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Márcio Ibrahim de Carvalho

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Pitcher Shoulder: Update Article*

Ombro do arremessador: Artigo de atualização

Benno Ejnisman[1] Paulo Henrique Schmidt Lara[1] Leandro Masini Ribeiro[1] Paulo Santoro Belangero[1]

[1] Shoulder and Elbow Group, Centro de Traumatologia do Esporte, Escola Paulista de Medicina, Universidade Federal de São Paulo, São Paulo, SP, Brazil

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Address for correspondence Paulo Henrique Schmidt Lara, MD, Centro de Traumatologia do Esporte, Escola Paulista de Medicina, Universidade Federal de São Paulo, Rua Estado de Israel, 636, Vila Clementino, São Paulo, SP, 04022-001, Brazil (e-mail: phslara@gmail.com; bennoale@uol.com.br).

Abstract

Most shoulder injuries occur due to repetitive overhead movements. Before studying the treatment of these shoulder injuries, it is paramount that health professionals have an understanding of the etiology of and the underlying mechanisms for shoulder pathologies. The act of overhead throwing is an eloquent full-body motion that requires tremendous coordination from the time of force generation to the end of the pitch. The shoulder is a crucial component of the upper-body kinetic chain, as it transmits force created in the lower body to the arm and hand to provide velocity and accuracy to the pitch.

Keywords

- shoulder
- joint instability
- athletic injuries

Resumo

A maioria das lesões do ombro ocorre devido aos movimentos repetitivos acima do nível da cabeça. Antes de estudar o tratamento dessas lesões, é fundamental que os profissionais de saúde tenham um entendimento da etiologia e dos mecanismos que causam essas patologias. O ato do arremesso acima do nível da cabeça exige considerável coordenação de todo o corpo, desde o momento de geração de força até o final do arremesso. O ombro é um componente crucial da cadeia cinética da extremidade superior, por transmitir a força gerada na extremidade inferior para o braço e mão para produzir velocidade e precisão no lançamento da bola.

Palavras-chave

- ombro
- instabilidade articular
- traumatismos em atletas

Introduction

Pitchers tend to have shoulder injuries as a result of the high forces to which this joint is submitted during the pitch. The dynamic stabilizers of the glenohumeral joint include the rotator cuff, the scapulothoracic muscles and the long head of the biceps tendon. The static stabilizers static include the bone anatomy, the fibrocartilaginous lip, and the joint capsule.

A single traumatic event can cause an injury; however, it is more common that the repetitive overload leads to failure of one or more structures. The act of pitching requires a coordinate action that progresses from the tip of the toes to the fingers of the hand. This string of events was described conceptually as kinetic chain.[1] In order for this to work effectively, a sequential muscular activity is necessary so that the energy generated in the lower part of the body is transmitted to the upper part and, lastly, to the ball.[2] The speed of the ball is determined by the efficiency of this process. Body

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rotation and the position of the scapula are key elements in the kinematic chain. In professional pitchers, there is a delicate balance between mobility of the shoulder and stability. The shoulder needs to be mobile enough so that the extreme points of the rotation are achieved and the speed is transmitted to the ball; however, at the same time, the shoulder must stay stable so that the humeral head stays within the glenoidal cavity, creating a stable hub for rotation, which is known as "thrower's paradox."[3] At each pitch, the soft tissue envelope that circles the shoulder is submitted to a load that is very close to the maximum load supported, which leads to the possibility of injury.[3] Even though the standards of the injuries in cases of pitcher shoulder are common and predictable, there still is controversy about the exact mechanisms that lead to these injuries. Recent biomechanical studies have helped improve the understanding of the pathogenesis of the injuries in pitchers.[4–6] Moreover, quantitative information about the normal or pathological biomechanics and kinematics have helped the development of strategies for the prevention and treatment of injuries, as well as for rehabilitation.[7–9]

Pitch Kinematics

The pitch was divided into six phases, which usually take less than two seconds to occur.[10,11] The first 3 phases consist of preparation, stride and arm elevation, and take approximately 1.5 seconds in total. Although the fourth phase, acceleration, lasts about 0.05 seconds, the highest angular speeds and the greatest change in rotation occur during this phase.[12] The last two phases are deceleration and execution, and, together, they last approximately 0.35 seconds[12] (►**Figure 1**). As certain lesions occur at certain stages, it is important to determine when pain or a problem occur.

The speed of the ball depends on a variety of biomechanical factors, but is more directly related to the amount of lateral rotation that the shoulder performs.[13] To generate maximum pitch speed in the most efficient way, the lower and upper extremities must work in a synchronized and coordinated way. Professional pitchers can generate ball speeds that exceed 144.8 km/h; to create such a speed, the shoulder reaches angular speeds of up to 7 thousand degrees/s.[13] After the release of the ball, the shoulder of a professional pitcher can be exposed to distracting forces of up to 950 N.[14] In the deceleration phase, there are compression forces created by the rotator cuff and deltoid muscles in the 1,090 N range, as well as posterior shear forces of up to 400 N.[14] The anterior part of the capsule resists approximately 800 N to 1200 N in individuals aged 20 to 30 years.[15] Therefore, if compressive forces do not counterbalance the high forces of distraction, injuries will occur.[15] The study by Kibler et al[1] largely contributed to the understanding of scapular dynamics, injury prevention and treatment. It is estimated that only half of the kinetic energy transmitted to the ball comes from the arm and shoulder. The other half is generated by the rotation of the trunk and lower limbs, and is transferred to the upper extremity through the scapular joint, making this joint an important, but often neglected, part of the kinetic chain.[16] A dynamic analysis of the shoulders during the pitch added to our current knowledge of normal and abnormal function and, by demonstrating which muscle groups are active during the pitch in each phase, it helped guide the development of prevention and rehabilitation programs.[17]

Pathogenesis of Lesions

The pitcher's shoulder is susceptible to injury due to the convergence of the following factors: attenuation of the constrictors of the anterior capsule, contracture of the posterior capsule, development of scapular dyskinesia, kinetic chain breakage and repetitive contact of the greater tuberosity and the posterosuperior lip. Each of these factors was evaluated and strategies were suggested for injury prevention.

Previous Capsule Laxity

Biomechanical studies have shown that the anterior capsule, particularly the anterior band of the lower glenohumeral ligament, is the main restrictor of the anterior humerus translation with the arm in abduction and lateral rotation.[18–20] Therefore, repetitive stress in this area and the pitcher's desire to reach increasing levels of lateral rotation lead to a laxity of the anterior capsule.[18–20] Although the assigned causes are controversial, pitchers in fact have more passive lateral rotation than rotation of the contralateral shoulder.[21,22] If the gain in lateral rotation is greater than the loss of medial rotation, there is laxity of the restrictors.[21,22] In support of this, a work by Jobe et al[23] describes the tensioning of the anterior capsule as a means for the athlete to resume pitching. Although in the study by Jobe et al[23] this procedure was successful for patients (68% of the patients presented excellent results and returned

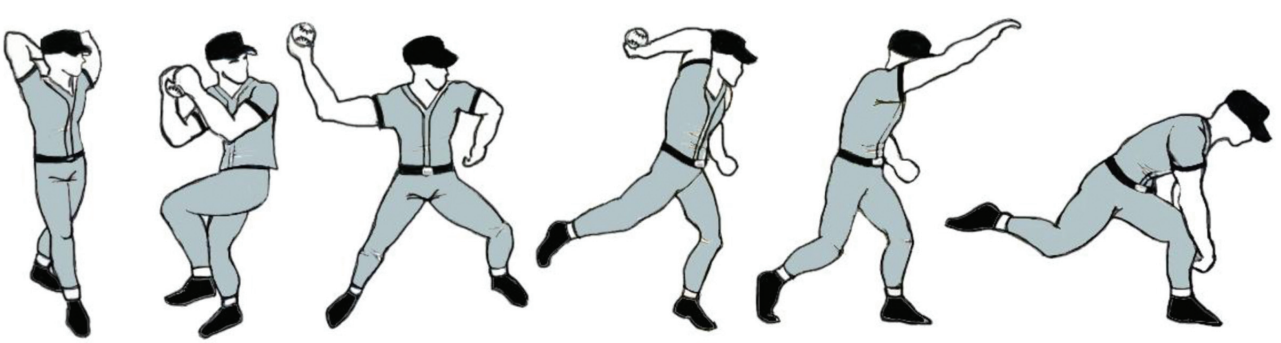

Fig. 1 Phases of the pitch: (1) preparation; (2) stride; (3) arm elevation; (4) acceleration; (5) deceleration; and (6) execution/finish. Source: Drawing by the author.

to their preinjury levels, and 96% were satisfied with the surgery), the violation of the subscapularis muscle and the excessive tension explain why not all patients were able to return to their pre-injury levels after the reconstruction. With the progression of the anterior laxity, there is increased lateral rotation and increased contact between the back of the cuff and the lip, which facilitates the occurrence of injuries.[24]

Subsequent Capsule Contracture

Over time, pitchers develop decreased medial rotation, especially when measured during abduction.[25] It is believed that this decrease in medial rotation occurs for two reasons. First, the increase in the retroversion of the humerus observed in pitchers manifests itself with a loss of medial rotation. However, this loss, due to bone remodeling, is accompanied by a symmetrical gain in lateral rotation.[25] Another means of medial-rotation loss is the contracture of the posterior capsule. It is believed that the median-rotation deficit of the glenohumeral joint occurs as a scar process in response to chronic distracting forces applied to the posterior capsule during the performance of the pitch.[25] Rotational loss due to capsular contracture is evident when the median-rotation deficit of the glenohumeral joint exceeds the one that can be explained only by bone remodeling (more than 12°), and when the loss of medial rotation exceeds the increase in lateral rotation compared to the contralateral side.[25]

Biomechanical Consequences of the Medial Rotation Deficit of the Glenohumeral Joint

Current clinical and biomechanical studies[26,27] have shown that the median-rotation deficit of the glenohumeral joint may be the sentinel event in the pathological cascade that many pitchers go through. The authors found that pitchers who had superior labial lesions had a median rotation deficit of the glenohumeral joint greater than 25°.[26,27] Even small degrees of medial-rotation deficit of the glenohumeral joint (such as 5°, for example) put the shoulder at risk of injury and eventual need for surgery.[26,27] The posterosuperior displacement that occurs with the median rotation deficit of the glenohumeral joint is due to posterior and lower capsular contracture, which does not enable the total lateral rotation of the humerus. Therefore, the athlete begins to rotate around a new center of rotation, which is more posterior and proximal. Essentially, a contracted posteroinferior capsule displaces the humerus more posteriorly and proximally (►**Figure 2**).[6]

Scapular Dyskinesia

Dyskinesia is a static or dynamic abnormality of the scapular position. Shoulder pain leads to an inhibition of the lower trapezius and anterior serratus muscles, and to a contracture of the upper trapezius and smaller pectoral muscles.[28–31] This muscle imbalance leads to a prostration of the scapula. Pitchers with loss of medial rotation due to capsular contracture end up using medial scapular rotation to perform the pitch. Over time, the scapula loses the static restrictors, and probably overloads the dynamic restrictors, and the scapula deviates from the midline and moves anteriorly.[32] Thomas et al[33] demonstrated that the greater the median rotation deficit, the greater the changes in the position and mobility of the scapula. They evaluated 43 professional baseball players, and, in 22 athletes, deficits greater than 15° were found, in which there was higher scapular dyskinesia, with statistical significance. In another study by Thomas et al,[34] a temporal relationship was demonstrated between scapular dyskinesia and the medial-rotation deficit of the glenohumeral joint, in which more experienced baseball players had greater deficits, with statistical significance.

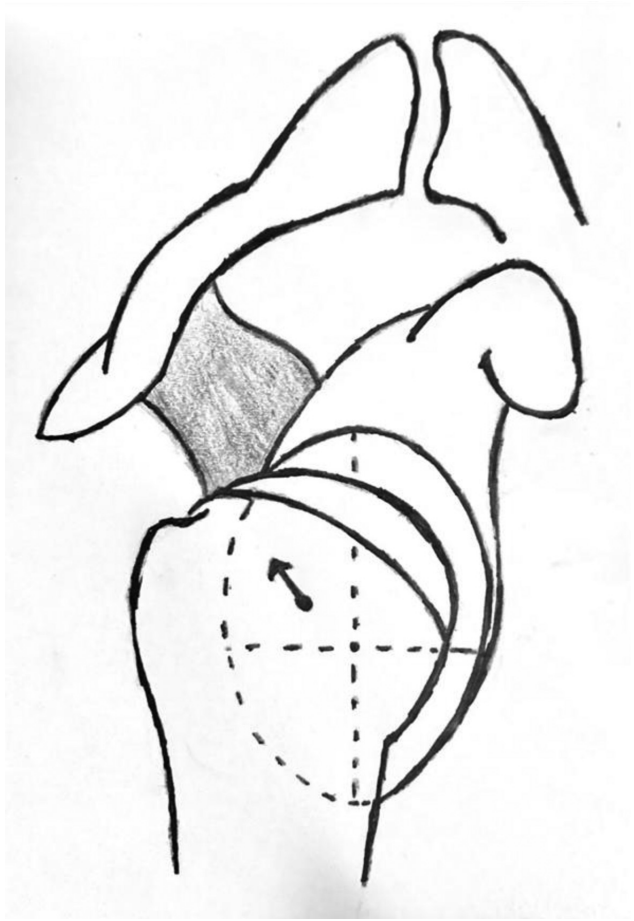

Fig. 2 Posterior and proximal displacement of the humeral head. Source: Drawing by the author.

Effects of Excessive Scapular Protraction

There are several biomechanical consequences of a scapula with excessive medial protraction or rotation. First, there is a weakness of the rotator cuff. As the rotator cuff complex essentially originates from the scapula, if there is an unstable platform, these muscles will not function properly.[35] In addition, increased protraction increases the version of the scapula, leading to anterior destabilization and increased overload in the anterior ligaments.[36] Excessive protraction also increases the degree of impact between the posterior rotator cuff and the posterior region of the glenoid during abduction and lateral rotation.[26] The study by Laudner et al[37] evaluated that pitchers diagnosed with pathological internal impact showed a statistical significant increase in the elevation of the sternoclavicular joint and scapular deviation during shoulder elevation in the plane of the scapula.

Common Pathological Conditions and Treatment Options

Mobility and Instability

Mobility is defined as passive movement of a joint in a special direction or rotation.[38,39] Hyperelasticity can be physiological or pathological, and may predispose to lesions. The term shoulder instability is reserved for the feeling of excessive humeral head movement in relation to the glenoid, which is usually associated with pain or discomfort. Few pitchers have symptoms of instability, although the term instability has been used in many studies to describe the syndrome that occurs in pitchers. While some degree of hyperelasticity can help the athlete compete at a high level in sports involving pitching, the excess may be responsible for the development of certain pathological conditions of the shoulder. This has been called atraumatic instability, which is believed to be due to the repetitive stress that occurs during pitches.[40] Kuhn et al[41] coined the term pathological hyperelasticity, which we also believe is a more accurate description of what is actually happening.

SLAP Injuries

The superior labral tear from anterior to posterior (SLAP) lesion is an important clinical cause of shoulder pain. Burkhart and Morgan[42] proposed that SLAP injuries in pitchers occur by the peel-back mechanism, which is defined as an increase in tension at the origin of the biceps during maximum lateral rotation during the pitch. Laboratory studies have shown that the long head of the biceps is an important dynamic restrictor of lateral rotation when the arm is abducted.[43] Conservative treatment is recommended initially, and its main objectives are to provide a decrease in pain, a gain in motion arc and a focus on dynamic strengthening, with an emphasis on the stabilizers of the scapula and rotator cuff.[42] If this fails, the surgical treatment is indicated, which usually is arthroscopic and varies according to the degree of the injury.[42]

Rotator-Cuff Injuries

About 62% of the injuries to the pitcher's rotator cuff are partial-joint injuries.[6] These injuries in pitchers are usually found posterosuperiorly at the junction of the adrenal and infraspinal insertions.[44,45] Physiotherapy should be considered the initial treatment for partial cuff injuries in pitchers. Simple debridement has not shown good results in pitchers. The study by Payne et al[46] evaluated athletes submitted to simple debridement who were divided into two groups (pitchers with traumatic injuries and non-traumatic injuries). In patients with traumatic injuries, there was a satisfactory result in 86% of the cases, and 64% returned to the sport. In the pitchers with non-traumatic injuries, there were satisfactory results in 66% of the cases, and return to the sport in 45% of the cases.

Impact

Different types of impact have been described in the literature, including the classic, subacromial, secondary and internal impacts.[47–52] The internal impact is a pathological phenomenon in which the rotator cuff meets the posterosuperior aspect of the lip with the shoulder at the maximum degree of abduction and lateral rotation.[53,54] Several studies have shown that this type of impact is most likely caused by fatigue of the scapular waist muscles due to lack of conditioning or overtraining.[55,56] These studies have shown that, during acceleration phase of the pitch, the humerus must be aligned with the scapular plane. From the moment the muscles become fatigued, the humerus comes out of the plane of the scapula, which is called hyperangulation, leading to an overload of the anterior capsule.[57]

General Treatment Guidelines

The treatment begins with conservative measures. The contracture of the posterior capsule should be addressed, and a stretching and mobilization program must be carried out. The stretching should isolate the glenohumeral joint so that scapular compensation is minimized.[26] The evaluation of the kinetic chain is essential. Lumbar contracture, weakness of the hip abductors and decreased medial-leg rotation should be investigated.[26] Scapular dyskinesia, which is commonly present, can usually be treated with exercises that help restore normal scapular mobility. The first step in scapular rehabilitation should focus on neuromuscular reeducation of the escaping stabilizing muscles. Strengthening should be initiated after this phase.[26] Strengthening the muscles of the rotator cuff should be performed, especially of the infraspinatus muscle, through lateral rotation exercises with resistance, which protects the rotator cuff from injury.[26]

The surgical treatment is indicated in cases of failure of the conservative treatment. Three to four months of physiotherapy are usually attempted, and the therapy should be prolonged if the athlete presents progressive improvement of the condition.[26] Most pitchers, especially younger ones, are able to recover from the moment there is resolution of the scapular dyskinesia and the medial-rotation deficit.

Final Considerations

The performance of pitchers is often limited by shoulder injuries. These problems are complex and, therefore, difficult to manage. The problems occur as a result of a combination of muscle imbalance, muscle fatigue, hyperlaxity of the anterior capsule, contracture of the posterior capsule, altered mechanics of the pitch, scapular dyskinesia, increased humeral retroversion, and repetitive microtraumas. As a result, in pitchers we have observed lesions involving the lip, the joint side of the back of the rotator cuff, and the proximal insertion of the long head of the biceps.

The mechanisms and etiologies of the injuries in pitchers are becoming more well-defined. Although there is controversy over what would be the initial event, the typical injury patterns remain the same.

Before we think about treatment options, it is essential to get a detailed history, and to perform a physical examination and additional imaging studies to get to the correct diagnosis. The treatment of shoulder injuries should be initiated with a protocol that focuses on restoring the arc of motion,

strengthening and specific stretching to promote stability of the scapula, shoulder and core muscles (deep muscles of the abdominal, lumbar and pelvic regions that aim to maintain the stability of this region). In addition, physicians, physiotherapists and trainers involved with pitchers should have extensive understanding of the entire pathophysiological cascade that leads to injuries in these athletes.

Conflict of Interests

The authors have no conflict of interests to declare.

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Current Options in Tendon Transfers for Irreparable Posterosuperior Rotator Cuff Tears*

Opções atuais de transferências tendíneas para lesões posterossuperiores irreparáveis do manguito rotador

Caio Santos Checchia[1] Luciana Andrade da Silva[1] Guilherme do Val Sella[1] Marcelo Fregoneze[1] Alberto Naoki Miyazaki[1]

[1] Department of Orthopedics and Traumatology, Faculdade de Ciências Médicas da Santa Casa de São Paulo, São Paulo, Brazil

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Address for correspondence Caio Santos Checchia, Grupo de Ombro e Cotovelo, Departamento de Ortopedia e Traumatologia, Faculdade de Ciências Médicas da Santa Casa de São Paulo, Rua Dr. Cesario Mota Junior, 112, Consolação, São Paulo, SP, 01221-020, Brazil (e-mail: caio.checchia@gmail.com).

Abstract

Massive irreparable posterosuperior rotator-cuff tears are debilitating lesions that usually require surgical treatment. Even though there is no consensus regarding the best surgical technique, tendinous transfers around the shoulder are the most commonly performed procedures. The latissimus dorsi tendon remains the most commonly used, but different modifications to the original technique have been shown to minimize complications and to improve functional results and satisfaction. Other techniques, such as the transfer of the lower trapezius tendon, are promising and should be considered, especially for patients with isolated loss of external rotation. The present paper is a literary review regarding tendon transfers for irreparable posterosuperior rotator-cuff tears.

Keywords
- shoulder
- rotator cuff injuries
- tendon transfers
- review

Resumo

As grandes lesões posterossuperiores irreparáveis do manguito rotador são debilitantes e, de modo geral, requerem tratamento cirúrgico. Embora não haja consenso sobre a melhor técnica cirúrgica, as transferências tendíneas no ombro são os procedimentos mais realizados. O tendão do grande dorsal continua a ser o mais utilizado, mas diferentes modificações na técnica original têm minimizado as complicações e melhorado os resultados funcionais e a satisfação com o procedimento. Outras técnicas, como a transferência do tendão do trapézio inferior, são promissoras e devem ser consideradas, principalmente em pacientes com perda isolada da rotação externa. Este artigo é uma revisão da literatura a respeito da transferência de tendões para tratamento das lesões posterossuperiores irreparáveis do manguito rotador.

Palavras-chave
- ombro
- lesões do manguito rotador
- transferências de tendão
- revisão

* *Work developed at the Department of Orthopedics and Traumatology, Faculdade de Ciências Médicas, Santa Casa de São Paulo, Pavilhão "Fernandinho Simonsen". Director: professor doctor Ivan Chakkour – São Paulo (SP), Brazil.*

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Introduction

Rotator-cuff-tear (RCT) repairs are among the most common shoulder surgeries.[1] However, tendon-to-bone healing is not always successful or predictable,[2] because it depends on a variety of factors, including biomechanical and biological ones, the latter being influenced by the patient's age.[3] As the population is rapidly aging, the prevalence of failed rotator-cuff repairs is also increasing.[1,3] The failure rates of massive posterosuperior rotator-cuff repairs are reported to range from 21% to as high as 91%.[4–6] Failures and complications following revisions are reported to be even significantly higher.[7,8]

There is no consensus regarding the definition of irreparable RCTs. That being said, whenever a lesion is determined to be irreparable, there are many treatment options, starting with nonsurgical treatments.[9] Regarding the surgical options, there is controversy about the best treatment available. Boileau el al[10] and Walch et al[11] showed satisfactory results after tenotomy of the long head of the biceps (LHB) alone in elderly patients. Other procedures have been reported, including rotator-cuff debridement (with or without concomitant suprascapular nerve release),[12] partial cuff repair,[13–15] tendon transfers,[16–19] and reverse shoulder arthroplasty (RSA).[20] The latter, however, is probably not the best option in younger and physically-active patients, because the longevity of these implants in this population is yet unknown, and also because RSAs can still be used as a salvage procedure after the failure of other techniques. More recently, superior shoulder capsular reconstruction[21–28] has been advocated, but its reported functional results are in their infancy,[23,29] and longer follow-up periods are needed to confirm its long-term efficacy.[30]

Despite being relatively difficult surgical procedures and requiring accurate patient selection, tendon transfers can significantly improve the quality of life of the patients.[16,18,31] This is especially important for young and physically-active patients with lesions graded as Hamada et al[32] stages 1 and 2 (that is, without both glenohumeral arthritis and static proximal humeral head migration), because they may be the only feasible definitive (that is, long-term) treatments available.[30]

The aim of the present paper is to review the literature regarding tendon transfers for irreparable posterosuperior RCTs (that is, the ones involving the supra- and infraspinatus tendons), as the posterosuperior is by far the most common type of RCT.[1] In this context, the latissimus dorsi tendon (LDT) –accompanied or not by the teres major tendon (TMT) – is the most commonly transferred tendon.[33] The alternatives include isolated TMT transfer[34–37] and the more recently described transfer of the lower trapezius tendon (LTT).[38,39]

Latissimus-Dorsi-Tendon (LDT) Transfer

The earliest and also most studied transfer is that of the LDT, which was originally described by Gerber et al,[17] and is performed using a double open-approach technique (a posterior approach and a superior transdeltoid approach). The transferred tendon is attached superolaterally to the greater tuberosity (by transosseous sutures) and anteriorly to the subscapularis tendon, therefore changing the latissimus dorsi into a shoulder abductor and external rotator (as opposed to its original role as an internal rotator an adductor) (►**Figure 1**). The rationale behind this procedure is: to restore humeral-head centering (as the intact anterior subscapularis force is now joined by the new posterior force[40]); and to improve active external rotation (ER) of the shoulder.

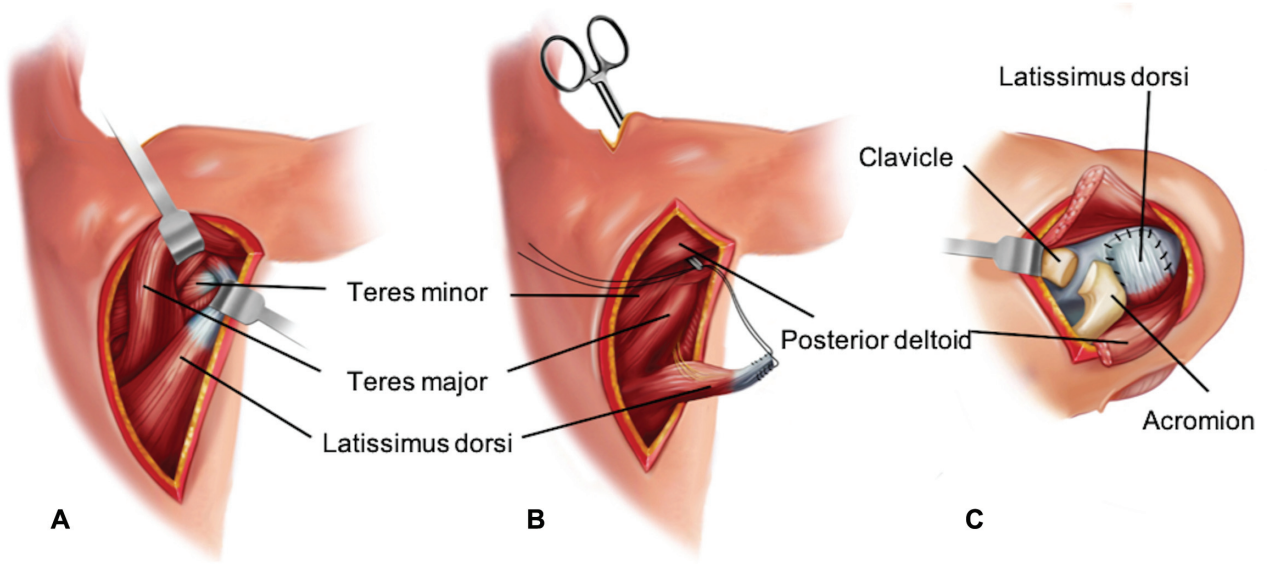

Fig. 1 (**A-C**) Latissimus dorsi transfer using a double-incision technique. Representation of a right shoulder. (**A**) Posterior view. A posterior incision is made over the lateral border of the palpable latissimus dorsi belly, which is then separated from the more superior and medial teres major muscle. (**B**) Posterior view. The tendon is detached from the humerus and then is transported to the subacromial space with a clamp that is brought from the superior to the posterior incision, placed between the posterior deltoid and the long head of the triceps muscle. (**C**) Superior view. The transferred tendon is then anchored to an osseous trough in the superolateral humeral head (over-the-top placement), and any remaining cuff is sutured to the transfer.

In 1992, Gerber[16] published his postoperative results. A total of 17 patients were followed for an average of 33 months postoperatively, showing that for the subgroup of patients with normal subscapularis function (12 of the total 17), around 80% of normal shoulder function was reestablished. Therefore, this was the first study indicating that the LDT could be a safe and valuable alternative for these patients.

Many other subsequent papers[18,19,31,33,41–48] have also shown that satisfactory results following LDT transfer could be achieved. However, these satisfactory results could not be easily predicted. The probable reason for that, besides the proper surgical technique, is that proper patient selection may also crucial in order to obtain satisfactory and predictable results, as it will be discussed subsequently.

While no upper age limit has been defined, a recent systematic review[46] noted a mean age of 59 years for LDT transfer, and showed that the indication could be even extended to elderly patients with Hamada et al[32] stage-3 arthropathies.

Preoperative integrity from both the deltoid and the subscapularis have been shown[19,44,45,49] to be really important in order to achieve good outcomes, as forward elevation and shoulder stability respectively drastically decrease with their insufficiency.[16,42,50–52] However, we should notice that patients with concomitant subscapularis lesions limited only to its proximal insertion (but without subscapular dysfunction – that is negative lift-off sign) have been successfully treated since Gerber's initial publication.[16,18,47,51]

Another likely predictor of worse postoperative outcomes and decreased active ER is preoperative atrophy and fatty infiltration (Goutallier 3 or higher) of the teres minor muscle.[47,52,53] Despite that, Moursy et al[52] noticed that even though patients with these findings fared worse overall, they were the ones with greater gain in postoperative ER; they concluded that this happened because preoperative degeneration of the teres minor muscle in all of their cases correlated with lesser preoperative active ER.[52]

Good preoperative shoulder movement is also essential, specifically passive forward flexion (FF) greater than 80°.[41] Furthermore, pseudoparetic shoulders (defined as active FF lower than 90°[54]) and previous surgical procedures have also been demonstrated to correlate with poorer outcomes.[18,55,56]

Different techniques for LDT transfer were also developed. Habermeyer et al[43] described a single-posterior-incision approach with a more posterior attachment site into the humeral head. Hertzberg et al[57] reported a similar technique, but instead, with a correction on the original site of insertion of the infraspinatus. However, the authors pointed that occasional proximal subscapularis lesions cannot be adequately treated through this approach. Nonetheless, Habermeyer et al[43] showed clinical results comparable to those of Gerber's two-incision method, with mean Constant-Murley scores improving from 46.5 points (29.3 to 66.7) preoperatively to 74.6 points (64.5 to 81.5) postoperatively.

Recently, there have been reports of arthroscopically-assisted transfers of this tendon.[31,48,58,59] Grimberg and Kany[31] reported outcomes equivalent to those of historical open approaches, and this one-incision arthroscopically-assisted approach provided better mechanical resistance to traction due to the tubularized tendon fixation using two suture threads, resulting in a total of four suture ends for fixation.[60]

In 2019, Miyazaki et al[61] described a new technique for open LDT transfer. The authors claimed that the original technique has two main drawbacks that could predispose to complications and unsatisfactory functional results: 1) postoperative rupture of the origin of the deltoid, as its detachment from the acromion is necessary during the superior approach; and 2) postoperative rupture of the transfer. In an attempt to avoid these problems, they developed the following modifications. Through a deltopectoral approach, the LDT is detached from the humerus shaft, and is then reinforced and elongated with a tendinous allograft (calcaneus or quadricipital grafts), and finally transferred around the humerus and fixed to the superolateral aspect of the greater tuberosity. (►**Fig. 4**) Nonetheless, no clinical results have been published so far.

We agree with the findings of Moursy et al[52] that it is difficult to assess the integrity of the transfer through magnetic resonance imaging (MRI). Regarding this matter, Kany et al[62] published in 2018 an interesting and insightful study. They evaluated 60 patients (after losing 6 patients to follow-up), with a mean postoperative follow-up of 35.2 months. The surgical technique in all of the patients involved placing three metallic markers distanced 2 cm, 4 cm and 6 cm from the tip of the tendon, therefore enabling an easy diagnosis of transfer ruptures with simple X-rays (►**Figure 2**). The results showed 23 (38.6%) ruptures (►**Figure 3**), which in itself was a major factor for worse postoperative functional results and satisfaction using 7 different functional and satisfaction scores ($p < 0.05$ in all of them).

Checchia et al[30] have hypothesized that the outcomes of LDT transfers would be determined not only by patient selection or concomitant subscapularis insufficiency, as mentioned by Gerber[16] and other authors,[19,44,45] but also by respecting five specific principles of tendon transfers:

1. Accurate positioning of the transferred tendon;
2. Physiological tensioning of the transferred muscle-tendon unit;
3. Strong bone fixation of the reimplanted tendon;
4. Minimally-invasive surgery to reduce muscle scarring (without hindering the excursion of the transfer);
5. A synergistic transfer.

1. The ideal fixation site probably varies according to the preoperative clinical presentation. According to Walch et al,[63] the clinical presentation of these patients is variable, especially regarding the drop sign (also known as Hornblower sign), which indicates deficiency of the external rotators. Painful, pseudoparetic shoulders with negative drop signs (described by Boileau et al[64] as a 'painful loss of active elevation'), should be treated, according to Gerber et al,[17] with an over-the-top transfer.

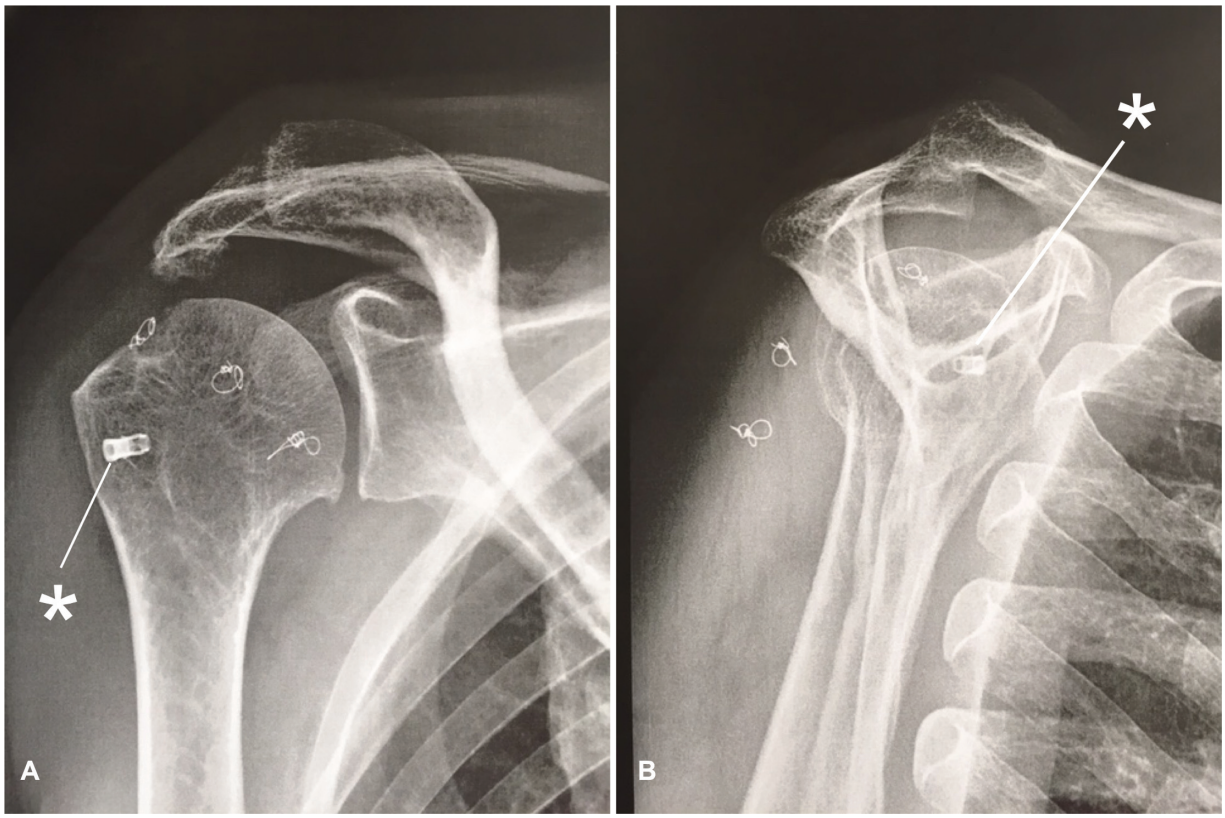

Fig. 2 (**A**, **B**) Postoperative radiographs after a latissimus dorsi transfer with 3 metal markers (placed at 2 cm, 4 cm and 6 cm from the tip of the tendon). The asterisks indicate the metallic anchor from a previous (failed) rotator-cuff repair. (**A**) Anteroposterior view. (**B**) Scapular profile view.

This means the tendon should be transferred above the joint's center of rotation in order to act mainly as a humeral-head depressor. For patients with isolated positive drop signs (described by Boileau et al[64] as 'isolated loss of external rotation'), the aim should be the fixation lateral to the joint's center of rotation.[43,57]

2. The second principle is to control the muscle-belly tension. One can reason that insufficient tension would lead to a non-effective transfer. Alternatively, excessive tension could damage the transferred muscle-tendon unit. It has been proposed[30] that, in order to obtain appropriate tension, before releasing the latissimus dorsi from its original attachment, one should place two landmarks on the muscle while the shoulder is in maximum abduction and ER (which is the position of maximal physiological tension of the latissimus dorsi). At the time of tendon reattachment, the muscle should be retensioned to match the prerelease distance between these two markers.
3. The third principle regards the mechanical resistance of tendon-to-bone fixation. Since the metaphyseal bone is fragile, a resistant fixation method should be used.[65] For open approaches, it is believed that transosseous sutures are strong enough, especially if augmented with some sort of cortical reinforcement, as suggested in an article by Gerber et al.[66]

   Arthroscopic techniques, however, require implants to achieve proper tendon-to-bone attachment. Diop et al[67] published a cadaveric biomechanical study that compared a standard anchor-fixation method (in a simple double-row manner) to a technique of fixation of the tubularized LDT to the greater tuberosity with an interference screw. They have shown that the latter presents higher biomechanical performance – in terms of stiffness, cyclic displacements and load to failure – despite resulting in more complications (especially greater tuberosity fracture during bone drilling).[67] For this reason, some authors[68] prefer fixation of the tubularized tendon with a cortical button positioned onto the bicipital groove, thereby avoiding drilling through the greater tuberosity. Another technique that improves tendon-to-bone healing involves removing cortical bony chips along with the LDT (by performing a delicate superficial osteotomy of the humeral cortex rather than a simple tenotomy). In fact, Moursy et al[52] have shown that this modification statistically results in fewer postoperative ruptures and better functional outcomes. Another possible alternative, as previously mentioned, is tendon reinforcement with the use of a tendinous allograft, as proposed by Miyazaki et al[61] (►**Fig. 4**).
4. The fourth principle aims to limit the surgical trauma to the tissues. As far as we are aware, this is not supported by any empirical data, except for the findings by Warner and Parsons[56] of suboptimal results regarding revisions or multiple simultaneous tendon transfers. However, we can reason that less trauma may improve healing because it minimizes iatrogenic devascularization, and it may also enable greater tendon excursion, as less scarring of the surrounding soft tissues is generated. Furthermore,

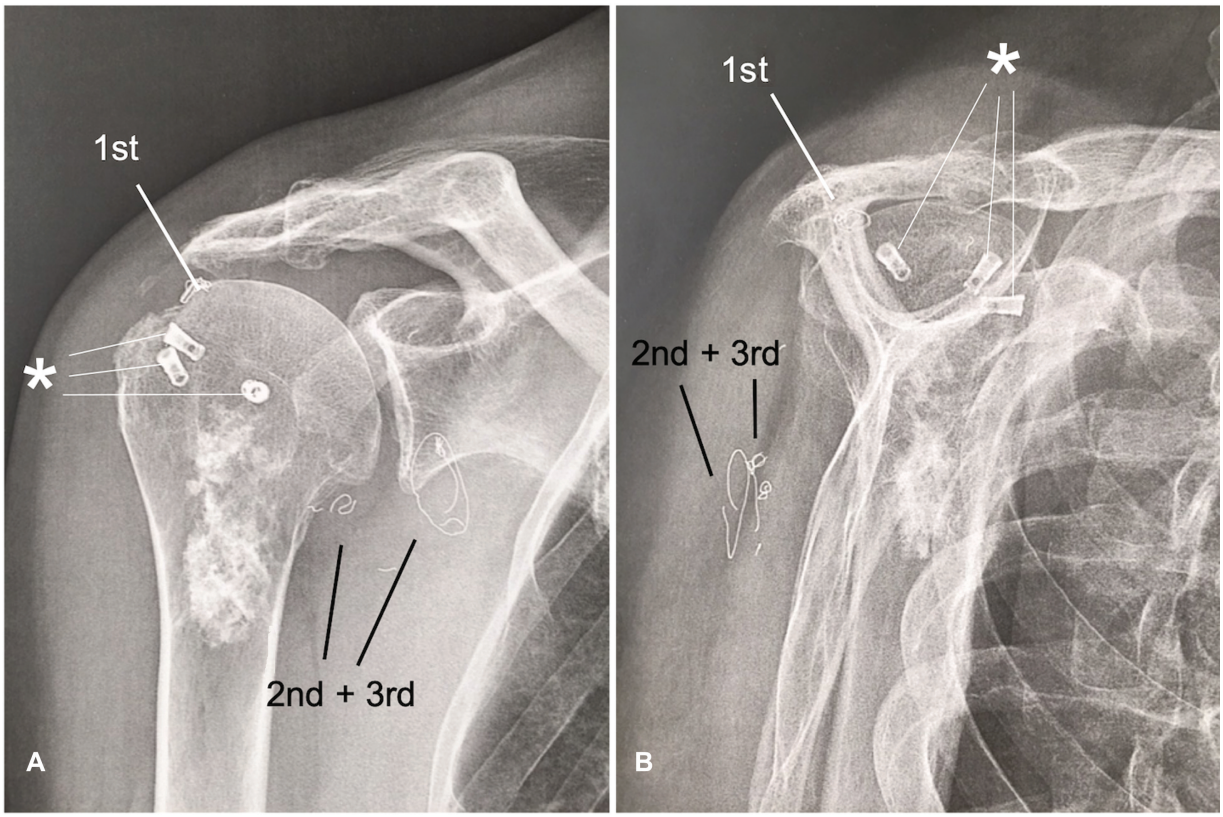

Fig. 3 (**A**, **B**) Postoperative rupture of a latissimus dorsi tendon transfer. Note the increased distance between the intact first marker (1st) and the displaced second and third (2nd and 3rd) metal markers. The asterisks indicate metallic anchors from a previous (failed) rotator-cuff repair. Note that the calcified lesion in the proximal part of the humerus is an enchondroma, not at all related to the procedure or the rotator-cuff tear. (**A**) Anteroposterior view. (**B**) Scapular profile view.

minimally-invasive techniques, as arthroscopic approaches, preserve the deltoid muscle belly, which is especially important to shoulder function in the setting of a rotator-cuff deficiency. Even though it has been shown that every step of the LDT transfer can be performed exclusively through an arthroscopic approach (Lafosse, Nice Shoulder Course, 2016, unpublished data), we believe that this should be avoided, once our experience has shown that failing to release the latissimus dorsi attachment to the apex of the scapula (which in our opinion cannot be performed arthroscopically) results in postoperative scapular winging.

5. It can also be argued that the LDT transfer does not respect the fifth principle of tendon transfer, because this muscle is not originally an agonist of both FF and ER, and its line of action is more inferior and more posterior than that of the original cuff tendons (►**Figure 5**). Perhaps this is the main reason for the reported controversial and imperfect electromyographic results,[43,47,69] as well as for some of the reported unsatisfactory clinical results.[18,70]

Teres-Major-Tendon (TMT) Transfer

There are very few published studies regarding isolated TMT transfers for irreparable RCTs. All of them were performed in patients with isolated infraspinatus deficiency. The first series was reported in 1998 by Celli et al,[35] who achieved patient satisfaction and satisfactory functional results for all of their 6 patients. More recently, Celli et al,[34] published the long-term results of 20 patients with maintenance of the improved postoperative Constant-Murley scores.[34]

More recently, Henseler et al[36] published short-term results of TMT transfers. At two years of follow-up, the patients had significant ($p < 0.05$) improvements in ER, FF, and visual analogue scale and Constant-Murley scores. With a medium-term follow-up (mean of six years), Mansat et al[37] evaluated the results of 12 TMTs, showing results similar to those of Henseler et al.[36] Interestingly, the authors[37] could identify negative preoperative prognostic factors that included previous surgery and RCTs involving the subscapularis, as well as two positive prognostic factors: isolated involvement of the infraspinatus and of the functional teres minor. Furthermore, Mansat et al[37] described the following recommendations for TMT transfer: the patients should be under the age of 55 years, should have proper understanding of the lesion and the treatment, and should have intact subscapularis and anterior supraspinatus cable.

Lower-Trapezius-Tendon (LTT) Transfer

The double incision (a technique of prolonged LTT transfer with a tendinous autograft or allograft) has been recently investigated as an alternative to the LDT transfer for irreparable posterior RCTs and for chronic isolated musculotendinous tears of the infraspinatus.[33,38,39,71] Besides probably

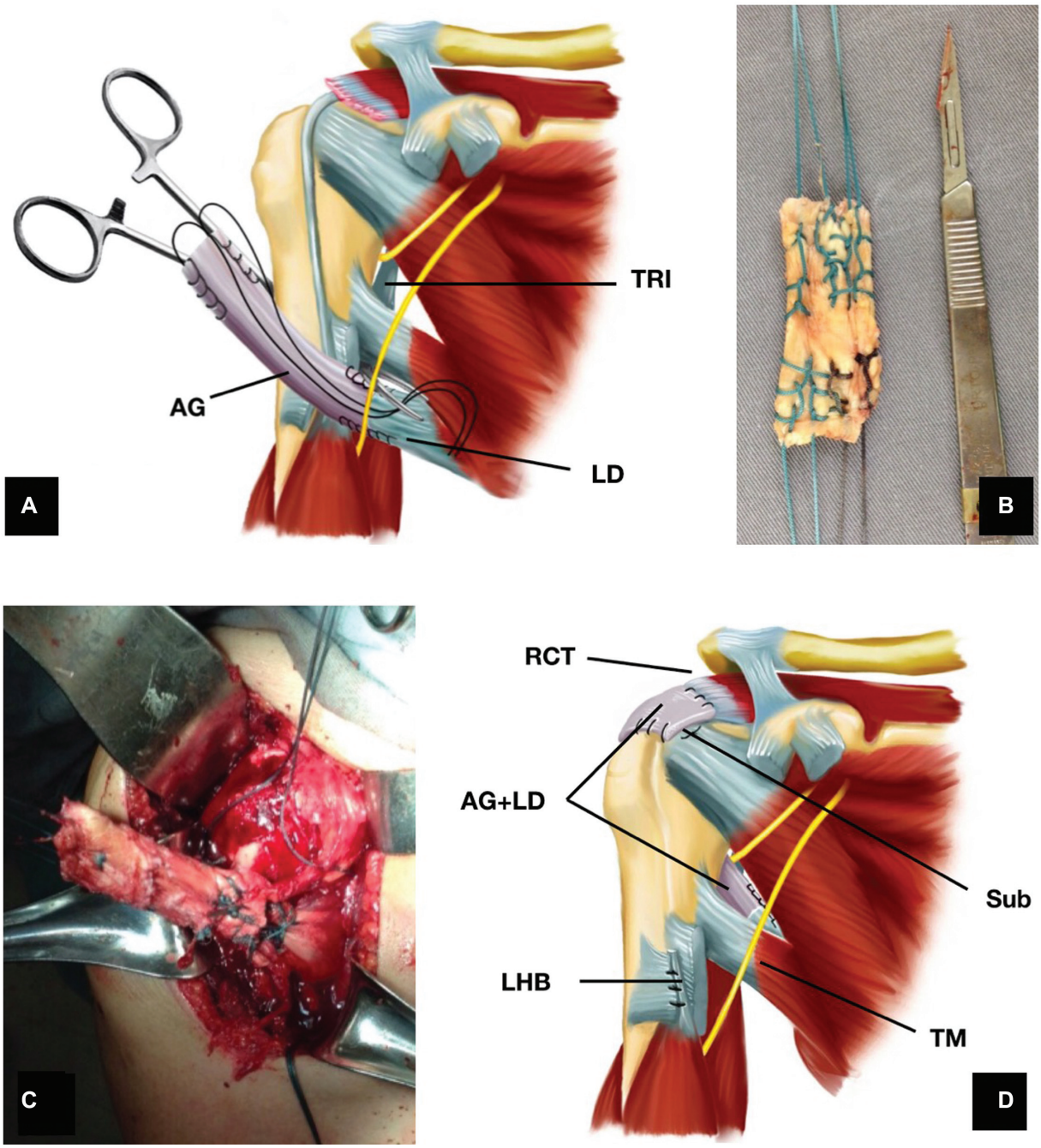

Fig. 4 (**A-D**) Latissimus dorsi tendon transfer elongated and reinforced with a tendinous allograft and performed through an isolated deltopectoral approach, as described by Miyazaki et al.[61] (**A**) Figure depicting tendon preparation before transfer. (**B**) Allograft preparation. (**C**) After passing the transfer behind the humerus. (**D**) Figure depicting final configuration of the latissimus dorsi tendon. Abbreviations: AG, allograft; TRI, triceps, LD, latissimus dorsi; RCT, rotator-Cuff Tear; LHB, long head of the biceps; TM, teres major; sub, subscapularis.

being technically easier than the LDT transfer, the line of pull of the lower-trapezius-muscle fibers more closely replicates those of the infraspinatus (►**Figure 5**). Furthermore, it has been shown that tension and excursion forces of the trapezius are very similar to those of the infraspinatus.[38,39]

In a cadaveric study, Omid et al[39] concluded that the LTT transfer was biomechanically superior to the LDT transfer, providing greater ER forces. Hartzler et al[38] also found improved ER with the arm at the side compared to LDT transfer, but the LDT transfer was better at restoring the FF as well as the ER at 90° of abduction. More recently, in 2019, Reddy et al,[72] showed through a three-dimensional (3D) biomechanical virtual study (performing virtual LDT and LTT transfers in a computer software), that the LTT provided better abduction and ER moment arms when transferred to the infraspinatus insertion. However, LDT performed better when transferred to the supraspinatus insertion. Overall, the LTT transfer showed a biomechanical advantage compared with the LDT transfer because of stronger abduction moment arms.

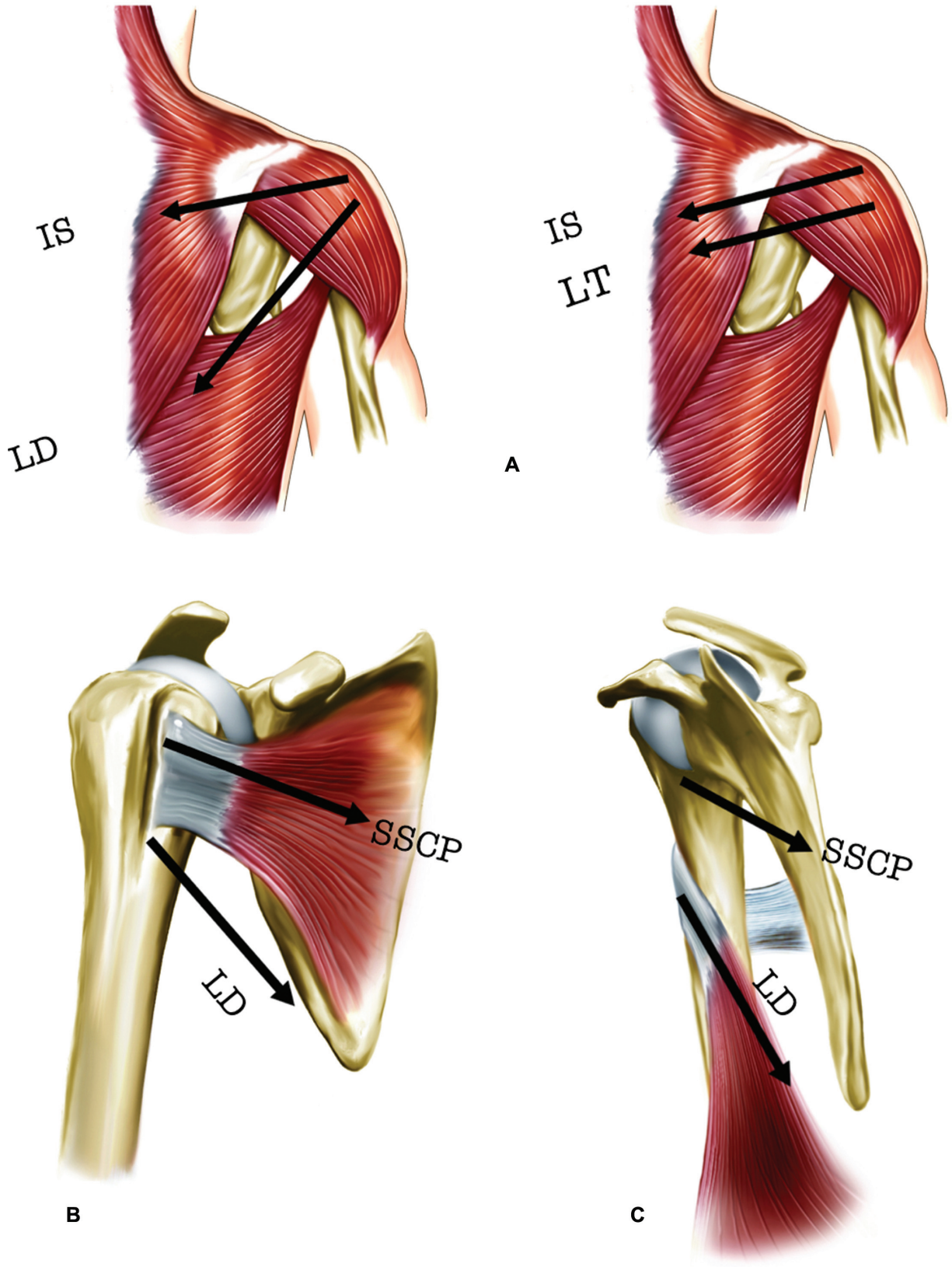

Fig. 5 (**A-C**) Drawings of the right shoulder. The line of pull from the lower trapezius (LT) more closely replicates the one from the infraspinatus (IS) than the one generated by the latissimus dorsi (LD). The line of pull from the LD closely replicates the line of pull from the subscapularis (SSCP). (**A**) Posterior view. (**B**) Anterior view. (**C**) Medial view.

In 2016, Elhassan et al,[71] were the first to report the outcomes following this technique. They evaluated 33 patients (26 men, with an average of 53 years of age; range: 31to 66 years) at an average follow-up of 47 months (range: 24 to 73 months). Except for one patient, who had a bone mass index of 36 kg/m^2, all achieved statistically significant improvements in pain, subjective shoulder value, and disabilities of the arm, shoulder and hand (DASH) score, as well as statistically significant improvements to all active shoulder motions. Their results were, therefore, the first to show that this mode of treatment may be a good alternative, at least at early and medium follow-up.

In 2016, Elhassan et al[73] described a modification to their original technique in which, instead of creating a second lateral open approach, they would instead fix the transfer to the greater tuberosity under arthroscopic visualization. Nonetheless, they haven't published the results following this modification. However, in 2018, Valenti and Werthel[74] published the results following almost the same technique as the one published by Elhassan et al,[73] the only difference being the use of a semitendinosus tendon autograft instead of an Achilles allograft. They evaluated 14 patients after a mean follow-up of 24 months (range 12 to 36 months). Their results have shown gain in external rotation with the arm at the side of 24° and, in 90° of abduction, of 40°. The lag sign and the Hornblower sign have disappeared from every patient in whom they were present preoperatively. The Constant-Murley score improved from 35 (preoperatively) to 60 points (postoperatively), the SST, from 3.5 to 7.5, the SSV, from 30 to 60%, and the pain decreased from 7 to 2 (visual analogue scale). There were two cases of hematomas, and one was revised because of infection.

We are unaware of any other published study showing the results of lower trapezius transfer for irreparable RCTs. Despite all that, to date there are no clinical studies that suggest the superiority of latissimus dorsi transfer or lower trapezius transfer over the other.

Conclusion

Irreparable posterosuperior RCTs can be debilitating, and failed cuff repairs are still challenging conditions to treat. Different techniques have been developed, and the proposed benefits of tendon transfers are pain relief and some increased range of motion with potential increase to shoulder strength. The LDT remains the most commonly used method, and different modifications to the original technique have been shown to minimize complications and to improve functional results and satisfaction. Nonetheless, LTT transfers are promising and should be considered, especially for patients with isolated loss of external rotation. Its results, however, are limited to two series of cases, both of which have reported only short to midterm follow-up.

Conflict of interests

The authors declare to have no conflict of interests.

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Rotator Cuff Healing

A cicatrização do manguito rotador

Ildeu Afonso de Almeida Filho[1,2] Daniel Andrade Coelho[2,3]

[1] Department of Orthopedics, Hospital Felício Rocho, Belo Horizonte, MG, Brazil
[2] Hospital Vera Cruz, Belo Horizonte, MG, Brazil
[3] Hospital Semper, Belo Horizonte, MG, Brazil

Address for correspondence Ildeu Afonso de Almeida Filho, Department of Orthopedics, Hospital Felício Rocho, Av. do Contorno, 9530, Barro Preto, Belo Horizonte, MG, 30190-130, Brazil (e-mail: ildeu1968@gmail.com).

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Abstract

The present article broadly addresses the aspects that interfere with the healing process of the rotator cuff. Life habits, such as smoking and alcoholism, are considered, systemic factors such as diabetes mellitus, hypertension, and obesity, as well as local factors, among which are those related to the pre, peri, and postoperative periods. From an extensive literature review, with the citation of 60 scientific articles from both Western and Eastern literature, the authors intend to deepen the theme by bringing to medical practice conducts based on new established concepts.

Keywords
- rotator cuff injuries/diagnosis
- rotator cuff injuries/epidemiology
- rotator cuff injuries/surgery
- wound healing

Resumo

O presente artigo aborda de forma ampla os aspectos que interferem no processo de cicatrização do manguito rotador. São considerados hábitos de vida como tabagismo e alcoolismo, fatores sistêmicos como diabetes mellitus, hipertensão arterial e obesidade bem como fatores locais, dentre os quais aqueles relacionados ao pré, per e pós operatório. A partir de uma extensa revisão da literatura, com a citação de 60 artigos científicos tanto da literatura ocidental como oriental, os autores pretendem aprofundar no tema trazendo para a prática médica condutas embasadas em novos conceitos estabelecidos.

Palavras-chave
- lesões do manguito rotador/diagnóstico
- lesões do manguito rotador/epidemiologia
- lesões do manguito rotador/cirurgia
- cicatrização

Introduction

The incidence of rotator cuff injuries has grown exponentially as the life expectancy of the population increases. Several technical explanations have been given to justify this increase. The issue revolves around the degenerative aspects related to the aging process of the organism, associated with some life habits, such as sports practice, profession, diet, use of medications, and the presence of associated diseases in addition to genetic issues, which has not received

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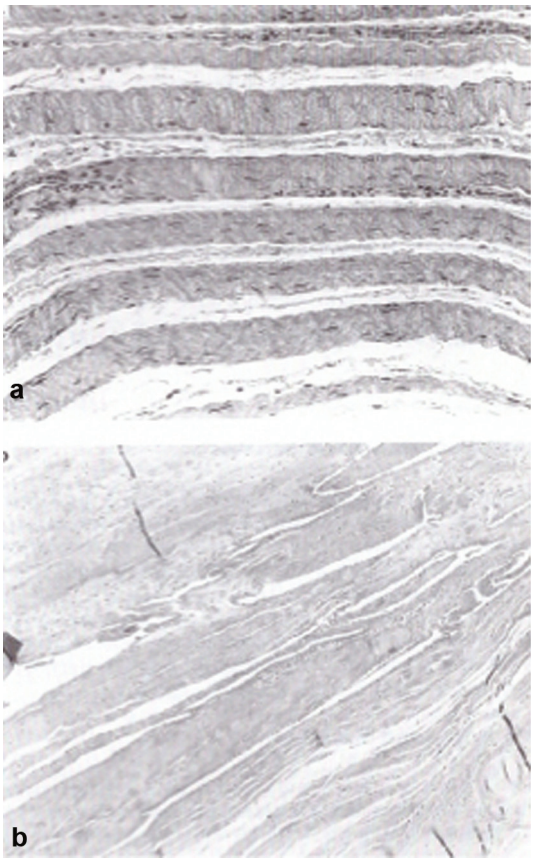

Fig. 1 In the young, the tendon insertion is organized in distinct layers (a) in the elderly, there is disorganization (b).

much attention in publications to date. Anatomical variations also participate in this process. Therefore, there are many factors that may influence the development of rotator cuff tendon injuries.

Hamada et al.[1] studied the histology of the human supraspinatus tendon, subdividing it into portions and observed that, in the youth, the tendon is organized into wavy layers and that in the older patients, this pattern changes to homogeneous, emaciated, and with hyaline degeneration (►**Figure 1**).

Uthoff and Ishii[2] analyzed the histology of tendinous insertion in the larger tubercle and observed, in the youth, the existence of a layered organization pattern. In the elderly, a disorganization occurs that is considered a degenerative process (►**Figure 2**). The author described the inflammatory reaction in the partial lesion of the rotator cuff as an attempt by the organism itself to heal it. However, Yamaguchi et al.[3] histologically studied the natural evolution of these lesions in a series of 58 cases and, in none of them, it was possible to observe the reduction of the size of the lesion. This fact shows that spontaneous healing of the rotator cuff is something that should not be expected by patients, let alone by surgeons.

Does the progressive increase in the incidence of injuries in the general population lead us to ask about what is considered normal for a determined age? How many carriers of cuff injury are asymptomatic? Milgron et al.[4] stated that the prevalence of lesions increases significantly in the population after 70 years

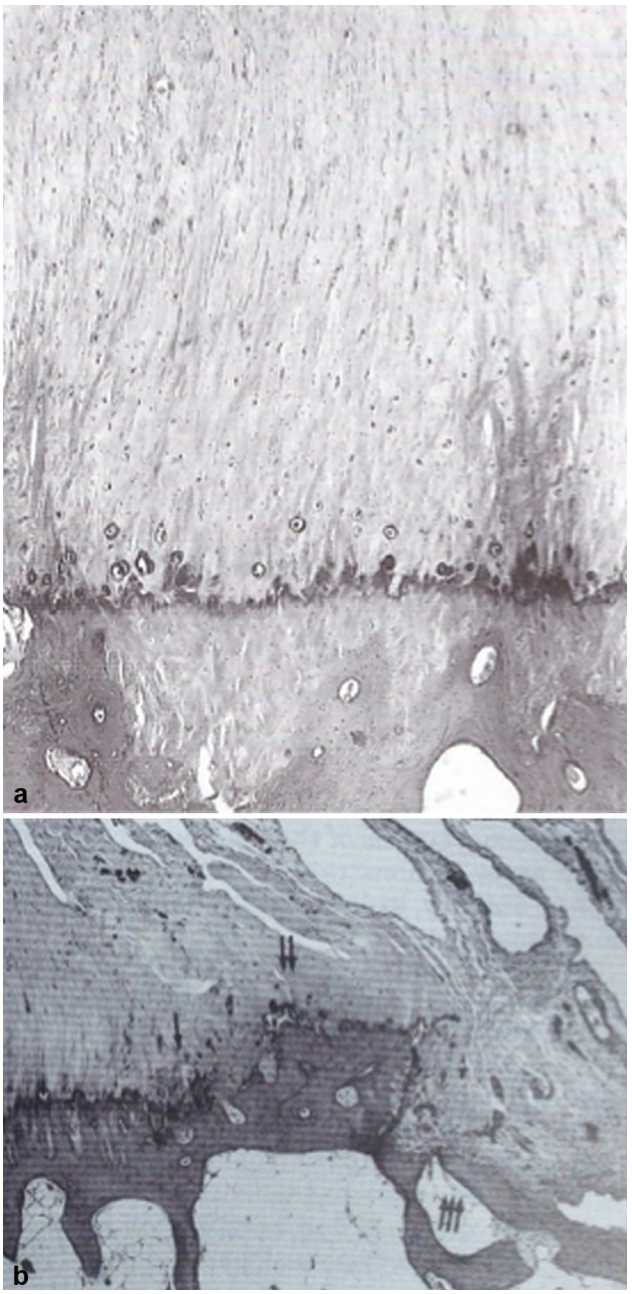

Fig. 2 Organization of the fibers of the supraspinatus tendon in layers in the young, and its progressive disorganization in the adult.

of age, and it is more frequent on the dominant side, a fact that has been proven by other authors.[5] In the seventh decade of life, this incidence increases to more than 80%.

During the last two decades, methods of treatment of cuff injuries have evolved substantially. The surgeries, which have previously been done openly, have started, in most reference centers, to be done arthroscopicly. Different types of sutures emerged, and high-strength threads began to be used routinely.

Local Factors

The main factors associated with rotator cuff healing are injury size, muscle quality (atrophy and fatty degeneration), tendon quality, presence of delamination, and shoulder morphology.

Injury Size

The first characteristic evaluated by most surgeons is the size of the lesion. The analysis, however, should be performed by evaluating the size of the lesion in the sagittal plane and coronal plane (medial retraction or tendon shortening), since they are independent characteristics with respect to the healing rate. From a general point of view, the increase in lesion size negatively influences healing rates, ranging from 97%, for small lesions, to only 6%, for large or massive lesions, in some series. [6–10]

Size Evaluated in the Sagittal Plan

Wylie et al.,[11] when evaluating the healing rate in this plan, showed that lesions $\geq$ 2.2 cm had a healing rate of 49%, and in lesions $\leq$ 2.2 cm the rate rose to 71%. Considering this cutoff value, the hypothesis was postulated that an injury exceeding 2 cm already presents significant involvement of the infraspinal,[12] which alters the kinematics of the humean head, generating unbalance in the forces.[13] This fact would put the repair at risk, thus justifying the increased risk of healing failure in lesions larger than 2.0 cm.

Evaluated Size in Coronal Plan (Shortening)

Myotendinous shortening is considered a direct result of muscle retraction. However, Meyer et al.[14] showed that, although the shortening is predominantly of muscle mass, retraction is also caused by shortening of the tendon itself, both due to the remaining substance in the tubercule after the initial injury and, in advanced stages, the resorption of the tendon itself. In a subsequent analysis, Tashjian et al.,[6] showed that patients with lesions in which the myotendinous junction (MTJ) is lateral to the face of the glenoid, the healing rate was 93%, while in patients with preoperative MTJ medial to the glenoid face, the healing rate was 55%. The analysis then concluded that the position of MTJ is an independent factor in healing. From the point of view of the size of the retraction itself, Wylie et al.[11] showed that lesions with shortening in relation to the footprint $\geq$ 2 cm presented a healing rate of 47%, as opposed to 76% healing in lesions with retraction $\leq$ 2 cm.

Muscle Quality (Fatty Atrophy and Degeneration)

When one thinks of rotator cuff healing, one goal to be achieved is the healing of the tendon-bone interface. Given this fact, most studies focus on methods to strengthen or positively interfere with this interface. However, analyzing large lesions, Jeong et al.[15] observed that muscle quality is more important than tendon quality in the new rupture index. According to the authors, the occupancy rate of the supraspinatus below 43% in relation to the totality of the supraspinatus fossa and a degree of fatty infiltration $\geq$ 2 according to Goutallier are independent risk factors for further rupture of the rotator cuff, with sensitivity of 98% and specificity of 83.6%. A systematic review by Khair et al.,[16] corroborates this fact, indicating that the quality of the preoperative muscle plays an important role in the rate of tendon healing. Low stages of Goutallier (0–1) are associated with low rates of new rupture (25%); in contrast, high stages (2–4) have high rates of rupture (59%).

Histological and Macroscopic Tendon Quality

Regarding the analysis of the histological and macroscopic quality of the tendon, it has been suggested that a worse quality tendon would lead to worse healing rates. However, Mazzoca et al.[17] showed that there is no correlation between the macroscopic appearance of the tendon in the arthroscopy, or in the histological analysis, and healing. Furthermore, they showed that the macroscopic appearance is not correlated with the histological quality of the tendon, and there is no association between the degree of histological tendinopathy, the macroscopic appearance and the healing index or clinical results of the repair. Therefore, the abnormal appearance should not influence negatively the stress or technique of repair.

Delamination

A chronic complete lesion is considered delaminated when there is a horizontal cleavage area in the ruptured tendon. The rotator cuff is composed of five layers, namely: the most superficial is composed of coracoumeral ligament fibers; the second layer is composed of parallel fibers between the supra and infraspinal; the third is composed of small fascicles that intersect the cuff tendons at an angle of 45 degrees; the fourth is composed of extracapsular loose connective tissue that previously connects with the deep portion of the coracoumeral ligament; and, finally, the fifth layer is basically composed of a joint capsule. The second and third layers are thicker, presenting different directions of collagen fibers.[18] It is precisely between these layers that tendon delamination occurs. In a recent study, Boileau et al.[19] showed a prevalence of 32% delamination, all of which involved a posterior component of the deep layer. This study showed that, in general, delamination has a deleterious effect on the healing rate, especially in large lesions. Kwon et al.,[20] in a study with 1,043 patients, confirmed the significantly lower healing rate in delaminated tendons, if the analysis is performed using a single variable. However, when performing multivariate analysis, it was noticed that delamination is not an independent risk factor for healing failure.

Shoulder Morphology

Heuberer et al.[21] analyzed the morphology of the acronym and correlated it with the chance of developing subacromial impact, impacto rotator cuff injury and arthropathy. There were three ways to evaluate acromial morphology, namely: critical shoulder angle (CSA), acromial index (AI) and lateral acromion angle (LAA). The authors concluded that the best way to predict the appearance of cuff-related lesions or the development of osteoarthrosis is through the CSA. This angle, which was described by Moor et al.,[22] has great benefit for combining the lateral extension of the acromion with glenoid angulation. It is calculated on anteroposterior radiography by the angle between the line of the lower edge to the upper edge of the glenoid and the line of the lower edge of the glenoid to the most inferolateral point of the acromion (►**Figure 3**). In the referred study, the authors demonstrated an association between rotator cuff injury for CSA $>$ 35° and

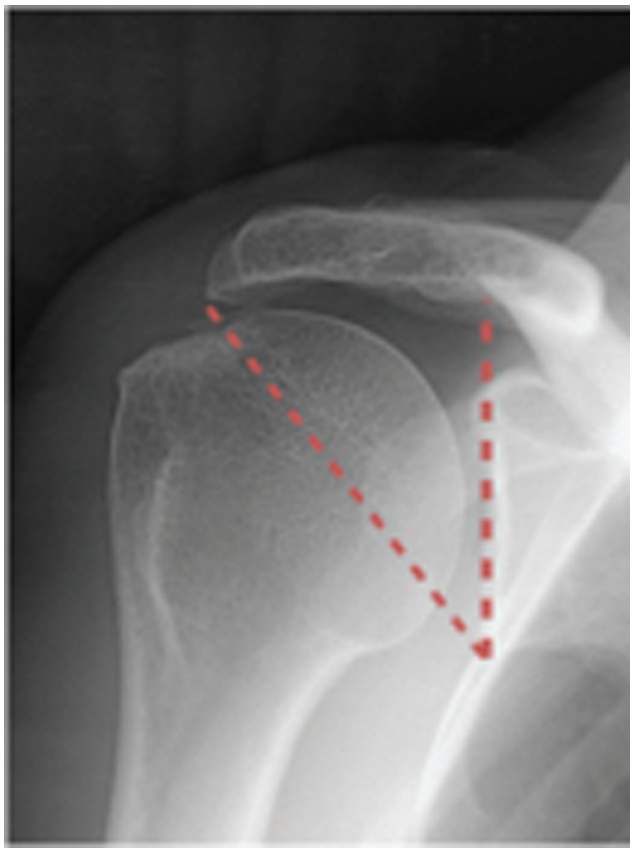

Fig. 3 Critical shoulder angle.

glenohumeral arthrosis in CSA < 30°. This fact has been demonstrated by other authors.[23]

A biomechanical study conducted by Gerber et al.[24] deepened the subject, demonstrating that CSA > 38° requires an increase of up to 33% in supraspinatus activity for shoulder stabilization during 6°-61° abduction. This fact could explain the findings of Moor et al.[22] and predict probable change in the healing rates of these patients. In fact, Garcia et al.[25] found a 14-fold vezes higher risk of rerupture ruptura in patients with CSA > 38°. A recent systematic review on the subject also confirmed the hypothesis, showing that CSA > 38° is associated with lower healing rate.[26] However, due to the heterogeneity of the relevant literature in the review in question, the strength of this finding is considered limited.

Systemic Factors

We will discuss here the various systemic factors that can influence tendon-bone or tendon-tendon healing.

Chronic alcohol use is an important factor regarding the increased incidence of injury as well as the severity of rotator cuff injury in both genders. The association between alcohol consumption and rotator cuff injuries showed that, in wine drinkers, there was more massive lesions than small lesions.[27]

In relation to smoking, it is known that nicotine acts in the expression of the so-called MMP-9, which is an enzyme involved in the degradation of the extracellular matrix, in tenocytes. This factor leads to the modification of the modulus of elasticity of the tendon and, according to Park et al.,[28] is an important risk factor for the spread of the lesion.

Regarding the influence of diabetes mellitus on the prognosis of cuff repair, it is known that the persistence of hyperglycemia in the postoperative period increases the possibility of non-healing of reconstructed the tendons. Therefore, blood glucose control after surgery becomes fundamental.[29]

The association between arterial hypertension and cuff injuries showed that, in relation to normotensive patients, hypertensive patients have twice as many large lesions and four times as many massive lesions.[30]

Cholesterol also influences the prognosis by increasing tendon stiffness through changes in its modulus of elasticity.[31]

Obese patients, those with increased body mass index, also present increased incidence and severity of rotator cuff injuries.[32]

Immunobiological factors, by interfering with the mechanisms associated with muscle homeostasis, aggravate the process of fatty degeneration, which, in sua turn, determines the worsening of the prognosis of tendon healing.[33]

Finally, age, which is an inexorable factor, also influences through the natural process of tendon degeneration, the modulus of elasticity in the rotator cuff.

Chung et al.[34] analyzed the main prognostic factors associated with poor results after surgical reconstruction of the rotator cuff. The mean age of the patients evaluated was 63.7 years. The authors observed the incidence of 39.8% of failure in the repair of rotator cuff lesions. The worst prognostic factors considered were fatty degeneration of the infraspinal muscle and reduction of subacromial space by cephalic migration of the humeral head.

Cho et al.[35] studied the factors that affect the integrity of rotator cuff reconstruction. The patients were divided into three groups, namely: < 50 years of age group I), between 51 and 60 years of age (group II), and > 60 years of age (group III). They observed that the older the age, the lower the incidence of healing (►**Table 1**). Nevertheless, the study recommends the reconstruction of lesions in elderly patients due to clinical improvement.

Deer et al.[36] evaluated the integrity of the repair and its relationship with the function on the shoulders of patients submitted to arthroscopic reconstruction after 65 years of age. For the study, the authors used the same sonographer to perform all imaging tests and found an incidence of 75% of tendon integrity with the University of California Los Angeles Shoulder Score (UCLA) improvement from 17 points to 32 points, which represents 85% of good and excellent results. There was also a significant reduction in the level of pain when the visual analog scale was used.

Table 1 Increased healing in younger patients

Groups:	< 50	51–60	> 60 years
N	49	68	52 patients
Healing	87.8%	79.4%	65.4%
N-healing	12.2%	20.6%	34.6%

Dezaly et al.[37] conducted a prospective, comparative, randomized study of two groups of patients. Group I underwent rotator cuff reconstruction, acromioplasty, and tenotomy of the long portion of the brachial biceps. Group II underwent biceps tenotomy and acromioplasty, without cuff reconstruction. There were 103 patients evaluated and, although the postoperative recovery time was shorter in group II, as expected, both the functional result by the Constant score (82 in group I and 73 in group II) and the subacromial distance measured in the imaging exams were favorable to group I. Interestingly, the best results were observed in the reconstructions of the most retracted lesions, suggesting that elderly patients with small lesions should be treated conservatively.

Many studies[38] have suggested that increasing age is related to a reduction in the potential for tendon healing, while biomechanical studies suggest that the reason for this should be due to an unfavorable environment, such as low-tissue perfusion and the reduction in the number of undifferentiated cells.

Perioperative Factors

The systemic and local factors mentioned above are inherent to the patient, and, therefore, in general, difficult to control on the part of the surgeon. For this reason, factors related to surgical techniques are of crucial importance in the results, since at this point the surgeon can actively act in the improvement of healing. Here, a good choice, focused on technical knowledge, can increase healing rates.

Single Row x Double Row

Apreleva et al.[39] showed that rotator cuff repair with single row (SR) anchors can restore only 67% of normal footprint, which could be an explanation for healing failures. Considering this, Lo and Burkhart[40] created the double row (DR) of anchors technique. This technique consists of using a row of medial anchors, next to the joint margin, and another row in the lateral aspect of the footprint. In this way, the width from medial to lateral is reestablished in an attempt to recreate the insertion of the rotator cuff and thus optimize the healing potential. From a biomechanical point of view, the addition of a second row of anchors increases the number of attachment points, increasing the initial strength of the construction, decreasing the load that each knot/anchor needs to resist and decreasing stress at the point of contact between each suture in the cuff. Biomechanical studies supported the technique, demonstrating a significant decrease in gap interval formation and strain deformation, associated with increased strength and initial stiffness, when compared to the single row technique.[41]

Despite demonstrating a biomechanical advantage, the clinical value of the technique is controversial, with an important part of the trials stating that there are no improvements in quality of life or clinical scores, despite an advantage in the healing rate of DR over SR.[42] A recent Brazilian study, with results of 1 to 4 years of the double row technique corroborates this fact, demonstrating no statistically significant difference in UCLA and American Shoulder and Elbow Score (ASES) scores between the two techniques.[43]

Given the above, to decide about the real advantage of the technique, and which patient would benefit from it, Xu et al.[44] performed a meta-analysis, with randomized clinical trials of levels 1 and 2 evidence, comparing the two methods. They concluded that, although the DR technique presented a lower rate of new rupture (23.8% DR x 40.2% SR), better ASES and improvement in medial rotation amplitude, there is no difference in the Constant score, UCLA score, anterior elevation, lateral rotation and muscle strength when compared to the SR technique in the overall analysis of the results. However, when analyzing subgroups by lesion size, in large lesions > 3 cm, DR repair showed statistically significant improvement in healing, UCLA and ASES. This result is corroborated by other authors, such as the summary of meta-analyses performed by Spiegl et al.[45] and the meta-analysis produced only with level 1 trials of evidence, conducted by Sheibani-Rad et al.[46]

Arthroscopic x Open

The most used methods for rotator cuff reconstruction are open, mini-open and arthroscopic. Both the mini-open and arthroscopic techniques maintain the integrity of the deltoid origin. In contrast, in the open technique, part of the deltoid is deserted from the edge of the acromion. Theoretically, this would be the main disadvantage of open reconstruction; however, a study by Cho et al.,[47] in postoperative magnetic resonance imaging (MRI) analysis, showed no significant difference between open and arthroscopic techniques regarding complications such as detachment of deltoid origin or muscle changes. Another disadvantage of the open technique would be increased pain in the initial postoperative phase, since it requires greater mobilization of soft tissues. This fact was also not confirmed, as demonstrated in meta-analysis with level 1 randomized controlled studies conducted by Ji et al.[48]

Regarding healing rates, a recent meta-analysis with high-quality studies and 770 patients showed similar healing rates between mini-open and arthroscopic techniques.[49] Moreover, there was no significant difference in clinical scores between the techniques.

Despite the similarity between the clinical results and healing rates, it is worth remembering that the arthroscopic technique offers advantage by providing easy access to glenohumeral joint associated with better cosmetic results.

Postoperative Factors

Chemical Factors: Anti-inflammatory

Healing is a gradual process, composed of overlapping phases, and the inflammatory phase is mandatory. Any factor that slows or alters its progress can affect it. Most studies on the subject are in vitro or with animal models and, as found by Constantinescu et al.,[50] in a systematic review, the current literature does not provide enough evidence for or against the use of nonsteroidal antiinflammatory drugs (NSAIDs). It is worth noting that this review found only one level 1

randomized clinical trial of evidence. The study in question, conducted by Oh et al.,[51] compared the analgesic side effects in the use of celecoxib (selective inhibitor COX-2), ibuprofen (non-selective NSAID), and tramadol (opioid). No significant differences were found between medications. In a second time, retrospectively, the healing rates were evaluated by MRI and ultrasound (US), and an important negative effect was observed with the use of selective COX-2 inhibitor (new rupture: 37% celecoxib $\times$ 7% ibuprofen $\times$ 4% tramadol). Therefore, despite presenting similar analgesia in the postoperative period, when compared with other NSAIDs and opioids, selective COX-2 inhibitors should not be used, since they can act negatively on healing after rotator cuff repair.

Mechanical Factors

The way to conduct the postoperative period may interfere with the healing process of the rotator cuff after a surgical reconstruction. Rehabilitation protocols consider the need for initial protection of reconstruction, associated with the intention of restoring shoulder function, preventing joint stiffness and muscle atrophy. Shoulder joint stiffness still has unclear etiology, but may be related to prolonged immobilization or conservative rehabilitation programs.[52] Biomechanical studies show that early loading is harmful to the organization of collagen fibers, and can generate microdamage at the bone/tendon interface, thus preventing the integration of collagen fibers into the bone or even complete healing failure.[53]

Early Mobilization vs. Late Mobilization

The protocols can be divided basically into two categories: early passive motion (EPM) and immobilization with delayed range motion (DRM).[54] The EPM protocol consists of minimal immobilization with sling, in which commuting movements are allowed plus passive movements of range of motion such as lateral rotation and elevation from the first postoperative day. On the other hand, the DRM protocol imposes the use of sling without passive movements, and only commuting exercises up to 2 to 4 weeks postoperatively are allowed. Performing analysis and review of published meta-analyses, Houck et al.,[55] concluded that the EPM protocol improves the range of motion, but increases the risk of further rupture of the cuff. It is noteworthy that, although shoulder stiffness is an important problem in the postoperative period of rotator cuff surgery, it is considered a complication, different from the recurrence of rupture, which is considered a treatment failure.

Sling Time

One of the first questions of the patients in the preoperative consultation concerns the time of use of the sling. There is a lot of divergence in the literature regarding the minimum time of use associated with better rotator cuff healing. Koh et al.[56] showed, in a level 1 study of evidence, that there are no benefits in healing when comparing immobilization for 4 weeks and immobilization for 8 weeks. Therefore, the literature does not support the use of sling for more than 4 weeks.

Velpeau Sling vs. Abduction Sling

Basically, anti-rotational sling keeps the arm close to the body in medial rotation. The abduction sling maintains the shoulder in various abduction and lateral rotation configurations. In the biomechanical analysis, Jackson et al.[57] found the optimal position to create the lowest level of supraspinatus and infraspinatus tension. This position would be with elevation of 21 to 45° and lateral rotation of 18 to 23°. However, in practice, the results do not prove the benefits of this position. Some authors show that there was no significant difference in clinical aspects or in the rate of new rupture. Other studies favorable to the use of abduction slings show advantages from the clinical point of view of pain and function, without evaluation of the the results in healing rates.[58] It is worth mentioning that, in general, studies on sling immobilization are based on the responses of patients' self-assessment in relation to the amount of time of use of the type; however, an important question is whether these patients actually use the sling as reported. Based on this questioning, Grubhofer et al.[59] showed, evaluating the use of abduction slings with digital sensors, that only 48% of patients used the sling in a way they considered satisfactory ($>$ 80% of the time). Moreover, when comparing the data obtained by the sensors and the patient information, the discrepancy was frightening, especially in patients who did not use the sling as recommended. The authors, therefore, suggest caution with the results of studies on type and time of use of slings.

Genetic Factors

Figueiredo et al.,[60] identified genetic factors associated with susceptibility of rotator cuff injury, reinforcing the role of extracellular matrix homeostasis in this context.

Final Considerations

The present review article allowed us to broaden the understanding of the factors that interfere in the healing process of rotator cuff tendons. It was clear that there are many variables, being local, systemic, mechanical, chemical, genetic or associated with life habits. Pre, peri, and postoperative factors have a decisive influence on this process. As a final message, it is suggested that the treatment of rotator cuff lesions be done individually, considering all the factors previously described and, in elderly patients, before the surgical option, that the attempt of conservative treatment should be considered.

Conflict of Interests

The authors declare that there is no conflict of interests.

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Shoulder Injury after Vaccination: A Systematic Review

Lesão de ombro após a vacinação: Uma revisão sistemática

Paul J. Cagle Jr[1]

[1] Department of Orthopaedic Surgery, Icahn School of Medicine at Mount Sinai, New York, New York, United States

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Address for correspondence Paul J. Cagle Jr, MD, Assistant Professor, Associate Program Director Department of Orthopaedic Surgery, Icahn School of Medicine at Mount Sinai, New York, NY, United State (e-mail: PaulJCagleMD@gmail.com).

Abstract

Adverse reactions to vaccine injections are usually mild and incredibly rare in nature, but multiple cases of shoulder events including bursitis, generalized pain or decreased range of motion have been reported following routine vaccine administrations. These events are known as Shoulder Injury Related to Vaccine Administration or SIRVA.

A systematic review of literature was performed to identify all published accounts of SIRVA. Twenty-seven papers reporting one or more accounts of SIRVA were identified. The most common vaccination involved was the Influenza vaccine. The most common symptoms were pain that began in 48 hours or less and loss of shoulder range of motion. The most common treatment modalities were physical therapy, corticosteroid injections and anti-inflammatory medication; but in some patients, surgery was required. Regardless of intervention, the vast majority of outcomes demonstrated improved pain and functional except in the occasions of nerve injury.

The etiology of SIRVA injuries has multiple possibilities including needle length, mechanical injury from needle overpenetration and the possibility of an immune inflammatory response from the vaccine components, but a unique definitive test or quantifiably result does not yet exist.

Keywords

- bursitis
- impingement, shoulder
- shoulder pain
- influenza vaccines

Resumo

As reações adversas às injeções de vacina tendem a ser brandas e são incrivelmente raras. No entanto, vários casos de eventos em ombros, como bursite, dor generalizada ou diminuição da amplitude de movimento, foram relatados após vacinações de rotina. Esses eventos são conhecidos como lesões em ombro relacionadas à administração de vacina (SIRVA, do inglês *shoulder injury related to vaccine administration*).

Uma revisão sistemática da literatura foi realizada para identificar todos os relatos publicados de SIRVA. Vinte e sete artigos que relataram um ou mais casos de SIRVA foram encontrados. A vacina mais comumente citada foi a vacina contra influenza. Os sintomas mais comuns foram dor com início em até 48 horas e perda da amplitude de movimento do ombro. As modalidades de tratamento mais comuns foram fisioterapia,

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Thieme Revinter Publicações Ltda., Rua do Matoso 170, Rio de Janeiro, RJ, CEP 20270-135, Brazil

Palavras-chave
- bursite
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injeções de corticosteroides e administração de medicamentos anti-inflamatórios; alguns pacientes, porém, precisaram de cirurgia. Independentemente da intervenção, a grande maioria dos casos apresentou melhora da dor e da função, à exceção dos pacientes com lesão nervosa.
A SIRVA tem múltiplas possíveis etiologias, inclusive comprimento da agulha, lesão mecânica por penetração excessiva da agulha e resposta inflamatória aos componentes da vacina; no entanto, ainda não há um exame definitivo ou resultado quantificável.

Introduction

Shoulder pain is a common finding in the primary care setting, and the prevalence in United States has been reported from 6.7% to 26%.[1,2] After the establishment of the Vaccine Adverse Event Reporting System in 1990, accounts of prolonged shoulder symptoms after vaccinations have been documented.[3,4] The Injection-Related Work Group of the U.S. Department of Health and Human Services Health Resources and Services Administration Centers for Disease Control published the 2011 Institute of Medicine Report, which generated "Proposals for Updates to the Vaccine Injury Table." This report suggests Shoulder Injury Related to Vaccination Administration (SIRVA) applies when the vaccine recipient had a shoulder without prior pain or dysfunction, and subsequently within 48 hours of vaccination had shoulder pain with limited range of motion.[5]

SIRVA represents a complex series of reported injuries, onset of symptoms, treatments and outcomes, and SIRVA was added to the Vaccine Injury Compensation Table published by the Health Resources and Services Administration.[6] The structures reportedly involved have included the rotator cuff, labrum, capsule, bursa, deltoid muscle, and this included diagnoses of bursitis, rotator cuff tears, adhesive capsulitis, chondral injury, nerve injury and infection.[7–33] The most common mechanism proposed is overpenetration of the deltoid muscle leading to injury either from a mechanical injury and/or from an immune response to the vaccine and/or adjuvants, and these events have frequently been correlated with an incorrect injection technique.[7–33] Thus, the primary outcome of this review was to identify unique features of SIRVA and the clinical results. The secondary outcome was to evaluated the etiology of the proposed injury mechanism with regard to the most commonly suggested reasons for a SIRVA (needle length, vaccination technique and autoimmune response).[7–33] We hypothesize that unique diagnostic findings will be identified and generalizable clinical results will be demonstrated, and we further hypothesize that a critical analysis of the factors associated with the proposed mechanism will provide guidance for avoiding additional shoulder injuries.

Methods

A systematic review of PubMed and Ovid MEDLINE was performed on February 1, 2020. The search terms "shoulder" and "vaccination" in were utilized in combination. Search results were completed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines[34] (PRISMA), and a PRISMA checklist was employed for analysis of the search results. In addition, a search of all citations present in the articles was performed. Level I to V studies published in English were considered under the inclusion criteria,[35] and any clinical outcomes including but not limited to pain, reduced range of motion, infection, tendon injury and chondral injury diagnoses. Exclusion criteria included biomechanical studies, non-human related publications, non-English publications, review articles without new cases reported or tumor events following vaccination.[36]

Results

Seventy-five unique studies were identified (►**Fig. 1**). After selecting for studies that included shoulder vaccination in humans, forty-four remained. Excluding papers that were not written in English left thirty-nine. Selecting out cadaveric, biomechanical, incomplete, or studies without clinical data excluded an additional twelve publications. The remaining twenty-seven studies were closely examined and reviewed.

A total of 56 reported accounts of shoulder pain, injury or infection were identified following a reported vaccination event. Data demonstrating vaccination type, time to onset of symptoms, time to presentation, and age are demonstrated in ►**Table 1**. The age range was 21 months to 90 years old. The most common type of vaccination reported was Influenza representing 61% of the cases (34/56). The second most common vaccination reported was the Pneumococcal Polyvalent Vaccination (PPV) representing 14% (8/56). The exact onset of symptoms was not reported in five cases, but 3 of those cases presented within two weeks of vaccination. In the remaining 51 accounts, the onset of pain was reported to have occurred in two days (48 hours) or less in 84% of the cases (43/51). Time to clinical presentation was not reported in 38% (21/56) of cases. In papers including clinical presentation time, time at clinical presentation was three weeks or less for 63% (22/35). Clinical findings, treatments and reported outcomes are demonstrated in ►**Table 2**. Clinical treatment methods were reported in all but two accounts. The two most common treatment modalities were physical therapy 41% (22/54) and CSI 33% (18/54). 12 cases (22%) were treated with surgery. Follow up clinical results were not available in 12 accounts (21%). In accounts reporting clinical

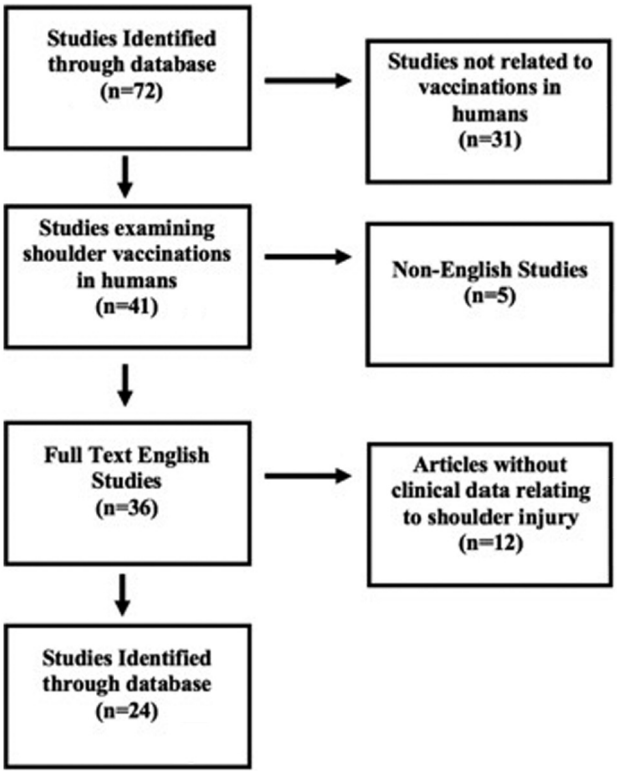

Fig. 1 Demonstration of Systematic Review Progression.

outcomes, 30% (13/44) were reported to have persistent symptoms beyond the follow up period. Nine of the 12 were part of one case series in which the presentation time for treatment was not reported.[7] The remaining 70% (31/44) of reports were noted to have improved functions and/or symptoms.

Discussion

The collection of data regarding vaccine-related shoulder dysfunction is relatively new with only 56 published reports. According to the Vaccine Injury Table,[6] the onset of symptoms needs to occur within 48 hours of the vaccination. This review demonstrated that 84% of the published accounts, with time to onset reported, actually met the 48 hours or less criteria, and this suggests a portion of the published literature would not fall under the Vaccine Injury table description of a SIRVA. In addition, the onset reporting symptoms was variable. Several of the presentations were reported greater than three months from the vaccination event, with the longest reported presentation event occurring 2 years later.[14,16,21,22,29] Multiple studies also referenced pathologies such as rotator cuff tears, and many of the accounts were in people over the age of 60. Several studies have demonstrated MRI findings such as rotator cuff tears may be found in asymptomatic individuals with rates of 50% progression to symptomatic tears in an average of 2.8 years.[7,37–39] Thus delays in initial presentation compounded with the potential for other underlying conditions does not allow for trend to be demonstrated, but the majority of studies did conform to the less than 48 hour definition.

The most common physical exam findings were consistent with impingement and loss of range of motion. Despite this, there was not one unique physical examination finding for SIRVA. There was also no clear correlation between a type of vaccine and severity of symptom presentation or duration. There was variability in the time before treatment was initiated. These treatments included physical therapy, corticosteroid injections, anti-inflammatory medications and/or surgical interventions, and patients who began a physician directed treatment pathways within three weeks of pain demonstrated a trend towards good to excellent outcomes. This was with the exception of patients who sustained a nerve injury or patients who ultimately required surgery. In the nerve injury patients, persistent symptoms were noted, and the surgical cases had a more prolonged course. Though many of the cases treated surgically were also noted to make an excellent recovery. Overall this demonstrates that there was not one particular physical exam findings unique to SIRVA patients, but in patients who do not sustain an neurologic injury, near or full recovery is the most common outcome. In addition, patients who begin treatment within three weeks of symptoms onset had overall good reported outcomes.

Imaging analysis with MRI did demonstrate a trend.[8,10,12,13,21,24,26,32] Salmon et al.[8] describes a MRI performed two days after the vaccination demonstrating a glenohumeral effusion, subacromial bursitis, subdeltoid bursitis and subscapular bursitis. A subsequent MRI 5 months later demonstrated regression of the joint effusion and decreased bursitis. Kuether et al.[13] illustrated an initial MRI with minor effusions in the subacromial and subdeltoid bursa. Subsequent MRIs at 4 months and 12 months demonstrated decreasing bursitis. Barnes et al.[10] demonstrated an MRI 8 weeks after a vaccination with an effusion in the subacromial bursa. Uchida et al.[26] also demonstrated an MRI with subacromial bursitis after a vaccination. Atanasoff reviewed 13 cases when MRI findings were available, and 69% of MRIs demonstrated fluid collections in the bursa or rotator cuff tendinitis. Thus, early MRI findings after a SIRVA event correlated with inflammatory changes such as increased fluid, bursitis and tendinitis, but MRIs taken months later may not be an accurate method of assessment.

As a secondary outcome of this review, the mechanism associated with SIRVA was evaluated. This is suggested to involve an overpenetration of the deltoid muscle allowing for a mechanical injury from the needle and/or an immune response from the injected material. One possible cause is utilization of a long needle. The Centers for Disease Control and Prevention guidelines recommend a 1-inch needle for patients in all but two categories.[40] The first is for females over 200 pounds and males over 260 pounds. In those settings, a 1.5 inch needle is recommended. The second exception is for newborns, where 5/8th inch needle is recommended.[38] Poland et al.[41] evaluated deltoid fat pad thickness with ultrasound and suggested a 1 inch needle for men but stratified the recommendation for women for 5/8ths inch needle for less than 60 kg, a 1 inch needle for 60-90 kg and a 1.5 inch needle for over 90 kg. A similar study was

Table 1 Reports of Vaccination Related Shoulder Injuries

AUTHOR	Onset Time	Presentation Time	N	Vaccination	Age
Barnes et al.	< 24 hours	3 weeks	1	Influenza	22
Shaikh et al.	< 1 week	1 month	1	Influenza	46
Messerschmitt et al.	< 24 hours	3 weeks	1	Influenza	46
Floyd et al.	< 24 hours	3 days	1	PPV	59
Kuether et al.	< 24 hours	4 weeks	1	Influenza	48
Terreri et al.	Unknown	1 week	1	BCG	21 months
Bodor et al.	2 days	5 months 2 months	2	PPV and Influenza	71 and 89
Cross et al.	< 24 hours	3 days	2	PPV and dTpa	82 and 23
Saleh et al.	< 24 hours	6 weeks 3 months 2 years	3	PPV and 2 Influenza	67, 30, 69
Hexter et al.	< 24 hours	Immediate	1	Influenza	50
Salmon et al.	< 24 hours	2 days	1	Revaxis®	26
Okur et al.	< 24 hours: 1/4 Unknown: 3/4	1-2 week: 3/4 2 months: 1/4	4	All Influenza	66, 59, 39, 36
Cook et al.	< 24 hours	3 days	1	Influenza	76
Arias et al.	< 24 hours: 3/8 < 1 week: 3/8 1-2 months: 2/8	Unknown	8	6/8 Influenza 1/8 PPV 1/8 Diptheria, Tetanus toxoid	22–89
Anasoff et al.	< 24 hours: 12/13 4 days: 1/13	Unknown	13	8 Influenza, 2 Td, 2 Tdap, 1 HPV	22–83
Degreef I and Debeer P	< 24 hours: 2/3 < 1 week: 1/3	2 months 2/3 6 months 1/3	3	Hep A, Influenza, Tetatus	36, 54, 73
McColgan BP and Borschke FA	< 24 hours	< 24 hours	1	PPV	73
Bathia NA and Stitik T	< 24 hours	3 weeks	1	Influenza	34
Shafer B and Burroughs K	< 24 hours	3 weeks	1	Influenza	25
Uchida et al.	< 24 hours	3 weeks	1	HPV	45
DeRogatis et al.	< 24 hours	1 week	1	PPV	90
Jotwani et al.	< 24 hours	2 weeks	1	Influenza	61
Imran et al.	< 24 hours	Unknown	1	Influenza	73
Meirelles et al.	< 24 hours	1 day	1	Influenza, Diphtheria, Tetanus	67
Erickson et al.	Unknown	2 weeks	1	Influenza	51
Shahbaz et al.	< 24 hours	1 hour	1	Influenza	34
Macomb et al.	< 24 hours	< 24 hours 4 days	2	PPV, Zoster	69, 84

Pneumococcal Polyvalent Vaccination (PPV); Bacillus Calmette-Guerin (BCG); Diphtheria, Tetanus, and *Pertussis (*dTpa); Diphtheria, Tetanus and Poliomyelitis (Revaxis®).
Human Papillomavirus (HPV); Tetanus, Diphtheria and *Pertussis* (Tdap).

performed by Lippert et al.[42] using 250 imaging series but focused on overpenetration. This study suggested needle overpenetration would have been experienced by 11% of patients with a 5/8th inch needle, 55% of patients with a 7/8th inch needle and 61% of patients with a 1 inch needle. They suggested a weight-based scale that could possibly eliminate overpenetration rates with a 10% risk of under penetration. Cook et al.[43] discussed the importance of understanding body mass index (BMI) demonstrating that in all males and females with a BMI less than 35 a 25 mm long needle could be safely utilized, but in females with a BMI greater than 35, a 32 mm needle would be required for adequate penetration. Atanasoffa et al.[7] examined thirteen patients with persistent shoulder pain without a history of shoulder injury and supported the possible correlation of a SIRVA event and needle size. Overall these studies have demonstrated that a one size fits all approach is not appropriate, and this has been supported by other authors analyzes.[44] Thus, it

Table 2 Clinical Findings, Treatments, and Outcomes

AUTHOR	Findings	Treatment	Outcome
Barnes et al.	Shoulder pain, loss of ROM	PT	Improvement in pain at 11 weeks Resolution of symptoms 16 months
Shaikh et al.	EMG – axonal denervation of deltoid and supraspinatus	Oral Prednisolone	Resolved pain but persistent "mild" weakness 8 months
Messerschmitt et al.	Shoulder Pain, loss of ROM, cartilage lesion	Surgery - hemiarthroplasty	Resolution of pain and symptoms at 3 years
Floyd et al.	Shoulder Pain, loss of ROM	Surgery – arthroscopic debridement	Resolution of pain and symptoms at 12 weeks
Kuether et al.	Shoulder Pain, osteonecrosis of humeral head	PT, Oral NSAIDs	Resolution of pain and symptoms at 6 months
Terreri et al.	Shoulder Pain, fever, osteitis	Antibiotics	Improved symptoms at 19 days after antibiotics
Bodor et al.	Shoulder Pain, loss of ROM, tendinitis	PT and CSI	Resolution of pain and symptoms at 5 and 6 months
Cross et al.	Shoulder Pain both, infection markers for one patient	1) Surgery – Debridement 2) PT and CSI	Resolution of pain and symptoms 1 month after surgery and 3 months after PT and CSI
Saleh et al.	All 3 Shoulder Pain and loss of ROM	PT 3/3 CSI 2/3	Resolution of pain and symptoms 50 days for one patient, unknown for second, no results for 3rd patient
Hexter et al.	Shoulder Pain	Surgical Debridement	Resolution of pain and symptoms
Salmon et al.	Shoulder Pain and effusion	NSAIDs and CSI	Resolution of pain and symptoms at 5 months
Okur et al.	Shoulder Pain	NSAIDs 3/4 No treatment 1/4	Resolution of pain and symptoms at 5 months 33 days, 5.5 months, 2 years and 2.5 years
Cook et al.	Shoulder Pain	CSI	Resolution of pain and symptoms at 1 months
Arias et al.	Shoulder Pain	Unknown	Unknown
Anasoff et al.	Shoulder Pain: 13/13 Loss of ROM: 11/13 Weakness: 4/13	NSAIDS: 8/13 CSI: 8/13 PT: 6/13 Surgery: 4/13	Full Recovery 4/13 Residual Symptoms: 9/13 Symptoms for at least 6 months 13/13
Degreef I and Debeer P	All 3 Shoulder Pain and loss of ROM	CSI: 1/3 PT: 3/3	Resolution of pain and symptoms at 1 month 6 weeks and 3 months
McColgan BP and Borschke FA	Shoulder Pain and Swelling	c	Improvement at 2 weeks postop
Bathia NA and Stitik T	Shoulder pain	Unknown	Unknown
Shafer B and Burroughs K	Shoulder Pain and loss of ROM	Unknown	Unknown
Uchida et al.	Shoulder pain	Surgery – arthroscopic debridement	Resolution of pain and symptoms at 1 year postop
DeRogatis et al.	Shoulder pain and infection	Surgical Debridement	Improvement at 2 weeks postop
Jotwani et al.	Shoulder pain	CSI	Improvement but no time frame noted
Imran et al.	Shoulder pain and weakness	PT	ROM limitations at 6 weeks follow up
Meirelles et al	Shoulder pain and weakness	PT	Significant recovery at 1 year, return of sensation and function at 31 months
Erickson et al	Shoulder pain	PT and CSI Surgical Debridement	Resolution of pain and symptoms at 1 year
Shahbaz et al.	Shoulder Pain and loss of ROM	PT and NSAIDs	8 month improvement with continued pain
Macomb et al.	Shoulder Pain and loss of ROM	NSAIDs, PT, CSI	Resolution of pain and symptoms at 1 month

Abbreviations: ROM, Range of Motion; PT, Physical Therapy; EMG, Electromyography; NSAIDs, Nonsteroidal anti-inflammatory medications; CSI, Corticosteroid Injection.

is conceivable that overpenetration is possible with lower weight, lower BMI, longer needles or a combination of needle length and lower body weight/BMI, but an appropriate needle length should significantly decrease the risk of overpenetration.

Vaccination technique is also commonly discussed with many of SIRVA cases reporting the vaccination was placed "Too High" (less than 3 cm from the lateral edge of the acromion).[7,8,12,14,15,19,20,26] One account attempted to measure the bursa of two patients demonstrating it to extend 3.5 cm from the acromion in a female patient and 4 cm in a male patient.[14] Beals et al.[45] examined the bursa of 17 cadaveric shoulders. They noted the average distance from the anterolateral corner of the acromion to the posterior bursal curtain was 2.8 cm and that the bursa margins were always 2 cm or more from the from the anterolateral corner of the bursal acromial surface. Avoidance of the bursa can potentially be obtained by a more distal placement of the injection. The national injection technique recommendations suggest the injection should be placed 2-3 finger breadths (2 inches) below the acromion and recommends "to avoid causing an injury, do not inject too high (near the acromion process) or too low",[46] but increasingly distal placement increases risk to the axillary nerve. Meirelles et al.[30] in fact illustrated a case of a 67 year old male who underwent a vaccination and experienced immediate pain and dysfunction. A nerve conduction study revealed axillary nerve compromise and return of function was not until 31 months. Imran et al.[29] described a case of a 73 year old male with acute pain following a vaccination. Physical examination and manual muscle testing demonstrated poor deltoid function, and the authors suggested a direct injury to the axillary nerve as the cause. This patient had follow up of 6 weeks demonstrating improvements in shoulder function but continued range of motion deficits. Thus shoulder vaccinations with overpenetration risks injury to the bursa with a superior location and risks injury to the axillary nerve with an inferior location.

Finally, penetration of the vaccination needle past the deltoid muscle also risks injection of the vaccine contents into the shoulder tissues. The capacity for an immune response from the injection material has been proposed by several authors.[7,8,12,13] Dumonde and Glynn[47] demonstrated the capacity to cause an intraarticular reaction using an animal model.[48,49] Jasin[50] also utilized a rabbit model to examine the mechanism of trapping of immune complexes in collagen tissues of joints and found the trapping depended on the presence of antibody in the extra-vascular space and the diffusion of antigen or soluble complexes into this space. Trollmo et al.[51] evaluated peripheral blood of six healthy adults before and 14 days after antigen exposure. They demonstrated the influenza virus antigen induces a strong systemic antibody response, but no significant systemic level difference was detected between subjects injected in the intra-articular space when compared with a subcutaneous injection.

Several accounts of suspected inflammatory reaction have been reported in the literature. Anasoff et al.[7] suggested that an injection into the subacromial space would have the potential to cause a reaction. Salmon et al.[8] report on an event following a vaccination where an MRI demonstrated a bony reaction. Kuether et al.[13] reported on a 48 year old woman who had demonstrated signs of osteonecrosis in the humeral head in MRI scan immediately, at 4 months and at 12 months after a vaccination. They state that a direct causal relationship cannot be confirmed but propose an immune response to the injection as a possible cause of the osteonecrosis. Messerschmitt et al.[12] discussed a 46 year old male with immediate shoulder pain following a vaccination. The patient was ultimately taken for surgery, and the biopsies obtained demonstrated inflammatory cells and granulation tissue.

Although the capacity to cause an immune response has been supported by animal data, a definitive clinical study demonstrating a quantitative link between a vaccine antigen and/or vaccine adjuvant and an immune mediate shoulder inflammation causing prolonged clinical symptomatology is still lacking. This is supported by the statements at the end of several of the SIRVA accounts. Kuether et al.[13] stated multiple times that a causal link could not be drawn. Messerschmitt et al.[12] suggested that they were uncertain if the chondrolytic changes predated the event. Uchida et at.[26] go further and stated that the consequences of improper injection technique are not currently known and the biopsy samples they obtained seven months after the vaccination cannot provide conclusive evidence. Furthermore, the diagnoses, duration and treatment following the cases reported in this review are heterogenous as were the types of vaccines which were reported. Thus, quantitative support for an immune response was not found in reported cases.

Conclusion

Overall this review demonstrated that in patients who do not sustain an neurologic injury, near or full recovery is the most common outcome. No unique physical exam feature was identified, but early MRI utilization may assist by demonstrating an increased fluid signal and bursitis. Because of the heterogenous treatments utilized, treatments such as physical therapy, CSIs, NSAIDs or surgery cannot be recommended cannot be individually recommended. Instead, a recommendation for treating the resulting pathology based on evidence based guidelines for the appropriate diagnoses would be appropriate. As patients who presented for treatment within three weeks of symptoms onset had overall good reported outcomes, a recommendation can be made that all patients who experience shoulder pain for greater than 14 days after a vaccination injection should seek immediate medical evaluation. In regards to needle length, a weight/BMI based scale should be utilized, and vaccination techniques must balance the need to avoid superior locations while minimizing axillary nerve risk. Finally it is still unclear as to whether or not shoulder injury related to vaccine administration "SIRVA" is a unique event. It would seem for SIRVA to remain a descriptive term these events would have to be unique to vaccinations and not simply an event that could happen with any over

penetrated injected material. Thus more data is needed to separate out a mechanical injury from an immune response.

Conflict of Interests

The authors have no conflict of interests to declare.

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Incidence and Risk Factors of the Complications Related to the Latarjet Surgery*

Incidência e fatores de risco das complicações da cirurgia de Latarjet

Marcio Cohen[1] Raphael Fonseca[1] Bernardo Gribel[1] Marcus Vinicius Galvão[1] Martim Monteiro[1] Geraldo Motta Filho[1]

[1] Shoulder and Elbow Surgery Center, Instituto Nacional de Traumatologia e Ortopedia Jamil Haddad, Rio de Janeiro, RJ, Brazil

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Address for correspondence Marcio Cohen, MD, Rua Almirante Guilhem, 127, Leblon, Rio de Janeiro, RJ, 22440-000, Brazil (e-mail: mcohen5@hotmail.com).

Abstract

Objective The Latarjet procedure is a well-accepted treatment of shoulder instability. This technique is associated with a unique set of complications with overall rates of up to 30%. The purpose of the present study was to investigate the incidence and risk factors associated with complications after open Latarjet procedure.

Methods We retrospectively reviewed 102 patients submitted to open Latarjet procedure. Complications were divided into three types: clinical; graft-related; and screw-related. All of the patients were submitted to radiography and computed tomography (CT). The risk factors analyzed were gender, age, previous surgery, epilepsy, experience of the surgeon.

Results A total of 102 consecutive patients (108 cases) underwent the Latarjet procedure. The mean age was 33.7 years old (18 to 61 years old), with 88 males and 14 females. The overall complication rate was 21.2%, being 12% clinical-related, 7.4% graft-related, and 2.7% screw-related. The most frequent were anterior apprehension (eight cases) and lateral overhang of the graft in six patients. Computed tomography scan at a minimum of 6 months was performed in 79 cases (73%), and graft union occurred in 75 patients (94.9%). There were no cases of instability in the remaining four cases of nonunion. Ten patients (9.2%) required revision surgery. The risk factors associated with complications were epilepsy ($p = 0.0325$), experience of the surgeon ($p = 0.0499$) and patients ≥ 40 years old at the time of the surgery ($p = 0.0151$). There was no correlation with gender and previous surgery.

Keywords
- articular instability/ complications
- risk factors
- glenohumeral dislocation

* *Study developed at the Shoulder and Elbow Surgery Center, Instituto Nacional de Traumatologia e Ortopedia Jamil Haddad, Rio de Janeiro, RJ, Brazil.*

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Conclusion The complication rate following the Latarjet procedure was 21.2%, with 9% requiring revision surgery. Epilepsy, age > 40 years old and experience of the surgeon were risk factors.

Resumo

Objetivo A cirurgia de Latarjet é bem estabelecida para o tratamento da instabilidade anterior do ombro. Apresenta complicações específicas com taxas de até 30%. Nosso objetivo é avaliar a incidência e os fatores de risco associados às complicações após a cirurgia de Latarjet.

Métodos Analisamos retrospectivamente 102 pacientes submetidos ao procedimento. Dividimos as complicações em três tipos: clínicas, relacionadas ao enxerto e relacionadas aos implantes. Todos os pacientes foram submetidos a radiografias e tomografia computadorizada (TC). Os fatores de risco analisados foram gênero, idade, cirurgia prévia, epilepsia e experiência do cirurgião.

Resultados Um total de 102 pacientes consecutivos (108 casos) foram avaliados. A média de idade foi 33,7 anos (18 a 61 anos), com 88 homens e 14 mulheres. A taxa de complicações foi de 21,2%, sendo 12% clínicas, 7,4% relacionadas ao enxerto e 2,7% relacionadas ao implante. As mais frequentes foram apreensão anterior (oito casos) e posicionamento lateral do enxerto, em seis casos. A TC foi realizada com o mínimo de 6 meses em 79 casos (73%), evidenciando a consolidação do enxerto em 75 pacientes (94.9%). Nenhum caso de não união apresentou instabilidade. Dez pacientes (9.2%) precisaram de cirurgia de revisão. Os fatores de risco relacionados às complicações foram epilepsia ($p = 0.0325$), experiência do cirurgião ($p = 0.0499$) e pacientes ≥ 40 anos ($p = 0.0151$). Não houve correlação com gênero e cirurgia prévia.

Conclusão A taxa de complicações após a cirurgia de Latarjet foi de 21,2%, com 9% necessitando de revisão cirúrgica. Epilepsia, idade > 40 anos e experiência do cirurgião foram fatores de risco.

Palavras-chave
- instabilidade articular/ complicações
- fatores de risco
- luxação glenoumeral

Introduction

Latarjet surgery has become an increasingly frequent option for the treatment of anterior glenohumeral instability.[1] Its main indications are glenoid bone injury, surgical revisions and in contact sports athletes. There are numerous described technical variations, but the basic principle of the procedure is the transfer of the coracoid process along conjoint tendon to the anterior glenoid border through an open or arthroscopic route.

Although the literature is clear in showing consistent joint stabilization results, few studies report the risk factors and incidence of Latarjet complications, which ranges from 0 to 30%.[2–12] The most frequently reported complications include neurological injury, infection, instability recurrence, fracture and graft pseudoarthrosis. In addition, the treatment of these complications often requires a surgical revision.

Shah et al.[5] observed 10% of neurological complications; the most common complication was the involvement of the axillary and musculocutaneous nerves. Athwal et al.[6] showed graft fracture in 7% of patients, with 2 cases requiring surgical revision.

In addition to the surgical technique knowledge, some authors have identified risk factors associated with a higher chance of complications. For Gartsman et al.,[7] advanced age was a risk factor, while Dauzère et al.[8] correlated the experience of the surgeon with the rate of complications.

The present study aimed to highlight the incidence of complications from Latarjet surgery and to correlate it with possible risk factors.

Methods

Patients undergoing Latarjet surgery for anterior glenohumeral instability treatment from January 2012 to June 2018 in a single institution were retrospectively evaluated to highlight any occurred complication. This technique was indicated in cases of glenoid or bipolar bone defect, failure of previous surgery and in contact sports athletes. The inclusion criteria for the present study were patients undergoing the classic Latarjet surgery with the graft positioned lying down and submitted to outpatient clinical and radiological postoperative follow-up for a minimum period of 6 months.

Complications were divided into three types: clinical, graft-related and implant-related complications. Clinical complications included hematoma, infection (both superficial or deep), neurological injury, subscapular tendon lesion and instability recurrence (anterior apprehension or dislocation). Graft-related complications included lateral or medial positioning, intra- or postoperative fracture and nonconsolidation, whereas implant-related complications included malposition or breaking of one or two screws.

Subscapularis tendon integrity was assessed through a physical examination using the Gerber and lift off tests.

Radiological examination consisted of simple x-rays in true anteroposterior (AP) view of the shoulder, scapular view and axillary lateral view, as well as computed tomography (CT) scans.

Positioning was considered a complication when CT showed that the graft was >1 mm lateral to the joint surface; the graft >1 mm medial to the surface was deemed a complication only in case of instability recurrence. Graft pseudoarthrosis was defined as the absence of a bone beam between the graft and the glenoid at CT examination.

Evaluated risk factors included gender, age younger or older than 40 years old, epilepsy, history of previous shoulder surgery, and experience of the surgeon. To assess the experience of the surgeon, patients were divided in two groups: the first group was operated on during the first half of the study, whereas the second group was operated on later.

Surgical Technique

All of the patients were placed in the beach chair position and submitted to general anesthesia with brachial plexus block. Antimicrobial prophylaxis was performed during anesthetic induction with intravenous administration of first-generation cephalosporin for 24 hours.

A deltopectoral approach with ~ 7 cm in length from the coracoid process towards the axillary fold was used. The coracoid process was exposed and individualized after releasing the pectoralis minor muscle and the coracoacromial ligament. Osteotomy was performed immediately distal to the coracoclavicular ligaments attachments using a curved osteotome to obtain a graft with at least 20 mm in size. The inferior face of the coracoid process was then decorticated and prepared with two holes at a 1-cm distance from each other. The joint was accessed by means of horizontal divulsion of the subscapularis muscle, between its middle and lower thirds, followed by a vertical capsulotomy. The anteroinferior border of the glenoid was prepared with labral resection and decortication. The coracoid process was positioned lying down and fixed with two screws. In all cases, screw sizes ranged from 30 to 36 mm. There was no capsular repair in 59 cases. In 37 patients, the coracoacromial ligament was preserved and sutured in the joint capsule, resulting in an intra-articular graft; in 12 patients, the capsule was sutured with an anchor (Gryphon; DePuy Synthes, Warsaw, IN, USA), resulting in an extra-articular graft.

Postoperatively, patients were immobilized with a sling for 4 weeks. Passive mobilization began after 2 weeks. Formal physical therapy started 4 weeks after the procedure to gain range of motion. Strengthening exercises started after 2 months. Activities were totally resumed after 4 to 6 months.

Statistical Analysis

The chi-squared and Fisher tests were used for categorical variables, while paired and unpaired T tests were used for continuous variables. Statistical significance was defined as $p < 0.05$.

Results

During the analyzed period, Latarjet surgery was performed in 142 patients (148 shoulders). Of these, 19 patients who did not perform the required minimum follow-up and 21 who underwent the technique described as congruent arc were excluded.[10] A total of 102 patients (108 shoulders) met the inclusion criteria.

The mean age was 33.7 years old (range, 18–61 years old), with 88 (86.3%) men (93 cases) and 14 (13.7%) women (15 cases). Latarjet surgery was the primary treatment for instability in 94 shoulders (87.1%). In 14 cases (12.9%), the procedure was performed as a revision due to previous surgery failure. A total of 11 patients (10.2%) had epilepsy. A total of 79 (73.1%) of the 108 cases underwent a CT scan after a minimum period of 6 months after surgery.

The mean follow-up period was 16.2 months (6–52 months). A total of 23 cases (21.2%) presented at least 1 complication, with 16 (14.8%) clinical, 8 (7.4%) graft-related, and 2 (1.8%) implant-related complications. Of this total, 10 revision procedures (9%) were required (►**Table 1**).

Clinical complications included 4 (3.7%) axillary neuropathies that resolved spontaneously in up to 6 months. There were 2 cases of infection; 1 was superficial (0.9%) and was treated with oral antibiotics, whereas the other was deep (0.9%) and was treated with surgical debridement and intravenous antibiotic therapy. Eight cases (7.4%) presented positive apprehension during the physical exam. One patient (0.9%), who had epilepsy, presented dislocation recurrence, and the deformity resulted in axial loss in both screws. A hematoma required drainage (0.9%), and 1 patient presented positive clinical tests indicating subscapularis injury (0.9%). One patient with positive apprehension had refractory pain and underwent an arthroscopic biopsy to diagnose infection, but no changes were found.

Graft-related complications included 6 cases (5.5%) of lateral positioning. Of these, one underwent lateral extremity regularization, one was repositioned, two were resolved with postconsolidation synthetic material removal and two required no surgical revision. There were three cases of medial positioning, but none of these patients presented instability, so they were not counted as complications. In addition, there were 2 cases (1.8%) of graft fracture detected at the first outpatient reassessment (►**Figures 1** and **2**); 1 was treated conservatively, whereas the other was submitted to resection of the fractured lateral fragment. Among the 79 cases submitted to CT, 75 (94.9%) presented graft consolidation and 4 (5.1%) had pseudoarthrosis. None of the patients with graft fractures or pseudoarthrosis developed instability recurrence.

Among implant-related complications, there were 2 cases (1.8%) of intraarticular screws; in the first one, the synthesis material was removed, but the other one evolved with early arthrosis and required a hemiarthroplasty.

Risk factors that significantly affected the complication rate were epilepsy, age >40 years old and experience of the surgeon. Patients with epilepsy had 45.4% of complications compared with 18.5% in cases of traumatic instability ($p = 0.0325$). Patients >40 years old presented 35.7% of complications

Table 1 Complications and respective surgical revisions

Complications	n	%	Intervention
Clinical Complications			
Hematoma	1	0.9	Surgical drainage
Superficial Infection	1	0.9	Oral antibiotic treatment
Deep Infection	1	0.9	Debridement and intravenous antibiotic treatment
Anterior Apprehension	8	7.4	No intervention required
Anterior Dislocation	1	0.9	No intervention required
Axillary Neuropathy	4	3.7	No intervention required
Subscapularis Injury	1	0.9	No intervention required
Refractive Pain	1	0.9	Diagnostic arthroscopy
Implant-Related Complication			
Intraarticular screw	2	1.8	1 RMS and 1 hemiarthroplasty
Graft-Related Complications			
Lateral Positioning	6	5.5	2 RMS, 1 regularization and 1 repositioning
Medial Positioning*	3	2.8	No intervention required
Fracture	2	1.8	1 lateral fragment resection
Pseudoarthrosis	4**	5.1	No intervention required

Abbreviations: n, absolute number of cases; RMS, synthetic material removal.
Source: hospital medical records.
*Not considered as complications since there was no development of anterior instability.
**from a total number of 79 patients undergoing computed tomography scans.

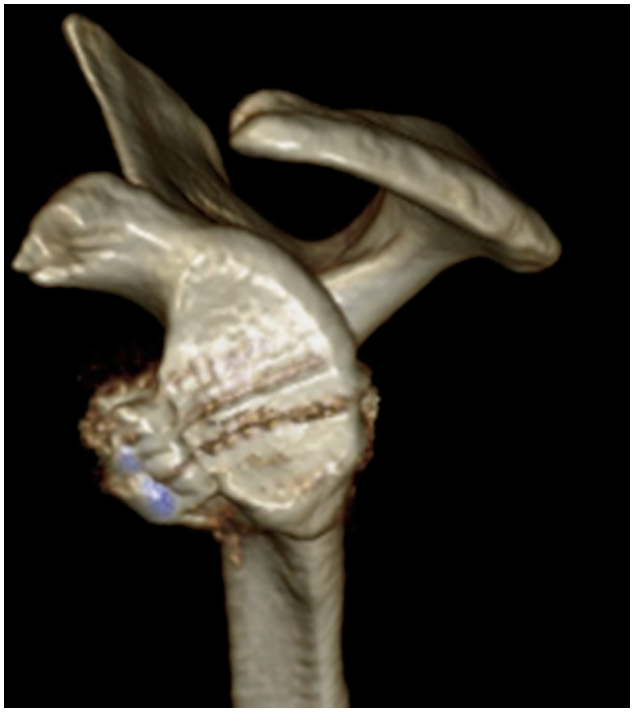

Fig. 1 Three-dimensional computed tomography scan in the immediate postoperative period showing a well-positioned graft.

compared with 19.4% of those < 40 years old ($p = 0.0151$). Likewise, the first half of the surgeries had a 27.7% complication rate versus 14.8% in the second half of the procedures ($p = 0.0499$). No statistical significance was observed regarding gender and history of previous surgeries (►**Table 2**).

Discussion

Latarjet surgery has become more and more indicated to treat anterior glenohumeral instability, resulting in an increase in reported complications. Unlike the arthroscopic surgery for capsulolabral repair, in which the main complication is dislocation recurrence, complications from Latarjet surgery are specific and their outcomes can be disastrous.[13]

Studies reporting Latarjet complications present some confusion regarding the definition of postoperative complications. Some authors differentiate problems from complications, while others divide complications as minor or major.[5,11] We differentiate complications into three types: clinical, graft-related and implant-related complications. With a mean follow-up time of 16.2 months, we observed a complication rate of 21.2%, with only 9% of the cases requiring surgical revision. In a recent study, Domos et al.[14] presented similar rates, with 21% of complications and 9% of surgical revision in patients > 40 years old submitted to the Latarjet technique.

Our series also presented results consistent with the literature regarding instability recurrence, with only 1 dislocation recurrence (0.9%) in a patient with epilepsy, and 8 (7.4%) subjects with positive apprehension at the physical examination.[1,10,15–17] Unlike Griesser et al.,[9] who identified the musculocutaneous nerve as the most frequently affected nerve in a systematic review, the most affected nerve in our series was the axillary nerve, with 4 cases (3.6%), as observed by Gartsman et al.[7] All of the cases were neuropathies with complete recovery within 4 months.

There were 4 cases (5%) of pseudoarthrosis, one of which requiring removal of the screws. None of these cases evolved

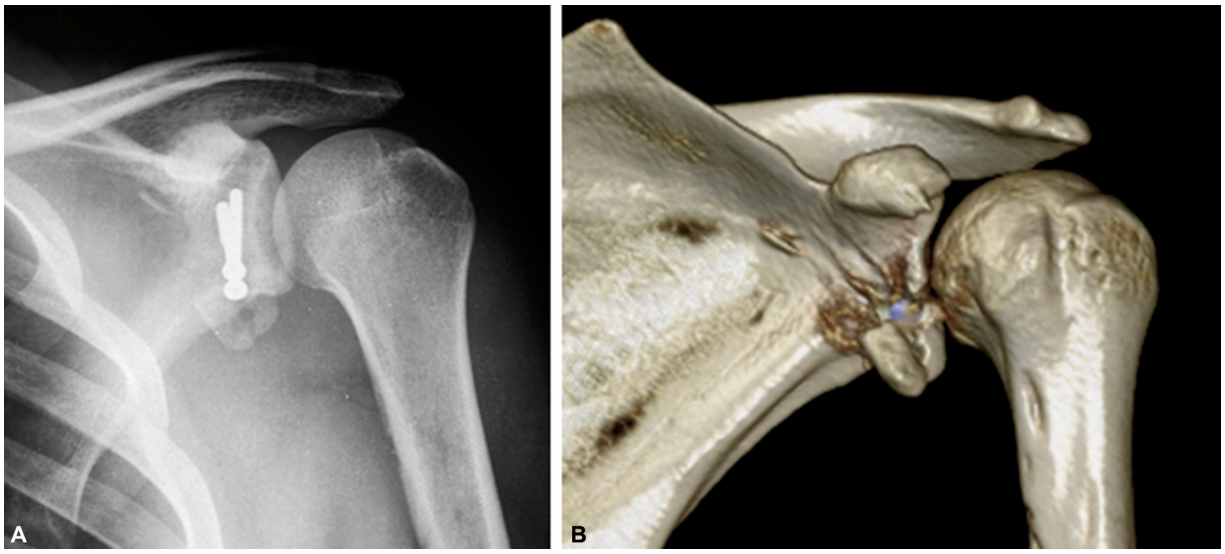

Fig. 2 Radiography (A) and three-dimensional computed tomography scan (B) 3 weeks after surgery showing graft fracture.

Table 2 Risk factors and *p-value*

Risk Factor	Without complications	With complications	*p*-value
Etiology			
Epilepsy	6	5	0.0325
Trauma	79	18	
Previous Surgery			
Previous surgery	10	4	0.2435
First surgery	75	19	
Gender			
Female	13	2	0.2271
Male	72	21	
Experience of the surgeon			
First Half	39	15	0.0499
Second Half	46	8	
Age			
$<$ 40 years old	67	13	0.0151
$>$ 40 years old	18	10	

Source: hospital medical records.

to instability. Shah et al.[5] observed that some patients with nonunion of the graft were asymptomatic and did not consider them as complications.

Lateral graft positioning and poor positioning of the screws are risk factors for secondary arthrosis.[18–20] There were 6 (5.5%) cases of laterally positioned graft, and 4 of them underwent surgical revision; in addition, there were 2 cases of intraarticular screws, with 1 rapidly evolving to secondary arthrosis with subsequent need for surgical revision and hemiarthroplasty.

Due to the technical complexity, the experience of the surgeon is associated with complications, as evidenced by Dauzère et al.[8] We found that patients operated on during the second half of the evaluated period had fewer complications. Other identified risk factors included epilepsy and age $>$ 40 years old.[14,21,22] Although some authors report an increased complication rate in patients with a history of previous surgeries, we did not observe such correlation

The strengths of the present study include populational homogeneity and the relatively large sample. Since this is a retrospective study, its limitations are the complications inherent to this type of study and new complications may arise with a greater follow-up period.

Conclusion

The complication rate after Latarjet surgery was 21.2%, with only 9% of the patients requiring surgical revision. Epilepsy, age $>$ 40 years old and the experience of the surgeon were risk factors for complications.

Conflict of Interests
The authors have no conflicts of interest to declare. There was no financial support from public, commercial, or non-profit sources.

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Return to Sports After High Tibial Osteotomy Using the Opening Wedge Technique*

Retorno ao esporte após osteotomia tibial alta com método de cunha de abertura

Alexandre Pedro Nicolini[1] Eduardo Suñe Christiano[1] Rene Jorge Abdalla[2] Moises Cohen[2] Rogério Teixeira de Carvalho[3]

[1] Sports Traumatology Center, Escola Paulista de Medicina, Universidade Federal de São Paulo, São Paulo, SP, Brazil
[2] Escola Paulista de Medicina, Universidade Federal de São Paulo, São Paulo, SP, Brazil
[3] Department of Orthopedics and Traumatology, Instituto de Assistência Médica ao Servidor Público Estadual de São Paulo, São Paulo, SP, Brazil

Address for correspondence Alexandre Pedro Nicolini, Centro de Traumatologia do Esporte, Rua Estado de Israel, 636, Vila Clementino, São Paulo, SP, 04022-001, Brazil (e-mail: apnicolini@uol.com.br).

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Abstract

Objective The present paper evaluates the resuming of physical activities by young, active patients who practiced some sport modality and underwent a high tibial osteotomy (HTO) using the opening wedge technique.

Methods A total of 12 patients submitted to HTO using the opening wedge technique were prospectively analyzed. All patients were not playing sports at that time. Pre- and postoperative Lysholm and International Knee Documentation Committee (IKDC) scores, visual analog scale for pain and performance level were compared. The average follow-up time was of 12 months.

Results One patient resumed sporting activities at a performance level significantly lower compared to the preoperative level, while eight patients returned at a slightly below level, two returned at the same level and one patient returned at a higher level in comparison with the preoperative period.

Conclusion For isolated medial osteoarthrosis treatment, HTO using the opening wedge technique has favorable clinical and functional results, allowing patients to resume their sporting activities.

Keywords
- osteoarthrosis
- osteotomy
- sports
- tibia

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Resumo

Objetivo Avaliar o retorno ao esporte em pacientes jovens e ativos praticantes de alguma modalidade esportiva submetidos a osteotomia tibial alta (OTA) com o método de cunha de abertura.

Métodos Foram analisados prospectivamente 12 pacientes submetidos ao procedimento de OTA utilizando-se método de cunha de abertura. Todos os pacientes estavam afastados do esporte. Foram utilizados os escores Lysholm, questionário International Knee Documentation Committee (IKDC, na sigla em inglês), escala analógica de dor e nível de retorno em comparação ao período pré-operatório. O tempo médio de seguimento foi de 12 meses.

Resultados Um paciente retornou ao esporte em nível muito abaixo do pré-operatório, oito pacientes retornaram em nível pouco abaixo, dois pacientes retornaram no mesmo nível e um paciente retornou em nível acima.

Conclusão A OTA com uso do método de cunha de adição como forma de tratamento para osteoartrose medial isolada demonstra resultados clínicos e funcionais favoráveis e permite o retorno ao esporte.

Palavras-chave

- osteoartrose
- osteotomia
- esportes
- tíbia

Introduction

The number of young adults with knee osteoarthritis (OA) has been increasing; however, their age and functional activity are incompatible with a total knee arthroplasty (TKA).[1–4] Over 25% of people < 70 years old have knee OA, and this figure is expected to exponentially increase in the future. Sports and recreational activities are very important for these subjects and OA limits such practice.[5]

Unicompartmental OA (UCOA) mainly involves the medial femorotibial compartment in varying degrees, according to the radiographic criteria defined by Ahlback. Predominant symptoms are pain that worsens under load and a progressive angular deformity.

The different therapeutic methods for UCOA include high tibial osteotomy (HTO), which is indicated for physiologically young patients (< 60 years old) with isolated medial OA, preserved range of motion (ROM), no ligament instability, minimum patellofemoral symptoms, and failed conservative treatment. Relative contraindications for HTO include age > 65 years old, advanced OA, three-compartment OA, inflammatory arthritis, decreased ROM (< 120°), smoking, obesity (body mass index [BMI] > 30), and contracture in flexion > 5°.[5]

There are three main types of HTO: with an opening wedge, with a subtraction wedge and the cupuliform procedure. The opening wedge technique has several advantages over the closing wedge method, such as greater precision and ease of correction in both the coronal and sagittal planes; in addition, it does not require a fibular osteotomy or an approach to the proximal tibiofibular joint (which protects the fibular nerve), sparing the bone stock and facilitating a conversion to TKA. The disadvantages of the opening wedge technique include the creation of a bone defect (which, depending on its size, may need a bone graft), risk of pseudarthrosis, potential loss of correction due to synthetic collapse, and a longer period of time in which load is not allowed; moreover, this procedure requires greater attention to the tibial slope.[3,4,6–8]

The technique was introduced by Jackson et al.[9] in 1961, but it only became popular in 1965, when Coventry[10] promoted it for treating medial OA with varus deformity. Since then, there have been countless advances in the technique, fixation, and selection of patients, leading to reduced complications and better outcomes.[3,4,6–8]

High tibial osteotomy aims to decrease the load in the involved compartment and transfer it to the healthy compartment, correcting the angular deformity and promoting symptomatic improvement of the affected knee.[1–3,7,8]

Because of the excellent HTO survival rates[11–19] and the potential TKA risks, such as loosening, material wear or periprosthetic fractures in subjects practicing high impact activities,[20] HTO is recommended for young adults. Johnstone suggested that young patients submitted to osteotomy may resume their work and sports activities. On the other hand, the rate of return to sports in patients undergoing TKA is of only 20%.[5]

Even though the HTO technique is well-described, few studies analyze the level of return to sports and the clinical outcome after the opening wedge procedure in young adults with UCOA.[2,3,22]

The present study aims to evaluate the resuming of physical activities by young, active patients who practiced some sport modality and underwent an HTO procedure using the opening wedge technique. Subjects were assessed using the Lysholm and International Knee Documentation Committee (IKDC) scores, visual analog scale for pain (VAS) and a comparison between pre- and postoperative sports performance level.

Material and Methods

The present study was performed at the Sports Traumatology Center from July 2017 to January 2018, under the approval of the institutional Research Ethics Committee

Sample Description

A total of 12 patients were assessed, including 2 women and 10 men, with a mean age of 34.3 years old (range, 30 to 44 years old) and an average BMI of 28.8 kg/m^2 (range, 24.4 to 33.7 kg/m^2). Preoperative ROM ranged from 90° to 132° (mean value, 108.3°) and the mechanical axis of the affected lower limb ranged from 6.4° in varus to 2° in valgus, with an average value of 3.4 ± 2.2° in varus.

Six subjects were street runners (lengths ranging from 5 to 21 kilometers), four were field soccer players, one was a handball player and one practiced mixed martial arts (MMA).

Adult patients aged 20 to 55 years old, with OA grade II to III according to the Ahlback criteria, BMI < 35, ROM > 90° and who were not practicing sports for at least 3 months were included in the study.

The following patients were excluded: those with a history of surgery on the affected knee; subjects with bicompartmental or tricompartmental arthrosis, varus deformity > 15°, symptomatic ligament instability, diabetes, inflammatory arthritis, and smokers.

Description of the Procedures

All patients underwent a previous clinical treatment for at least 6 months before surgery. All of them underwent an HTO procedure according to the wedge opening technique, using a wedge plate Puddu,[23] and they were submitted to the same rehabilitation protocol.

Preoperative planning employed long panoramic radiographs, analyzing mechanical and anatomical axes to calculate the size of the required wedge according to the noyes and Dugdale method.[24,25]

High tibial osteotomy was performed following the concept, in which the load axis of the lower limb is kept in a neutral position and an hypercorrection of ~ 2° to 5° in valgus is performed; as such, the mechanical axis passes laterally to the center of the knee joint, ideally between the middle and lateral portion of the lateral condyle (62%), and slightly lateral to the lateral intercondylar eminence.[3,24]

Opening wedges of up to 15 mm were made. Up to 10 mm, a plate spacer was used alone; between 10 and 15 mm, an autologous tricortical graft from the ipsilateral iliac crest was added.

Load bearing was allowed only after radiographic consolidation of the fracture. All subjects answered questionnaires before surgery and at 6 weeks, 3 months, 6 months, and 12 months postoperatively. The IKDC and Lysholm scores assessed the return to sports, daily activities, clinical parameters, and personal satisfaction from each patient. In addition, VAS was analyzed before surgery and 6 months after the procedure.

Using long panoramic anteroposterior radiographs, the anatomical axis (femorotibial axis) and the mechanical axis of the lower limb were recorded pre- and postoperatively, as well as the arthrosis degree according to the Ahlback criteria.

Patients were asked about their performance level when resuming sports, with the following answers: they did not return to sports; they returned at a significant lower level in comparison with the preoperative period; they returned at a slightly lower level compared with the preoperative period; they returned at the same level compared with the preoperative period; and they returned at a higher level in comparison with the preoperative period.

Statistical analysis used the Spearman correlation coefficient to measure the degree of relationship between all quantitative variables at all times: ROM, anatomical axis, VAS, healing time, Lysholm score, IKDC score and BMI.

The Mann-Whitney test compared the degree of arthrosis for some quantitative variables: preoperative anatomical axis, VAS gain, Lysholm score, IKDC score, and healing time. Results were expressed as mean and standard deviation (SD).

Results

Radiographic healing time ranged from 7 to 11 weeks (mean, 9.16 weeks). This value was correlated with the symptoms of the patients and the time in which partial progressive load bearing was allowed.

The mean Lysholm score was 83.8 ± 8.2 points, ranging from 70 to 94 points ($p < 0.05$). In this evaluation, 7 patients (58.33%) had good results and 5 subjects (41.66%) presented regular results.

After standardization in percentage, the average IKDC questionnaire score was 75.8 ± 9.8, with values ranging from 62 to 84% ($p < 0.05$).

One patient presented delayed healing, requiring a new procedure to place an autologous graft 6 months after the index surgery. This patient progressed satisfactorily 1 year after the first procedure.

One patient resumed sporting activities at a performance level significantly lower compared with the preoperative level, while eight patients returned at a slightly below level, two returned at the same level and one patient returned at a higher level in comparison with the preoperative period.

Both ROM and VAS presented significant statistical differences between pre- and postoperative values. The mean VAS decreased from 6.83 to 3.53, whereas the mean ROM increased from 108.33° to 123.92° ($p < 0.001$) (►**Table 1**).

The Spearman correlation assessed the degree of relationship between all quantitative variables at all times. A correlation test validated these findings, which were expressed as a percentage. In this scale, values between 0 and 20% indicate a bad correlation; from 20 to 40%, a very bad correlation; from 40 to 60%, a regular correlation; from 60 to 80%, a good correlation; and from 80 to 100%, an excellent correlation.

This analysis (►**Table 2**) showed some statistically significant correlations: between the preoperative

Table 1 Comparison between pre- and postoperative findings

Finding		Mean	Median	Standard Deviation	Q1	Q3	*n*	CI	*p* value
Range of motion	Pre-	108.33	105.0	12.64	101.5	115.0	12	7.15	<0.001
	Post-	123.92	124.0	7.49	119.5	130.0	12	4.24	
Anatomical axis	Pre-	−3.32	−3.9	2.75	−5.4	−2.0	12	1.56	<0.001
	Post-	6.38	6.5	1.89	4.8	8.0	12	1.07	
Visual analog scale for pain	Pre-	6.83	6.4	1.12	6.0	7.9	12	0.64	<0.001
	Post-	3.53	3.4	0.77	3.1	4.1	12	0.44	

Abbreviations: CI, Confidence interval; post-, postoperative; pre-, preoperative.

anatomical axis and the Lysholm score of + 65.4%, indicating that the greater the preoperative deformity, the better the subjective Lysholm score; between the preoperative anatomical axis and a VAS score gain of + 48.5%; between the preoperative anatomical axis and an IKDC score of + 48.5%. In addition, there was an inversely proportional correlation between the preoperative anatomical axis and ROM gain value of 42.4%, indicating that the greater the preoperative deformity, the lower the ROM gain ($p < 0.001$).

Other correlations that deserve being highlighted were between BMI and an IKDC score of - 58.8% and between preoperative ROM and an IKDC score of + 60.8.

The Mann-Whitney test concluded that there was no statistically significant difference between the degrees of arthrosis for the variables analyzed: preoperative anatomical axis, VAS gain, Lysholm score, IKDC score and healing time (►**Table 3**).

Discussion

There are several questions about outcomes and the effective ability of patients undergoing HTO to resume sporting, daily living and recreational activities with no limitations or pain.

The literature reports excellent to good outcomes from HTO with an opening wedge for UCOA and poor alignment

Table 2 Variables correlation

			Range of Motion			Anatomical Axis			Analog Visual Scale for Pain			Healing time	Lysholm Score	IKDC Score
			Pre-	Post-	Gain	Pre-	Post-	Gain	Pre-	Post-	Gain			
Range of motion	Post-	Corr	76.50%											
		p-value	0.004											
	Gain	Corr	−67.00%	−19.70%										
		p-value	0.017	0.539										
	Pre-	Corr	57.90%	58.00%	−42.40%									
		p-value	0.049	0.048	0.169									
Anatomical axis	Post-	Corr	21.40%	11.30%	−8.70%	35%								
		p-value	0.503	0.727	0.789	0.264								
	Gain	Corr	−56.10%	−74.50%	32.70%	−87.90%	−4.60%							
		p-value	0.058	0.005	0.299	<0.001	0.888							
	Pre-	Corr	7.80%	−3.40%	−19.80%	−32.50%	4.40%	21.20%						
		p	0.810	0.917	0.538	0.303	0.892	0.506						
Visual analog scale for pain	Post-	Corr	7.20%	−7.80%	−20.90%	3.20%	−43.80%	−1.20%	17.20%					
		p-value	0.824	0.811	0.514	0.922	0.155	0.97	0.594					
	Gain	Corr	0.90%	−6.10%	−5.30%	48.50%	−3.90%	−27.50%	−87.90%	15.70%				
		p-value	0.978	0.874	0.869	0.110	0.905	0.388	< 0.001	0.626				
Healing time		Corr	50.80%	61.20%	−37.60%	34.40%	−47.50%	−58.30%	−19.90%	24.60%	19.60%			
		p-value	0.092	0.035	0.228	0.274	0.119	0.047	0.536	0.441	0.541			
Lysholm score		Corr	64.60%	52.80%	−52.90%	65.40%	11.10%	−67.40%	9.80%	33.70%	9.00%	30.80%		
		p-value	0.023	0.077	0.077	0.021	0.731	0.016	0.763	0.284	0.781	0.331		
IKDC score		Corr	60.80%	53.40%	−23.80%	43.90%	45.60%	−36.40%	44.90%	−3.70%	−32.00%	−6.50%	54.90%	
		p-value	0.036	0.074	0.456	0.153	0.136	0.244	0.144	0.909	0.311	0.842	0.064	
Body mass index		Corr	−39.20%	−45.20%	−12.00%	−52.20%	−51.90%	34.60%	7.10%	14.20%	−5.10%	12.70%	−12.00%	−68.80%
		p-value	0.208	0.140	0.709	0.082	0.084	0.271	0.827	0.659	0.875	0.693	0.711	0.044

Abbreviations: Corr, Correlation; IKDC, International Knee Documentation Committee; post-, postoperative; pre-, preoperative.

Table 3 Arthrosis grade comparison

Arthrosis Grade (Ahlback)		Mean	Median	Standard Deviation	Q1	Q3	*n*	CI	*p-value*
Preoperative anatomical axis	Grade II	−2.80	−2.2	3.55	−6.2	−1.2	5	3.11	0.808
	Grade III	−3.69	−4.2	2.25	−4.8	−3.5	7	1.67	
Pain gain	Grade II	−3.48	−4.0	0.98	−4.0	−3.0	5	0.86	0.935
	Grade III	−3.17	−3.2	1.34	−4.2	−2.5	7	0.99	
Lysholm score	Grade II	82.00	82.0	9.27	76.0	90.0	5	8.13	0.624
	Grade III	85.14	88.0	8.07	80.0	90.0	7	5.98	
IKDC score	Grade II	78.40	80.0	5.18	74.0	82.0	5	4.54	0.414
	Grade III	74.00	76.0	8.16	69.0	79.0	7	6.05	
Healing time	Grade II	9.40	10.0	1.34	8.0	10.0	5	1.18	0.618
	Grade III	9.00	9.0	1.29	8.5	9.5	7	0.96	

Abbreviations: CI, Confidence interval; IKDC, International Knee Documentation Committee.

treatment: Hernigou et al.[13] described 81% of excellent or good results after 10 years of follow-up with 53 patients. Aglietti et al.[26] performed a clinical follow-up of 61 patients for up to 21 years after HTO and observed that 79% of them had no pain or presented mild pain in the operated knee.

Regarding post-HTO sports practice, some previous studies have shown good outcomes and high rates of return. Salzmann et al.[22] noted that 90.9% of patients were participating in sports and recreational activities, compared with 87.9% before surgery. The Lysholm score and VAS increased significantly, from 42.4 to 69.6 and from 6.9 to 2.9, respectively ($p < 0.01$).

Faschingbauer et al.[21] analyzed the rate of return to work and sports in 51 patients submitted to HTO. According to these authors, 92.3% of the patients returned to sports in similar performance levels compared with the preoperative period; in addition, they observed a shift from high impact to low impact activities, and they noticed a decrease in the duration and amount of sports activity.

Hoorntje et al.[27] conducted a systematic review on this subject, which revealed an 82% rate of return to sport in studies with sound methodology and low risk of bias (totaling 11 studies). They also reported a survival rate of 87 to 99% at 5 years and of 66 to 84% at 10 years after HTO. The studies differed considerably in terms of sports activity assessment (level of practice).

In another systematic review, Ekhtiari et al.[28] analyze the return to work and sports activities after HTO. This review included 11 studies, totaling 250 patients with a mean age of 46.2 years old. The opening wedge was the most used technique. After the procedure, 87.2% of the patients returned to sports, with 78.6% resuming their activities in equal or higher levels. Among competitive athletes, 54% returned to competitions. Approximately 90% of the patients who returned to work and sports activities did so within 1 year. In addition, 7% underwent TKA after an average period of 6.7 years. Several methods were used to measure the level of physical activity.

Bastard et al.[29] retrospectively analyzed 30 patients for a mean follow-up period of 1.3 years and observed that all subjects returned to sports within 1 year, including 73.3% at the same preoperative performance level and 23.3% at higher levels.

W-Dahl et al.[30] followed-up 79 HTO patients for 10 years. After this period, 25 subjects underwent TKA. These authors concluded that HTO is an excellent solution for young patients with OA who present moderate degeneration over time, providing the possibility of physical activity and quality of life. Two years after HTO, patients increased their physical activity, and more than half of them participated in sports such as golf, dance, walking and water aerobics. After 10 years, almost half were still involved in the same activities.

Our study corroborates these findings and demonstrates that opening wedge HTO has good functional outcomes. The anatomical axis was satisfactorily corrected from $3.31 \pm 1.2°$ in varus for an average value of 6.38 ± 1.8 degrees in valgus. One patient did not present overcorrection, with an alignment to 3.6 degrees in valgus. This patient had the worst functional outcomes, with a Lysholm score of 70 and an IKDC score of 62%. The importance of proper preoperative planning, anatomical and mechanical axis calculation and wedge size determination must be highlighted, since these factors will have a direct impact on the outcome.

In a specific analysis, the Lysholm and IKDC scores were significant, with 7 patients (58.33%) presenting a good Lysholm score and a mean percentual IKDC 75.8 ± 9.8 ($p < 0.05$) at an 84% index.

There was a significant improvement in ROM gain and VAS. The present study reinforces the use of HTO with an opening wedge with good outcomes and potentially resuming activities in levels which are close to the preoperative ones.

The present study has some limitations: small sample; lack of control group; short follow-up time, possibly interfering with the level of return to sports; and lack of training periodicity, intensity, and volume assessment. These are preliminary findings and we plan to add more patients to our research for further evaluation to achieve more significant statistical results.

Conclusion

Open wedge HTO as treatment for isolated medial osteoarthrosis demonstrates favorable clinical and functional outcomes, allowing the patient to resume sports activities.

Declarations
- The present study was approved by the Ethics Committee from UNIFESP.
- All study participants signed an informed consent form.
- All analyzed material/data is included in the article.
- Financial support.

There was no financial support. All costs for collection, analysis, data interpretation, and manuscript writing were provided exclusively by the authors.

Authors Contribution

Nicolini A. P. was responsible for conception and design, acquisition of study patients, data analysis and interpretation, manuscript writing, and final approval of the submitted version.

Christiano E. S. was responsible for conception and design, logistical support, manuscript writing, and final approval of the submitted version.

Cohen M. was responsible for conception and design, writing of the manuscript, statistical expertise, technical support, and final approval of the submitted version.

Abdallah R. J. was responsible for conception and design, manuscript writing, and final approval of the submitted version.

Carvalho R. T. was responsible for conception and design, data analysis and interpretation, critical review, acquisition of the study patients, manuscript writing, and final approval of the submitted version.

Conflict of Interests

The authors have no conflict of interests to declare.

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Functional Outcome of Patients Undergoing Knee Arthrodesis after Infected Total Arthroplasty*

Resultado funcional dos pacientes submetidos a artrodese de joelho após artroplastia total infectada

Thiago Vivacqua[1] Rui Moraes[1] João Barretto[1] Naasson Cavanelas[1] Rodrigo Albuquerque[1] Alan Mozella[1]

[1] Instituto Nacional de Traumatologia e Ortopedia Jamill Haddad, Rio de Janeiro, RJ, Brazil

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Address for correspondence Thiago Vivacqua, MD, Instituto Nacional de Traumatologia e Ortopedia Jamil Haddad, Av. Brasil, 500, Caju, Centro de Cirurgia do Joelho, Rio de Janeiro, RJ, 20940-070, Brazil (e-mail: drthiagovivacqua@gmail.com).

Abstract

Objective Retrospectively assess the functional outcome of patients undergoing arthrodesis after septic failure of total knee arthroplasty.

Methods Eighteen patients were evaluated, with a mean time of 3.7 years of follow-up. Arthrodesis surgery was performed using a narrow anterior dynamic compression plate, and medial or external fixator in two planes of the joint (Orthofix Bone Growth Therapy, Lewisville, TS, USA), at the surgeon's discretion.

Results The most frequent pathogen found was *Staphylococcus aureus* methicillin sensitive (38.9%). The mean lower limb discrepancy was 3.63 cm. The mean knee society score was 68 points. According to the visual analog scale for pain, 44% of the patients had a 0 score at the time of assessment, and 22.2% were very dissatisfied, despite the bone healing achieved. Patients were assessed for the ability to walk with or without assistance.

Conclusion Knee arthrodesis surgery was effective in controlling the infectious process and decreasing pain complaints, but satisfaction with the procedure was low.

Keywords
- arthrodesis
- knee
- arthroplasty, replacement, knee
- infection

Resumo

Objetivo Avaliar de modo retrospectivo o resultado funcional dos pacientes submetidos a artrodese após falha séptica da artroplastia total de joelho.

Métodos Foram avaliados 18 pacientes com tempo médio de 3,7 anos de seguimento. A cirurgia de artrodese foi realizada com placa do tipo *dynamic compression*

* Work developed at the Instituto Nacional de Traumatologia e Ortopedia Jamill Haddad, Rio de Janeiro, RJ, Brazil.

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plate (DCP) estreita, anterior e medial, ou fixador externo em dois planos da articulação (Orthofix Bone Growth Therapy, Lewisville, TS, EUA), a critério do cirurgião.

Resultados O patógeno mais frequentemente encontrado foi o *Staphylococcus aureus* sensível a meticilina (38,9%). A discrepância de membros inferiores média foi de 3,63 cm. O da *knee society score* (KSS) médio foi de 68 pontos. Segundo a escala analógica visual de dor, 44% dos pacientes apresentaram pontuação zero no momento da avaliação, e 22,2% estavam muito insatisfeitos a despeito da consolidação óssea obtida. Os pacientes foram avaliados quanto à capacidade de deambular com ou sem auxílio de apoio.

Conclusão A cirurgia de artrodese do joelho se mostrou eficiente quanto ao controle do processo infeccioso e diminuição das queixas álgicas, porém a satisfação com o procedimento é baixa.

Palavras-chave
- artrodese
- joelho
- artroplastia do joelho
- infecção

Introduction

Infection after total knee arthroplasty (TKA) represents a serious complication with an incidence ranging from 0.5 to 3%. Such complication can have severe functional and psychological consequences for patients. Adequate treatment remains controversial in the literature, even today, representing a huge challenge for the orthopedic surgeon.[1,2]

Patients with inflammatory symptoms less than 3 weeks are classified as having acute infection after TKA and are often treated with surgical debridement associated with venous antibiotic therapy. Success rates are variable, and implant retention occurs in between 44 and 84% of cases.[3–6] Two-stage revision surgery is described as the gold standard for the treatment of patients with chronic infection after TKA.[7] The success rate of the procedure varies between 80 and 90% in most series in short-term follow-up.[2,7,8] Current studies question these results. Mahmud et al[9] found a recurrence of infection of 22% in 10 years of follow-up of patients treated with a two-stage revision. The identification of a methicillin-resistant microbial agent may be associated with reinfection in up to 24% of cases.[10] Despite the good results described with the two-stage revision procedure after septic failure of the TKA, functional changes in the limb, residual pain, and joint stiffness are described.[11]

In patients with refractory infection after TKA, the treatment options described are amputation above the knee, resection arthroplasty, suppressive antibiotic therapy, or joint arthrodesis. Suppressive antibiotic therapy is restricted to patients infected with low-virulence bacteria sensitive to oral antibiotic therapy and high surgical risk.[12,13] Patients undergoing knee resection arthroplasty after infected TKA evolve with healing of the infectious process in 92 to 100% of cases, but the maintenance of mild-to-moderate joint pain has been described in 64% of the cases in the largest series described in the literature.[14]

Knee arthrodesis surgery or amputation above the knee are the methods most used by the orthopedic surgeon in the context of refractory infection after TKA. Considering the functional limitations, and the low percentage of success in prosthesis and assisted walking in patients undergoing amputation above the knee, arthrodesis surgery should be attempted in patients with permissive surgical risk.[15] Other indications for knee arthrodesis surgery are: massive injury to the knee extensor mechanism, inadequate soft-tissue coverage after TKA failure, and severe ligament instability.[15,16] Young patients with high functional demand with secondary or inflammatory osteoarthritis can be considered suitable for knee arthrodesis. To stabilize arthrodesis, external fixator in one or two planes, circular external fixator, double compression plate, or intramedullary nail can be used.[16,17]

The main objective of our study was to retrospectively assess the functional outcome of patients undergoing knee arthrodesis after infected TKA using an external fixator or a double compression plate. As secondary objectives, satisfaction with the procedure, the healing capacity of the infectious process, the presence of residual pain at the end of the follow-up, and the leg length discrepancy (LLD) were evaluated.

Material and Methods

After approval by the teaching and research committee of the National Institute of Traumatology and Orthopedics (CAAE 71750317.8.0000.5273), 23 patients were selected from the hospital database; the patients undergoing knee arthrodesis after septic failure of the TKA in the period from January 2010 to December 2016. Two patients who refused to attend the evaluation visit, and three patients who underwent amputation after arthrodesis failure, were excluded from the study. The patients were operated via anteromedial access to the knee using a narrow anterior and medial dynamic compression plate (DCP) plate (6 cases) or external fixator in two planes of the joint (Orthofix Bone Growth Therapy, Lewisville, TS, USA) at the surgeon's discretion (12 cases).

The visual analog scale for pain was used to assess the presence of residual pain after consolidation of arthrodesis. For functional evaluation, the knee society score (KSS) scores, validated for Portuguese, were used.[18] Patients were asked about their satisfaction with the procedure, ranging from: very satisfied, satisfied, dissatisfied and very dissatisfied, according to the method proposed by Mhomed et al.[19] The ability to walk was evaluated between: community walker with support

assistance (crutch or cane), community walker without support assistance, household walker with support assistance (crutch, cane), and non-walker (wheelchair users).

The discrepancy of the lower limbs was assessed by the comfort in the block test method.[20]

The germs identified in the bone fragments submitted to culture for aerobic and anaerobic bacteria were recorded as well as the number of surgeries before the knee arthrodesis procedure. Control of the infectious process was defined by the absence of local fistula or joint effusion associated with local inflammatory signs.

Statistical Analysis

The data collected from the research instruments were displayed in an electronic spreadsheet of the Microsoft Excel 2013 software (Microsoft Corp., Redmond, WA, USA), thus building the research database. The Microsoft Excel software (Microsoft Corp.) was also used to build some descriptive graphics. Any other statistical analysis of the data was done through the IBM SPSS version 22.0 (IBM Corp. Armonk, NY, USA) software.

The descriptive analysis of the data aimed to describe the characteristic profiles of the patients, and the distributions of the measures of interest. Descriptive analysis was performed based on the construction of graphs, frequency distributions, and calculation of descriptive statistics (proportions of interest for all variables and calculation of minimum, maximum, mean, median, standard deviation, coefficient of variation (CV) for quantitative variables). The variability in the distribution of a quantitative variable was considered low if $CV < 0.20$, moderate if $0.20 \leq CV < 0.40$, and high if $CV \geq 0.40$.

The correlation between two quantitative variables was assessed using the Spearman rank-order correlation coefficient. A correlation was considered strong only if its absolute value was greater than 0.7.

Results

Eighteen patients with a mean of 3.7 years of follow-up after knee arthrodesis surgery were evaluated. The frequency distributions of patients' epidemiological variables are shown in ►**Table 1**.

Pathogens identified through periprosthetic tissue culture after the primary TKA procedure are described in ►**Table 2**. The most frequently pathogen found was the *Staphylococcus aureus* methicillin-sensitive (7 cases, 38.9%), the 2nd most frequent was the *Enterobacter cloacae* (3 cases, 16.7%), and *Escherichia coli* was found in 2 cases (11.1%).

►**Table 3** brings the LLD frequency distribution with the comfort in the block test. The discrepancy varied from 1.5 to 12 cm, being more frequent in the range of 1.5 to 3.5 cm (55.6%). The average was 3.63 cm. In 33.3% of the patients, a discrepancy between 3.5 and 5.5 cm was identified. The values described represent the limb shortening after the joint fusion procedure.

►**Table 4** brings the frequency distribution of the KSS score. The most frequent score range was from 70 to 80 (55.6%), but the KSS scores ranged from 43 to 76, with a mean of 68.

Table 1 Frequency distributions of epidemiological variables

Variable	Frequency	
	F	%
Sex		
Female	9	50.0%
Male	9	50.0%
Knee operated side		
Left	11	61.1%
Right	7	38.9%
Age (years)		
46–53	2	11.1%
53–60	4	22.2%
60–65	6	33.3%
65–72	3	16.7%
74–81	3	16.7%
TKA indication		
Primary OA	10	55.6%
Posttraumatic	3	16.7%
RA	3	16.7%
SA sequel	1	5.6%
Posttraumatic OA	1	5.6%
Surgery prior to TKA		
None	15	83.3%
One surgery	1	5.6%
Two surgeries	2	11.1%
Comorbidities		
SAH	17	94.4%
Obesity	10	55.6%
DM	6	33.3%
RA	3	16.7%
Hypothyroidism	2	11.1%
SLE	1	5.6%
COPD	1	5.6%

Abbreviations: RA rheumatoid arthritis; SA, septic arthritis; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; OA, osteoarthritis; SAH, systemic arterial hypertension; SLE, systemic lupus erythematosus; TKA, total knee arthroplasty.

►**Table 5** brings the frequency distribution of the pain score assessed by the patient using the pain VAS. No patient had a VAS scale greater than 5, considering its variation between score 0 for complete absence of pain and 10 as the maximum score.

In all 18 cases evaluated, bone consolidation of arthrodesis occurred. Our group considers as consolidated the absence of mobility in dynamic examination by fluoroscopy and the presence of consolidation in the anterior, posterior, medial, and lateral cortical areas seen on radiograph of the knee. Three patients (16.7%) presented an active fistula at the time of the assessment, characterizing the maintenance of

Table 2 Results of culture tests for infections after primary total knee arthroplasty

Germ isolated	Frequency	%
Escherichia coli	2	11.1
Enterobacter cloacae	3	16.7
K. pneumoniae	1	5.6
Morganella morgani	1	5.6
Proteus mirabilis	1	5.6
Pseudomonas aeruginosa	1	5.6
*S. aureus**	1	5.6
*S. aureus***	7	38.9
Negative culture	1	5.6
Total	1	100.0

*(methicillin-resistant).
***(methicillin-sensitive).

Table 3 Frequency distribution of the lower limb discrepancy with the block test

Discrepancy	F	%
1.5–3.5 cm	10	55.6%
3.5–5.5 cm	6	33.3%
6.5 cm	1	5.6%
12 cm	1	5.6%

Table 4 Frequency distribution of the knee society score

KSS	F	%
40–50	1	5.6%
50–60	1	5.6%
60–70	6	33.3%
70–80	10	55.6%

Abbreviation: KSS, knee society score.

Table 5 Frequency distribution of the pain score assessed by the patient using the visual analog scale

VAS	F	%
0	8	44.4
1	2	11.1
2	5	27.8
3	1	5.6
4	1	5.6
5	1	5.6

Abbreviation: VAS, visual analog scale.

the infectious process despite the consolidation of the arthrodesis focus. Seven patients evaluated underwent some type of microsurgical procedure for the treatment of cutaneous complications in the surgical wound: total free skin graft or pedicled flap of the gastrocnemius muscle. Among these patients, five underwent arthrodesis surgery at the time of removal of primary prosthetic implants in view of the extensive damage to the local skin cover (mentioned above).

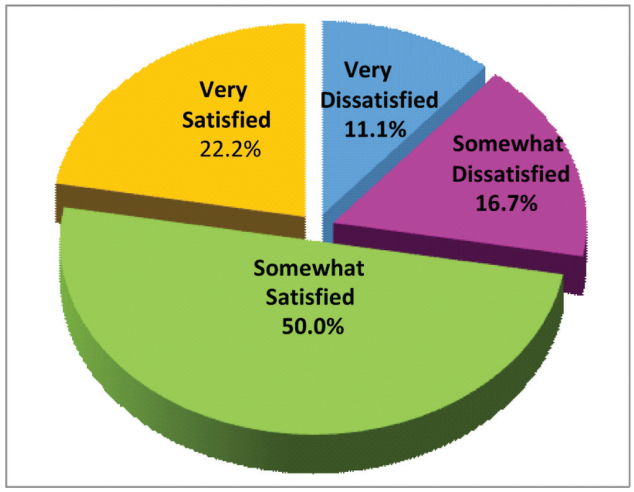

Fig. 1 Declaration of patient satisfaction with the treatment.

Regarding the final walking condition, the following were observed: 10 community walking patients with support assistance (crutch or cane), one community walking patient without support assistance, five home walking patients with support assistance (crutch, cane or walker), two non-walking patients, restricted to bed.

When assessing the patients' satisfaction with the treatment, two very dissatisfied patients were found, three were somewhat dissatisfied, nine were somewhat satisfied, and four were very satisfied, as shown by the distribution of ►**Figure 1**.

Discussion

Refractory infection after TKA represents the main indication for knee arthrodesis. The most used fixation methods are the use of nail, external fixator, and double plate fixation. Stabilization with intramedullary nail reduces the discrepancy in the length of the lower limb, presents a higher percentage of consolidation, but has a higher rate of recurrence of the infectious process. The use of an external fixator avoids the maintenance of a metallic implant in the infected joint and allows joint stabilization in multiple planes.[21,22]

Amputation above the knee represents a treatment option in the event of arthrodesis failure or in patients not candidates for the arthrodesis procedure after refractory infection after TKA—ipsilateral hip or ankle joint disease, extensive bone loss, contralateral lower limb amputation and disease in the other knee joint.[13] Sierra et al[23] identified only 20% of patients able to walk with assistance after amputation above the knee for the treatment of refractory infection after TKA. De Paula et al[24] evaluated the outcome of patients amputated after TKA failure and identified that only 37.5% were able to walk with assistance for a distance greater than a block. Such results make amputation above the knee an option in case of failure of bone consolidation with the knee arthrodesis procedure or in patients with infection refractory to arthrodesis surgery.

Complete joint fusion represents a method of controlling the infectious process as well as the patient's pain complaints. In the group of patients evaluated, despite bone consolidation of arthrodesis, 83.3% had pain between 0 and 2 in the evaluation using the VAS scale. Three patients had an active low-output fistula at the time of assessment. When the patients were asked about their satisfaction at the time of assessment, 27.8% were dissatisfied. Despite this fact, 61.2% of patients reported being able to walk in the community at the time of assessment. There was no correlation between the control of pain symptoms and the degree of satisfaction after consolidation of arthrodesis.

Shortening of the limb represents a common concern for the patient and the surgeon after the arthrodesis procedure, after septic failure of the TKA. However, in the studied group, the LLD assessed by the comfort in the block test was 3.63 cm. Balci et al[25] evaluated the result of knee arthrodesis in the treatment of refractory infection after TKA using an external fixator in 17 patients. The authors obtained a mean discrepancy between the lower limbs of 2.9 cm. Robinson et al[26] evaluated 23 patients who underwent knee arthrodesis after two-stage review after septic failure of the TKA. After bone fusion, the mean lower limb discrepancy (LLD) was 4.85 cm and the KSS obtained was 44 points. Conway et al[27] consider performing femoral bone elongation during the period of bone healing of arthrodesis in cases with lower limb discrepancies greater than 5.0 cm. The authors argue that the time taken to consolidate the regenerated bone is less than the time to consolidate arthrodesis.

Balato et al,[28] in a literature review and meta-analysis, compared the results of knee arthrodesis with an external fixator or intramedullary nail in the treatment of septic failure of TKA. Patients treated with an external fixator had a shortening of the larger limb, but a lower percentage of reinfection (5.4%) than patients treated with an intramedullary nail (10.6%). The analysis of the VAS scale of 49 patients in 3 studies identified an average score of 2.9 in the patients treated with an external fixator, and the discrepancy between the lower limbs presented a mean of 4.04 cm after evaluating seven studies and 108 patients.

Rohner et al[29] retrospectively assessed the functional outcome of patients undergoing arthrodesis with an intramedullary nail covered with antibiotic cement after septic TKA failure. In the evaluated group, reinfection was diagnosed in 50% of the patients. The average KSS score was 40, and 73% of patients described pain above 3 on the VAS scale. The authors do not recommend the use of an intramedullary device to perform knee arthrodesis in the context of septic failure after TKA. In our study group, the average score obtained by the KSS assessment was 68 out of 100 possible points.

In our case series, the most frequently identified germ was the *S. aureus* sensitive to methicillin, corresponding to 38.9% of cases. The need to perform a skin flap is associated with a higher incidence of reinfection after the two-stage review in the treatment of septic failure after TKA.[30] In our institute, such complications after TKA surgery are associated with worse functional results in patients with infection after primary TKA or revision and prolongation of hospital stay. The choice between using a double plate or external fixator was based on the patient's skin condition, implant availability, and surgeon's expertise.

The limitations of the present study are related to the small number of cases evaluated, the retrospective characteristic of the study and the absence of comparative analysis. The blocks discrepancy test performed represents a subjective method of assessment but used in clinical practice. The follow-up time is considered short considering the biomechanical changes to which the hip and ankle joints were subjected after knee arthrodesis surgery. The distance that patients were able to walk after surgery was not objectively assessed. Finally, the KSS score used has the limitation of having been designed to assess patients with joint mobility; however, there is no description in the literature of a specific score for patients undergoing knee arthrodesis, with no consensus on which would be the ideal method for the functional assessment of these patients.

Conclusion

Knee arthrodesis surgery was effective in controlling the infectious process and reducing pain complaints in the operated limb. Most patients were able to walk at home after the evaluated follow-up, but satisfaction with the procedure is low. Arthrodesis surgery provides a functional limb, being an option in cases of refractory infection after TKA.

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Conflict of interests
The authors declare that have no conflict of interests.

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Evaluation of the CTX-II Biomarker in Patients with Anterior Cruciate Ligament Tear: Pilot Study*

Avaliação do biomarcador CTX-II em pacientes com ruptura do ligamento cruzado anterior: Estudo piloto

Alexandre Pedro Nicolini[1] Nacime Salomão Barbachan Mansur[1] Juliana Luporini Dreyfuss[2] Benno Ejnisman[1] Moises Cohen[1] Diego Costa Astur[1]

[1] Department of Orthopedics and Traumatology, Centro de Traumatologia do Esporte, Escola Paulista de Medicina, Universidade Federal de São Paulo, São Paulo, SP, Brazil
[2] Division of Molecular Biology, Departamento de Bioquímica, Universidade Federal de São Paulo, Escola Paulista de Medicina, São Paulo, SP, Brazil

Address for correspondence Alexandre Pedro Nicolini, MD, Rua Estado de Israel, 636, São Paulo, SP, 04022-001, Brazil (e-mail: apnicolini@uol.com.br).

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Abstract

Objective The aim of the present study was to quantify the urinary concentration of the C-terminal cross-linked telopeptide of type-II collagen (CTX-II) biomarker in patients who suffered an isolated ACL injury, and to compare the concentrations found in this population with a control group of patients with no metabolic changes in the knee that could lead to cartilage degeneration.

Methods A cross-sectional pilot study was performed in two groups: patients with ACL tears and a control group (each group with 10 male subjects, with an age range between 18 and 35 years, and body mass index below 30 kg/m^2). In both groups, urine concentrations of a biomarker related to the degradation of type-II collagen (CTX-II) was measured. For the group with ACL tears, a temporal relationship between the time after the injury and the amount of the biomarker was also examined.

Results There were significant differences in the concentrations of urinary CTX-II between the ACL group and the control group ($p = 0.009$). No significant relationship was observed between the time after the injury and the quantity of the biomarker.

Conclusions Patients with ACL injury had higher concentrations of urinary CTX-II biomarker than those with no ACL injury ($p = 0.009$). However, there was no correlation between the concentration of this biomarker and the elapsed time after the injury ($p > 0.05$).

Keywords
- osteoarthritis
- biomarkers
- anterior cruciate ligament injuries

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Resumo

Objetivo Quantificar a concentração urinária do biomarcador telopeptídeo C de colágeno de tipo II (*C-terminal cross-linked telopeptide of type-II collagen*, CTX-II) em casos de lesão isolada do ligamento cruzado anterior (LCA), e comparar as concentrações observadas nessa população com um grupo controle composto por pacientes sem alterações metabólicas no joelho que possam levar à degeneração da cartilagem.

Métodos Este é um estudo piloto transversal com dois grupos: pacientes com ruptura do LCA e grupo controle (cada grupo era composto por 10 indivíduos do sexo masculino, com 18 a 35 anos de idade, e índice de massa corporal inferior a 30 kg/m^2). Nos dois grupos, as concentrações urinárias de um biomarcador relacionado à degradação do colágeno de tipo II (CTX-II) foram medidas. No grupo com ruptura do LCA, a relação entre o tempo pós-lesão e a quantidade do biomarcador também foi analisada.

Resultados Houve diferenças significativas nas concentrações urinárias de CTX-II entre o grupo LCA e o grupo controle ($p = 0{,}009$). Não foi observada relação significativa entre o tempo de lesão e a quantidade do biomarcador.

Conclusões Pacientes com lesão do LCA apresentaram maiores concentrações urinárias do biomarcador CTX-II do que aqueles sem lesão do LCA ($p = 0{,}009$). No entanto, não houve correlação entre a concentração desse biomarcador e o tempo decorrido após a lesão ($p > 0{,}05$).

Palavras-chave

- osteoartrite
- biomarcadores
- lesões do ligamento cruzado anterior

Introduction

Anterior cruciate ligament (ACL) injury causes knee instability. Other intra-articular lesions commonly accompany ACL tears, especially those of the cartilage and menisci. The treatment of these lesions involves surgical reconstruction to reestablish the anatomy and biomechanics of the native ligament, mitigating symptoms and enabling the return to activities.[1]

One of the main postoperative sequelae of ACL injury is not completely eliminated after ligament reconstruction: the onset of osteoarthritis (OA) of the knee. On average, the signs and symptoms appear 10 to 15 years following ligament reconstruction, with an incidence ranging from 0% to 86% of cases.[2–6]

The diagnosis of OA is clinical. The imaging tests have low sensitivity and specificity to detect early changes and monitor the progression of the disease during a short-term follow-up. Visible radiographic changes occur on average two years after the onset of the disease.[1,6] The lack of a universal measurement standard with adequate sensitivity and specificity makes it difficult to measure the early degenerative processes after injury or ACL reconstruction, making a more accurate, short-term screening modality desirable.[4] The use of biomarkers enables an early, non-invasive measurement of the processes of cartilage degeneration. These biochemical markers of connective tissue are released into the systemic circulation, and can be measured in the blood, the urine or the synovial fluid. One of the main biomarkers for the diagnosis and prognosis of OA is C-terminal cross-linked telopeptide of type-II collagen (CTX-II).[7–11] This biomarker is released during the dynamic process of type-II collagen degeneration, and, consequently, it correlates with the destruction and formation of cartilage.[8,12–18] Mouritzen et al[19] showed that CTX-II has a specificity for OA of the knee. Rotational trauma and intra-articular bleeding associated with ACL tear are thought to cause an acute metabolic alteration of the cartilage and subchondral bone, resulting in the onset of the long-term degeneration of the articular cartilage. One of the biomarkers of this process is CTX-II.[8]

In the literature, no study has evaluated the correlation of the CTX-II biomarker in a homogeneous sample with isolated ACL injury, what makes the study unique and innovative. The aim of the present study was to quantify the urinary concentration of the CTX-II biomarker in patients who suffered an isolated ACL injury and to compare the concentrations found in this population with those of a control group of patients with no knee injury. Our hypothesis was that the urine concentrations of CTX-II would be higher in patients with ACL rupture and, therefore, the biomarker would be useful as a prognostic indicator of the development of OA.

Methods

Study Design

The present study was evaluated and approved by the Ethics in Research Committee of the author's institution. The present was a cross-sectional, observational, single-center, pilot study comparing the presence of a type-II collagen degradation urinary biomarker in patients with ACL injury of the knee and healthy patients without knee injury (control group).

Between June 2017 and February 2018, 10 male subjects with a history of isolated ACL lesion (group 1–treatment) and 10 males with no history of knee ligament injury (group 2–control) were evaluated and included in the study.

The inclusion criteria were: male gender; age between 18 and 35 years; body mass index (BMI) lower than 30 kg/m^2; isolated ACL lesions or absence of knee injuries; and patients who did not practice sports, since some previous studies suggest

an increase in the levels of CTX-II after the practice of sports in certain conditions.[20,21] The exclusion criteria were: female gender; presence of degenerative knee or other joint disease; systemic, autoimmune or infectious diseases; other knee ligament injuries; history of knee surgery; lesions of the meniscus or of the associated cartilage (bone bruises on the magnetic resonance imaging [MRI] scans were not considered cartilage lesions, and were included in the study); any previous ACL surgical treatment; and use of nonsteroidal anti-inflammatory drugs for at least 1 month before the evaluation. With these selection criteria, we tried to make our sample as homogeneous as possible and to obtain the lowest risk to present idiopathic OA or other pathologies such as osteoporosis.

The patients were selected from the outpatient care population with clinical and radiologic findings of the ACL tear. The anterior drawer, Lachman, and pivot-shift maneuvers were used during the physical examination, along with MRI diagnostic confirmation of ACL rupture for Group-1 subjects. These evaluations were performed just before the urine collection, excluding all pathologies that could interfere in the analysis (meniscal lesions, cartilage lesions, osteoarthritis). The maximum time postinjury was stablished as 2 years.

Urine Sample Collection

A single, clean-catch urine collection of all participants was performed, following the same aseptic protocol: after the genital region was topically sterilized, collection of either the first urination of the day or urination two hours after the previous urination (exactly as described in the CTX-II kit instruction manual), during the middle urination stream (neglecting the initial and final phases), using a sterile flask was completed. These urine samples were kept in a refrigerated environment for a maximum duration of 12 hours before centrifugation and frozen at -20°C for the period (1 week to 7 months) prior to the analysis. In the ACL group, the urine samples were obtained in the patients' first visit to the office before any treatment.

Urinalysis and Presence of CTX-II

The urine samples were thawed simultaneously at room temperature for thirty minutes prior to the quantitative measurement of CTX-II. An enzyme-linked immunosorbent assay (ELISA, Elabscience, Houston, TX, US) was performed on each sample. This ELISA kit used the ELISA-sandwich principle for sample analyses. Using this methodology, the supplied ELISA plate is precoated with an antibody specific for human CTX-II. The collected samples (urine) were poured into the wells of the ELISA plate and homogenized with the specific antibody, forming a conjugate (antigen–antibody complex).

Then, a biotinylated detection antibody specific for avidin-horseradish peroxidase (HRP) conjugate was added to the plate and incubated. The free components were removed during a wash. The substrate solution was added to each well, and only the wells containing human CTX-II/conjugate would appear blue. The enzyme-substrate reaction was terminated by the addition of a stop solution, and the color then became yellow. Immediately following this, the optical density (OD) was measured spectrophotometrically at a wavelength of 450 nm $\pm$ 2 nm (EZ Read 400 Biochrom spectrometer, Cambourne, Cambridge, UK). The value of the OD is proportional to the concentration of human CTX-II present in the sample. The calculation of the concentration of CTX-II in the samples was then performed by comparing the values calculated based on a standard curve.

The specifications of the ELISA test for the detection of the degradation of type-II collagen (CTX-II kit) according to the manufacturer were as follows: sensitivity: 0.10 ng/mL; detection range: 0.16 ng/mL to 10 ng/mL; reproducibility: coefficient of variation $< 10\%$

All analyses were performed simultaneously in the same laboratory (at the Molecular Biology Division) on the same equipment. The results were evaluated and compared between groups.

Statistical Analysis

Summary statistics (mean, standard deviation, median, minimum, and maximum) were used to describe the characteristics of the patients and the biomarker concentrations within each group. The Mann-Whitney test was used to compare the groups in relation to the concentration of CTX-II. The Spearman correlation was used to evaluate the relationship between the time after the injury and the presence of urinary CTX-II. Values of p lower than 5% (0.05) were defined as statistically significant differences.

Results

The patients in the ACL group had a mean age of 20.8 years and a mean BMI of 25 kg/m^2. The patients in control group had a mean age of 28.2 years and a mean BMI of 24.5 kg/m^2. The individuals in the ACL group were younger than those of the control group ($p< 0.001$), and there was no significant difference between the groups in terms of BMI ($p> 0.05$) (►**Table 1**).

The mean concentration of CTX-II in the ACL group was of 8.9 $\pm$ 0.7 ng/mL (range: 7.7 ng/mL to 9.8 ng/mL), which was higher than that of the control group: 6.7 $\pm$ 2.6 mg/mL (range 0.7 ng/mL to 9.4 ng/mL; $p = 0.009$) (►**Table 2** and ►**Fig. 1**). The time postinjury varied between 2 and 18 months, and there was no difference between the time post-injury and the CTX-II levels for the ACL group ($p = 0.521$; r = -0.231) (►**Fig. 2** and ►**Table 1**).

Discussion

Our hypothesis was supported by the results of this study. Subjects with ACL rupture had significantly higher concentrations of urinary CTX-II than the subjects without injury ($p = 0.009$), regardless of the time postinjury. This finding supports the notion that metabolic changes in the articular cartilage occurring soon after the initial ACL rupture appear to predispose patients to degenerative knee pathology, as seen in other previous studies.[4,14,15,17,22–25]

Interleukins (IL-6, IL-8) and matrix metalloproteases (MMP-3 and MMP-13) are some of the cytokines thought

Table 1 Descriptive characteristics evaluated according to each group and results of the comparative testing

Variable	Groups		Total	*p*-value
Age (years)	Control ($n = 10$)	Anterior cruciate ligament ($n = 10$)	($n = 20$)	$<$ **0.001**
Mean $\pm$ standard deviation	28.2 $\pm$ 3.8	20.8 $\pm$ 2.6	24.5 $\pm$ 5	
Median (minimum; maximum)	28.5 (22; 35)	20 (18; 25)	24 (18; 35)	
Body mass index (Kg/m^2)				0.853
Mean $\pm$ standard deviation	24.5 $\pm$ 3.4	25 $\pm$ 2.3	24.8 $\pm$ 2.8	
Median (minimum; maximum)	24.5 (18; 29)	24 (22; 29)	24 (18; 29)	
Time postinjury (months)				
Mean $\pm$ standard deviation		6.8 $\pm$ 4.7	6.8 $\pm$ 4.7	
Median (minimum; maximum)		5.5 (2; 18)	5.5 (2; 18)	

Table 2 Quantitative analysis of the CTX-II urine biomarker according to each group and results of the comparative testing

	CTX-II Urine Concentration (ng/mL)						
Groups	**n**	**Mean**	**SD**	**Median**	**Minimum**	**Maximum**	***p*-value**
ACL (1)	10	8.9	0.7	9	7.7	9.8	
Control (2)	10	6.7	2.6	7.2	0.7	9.4	$p = 0.009$
Total	20	7.8	2.1	8.4	0.7	9.8	

Abbreviations: ACL, anterior cruciate ligament; CTX-II, C-terminal cross-linked telopeptide of type-II collagen; SD, standard deviation.

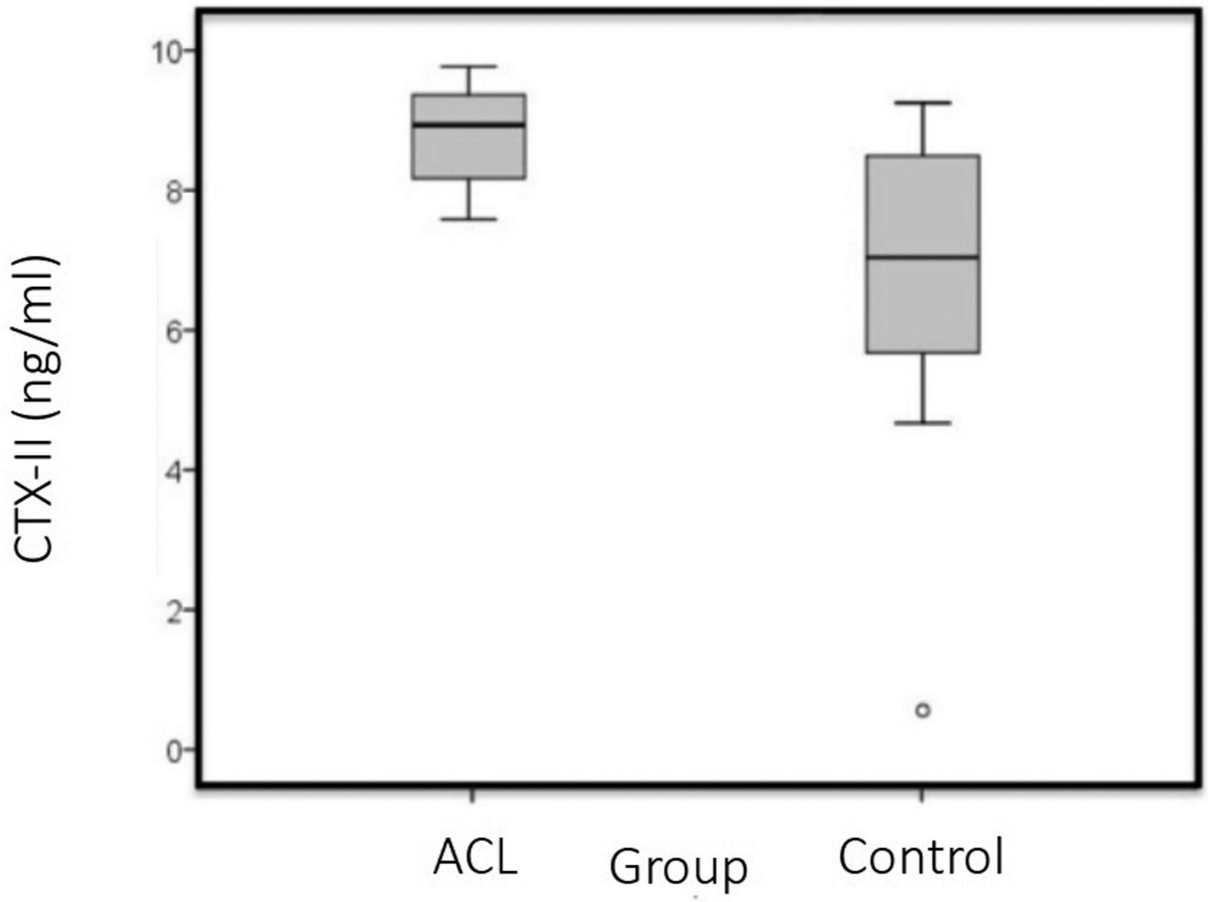

Fig. 1 Mean value of the C-terminal cross-linked telopeptide of type-II collagen (CTX-II): anterior cruciate ligament (ACL) group versus control group. The mean value of the CTX-II in the ACL group was of 8.9 $\pm$ 0.7 ng/mL (range: 7.7 ng/mL to 9.8 ng/mL), which was higher than that of the control group: 6.7 $\pm$ 2.6 ng/mL (range 0.7 ng/mL to 9.4 ng/mL) ($p = 0.009$).

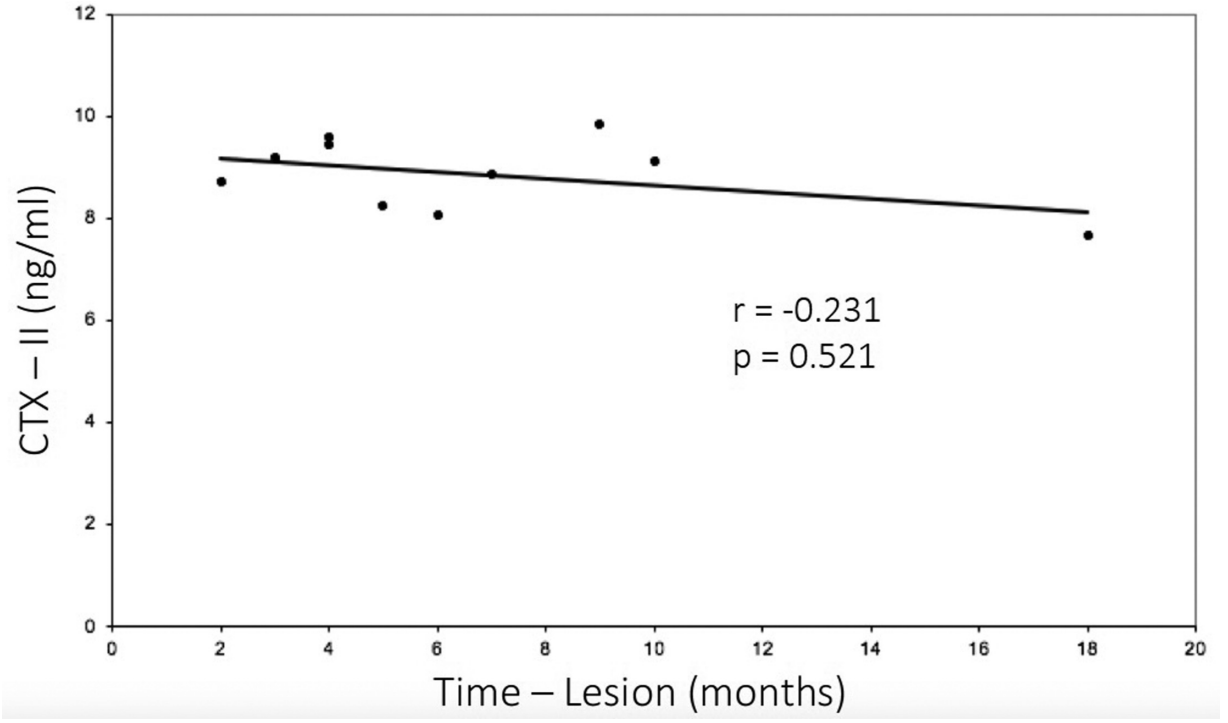

Fig. 2 Relationship between time postinjury and CTX-II concentration. There was no difference between the time postinjury and the CTX-II concentration in the ACL group ($p = 0.521$; r = -0.231).

to be intimately related to the degradation of type-II collagen.[1,5] On average, OA becomes symptomatic and hinders the patients from performing activities 10 to 15 years after the initial traumatic event.[7,9,12] However, this degenerative process does not affect all patients with a history of ACL tear, as evidenced by the wide range of incidence in this population (0% to 86%).[2–6]

Until now, there has not been a reliable, early prognostic marker for this process. As an established marker of type-II cartilage breakdown, CTX-II can be measured in the blood, the synovial fluid, and the urine because the molecule is not altered after renal filtration. The advantage of the urinary measurement is the ease of collection. Moreover, because it is considered a burden-of-disease type biomarker according to the burden of disease, investigative, prognostic, efficacy of intervention and diagnostic (BIPED) classification,[10] the correlation between the severity of the degenerative changes of the OA and the CTX-II biomarker concentrations support its use as a diagnostic and prognostic tool.[10,25–27]

Because of the intrinsic characteristics of each method of biomarker quantification (manufacturer, as well as gender, age, BMI and articular joint of the studied patients) there are no uniform or reference values described in the literature, and even the units of measurement differ according to the kit used.[19] Several biomarkers of inflammation quantification such as the cartilage oligomeric matrix protein (COMP), aggrecan degradation products (ARGS) and even inflammatory cytokines have been associated with degenerative processes in the knee cartilage.[5] Despite this variability in the analysis of biomarkers, previous studies in the literature concluded that there is a quantitative increase in biomarkers after an ACL injury.[3,24] However, these studies did not control for isolated ACL injury, the stage of the disease, or use of the same biomarker.

Comparing with previous studies involving CTX-II and OA, Garnero et al[28] compared 67 patients with knee OA and 67 healthy subjects, and a found significant difference between both groups concerning the concentration of urinary CTX-II (mean value: 431 ng/mmol Creatinine and 345 ng/mmol Cr respectively). In another study comparing 17 healthy individuals and 329 patients with any kind of knee injury (ACL/ACL combined with another ligament or meniscus tear, or an isolated meniscus tear), Lohmander et al[18] found a significant difference in the serum CTX-II measurement (mean: 1.4 ng/mL and 9.5 ng/mL respectively). Saberi Hosnijeh et al,[29] in a large cohort study, evaluated 1,335 participants with and without OA and the relationship with several biomarkers, including CTX-II, and showed as result values of 2.4 ng/mmol Cr for the CTX-II in the group that developed OA, and of 2.27 ng/mmol Cr in the group without OA (a small but significant difference).

The present study measured only the preoperative urine CTX-II concentrations; therefore, our study is unique in its aim to identify an early prognostic OA biomarker. Two other studies quantified CTX-II following surgical ligament reconstruction. Larsson et al[26] found no difference in CTX-II biomarker concentrations in the serum, urine, and synovial fluid when comparing the values before and after surgery. Chmielewski et al[8] performed serial urine CTX-II measurements after surgery and found that the concentration decreased over time.

Nevertheless, to demonstrate the specificity of a biomarker and its prognostic power, the homogeneity of the sample is crucial. Furthermore, the markers must be measured

accurately and reproducibly, with coefficients of variation lower than 10%. Because patient characteristics such as gender, age and BMI vary, it is necessary to minimize the variability between the compared groups, or to stratify the study according to the analyzed variable. The present study is unique in its methodology, because care was taken to evaluate only patients with isolated ACL injuries, establishing the specificity of this biomarker for post-ACL injury cartilage degeneration in a homogeneous group. According to Deshpande et al,[30] the risk of OA in male, non-obese patients, under 35 years of age is lower than 1%.

The temporal trend of the concentration of the CTX-II biomarker was also evaluated. However, no statistically significant trend was found ($p > 0.05$). One of the inclusion criteria for the study was an injury sustained at a maximum of 2 years prior to enrollment, and the postinjury time ranged from 2 to 18 months. The absence of a temporal trend can be explained in two ways: the small sample population, and the possibility of type-II collagen degradation occurring after the trauma sooner than our analysis. These levels could remain chronically elevated, unless a new event occurs, including surgical treatment or some other non-surgical treatment.[26]

Despite the fact that our inclusion criteria were designed to identify demographically similar patients, there was a significant difference between the mean ages of the groups. The control group had a higher average age (28.2 ± 3.8 years) than the ACL group (20.8 ± 2.6 years). If the result were the opposite, we might consider this an important bias, once CTX-II values are increased in older patients.

We acknowledge the limitations of the present study. This cross-sectional pilot study provided a statistical evaluation of biomarker concentration in both injured and control populations. Biomarker concentrations are known to change with time and stage of cartilage degeneration. In addition, biomarker concentrations are known to vary with interventions, both surgical and/or clinical.[8,26] Prospective studies tend to provide better information regarding the temporal trends of biomarker concentrations and their related pathological severity. Another limitation of the present study is the small sample size ($n = 20$). While this limitation may reduce the robustness of the conclusions, the sample size provided ample power to provide statistically significant results. A study with a larger sample will ultimately provide more conclusive data and may better elucidate the changes in CTX-II concentrations over time. The final limitation is the exclusion of female patients, because the main objective of the selection criteria was to homogenize the sample. This analysis will be necessary in future studies with larger samples of patients of both genders.

Further studies may better elucidate how to inhibit the process of cartilage degeneration after an ACL injury or other joint conditions. Biomarker measurement may play an important role in achieving this goal, because they help in the early diagnosis of metabolic alterations both qualitatively and quantitatively, in terms of disease severity. Finally, they may be used in therapeutic studies to evaluate treatment efficacy.

Perspective

Previous studies have shown that inflammatory cytokine levels increase after ACL rupture, and that this phenomenon may be associated with OA.[2–4,17,24] Another way to show an alteration in cartilage metabolism after knee trauma is using biomarkers, such as COMP and CTX-II.[5,15] The importance of the present study is to show the increase in CTX-II concentrations after an ACL tear, and other studies are being conducted after these results. This also could be useful for other pathologies, such as meniscal or cartilaginous injuries and other ligament injuries. It may also be useful to test or compare surgical techniques, medications or interventions to prevent OA. C-terminal cross-linked C-telopeptide of type-II collagen, among other biomarkers, has the advantage of being measured in the urine; therefore, it is an easy and non-invasive way to show and follow cartilage formation and degradation.

Conclusion

Patients with ACL injury had higher concentrations of urinary CTX-II than those with no ACL injury ($p = 0.009$). Nevertheless, there was no correlation between the concentration of this biomarker and the elapsed time postinjury ($p > 0.05$).

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Conflict of Interests

The authors have no conflict interests to declare.

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Larger Chondral Lesions Treated with Collagen Membrane – Matrix-Induced Autologous Chondrogenesis – Show Larger Increase in Clinical Scores

Lesões condrais maiores tratadas com uso de membrana de colágeno – condrogênese autóloga induzida por matriz – apresentam maior aumento nos escores clínicos

Mateus Kenji Christo Miyahira[1] João Victor Novaretti[2] Diego Costa Astur[2] Camila Cohen Kaleka[1] Joicemar Tarouco Amaro[1] Moisés Cohen[2]

[1] Cohen Institute of Orthopedics, Reabilitation and Sports Medicine, São Paulo, SP, Brazil
[2] Department of Orthopedics and Traumatology, Escola Paulista de Medicina, Universidade Federal de São Paulo, São Paulo, SP, Brazil

Address for correspondence Mateus Kenji Christo Miyahira, Instituto Cohen, Av Lineu de Paula Machado, 660, Cidade Jardim, São Paulo, SP, 05601-000, Brazil (e-mail: kenjimiyahira23@hotmail.com).

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Abstract

Objective To evaluate clinically and radiologically the results of the treatment of chondral lesions using collagen membrane - autologous matrix-induced chondrogenesis (AMIC).

Methods This is a series of observational cases, in which 15 patients undergoing AMIC were analyzed. The clinical evaluation was made by comparing the Lysholm and International Knee Document Commitee (IKDC) scores in the pre- and postoperative period of 12 months, and radiological evaluation using the Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) score in the same postoperative period.

Results The mean age of the patients was 39.2 years old, and the mean size of the chondral lesions was 1.55cm^2. There was a significant improvement in clinical scores, with a mean increase of 24.6 points on Lysholm and of 24.3 on IKDC after 12 months. In the radiological evaluation, MOCART had a mean of 65 points. It was observed that the larger the size of the lesion, the greater the improvement in scores.

Conclusion Evaluating subjective clinical scores, the treatment of chondral lesions with the collagen membrane showed good results, as well as the evaluation of MOCART, with greater benefit in larger lesions.

Keywords
- articular cartilage
- chondrogenesis
- collagen
- knee injuries

* Work developed at the Department of Orthopedics and Traumatology, Universidade Federal de São Paulo (UNIFESP), São Paulo, SP, Brazil.

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Resumo

Objetivo Avaliar clínica e radiologicamente os resultados do tratamento das lesões condrais com a membrana de colágeno – condrogênese autóloga induzida por matriz.

Métodos Trata-se de uma série de casos observacional, na qual foram analisados 15 pacientes submetidos a condrogênese autóloga induzida por matriz. A avaliação clínica foi feita comparando os escores de Lysholm e International Knee Document Commitee (IKDC, na sigla em inglês) no pré- e pós-operatório de 12 meses, e avaliação radiológica através do escore de Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART, na sigla em inglês) no mesmo período de pós-operatório.

Resultados A média de idade dos pacientes foi 39,2 anos, e a média do tamanho das lesões condrais foi de 1,55cm^2. Houve uma melhora significativa nos escores clínicos, com média de aumento de 24,6 pontos no Lysholm e de 24,3 no IKDC, após 12 meses. Na avaliação radiológica, o MOCART teve média de 65 pontos. Observou-se que quanto maior o tamanho da lesão, maior foi a melhora nos escores.

Conclusão Avaliando escores clínicos subjetivos, o tratamento das lesões condrais com a membrana de colágeno mostrou bons resultados, assim como a avaliação de MOCART, com maior benefício em lesões maiores.

Palavras-chave

- cartilagem articular
- condrogênese
- colágeno
- traumatismos do joelho

Introduction

The biomechanical function of the matrix of proteoglycans and collagen fibers of the cartilage is to absorb compressive and tension loads that act on the joint.[1] Cartilage injuries are seen in up to 11% of arthroscopies, half of which are > 2 cm^2 in size.[2] Most are related to trauma or osteochondritis dissecans.

The healing capacity of cartilage is limited[3,4] and may lead to osteoarthritis.[5] One of the greatest challenges for the orthopedic surgeon remains the treatment of chondral injuries.[6] Due to the low healing potential, and the degree of discomfort that these lesions cause, surgical intervention has been widely used in an attempt to fill cartilage defects.[7,8] Mesenchymal cells are the source for regeneration.[9]

Pridie,[10] in 1959, was the first to stimulate repair using blood from the bone marrow. Steadman et al.,[11] in 2001, introduced the microfracture technique. Microfracture is a technique for recruiting mesenchymal cells, as the clot provides a favorable medium for cartilage repair tissue.[12] The "fibrocartilage-like" scar tissue[13] prevents osteoarthritis and improves patient symptoms.[14]

As the formed clot does not have good mechanical resistance, the use of the collagen membrane has been proposed.[15–17] Autologous matrix-induced chondrogenesis (AMIC) is a technique that combines microfractures with the collagen membrane.[18] While microperforations are indicated for defects < 2 cm^2, AMIC is indicated for larger defects.[19]

The objective of the present study is to evaluate clinically and radiologically the results of the treatment for chondral lesions of the knee using the collagen membrane – AMIC.

Methodology

The present study is an observational case series of patients with chondral injuries of the knee, operated between 2015 and 2018 using collagen membrane by the AMIC technique, and approved by the ethics committee of the institution.

All of the patients participating in the present study were informed about the surgical technique indicated and other treatment options, its advantages and disadvantages, and agreed with the performance of the chosen procedure.

The indications were patients between 15 and 55 years of age, with chondral lesions of 0.5 to 5.0 centimeters in diameter, in the patella, trochlea or femoral condyles, grades III or IV of ICRS (Internacional cartilage repair society), active and symptomatic. Patients with a history of previous surgery for cartilage, poor alignment of the affected lower limb or ligament instability that were not corrected previously or concurrently with the procedure, were not included. The exclusion criteria were patients who abandoned outpatient follow-up or did not agree to participate.

A total of 15 patients were included in the study, 12 men and 3 women, all operated by the same surgeon.

Preoperative evaluation

Patients who had suspected chondral lesions in the knee, according to anamnesis and physical examination, underwent complementary imaging tests for diagnostic completion, with radiographs and magnetic resonance imaging (MRI), being able to characterize and measure chondral lesion and to identify ligament injuries or poor alignment of the lower limbs. Thus, patients who met the criteria for inclusion in the study were identified.

Surgical technique

First, arthroscopy of the affected knee was performed, to locate the chondral lesion, and to evaluate the ligaments and menisci. Then, afterwards, a longitudinal parapatellar arthrotomy was performed according to the joint region to be operated. When there was any other concomitant surgical procedure, such as reconstruction of the anterior cruciate ligament or valgus osteotomy of the tibia, chondroplasty was always performed last.

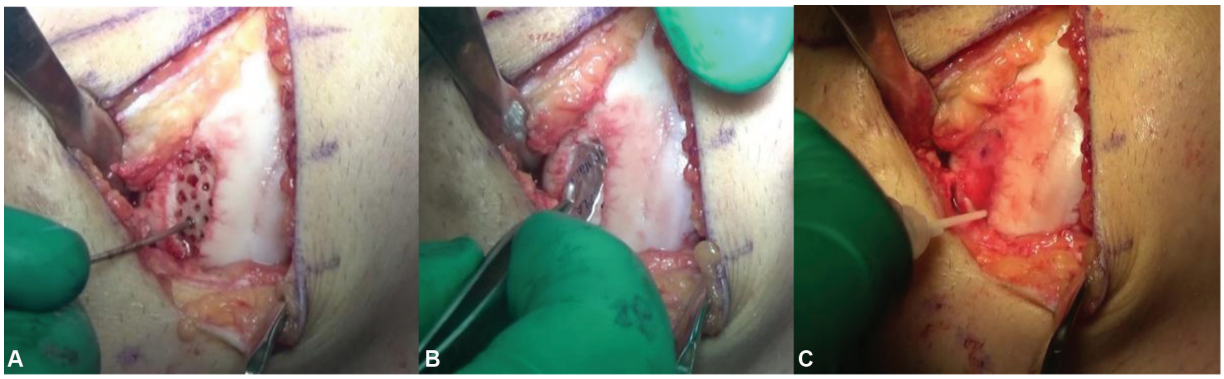

Fig. 1 A, debrided and microperforated chondral lesion area. B, metallic mold used to measure dimensions of the lesion. C, final aspect showing the collagen membrane fixed by fibrin glue.

After debridement of the chondral defect, removal of degenerate and unviable cartilaginous tissue, curettage of the lesion bed was performed, removing the whole calcified layer and preserving the subchondral bone (►**Figure 1**).

Using a metallic template, the size and shape of the lesion was precisely defined, and the porcine type I/III collagen membrane (Chondrogide; Geistlich Pharma AG, Wolhusen, Switzerland) that would cover the defect was cut out. Then, microperforations were made in the subchondral bone, freehand, with 2 to 4 mm of distance between them. The membrane was then placed over the defect and provisionally fixed with two needles. The definitive fixation of the membrane was made with absorbable monocryl 5.0 thread and complemented with fibrin glue at the edges of the lesion.

Rehabilitation

Despite the different surgical procedures associated with the use of the collagen membrane, the rehabilitation protocol started with three weeks of immobilization with joint brace and without weight unloading on the operated limb.

In order to reduce the inflammatory condition, until the 5th week, an increase in the range of motion and activation of the quadriceps muscle was initiated. After that, until the 8th week, the patient was encouraged to walk without using an orthosis, progressively, until the gait normalized. Between 6 and 8 months, the patient was allowed to play contact sports.

Data Collection

Demographic data such as age, gender, laterality, size and location of the chondral lesion, and associated procedures were collected from the database. The preoperative clinical evaluation was performed using the Lysholm[20] and the International Knee Document Commitee (IKDC)[21] scores, and the 1-year postoperative follow-up, through Lysholm, IKDC, and the Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) radiological score.[22] This score is a rating system that seeks to assess the repair tissue in its extent, signal strength, defect filling, integration with the adjacent cartilage, among others.

Statistical analysis

Initially, all variables were analyzed descriptively. For quantitative variables, this analysis was performed by observing the minimum and maximum values, and calculating means, standard deviations (SDs) and quartiles. For qualitative variables, absolute and relative frequencies were calculated. For the comparison of means of two evaluation moments, the paired Student t test was used.[23] To study the correlations between the deltas of the scores and variables evaluated in the study, the Pearson correlation coefficient was used. The software used for the calculations was SPSS Statistics for Windows, Version 17.0 (SPSS Inc., Chicago, IL, USA). The level of significance used for the tests was 5%.

Results

A total of 15 patients aged between 15 and 54 years old (mean of 39.2 years old) were evaluated, 3 women and 12 men. The lesions affected the femoral trochlea in six cases, the patella in five cases and the femoral condyles in four cases. ►**Table 1** presents the frequency distribution of the lesion site.

The size of the lesions ranged from 0.6 cm^2 to 2.34 cm^2, measured using preoperative MRIs, and the body mass index (BMI) ranged from 21.6 kg/m^2 to 32.5 kg/m^2, as shown in ►**Table 2**, with the descriptive values of these variables.

The Lysholm and IKDC scores were assessed before and after surgery, at 12 months. There was a significant increase in the means of the Lysholm score (55.9 versus 80.5) and of the IKDC score (51.6 versus 75.9) from pre- to postoperative ($p < 0.001$) (►**Figures 2** and **3**).

The Tegner and MOCART scores were evaluated in a single moment and are described in ►**Table 3**. Through the results obtained with MRI scans after 1 year, it was shown that all patients maintained the filling of the chondral lesion with repair tissue, with good integration of the edges. The average MOCART score was 65 points, ranging from 50 to 75.

For the study of possible correlations between variables, and the pre- and postoperative variation of the scores, the delta of variation of the scores presented in ►**Table 4** was calculated.

In ►**Table 5**, the correlation coefficients between age, lesion size, BMI and the deltas of variation of the Lysholm and IKDC scores are presented. There is a positive and significant correlation between the size of the lesion and the delta of variation of the IKDC score. Therefore, the greater the lesion size, the greater the delta of variation of the IKDC

Table 1 Frequency distribution of the lesion site for the 15 patients evaluated

Lesion site	n	%
MFC + LFC	1	6.7
MFC R	3	20.0
Patella R	3	20.0
Patella L	2	13.3
Trochlea R	4	26.7
Trochlea L	2	13.3
Total	15	100.0

Abbreviations: L, left; LFC, lateral femoral condyle; MFC, medial femoral condyle; R, right.

Table 2 Descriptive values of lesion size and body mass index of the 15 patients

Variable	n	Mean	SD	Minimum	Maximum
Size	15	1.55	0.58	0.60	2.34
BMI	15	27.6	2.6	21.6	32.5

Abbreviations: BMI, body mass index; SD, standard deviation.

score (►**Figure 4**). No relationship was found between the observed improvement, age and BMI.

Discussion

The most important finding of the present study was that patients with larger chondral lesions had a greater increase in clinical scores, therefore a greater benefit with the treatment. These results show agreement with the previous study published by our group.[24] There was no significant impact of age and BMI on the results found in the present study.

The AMIC technique has been used by several surgeons, being established as an option in the treatment of cartilage defects. Previous studies have shown the ability of microfractures in the subchondral bone to take mesenchymal cells from the bone marrow to the cartilage region, promoting the supply of growth factors and cytokines. *In vitro* tests have already shown that the collagen membrane can retain mesenchymal cells, which can improve the regenerative capacity of the microfracture technique.[15]

A 2008 study compared the results of treating chondral lesions with microfractures, using or not the collagen membrane in acetabular lesions. It was shown that a more sustained improvement in clinical scores was achieved with the use of the membrane.[25]

Compared with other surgical procedures to treat cartilage defects, the combination of microfractures with the collagen membrane is a good option, with a low-cost surgical time, without morbidity of a healthy donor area or need for cell proliferation in vitro, as in autologous osteochondral transplantation and autologous chondrocyte transplantation, respectively. The same technique of the present study, performed arthroscopically, has already been described by Piontek et al., presenting promising results.[26] Schagemann et al.,[27] in 2018, compared the AMIC arthroscopic technique with the *mini open* technique, similar to our work, concluding that there is no difference in the results in the medium term, with 2 years of follow-up.

Dhollander et al.[28] have already reported satisfactory improvements 2 years after the operation, but with a tendency to deterioration of the repair tissue, analyzed

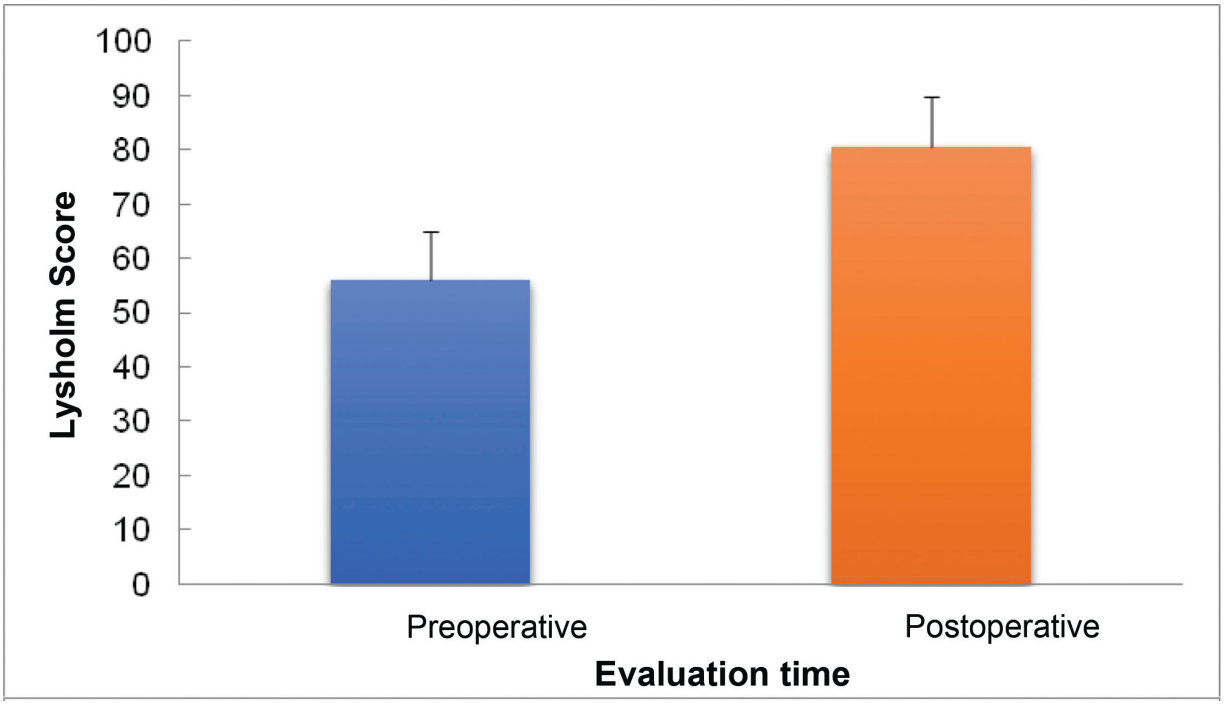

Fig. 2 Mean and standard deviation of the Lysholm score in the pre- and postoperative period.

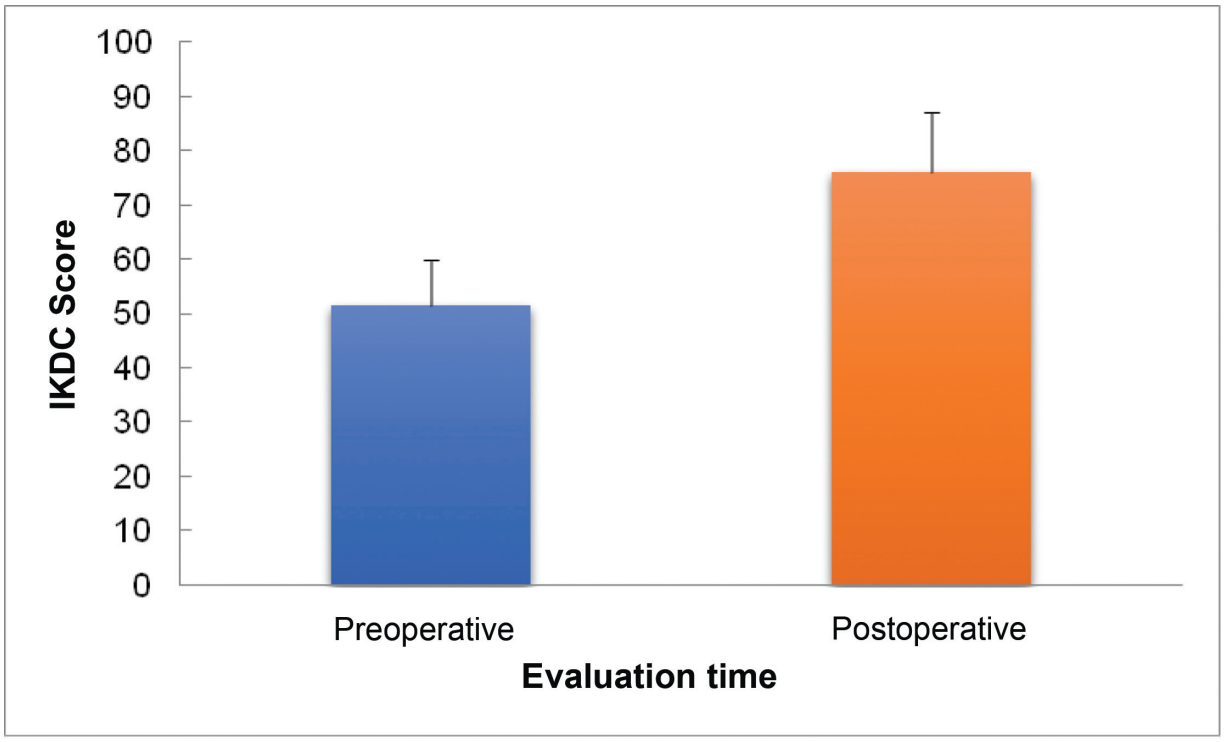

Fig. 3 Mean and standard deviation of the International Knee Documentation Committee (IKDC) score in the pre- and postoperative period.

Table 3 Descriptive values of the Tegner and Mocart scores of the 15 patients

Variable	n	Mean	SD	Minimum	Maximum
Tegner	15	3.9	1.1	2.0	6.0
MOCART	15	65.0	7.8	50.0	75.0

Abbreviations: MOCART, Magnetic Resonance Observation of Cartilage Repair Tissue; SD, standard deviation.

Table 4 Descriptive values of the delta scores of variations of the Lysholm and International Knee Documentation Committee scores of the 15 patients

Variable	n	Mean	SD	Minimum	Minimum
Lysholm	15	24.6	9.0	11.0	41.0
IKDC	15	24.3	7.1	12.6	33.4

Abbreviations: IKDC, International Knee Documentation Committee; SD, standard deviation.

by MRI. In our series of cases, the improvements were good or excellent. Through imaging exams, no repair tissue thinning or overgrowth was observed. Other studies have already shown that there is no clinical improvement at the same pace as the repair tissue evolution observed by MRI scans.[22] We believe that the radiological evaluation can be indicative of treatment failure, but not an indication of success.

Table 5 Pearson correlation coefficients

		Lysholm Delta	IKDC Delta
Age	r	0.266	-0.188
	p-value	0.338	0.502
	n	15	15
Size	r	-0.143	0.593
	p-value	0.610	0.020
	n	15	15
BMI	r	0.450	-0.017
	p-value	0.092	0.953
	n	15	15

Abbreviation: BMI, body mass index; IKDC, International Knee Documentation Committee.

There are limitations that must be considered when evaluating the present work. The small number of patients reflects a reality for the surgeons of the country, due to the access to the necessary material for the procedure. Because of this, the lesions are described in different parts of the joint, with various concurrent procedures, making the sample more heterogeneous.

Conclusion

Evaluating subjective clinical scores, the treatment of chondral lesions with the collagen membrane showed good

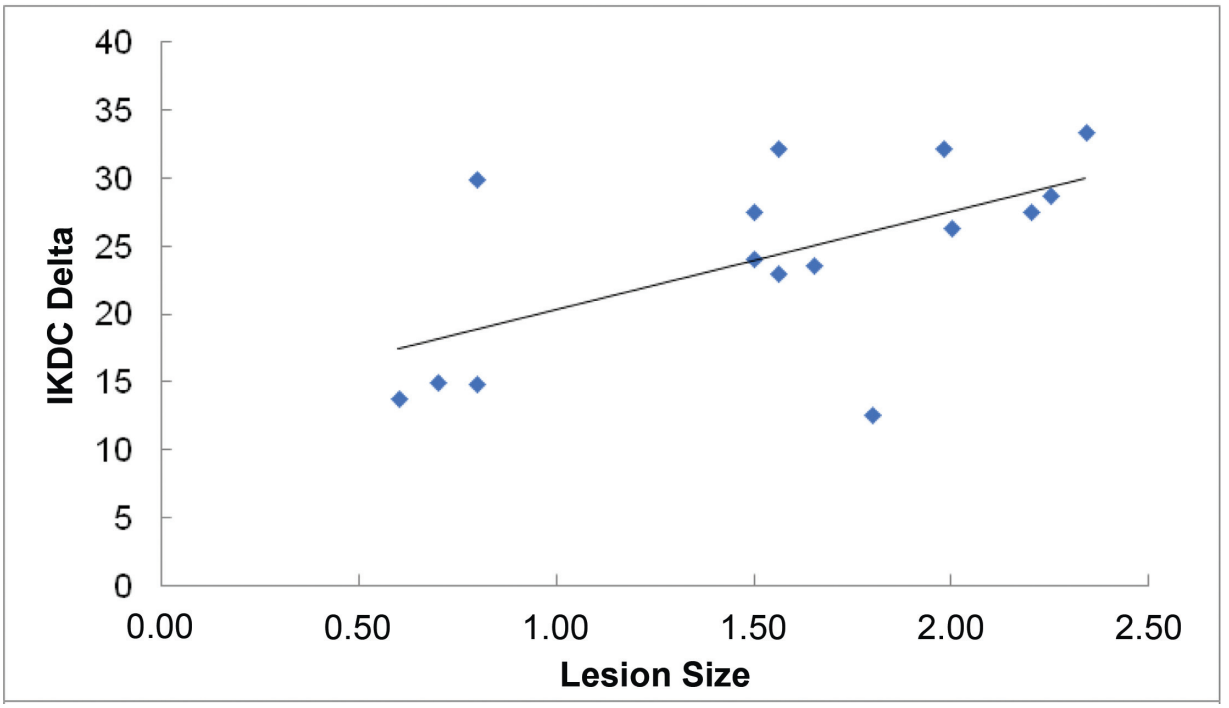

Fig. 4 Scatter plot of lesion size and delta variation of the International Knee Documentation Committee (IKDC) score.

results, as well as the MOCART evaluation, and that there is a greater benefit in larger lesions.

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Conflict of Interests
The authors have no conflict of interests to declare.

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Diagnostic Failure Rate in Detecting Perilunate Carpal Fractures and Dislocations Using Plain Wrist X-Rays*

Índice de falha diagnóstica na detecção de fraturas e luxações perilunares do carpo utilizando radiografias simples do punho

Aleixo Abreu Tanure[1] Fernanda Ruiz de Andrade[1] Luis Guilherme Rosifini Alves Rezende[1] Amanda Favaro Cagnolati[1] Luiz Garcia Mandarano-Filho[1] Nilton Mazzer[2]

[1] Hand Surgery Program, Hospital das Clínicas, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo (HC-FMRP-USP), Ribeirão Preto, SP, Brazil
[2] Hand Surgery Division, Hospital das Clínicas, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo (HC-FMRP-USP), Ribeirão Preto, SP, Brazil

Address for correspondence Luis Guilherme Rosifini Alves Rezende, MD, Av. Bandeirantes, 3900, Vila Monte Alegre, Ribeirão Preto, SP, 14049-900, Brazil (e-mail: lugui.rezende@yahoo.com.br).

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Abstract

Objectives The present study aimed to evaluate the diagnostic failure rate in detecting perilunate fractures and dislocations using plain wrist radiographs by orthopedists and orthopedic residents. A secondary objective was to identify possible groups with a greater or lesser chance of establishing a correct diagnosis.

Methods An online questionnaire was sent to several orthopedists through e-mail, social networks, and smartphone-based communication applications to assess the rate of diagnostic failure in detecting perilunate fractures and dislocations using plain radiographs.

Results A total of 511 responses was obtained, with a diagnostic error rate of 8.81% for simple dislocations and 1.76% for trans-scaphoid perilunate fractures. Group stratification showed that residents presented the highest error rates in simple perilunate dislocations (23.91%), whereas hand surgeons presented the lowest error rates (1.74%).

Conclusion Compared with the literature, the failure rates found were lower, suggesting that plain radiography is effective and that the error rate may not be as high as reported.

Keywords
- carpal bones/injuries
- wrist injuries
- joint dislocations
- fractures, bone

* *Study performed at Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo, Ribeirão Preto, SP, Brazil.*

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Resumo

Objetivos O presente estude teve como objetivo avaliar o índice de falha diagnóstica na detecção de fraturas e luxações perilunares do carpo utilizando radiografias simples do punho por ortopedistas e residentes de ortopedia. Secundariamente, identificar possíveis grupos que apresentem maior ou menor chance de acerto diagnóstico.

Métodos Foi aplicado um questionário online a diversos ortopedistas através de e-mail, redes sociais e aplicativos de comunicação via *smartphone*, para avaliar o índice de falha diagnóstica na detecção de fraturas e luxações perilunares utilizando radiografias simples.

Resultados Foram obtidas 511 respostas e observado um índice de erro diagnóstico de 8,81% para as luxações simples e 1,76% para fratura transescafoperilunar. Ao estratificar por grupos, os médicos residentes obtiveram os maiores índices de erro nas luxações perilunares simples (23,91%), já os cirurgiões de mão obtiveram os índices mais baixos (1,74%).

Conclusão Ao comparar com a literatura, os índices de falha encontrados foram menores, sugerindo que a radiografia simples é eficaz e que o índice de erro pode não ser tão elevado quanto o relatado na literatura.

Palavras-chave

- ossos do carpo/lesões
- traumatismos do punho
- luxações articulares
- fraturas ósseas

Introduction

Wrist perilunate fractures and dislocations are uncommon conditions, corresponding to approximately 7% of all carpal injuries.[1] These lesions have serious repercussions for affected patients if not properly diagnosed and treated. Perilunate fractures and dislocations are caused by high-energy traumas, such as car accidents, falls from height and contact sports, and they are often associated with other traumatic injuries. Patients present with diffuse wrist pain, edema, loss of range of motion and fingers in a semi-flexed position. Subjects may also complaint of paresthesia in the median nerve territory and acute carpal tunnel syndrome.[2]

Radiographic evaluation is essential to manage these patients, and posteroanterior (PA) and lateral (L) views are sufficient for diagnosis. Posteroanterior radiography with ulnar deviation of the wrist helps to assess trans-scaphoid perilunate fracture-dislocations.[2] On PA radiography, it is important to observe Gilula lines, which are imaginary lines drawn through the proximal and distal aspects of the proximal row and the proximal aspect of the distal row. These three lines should be smooth, parallel arches, and breaks suggest carpal incongruity.[3] Lateral radiographies show the alignment of the capitate, lunate and radius bones. These bones must be properly aligned, and any alignment change strongly suggests a perilunate dislocation. Computed tomography scans can be useful when there are associated complex fractures, such as scaphoid and pyramidal fractures, and they must be performed after dislocation reduction.[4]

In 1980, Mayfield et al.[5] performed a cadaveric study and classified this condition in four progressive stages. An axial force was applied with wrist hyperextension associated with ulnar deviation and intercarpal supination to reproduce the injury. In stage I, they observed scapholunate ligament rupture or scaphoid fracture. In stage II, a lunate-capitate subluxation was observed, and some cases may present capitate fractures. Stage III was characterized by lunate-pyramidal ligament injury or pyramidal fracture, with a dorsal perilunate dislocation of the entire carpus. Stage IV presented palmar lunate dislocation towards the carpal tunnel when the capitate is reduced to the lunate fossa.[5]

Due to the low frequency of these injuries and low familiarity of most orthopedists with the complex anatomy of carpal bones, perilunate dislocations often are not diagnosed at the first visit.[1,2] In a multicenter study with 166 patients, Herzberg et al.[6] demonstrated that diagnosis was not made at the initial evaluation in 25% of the cases of simple dislocations and trans-scaphoid lunate fracture-dislocations. This data is troublesome, since early diagnosis and treatment are critical to minimize serious complications such as stiffness, chronic pain and posttraumatic arthrosis.[2,4,7,8] In addition, treatment delay was shown to negatively impact the final outcome.[6,9]

This reality reported by international studies does not seem to be different from the Brazilian reality. Our service, which specializes in hand surgery, receives many patients with chronic perilunate dislocations who were not properly diagnosed at a first orthopedic visit, affecting the treatment outcome.

The present study aimed to evaluate the failure rate in perilunate fractures and dislocations diagnosis using plain wrist radiographs by orthopedists and orthopedic residents. In addition, this study attempted to identify possible groups presenting a greater or lesser chance of a correct diagnosis.

Materials and Methods

An online questionnaire was prepared and applied using the Google Forms platform (Google LLC, Menlo Park, CA, USA) [10] and sent to orthopedists and orthopedic residents through e-mail, social networks (Workplace from Facebook [Facebook Inc., Menlo Park, CA, USA] from *Sociedade Brasileira de Ortopedia e*

Traumatologia [SBOT]), and smartphone-based communication applications (WhatsApp [Facebook Inc.]). These platforms were chosen because they can provide a wide reach for the questionnaire and provide a convenient way for orthopedists and orthopedics residents to answer it. The questionnaire consisted of four initial questions to analyze the profile of the study subjects. These questions were related to time (in years) since medical residency, area of activity, SBOT accreditation, and work in urgency/emergency units for patients with upper limb trauma. In the second stage of the questionnaire, eight PA and lateral radiographs of the wrist were shown, with three normal images and five with pathological findings. Pathological radiographs include a simple perilunate dislocation, a perilunate fracture-dislocation, a scaphoid fracture, and two images showing a distal radial fracture. After analysis, professionals answered whether the radiograph was normal or if there was a fracture and/or dislocation. Radiographs were presented in a random order. Questionnaires answered in an incomplete or contradictory way were excluded. A chi-square test was used to verify the association between qualitative variables. In addition, this association was quantified using logistic regression models[11] to calculate the gross odds ratio (OR) and their respective 95% confidence intervals.

This work was approved by the institutional ethics committee under CAAE number 84365318.3.0000.5440.

Results

A total of 511 responses were obtained. Of these, 194 (38%) orthopedists had more than 10 years of experience, 225 (44%) had less than 10 years of experience, and 92 (18%) were residents. Of the 419 trained orthopedists, 352 (84%) were accredited by the SBOT, and 67 (16%) did not have a specialist title recognized by SBOT. In addition, among these 419 orthopedists, 172 (41%) work in hand surgery, 90 (21.5%) are general orthopedists, and 157 (37.5%) work as specialists in other areas, such as spine, knee, and shoulder. Of the 511 professionals, 436 currently work in an emergency unit treating upper limb trauma (85.3%).

►**Figure 1** shows a radiograph from a simple, Mayfield stage III perilunate dislocation. The diagnostic error rate was 8.81%. This error rate was 23.91% among residents and 5.49% among trained orthopedists (►**Figure 2**). The chance of a resident missing a diagnosis (OR) was 4.3 times higher compared to orthopedists with more than 10 years of experience and 6.7 times higher compared to orthopedists with less than 10 years of experience. When compared by surgical area, hand surgeons had the lowest error rate, of 1.74%. The chance of a general orthopedist and a specialized orthopedist making a mistake was about 5 times higher compared to hand surgeons (OR 0.211 and 0.197, respectively). Comparing residents with hand surgeons, the chance of error was about 17.5 times higher (OR 0.057). P values were lower than 0.001 (►**Table 1**).

The radiograph from ►**Figure 3** shows a stage III transscaphoid perilunate fracture. The global diagnostic error rate was 1.76%. Error rate was 7.61% among residents and 0.48% among orthopedists (►**Figure 2**). This represents an OR of 9.1 for orthopedists with less than 10 years of experience and 3.6 for general orthopedists, with a p-value < 0.001. All orthopedists with more than 10 years of experience, hand surgeons, and specialized orthopedists correctly diagnosed this radiography (►**Table 2**).

There were no relevant differences between trained orthopedists with SBOT, accreditated or not. As for the

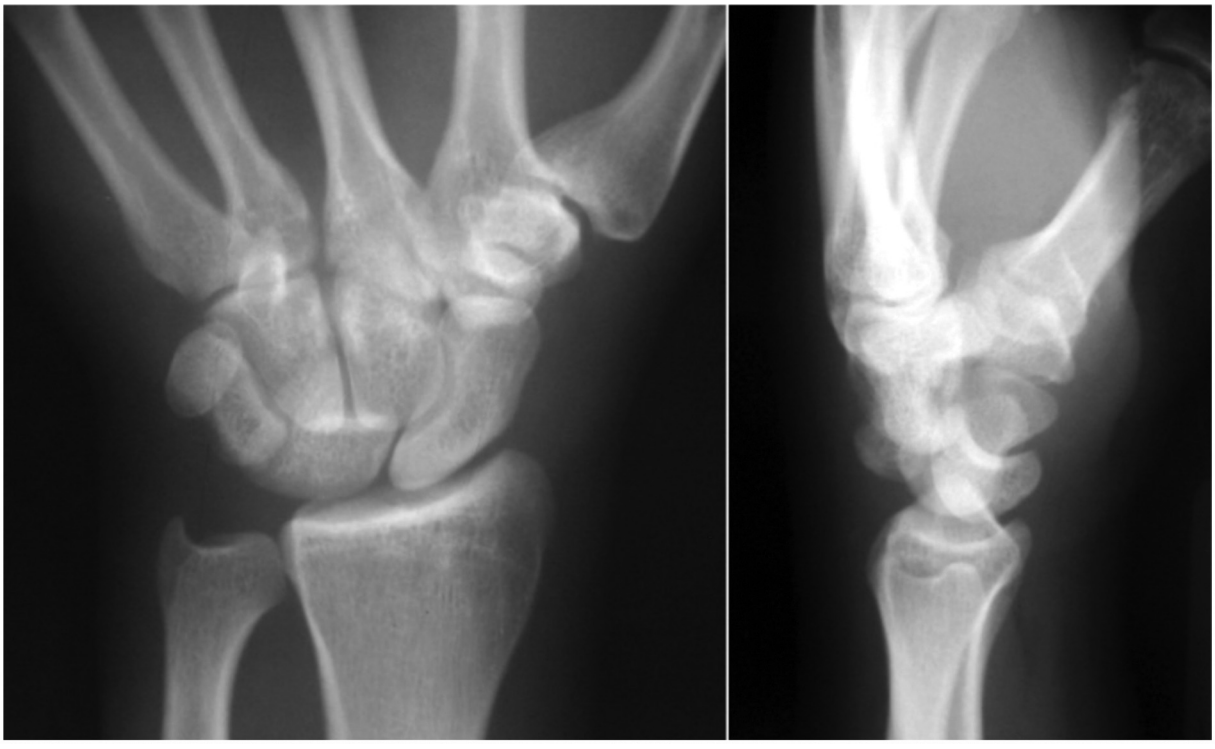

Fig. 1 Perilunate dislocation, Mayfield stage III.

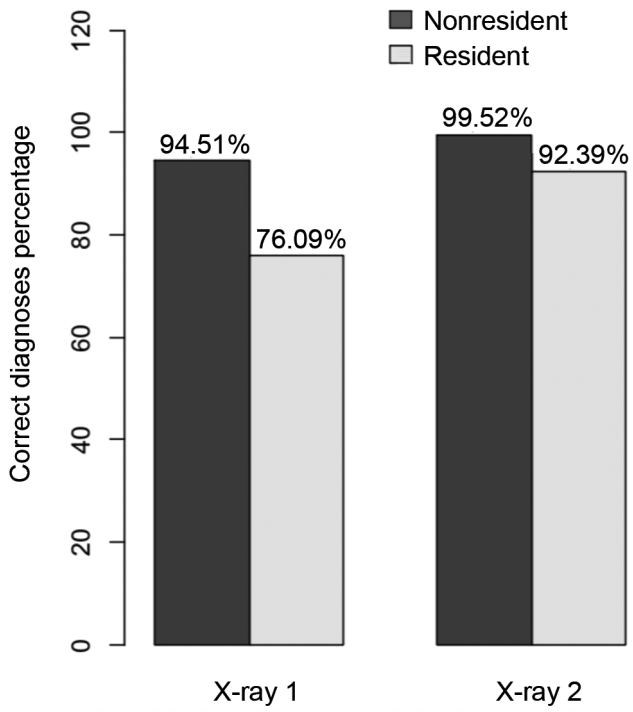

Fig. 2 Correct diagnoses percentage: Residents versus Nonresidents.

normal radiographs presented in the questionnaire, 38.49% of the answers classified them as pathological.

Discussion

There was a very significant number of responses, with good participation from the orthopedic community. The 511 responses obtained correspond to approximately 3% of Brazilian orthopedists.[12] However, this was a convenience sample, which may limit the external validity of the study and may not necessarily be representative of all geographic regions of the country.

Most articles regarding the diagnostic failure rate in simple or complex perilunate dislocation cite a study from Herzberg et al.,[6] performed in Europe in 1993. These authors reported a 25% rate, with no discrimination between simple and complex dislocations. In a more recent study published in Turkey in 2018, there was a 22.7% rate of diagnostic failure in 44 patients with perilunate dislocation or fracture-dislocation. The only risk factor found was the orthopedist inexperience with the condition. Among the surgeons missing the diagnosis, 70% said it was the first time they encountered this condition.[13] Another recent study, published in 2018, evaluated perilunate dislocation and fracture-dislocation in a population of military personnel in the United States and found a diagnostic failure at

Table 1 Frequencies and logistical regression for X-ray 1

	X-ray 1					
	Miss (0)	Hit (1)				
	n (%)	n (%)	Total	*p*-value*	Gross odds ratio	Confidence interval (95%)
Question 1: What is your current degree?						
1	13 (2.54)	181 (35.42)	194 (37.96)	< **0.001**	4.376	**(2.090–9.163)**
2	10 (1.96)	215 (42.07)	225 (44.03)		6.757	**(3.052–14.958)**
3	22 (4.31)	70 (13.70)	92 (18.00)		1.000	Reference
Question 2: What is your area of expertise?						
1	3 (0.59)	169 (33.07)	172 (33.66)	< **0.001**	1.000	Reference
2	7 (1.37)	83 (16.24)	90 (17.61)		0.211	**(0.053–0.835)**
3	13 (2.54)	144 (28.18)	157 (30.72)		0.197	**(0.055–0.704)**
4	22 (4.31)	70 (13.70)	92 (18.00)		0.057	**(0.016–0.195)**
Question 3: Are you an orthopedist/traumatologist accredited by *Sociedade Brasileira de Ortopedia e Traumatologia* (SBOT)?						
1	19 (3.72)	333 (65.17)	352 (68.88)	< **0.001**	5.508	**(2.831–10.719)**
2	4 (0.78)	63 (12.33)	67 (13.11)		4.950	**(1.618–15.147)**
3	22 (4.31)	70 (13.70)	92 (18.00)		1.000	Reference
Question 4: Do you currently work in an urgency/emergency unit for upper limb trauma orthopedic treatment?						
1	37 (7.24)	399 (78.08)	436 (85.32)	0.5382	1.288	(0.575–2.886)
2	8 (1.57)	67 (13.11)	75 (14.68)		1.000	Reference

*p-value for Chi-square test. Modeled probability 1 = hit.
Question 1. 1: I completed my residency more than 10 years ago; 2: I completed my residency less than 10 years ago; 3: I am a resident in orthopedics and traumatology.
Question 2. 1: Hand surgery; 2: General orthopedics; 3: Other areas (e.g., knee, hip, spine surgery); 4: I am a resident physician in orthopedics and traumatology.
Question 3. 1: Yes; 2: No; 3: I am a resident physician in orthopedics and traumatology.
Question 4. 1: Yes; 2: No.

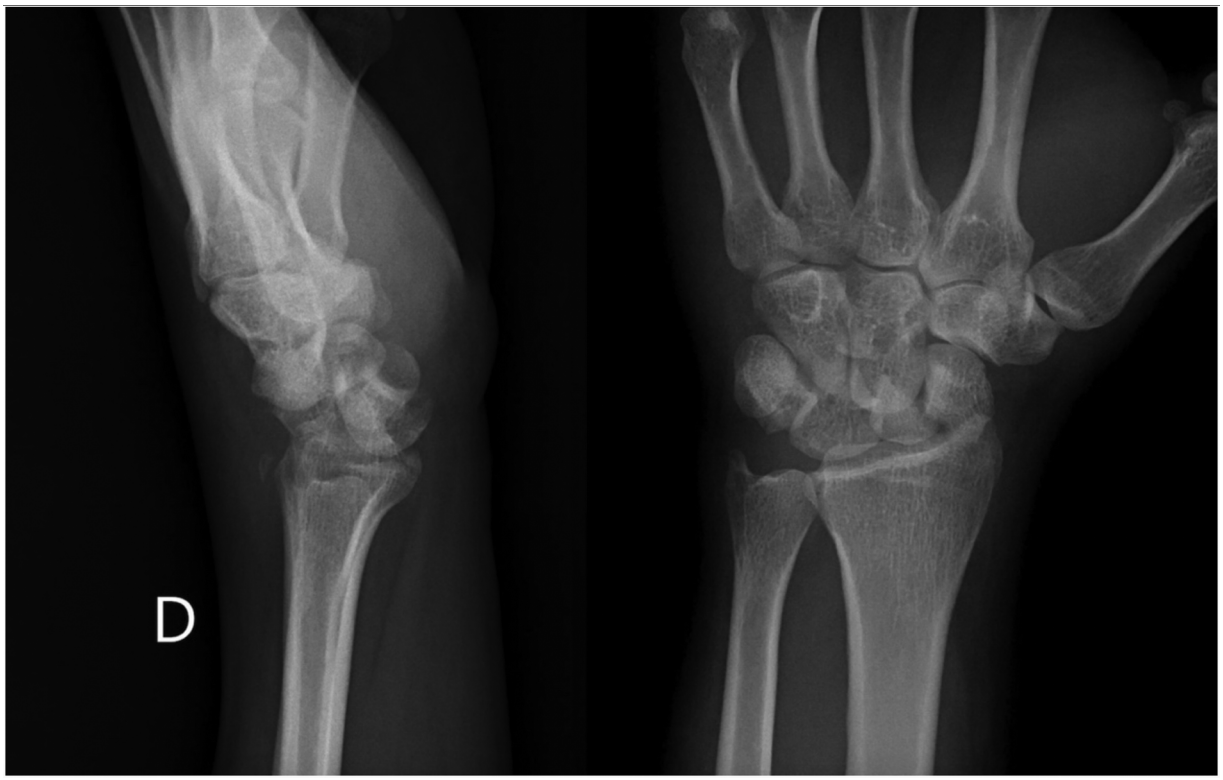

Fig. 3 Trans-scaphoid lunate fracture-dislocation, Mayfield stage III.

Table 2 Frequencies and logistical regression for X-ray 2.

	X-ray 2					
	Miss (0)	Hit (1)				
	n (%)	n (%)	Total	*p*-value*	Gross odds ratio	Confidence interval (95%)
Question 1: What is your current degree?						
1	0 (0.00)	194 (37.96)	194 (37.96)	< **0.001**	–	–
2	2 (0.39)	223 (43.64)	225 (44.03)		9.182	**(1.870–45.082)**
3	7 (1.37)	85 (16.63)	92 (18.00)		1.000	Reference
Question 2: What is your area of expertise?						
1	0 (0.00)	172 (33.66)	172 (33.66)	< **0.001**	–	–
2	2 (0.39)	88 (17.22)	90 (17.61)		3.624	(0.732–17.938)
3	0 (0.00)	157 (30.72)	157 (30.72)		–	–
4	7 (1.37)	85 (16.63)	92 (18.00)		1.000	Reference
Question 3: Are you an orthopedist/traumatologist accredited by *Sociedade Brasileira de Ortopedia e Traumatologia* (SBOT)?						
1	1 (0.20)	351 (68.69)	352 (68.88)	< **0.001**	28.906	**(3.509–238.094)**
2	1 (0.20)	66 (12.92)	67 (13.11)		5.435	(0.653–45.274)
3	7 (1.37)	85 (16.63)	92 (18.00)		1.000	Reference
Question 4: Do you currently work in an urgency/emergency unit for upper limb trauma orthopedic treatment?						
1	7 (1.37)	429 (83.95)	436 (85.32)	0.5187	1.679	(0.342–8.241)
2	2 (0.39)	73 (14.29)	75 (14.68)		1.000	Reference

*p-value for Chi-square test. Modeled probability 1 = hit.
Question 1. 1: I completed my residency more than 10 years ago; 2: I completed my residency less than 10 years ago; 3: I am a resident in orthopedics and traumatology.
Question 2. 1: Hand surgery; 2: General orthopedics; 3: Other areas (e.g., knee, hip, spine surgery); 4: I am a resident physician in orthopedics and traumatology.
Question 3. 1: Yes; 2: No; 3: I am a resident physician in orthopedics and traumatology.
Question 4. 1: Yes; 2: No.

initial care in 27.5% of cases.[14] We found significantly lower error rates, of 8.81% for simple perilunate dislocations and 1.76% for perilunate fractures-dislocations. Such results may be due to a high suspicion rate among orthopedists, who, feeling observed and tested, may have changed their behavior for fear of making mistakes. This is indicated by findings of fractures or dislocations in 38.49% of the answers related to normal radiographs. Another aspect interfering with the diagnostic accuracy rate is the time the patient was seen in the emergency room and the amount of rest the doctor had.[13,15] In Turkey, Çolak et al.[13] reported that 70% of patients diagnosed incorrectly were admitted to the emergency room at night. The design of our study did not allow an analysis of this variable, which is a particular feature of the clinical practice.

It should also be considered that the questionnaire does not correspond to the clinical practice, in which it is possible to take the history and perform a physical examination of the patient, generating a greater or lesser index of suspicion for a given condition depending on the clinical findings. However, our study may suggest that the diagnostic failure rate is not as high as previously thought and that the European study from Herzberg et al.[6] does not represent the Brazilian reality. Another hypothesis is that errors may be decreasing due to the improved training of physicians in residency programs since 1993, when Herzberg's study was carried out. One aspect that corroborates this last hypothesis is that there was a significant difference between resident doctors and trained orthopedists (23.9% versus 5.49%), thus demonstrating that the orthopedics and traumatology residency is effective in instructing residents to identify this condition on plain radiographs.

Hand surgeons had the lowest error rates, as expected, due to their greater familiarity with the condition. In contrast, SBOT accreditation as a specialist was not related to differences in the correct diagnosis rate.

Our study indicates that the diagnostic error rate for perilunate dislocations may be lower than that described in the classical literature. However, this statement requires studies with a higher level of scientific evidence in order to be confirmed. A suitable option would be a multicenter case-control study, as it reflects clinical practice with greater reliability and provides a satisfactory number of cases, since perilunate dislocations are not common and one hospital alone could bias the study due to its specific demographic features.

Conclusion

The diagnostic error rate of plain radiographs was 8.91% for isolated perilunate dislocations and 1.76% for perilunate fractures-dislocations, suggesting that this is an effective method and that the error rate may not be as high as expected. Hand surgeons and orthopedic residents, respectively, presented the lowest and highest diagnostic error rates.

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Conflict of Interests
The authors declare that there is no conflict of interests.

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Onset of Trigger Finger after Carpal Tunnel Syndrome Surgery: Assessment of Open and Endoscopic Techniques*

Frequência do aparecimento de dedo em gatilho no pós operatório da síndrome do túnel do carpo em duas técnicas cirúrgicas: Aberta e endoscópica

Marcela Fernandes[1,2] João Carlos Belloti[1,2] Aldo Okamura[1,2] Jorge Raduan Neto[1,2] Rafael Tajiri[2] Flávio Faloppa[1] Vinícius Ynoe de Moraes[1–3]

[1] Orthopedics and Traumatology Department, Universidade Federal de São Paulo, São Paulo, SP, Brazil
[2] Hand Surgery Service, Hospital Alvorada, Moema, São Paulo, SP, Brazil
[3] Ortocity Serviços Médicos, São Paulo, SP, Brazil

Address for correspondence Vinícius Ynoe de Moraes, PhD, Rua Borges Lagoa, 786, São Paulo, SP, 04041050, Brazil (e-mail: vymoraes@gmail.com).

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Abstract

Objective The present study aimed to determine the frequency of trigger finger (TF) onset after surgery for carpal tunnel syndrome (CTS) using an open (OT) or an endoscopic technique (ET). As a secondary endpoint, the present study also compared paresthesia remission and residual pain rates in patients submitted to both techniques.

Methods Trigger finger onset and remission rates of paresthesia and pain at the median nerve territory was verified prospectively in a series of adult patients submitted to an OT procedure ($n = 34$). These findings were compared with a retrospective cohort submitted to ET ($n = 33$) by the same surgical team. Patients were evaluated with a structured questionnaire in a return visit at least 6 months after surgery.

Results Sixty-seven patients were evaluated. There was no difference regarding trigger finger onset (OT, 26.5% versus ET, 27.3%; $p = 0.94$) and pain (OT, 76.5% versus ET, 84.8%; $p = 0.38$). Patients submitted to OT had fewer paresthesia complaints compared with those operated using ET (OT, 5.9% versus ET, 24.2%; $p = 0.03$).

Conclusions In our series, the surgical technique did not influence trigger finger onset and residual pain rates. Patients submitted to OT had less complaints of residual postoperative paresthesia.

Keywords
- carpal tunnel syndrome
- paresthesia
- comparative study
- endoscopy
- trigger finger disorder

* *Study developed at the Medical Residence Service in Hand Surgery and Microsurgery, Hospital Alvorada, São Paulo, SP, Brazil.*

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Resumo

Objetivo Determinar a frequência do aparecimento de dedo em gatilho (DG) no pós-operatório da síndrome do túnel do carpo (STC) em duas técnicas: aberta (TA) e endoscópica (TE). Como desfecho secundário, comparar as taxas de remissão da parestesia e dor residual entre as duas técnicas.

Métodos De forma prospectiva, verificamos o aparecimento de dedo em gatilho e taxa de remissão da parestesia e dor no território do nervo mediano em série de pacientes adultos operados pela TA ($n = 34$). Comparamos com coorte retrospectiva operada pela TE ($n = 33$), pela mesma equipe de cirurgiões. A avaliação dos pacientes ocorreu por meio de questionário estruturado em consulta de retorno, com mínimo de 6 meses de pós-operatório.

Resultados Sessenta e sete pacientes foram avaliados. Não houve diferença quanto ao aparecimento de dedo em gatilho (TA, 26,5% *versus* TE, 27,3%; $p = 0,94$) e dor (TA, 76,5% *versus* TE, 84.8%; $p = 0,38$). Os pacientes operados pela TA apresentaram menos queixas de parestesia do que os operados pela TE (TA 5,9% *versus* TE 24,2%; $p = 0,03$).

Conclusões Em nossa série, a técnica cirúrgica não influenciou o aparecimento de dedos em gatilho e dor residual. Os pacientes operados pela técnica aberta apresentaram menos queixa de parestesia residual pós-operatória.

Palavras-chave

- síndrome do túnel do carpo
- parestesia
- estudo comparativo
- endoscopia
- dedo em gatilho

Introduction

Carpal tunnel syndrome (CTS) is defined as a set of signs and symptoms resulting from median nerve compression at the wrist level.[1] This compression may be associated with tenosynovitis or anomalous structures within the carpal tunnel.[2] Carpal tunnel syndrome is the most prevalent compressive neuropathy, affecting $\sim$ 2.7% of the general population[3] It is more common in specific populations, such as diabetic patients and manual workers.[3]

The diagnosis of CTS is based on clinical history, symptoms, and specific maneuvers.[1] Common symptoms include numbness, paresthesia, pain, and loss of strength in the hand and the wrist. When indicated, surgical treatment is based on carpal tunnel decompression, using either an open or an endoscopic technique.[4–6]

Stenosing tenosynovitis at the flexor tendons of the fingers, that is, "trigger finger" (TF), is characterized by an inflammatory process involving the sheath of the flexor tendons at the first annular pulley (A1) level. Trigger finger is related to sheath thickening and to the potential development of a nodule at the flexor tendon. As a result, tendon diameter increases, leading to friction with the A1 pulley.[7] Some conditions are believed to predispose TF development, such as rheumatoid arthritis, diabetes, hypothyroidism, and amyloidosis.[8]

Trigger finger onset after CTS surgical treatment is common. Studies reported a frequency range from 10 to 13% in Jordanian, Brazilian, and American series.[9–11] Meanwhile, this cause-effect relationship has been discussed by several authors,[9–12] but details remain unclear.

Surgical treatment options include decompression by a traditional open approach, consisting in wide access to the skin and palmar fascia, or by an endoscopic approach.[2] We hypothesized, based on some previous studies,[10,11] that a minimally invasive technique, such as endoscopy, results in a lower frequency of TF because it spares structures such as the palmar fascia and the skin immediately anterior to the carpal transverse ligament, potentially mitigating the arc effect resulting from carpal tunnel decompression.[9–11]

The present study aimed to determine the frequency of TF onset after surgical CTS decompression using an open (OT) or an endoscopic technique (ET). As a secondary endpoint, the present study also compared paresthesia remission and residual pain rates in patients submitted to both techniques.

Materials and Methods

The present study was approved by the research ethics committee under the number 17597019.7.0000.5533. It was developed at the hand surgery medical residency service of the Hospital Alvorada-Moema (São Paulo, SP, Brazil) and Ortocity orthopedic clinics (São Paulo, SP, Brazil). This is a case series study with a prospective sample compared with a retrospective historical cohort.

The sample consisted of adult patients, $>$ 18 years old, from both genders, who were operated on by the team of hand surgeons (Moraes V. Y., Belloti J. C., Fernandes M., AO, Raduan Neto J.) using either the open or endoscopic techniques in São Paulo, SP, Brazil, and who completed the minimum postoperative follow-up of 6 months.

Patients with other hand conditions or deformities were not included in the study.

Inclusion criteria

- Patients undergoing open or endoscopic surgical treatment for CTS;
- Minimum postoperative follow-up of 6 months;
- No intraoperative complications

Exclusion criteria

- Patients who did not comply with participating in the study;
- Patients with TF prior to the surgical procedure for CTS (previous clinical diagnosis informed by the patient)

Data collection method

Patients operated using the open technique

This is a convenience sample from the specialized outpatient clinic. Initially, these patients were treated conservatively, with corticosteroids and nighttime orthosis, for a minimum period of 4 weeks. If the conservative treatment was unsuccessful, patients were operated on according to the following diagnostic criteria: 1) presence of nocturnal paresthesia at the median nerve territory; 2) loss of two-point discrimination capacity; 3) positive Phalen test; 4) positive Tinel sign at the carpal tunnel level; 5) paresthesia at the median territory; 6) loss of hand strength. Surgical treatment was indicated to patients with at least three of the aforementioned criteria.

Patients operated using the endoscopic technique (retrospective control)

We carried out a survey of patients operated using the endoscopic technique with the help of the surgical control records of the team. These patients were operated on from 2016 to 2019. They were identified and demographic data, including age, gender, occupation, dominant hand, preexisting conditions, and disease/intervention data, were collected (**Annex 1**). Using these data, patients submitted to the ET were paired with those submitted to the OT for group comparison. Data collection was performed preferably in a face-to-face return visit. Alternatively, some contacts were made by telephone using a structured questionnaire.

Collection determination of pertinent variables

The diagnosis of TF was based on the following questions: 1) Is any finger stuck or presenting difficulty to "bend" or "stretch"?; 2) do you feel pain at the "base" or "root" of the fingers? Paresthesia and pain were diagnosed with the following questions: 1) Do you present a tingling sensation in your hands?; 2) do you present any hand discomfort disturbing your sleep?; 3) do you feel any pain or discomfort in the hands? One or more "yes" answers were considered "events" for the purposes of the present study.

Statistical Analysis

At the descriptive statistical analysis, continuous data were shown as mean values and their standard deviations (SDs), while categorical data were shown as absolute values and percentages. Inferential statistical analyses used nonparametric tests, namely the U Mann-Whitney test for continuous variables and the Fisher F test for categorical variables. Statistical significance was defined at $p < 0.05$ to determine differences between groups.

Results

Group characterization: open versus endoscopic technique

Sixty-seven patients were included. All subjects had a clinical diagnosis consistent with CTS. Thirty-three patients were operated using ET, and 34, OT. Their demographics are shown in ►**Table 1**.

Table 1 Sample characteristics and clinical outcomes: Open and Endoscopic Techniques

	Open Technique	Endoscopic Technique	*p-value*
Age (mean, standard deviation)	58.7 (3.5)	52.2 (3.7)	**0.02**
Female gender (n, %)	28 (82.4)	27 (81.8)	0.95
Right-sided dominance (n, %)	30 (88.2)	28 (84.8)	0.68
Comorbidities (n, %)	21 (61.8)	14 (42.4)	0.11
Diabetes (n, %)	9 (26.5)	8 (24.2)	0.83
Trigger finger (n, %)	9 (26.5)	9 (27.3)	0.94
Paresthesia improvement (n, %)	32(94.1)	25 (75.8)	**0.03**
Pain improvement (n, %)	26 (76.5)	28 (84.8)	0.38

Postoperative variables: trigger presence, pain improvement and paresthesia remission

Trigger finger occurred in 26.9% of the patients. There was no difference in the frequency of TF onset after different techniques: OT, 26.5% versus ET, 27.3%; $p = 0.94$. Regarding pain improvement, there was no difference between groups: OT, 76.5% versus ET, 84.8%; $p = 0.38$. For paresthesia improvement, the OT proved to be more effective than the ET (94.1% versus 75.8%; $p = 0.03$).

Discussion

It is known that patients with CTS are predisposed to TF, with a reported incidence of $\sim$ 0.2 to 31.7% in some studies.[9,11,13,14] However, few studies correlated TF onset to the postoperative period in CTS. A study[11] analyzing 132 operated hands found a 22% frequency of TF. In another prospective study with 164 hands, Hayashi et al.[14] found a TF frequency of 31.7%. Our series is consistent with the literature, with a TF frequency ranging from 26.5 to 27.3%. This finding strengthens the representativeness of our sample, despite its relatively small size. In this scenario, it seemed important to control comorbidities, especially diabetes, as there is a consensus that TF incidence is higher in diabetic patients, with a three-fold increase compared to nondiabetic subjects.[15] In our series, both groups were comparable in terms of comorbidities and diabetes frequency, corroborating the robustness of our results. Studies[10,11] suggest that carpal tunnel release would be a risk factor for TF development due to anatomical and mechanical changes. Transverse carpal ligament release is hypothesized to alter the biomechanics of the action of the flexor tendons, increasing its distal "attack angle" and resulting in greater friction at the osteofibrous tunnel entrance level. This event may contribute to TF onset or worsen a previous condition. As such, endoscopic release would represent less tissue damage due to the smaller access route and because it spares structures anterior to the carpal transverse ligament, such as the skin and palmar fascia.

However, our results did not prove this hypothesis, since the TF frequency was quite similar between groups.

We observed a statistical difference between groups regarding paresthesia improvement, indicating a better performance for the OT. Although this difference is robust, we must keep in mind that it can result from a measurement bias, since these cohorts are not simultaneous and present different disease evolution times. Several studies[16–19] compare the same interventions and outcomes. These authors report a similar rate of paresthesia or sensitivity improvement 6 to 12 months after surgery. With a population similar to ours, Okamura et al.[20] reported consistent, excellent results from the ET in objective functional outcomes and in the Boston questionnaire. Although this study includes a relevant number of patients, it lacks a comparison group. Regarding another relevant outcome, pain, we did not identify any benefit for any of the techniques. It must be considered that part of the literature refers to benefits of the ET, especially within the 1st month.[2]

Some observations must be made about the internal validity[21] of our findings: 1) this is a small sample, which may have limited the representativeness of our data; 2) there is a retrospective component regarding the initial diagnosis and conservative treatment; and 3) the nature of our study does not allow the attribution of a cause-effect relationship, but it establishes an association between both conditions.

Conclusion

In this sample, we demonstrate that the surgical technique does not seem to influence postoperative TF onset and pain. Patients submitted to the OT showed greater paresthesia remission when compared to the ET.

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Conflict of Interests
The authors have no conflict of interests to declare.

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Annex 1 Study questionnaire - Carpal tunnel syndrome and trigger finger onset

1–FULL NAME
_____
2–AGE
( ) YEARS OLD
3–GENDER
( ) MALE ( ) FEMALE
4–OPERATED HAND
( ) RIGHT ( ) LEFT
5–DOMINANT HAND
( ) RIGHT ( ) LEFT
6–PREVIOUS CONDITIONS
_____
7–WAS THERE TRIGGER FINGER ONSET?
( ) YES ( ) NO
8–HOW LONG AFTER SURGERY?
( ) MONTHS
9–DID TRIGGER FINGER OCCUR IN THE OPERATED HAND?
( ) YES ( ) NO
10 – WHICH FINGER WAS AFFECTED?
( ) 1^{st} ( ) 2^{nd} ( ) 3^{rd} ( ) 4^{th} ( ) 5^{th}
10–SURGERY WAS PERFORMED USING THE OPEN OR ENDOSCOPIC APPROACH?
( ) OPEN ( ) ENDOSCOPIC
11–DID CARPAL TUNNEL SYNDROME SYMPTOMS IMPROVE?
Pain
( ) YES ( ) NO
Paresthesia
( ) YES ( ) NO
Nocturnal Paresthesia
( ) YES ( ) NO

Serum Levels of Vitamin D in Children with or without Isolated Distal Radius Fractures: A Prospective Clinical Study*

Níveis séricos de vitamina D de crianças com ou sum fraturas isoladas da extremidade distal do rádio: Um estudo clínico prospectivo

Mehmet Ali Talmac[1] Mehmer Akif Gorgel[1] Ali Varol[2] Semih Ak[3] Bekir Eray Kilinc[3] Hacı Mustafa Ozdemir[1]

[1] Department of Orthopedic Surgery and Traumatology, Sisli Hamidiye Etfal Training and Research Hospital, Istanbul, Turkey
[2] Health Ministry, Department of Orthopedic Surgery and Traumatology, Silopi State Hospital, Sirnak, Turkey
[3] Department of Orthopedic Surgery and Traumatology, Fatih Sultan Mehmet Education and Research Hospital, Istanbul, Turkey

Address for correspondence Bekir Eray Kilinc, MD, İçerenköy Mahallesi Zübeyde Hanım Sok., Şekerevler Sitesi No:1 D:B43, Ataşehir/Istanbul (e-mail: dreraykilinc@gmail.com).

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Abstract

Objective To compare the serum levels of vitamin D and minerals in children with or without isolated distal radius fractures.

Methods The present prospective clinical study included 50 children (aged between 5 and 15 years) with isolated distal radius fractures who were admitted to our emergency unit between February and May 2018 as the study group (group A), and 50 healthy children with no history of fracture as the control group (group B). Peripheral venous blood samples were obtained and analyzed for measurements of 25-hydroxyvitamin D (25(OH)D), calcium (Ca), magnesium (Mg), phosphorus (P), alkaline phosphatase (ALP), and parathyroid hormone (PTH) in both groups. Patient characteristics and peripheral venous blood samples were compared between the groups.

Results The mean age, height, weight, body mass index (BMI) and gender distribution were similar in both groups. There were no statistical differences in the blood analyses, including Ca, Mg, P, ALP, and PTH. However, the serum levels of 25(OH)D were statistically lower in group A when compared to group B ($p < 0.001$), and the number of

Keywords
- alkaline phosphatase
- children
- parathyroid hormone
- radius fractures
- vitamin D

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patients with 25(OH)D insufficiency was statistically higher in group A than in group B ($p = 0.012$).
Conclusion Children with isolated distal radius fracture should be informed about vitamin D deficiency, and, in children with low levels of vitamin D, supplementation may be considered.

Resumo

Objetivo Comparar os níveis séricos de vitamina D e minerais de crianças com ou sem fraturas isoladas da extremidade distal do rádio.
Métodos Este estudo clínico prospectivo incluiu 50 crianças (com idade entre 5 e 15 anos) com fratura isolada distal do rádio que deram entrada em nossa unidade de emergência entre fevereiro e maio de 2018 como grupo de estudo (grupo A), e 50 crianças saudáveis sem histórico de fratura como grupo controle (grupo B). Foram obtidas e analisadas amostras de sangue venoso periférico para medições de 25-hidroxivitamina D (25(OH)D), Cálcio (Ca), Magnésio (Mg), Fósforo (P), fosfatase alcalina (FA) e hormônio da paratireoide (HPT) em ambos os grupos. As características dos pacientes e as amostras de sangue venoso periférico foram comparadas entre os grupos.
Resultados A média de idade, altura, peso, índice de massa corporal (IMC) e distribuição de gênero foram semelhantes em ambos os grupos. Não houve diferenças estatísticas nas análises sanguíneas, incluindo Ca, Mg, P, FA e HPT. No entanto, os níveis séricos de 25(OH)D foram estatisticamente menores no grupo A do que no grupo B ($p < 0{,}001$), e o número de pacientes com insuficiência de 25(OH)D foi estatisticamente maior no grupo A do que no grupo B ($p = 0{,}012$).
Conclusão Crianças com fratura isolada distal do rádio devem ser informadas sobre deficiência de vitamina D, e, em crianças com baixos níveis de vitamina D, a suplementação pode ser considerada.

Palavras-chave
- fosfatase alcalina
- crianças
- hormônio da paratireoide
- fraturas do rádio
- vitamina D

Introduction

Distal radius fractures are one of the most common types of fractures, with an incidence of 25% in the pediatric population.[1] With puberty, the incidence of these fractures rises, with a peak in the age group between 8 and 11 years in girls, and between 11 and 14 years in boys.[2] Although the exact cause has not yet been discovered, the incidence has demonstrated a steady increase over the past 40 years.[2,3] Several studies have been conducted to find out the source of the increased rates, trying to carefully elucidate the potential factors. A general increase in the participation in sports-related activities, gender, ethnic and racial differences, and nutritional status are some of the factors which have been investigated in the literature related with the occurrence of distal radius fractures in the pediatric population.[4,5]

The positive effects of vitamin D on bone density and the association between vitamin D deficiency and low bone density have been established with several studies.[4–6] Low dietary intake of minerals, such as calcium, magnesium, and phosphate, also causes decreased bone mineral density and increased risk of osteoporotic fracture.[7–9] Primary or secondary osteoporosis caused by various underlying chronic illnesses may lead to low serum levels of minerals and vitamin D in the pediatric population, as well as to an increase in the risk of pediatric fracture.[10,11] Although there is a consensus in the literature about the direct correlation between low dietary mineral intake or low levels of vitamin D and osteoporotic fractures in adults, there is no adequate data to find any correlation between the serum levels of vitamin D and minerals and isolated distal radius fractures in children. Therefore, we aimed to compare the serum levels of vitamin D and minerals in children with and without isolated distal radius fractures.

Materials and Methods

The present prospective clinical study was performed with the approval of the Insitutional Review Board (approval number: 19/12/2017-2427) and in line with the ethical principles of the Declaration of Helsinki. After the approval, informed consent was obtained from the guardians of all participants.

The inclusion criteria were: children aged between 5 and 15 years, with similar socioeconomic background, no history of malnutrition or undernutrition, those needing to examine the bone mineral density, with adequate sunlight exposure, otherwise healthy apart from the distal radius fracture after mild trauma, with no history of upper-extremity surgery, and no neurological diseases. The exclusion criteria were: children with concurrent ulnar fractures, history of major trauma, with mineralization disorders (osteopenia, osteogenesis imperfecta, etc.), undergoing steroid treatment, and with chronic diseases or cerebral palsy.

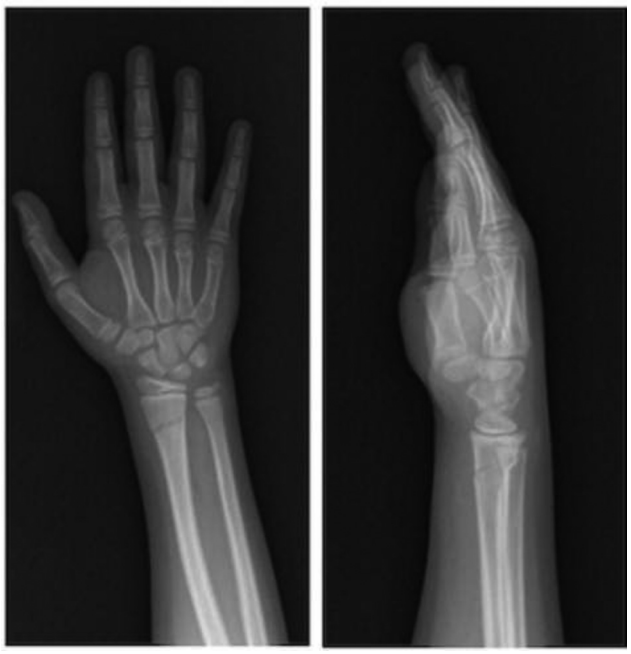

Fig. 1 Anteroposterior and lateral radiograps of an isolated distal radius fracture.

In total, 50 children who were admitted to our emergency unit between February and May 2018 with isolated distal radius fractures (►**Fig. 1**) were included in the study group (group A), and 50 healthy children with no history of fracture were included as the control group (group B). The patients in group B were randomly recruited from pediatric outpatient units; they had upper respiratory tract infection or were being submitted to routine examinations.

The following characteristics of the study sample were included: age (years), gender distribution, height (cm), weight (kg), and body mass index (BMI; kg/m^2). Peripheral venous blood samples were obtained and analyzed for measurements of 25-hydroxyvitamin D (25(OH)D), calcium (Ca), magnesium (Mg), phosphorus (P), alkaline phosphatase (ALP), and parathyroid hormone (PTH).

Statistical Analysis

The Statistical Package for the Social Sciences (SPSS, IBM Corp., Armonk, NY, US) software, version 22.0 for Windows 7, was used for all statistical analyses. The data was presented as means and standard deviations, medians, minimum and maximum ranges, frequencies and rates. The distributions of the parametric data were analyzed with the aid of the Student *t*-test, and the Mann-Whitney U test was used for the non-parametric data. The Chi-squared test was employed to compare the rates between the two groups. Values of $p < 0.05$ were considered statistically significant.

Results

The sample was composed of 100 patients, with 50 patients in the control group and 50 in the study group. All patients in the study group had isolated distal radius fractures, and those in the control group had no history of fracture.

The mean age, height, weight, BMI and gender distribution were similar in both groups (►**Table 1**). In addition, there were no obese patients (BMI > 30) in the sample. There were no statistical differences in the blood analyses, including Ca, Mg, P, ALP, and PTH (►**Table 2**). However, the serum levels of 25(OH)D were statistically lower in the group A when compared to group B ($p < 0.001$), and the number of patients with 25(OH)D insufficiency was statistically higher in group A than in group B ($p = 0.012$).

Discussion

Fractures compose around 10% to 25% of all pediatric injuries, and one of the most common in the pediatric population is distal radius fracture.[12,13] Approximately 1 in 100 children are hospitalized for orthopedic surgery after distal radius fractures yearly. The wide spectrum of fracture presentation, the variety of surgical and non-surgical techniques, the growth potential of the skeletal structure of the children, and family expectations are some of the challenging factors in the treatment of distal radius fractures, especially in the pediatric population.[14] Due to accelerated skeletal maturation, children and adolescents are at a high risk for these fractures. Ryan et al.[15] revealed a significant higher rate of fractures caused by minor trauma in the age group between 10 and 14 years in comparison with the age group between 5 and 9 years. This finding implies that rapid skeletal development may jeopardize bone mineralization, which is disproportional to the growth rate, and may lead to a distal radius fracture even after a minor trauma.

Solar ultraviolet B (UV-B) radiation is the primary source of vitamin D (other than dietary intake). Vitamin D3, which is produced by the skin with the action of sunlight, and dietary vitamin D undergo two consecutive hydroxylations: in the liver,

Table 1 Comparison of the patient characteristics

	Group A (n = 50)	Group B (n = 50)	*p*-value
Age (years)	8.3 ± 2.8 (5–15)	7.9 ± 3.4 (5–15)	0.352
Gender (female); n (%)	18 (36.0)	16 (32.0)	0.765
Height (cm)	118.8 ± 22.3 (90–165)	116.4 ± 24.9 (76–160)	0.716
Weight (kg)	29.8 ± 9.8 (15–56)	27.8 ± 11.9 (13–55)	0.268
Body mass index (kg/m^2)	21.4 ± 4.9 (13.6–29.6)	20.5 ± 3.2 (12.2–28.1)	0.412

Note: The values are expressed as means ± standard deviations, minimum–maximum ranges, or as numbers of patients and percentages.

Table 2 Comparison of the peripheral venous blood analyses of the patients

	Group A (n = 50)	Group B (n = 50)	*p*-value
Calcium (mg/dL)	10.0 ± 0.4 (9.4–10.7)	10.1 ± 0.6 (9.1–11.4)	0.542
Magnesium (mg/dL)	2.11 ± 0.14 (1.8–2.4)	2.10 ± 0.15 (1.9–2.4)	0.830
Phosphorus (mg/dL)	5.0 ± 0.40 (4.3–5.8)	5.12 ± 0.48 (4–6.3)	0.350
Alkaline phosphatase (IU/L)	276.4 ± 69.4 (200–482)	286.6 ± 72.6 (167–447)	0.478
Parathyroid hormone (pg/mL)	41.7 ± 22.3 (10.9–97.1)	40.1 ± 19.1 (18.6–77.2)	0.676
25-hydroxyvitamin D (ng/mL)	19.4 ± 4.2 (10.7–28.3)	29.4 ± 11.1 (13–48.7)	< 0.001
25-hydroxyvitamin D insufficiency; n (%)	22 (44.0)	6 (12.0)	0.012

Note: The values are expressed as means ± standard deviations, minimum–maximum ranges, or as numbers of patients and percentages.

the former becomes 25(OH)D, and, in the kidneys, the latter takes on its biologically-active form, 1,25-dihydroxyvitamin D (1,25(OH)2D); 1,25(OH)2D enhances the serum levels of calcium and phosphorus by increasing the intestinal absorption of these minerals, which are involved in the processes of bone formation, mineralization, and resorption.[16] Serum 25(OH)D is a major circulating metabolite of vitamin D, and it clinically reflects the status of this vitamin, which may be used as an indicator of the lifestyle and dietary habits of the patients. The serum concentrations of 25(OH)D that indicate deficiency or insufficiency of vitamin D are controversial, and the cut-off values are not well–established. The American Academy of Pediatrics (AAP) and the Institute of Medicine (IOM) both define vitamin D insufficiency as concentrations of 25(OH) D < 20 ng/mL in the pediatric population.[10] We used the Endocrine Society guideline, which defines the deficiency of 25(OH)D as levels < 20 ng/mL, and the insufficiency as levels < 30 ng/mL.[17]

Vitamin D deficiency affects the intestinal absorption of calcium and phosphorus, which results in decreased serum levels of those minerals. The parathyroid gland releases hormone to increase the serum calcium back into the adequate range. The PTH increases the calcium reabsorption in the kidneys and the excretion of phosphorus. Meanwhile, it has also negative effects on bone mineralization, with the aim of increasing the serum levels of calcium.

Over time, chronic severe vitamin D deficiency in infants and children causes stunted growth, osteomalacia, and rickets.[10] Moore et al.[18] reported that vitamin D deficiency has a higher incidence among obese children and those with darker skin. Similarly, vitamin D deficiency was found to be more frequent in girls than in boys.

Vitamin D, PTH and calcium levels have been correlated with bone mineral density.[19] The association between 25(OH) D and bone mineral density has been examined in several studies.[20–23] Most of these studies showed a connection between the adequate intake of vitamin D and high bone mineral density. Low bone mineral density may increase the rate of fracture both in the adult and pediatric populations.[23–25] A study[21] that assessed the status of vitamin D in adolescent girls during winter found that low levels of vitamin D have a negative effect on bone mineral density. Another study,[24] which analyzed calcium supplementation and bone mineral density, showed a positive effect of vitamin D supplementation on high bone mineral density, which may reduce the rate of pediatric fracture. In the present study, we found that children with distal radius fracture have statistically lower levels of vitamin D than the healthy group. On the other hand, between the two groups there were no statistically significant differences regarding the levels of Ca, Mg, P, ALP, and PTH.

Adolescents are prone to vitamin D insufficiency due to the mineral demands of their growing skeleton. A study[25] conducted in northern India found a high prevalence of clinical and biochemical hypovitaminosis D in healthy schoolchildren. Vitamin D deficiency in healthy children has been subjected to several studies,[26–29] which showed that sunlight exposure alone is not enough to prevent hypovitaminosis D, and that nutritional habits (high dietary phytate intake) or genetic tendency (Asian) may lead to vitamin D deficiency. In the present study, we observed that 12% of the healthy children had vitamin D levels < 20 ng/mL, which are considered deficient.

One of the limitations of the present study is that the blood samples were collected from the children regardless of the season; thus, some children may not have had enough time to produce vitamin D, especially at the end of winter. Another limitation of the study is the lack of information about the dietary habits of the children in the sample. More detailed studies with larger samples are needed in order to find more convincing data about the correlation of vitamin D and pediatric fractures.

Conclusion

Although optimal vitamin D levels have not been well-established in the literature, they have been used to determine bone health.[29] Besides vitamin D levels, minerals such as Ca, Mg and P or endocrine hormones (PTH) have also been used as determinants of bone turnover. In adults, an association between hypovitaminosis D and osteoporotic fractures has been examined in several studies.[26,28] However, in the pediatric population, there is no adequate study to determine any correlation between pediatric fractures and vitamin D deficiency. With the present study, we have shown that the status of vitamin D may be used as a predictor of pediatric fractures. Especially in spring and summer, families with children with

isolated distal radius fractures should be informed about vitamin D deficiency, and, in children with low levels of vitamin D, supplementation may be considered.

Conflict of Interests

The authors have no conflict of interests to declare.

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Electrodiagnostic Testing Characteristics of Diabetic People with Carpal Tunnel Syndrome*

Características eletrofisiológicas das pessoas diabéticas com síndrome do túnel do carpo

Henver Ribeiro Paiva Filho[1] Alex Timóteo Rodrigues Reis[2] Gabriel Antonio Matos[2] Valdênia Graças Nascimento Paiva[3] Elias Felix Oliveira[4] Murilo Antônio Rocha[5]

[1] Universidade Federal do Triângulo Mineiro, Uberaba, MG, Brazil
[2] Orthopedics and Traumatology Service, Universidade Federal do Triângulo Mineiro, Uberaba, MG, Brazil
[3] Hand Surgery, Orthopedics and Traumatology Service, Universidade Federal do Triângulo Mineiro, Uberaba, MG, Brazil
[4] Orthopedics and Traumatology Service, Universidade Federal do Triângulo Mineiro, Uberaba, MG, Brazil
[5] Foot Surgery, Orthopedics and Traumatology Service, Universidade Federal do Triângulo Mineiro, Uberaba, MG, Brazil

Address for correspondence Valdênia das Graças Nascimento Paiva, MD, Ambulatório Maria da Glória – Ortopedia e Traumatologia, Hospital de Clínicas da Universidade Federal do Triângulo Mineiro, Uberaba, MG, Brazil (e-mail: vallfmtm@yahoo.com.br).

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Abstract

Objective The present study aimed to correlate electroneuromyography (ENMG) findings in diabetic and nondiabetic subjects with carpal tunnel syndrome (CTS).

Methods In total, 154 patients were evaluated in a hand surgery outpatient clinic. All ENMG tests were bilaterally performed by a single neurologist. Qualitative variables were described for all patients with CTS according to their diabetic status, and the chi-squared test was used to reveal any association. A joint model was adjusted to determine the influence of diabetes on ENMG severity in CTS patients.

Results The sample consisted of 117 women and 37 men, with an average age of 56.9 years old. Electroneuromyography demonstrated bilateral CTS in 82.5% of the patients. Diabetes was identified in 21.4% of the cases. Severe ENMG was prevalent.

Conclusion There was no association between diabetes and ENMG severity in patients with CTS. Level of evidence IV, case series.

Keywords
- diabetes
- electromyography
- median neuropathy
- paresthesia
- carpal tunnel syndrome

Resumo

Objetivo O presente trabalho teve por objetivo verificar se existe correlação entre a síndrome do túnel do carpo (STC) e eletroneuromiografia (ENMG) de pacientes diabéticos e não diabéticos.

* *Study developed at the Orthopedics and Traumatology Department, Hand Surgery, Universidade Federal do Triângulo Mineiro, Uberaba, MG,, Brazil.*

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Métodos Foram avaliados 154 pacientes em um ambulatório de cirurgia da mão. Todas as ENMGs avaliadas foram realizadas por um único neurologista, bilateralmente. As variáveis qualitativas foram descritas para todas as pessoas em acompanhamento devido à STC segundo a presença de diabetes e foi verificada a associação com uso do teste qui-quadrado. Foi ajustado o modelo conjunto para verificar a influência da diabetes na gravidade da ENMG em pacientes com STC.

Resultados Foram incluídos no presente estudo 117 mulheres e 37 homens, com média de idade de 56,9 anos. Eletroneuromiografia demonstrando STC bilateral foi observada em 82,5% das pessoas. Pessoas diabéticas foram identificadas em 21,4% dos casos. Eletroneuromiografia com padrão grave foi prevalente.

Conclusão Não houve associação entre a presença de diabetes e a gravidade da ENMG em pessoas com STC. Nível de evidência IV, série de casos.

Palavras-chave
- diabetes
- eletromiografia
- neuropatia mediana
- parestesia
- síndrome do túnel do carpo

Introduction

Carpal tunnel syndrome (CTS) is a frequent neuropathy in diabetic patients, affecting 14% of diabetics with no neuropathy and 30% of subjects with diabetic neuropathy.[1,2] Carpal tunnel syndrome is common in diabetic patients because of surrounding synovial tissue changes and secondary nerve damage due to elevated blood glucose levels.[3]

The most common neurological complications in diabetic subjects include symmetric sensorimotor polyneuropathies and focal neuropathies; compressive neuropathies of the upper extremity are the most frequent complications in any stage of diabetes.[4]

The potential pathogenesis of diabetic CTS involves increased circulating levels of inflammatory cytokines resulting from the final glycation product, which causes demyelination and peripheral axonal loss, and increases the susceptibility of several nerves, including the median nerve, to compression.[5]

Although the literature reports characteristics of diabetic subjects with and without CTS,[3] few recent publications demonstrate clinical, epidemiological and electroneuromyographic findings in CTS patients with diabetes or not. The present study aimed to describe any differences in clinical and electroneuromyography (ENMG) findings in both diabetic and nondiabetic subjects with CTS.

Casuistry and Methods

Cross-sectional study performed at a hand surgery outpatient clinic and evaluating 154 patients. The procedures complied with the Research Ethics Committee, authorization number 3.640.789, and with the Declaration of Helsinki from 1964. All participants signed an informed consent form.

Both male and female subjects, aged > 18 years old, with positive upper limb ENMG for CTS were included in the study. Pregnant women, patients with type I diabetes or with a history of previous wrist surgery were excluded from the sample.

All ENMGs were bilaterally performed by a single neurologist, unrelated to this study, using a Neuropack EMG electroneuromyograph (S1, MEB-9400K, Nihon Kohden Corporation, Tokyo, Japan).

The electroneuromyographic findings were classified according to the Stevens system as mild (sensory conduction changes alone), moderate (sensory and motor conduction changes) and severe (altered sensory and motor conduction in addition to denervation signs on needle electromyography).[6]

Age, as a quantitative variable, was described as mean and standard deviation (SD) values. Qualitative variables were described for all patients with CTS and positive ENMG findings according to their diabetic status, and the chi-squared test was used to reveal any association.[7]

In total, 159 subjects with positive ENMG findings for CTS were treated; since 5 subjects were excluded due to incomplete reports, the final study sample consisted of 154 participants.

Regarding gender, 117 (76.0%) women and 37 men (24.0%) were included. The average age was 56.9 ± 10.9 years old (mean and SD). Body mass index (BMI) was within the normal range in 71 (46.1%) subjects, with 51 (33.1%) overweight and 32 (20.8%) obese patients. The ENMG demonstrated bilateral CTS in 127 (82.5%) subjects and unilateral CTS in 27 (17.5%) subjects. Thirty-three (21.4%) patients were diagnosed with diabetes, and 121 (78.6%) were not diabetics. Fifty-two (33.8%) subjects had only one systemic disease in addition to diabetes, whereas 52 (33.8%) had ≥ 2 diseases, and 50 (32.4%) presented no comorbidities.

For statistical analysis, a joint model was adjusted to determine the influence of diabetes on ENMG severity in CTS patients. Variables with a descriptive level < 0.20 in bivariate tests ($p < 0.20$) were inserted in the model. Significance was set at a 5% level.

Results

Eighteen (11.7%) subjects presented a mild ENMG pattern, whereas 64 (41.6%) had a moderate pattern and 72 (46.7%) had a severe pattern.

►**Table 1** shows that diabetes was more frequent among women with CTS ($p = 0.023$). In addition, the frequency of associated systemic diseases was higher in diabetic patients compared with nondiabetic patients ($p < 0.001$).

Table 1 Characteristics of subjects with carpal tunnel syndrome and diabetes

Variable	Diabetes		*p-value*
	No ($n = 121$)	Yes ($n = 33$)	
Age (years old)			0.244*
Mean ± standard deviation	56.4 ± 10.9	58.9 ± 11	
Median (minimum; maximum value)	56 (30; 84)	58 (33; 89)	
Gender,*n* (%)			**0.023**
Female	87 (71.9)	30 (90.9)	
Male	34 (28.1)	3 (9.1)	
BMI classification,*n* (%)			0.121
Normal	61 (50.4)	10 (30.3)	
Overweight	37 (30.6)	14 (42.4)	
Obesity	23 (19)	9 (27.3)	
ENMG laterality,*n* (%)			0.150
Unilateral	24 (19.8)	3 (9.1)	
Bilateral	97 (80.2)	30 (90.9)	
Systemic conditions,*n* (%)			**<0.001**
1	50 (41.3)	2 (6.1)	
≥ 2	21 (17.4)	31 (93.9)	
None	50 (41.3)	0 (0)	

Abbreviations: BMI, Body mass index; ENMG, electroneuromyography. Chi-squared test.
*T-Student test.

►**Table 2** shows that only CTS laterality was associated with CTS severity ($p < 0.001$), and patients with bilateral CTS had more severe ENMG findings.

Diabetes was not statistically associated with ENMG severity ($p = 0.466$).

►**Table 3** shows that CTS laterality in ENMG was influenced in a statistically significant way ($p = 0.023$). Bilateral CTS patients had ENMG grades 44% more severe compared with patients with unilateral positive findings.

Diabetes did not influence the ENMG grade for CTS ($p = 0.927$).

Discussion

In population-based studies, the prevalence of CTS is higher in women and increases with age;[4] it is estimated that the incidence in females is up to three-fold higher when compared with males.[8] According to Papanas et al.,[9] the prevalence of CTS in diabetics ranges from 11 to 25%, and the condition is more common in women. Our results were consistent with the literature, with an increased prevalence of CTS in women with a mean age of 56 years old in nondiabetics and 58 years old in diabetic subjects.

Table 2 Description of carpal tunnel syndrome grades according to the characteristics evaluated and statistical tests results

Variable	ENMG Classification			*p-value*
	Mild	Moderate	Severe	
Age (years old)				0.081*
Mean ± standard deviation	56.3 ± 10.6	54.8 ± 10.8	58.9 ± 10.8	
Median (minimum; maximum value)	54.5 (42; 83)	55 (30; 81)	58 (41; 89)	
Gender,*n* (%)				0.373
Female	14 (12)	45 (38.5)	58 (49.6)	
Male	4 (10.8)	19 (51.4)	14 (37.8)	
BMI classification, *n* (%)				0.821
Normal	8 (11.3)	31 (43.7)	32 (45.1)	
Overweight	6 (11.8)	18 (35.3)	27 (52.9)	
Obesity	4 (12.5)	15 (46.9)	13 (40.6)	
ENMG laterality,*n* (%)				**< 0.001**
Unilateral	10 (37)	15 (55.6)	2 (7.4)	
Bilateral	8 (6.3)	49 (38.6)	70 (55.1)	
Systemic conditions, *n* (%)				0.516
1	7 (13.5)	19 (36.5)	26 (50)	
≥ 2	4 (7.7)	21 (40.4)	27 (51.9)	
None	7 (14)	24 (48)	19 (38)	
Diabetes				0.466
No	16 (13.2)	50 (41.3)	55 (45.5)	
Yes	2 (6.1)	14 (42.4)	17 (51.5)	

Abbreviations: BMI, Body mass index; ENMG, electroneuromyography. Chi-squared test.
*ANOVA.

Table 3 Model explaining the electroneuromyography grade and carpal tunnel syndrome relationship according to evaluated characteristics

Variable	Coefficient	95% Confidence interval		*p-value*
		Inferior value	Superior value	
ENMG (bilateral)	1.44	1.05	1.98	**0.023**
Diabetes	1.01	0.79	1.30	0.927
Age (years old)	1.001	0.991	1.011	0.836

Abbreviation: ENMG, electroneuromyography.
Generalized linear model with Poisson distribution and logarithmic link function.

Phalen[10] reported that the median nerve from diabetic subjects may be more susceptible to compression within the carpal tunnel when compared with nondiabetics. In the

1960s, Mulder et al.[11] found a 9% prevalence of diabetes in people with CTS, whereas Blodgett et al.[12] reported a 6.4% prevalence. In 1985, Comi et al.[13] reported a 7.7% prevalence, and Kouyoumdjian,[14] 4.4%. The number of diabetics in our sample (21.4%) was considerably higher compared with the literature. We believe this is due to our service being a regional reference, with a high number of cases.

According to Becker et al.,[15] a high BMI constitutes a risk factor for CTS; other risk factors include female gender, age ranging from 40 to 60 years old and diabetes. For Bland,[16] diabetic patients with CTS have a higher frequency of overweight and obesity compared to those with normal BMI. Our results are consistent with those from the aforementioned authors, with a higher prevalence in women aged 56 years old. Although 69.7% of the diabetics with CTS were overweight or obese, there was no difference compared with nondiabetics (49.6%).

Spahn et al.[17] found bilateral CTS in 50 to 60% of cases. In our sample, 82.46% of the patients had bilateral electroneuromyographic changes, with 44% of them presenting severe ENMG. However, there was no correlation between laterality and ENMG severity ($p = 0.023$).

We observed a considerable number of people with common systemic conditions, including hypertension, rheumatological and cardiological diseases (67.6%), with significant differences between diabetics and nondiabetics. On the other hand, no statistical difference was found in ENMG between diabetic and nondiabetic CTS patients ($p = 0.927$). This may be related to the heterogeneity of the evaluated group, since age, female gender, high BMI, time of evolution, and adequate or inadequate clinical control were shown to be independent risk factors for CTS.

The evaluation of CTS patients at a regional reference service to assess the relationship between diabetes and ENMG severity is a positive point of our study.

A limitation of the present study may be related to the fact that CTS patients may not represent the real influence of diabetes on the severity of ENMG for assessing this condition, since many diabetics are followed-up at the endocrinology service.

It is also not possible to affirm peremptorily that there is a relationship between the greater severity of electroneuromyographic findings and CTS bilaterality. Further studies, with a larger sample and more comprehensive inclusion criteria, are required to assess this relationship.

Conclusion

We conclude that CTS is prevalent in women at the 5th decade of life, both diabetics and nondiabetics, and that there is no association between diabetes and ENMG severity in subjects with CTS.

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Conflict of Interests
The authors have no conflict of interests to declare.

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Unmet Needs of Surgical Care for Children: A Case Study in the Brazilian Publicly-Financed Health System*

Necessidades não atendidas de cuidados cirúrgicos para crianças: Estudo de caso no Sistema Único de Saúde financiado pelo governo no Brasil

Mario Bressan-Neto[1] Marina Rosa Filezio[2] Fabio Ferri-de-Barros[2] Helton Luiz Aparecido Defino[3]

[1] Department of Orthopedics and Anesthesiology, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, São Paulo, Brazil
[2] Division of Pediatric Orthopadics, Cumming School of Medicine, University of Calgary, Calgary, AB, Canada
[3] Department of Biomechanics, Medicine and Rehabilitation, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, São Paulo, Brazil

Address for correspondence Mario Bressan-Neto, MSc, Departamento de Ortopedia e Anestesiologia, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Avenida dos Bandeirantes 3.900, 11° andar, Ribeirão Preto, SP, 14048-900, Brazil (e-mail: mbressan@hotmail.com).

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Abstract

Objective To measure and document the clinical impact of the waiting time for surgical treatment of patients with spinal deformities in a quaternary center in Brazil.

Methods In total, 59 patients with spinal deformity waiting for surgery on our hospital's list were evaluated to observe the impact of the waiting time on the progression of the deformity. Patient evaluation was performed using the SRS-22r questionnaire for health-related quality of life (HRQL) and radiographic images to evaluate the deformity of the spine at the time the patients were included in the waiting list and at the most recent appointment. The radiographic parameters selected for comparison were: Cobb angle of the primary and secondary curves, coronal alignment, apical vertebral translation, pelvic obliquity, sagittal vertebral axis, kyphosis (T5-T12), and lordosis (L1-S1).

Results Low HRQL scores according to the SRS-22r questionnaire were observed in patients waiting for surgery. The radiographic parameters showed progression of the deformity on the initial evaluation when compared with the most recent follow-up evaluation.

Conclusion The patients waiting for surgical treatment of spinal deformities in our center showed relatively low HRQL scores and radiographic progression of the deformity.

Keywords
- spine
- scoliosis
- waiting list
- vertebral curvatures
- health policy

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Resumo

Objetivo Medir e documentar o impacto clínico do tempo de espera para tratamento cirúrgico de pacientes com deformidades na coluna vertebral em um centro quaternário no Brasil.

Métodos No total, 59 pacientes com deformidade espinhal à espera de cirurgia na lista do nosso hospital foram avaliados para observar o impacto dos tempos de espera na progressão da deformidade. A avaliação do paciente foi realizada utilizando o questionário SRS-22r para qualidade de vida relacionada à saúde (QLRS), e imagens radiográficas para avaliar a deformidade da coluna vertebral quando os pacientes foram incluídos na lista de espera e na consulta mais recente. Os parâmetros radiográficos selecionados para comparação foram: ângulo de Cobb de curvas primárias e secundárias, alinhamento coronal, translação de vértebra apical, obliquidade pélvica, eixovertebral sagital, cifose (T5-T12), e lordose (L1-S1).

Resultados Baixos escores de QLRS segundo o questionário SRS-22r foram observados em pacientes que aguardavam cirurgia. Os parâmetros radiográficos mostraram progressão da deformidade na avaliação inicial em comparação com a avaliação de seguimento mais recente.

Conclusão Os pacientes que aguardavam tratamento cirúrgico de deformidade espinhal em nosso centro apresentaram escores de QLRS e progressão radiográfica de deformidade relativamente baixos.

Palavras-chave

- coluna
- escoliose
- listas de espera
- curvaturas vertebrais
- política de saúde

Introduction

The organization of the Brazilian Unified Health System (Sistema ùnico de Saúde, SUS, in Portuguese) determines that the surgical treatment of spinal deformities should be performed in specialized tertiary centers.[1] The patients referred to tertiary centers are then placed on a waiting list.

The surgical treatment of spinal deformities has special features (long duration of surgeries, the requirement of specialized human resources, high cost of the implants and technical resources). This, associated with the underfunding of SUS, has led to a steadily increase in the surgical waiting list.[2,3]

Emerging evidence suggest that the treatment for scoliosis is time-sensitive, as scoliosis worsens with spinal growth and over time.[4–7] As patients wait for treatment, particularly children and youths, their spine deformities deteriorate, becoming more complex and morbid, thus causing undue emotional distress for the patients and their families.[8] Moreover, the risk of complications of the surgical treatment of larger spinal deformities is substantially higher,[9] and so is the cost of the treatment.[10,11] A few studies have shown the impact of long waiting times for the surgical treatment of scoliosis in Canada[4,7,12] and in Brazil.[3,13,14]

Despite improvements in primary health care, the SUS has faced challenges in delivering universal and equitable health care to 209 million Brazilians.[15] Allocation decisions and planning occur at National Health Conferences, which are held every four years in accordance with a federal law.[16] The current decision-making process for the allocation of health resources for the SUS has systematically failed to account for unmet needs of surgical care for children and youths who are disproportionally burdened with the lack of access to hospital care in Brazil.[17–19]

In one of the largest quaternary academic hospitals in Brazil, one of the senior authors noticed over the last ten years a dramatic impact of the growing burden of scoliosis as a result of the current public health policy, or the lack thereof, to allocate surgical resources for children and youths with spinal deformities. The purpose of the present case study is to measure and to document the clinical impact of surgical waiting times for the treatment of patients with complex spinal deformities in a quaternary center in Brazil.

Materials and Methods

The present retrospective case series was approved by the ethics and research committee under number 833.475. We evaluated a cohort of 59 patients with spinal deformities on the surgical waiting list as of December 2013 in a quaternary center in Brazil. Only pediatric deformities, defined by the age and etiology of the diagnosis, were considered in the study. Adult or degenerative deformities were excluded, as well as one patient who was on the waiting list, but had already undergone surgery in another hospital.

The medical records and spine radiographs of the patients were reviewed. The main outcome measures included the waiting time for the surgery (how long the patients had been waiting for the surgical treatment until December 2013) and health-related quality of life (HRQL) using the SRS-22r® questionnaire validated in Portuguese.[20] The questionnaire was applied to patients aged more than 10 years with full cognitive function.

The radiographic images were evaluated at the time the surgical treatment was recommended (inclusion in the waiting list) and at the most recent follow-up appointment. The radiographic measurements were performed manually

on printed and digital radiographic images[21] using the Osirix software (Pixmeo Sarl, Bernex, Switzerland). The radiographic parameters selected for comparison were: Cobb angle of the primary and secondary curves, coronal alignment, apical vertebral translation, pelvic obliquity, sagittal vertebral axis, kyphosis (T5-T12) and lordosis (L1-S1). For patients with neuromuscular scoliosis, the pelvic obliquity was evaluated according to Gupta et al.[22]

We analyzed the data using the John's Macintosh Project (JMP, SAS Institute, Inc., Cary, North Carolina, US) software. We used the Student *t*-test for averages and standard deviations for the normal distribution data. For data with non-parametric distribution, we calculated medians and interquartile ranges (IQRs), which were analyzed with analysis of variance (ANOVA) and the Mann-Whitney U-test (intergroup analysis). Paired Student *t*-tests were used for the intragroup analysis. The matching analysis was described with the average difference and 95% confidence interval (95%CI). The significance level (α) was established as 0.05.

Results

In total, 59 patients (40 females) who were on the surgical waiting list for the treatment of spinal deformities on December 31, 2013 were evaluated. The age of the patients ranged from 3 to 23 years (average: 13.5 ± 3.7 years). The etiology of the deformities was: neuromuscular (17 patients; 28.3%), congenital (16 patients; 26.7%), idiopathic (15 patients; 25.0%), syndromic (10 patients;16.7%), Marfan syndrome (1 patient; 1.7%) and neurofibromatosis (1 patient; 1.7%). The waiting time for surgery in December 2013 ranged from 2 to 117 months (median: 13.5; IQR: 13.8 months).

The HRQL evaluation was performed with the SRS-22r questionnaire in 36 patients with the following etiologies: 11 (30.6%) – neuromuscular; 10 (27.8%) – idiopathic; 8 (22.2%) – congenital; 5 (13.9%) – syndromic, 1 (2.8%) – Marfan syndrome; and 1 (2.8%) – neurofibromatosis. The median score for each category was: function – 3.60 (IQR: 1.00); pain – 4.00 (IQR: 1.40); self- image – 3.00 (IQR: 0.80); mental health – 3.80 (IQR: 1.00); and satisfaction – 4.00 (IQR: 1.00) (►**Fig. 1**).

The radiographic parameters showed statistically significant differences comparing the evaluation at the time of the surgical indication and the follow-up assessment. A statistical difference was observed in the coronal and sagittal parameters, indicating the progression of the deformity (►**Table 1**, ►**Figs. 1**, **2**, **3** and **4**). Among the skeletally-immature patients at the initial evaluation, 18 (58.1%) reached skeletal maturity while waiting for surgery.

On the coronal plane, the Cobb angle of the main deformity increased an average of 18.6° (95%CI: 13.9° to 23.4°"; $p < 0.0001$). The increase in the deformity was observed in all etiologies (►**Fig. 5**). The Cobb angle of the secondary curve increased an average of 10.7° (95%CI: 7.7° to 13.6°; $p < 0.0001$) (►**Fig. 6**).

Discussion

The present study documents the impact of the long waiting time for the surgical treatment of spinal deformities in

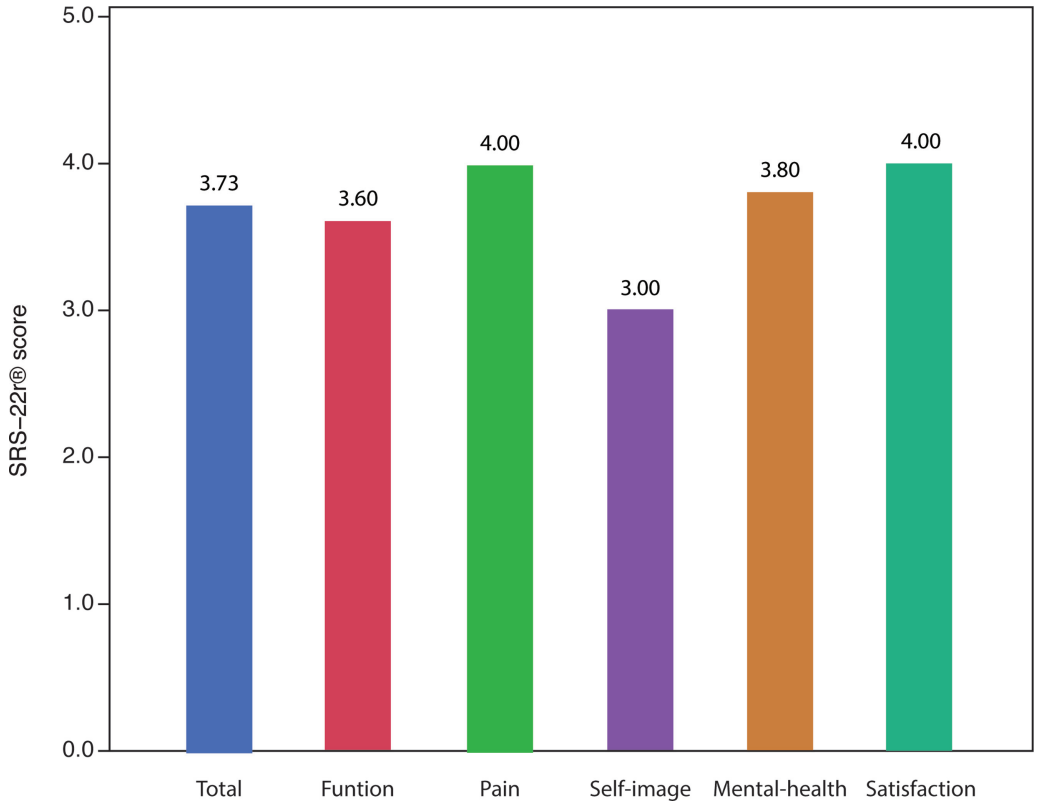

Fig. 1 Outcomes of the patients on the surgical waiting list according to the scores on the SRS-22r questionnaire. Each bar corresponds to the average score of each domain in the questionnaire.

Table 1 Summary of the radiographic parameters on the initial and final evaluations, average difference, 95% confidence interval and *p* value for the paired analysis

Radiographic parameters	Initial	Final	Average difference	95%CI	*p*-value
Coronal plane					
Main curve	61.19°	79.81°	18.61°	13.88°–23.35°	< 0.0001*
Secondary curve 1	39.07°	49.73°	10.66°	7.73°–13.58°	<0.0001*
Secondary curve 2	21.16°	26.78°	5.63°	1.54°–9.72°	0.0086*
C7–CSVL (millimeters)	21.54	31.73	10.20	2.44–17.95	0.0113*
AVT (millimeters)	38.56	55.85	17.28	8.6–25.97	0.0003*
Pelvic obliquity (horizontal)	8.88°	12.68°	3.80°	0.43°–7.17°	0.0287*
Pelvic obliquity (T1)	12.44°	16.48°	4.04°	0.27°–7.81°	0.0369*
Sagittal plane					
SVA (millimeters)	29.53	41.00	11.47	1.55–21.39	0.0245*
Kyphosis (T5–T12)	33.74°	39.62°	5.88°	-0.04°–11.80°	0.05
Lordosis (L1–S1)	-54.80°	-57.05	-0.25°	-6.59°–6.09°	0.937
Main sagittal deformity	69.15°	87.92°	18.77°	10.51°–27.03°	0.0003*

Abbreviations: 95%CI, 95% confidence interval; AVT, apical vertebral translation; CSVL, central sacral vertical line; SVA, sagittal vertical axis. **Note:** * statistical significance.

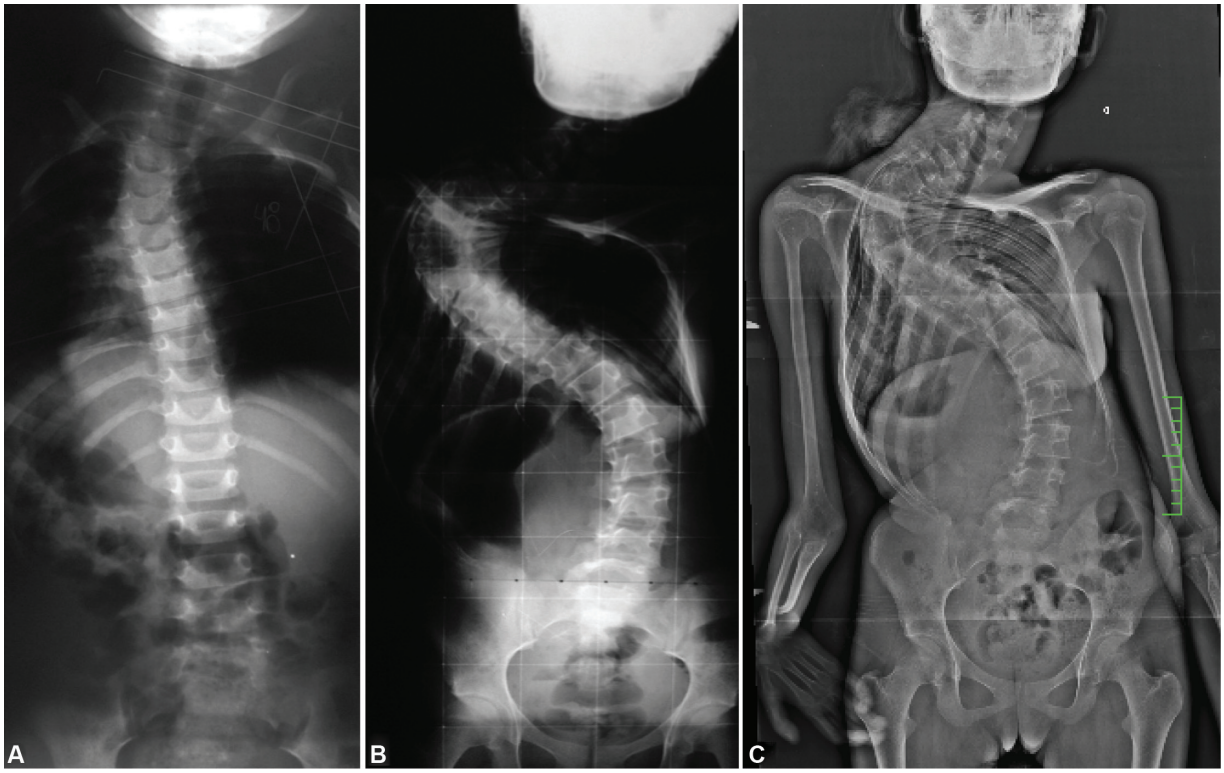

Fig. 2 Radiographic progression of adolescent idiopathic scoliosis from 2005 (**A**), in 2010 (**B**), and in 2013 (**C**).

children and youths in a quaternary center in the Brazilian publicly-financed health care system (SUS). The evaluation of the patients in our waiting list showed progression of the deformities and a decrease in the HRQL scores. We challenge the term "waiting for surgery" because many patients have never been operated on to date. Performing surgical treatment for larger vertebral deformities, as they progress with time, represents increased cost and morbidity, and, in some extreme cases, the high risk of life-threatening complications may prevent the surgeons from performing the recommended surgical treatment. The growing number of judicial proceedings for hospital medical treatment in Brazil[23] illustrates this complex health policy problem and the challenges involved in incorporating technology and complex

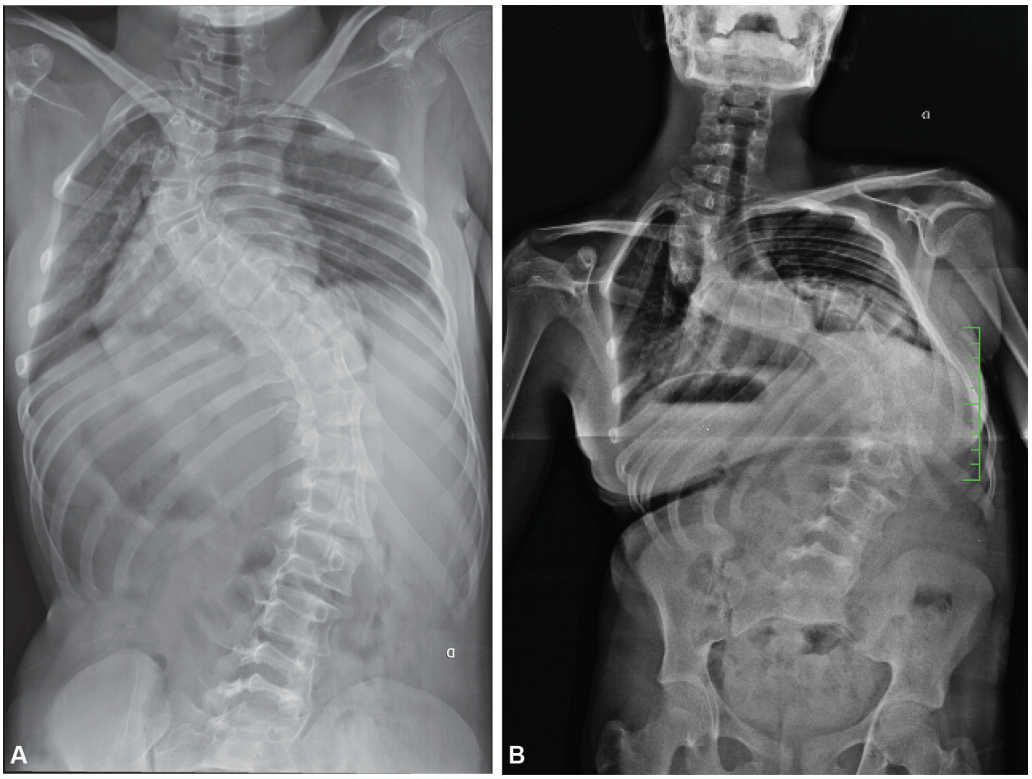

Fig. 3 Progression of syndromic scoliosis in a 10 year-old female patient from February 2013 (**A**) to January 2014 (**B**).

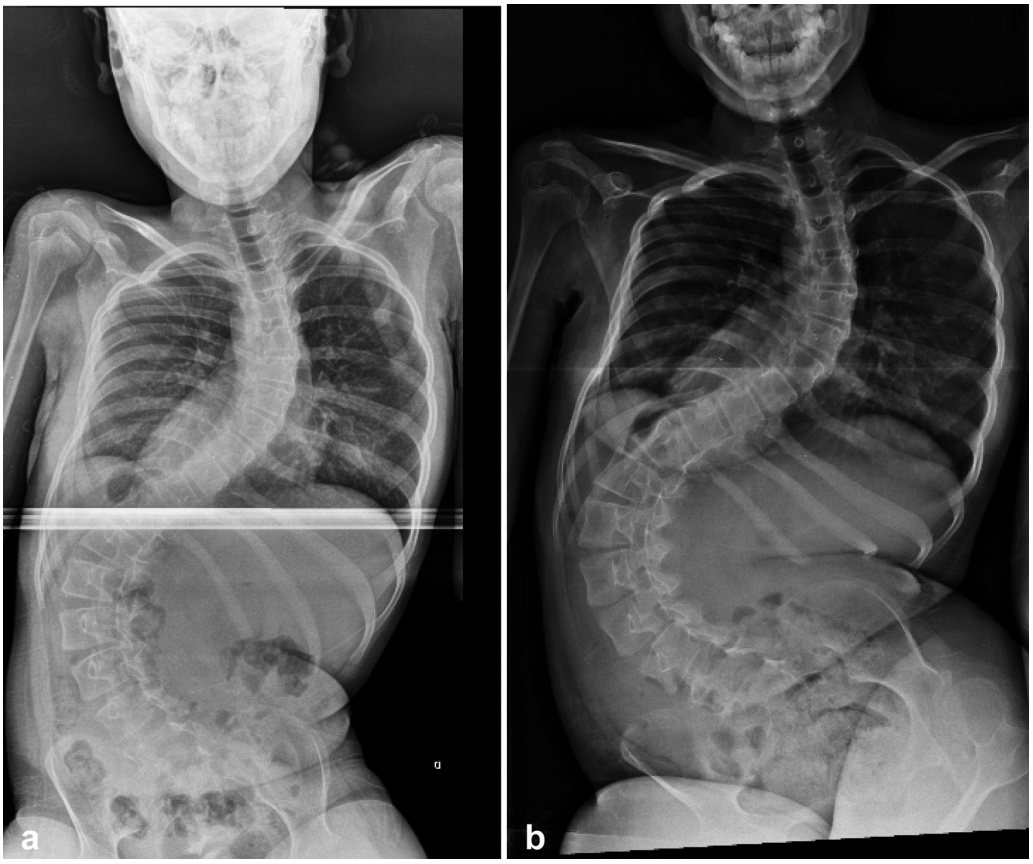

Fig. 4 Progression of the deformity from January (**A**) to October 2013 (**B**) in a patient with spinal amyotrophy.

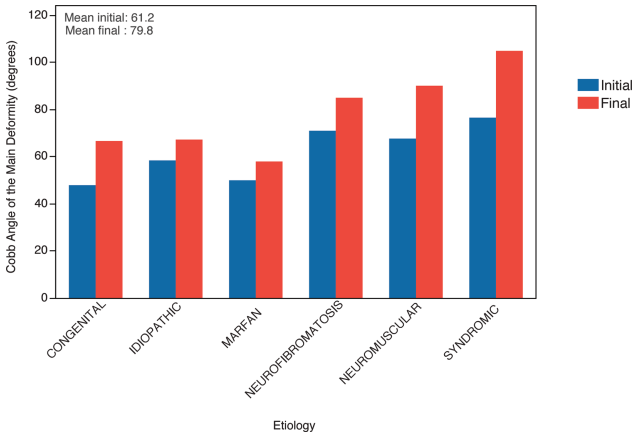

Fig. 5 Comparison between the initial and final Cobb angles of the main deformity curve in the different etiologies, showing worsening of the deformity in all subgroups of patients.

treatments (and their inherent costs) in a health care system with limited financial resources.[24]

The patients on the waitlist in the present study were managed according to current SUS health policies; however, this approach has not been effective, as our data shows. The SUS was created after the 1988 Brazilian Constitution recognized health as a citizen's right and duty of the state.[15,16] Problems related to waiting times for the treatment of spinal deformities have been reported in Brazil[3,13,14] and in other countries like Canada, the United Kingdom,[10] and New Zeland.[8] The average waiting time was of 1 year in Canada,[4,7,12] of 5 to 9 months in the United Kingdom (according to Clark[10]), and of 2.5 weeks to 2.9 years in New Zeland.[8] The hazards of prolonged waiting times are all too well-known and characterized by curve progression, increase in symptoms, and a negative impact on the mental health and quality of life of the patients.[6,7,25] The results observed in the present study just corroborate and agree with the previous reports.

While studying the HRQL of patients on the waiting list, we could observe low scores on the specific HRQL questionnaire for patients with spinal deformities (SRS-22r). Accordingly, Calman et al.[8] evaluated the impact of delaying the surgical treatment for patients with idiopathic scoliosis, which correlated with progressive worsening of the HRQL. In the present study, by the time the surgical decision was made, there were no baseline HRQL data, and this is a limitation. Regardless of this, we could observe lower SRS-22 scores than those described in the literature. Camarini et al.,[20] in the study that resulted on the validation of the SRS-22r for the Brazilian population, applied the questionnaire to patients with idiopathic scoliosis and obtained higher scores than those of the present study, except in the categories "pain " and "mental health", which were the same as ours. Farley et al.[26] applied the

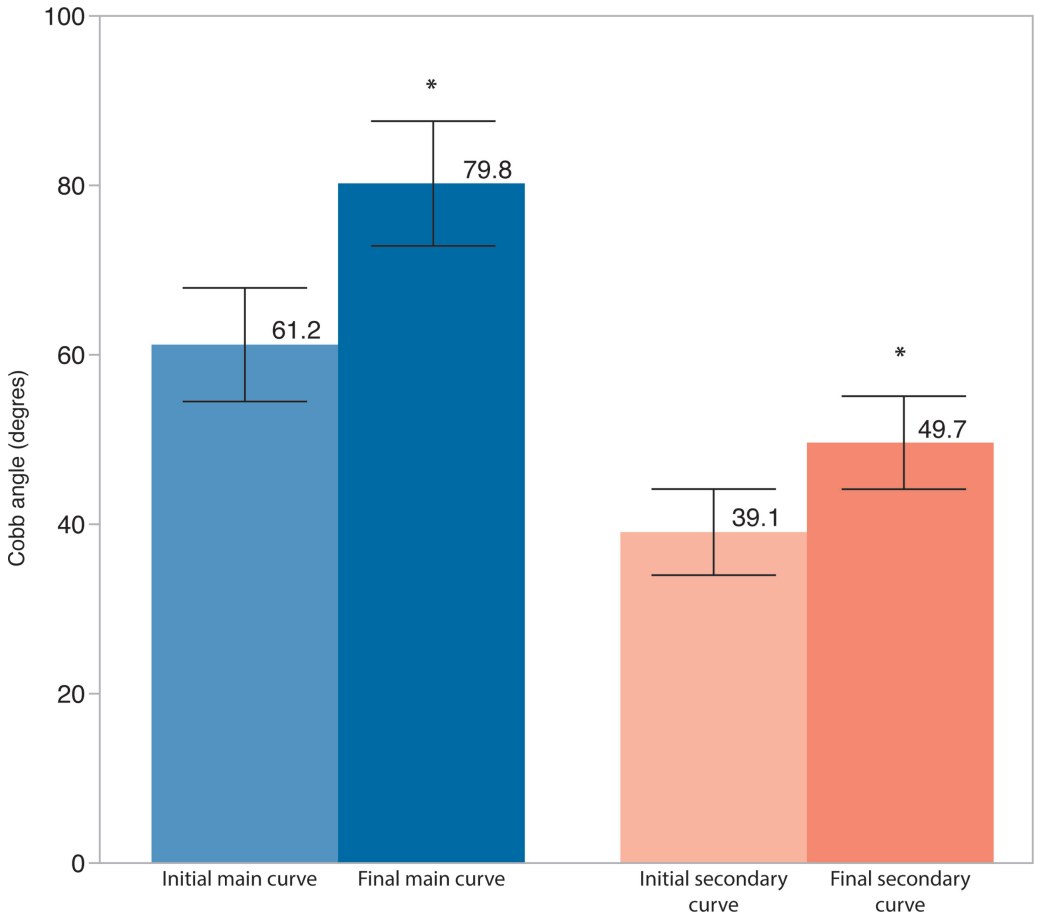

Fig. 6 Comparison between the initial and final Cobb angles of the main and secondary curves. The bars and numbers represent the average Cobb angle and the error bars represent the 95%CI. The asterisk (*) indicates statistical difference.

Table 2 Comparison between the score on the SRS-22r questionnaire and literature data

Domain (SRS-22r)	Surgical waiting list (clinical evaluation)†	Idiopathic scoliosis[20]	Congenital scoliosis[26]
Function	3.60 (1.00)	4.08 ± 0.75	4.64 ± 0.5
Pain	4.00 (1.40)	3.99 ± 0.87	4.53 ± 0.47
Self-image	3.00 (0.80)	3.53 ± 0.83	3.73 ± 0.85
Mental health	3.80 (1.00)	3.73 ± 0.75	4.21 ± 0.59
Satisfaction	4.00 (1.00)	4.28 ± 0.83	4.02 ± 0.88
Total	3.73 (0.91)	Unavailable	4.23 ± 0.52

†Data expressed as median and interquartile range (in parenthesis); *data expressed as average and standard deviation; adapted from Camarini et al.[20] and Farley et al.[26]

SRS-22r questionnaire to patients with congenital scoliosis and obtained higher scores in every category (►**Table 2**).

The evaluation of the radiographic consequences showed worsening og the deformities of the patients while they were waiting for the surgical procedure. There was an increase in the angles of the primary and secondary deformities, progression of the unbalance on the coronal and sagittal planes, and an increase in the number of patients with pelvic obliquity. Accordingly, Dabke et al.[6] performed a retrospective analysis on adolescent patients with idiopathic scoliosis treated surgically, and reported significant worsening of the deformity while waiting for surgery, resulting in more complex surgeries to be performed than the ones previously planned in 16.7% of the cases. Miyanji et al.[9] reviewed the treatment of 325 patients with idiopathic scoliosis and correlated the deformity increase with the surgical time, the number of levels included in surgery, and the risk of need for blood transfusion. Even though the study did not include an analysis of the surgical costs, the authors concluded that the increase in the use of resources results in an increase in treatment expenses. In another study, Miyanji et al.[7] analyzed the perspective of the surgeons responsible for the treatment of patients with spinal deformities, and stated that the increase in the severity of the deformity while waiting for the surgical procedure leads to surgeons planning for a more difficult and morbid procedure. In other words, according to the literature, the radiographic worsening observed in the present study means more complex procedures, with clinical consequences for patients and financial consequences for the health system. In the present study, beyond the rise in the severity of the deformity and consequent imbalance observed while the patients wait for the surgical treatment, there was also an increase in the number of patients with pelvic obliquity who needed spinal-pelvic instrumentation. The inclusion of the pelvis leads to an increase in surgical timing, blood loss, and risk of infection.[27–30] Martin et al.[31] analyzed a multi-centric database with 1,890 patients submitted to surgery due to pediatric spinal deformity, and identified an increase in the complexity of the procedure, particularly among patients who included pelvic fixation, as a risk factor for unplanned hospital readmission on the first 30 postoperative days. Since it results in higher risk of complication, hospital readmission and higher costs of the pelvic implant, the authors concluded that patients with pelvic obliquity will need more expensive surgeries.

Waiting lists are common in all publicly-funded services worldwide.[25,32] Long waiting times for surgical treatment have eroded the confidence of the citizens in the health care system.[33] As such, surgical waiting times have become an important social and political issue. The negative impact of prolonged waiting times for spine deformity surgery has been recognized. Attempts have been made to establish a maximal acceptable waiting time based on minimizing the risk of additional surgery due to progression of the deformity. As an example, the Canadian Pediatric Surgical Times Project proposed a maximum waiting time of six months based on the opinion of an expert opinion, which has been challenged and revised to three months based on empirical data.[4]

In the present study, we evaluated all the patients who were waiting for surgical correction of their deformity, not only the patients who did receive the treatment. We acknowledge that the waiting time for surgery and the consequences of this delay may be underestimated. However, some of these patients may never receive the desired treatment, and would, otherwise, not be recognized. The present study adds to the literature calling for improved health policies to account for the unmet needs of surgical care for Brazilian children and youths. Further research on this topic is needed to facilitate evidence-informed health policy making in Brazil.

Conclusion

In the present study, with the median waiting time of 13 months for the surgical treatment of spinal deformities of diverse etiologies, we have documented the worsening of the deformities and the deterioration of the HRQL of the patients, which is in agreement with previous studies. This represents a preventable increase in the burden of disease and in the cost of the treatment. Public health policies regarding the management of patients with spine deformities in Brazil should aim at improving the access to surgical care for children and youths to mitigate this preventable burden.

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Conflict of Interests
The authors have no conflict of interests to declare.

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Modifiable Risk Factors of Plantar Fasciitis in Non-Athletic Patients and Proposal of a New Objective Assessment System – RKISP

Fatores de risco modificáveis para fasciíte plantar em pacientes não atletas e proposta de um novo sistema de avaliação objetiva – RKISP

Ranjeet Choudhary[1] Kishor Kunal[2]

[1] Assistant Professor, AIIMS, Raipur, Chattisgarh, India
[2] Department of Orthopedics, AIIMS, Jodhpur, Rajasthan, India

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Address for correspondence Kishor Kunal, Department of Orthopedics, AIIMS, Jodhpur, Rajasthan, 342005, India (e-mail: drkunal2408@gmail.com).

Abstract

Objective To determine the modifiable risk factors associated with severity of plantar fasciitis and to formulate an objective scoring system for indexing plantar fasciitis in the non-athletic population.

Methods This was a prospective observational study. The main outcome measure was the association of a modifiable risk factor, which was measured with the Pearson coefficient (R-value) and the level of significance, which was kept as $p < 0.05$.

Result In a sample size of 50 patients, the body mass index (BMI) and ill-cushioned shoes were found to be significantly associated with pain in plantar fasciitis. All the other risk factors were either non-modifiable or had no significant association.

Conclusion Based on available data and further interpretation, an index was be formulated, named as Ranjeet-Kunal Index for Scoring Plantar fasciitis (RKISP), which can be successfully used for not only grading plantar fasciitis but also prognosticating the conservative management of the same, thus deciding the modality of treatment.

Keywords
- risk factors
- plantar fasciitis
- chronic heel pain

Resumo

Objetivo Determinar os fatores de risco modificáveis associados à gravidade da fasciíte plantar e formular um sistema objetivo de pontuação para indexação da doença na população não atlética.

Métodos Estudo observacional prospectivo. A principal medida de desfecho foi a associação de um fator de risco modificável, mensurada pelo valor de R (coeficiente de Pearson) e pelo nível de significância de $p < 0,05$.

Resultados Em uma amostra de 50 pacientes, o índice de massa corporal (IMC) e calçados com amortecimento inadequado foram associados de maneira significativa à dor na fasciíte plantar. Todos os demais fatores de risco eram não modificáveis ou não apresentaram associação significativa.

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Palavras-chave
- fatores de risco
- fasciíte plantar
- dor crônica

Conclusão Com base nos dados à disposição e sua interpretação, um índice, denominado Índice de Ranjeet-Kunal de Pontuação da Fasciíte Plantar (RKISP, em inglês) , foi formulado e utilizado com sucesso não apenas na classificação da fasciíte plantar, mas também na determinação do prognóstico de seu tratamento conservativo, auxiliando a escolha da modalidade terapêutica.

Introduction

Plantar fasciitis (PF) is the most common cause of chronic plantar heel pain.[1] It is a degenerative syndrome of the plantar fascia resulting from repeated trauma at its origin on the calcaneus. Flexible foot, tibia vara, ankle equinus, rear foot varus, forefoot varus, compensated forefoot valgus, and limb length inequality can cause an abnormal pronatory force. Increased pronation produces additional stress on the anatomic central band of the plantar fascia and may ultimately lead to plantar fascitis.[2] Running has also been found to be a risk factor for developing plantar fascitis.[3] Weight gain, occupation-related activity, anatomical variations, poor biomechanics, overexertion, and inadequate footwear are contributing factors for the same.[4]

Excessive BMI (especially weight as the contributing factor) has a strong association with PF in the non-athletic population.[5,6] Risk factors can be broadly divided into intrinsic and extrinsic factors. Intrinsic factors can be further subdivided into anatomic and biomechanic, while extrinsic factors include poor alignment, hard surface, walking barefoot, prolonged weight bearing, and low-quality footwear. Anatomic factors include obesity, pes planus, pes cavus and shortened Achilles tendon, and biomechanic factors include over-pronation, limited dorsal ankle flexion, weak intrinsic muscles, and weak plantar flexor muscles.[5,7]

There is no specific scoring system catered to plantar fasciitis for severity of illness and assessment with treatment. Though other common scores, such as the visual analog scale (VAS), the Foot and Ankle Ability Measure (FAAM), the Foot and Ankle Disability Index (FADI), and the American Foot and Ankle Society (AOFAS), have been traditionally used for objective and subjective assessments of plantar fasciitis, they are either too generalized for the foot and ankle (FAAM, FADI and AOFAS) or to pain anywhere else in body (VAS).[8–11]

In the present study, we have attempted to find out modifiable risk factors that could be used for assessment of plantar fasciitis and using those risk factors to formulate a scoring system for quantifying the problem at presentation and in follow-up.

Methodology (►Figure 1)

In a study conducted at a tertiary health care facility at LHMC, New Delhi, India, "To evaluate various causes of Heel Pain and Efficacy of Autologous Platelet Rich Plasma Injection in Cases of Proximal Plantar Fasciitis Which Have Failed Conservative Management," the modifiable risk factors were studied with help of Pearson coefficient (R).

Since the most frequently reported complaint in plantar fasciitis is chronic heel pain, an attempt was made to find an association between the VAS and risk factors. Body mass index, fitting of shoes, cushioning of shoes, and level of activity were considered as variables that could affect the pain in plantar fasciitis based on the available literature. Age and sex were considered non-modifiable risk factors along with all the other anatomic factors requiring surgical correction. On the basis of significant association, an index was formulated for objective assessment of plantar fasciitis at presentation and following treatment. All those risk factors that are modifiable but need surgical intervention for modification were not considered modifiable due to technical reasons for modifications. Body mass index (values corresponding to obesity I and II i.e., $>$24.99 and $>$29.99, by WHO) an VAS are quantitative variables and others are qualitative variables;[12,13] therefore, a quantification was done based on the available literature for grading in the scoring system. On the basis of significance of the above mentioned associations with the symptomatology, a novel index system for quantitative objective assessment of plantar fasciitis is proposed. The purpose of the objective assessment is to create an unbiased assessment system for quantification of the disease during its presentation and treatment process, which cannot be achieved with subjective assessment, that tends to quantify the "problem" associated with disease rather than the disease and may have high inter-observer and intraobserver variation.

Results

A total of 50 patients were studied, 23 male and 27 female, with a mean age of 41.94 years and standard deviation (SD) of 8.94. The mean BMI was 28.79 (29.82 for females and 27.57 for males) kg/m^2. The Pearson correlation of various factors with VAS is shown in ►**Table 1**.

Body mass index showed a strong positive correlation with VAS, with an R-value of 0.64 and a p-value < 0.0001. For footwear, well-fitting shoes showed a negative correlation, with an R-value of - 0.16 and a p-value of 0.26, thus showing no significant association. For cushioning of shoes, well-cushioned shoes showed a strong negative correlation, with an R-value of - 0.41, showing a significant association with symptoms of patient, with a p-value of 0.0033. Level of activity was divided in 3 tiers: sedentary lifestyle, moderate activity, and heavy activity, and though there was a weak positive correlation, with R-value of 0.05, it showed no significant association with symptomatology (p-value $= 0.72$)

Table 1 R-value (Pearson coefficient) and level of significance of association between disease severity (pain) and modifiable risk factors

	R-value	*p*-value
BMI	0.64	< 0.0001
Well-fitting shoes	−0.16	0.26
Well cushioned shoes	−0.41	0.0033
Level of activity	0.05	0.72

Abbreviation: BMI, body mass index.

Based upon the significance levels, a novel index system for quantitative assessment of plantar fasciitis was proposed based on VAS, BMI levels for obesity I and obesity II, and cushioning of shoes (discussed in detail in the Discussion section).

Discussion

Plantar fasciitis is a cause of chronic heel pain. The chronicity is what makes a person accommodating to the pain and usual late presentations, but what physicians often fail to understand is that not only the disease is chronic and so can be the risk factors—which on one hand may not cause any significant distress to the patient because of chronicity, while on other can be a significant contributor to the progression of disease process. We can understand this in terms of the aforementioned risk factors, such as obesity and ill-cushioned shoes. The shoe a man wears is often a statement of his comfort rather than his status, and, thus, well-cushioned shoes may look inviting to be worn but the person tends to get accommodated to his or her footwear with time—which acts as a slow poison for the plantar fascia and works unremarkably. Similarly, obesity is often slow to acquire and the patient often gets used to it until it starts causing severe health problems, which is often not found in young grade I obesity patients. Thus, it can be understood that though chronicity is itself a statement of plantar fasciitis, this chronicity is the statement of otherwise neglected risk factors, such as ill-cushioned shoes (which in many cases can be rather comfortable for the patient to wear) and obesity —especially in the new onset and early phases—when it is causing less impacts on health. It should also be understood that this scoring system is for the non-athletic population, who usually do not suffer wear and tear of plantar fascia.

Now, let us understand each of the individual components of Ranjeet- Kunal Index for Scoring Plantar fasciitis (RKISP). Based on the above data, it can be understood that BMI, as indicated by earlier studies, has a strong positive correlation with the symptomatology and the VAS in plantar fasciitis. Since obesity shows a very significant association, obesity can be further divided on the basis of the WHO grading of BMI for the Indian population, with BMI > 24.99 defined as obesity I and > 29.99 as obesity II.[12] This grading is for Asian population and might be different in the western population, as the grading of obesity is different in their scenario and can be modified based on the WHO grading of obesity for the western population. Based on the severity of obesity, grading in the index can be done by assigning 1 point to the former and 2 points to the latter.

Table 2 Ranjeet-Kunal Index for Scoring Plantar fasciitis (RKISP) (*The patient needs to have a chronic heel pain with a visual analog scale [VAS] > 4.5 in order to qualify for being evaluated by the RKISP). For more details, see text)*

BMI	> 24.99 (obesity I)	1
	> 29.99 (obesity II)	2
Worn out cushion		1
VAS	**> 4.5**	**1**
	> 7.5	**2**
Total		5

Abbreviation: VAS, visual analog scale.

The VAS is a scale that has been commonly used for quantifying pain in patients with different etiologies. A VAS > 7.5 is a measure of severe torment for the patient.[13] A VAS < 4.5 usually defines unremarkable pain and, hence, has not been included in the index. Severe pain, with VAS > 7.5, has been assigned 2 points in the score.

Since cushioned footwear showed a strong negative correlation to the symptomatology, it becomes obvious that changing an ill-cushioned shoe will provide a dramatic response in both prevention and treatment of symptomatology of plantar fasciitis. A change in footwear, thus, becomes an obvious part of management, and, not only that, it shall become an important part in the quantifying assessment of the disease.

As shown in ►**Table 2**, three parameters have been considered for objective assessment of plantar fasciitis in the pre and posttreatment periods. The RKISP includes these three parameters that add up to a maximum value of 5 and a minimum value of 1 (the minimum criteria for indexing was considered VAS > 4.5, which is the criteria for remarkable pain by Hawker et al.[13]). The RKISP can be used for grading plantar fasciitis.

Implications of the RKISP

- Objective assessment at the time of presentation of plantar fasciitis and at consecutive follow-ups. Objective assessment not only helps in unbiased quantification of disease but also leads to uniformity of treatment and research protocols.
- Grading of plantar fasciitis. Grading can be done based on additional parameters which may worsen the pain in plantar fasciitis patients.
- Prognosis of conservative management is inversely proportional to index. This can be understood in a way that a higher index is prone to have more conservative ways of management that can be used. For example, a patient that presents with an index of 2 with a VAS of 9/10 but wears a well-cushioned shoe and has a BMI < 24.99 will have a

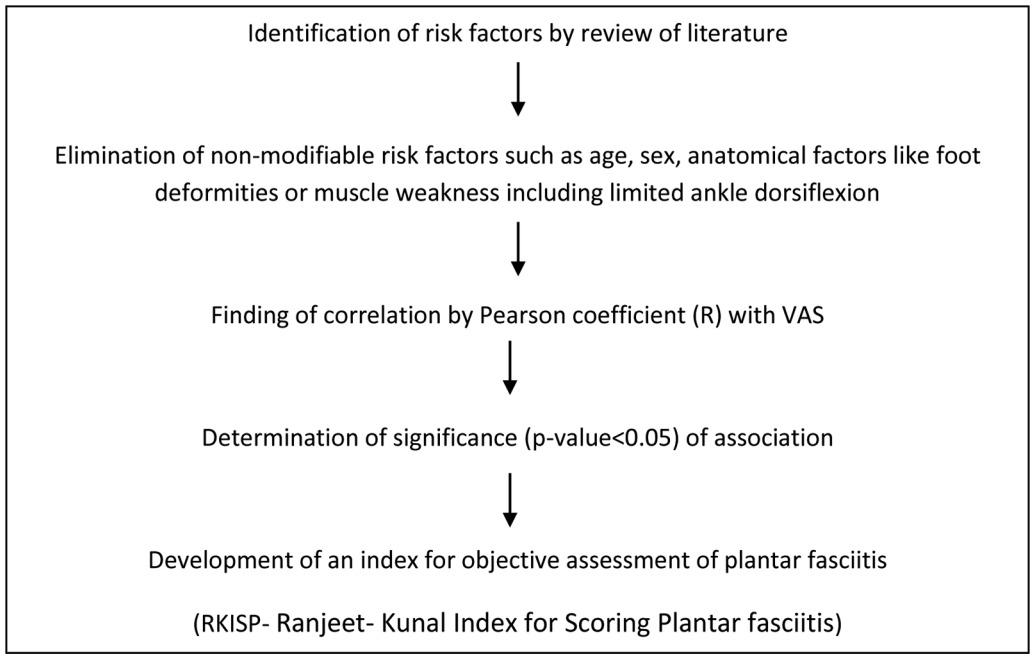

Fig. 1 Flowchart of the methodology employed to determine the objective scoring system for evaluation of plantar fasciitis in non-athletic patients.

worse prognosis than a patient with an index of 4 wearing worn out shoes and classified with obesity II with a VAS of 5 with conservative management.

Conclusion

An objective assessment can be achieved with RKISP, quantifying the disease in terms of problem and risk factors. This index can be further used for grading and prognosticating plantar fasciitis at the time of presentation and during treatment, as explained above. Further research needs to be done on larger samples for validation of RKISP. The authors also recommend the use of objective assessment systems for plantar fasciitis in addition to the widely used subjective systems.

Conflict of Interests

The authors have no conflict of interests to declare.

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Evaluation of the Reproducibility of Lauge-Hansen, Danis-Weber, and AO Classifications for Ankle Fractures*

Avaliação da reprodutibilidade das classificações Lauge-Hansen, Danis-Weber e AO para fraturas do tornozelo

Lucas Sacramento Ramos[1] Henrique Mansur Gonçalves[2] Anderson Freitas[3] Marcio de Paiva Oliveira[3] Diogo Marcelino Santos Lima[4] Welvis Soares Carmargo[1]

[1] Orthopedics and Traumatology Department, Hospital Regional do Gama, Brasília, DF, Brazil
[2] Department of Medicine, Universidade de Brasília, Brasília, DF, Brazil
[3] Instituto de Pesquisa e Ensino do Hospital Ortopédico e Medicina Especializada, Brasília, DF, Brazil
[4] Department of Medicine, Centro Universitário de Brasília (CEUB), Brasília, DF, Brazil

Address for correspondence Lucas Sacramento Ramos, SQS 214, bloco C, apartamento 605, Asa Sul, Brasília, DF, 70293-030, Brazil (e-mail: lucas.sacramentoramos@gmail.com).

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Abstract

Objective The present study aims to analyze the intra- and interobserver reproducibility of the Lauge-Hansen, Danis-Weber, and Arbeitsgemeinschaft für Osteosynthesefragen (AO) classifications for ankle fractures, and the influence of evaluators training stage in these assessments.

Methods Anteroposterior (AP), lateral and true AP radiographs from 30 patients with ankle fractures were selected. All images were evaluated by 11 evaluators at different stages of professional training (5 residents and 6 orthopedic surgeons), at 2 different times. Intra- and interobserver agreement was analyzed using the weighted Kappa coefficient. Student t-tests for paired samples were applied to detect significant differences in the degree of interobserver agreement between instruments.

Results Intraobserver analysis alone had a significant agreement in all classifications. Moderate to excellent interobserver agreement was highly significant ($p \leq 0.0001$) for the Danis-Weber classification. The Danis-Weber classification showed, on average, a significantly higher degree of agreement than the remaining classification systems ($p \leq 0.0001$).

Conclusion The Danis-Weber classification presented the highest reproducibility among instruments and the evaluator's little experience had no negative influence on the reproducibility of ankle fracture classifications. *Level of Evidence II, Diagnostic Studies – Investigating a Diagnostic Test.*

Keywords
- ankle fractures
- classification
- reproducibility of results

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Resumo

Objetivo Avaliar a reprodutibilidade intra- e interobservador das classificações de Lauge-Hansen, Danis-Weber e Arbeitsgemeinschaft für Osteosynthesefragen (AO) para as fraturas de tornozelo, e a influência do estágio de formação dos participantes na avaliação.

Métodos Foram selecionadas radiografias de 30 pacientes com fratura de tornozelo nas incidências anteroposterior (AP), perfil e AP verdadeiro. Todas as imagens foram avaliadas por 11 participantes em diferentes estágios de formação profissional (cinco residentes e seis cirurgiões ortopédicos), em dois momentos distintos. Analisou-se a concordância inter- e intraobservador por meio do coeficiente Kappa ponderado. O teste t de Student para amostras pareadas foi aplicado para verificar se havia diferença significativa no grau de concordância interobservador entre os instrumentos.

Resultado Observou-se que existe concordância significativa em todas as classificações quando da análise intraobservador isolada. Existe concordância interobservador altamente significativa de grau moderado a ótimo na classificação de Danis-Weber ($p \leq 0{,}0001$). A classificação de Danis-Weber apresentou, em média, grau de concordância significativamente maior que as outras classificações ($p \leq 0{,}0001$).

Conclusão A classificação de Danis-Weber se mostrou a mais reprodutiva entre os instrumentos avaliados, e a pouca experiência do avaliador não influencia negativamente a reprodutibilidade das classificações das fraturas do tornozelo. *Nível de Evidência II, Estudos Diagnósticos - Investigação de um Exame para Diagnóstico.*

Palavras-chave

- fraturas do tornozelo
- classificação
- reprodutibilidade dos testes

Introduction

Ankle fractures comprise ~ 10% of all human body fractures; these injuries are more common in women and are associated with obesity and smoking.[1,2] The demographic transition resulted in an approximately 3-fold increase in the incidence of these fractures in elderly patients for the last 30 years.[1–3] At the ankle joint, the talus body fits into the malleolar clamp, functioning as a modified trochlea, and it is stabilized by lateral, medial and syndesmotic ligament complexes.[4] When subjected to deforming forces, mainly rotational, this complex bone-capsule-ligament anatomy suffers a number of injuries that must be studied. Ankle fractures diagnosis is based on clinical history, physical examination, and regional image evaluation, usually with simple ankle radiographs in anteroposterior (AP), lateral and true AP (with 20° internal rotation) views.[1,4]

Classification systems are important tools for prognosis definition and to guide the most appropriate treatment. A good classification system must have simple language and provide reliable information for correct propaedeutics.[5] In addition, it must be feasible, reliable, and reproducible. This latter feature depends on intra- and interobserver agreement[5,6] Reproducibility studies are classical in the literature to assess the quality of a classification system, especially in orthopedics, since they help to define which instrument provides greater agreement and understanding in the scientific community.[7]

The Lauge-Hansen classification for ankle fractures was the most used system for many years. It is based on trauma mechanism and it considers both foot positioning and the deforming force direction (i.e., pronation with abduction, pronation with external rotation, supination with adduction and supination with external rotation). The Danis-Weber classification is mostly anatomical and is based on the topography of the lateral malleolus and line type. Injuries are classified as infrasyndesmotic (A), transsyndesmotic (B) and suprasyndesmotic (C). The Arbeitsgemeinschaft für Osteosynthesefragen (AO) Group classification redefines the three types of Danis-Weber classification by taking into account medial injuries. Therefore, lesions are classified as infrasyndesmotic (isolated [A1], with medial malleolus injury [A2] or with postmedial fracture [A3]), transsyndesmotic (isolated [B1], with medial injury [B2] or with medial and posterolateral injuries [B3]) and suprasyndesmotic (simple fracture [C1], multifragmentary fracture [C2] or proximal fibular fracture [C3]).[1,8–10]

Although there are some studies in the literature evaluating the reproducibility of the various classification systems for ankle fractures, they are controversial and there is no consensus on which one is the most appropriate. In addition, little has been discussed about the relationship between the reproducibility of the instruments and the evaluator's experience.[11,12] Thus, the present study aims to analyze which of the three main classification systems for ankle fracture has the highest intra- and interobserver reproducibility, and whether the training stage of the evaluators influences the assessment. We believe that more complex classification systems present lower reproducibility and that more experienced evaluators will achieve greater agreement rates.

Material and Methods

Patients with ankle fractures in 2018 were selected after approval by the Research Ethics Committee with the opinion number 2.697.068/18. The study met all requirements regarding human rights.

Skeletally mature patients with a diagnosis of ankle fracture and AP, lateral, and true AP (with 20° internal rotation of the ankle) radiographic images were included randomly as they were seen in the hospital emergency room, up to a total of 30 subjects. Patients with no radiographs in the aforementioned views, with tests deemed low-quality by the researchers, or those who did not agree to participate in the study were excluded.

Radiographs were photographed and digitalized in the personal file of the main researcher. All images were inserted into Survey Monkey Canada Inc., Ottawa, Canada, which generated a virtual questionnaire for their classification by evaluators according to the Danis-Weber, Lauge-Hansen, and AO Group systems. The questionnaire also had illustrations of each classification system that the evaluators could consult at any time (►**Figures 1**, **2**, and **3**). The virtual questionnaire was sent to a total of 11 orthopedists in different stages of training, including 6 members of the Sociedade Brasileira de Ortopedia e Traumatologia (SBOT, in the Portuguese acronym), 2 specialists in foot and ankle surgery (from the Associação Brasileira de Medicina e Cirurgia do Tornozelo e Pé [ABTPé, in the Portuguese acronym), 4 non-specialists, and 5 resident physicians, 1 in the 1st year (R1), 2 in the 2nd year (R2) and 2 in the 3rd year (R3) of training to assess interobserver agreement. To assess intraobserver agreement, the same questionnaire was sent to these evaluators to repeat the process after one month.

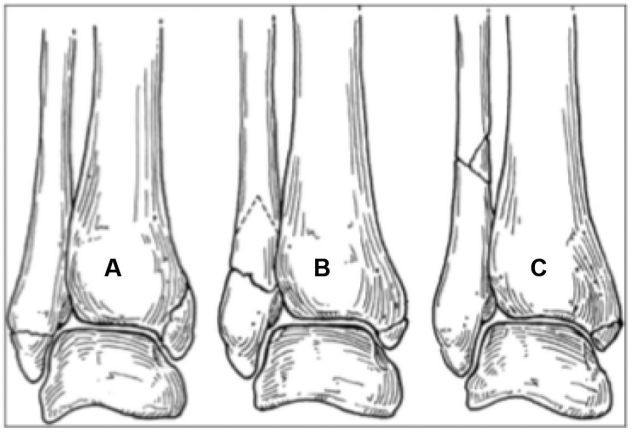

Fig. 1 Weber classification.

Statistical Analysis

The descriptive analysis presented data expressed as frequency (n) and percentage (%) in tables. The inferential analysis was composed by the weighted Kappa coefficient for intra- and interobserver agreement analysis of the Danis-Weber, Lauge-Hansen, and AO classification instruments in two time points. The Student t-tests for paired samples determined whether there was a significant difference in the degree of interobserver agreement between these instruments.

Intra- and interobserver reliability were assessed by the weighted Kappa coefficient, which determined whether there was a significant agreement, on an ordinal scale, for the Danis-Weber (3 levels), Lauge-Hansen (4 levels), and AO (9 levels) classification systems between the 2 time points (M1 and M2, i.e., 1 month after M1) in the sample of 30 radiographic studies. It is known that Kappa coefficients closer to 1 indicate stronger (or perfect) agreement between observers; in this case, observers are similar under the qualitative aspect of the assessment. On the other hand, Kappa coefficients closer to 0 indicate greater disagreement, i.e., there is no reproducibility and observed differences do not happen by chance.

The samples correspond to the Kappa coefficients of the 55 comparisons between evaluators, and there are 55 comparisons in the total sample; the subsample consisting of specialists alone has 15 comparisons, whereas the subsample consisting of residents alone has 10 comparisons, and the subsample of specialists versus residents presents 30 comparisons.

Significance was determined at a 5% level. The statistical analysis was performed using the statistical software SAS System, version 6.11 (SAS Institute, Inc., Cary, NC, USA).

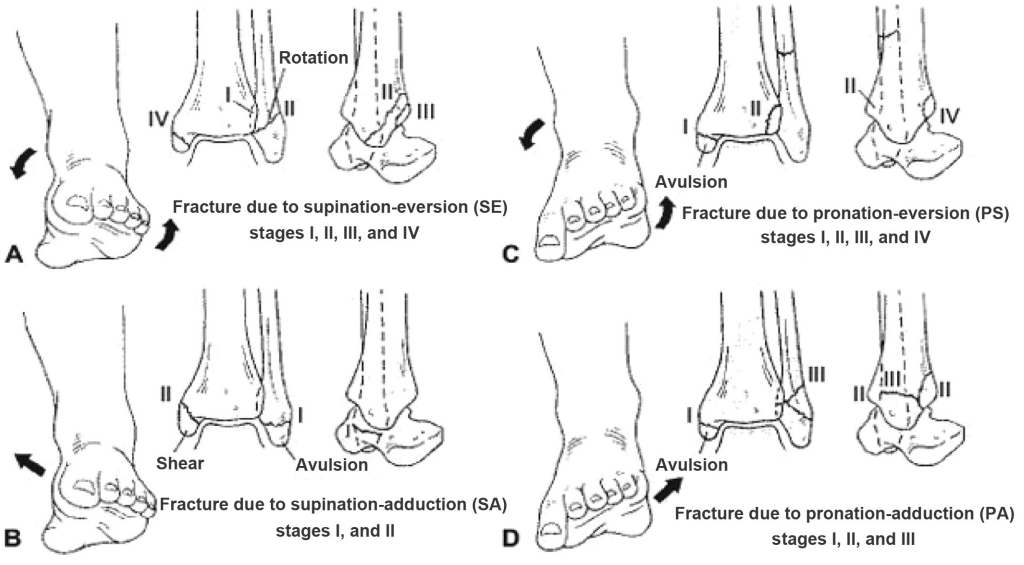

Fig. 2 Lauge-Hansen classification.

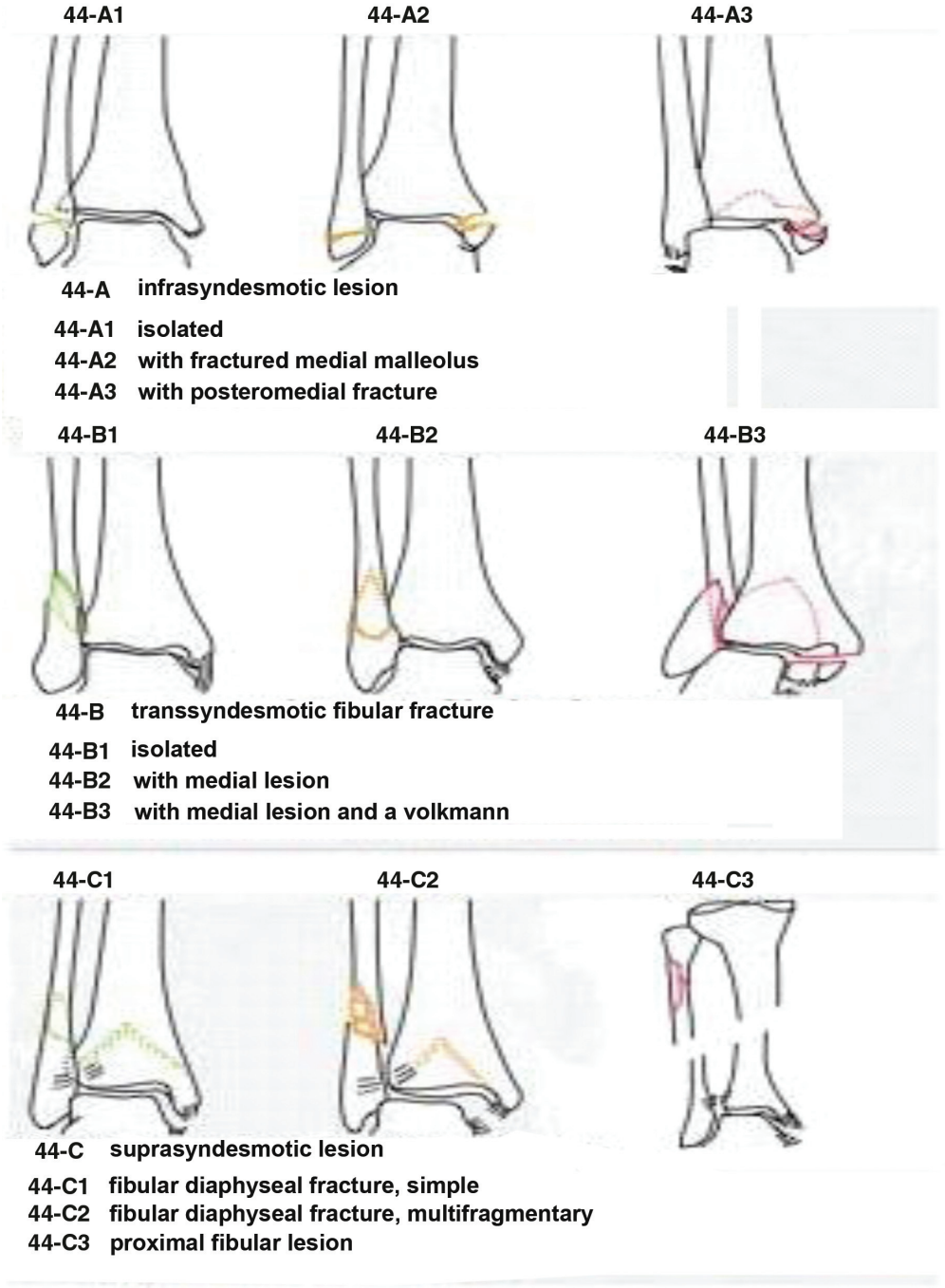

Fig. 3 AO classification for ankle fractures.[7]

Results

There was a significant agreement for intraobserver reproducibility for all 11 evaluators using the Danis-Weber classification ($p \leq 0.0001$); for 9 evaluators using the Lauge-Hansen classification, with 1 specialist ($p = 0.65$) and 1 resident ($p = 0.30$) showing no reproducibility between time points; and for 10 professionals using the AO classification, but with a specialist ($p = 0.071$) with no reproducibility between time points. In general, residents showed better intraobserver agreement than specialists.

There was a highly significant agreement ($p < 0.0001$), of moderate to excellent degree, in interobserver reproducibility for the Danis-Weber classification for all evaluators in both time points. Although there was a highly significant correlation ($p \leq 0.0001$) for most pairs in the Lauge-Hansen classification system, 7 pairs from the M1 time point and 3 pairs from the M2 time point showed no statistical significance. There was a highly significant agreement ($p \leq 0.0001$) for most pairs in the AO classification, but 7 pairs from the M1 time point showed no statistical relevance.

Table 1 Concordance degree among instruments

Sample*	Instrument	M1					M2				
		mean		SD	instrument pairs	*p* value[a]	mean		SD	instrument pairs	*p* value[a]
Total (n = 55)	W (1)	0.81	±	0.11	1 *vs* 2	< 0.0001	0.79	±	0.11	1 *vs* 2	< 0.0001
	LG (2)	0.43	±	0.21	1 *vs* 3	< 0.0001	0.52	±	0.18	1 *vs* 3	< 0.0001
	AO (3)	0.43	±	0.19	2 *vs* 3	0.83	0.48	±	0.21	2 *vs* 3	0.18
only among specialists (n = 15)	W (1)	0.76	±	0.10	1 *vs* 2	< 0.0001	0.79	±	0.13	1 *vs* 2	< 0.0001
	LG (2)	0.29	±	0.15	1 *vs* 3	< 0.0001	0.49	±	0.15	1 *vs* 3	< 0.0001
	AO (3)	0.30	±	0.17	2 *vs* 3	0.82	0.41	±	0.27	2 *vs* 3	0.15
only among residents (n = 10)	W (1)	0.86	±	0.08	1 *vs* 2	0.0008	0.76	±	0.08	1 *vs* 2	0.003
	LG (2)	0.59	±	0.19	1 *vs* 3	0.0001	0.54	±	0.18	1 *vs* 3	0.0005
	AO (3)	0.61	±	0.10	2 *vs* 3	0.85	0.54	±	0.12	2 *vs* 3	0.84
specialists *vs* residents (n = 30)	W (1)	0.82	±	0.11	1 *vs* 2	< 0.0001	0.80	±	0.11	1 *vs* 2	< 0.0001
	LG (2)	0.44	±	0.20	1 *vs* 3	< 0.0001	0.52	±	0.20	1 *vs* 3	< 0.0001
	AO (3)	0.44	±	0.18	2 *vs* 3	0.99	0.50	±	0.21	2 *vs* 3	0.61

Abbreviations: AO, Arbeitsgemeinschaft für Osteosynthesefragen; LG, classificação Lauge-Hansen; SD, standard deviation; W, classificação Danis-Weber.
*Kappa-weighted statistical sample.
[a]Student *t* test for paired samples.

In addition, correlations in the degree of interobserver agreement between instruments in the total sample and subsamples of evaluators were assessed. ►**Table 1** shows mean and standard deviation (SD) values for the degree of interobserver agreement (weighted Kappa coefficient) of the three instruments in the total sample and subsamples of evaluators from M1 and M2 time points. The Danis-Weber classification system presented, on average, a significantly higher degree of agreement than the Lauge-Hansen and AO systems in the total sample and subsamples both in M1 and M2 time points. There was no significant difference, at the 5% level, in the degree of agreement between the Lauge-Hansen and AO classification systems in the total sample and subsamples both in M1 and M2 time points.

Regarding the influence of the training stage of evaluators on reproducibility, it was observed that, in general, residents showed better intraobserver agreement, with values greater than the Kappa for the three classification systems and statistically significant differences for the two evaluated time points ($p < 0.05$).

Discussion

The main findings of the present study are partially consistent with our initial hypotheses. More complex classification systems for ankle fractures presented lower reproducibility. In contrast, however, more experienced evaluators agreed less in their responses at two different times.

In our study, 11 evaluators in different stages of training (residents, orthopedists and specialists in foot and ankle surgery) were asked to classify ankle fractures in 30 radiographic images, and their answers were statistically analyzed using the weighted Kappa method. Audigè et al.[13] carried out a systematic review on reproducibility studies of fracture classification systems and concluded that all of them relied on the Kappa method, but interpretation varied a lot due to confidence intervals (CIs). To avoid this bias, we used the CI defined by Landi et al.[14]

Fonseca et al.[11] evaluated the same classification systems for ankle fractures (namely, Danis-Weber, Lauge-Hansen, and AO), with 6 evaluators and 83 images; however, they considered AP and lateral radiographs alone. This study revealed a greater reproducibility for the Danis-Weber classification ($\kappa = 0.49$), with lower rates for the Lauge-Hansen ($\kappa = 0.32$) and AO ($\kappa = 0.38$) classification systems, which presented low agreement. Similar results were found by Alexandropoulos et al.,[12] who used three evaluators to classify 294 images of ankle fractures. They reported poor agreement for three classification systems ($\kappa = 0.327$–0.408, 0.174–0.476, and 0.397–0.483 for Broos-Bisschop, Lauge-Hansen, and AO, respectively).[12] Our study, in contrast, observed a highly significant degree of interobserver agreement for all classification systems, with values higher compared to previous studies ($\kappa = 0.79$, 0.52 and 0.48 for Danis-Weber, Lauge-Hansen, and AO, respectively). We believe that the high degree of agreement obtained in our study is related to the higher number of radiographic views compared with previous studies.[11,15,16] A most complete radiographic study certainly contributed to a more accurate diagnosis, facilitating lesion classification.

Few studies similar to ours evaluate intraobserver agreement.[11] Tenório et al.[15] reported that intraobserver agreement was moderate to high for the Lauge-Hansen classification ($\kappa = 0.58$) and moderate to almost perfect for the Danis-Weber classification ($\kappa = 0.76$). In our study, with 11 professionals, intraobserver agreement was significant ($p < 0.05$) among all evaluators for the Danis-Weber classification, for 9 evaluators using the Lauge-Hansen classification and for 10 evaluators

using the AO classification. We believe this happened because the questionnaire was large, resulting in less accuracy at the second evaluation. In addition, the greater complexity of the Lauge-Hansen and AO classification systems and the need to understand the fracture trauma mechanism for their correct use decrease their reproducibility.[11,15]

One of the goals of our work was to assess the influence of different stages of knowledge on practical activity. It is expected that as people study and become accustomed to a particular classification system, agreement between them and within their own observations would increase.[5] Fonseca et al.[11] reported that this variable did not influence the reproducibility rates of the studied classifications. However, since the authors only performed an interobserver agreement analysis, their understanding is partially limited. In our study, residents showed better intraobserver agreement, contrary to common sense. We believe that while residents resorted more often to the template illustrations provided for each classification system, most experienced evaluators classified fractures according to memory. This fact highlights the importance of knowing the instruments and their subtypes when using them to classify a fracture, since it often helps in the decision-making of surgical treatment.[17]

Based on our results, we conclude that a complete radiographic study, including AP, lateral and true AP views, is essential to classify ankle fractures, as well as the detailed knowledge of the instrument used and the occasional use of templates. Among the classification systems evaluated, although the Danis-Weber classification has proven to be the most reproducible, it provides insufficient information to guide fracture treatment, requiring an additional assessment of ankle joint stability for proper surgical indication. We believe that there is no ideal radiographic classification for malleolar fractures that presents high reproducibility and, at the same time, enables correct surgical planning. Thus, in more complex fractures, preoperative evaluation using computed tomography (CT) helps to understand the injury, especially trimalleolar lesions with posterior malleolus fragmentation.[18] Black et al. showed that CT plays an important role in fracture-dislocation, trimalleolar and suprasyndesmotic fractures, improving the preoperative study and surgical planning.[19]

We are aware of the limitations of our study. The main one is the number of radiographic images evaluated, which is lower compared to similar works. There are several articles in the literature evaluating the reproducibility of various classification systems for fractures in an attempt to define which one is the best.[10,20] However, there is still no consensus on the ideal methodology, since the number of analyzed images and evaluators influences the agreement on answers.[13,20] Numbers too small or too large decrease agreement.[14] Tenório et al.[15] used a total of 50 radiographs and 8 evaluators, whereas, in another study,[11] 6 evaluators classified 83 radiographs. We increased the number of evaluators to elevate the statistical power of interobserver agreement. In addition, the interval of 1 month between the 2 time points of questionnaire application differs from most previous studies including intraobserver analysis. This fact may have decreased the agreement, since the memory response is impaired. However, we were able to achieve the goal of the present study, which was the evaluation of responses from each evaluator alone.

Conclusion

The Danis-Weber classification was shown to be more reproducible compared with the Lauge-Hansen and AO systems, with a moderate to high degree of both intra- and interobserver agreement. The Lauge-Hansen and AO classification systems, on the other hand, presented similar low to moderate intra- and interobserver agreement.

In addition, residents showed a higher intraobserver agreement in all classifications, demonstrating that the little experience of the evaluator has no negative influence on the reproducibility of ankle fracture classifications.

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Conflict of Interests
The authors have no conflict of interests to declare.

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Surgical Gloves in Orthopedic Trauma Procedures: How Many Lose Their Integrity?*

Luvas cirúrgicas em procedimentos ortopédicos de trauma: Quantas perdem a integridade?

Maurício Pandini Monteiro de Barros[1] Thales Thiago Ferreira Godoi[1] Mario Ferretti Filho[1] Helio Jorge Alchavian Fernandes[1] Fernando Baldy dos Reis[1]

[1] Department of Orthopedics and Traumatology, Escola Paulista de Medicina, Universidade Federal de São Paulo (Unifesp), São Paulo, SP, Brazil

Address for correspondence Maurício Pandini Monteiro de Barros, Correia de Lemos Street, 571, Apt 142, CEP 04140-000, Chácara Inglesa, São Paulo, SP, Brazil (e-mail: mpmbarros@gmail.com).

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Abstract

Introduction The possibility of perforation of gloves during orthopedic surgeries can reach 56.8%, and it mainly related to the manipulation of blunt instruments. Surgeries for the treatment of fractures and trauma present additional risk due to contact with bone spires.

Objective Analysis of the prevalence of loss of integrity of surgical gloves in orthopedic trauma procedures, especially fractures, and evaluation of the surgeon's exposure and contact with secretions from the patient.

Methods Macroscopic inspection of the gloves of two surgeons specialized in trauma, over a period of 4 months. Both used two gloves for all procedures and, at the end of the surgery, analyzed the presence or absence of blood stains on the internal gloves and/or fingers. The procedures were categorized according to the time and type of surgery. The intercurrence investigated was the perforation of one or two gloves; if the tear was perceived immediately or only at the end of the surgery, and the location of and reason for the tear, if identified.

Results A total of 210 surgeries were included, 87 of which presented perforations, with 17 cases occurring in both gloves and 70 only in the outer glove. Finally, there was a more significant relationship with open focus surgeries and duration $>$ 60 minutes.

Conclusion Our results suggest that greater care and inspection of gloves to look for damage are needed in prolonged surgeries with an open focus.

Keywords

- orthopedic surgeons
- gloves, surgical
- protection
- traumatology

* *Work developed in the Department of Orthopedics and Traumatology, Escola Paulista de Medicina, Universidade Federal de São Paulo (Unifesp), São Paulo, SP, Brazil.*

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Resumo

Introdução Cirurgias ortopédicas apresentam a possibilidade de perfuração das luvas, que pode chegar a 56,8%, relacionada principalmente à manipulação de instrumentos cortantes. O tratamento de fraturas e cirurgias de trauma apresenta risco adicional pelo contato com espiculas ósseas.

Objetivo Análise da prevalência de perda de integridade das luvas cirúrgicas em procedimentos ortopédicos de trauma, principalmente fraturas, avaliando a exposição do cirurgião e o contato com secreções provenientes do paciente.

Métodos Inspeção macroscópica das luvas de dois cirurgiões especializados em trauma, durante um período de 4 meses. Ambos usaram duas luvas para todos os procedimentos e, ao término da cirurgia, analisaram a presença ou ausência de manchas de sangue nas luvas internas e/ou nos dedos. Os procedimentos foram categorizados quanto ao tempo e tipo de cirurgia. A intercorrência investigada foi a perfuração de uma ou duas luvas; se a perfuração foi percebida imediatamente ou apenas ao final da cirurgia, e qual o local e o motivo do rasgo, se identificado.

Resultados Foram incluídas 210 cirurgias, das quais 87 apresentaram perfurações, sendo 17 casos em ambas as luvas e 70 apenas na luva externa. Um total de 27,5% dos danos foram descobertos apenas no final da cirurgia; os rasgos se concentraram no indicador esquerdo em 62,5% dos casos. Por último, houve uma relação mais significativa com cirurgias de foco aberto e com duração superior a 60 minutos.

Conclusão O nosso resultado sugere que em cirurgias prolongadas e com foco aberto, é necessário maior cuidado e inspeção à procura de danos nas luvas.

Palavras-chave

- cirurgiões ortopédicos
- luvas cirúrgicas
- proteção
- traumatologia

Introduction

Orthopedic surgeries have a greater possibility of perforations in gloves, with handling of blunt and sharp instruments (drills, screws, metal wires, among others),[1] in addition to bone spicules that can injure the surgeon's hand and offer risk of contamination.

Some studies have evaluated the hypothesis of increased infection in procedures in which the surgeon's glove loses integrity, but the results indicated no correlation.[1–4]

The perforation of gloves occurs in 3.5[5] to 56.8%[3] of surgeries; in up to 89% of these, the surgeon may not be aware of the contamination.[6] In addition, perforations are concentrated in the index finger and in the thumb of the non-dominant hand.[1]

Using two gloves decreases the chance of contamination of the surgeon in cases of tears by 87%, and, in the case of perforation of the surgeon's hand with a solid needle, there is a retention of up to 95% of the blood in the gloves, thus minimizing a possible transmission of diseases.[1] The additional pair of gloves decreases the possibility of perforation of the inner glove, reducing the risk of contamination by up to 13 times fold.[7]

There are no studies in the literature that evaluated glove tears only in orthopedic traumatology and fracture correction procedures. Our objective is to evaluate the exposure of the patient and surgeon, determining the prevalence of glove perforations in this type of surgery.

Materials and Methods

Two orthopedic surgeons with specialization in orthopedic trauma, M. B. and T. G., with 4 and 5 years of training, respectively, both right-handed, inspected the gloves during and after the surgeries, in the period of 4 months, from July 1, 2019 to October 30, 2019, in the hospitals where they undergo surgical routine (Hospital Santa Cecilia, Hospital Sancta Maggiore Mooca, Hospital Salvalus and General Hospital of Carapicuíba).

The inclusion criteria were orthopedic trauma surgeries, in which one of the two surgeons involved in this study participated as the main surgeon; procedures for correction and fixation of fractures; removal of synthesis materials (plates or rods); revisions, and pseudarthrosis.

The exclusion criteria were soft-tissue surgeries (tendon or ligament repairs), without the use of orthopedic implants, or removal of percutaneous synthesis materials.

Both surgeons routinely use two pairs of gloves (inner glove and outer glove). All gloves used in the services and hospitals frequented by our team are natural rubber latex, of brands authorized by the quality regulatory body for sterile surgical use.

At the end of the surgery (if there was no perceived perforation throughout the procedure and the change was already made), the outer glove of each hand was removed separately and inspected visually and thoroughly for signs of blood stains in the inner glove (►**Figure 1**). The same procedure was repeated with the internal glove, in search of contamination in the surgeon's hands (►**Figure 1**).

The surgeries were divided into duration greater than or lower than 60 minutes. In addition, we separated them into three groups regarding the type of surgery: percutaneous (such as fixation of distal radius with Kirchner wire); closed-focus surgeries (such as intramedullary tibia or femur stems

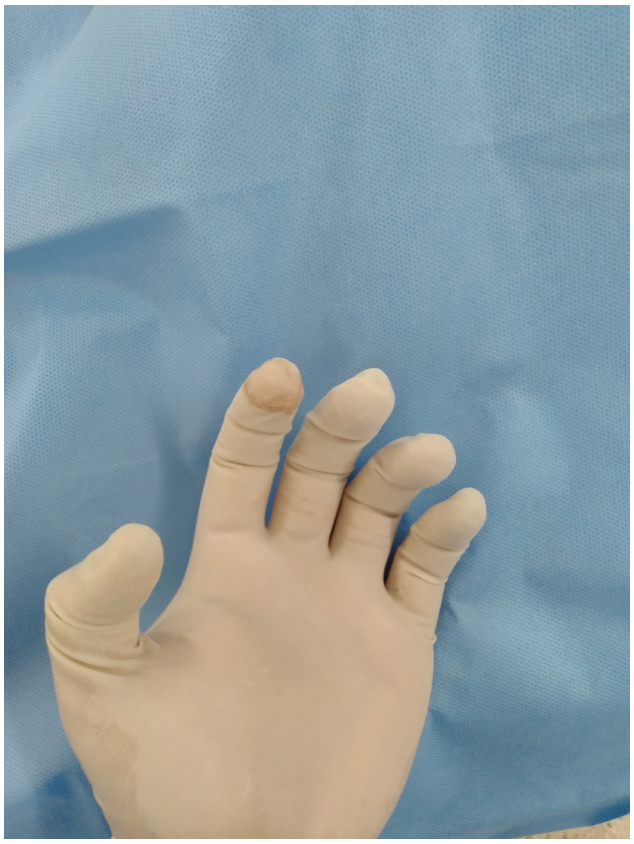

Fig. 1 Internal glove showing loss of integrity of the left index finger perceived at the end of surgery.

with indirect reduction), and open focus surgeries (direct reduction and manipulation of bone fragments, such as forearm or joint fractures)

Regarding the loss of integrity of the gloves, we divided them into two groups: according to perforation and details; these were subdivided as follows:

Regarding perforation, the outcomes may be: Group A: "No tears": unidentified perforation during the procedure and, at the end, without stains on the internal gloves. Group B "one glove during": loss of integrity only of the external glove noted during the procedure, but without damage to the inner glove. Group C "two gloves during": loss of integrity of both gloves perceived during the procedure, with stains on the inner glove and hand of the surgeon. Group D "one glove in the end": only at the end of the surgery there was staining on the inner glove, and the moment at which the perforation occurred was not identified. Finally, Group E "two gloves in the end": damage to the internal and external glove, with contamination including the surgeon's hand, not noticed during the procedure.

Regarding the details, we divided them into finger and side, record as to the region and laterality of the perforations; and moment and mode, if perceived during the procedure and reason for the tear, such as contact with bone spicules, Kirchner wires, during handling of the punch, or when positioning Hohmann-type retractor or reduction calipers.

At the end, a statistical analysis of the variables was performed, using a chi-squared test to compare the various variables found.

Table 1 Relationship between surgery time and perforations

	Surgical time		Total
	< 60 minutes	> 60 minutes	
Total	116	94	210
Damaged gloves	24 (20.6%)	63 (67.0%)	87 (41.4%)
Integral gloves	92 (79.3%)	31 (32.9%)	123 (58.5%)

Results

A total of 210 surgical procedures involving internal fixation materials, such as fractures, revisions, removals of material, were evaluated. Regarding time, 116 (55.2%) lasted less than 60 minutes, and 94 (44.7%) more than 60 minutes. Regarding the type of surgery, 20 surgeries were percutaneous, 60 were closed focus, and 130 were open focus. Regarding the loss of integrity, 41.4% of the procedures had perforations or damage to the gloves.

Regarding time, procedures with duration greater than 60 minutes presented a higher rate of tears, with 67%. In surgeries that lasted less than an hour, there was a 20.6% loss of integrity ($p < 0.001$) (►**Table 1**).

Regarding the type of surgery, open focus procedures stood out, with 49.2% of them presenting perforations. On the other hand, 33.3% of closed focus surgeries and 15% of percutaneous surgeries had glove damage ($p = 0.005$) (►**Table 2**).

Regarding the outcomes, considering the 87 surgeries in which there was perforation, the situation of perceiving the tear only in the external glove (group B) during the surgery had a higher rate, with 24.2%. On the other hand, the cases in which there was loss of integrity of two gloves noticed during surgery (group C) accounted for 5.7%. The procedures in which the tear was discovered only at the end of the surgery corresponded to 9% in the external glove only (group D) and 2.3% with perforation of both gloves (group E) (►**Table 3**).

Regarding perception, when there were tears, 63 cases were identified at the time of the surgery. On the other hand, 24 of the perforations were noted only at the end of the surgery during the inspection. In 80% of the cases in which there was a tear, the internal glove remained intact, serving as a barrier to direct contact between patient and surgeon.

Table 2 Relationship between type of surgery and perforations

	Type of surgery			Total
	Percutaneous	Closed focus	Open focus	
Total	20	60	130	210
Damaged gloves	3 (15%)	20 (33.3%)	64 (49.2%)	87 (41.4%)
Integral gloves	17(85%)	40 (66.6%)	66 (59.7%)	123 (58.5%)

Table 3 Relation to perforation perception

Perforations - perception				
Group A	Group B	Group C	Group D	Group E
123 (58.5%)	51 (24.2%)	12 (5.7%)	19 (9.0%)	5 (2.3%)
Total	87 (41.4%)			

The site that had the most perforations was the index finger of the non-dominant hand (left), with 62.5% of the cases, followed by the right index finger, with 19.2%, and in third, the left thumb with 9.6% (►**Table 4**).

In cases of loss of integrity in which the reason was identified, the greatest factor responsible was contact with bone spicules, in 45% of cases, followed by perforations with Kirchner wires or guide wires, with 22.5%. Tears during handling of the punch were the causative agent in 12.5%, and the act of positioning a Hohmann-type retractor or reduction clamp in 10% of cases (►**Table 5**).

Discussion

In the literature, we found different analyses on the subject. Some authors, like Nicolai et al.[8] and Chan et al.,[5] evaluated the gloves of the surgical team, reaching percentages of 14.6% and 3.5%, respectively. Laine and Aarnio[7] and Sanders et al.[2] obtained larger numbers analyzing only surgeons' gloves, with 31.4% and 52% of perforations, respectively. In our study, we found a perforation prevalence of 41.4%.

Surgical time is a factor clearly related to the loss of glove integrity. Louis et al.[9] indicated that 90% of perforations are concentrated in procedures with more than 2 hours. Enz et al.[10] also found more perforations in arthroplasty reviews, which last an average of 116 minutes. Laine and Aarnio[7] indicated a difference of 3.6% of tears in surgeries with less than 1 hour to 14.6% in those of more than 1 hour. Sanders et al.[2] also stated that in the analysis of gloves in procedures with more than 3 hours, 100% presented perforations. Our article indicated a difference of 20.6% of tears in shorter procedures to 67% in long surgeries.

Although not including only orthopedic trauma procedures in their study, Chan et al.,[5] analyzed their results, also dividing by type of surgery. The result was a higher perforation rate in fixation procedures with intramedullary nail, indicating 33% of perforations, followed by 19% of tears in surgeries with open reduction. Diverging from this information, our work in internal fixations with open focus presented 49.2% of perforations, and in closed focus procedures with intramedullary stems, the result was similar to that of Chan et al.,[5] 33.3%.

Loius et al.[9] and Mafulli et al.[6] had 80% and 89% of the perforations noted only at the end of the surgery; Laine and Aarnio[7] indicated 23% of intraoperative perception when using only one glove and 36% with two gloves. Nicolai et al.[8] presented perception in 10.2% in the group with conventional gloves. Our article obtained an inverse result in relation to these values; we obtained 72.4% intraoperative identification of perforations. In addition, we concluded that the use of double gloves protected the surgeon's hands in 80.4% of the procedures in which there was loss of integrity of the glove, in these cases the inner glove remained undamaged; just as Tanner and Parkinson's[1] indicated as a protective factor.

Regarding the location of the perforations, Nicolai et al.[8] and Laine and Aarnio[7] indicated the occurrence of 73.6 and 70% of tears in the non-dominant hand; our analysis found a similar value, with 76.6%. Lee et al.[11] found a higher prevalence distribution of holes in the non-dominant index, followed by the dominant index finger and the non-dominant thumb, which agreed with our results. Our article identified 62.5% of the tears located in the index finger of the left hand, 19.2% in the right index finger, and 9.6% in the left thumb.

As a limitation of the present work, the method of detecting the loss of integrity differs from that recognized and standardized in the United States and in Europe (The American Society for Testing and Materials and The European Standards Committee), which consists in filling the glove with 1,000 ml of water and suspending it with a clamp by the collar, thus allowing water to flow through possible perforations. Another option found in the literature is to fill the glove with 500 ml of water and squeeze it to evaluate water leakage.[12] Another limitation was the non-detailing of the population or type of surgery.

Table 4 Distribution of the tear site

Perforations - local (finger)							Total
Left index	Right index	Left thumb	Right thumb	Left ring finger	Left middle finger	Palmar region	
65 (62.5%)	20 (19.2%)	10 (9.6%)	4 (3.8%)	3 (2.8%)	1 (0.9%)	1 (0.9%)	104

Table 5 Reason for perforations

Perforations - reason (when) identified						Total
Bone spicules	Kirchner wire/ guide wire	Punch	Positioning Hohmann or reduction caliper	Awl	Palpar screw to fit key	
18 (45%)	9 (22.5%)	5 (12.5%)	4 (10%)	2 (5%)	2 (5%)	40

Conclusion

Our study indicated 67% of perforations in longer surgeries against 20.6% in surgeries with duration of less than 1 hour. Open reduction surgeries showed loss of integrity in 49.2% of cases, closed reduction surgeries, in 33.3%, while percutaneous surgeries only showed loss of integrity in 15% of cases. The most affected finger was the index of the non-dominant hand, responsible for 62.5% of the perforations. In addition, in 72.4% of the times, the tear was perceived throughout the surgery, and the most frequent reason was contact with bone spiculae.

Conflict of Interests

The authors declare that there is no conflict of interests.

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Treatment of Distal Radio Vicious Consolidation: Corrective Osteotomy Through 3D Printing Prototyping*

Tratamento da consolidação viciosa do rádio distal: Osteotomia corretiva mediante planejamento com prototipagem em impressão 3D

João Carlos Belloti[1] Bernardo Vaz Peres Alves[1] Nicola Archetti[1] Luis Renato Nakachima[1] Flavio Faloppa[1] Marcel Jun Sugawara Tamaoki[1]

[1] Hand Surgery Discipline, Orthopedics and Traumatology Department, Escola Paulista de Medicina, Universidade Federal de São Paulo, São Paulo, SP, Brazil

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Address for correspondence João Carlos Belloti, Hand Surgery Discipline, Orthopedics and Traumatology Department, Rua Borges Lagoa, 786, Vila Clementino, São Paulo, SP, 04038-002, Brazil (e-mail: jcbelloti@gmail.com).

Abstract

Distal radial fractures are very common. Vicious consolidation can occur in up to one third of these fractures, resulting in wrist pain, restricted movement, and, eventually, physical limitation or disability. The treatment of this condition consists in corrective osteotomy, which requires careful preoperative planning due to its three-dimensional complexity, especially in injuries with joint involvement. Recently, prototyping based on three-dimensional (3D) reconstruction of computed tomography (CT) scans has been used for osteotomy planning in a 3D anatomical model. It allows a better understanding of the deformity in a realistic surgical approach, leading to safer, faster, and more predictable procedures. The aim of the present study is to present this technique and show its use in two clinical cases.

Keywords
- radial deformity
- radial fractures complications
- x-ray tomography
- three-dimensional printing

Resumo

As fraturas da porção distal do rádio estão entre as mais comuns do esqueleto. A consolidação viciosa pode ocorrer em até um terço dessas fraturas e acarretar restrição de movimento e dor no punho, com consequente limitação ou incapacidade laboral. O tratamento desta condição implica em osteotomia corretiva das deformidades, o que necessita de um planejamento pré-operatório criterioso em virtude de sua complexidade tridimensional, notadamente naquelas em que há acometimento articular. Assim, recentemente, tem sido utilizada a prototipagem a partir da reconstrução 3D da tomografia computadorizada (TC), o que permite o planejamento com realização da osteotomia em modelo anatômico tridimensional, com o melhor

Palavras-chave
- deformidade do rádio
- complicações fraturas do rádio
- tomografia por raios x
- impressão tridimensional

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entendimento da deformidade, aproximando-se da situação realística da cirurgia, o que torna o procedimento mais seguro, ágil e previsível. O objetivo do presente estudo é apresentar esta técnica e seu emprego em dois casos clínicos.

Introduction

Distal radial fractures are very common, accounting for up to 75% of forearm fractures.[1] Their distribution is bimodal, affecting mostly young men subjected to high-energy trauma, or patients > 65 years old, predominantly females, with bone fragility-osteopenia who suffered low-energy trauma.[1,2] An epidemiological study carried out from 1999 to 2010 in Sweden, with a population of 11.2 million inhabitants, revealed an incidence of 278 distal radial fractures for every 100,000 people, with a gender ratio of three women per man.[2] Correspondingly, the city of São Paulo, Brazil, with a population of 12.2 million inhabitants, would have > 41,000 fractures in the same period; considering that up to 33% of these fractures evolve with vicious consolidation,[3,4] approximately 13,000 patients would be affected. These figures demonstrate the importance of studies promoting the prevention and treatment of this clinical condition.

There is still no consensus on the best way to treat distal radial fractures[3] Despite constant developments in surgical techniques and implants, complications still occur; the most common include posttraumatic arthrosis, tendon rupture, median nerve compression, and vicious consolidation.[3,4] Vicious consolidation can occur in up to 33% of cases,[4] mostly after nonsurgical treatment.

Vicious distal radial consolidation can lead to a range of functional and painful limitations depending on the deformity type. Angular deformities result in an abnormal compensatory movement in the midcarpal joint that causes wrist instability followed by pain, limited movement, and degenerative arthrosis. Radial shortening deformities can lead to ulnocarpal impingement and instability of the distal radioulnar joint. Joint step deformities are highly probable of evolving with degenerative wrist changes. Knirk et al.[5] assessed functional outcomes from distal radial treatment in young adults and found out that joint congruence was a critical factor for success. Post-traumatic arthrosis occurred in 11% of patients with no joint step deformities, compared to 91% subjects with non-congruent joints.[5] These changes resulted in functional limitations that can lead to permanent work disability.

Corrective osteotomies for vicious distal radial consolidation aim to recover the normal bone anatomy for functional improvement and pain relief; in addition, these procedures prevent the progression of degenerative changes at the wrist joint. Since vicious consolidation presentations are widely variable, there are many corrective osteotomy techniques, but the common point for their indication is the presence of pain and functional limitation in patients with no advanced radiocarpal arthrosis. Surgical correction has a significant clinical benefit.[6]

Clinical and radiological analysis are critical for the good outcome of deformity correction. In addition to posteroanterior and true lateral radiographic views of both the affected and contralateral wrist, the use of computed tomography (CT) is essential to assess joint impairment and improve surgical planning, especially in vicious consolidations with joint involvement.[7]

Recently, CT with three-dimensional (3D) reconstruction has been used for prototyping in a 3D model using polylactic acid (PLA). It allows for a better understanding of the deformity, and it has great value for surgical planning.[6,7] Careful planning prior to the surgical procedure, in a 3D model with the actual dimensions from the patient, allows the surgeon to validate the type of implant to be used and to predict procedural steps and strategies. This approach reduces surgical time, improves implant selection and placement, and validates the exact location and direction of the osteotomy required for deformity correction.[7,8] About 2 years ago, a prototyping laboratory with 3D printing resources was implemented with the support from the São Paulo Research Foundation (*Fundação de Amparo à Pesquisa do Estado de São Paulo* [FAPESP, in the Portuguese acronym]), allowing us to start the development of studies using the technique described below.

Indications and Contraindications

Preoperative planning using 3D printing in a prototyped model (PLA) of distal radial vicious consolidation is recommended for all corrective surgeries due to the complex anatomical distortion related to this clinical condition. This strategy allows for a better 3D understanding and real correction in patients who present anatomical deformity and significant functional limitation.

Corrective osteotomies for distal radial vicious consolidation are contraindicated in patients with low demand for daily activities, mild anatomical deformity, little functional restriction, long-standing injury, or radiocarpal degenerative osteoarthritis. Thus, in deformities with sustained articular or extra-articular incongruence, we recommend a more specific assessment of the degree of joint cartilage degeneration using nuclear magnetic resonance or wrist arthroscopy; correction with osteotomy is contraindicated if severe joint degeneration is present.

Preoperative Technique

Bilateral CT scans of the wrists must be performed in 1 mm-thickness sections. The file is generated in Digital Imaging and Communications in Medicine (DICOM) format and standardization and then imported into a 3D medical image processing and reconstruction software (InVesalius version

3.1.1, Centro de Tecnologia da Informação Renato Archer, Campinas, SP, Brazil). This 3D model of the distal radio is exported as a Standart Tessellation Language/STereo-Lithography (STL) file and the Simplify3D software (Simplify3D: Cincinnati, Ohio, USA) translates the information from the . stl file into instructions for the 3D printer. The material for 3D printing is PLA.

The corrective osteotomy was planned after preparing prototypes from the deformed distal radius and the normal contralateral bone. Plate positioning, screw length, and osteotomy location must be evaluated using C-arm fluoroscopy for proper selection of surgical materials.

Surgical programming with 3D reconstruction and PLA model prototyping allows the surgeon to better understand the deformity, plan the exact osteotomy location under real perspective and determine the best type of implants and their specifications. As such, it anticipates and optimizes surgical stages, resulting in a safer, faster, more predictable deformity correction. This research project was analyzed and approved by the ethics committee under the number 9253251119.

Selected Cases

Case 1–Female patient, 46 years old, with sequelae from a left distal radial fracture. This injury occurred 4 years ago, when it was treated with plastered immobilization. She presents pain and limited flexion at the left wrist. Posteroanterior and true lateral radiographies of the left wrist show vicious consolidation (►**Figure 1**). Bilateral distal radius prototyping based on CT scans with 3D reconstruction improved deformity understanding and surgical planning (►**Figure 2**).

Case 2–Male patient, 47 years old. The subject presented a distal fracture at the right radius 4 months ago, which was submitted to nonsurgical treatment. Wrist radiographs show vicious consolidation with loss of volar inclination and widening of the joint surface of the distal radius with radiocarpal joint step (►**Figure 3**). As in the previous case, a PLA model from both distal radial bones of the patient was printed and used to outline the osteotomy point and deformity correction. (►**Figures 4** and **5**).

Discussion

In the early 1980s, Charles Hull developed and conceptualized 3D printing, allowing the creation of objects based on material deposition layer by layer. Since then, 3D printing advanced and models present better resolution, faster production, and lower cost; in addition, there is a greater variety of materials for printing.[7]

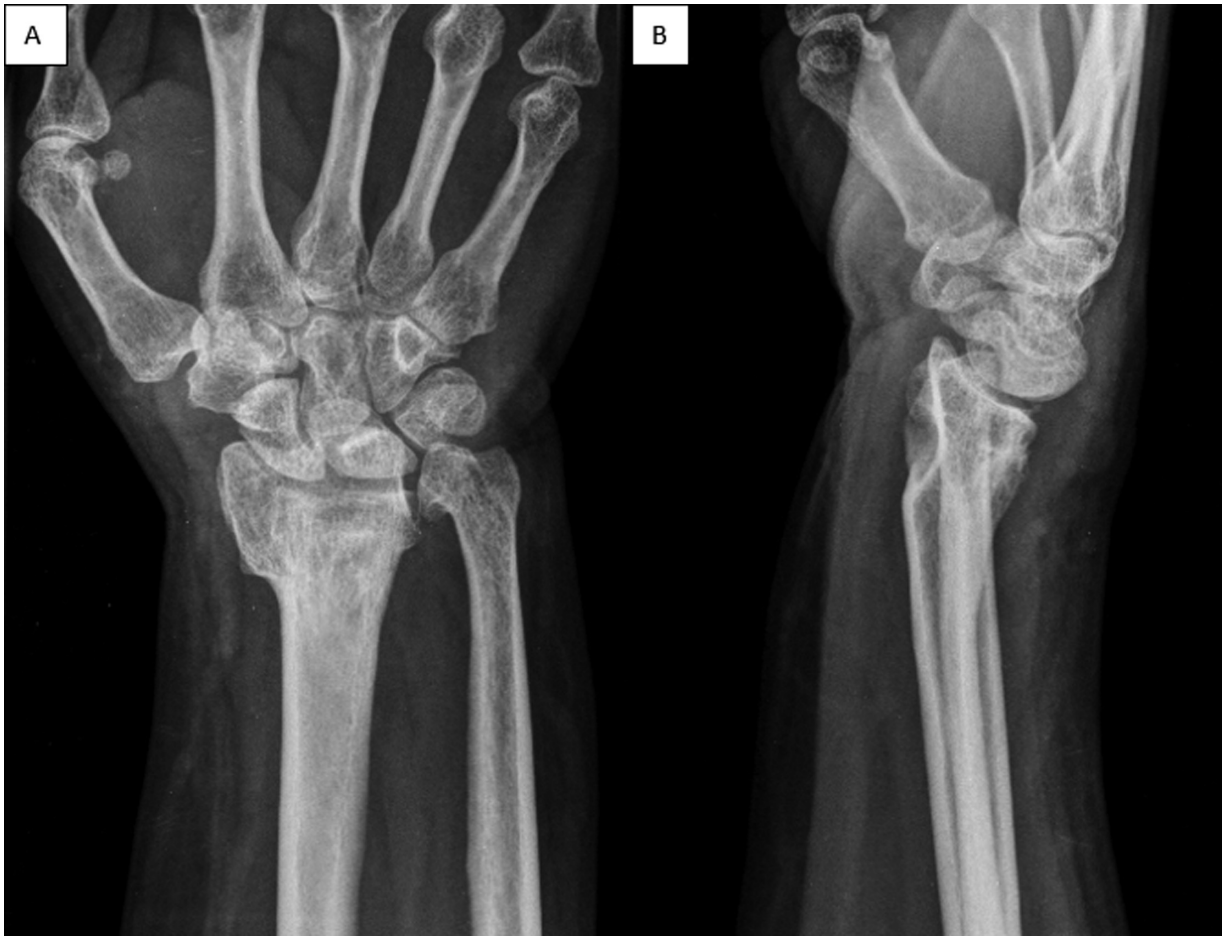

Fig. 1 Posteroanterior (A) and true lateral (B) radiographies of the left wrist showing vicious consolidation with dorsal deviation, radial shortening, ulnar head deformity, and adaptive carpal instability.

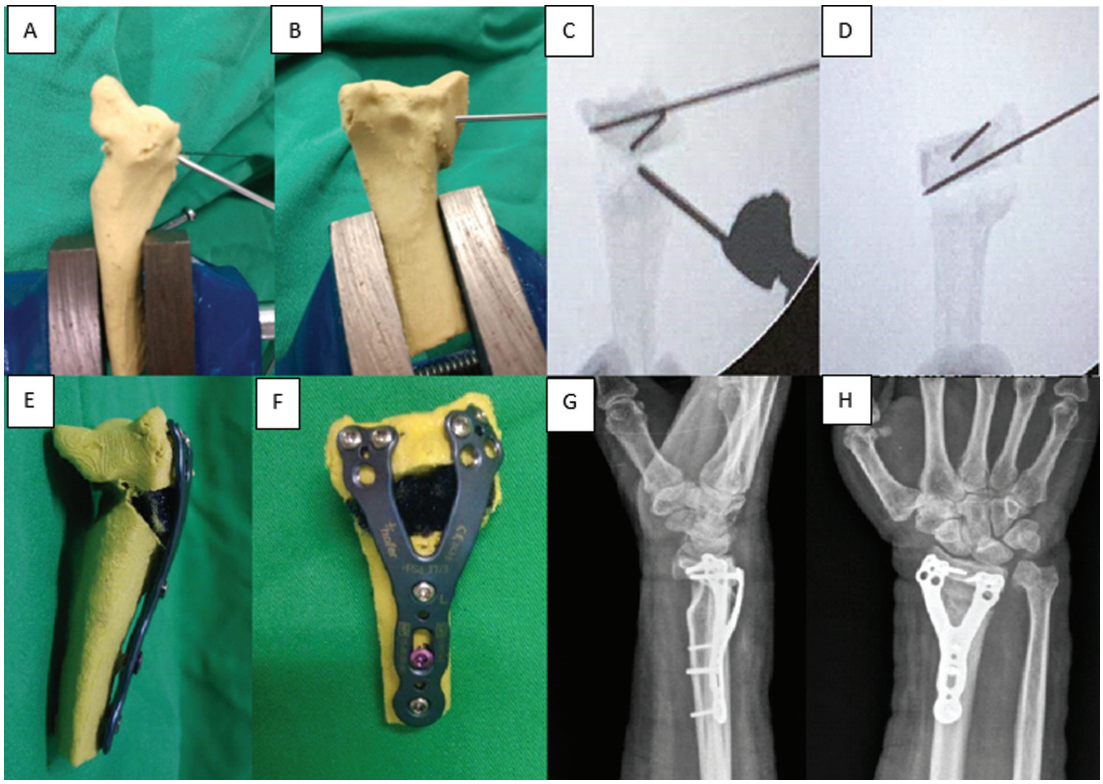

Fig. 2 Planning and surgery with prototyping in a PLA model: guidewires placement for osteotomy in model (A, B) and fluoroscopic control of model osteotomy (C, D), prototyping after corrective osteotomy and dorsal plate fixation (E, F). Postoperative follow-up radiographies (G, H).

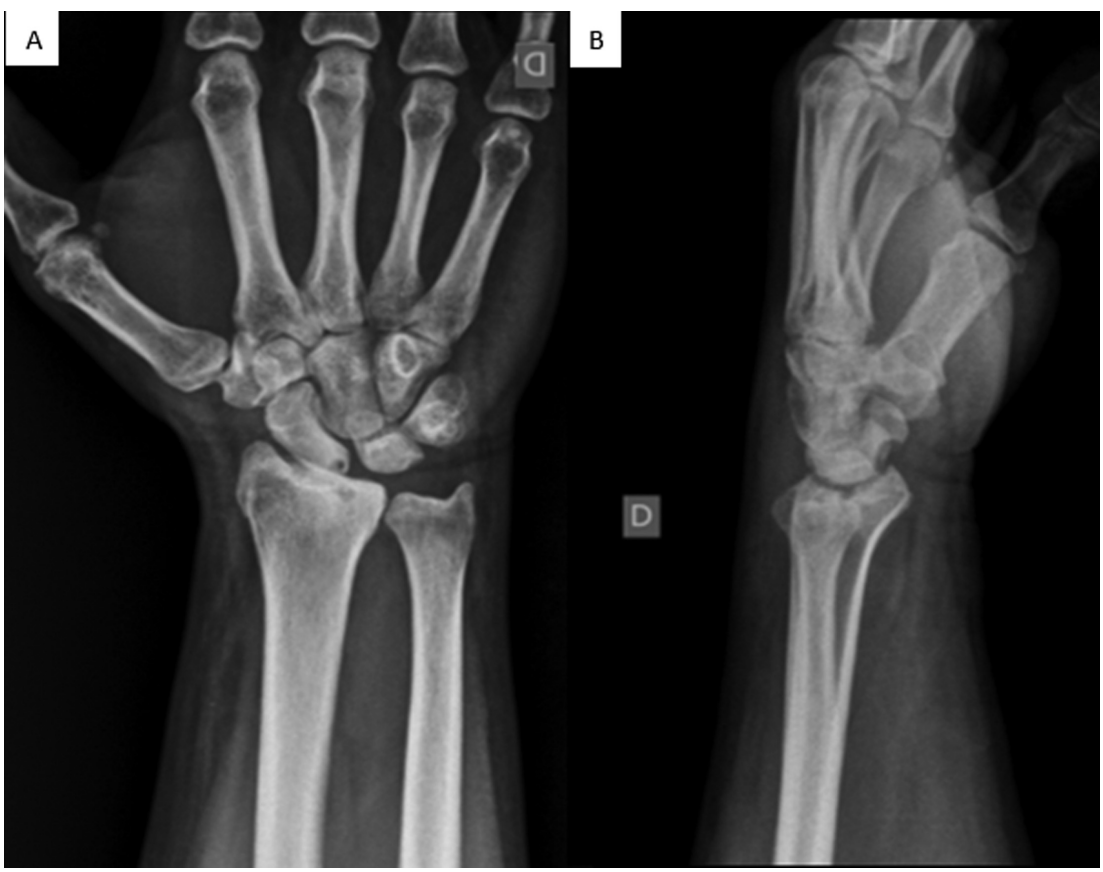

Fig. 3 Posteroanterior (A) and lateral (B) radiographies of the distal portion of the right radius showing vicious consolidation with radiocarpal joint step and loss of normal radial volar tilt.

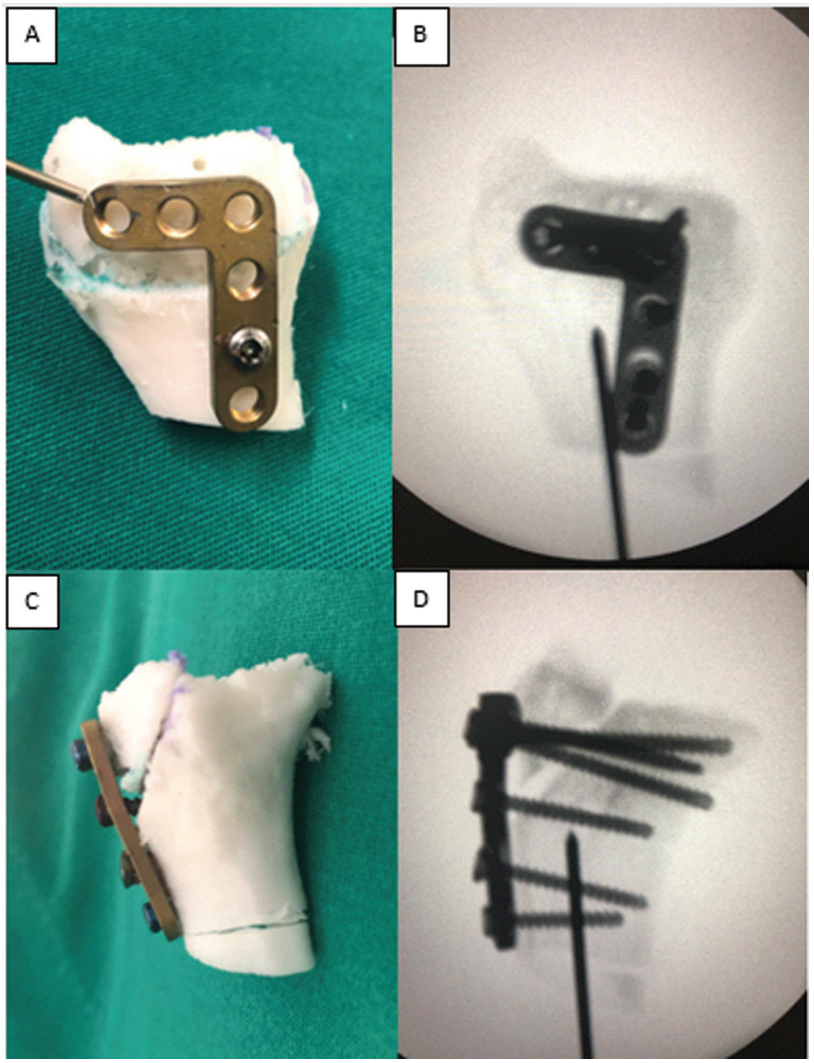

Fig. 4 Dorsal view: planning of the corrective articular osteotomy of the distal portion of the right radius in a printed model (A), and fluoroscopic image after locked dorsal plate fixation at the distal radius (B). Lateral view: articular osteotomy of the distal radius and locked dorsal plate fixation in a printed model (C), and fluoroscopic image with corrected radiographic parameters (D).

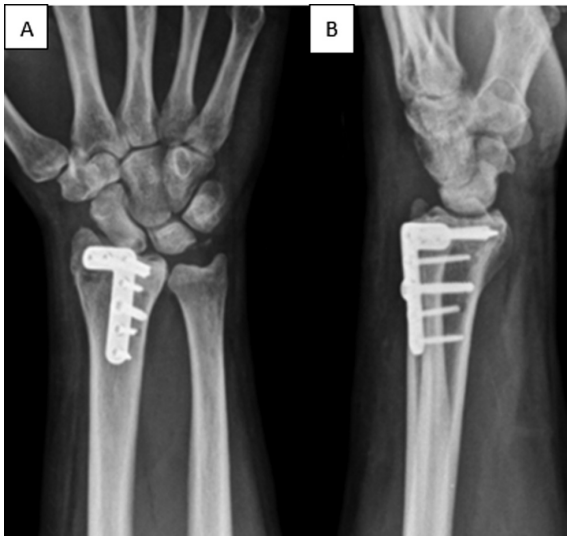

Fig. 5 Posteroanterior (A) and lateral (B) radiographies 4 weeks after surgery. Joint step reduction and enlargement of the radial articular surface as performed during the preoperative planning in a PLA model.

The use of 3D prototyping in orthopedic surgery allows for a better 3D understanding of the fracture or its vicious consolidation. Visualization and manipulation of models, which are true to the patient's anatomy, help surgical programming and intraoperative decision making.

Final Considerations

In cases of vicious consolidation of the distal portion of the radius, printing a model based on the 3D reconstruction of CT scans helps the surgeon to select proper implants and determine the direction and location for corrective osteotomy. This preoperative planning saves surgical time, resulting in a lower rate of complications and in a more favorable functional outcome.

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Conflict of Interests
The authors have no conflict of interests to declare.

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Candida parapsilosis Infection after Lumbosacral Arthrodesis with a PEEK TLIF Interbody Fusion Device: Case Report

Infecção por Candida parapsilosis em pós-operatório de artrodese lombossacra com dispositivo de fusão intersomático TLIF em PEEK: Relato de caso

Marcelo Wajchenberg[1,2] Nelson Astur[1,3] Michel Kanas[1,2] Thiago Zinsly Sampaio Camargo[1] Sérgio Barsanti Wey[1] Délio Eulalio Martins[1,4]

[1] Hospital Israelita Albert Einstein, São Paulo, SP, Brazil
[2] Orthopedics and Traumatology Department, Universidade Federal de São Paulo, São Paulo, SP, Brazil
[3] Santa Casa de Misericórdia de São Paulo, São Paulo, SP, Brazil
[4] Universidade Anhembi Morumbi, São Paulo, SP, Brazil

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Address for correspondence Marcelo Wajchenberg, MD, PhD, Av. Albert Einstein, 627/701, consultório 306, 3º andar, bloco A1, Morumbi, São Paulo, SP, 5652-900, Brazil (e-mail: marcelow@einstein.br).

Abstract

Spondylodiscitis is an uncommon but serious complication after spine surgeries, and its main etiologic agent is *Staphylococcus aureus*. Fungal infections are rare and mostly caused by *Candida albicans*. We report the clinical case of a 69-year-old male patient who underwent a L2-S1 arthrodesis for degenerative scoliosis correction. He presented an infection 2.5 months after the procedure, a spondylodiscitis at L5-S1 levels, caused by *Candida parapsilosis*. The treatment consisted of surgical material removal, tricortical iliac graft placement in an anterior approach (L5-S1), lumbopelvic fixation (from T10 to the pelvis) in a posterior approach, and drug treatment with anidulafungin and fluconazole. This last medication was administered for 12 months, with good clinical outcomes.

Keywords
- fungal infections
- spondylodiscitis
- *Candida parapsilosis*

Resumo

As espondilodiscites são complicações infrequentes, porém graves em pós-operatórios de cirurgias da coluna vertebral, tendo como principal agente etiológico o *Staphylococcus aureus*. As infecções fúngicas são raras, sendo a *Candida albicans* a principal representante desse grupo. Relatamos o caso clínico de um paciente do sexo masculino, 69 anos, operado com artrodese de L2 a S1 para correção de escoliose degenerativa. O paciente apresentou quadro clínico infeccioso 2 meses e meio após o procedimento, relacionado à espondilodiscite L5-S1, causada por *Candida parapsilosis*. O tratamento consistiu na remoção do material cirúrgico, colocação de enxerto tricortical de ilíaco pela via anterior (L5-S1) e fixação lombopélvica (de T10 à pelve) pela via posterior, além de iniciar o tratamento medicamentoso com anidulafungina e fluconazol, mantendo essa última medicação por 12 meses, com boa evolução clínica.

Palavras-chave
- infecções fúngicas
- espondilodiscite
- *Candida parapsilosis*

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Introduction

Infections after spinal surgeries are infrequent but potentially serious. This is especially true when implants are involved, since they can perpetuate the infectious process and result in chronic spondylodiscitis.[1] In these cases, the main etiologic agent is *Staphylococcus aureus*, but other bacteria, including *Streptococcus* spp. and gram-negative bacilli, can cause infection, in addition to other organisms, such as *Mycobacterium tuberculosis* and, more rarely, fungi.[2] *Candida albicans* is the most frequent fungi in these cases, affecting mainly immunosuppressed and alcoholic subjects.[2]

We report the case of a healthy 69-year-old patient who developed an infection after a lumbosacral spine arthrodesis. *Candida parapsilosis* was isolated at the L5-S1 level, which had an interbody fusion device with a polyether ether ketone (PEEK) structure.

Case Report

A healthy 69-year-old male patient was unsuccessfully clinically treated for low back pain for > 6 months and underwent surgery in October 2018 for L4-L5 and L5-S1 neural decompression and disc herniation removal. The patient had partial improvement but symptoms progressively recurred, with no signs of infection.

Due to the persistence of symptoms and degenerative spinal disease, in addition to the need for neural decompression expansion, a broad laminectomy was performed at the L4-L5 and L5-S1 levels. This procedure corrected the scoliotic deformity, using PEEK interbody devices, bone grafting at L3-L4, L4-L5 and L5-S1 levels, and bilateral fixation with pedicle screws between L2 and S1 in January 2019.

Two and a half months after surgery, the patient reported progressively increased low back pain, irradiating mainly to the right leg, and febrile episodes. The patient was hospitalized, and a magnetic resonance imaging (MRI) (►**Figure 1**) revealed signs of spondylodiscitis at L5-S1, and a collection (abscess) within the vertebral canal compressing the dural sac.

Based on the clinical picture and MRI findings, a surgery was performed for neural decompression with implants maintenance and infectious collection drainage. The specimens were sent for microbiological analysis, revealing *C. parapsilosis*.

Specific treatment was started, with intravenous administration of antifungal drugs, anidulafungin and fluconazole, and a good clinical response. After 20 days, the patient reported pain recurrence and worsening general clinical condition. A computed tomography (CT) scan (►**Figure 2**) and a follow-up MRI (►**Figure 3**) showed an increased collection in the L5-S1 disc space and signs of S1 screws loosening, mainly on the right side.

Thus, 1.5 month after surgical cleaning, which revealed the organism, a new surgery was performed, with an initial posterior approach to remove the L5-S1 screws, extending fixation to the pelvis with iliac screws and removing the graft from the iliac crest by an anterior approach.

Next, the patient was placed in the supine position and a retroperitoneal approach was performed to remove the L5-S1 interbody device (TLIF), which was loose, with no signs of consolidation. Extensive surgical cleaning, debridement, and collection of material for culture were followed by placement of a tricortical iliac graft under pressure.

The material collected during surgery confirmed the presence of *C. parapsilosis*. After surgery, the patient was treated clinically with fluconazole for 12 months, with no complications and gradual improvement. Follow-up tests

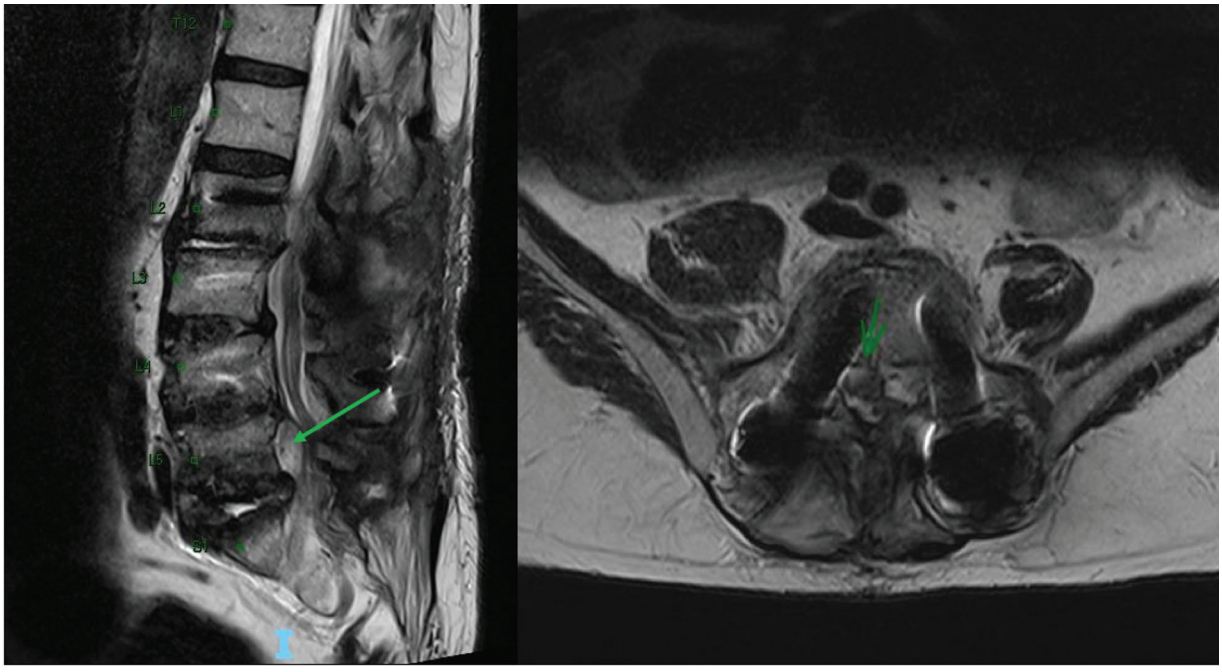

Fig. 1 Left sagittal and right axial T2-weighted magnetic resonance images showing an abscess posterior to the L5 vertebral body.

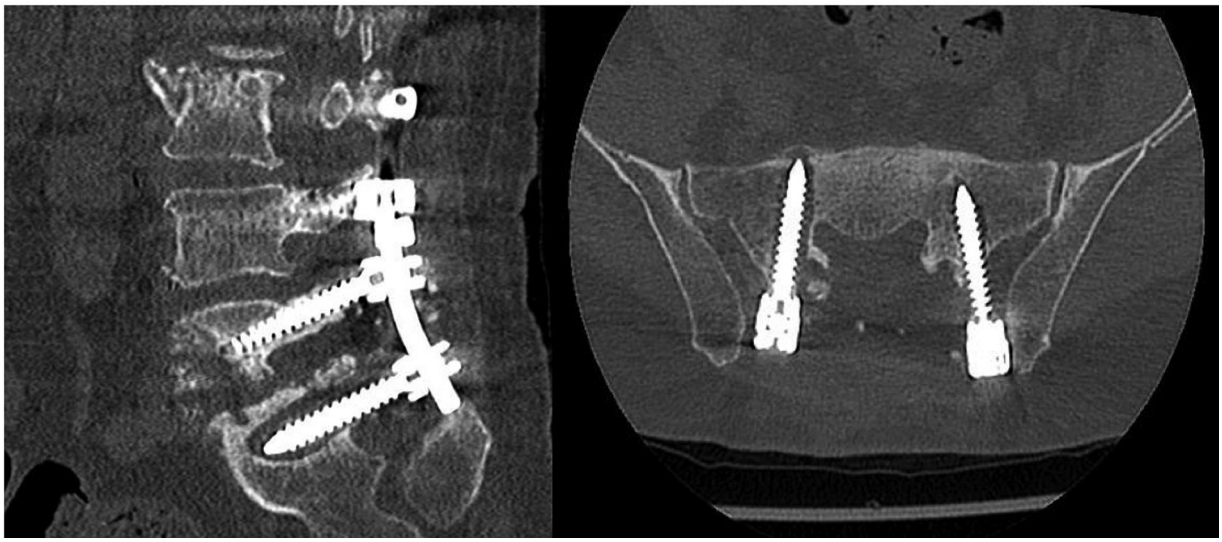

Fig. 2 Left sagittal and right axial computed tomography scans showing signs of S1 pedicle screws loosening, mainly on the right side.

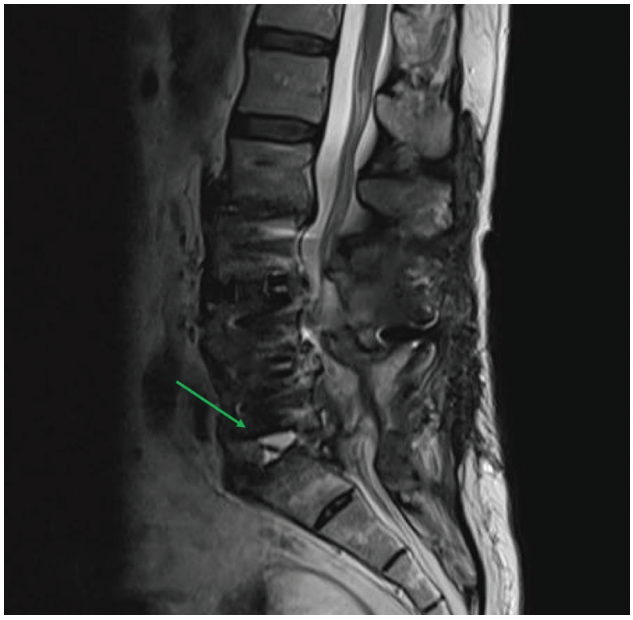

Fig. 3 Sagittal T2-weighted magnetic resonance image showing hypersignal at the L5-S1 disc space referring to the local fluid collection.

(lumbosacral spine x-rays) showed signs of lumbosacral arthrodesis consolidation (►**Figure 4**).

Discussion

Spinal fungal infections occur mainly in subjects with some degree of immunodeficiency, which can be caused by excessive use of alcohol or drugs, malnutrition or wasting conditions.[1–4] Colombo reports that most cases of systemic infection by *Candida* spp. are endogenous, resulting from the translocation of the organism through the gastrointestinal tract, which is richly colonized by *Candida* spp. in up to 70% of the normal population.[4] Such translocation may occur after major surgeries due to ileus and antibiotic therapy.

In addition, contamination may be exogenous, through the hands of health professionals, in patients with central vascular catheters or receiving contaminated prostheses or parenterally administered contaminated solutions.[4]

In the case reported here, the patient complained of fever, increased lower back pain, and decreased strength in the lower limbs, all signs related to the formation of a collection (abscess) within the vertebral canal. These signs were reported by Cho et al.,[1] who emphasized that up to 20% of the patients may present worsened neurological condition.

As for specific treatment, there are few reports of an infectious process associated with some type of implant. According to Colombo et al.,[4] *C. parapsilosis* proliferates in glucose solutions with a great capacity for biofilm production, justifying the lack of an adequate clinical response only with specific medications and surgical cleaning, with no implant removal.

Blecher et al.[3] reported a case of a chronic alcoholic patient who developed a *C. parapsilosis* infection after receiving an eXtreme Lateral Interbody Fusion (XLIF) type implant (also in PEEK) through a minimally invasive (anterolateral) approach at the L3-L4 level with previous L4-S1 arthrodesis.

Richauld et al.,[5] in a series of 28 patients with *Candida* spondylodiscitis, noted that the prolonged use ($>$ 6 months) of antifungal medication led to fewer deaths and neurological complications and that the initial administration of combined medications provided better outcomes, with fewer sequelae.

Spondylodiscitis caused by *C. parapsilosis* is a serious complication of spine surgery, and it must be diagnosed and treated early through a surgical approach for abscess drainage. In addition, a specimen must be collected for organism identification to determine the appropriate drug therapy, which must start with two drugs and use of fluconazole for $>$ 6 months.

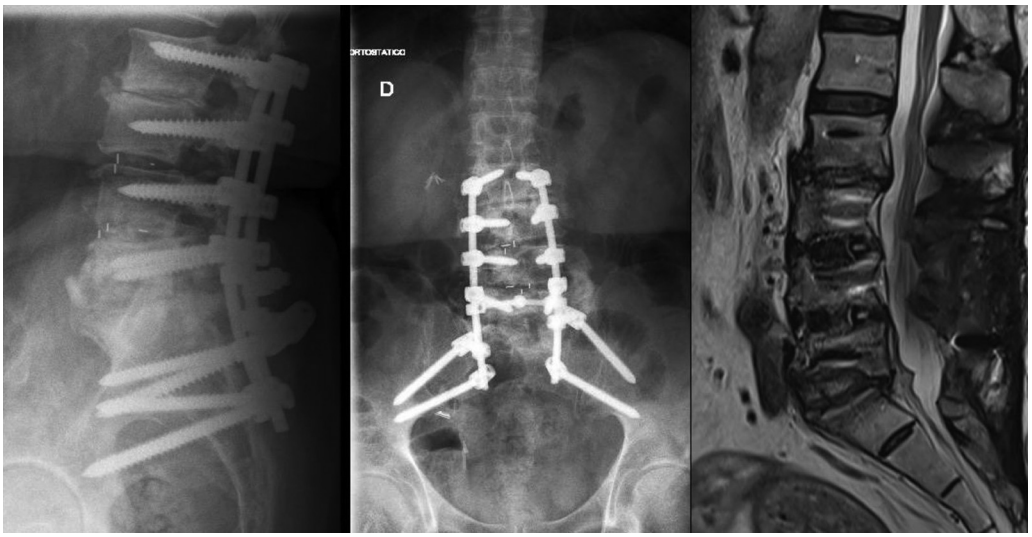

Fig. 4 Lateral (left) and front (center) spine radiographs showing signs of arthrodesis (L2-S1 fusion) and sagittal T2-weighted magnetic resonance image (right) showing signs of infection resolution.

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Conflicts of Interest
The authors have no conflicts of interest to declare.

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Osteonecrosis of the Intermediate Cuneiform: A Case Report*

Osteonecrose do cuneiforme intermédio: Relato de caso

Gustavo Araujo Nunes[1,2,3] Matheus Levy Almeida Taveira de Souza[4] Bruno Maciel Braga[5] Mateus Martins Marcatti[1,2] Fabrício Melo Bertolini[2] Otaviano de Oliveira Junior[1,2]

[1] Department of Orthopedics, Instituto Orizonti, Belo Horizonte, MG, Brazil
[2] Foot and Ankle Surgery Group, Hospital Universitário Ciências Médicas (FCMMG), Belo Horizonte, MG, Brazil
[3] Department of Orthopedics, Hospital da Baleia, Belo Horizonte, MG, Brazil
[4] Department of Orthopedics, Hospital Mater Dei, Belo Horizonte, MG, Brazil
[5] Department of Orthopedics, Hospital São José, Conselheiro Lafaiete, MG, Brazil

Address for correspondence Gustavo Araujo Nunes, MD, Rua Prof. Otavio Coelho de Magalhaes, 111, Mangabeiras, Belo Horizonte, MG, 30210-300, Brazil (e-mail: gustavoanunes@hotmail.com).

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Abstract

Osteonecrosis is a disease that rarely affects the bones of the foot. When present, it is more common in the talus and in the navicular. Cases of osteonecrosis of the intermediate cuneiform are extremely rare, and after a thorough bibliographic review, we found only five reports in the literature, all of them in pediatric patients. Below, we present the case of an adult patient with osteonecrosis of the intermediate cuneiform that was resistant to conservative treatment. Thus, we proposed a surgical approach with good results. *Level of Evidence V; Therapeutic Studies; Expert Opinion*.

Keywords
- osteonecrosis
- cuneiform bones
- adult

Resumo

A osteonecrose é uma doença que raramente afeta os ossos do pé. Quando presente, ela é mais comum no tálus e no navicular. Casos de osteonecrose do cuneiforme intermédio são extremamente raros, e após uma revisão bibliográfica minuciosa encontramos apenas cinco relatos na literatura, sendo todos eles em pacientes pediátricos. A seguir, apresentamos o caso de um paciente adulto com osteonecrose do cuneiforme intermédio em resistente ao tratamento conservador. Portanto, propusemos uma abordagem cirúrgica com bom resultado. *Nível de Evidência V; Estudos Terapêuticos; Opinião de Especialista*.

Palavras-chave
- osteonecrose
- ossos cuneiformes
- adulto

* *Study conducted at the University Hospital of Medical Sciences (FCMMG), Belo Horizonte, MG, Brazil.*

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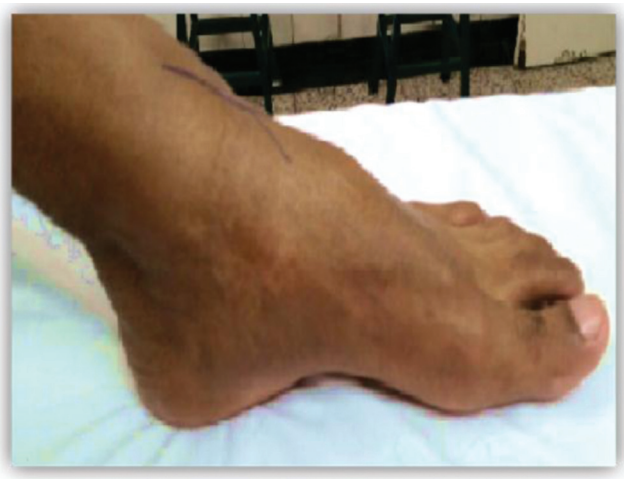

Fig. 1 Foot photograph in profile. Edema is noted in the dorsal region of the midfoot associated with an increase in the medial plantar arch. Source: Author's personal archive.

Introduction

Osteonecrosis, also known as avascular necrosis, is caused by the reduction of blood supply to the bones, which leads to failure of the bone replacement mechanism. If not diagnosed and treated correctly, it can evolve with collapse and joint degeneration.[1] It is not common in the bones of the foot, and, when it occurs, it is more prevalent in the talus and navicular.[1,2] Affection of the intermediate cuneiform is extremely rare, with only five case reports described in the literature,[3] all in pediatric patients.

This pathology usually affects athletes and/or military personnel subject to repetitive microtrauma and stress fractures, or those with rheumatological diseases in chronic use of corticosteroids. Other associated risk factors are radiation therapy, chemotherapy, organ transplantation, and alcohol abuse.[2] The initial treatment is conservative, with non-weight-bearing, use of orthoses, and physical therapy. In cases in which there is no pain relief, surgical intervention is indicated. There are some techniques reported in the literature, but due to the rarity and scarcity of studies of this pathology in the cuneiform bone, the treatment remains controversial and challenging.[1,2]

The aim of the present article is to report a rare case of osteonecrosis of the intermediate cuneiform bone in an adult patient treated using the surgical approach proposed by the authors.

Case Report

The present work was submitted to the ethics committee with registration at Plataforma Brasil under the CAAE number: 99919318.6.0000.5122.

The patient DL, male, 24 years old, military, without comorbidities, presented pain and edema in the dorsal region of the foot, with no history of trauma, associated with limited sports activities, with progressive worsening for approximately 6 months.

On physical examination, a subtle, flexible cavovarus foot was observed that corrected itself in the first stage of the Coleman block test, associated with a shortening of the gastrocnemius muscle demonstrated by the Silverskiold test, in addition to edema and pain on palpation on the midfoot. (►**Figure 1**). There were no signs of ligament instability and associated tendinopathies. On the radiographic examination (►**Figure 2A**), a radiolucent line was noted in the dorsal cortex of the cuneiform bone, the angle formed between the ground and the lower edge of the calcaneus (pitch of the calcaneus) showed a slight increase, with a value of 27°, and a normal angle between the axis of the talus and the first metatarsal (Meary angle). In T2-weighted sequences, the magnetic resonance imaging (MRI) showed diffuse areas with hypersignal (bone edema), associated with vertical lines with hyposignal, suggesting areas of bone necrosis. (►**Figure 2B**).

The patient was initially submitted to conservative treatment performed with non-weight-bearing restrictions and using an orthosis until the pain decreased, followed by physiotherapy rehabilitation and an attempt to gradually return to daily activities. There was no satisfactory evolution

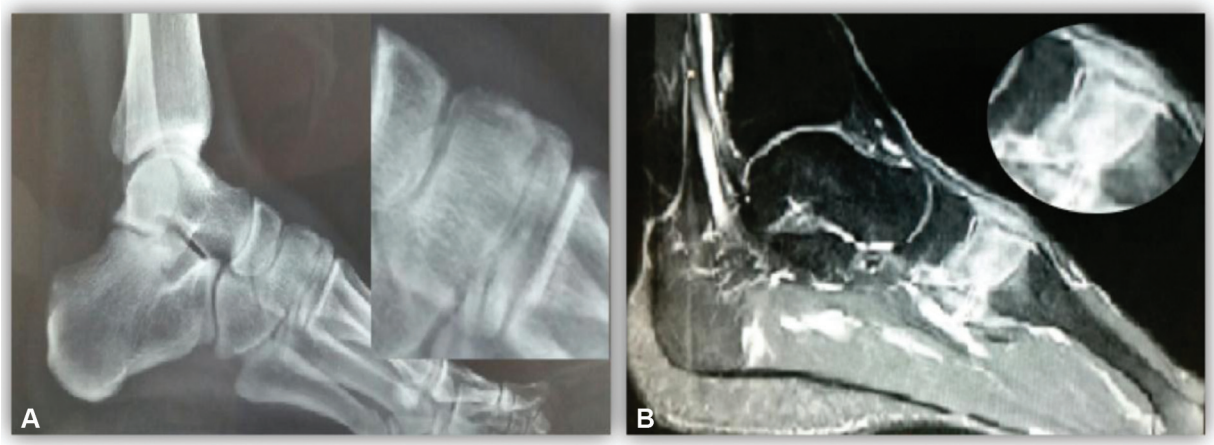

Fig. 2 (A) Radiographic examination in profile view. A radiolucent line can be seen in the dorsal cortex of the cuneiform. (B) T1-weighted sagittal magnetic resonance imaging demonstrating a mixed pattern of a diffuse hypersignal alternating with areas of hyposignal.

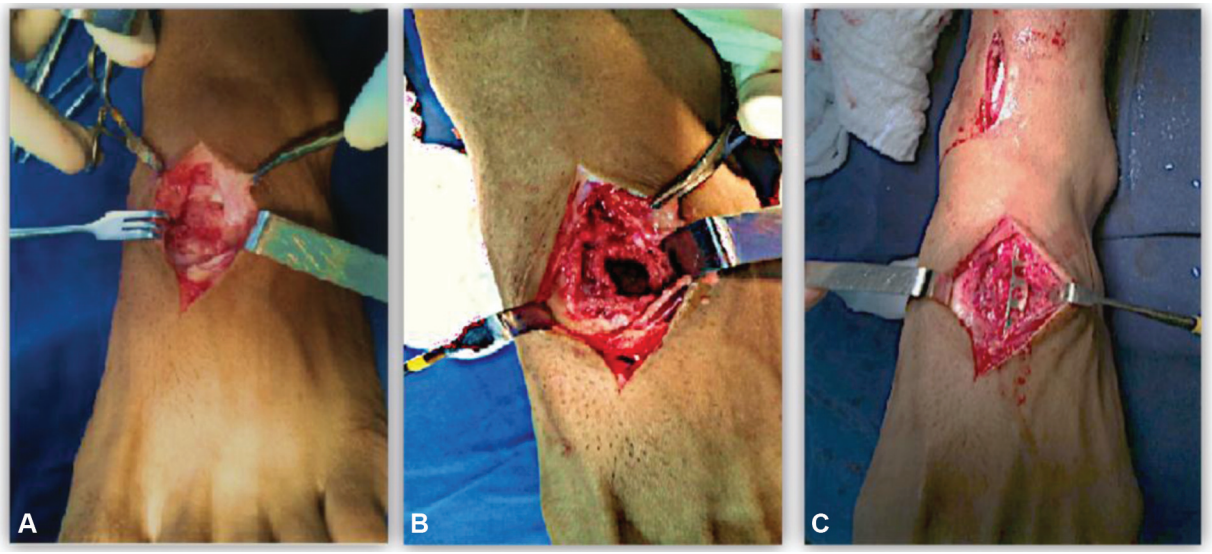

Fig. 3 (A) Dorsal surgical access to the intermediate cuneiform. Necrotic bone with ill-defined edges is observed. (B) Dorsal bone window followed by bone curettage and resection of devitalized and necrotic tissue. (C) Bone filling with autologous graft fixed with bridge plate. Source: Author's personal archive.

with conservative treatment and due to this, the evolution time, and the findings in the image examination (MRI), surgical treatment was chosen.

The first surgery was performed through dorsal surgical access to the intermediate cuneiform bone, in which we visualized a necrotic bone with an extensive resorption zone, preserving only the joint surfaces. A bone opening was made with a dorsal window, debridement, and curettage, to remove necrotic and devitalized tissue. After this stage, we performed the filling of the medial cuneiform medullary cavity with autologous spongy bone graft, removed from the distal tibia. The cortical bone window removed at the beginning of the procedure was repositioned, and a 2.8-mm bridge plate was fixed (to the navicular and 2nd metatarsal bones) in order to stabilize the graft and dissipate forces from the midfoot. The sequence of the surgical technique is demonstrated in ►**Figure 3**. The necrotic and devitalized bone tissue removed from the cuneiform bone was sent for anatomopathological examination, which confirmed the diagnosis of osteonecrosis.

Weight-bearing was not allowed for 8 weeks, followed by 3 months of physical rehabilitation. At that time, the patient already had significant clinical improvement. During follow-up, control imaging tests showed incorporation of the bone graft into the intermediate cuneiform (►**Figure 4**).

After total consolidation, we proceeded to the second treatment period, which occurred 6 months after the first surgery. In this second intervention, the removal of the synthesis material and correction of the subtle cavovarus foot deformity were performed. Through previous dorsal access, the plate was removed, and a biologically viable, stable intermediate cuneiform was visualized with incorporation of the bone graft (►**Figure 5**). After removing the plaque and releasing the joint, we performed the treatment of the subtle cavovarus foot with osteotomy extending the 1st metatarsus, releasing the plantar fascia, and stretching the medial gastrocnemius.

The patient showed excellent evolution, underwent physical rehabilitation with return to sports activities without complications. Three months after the second surgery, the patient was already practicing light running and exercises without impact at the gym.

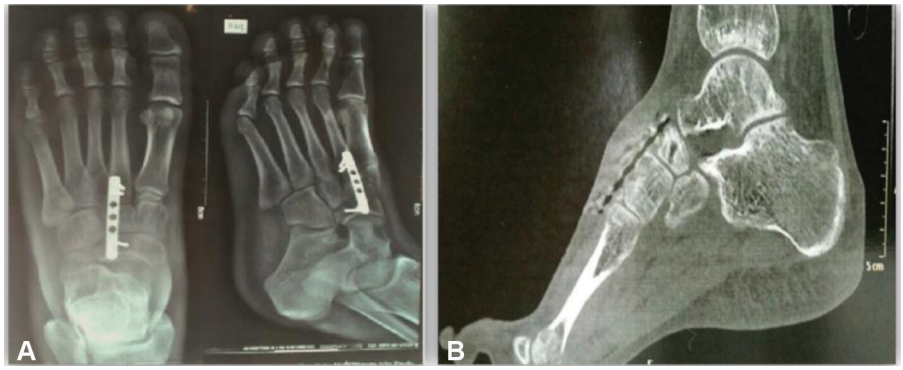

Fig. 4 Imaging tests performed six months after surgery. We evidenced incorporation of the bone graft. (A) Radiography. (B) Computed tomography.

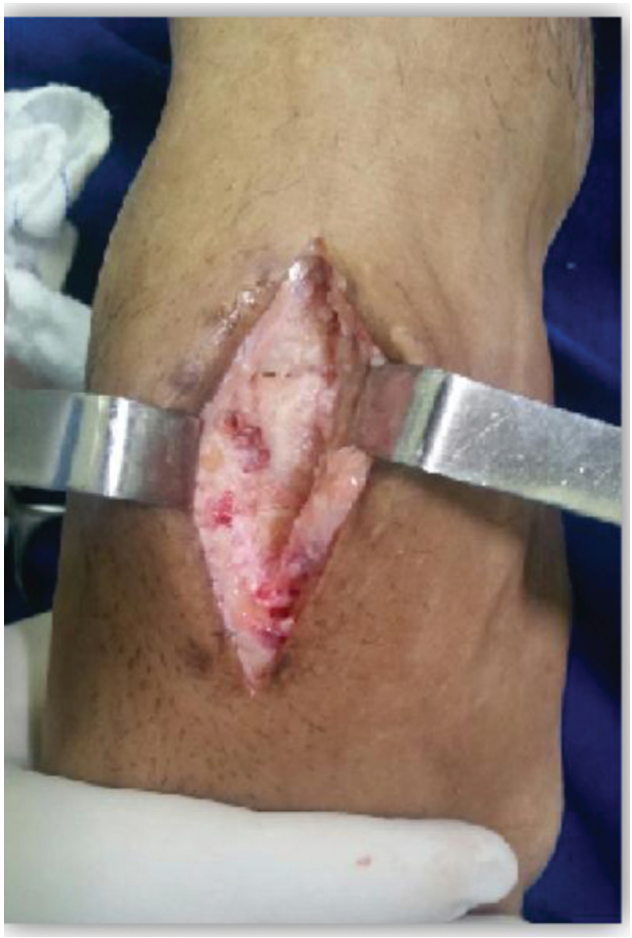

Fig. 5 Dorsal view of the midfoot showing the intraoperative appearance of the intermediate cuneiform bone after plaque removal. Source: Author's personal archive.

In the last evaluation, 16 months after the 2nd surgery, the patient reported that he performed running and impact activities without limitations or pain complaints. He classified the result as excellent and reports that he would perform the procedure again.

Discussion

There are different forms of approach for the treatment of osteonecrosis, but most publications address the treatment of necrosis of the femoral head. In the foot and in the ankle joint, the literature makes reference with greater emphasis to the involvement of the talus and the navicular.[1,2] After reviewing the literature, only five articles were found reporting cases of osteonecrosis of the intermediate cuneiform bone in pediatric patients treated conservatively.[3–5] No report of this pathology was found in the national literature.

The treatment of avascular necrosis of the tarsal bones is still controversial and does not have specific protocols, so it is possible to state that the first choice should be conservative with rest, weight-bearing restrictions, orthoses, and physical therapy.[1,2] In several reports of this pathology in other anatomical sites, patients showed clinical improvement with this conduct.[2–4]

Regarding surgical treatment, in the earliest cases without joint degeneration, surgeries that preserve the joint are indicated. This approach can be achieved by some surgical techniques, such as intramedullary bone decompression, performed alone or associated with the use of bone graft that can be vascularized or not. The vascularized bone graft of the cuboid is a surgery described to treat initial cases of talus osteonecrosis with minimal subchondral collapse.[6] Some authors have shown excellent results from patients with talus osteonecrosis treated with this technique.[6] In contrast, Chew et al.[7] showed medial cuneiform osteonecrosis treated only through microperforations with good clinical and radiographic results. Considering the rarity and heterogeneity of this pathology, there are no comparative studies that contemplate a superior technique for the treatment of osteonecrosis in the early stages.[6] What we can actually say is that in advanced cases with joint degeneration, arthrodesis is the ideal procedure that allows the maintenance of bone length and architecture.[3] Although the patient in the study did not present any degenerative signs, it was an advanced osteonecrosis because during the surgical approach, bone involvement of the entire length of the intermediate cuneiform was observed, associated with subchondral involvement, and, because of this, the authors opted for the use of non-vascularized bone graft in large quantity for complete filling of the medullary canal.

Another treatment variant is the way to fix the graft. McLeod et al.[2] showed a case of tibial osteonecrosis in which the lesion was opened with an anterior bone window, curettage, and removal of necrotic tissues, followed by filling with bone graft and fixation with a plate to stabilize the graft. This approach was used in the present study when performing a fixation with a bridge plate, which was fixed to the navicular and the second metatarsal. The authors believe that graft stabilization is essential for a successful treatment. Fixation with a plate, in addition to stabilizing the graft, helps to reduce mechanical stress by dissipating energy in that region, favoring the process of bone reintegration.

Osteonecrosis can be secondary to stress fractures caused by recurrent microtrauma and intrinsic factors represented by muscle deformities and imbalances that alter biomechanics and the load distribution in the lower limbs. In their study, Li et al.[9] observed the relationship between hindfoot alignment and navicular osteonecrosis. They treated 14 feet with necrosis of the navicular only with realignment of the hindfoot, performed through the valgus osteotomy of the calcaneus, without directly addressing the navicular. They observed excellent clinical and radiographic results, reinforcing the relationship of alignment and biomechanical overload that occurs in the midfoot through lower limb deformities.[9] According to Bui-Mansfield et al.,[10] cuneiforms, due to their anatomical location, are susceptible to compression forces, which can be exacerbated by changes in the mechanical axis, muscle imbalances and specifically by pathologies of the plantar fascia. The patient in this study had a subtle cavovarus foot as an intrinsic factor associated with a shortening of the gastrocnemius, and, due to this, after removing the plaque, the cavovarus foot correction was

achieved with the first metatarsal extension osteotomy, plantar fasciotomy, and gastrocnemius elongation. The authors emphasize that the restoration of biomechanics must be a complementary stage of treatment, since it corrects an intrinsic factor related to the genesis of the pathology in question, improving the functional results and reducing the chance of recurrence. Regarding the correction of the deformity, as it is a subtle, flexible cavovarus foot, originating from an increased equinus deformity of the first ray, which was corrected in the first stage of the Coleman blocks, the treatment occurred through an osteotomy of extension of the first metatarsus associated to the soft tissue procedures already described.

The authors present a rare case of osteonecrosis of the intermediate cuneiform in an adult patient treated surgically with decompression and bone grafting temporarily fixed with a bridge plate, followed by realignment of the mechanical axis, with excellent clinical result.

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Conflicts of Interest
The authors declare that there are no conflicts of interest.

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Missed Tillaux Fracture and Syndesmosis Injury in Adult: Arthroscopic Assisted Reduction and Fixation*

Fratura de Tillaux não percebida e lesão por sindesmose em adultos: Redução e fixação artroscópica assistida

Nuno Oliveira[1] Pedro Pinho[1] Mário Baptista[1] Daniel Freitas[1] Pedro Varanda[1,2] Bruno S. Pereira[1,2,3,4]

[1] Orthopedics and Trauma Surgery Department, Hospital de Braga, Sete Fontes, São Victor, Braga, Portugal
[2] Instituto de Investigação em Ciências da Vida e Saúde (ICVS), Escola de Medicina, Universidade do Minho, Braga, Portugal
[3] Clínica do Dragão, Espregueira Mendes Sports Center, FIFA Medical Center of Excellence, Estádio do Dragão, Porto, Portugal
[4] Universitat de Barcelona, Gran Via de les Corts Catalanes, Barcelona, Spain

Address for correspondence Nuno Oliveira, MD, Orthopedics and Trauma Surgery Department, Hospital de Braga, Victor, Braga, 4710-243, Portugal (e-mail: nunocruzoliveira1@gmail.com).

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Abstract

Tillaux fractures are fractures of the lateral margin of the distal tibia, usually reported in children between 12 and 14 years old. As intraarticular fractures, they require anatomic reduction and fixation to avoid posttraumatic complications. Since the injury mechanism is external rotation of the foot on the leg, these injuries are commonly associated with other fractures or ligamentous lesions. Currently, arthroscopy is being increasingly used to assist and improve surgical treatment of ankle fractures. The authors describe a 12-month follow-up of a rare case of a missed Tillaux fracture associated with syndesmosis injury in a 76-year-old polytrauma patient, successfully treated by arthroscopically-assisted reduction and internal fixation.

Keywords
- ankle fractures
- ankle injuries
- arthroplasty, replacement, ankle
- minimally invasive surgical procedures

Resumo

As fraturas de Tillaux são fraturas da margem lateral da tíbia distal, geralmente relatadas em crianças entre 12 e 14 anos. Como fraturas intra-articulares, requerem redução e fixação anatômica para evitar complicações pós-traumáticas. Como o mecanismo de lesão é a rotação externa do pé na perna, essas lesões são comumente associadas a outras fraturas ou lesões ligamentares. Atualmente, a artroscopia está sendo cada vez mais utilizada para auxiliar e melhorar o tratamento cirúrgico das fraturas do tornozelo. Os autores descrevem um acompanhamento de 12 meses de um caso raro de uma fratura não percebida de Tillaux associada a lesão por sindesmose em um paciente de politrauma com 76 anos de idade, tratado com sucesso por redução e fixação interna assistida por artroscopia.

Palavras-chave
- fraturas no tornozelo
- lesões no tornozelo
- artroplastia de substituição do tornozelo
- procedimentos cirúrgicos minimamente invasivos

* *Work developed at Serviço de Ortopedia e Traumatologia do Hospital de Braga, Braga, Portugal.*

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Introduction

Tillaux fractures are intraarticular fractures of the distal tibia caused by avulsion of the anterolateral distal tibia surface by traction exerted on the anterior tibiofibular ligament. These are uncommon injuries mostly seen in adolescents with partially closed distal tibia physis, usually between 12 and 14 years of age, corresponding to a Salter Harris type-III fracture. The injury is commonly called juvenile Tillaux fracture.[1] This type of injury is rarely seen in adults with skeletal maturity because anterior tibiofibular ligament usually tears first.[2–5]

Intraarticular fractures require anatomic reduction and stabilization to avoid complications such as ankle instability, ankle pain, and posttraumatic osteoarthritis.[4,6]

Arthroscopy has several advantages over open approaches, allowing a less aggressive approach, treatment of associated lesions, improvement of intraarticular reduction and with fewer complications.[7]

The authors report arthroscopic assisted treatment of a rare case of Tillaux fracture in adult, associated with syndesmosis injury that was initially missed in a polytrauma patient.

Case Report

A 76-year-old man was admitted in the emergency department following a motor vehicle accident. He sustained severe head and thoracic trauma, with sternum and several rib fractures, a non-displaced scapula fracture, hemopneumothorax, and pulmonary contusion. Spine and pelvic injury were excluded, and the patient was admitted to the intensive care unit (ICU). Three weeks after the initial trauma, the patient complained of pain in his right ankle when he first tried to stand and could not bear weight. A focused physical examination of the right ankle and foot revealed minimal swelling on the lateral aspect of the ankle, moderate tenderness on palpation over the lateral malleoli, and mild restriction of the ankle's range of motion. Initial radiological evaluation with ankle radiographs showed a widened lateral ankle mortise and intraarticular bone fragments (►**Figura 1**). Computed tomography (CT) showed a displaced Tillaux fracture associated with anterior displacement of the fibula, suggesting syndesmosis injury (►**Figura 2**).

Under general anesthesia, in supine position and with a tourniquet applied to the right proximal thigh, the patient underwent anterior ankle arthroscopy through standard anteromedial and anterolateral portals. Extensive fibrosis was present. After debridement and loose body removal, fracture and syndesmotic injury were both easily visualized. Fracture reduction was achieved under direct visualization and fixed with one 3.0 mm cannulated interfragmentary screw placed through the anterolateral portal. Syndesmotic lesion was reduced and fixed with two percutaneous 4.5 mm transsyndesmotic cortical screws. Arthroscopic exploration after fixation confirmed satisfactory reduction, which was also confirmed with fluoroscopy (►**Figs. 3** and **4**, video 1). No immobilization was used after the surgery, enabling early passive and active mobilization.

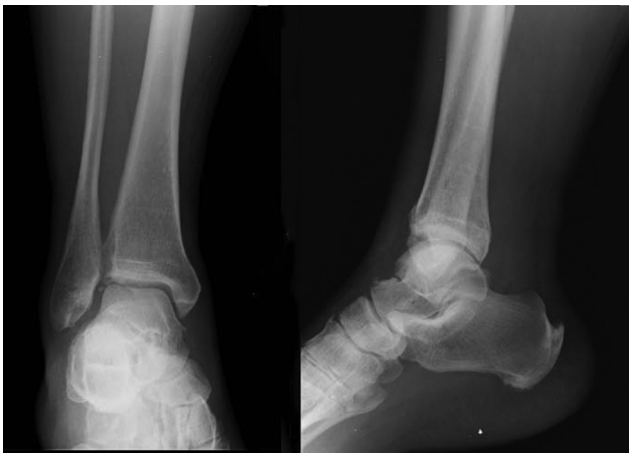

Fig. 1 Initial standard right ankle radiograph.

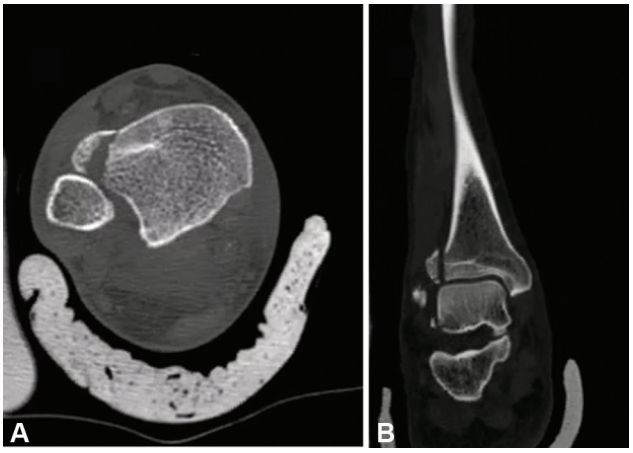

Fig. 2 Computed tomography of right ankle. **(A)** Axial view; **(B)** Sagittal view.

Video 1

Highlights of arthroscopic procedure.

Transsyndesmotic screws were removed at 8 weeks follow-up, and the patient started weight bearing.

At the 6th month, the patient was asymptomatic with symmetric ankle range of motion and no limitations during daily activities (►**Fig. 5**). Follow-up continued up to 12 months, and no complications were reported.

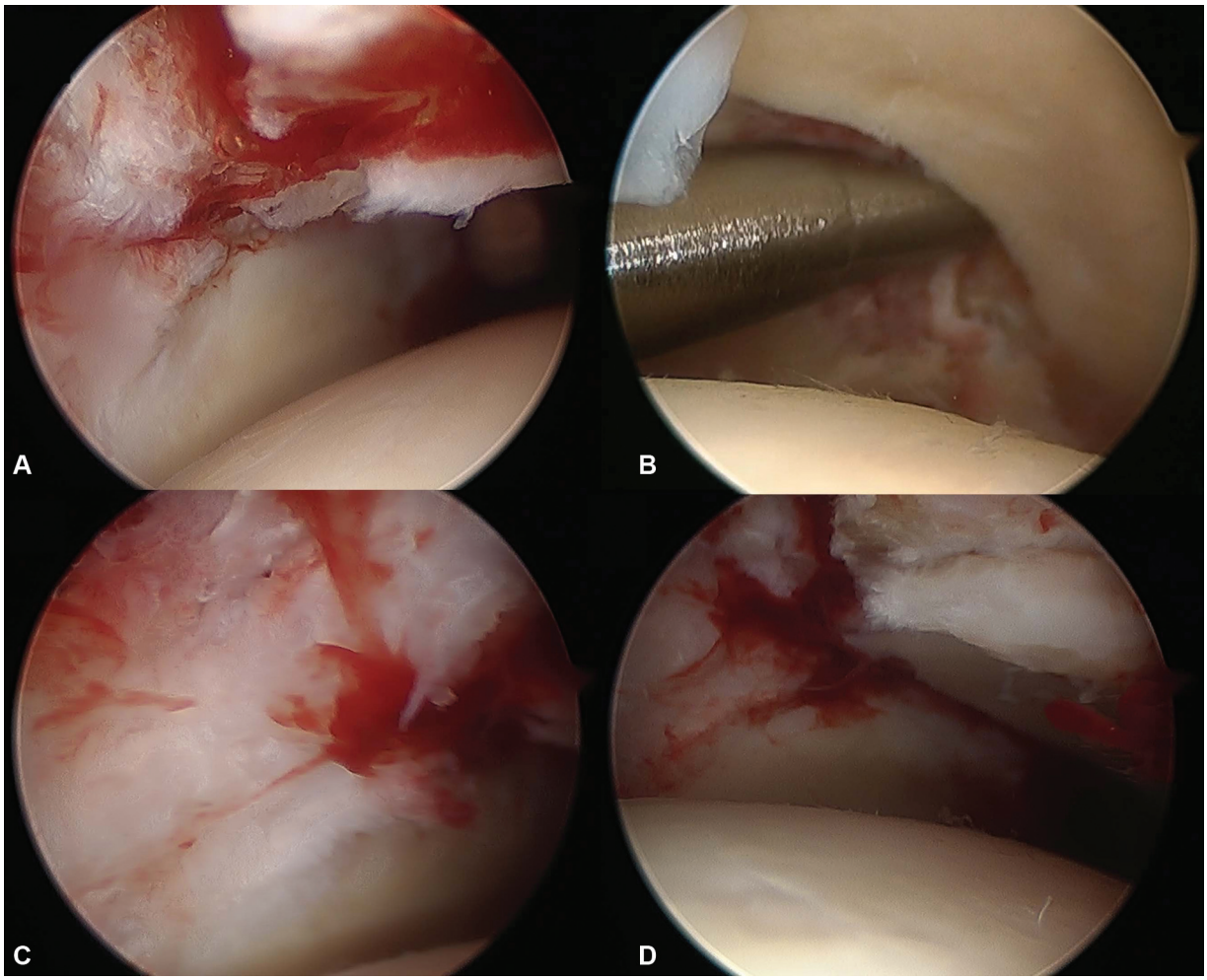

Fig. 3 Arthroscopy view. (**A**) Fracture displacement and ankle joint incongruity; (**B**) Widening of syndesmosis; (**C**) Fracture after reduction and fixation; (**D**) Syndesmosis after reduction and fixation.

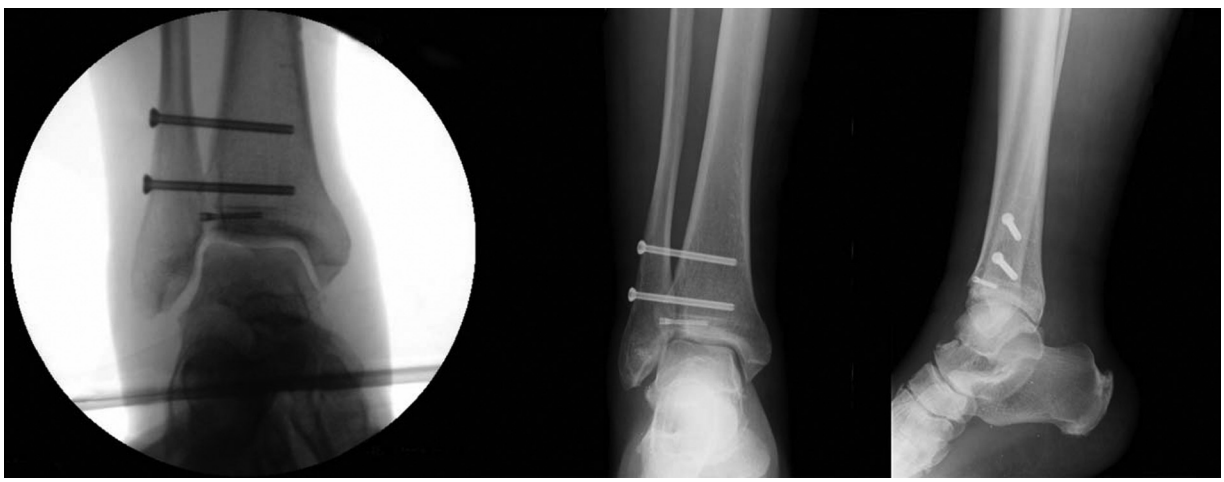

Fig. 4 Intraoperative fluoroscopy control – left; Postoperative radiograph – right.

Discussion

The injury mechanism of the Tillaux fracture is external rotational force of the foot on the leg, which makes the antero-inferior tibiofibular ligament the deforming force.[1] Although this may sometimes occur in adolescents with partially closed physis, it is very rare in skeletally mature adults. When there is less than 2 mm displacement and syndesmosis injury is excluded, these fractures can be managed with conservative treatment by immobilization in a

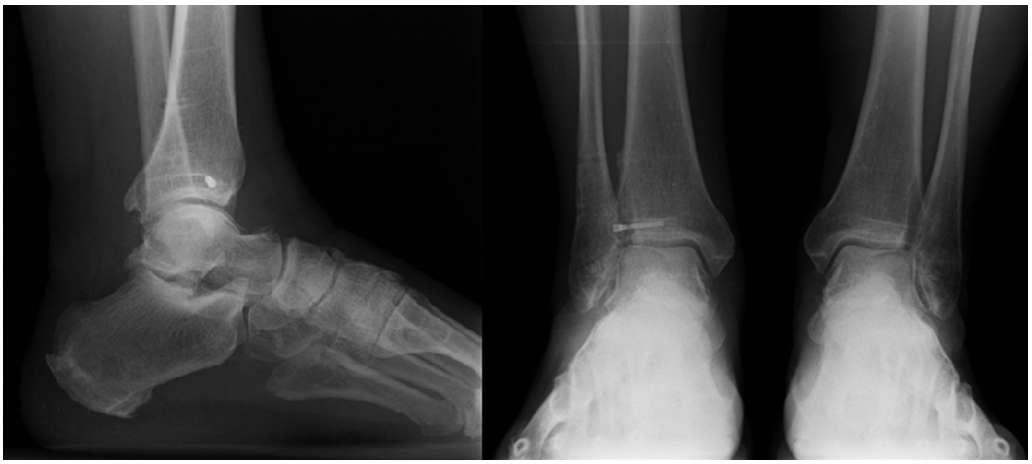

Fig. 5 Weight bearing radiograph at 6 months follow-up.

non-weight bearing cast or ankle braces. Displaced fractures over 2 mm should be managed surgically.[4,6]

Fracture fragments may be small and may be missed in traditional ankle radiographs; thus, oblique views may be required. A CT scan is more accurate than plain radiographs and allows better assessment of fracture displacement, pattern, and joint congruity.[6]

Arthroscopy has been increasingly used to assist surgical treatment of ankle fractures and to manage posttraumatic complications.[7] It is a valuable tool because it allows direct visualization of the articular surface needed for anatomical reduction, requires smaller skin incision and dissection, less disruption of the osseous blood supply and less risks of wound complications, infection, delayed union, and nonunion. It also allows the diagnosis and potential treatment of associated lesions, as, for instance, chondral lesions.[7–9] In our case, in addition to the advantages previously mentioned, arthroscopy allowed a smoother and less aggressive debridement of fibrotic tissue and callus that was already formed at 3 weeks after the injury. Open reduction and internal fixation have been reported to have good to excellent results in up to 80% of cases.[10] Feng et al.[6] reported good and excellent results in 100% of cases in a series of 19 patients with Tillaux fractures treated with arthroscopy support at 6 months follow-up.

When a fracture of the lateral margin of the distal tibia is present, it usually means that the anterior tibiofibular ligaments are intact. However, tibiofibular syndesmosis injury can also occur.[1,4] Syndesmosis injury should always be assessed in ankle fractures, whether with preoperative stress radiographs or intraoperative direct visualization of diastasis with stress maneuvers. In this case, syndesmosis injury was evident in both the preoperative radiograph and CT studies and posteriorly confirmed with direct arthroscopic visualization. It required an extensive debridement before reduction due to fibrotic changes that were already present. Anatomic reduction was achieved with minimal aggression to soft-tissue structures, which provided excellent results and fast rehabilitation.

It is important that these lesions are diagnosed in the emergency room to allow an early management and avoid potential complications. Polytrauma patients may have more life-threatening lesions that might defocus clinical evaluation of peripheral injuries, but a comprehensive extremity examination should be conducted as soon as possible, especially in high-energy traumatic lesions.

Financial Support
There was no financial support from public, commercial, or non-profit sources.

Conflict of Interests
The authors have no conflict of interests to declare.

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Letter to the Editor Regarding the article: "Obstetric Paralysis: Who is to blame? A systematic literature review" – Galbiatti JA, Cardoso FL, Galbiatti MGP. Rev Bras Ortop 2020;55(2):139-146

Andreas Rehm[1] Azeem Thahir[2]

[1] Department of Paediatric Orthopaedics, Paediatric Division, Cambridge University Hospitals NHS Trust, Cambridge, United Kingdom
[2] Department of Trauma & Orthopaedics, Cambridge University Hospitals NHS Trust, Cambridge, United Kingdom

Address for correspondence Andreas Rehm, MD, Consultant Paediatric Orthopaedic Surgeon, Addenbrooke's Hospital, Cambridge University Hospitals NHS Trust, Hills Road, Cambridge, CB2 0QQ, United Kingdom (e-mail: leoreporting@yahoo.co.uk).

Rev Bras Ortop 2021;56(3):403–404.

Dear Editor,

We read with interest the recent publication by Galbiatti and colleagues: "Obstetric Paralysis: Who is to blame? A systematic literature review." The title is incorrect, since the review described in the publication is a narrative literature review, which is limited to review articles, and not a systematic review (SR). A SR should only include original research and not review articles. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (27-item checklist), with a flow diagram, should be used, and it is advisable to register a SR with a protocol registry (Campbell or Cochrane Collaboration, International Prospective Register of Systematic Reviews [PROSPERO]). Randomized controlled trials provide the highest validity and the least bias, followed by prospective cohort studies, case-control/retrospective cohort studies, and case series with increasing bias. There are multiple tools available to assess the quality of the evidence used for SRs, such as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, which rates the certainty of evidence, and the Quality in Prognosis Studies (QUIPS) tool, which assesses the risk of bias.

Galbiatti et al.[1] stated that the literature is changing its direction and that, with their study, they helped to break the paradigm that obstetric palsy (OP) is compulsorily associated with shoulder dystocia and that its occurrence necessarily implies negligence, malpractice, or recklessness of the team involved. We are not aware that such a paradigm exists or has existed in the medical literature for over 20 years, with the direction having been changed already a long time ago. Jennett et al.[2] reported, in 1992, that only 43% of their OP cases were associated with shoulder dystocia and that the data were strongly suggestive that intrauterine maladaption may play a role in OP and should not be taken as prima facie evidence of a birth-process injury.

Gilbert et al.[3] reported, in 1999, on 1,611 OP cases born in California in 1994 and 1995, identifying large birth weight (> 4.5 kg), malpresentation, maternal diabetes, and operative vaginal deliveries, in addition to shoulder dystocia, as risk factors without indicating an association to training, experience, or malpractice of the team.

Galbiatti et al.[1] indicated that the incidence of OB does not differ if the baby is delivered by young obstetricians or surgeons with extensive experience. This is contradicted by Murphy et al.,[4] who reported on 393 operative deliveries of term singletons with 59 cases of head trauma and brachial plexus palsy. Ninety-eight percent of deliveries were performed by a trainee, and 2% by a consultant obstetrician. The six most severe cases of neonatal morbidity were initiated by a trainee. The authors concluded: "Operator experience clearly played a role in the frequency of excessive pulls and the use of multiple instruments."

Inglis et al.[5] reported, in 2011, that training of maternity staff resulted in a decrease of the OP rate in vaginal deliveries from 0.4 to 0.14%, and after shoulder dystocia from 30 to 10.67%. Ameh et al.[6] reported, in 2019, that staff training, adherence to protocols, communication, team working, and

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resuscitation technique reduce trauma after shoulder dystocia and neonatal hypothermia and hypoxia.

The change that has taken place is the acknowledgement that communication and training on how to manage complex deliveries with shoulder dystocia can reduce the risk of OP.

Conflict of Interests

The authors have no conflict of interests to declare.

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Answer to the Letter to the Editor Regarding the Article "Obstetric Paralysis: Who is to Blame? A Systematic Literature Review"

Resposta à carta ao editor referente ao artigo "Paralisia obstétrica: De quem é a culpa? Uma revisão sistemática da literatura"

José Antonio Galbiatti[1] Fabrício Luz Cardoso[2] Marília Gabriela Palacio Galbiatti[3]

[1] Orthopedics and Traumatology Service, Santa Casa de Misericórdia de Marília, Marília, SP, Brazil
[2] Discipline of Human Anatomy, Faculdade de Medicina de Marília (FAMEMA), Marília, SP, Brazil
[3] Faculdade de Medicina, Universidade de Marília (UNIMAR), Marília, SP, Brazil

Address for correspondence Fabrício Luz Cardoso, MD, Av. Monte Carmelo, 800, Fragata, Marília, SP, 17519-030, Brazil (e-mail: fabricioramalhense@gmail.com).

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We appreciate your considerations to the article. Our aim was to debate how the evolving medical knowledge, now supported by the digital revolution, has challenged some long-standing, classic definitions. We discussed data from the former Medical Insurance Association of America, from January 1985 to December 2001, referring to malpractice charges to the birth attendant physician in cases of obstetric paralysis.[1] Since the publication of the study by Jennett et al.,[2] in 1992, we believe that publications from the last 20 years or so have been changing how brachial plexus injury at birth is viewed; in our opinion, this is a better denomination than obstetric paralysis.

Regarding the title, a systematic literature review is defined as a secondary study with the aim of grouping similar studies, published or not. It critically evaluates the methodology of these studies and, whenever possible, includes a statistical analysis, in a so-called meta-analysis. Since it synthesizes data from similar primary studies of relevant scientific quality, it is considered the best level of evidence to make therapeutic decisions and establish medical management strategies.[3,4]

To avoid an analysis bias in a systematic review, data selection and assessment methods are defined beforehand in a well-defined, rigorous process. Initially, a clinical hypothesis is elaborated to define the focus of the study. Next, a wide literature search is carried out to identify the largest possible number of studies related to the subject. Papers are selected, and then their methodological quality is assessed based on the original study.[5]

Therefore, we partially agree with the criticism regarding the title and classification of our study. The study was called "systematic review of literature", and not just "systematic review", because it uses all the elements required to make a classic systematic review, which assesses primary studies, that is, randomized clinical trials, summarizing findings from systematic review articles alone. Thus, we used only outcomes from these systematic reviews that are important for evidence-based medicine, obtained from the primary studies previously evaluated by these reviews. Such (systematic) organization assures the same technical-scientific quality for our study, since several primary studies were indirectly evaluated.

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Although systematic reviews of randomized clinical trials are more frequent, there is an increasing number of reviews based on observational investigations, such as case-control, cross-sectional, cohort, report, and case series studies, in addition to qualitative studies and economic assessments.[6] For this reason, we believe in the validity of our study, whose methodolgy contained a detailed explanation of how the study was produced, strictly following the steps of a good systematic review: 1) development of a research hypothesis; 2) active literature search; 3) selection of articles of interest; 4) data extraction; 5) assessment of methodological quality; 6) data synthesis/meta-analysis (the only step not performed in our article); 7) evaluation of the quality of the evidence; and 8) writing and publication of theg findings.[7]

Our review demonstrates a change in the main etiology of obstetric paralysis, removing the high burden of malpractice from the attending physician and his/her team.[8,9] In addition, we also argue that shoulder dystocia is not the main cause, as previously described.[10–16]

A paradigm shift has been indicated by the literature. For more than 100 years, since Duchenne (1872) and Erb (1874), the person responsible for childbirth was deemed guilty of the obstetric paralysis. Our intention is to review who is to blame, which is certainly not just the doctor or any professional delivering the child.

Conflict of Interests

The authors have no conflict of interests to declare.

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Obituary

Márcio Ibrahim de Carvalho

Leonardo Silluzio Ferreira[1] Marcelo Back Sternick[1]

[1] Hospital Felício Rocho, Belo Horizonte, MG, Brazil

Rev Bras Ortop 2021;56(3):407–409.

Emeritus Member of the Medical Academy from Minas Gerais (Academia Mineira de Medicina, occupying the Chair 22 from November 17, 1998, to March 1st, 2007);

Member of the Brazilian Society of Orthopedics and Traumatology (Sociedade Brasileira de Ortopedia e Traumatologia, SBOT);

Emeritus Member of the Latin American Society of Orthopedics and Traumatology (Sociedade Latino-Americana de Ortopedia e Traumatologia, SLAOT) and Société Française de Chirurgie Orthopédique et Traumatologique (SoFCOT);

Honorary Member of the American Academy of Orthopaedic Surgeons (AAOS);

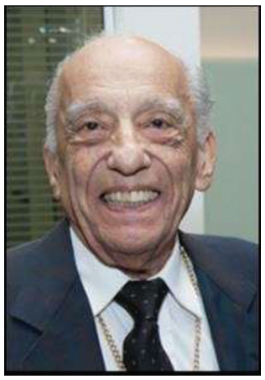
Reciprocal Member of the Société Internationale de Chirurgie Orthopédique et de Traumatologie (SICOT);

Emeritus Member of the Brazilian College of Surgeons (Colégio Brasileiro de Cirurgiões).

Son of José Ibrahim de Carvalho, a physician, and Maria da Glória Medeiros de Carvalho, Dr. Carvalho was born in São Gonçalo do Sapucaí, Minas Gerais, Brazil, on September 28, 1928.

Dr. Carvalho graduated as a doctor in 1952 at the School of Medicine from Universidade Federal de Minas Gerais (UFMG). In 1954, he moved to the United States to complete his training, graduating in Orthopedics at the School of Medicine from University of Pennsylvania, Philadelphia, in May 1955. At the University of California San Francisco School of Medicine, he completed the course "Basic Science for Orthopedics," and his residency in Orthopedics (from July 1955 to November 1956). Dr. Carvalho returned to Brazil in November 1956. In May 1968, he earned his PhD degree and, the following November, became a full professor at the School of Medicine from UFMG.

Upon returning to Brazil, two events deeply marked his personal and professional life. In February 1957, Dr. Carvalho married Jane Bunte, whom he had met in San Francisco. Together, they had four children (Márcio Luiz, Nanci, Teresa, and André). Since the marriage, Mrs. Carvalho was his permanent support and had an active role in his accomplishments; Dr. Carvalho credited the better half of his achievements to her.



Márcio Ibrahim de Carvalho

In June 1957, Dr. Carvalho introduced the Orthopedics Service at the Felício Rocho Hospital, beginning a lifelong relationship. During these 60 years, he was a constant collaborator at Felício Rocho, a philanthropic hospital. Dr. Carvalho was a member of the Technical Council and the Board of Directors for three non-consecutive terms. At the end of the last term, he received the title of "Consultant Physician." For another 20 years, he was a member of the Superior Council, a position he held until a few weeks before his death. None of these positions were paid. The 60th anniversary of the Orthopedics Service from the Felício Rocho Hospital was celebrated in July 2017.

From 1993 to 1997, Dr. Carvalho was discharged from his activities at Felício Rocho Hospital, closing his office, to work as an assistant chief surgeon and coordinate the Sarah Network of Hospitals (located in Brasília, Salvador, and São Luiz) and, in particular, transform the Sarah Hospital from Belo Horizonte, Minas Gerais, into a Rehabilitation Hospital for its inclusion at the network. This represented a great achievement for the state of Minas Gerais. For the first time, patients with spinal or brain injury and severe disability started to receive free, high-level, specialized assistance.

Endereço para correspondência Leonardo Silluzio Ferreira, (e-mail: leosilluzio@hotmail.com).

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After 5 years of orthopedics practice, Dr. Carvalho was accepted as a member of the Brazilian Society of Orthopedics and Traumatology (Sociedade Brasileira de Ortopedia e Traumatologia, SBOT). In 1960, he was elected president of the Regional Department of SBOT in Minas Gerais. Dr. Carvalho was elected to the National Directorate in 1963, where he remained for 14 years as director and hold several positions, including as President (from July 1975 to July 1977).

In preparation for the XVII SBOT Congress (Belo Horizonte, July 1967), Dr. Carvalho founded Revista Brasileira de Ortopedia, the official scientific publication from SBOT. He was the journal's director for 5 years, a member from the Editorial Board for 26 years, and an Editor Emeritus for more than a decade. At that Congress, in 1967, SBOT's Teaching and Training Commission was created. As its president, in 1972, Dr. Carvalho organized the first exam for the Specialist title, which had to be taken by residents after 2 years of approved in-service training. This examination, conducted by a board of professionals from several Brazilian regions, required an infrastructure that seemed unrealizable due to its cost. Volunteer examiners traveled on their own and paid for their accommodation. The Cultural Institute Brazil-United States (ICBEU) made its entire structure available free of charge, thanks to the support of its director, Mrs. Jane Bunte de Carvalho, Dr. Carvalho's wife. Under a new presidency, an attempt was made to carry the test out in Brasília, with no success.

Back in Belo Horizonte, another five tests were coordinated by Mrs. Carvalho at ICBEU; then, the test was transferred to the School of Medicine from Ribeirão Preto. In 2021, the 49th Examination for the Title of Specialist in Orthopedics and Traumatology (TEOT) was held in the city of Campinas, São Paulo. An innovation was introduced each year. Today, under companies funding, the test is fully electronic and performed in a hotel. The TEOT examination is a model for other specialties, including abroad.

In 1958, Dr. Carvalho was one of the founders of the Rotary Club Belo Horizonte – West, in addition of being a board member from ICBEU. Dr. Carvalho presided the I Brazilian Congress of Hip Surgery (Salvador, 1981), the III National Congress of Foot Surgery (Belo Horizonte, 1983), and XVI Brazilian Congress of Orthopedics (Belo Horizonte, 1984). In 1966, he was one of the ten Brazilians invited by the British Orthopedics Society for a 4-week visit to eight Orthopedics Services in England and to participate at the Annual Congress in Edinburgh, Scotland, held in October. In 1973, Dr. Carvalho was elected an effective member of Conselho Regional de Medicina (Regional Council of Medicine, CRM) from Minas Gerais up to 1978. He was one of the founders of the Minas Gerais Institute for the History of Medicine, occupying chair 10, whose patron is his father, José Ibrahim de Carvalho. In 1991, Dr. Carvalho won the David Rabelo Prize from the same Institute. In June 1986, he was one of the 20 delegates of the American "Citizen Ambassador Program" to conduct orthopedic seminars in hospitals in China for 3 weeks (coordinated by Alan Freeland, from the University of Mississippi). The main hospitals and academic centers from Nanjing, Tianjin, Beijing, Suzhou, and Shanghai were visited. These seminars had very interesting, fruitful debates, often with the participation of patients.

Dr. Carvalho represented Brazil at the I East-West Congress of Orthopedics in Belgrade, Yugoslavia, which was complemented by another meeting in Prague, in October 1988. In 1989, he was elected for a 3 year-term as Delegate for Brazil at the Executive Committee of Societé Internacionale de Chirurgie Orthopedique et de Traumatologie (SICOT), being re-elected twice up to 1998. As a member of the Scientific Committee, Dr. Carvalho participated in the organization of congresses in Seoul (Korea), Alexandria (Egypt), Izmir (Turkey), and Montreal (Canada). He was part of the Medical Scientific Council of Philanthropic Hospitals (now Federassantas), working as a coordinator in 1994. He authored 37 national and international publications, in addition to chapters in 10 books. Dr. Carvalho participated in 314 congresses in Brazil and abroad. He was part of 36 Examining Boards for Master, PhD, and Full Professor positions in several Brazilian states.

Decorations:

- Grand Cross Commendation from the National Order of Scientific Merit – National Personality –Fernando Henrique Cardoso, President of Brazil, 1998;
- Inconfidência Medal – Eduardo Azeredo, 1996;
- Honorary Citizenship of Belo Horizonte – City Council, 2000;
- Juscelino Kubitscheck Medal – Minas Gerais Medical Association, 2002;
- Juscelino Kubitscheck Medal of Honor – Itamar Franco, Governor of Minas Gerais, 2002;
- Santos Dumont Medal – Fernando Pimentel, Governor of Minas Gerais, Cabangu, 2015;
- "Honor to Ethics" Certificate – Regional Council of Medicine, Minas Gerais, 2011;
- Recognition of Outstanding Contribution to Orthopedics and Traumatology – Societé Internacionale de Chirurgie Orthopedique et de Traumatologie (SICOT), Brussels, 1998;
- Nicholas Andry Medal for Brazilian Orthopedic Merit "For Contributing to the Development and Progress of the Specialty in the Country" – SBOT, 2014;
- Vital Brasil Medal – Minas Gerais Medical Academy, 2011;
- Academic Palm – Minas Gerais Medical Academy, 2010;
- Minas Gerais Medical Personality – Minas Gerais Medical Academy, Regional Council of Medicine at Minas Gerais, SINMED Minas Gerais, 2013.

Medals and plaques received during professional practice:

- 30th SBOT Congress, Curitiba, 1996–Special Tribute. Initiator of the Residency Teaching Program 30 years ago;
- SBOT's Teaching Commission, Campinas, 2009, Commemoration of the success of the Specialist Title Examination;
- Minas Gerais Congress of Orthopedics, Poços de Caldas, 2005–Recognition of great contribution to the specialty in Brazil;

- International Symposium in Regenerative Medicine, School of Medicine, Uberaba, 2009–Homage of the First Symposium to his pioneering thesis in 1968;
- Residents of the Mater Dei Hospital, 2011–Acknowledgment for Scientific Coordination;
- Professor José Henrique Mata Machado Alumni Meeting, 2006–Dedication to Teaching;
- The Márcio Ibrahim de Carvalho Symposium, held every 2 years since 2005, by former residents committed in maintaining the tradition of ethics and humanism in dealing with patients.

In addition, Dr. Carvalho was:

Emeritus Member of the Medical Academy from Minas Gerais (Academia Mineira de Medicina, occupying the Chair 22 from November 17, 1998, to March 1st, 2007);
Member of the Brazilian Society of Orthopedics and Traumatology (Sociedade Brasileira de Ortopedia e Traumatologia, SBOT);
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Reciprocal Member of the Société Internationale de Chirurgie Orthopédique et de Traumatologie (SICOT);
Emeritus Member of Brazilian College of Surgeons (Colégio Brasileiro de Cirurgiões).

In his personal life, Dr. Carvalho (or Dr. Márcio, as we used to call him), was always very demanding from himself, his team, and residents but he was the first to defend them from any unjust act. Owner of a vast orthopedic culture and an enviable memory, he always added current information in any area of orthopedics. Dr. Carvalho continued to participate in the clinical meetings of the orthopedics team until two weeks ago. An innovative physician, he has always sought to combine modernity with an effective gain in the quality of care for patients. He was extremely proud of his former residents and very happy with the achievement of each one of them. When recording the show "Orthopedics Memory" ("Memória da Ortopedia)" at SBOT-MG, he said that his main achievement was training the team from Felício Rocho Hospital and a legion of orthopedists. Outside the work environment, he was a discreet person and a gentleman. When receiving friends, he loved to talk and tell stories about orthopedics. Even in his last few days, he was always consulted for advice and cheers.

We, his disciples, will continue to keep as a principle a phrase he quoted several times: "***Primun non Nocere***."

Orthopedics Team, Felício Rocho Hospital

Revista Brasileira de Ortopedia

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The Revista Brasileira de Ortopedia (RBO) is the Official Scientific Publication of the Brazilian Society of Orthopedics and Traumatology (Sociedade Brasileira de Ortopedia e Traumatologia, SBOT) and it aims to disseminate papers that contribute towards improving and developing the practice, research and teaching of orthopedics and related specialties. It is published bimonthly in February, April, June, August, October and December, and has been published regularly since its first edition in 1965. The journal is dedicated to orthopedists who are linked to the SBOT, healthcare professionals who are dedicated to similar activities and orthopedists in other countries.

Peer Reviewing Process

The journal follows a double-blind peer-review process where neither author and reviewer does not get to know the identity of each other.

At least two random reviewers based on their technical and clinical expertise are assigned by the Chief Editor on each manuscript. The decision is taken based on the comparative reviews that the manuscript receives during the review process.

MANUSCRIPT FORMAT

Article Types

The following graph shows what types of articles are accepted for publication, and what requirement they may have.

Article Type	Abstract Limit	Keywords Limit	Title Limit	Figures/Tables	Reference
Original Article (Up to 2,500 words)	Up to 250 words	6	not applicable	10 Figures e 6 Tables	Up to 30 References
Update Articles (Up to 4,000 words)	Up to 250 words	6	not applicable	3 Figures and 2 Tables	Up to 60 References
Systematic Reviews and Meta-analysis (Up to 4,000 words)	Up to 250 words	6	not applicable	3 Figures e 2 Tables	Up to 60 References
Case Report (Up to1,000 words)	Up to 250 words	6	not applicable	5 Figures	Up to 10 References
Technical Notes (Up to 1,500 words)	Up to 250 words	6	not applicable	5 Figures e 2 Tables	Up to 8 References
Letters to the Editor (Up to 500 words	N/A	N/A	not applicable	2 Figures	Up to 4 References
Editorial (Up to 500 words)	N/A	N/A	not applicable	N/A	N/A

- **Original Article**: It describes prospective or retrospective experimental research or clinical investigations, which may be randomized or double blind. It should have a Title, Structured Abstract (Objective, Methods, Results, and Conclusion), keywords, introduction, materials and methods, results, discussion, conclusions and references. Can have maximum of 6 authors. Maximum of 2,500 words, 30 references, 10 figures and 6 tables.
- **Update Articles**: These are reviews of the state of the art on a given topic, written by specialists on invitation from the Editor-in-Chief. They should have Title, Unstructured abstract keywords, and references. Maximum of 4,000 words, 60 references, 3 figures and 2 tables.
- **Systematic Reviews and Meta-analysis**: These have the purpose of examining the published bibliography on a given subject, in order to make a critical and systematized assessment on a certain specific topic and present the important conclusions based on this literature. They should have Title, an Unstructured abstract, keywords, and references. Maximum of 4,000 words, 60 references, 3 figures and 2 tables.
- **Case Report:** It should be informative and should not contain irrelevant details. Only clinical case reports of interest, either for its rarity as a nosological entity, or for the unusual form of presentation. It should have a title, unstructured abstract, keywords and references. Maximum of 1,000 words, 10 references, 5 figures. **Note: Case report articles will have a individualized editing time and will not follow the same evaluation and publication time of the other articles.**
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- **Letters to the Editor:** These have the aim of commenting on or discussing studies published in the journal or reporting on original research that is in progress. They will be published at the editors' discretion, with the respective reply, when appropriate.
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See the section Article Types for word limits.

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A structured abstract, by means of appropriate headings, should provide the context or background for the research and should state its purpose, basic procedures (selection of study subjects or laboratory animals, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), and principal conclusions. It should emphasize new and important aspects of the study or observations.

The abstracts should be a maximum of 250 words and structured in the following format: Purpose: One or two sentences that simply state purpose with no background information. Methods: Provide details about the methods of the study, including data analysis. Results: Present most important findings of the study. Please provide numbers (means with standard deviations or medians with ranges) to support your findings, and results of significance tests, e.g. p-values. Conclusions: One or two sentences that state only what your study identified and actually demonstrated. Please do not include comments or information not supported by the data of your study. Level of Evidence (for human studies) or Clinical relevance (basic science in-vitro or in-vivo study: why is this study important from a clinical standpoint?).

Immediately after the abstract, provide a maximum of 6 keywords in alphabetical order and separated by semicolon, to represent the content of the article. The descriptors or keywords should be based on the Health Science Descriptors (Descritores em Cincias da Sade, DECS), which are available at the electronic address http://www.decs.bvs.br; or on the Medical Subject Headings (MeSH), from www.nlm.nih.gov/mesh/ MBrowser.html.

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References should be the most recent and pertinent literature available. It is essential that they are complete and thoroughly checked. If the reference information is incomplete, good online sites to search for full details are the National Library of Medicine: www.nlm.nih.gov; Books in Print: www.booksinprint.com; PubMed: www.ncbi.nlm.nih.gov/PubMed/; or individual publisher Web sites.

- References must be listed in AMA style, using Index Medicus journal title abbreviations.
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- Figures include photographs or radiographs, drawings, graphs, bar charts, flow charts, and pathways, but NOT lists or tables.
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- The following formats are acceptable: *.avi, *.mov and *.mpg.
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DIGITAL ARTWORK PREPARATION

General Guidelines

- It is best to use Adobe Photoshop to create and save images, and Adobe Illustrator for line art and labels.
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- Save each figure in a separate file.
- Do not compress files.
- All black-and-white and color artwork should be at a resolution of 300 dpi (dots per inch) in TIFF format. Line art should be 1,200 dpi in EPS or TIFF format. Contact the Production Editor at Thieme if you are unsure of the final size.
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- If possible, do not send color art for conversion to black-and-white. Do the conversion yourself so that you can check the results and confirm in advance that no critical details are lost or obscured by the change to black-and-white.
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- All color artwork should be saved in CMYK, not RGB.

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- Arrows, asterisks, and arrowheads (or other markers) should be white in dark or black areas and black in light or white areas, and large in size. If not, these highlighting marks may become difficult to see when figures are reduced in size during the typesetting process.

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Prof. Dr. Sergio L Checchia, MD, PhD
Sociedade Brasileira de Ortopedia e Traumatologia
Alameda Lorena, 427 - 2o. Andar - Jd. Paulista, SP, Brazil
rbo@sbot.org.br
T: +55 11 2137 5400

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