed for at least one year[13].

In a study examining wound complications after 2-octylcyanoacrylate skin closure following total joint arthroplasty, Michalowitz *et al*[14] found a 19.2% superficial wound complication rate in hip and knee arthroplasty cases when Dermabond Prineo™ was used. As a retrospective cohort study, the specifics of what defined a superficial wound complication were not described[14].

Davis and Stuart[15] reported a single case of a 72-year-old woman who was found to have severe ACD following a left TKA that subsequently was found to have an extreme patch test reaction to Prineo™ upon patch testing. This patient reported a similar but milder rash a year prior when she underwent right TKA. This case study provides further evidence that occurrence and severity of ACD to Dermabond Prineo™ may be related to second exposure. Similar to other reported cases, it should be noted that their patient's symptoms resolved over a 3-4 wk treatment of topical corticosteroids[15].

Regarding current treatment standards, once surgical site infection is ruled out, the treatment of ACD requires an accurate severity assessment. In the post-operative setting, orthopaedic surgeons need to have a high index of suspicion for any dermatitis following the use of skin adhesives and treat immediately based on the severity of the dermatitis. In accordance with the International Contact Dermatitis Research Group classification, a mild reaction (1+ grade) has light erythema and is nonvesicular[16]. Mild reactions can be monitored for progression and consideration can be given to remove the Prineo™ dressing[17]. Conservative treatment entails dressing removal and oral antihistamines for pruritus. A moderate reaction (2+ grade) has edema, erythema, and discrete vesicles[16]. The removal of the Prineo™ dressing is necessary and the ACD is treated with topical steroids and oral antihistamines[17]. A severe reaction has coalescing vesiculobullous papules and is treated the same as a moderate reaction with the additional consideration of oral steroids[16,17]. The current guidance from the American Academy of Allergy, Asthma, and Immunology is to use 0.5 to 1 mg/kg daily oral steroids for 7 d when more than 20% of the body surface area is affected[16]. The selection of topical steroid potency is based on the location of the dermatitis, the lesion size, and the severity of the reaction[16]. In orthopaedic cases that do not involve flexural surfaces, mid to high potency topical steroids, such as triamcinolone 0.1% or clobetasol 0.05%, are appropriate[18]. Topical steroids application should be after hydration of the skin for optimal effectiveness[16]. In our cases, we did not use corticosteroids due to concerns with wound complications that have been previously reported with steroid use and postoperative incisions[19,20].

In a case report by Dunst *et al*[21], a 44-year-old woman who underwent reduction mammoplasty with Prineo™ wound closure presented 10 d postoperatively complaining of severe itching with an extensive skin reaction in the vicinity of the Prineo™ skin closure device. She was referred to dermatology and underwent allergy testing where a moderate positive allergic reaction to both components of the Prineo™ wound closure device was noted. The authors described a noticeable reduction in operating time in their use of Prineo™ in over 50 cases of excisional body contouring procedures with this case being the only instance of any dermatitis complication[21].

While there are some reports of Prineo™ reactions, there are several studies demonstrating the benefits of shorter operative times. Shippert[1] performed a randomized controlled trial showing decreased operative time, leading to decreased costs[1]. Another randomized study concluded that Prineo™ has significantly faster closure and increased post-operative patient comfort[8]. The low risk of adverse reaction to Prineo™ combined with the benefits of increased patient comfort and operative efficiency provide rationale for its continued use. In the current era with a focus on cost savings, Prineo™ can significantly decrease operative times leading to overall cost savings for hospital systems and surgical facilities. Any previous occurrence of allergic dermatitis following use of Dermabond™ or Prineo™, however, should prompt a thorough history and further use of Prineo™ should be carefully considered, if not completely avoided.

CONCLUSION

This case report elucidates the rare complication of allergic dermatitis following second exposure use of Prineo™. This case report also brings forth the first, to our knowledge, reported cases of such allergic dermatitis in response to Prineo™ within the pediatric population. With the increased use of Prineo™ as a wound closure alternative, surgeons should be aware of potential risks, especially in cases with previous exposure to Dermabond™ or Prineo™.

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CASE REPORT

Pathological humerus fracture due to anti-interferon-gamma autoantibodies: A case report

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Abstract

BACKGROUND

Various etiologies contribute to pathological fractures, including bone infections. Recently, non-tuberculosis *Mycobacterium*-related bone infections among patients with anti-interferon-gamma autoantibody-induced adult-onset immunodeficiency has raised concerns in Southeast Asia, with the common presentations including osteomyelitis. However, it also rarely manifests as traumatic fractures, as reported in this case.

CASE SUMMARY

A diabetic female fractured her humerus after a traumatic accident and received fixation surgery. Abnormal necrotic bone tissue and abscess formation were noted, and she was diagnosed with a pathological fracture due to non-tuberculosis *Mycobacterium* infection. Multiple bone involvement was also revealed in a bone scan. Anti-interferon-gamma autoantibodies were then checked due to an unexplained immunocompromised status and found to be positive. Her humerus fracture and multiple bone infections healed after steroid and anti-non-tuberculosis *Mycobacterium* medication treatment following fixation surgery.

CONCLUSION

Comprehensive preoperative evaluations may help identify pathological fractures and guide the treatment course.

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Core Tip: Identifying neutralizing anti-interferon-gamma autoantibody-related non-tuberculosis *Mycobacterium* bone infections requires careful history taking and physical examinations. While a biopsy of the bone lesion is the gold standard for diagnosis, it is advisable to check co-existing lymphadenopathy, dermatoses, and lung and blood-stream infections, as they provide easily accessible specimens for culturing and cytopathology. Serum tests of immune profiles are also important for atypical or opportunistic infections. These pre-operative evaluations may guide the choice of surgical modality, medical treatment that accompanies surgery, and decide the prognosis of healing.

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INTRODUCTION

Pathological fractures can be secondary to conditions ranging from metabolic diseases to tumors, infections, or neuromuscular pathologies. Unfortunately, those due to infections can be mistaken for malignant tumors[1]. Distinguishing between hematogenous osteomyelitis and bone tumors is difficult when there are no obvious clinical clues, and radiographic changes in osteomyelitis are often mistaken for tumors[2]. Herein, we present a diabetic female diagnosed with a humerus fracture after a traumatic injury. The purpose of this case report is to remind orthopedic surgeons not to overlook the possible diagnosis of a pathological fracture secondary to non-tuberculosis *Mycobacterium* (NTM) bone infections due to anti-interferon-gamma autoantibody (AIGA)-induced adult-onset immunodeficiency, a disease with increasing incidence in Southeast Asia in the recent decade, that can present as a traumatic fracture.

In this case, the AIGA presence itself was proposed to have occurred due to genetic susceptibility of human leukocyte antigen (HLA) genes[3] and through molecular mimicry, such as an epitope of interferon-gamma that mimics *Aspergillus* antigen (Noc-2 protein)[4], a known cause of this type of autoimmunity. The accumulation of environmental *Aspergillus* antigen exposure might gradually trigger an immune response, producing auto-antibody against human interferon-gamma and thereby resulting in opportunistic infections. Among these infections, NTM has prompted greater concern due to its being an important component of opportunistic infections. In this case report, we aimed to elucidate the NTM bone infection due to AIGA-induced adult-onset immunodeficiency that caused pathologic fracture which was overlooked as traumatic fracture.

CASE PRESENTATION

Chief complaints

A 69-year-old diabetic female presented with right upper arm pain with deformity.

History of present illness

The patient fell from her bed during the night and fractured her right humerus (Figure 1). She was then admitted for surgical fixation (Figure 2).

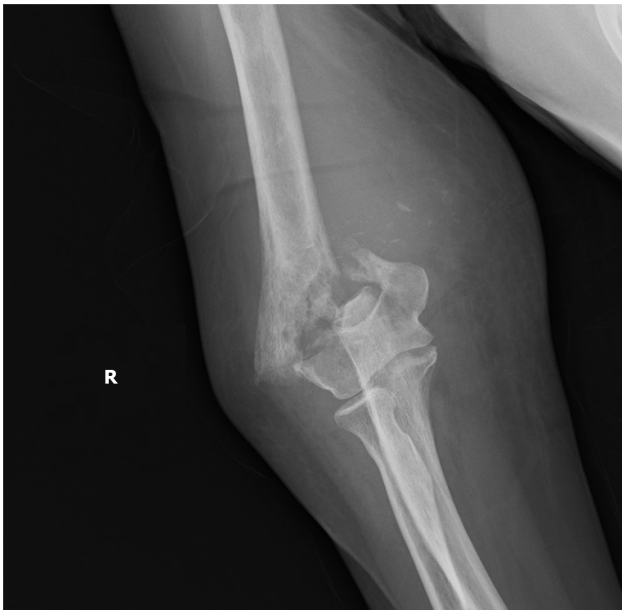


Figure 1 Displaced supracondylar humerus fracture of the right elbow on plain X-ray.



Figure 2 Displaced supracondylar humerus fracture status post-open reduction and internal fixation with screws and Kirschner wires.

History of past illness

The patient had diabetes mellitus type 2 with a hemoglobin A1c level of 5.8, under treatment with glipizide 1# twice daily.

Personal and family history

The patient had no hereditary malignancies or bone diseases and denied smoking cigarettes or drinking alcohol.

Physical examination

A painful right elbow deformity, tenderness, and limited range of motion were noted. After the fracture fixation surgery, the patient's family found a non-healing wound with abscess formation that had developed on her chest wall near the sternum. Bilateral axillary lymphadenopathy was also noted.

Laboratory examinations

Unlike an acute traumatic fracture, necrotic bone tissues were noted and sequestrated intraoperatively (Figure 3). The specimen consisted of more than 10 tissue fragments, measuring up to 1.9 cm × 1.2 cm × 0.5 cm. Representative sections were taken, showing bone and fibrosynovial tissue with necrosis, granulation tissue proliferation, and marked acute and chronic inflammatory cell infiltration. A malignancy-related pathological fracture was suspected. Sternum abscess excision and pathology revealed skin tissue with subcutaneous necrosis, fat necrosis, and dense acute and chronic inflammatory cell infiltration, without malignancy. *Mycobacterium intracellulare* was cultured *via* pus drainage. A lymph node excision biopsy was also performed, and the pathology revealed necrotizing granulation without malignancy. An immunosuppression status was suspected due to opportunistic infections. The patient had a normal lymphocyte subpopulation and tested negative for human immunodeficiency virus (HIV). Neutralizing (n)AIGAs were then considered. Serologically, high titers of AIGAs ($1:10^6$) were observed.

Imaging examinations

Plain X-ray revealed a displaced supracondylar humerus fracture of the right elbow (Figure 1). A bone scan revealed increased uptake over the skull, spine, bilateral pelvis, femur, tibia, tarsal bones, scapulae, clavicles, humeri, right forearm, sternum, and rib cage, indicating probable multiple metastases (Figure 4).

FINAL DIAGNOSIS

Disseminated (d)NTM infection with lymphadenopathy and multiple bone lesions causing a right humerus pathological fracture and sternum abscess formation. nAIGA-induced adult-onset immunodeficiency.

TREATMENT

The patient was treated with open reduction and internal fixation with cancellous screws and Kirschner wires (Figure 2) for the fracture. She was administered cortisone (4 mg) 1# orally twice daily for the autoantibodies, and rifampicin, ethambutol, and clarithromycin for the dNTM infection.

OUTCOME AND FOLLOW-UP

After a 1-mo treatment course, a physical examination showed that the humerus fracture had healed, and the sternum infection had also gradually healed along with the other infected bones. The patient will continue to receive regular treatment during future outpatient visits.

DISCUSSION

Etiologies of pathological fractures include bone infection, malignancy, endocrinopathy, osteomalacia, drug-related, rheumatological diseases, and inflammatory bowel disease[5]. While the underlying mechanism of a pathological fracture is important, as a general rule a pathological fracture is caused by minor trauma that typically would not cause the type of fracture observed. In bone infection-induced pathological fractures, the infection must be treated first, and the fractures can only heal once a favorable metabolic environment has been restored[1].

Various pathogens can cause bone infections, among which NTM is a rare but noteworthy cause, as is the present case. The incidence of NTM infection has increased in recent years, likely due to advances in diagnostic technology. In addition, the rate of dNTM infection in HIV carriers has fallen from 16% in 1996 to less than 1% today due to the introduction of effective anti-viral therapy for HIV and macrolide prophylaxis [6]. The cause of other non-HIV-related immunocompromising conditions in patients with dNTM infection is thus of concern, most notably nAIGA-induced adult-onset immunodeficiency. nAIGAs are detected in 88% of Asian adults with multiple

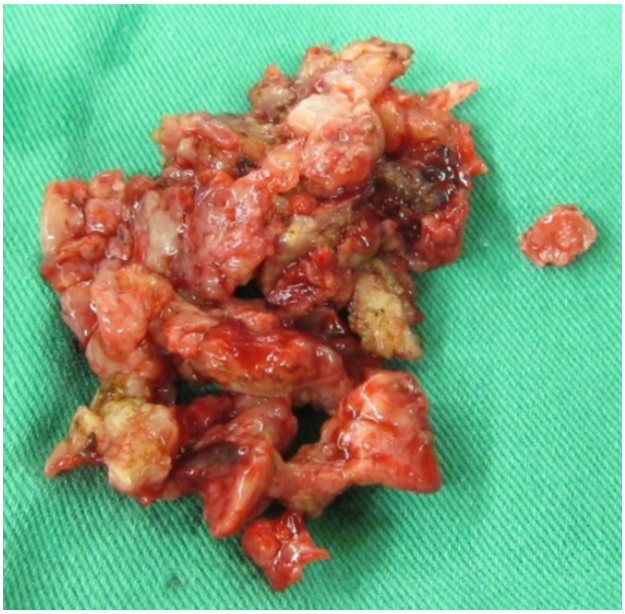


Figure 3 Intraoperative finding of unusual necrotic bone tissues, status post-sequestrectomy.

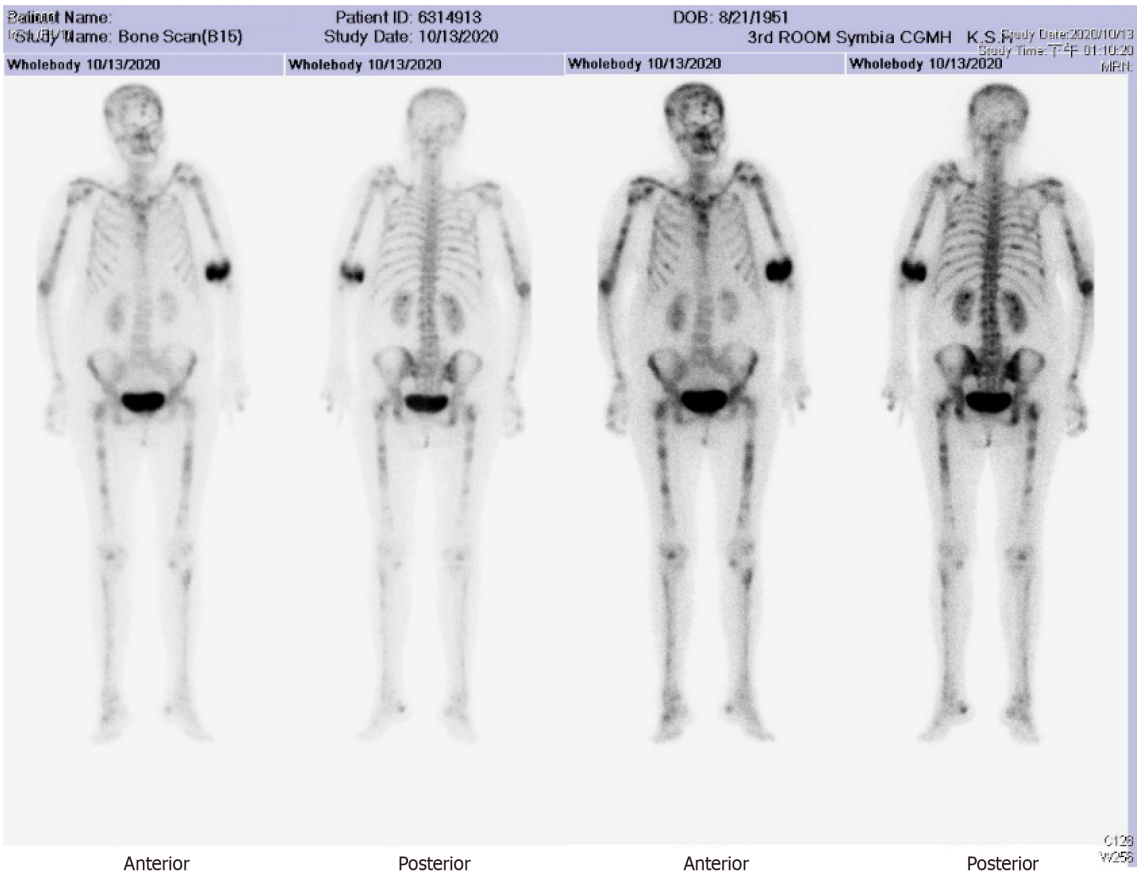


Figure 4 Bone scan revealed multiple uptake.

opportunistic infections without HIV infection[7]. nAIGA-induced adult-onset immunodeficiency is an autoimmune disease associated with HLA-DQB1/DRB1 and depleted interferon-gamma/interleukin 12-mediated cellular immunity, with increased susceptibility to opportunistic NTM infections frequently involving the lungs, lymphadenopathy, cutaneous, and the musculoskeletal system, as in our case.

However, an acute and accurate diagnosis of musculoskeletal NTM infection is often difficult because of the indolent clinical course and difficulty in isolating

pathogens[8]. A recent prospective case-control study in Taiwan[9] reported an average 1.6 year delay in the diagnosis of nAIGA-related dNTM due to protean manifestations mimicking other systemic illnesses, including mycobacterial tuberculosis, malignancy, and connective tissue diseases. Multivariate analysis revealed that slow-growing NTM species (*i.e., Mycobacterium intracellulare*) in nAIGA cases were associated with multiple bone involvement. These findings are comparable with our case. Osteomyelitis and bone marrow infections have also been associated with bone manifestations of dNTM in nAIGA patients in previous studies. In contrast, a pathological fracture was the initial presentation in our case. It is important to note that NTM osteomyelitis often arises from previous trauma or surgical sites among patients with weak immunity and dNTM infection, and osteomyelitis is also considered to be a presentation of immune reconstruction inflammatory syndrome[8].

Our case also impressed as a traumatic fracture initially according to the patient's injury history but was later found to have an NTM bone infection-related pathological fracture mimicking metastatic malignancy. Interestingly, in addition to granulomatous disease-induced bone loss, nAIGA can also induce an increase in osteoclast formation and bone resorption *via* RANKL-induced activation of the NF-kB pathway, thereby worsening NTM infection-induced bone erosion[10]. We therefore suggest that nAIGA should be considered an independent risk factor for pathological fractures.

As relatively few reports on NTM-related pathological fractures are available, our case provides valuable insight into the comparison with malignancy-related pathological fractures. Risk factors associated with the prognosis of malignancy-related pathological fractures include primary cancer type, spinal involvement, Eastern Cooperative Oncology Group status, and whether the patient received chemotherapy/radiotherapy. The median survival is 4.1 mo. Surgical treatment for pathological fractures includes intramedullary nails, plate fixation, and arthroplasty.

A retrospective cohort study[11] found that fracture site, method of fixation, and use of cement augmentation did not have a statistically significant impact on survival post-fracture. Another case-control study[12] found that cement fixation, in addition to open reduction and internal fixation, could result in immediate stabilization and thus better pain control without impairing the range of motion. In our case, the orthopedic doctor discussed the risks and benefits of different treatment methods with the patient. She chose to receive open reduction and internal fixation and subsequently underwent cancellous screw with Kirschner wire fixation for the humerus fracture. However, if we had noticed her sternum abscess lesion prior to surgery, we may have chosen a more intense fixation method under the suspicion/evidence of a pathological fracture. A more complete physical examination with preoperative planning may be helpful in such cases. In addition, further studies are warranted to investigate the preferred method of surgery, prognostic factors, and median survival of bone infection (such as NTM)-related fractures.

CONCLUSION

As T lymphocyte dysfunction predisposes patients to dNTM infection, we advise screening for nAIGA in HIV-negative Asian patients with NTM bone infection-related pathological fractures, especially when combined with other unexplained opportunistic infection history such as zoster, salmonellosis, histoplasmosis, and aspergillosis[7]. The histopathologic features of NTM bone infection show a spectrum of inflammatory changes, including granulomatous lesions with or without caseation [13]. With regards to treatment, it is necessary to differentiate nAIGA-related dNTM bone disease from Pott's disease, monoclonal gammopathies, and other malignancies sharing similar features. Efficacy and drug resistance should be carefully evaluated for long-term anti-NTM treatment, and it is important that this is accompanied by surgical debridement and fracture treatment[8].

The immunosuppressants used for nAIGA include corticosteroids and cyclophosphamide, while rituximab has also been reported to be effective[7,14]. nAIGA titers have been reported to decrease over time even without immunosuppressive treatment. However, rates of chronic opportunistic infections and death remain high[10]. Screening for nAIGA in dNTM-related pathological fractures is recommended to allow for appropriate treatment, thereby decreasing morbidity. A careful preoperative survey is important in potential pathological fracture cases.

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CASE REPORT

Spontaneous pneumothorax in a 17-year-old male patient with multiple exostoses: A case report and review of the literature

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Author contributions: Shimamoto A and Kaneda S were the patient's surgeons; Nakamura K and Asanuma K wrote the manuscript; Nakamura K collected the previous reports; and All authors were involved in revising the first draft and approved the final version of the manuscript.

Informed consent statement: Written informed consent was obtained from the patient and his parent.

Conflict-of-interest statement: The authors declare that they have no conflict of interest.

CARE Checklist (2016) statement: The authors have read the CARE Checklist (2016), and the manuscript was prepared and revised according to the CARE Checklist (2016).

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Abstract

BACKGROUND

Multiple exostoses generally develop in the first decade of life. They most frequently arise from the distal femur, proximal tibia, fibula, and proximal humerus. Costal exostoses are rare, contributing to 1%–2% of all exostoses in hereditary multiple exostoses (HME). They are usually asymptomatic, but a few cases have resulted in severe thoracic injuries. Pneumothorax caused by costal exostoses is rare, with only 13 previously reported cases. We report a new case of pneumothorax caused by costal exostoses.

CASE SUMMARY

A 17-year-old male with HME underwent surgery for removal of exostoses around his right knee. Four months following the operation, he felt chest pain when he was playing the trumpet; however, he did not stop playing for a week. He was referred to our hospital with a chief complaint of chest pain. The computed tomography (CT) scan revealed right pneumothorax and multiple exostoses in his right ribs. The CT scan also revealed visceral pleura thickness and damaged lung tissues facing the exostosis of the seventh rib. We diagnosed that exostosis of the seventh rib induced pneumothorax. Costal exostosis resection was performed by video-assisted thoracoscopic surgery (VATS) 2 wk after the onset. The patient's postoperative course was uneventful, and there was no recurrence of pneumothorax for 2 years.

CONCLUSION

Costal exostoses causing thoracic injuries should be resected regardless of age. VATS must be considered in cases with apparently benign and relatively small

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exostoses or HME.

Key Words: Costal exostosis; Pneumothorax; Video-assisted thoracoscopic surgery; Hereditary multiple exostoses; Case report; Treatment

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Core Tip: We report a case of pneumothorax caused by costal exostoses in a patient with hereditary multiple exostoses (HME). The computed tomography scan revealed exostoses and clarified the relationship between exostoses and the surrounding structures, which enabled us to identify the cause of the pneumothorax. Costal exostoses causing thoracic injuries should be removed regardless of age; thoracic complications are serious, and there is no apparent correlation between age at the time of operation and recurrence of thoracic complications after surgery. The application of video-assisted thoracoscopic surgery (VATS) is worthy of consideration for patients with apparently benign and relatively small exostoses or patients with HME as redo VATS may be easily offered.

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INTRODUCTION

Multiple exostoses generally develop in the first decade of life and stop growing with skeletal maturity[1]. Exostoses most frequently arise from the distal femur, proximal tibia, fibula, and proximal humerus[2]. Exostoses of the ribs are rare, contributing to approximately 1%–2% of all exostoses in hereditary multiple exostoses (HME)[2,3]. Exostosis can transform into chondrosarcoma in up to 10% of patients with HME[4]. A differential diagnosis is Ewing sarcoma, which is more common among children[5]. Suggestive malignant costal bone tumor and worsening visible deformity are operative indications.

Costal exostoses are usually asymptomatic; however, in a few cases, they can induce specific yet severe symptoms due to the nature of the ribs. Costal exostoses have been reported to cause hemothorax, pneumothorax, pericardial injuries, diaphragmatic injuries, and visceral pleural injuries[6-9]. Surgical treatment was performed in many of these cases.

To the best of our knowledge, only 13 cases of pneumothorax caused by costal exostoses have been reported to date. Here, we report a new case of pneumothorax caused by costal exostoses that was successfully treated by video-assisted thoracoscopic surgery (VATS).

CASE PRESENTATION

Chief complaints

A 17-year-old male with HME was referred to Mie University Hospital with a chief complaint of consistent chest pain.

History of present illness

The patient felt chest pain when he was playing the trumpet; however, he did not stop playing for a week.

History of past illness

The patient was diagnosed with HME at the age of 6 years and had undergone surgery

for removal of exostoses around his right knee 4 mo before chest pain.

Personal and family history

The patient had multiple bony protrusions in the bilateral humerus, scapula, clavicle, fibula, tibia, femur, and ilium. The patient's father had bony protrusion around his knees, but his family members did not undergo a full body skeletal imaging.

Physical examination

The patient's temperature was 36.8°C, heart rate was 95 bpm, respiratory rate was 16 breaths per minute, blood pressure was 147/79 mmHg, and oxygen saturation in room air was 96%. There was no subcutaneous swelling, coughing, or sputum.

Laboratory examinations

Laboratory examinations were normal.

Imaging examinations

Chest X-ray showed right-sided pneumothorax (Figure 1A). Computed tomography (CT) scan confirmed the presence of a pneumothorax (Figure 1B) and revealed four exostoses in his right ribs and one exostosis in his left rib (Figure 2). Exostoses arising from the right first and seventh ribs were protruded into the thoracic cavity; in particular, the exostosis from the right seventh rib was sharp and directly in contact with the visceral pleura. CT scan also revealed thickness of the visceral pleura and damaged lung tissues facing the exostosis of the right seventh rib (Figure 3).

MULTIDISCIPLINARY EXPERT CONSULTATION

Akira Shimamoto, MD, PhD, Associate Professor, Department of Thoracic and Cardiovascular Surgery, Mie University Graduate School of Medicine; Shinji Kaneda, MD, PhD, Assistant Professor, Mie University Graduate School of Medicine; and Motoshi Takao, MD, PhD, Professor, Department of Thoracic and Cardiovascular Surgery, Mie University Graduate School of Medicine.

FINAL DIAGNOSIS

Pneumothorax caused by the exostosis of the seventh rib.

TREATMENT

A chest tube was not inserted because the sharp margin of the exostosis would have scratched the re-expanded lung again. Since the exostosis of the right seventh rib could potentially cause the recurrence of the thoracic complications, we decided to remove the costal exostosis.

Resection of costal exostosis was performed by VATS 2 wk after the onset of symptoms. After induction of anesthesia, the patient was positioned in the left lateral decubitus position. The first incision was made in the midaxillary line of the right eighth intercostal space to insert the 5.5 mm thoracoport. A 5 mm camera was then inserted through the thoracoport, which revealed the bony protrusion of the right seventh rib; the protrusion was a bone mass measuring 5 mm in length on the midaxillary line directed toward the intrathoracic cavity (Figure 4). The second port was placed in the anterior axially line of the right seventh intercostal space to operate the forceps. Thoracoscopic observation revealed that the exostosis of the right seventh rib had sharp margins and the parietal pleura was lacerated; it was the apparent cause of injuries in the visceral pleura. The bony spur of the right seventh rib was removed using forceps and the arthroscopic burr was used to scrape down the spinous lesion. Other spurs were not treated because their edges were dull, and parietal pleura on the spurs was not peeled off. Mechanical pleurodesis was accomplished by abrasing the damaged visceral pleura using electrocautery. A 20 F chest tube was placed in the apex of the thoracic cavity.

Pathological examination revealed that the resected specimen was histologically composed of mature bone, hyaline cartilage, and fibrocartilage with no sign of

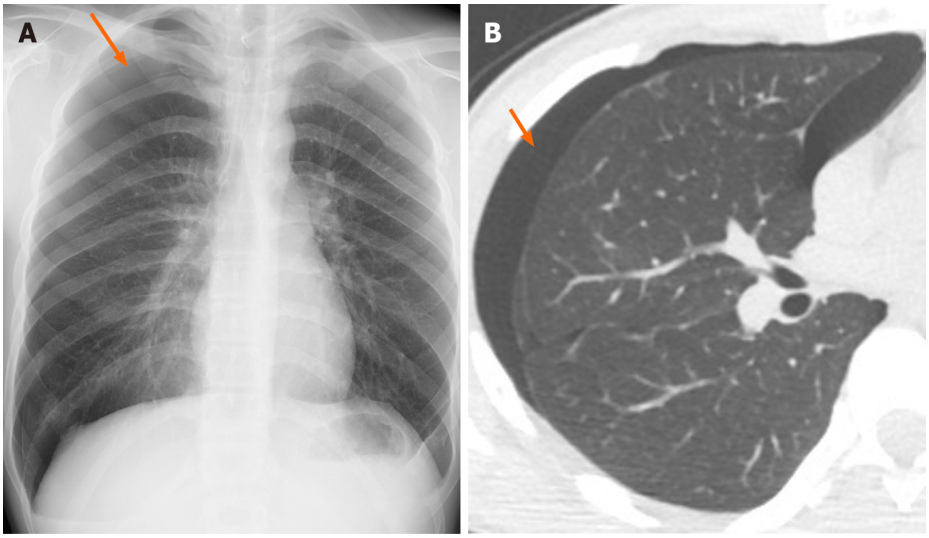


Figure 1 Chest X-ray and computed tomography scan revealed right-sided pneumothorax. A: Chest X ray in anterior-posterior view; B: Computed tomography scan in axial plane.

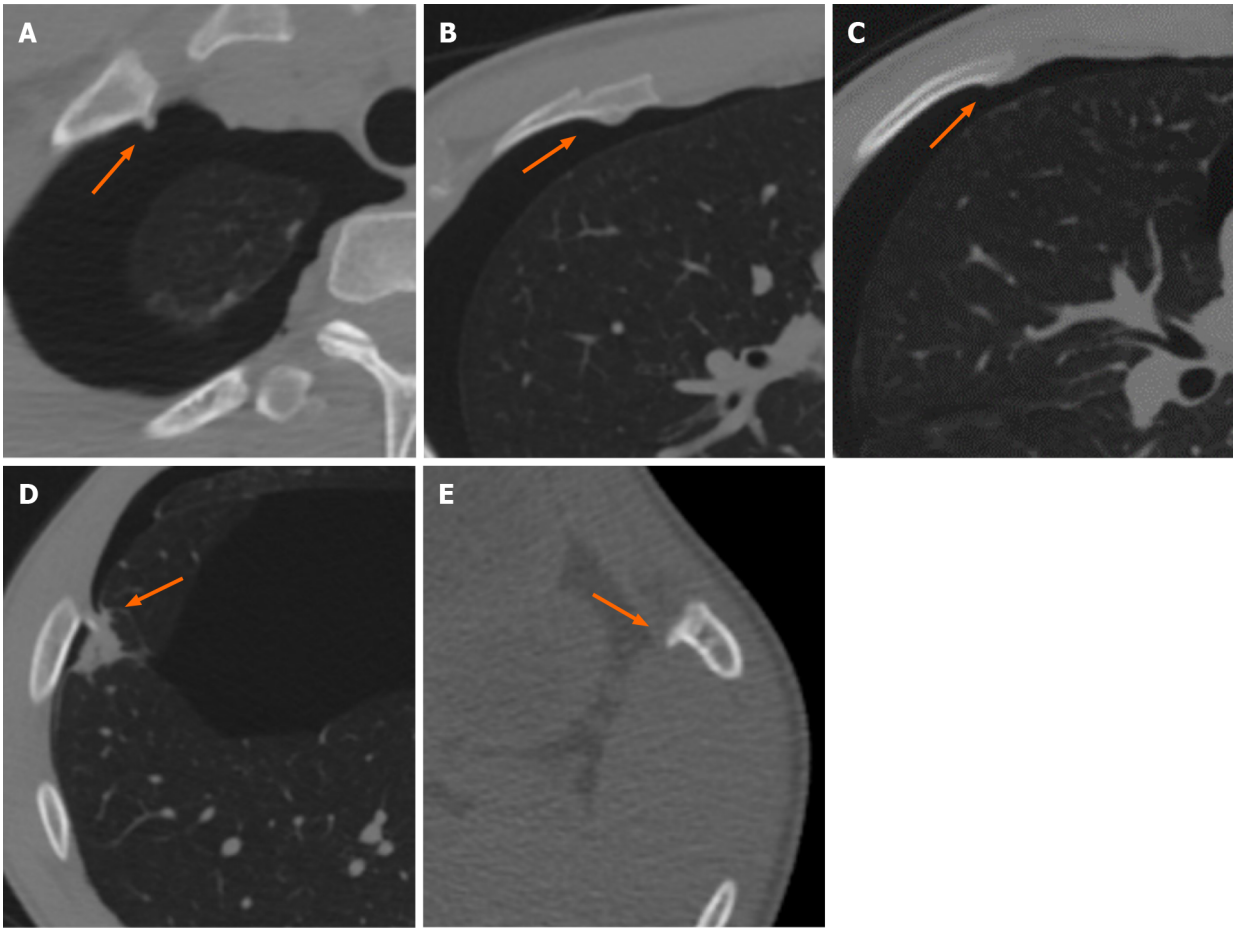


Figure 2 Computed tomography scan shows exostoses of five ribs. The right first and seventh ribs were sharp and protruded into the thoracic cavity. A: Rt. (right) first rib; B: Rt. third rib; C: Rt. fourth rib; D: Rt. seventh; E: Left ninth rib. Rt.: Right.

malignant transformation (Figure 5). These findings confirmed the diagnosis of exostosis.

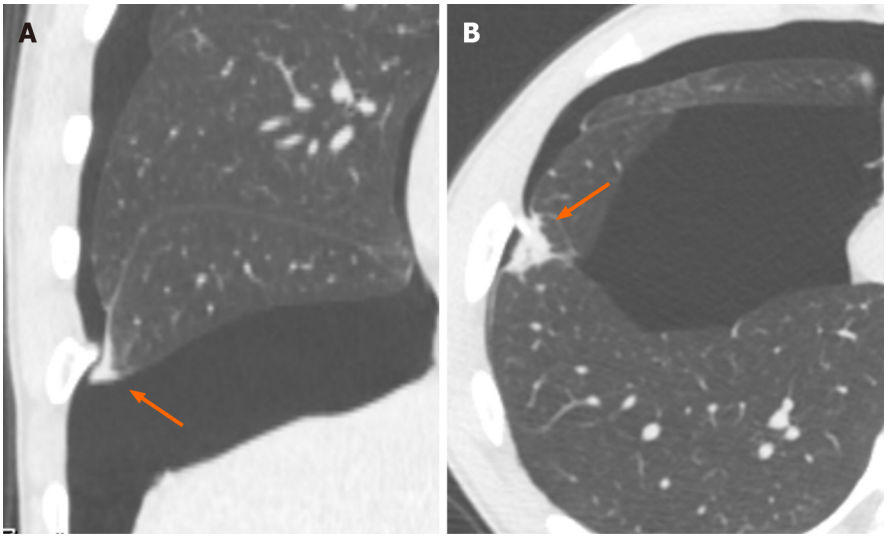


Figure 3 Damaged pleura and lung tissues confronted with the exostosis of the right seventh rib. A: Coronal plane, thickness of visceral pleura; B: Axial plane, damaged lung tissues.

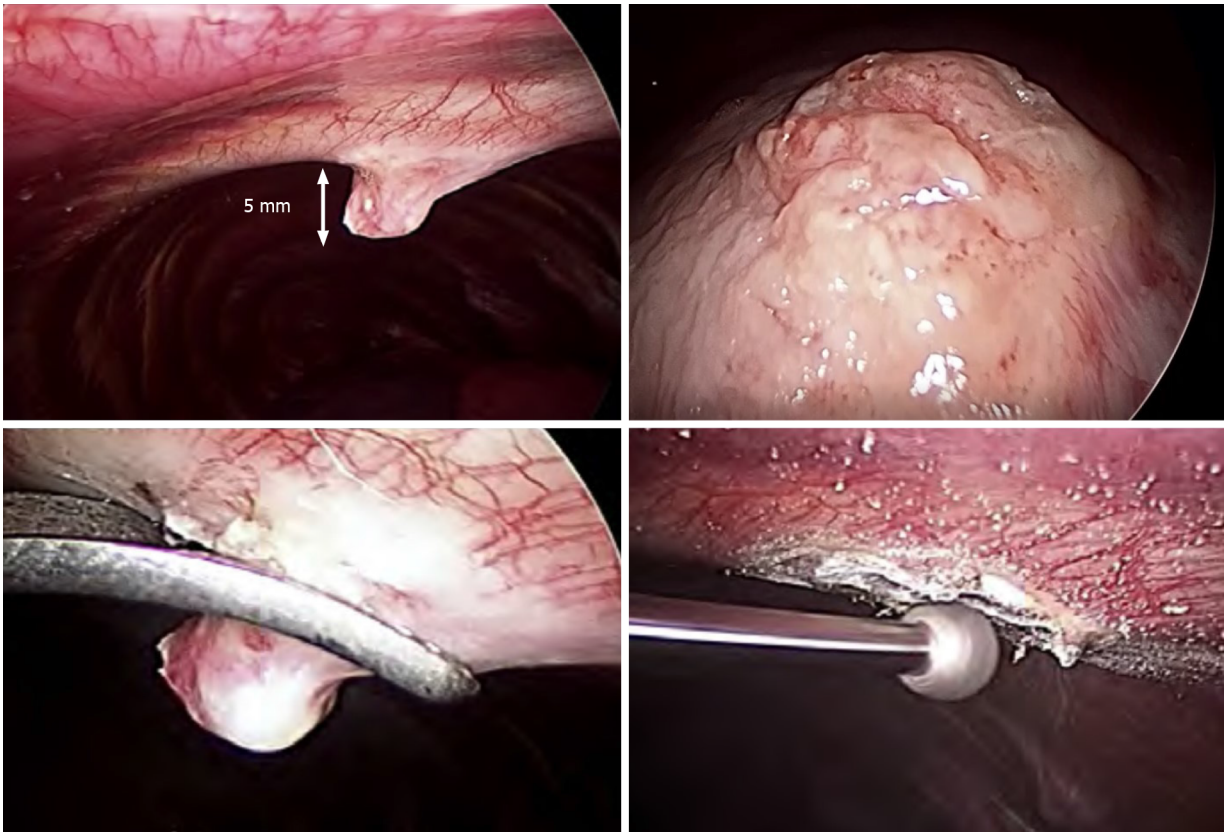


Figure 4 Intraoperative findings and treatment. The bony spur was removed using forceps. The spinous lesion of the rib surface was scraped down by arthroscopic burr.

OUTCOME AND FOLLOW-UP

The patient's postoperative course was uneventful, and there was no recurrence of pneumothorax during 2 years of follow-up.

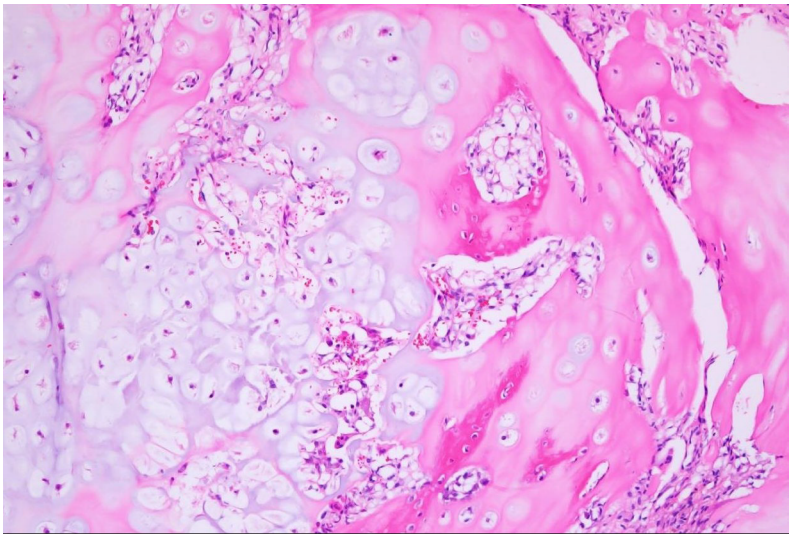


Figure 5 Pathological findings (hematoxylin and eosin stain, ×200). The resected specimen was histologically composed of mature bone, hyaline cartilage, and fibrocartilage with no sign of malignant transformation.

DISCUSSION

Most cases of costal exostoses are asymptomatic; therefore, thoracic complications caused by costal exostoses are rare[7,10,11]. Resection of costal exostoses has been reported for at least 87 cases, whereas hemothorax caused by costal exostoses has been reported in 38 cases. Pneumothorax caused by costal exostoses has only been reported in 13 cases. The details of which are presented in Table 1.

During review of literature, we found that tumor size was ≥ 1 cm in cases of pneumothorax or hemothorax caused by costal exostoses[3,6,12]. In our case, the maximum tumor size was 5 mm, which was smaller than that reported in previous case reports describing the thoracic complications caused by costal exostoses.

Significant traumatic events prior to symptom onset were not described in most of the case reports. However, a few patients with HME had a history of athletic activity and labor prior to pneumothorax[3,13]. In our case, pneumothorax might have been caused by a synergetic effect of the respiratory motion while playing the trumpet and the sharpness of the bony spur. In our case, costal exostoses were too small to be identified with chest X-ray; however, a CT scan revealed the presence of costal exostoses. Thus, a patient with HME who presents with an acute onset of symptoms in the chest should be assessed for pneumothorax and should undergo CT scanning to determine the cause of the symptoms in the chest.

Among the 13 previously reported cases, pneumothorax was treated with supportive care in the form of rest, wait, and see in seven cases; chest drainage in five cases; and unknown in one case.

In general, asymptomatic costal exostoses are not treated prophylactically[14]. Surgical management of costal exostoses is done for symptom control, establishing a histological diagnosis, and prevention of thoracic complications[4]. Among the cases reviewed by us, including our case, 13 cases required surgical treatment for costal exostoses.

Among all cases of pneumothorax, including ours, 10 cases occurred in patients under the age of 18 years. Of these, nine underwent surgery. Furthermore, the review of literature revealed that costal exostoses were actively resected in cases of thoracic complications caused by exostoses, even if prior to adolescence[4,15]. Thoracic complications caused by costal exostoses are serious. Therefore, similar to our case, regardless of age, risk aversion of thoracic injuries was considered more important than the risk of reoperation in previous case reports.

Compared to major thoracotomy, VATS has become an increasingly popular method for treating the intrathoracic lesions because it is a minimally invasive procedure[3]. VATS appears to be the best option for surgical resection of exostoses to prevent thoracic complications in cases of apparently benign exostoses[15,16]. In addition, VATS may be easily offered in cases of HME because redo VATS is less invasive[15]. The application of VATS for the removal of suggestive malignant exostoses has not been fully discussed; however, small tissue fragments may spread

Table 1 Review of the pneumothoraxes caused by costal exostoses

No	Ref.	Year	Age	Exostosis location	Tumor size	Primary treatment	Treatment		Outcome
1	[26]	1952	27	Lt. 8th rib	2-5 cm	Rest	Thoracotomy	Wide resection of the rib. Rubbed over talc to the pleura	Recurrence
2	[27]	1991	21	Rt. 6,7th ribs	N/A	Rest	Thoracotomy	Wide resection of the ribs. Suturing of lung and pleura	Good
3	[3]	2010	17	Lt. 5th rib	2.8 cm	Rest	VATS	Bony spur resection. Scraped down the surface	Good
4	[31]	2011	15	Lt. rib	3 cm	Rest	Observation		Good
5	[28]	2012	30	Rt. 4th rib	1.3 cm	Rest	VATS and Thoracotomy	Wide resection of the rib. Wedged resection of the lobe. Reconstruction with metal plate	Good
6	[32]	2013	12	Lt. 4th rib	N/A	Drainage	VATS	Bony spur resection	Good
7				Rt. rib	N/A	Drainage	VATS	Bony spur resection	
8	[23]	2013	12	Rt. 5th rib	2.5 cm	Drainage	VATS	Bony spur resection	Good
9	[4]	2014	15	Lt. 3rd rib	N/A	N/A	Thoracotomy	Bony spur resection	Good
10	[24]	2014	16	Rt. 7,8th rib	N/A	Drainage	VATS	Bony spur resection	Good
11	[29]	2017	13	Lt. 5th rib	N/A	Drainage	VATS	Bony spur resection. Wedged resection of the lobe	Good
12	[25]	2018	32	Lt. 4,5th rib	N/A	Rest	VATS	Bony spur resections	Good
13	[13]	2020	15	Lt. 6th rib	4 cm	Rest	VATS	Bony spur resection. Diathermic coagulation of the pleura	Good
14	Our case	2021	17	Rt. 7th rib	5 mm	Rest	VATS	Bony spur resection. Scraped down the surface	Good

Lt.: Left; Rt.: Right; N/A: Not available; VATS: Video-assisted thoracoscopic surgery.

accidentally into the pleural cavity[15].

Thoracotomy is mainly done in cases of extensive rib resection. Thoracotomy enables surgeons to cope with active bleeding from the diaphragm[6] and bowel obstruction caused by the diaphragmatic ruptures[17] or malignant tumors[4]. Extensive rib resections or relatively large tumor resections are often performed with thoracotomy only or by mini-thoracotomy using thoracoscopic-guidance[18]. Among the cases reviewed by us, five had a tumor measuring ≥ 5 cm, and four were treated by thoracotomy[16,19-22] and one with VATS[20]. However, it seems that there is no correlation between age at the time of operation and operative approach[15].

Of the 14 cases of pneumothorax caused by costal exostoses, including ours, nine were treated with VATS[3,23-25], three with thoracotomy[4,26,27], one with a combination of VATS and mini-thoracotomy, and one with observation (Table 1). Of the 12 previously reported cases of pneumothorax since 2000, 10 were treated with VATS (83.3%).

Most case reports did not describe their method of resection in detail; however, in general, forceps or a rongeur was used. After bone spur resection, an arthroscopic burr was used to scrape down the spinous lesion in only one previous case and our case[9]. In our case, forceps in combination with an arthroscopic burr enabled us to treat costal exostosis by complete VATS.

Furthermore, review of literature revealed that the damaged lung tissues were treated by wedge resection of the lobe[28,29]. Mechanical pleurodesis was accomplished by abrasing the pleura with an electrocautery scratch pad[13,28]. A partial rib defect was reconstructed with a metal plate to stabilize the anterior chest wall[28]. In a 2-year-old girl, a Gore-Tex sheet was used to cover a 12 cm × 6 cm defect of the chest wall caused by rib resection[30].

Morphology of sharp tip of the exostosis and laceration of the parietal pleura are suggestive of the potential risk of lung injuries. The location of the costal exostosis is associated with lung injuries because the respiratory motion of the lower lobe is greater than that of the middle and upper lobe[24]. In our case, exostosis of the right seventh rib was removed due to the risk of re-injury of the lung. In contrast, other costal exostoses were not removed because their tips were dull, and no parietal pleura

laceration was found. The spurs of the right first, third, and fourth ribs were not confronted with the lower lobe. Moreover, their spurs were less likely to grow further and re-injure the lung due to the completion of bone maturity.

The outcomes of surgical management of the costal exostoses were favorable in most of the cases with no significant complications, except for in two cases; pneumothorax recurred in one case reported more than a half century ago[26], and thoracic pain did not disappear for 2 years after surgery due to intercostal nerve damage in another case[15]. It appears that there is no correlation between age at the time of operation and recurrence of pneumothorax after surgery. In our case, VATS was successful and the post-operative course was uneventful; this was also observed in previous reports.

The present case has the following limitation: Postoperative follow-up period was short (2 years), and treatment experience was compared between different institutions and different times. It is necessary to investigate long-term results after the surgery.

CONCLUSION

We reported our experience of pneumothorax caused by costal exostoses because it is extremely rare. Damaged lung tissues due to costal exostoses should be suspected in HME patients with symptoms in the chest. CT scan was useful in diagnosing thoracic damage caused by costal exostoses. Costal exostoses causing thoracic injuries should be removed regardless of age; thoracic complications are serious, and there is no apparent correlation between age at the time of operation and recurrence of thoracic complications after surgery. VATS enabled us to resect the costal exostoses using a less invasive approach. VATS is worthy of consideration in patients with apparently benign and relatively small exostoses or patients with HME because redo VATS may be easily offered.

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CASE REPORT

Management of acute length-unstable Monteggia fractures in children: A case report

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Abstract

BACKGROUND

Monteggia fractures are uncommon injuries in paediatric age. Treatment algorithms assert that length-unstable fractures are treated with plate fixation. In this case report, intramedullary fixation of an acute length-unstable Monteggia fracture allowed a stable reduction to be achieved, along with an appropriate ulnar length and alignment as well as radio capitellar reduction despite the fact that the orthopaedic surgeon did not use a plate for the ulnar fracture. The scope of treatment is to avoid the use of a plate that causes periosteal stripping and blood circulation disruption around the fracture.

CASE SUMMARY

A four-year-old girl presented at the Emergency Department following an accidental fall off a chair onto the right forearm. The X-ray highlighted a length-unstable acute Bado type 1 Monteggia fracture of the right forearm. On the same day, the patient underwent surgical treatment of the Monteggia fracture. The surgeon preferred not to use a plate to avoid a delay in fracture healing and to allow the micromotion necessary for callus formation. The operation comprised percutaneous fixation with an elastic intramedullary K-wire of the ulnar fracture and, subsequently, humeroradial joint reduction through manual manipulation.

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The orthopaedic surgeon assessed the stability of the radial head reduction under fluoroscopic control through flexion, extension, pronation and supination of the forearm. Healing of the fracture occurred within six weeks after surgery, as indicated by the presence of calluses on at least three cortices on standard radiographs. Dislocation/subluxation or loss of ulnar reduction was not apparent at the final X-ray examination.

CONCLUSION

Intramedullary fixation of unstable Monteggia fractures results in excellent outcomes, provides reliable reduction and causes fewer complications.

Key Words: Monteggia fractures; Children; Management; Outcome; Case report

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Core Tip: Treatment algorithms assert that acute length-stable Monteggia fractures are treated with an intramedullary device, while acute length-unstable fractures are treated with plates. Intramedullary devices have the advantage of smaller skin incisions, less soft tissue disruption, shorter operative times and easier device removal. Plates allow more anatomical restoration of the ulnar fracture and the radial bow, although they can cause delayed union due to blood circulation disruption around the fracture. Intramedullary wires can be used for the treatment of acute length-unstable Monteggia fractures instead of plates as these are associated with excellent results and fewer complications.

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INTRODUCTION

Monteggia fractures are uncommon injuries in paediatric age. In the nineteenth century, an Italian surgeon named Giovanni Monteggia described a traumatic injury involving a fracture of the proximal ulna with an associated dislocation of the radial head and disruption of the radioulnar joint[1]. Subsequently, these fractures were classified by Bado[2] into four types according to the direction of dislocation of the radial head.

The mechanism of injury is caused by direct trauma and hyperpronation as well as hyperextension[3]. The occurrence of paediatric Monteggia fractures covers between 1. Of 5% and 3% of all childhood elbow injuries[3,4]. Monteggia fractures remain a challenge for paediatric orthopaedic surgeons because of the difficulty involved in diagnosis and in the treatment of missed radial head dislocation and late instability. The aim of treatment is to achieve stable reduction of the ulnar fracture and radial head dislocation. Nowadays, the surgical treatment modalities available for these acute fractures include plates, intramedullary Kirschnerwires or elastic stable intramedullary nailing and, more recently, external fixation devices[5]. Although plates and intramedullary devices have comparable outcomes and complications, nailing or K-wires have the advantage of smaller skin incisions, less soft tissue disruption, shorter operative times and easier device removal. Furthermore, intramedullary wire fixations, due to their lack of rigidity, allow micromotion and callus formation[5]. Mechanical properties of intramedullary wires are based on a three-point fixation of the inner cortex and on a spread of the interosseous membrane [5]. Nowadays, there is no consensus regarding the preferred nail diameter, although, in the literature, authors suggest that the diameter of the wire should be approximately two-thirds of the medullary canal, measured atthe isthmus level[6]. Intramedullary devices may cause skin irritation, refractures, malunion, secondary displacement and nerve injury. The use of plates is associated with a more anatomical

restoration of the ulnar fracture and the radial bow, and a more rigid fixation, which requires reduced post-operative immobilization[6]. Despite this, open reduction and plate fixation cause periosteal stripping and blood circulation disruption around the fracture, resulting in a greater likelihood of delayed union or more rarely non-union [6].

The aim of this case report was to assess the efficacy of intramedullary wires for the treatment of acute length-unstable Monteggia fractures instead of plate fixation and to review the literature.

CASE PRESENTATION

Chief complaints

A four-year-old right-hand-dominant girl presented at the Emergency Department of our hospital following an accidental fall off a chair onto the right forearm. The mother reported a direct trauma to the floor of the right forearm with hyperextension and hyperpronation.

History of present illness

Post-trauma, the child reported pain in the right forearm along with inability to bend the elbow.

History of past illness

The patient had a free previous surgical history.

Physical examination

The child had forearm deformities with swelling and local tenderness around the elbow. Furthermore, active and passive motion of the elbow was impossible and accompanied by pain.

Imaging examinations

The X-rays appeared to show a fracture of the proximal ulna with an associated anterior dislocation of the radial head of the right elbow (Figure 1). The ulnar injury consisted of a long oblique fracture with a line measuring more than twice the cortical diameter. Radial head dislocation may be diagnosed when the radiocapitellar line, drawn through the axis of the radial neck on a lateral radiograph, regardless of the degree of flexion or extension of the elbow, crosses the humeral capitellum anterior to this normal position.

FINAL DIAGNOSIS

The X-ray highlighted a length-unstable acute Bado type1 Monteggia fracture of the right forearm.

TREATMENT

On the same day, the patient underwent surgical treatment of the Monteggia fracture. The surgeon preferred not to use a plate to avoid a delay in fracture healing and to allow the micromotion necessary for callus formation. The operation comprised percutaneous fixation with an elastic intramedullary K-wire of the ulnar fracture and, subsequently, humeroradial joint reduction through a combination of longitudinal traction and manual manipulation. The wire was inserted through the tip of the olecranon and advanced across the fracture site after a reduction is obtained. The reduction of the radial head may be considered stable under fluoroscopic control if the intramedullary fixation of the ulnar fracture maintains its reduced position through flexion, extension, pronation and supination. Alignment of the ulnar injury by K-wire had simultaneously reduced and stabilized the radial head dislocation. No other K-wire was used to maintain the reduction of the radial head. The K-wire can be bent and cut outside the skin to facilitate easy removal. A long arm cast was applied at the end of the operation with the elbow at 90° of flexion and the forearm in supination. Adequate analgesia was provided after surgery, the affected limb was elevated,

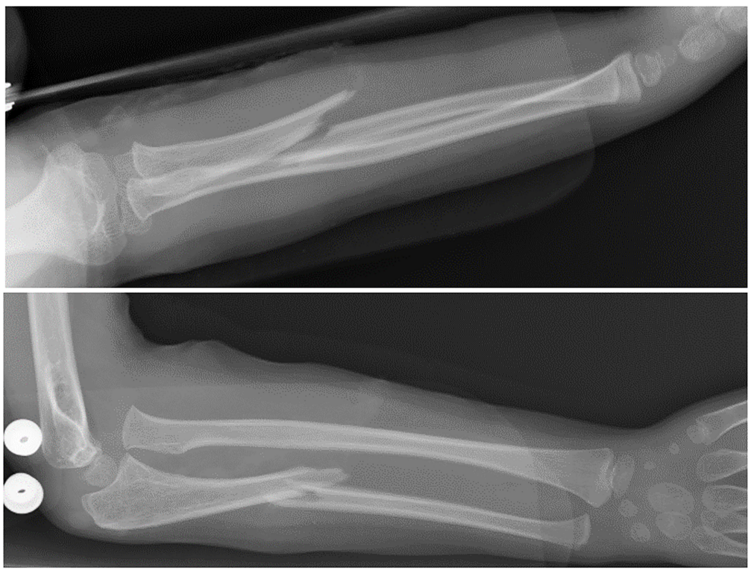


Figure 1 Plain X-ray taken at the time of injury revealing a fracture of the proximal third of the ulna andanterior dislocation of the radial head.

cryotherapy applied and circulation of the fingers monitored. The girl's parents were taught how to manage post-operative swelling and pain over the following days. Cast immobilization was used after the surgical treatment until there was radiographic evidence of fracture union.

OUTCOME AND FOLLOW-UP

At the first (5 d) and second (10 d) follow-up, control two-plane radiographs were obtained to assess any possible loss of articular contact between the proximal radius and humeral capitellum and loss of ulnar reduction (> 10 degree increase in the ulnar angle). Healing of the fracture occurred within six weeks after surgery. In children, although the fracture may still be visible at six weeks, adequate healing is represented by a callus on at least three cortices on standard radiographs (Figure 2). At the last follow-up (6 wk), the cast and the intramedullary wire were removed. Dislocation /subluxation, defined as a loss of articular contact between the proximal radius and capitellum, or loss of ulnar reduction, was not apparent in the final X-ray examination. Active range of motion exercises were started on the first day after removal of the cast and K-wire with the aid of a physiotherapist until full elbow range of motion was achieved. No pain, limitations in range of motion or function, or any complications (recurrent dislocation, elbow dysfunction or stiffness, refracture, transient neuropraxias) were observed at the end of the rehabilitative treatment. The patient had excellent results and complete return of elbow motion at short-term clinical follow-up (6 wk after physiotherapy). Complete fracture healing, defined as full return to activities of daily living and sports, occurred four months after the trauma.

DISCUSSION

If the radial head dislocation or subluxation in Monteggia fractures is not diagnosed and adequately treated, it may lead to chronic elbow disability, pain, progressive valgus deformity, neurologic problems (posterior interosseous nerve palsy), radial head dysplasia and degenerative arthritis, elbow stiffness and loss of motion, particularly supination and pronation[4,7,8]. Foran *et al*[4], in a retrospective study performed on 94 patients, asserts that 83% of patients are successfully managed with a cast and do not require surgical stabilization. Reduction of the deformity of the ulnar fracture is achieved through a combination of longitudinal traction, elbow rotation and manual manipulation; when the ulnar length has been re-established, the radiocapitellar joint will often reduce spontaneously or as a result of pressure on the radial head. The author asserts that paediatric Monteggia fractures, including in patients

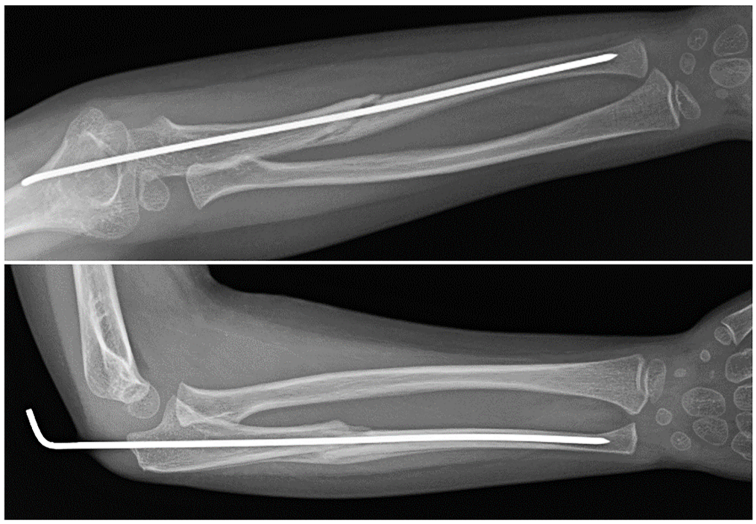


Figure 2 Radiographs at six weeks of follow-up showing reduction of the radial head dislocationand adequate healing of the proximal ulna fracture.

with length-unstable ulna fractures, can initially be managed non-operatively, without compromising outcomes or complications; surgery should only be pursued when a conservative approach fails, with the aim of avoiding surgical overtreatment of these injuries. Compared with adults, children with Monteggia fractures have a higher chance of success without surgery for several reasons, including their thicker periosteum (which helps maintain stability of the ulna), less complex ulna fracture patterns, typically lower energy mechanisms, faster healing times and greater remodeling potential[9,10]. Failure or loss of reduction and late instability may occur in up to 20% of cases with this conservative treatment because of the deforming muscular forces and joint disruption[11,12]. Therefore, although most acute Monteggia fractures are treated non-operatively, certain fracture patterns require surgical stabilization[4]. The indications for surgical treatment are complete fracture, unstable and irreducible fractures, open fractures, and fractures with neurovascular compromise[5]. Variations in the treatment of Monteggia fractures can be found among multiple authors. Ring *et al*[13] affirmed that maintaining ulnar length and anatomic alignment was the key to treating acute Monteggia injuries, because the radial head will remain reduced through healing of the ulnar fracture. Treatment algorithms, based upon the ulnar fracture pattern, have the purpose of minimizing complications and maximizing outcomes through restoration and maintenance of ulnar alignment. The treatment algorithms assert that length-stable fracture patterns with incomplete fracture or plastic deformation of the ulna are treated with closed reduction and casting; length-stable fractures with a complete fracture of the ulna (transverse or short oblique) are treated with intramedullary pin fixation; and length-unstable fractures with comminution of the ulna or a long oblique fracture (fracture line measuring more than twice the cortical diameter) of the ulna are treated with plate fixation[13]. The objective of this algorithm is to avoid loss of reduction and its associated morbidity. Ramski *et al*[11], in a retrospective study performed on 112 patients, asserts that recurrent instability of the radial head and loss of ulnar fracture reduction only occurred in patients who were not treated according to the ulnar-based algorithm. Failures occurred in patients treated less rigorously than the recommended algorithm, and in particular, failures occurred in complete fractures treated non-operatively with closed reduction and cast immobilization[11]. Furthermore, the authors observed that although the algorithm strategy recommends plate fixation for all long oblique or comminuted fractures, there were no failures of intramedullary pin fixation of long oblique fractures in this clinical study.

Nevertheless, several authors advocate more aggressive treatment with open reduction and plate fixation for unstable fractures[14]. Leonidou *et al*[14], in a retrospective study of 40 paediatric Monteggia fractures, asserts that although conservative management has been shown to correlate with good results, unstable fractures of the ulna need to be treated with plate fixation to ensure good reduction of the radial head and to avoid the possibility of prolonged immobilization leading to elbow stiffness in children[14]. Moreover, Hetthéssy *et al*[3] in a retrospective analysis of 23

acute pediatric Monteggia fractures, affirms that if the dislocation of the radial head is accompanied by an unstable fracture of the ulna, a more stable osteosynthesis plate is required.

Nowadays, intramedullary nailing fixation is the main method of fracture stabilization in acute, stable and unstable Monteggia injuries, while plate fixations are widely used in patients with neglected Monteggia fractures[15]. Many authors use a cut-off of fourweeks before considering a Monteggia fracture to be "neglected". He *et al*[15], through a retrospective comparison study of 42 patients, showed that the rate of patients that needed open reduction or complex immobilization methods was higher in the neglected group than in the acute group. Therefore, only for early diagnosis of Monteggia injury can we rely upon minimally invasive methods such as intramedullary pin fixation[15-17]. Open reduction combined with ulnar plate fixation is the most common approach to treating missed Monteggia fractures or acute Monteggia fractures in the case of failure of closed radiocapitellar joint reduction[15].

In contrast to short oblique or transverse ulna fractures, long oblique and comminuted fractures are considered "length unstable" and therefore are treated with plate and screw fixation; open reduction and plate fixation are frequently indicated by some orthopaedists because angulation, malalignment and shortening of the ulna often occur after closed reduction and intramedullary wire fixation. In this case report, intramedullary fixation of the ulna allowed a stable reduction and ulnar length and alignment to be achieved as well as radio capitellar reduction despite the fact that the orthopaedic surgeon did not use the plate and screws for ulnar fracture. Therefore, even if not indicated in treatment algorithms, length-unstable Monteggia fractures can be successfully treated with an elastic intramedullary device with the aim of using a minimally invasive technique and enablinga low complication rate.

CONCLUSION

Treatment of acute paediatric Monteggia fractures is still being debated and there is currently no standard treatment. In fresh Monteggia fractures, the decision to treat the ulna with an intramedullary device or plateismade according tothe surgeon'sown preference with the aim offacilitating the correct alignment of the radiocapitellar joint and avoiding recurrent dislocation. In recent years, the use of intramedullary nails for the management of acute Monteggia fractures in children has gained popularity regardless of the ulnar fracture type. Delayed diagnosis and inadequate treatment of radial head dislocation will cause complications such as elbow pain, decreased joint range of motion, increased valgus deformity and neurologic problems. Flexible nails or wires are excellent devices combining stability and elasticity in children with fractures. Intramedullary fixation of unstable Monteggia fractures results in excellent outcomes, providing reliable reduction and causing fewer complications.

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MINIREVIEWS

Far lateral lumbar disc herniation part 1: Imaging, neurophysiology and clinical features

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Abstract

Far lateral lumbar disc herniations (FLLDH) represent a separate category of disc pathology which includes both intraforaminal and extraforaminal lumbar disc herniations, that are characterized by a peculiar clinical presentation, diagnostic and treatment modalities as compared to the more frequent median and paramedian disc hernias. Surgical treatment often represents the only effective weapon for the cure of this disease and over the years different approaches have been developed that can reach the region of the foramen or external to it, with different degrees of invasiveness. The diagnosis is more demanding and still underestimated as it requires a more detailed knowledge in the spine anatomy and dedicated radiological studies. Computerized tomography and in particular magnetic resonance imaging are the appropriate tools for the diagnosis of FLLDH. Despite the widespread use of these diagnostic tests, many cases of FLLDH are overlooked due to insufficiently detailed radiological examinations or due to the execution of exams not focused to the foraminal or the extraforaminal region. Neurophysiological studies represent a valid aid in the diagnostic classification of this pathology and in some cases they can facilitate the differential diagnosis with

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other types of radiculopathies. In the present study, a comprehensive review of the clinical presentation, epidemiology, radiological study and the neurophysiological aspects is presented.

Key Words: Far lateral lumbar disc herniaton; Magnetic resonance imaging diagnosis; Clinical presentation; Neurophysiology; Epidemiology

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Core Tip: Far lateral lumbar disc herniations constitute a distinct category of lumbar disc herniations. Clinical presentation, diagnosis and treatment are more demanding and require specific knowledge. A comprehensive review of the clinical presentation, epidemiology, radiological study, and neurophysiological aspects is presented in the present study.

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INTRODUCTION

Approximately 10% of symptomatic lumbar disc herniations are located within the neural foramen or lateral to it. These intraforaminal and extraforaminal lumbar disc herniations, usually referred to as far-lateral lumbar disc herniations (FLLDH), can compress the spinal nerve and dorsal root ganglion leading to severe, sometimes excruciating pain that often does not respond to conservative management and requires surgery.

FLLDH represent therefore a distinct category of lumbar disc herniation, which are characterized by unique clinical manifestations and require a greater diagnostic and therapeutic effort than the more usual median and paramedian localizations of disc hernias.

In this review, we analyze the clinical features, the radiological imaging aspects and the neurophysiological characteristics.

EPIDEMIOLOGY AND CLINICAL PRESENTATION

More than 90% of lumbar disc herniations happen at the disc's posterior edge, which is located within the spinal canal. There are two types of intracanalicular herniations: median and paramedian (or postero-lateral). By impinging the nerve root in the lateral recess, shortly as it emerges from the thecal sac, they can produce radiculopathy. As a result, the root that exits the canal through the foramen of the caudal interspace at the afflicted disc is the one that is involved (*e.g.*, in the case of a far lateral L4-L5 herniation, the L4 root)[1].

FLLDH are herniations that occur outside the spinal canal, within the neural foramen (the space bounded cranially and caudally by the pedicles), or in the extraforaminal area (the space beyond the lateral margin of the pedicles).

The herniation involves the root that exits into the foramen of the same intervertebral space (*e.g.*, in the case of an L4-L5 paramedian herniation, the L4 root) (Figures 1-3).

Macnab described extraforaminal disc herniations and the associated symptoms caused by compression of the exiting nerve root in his 1971 paper about negative surgical disc space explorations in patients with radiculopathy[2].

Lateral disc herniation has different clinical features from medial disc herniation. Patients with lateral disc herniation may manifest with more severe clinical symptoms, like severe radicular pain, and motor and sensory neurologic deficits are more frequent than those with medial disc herniation. The cause is that the herniated disc

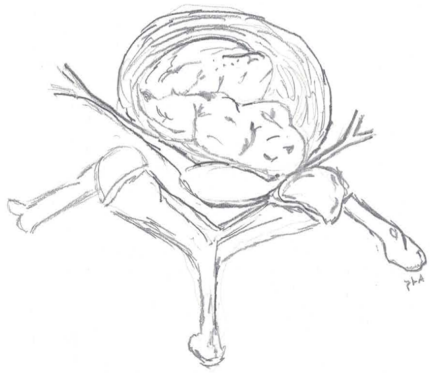


Figure 1 Artist illustration: Intraforaminal herniation compressing the nerve root and ganglion.

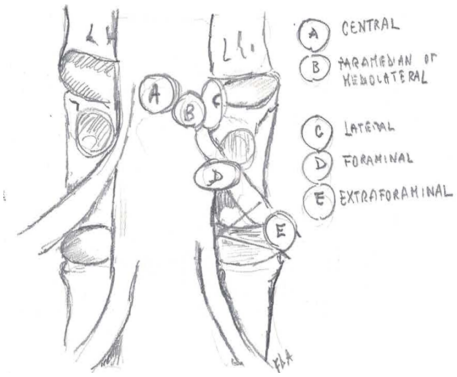


Figure 2 Schematic drawing, coronal view: Relationship between dural sac and nerve roots of disc herniations in different locations.

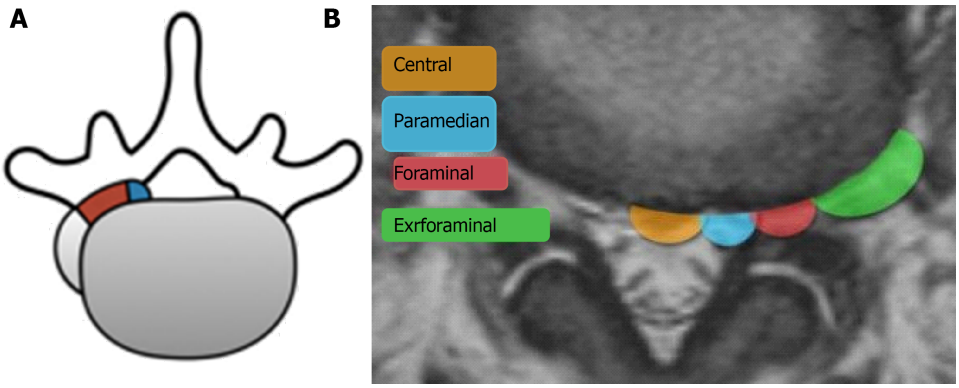


Figure 3 Schematic axial view. A: Schematic drawing, axial view: Relationship between dural sac and nerve roots of disc herniations in different locations. Blue: preforaminal. Red: intraforaminal. Grey: extraforaminal. The herniation can be combined (*e.g.* intra/extraformainal, pre/intraforaminal) (adapted from Lofrese); B: Magnetic resonance imaging schematic axial view.

fragment compresses the nerve root inside a narrow radicular foramen, resulting in direct compression of the dorsal radicular ganglion, which is a pain-sensitive structure.

In 1975, Abdullah and colleagues[3] published a detailed description of the clinical syndrome caused by FLLDH. The "extreme lateral" syndrome described by Abdullah is well defined and includes severe pain due to dorsal root ganglion involvement, as well as a higher risk of neurological deficits than common posterolateral herniations.

FLLDH is responsible for 6.5% to 12% of all lumbar disc herniations[4,5]. Intraforaminal and extraforaminal lesions appear to be almost equally common (3 percent and 4%, respectively)[6]. L3-L4 and L4-L5 are the most involved levels, followed by L5-S1. With a reported frequency of 28 percent of all FLLDH, proximal levels (L2-L3 and L1-L2) are less prevalent but comparatively more common than typical postero-

lateral herniations. The average patient age is between 50 and 78 years old, with a male to female ratio ranging from 1:1 to 2:1[7,8]. Extreme radicular pain is the most prevalent clinical manifestation, which is commonly accompanied by sensory and motor dysfunction as well as a reduced patellar reflex[9]. Back pain is a common symptom in intracanalicular herniations, but it is usually less severe. The femoral stretch test (reverse - Laségue) may show a significant positive result. By bending to the side of the lesion, radicular pain and paresthesia can be replicated, and this is thought to be a sign of intraforaminal root compression[3]. FLLDH at the L3-L4 Level, causing compression of the L3 root, result in pain in the anterior aspect of the tight. FLLDH at the L4-L5 Level, causing compression of the L4 root, are associated with pain in the anterior aspect of the tight, medial malleolus, and medial foot. FLLDH at the L5-S1 Level, where the compressed root is L5, are associated with pain in the postero-lateral aspect of the tight and leg. The clinical characteristics of postero-lateral and far-lateral herniations are summarized in Tables 1 and 2. Despite the heavy clinical manifestations of FLLDH, the natural history is favorable with a reported cure rate with conservative treatment of approximately 71%[10].

DIAGNOSTIC IMAGING

The correct surgical strategy depends on a preoperative diagnosis and thorough location of an extracanalicular herniated disc. FLLDH were difficult to detect until the advent of computed tomography (CT): In fact, root compression lies beyond the lateral extension of the subarachnoid space, therefore it cannot be seen on myelographic images[2]. Both magnetic resonance imaging (MRI) and computed tomography (CT) can now show disc herniations in intra- and extraforaminal locations in high detail. Despite advancements in neuroimaging, however, diagnosing FLLDH may be difficult. In fact, routine spine imaging is frequently limited by slice thickness and field lateral extension. Furthermore, concurrent degenerative alterations like stenosis or intracanalicular disc bulging might make radicular compression inside or laterally to the foramen difficult to visualize[11]. Osborn and colleagues discovered a 30% probability of misdiagnosis on the first CT or MR report in one study. Intracanalicular herniations, on the other hand, are rarely ignored[12]. Osteophytes, nerve root sheath pathologies (such as conjoined roots, arachnoid, perineural, and synovial cysts), and schwannomas, neurofibromas, and ectatic epidural venous plexuses are among the differential diagnoses for FLLDH[12]. When compared to the adjacent intersomatic non herniated disc, the extruded disc material is frequently hyperdense on CT images. (Figure 4). Bone windows make it easier to identify osteophytes. The herniation to the intersomatic disc is often hypointense in T1 and hyperintense in T2 on MR; osteophytes show a signal void in both sequences (Figure 5). The best imaging approach for detecting FLLDH is magnetic resonance imaging (MRI). CT detects radicular compression less reliably than MR and has lesser resolution for spinal and paraspinal soft tissues (Figures 6-8). CT imaging, on the other hand, can be effective in detecting osteophytes and calcifications[11,12]. There may be one or more of the following MR findings: (1) disc margin focal eccentricity; (2) perineural fat tissue obliteration; (3) nerve root thickness alterations; and (4) nerve root dislocation The herniated disc compresses the nerve roots directly, causing thinning, whereas edema can produce thickening. Furthermore, a closer examination usually indicates that epidural fat tissue obliteration is predominantly medial to the root in exclusively intraforaminal herniations, whereas it is observed both medially and laterally to the root in intra-extraforaminal herniations. As previously stated, standard MR examinations are frequently not focused on extraforaminal locations, and imaging this region can be particularly difficult at L5-S1 since the sacral alae and iliac bones' bony features tend to overlap. Furthermore, degenerative changes to the L5-S1 disc are common, reducing its height and making research difficult. Misdiagnosis is frequently caused by an improper MR methodology. Axial slices must be parallel to the intersomatic disc when centered on the sagittal plane. This is necessary in order to detect even minor disc margin focal eccentricities and distinguish real root dislocations from non-pathological asymmetries between the two sides' roots. In order to locate the route of roots and proximal spinal nerves, paracoronal sections (angled 15 to 30 degrees) as well as sagittal sections reaching far laterally and spanning the entire length of the foramina are necessary in the search for a far-lateral herniation[11,12]. Contrast agent administration is not usually required. Differentiating a sequestered disc fragment from other diseases such as schwannomas may need contrast-enhanced imaging. In such circumstances, fat-saturation pulse T1-weighted spin-echo sequences with axial

Table 1 Clinical differences between postero-lateral and far-lateral herniations

Clinical findings	PLH	FLH
Nerve root invovled	At the level below the disc herniation	At the same level of disc herniation
Femoral stretch test	Not always significantly reliable	Markedly positive
Lateral bending	Do not reproduce radicular symptoms	Usually reproduces pain and paresthesia
Severity of pain	Variable	Strong, related to dorsal root ganglion compression

PLH: Postero-lateral herniations; FLH: Far-lateral herniations.

Table 2 Clinical picture of postero-lateral and far-lateral herniations at different levels

Root	PLH level	FLH level	Pain/radiation/sensory involvement	Motor involvement	Deep tendon reflex	Radicular stretching test
L3	L2-L3	L3-L4	Anterior aspect of the tigh	Iliopsoas and/or quadriceps	Patellar	Femoral
L4	L3-L4	L4-L5	Anterior aspect of the tigh, medial malleolus and medial foot	Quadriceps and anterior compartment fo the leg	Patellar	Femoral
L5	L4-L5	L5-S1	Postero-lateral tigh and leg	Extensor hallucis longus and dorsiflexors	None	Lasègue
S1	L5-S1		Posterior thigh and leg, foot (plantar)	Triceps surae	Achilles	Lasègue

PLH: Postero-lateral herniations; FLH: Far-lateral herniations.



Figure 4 Computed tomography: Right intra-extraforaminal disc herniation, partially calcified (arrow). The normal course of the contralateral root is shown by arrowhead.

and sagittal T1-weighted spin-echo can be employed. The sequestered fragment normally improves in the periphery, most likely as a result of an inflammatory reaction in the surrounding area[13].

NEUROPHYSIOLOGY

Neurophysiology is a complimentary yet crucial tool in the diagnosis of FLLDH, as it aids in the differential diagnosis of radiculopathy and other disorders, as well as the verification of the implicated level. It may also reveal the extent of the damage to the brain. This evaluation is aided by a variety of ways. Electromyography, as well as findings from nerve conduction tests, H reflex, and F wave studies, are used to determine the appropriate workout. (1) signs of neurogenic injury in muscles pertaining to the same spinal root with normal (or relatively spared) findings in muscles pertaining to nearby roots; (2) involvement of the proximal part of the peripheral nervous system; and (3) exclusion of other possible sites of injury that can mimic a radicular lesion, such as the lumbo-sacral plexus or single nerves.

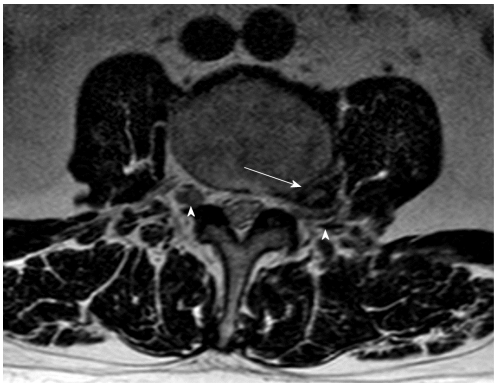


Figure 5 Magnetic resonance (T2 axial sequence): Left extraforaminal disc herniation (arrow). Nerve roots are clearly depicted (arrowheads), the left one being thinned, kinked and dislocated postero-superiorly by the herniation.



Figure 6 Magnetic resonance (T1 sagittal sequence): L3-L4 intraforaminal herniation compressing the L3 root. Perineural fat obliteration is evident.

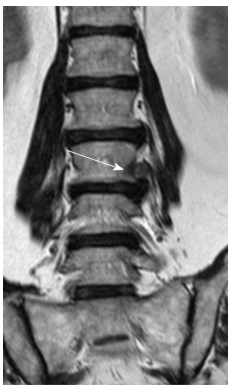


Figure 7 Magnetic resonance (T1 paracoronal sequence): Left L3-L4 extraforaminal herniation.

Electromyography

The pattern distribution of anomalies is commonly used to identify the afflicted root. As a result, needle electromyography is done on a large number of muscles, looking for anomalies in muscles belonging to a single root and normal findings in muscles belonging to other roots. Normal results in muscles innervated by distinct roots but belonging to the same nerve or plexus may also assist in distinguishing nerve or plexus injury from radiculopathy. Unfortunately, each muscle is frequently assigned to one of several nearby roots, and each root feeds multiple muscles, making differential diagnosis difficult. Because the motor regions of roots L2, L3, and L4 are significantly overlapping, this is especially noticeable when examining upper lumbar radiculopathies[14]. In such cases, assessing the paraspinal muscles can be helpful in determining the affected level. This should concentrate on the multifidus muscle,

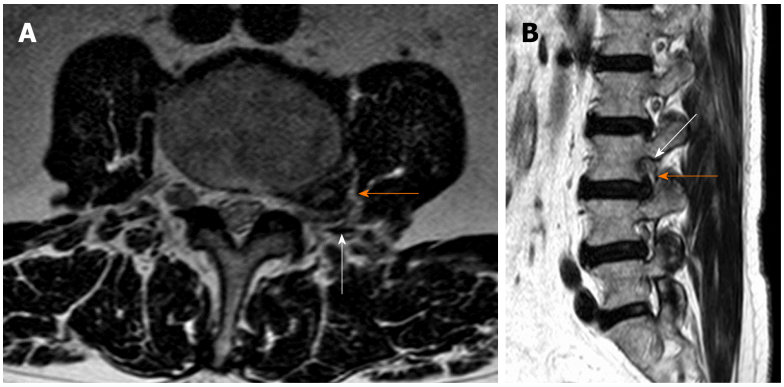


Figure 8 Axial (A) and sagittal (B) T2 magnetic resonance imaging showing a left L3-L4 extraforaminal far lateral lumbar disc herniations (orange arrow). The L3 root is severely compressed against the posterior border of the neural foramen (white arrow).

which, unlike other paraspinal muscles, is thought to be innervated by a single root [15]. In any event, there are certain limits to paraspinal muscle examination: fibrillation can be absent in paraspinal muscles in some cases of root injury, and these muscles can be difficult to assess, especially in obese individuals or those who are unable to relax the target muscles. Furthermore, after back surgery, residual neurogenic alterations due to local trauma can be found in paraspinal muscles, making postoperative testing useless[13] (Daube, 2009). Electromyography can also reveal information about the disease's progression and severity. The first expected observation after acute axonal injury is a decrease in motor unit potential (MUP) recruitment proportionate to the amount of the lesion. After 2-3 weeks, fibrillation potentials arise, and their quantity is a good measure of the amount of destroyed motor axons. Denervated muscle fibers will gradually be recruited in surviving motor units, resulting in distinct modifications in the weeks and months ahead (at first an increase in MUP duration and number of phases, and then of MUP amplitude)[16]. Increased duration and amplitude of compound potentials are a static finding that lasts indefinitely (assuming the larger motor units aren't successively harmed), therefore they shouldn't be considered indicative of continuous root injury since MUP changes are secondary to motor unit remodeling[17]. If the axonal loss is so minor that MUP changes aren't noticeable, fibrillation potentials may be the only aberrant finding in some radicular lesions[17]. Fibrillation generally fades and eventually vanishes when the motor unit remodels, but it can be recorded indefinitely in severe or continuing lesions. In isolated injuries that do not permanently damage axons, recruitment alterations can return to normal (like neurapraxic or myelin lesions). The discovery of fibrillation potentials, recruitment deficits, and MUP changes all occur at the same time, which aids in determining the initiation of injury and the severity of axonal loss. As a result, the presence of fibrillation in the lack of MUP changes usually indicates an acute injury, whereas MUP changes in the absence of fibrillation indicate a static or slowly progressive injury.

Sensory and motor nerve conduction studies

Even in the face of a clinical sensory impairment, involvement of the dorsal root between the spine and the dorsal root ganglion might spare sensory nerve action potential (SNAP) amplitudes, demonstrating radicular involvement and possibly excluding plexus or nerve lesions. Far lateral disc herniations, on the other hand, typically compress the dorsal root in the intervertebral canal and/or extraforaminal region, causing a lesion of the dorsal root ganglion or even a more distant component of the root. As a result, the amplitude of the SNAP signal may be reduced. As a result, sensory conduction tests can be deceiving, and they are insufficient to distinguish radicular from more distant sites of injury. They will, in any case, provide information that will help identify or rule out additional PNS illnesses. In muscles belonging to the afflicted root, motor conduction investigations can reveal a drop in compound muscle action potential (CMAP) amplitude, especially if the axonal loss is extensive and the muscle is weak. The CMAP and distal nerve conduction velocity can be unchanged in lesser root injuries or if the lesion does not produce axonal loss (*i.e.* in a neurapraxic lesion). It is important to remember that acute lesions involving both sensory and motor axonal loss cause changes in CMAP only after a period of time has passed (CMAP and SNAP amplitudes halve by 5-7 days after injury), *i.e.* when the nerve fiber

and the neuromuscular endplate become unexcitable due to Wallerian degeneration [18].

H reflex and F wave

The H reflex and the F wave may be relevant in the diagnosis of FLLDH on rare occasions. The H reflex is the myotactic tendon reflex's neurophysiological counterpart. It's a potential recorded from muscle fibers that's induced by electrical stimulation of a motor nerve at a lesser intensity than the CMAP[16]. It's easy to assess in the soleus muscle, and it's generally aberrant with S1 radicular lesions, but it's less reliable in other limb muscles[19]. Changes in a modified H reflex from the tibialis anterior muscle were only anecdotally linked to L4 and L5 radiculopathies (after stimulation of peroneal nerve). This explains why the H reflex isn't very useful in determining whether or not someone has FLLDH. The F wave, on the other hand, may be detected in almost all muscles. It's a minor potential measured from muscle fibers that occurs after the CMAP and is caused by anterior horn cells activating in an antidromically conducted stimulus backfiring. The F wave is a method of assessing conduction along proximal nerve segments that can be recorded from any nerve. Theoretically, clear aberrant F wave values paired with normal distal conduction parameters can detect injuries in proximal PNS sites. Unfortunately, this technique's sensitivity is poor, and normal results do not rule out a radicular lesion. Furthermore, in normal persons, the response from some nerves, such as the peroneus profundus, may be absent. As a result, the F wave's utility in the identification of radicular lesions is regarded as restricted[20]. Finally, when radiculopathy is suspected, a neurophysiological evaluation can help identify the injured root(s) and offer a semi-quantitative measurement of the root injury's size and stage. However, there are a few limitations to neurophysiological investigations in this context that must be addressed. First, neurophysiology may not be sensitive enough to rule out a radicular injury in compressive radiculopathies. Second, neurophysiological examination alone cannot determine the source of a radicular lesion, and confounding factors such as anatomical characteristics and patient comorbidities frequently prevent precise determination of the injury site[17,21].

CONCLUSION

Far-lateral disc herniations differ from their more common postero-lateral counterparts in the following ways: (1) they involve the nerve root exiting at the same level; (2) they may have a positive femoral stretch test; (3) pain and paresthesia can be reproduced by lateral bending to the side of the disc herniation; and (4) pain is often more severe than in central disc herniations, possibly due to direct compression of the dorsal root ganglion. If an appropriate procedure is followed, MR is the best imaging modality for identifying FLLDH. If an MR scan is not possible, a multi-slice CT scan is a good option. The distinction between intraforaminal and extraforaminal herniations must be correctly diagnosed before the right surgical strategy can be chosen. Despite their limitations, neurophysiological tests are a useful tool in the diagnosis and follow-up of FLLDH patients.

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MINIREVIEWS

Total hip arthroplasty in fused hips with spine stiffness in ankylosing spondylitis

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Abstract

Ankylosing spondylitis (AS) is characterized by involvement of the spine and hip joints with progressive stiffness and loss of function. Functional impairment is significant, with spine and hip involvement, and is predominantly seen in the younger age group. Total hip arthroplasty (THA) for fused hips with stiff spines in AS results in considerable improvement of mobility and function. Spine stiffness associated with AS needs evaluation before THA. Preoperative assessment with lateral spine radiographs shows loss of lumbar lordosis. Spinopelvic mobility is reduced with change in sacral slope from sitting to standing less than 10 degrees conforming to the stiff pattern. Care should be taken to reduce acetabular component anteversion at THA in these fused hips, as the posterior pelvic tilt would increase the risk of posterior impingement and anterior dislocation. Fused hips require femoral neck osteotomy, true acetabular floor identification and restoration of the hip center with horizontal and vertical offset to achieve a good functional outcome. Cementless and cemented fixation have shown comparable long-term results with the choice dependent on bone stock at THA. Risks at THA in AS include intraoperative fractures, dislocation, heterotopic ossification, among others. There is significant improvement of functional scores and quality of life following THA in these deserving young individuals with fused hips and spine stiffness.

Key Words: Ankylosing spondylitis; Total hip arthroplasty; Stiff hips; Stiff spine; Spinopelvic mobility; Functional outcome

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Grade A (Excellent): 0
Grade B (Very good): B, B
Grade C (Good): 0
Grade D (Fair): 0
Grade E (Poor): 0

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Core Tip: Progressive spine stiffness associated with stiff hips in ankylosing spondylitis (AS) results in mobility restriction and reduces the quality of life in young individuals. Preoperative planning for total hip arthroplasty (THA) in AS requires spinopelvic mobility assessment. Sacral slope change is reduced (< 10 degrees) with a predominant stuck sitting pattern and posterior pelvic tilt. Care needs to be exercised to reduce acetabular anteversion preventing posterior impingement and anterior dislocation. Risks at THA in AS include intraoperative fractures, postop dislocation (1.9%), heterotopic ossification, among others, with revision-free survivorship of 82% at 20 years. Significant functional and mobility improvement justifies THA in AS with stiff hips and spine.

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INTRODUCTION

Ankylosing spondylitis (AS) belongs to the spondyloarthropathy group of disorders affecting the young with progressive stiffness of the spine and hip joints. Inflammation of the spine leads to progressive changes with ankylosis and decreased spinal mobility [1,2]. Chronic inflammation in AS of unknown etiology leads to progressive involvement of the spine, hips, knees, shoulders, among other joints[2-5]. Sacroiliac joints are involved in 100% of AS, followed by lumbosacral spine and cervical spine[4, 6]. Hip disease is evident in 19%-36% of AS[4], and shoulder involvement is seen in 20% of the disease[7]. Small joints of the hand are rarely involved[6]. Early hip involvement is marked by synovitis with synovial thickening and increased synovial fluid, as evidenced) by magnetic resonance imaging even in asymptomatic hips with AS[8]. Hip involvement with inflammation and edema is accompanied by involvement of the sacroiliac joint, symphysis pubis and shoulders. Subcortical edema in AS is typical with inflammation of the insertion sites of the tendons, ligaments and capsule, referred to as enthesitis[4]. Inflammation with pathological new bone formation is characteristic of AS with hip and spine involvement. The hip joint radiographs reveal concentric osteoproliferation and acetabular erosion[4]. Synovial and capsular inflammation responsible for pain and decreased movement, with other incompletely specified mechanisms, eventually leads to hip degeneration in AS[4,8]. The hip disease progression seems more significant in males with younger age of onset, eventually requiring total hip arthroplasty (THA)[9-12]. Duration of hip disease in AS is reported as 10-20 years, which is less than duration of AS with spine involvement[4,5,13]. Younger age of onset is associated with more hip disease[4]. Disability is predominantly due to decreased mobility resulting in stiffness and activity restriction. Hip disease is seen largely in the younger age group with significant functional impairment[4,14]. Most AS hips have fixed deformities with stiff spines and loss of spinopelvic mobility. THA improves functional outcome in these patients with significant activity limitations and progressive stiffness in their spine and hips.

THA in AS provides significant improvement in the range of movement with marked improvement in function and mobility[15]. However, the associated risks for consideration are heterotopic ossification (HO), reduced range of movement and re-ankylosis after THA in AS[11].

EPIDEMIOLOGY

The estimated prevalence of Ankylosing Spondylitis (AS) globally is 0.1%-1.4%[16,17] Mean prevalence of 17.6 per 10000 has been reported in Asia[16], with approximately 0.31% (11 to 37.1 per 10,000) reported in China and 7 to 9.8 per 10000 in India[18]. Approximately 25%-50% of patients have hip joint involvement[19], with bilateral hip

disease seen in 50%-90% of in AS[12,15,20,21]. Hip involvement in AS varies from 24%-36% according to data reported from Belgium, Spain and South America[4]. Functional impairment predominantly due to hip disease in AS is evident from functional indicator scores such as the Bath Ankylosing Spondylitis Functional Index [1,4]. The Bath Ankylosing Spondylitis Disease Activity Index and other indicators are used in the assessment of functional impairment due to hip disease in AS[4]. Hip involvement presents with varying degrees of stiffness, with bony ankylosis seen in about 40% at THA[22].

CONSIDERATIONS FOR THA IN AS

Progressive hip stiffness is seen in AS results in loss of function and limitation of activities of daily living. Hip stiffness combined with spine stiffness results in significant reduction of mobility. The progressive disease leads to fixed deformities of the hip. The fused hips at THA have flexion, abduction or extension deformities[11,23,24]. The individuals are unable to sit comfortably due to the absence of a normal spinopelvic mobility pattern that occurs from standing to sitting position.

AS with restricted spine and hip mobility presents with advanced disease for THA due to various social and other reasons. There is a significant reduction in the range of movement in these affected hips with fixed flexion and rotational deformities. AS with fused hips and stiff spines causes significant activity restriction and loss of function. The indication for THA is a significant loss of mobility rather than pain[15].

AS patients for THA need preoperative assessment and anesthetic evaluation for optimal perioperative care[15]. Airway, respiratory and cardiovascular status needs preoperative assessment. The medical management with disease-modifying antirheumatic drugs, such as anti-tumor necrosis factor alpha agents, must be stopped with rheumatology input and restarted later to minimize risks associated with wound healing reported at 0.9%[15].

Fused hips with AS have a loss of spinopelvic mobility from the stiffness of the spine and this needs to be recognized before THA for adequate preoperative planning. Preoperative templating is essential to plan for correct acetabular component size and restoration of the hip center. THA with cementless fixation would achieve a good outcome[11,23,25,26], however, cemented fixation would be required in hips with capacious femoral (Dorr C) and poor bone stock[15,21,27]. Cementless acetabular components may require additional screw fixation. Cementless fixation preserves bone stock which, would help in future revisions[15]. The bone stock could be compromised due to significant hip and spine stiffness with prolonged restriction of mobility. Comparison for both cemented and cementless fixation at THA have shown good long-term survivorship in AS[17,28].

APPROACHES FOR THA IN AS

THA in stiff hips with AS have fixed deformities[23]. Flexion deformity is the most common[3,10,11], and an extension abduction deformity occurs rarely[24]. External rotation deformities also coexist indicating contracture of the internal rotators and posterior capsule. The surgical approach for THA should ensure the release of the tight capsular tissue and soft tissue to enable full correction at THA. The flexion deformity would require a comprehensive anterior release while the abduction extension deformities would require the release of the lateral structures including the Iliotibial band

The posterior approach has been the most common in AS[11,15]. The lateral approach has also been used for THA in AS and has been advocated for its lower dislocation rates[29,30]. The modified lateral approach would not compromise the abductors further especially in AS, and this would ensure a comprehensive release in these fused hips with flexion deformity[29-32]. Anterior approach has been reported with favorable outcomes in AS with stiff hips[33,34].

The surgical approach chosen should ensure complete release to correct the fixed deformity in these fused hips without compromising the inherently weak abductors [15]. Trochanteric osteotomy aiding exposure has been associated with increased risk of HO. This approach has been gradually abandoned, although it improves exposure [11,15].

FUSED HIPS

AS with progressive hip stiffness and bilateral hip involvement present as fused hips at THA. Hips with ankylosis require *in situ* femoral neck osteotomy, identification of acetabular margins, reaming into the femoral head and identification of true acetabular floor to achieve correct acetabular component placement (Figures 1 and 2). Femoral neck osteotomy needs to be done with care to prevent damage to the greater trochanter and the posterior acetabular margin[15]. Identification of the true floor is aided by the pulvinar tissue, with care exercised not to medialize the acetabulum[23]. Hip fusion could present with proximal migration of the hip center requiring restoration of the hip center. Subtrochanteric femoral shortening may be required in fused hips with a high hip center[35] (Figures 3 and 4).

SPINE STIFFNESS WITH FUSED HIPS

Spinopelvic movement from standing to sitting is determined by three factors, which include the lumbar spine, spinopelvic mobility and hip flexion[36,37]. Spinopelvic mobility is dependent on sagittal pelvic movement as the anterior pelvic tilt, with lumbar lordosis in the standing position changes to the posterior tilt in the sitting position[38]. Spinopelvic mobility is an essential component in preoperative THA planning, which could lead to early or delayed complications[38-43]. Spinopelvic mobility patterns have also been well described, with recommendations for acetabular component placement at THA[38,39,44]. The preoperative assessment for THA includes a radiological spine assessment, especially with concurrent spinal involvement.

The spine in AS is stiff, and the normal change from sitting to standing is dependent on all three factors that are affected in AS. The change in sacral slope from sitting to standing (< 10 degrees) conforms to the stiff spine pattern[36-38,43]. The stuck sitting pattern with posterior pelvic tilt is common in AS (Figure 5). The stuck standing pattern is not infrequent in AS, as the lumbar spine stiffness may occur with lordosis (Figure 6).

Spine stiffness and altered spinopelvic mobility coexistent with hip disease in AS at THA has been described[41]. Spinopelvic mobility is gradually lost in these young individuals, with the stiffness of both hips and spine causing significant activity restriction. The posterior pelvic tilt with low pelvic incidence had marginal change (< 10 degrees) before and after THA (Figures 5 and 6) conforms to the stiff pattern. The spinopelvic mobility pattern would fall into the rigid unbalanced category[45].

The stiff spine requires preoperative assessment to evaluate change with THA[36,37,43,46]. Hu *et al*[47] have recommended correction of thoracolumbar kyphosis before THA. However, most AS individuals with stiff hips and spines undergo THA to achieve improvement in mobility and function. The understanding of the normal hip spine relationship and the different patterns brings out the importance of acetabular component anteversion in THA[36,38-40,45]. Progressive loss of spine mobility is common in AS with the loss of normal spinopelvic mobility. Spine stiffness with stiff hips in AS contributes to loss of spinopelvic mobility from sitting to standing. Preoperative assessment includes lateral radiographs of the lumbosacral spine in sitting and standing positions to evaluate the spinopelvic mobility pattern. Preoperative sitting radiographs may not be possible in AS with stiff hips, as these individuals with significant spine stiffness are often unable to sit with the thighs parallel to the floor.

Acetabular anteversion of 15-25 degrees needs to be reduced in these hips with decreased spinopelvic mobility[17,48]. Posterior pelvic tilt with spine stiffness has an associated risk of posterior impingement with subsequent anterior dislocation. Care should be taken to avoid excessive anteversion as this would increase the risk of posterior impingement and anterior dislocation[42,49]. The normal change in inclination and anteversion from sitting to standing is absent[38-40]. Dual mobility hips have been recommended for fused hips associated with a stiff lumbar spine and posterior pelvic tilt to reduce the risk of impingement and dislocation[38,40].

PROTRUSIO

Protrusio in stiff hips is not uncommon in AS. The reason for the medialization of the femoral head beyond the ilioischial line is not fully understood[21,50,51]. Protrusio has



Figure 1 Bilateral fused hips with ankylosing spondylitis in a 43-year-old male at total hip arthroplasty-pre op.

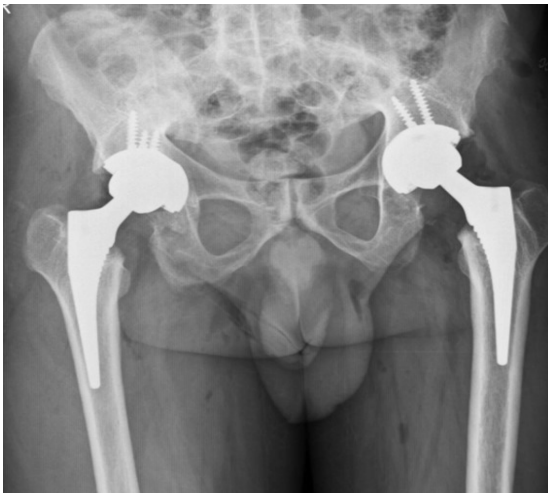


Figure 2 Bilateral fused hips-post op bilateral total hip arthroplasty (Pre op Figure 3) with cementless fixation in 43-year-old male.

been reported in about 17% of hip disease with AS[50]. Preoperative planning includes templating and medial defect bone grafting with reverse reaming for the protrusio with cementless acetabular components. Dislocation of the femoral head during THA in these cases could be challenging, and osteotomy of the neck and head removal may be necessary to avoid intraoperative fractures. The acetabular floor is prepared with caution to prevent medialization, and hip center restoration is essential with autogenous bone grafting and primary cementless acetabular fixation[52] (Figure 7). The protrusio in these hips may present with proximal migration and resorption of the femoral head as well.

FUNCTIONAL OUTCOME

THA in AS with stiff hips restores mobility with significant improvement in activity limitation. The mobility is restored with a significant increase in range of movement and good functional outcome[12,21,25,26,33]. Thirty-six item Short Form Survey scores and health-related quality of life are significantly affected in AS[53]. Functional scores have shown significant improvement for bilateral THA with an average change in HSS scores by 60.6 points reported[15]. Harris Hip Score showed improvement from 48 to 73 and 53 to 82 for historical and recent data in the same series[17] (Table 1). The improvement in functional outcome and quality of life have supported the increased incidence of THA in these stiff hips in AS.

Table 1 Comparison of outcome of total hip arthroplasty in ankylosing spondylitis

Ref.	Patients (Hips)	Follow up in mo	Pain relief (%)	Final MHHS	ROM score/ Mean flexion	Approach	Complications (%)
Bisla *et al*[58], 1976	23 (34)	42.5	91	NS	ROM-3	NS	5.88
Resnick *et al* [59], 1976	11 (21)	36	NS	NS	NS	NS	30 re-ankylosis; 6/20 hips
Williams *et al* [60], 1977	56 (99)	36	NS	NS	NS	NS	10
Baldursonn *et al* [61], 1977	10 (18)	45.6	94	NS	Flexion-90	NS	0
Shanahan *et al* [62], 1982	12 (16)	89	94	NS	NS	NS	6.25
Finsterbush *et al* [63], 1988	23 (35)	90	NS	NS	Flexion-86	NS	14.28
Walker *et al*[9], 1991	19 (29)	58	97	NS	ROM-4	NS	15; 3 hips re-ankylosis
Gualtieri *et al* [64], 1992	39 (73)	90	89	NS	NS	NS	0
Brinker *et al*[10], 1996	12 (20)	75	90	89.1	ROM-4	Posterior, Lateral	0
Sochart *et al*[55], 1997	24 (43)	276	100	NS	ROM-4	NS	27.9
Lehtimaki *et al* [56], 2001	54 (76)	240	NS	NS	NS	NS	3.94
Joshi *et al*[27], 2002	103 (181)	120	96	NS	NS	Lateral, Hardinge	10.5
Kim YL *et al* [65], 2007	12 (24)	132	NS	82.3	NS	Lateral	12.5
Bhan *et al*[11], 2008	54 (92)	102	62	82.6	ROM-4	Posterior	14
Li *et al*[66], 2009	24 (39)	36	NS	91	ROM-4	Posterolateral	2.5
Tang *et al*[12], 2000	58 (95)	135.4	94	88.8	ROM-4.2	Posterior	20
Bangjian *et al* [54], 2012	12 (24)	50.4	100	86.25	Flexion-84	Posterolateral	8.3; 2 intraoperative femur fractures; 2 osteolysis, polyethylene wear
Malhotra *et al* [67], 2012	23 (32)	42	NS	87.1	ROM-4	Posterior	3.1
Siavashi *et al* [68], 2014	77 (NA)	12	NS	88.22	ROM-5	Posterior, lateral	20.8
Xu *et al*[26], 2017	54 (81)	42	NS	86.1	Flexion-82.5	Posterolateral	0
Guo *et al*[69], 2019	26 (31)	46.5	80.6	87.1	Flexion90.8	Smith Peterson; lateral, Posterior	1 dislocation; Closed reduction; 12.9% HO
Bukowski BR *et al*[17], 2021	219 (309)	16 yr (192 mo)	NS	76	NS	Transtrochanteric (45%); Posterior (25%); Anterolateral (29%)	17.5% at 20 yr

Complications as percentage. Revision, dislocation, fractures, infection. HO: Heterotopic ossification; ROM: Reduced range of movement; MHHS: Modified Harris Hip Score; NS: Not specified.

COMPLICATIONS

AS with stiff hips could present with poor bone stock due to prolonged immobility and stiffness. Care needs to be exercised during THA to prevent intraoperative fractures reported at 4.3%[11,15,27,54]. Wu *et al*[33] reported 1 case of greater

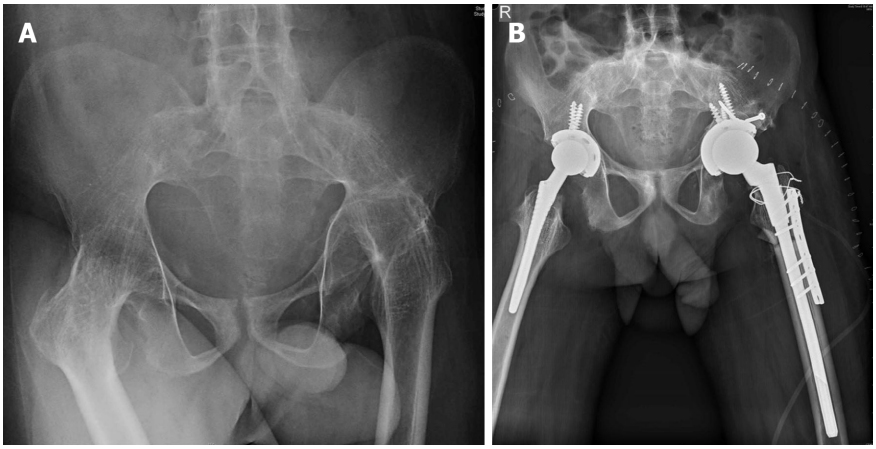


Figure 3 Bilateral fused hips and ankylosing spondylitis in a 31-year-old male. A: Proximal migration of the left hip with femoral head and acetabular type 3b acetabular deficiency; B: Bilateral total hip arthroplasty with left hip femoral shortening. Acetabulum medial wall fracture, defect managed with bone graft and screws for superior augmentation. Sacral slope wire for proximal femur incomplete split, femur plate for additional rotational stability.

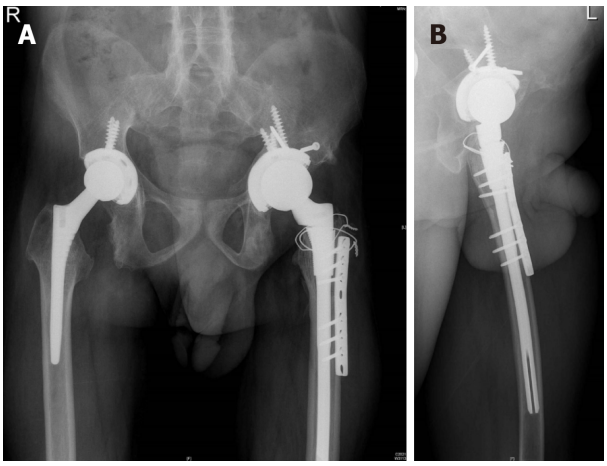


Figure 4 Follow up bilateral fused hips total hip arthroplasty in 31-year-old male with proximal migration left hip (pre op Figure 3). A: 15 mo follow-up with osteotomy site union, acetabulum graft well united; B: Lateral view confirming osteotomy site union.

trochanter fracture in their series with DAA for THA in AS. Fracture risk is associated with cementless fixation with inadequate bone stock. Fractures have been reported at femoral stem insertion managed with wiring and delayed weight bearing[15]. Bukowski *et al*[17] reported 3 proximal femur fractures and 1 acetabular fracture treated with femur wiring and acetabular component retention in their series. Hips for THA with poor bone stock and wide femoral canal (Dorr C) should be planned for cemented fixation. The identification of the medial wall during acetabular preparation and reaming is crucial in achieving the ideal component position at THA in fused hips. Restoration of the hip center with vertical and horizontal offset is essential in achieving THA with a good functional outcome.

Dislocation is a common mode of failure after THA in AS, with earlier reports of 3%-5% at 10 years[11]. Dislocation after THA in AS has been reported at 1.75% managed by closed reduction with successful outcome[15] (Figure 8). Eight dislocations requiring closed reduction were reported in a series of 309 AS hips[17]. Tang *et al*[12] reported 2 (2 out of 3) anterior dislocations in their series with posterior approach THA, attributed to hip hyperextension. Dislocation has been reported by Bhan *et al*[11] at 4.3% with the posterior approach and Joshi *et al*[27] reported a rate of 2.2% with the lateral approach. Wu *et al*[33] had reported two dislocations in the posterolateral approach when compared to DAA in their series. Cumulative dislocation requiring open or closed reduction has been reported at 1.9% at 2 years and 10 years and 2.9% at 20 years[17]. Dislocation was predominantly posterior with one out of three hips requiring revision with a constrained liner[17].

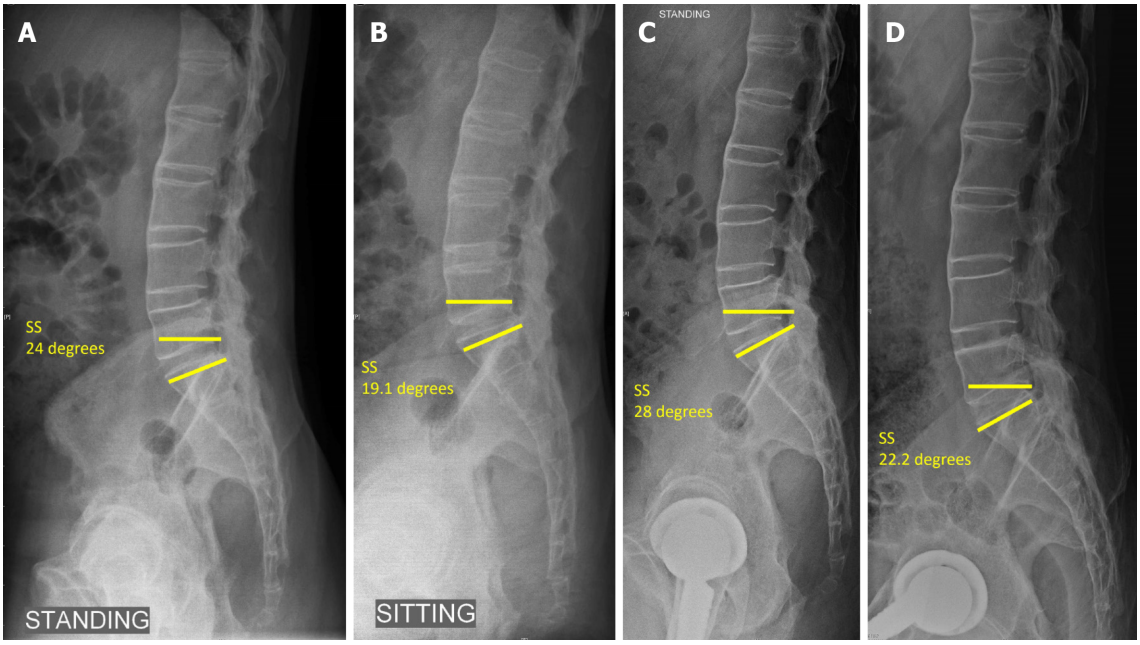


Figure 5 Lateral lumbosacral spine radiographs. A: Pre op standing; B: Sitting compared to; C: Post op standing; D: Sitting showing the change in sacral slope < 10 degrees with reduced sacral slope indicating posterior pelvic tilt and stuck sitting pattern in ankylosing spondylitis (sacral slope < 30 degrees on sitting and standing typical of stuck sitting pattern). SS: Sacral slope.

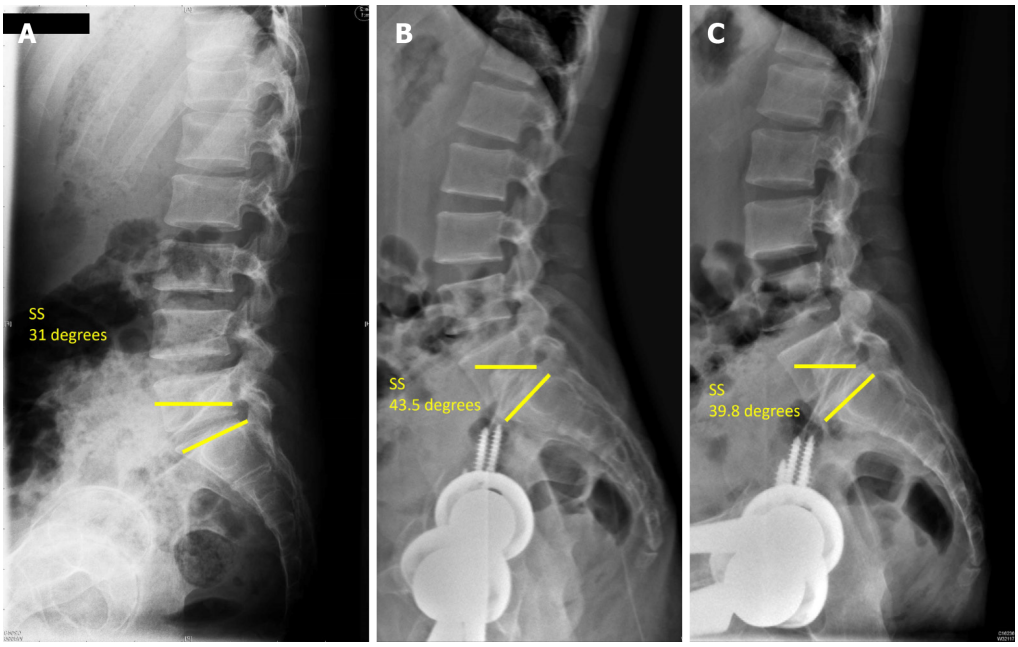


Figure 6 Spinopelvic mobility in a 51-year-old male with flexion deformity and inability to sit comfortably prior to total hip arthroplasty, pre op and 29 mo post bilateral total hip arthroplasty ankylosing spondylitis. A: Pre op sacral slope (SS) standing; B: Post total hip arthroplasty SS standing; C: Sitting SS > 30 degrees sitting and standing demonstrates the stuck standing pattern. SS: Sacral slope.

The other complications reported included superficial wound infections requiring oral antibiotics in five hips and hematoma formation in five hips in THA for AS[17].

Nerve injuries have been reported with a slightly higher incidence (2.6%) after bilateral THA for AS[15]. Neuropraxia of the femoral, sciatic and peroneal nerves have been reported with recovery rates between 3 wk and 6 mo.

Long-term survivorship following THA in AS has been reported as 92%-100% at 10 years, with rates falling to 66%-81% at 15 years[12,27,55,56]. Aseptic loosening requiring revision in AS has been reported at 9.7%, 14% and 11% at 16-, 9- and 5-year follow-up, respectively[11,17,21]. Cemented fixation in AS had longer survivorship with lower revision rates compared to cementless fixation, which was considered to

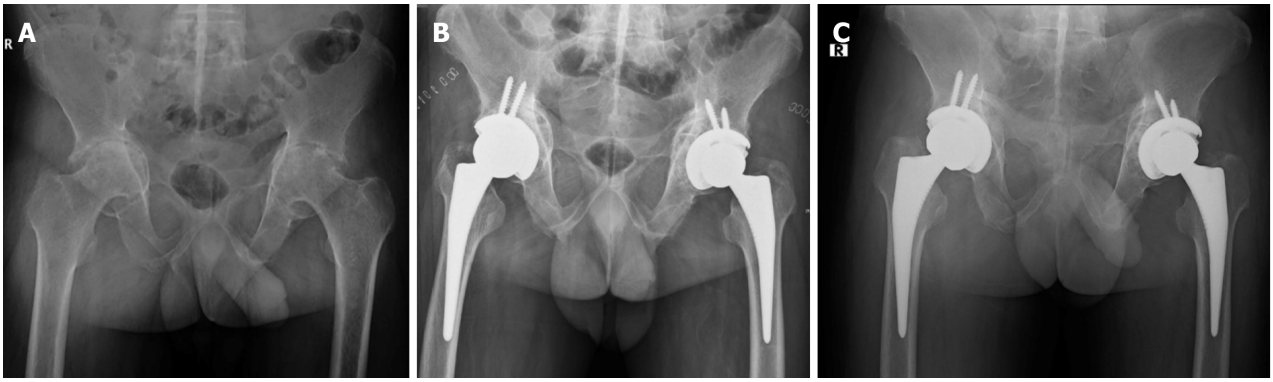


Figure 7 Bilateral hip protrusion in 48-year-old male with ankylosing spondylitis and fused sacroiliac joints. A: Pre op bilateral stiff hips; B: Post op total hip arthroplasty with bone grafting (autograft) reverse reaming for graft impaction; C: 1-year follow-up with graft integration.

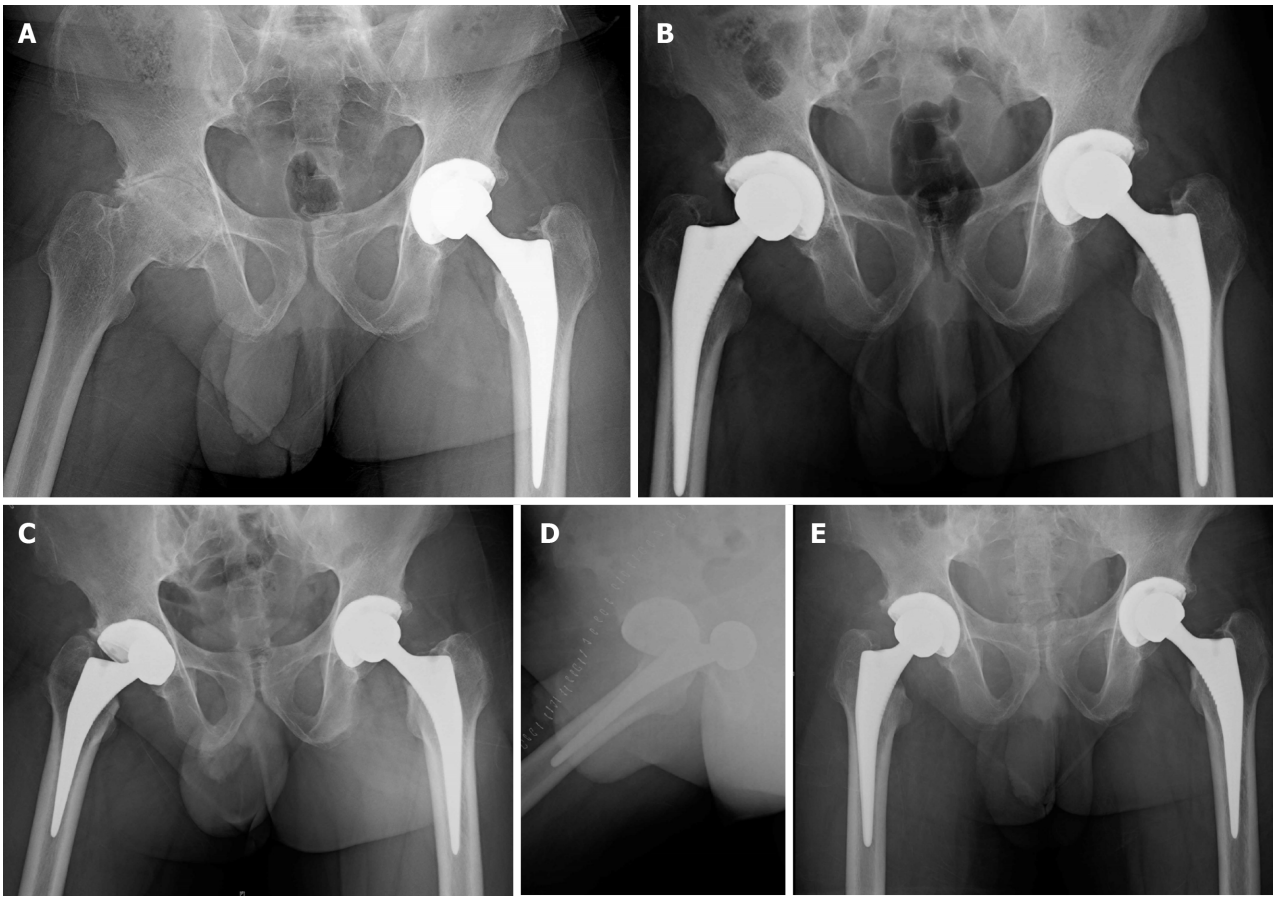


Figure 8 Left total hip arthroplasty with right hip arthritis in a 34-year-old male with ankylosing spondylitis. A: Pre op stiff right hip; B: Post op right total hip arthroplasty; C: With dislocation at day 5 following a fall; D: Lateral view; E: 1-year follow-up after closed reduction.

have better results[17,28].

HETEROTOPIC OSSIFICATION

The incidence of HO in AS after THA has been reported at 11%-13%, with findings of Brooker class 1 in most hips[21,28]. Brooker 3 or 4 (Figure 9), referred to as clinically relevant HO, was seen in 8% of hips[17]. Data in the literature suggest incidence of HO following THA in AS is 9%-77%[9,10]. Re-ankylosis has also been reported with significant HO following THA in AS associated with a reduced range of movement. Trochanteric osteotomy approach has been attributed to increased incidence of HO and re-ankylosis in earlier reports[3,11,57]. HO following THA in AS is probably due

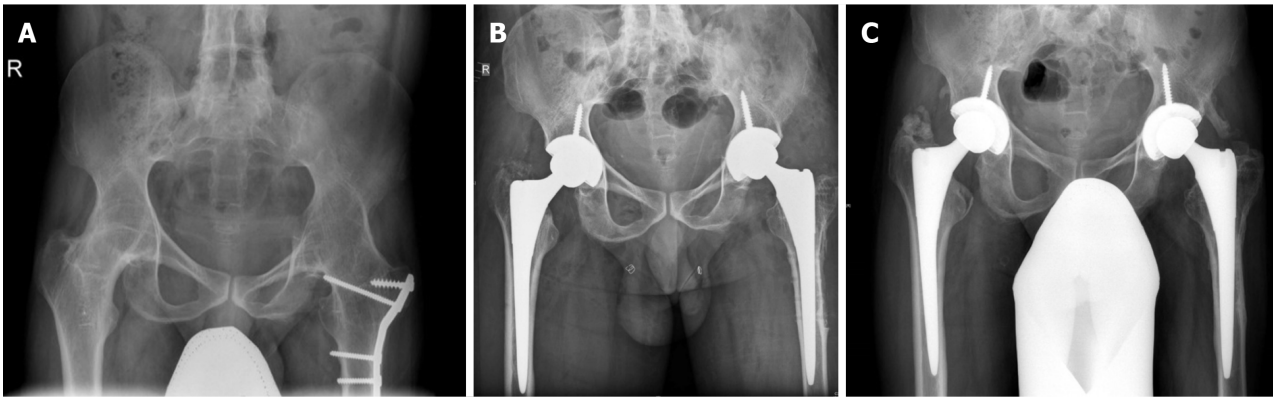


Figure 9 Bilateral hip ankylosis in a 33-year-old male with ankylosing spondylitis. A: Pre op total hip arthroplasty, 12-year post op fracture fixation left proximal femur; B: Post op bilateral total hip arthroplasty; C: Follow-up with Brooker grade 3 heterotopic ossification left hip and good hip function (Harris hip score improved from 34 to 81 at 24 mo follow-up).

to chronic inflammation seen in the joint as well as the surrounding tissues with varying degrees of stiffness. Indomethacin plays an effective role in HO treatment and prevention in these cases[21]. Careful soft tissue handling and copious lavage to ensure removal of excess bone debris before closure after THA play a significant role in HO prevention in these stiff hips.

CONCLUSION

AS with stiff hips and spine have reduced mobility and function. THA enhances movement and functional activity with significant improvement in outcome. The spinopelvic mobility pattern in AS belongs to the stiff category with minimal change from sitting to standing (< 10 degrees). Preoperative sitting and standing spine lateral radiographs are essential for assessment. THA for fused hips in AS requires *in situ* femoral neck osteotomy, identification of the true acetabular floor and restoration of hip center, vertical and horizontal offset. Cementless and cemented THA have shown good long-term results. Care should be taken to avoid increased anteversion to avoid posterior impingement and anterior dislocation in fused hips with posterior pelvic tilt. Functional outcome significantly improves in these stiff hips. Risks with THA in AS includes intraoperative fractures (4.3%), dislocation (1.9% to 2.9 %), HO (13%), along with other factors including re-ankylosis (6%) and aseptic loosening (14%).

Stiff hips with spine stiffness in AS warrant THA with knowledge of spinopelvic mobility and overall risks to improve long-term functional outcomes.

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ORIGINAL ARTICLE

Basic Study

Assessing the accuracy of arthroscopic and open measurements of the size of rotator cuff tears: A simulation-based study

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Author contributions: Kitridis D wrote the manuscript and conducted the statistical analysis; Alaseirlis D designed and coordinated the study; Malliaropoulos N interpreted the data; Chalidis B conducted the literature search; McMahon P and Debski R performed the experiments, acquired and analyzed data; Givissis P supervised the paper; all authors read and approved the final manuscript.

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Abstract

BACKGROUND

Arthroscopic procedures are commonly performed for rotator cuff pathology. Repair of rotator cuff tears is a commonly performed procedure. The intraoperative evaluation of the tear size and pattern contributes to the choice and completion of the technique and the prognosis of the repair.

AIM

To compare the arthroscopic and open measurements with the real dimensions of three different patterns of simulated rotator cuff tears of known size using a plastic shoulder model.

METHODS

We created three sizes and patterns of simulated supraspinatus tears on a plastic shoulder model (small and large U-shaped, oval-shaped). Six orthopaedic surgeons with three levels of experience measured the dimensions of the tears arthroscopically, using a 5 mm probe, repeating the procedure three times, and then using a ruler (open technique). Arthroscopic, open and computerized measurements were compared.

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Specialty type: Orthopedics

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Grade B (Very good): 0
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Grade D (Fair): 0
Grade E (Poor): 0

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RESULTS

A constant underestimation of specific dimensions of the tears was found when measured with an arthroscope, compared to both the open and computerized measurements (mean differences up to -7.5 ± 5.8 mm, $P < 0.001$). No differences were observed between the open and computerized measurements (mean difference -0.4 ± 1.6 mm). The accuracy of arthroscopic and open measurements was 90.5% and 98.5%, respectively. When comparing between levels of experience, senior residents reported smaller tear dimensions when compared both to staff surgeons and fellows.

CONCLUSION

This study suggests that arthroscopic measurements of full-thickness rotator cuff tears constantly underestimate the dimensions of the tears. Development of more precise arthroscopic techniques or tools for the evaluation of the size and type of rotator cuff tears are necessary.

Key Words: Shoulder; Arthroscopy; Simulation model; Rotator cuff tear; Supraspinatus tear; Cuff tear size

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Core Tip: The intraoperative evaluation of the rotator cuff tear size and pattern contributes to the choice of the technique and the prognosis of the repair. The purpose of the study was to determine the accuracy of arthroscopic measurement of the tears' size comparing them with the open technique. A constant underestimation of specific dimensions of the tears was found when measured with an arthroscopic probe compared to the open measurements.

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INTRODUCTION

Rotator cuff (RC) tears are the most common tendon injury in adults, often resulting in debilitating symptoms related to both daily and sports activities[1-3]. After the failure of conservative regimens, these patients are usually treated with surgical repair of the tear[1]. Arthroscopy is the preferred surgical option for rotator cuff repair, giving a better intraoperative evaluation of the dynamic shoulder anatomy, preserves the muscle integrity, is associated with lower postoperative morbidity, and provides equal or better results compared to open techniques[4,5].

Repair techniques are based on many factors including patient characteristics, muscle quality, mobility of the tendons, and intraoperative evaluation of the size of the tear[4,6-9]. Therefore, accurate intraoperative measurement of the size of the rotator cuff tear is crucial. Especially in certain techniques such as superior capsule reconstruction, precise measurements of the tears' dimensions are crucial for the correct sizing of the graft[10-12]. Previous studies have compared magnetic resonance imaging (MRI) measurements with arthroscopic evaluation, and focused on the MRIs ability to detect shoulder pathology in general, and not on the arthroscopic accuracy to evaluate the dimensions of different types of rotator cuff tears[13-15].

Our purpose was to compare the arthroscopic and open measurements with the real dimensions of three different patterns of simulated rotator cuff tears of known size using a plastic shoulder model. We utilized surgeons of three different levels of experience and compared the accuracy between them. The hypothesis of our study was that the size of a rotator cuff tear can be estimated accurately and equally with both arthroscopic and open techniques. To our knowledge, there is currently no research implementing this study design.

MATERIALS AND METHODS

The study took place at the Musculoskeletal Research Center in Pittsburgh, PA, USA. A plastic shoulder model (ALEX shoulder model, Sawbones Inc, Vashon, WA, Figure 1), a 30-degree arthroscope (Linvatec, Largo, FL) through the posterior portal, and a high-definition video system were utilized. Three sizes and patterns of full-thickness rotator cuff tears (a small U-shaped, a larger U-shaped, and a crescent-type, Figure 2) were created using computer software. Dimensions close to the cut-off point of medium and large tears (3 cm) were chosen, according to the DeOrio and Cofield classification system (Table 1)[16]. The simulated tear patterns were printed on paper with adhesive backing and placed in the location of the soft tissue element of the model simulating the supraspinatus tears location. The simulated tears with these computerized measurements had a precision of 0.1 mm.

Six orthopaedic surgeons were enrolled in the study and they were blinded to the computerized measurements: two senior residents with fellowship training, two fellows and two senior staff surgeons, all of the Sports Injuries and Shoulder Surgery Department. We asked them to measure the dimensions of the tears arthroscopically, repeating the procedure three times at weekly intervals. Viewing was from the lateral portal and measuring from the lateral portal, constantly. We used a probe calibrated in 5mm intervals and with a 5 mm tip, reflecting the usual practice. During all arthroscopic measurements, the shoulder model was completely covered, so the observers could not have direct vision of the simulated tears (Figure 1B). When all arthroscopic measurements were completed, the shoulder model was uncovered and the plastic cover was also removed. Each surgeon used a surgical ruler for a single measurement to simulate the open technique.

Statistical analysis

The mean differences between the arthroscopic measurements of the tears compared to the open and computerized measurements were calculated. Comparisons between the overall mean differences between the groups in pairs, using Wilcoxon signed ranks test, with $P < 0.016$ as the level of significance using the Bonferroni correction were then performed.

Subsequently, the subgroups of the separate dimensions' measurements were evaluated, using Wilcoxon signed ranks test, with $P < 0.05$ as the level of significance. Finally, the measurements between the surgeons with the different levels of experience were compared using Wilcoxon signed ranks test, with $P < 0.016$ as the level of significance using the Bonferroni correction.

The mean value of the three consecutive arthroscopic measurements were used for the analyses that was then performed with the Statistical Package for Social Sciences (SPSS, IBM) software version 24.

RESULTS

Arthroscopic vs computerized measurements

A statistically significant underestimation of the dimensions of the tears when measured arthroscopically was observed ($P < 0.001$) (Table 2). The largest mean differences of the separate measurements were -7.6 ± 5.8 mm in the contour length of the small U-shape tear, -4.5 ± 3.1 mm in the anterior to posterior height of the crescent-type tear, and -3.1 ± 3.1 mm in the contour length of the large U-shaped tear (Table 3). All mean differences were negative (Table 3), showing the constant underestimation of the dimensions. The accuracy of the arthroscopic measurements was 90.5%.

Arthroscopic vs open measurements

The overall mean difference between arthroscopic and open measurements confirmed the trend of underestimation of the dimensions, when measured arthroscopically ($P < 0.001$) (Table 2). The differences between separate measurements were all negative, and some of them were statistically significant (Table 3).

Open vs computerized measurements

The overall mean difference between open and computerized differences was smaller than between arthroscopic and computerized; -0.4 ± 1.6 mm *vs* -2.4 ± 3.2 mm. The difference was statistically significant for the corrected level of significance between the groups ($P < 0.016$), but we considered the mean value of 0.4 mm clinically insigni-

Table 1 The dimensions of the simulated tears measured by the surgeons (Layouts in Figure 2)

ID	Description	Standardized technique	Computerized dimensions (mm)
A1	Basis length	Anterior to posterior	15.2
A2	Contour length	Anterior to posterior	53.5
A3	Height	Medial to lateral, most distal length	22.9
B1	Basis length	Anterior to posterior	20.3
B2	Contour length	Anterior to posterior	31.9
B3	Height	Medial to lateral, most distal length	10.2
C1	Medial contour length	Upper in Figure 2	31.9
C2	Lateral contour length	Lower in Figure 2	31.6
C3	Medial to lateral height	Short height in Figure 2	7.6
C4	Anterior to posterior height	Long height in Figure 2	31.0

Table 2 Overall mean difference between the groups of measurements

Groups	mean difference, mm	*P*[1] value
Arthroscopic *vs* computerized	-2.4 ± 3.2	< 0.001
Arthroscopic *vs* open	-2 ± 2.6	< 0.001
Open *vs* computerized	-0.4 ± 1.6	0.014

[1]Wilcoxon signed ranks test, level of significance $P = 0.016$ (Bonferroni correction).

Table 3 Comparison of mean differences between arthroscopic versus computerized, and arthroscopic and open measurements in millimeters (mean ± SD)

Dimension	Arthroscopic *vs* computerized	*P*[1] value	Arthroscopic *vs* open	*P*[1] value
A1	-0.5 ± 1.2	0.92	-0.3 ± 1.2	0.92
A2	-7.6 ± 5.8	0.03	-3.7 ± 4.9	0.12
A3	-2.1 ± 2.7	0.17	-2.0 ± 2.5	0.14
B1	-2.3 ± 1.9	0.03	-1.9 ± 1.9	0.04
B2	-3.1 ± 3.1	0.12	-3.2 ± 2.3	0.04
B3	-0.7 ± 0.8	0.05	-0.5 ± 0.8	0.20
C1	-1.8 ± 1.6	0.05	-2.5 ± 2.4	0.05
C2	-1.8 ± 1.8	0.05	-2.8 ± 2.1	0.03
C3	-0.1 ± 0.5	0.91	-0.3 ± 0.4	0.18
C4	-4.5 ± 3.1	0.03	-3.1 ± 3.5	0.06

[1]Wilcoxon Signed Ranks Test, level of significance $P = 0.05$.

ficant for the surgical decision-making. The accuracy of the open measurements was 98.5%.

Precision between surgeons with different levels of experience

No significant differences were observed between the senior staff surgeons and the fellows ($P = 0.07$). On the contrary, the senior residents reported smaller tear dimensions when compared both to the staff surgeons and the fellows ($P < 0.001$ for both comparisons). Measurements with the open technique were precise among all surgeons ($P = 0.96$), showing excellent inter-observer reliability.

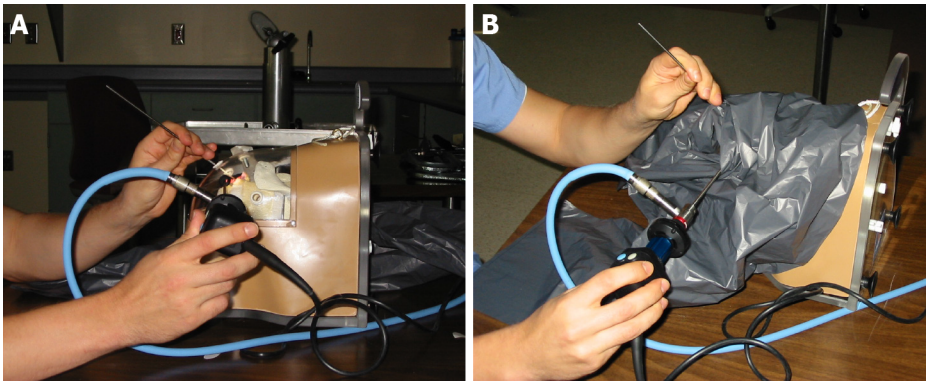


Figure 1 The ALEX plastic shoulder model. A: The model used for the procedures; B: The shoulder model covered for obstructing direct vision.

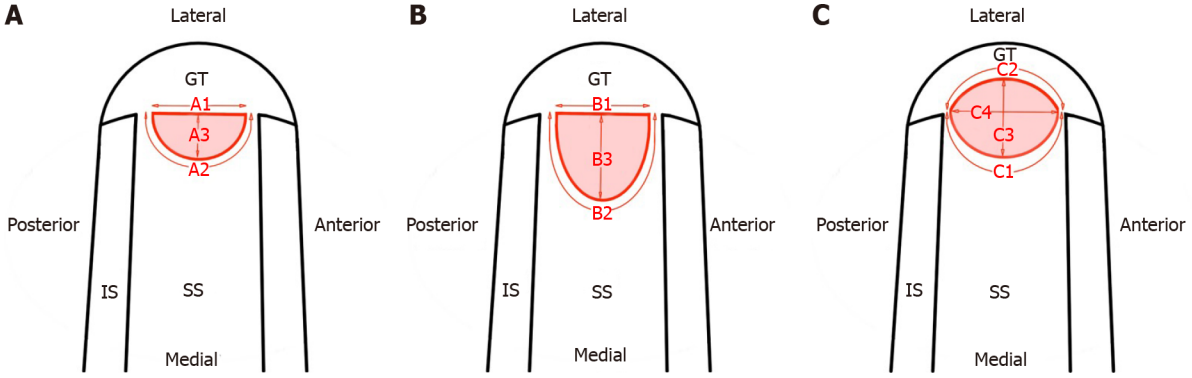


Figure 2 Three pattern of supraspinatus tears were created using computer software and were printed on paper with adhesive backing. A: Small U-shaped; B: Larger U-shaped; C: Crescent-type. The dimensions of the tears are reported in Table 1. GT: Greater tuberosity; IS: Infraspinatus; SS: Supraspinatus.

DISCUSSION

Surgeons of three different levels of experience were found to constantly underestimate given dimensions of simulated rotator cuff tears with the arthroscopic technique. We utilized three common patterns of rotator tears (a small U-shaped, a larger U-shaped, and a crescent-type). We observed a constant underestimation of the dimensions of the tears when measured with a standard 5 mm probe arthroscopically.

We observed mean differences up to 7.5 mm when comparing the separate measurements of the tears' dimensions compared to the computerized measurements. The accuracy of the arthroscopic and open measurements was 90.5% and 98.5%, respectively. When comparing the different levels of experience, the senior residents reported smaller tear dimensions when compared both to the staff surgeons and the fellows. It seems that more experienced surgeons tend to be more accurate, although the underestimation is constant to all levels of experience, implicating that the instrumentation used is not suitable for precise measurements. Measurements with an open technique were both accurate and precise.

There are numerous studies considering the intraoperative evaluation of the size of the tear as a factor influencing the choice of the most indicated repair technique and the outcomes of the repair. Park *et al*[4] reported that large-to-massive tears (> 3 cm) repaired with double-row fixation had significantly improved outcomes in terms of functional outcomes in comparison with those repaired with single-row fixation. Duquin *et al*[7] analyzed data from 23 studies and found re-tearrates significantly lower for double-row repairs when compared with single-row, especially for tears greater than 5 cm. A summary of meta-analyses reported that six meta-analyses found double row repair to be superior for tears greater than 3 cm, and recent studies also report that larger tears size increases re-tear risk[9,17-19]. Of course, several other factors influence the surgeon's decision-making of the appropriate surgical technique, including patient characteristics, muscle quality, and mobility of the tendons, as mentioned before[4,6-9]. However, recent research has shown that the rotator cuff tear size at the time of surgery significantly affects supraspinatus integrity in the long-term,

thus greatly influences the prognosis of clinical and functional outcomes and patient satisfaction[20]. Moreover, in certain techniques such as superior capsule reconstruction for irreparable rotator cuff tears or reinforcement of cuff repair, precise measurements of the tears' dimensions are crucial for the technique per se[10,11].

In the current study, we observed a constant underestimation of the tears' dimensions with mean differences up to 7.5 mm, when measured arthroscopically. These differences could lead to inappropriate selection of procedures during surgery and affect the patients' outcomes and prognosis. Our results agree with Bryant *et al* [21], who reported arthroscopic measurements to have a 12% underestimation of the tear size compared to measurements with an open technique.

Previous studies have compared MRI measurements with the arthroscopic evaluation of rotator cuff tears and reported high sensitivity and specificity both for full and partial thickness tears[13,14]. However, Bryant *et al*[21] reported magnetic resonance imaging to underestimate the size of rotator cuff tears by 30%. Additionally, Eren *et al*[14] found significantly larger measurements during surgery when compared with MRI.

In our study, arthroscopic and open techniques were compared but the accuracy and precision were also determined. Combined with the three different levels of experience of the surgeons and the common clinical use of the 5 mm probe, our procedure is very close to daily routine surgical practice.

Limitations of the study

We used a relatively small sample size. The rationale for the sample selection was that separate measurements for ten specific tear dimensions provided a total of sixty observations in each group (arthroscopic, open, and computerized measurements), which were enough to draw conclusions. Secondly, the measurements were conducted in a plastic simulation shoulder model and not in real patients so that comparisons could be made to computerized measurements.

CONCLUSION

This study suggests that arthroscopic measurements of full-thickness rotator cuff tears constantly underestimate the dimensions of the tears. This underestimation, especially of specific dimensions (contour length of the small U-shape tear, anterior to posterior height of the crescent-type tear, and contour length of the large U-shaped tear), could lead to false documentation during surgery, unreliable prognostic suggestions, and even postoperative failures. Measurements with an open technique were accurate and precise. These observations raise the need for the development of better arthroscopic tools and techniques for the evaluation of the size of the rotator cuff tears.

ARTICLE HIGHLIGHTS

Research background

Arthroscopic procedures are commonly performed for rotator cuff pathology. The intraoperative evaluation of the tear size and pattern contributes to the choice and completion of the technique and the prognosis of the repair.

Research motivation

The accuracy of common arthroscopic instruments to evaluate the dimensions of different types of rotator cuff tears is not yet evaluated.

Research objectives

The purpose of the current study was to compare the arthroscopic and open measurements with the real dimensions of three different patterns of simulated rotator cuff tears of known size using a plastic shoulder model.

Research methods

Three sizes and patterns of simulated supraspinatus tears on a plastic shoulder model (small and large U-shaped, oval-shaped) were created. Six orthopaedic surgeons with three levels of experience measured the dimensions of the tears arthroscopically, using a 5 mm probe, repeating the procedure three times, and then using a ruler (open

technique). Arthroscopic, open and computerized measurements were compared.

Research results

A constant underestimation of specific dimensions of the tears was found when measured with an arthroscope, compared to both the open and computerized measurements. No differences were observed between the open and computerized measurements. The accuracy of arthroscopic and open measurements was 90.5% and 98.5%, respectively. When comparing between levels of experience, senior residents reported smaller tear dimensions when compared both to staff surgeons and fellows.

Research conclusions

This study suggests that arthroscopic measurements of full-thickness rotator cuff tears constantly underestimate the dimensions of the tears. This underestimation could lead to false documentation during surgery, unreliable prognostic suggestions, and even postoperative failures.

Research perspectives

Development of more precise arthroscopic techniques or tools for the evaluation of the size and type of rotator cuff tears are necessary.

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ORIGINAL ARTICLE

Case Control Study

Role of biomechanical assessment in rotator cuff tear repair: Arthroscopic *vs* mini-open approach

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Abstract

BACKGROUND

Rotator cuff (RC) tears are one of the most frequent pathologies within the shoulder girdle. Hand dominance and older age are associated with RC tears. Two different surgical procedures, the mini-open (MO) and all-arthroscopic (AA) approach, represented the standard of treatment.

AIM

To compare the clinical and biomechanical outcomes of two surgical techniques (AA *vs* MO procedure) performed to address the painful shoulder syndrome with partial or total supraspinatus tendon tear.

METHODS

Eighty-eight participants, 50 following RC repair with AA and 38 with MO approach, were recruited in the present cross-sectional case-control study (ORTHO-SHOULDER, Prot. 0054602). All patients underwent postoperative clinical evaluation for pain (Visual analogic scale), impairment, and disability (disability of the arm, shoulder, and hand) and limitation in daily activity (Constant-Murley score). Patients' shoulder mobility was also assessed in our

statement: The study was approved by the Local Ethical Committee (ORTHO-SHOULDER, n. 6480, Prot. n. 0054602).

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Laboratory of Functional Movement through a wearable inertial sensor and surface electromyography to monitor kinematics and muscle activity during the movement on the frontal (abduction/adduction) and sagittal (flexion-extension) planes.

RESULTS

No statistically significant differences between the two procedures were observed in either main clinical score or range of motion. A significant increase in velocity during the movement execution and a higher contribution of upper trapezius muscles were found in the AA group compared with MO patients.

CONCLUSION

In terms of clinical scores, our findings were in line with previous results. However, the use of technology-based assessment of shoulder mobility has revealed significant differences between the two techniques in terms of mean velocity and pattern of muscle activation.

Key Words: Rotator cuff tear; Arthroscopic; Mini-open; Wearable sensors; Surface electromyography

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Core Tip: Wearable technologies could be useful in clinical practice since they could provide clinical information during the performance of a motor task. The present work represents a preliminary attempt in making use of novel wearable technologies in common clinical practice.

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INTRODUCTION

An important group of the population suffers from shoulder pain due to acute or chronic tendon injuries. It is becoming a considerable cause of work disability. Rotator cuff tendinopathy and tears (RCTs) are the most common lesions. After the supraspinatus tendon, the most common injured structure of the rotator cuff (RC) complex, the biceps tendon is the second most commonly injured structure, as it is an element of compensation of the abnormal forces. Biceps' tears predispose the patient's rotator cuff to subsequent instability and further subscapularis tendon tears. Multi-tendon shoulder injuries, moreover, complicate the process of diagnosis, treatment, and rehabilitation[1,2]. The overall prevalence of RC abnormalities, regardless of symptoms, ranged from 9.7% in patients younger than or equal to 20 years and increased to 62% in patients aged 80 years and older ($P < 0.001$)[3]. Many RCTs also cause restriction of shoulder function. Surgical repair of the RC is a cost-effective solution for all populations and reduces the societal burden of the disease. The choice of surgery varies from surgeon-to-surgeon with arthroscopy more common at the present time. Mini-open (MO) technique has represented the gold standard for years, with a 90% success rate[4], since it guaranteed stronger suture fixation and a shorter learning curve[5]. However, the development of dedicated surgical instruments and improvement of the surgical technique have allowed surgeons to perform all-arthroscopic (AA) techniques in rotator cuff repair surgery[6]. The ideal repair of the RC tear must have the potential to withstand physiological loads while allowing simultaneous healing to occur. Currently, no significant superiority of one procedure has been demonstrated over the other[3,7,8], although RCTs in evaluating short- and long-term outcomes of both approaches are limited[9]. Recently, Liu and colleagues performed a RCT in 50 patients who had undergone AA repair and 50 patients who had undergone

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MO repair with a minimum 1-year follow-up. They concluded that the AA procedure has better recovery at short-term follow-ups, while both techniques are equivalent regarding long-term outcomes[10].

Motion analysis techniques can provide a more thorough description of 3-dimensional kinematics and offer a noninvasive, dynamic, quantitative alternative to radiographic methods. Motion analysis has been widely used to assess the motor abilities of people with neurological and musculoskeletal impairments[11]. To our knowledge, there is limited study regarding what biomechanical effect RTC tears have on different motion tasks and muscle activities after surgical treatment of RC tears. In 2007, Pearsall *et al*[12] prospectively evaluated patients who underwent a "mini-open" repair *vs* a completely arthroscopic technique for small to large size rotator cuff tears. They found no statistical difference in outcome between the two groups, indicating that either procedure was efficacious. In 2017, Fritz *et al*[13] applied a quantitative, validated upper extremity model to assess the kinematics and muscle activity of the shoulder following repair of the supraspinatus RC tendon compared to that in healthy shoulders in different activities of daily living (ADLs). They found that the RC repair group participants could accomplish the ADLs within the same time frame and through thoracolumbar joint kinematics, similar to those in the healthy shoulder group participants.

Wearable sensors are acquiring more and more influence in the diagnostic and rehabilitation field to assess the motor abilities of aging populations[14]. In a recent systematic literature review, Carnevale *et al*[15] analyzed the wearable systems for monitoring shoulder kinematics and their applicability in clinical settings and rehabilitation. However, to date, no studies have been carried out with wearable technologies in the assessment of quantitative functional recovery of RC tear healing. The present paper aims at comparing the clinical and biomechanical outcomes of two surgical techniques (AA *vs* MO procedure) to address the painful shoulder syndrome with partial or total supraspinatus tendon tear.

MATERIALS AND METHODS

Study population and design

A total of 88 participants, 50 following RC repair with AA and 38 with MO, were recruited for this study. Each participant provided written informed consent to participate in the study approved by the Local Ethical Committee (ORTHO-SHOULDER, n. 6480, Prot. n. 0054602).

Inclusion criteria were: (1) Aged between 40-years-old and 70-years-old; (2) absence of shoulder pathology in the contralateral side; and (3) surgical procedure between January 2018 and October 2019. Exclusion criteria were: (1) Neurological impairments; (2) other pathological conditions that limited shoulder stability; and (3) previous surgical procedures on the ipsilateral side.

Surgical treatments

The surgeries were performed by single senior shoulder surgeons experienced in both the AA and MO repair techniques. In the case of arthroscopic surgery, the patient is positioned in lateral decubitus with the affected upper limb maintained by dedicated support. The arthroscope was placed in the subacromial space through a standard posterior portal; lateral and posterolateral accessory portals were subsequently established. The tear was adequately mobilized and repaired by attaching the supraspinatus to the prepared greater tuberosity using the single-row repair technique with a suture anchor. The procedure usually starts with the evaluation of the shoulder using the SCOI 15 points exam. The number of anchors and sutures used depended on the tear size and pattern. In the case of mini-open surgery, the patient is positioned in a beach chair position. The approach begins with a 5-cm lateral incision at the anterior border of the acromion. The fibers of the deltoid muscle are split by blunt dissection, and maximal visualization was established using a soft tissue retractor. It is very important not to damage the axillary nerve running close to the distal edge of the incision and to minimize detachment of deltoid muscle fibers from the lateral part of the acromion. A partial bursectomy is performed using dissection scissors. The rest of the procedure is basically the same for both techniques[10]. Both groups used the same rehabilitation protocol.

Follow-up procedures

Each participant underwent concurrent, synchronized motion and electromyography (EMG) analysis. Postoperative outcome measurements were collected by two medical doctors and a bioengineer.

The primary outcome measures were the Constant-Murley score (CMS), the visual analogue scale (VAS) and, the disability of the arm, shoulder, and hand (DASH) score [16,17]. Secondary outcome measures were the biomechanical parameters in terms of the Range of Motion (ROM), quality of movement (velocity and acceleration), and muscle activation.

Biomechanical assessment

Kinematics and EMG data of patients were collected in our Laboratory of Functional Movement through the "Shoulder mobility" protocol. Tasks were explained clearly. The beginning and the end were signaled orally by the researcher to all participants. They were told to perform the movements to the highest position they could reach their preferred speed. They were placed standing in a neutral position to perform shoulder abduction in the coronal plane and shoulder flexion in the sagittal plane. They were told to perform both tasks with the elbow extended, the wrist in a neutral position, and the palm of the hand toward the midline at the beginning and end of the movement. They performed two series of five repetitions of both tasks, with a break of about 3 min between each series.

Upper arm active movements were detected with a wireless inertial sensor (BTS G-Sensor, BTS SpA, Milano, Italy), positioned on the arm aligned with the humerus at the level of the lateral epicondyle. The sensor, which communicates with the receiving unit (personal computer) *via* a Bluetooth link, was used for kinematic information, and BTS EMG-Analyzer software was used for data recording, processing, reporting, and storage. The same software also integrated data from four surface EMG [sEMG, BTS FREEEMG 1000 (BTS SpA, Milano, Italy)] attached to selected muscles according to SENIAM recommendations[18]. Muscle activity was assessed in the injured upper limb muscles (Biceps Brachialis Caput Longus, Upper Trapezius, Deltoid Anterior, Infraspinatus). To detect signals, adhesive Ag/AgCl electrodes (Kendall™ ECG Electrodes H124SG) with an effective diameter of 10 mm and an inter-electrode distance of 20 mm (center to center) were used. Proprietary algorithms fuse sensor data at 200 Hz. After positioning electrodes, patients were instructed to execute the two movements at their natural pace with the inertial sensor synchronized with EMG to identify the different cycles and phases of respectively abduction/adduction and flexion/extension.

ROM (°), acceleration (m/s^2), and velocity (v, m/s) were extracted for each cycle in both forward and return direction from the inertial sensor, in the same way muscle activity has been quantified as root mean square (RMS, uV) and percentage of activation with respect to the peak dynamic value of the cycle (%) for each cycle in both directions.

Statistical analysis

SPSS v23.0 was used for all statistical computations. A P value of ≤ 0.05 was considered statistically significant. Descriptive statistics (mean ± SD) were calculated for age, height, weight, and body mass index (BMI). Standard procedures were used to calculate means and SDs. The Kolmogorov–Smirnov test showed a normal distribution of the data ($P > 0.05$). Independent t-tests have been used to compare the two surgical treatments (arthroscopic *vs* mini-open), while the mixed ANOVA test has been performed to understand if there is an interaction between the two treatments (between factor, arthroscopic *vs* mini-open) on the response of different muscles (within factor) for the selected body plane.

The Pearson χ^2 test was used for between-group comparisons. The Fisher exact test was used for group comparisons when appropriate. Correlation between clinical and self-reported outcomes and biomechanical variables was calculated by Pearson's correlation (r) and P value.

RESULTS

Socio-demographic characteristics of the study sample were shown in Table 1. Eighty-eight patients were finally enrolled in the study [female = 37 (42.1%), mean age = 59.3-years-old] with mean follow-up of 13 mo. Fifty-one patients presented a RC injury on the right side. Fifty patients underwent arthroscopic repair [female = 20 (40%), mean

Table 1 Characteristics of the sample (*n* = 88)

Characteristics	mean ± SD
Age (yr)	59.27 ± 8.94
BMI (kg/m^2)	28.06 ± 4.58
Gender (Female), *n* (%)	37 (42.05)
Affected Side (Right), *n* (%)	51 (57.95)
Surgical treatment, *n* (%)	
AA	50 (56.8)
MO	38 (43.2)
Follow up (mo)	13.62 ± 5.08
VAS	3.16 ± 2.7
CMS	69.5 ± 14.41
DASH	23.01 ± 21.07
SF-12, *n* (%)	
Physical	43.31 (9.53)
Mental	46.53 (11.88)

AA: All-arthroscopic approach; BMI: Body mass index; CMS: Constant-Murley score; DASH: Disability of the Arm, shoulder, and hand; MO: Mini-open approach; SD: Standard deviation; SF-12: The 12-item short form survey; VAS: Visual analogic scale.

age = 58.5-years-old] and 38 underwent repair with a mini-open incision [female = 14 (36.8%), mean age = 60.3-years-old]. At the time of the examination, almost all the patients reported low pain scores and good health status. No differences emerged between groups in terms of demographic features (age, gender, BMI, and affected side).

Table 2 summarized the main results in terms of comparisons of clinical, self-reported, and biomechanical outcomes between the two surgical procedures. Clinical scores (CMS, DASH, and VAS) did not differ significantly between groups as either self-reported health status ($P > 0.05$).

A strong inverse correlation has been found among the two clinical scores of shoulder abilities ($r = -0.63$, $P < 0.01$): lower level of pain and improved ability to carry out the normal daily activities of the patient (increasing CMS scores) were associated with a lower level of shoulder impairment (decreasing DASH scores). Furthermore, only the DASH score was positively related to pain level (VAS, $r = 0.68$) and both physical and mental components of SF-12, indicating that lower levels of shoulder impairment were associated with lower pain and better health status.

Significant differences emerged in terms of mean activation of the upper trapezius muscle in both abduction and flexion movements. In the AA group, the trapezius muscle was more active than the MO group during both the forward and return phase of both abduction and flexion movements, thus indicating a significant contribution of this muscle in joint mobility and stability.

However, no significant differences were found between groups in the post-operative range of motion either in sagittal (abduction, $P = 0.41$) or frontal planes (flexion-extension, $P = 0.34$). Moreover, we observed a significant difference between groups in the average velocity required to complete the flexion movement either in the forward or return phase. Patients who were treated with the MO surgery reported significantly lower velocity in the execution of the movement than patients in the AA group. A possible explanation may be found in the different contributions of observed muscles' recruitment during the movement: in the AA group, the deltoid anterior and upper trapezius showed a high percentage of mean activation, while in the MO group, the deltoid anterior contributed more than fifty percent of the overall activation.

An overview of the mean contribution of each recorded muscle during the movement is shown in Figure 1. The results of mixed ANOVA revealed that significant interactions were present between the adopted surgical procedure and the contribution of muscles (%) in both abduction ($F_{1.618} = 3.707$, $P = 0.05$) and flexion ($F_{2.035} = 8.732$, $P < 0.01$) movements. In the abduction movement, the activation of the deltoid

Table 2 Clinical, self-reported health and biomechanical outcomes according to the surgical treatment

	AA (*n* = 50)	MO (*n* = 38)	*P* value
Clinical score			
VAS	3 (2.62)	3.37 (2.97)	0.78
CONSTANT	65 (10.32)	75.12 (17.38)	0.14
DASH	24.12 (20.59)	21.63 (23)	0.81
Self-reported health measures			
$SF\text{-}12_{PH}$	43.17 (9.41)	43.5 (10.34)	0.94
$SF\text{-}12_{ME}$	48.86 (9.86)	43.63 (14.16)	0.37
Biomechanical tests			
ROM_{ABD}	110.88 (21.9)	120.76 (27.91)	0.41
$RMS_{ABD,F,TRAP}$	125.78 (77.49)	54.52 (58.25)	0.05[1]
$RMS_{ABD,R,TRAP}$	59.5 (30.42)	28.34 (26.39)	0.04[1]
$PERC_{ABD,BBCL}$	8.23 (2.64)	19.23 (12.15)	0.04[1]
$PERC_{ABD,TRAP}$	35.99 (14.39)	19.57 (15.97)	0.04[1]
ROM_{FLEX}	127.95 (25.55)	141.75 (33.51)	0.34
$VEL_{FLEX,F}$	73.97 (31.74)	46.26 (16.04)	0.03[1]
$VEL_{FLEX,R}$	88.65 (30.9)	56.13 (23.72)	0.03[1]
$RMS_{FLEX,F,TRAP}$	91.19 (49.57)	41.35 (45.43)	0.04[1]
$RMS_{FLEX,R,TRAP}$	47.15 (24.04)	22.99 (19.58)	0.04[1]
$PERC_{FLEX,DLTA}$	43.18 (6.9)	58.65 (9.6)	< 0.01[1]
$PERC_{FLEX,TRAP}$	29.97 (11.21)	14.2 (9.04)	< 0.01[1]

[1]Significant differences. ABD: Abduction; F: Forward; R: Return; BBCL: Biceps brachialis caput longus; CMS: Constant-Murley score; DASH: Disability of the arm, shoulder, and hand; DLTA: Deltoid anterior; ME: Mental components; PERC: Peak dynamic value of the cycle; PH: Physical component; RMS: Root mean square; ROM: Range of motion; SF-12: The 12-item short form survey; TRAP: Upper trapezius; VAS: Visual analogic scale; VEL: Velocity; FLEX: Flexion.

anterior was significantly higher than other muscles while the contribution of upper trapezius and infraspinatus muscles did not show any difference between each other. Similar results were found in the flexion movement, where the percentage activation of the deltoid anterior was significantly higher than other contributions.

DISCUSSION

Rotator cuff tears are the most common shoulder injury. Treatment options include nonoperative management, arthroscopic debridement with a biceps tenotomy, or tenodesis, partial repair, complete repair, muscle-tendon transfer, superior capsular reconstruction, patch augmentation, and reverse total shoulder arthroplasty[19]. The treatment can be performed with two different approaches: Mini-open (MO) or all-arthroscopic (AA) technique. The ideal repair of the RC tear should withstand the physiological loads while allowing simultaneous tendon healing to occur. Recently, Liu *et al*[10] performed an RCT in 50 patients who had undergone AA repair and 50 patients who had undergone MO repair with a minimum 1-year follow-up. They concluded that the AA procedure has better recovery at short-term follow-ups, while both techniques are equivalent regarding long-term outcomes. Although there is still an open debate on the superiority of surgical treatment over the other[20,21], few attempts have been made in promoting the use of motion capture technologies to analyze kinematics and muscle activity of shoulder mobility in the postoperative phase, especially with the advancing in wearable devices.

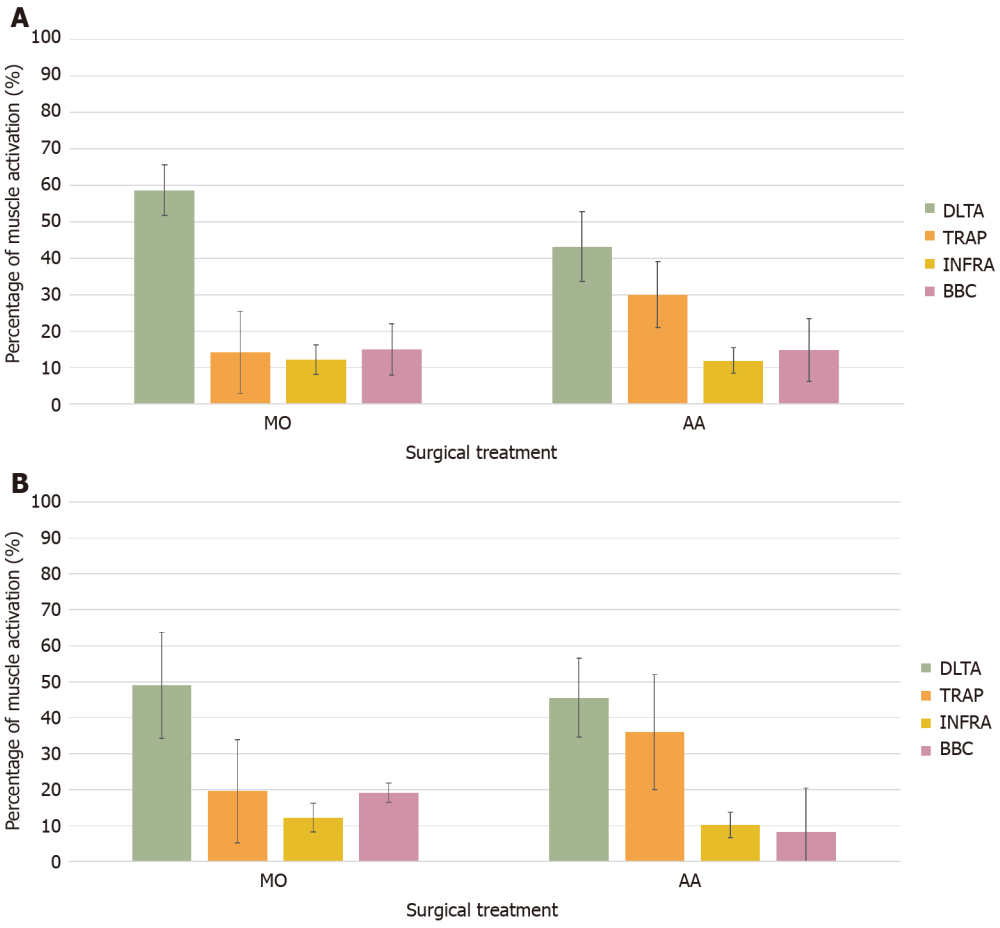


Figure 1 Bar plots of the percentage of activation of all selected muscle. A: During flexion/extension movements for the two surgical treatments; B: During abduction/adduction movements for the two surgical treatments. AA: All-arthroscopic approach; BBC: Biceps brachialis caput longus; DLTA: Deltoid anterior; INFRA: Infraspinatus; MO: Mini-open approach; TRAP: Upper trapezius.

The present cross-sectional study enrolled a sample of patients who had undergone AA/MO repair with a minimum 1-year follow-up. Patients were then evaluated using both clinical and biomechanical tests to assess whether there were relevant effects of the surgical treatment on the selected outcomes.

Our findings reported no statistically significant difference in terms of clinical scores and joint excursions after RC repair, in line with what emerged from previous studies [10,12,21]. However, significant differences emerged in terms of other kinematic factors and muscle activation. Patients treated with the MO surgery reported significantly lower velocities in the execution of the movement compared with the AA group. The upper trapezius muscle in the AA group showed higher mean activation (RMS) than the MO group during both the forward and return phases of both abduction and flexion movements. Furthermore, in the AA group, deltoid anterior and upper trapezius showed a higher percentage of mean activation, while in the MO group deltoid anterior contributed more than fifty percent of the overall activation.

While different normalization processes and range of movement prevent direct comparison with the current study, previous EMG research during coronal plane abduction indicates that high contraction intensities throughout the abduction movement in healthy subjects were seen for glenohumeral and scapulothoracic prime movers such as anterior and middle deltoid, supraspinatus, serratus anterior, rhomboids, and upper, middle, and lower trapezius[22].

Rehabilitation probably plays a role in the increased ROM and muscular strength, due to the position and kinematics of the scapula. They can influence patient symptoms. Consequently, motivation and cooperation during the rehabilitation process can influence the results[23].

Previous investigations on the role of shoulder muscles in flexion and abduction movements have been carried out mostly in healthy subjects[24,25] showing that deltoids were the largest muscle contributor to humeral elevation during flexion tasks, while trapezius and serratus anterior combined to do more work than deltoids for every task including flexion.

CONCLUSION

Wearable technologies could support clinical practice since they provide clinical information during the performance of a motor task, and their adoption should grow in shoulder evaluation and therapy. The present work represents a preliminary attempt at promoting novel wearable technologies in clinical practice. We compared the postoperative effects of two surgical treatments through clinical scores, standardized protocol, and wearable sensors. Our findings were almost in line with previous investigations regarding clinical scores. However, our analysis highlighted a different response in muscle activation during the shoulder movement in both flexion/extension and abduction/adduction. A significant interaction effect emerged for mean activation of deltoid anterior and upper trapezius with surgical procedure, thus indicating that the adopted treatment influenced the functional recovery of the joint. Further studies with larger samples are needed to confirm our findings and open new scenarios in surgical planning and rehabilitation of shoulder instability.

ARTICLE HIGHLIGHTS

Research background

Rotator cuff (RC) tears are one of the most frequent pathologies within the shoulder girdle. Hand dominance and older age are associated with RC tears. Two different surgical procedures, the mini-open (MO) and all-arthroscopic (AA) approach represented the standard of treatment.

Research motivation

To understand if AA and MO procedures provide comparable clinical results in the repairment of RC tears.

Research objectives

The present paper aims at comparing the clinical and biomechanical outcomes of two surgical techniques (AA *vs* MO procedure) to address the painful shoulder syndrome with partial or total supraspinatus tendon tear.

Research methods

Eighty-eight participants, 50 following RC repair with AA and 38 with MO approach, were recruited in the present cross-sectional case-control study. All the patients underwent postoperative clinical evaluation for pain, impairment, and disability and limitation in daily activity.

Research results

No statistically significant differences between the two procedures were observed in either main clinical score or range of motion. A significant increase in velocity during the movement execution and a higher contribution of upper trapezius muscles were found in the AA group compared with MO patients.

Research conclusions

In terms of clinical scores, our findings were in line with previous results. However, the use of technology-based assessment of shoulder mobility has revealed significant differences between the two techniques in terms of mean velocity and scheme of muscle activation.

Research perspectives

Further studies with larger samples are needed to confirm such findings and open new scenarios in the surgical planning and the rehabilitation of shoulder instability.

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ORIGINAL ARTICLE

Retrospective Study

Rates of readmission and reoperation after operative management of midshaft clavicle fractures in adolescents

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Author contributions: Swarup I designed the research study; Carrillo LA, Chopra A, and Callahan M collected data and performed data analysis; Carrillo LA, Chopra A, and Wu HH prepared the manuscript; Katyal T, Wu HH, and Swarup I reviewed the final manuscript.

Institutional review board statement: This study is a database study using data obtained from the Healthcare Cost and Utilization Project (HCUP). Therefore, no IRB approval letter was required.

Informed consent statement: This retrospective study was IRB exempt and no signed consent forms were required.

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Abstract

BACKGROUND

The national rates of readmission and reoperation after open reduction internal fixation (ORIF) of midshaft clavicle fractures in adolescents is unknown.

AIM

To determine rates of and risk factors for readmission and reoperation after ORIF of midshaft clavicle fractures in adolescents.

METHODS

This retrospective study utilized data from the Healthcare Cost and Utilization Project State Inpatient Database for California and Florida and included 11728 patients 10–18 years of age that underwent ORIF of midshaft clavicle fracture between 2005 and 2012. Readmissions within ninety days, reoperations within two years, and differences in patient demographic factors were determined through descriptive, univariate, and multivariate analyses.

RESULTS

In total, 3.29% (n = 11) of patients were readmitted within 90 d to a hospital at an average of 18.91 ± 18 d after discharge, while 15.87% (n = 53) of patients underwent a reoperation within two years at an average of 209.53 ± 151 d since the index surgery. The most common reason for readmission was a postoperative infection (n < 10). Reasons for reoperation included implant removal (n = 49) at an average time of 202.39 ± 138 d after surgery, and revision ORIF (n < 10) with an average time of 297 ± 289 d after index surgery. The odds of reoperation were

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Grade C (Good): 0
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Grade E (Poor): 0

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higher for females ($P < 0.01$) and outpatients ($P < 0.01$), while the odds of reoperation were lower for patients who underwent surgery in California ($P = 0.02$).

CONCLUSION
There is a low rate of readmission and a high rate of reoperation after ORIF for midshaft clavicle fractures in adolescents. There are significant differences for reoperation based on patient sex, location, and hospital type.

Key Words: Adolescent; Clavicle fracture; Reoperation; Readmission

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Core Tip: There is a low rate of readmission and a high rate of reoperation after open reduction internal fixation for midshaft clavicle fractures in adolescents. There are significant differences for reoperation based on patient sex, location, and hospital type.

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INTRODUCTION

In the past decade, there has been a shift in the paradigm for the treatment of clavicle fractures[1]. In both adolescents and adults, the trend has been towards increasing rates of operative management[1-4]. In the pediatric population, demand for return to sport and year-round sporting activity have also made surgical management a more popular treatment option[3]. However, it is unclear if the literature supports the superiority of open reduction internal fixation (ORIF) to nonoperative management in the management of closed midshaft clavicle fractures in adolescents. Recent studies have shown improved outcomes with ORIF in skeletally mature patients[5-7]; however, studies in adolescent patients have shown no difference in functional outcomes[8,9]. Recent literature also suggests surgical complication rates ranging from 21%-86% with close to 50% of patients requiring a second surgery for implant removal [10-12]. To our knowledge, there are no studies that have examined the rates of readmission and reoperation after ORIF of midshaft clavicle fractures in adolescents.

The purpose of this paper is to determine the rates of 90-d readmission and two-year reoperation after surgical management of midshaft clavicle fractures in adolescents. We hypothesized that the rates of readmission and reoperation would be low after surgical management of clavicle fractures in adolescents.

MATERIALS AND METHODS

The Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (SID) was evaluated for the years 2005-2012. This database, sponsored by the Agency for Healthcare Research and Quality, provides publicly available all-payer statewide data related to inpatient discharge records from community hospitals in participating states [13]. At the time of data collection, 48 States and the District of Columbia provide inpatient data to HCUP[14]. Data for this study were obtained from the Florida (2005-2012) and California (2005-2009) HCUP SID. These states were chosen due to the availability of data over consecutive years, which allowed for a comprehensive review of ninety-day readmissions and two-year reoperations. This study was exempt from Institutional Review Board oversight.

International Classification of Diseases, 9th Revision Clinical Modification (ICD-9 CM) diagnosis codes, and the current procedural terminology (CPT) codes were used to identify adolescent patients between the ages of 10 and 18 inclusive, who presented

with a midshaft clavicle fracture and underwent an ORIF from January 1, 2005 to December 31, 2012 (ICD-9-CM 79.39, CPT: 23515). Data collection included patient age, sex, race, insurance type, hospital type, and income percentile. We determined the rates of readmission within ninety-days and reoperation within two-years. We compared demographic and socioeconomic factors to determine predictors of readmission and reoperation.

Statistical methods

Descriptive statistics were performed including *t*-test and χ^2 analysis to determine statistical significance of adolescent reoperation rates. Multivariate logistic regression was used to compare differences between patients that did or did not require a readmission, and patients that did or did not require a reoperation. Specific predictor variables that were controlled for and analyzed included patient sex, age, race, payer type, hospital type, and state. All statistical analysis was performed using SAS Studio statistical software. Statistical significance was set at $P < 0.05$.

RESULTS

Overall, 11728 adolescent clavicle fractures were analyzed between 2005-2012 in Florida and 2005-2009 in California. Within this cohort, there were 334 clavicle fractures that were managed operatively (2.8%). The surgical cohort consisted of 80.5% ($n = 265$) male and 19.5% ($n = 64$) female patients, and the mean age at time of injury was 16.0 ± 1.7 years (Range: 10-18 years). In total, 3.3% ($n = 11$) of patients were readmitted within 90 d to a hospital at an average of 18.9 ± 18 d after discharge, while 15.9% ($n = 53$) of patients underwent a reoperation within two years at an average of 209.5 ± 151 d since the index surgery.

Of the 334 patients who underwent clavicle ORIF, only 11 patients were readmitted within 90 d after discharge, and the most common reason was a postoperative infection ($n < 10$). Per database reporting restrictions, there is insufficient data for additional analysis.

The most common reason for reoperation was removal of implant (92.5%, $n = 49$) at an average of 202.4 ± 138 d after index surgery. The second most common reason for reoperation was revision ORIF (7.6%, $n = 4$) at an average of 297 ± 289 d after index surgery. There were a greater number of male patients who underwent ORIF (68% *vs* 32%, $P = 0.01$) compared to females, and there were more reoperations in the state of Florida compared to California (98% *vs* 2%) ($P < 0.01$) over the study period (Table 1). There were no significant differences in age, race, payer type, median income quartile, and hospital type observed in patients who did or did not have a reoperation within two years ($P > 0.05$). In the multivariate analysis, female patients had greater odds of undergoing reoperation compared to male patients [odds ratio (OR) = 3.49 (1.66-7.33), $P < 0.01$], and patients in California had lower odds of having a reoperation than patients in Florida [OR = 0.08 (0.01-0.66), $P = 0.02$] (Table 2). Additionally, it was demonstrated that patients who had their index surgery at an outpatient center had greater odds of having a reoperation when compared to patients who had their index surgery at a community hospital [OR = 10.76 (2.04-56.83), $P < 0.01$].

DISCUSSION

Recent literature has suggested improved functional outcomes after ORIF for displaced midshaft clavicle fractures in adults[5]. However, these studies have not focused on pediatric or adolescent patients, and the superiority of surgical management in these patients is unclear. There has also been a recent increase in the rates of surgical management of midshaft clavicle fractures in adolescents, and it is important that we understand the rates and reasons for readmission and reoperation after surgery[2,4]. A few studies have described such rates, but these studies have been limited by small samples sizes. To our knowledge, this is the first study to investigate these factors using a large database[12,15-17].

In this study, we found a low rate of readmission but a significantly high rate of reoperation after surgical management of midshaft clavicle fractures in adolescents. Although rates of readmission were low, the most common reason for readmission was postoperative infection. In a previous study by Li *et al*[12], 2/85 pediatric patients experienced a wound dehiscence or infection after ORIF. The rate of readmission is

Table 1 Adolescent fracture demographics: Reoperation *vs* no reoperation

Predictor variables		Cohort proportion (%)	Cohort total (*n*)	Cohort proportion (%)	Cohort total (*n*)	*P*-value
Sex	Male	0.68	36	0.83	229	0.01
	Female	0.32	17	0.17	47	
Race	White	0.79	42	0.78	209	0.86
	Hispanic	0.13	7	0.12	31	
	Black	0.04	2	0.05	14	
	Other	0.02	1	0.05	13	
Payer type	Commercial	0.74	39	0.62	175	0.47
	Medicaid	0.19	10	0.24	67	
	Self-pay	0.02	1	0.06	17	
	Other	0.06	3	0.08	22	
State	CA	0.02	1	0.20	55	< 0.01
	FL	0.98	52	0.80	226	
Median income quartile	0-25th (%)	0.16	7	0.20	42	0.64
	26th-50th (%)	0.34	16	0.34	70	
	51st-75th (%)	0.28	13	0.29	61	
	76th-100th (%)	0.23	11	0.16	34	
Hospital type	Academic	0.04	2	0.07	19	0.07
	Children's	0.00	0	0.02	6	
	Community	0.75	40	0.77	215	
	County	0.13	7	0.14	38	
	Outpatient	0.08	4	0.01	3	
Age	Mean	15.87 ± 1.8	53	16.08 ± 1.7	281	0.41

likely low after surgical management of midshaft clavicle fractures in adolescents, but additional multicenter studies are needed to validate these results.

Most reoperations were performed due to removal of implant (n = 49; 92.45%). This finding is comparable to other reports in the literature. For example, Vander *et al*[15] reported 17.6% of adolescent patients underwent implant removal after the operative treatment of a closed midshaft clavicle fracture. This instrumentation removal rate is much lower compared to other studies that have reported rates ranging from 41%-59% [12,15-17]. Reasons for these differences could be related to population differences and differences in regional surgical practice and trends. Overall the high rate of reoperation (15.9%) found among adolescents surgically treated for midshaft clavicle fractures is similar to the reoperation rate reported by Kruppa *et al*[18] among children and adolescents surgically treated for femoral shaft fractures (14.3%).

We found significant differences in patients that did or did not undergo a reoperation. We found that female adolescents had a 249% greater odds of undergoing reoperation, which contrasts with findings published by Li *et al*[12]. In the adult literature, female sex has been identified as a risk factor for implant removal after ORIF[19,20]. Reasons for this difference have been postulated to relate to a thinner physique and implant irritation with clothing[19-21]. Thus, this may explain why adolescent females were more likely to undergo reoperations in this study. We also found that patients who had their initial surgery performed at an outpatient center had a higher likelihood to undergo reoperation. Additionally, patients in Florida had a higher likelihood to undergo reoperation. Such differences may reflect differences in regional practice and require further investigation.

The results from this study have several implications to clinical practice. First, it provides surgeons with a general idea of the rates of readmission and reoperation after surgical management. Secondly, it allows surgeons to adequately counsel patients regarding risk factors for reoperation. Surgeons may want to consider such characteristics when counseling patients and parents prior to ORIF to ensure no additional

Table 2 Adolescent fracture demographics: Multivariate analysis

Predictor variables	Odds ratio	95%CI	*P* value
Sex			
Female *vs* male	3.49	1.66-7.33	< 0.01
Race			
Black *vs* white	1.03	0.20-5.19	0.97
Hispanic *vs* white	1.23	0.45-3.37	0.69
Other *vs* white	0.52	0.06-4.50	0.55
Payer type			
Commercial *vs* self-pay	4.70	0.52-42.17	0.17
Medicaid *vs* self-pay	4.67	0.49-44.93	0.18
Other *vs* self-pay	2.96	0.24-37.06	0.40
State			
CA *vs* FL	0.08	0.01-0.66	0.02
Hospital type			
Academic *vs* community	0.55	0.11-2.75	0.46
Children's *vs* community	< 0.01	0.01 < x < 999	0.98
County *vs* community	0.92	0.36-2.33	0.86
Outpatient *vs* community	10.76	2.04-56.83	< 0.01
Age	0.91	0.75-1.10	0.33

concerns arise if a reoperation is later needed. For example, it is more likely that female patients will undergo removal of implant after surgical management. Finally, these results provide the framework for additional research to investigate geographic differences and differences in rates based on hospital setting.

Several limitations were present. Given the nature of database studies, we were limited to the data available and did not have access to clinical or radiographic outcomes or patient-reported outcome measures, which may be valuable in future studies. Additionally, we are unable to clearly investigate reasons for readmission and reoperation due to limitations of the database. We were also unable to determine how many patients had implant-related complaints *vs* elective implant removal, which may have been recommended by the pediatric surgeon[12]. This study was also limited to two states (California and Florida) due to the lack of data available over consecutive years in the remaining states. Additional studies are needed to understand the applicability of the results nationally and improve the generalizability of these results. As this study is unable to comment on long-term outcomes, future prospective studies are needed to review short, mid, and long-term outcomes, patient reported outcomes, and complications. Despite these limitations, this study is the first to our knowledge to explore readmission and reoperation rates among surgically treated clavicle fractures in adolescents using a large database cohort.

CONCLUSION

In conclusion, the rates of readmission are low after surgical management of midshaft clavicle fractures in adolescents. However, the rates of reoperation are relatively high, and removal of implant remains the primary reason for reoperation. Rates of reoperation significantly differ based on sex and the geographic location of the index surgery. Future multicenter prospective studies are needed to further investigate these findings and ultimately decrease the need for readmission and reoperation after surgical management of midshaft clavicle fractures in adolescents.

ARTICLE HIGHLIGHTS

Research background

In the past decade, there has been a shift in the paradigm for the treatment of clavicle fractures. In both adolescents and adults, the trend has been towards increasing rates of operative management.

Research motivation

It is unclear if the literature supports the superiority of open reduction internal fixation (ORIF) to nonoperative management in the management of closed midshaft clavicle fractures in adolescents.

Research objectives

The primary objective of this paper is to determine the rates of 90-d readmission and two-year reoperation after surgical management of midshaft clavicle fractures in adolescents.

Research methods

This retrospective study utilized data from the Healthcare Cost and Utilization Project State Inpatient Database for California and Florida and included patients 10–18 years of age that underwent ORIF of midshaft clavicle fracture between 2005 and 2012.

Research results

In total, 3.29% (n = 11) of patients were readmitted within 90 days to a hospital at an average of 18.91 ± 18 d after discharge, while 15.87% (n = 53) of patients underwent a reoperation within two years at an average of 209.53 ± 151 d since the index surgery. The most common reason for readmission was a postoperative infection (n < 10). Reasons for reoperation included implant removal (n = 49) at an average time of 202.39 ± 138 d after surgery, and revision ORIF (n < 10) with an average time of 297 ± 289 days after index surgery. The odds of reoperation were higher for females (P < 0.01) and outpatients (P < 0.01), while the odds of reoperation were lower for patients who underwent surgery in California (P = 0.02).

Research conclusions

There is a low rate of readmission and a high rate of reoperation after ORIF for midshaft clavicle fractures in adolescents. There are significant differences for reoperation based on patient sex, location, and hospital type.

Research perspectives

Future studies are needed to understand the applicability of the results nationally and improve the generalizability of these results. Additional prospective studies are needed to review short, mid, long-term outcomes, patient reported outcomes, and complications for the patient population.

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ORIGINAL ARTICLE

Retrospective Study

Surgical treatment outcome of painful traumatic neuroma of the infrapatellar branch of the saphenous nerve during total knee arthroplasty

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Abstract

BACKGROUND

Development of infrapatellar saphenous neuroma (ISN) is a well-recognized reason for knee pain following total knee arthroplasty (TKA). So far, very few studies have addressed the development of painful ISN after TKA and its impact on functional outcome and patient satisfaction.

AIM

To present the results of surgical treatment for ISN after primary TKA, the level of pain relief, and the improvement of knee motion and function.

METHODS

Fifteen patients (13 women, 2 men) with persistent medial pain for more than six months after primary TKA, due to osteoarthritis, underwent surgical excision of ISN. ISN diagnosis was confirmed with the presence of Tinel's sign along the course of the infrapatellar branch of the saphenous nerve and with pain relief after selective nerve block using local anesthetic. Component loosening, malalignment, instability and infection were excluded systematically in all patients as a source of pain. Pain relief in terms of visual analog scale (VAS), active knee range of motion (ROM), and the Knee Society Score (KSS) for pain and function were evaluated preoperatively and at least six months postoperatively.

RESULTS

The mean patients' age was 71.3 ± 5.4 years old. The mean interval between TKA and neuroma excision was 10 mo (range, 6 to 14 mo), while the mean follow-up was 8 mo (range: 6 to 11 mo). All 15 patients experienced almost complete immediate pain relief and resolution of allodynia and hyperesthesia after surgery. Pain on the VAS scale improved from 8.6 ± 1.3 preoperatively to 0.8 ± 0.9 at the final follow-up (P = 0.001). KSS pain and function scores were improved from 49.3

reviewed.

Peer-review model: Single blind

Peer-review report's scientific quality classification
Grade A (Excellent): 0
Grade B (Very good): B
Grade C (Good): 0
Grade D (Fair): 0
Grade E (Poor): 0

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± 5.9 and 62.7 ± 12.8 before surgery to 91.8 ± 4.2 and 75.3 ± 11.3 after surgery, respectively (P = 0.001 and P = 0.015). Active knee ROM was also increased postoperatively from 96 ± 4 to 105 ± 6 degrees (P = 0.001). There were no complications and no further operations required.

CONCLUSION
ISN should be considered a potential cause of persistent pain following TKA. Neuroma excision not only provides immediate pain relief and resolution of symptoms but may also improve the knee range of motion.

Key Words: Total knee arthroplasty; Infrapatellar branch of saphenous nerve; Neuroma; Neurogenic pain; Knee osteoarthritis

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Core Tip: Development of infrapatellar saphenous neuroma after total knee arthroplasty should be considered a potential reason for persistent pain in an otherwise non-infected, well-fixed, and well-aligned joint. Before total knee arthroplasty, patients should be warned for the risk of nerve injury and neuroma formation. Neuroma excision provides excellent pain relief and improves knee function and range of motion.

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INTRODUCTION

Postoperative pain after total knee arthroplasty (TKA) is a complex and multifactorial issue. Infection, loosening, instability, component malalignment, poor ligament balance, and complex regional pain syndrome may lead to knee pain, stiffness, and poor functional outcome[1,2].

Although very rare, the development of infrapatellar saphenous neuroma (ISN) is a well-recognized factor of knee pain following not only TKA but also patellar and hamstring tendon harvest during anterior cruciate ligament reconstruction, open and arthroscopic repairs, tibial nailing, and vascular surgery of the lower extremity[3,4]. The prevalence of postoperative infrapatellar branch of the saphenous nerve (IPSN) damage has been reported to range between 0.5 to 53%[4] and may be apparent up to 9.7% and 21% of patients after primary and revision TKA, respectively[5], causing neuralgia or hypersensitivity, paresthesia, and loss of sensation at the medial joint area [4].

The IPSN is a purely sensory nerve that derives from the saphenous nerve. The latter arises as a division of the femoral nerve and leaves the adductor canal between the tendons of gracilis and semitendinosus[6]. It then divides into the main saphenous branch, which continues down to the ankle, and the IPSN that crosses the inferior knee from medial to lateral and innervates the skin below the patella as well as the anterior inferior knee capsule[3]. During TKA, the nerve is inevitably sectioned during the midline skin incision and anteromedial approach. Medial retractors, knee position in flexion, and a thigh tourniquet may further increase the tension over the course of the nerve and impede uneventful recovery[7]. Although the area of postoperative hypesthesia at the distribution of IPSN is usually decreased during the time, a painful neuroma can occur and further surgical intervention may be required[8]. The risk is even higher when the nerve is traumatized close to its origin and before its terminal branches[9].

So far, very few studies have addressed the issue of the development of painful ISN after TKA, and no clear evidence regarding its importance on functional outcome and patient satisfaction exists. In the current clinical study, we present the results of

surgical treatment of ISN after primary TKA. The level of pain relief and improvement of knee motion and function are also described.

MATERIALS AND METHODS

Between 2012 and 2018, 2054 patients underwent primary TKA due to osteoarthritis in our department. Patients with previous open knee operations and skin incisions were excluded from further evaluation. All operations were performed using a thigh tourniquet and a standard midline skin incision with a medial parapatellar knee approach were applied. Twenty-nine patients (1.4%) complained of postoperative medial knee pain that was frequently accompanied by burning and tingling sensation, hyperesthesia, and allodynia after the index procedure.

All patients were evaluated with X-Rays, computed tomography (CT) scan, and bone scan to exclude any component malalignment and/or implant failure. Infection was also ruled out performing erythrocyte sedimentation rate and C-reactive protein blood tests as well as knee aspiration. The joint fluid sample was sent to laboratory for culture and evaluation of synovial white blood (WBC) and its proportion of polymorphonuclear (PMN) cells according to the criteria for the diagnosis of periprosthetic joint infection as proposed by the Musculoskeletal Infection Society and the International Consensus Meeting[10]. WBC > 3.000 cells/μL and PMN > 80% were considered indicative for knee infection and additional diagnostic and operative procedures were performed[10].

The diagnosis of ISN was based on the presence of Tinel's sign along the course of IPSN and confirmed with an injection of 1 mL lidocaine 1% and 2 mL ropivacaine 0.2%. In case of pain relief, the patient was suggested to follow a protocol that included injection with betamethasone acetate/betamethasone sodium phosphate (Celestone Chronodose) at the neuroma site and pregabalin intake (50 mg or 75 mg three times per day).

Fifteen patients (13 women, 2 men) failed to respond to conservative treatment (partial or temporary resolution of symptoms) and therefore required neuroma excision. The latter occurred *via* medial skin incision following the course of IPSN and the area of greatest tenderness that was marked before surgery (Figure 1). After dissection of the subcutaneous soft tissues, the nerve was explored and a neuroma surrounded by scar tissue was identified (Figure 2 and Figure 3). The fibrous nodule containing the neuroma was removed. The nerve was sharply transected approximately 1-2 cm proximal to the neuroma and its proximal stump was buried to adjacent soft tissues to prevent recurrence (Figure 4). Postoperatively, no restrictions in terms of motion and weight-bearing were applied and patients were encouraged to perform knee flexion and extension exercises and gradually increase their activity level. Pregabalin was continued to a lower dose of 25 mg two or three times per day for one more month.

Active knee range of motion (ROM), visual analog scale (VAS) for pain, Knee Society Score (KSS) for pain and function were evaluated before and at least 6 mo after neuroma excision[11]. Interpretation of the VAS change scores was based on the minimum clinically important difference (MCID) for adequate pain control of -3 (in a VAS scale from 0 to 10)[12,13].

Mean preoperative and follow-up values were compared with Wilcoxon signed ranks test. The level of significance was set at $P < 0.05$ and SPSS software version 24 was used.

RESULTS

The mean patients' age was 71.3 ± 5.4 years old. The mean interval between TKA and neuroma excision was 10 mo (range, 6 to 14 mo) and the mean follow-up was 8 mo (range: 6 to 11 mo). Patients' demographics are presented in Table 1.

All patients experienced almost immediate and complete pain relief and resolution of allodynia and hyperesthesia after surgery (Table 2). Mean pain relief in terms of VAS exceeded the MCID for adequate pain control (mean difference -7.8 ± 1.9, $P = 0.001$). Only two patients reported some residual numbness that gradually resolved during the time but didn't cause any functional deficit.

The KSS pain and function scores were significantly improved from 49.3 ± 5.9 and 62.7 ± 12.8 before surgery to 91.8 ± 4.2 and 75.3 ± 11.3 after surgery, respectively ($P = 0.001$ and $P = 0.015$). Active knee ROM was also increased postoperatively from 96 ± 4

Table 1 Patients' demographics

Patient No.	Gender	Age, yr	Height, m	Weight, kg	BMI	Interval from TKA to neuroma excision, mo	Follow-up, mo
1	F	70	1.56	68	27.9	10	6
2	F	72	1.53	72	30.8	8	8
3	F	69	1.65	82	30.1	13	7
4	M	76	1.75	95	31.0	9	11
5	F	65	1.58	70	28.0	8	9
6	F	71	1.67	83	29.8	11	8
7	F	74	1.53	51	21.8	9	7
8	F	70	1.55	69	28.7	6	9
9	F	57	1.68	81	28.7	11	6
10	M	72	1.71	85	29.1	11	7
11	F	70	1.53	73	31.2	6	8
12	F	79	1.57	65	26.4	10	10
13	F	72	1.54	50	21.1	13	8
14	F	79	1.54	79	33.3	10	6
15	F	74	1.52	76	32.9	14	10
mean ± SD		71.3 ± 5.4	1.59 ± 0.08	73.3 ± 12.1	28.7 ± 3.5	10 ± 2	8 ± 2

F: Female; M: Male; BMI: Body mass index; TKA: Total knee arthroplasty.

Table 2 Pain relief, range of motion, and functional outcomes

VAS for pain		Active ROM (degrees)		KSS pain		KSS function
Postoperative	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
0.8 ± 0.9	96 ± 4	105 ± 6	49.3 ± 5.9	91.8 ± 4.2	62.7 ± 12.8	75.3 ± 11.3
[a]P = 0.001		[a]P = 0.001		[a]P = 0.001		[a]P = 0.015

[a]Wilcoxon signed ranks test.
VAS: Visual Analog Scale; ROM: Range of motion; KSS: Knee Society Score.

to 105 ± 6 degrees (P = 0.001) (Table 2).

There were no complications and no further operations required.

DISCUSSION

Iatrogenic injury of IPSN is a rare cause of postoperative pain and stiffness after TKA. The diagnosis is one of the exclusion as no specific clinical and laboratory findings can accurately diagnose the condition. Periprosthetic joint infection, malalignment, and ligamentous instability should be ruled out before the suspicion of neuroma development is taken into consideration[1]. The presence of positive Tinel's sign along the course of the nerve and the marked improvement of the symptoms of more than 50% after diagnostic injection can confirm to a great extent the neurogenic source of pain and disability. So far, very few studies with a small number of patients and case reports have described the impact of the development of ISN on knee function after TKA and the results of conservative or surgical treatment.

Conservative management is usually the first approach utilized, including local injection of analgesics, corticosteroids, and physical therapy[14]. However, the published results are quite conflicting regarding their efficacy in alleviating pain and improving knee function. Clendenen *et al*[7] found that local treatment with

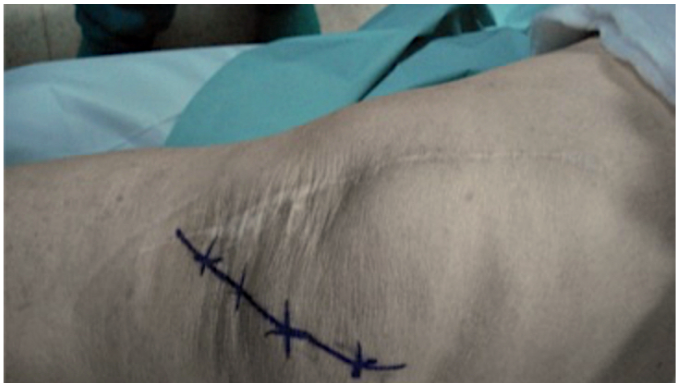


Figure 1 Postoperative neuroma in a 76 years-old patient after total knee arthroplasty (Case 4). Medial side knee incision following the course of infrapatellar branch of the saphenous nerve.

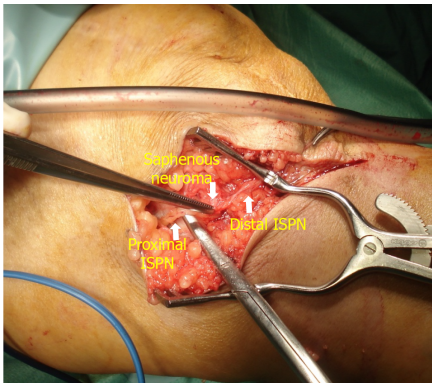


Figure 2 Surgical exploration revealed neuroma of the infrapatellar branch of the saphenous nerve. ISPN: Infrapatellar branch of the saphenous nerve.

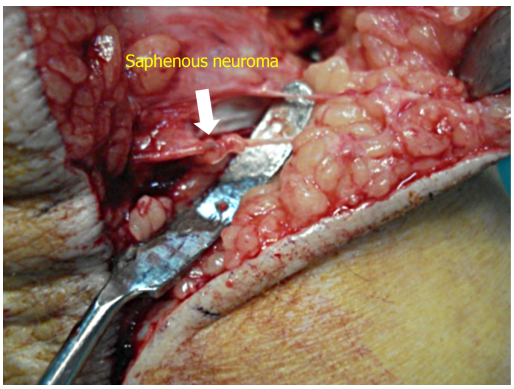


Figure 3 Development of painful saphenous neuroma in a 79 years-old patient after primary total knee arthroplasty (Case 12). The damaged and degenerated nerve was surrounded by scar tissue.

hydrodissection of the IPSN from the adjacent interfascial planes followed by corticosteroid injection was effective in reducing persistent medial knee pain after TKA in nine out of 16 patients (VAS score of 0 or 1) with one (eight patients) or two (one patient) procedures. Three patients reported less pain improvement to VAS levels of 3 to 4. Of the remaining four patients, two did not have improvement with VAS scores of 8, and two underwent subsequent radiofrequency ablation of the IPSN with resolution of pain in one patient. Similarly, Shi *et al*[14] found that after ultrasound-guided local treatment by hydrodissection and corticosteroid injection of ISN, the median numeric VAS pain score was improved from 9 (range, 5 to 10) to 5 (range, 0 to 10) at both one-month and midterm follow-up ($P < 0.001$). The authors reported that females and a previous TKA revision were associated with less pain relief and poor results. On the

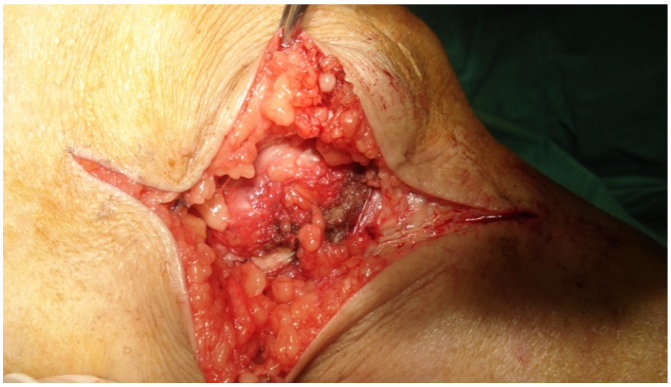


Figure 4 The fibrous nodule containing the neuroma was removed and the nerve was sharply transected approximately 1-2 cm proximal to the neuroma. Its proximal stump was buried to adjacent sift tissues to prevent recurrence.

other hand, Worth *et al*[15] reported no significant resolution of pain after local injection of the saphenous nerve in 14 patients with prior knee surgery.

In case of failed conservative treatment, surgical intervention with neurolysis, neurectomy, and selective knee denervation are utilized. The proximal nerve stump is cauterized and buried deeply in the adjacent tissues to prevent recurrence[9]. Nahabedian *et al*[16] excised 62 nerves in 25 patients including the IPSN in 24 cases. Complete pain relief was obtained in 11 patients (44%), partial pain relief in 10 patients (40%), and no pain relief in 4 patients (16%). The overall patient satisfaction rate was 84% (21 out of 25 patients) and none reported a worse outcome after surgery. Shi *et al*[1] performed selective denervation in 50 patients suffering from neuroma pain after TKA. The procedure was applied not only to IPSN but also to the other sensory nerves around the knee according to symptoms and Tinel's sign location. Thirty-two patients (64%) rated their outcome as excellent, 10 (20%) as good, 3 (6%) as fair, and 2 (4%) reported no change. The mean VAS pain score was improved from 9.4 ± 0.8 preoperatively to 1.1 ± 1.6 postoperatively ($P < 0.001$). The mean Knee Society Scores was also increased from 45.5 ± 14.3 before surgery to 94.1 ± 8.6 after surgery ($P < 0.0001$). Three patients (6%) required a second neurectomy due to recurrent pain. In our series of 15 patients, exclusive denervation of IPSN was associated with statistically significant pain resolution (mean VAS increase -7.8 ± 1.9) and improvement of knee function (KSS pain and function scores increased from 49.3 ± 5.9 and 62.7 ± 12.8 to 91.8 ± 4.2 and 75.3 ± 11.3, respectively) and range of motion (from 96 ± 4 to 105 ± 6 degrees).

The common applied medial parapatellar approach in TKA may increase the likelihood of the development of ISN[9]. James *et al*[2] performed a clinical study in primary TKA patients to identify the location of the IPSN and determine whether it could be transected during a standard medial arthrotomy. They found that the nerve was, on average, between 2.58 and 3.06 cm below the inferior pole of the patella. No demographic predictors of nerve location were found, including sex, height, and BMI. Kartus *et al*[17] reported that the IPSN passes through the area between the apex of the patella and the tibial tubercle in 59 of 60 examined specimens and the distance from the apex of the patella to the IPSN or its uppermost branch was 30 mm. Kerver *et al*[18] in a cadaveric study identified that anatomic variation of topographic anatomy of IPSN is high and the nerve is at risk for iatrogenic damage in any anteromedial knee surgery, especially when longitudinal incisions are made.

The current study has certain limitations. Firstly, it represents a case series study with a relatively small sample size and no control group. It is also a single institution's report, with scarce literature to provide an adequate comparison of data. On the other hand, it contains a homogenous group of patients that underwent only primary TKA with the same type of knee approach.

CONCLUSION

Iatrogenic injury of IPSN may cause persistent pain after TKA in an otherwise non-infected, well-fixed, and well-aligned joint. Therefore, and before TKA, patients should be warned of the risk of nerve injury and neuroma formation. After confirmation of the diagnosis with local anesthetic infiltration of the painful site, neuroma excision provides excellent pain relief and can improve the knee function and range of motion.

ARTICLE HIGHLIGHTS

Research background

Development of infrapatellar saphenous neuroma (ISN) is a well-recognized source of knee pain after total knee arthroplasty (TKA).

Research motivation

So far, very few studies have addressed the issue of the development of painful ISN after TKA, and no clear evidence regarding its importance on functional outcome and patient satisfaction exists.

Research objectives

The current clinical study aims to evaluate the results of surgical treatment of ISN after primary TKA, the level of pain relief, and the improvement of knee motion and function.

Research methods

This study is a clinical series of 15 patients (13 women, 2 men) with persistent pain for more than six months after primary TKA due to osteoarthritis, who underwent surgical excision of ISN. Active knee range of motion (ROM), visual analog scale (VAS) for pain, Knee Society Score (KSS) for pain and function were evaluated before and at least 6 mo after neuroma excision, with a mean follow-up of 8 mo (range: 6 to 11 mo).

Research results

The mean patients' age was 71.3 ± 5.4 years old. The mean interval between TKA and neuroma excision was 10 mo (range, 6 to 14 mo). All patients experienced almost immediate and complete pain relief and resolution of allodynia and hyperesthesia after surgery. Mean pain relief in terms of VAS exceeded the MCID for adequate pain control (mean difference -7.8 ± 1.9, P = 0.001). Only two patients reported some residual numbness that gradually resolved during the time but didn't cause any functional deficit. The KSS pain and function scores were significantly improved from 49.3 ± 5.9 and 62.7 ± 12.8 before surgery to 91.8 ± 4.2 and 75.3 ± 11.3 after surgery, respectively (P = 0.001 and P = 0.015). Active knee ROM was also increased postoperatively from 96 ± 4 to 105 ± 6 degrees (P = 0.001). There were no complications and no further operations required

Research conclusions

Iatrogenic injury of IPSN may cause persistent pain after TKA in an otherwise non-infected, well-fixed, and well-aligned prosthetic joint. Neuroma excision can provide excellent pain relief and improve the knee function and range of motion.

Research perspectives

Further clinical studies are required to identify the predisposing factors for development of traumatic ISN during TKA as well as the optimal treatment approach of postoperative neurogenic pain around the knee joint area.

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ORIGINAL ARTICLE

Prospective Study

Arthroscopic *vs* open ankle arthrodesis: A prospective case series with seven years follow-up

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Author contributions: Morelli F, Princi G did work design; Princi G, Cantagalli MR, and Rossini M did data acquisition; Princi G did data analysis; Princi G, Cantagalli MR, Rossini M, Caperna L and Mazza D drafted the work; Morelli F, Princi G, Caperna L, Mazza D and Ferretti A did critical revision for important intellectual content; All authors did final approval of the version to be published.

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Abstract

BACKGROUND

The osteoarthritis of the ankle, although less common than other joints, is associated with severe functional limitation. Surgical options are ankle arthroscopic debridement, osteotomies, ankle arthrodesis and ankle arthroplasty. Ankle arthroplasty is increasingly used thanks to the new implants design, but ankle arthrodesis still represents the most used technique and it can be performed arthroscopically or with an open procedure.

AIM

To compare mid-term results of arthroscopic *vs* open ankle arthrodesis of patients affected by end-stage ankle arthritis.

METHODS

This study enrolled 23 patients, which underwent ankle arthrodesis. The patients were divided into 2 groups: group A (open procedure; n = 11) and group B (arthroscopic procedure, n = 12), the two groups were homogeneous with regard to age and body mass index (P = 0.347). The American Orthopaedic Foot and Ankle score (AOFAS), Freiburg Ankle score (FAS) and visual analogue scale for pain intensity were evaluated preoperatively, at six months and at final follow-up of 7.6 years in group A and 7.3 years in group B (P = 0.364).

RESULTS

Patients in the arthroscopic group showed better results at six-month follow-up compared to the open group at the AOFAS (group A, 62.2; group B, 78.5; $P < 0.05$) and the FAS (group A, 61.1; group B, 70.3; P = 0.015) scores. Pain relief was achieved in both groups at six-month follow-up (group A, 1.4; group B, 0.9; P = 0.162). Both open and arthroscopic groups showed improved clinical outcomes

from baseline to final follow-up ($P > 0.05$). Hospital stay was shorter in group B than in group A ($P = 0.001$). More complications were reported in the open group than in the arthroscopic group ($P = 0.459$).

CONCLUSION

The arthroscopic and the open arthrodesis are valid and safe options for the treatment of ankle arthritis on the basis of clinical outcomes at 7 years follow-up. Moreover, the arthroscopic treatment shows faster improvement at six-month follow-up in comparison with the open group.

Key Words: Ankle; Osteoarthritis; Arthrodesis; Arthroscopy; Arthroplasty; Surgery

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Core Tip: Purpose of this study is to evaluate arthrodesis as surgical treatment in patients with end-stage ankle osteoarthritis. The open procedure is compared with the arthroscopic procedure, evaluating the medium to long-term results through The American Orthopedic Foot and Ankle score, Freiburg Ankle score and visual analogue scale for pain intensity. Bone fusion timing is analyzed utilizing X-rays. The results suggest that both treatments are valid and safe, and that the arthroscopic procedure shows faster improvements in the medium term. It is also interesting to note that the group treated with arthroscopic procedure in the medium term control, has a shorter hospital stay and a better union rate.

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INTRODUCTION

End-stage ankle arthritis is a clinical condition associated with pain and severe function limitation. The ankle joint, even though subjected to more weight-bearing force per square centimeter and to injury than any other joint, is relatively less affected by osteoarthritis, up to nine times lower than knee and hip[1]. The most frequent cause of ankle arthritis is post-traumatic, which includes almost 80% of all osteoarthritis of this joint[2-4]; more rarely other clinical diseases as arthropathies, infections, tumors and neuropathic arthropathies are involved. Initial management of ankle arthritis consist of conservative options: first-line consist of weight management, exercise, braces, orthoses, and assistive devices, followed by adjunction of pharmacologic agents (non-steroidal anti-inflammatory drug) and intra-articular injection (corticosteroid, hyaluronic acid, *etc*)[5]. In case of failure of conservative treatment, surgery is indicated. Possible surgical options are ankle arthroscopic debridement, osteotomies, ankle fusion and tibio-talar arthroplasty. Despite the development of new implant designs for ankle replacement that are improving its utilization and outcome, arthrodesis still represents the main surgical method to treat ankle arthritis, offering safe and stable results as regards in pain and function[6-9].

Ankle fusion is indicated for end-stage arthritis, residual joint destruction after infection, avascular talar necrosis, Charcot neuroarthropathy, and total ankle replacement failure[8]. For many years ankle arthrodesis has been considered a reliable procedure and for many authors it is still the reference standard for the treatment of end-stage ankle arthritis[10]. Success rate ranging from 80% to 100% has been reported for isolated tibio-talar fusion with patient satisfaction rates around 80% [11,12].

Since the first description by Schneider[13] in 1983, arthroscopic ankle arthrodesis has seen increase in popularity and utilization because of numerous advantages. Several studies in literature in fact, show reduced postoperative pain and a lower use of painkiller drugs[14,15], as well as decreased morbidity, duration of hospitalization,

presented data are anonymized and risk of identification is low.

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lower infection rate and more rapid return to daily activities[16,17], preserving a better fusion rate and time to union[18]. Moreover, with arthroscopic procedure the indication for arthrodesis can be extended to patients with high wound complications risk such as diabetes or skin problems.

The purpose of the present study was to compare two cohorts of patients who were managed with either an open or an arthroscopic arthrodesis for the treatment of end-stage ankle arthritis: clinical outcome, morbidity and length of hospital stay are reported for both groups.

MATERIALS AND METHODS

This is a comparative case series. Between June 2008 and January 2012, forty patients (40 ankles) with end-stage ankle arthritis that needed ankle fusion surgery, were selected for this prospective study. Institutional review board approval was granted, and informed consent was obtained from all study participants.

Decision on which surgical procedure to be utilized was based on the grade of varus or valgus malalignment of the involved ankle. Therefore patients were divided in two groups: In group A (open procedure), were included patients with end-stage ankle arthritis with severe varus or valgus deformity (≥ 10°); in group B (arthroscopic procedure) those with minor ankle malalignment (< 10°).

Exclusion criteria were the following: diabetes mellitus, Charcot neuroarthropathy, osteomyelitis, previous total ankle arthroplasty, subtalar arthritis requiring fusion at same time of the tibio-talar procedure, neurological diseases.

Following the aforementioned criteria, we enrolled 23 patients (23 ankle) for this study, 11 patients in group A and 12 patients in group B. No significant difference were found between the two groups regarding average age (respectively 67.0 ± 2.6 and 64.6 ± 1.9), body mass index (BMI, 23.6 ± 1.0 and 23.8 ± 1.0), sex (open group shows 8 male/3 female and arthroscopic group 5 male/7 female) and dominant side (8/3 and 9/3). Details of all demographic data are shown in Table 1.

Seventeen patients were excluded from further analysis: 7 patients with incomplete clinical follow-up, 7 patients performed triple arthrodesis, 3 patients affected by diabetes mellitus.

All patients had a minimum follow-up of 5 years and mean FU of 7.4 years.

Analyzing the etiology of the ankle arthritis, the two groups showed comparable data. The main cause was post-traumatic, that include 72.7% (8 patients) and 83.3% (10 patients) of the cases respectively in group A and in group B. In the open group, we found out a similar percentage of idiopathic arthritis compared to the arthroscopic group (group A, 9.0%, 1 patient; group B, 8.5%, 1 patient); two patients of group A were affected by Rheumatoid arthritis (18.1%) counter to 1 in the arthroscopic group (8.5%).

Surgical procedures

In the open group the approach entailed a longitudinal lateral incision combined with an ancillary antero-medial incision to obtain a good congruence of bone surfaces. The lateral dissection included osteotomy and removal of the cortical portion of the distal fibula, with subsequent placement of the remaining lateral aspect of the distal fibula and onlay graft before wound closure. All of the residual cartilage and subchondral bone was removed from the distal tibia, talar dome, lateral talus and medial gutter. The deformity was corrected with planar cuts to place the foot and the ankle in a neutral fusion position. The subchondral plate was preserved unless the deformity required planal resection, after which the subchondral plate was fenestrated and drilled, and fish scaled with a curved osteotome. The desired position of fusion was then ensured by means of direct visualization and fluoroscopy, after which the fusion was stabilized in 7 cases with 2 or 3 large diameter (≥ 6.5 mm) cannulated screws, interfragmentary compression screws reinforced with the before mentioned fibular onlay graft. In 4 cases the IOFIX (Extremity Medical, New Jersey, United States) system was used.

Arthroscopic procedure was performed with anteromedial and anterolateral portals using noninvasive distraction. Adequate inflow was achieved with use of a 2.9 mm arthroscope within a 4.0 mm fenestrated cannula or a 4.0 mm arthroscope with a 5.5 mm fenestrated cannula and a pump with 30 mmHg of inflow pressure at the surgeon's discretion. After removal of articular cartilage, the subchondral bone was prepared with a 2 mm drill and osteotome or high-speed burr. Osseous contours were preserved, and fusion sites were stabilized with two or three compression screws (7

Table 1 Demographic data

Variable	Group A (open) *n* = 11	Group B (arthroscopic) *n* = 12	*P*
Average age ± SD	67.0 ± 2.6	64.6 ± 1.9	0.162
Sex (M/F)	8/3	5/7	0.219
BMI ± SD	23.6 ± 1.0	23.8 ± 1.0	0.347
Dominant side (R/L)	8/3	9/3	0.952
Affected side (R/L)	7/4	5/7	0.390
Hospital stay (d) ± SD	5.4 ± 0.8	3.6 ± 0.5	**0.001**[b]
Follow-up (yr) ± SD	7.6 ± 1.1	7.3 ± 1.1	0.364
Device (screws/IOFIX)	7/4	7/5	0.390

[b]$P < 0.05$.

Boldface indicates statistical significance. BMI: Body mass index.

cases) or with the IOFIX system (4 cases).

Postoperative protocol

The same postoperative protocol was used for both groups. After surgery, patients were managed with ankle immobilization in a below-the-knee plaster cast without weight-bearing for the first six weeks. Progressive weight-bearing was allowed from seventh to twelfth week, when the cast was removed. Anti-thrombotic prophylaxis protocol was performed for 6 wk with enoxaparin 4000 UI/die.

Outcomes evaluation

Clinical evaluation was obtained using the American Orthopaedic Foot and Ankle score (AOFAS)[19], Freiburg Ankle score (FAS)[20] and visual analogue scale (VAS) for pain evaluation that were collected pre-operatively, at six months and at final follow-up.

Demographic data were collected preoperatively. Secondary outcome measures also included length of the hospital stay and radiographic evaluation. Antero-posterior, lateral radiographs and Saltzman view were made at baseline, monthly until bone healing at the arthrodesis site was achieved, at sixth-month and at final follow-up[21-23] (Figures 1 and 2).

To eliminate interobserver variability, all radiographic measurements were completed by a single independent radiographic reviewer who was blinded to the treatment. The alignment was measured using the ruler application in the Centricity Enterprise Web V2.1 PACS viewing system (GE Healthcare, Chalfont St. Giles, Buckinghamshire, United Kingdom).

Statistical analysis

The data were analysed by using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, N.Y., United States). All the data was first analysed for normality of distribution using the Kolmogorov–Smirnov test. Continuous variables were expressed as mean ± SD, categorical variables displayed as frequencies and the appropriate parametric (student *t* test) or non-parametric test (Mann–Whitney U test or χ^2 test) was used to assess the significance of the differences between groups. All of the intergroup comparisons were two-sided and statistical significance was set at $P < 0.05$.

RESULTS

The study sample consisted of twenty three patients allocated in two groups: group A (open procedure group; $n = 11$) and group B (arthroscopic procedure group; $n = 12$). The groups were homogeneous with regard to age, BMI, dominant side and fixation device ($P > 0.05$) (Table 1).

Clinical outcomes intergroup comparison at baseline, at six months and final follow-up are reported in Table 2.

Table 2 Clinical outcomes

Variable	Group A (open) *n* = 11	Group B (arthroscopic) *n* = 12	*P*
AOFAS ± SD			
Pre-operative	33.6 ± 11.7	32.1 ± 4.1	0.411
Six months	62.2 ± 3.2	78.5 ± 3.9	**0.00001**[b]
Final follow-up	79.3 ± 3.6	81.3 ± 3.7	0.462
FAS ± SD			
Pre-operative	44.1 ± 6.9	48.8 ± 2.9	0.244
Six months	61.1 ± 6.1	70.3 ± 2.8	**0.015**[b]
Final follow-up	74.7 ± 2.7	75.8 ± 2.7	0.593
Pain VAS ± SD			
Pre-operative	4.3 ± 0.7	4.3 ± 0.6	0.903
Six months	1.4 ± 0.4	0.9 ± 0.4	0.162
Final follow-up	0.8 ± 0.6	0.6 ± 0.4	0.507
Bone fusion (wk) ± SD	15.1 ± 1.1	11.2 ± 0.7	**0.00001**[b]
Complications	1 nonunion, 2 wound dehiscence	1 screws removed	0.459

[b]$P < 0.05$.

Boldface indicates statistical significance. AOFAS: American Orthopaedic Foot and Ankle score; FAS: Freiburg Ankle score; VAS: Visual analogue scale.



Figure 1 X-rays (IOFIX system). A and B: Preoperative, anterior-posterior (AP) and lateral (L); C and D: 6 mo follow-up, AP and L.

Average preoperative AOFAS was 33.6 in group A and 32.1 in group B ($P = 0.411$); at six-month follow-up results showed significant differences between the two groups, the mean score was 62.2 in group A and 78.5 in group B ($P = 0.00001$); at final follow up, AOFAS average score was 79.3 in the open group and 81.3 in the arthroscopic group ($P = 0.462$).

The FAS increased in group A from 44.1 at baseline to 61.1 at six months, and to 74.7 at final follow-up; in group B it increased from 48.8 at baseline, to 70.3 at six months,



Figure 2 X-rays (screw fixation). A and B: Preoperative, anterior-posterior (AP) and lateral (L); C and D: 6 mo follow-up, AP and L.

and to 75.8 at final follow-up. Results were statistically significant at six-month follow-up (P = 0.015), no statistical significance was found neither at baseline (P = 0.244) nor at final follow-up (P = 0.593).

The preoperative VAS score was 4.3 in group A and 4.3 in group B (P = 0.903); Pain relief was achieved in both groups at six-month follow-up, VAS score was 1.4 in the open group and 0.9 in the arthroscopic group (P = 0.162). The average score at final follow was 0.8 in group A and 0.6 in group B (P = 0.507).

The patients which underwent open surgery stayed in the hospital for an average of 5.4 d, whereas patients treated arthroscopically for 3.6 d (P = 0.001).

Statistical significance was found in bone fusion time, ten patients out of eleven in group A achieved satisfactory consolidation in 15.1 wk at X-ray evaluation with a union rate of 90.9%. All patients in group B (100%) showed good consolidation at 11.2 wk (P = 0.00001).

One patient in group A underwent revision surgery for symptomatic nonunion within twenty-four months from first surgery. In one patient of group B screws were removed three years after surgery due to pain and discomfort. We reported two cases of wound dehiscence in the open group that were successfully treated with medical therapy.

DISCUSSION

Ankle arthrodesis is considered a safe option for surgical management of end-stage ankle arthritis with good clinical results even compared with total ankle arthroplasty [5]. To authors' knowledge there were few clinical studies comparing mid-term results between arthroscopic ankle arthrodesis (AAA) and open ankle arthrodesis (OAA); our average follow-up of 7.4 years can be considered a long-term follow-up compared with literature.

Clinical results reported by other authors are good both for AAA and OAA with slightly better results for OAA although often not statistically significant[9]. Many authors considered it as relative contraindication for arthroscopic ankle arthrodesis a large coronal plane deformity)[15,24]. Townshend *et al*[25], however, achieved technical success for coronal plane deformities up to 30° with arthroscopy and up to 36° for open arthrodesis. They also evaluated the results of open and arthroscopic ankle arthrodesis in a comparative case series with two years follow-up. They reported significantly greater improvement in the ankle osteoarthritis scale at one and two

years and shorter hospital stay in the arthroscopic group. Those data are partially congruent to our results. We found better clinical results for arthroscopic procedure at six months, but similar results at final follow-up between two groups.

Woo *et al*[26] demonstrated that patients who underwent arthroscopic ankle arthrodesis reported a higher SF-36 score on physical functioning at 6 mo and higher AOFAS at 24-mo, the analysis of VAS scores demonstrated significant less pain during the perioperative period compared with the open group and no significant difference among the two groups at 6 and 24 mo. In this study, it is shown an improvement at 6 mo at the AOFAS (P = 0.00001) and at the FAS (P = 0.015) and at final follow-up at the AOFAS (P = 0.462) and at the FAS (P = 0.593); the VAS showed that pain relief was achieved in both groups at six-month (P = 0.162) and at final follow-up (P = 0.507).

A systematic review by Park *et al*[27] reported that the mean AOFAS score was statistically significant greater in the arthroscopic group at 6 and 12 mo, and a greater improvement in the AOS scores at 1 and 2 years in the arthroscopic group with statistical significance. The SF-36 mental component summary the scores at 1 and 2 years were without a statistical difference greater in the arthroscopic group, The SF-36 physical component summary scores were higher in the arthroscopic group at 1 and 2 years, but the difference was only statistically significant at 1 year.

This study showed that complication rates were overall higher in the group A (27%; 1 revision and 2 wound dehiscence) than in the group B (8%; 1 screws removed) in accordance with the systematic review by Park *et al*[27] in which the most common reoperation was screw removal (open group, 5.1%; arthroscopic group, 9.5%) and the second most common was re-arthrodesis (open group, 2.5%; arthroscopic group, 4%). Another study by Woo *et al*[26] did not reported postoperative complications in the arthroscopic group, but complication rate was 20% in the open group, 16% of these required revision surgery. Quayle *et al*[18] identified that open ankle arthrodesis and a low BMI were the strongest predictors of developing a complication.

Ogilvie-Harris *et al*[15] reported prospectively collected data on nineteen arthroscopic arthrodesis and demonstrated an average length of stay of only one day. Zvijac *et al*[28] reported an average duration of hospitalization of 3 d for open arthrodesis and 1 d for arthroscopic procedure. Similarly, in our results the arthroscopic group showed shorter hospitalization time (P = 0.001).

Time of consolidation of the arthrodesis is a key factor for the success of this surgical technique. Myerson *et al*[16] and other authors reported that traditional open arthrodesis requires approximately 14 wk to achieve satisfactory consolidation[9,18,26,27,29]. On the other hand, regarding arthroscopic procedure, there was no consensus on the fusion timing; Collman *et al*[30] reported that arthroscopic procedures required an average 47 days to achieve bone fusion, while Glick *et al*[31] reported an average time to fusion of 9 wk. A systematic review and meta-analysis by Honnenahalli Chandrappa *et al*[32] showed that the fusion rate was significantly lower in the open group than in the arthroscopic group. Moreover, it has been shown by Collman *et al*[30] and Winson *et al*[33] that arthroscopic ankle arthrodesis achieves high union rates, facilitates short time to union, and permits rapid patient mobility. In this study, the open group required approximately 15 wk to achieve satisfactory consolidation of the fusion at X-ray evaluation with a rate of 90.9% and the arthroscopic group required approximately 11 wk, with a fusion rate of 100%. The pre-operative hindfoot alignment and the shorter time to fusion in the arthroscopic group, could explain the better clinical results compared with open procedure. In this study, the improvement in clinical outcomes was greater and more rapid in the arthroscopic group than in the open treatment group, with maximum improvement achieved at six months follow-up. The arthroscopic arthrodesis is less invasive than open procedure and there is less soft-tissue disruption associated which may reduce the degree of permanent functional impairment of joints and soft tissues adjacent to the arthrodesis site. Furthermore, It appears to allow more rapid activation of the bone-healing cascade, leading to more rapid bone healing and fast functional improvements[25].

The present study is limited by a lack of randomization, a large number of patients lost at final follow-up, and a small sample. Patients were not consecutive, and, in the early period, an open technique was preferred for some of the more difficult cases at the center at which the arthroscopic procedures were performed. Secondly, we did not evaluate the postoperative alignment, furthermore there was no intermediate follow-up between six-month and final follow up.

The main finding of the present study was that ankle arthrodesis is a safe and effective procedure to treat end-stage arthritis with long-term good clinical outcomes, but arthroscopic procedures had a more rapid improvement, with maximum achieved by six months.

CONCLUSION

In this comparative case series, it has been shown that both open and arthroscopic ankle arthrodesis were associated with good clinical outcomes at a long term follow-up on the basis of validated outcome measures. The arthroscopic treatment group showed a more rapid improvement of clinical scores at six months in comparison with the open group, beyond that a shorter hospital stay and a better union rate.

ARTICLE HIGHLIGHTS

Research background

Ankle arthrodesis is a commonly used treatment for end stage ankle arthrosis. There are two different surgical approaches: open arthrodesis and arthroscopic arthrodesis.

Research motivation

To compare the results of arthroscopic arthrodesis *vs* open arthrodesis and evaluate the different efficacy of these surgical approaches.

Research objectives

The aim of the study was to analyze the medium and long term results of the two surgical treatments using the clinical evaluation scales for the ankle.

Research methods

Patients treated with open and arthroscopic technique were divided into two groups. To evaluate the surgical treatments we used The American Orthopaedic Foot and Ankle score (AOFAS), Freiburg Ankle score (FAS) and visual analogue scale for pain intensity. This study enrolled 23 patients which were evaluated preoperatively, at six months and at final follow-up (7 years).

Research results

Arthroscopic treatment shows better results at six months with the AOFAS and FAS. The decrease of pain at six months is present in both groups. At the final follow up both treatments show good clinical results. To be noted is the data relating to hospital stay, which appears to be lower for arthroscopic treatment.

Research conclusions

There are no differences between open and arthroscopic treatments at clinical results at a medium to long term follow-up, and in both cases it was possible to achieve excellent results.

Research perspectives

In perspective, despite being a medium-long term follow up, it is possible to re-evaluate the same court of patients at a greater distance to verify the stability of these results.

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ORIGINAL ARTICLE

Randomized Controlled Trial

Decision aids can decrease decisional conflict in patients with hip or knee osteoarthritis: Randomized controlled trial

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Abstract

BACKGROUND

The interest in shared decision making has increased considerably over the last couple of decades. Decision aids (DAs) can help in shared decision making. Especially when there is more than one reasonable option and outcomes between treatments are comparable.

AIM

To investigate if the use of DAs decreases decisional conflict in patients when choosing treatment for knee or hip osteoarthritis (OA).

METHODS

In this multi-center unblinded randomized controlled trial of patients with knee or hip OA were included from four secondary and tertiary referral centers. One-hundred-thirty-one patients who consulted an orthopedic surgeon for the first time with knee or hip OA were included between December 2014 and January 2016. After the first consultation, patients were randomly assigned by a computer to the control group which was treated according to standard care, or to the intervention group which was treated with standard care and provided with a DA. After the first consultation, patients were asked to complete questionnaires about decisional conflict (DCS), satisfaction, anxiety (PASS-20), gained knowledge, stage of decision making and preferred treatment. Follow-up was

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carried out after 26 wk and evaluated decisional conflict, satisfaction, anxiety, health outcomes (HOOS/KOOS), quality of life (EQ5D) and chosen treatment.

RESULTS
After the first consultation, patients in the intervention group (mean DCS: 25 out of 100, SD: 13) had significantly (*P* value: 0.00) less decisional conflict compared to patients in the control group (mean DCS: 39 out of 100, SD 11). The mean satisfaction score for the given information (7.6 out of 10, SD: 1.8 *vs* 8.6 out of 10, SD: 1.1) (*P* value: 0.00), mean satisfaction score with the physician (8.3 out of 10, SD: 1.7 *vs* 8.9 out of 10, SD: 0.9) (*P* value: 0.01) and the mean knowledge score (3.3 out of 4, SD: 0.9 *vs* 3.7 out of, SD: 0.6) (*P* value: 0.01) were all significantly higher in the intervention group. At 26-wk follow-up, only 75 of 131 patients (57%) were available for analysis. This sample is too small for meaningful analysis.

CONCLUSION
Providing patients with an additional DA may have a positive effect on decisional conflict after the first consultation. Due to loss to follow-up we are unsure if this effect remains over time.

Key Words: Decision aid; Decisional conflict; Shared decision making; Anxiety; Hip osteoarthritis; Knee osteoarthritis

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Core Tip: Patients with knee or hip osteoarthritis provided with an additional decision aid appear to have less decisional conflict, more knowledge about their treatment, more satisfaction with the given information by their physician and therefore more satisfaction with their physician after their first consultation with the physician.

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INTRODUCTION

For patients with knee or hip osteoarthritis (OA) there are multiple treatment options. These treatment options vary from lifestyle adjustments to surgery. When a patient has radiographically end-stage OA combined with a lot of pain, other forms of treatment including physical therapy and corticosteroid injections have been unsuccessful, the choice for a knee or hip arthroplasty seems obvious. However, surgery comes with multiple risks and a period of rehabilitation, which are important factors for patients considering total joint arthroplasty. In the stages before end-stage OA, the choice of treatment is demanding because the results of conservative and operative treatment are comparable[1]. Therefore, in the treatment of OA it is preferable to use shared decision making. Physicians need to give complete, correct and neutral information about the possible treatments to aid the patient in making a shared decision[2]. Furthermore, it is necessary that patients share their own values about the benefits, risks and side effects of a treatment. Due to limited time during clinical visits and the complexity of the information, in many cases it is difficult to establish clear communication between the physician and the patient to make a shared decision. Therefore, it is difficult for the patient to define their values, and this can lead to worse outcomes of the surgery, followed by disappointment, and sometimes regret [3]. Decision aids (DAs) have been developed to support the decision-making process and provide evidence-based information to the patient[4,5]. A DA should be used as an addition to the information explained by the physician, not as a substitution for medical consultation[6]. On top of that with a DA the patient can reread the given information at home.

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Positive effects of DAs related to decisional conflict and knowledge are reflected in previous studies[7,8]. Achaval *et al*[7] investigated the effect of an education booklet, video booklet and decision tool on the decisional conflict among patients with knee OA. It showed a significant overall reduction in decisional conflict. A recent systematic review by Riddle *et al*[8] looked primarily at the effect of DAs on patients' knowledge considering total knee arthroplasty. They found a positive effect on the knowledge of patients, but no effect on patients' anxiety, satisfaction or decisional conflict.

The primary objective of this study is to investigate if a DA reduces decisional conflict in patients choosing treatment for knee and hip OA after the first consultation with their physician. The secondary objective is to investigate if providing patients with a DA increases satisfaction, gained knowledge, influenced stage of decision making, preferred treatment or decreased anxiety after the first consultation and if it reduces decisional conflict, decreases anxiety, increases knowledge, satisfaction, quality of life or physical function and changes preferred treatment at enrollment after 26 wk of follow-up.

MATERIALS AND METHODS

Study design and participants

A multicenter unblinded randomized controlled trial (RCT) was carried out at four secondary and tertiary referral centers in the Netherlands after approval of the Institutional Research Board. Patients were included when they met the following inclusion criteria: Adult patients (18 years or older), newly diagnosed with OA of the knee or hip, Dutch fluency and literacy, and first consultation by an orthopedic surgeon for the complaint.

Study setting

Patients received the diagnosis OA of the knee or hip at one of the participating centers. After the first consultation, patients were asked if they wanted to participate in this trial. When this was the case, the patients were randomized by a computer-generated randomization sequence by one of the research fellows into the control group or intervention group. The control group was treated with standard care. This consists of a thorough case history, physical examination, an X-ray of knee or hip followed by explanation about treatment options for OA. The intervention group was also treated with standard care and received an online DA for their specific diagnosis (knee or hip OA) after the first consultation.

An implementation workshop was conducted prior to the start of this trial to support the treating physicians in using the DAs. In total 14 physicians received the implementation workshop and the included patients. The online DAs were developed by patients and physicians according to the International Patient Decision Aids Standards and based on a previous study, carried out by this research group, assessing patients and physicians needs when deciding about the optimal treatment[3,9]. The DA consists of 5 steps comparing operative treatment, defined as total joint prosthesis, with non-operative treatment, defined as lifestyle advice, painkillers and corticosteroid injections (Supplementary material).

Outcome measures

Our primary outcome was the difference in decisional conflict after the first consultation (mean: 11 d, range: 5-11) measured through the Decisional Conflict Scale (DCS)[10]. The DCS is a validated and reliable questionnaire that consists of 16 questions, divided into 3 categories: a) the level of uncertainty, b) factors contributing to uncertainty such as feeling uninformed, unclear about personal values, or unsupported in decision-making and c) effective decision making such as feeling the choice is informed, values-based, likely to be implemented, and expressing satisfaction with the choice. The total score ranges from 0 (no decisional conflict) to 100 (highest level of decisional conflict).

Our secondary outcomes were satisfaction, anxiety, gained knowledge, stage of decision making, preferred treatment options and if a final choice was made after the first consultation. At 26 wk (mean: 50 wk, range: 26-91) we evaluated differences in decisional conflict, satisfaction, anxiety, final choice, health outcomes and quality of life. The satisfaction questionnaire consisted of three questions to measure patients' satisfaction with the given information, the clinic and the physician. Patients could score each question from 0 (no satisfaction) to 10 (complete satisfaction). As outcome measurement for anxiety, we used the short Pain Anxiety Symptoms Scale (PASS-20)

questionnaire to measure patients' pain-related anxiety and fear. It consisted of 20 questions with a score ranging from 0 (no anxiety and fear) to 100 (extreme anxiety and fear)[11]. The knowledge questionnaire consisted of 4 questions and was used to measure the patients' knowledge of treatment options and risks. The score ranged from 0 (no correct answers) to 4 (all correct answers). The decision questionnaires contained 2 separate questionnaires. One questionnaire inquired what phase of decision making patients were in and which treatment they preferred. The second questionnaire was to determine whether patients had made their definitive decision. Health outcomes measured by the Hip Disability and Osteoarthritis Outcome Score (HOOS) and the Knee Injury and Osteoarthritis Outcome Score (KOOS)[12,13]. Both questionnaires include questions about patients' symptoms, pain, activity limitations in daily life, sport, recreation and quality of life. The EuroQol 5 Dimensions (EQ-5D) questionnaire was used to measure health-related quality of life[14]. It consisted of 5 questions concerning mobility, self-care, usual activities, pain /discomfort and anxiety/depression.

Statistical analysis

We calculated a sample size of 128 patients to identify an effect size of 0.5 SD on the decisional conflict scale with a type 1 error (0.05) and type 2 error (0.20) based on a two-tailed prediction. To report continuous data, we used mean and SD when the group was normally distributed. To compare the control and intervention group we used the Student t-test for continuous dependent variables and dichotomous independent variables when normally distributed. In the case of skewed data, we used the Mann-Whitney U-test. For ordinal data the Kruskal Wallis test was used. We investigated the association between continuous dependent and continuous independent variables in bivariate analysis using Spearman correlation. Associations with a *P* value less than 0.05 were considered statistically significant

RESULTS

Participants

Between December 2014 and January 2016, 145 patients were eligible to participate in this study. Sixty-nine patients were assigned to the control group and 76 patients to the intervention group. Of these 145 patients, 4 patients in the control group and 10 patients in the intervention group did not complete the first questionnaires resulting in a total of 131 participants. Fifty-six patients, 29 in the control group and 27 in the intervention group, did not respond at follow-up (Figure 1).

The control group comprised of 30 men and 35 women, who were on average 66-years-old (SD: 10). The intervention group comprised 33 men and 33 women, who were on average 68-years-old (SD: 11). The baseline demographics are shown in Table 1.

After first consultation

When we compared the total DCS after the first consultation, the total DCS of the intervention group (mean: 25) was significantly ($P = 0.00$) lower than the total DCS in the control group (mean: 39). This means there was significantly less decisional conflict in the intervention group. The intervention group had significantly lower DCS-subscales (information, values clarity, support, uncertainty, and effective decision making) than the control group (Table 2).

Patients in the intervention group scored significantly higher on the knowledge scale than the patients in the control group ($P < 0.01$), they were significantly more satisfied with the given information (mean: 8.6 *vs* mean: 7.6; $P < 0.001$) and their physician (mean: 8.9 *vs* mean: 8.3; $P = 0.01$) compared to the patients in the control group. There was no significant difference in satisfaction with the visit to the outpatient clinic ($P = 0.30$) and anxiety ($P = 0.29$).

Follow-up at 26 wk

Only 75 of 131 patients (57%) were available for analysis at this follow-up point. This sample was too small for meaningful analysis.

Table 1 Baseline characteristics of the patients, *n* (%)

	Without DA	With DA
Sex		
Male	30 (46)	33 (50)
Female	35 (54)	33 (50)
Age (yr; mean ± SD)	66 ± 10	68 ± 11
Level of education		
Pre-vocational secondary or secondary vocational education	15 (23)	22 (33)
Senior general secondary education	10 (16)	8 (12)
Pre-university education	30 (46)	24 (37)
Higher professional education or university	8 (12)	10 (15)
Unknown	2 (3)	2 (3)
Duration of pain in d (mean ± SD)	47 ± 75	55 ± 76
Marital status		
Single	13 (20)	16 (24)
Unmarried	8 (12)	8 (12)
Married	37 (57)	30 (45)
Divorced	2 (3)	1 (2)
Widowed	4 (6)	9 (14)
Unknown	1 (2)	2 (3)
Working status		
Working, full time	8 (12)	16 (24)
Working, part time	12 (18)	7 (10)
Sickleave	2 (3)	1 (2)
Retired	36 (55)	34 (51)
Unemployed, able to work	3 (5)	1 (2)
Unemployed, unable to work	3 (5)	3 (5)
Unknown	1 (2)	4 (6)
Location		
Left hip	10 (15)	9 (14)
Right hip	24 (37)	15 (23)
Both hips	6 (9)	3 (5)
Left knee	13 (20)	13 (20)
Right knee	9 (14)	18 (26)
Both knees	3 (5)	6 (9)
Unknown	0 (0)	2 (3)
Had non-operative treatment before		
Yes	18 (28)	25 (38)
No	47 (72)	39 (59)
Unknown	0 (0)	2 (3)
Hospital		
Hospital 1	2 (3)	9 (14)
Hospital 2	23 (35)	21 (32)

Hospital 3	27 (42)	26 (39)
Hospital 4	13 (20)	10 (15)

DA: Decision aid.

DISCUSSION

Our research shows that patients using a DA in making a shared decision had significantly less decisional conflict, increased satisfaction with the given information and the treating physician after their first consultation and more knowledge about their given treatment.

In previous studies, low decisional conflict was related to DCS scores of 25 or lower. Scores of 39 and higher were related to higher mental conflict which can result in delays in decision making[10,15]. The finding that patients provided with a DA experienced less decisional conflict after the first consultation compared to patients treated without a DA is in concordance with previous studies[6]. The systematic review by Stacey *et al*[16] included 105 studies comparing treatment with DAs to usual care. Sixty-three of the 105 studies used the DCS. A significant average decrease in the level of decisional conflict was observed in the DA group.

In the systematic review by Stacey *et al*[5], the level of satisfaction with the given information and the treating physician at enrollment seems to be positively influenced by DAs. Eleven studies measured satisfaction with the decision-making process, 4 measured satisfaction with the given information and 1 measured satisfaction with participating in the decision making. In these 16 studies, mixed outcomes were found for satisfaction, but none of the studies showed significantly less satisfaction in the DA group. A possible explanation for the positive effect of the DA on the level of satisfaction with the given information could be that patients were able to repeat the information that was given by the physician by reading the DA and have a better recollection. This could also make the patient feel more satisfied with the physician. A crucial factor in patients' satisfaction with their treating physician is how they communicate. An essential part of communication is how the physician provides information about treatments. If the patient is more satisfied with the information because of the DA, this could influence the satisfaction with the physician in a positive way[17-19].

The finding that DAs did not have an effect on the level of anxiety is also accordant with previous studies[5]. Thirty-one studies measured anxiety, and none of these studies showed differences in the effect on patients stated anxiety after one month, three months or one year. Our expectation was that if a patient knows more about potential risks then they might be more anxious. This was not seen in our results.

A well-designed DA should be substantiated by evidence-based research. This means that if one of the treatments has better results this will be seen in the DA. However, every treatment has disadvantages, which will also be reflected in the DA. It is then up to the patient to decide if the advantages are more important than the disadvantages. This means that after the implementation of a DA the preference for a certain treatment can change.

The positive effect of DAs in our results supports the use of DAs in clinical practice. It can help physicians to inform their patient in a better, easier and more complete way. For example, with knee OA, not many patients decide during the first consultation that they are ready for a total knee arthroplasty. In the majority of cases there will be a second and a third consultation. If the orthopedic surgeon provides the patient with a DA in the first consultation, the patient will return better informed. The orthopedic surgeon will have more time to personalize the consultation instead of giving only basic information about the treatments. The patient can ask more specific questions to support their decision. In this way, consultations can be more efficient, and this will be of benefit to the patient and the physician.

Further research is required to determine the positive effect on patients and physicians. In addition, the effect of individualized DAs and their cost-effectiveness should be investigated.

The strength of this study is that this RCT was performed in secondary as well as tertiary referral centers.

The first limitation of this study is the high loss to follow-up at 26 wk (Figure 1). After 26 wk, 56 patients (43%) did not respond during the follow-up period. Additionally, the initial follow-up period was set at 26 wk after the first consultation.

Table 2 Outcomes after the first consultation, *n* (%)

	Without DA	With DA	*P* value
Decisional conflict scale (mean, SD)			
Informed subscore	39 (20)	32 (20)	0.03
Values clarity subscore	50 (22)	25 (16)	0.00
Support subscore	45 (16)	27 (13)	0.00
Uncertainty subscore	35 (15)	23 (16)	0.00
Effective decision subscore	28 (13)	20 (15)	0.00
Total score	39 (11)	25 (12)	0.00
Satisfaction (mean, SD)			
Information	7.6 (1.8)	8.6 (1.1)	0.00
Visit outpatient clinic	8.0 (1.7)	8.3 (1.5)	0.30
Physician	8.3 (1.7)	8.9 (0.9)	0.01
Anxiety (mean, SD)	23 (19)	20 (17)	0.29
Knowledge (mean, SD)	3.3 (0.9)	3.7 (0.6)	0.01
Stage of decision making			0.11
Have not begun to think about the treatment options	2 (3)	1 (1.5)	
Have not begun to think about the treatment options, but I am interested to do so	6 (9)	0 (0)	
I am considering the treatment options now	9 (14)	10 (15)	
I am close to selecting an option	1 (2)	3 (4.5)	
I have already made a decision, but am still willing to reconsider	10 (15)	15 (23)	
I have already made a decision and I am unlikely to change my mind	37 (57)	37 (56)	
What treatment option do you prefer?			0.46
Watchful waiting	3 (5)	5 (8)	
Lifestyle changes	3 (5)	1 (2)	
Physiotherapy	13 (20)	22 (33)	
Painkillers	3 (5)	3 (5)	
Corticosteroid injection	12 (18)	7 (11)	
Prosthesis	27 (41)	26 (38)	
Other	4 (6)	2 (3)	
Did you make a final choice			0.84
Yes	51 (78)	50 (76)	
No	14 (22)	16 (24)	
If yes, what did you choose			0.26
Watchful waiting	2 (4)	4 (8)	
Lifestyle changes	3 (6)	1 (2)	
Physiotherapy	8 (16)	16 (32)	
Painkillers	2 (3)	1 (2)	
Corticosteroid injection	11 (22)	6 (12)	
Prosthesis	25 (49)	21 (42)	
Other	0 (0)	1 (2)	

DA: Decision aid.

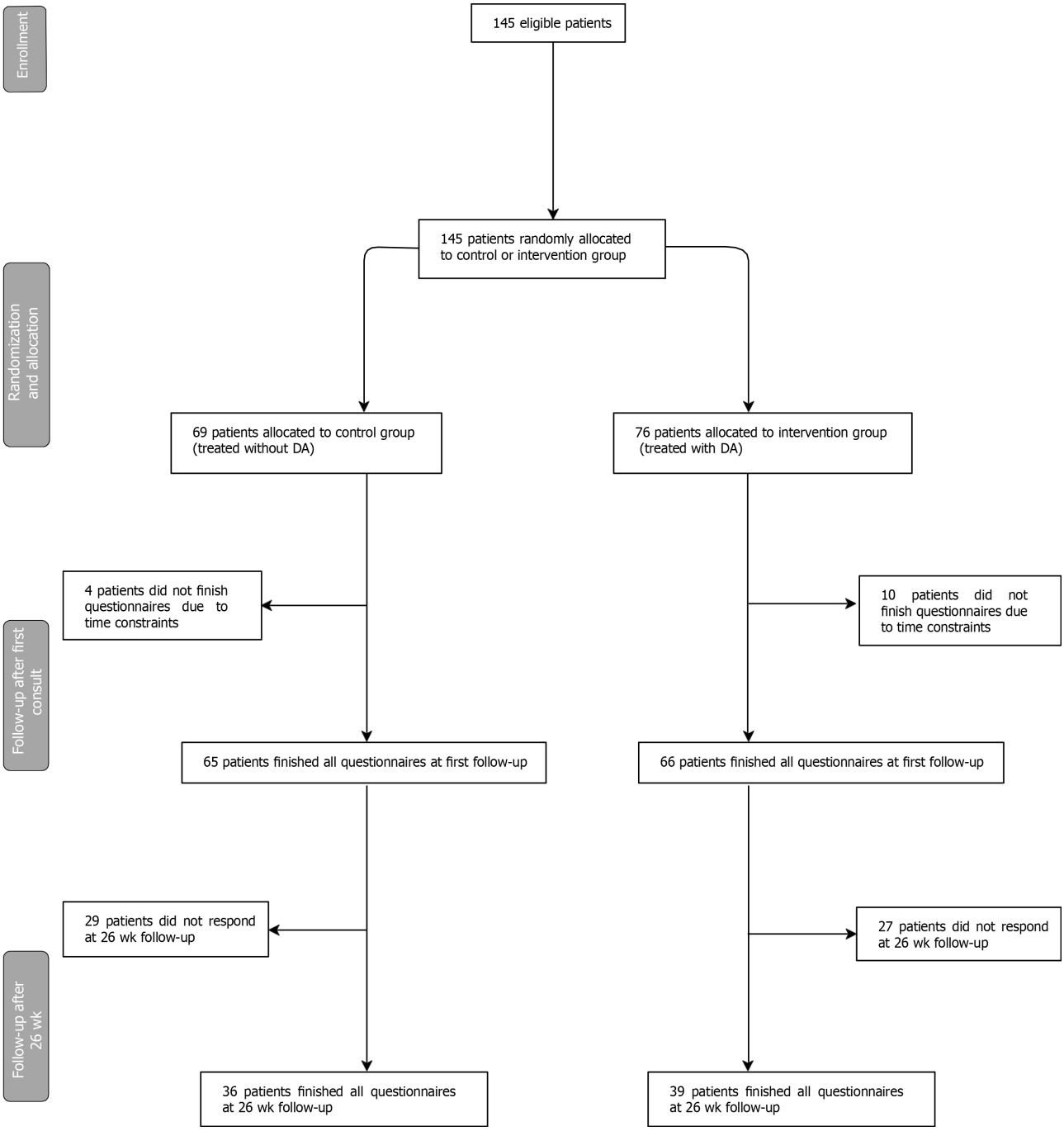


Figure 1 Flow of the patients in the study.

However, eventually, the mean follow-up period was 350 d, thus closer to 52 wk than the anticipated 26 wk. Although the loss to follow-up in both groups was approximately the same, no conclusion can be drawn from the follow-up results. The loss to follow-up was due to time constraints, even though great effort was made to try and contact these patients.

The second limitation was the exclusion of 14 patients, 4 patients in the control group and 10 patients in the intervention group, who did not complete the questionnaires after the first consultation due to time constraints at the outpatient clinic.

The third limitation was that knee or hip OA patients may experience different levels of decisional conflict related to their stage of the OA. We did not categorize patients into different stages of OA. However, due to randomization we expect that patients with varying stages of OA were equally divided over both groups.

CONCLUSION

Providing patients with an additional DA may have a positive effect on decisional conflict after the first consultation. Due to loss to follow-up we are unsure if this effect remains over time.

ARTICLE HIGHLIGHTS

Research background

Shared decision making has become more popular over the years. A decision aid (DA) can help the patient and the physician with the shared decision making process in case a diagnosis has multiple treatment options.

Research motivation

To determine if DAs can help in optimizing orthopedic healthcare we provide to patients with hip or knee osteoarthritis (OA).

Research objectives

The objective of this study was to determine the influence of a DA on decisional conflict in patients that require treatment for hip or knee OA.

Research methods

A multi-center unblinded randomized controlled trial was conducted in which we compared decisional conflict in patients with hip or knee OA. The control group was treated with standard care, and the intervention group was treated with standard care and was provided with a DA.

Research results

In the intervention group, we observed a significant decrease in decisional conflict after their first consultation with the physician. At 26 wk the sample was too small for analysis due to excessive loss to follow-up.

Research conclusions

Patients with hip or knee OA choosing treatment seem to have less decisional conflict after their first consultation with their physician when treated with an additional DA.

Research perspectives

In further research we should investigate the cost-effectiveness of decision aids and the satisfaction among physicians.

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SYSTEMATIC REVIEWS

Intraosseous device for arthrodesis in foot and ankle surgery: Review of the literature and biomechanical properties

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Abstract

BACKGROUND

Arthrodesis is the surgical fusion of a diseased joint for the purposes of obtaining pain relief and stability. There have been numerous fixation devices described in literature for foot and ankle arthrodesis, each with their own benefits and drawbacks.

AIM

To review the use of intraosseous devices in foot and ankle surgery.

METHODS

There were 9 papers included in the review (6 clinical and 3 experimental studies) all evaluating arthrodesis in the foot and ankle using the IOFIX device (Extremity Medical™, Parsippany, NJ, United States). Outcome scores, union rates, as well as complications were analysed.

RESULTS

IOFIX appears to be safe and effective in achieving arthrodesis of the 1st metatarsophalangeal, and talonavicular joints with early rehabilitation. In comparison to plate/screw constructs there were fewer soft tissue complications and issues of metalwork prominence. Cadaveric and biomechanical studies on the use of intramedullary fixation for fusion of the tarsometatarsal and ankle joint showed decreased load to failure, cycles to failure and stiffness in comparison to traditional fusion methods using plates and screws, however IOFIX devices produced higher compressive forces at the joint.

CONCLUSION

We describe the reasons for which this biomechanical behavior of the intraosseous fixation may be favorable, until prospective and comparative studies with larger

Peer-review model: Single blind

Peer-review report's scientific quality classification
Grade A (Excellent): 0
Grade B (Very good): B
Grade C (Good): 0
Grade D (Fair): D
Grade E (Poor): 0

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sample size and longer follow-up confirm the effectiveness and limitations of the method.

Key Words: Intra-osseous fixation; Foot; Ankle; Arthrodesis; Biomechanical; IOFIX

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Core Tip: Numerous fixation devices have been described in literature for foot and ankle arthrodesis. This review article looked into the use of an intraosseous device IOFIX. Outcome scores, union rates, as well as complications described in 9 related publications were analysed. IOFIX appears to be safe and effective in achieving arthrodesis of the 1st metatarsophalangeal and talonavicular joints with early rehabilitation. However, cadaveric and biomechanical studies on the use in tarsometatarsal and ankle joint showed some concerns for which further clinical trials are required.

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INTRODUCTION

Arthrodesis is the surgical fusion of a diseased joint for the purposes of obtaining pain relief and stability. The fundamental principles of arthrodesis include (1) Adequate exposure and preparation of joint surfaces; (2) Coaptation of the surfaces; and (3) Rigid fixation of the surfaces until union[1,2].

Compression, rigidity and co-aptation are interrelated. With perfect co-aptation and compression, significant rigidity can be achieved. Compression neutralises the shear and bending forces. This in turn prevents separation of the surfaces. When compression is applied across an arthrodesis, the pressure is initially concentrated on the uneven areas of the cut surfaces. The resulting osteoclastic resorption brings the surfaces into closer co-aptation. Under the influence of moderate dynamic compression, osteoblastic stimulation occurs resulting in union across the arthrodesis[1]. However, excessive compression leads to bone resorption[2]. The ideal arthrodesis should therefore have moderate compression and near perfect coaptation. Decreased stiffness of fixation and micro-motion improve union provided the magnitude of strain and force of application are not excessive[3,4].

In foot and ankle surgery, common joints where arthrodesis is performed include ankle, subtalar (ST), talonavicular (TN), calcaneocuboid (CC), tarsometatarsal (TMT) and the 1st metatarsophalangeal (MTP) joint. There have been numerous fixation devices such as compression screws, staples, locking and nonlocking plates, as well as combined fixation of screws, staples, and/or plates described in literature each with their own benefits and drawbacks.

The IOFIX (an Intra-Osseous FIXation device, Extremity medical, New Jersey, United States) is a fixed angle device consisting of a "Post" and a lag screw. The "Post" is inserted parallel to the joint surface. The "post" has an eyelet in its head through which a lag screw can be passed across the arthrodesis site at a 60° angle (Figures 1 and 2A). The lag screw gets engaged in the morse taper of the eyelet resulting in a more uniform compression across the fusion site. Since the entire construct is embedded in the bone there is less risk of soft tissue irritation and prominence of metalwork. Furthermore, in comparison with a plate and screw construct there is less soft tissue damage and periosteal damage needed to prepare the articular surfaces and apply the implant.

There have been a number of publications in literature regarding the use of the Intraosseous devices in different joint arthrodesis[5-12]. The aim of this article is to review these publications, assess the overall efficacy of the device across the various joints that are commonly arthrodesed in foot and ankle surgery and correlate the results with its biomechanical properties.

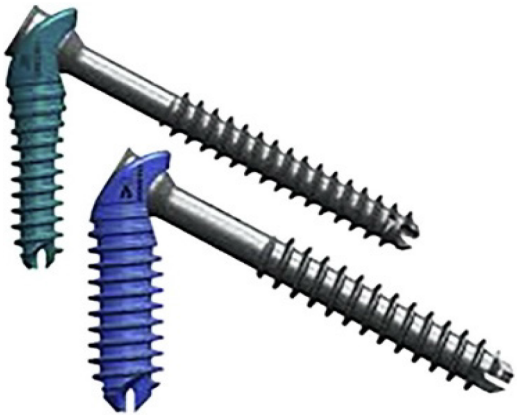


Figure 1 IOFIX device with post (6.5/6.9 mm diameters) and lag screw (4.3/5 mm diameters).



Figure 2 X ray. A: Final position of IOFIX implant; B: Post-operative x ray of a 1st metatarsophalangeal joint fusion using an Intramedullary device at 12 wk.

MATERIALS AND METHODS

A literature search was done in several databases; PubMed Central, Cochrane Central and MEDLINE. The search was restricted to articles in English language. Only fully published studies with details of the use of intra osseous devices were included. Key words used in search were "Intra osseous fixation", "foot", "ankle" and "arthrodesis".

Data extracted included study design, selection criteria, population demographics, type of intervention, initial and final outcome scores, union rates, as well as complications if any. Results of all the included studies were described in a table format. Key outcomes assessed were union rates, patient reported outcome scores and complications.

RESULTS

There have been 9 publications on this topic[5-13] (Table 1). Six of these were clinical studies (5 on 1st MTP joint and 1 on TN joint). Two were cadaveric (1 each on ankle and TMT joint) and one was a synthetic bone study (TMT joint). All the clinical studies had patient reported outcome scores as well as arthrodesis union rates reported.

Radiographic union of the fusion site was defined by observing complete callus or trabeculation across 3 cortices. Position of fusion of the 1st MTP joint was assessed by analysing the intermetatarsal angle, hallux valgus angle (HVA), and 1st MTP joint dorsiflexion angle (DA) using weightbearing anteroposterior and lateral views of the foot.

Table 1 Characteristics of included studies

No	Ref.	Joint arthrodesed	Number of joints	Follow up (mo)	Outcome
1	Segal *et al*[5], 2020	1st MTP joint	30	36	Mean postop AOFAS score: 80.5
2	Patel *et al*[6], 2019	1st MTP joint	54	12	Mean MOXFQ improved from 46.4 to 18.4
3	Singhal *et al*[7], 2018	1st MTP joint	21	28	Mean MOXFQ improved from 49.7 to 17.9
4	Drampalos *et al*[8], 2017	1st MTP joint	12	15	Mean AOFAS score improved from 29.4 to 73.3
5	Drampalos *et al*[9], 2016	1st MTP joint	23	19	Mean AOFAS score improved from 29 to 75.4
6	Shymon *et al*[10], 2016	Talonavicular	12	12	VAS pain level decreased from 7.3 to 2.1
7	Parker *et al*[11], 2014	Tibio talar joint	10 cadaveric		Higher forces within the arthrodesis (3.95 kg *vs* 2.35 kg) in IOFIX
8	Burchard *et al*[12], 2018	1st MTP joint	9 synthetic		Lower load to failure and less stiffness in IOFIX
9	Roth *et al*[13], 2014	1st MTP joint	7 cadaveric		Lesser cycles to failure in IOFIX

VAS: Visual analogue scale; MTP: Metatarsophalangeal.

1st MTP joint (clinical study)

Segal *et al*[5] from Tel Aviv, Israel, conducted a retrospective review on union rates following the use of IOFIX. Standard operative technique was used. The study included 30 cases with an average follow up of 36.2 ± 12.31 mo. Plain radiographic studies were taken at 6 wk, 3–6-12 mo, and at 24 mo when applicable. Clinical union was when the patients could fully bear weight on their feet without pain, and had no pain when applying external force on the 1st MTP joint. Radiographic union was obtained in 28 (93.33%) patients. None of the patients requested removal of hardware due to prominence. The mean postoperative AOFAS score[14,15] was 80.5 ± 10.87. One patient had asymptomatic nonunion. One patient underwent repeat surgery for symptomatic nonunion but still did not go on to union. There were no cases of loss of position or implant breakage.

Patel *et al*[6] from London, United Kingdom, analysed 54 feet for clinical and radiological union with a minimum follow up of 1 year. Patients were allowed to fully bear weight in a rigid-soled shoe with 2 crutches to assist walking immediately after surgery. Arthrodesis was achieved in 52 (96.3%) feet at a mean of 61 ± 16 d. Nonunion was observed in 2 (3.7%) feet with one person opting for repeat surgery using a dorsal plate. There were 2 (3.7%) superficial wound infections that responded to oral antibiotics without further complications. Removal of implant due to metalware impingement on soft tissues was performed in 3 (5.6%) feet after union. The mean Manchester-Oxford Foot Questionnaire score[16] improved from 46.4 ± 13.3 to 18.4 ± 9.4 ($P < 0.001$) at latest follow-up. There were no cases of loss of position or implant breakage.

Singhal *et al*[7] from Liverpool, United Kingdom, did a retrospective review of 21 patients with a mean follow up of 28 mo. Postoperatively patients were allowed to heel weight bear in a firm soled sandal with the aid of crutches. Complete fusion of the 1st MTP joint was achieved in twenty (95%) patients. One patient had a non-union and another patient developed a delayed union. The non-union was revised 14 mo after the initial procedure with a locking plate and bone graft and this has gone on to unite. The mean preoperative MOXFQ score improved from 49.7 (95% confidence interval: 46-52) to 17.9 (95% confidence interval: 12-22), $P < 0.05$.

Drampalos *et al*[8] from Manchester, United Kingdom, published their results on twelve consecutive patients operated with this method. Postoperatively, a C-slab was applied, followed by immediate heel weight bearing in stiff soled shoe. After 6–12 wk, the patients were allowed unrestricted activities provided a satisfactory progression of fusion was evident on radiographs. The mean follow up was 15 mo. Fusion of the MTP joint was obtained in 11 toes (91%). The AOFAS score improved significantly from a preoperative mean of 29.4 (range 10–54), to a postoperative mean of 73.3 (range 59–90) ($P < 0.0001$). The patient with nonunion had only minor improvement from the procedure with persisting symptoms but did not want a revision surgery. There was one patient diagnosed with transfer metatarsalgia who had a malalignment with a

HVA of 4°. This patient had a poor improvement of the AOFAS score (from 30 preoperatively to 59 after the operation) but was still satisfied with the result.

In another series, Drampalos *et al*[9] from Manchester, United Kingdom, reviewed the results of arthrodesis of the 1st MTP joint in 23 patients using the IOFIX or HALUX (Extremity Medical, Parsippany NJ, a similar intramedullary device with an anchored post and a lag screw) (Figure 2B). Patients were followed up for a mean of 19 mo. The mean AOFAS score improved from 29 to 75.4 ($P < 0.0001$) and the mean VAS for pain improved from 8.1 to 2.4 ($P < 0.0001$). Twenty (86%) of the patients were satisfied with the outcome. Twenty-one (91%) of the patients achieved arthrodesis. 2 patients underwent revision surgery for failed fusion (HALUX) and infected non-union (IOFIX).

Talonavicular joint (clinical study)

Shymon *et al*[10] from California, United States, investigated postoperative bony union and functional outcomes of 12 consecutive patients who underwent TN arthrodesis with the IOFIX device. Surgical indications included posttraumatic arthritis, rheumatoid arthritis, and idiopathic arthritis. Post operatively, a short leg, well-padded splint was applied. Patients were advised to be non–weight bearing. At 1 wk, they were placed in a controlled ankle movement boot and allowed to weight bear if pain allowed it. Patients were followed up for a minimum of 1 year. The VAS pain level decreased from 7.3 ± 0.9 preoperatively to 2.1 ± 0.7 postoperatively ($P < 0.001$) and the SF-12 physical component improved from 27.9 ± 4.2 preoperatively to 42.2 ± 3.5 postoperatively ($P < 0.001$). Radiographic union was achieved in all the 12 patients at 9.6 ± 0.4 wk. Three patients had a superficial wound infection that resolved with oral antibiotics for 10 d. On average, patients were able to weight bear by 3.5 wk (range 2.2-5.5 wk)

Tibiotalar joint (cadaveric study)

Parker *et al*[11] from London, United Kingdom, conducted a cadaveric experiment on 10 ankles where they compared the magnitude and distribution of force created across an ankle arthrodesis between IOFIX and traditional AO 6.5 mm cancellous partially-threaded bone screws (Figure 3). The soft tissues from the ankles were removed and the articular surfaces of the distal tibia and talus were prepared with a 2.5 cm wide saw to create uniformly flat arthrodesis cuts. The 10 ankles received both treatments in a randomized fashion in order to allow direct comparisons between repeated measurements. Compression forces were measured using a Tekscan/Iscan (Tekscan Inc. South Boston MA, United States) pressure transducer calibrated to display force in kilograms (kg) and contact area in cm^2 and inserted into the arthrodesis.

The IOFIX created significantly higher median average forces within the arthrodesis (3.95 kg compared with 2.35 kg, $P \leq 0.01$). The IOFIX also created a more uniform pressure across the arthrodesis as well as a higher median average uniform contact area (3.41 cm^2 *vs* 2.42 cm^2, $P \leq 0.03$).

1st TMT joint (in vitro study & cadaveric study)

Burchard *et al*[12] from Witten, Germany, conducted an experimental study using 9 synthetic bones to study the use of a medial locking plate (Double bridge plate® (Konigsee Implantate GmbH, Allendorf, Germany), a plantar locking plate (PEDUS L Plantar Lapidus Plate® (Axomed GmbH, Freiburg, Germany), or an intraosseous locking device [IOFIX (Extremity Medicals, Parsippany, United States)] in 1st TMT joint arthrodesis. They looked into the difference in the initial compression of the osteosynthesis as well as loss of stability and load to failure. The highest initial compression force was provided by the IOFIX implant (131 ± 55 N), followed by the medial locking plate (87 ± 51 N) and the plantar plate (3 ± 1 N). The stiffness provided by the plantar plate was superior compared to both of the other fixation methods (*vs* medial plate $P \leq 0.000$, *vs* IOFIX $P \leq 0.000$). Load to failure was in the following order: (1) IOFIX (173 ± 8 N); (2) Medial plate (324 ± 24 N); and (3) Plantar plate (377 ± 41 N).

Roth *et al*[13] from Mainz, Germany, performed a study on 7 pairs of freshly frozen cadaveric feet to compare the intra- medullary implant IOFIX (Extremity Medical TM, Parsippany, NJ, United States) with plantar locking plate (Wright Medical Technology, Inc, Arlington, TX, United States) in osteosynthesis of the 1st TMT joint. Cycles until failure, failure load, displacement, and plantar gapping were recorded. On average the plates failed after 7517 cycles and a maxi- mum load of 167.1 N while the screw and post implants failed on average after 2946 cycles and a maximum load of 68.6 N. After 8167 cycles 50% of the plates had failed while the same failure rate was observed after 2269 cycles in the IOFIX group. Initial and final stiffness were all higher on average in

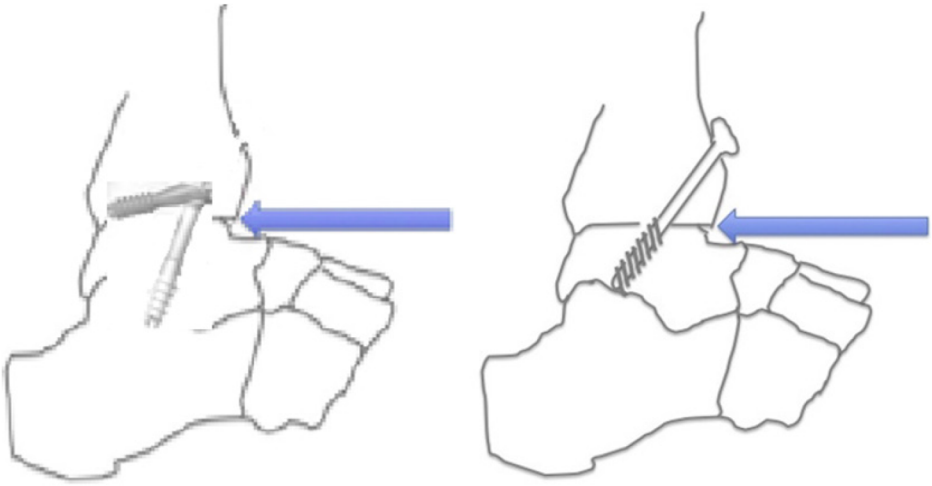


Figure 3 Diagrammatic representation of IOFIX and cancellous screws used in tibiotalar joint arthrodesis.

the plate-treated group than in the screw and post group.

DISCUSSION

The majority of studies on the use of intraosseus fixation devices for arthrodesis involve the first MTP joint and it is considered that the type of implant used to stabilise the fusion site influences the outcome. In general literature the union rates of primary first MTP joint arthrodesis has been excellent and reported to be up to 100% [17]. Patient's satisfaction after MTP arthrodesis varies from 78% to 93%[18-20]. Larger implants have a higher rate of successful fusion but they also have higher implant removal rate, up to 30%, due to nonunion, malalignment, pain and hardware impingement of the soft tissues[21-23]. The intraosseous advantages of IOFIX include the facts that it is of "low profile" and provides uniform compression with a stable fixation[24]. In the series of studies reviewed, IOFIX appears to be safe and effective in achieving arthrodesis of the first MTPJ and immediate weightbearing can be allowed. Concerns have been raised about the cost of the IOFIX implant[5]. However, with the reduced requirement for further surgery and excellent union rates, the pros could outweigh the cons.

The TN arthrodesis study[10] suggests that the IOFIX device improves patient outcomes with a quick return to weight bearing. Historically, post-TN arthrodesis nonunion has been reported in up to 37% of cases of rheumatoid arthritis[25]. In this study, that included 3 patients with rheumatoid arthritis, there were no cases of nonunion.

The experimental study on ankle arthrodesis[11] showed that the IOFIX exhibited a more uniform contact area. The AO lag-screw and washer tended to concentrate stress nearest where it was inserted. Bone resorption in areas of high peak contact stress within an arthrodesis may lead to progressive loss of bone interdigitation, gapping and non-union at the interface. Therefore, theoretically, IOFIX has an advantage over the lag screw fixation methods. But there were no clinical studies available.

In the TMT studies[12,13], IOFIX demonstrated the highest initial compression force of the three tested implants but the load to failure, cycles to failure and stiffness were significantly lesser. The plantar locking plate showed the best overall stability and stiffer construct during cyclic weight-bearing simulation. This does not necessarily mean higher union rates when a plate is being used. In case of a fracture or a fusion there is a range of instability/rigidity which may be tolerated in different biomechanical scenarios. A fusion may be achieved despite instability (or decreased stiffness) while minimal instability may be detrimental in rigidly fixed constructs with small gaps.

The Perren's theory of strain describes the minimum and maximum degrees of rigidity which will be tolerated leading to primary bone healing and induction of callus formation[26]. The decisive factor for tissue differentiation is deformation or strain of the repair tissue and not rigidity/mobility. While tissue strain relates with mobility, it depends even more so on the distance between the movement of the

opposing surfaces. The biological parameters of damage to the blood supply and bone necrosis emphasize the importance of avoiding extensive periosteal stripping and contact of the implant with bone. A balance between rigidity, compression and co-aptation is probably more important. Primary union is seen when rigid stabilisation with perfect co-aptation and minimal interfragmentary motion is applied. Osteoclasts make up the head of a "cutting cone", followed by capillaries and then osteoblasts which lay down the osteoid to fill the "cutting cone". Small gaps are filled by woven bone which later remodels to lamellar bone. There is no external callus and bone strength is not restored for many months. However, in less rigidly fixed fractures, external callus is seen and bone is remodelled quicker in accordance with Wolff's law and Perrens's strain theory[3]. The intraosseous device offers an advantage in this regard. Further research and clinical data is necessary to study the efficacy of IOFIX in TMT fusions. The senior authors of our team have used the IOFIX device for 1st TMT joint fusions with encouraging results and is in the process of publishing them.

The limitation of this review is the few papers available on the device. There were also no clinical papers on the use of intraosseous devices in joints other than the 1st MTPJ and a single article on the talonavicular joint.

CONCLUSION

The intraosseous fixation device IOFIX reviewed in our study appears to be a safe and effective device to achieve arthrodesis with the advantages of early weight bearing. They provide good patient reported outcomes satisfaction and bone union as well as avoiding prominent hardware complications and soft tissue irritation. However, further prospective and comparative studies with larger sample size and longer follow-up are needed to confirm these findings.

ARTICLE HIGHLIGHTS

Research background

Numerous fixation devices have been described in literature for foot and ankle arthrodesis. Each of these devices have their own benefits and drawbacks

Research motivation

This review article looked into the use of an intraosseous device IOFIX. Since the entire construct of IOFIX is embedded in the bone, there is less risk of soft tissue irritation and prominence of metalwork.

Research objectives

Outcome scores, union rates, as well as complications associated with the use of IOFIX was looked into.

Research methods

Fully published studies with details of the use of intra osseous devices were included in the study. These were identified by a search through available English literature. Nine related publications were identified and analysed.

Research results

In comparison to plate/screw constructs there were fewer soft tissue complications and issues of metalwork prominence. It also provided adequate compression across the arthrodesis site.

Research conclusions

IOFIX appears to be safe and effective in achieving arthrodesis of the 1st metatarsophalangeal and talonavicular joints with early rehabilitation. However, cadaveric and biomechanical studies on the use in tarsometatarsal and ankle joint showed some concerns with decreased load to failure and cycles to failure.

Research perspectives

Further clinical trials are required. Prospective and comparative studies with larger sample size and longer follow-up could confirm the effectiveness and limitations of

the method.

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