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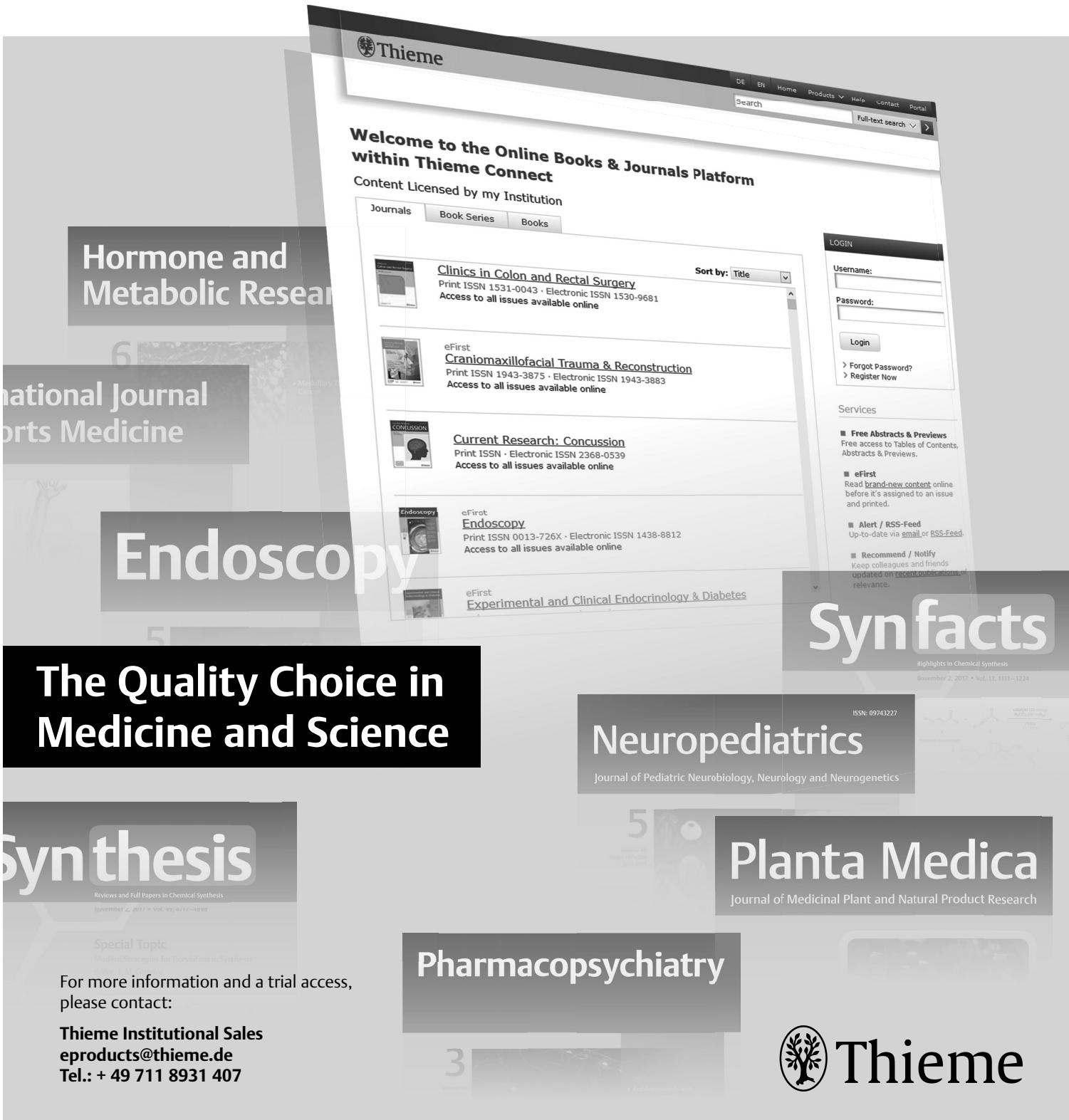
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Answer to the Letter to the Editor Regarding the Article "Radiological Evaluation of Postoperative Alignment in Total Knee Arthroplasty"

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Congenital Clubfoot – Is the Ponseti Method the Definitive Solution?*

Pé torto congênito – O método Ponseti é a solução definitiva?

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Abstract

Congenital clubfoot is one of the most common deformities at birth. The inadequacy or absence of treatment causes serious limitations for people with this condition. The initial treatment using the Ponseti method ensures functional results superior to other treatment modalities previously proposed. However, recurrences and neglected feet are still a challenge today. An understanding of the pathophysiology of the disease, as well as of the anatomy and local biomechanics and a thorough clinical and radiological evaluation of patients are essential to understanding the limits of the method and choosing the best treatment.

Keywords
- foot deformities
- talipes/therapy
- congenital abnormalities
- treatment

Resumo

O pé torto congênito é uma das deformidades mais comuns ao nascimento. A inadequação ou ausência do tratamento provoca sérias limitações aos portadores desta condição. O tratamento inicial pelo método Ponseti garante resultados funcionais superiores a outras modalidades de tratamento propostas anteriormente, porém as recidivas e os pés negligenciados ainda são um desafio na atualidade. O entendimento da fisiopatologia da doença, da anatomia e biomecânica local e uma minuciosa avaliação clínica e radiológica dos pacientes são imprescindíveis para entendermos o limite do método e escolhermos o melhor tratamento.

Palavras-chave
- deformidades do pé
- pé torto/terapia
- anormalidades congênitas
- tratamento

Introduction

Congenital clubfoot (CCF) is one of the most common musculoskeletal deformities at birth, affecting ~ 1 to 2 per 1,000 live births.[1] It is characterized by a three-dimensional deformity of the foot, in which four elements are present:

* The present study was carried out at the Institute of Orthopedics and Traumatology, Hospital das Clínicas, School of Medical Sciences, Universidade de São Paulo, São Paulo, SP, Brazil.

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cavus, forefoot adduction, hindfoot varus, and equine. The presence of the four deformities in the newborn without other comorbidities, not reducible to clinical examination, define the diagnosis of idiopathic CCF.

The method developed by Ignácio Ponseti is widely recognized as the gold standard for the treatment of this pathology, consisting of serial manipulations and application of plasters in weekly exchanges, in order to lengthen the contracted posteromedial structures and restore the anatomical relationships between the bones. Then, most of the time, a percutaneous tenotomy of the calcaneus tendon is required to correct the hindfoot equine. It continues in a period of correction maintenance with the use of a foot abduction orthosis to avoid recurrence of deformities.[2]

When applied early, performed by trained professionals, and observing the appropriate methodology, the method results in the correction of the deformity in most cases. It is important to highlight that the treatment goes beyond the plaster phase and requires care to ensure good results. The final success of the treatment is based not only on the knowledge and medical technique obtained, but on the effective orientation of parents and monitoring of adherence to the orthosis, which has been the main responsible for maintaining the correction obtained in the plaster phase.[3]

The protocol for the use of the abduction orthosis is of 23 hours a day until 3 months after the removal of the last plaster made at the time of tenotomy, and 14 hours a day until the child is 4 years old. This protocol is based on studies by Ponseti that showed that the risk of recurrence is higher in the first 5 years of life.[4] Ponseti reports that in the first 20 years of his practice, when there was still no awareness from parents about the use of the orthosis up until the child reached 3 or 4 years old, there was recurrence in half of the cases, on average, at $\sim$ 2 and a half years old.[4]

Nonadherence to the use of the orthosis, either due to family or socioeconomic problems or to the lack of knowledge of the protocol itself, is the main factor associated with recurrence of CCF.[5] According to Ponseti, the use of the orthosis favors continuous stretching and prevents the formation of a new fibrosis in the ligaments and tendons around the medial aspect of the foot and ankle that lead to the return of the deformity. Nevertheless, the nonadherence to the orthosis does not explain all cases of recurrence that occur and, therefore, several studies have been published with the intention of identifying factors that may indicate a higher chance of recurrence of deformities.

Neurological, radiological,[6,7] electromyographic, and histological[8] studies found high rates of neural and myopathic alterations, including an increase in type I muscle fibers, fatty degeneration, and fibrosis.[8] Gelfer et al.[9] found that recurrence occurred in 16% of the children with idiopathic clubfoot, and showed that decreased activity of the right-hand muscles (short fibular, long fibular, and third fibular) is highly predictive of recurrence and has a greater need for surgical intervention after 2 years of follow-up. Little et al.[10] suggested that the activity of the reverse muscles should be measured and added to the initial evaluation of the patient to propose a strategy to prevent recurrence. Factors such as age at presentation, initial Pirani score, and number of exchanges in the case were not significant indicators of recurrence or of need for additional surgical intervention.

Recurrence remains a challenge throughout childhood. Relapses occur more frequently and rapidly during the first 5 years of life, being extremely rare after the age of 7 years old.[4] In CCF adequately treated by the Ponseti method, recurrence rates range from 26 to 48%.[11] As this problem is not resolved spontaneously, early detection and immediate treatment of the affected feet are essential. The prevention of recurrence is one of the major challenges during the treatment of patients with idiopathic CCF initially treated by the method.

A recent systematic review reveals that few studies have a follow-up of patients beyond the age of 8 years old, and that this may reflect an underreporting of relapses in children older than this age.[12] In this same study, the authors found that the number of surgeries increases as follow-up increases.

Relapse and the Ponseti Method

Knowledge of the pathogenesis of the clubfoot is essential for the prevention, recognition and understanding of recurrence. According to Ponseti et al.,[13] recurrences are caused by the same pathology that initiated the deformity and it is a mistake to believe that the recurrent deformity would be the same as the first, which has not completely corrected during treatment. The development of the deformity begins in the 2nd trimester of pregnancy and muscle and ligament changes continue to occur until the 3rd or 4th year of life.

The disease involves the entire posterior and medial region of the leg, ankle, and foot. There is a slight decrease in muscle size and an excess of collagen synthesis with fibrosis and retraction in the medial and posterior tarsal ligaments, in the deep fascia, in the Achilles tendon, and in the posterior tibial tendon. In 2012, Ippolito et al.[14] found a mean difference in volume and length between the three muscle compartments of the leg of the patients with diagnosis of unilateral CCF, with the muscles on the side of the foot slender and shorter than those on the normal side, showing involvement of the entire distal segment of the lower limb.

Histological studies showed fibrotic changes in tissues extracted from patients with CCF. Molecular studies revealed changes in the amount of type I, III, VI and profibrotic cytokines, such as transformative growth factor (TGF-β) and platelet-derived growth factor (PDGF). These studies have confirmed the presence of tissue with fibrosis, especially in the medial aspect, focusing on the medial malleolus, on the talus support, and on the navicular bone. This area presents a rigid nature with hyperproduction of extracellular matrix components.[15]

To fulfill the lack of prognosis, other possible methods to predict recurrence have been tested. Recently, a low eversor muscle activity has been considered as a significant recurrence parameter in CCF. The short, long, and third fibular evertor muscles of the foot have variable activity in patients with CCF. Gelfer et al.[9] revealed a rate of 16% in children with low eversor muscle activity. The form of evaluation followed the same pattern of the Pirani scale, in which 0 indicated normal muscle activity, 0.5 some activity, and 1 absence of muscle activity. In noncollaborative children, muscle strength was tested by manual stimuli in the lateral region of the foot and ankle.

Deformities that occur in an early treated foot may be residual or relapsed. Although it is not easily identifiable which were the deformities that returned to the old pattern versus those that were not corrected, the implication of this differentiation interferes little in the indication of treatment. However, late causes of recurrence require investigation of other associated diagnoses, such as neurological causes.

Recurrence severity considers the time, foot position, and stiffness of the deformity. Although the classifications for primary deformity are reproducible, relapses do not yet have a validated classification, perhaps due to the heterogeneity of presentation and different combinations of poor positioning of the bones of the foot or recurrences of some components in feet that have never been completely corrected. The most common order of recurrence is the return of the equine, followed by the varus. But this is not a rule. The equine may relapse on feet with hindfoot varus never previously corrected. With gait, mainly with equine and varus, the adduction and supination are installed, the latter also contributing to anterior tibial tendon hyperactivity. The muscle imbalance caused by weakness of the eversor muscles of the foot causes the anterior tibial tendon to present with greater activity. The lack of opposing strength to the action of the anterior tibial muscle, associated with its more medial and plantar insertion in the CCF, favors the development of dynamic supination during gait. The presence of tendon hyperactivity is an important factor to be evaluated in the dynamic inspection of the patient.

The correct evaluation of the existing deformity is the best way to establish the treatment plan. The clinical evaluation depends on static and dynamic inspection, palpation, and special maneuvers. Recently, Pierz et al.[16] conducted a gait analysis study in a patient with recurrent idiopathic clubfoot and concluded that these patients presented changes in gait pattern explained by impaired ankle joint and compensation in the knee, hip, and pelvis. In this study, patients with unilateral clubfoot presented decreased dorsiflexion range of motion and greater associated gait impacts and compensations. Thus, the instrumented gait examination has proved to be an ally for the evaluation of dynamic changes during the gait of the child with foot deformity. However, its availability is low in most treatment centers, rendering it unusable at the moment.

Static evaluation with the patient initially standing is useful for detecting the presence of the varus (support of the calcaneus in the soil is displaced medially in relation to the midline of the leg) and of the equine (in case of not supporting the calcaneus or doing knee hyperextension). In dynamic gait inspection, the position of the varus support of the calcaneus is verified if it occurs in conjunction with the action of the anterior tibial with dynamic supination of the forefoot. Internal progression of the feet also occurs due to the presence of forefoot adduction and to the inversion of the subtalar, which is the most important factor.[17]

Podography or even the assessment of dirt or of calluses can give us important clues about the place of foot support in the gait. In the functional examination, plantar flexion and maximum dorsiflexion should be verified both passively and actively. Active dorsiflexion may be limited by a sural triceps contracture and may also reveal the tendency to inversion of the feet, evidencing the insertion of the anterior tibial in a more plantar region.

Although anamnesis and clinical examination combined with patient expectation are paramount in the decision-making process, radiographic evaluation is an important ally in this planning. A complete understanding of the alignment of the bones and joints of the medial and lateral columns as well as of the relationships between the hindfoot bones is essential to assess the severity of the foot. The three-dimensional relationship and understanding of residual or acquired bone deformities may be key to deciding on the best treatment method.

This investigation is primarily performed by radiographs and can be complemented with computed tomography (CT) and magnetic resonance imaging (MRI).[18] The radiographic series must include the anteroposterior incidences of the bearing, the axial, and the calcaneus, the Saltzman incidence, and the ankle anteroposterior incidence. Magnetic resonance imaging may demonstrate alterations related to the involvement of soft tissues and cartilaginous or fibrous joints between the bones. Although it is very useful for the evaluation of cases with late or repeated recurrences, MRI has the limitation of requiring sedation in younger children; therefore, its use is limited. Recent studies consider that the use of CT with 3D reconstruction can determine and classify the congenital clubfoot severity, as well as assess the progress of the intervention based on the relative position of the tarsus bones.[19] The three-dimensional relationship and the understanding of residual or acquired bone deformities may be key to deciding on the best treatment method.

The Choice of Treatment Method: The Ponseti Limit

Correction by the Ponseti method is based on promoting the eversion of the subtalar joint and the abduction of the calcaneus under the talus; the block of the middle foot and forefoot accompany the correction, until the talus is covered by the navicular. Tissue elasticity allows

correction and congruence between bones and is facilitated by the ability of cartilage to reshape as it changes position.

The choice of treatment of recurrent clubfoot depends on several factors, such as the previous treatment method and the stiffness of the deformity. The Ponseti method can also be used for resistant and recurrent CCF.[3,5,11,20] The option for this method at a later stage goes beyond the severity of the deformity but should also consider individual and family characteristics. The limit of the method depends on anatomical changes such as the presence of degenerative joint changes, bone deformities, and tarsal coalitions, as well as tolerance and desire of the patient to regarding plastered treatment and the subsequent use of the foot abduction orthosis. In older children, complete correction is no longer possible due to intrinsic bone deformations, but the goal remains to attain functional plant position and absence of pain.

Eidelman et al.[21] nosologically divided the recurrences into three groups:

- Early relapse (from 6 months to 30 months old)
- Late recurrence (between 30 months and 8 years old)
- Relapse in adolescents ($\geq$ 9 years old)

This classification would make it easier to find the main reason for recurrence and, thus, define the best treatment method.

Early recurrences occur mainly due to failure to adhere to the orthosis. The first sign that should be observed during follow-up consultations is the loss of dorsiflexion. The foot ends up slipping through the orthosis and not settling in the correct way, which can cause wounds or areas of hyperpressure.

In the group of late relapses, children aged between 2.5 and 8 years old stopped using the orthosis either by medical recommendation or due to loss of follow-up. Many, however, have muscle factors that predispose the return of deformities. Recurrences in this group range from mild dynamic supination of the forefoot during walking to the multiple components of the deformity of the left foot (cavus, adduction, varus, and equine). The group classified as recurrence of adolescents usually has rigid deformity, and, with the dissemination of the method, recurrences in this age group are currently less common.

In all relapses, the principles of Ponseti may be sufficient to restore foot correction.[11] The goal of returning to the plaster is to recover the angle of 60 to 70° of abduction of the foot that was achieved in the initial treatment and to obtain the maximum dorsiflexion. Again, it is imperative to institute a vigorous orthosis program to maintain the correction achieved. In patients with late recurrences $>$ 2.5 years old who present a dynamic supination component of the forefoot, adjuvant treatment through transfer of the anterior tibial tendon to the third cuneiform should be evaluated. It is worth remembering that this procedure will only have the expected success if the deformities of the foot are better corrected.[22]

Most authors recommend that all patients with recurrences should return to treatment by the Ponseti method, since even if we do not get a full correction of deformities, we can improve the position and avoid very extensive surgeries.[3,5,11,20,23] In these cases, other methods should be considered: open release, osteotomies, or gradual distraction with external fixator.[24] In nonreducible deformities, bone procedures are often necessary to treat structural abnormalities.

In a study with a cohort of 33 patients with residual deformity and 55 patients with recurrent clubfoot, half of the patients underwent treatment by the Ponseti method; one quarter of them also required adaptation with the foot abduction orthosis protocol, and a quarter required surgery.[20] The Ponseti method was effective when recurrences or residual deformities were present before 5 years of age.

The eversion of the subtalar is the primary objective to be achieved, and this condition must necessarily be evaluated in the case of recurrences. The absence of adequate positioning of the navicular in relation to the talus in the radiographic evaluation, without proper correction of the Kite angle, indicates that the calcaneus was also not abducted under the talus, so the method is indicated to perform this correction.

Treatment of progressive loss of dorsiflexion can be challenging. Repeated percutaneous tenotomies can make tissue increasingly rigid and fibrotic. Open procedures of tendinous stretching, capsulotomy, and even anterior hemiepifyosis of the distal tibia[25] have been described and used.

In some patients, it is no longer possible to obtain the rotation of the subtalar, either due to the stiffness of this joint in older children or to the union between the talus and the calcaneus. In them, the incongruity between the bones does not allow peritalar release. Also, often, the alignment of the forefoot and middle foot is corrected, and the deformity is concentrated in the hindfoot. In such cases, many procedures can be used to improve alignment. The understanding of clinical and radiological deformities, through CT with triplanar reconstruction, allows an individualized evaluation, being essential for decision-making.[18,19]

Soft tissue release procedures can be associated with bone procedures to obtain a plantigrade and functional foot. Fasciotomy, associated with the releases of the plantar capsules of the medial spine joints, as well as the stretching of the achilles tendon and flexor of the fingers and allux, are the most common soft tissue release procedures. Among the bone procedures, the correction of the heel varus can be performed through the osteotomy of lateral wedge resection, as well as by insertion of a medial wedge (usually removal of the cuboid) to correct the adduction. This prevents shortening and improves the arm and lever of the sural triceps. The adduction can be improved with a combined medial opening wedge osteotomy (medial cuneiform) lateral closing wedge.[26] The cavus can be treated by osteotomy of dorsal wedge removal from the middle foot, while residual spupination can be corrected by elevating

osteotomy of the first metatarsal, associated with stretching of the anterior tibial tendon or through its transfer to the lateral wedge.

In more severe cases, other procedures can be performed: naviculectomy combined with lateral calcaneus-cuboid shortening, as described by Mubarak et al.,[27] or talectomy associated with shortening and fusion of the lateral spine.[28] Modelling triple arthrodesis is reserved for patients >12 years old with complaints of severe pain and deformities. The use of circular external fixators with or without additional osteotomies is also a method that can be used, allowing for a correction in multiple planes and gradual deformity.[24]

Final Considerations

The initial treatment of congenital clubfoot has a very well-defined protocol. However, despite the good results of the Ponseti method, the prevention and treatment of relapses remains a challenge. Knowledge of pathogenesis, strict regular follow-up, and regular use of abduction orthotics are crucial for treatment success. Identification of factors with worse prognosis and early recognition of relapses make the treatment more effective.

In relapses, especially in the presence of rigid deformities, the association of open surgical procedures may be indicated. For the surgeon, it is essential to know the entire surgical arsenal, which should include soft tissue release procedures, stretching and tendon transfers, osteotomies, addition or resection of wedges, and modeling bone fusions. Thus, from the identification of the deformity and stiffness of the patient, they will be able to choose the best technique to achieve an aligned and stable foot.

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The authors have no conflict of interests to declare.

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Ankle Osteoarthritis*

Osteoartrite do tornozelo

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Abstract

Osteoarthritis (OA) is characterized by a chronic, progressive and irreversible degradation of the joint surface associated with joint inflammation. The main etiology of ankle OA is post-traumatic and its prevalence is higher among young and obese people. Despite advances in the treatment of fractures around the ankle, the overall risk of developing post-traumatic ankle OA after 20 years is almost 40%, especially in Weber type B and C bimalleolar fractures and in fractures involving the posterior tibial border. In talus fractures, this prevalence approaches 100%, depending on the severity of the lesion and the time of follow-up. In this context, the current understanding of the molecular signaling pathways involved in senescence and chondrocyte apoptosis is fundamental. The treatment of ankle OA is staged and guided by the classification systems and local and patient conditions. The main problems are the limited ability to regenerate articular cartilage, low blood supply, and a shortage of progenitor stem cells.

The present update summarizes recent scientific evidence of post-traumatic ankle OA with a major focus on changes of the synovia, cartilage and synovial fluid; as well as the epidemiology, pathophysiology, clinical implications, treatment options and potential targets for therapeutic agents.

Keywords
- osteoarthritis
- ankle
- cartilage
- synovial fluid
- therapeutics

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Resumo

A osteoartrite (OA) é caracterizada por uma degradação crônica, progressiva e irreversível da superfície articular, associada a inflamação articular. A principal etiologia da OA do tornozelo é pós-traumática e sua prevalência é maior entre os jovens e obesos. Apesar dos avanços no tratamento das fraturas ao redor do tornozelo, o risco geral de desenvolver OA pós-traumática do tornozelo após 20 anos do trauma é de quase 40%; especialmente nas fraturas bimaleolares de Weber tipo B e C e fraturas envolvendo a borda tibial posterior. Nas fraturas do tálus, essa prevalência se aproxima de 100%, dependendo da gravidade da lesão e do tempo de seguimento. Nesse cenário, é fundamental a compreensão atual das vias de sinalização moleculares envolvidas na senescência e apoptose dos condrócitos. O tratamento da OA do tornozelo é estagiado e guiado pelos sistemas de classificação, condições locais e do paciente. Os principais problemas são a limitada capacidade de regeneração da cartilagem articular, o baixo suprimento de sangue e a escassez de células-tronco progenitoras.

A presente atualização resume evidências científicas básicas recentes da OA pós-traumática do tornozelo, com foco principal nas alterações metabólicas da sinóvia, da cartilagem e do líquido sinovial. Epidemiologia, fisiopatologia, implicações clínicas, e opções de tratamento são também discutidas.

Palavras-chave

- osteoartrite
- artrose
- tornozelo
- cartilagem
- líquido sinovial
- terapêutica

Introduction

Osteoarthritis (OA) is a syndrome characterized by articular cartilage degeneration, subchondral bone changes, intra-articular inflammation and periarticular bone growth, often associated with typical symptoms of stiffness, swelling and pain in the affected joint.[1–4] An effective cure for this syndrome is still far away, be it through prevention methods, delaying its progression or proposed symptomatic treatments.[1–3,5,6]

Lower limbs OA affects ~ 15% of the world population, and it is a major cause of disability, since global estimates suggest that 250 million people are currently affected; in the United States, ~ 60 billion dollars/year are spent on its direct treatment.[1,7,8] Tibiotarsal joint OA is present in 1 to 4% of patients seeking orthopedic care due to lower limbs OA; the average age of patients at the final stage of the condition is 55.7 years. The socioeconomic impact of the disease increased along with its 300% prevalence elevation between the 1970s and the 2000s.[9]

In contrast to OA in other lower limb joints, such as the hip and the knee, which have primary and nontraumatic origin in 58% and 67% of the cases, respectively, this etiology represents only 9% of the tibiotarsal OA cases. Other secondary causes, including rheumatoid arthritis, hemochromatosis, hemophilia or osteonecrosis, are present in 13% of the cases; post-traumatic origin is the main cause, representing ~ 78% of etiologies, due to ankle fractures, ligament injuries, distal tibial fractures, tibial shaft fractures, talus fractures and combined fractures of the ankle and foot.[8–10]

Pathophysiology of post-traumatic ankle osteoarthritis

The ankle is a high congruence and stability joint, receiving high contact forces along a very thin layer of articular cartilage. This chondral structure has unique features, including more crosslinked glycosaminoglycans and fewer collagenase and interleukin (IL)-1 receptors (IL-1R) than other types of joint cartilage, which provides high rigidity and tensile strength.[11,12] As such, a change in joint congruence must occur for post-traumatic ankle osteoarthritis (OAPTT) to develop, leading to increased shear forces and accelerated degeneration.

The total area of the tibiotarsal joint is 350 mm^2, which is subjected to ~ 500 N of axial force; for comparison, the hip and knee, with joint areas of 1,100 mm^2 and 1,120 mm^2, respectively, are subjected to the same amount of force.[13–15] Thus, the pressure on the ankle joint cartilage can be up to three times greater than in other lower limb joints. The tibiotarsal cartilage thickness ranges from 1.0 to 1.62 mm, being thinner compared to the hip (1.35 to 2.0 mm) and the knee (1.69 to 2.55 mm).[16]

An acute ankle injury initiates a sequence of events in the joint milieu that can potentially lead to progressive joint surface damage in addition to direct injury to chondrocytes at the time of trauma. An increase in proinflammatory cytokines, with proteoglycan and collagen remodeling dysregulation, may play an important role in the pathogenesis of post-traumatic OA.[17–19] This can be explained by the articular cartilage limited recovery ability from a direct injury; moreover, an amplified inflammatory response of the synovial tissue is a key factor in the development of OAPTT.[20]

Recent studies have focused separately on different tissues, that is, cartilage, synovial tissue and synovial fluid. Researchers led by Adams demonstrated acute changes in the synovial fluid after an intra-articular ankle fracture. Elevation of proinflammatory cytokines, such as IL-6, IL-8, matrix metalloproteinase (MMP)-1, MMP-2, MMP-3, MMP-9 and MMP-10 can be seen within hours after a trauma. These elevations are sustained for the subacute period; in addition, an increase in other cytokines (IL-1Ra, IL-6, IL-8, IL-10, IL-15

and monocyte chemoattractant protein [MCP]-1) are observed 6 months after the injury.[21–24]

Clinical diagnosis, classification systems and supplementary investigation

In this scenario, pain is the dominant symptom and constitutes the main factor in the therapeutic decision-making process.[1] The most common clinical presentation is joint line pain associated or not with swelling (joint effusion), limited joint range of motion, and reduced locomotor function both in work-related and leisure activities.[25] Other associated clinical changes are leg muscle hypotrophy and gait pattern alterations, mainly in kinematics and kinetics.[26–29] The initial imaging investigation is performed with radiographs under load that can show different degrees of decreased joint space, formation of osteophytes, sclerosis and subchondral cysts.

The most used classification systems are the following: Kellgren-Lawrence Arthritis Grading Scale, Takakura Classification System, Morrey and Wiedeman Classification, and Classification of Osteoarthritic Changes in the Ankle (van Dijk) (►**Box 1**)[30,31]

Claessen et al evaluated the reliability of the (1) van Dijk, (2) Kellgren and (3) Takakura classification systems for posttraumatic ankle osteoarthritis and found a low grade of interobserver agreement.[31]

The most appropriate diagnostic modality for early OA detection in younger patients is magnetic resonance imaging (MRI). New techniques, such as cartilage mapping, are capable of detecting early changes in cartilaginous microstructure, extracellular matrix composition and chondrocyte biomechanics. T1ρ mapping is an important modality for assessing proteoglycan content,[32] while collagen organization is appreciated in T2 relaxation times.[33] T2 mapping has reduced sensitivity to assess deep cartilage layers, since their highly organized structural properties result in extremely short T2 relaxation times. As such, Ultrashort Echo Time (UTE) - T2 is more sensitive for accurately determining collagen integrity and cartilage degeneration.[34–36]

Single photon emission computed tomography/computed tomography (SPECT-CT) has been used in OAPTT patients to assess the extension of degenerative changes and their biological activities.[37] This imaging modality combines bone scan and immunoassay data with CT and demonstrated significantly greater inter- and intraobserver reliability compared to isolated CT or CT with bone scan.[38] In addition, SPECT-CT allows the accurate checking of mechanical misalignment effects on the cartilage. Ankles with varus deformities showed significantly higher radioisotope uptake in the medial joint compartment compared to the lateral compartment. In contrast, valgus ankles showed significantly higher uptake in lateral areas.[39,40] Computed tomography under load is an innovation in the ankle and foot field and it has shown great accuracy for diagnosis, planning and post-treatment control of ankle osteoarthritis.[41]

Box 1 Original classification systems for ankle osteoarthritis according to the Kellgren-Lawrence Arthritis Grading Scale, the Takakura classification system, the Morrey and Wiedeman classification and the Classification of osteoarthritic changes in the ankle (van Dijk)

The Kellgren-Lawrence Arthritis Grading Scale
0 - no detectable osteoarthritis
1 - doubtful narrowing of the joint space, possible osteophyte
2 - defined osteophytes, definitive narrowing of the joint space
3 - multiple osteophytes, joint space narrowing, some sclerosis
3 - large osteophytes, marked joint space narrowing, severe sclerosis.
Takakura classification system
I - early sclerosis and osteophytes formation, no joint narrowing.
II - medial joint space narrowing, no subchondral bone contact.
IIIA - medial joint space obliteration, subchondral bone contact.
IIIB - articular space obliteration over the talar domus, subchondral bone contact.
IV - joint space obliteration with complete bone contact.
Morrey and Wiedeman classification
0 - normal ankle.
1 - small osteophytes and minimal joint narrowing.
2 - moderate osteophytes and moderate joint narrowing.
3 - significant joint narrowing with joint deformation or fusion.
Classification of osteoarthritic changes in the ankle (van Dijk)
0 - normal joint or subcentral sclerosis.
I - osteophytes with no joint space narrowing.
II - joint space narrowing with or without osteophytes.
III - (sub)total joint disappearance or joint space deformation.

Biomarkers

Biomarkers are released in different body fluids after an acute fracture and can be quantified by gene expression analysis.[42,43] As OA is an inflammatory process, inflammation biomarkers can be the first signs of OAPTT. Biomarkers can be measured in blood, urine and synovial fluid. Although tumor necrosis factor alpha (TNF-α), IL-1 and some MMPs have been studied, the best marker is not yet established[44] Collagen II precursors and metabolites are more specific markers of chondrocyte metabolism and may indicate necrosis or apoptosis of such cells.[45] However, a biomarker

systematization to provide prognostic information for monitoring the clinical response to OAPTT treatments is still lacking.

Staged Treatment

The therapeutic decision must be based on the following factors:

- Intensity of joint degeneration
- Osteoarthritis etiology
- Affected joint area – asymmetric OA
- Bone quality
- Lower limb alignment
- Joint stability
- Medical history
- Condition of the patient (total arthroplasty x ankle arthrodesis)
- Experience of the surgeon

In addition, it must consider the four proposed treatment stages:

1. Nonsurgical treatment
2. Joint-sparing surgery
3. Total ankle arthroplasty
4. Ankle arthrodesis

Stage I. Nonsurgical treatment - It represents the therapeutic option for patients with initial osteoarthritis and mild, nondaily pain, with little functional limitation, good bone quality, adequate lower limb alignment, stable joint and any age group. Its goals are to improve symptoms and maintain the range of motion for a potential future surgical treatment.[10]

Orthotics and insoles

Orthotics and insoles reposition the joint, align the mechanical axis of the lower limb and correct minor changes in physiological alignment, resulting in symptomatic improvement. There is no evidence in the literature regarding clinical outcomes at long-term follow-up times.[46–48]

Physical Therapy

The literature on knee osteoarthritis rehabilitation presents good level I and II studies. However, randomized clinical studies are still required to improve evidence regarding the real role of physical therapy for articular degeneration in other joints, including the hip, hand, foot, ankle, shoulder and spine.[49]

In mild and moderate OAPTT, physical therapy helps preserving the range of motion because it increases joint stability through muscle strengthening; this is a useful feature even for future treatments through total ankle arthroplasty.[9]

Medication

Despite the high prevalence of OAPTT, there is little clinical evidence on the impact of drug treatment, since the existing literature is based on studies with small sample sizes and methodological limitations. Guidelines for drug use in foot and ankle conditions are generally extrapolated from studies in other lower limb joints. Low-dose acetaminophen and topical nonsteroid anti-inflammatory drugs (NSAIDs) are considered adjuvant for pain treatment. In case of failure, oral NSAIDs or cyclooxygenase (COX)-2 inhibitors can be added to this first line of therapy.[50]

Intra-articular injections

Evidence on steroid injections for ankle osteoarthritis is limited to four case series, totaling 298 people, with positive symptomatic responses to triamcinolone and betamethasone consisting in partial reductions of average visual analog scale (VAS) values for pain in 35% of patients.[51]

Nineteen studies present evidence on viscosupplementation with hyaluronic acid (HA), including 11 case series, totaling $\sim$ 400 patients. Positive symptomatic responses based on pain and mobility scores, VAS and SF-36 were observed in 68% of the patients. Most studies have found significant benefits from 6 to 18 months.[46–48]

Evidence on platelet-rich plasma (PRP) is based on case series totaling 45 subjects with unsatisfactory or partial responses at VAS for pain, Japanese Society for Surgery of the Foot (JSSF) ankle/hindfoot scale and the Self-Administered Foot Evaluation Questionnaire (SAFE-Q).[33–35]

Stage II. Joint-sparing surgery - This is a therapeutic option for patients with moderate osteoarthritis, significant, daily pain, small to moderate functional limitation, posttraumatic or primary etiology, good bone quality and asymmetric alignment of the lower limbs associated or not with joint instability; it is mostly indicated for young people and patients with no systemic comorbidities.

Its goals are to reestablish joint biomechanics, alignment and stability, in addition to slow down joint degeneration evolution at the most affected compartment, allowing postponement of more invasive procedures for 5 to 10 years.[10]

Articular debridement and distraction

Nonsparing procedures may not be the treatment of choice, especially in younger patients with moderate OAPTT, due to the potential for late complications and the high rates of reoperation, prosthesis failures and/or the development of secondary OA in adjacent joints.

Such patients may be submitted to open or arthroscopic debridement to relief symptoms and provide a better joint assessment[52]

Joint distraction is a viable treatment option for selected patients with OAPTT and preserved hindfoot mobility[53] The current literature does not demonstrate superior outcomes for these modalities in comparison to other joint sparing procedures.

Herrera-Perez et al demonstrated some different outcomes in a prospective, randomized study comparing isolated joint debridement and joint debridement associated with distraction. These authors observed that patients undergoing isolated debridement had a higher level of pain at the 3-year follow-up compared with the group submitted to the combined

procedure. Both treatment options can help delay the need for nonsparing procedures (arthrodesis or arthroplasty).[54,55]

Osteotomies around the ankle

The role of supramalleolar osteotomies is based on force rebalancing in the ankle joint; these procedures aim to realign the hindfoot, transfer the joint support axis to the less degenerate compartment and normalize the direction of the sural triceps force vector to delay ankle joint arthritis progression.[56–58]

The principles of supramalleolar osteotomy are the following:

1. To locate the deformity apex: the deformity vertex is often close to the joint surface or positioned within the joint; in this situation, correction through the apex may not be possible. Corrections made outside the proper level result in distal fragment translation. As such,
   - wedge osteotomies proximal to the apex lead to ankle joint medialization when valgus is corrected
   - wedge osteotomies proximal to the apex lead to ankle lateralization during varus correction

   In these cases, lateral overload on ankles with valgus OA and medial overload on the ankles with varus OA will be sustained, and additional compensatory translation is critical:
   - lateral translation in valgus ankles
   - medial translation in varus ankles
2. To recognize the joint pattern: congruent or incongruous type
3. To perform additional procedures if required
   - sagittal plane correction
   - distal fibula length and orientation adjustment
   - soft tissue balancing

The authors observed encouraging medium-term outcomes after supramalleolar osteotomies in patients with intermediate-staged OAPTT, with significant pain relief and functional hindfoot improvement according to the American Orthopaedic Foot and Ankle Society (AOFAS) score, often requiring additional procedures.[56–58]

Stage III. Total ankle arthroplasty - This is a therapeutic option to address severe osteoarthritis associated with high-intensity daily pain and high functional limitation. It presents better outcomes in young patients with post-traumatic conditions, adequate bone stock, proper lower limbs alignment or mild asymmetry and joint stability who do not present serious systemic comorbidities. This procedure can be indicated for patients with severe OA but not the previously described features; however, in these cases, complication (including infection, dehiscence, residual pain and reduced range of motion) and reoperation rates are high.[59–61]

Absolute contraindications to total ankle arthroplasty (ATT) include:

- acute or chronic infections, with or without osteomyelitis
- total avascular necrosis of the talus body

Relative contraindications include:

- severe osteoporosis
- bad bone quality
- diabetes mellitus
- smoking
- overweight/obesity

Patients already submitted to ankle prosthesis procedures and presenting with component failure or wear may require a review arthroplasty; however, this is a technically demanding surgery. Painful pseudoarthrosis or vicious arthrodesis consolidation are another specific indication for total ankle replacement.[59]

Modern implants are three-component systems: a talar component, a tibial base component and a modular tibial joint surface. Recent advances related to implant design provide less bone resection, better bone-implant fixation and longer component durability. The procedure can be performed through an anterior or lateral transfibular access route.[59–61]

Total ankle arthroplasty studies show clinical and pain scores improvement in up to 64% of the cases. Total ankle arthroplasty using modern implants shows success rates of 70 to 90% in 10 years. Although age, body mass index (BMI) and preoperative deformity degree are not associated with higher failure rates, patients with hindfoot arthrodesis presented a significantly higher risk of implant failure (►**Figure 1**)[59–62]

Stage IV. Ankle arthrodesis - Arthrodesis is mainly indicated for cases of severe osteoarthritis, failure of the previous options, high functional limitation, secondary to any etiology, and in patients of any age group.

Total ankle replacement and tibiotarsal arthrodesis are the treatment modalities for end-stage ankle osteoarthritis. Formerly recognized as the gold standard, ankle arthrodesis was indicated in the vast majority of cases due to its predictable results and lower complication rates. The development of ATT modified this therapeutic decision-making algorithm, demonstrating, at least, better biomechanical and functional outcomes. The increase in movements of adjacent joints during postarthrodesis follow-up, as a form of biomechanical compensation, is not a consensus yet, and these joints may suffer medium- and long-term progressive degeneration.[63–67]

There are four main differences in the biomechanical function of arthroplasty compared to arthrodesis:

- faster walking speed
- increased forefoot joint range of motion at the sagittal plane
- increased sagittal hindfoot movement
- increased ankle plantar flexion

For mild and moderate deformities, the arthroscopic or mini-open route are safe options; for severe deformities, however, the anterior and lateral transfibular routes are more indicated.[68]

Consolidation rates for these techniques range from 72 to 93%, but nonunion rates in smokers are as high as 54%.[69] The most frequent complications are wound dehiscence,

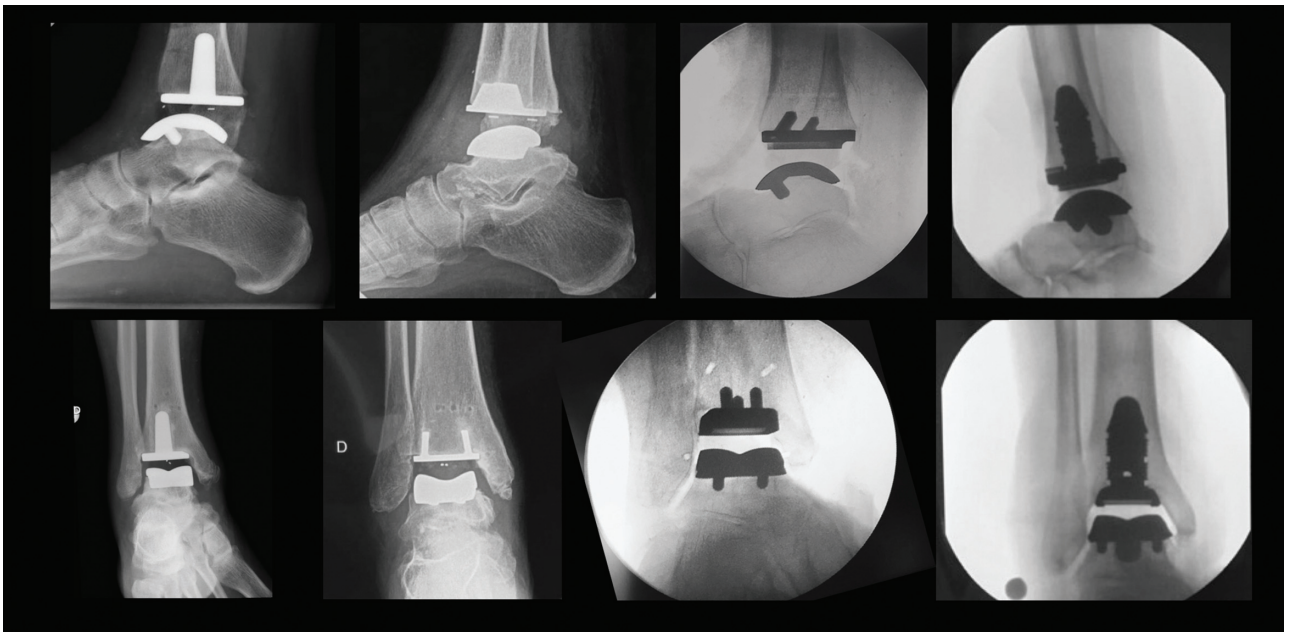


Fig. 1 Drawings of total ankle prostheses available in Brazil in lateral (upper column) and anteroposterior (lower column) views. ZENITH / Corin Group, TARIC / ImplanCast, INFINITY / Wrigth Medical, INBONE / Wrigth Medical.

superficial infection and neuroma; review procedures are required in 7 to 9% of cases, regardless of the technique used[70]

Final Considerations

Ankle OA is a different clinical situation from knee and hip OA, and it is mainly caused by traumatic injuries. The identification of molecular and cellular mechanisms involved in this condition are in focus in the literature. In the near future, the use of intra-articular and systemic medications that modulate the inflammatory joint response will probably play an important role in functional outcomes of fractures around the ankle, preventing even more dramatic results for this OA.

The most affected age group is composed by young adults; treatment is performed in stages and the therapeutic decision is multifactorial. Surgical options have well-defined principles and predictable functional outcomes. Viscosupplementation with hyaluronic acid and triamcinolone can be considered for nonsurgical treatment of early ankle OA.

Joint debridement associated or not with distraction represents a safe option for the treatment of stage II ankle OA. In final stages, total ankle arthroplasty and arthrodesis are the most appropriate procedures and must be discussed with the patient to make the best therapeutic decision.

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

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Prophylaxis of Venous Thromboembolism in Ankle and Foot Surgeries

Profilaxia do tromboembolismo venoso nas cirurgias do tornozelo e do pé

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Abstract

Venous thromboembolism (VTE) is among the most feared complications by orthopedists both for due to its potentially lethal outcome and the uncertainties related to its prevention. Despite the vast literature on VTE prevention in major orthopedic surgeries, little is known about it in ankle and foot procedures. In orthopedics, adequate thromboprophylaxis requires a careful assessment of the thrombotic and hemorrhagic risks based on the procedure to be performed, as well as and knowledge on anticoagulant agents. The presentis review has the goal of assessing the risk of developingdiscusses VTE risk assessment, the modalities of thromboprophylaxis modalities, and the drugs used, with an emphasis on foot and ankle surgeries.

Keywords
- thrombosis
- orthopedics
- surgery
- foot
- ankle
- pre-exposure prophylaxis

Resumo

O tromboembolismo venoso (TEV) é uma das complicações mais temidas pelos ortopedistas, tanto pelo seu desfecho potencialmente letal quanto pelas incertezas relacionadas àa sua prevenção. Apesar da vasta literatura existente sobre a prevenção de TEV nas grandes cirurgias ortopédicas, pouco se sabe sobre sua prevenção nas cirurgias do tornozelo e do pé. Uma adequada prescrição da tromboprofilaxia em ortopedia exige criteriosa avaliação dos riscos trombóticos e hemorrágicos mediante com base no tipo de cirurgia a ser realizada, além do conhecimento sobre os anticoagulantes. Esta revisão tem como objetivos abordar a avaliação do risco de desenvolver TEV, as modalidades de tromboprofilaxia, e os fármacos utilizados, tendo como ênfase as cirurgias do pé e do tornozelo.

Palavras-chave
- trombose
- ortopedia
- cirurgia
- pé
- tornozelo
- profilaxia pré-exposição

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Introduction

Venous thromboembolism (VTE) is the main cause of preventable death at hospital environments,[1] and one of the most known and feared complications of orthopedic surgeries. It usually presents as deep-vein thrombosis (DVT) and pulmonary thromboembolism (PTE). Deep-vein thrombosis can be complicated by postthrombotic syndrome (PTS) and PTE; in turn, PTE may result in chronic thromboembolic pulmonary hypertension (CTHP) and death.[2] The incidence of VTE in the general population is of approximately 1 to 2:1,000 people per year.[3]

Most data on VTE prevention in orthopedics relates to major orthopedic surgeries, such as knee and hip arthroplasties.[4–6] The main guidelines on the subject refer to objective recommendations for surgical prophylaxis,[1,4,7] including clear definitions on the type of drug and the duration of the treatment.

For surgeries below the level of the knee, however, the approaches and recommendations remain unclear. The guideline of the American College of Chest Physicians (ACCP) suggests not using pharmacological thromboprophylaxis for isolated lesions below the knee.[4] Similarly, the American Academy of Orthopedic Surgeons states that there is no specific guideline for prophylaxis in ankle and foot surgeries.[8] Another consensus establishes guidelines related to risk factors, but it does not define objective parameters for pharmacological thromboprophylaxis or the ideal moment to start it.[9] The most recent reccomendation of the American Society of Hematology does not mention ankle and foot injuries at all.[7]

The present review aims to present data on the incidence of VTE in ankle and foot surgeries, to identify the main risk factors in these scenarios, and to discuss the tools for the prediction of the risk and the alternatives for thromboprophylaxis.

Incidence

Lower-limb DVT (LL-DVT) rarely occurs after an ankle and foot orthopedic intervention; this is in contrast with major hip and knee surgeries, in which the incidence of LL-DVT ranges from 40% to 60%.[1]

In a meta-analysis with 43,381 patients, the incidence of symptomatic VTE was of 0.6% (95% confidence interval [95% CI]: 0.4% to 0.8%) in patients undergoing miscellaneous foot or ankle procedures, including cases of trauma or elective surgeries, with no thromboprophylaxis. Among those receiving some type of prophylaxis, the incidence of VTE was of 1.0% (95%CI: 0.2% to 1.7%),[9] possibly because these patients were in a more severe condition and/or had more risk factors for VTE.

In a retrospective cohort[10] with 22,486 patients undergoing ankle and/or foot surgery between 2008 and 2011, 173 (0.8%) patients had symptomatic VTE within 6 months following the procedure.[10] When assessed according to surgical site and the occurrence of thrombosis, 65.6% of VTE cases were associated to hindfoot and ankle surgeries, whereas 11.1% were related to midfoot surgeries, and 26.7%, to forefoot procedures.

It is known that rupture of the Achilles tendon is the foot-and-ankle condition most often associated with VTE. Data from a meta-analysis[9] show that in 1,060 patients with rupture of the Achilles tendon clinically assessed for VTE, the condition was confirmed in a total of 74 (7%) subjects.[9] From 1997 to 2015, 28,546 patients with acute rupture of the Achilles tendon submitted to surgical or non-surgical treatment were assessed for VTE.[11] Among them, 389 (1.36%) were diagnosed with thrombosis, including 278 (0.97%) cases of LL-DVT and 138 (0.48%) cases of PTE. In another prospective cohort study[12] with 291 patients with acute rupture of the Achilles tendon, 14 patients (4.81%) were diagnosed with VTE within 33 days after surgery.[12]

It is worth noting that most thromboembolic events reported in the aforementioned studies were asymptomatic, diagnosed by postoperative screening imaging tests alone. Therefore, most of these events are of little or no clinical relevance. For instance, in a prospective cohort study[13] including 114 elective foot and/or ankle surgeries performed on 111 patients, 29 subjects (25.4%) had DVT, but most cases (20/29, or 68.9%) were diagnosed on a screening ultrasound 2 weeks after surgery.[13] In another prospective cohort study,[14] 216 patients undergoing miscellaneous foot or ankle surgery were screened for DVT using an ultrasound of the lower limbs 2 to 6 weeks after surgery. The incidence of VTE was of 5.09% (11/216), and 3/11 patients had asymptomatic DVT.[14] Thus, since most asymptomatic venous thromboembolic events have little clinical repercussion and less than 10% of the cases of symptomatic distal LL-DVT present proximal extension,[15] VTE screening using ultrasound in asymptomatic patients undergoing surgery below the level of the knee should not be routinely performed. This test should be indicated for subjects with clinical suspicion of DVT.[9]

Still, the great difficulty in determining the risk of developing VTE in patients with injuries below the level of the knee stems from the following: 1) most studies are based on case series; 2) these studies provide inadequate information on the eventual use of thromboprophylaxis; 3) due to the low incidence, the number of VTE patients in these studies does not enable sufficiently robust conclusions;[16] and 4) the scarcity of studies assessing the impact of associated risk factors on the occurrence of VTE in patients submitted to surgical procedures below the level of the knee.[9,17–19]

Risk factors

Orthopedic surgeries, especially major hip and knee procedures, are high-risk interventions for VTE.[3] However, even though the thrombotic risk is lower, ankle and foot procedures usually require some time of restricted lower-limb support on the ground and/or immobilization, adding to the risk of developing VTE.[9,17]

Immobilization of a lower limb to prevent contraction of the calf muscles has been shown as an important isolated risk factor for VTE after procedures below the level of the knee.[20,21] In addition, it is known that the longer the immobilization time, the greater the risk of developing VTE.[22] Moreover, the

lack of ground support for the lower limb is associated with an increased risk of developing VTE, and, along with immobilization, it adds up as a major risk factor.[23] Immobilization with no support for a period of 2 to 8 weeks is associated with a 9-fold higher risk of developing VTE (odds ratio [OR]: 9.0; 95%CI: 1.8 to 44.3) compared to immobilization for a shorter period of time.[10] Although some authors consider that support of the lower limb on the ground enables the termination of the pharmacological prophylaxis[14] because the support provides greater mobility to the patient, this measure still requires additional studies to prove its effectiveness.

To date, the main risk factor for the development of VTE in patients submitted to procedures below the level of the knee is the history of previous thrombosis,[9–11,24] although this is considered a minor risk factor when the surgeon assesses an orthopedic patient.[17,25] The identification of this risk factor is considered the only formal indication to prescribe pharmacological thromboprophylaxis in this population.[4]

Other high risk factors for the development of VTE in ankle and foot surgeries are obesity (body mass index [BMI] above 30 kg/m^2),[9,10,18,26] age over 50 years,[9–11,17,26] and use of estrogenic compounds in women. Oral contraceptives and hormone-replacement therapy are risk factors for the development of classic VTE in the general population, being identified in most patients with VTE after ankle and foot surgeries or immobilization.[9,10,17,19] In addition, genetic risk factors, such as factor V Leiden, non-O blood type or elevated factor VIII levels must be considered when assessing the risk of developing VTE in foot and ankle surgeries, since they are known risk factors for other orthopedic procedures.[21,27,28]

An interesting question regarding ankle and foot conditions is the impact of the surgical site on the development of VTE. Patients surgically treated for injuries to the Achilles tendon appear to be those most at risk, with an incidence of VTE ranging from 1.36% to 7.00%.[9,11,18,19] The incidence of VTE also appears to be increased in ankle (1.0%),[26] hindfoot (0.14% to 1.1%)[18,29] and forefoot (0.03% to 4.00%) conditions.[14,26,30]

Risk-assessment tools

A major challenge for orthopedists treating ankle and foot injuries is to define which subjects are at greatest risk of developing VTE and, therefore, could benefit from pharmacological thromboprophylaxis. Due to the low incidence of VTE in ankle and foot surgeries and the miscellaneous VTE-related risk factors and comorbidities, this is a difficult task, since complications resulting from VTE (mainly from LL-DVT), such as PTE and PTS, although rare, are extremely harmful.[10]

Several tools have been developed to assess the patient's individual risk of developing VTE. Saragas et al.[14] analyzed the Thrombosis Risk Factor Assessment form, in which risk factors are scored and added to quantify the risk of developing VTE. These authors evaluated 216 patients with ankle and foot injuries treated by surgery, from hindfoot deformities to fractures and correction og bilateral halux valgus. They identified that the average score of the group that developed VTE was 7.7 (range, 4 to 13 points), with 90.9% of these patients scoring 5 or more points. Thus, they recommend a score of 5 as the cutoff point to initiate pharmacological thromboprophylaxis in patients undergoing ankle and foot orthopedic surgeries.

Another tool used in the assessment of the risk of developing VTE is from the National Institute for Health and Care Excellence (NICE), in the United Kingdom.[31] One of the advantages of this tool is its ability to assess all inpatients, not surgical subjects alone. In addition, the tool analyzes three important points: patient mobility, the risk factors for the development of VTE, and the risk of developing bleeding. The usefulness of this tool has been confirmed in prospective studies including patients with ankle fractures, injuries to bones of the foot, and ruptures of the Achilles tendon who received an immobilizing plaster cast or were surgically treated.[12,32] Nevertheless, despite the great advantage of considering the risk of developing bleeding in the analysis, the concept of mobility is not well defined, which can lead to misinterpretations and wrong decisions.

The Caprini score, which was developed for surgical patients in general[25,33] analyzes patient- and procedure-related risk factors; a total score $\geq$ 3 points indicates high risk (►**Figure 1**).[25] Although it has not yet been validated for general orthopedic surgery, the Caprini score has already been validated for some specific orthopedic surgeries, such as hip fractures,[34] hip and knee arthroplasties,[35] and general fractures.[36] In addition, it has also been validated for other surgical specialities, such as plastic surgery,[37,38] ear, nose and throat surgery,[39] and oncologic gynecology surgery.[40]

Since the Caprini score has already been validated in several surgical areas, it seems to be the most reliable and comprehensive for general orthopedic surgeries. However, the concept of assessment of the thrombotic risk in general orthopedic surgeries, and not in hip and knee surgeries alone, needs to be disseminated in the clinical practice. This will improve the prediction of the risk of developing VTE and result in more suitable thromboprophylaxis protocols for different groups at a higher risk of developing thrombosis.

Thromboprophylaxis modalities

Mechanical thromboprophylaxis

Mechanical thromboprophylaxis is based on gradual compression of muscles over veins, bolstering venous return.[16] In orthopedic surgeries, mechanical thromboprophylaxis can be performed using intermittent pneumatic compression devices (IPCDs) and elastic compression stockings.[41] In a recent meta-analysis[42] with 16,164 patients, IPCDs were effective in reducing VTE in hospitalized subjects when compared to placebo, with a relative risk (RR) of developing DVT of 0.43 (95%CI: 0.36 to 0.52) and an RR of developing PTE of 0.48 (95%CI: 0.33 to 0.69).[42] As advantages, these devices do not have the adverse effects presented by anticoagulant drugs, such as bleeding, nor do they require

Each risk factor represents 1 point			
Age 41-60 years		Acute myocardial infarction	
Swollen legs (current)		Congestive heart failure (<1 month)	
Varicose veins		History of prior major surgery (<1 month)	
Minor surgery planned		History of inflammatory bowel disease	
Sepsis (<1 month)		Abnormal pulmonary function (COPD)	
Obesity (BMI > 25)		Serious lung disease including pneumonia (<1 month)	
Medical patient currently at bed rest			
Oral contraceptive or hormone replacement therapy			
Pregnancy os postpartum			
History of unexplained stillborn infant, recurrent spontaneous abortion (≥3), premature birth with toxemia or growth-restricted infant			
Other risk factors			

Each risk factor represents 5 points	
Stroke (<1 month)	
Multiple trauma (<1 month)	
Elective major lower extremity arthroplasty	
Hip, pelvis or leg fracture (<1 month)	
Acute spina nord injury (paralysis) (<1 month)	

Each risk factor represents 2 points	
Age 61-74 years	
Malignancy (present or previous)	
Major surgery, including laparoscopic surgery (<45 minutes)	
Immobilizing plaster cast (<1 month)	
Central venous access	
Arthroscopic surgery	
Patient confined to bed (>72 hours)	

Each risk factor represents 3 points	
Age 75 years or older	
History of DVT/PE	
Family history of thrombosis	
Positive Factor V Leiden	
Positive Prothrombin 20210A	
Positive Lupus anticoagulant	
Heparin-induced thrombocytopenia (HIT)	
Elevated serum homocysteine	
Elevated anticardiolipin antibodies	
Other congenital or acquired thrombophilia	

Fig. 1 Caprini score. Abbreviations: BMI, body mass index; COPD, chronic obstructive pulmonary disease; DVT, deep venous thrombosis; h, hours; LLs, lower limbs; VTE, venous thromboembolism. Source: Adapted from Caprini JA. Risk assessment as a guide for the prevention of the many faces of venous thromboembolism. Am J Surg 2010;*199* (1 Suppl):S3–10[25].

laboratory monitoring.[43] However, they present an important disadvantage, that is, low postoperative adherence, since many patients undergoing ankle and foot surgery are immobilized, which prevents using these devices on the operated limb. Thus, IPCDs are reserved for the contralateral limb during hospitalization. It should be noted that the simplest mechanical method for the prevention of VTE is early walking.[22,43]

Pharmacological thromboprophylaxis

The use of drugs for VTE prophylaxis (pharmacological prophylaxis) in ankle and foot surgeries is more widespread than mechanical prophylaxis. This is due to the lower availability of compression devices, the costs of the compressive stockings, the lower ease of use and local factors, such as the need for lower-limb immobilization after these procedures.

The drugs approved for thromboprophylaxis in orthopedic surgeries include acetylsalicylic acid (ASA), heparins (both unfractionated heparin [UFH] and low-molecular-weight heparin [LMWH]), direct-acting oral anticoagulants, and warfarin. If these medications are used before surgery, it is important to observe the necessary withdrawal period prior to the procedure to avoid bleeding (►**Table 1**). Each of these drugs acts at a certain stage of the coagulation pathway, inhibiting different factors (►**Figure 2**).

Acetylsalicylic acid inhibits cyclooxygenase, decreasing the synthesis of prostaglandins and thromboxane, resulting in inhibition of platelet aggregation. It is an easily accessible, inexpensive drug with a long history of use. Although the literature is controversial on recommending ASA as a single agent for thromboprophylaxis, recent studies[44] demonstrate that it can be used after a short five-day cycle of a direct-acting oral anticoagulant (rivaroxaban) in hip and knee arthroplasties.[45,46] Studies on ASA as a thromboprophylaxis agent in ankle and foot surgeries are still scarce, as noted in a recent consensus on the subject.[17]

Unfractionated heparin and LMWH inhibit several coagulation proteases (►**Figure 2**). Unfractionated heparin acts indirectly, binding to antithrombin (a natural anticoagulant) and bolstering its inhibitory action on various coagulation proteases, including thrombin (factor IIa) and factor Xa.[41] Low-molecular-weight heparin results from the partial digestion of UFH, and it presents a reduced ability to bind to other plasma proteins and a greater specificity against factor Xa. Both forms are effective, safe, and administered by subcutaneous route. However, LMWH is easiest to use (single daily dose) and related with a lower risk of heparin-induced thrombocytopenia and lower osteopenia-inducing effects.[47] Thus, LMWH is the most recommended anticoagulant for VTE prophylaxis in ankle and foot surgeries, even according to the most recent guidelines;[9,17] so far, LMWH is the drug of choice for both surgical and non-surgical patients at risk of developing VTE as long as they are immobilized.[17]

Direct-acting oral anticoagulants (DAOAs) are a new class of drugs specifically targeted to counter factor Xa (apixaban, rivaroxaban, edoxaban, betrixaban) or factor IIa (dabigatran). Their main advantage is the lack of requirement for periodic monitoring through laboratory tests or parenteral/subcutaneous administration. In addition, they are safer drugs compared to warfarin regarding severe bleeding, even though DAOAs are more commonly related to gastrointestinal hemorrhage.

Rivaroxaban, apixaban and dabigatran have been approved for VTE prophylaxis in knee and hip arthroplasties.[48,49] Still, none of these drugs were approved for use in proximal femur and hip fractures.[4,7,50] Despite the approval of the use of DAOAs in major orthopedic surgeries, current data refer only to rivaroxaban for VTE prophylaxis in

Table 1 Drugs most used for the prophylaxis of venous thromboembolism in orthopedic surgeries

Drug	Dose	Time for withdrawal from the preoperative therapy	Notes
Acetylsalicylic acid	100 mg/day, single dose, orally	5 to 10 days before surgery	It should not be used as a monotherapy. Use as extended therapy after 5 days of rivaroxaban in patients with low thrombotic risk
LMWH - enoxaparin	40 mg/day, single dose, subcutaneous	12 hours if low risk of bleeding; 24 hours if high risk of bleeding	Start 12 hours after surgery
LMWH - dalteparin	5,000 IU/day, single dose, subcutaneous	12 hours if low risk of bleeding; 24 hours if high risk of bleeding	Start 12 hours after surgery
LMWH - nadroparin	38 IU of anti-Xa per kilogram of body weight (0.2 to 0.4 mL); increase by 50% on the fourth postoperative day (0.3 to 0.6 mL).	12 hours if low risk of bleeding; 24 hours if high risk of bleeding	Start 12 hours after surgery
Rivaroxaban	10 mg/day, orally	24 hours if low risk of bleeding; 48 hours if moderate or high risk of bleeding, or in elderly patients	Start $>$ 6 hours after surgery
Dabigatran	220 mg/day, orally	48 to 72 hours if normal renal function; minimum of 5 days for major orthopedic surgeries	Start with 110 mg 1 to 4 hours after surgery, followed by 220 mg once a day
Apixaban	2.5 mg orally, twice a day	24 hours if low risk of bleeding; 48 hours if moderate or high risk of bleeding	Start $\geq$ 12 hours after surgery
Warfarin	In most cases, 5-10 mg/day, orally	3 to 5 days	After the third day, adjust per INR with a therapeutic target of 1.5 to 2.5. Start 12 to 24 hours after surgery. We suggest a validated warfarin dose-adjustment nomogram

Abbreviations: INR, international normalized ratio; LMWH, low-molecular-weight heparin.

surgeries below the level of the knee. In a randomized study with 3,604 patients treated with 40 mg of subcutaneous enoxaparin or 10 mg of oral rivaroxaban, both administered once a day, rivaroxaban was more effective in preventing VTE than enoxaparin (RR: 0.25; 95%CI: 0.09 to 0.75), with no increased risk of bleeding.[51]

Warfarin is a vitamin K antagonist that inhibits the synthesis of calcium-dependent coagulation factors (factors II, VII, IX and X), as well as proteins C, S and Z.[41] The recommended dose varies, mostly ranging from 5 mg to 10 mg a day during the postoperative period.[41] Although cheap and widely available, warfarin should only be used as a thromboprophylactic agent in orthopedic surgeries when heparins or DAOAs are not available. Warfarin requires continuous monitoring of prothrombin time and its derivative, the international normalized ratio (INR), which should have a target value between 2 and 3 in order to be considered adequate for VTE prevention. Since its average half-life is of 2.5 days, the administration of warfarin must be terminated at least 3 days before surgery.[52]

Duration of the thromboprophylaxis

Pharmacological thromboprophylaxis must started 12 hours after surgery if the patient has no active bleeding or high risk of developing bleeding.[53]

The duration of the pharmacological thromboprophylaxis is well defined in certain orthopedic procedures, such as major orthopedic surgeries (hip and knee arthroplasties), in which postoperative anticoagulation must be performed for at least 10 to 14 days, and can reach up to 35 days.[4] Anticoagulation may be suspended until the patient starts to walk, as long as it has been performed for at least 10 to 14 days. However, the simple replication of these time periods in ankle and foot surgeries is not adequate.

The use of some sort of immobilization in the treatment of ankle and foot conditions is associated with VTE in 4.3% to 40.0% of patients, regardless of the fact that they have been treated surgically or clinically.[54] The lack of lower-limb support on the ground and the use of a partial support are risk factors for the development of DVT.[23,55] As a result, immobilization and the fact that the foot is not resting on the ground must be considered when defining the duration of the prophylaxis.

Specialists usually agree that prophylaxis must be sustained throughout the immobilization period,[17] or at least while the patient remains with no support, but immobilized. Prophylaxis may be terminated as soon as the treated lower limb is supported or after the removal of the immobilization even without support, which will enable the active contraction of calf muscles, reducing the risk of developing VTE.[14]

Complications

The major debate about prophylaxis lies on the potential complications resulting from the thr administration of anticoagulant agents, especially in major surgeries. However, information on the occurrence of pharmacological prophylaxis-related complications in ankle and foot surgeries is scarce.

A possible anticoagulant-related complication in lower-limb surgery is bleeding, which occurs in 0.3% to 1% of cases.[49,56] The factors associated with increased postoperative bleeding in this group of patients are revision surgeries, perioperative bleeding greater than expected, aggressive soft-tissue dissection, recent gastrointestinal or genitourinary bleeding, concomitant anti-platelet therapy, and advanced kidney disease.[57]

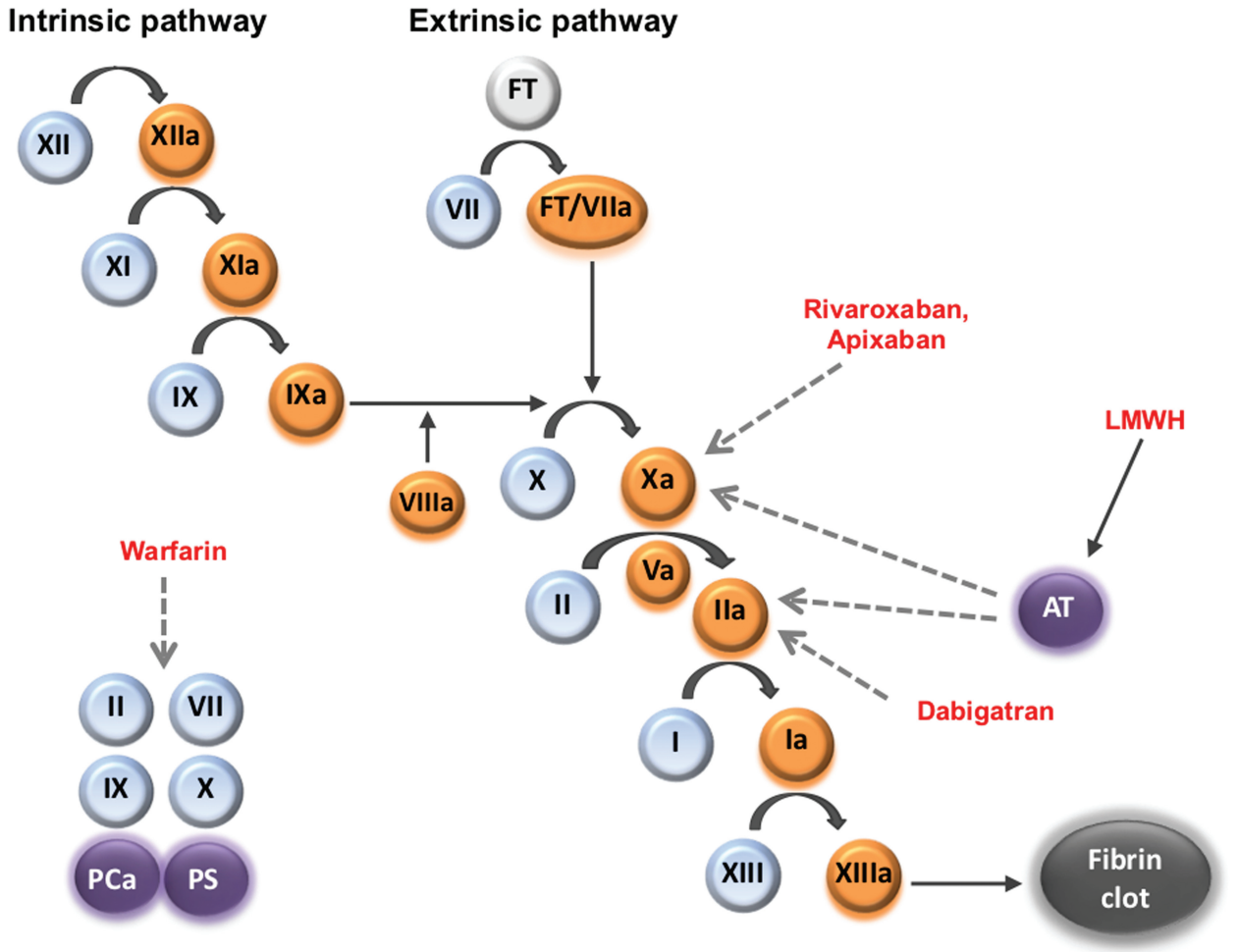


Fig. 2 Schematic representation of coagulation control and sites of activit of the main anticoagulants. Abbreviations: a, activated; AT, antithrombin; FT, tissue factor; LMWH: low-molecular-weight heparin.

Other potential local complications are bruises,[49] which can result in surgical wound dehiscence and infection, often with dramatic presentation in ankle and foot surgeries. In addition, heparin-induced thrombocytopenia, a complication considered severe due to the increased risk of thrombotic events, is more common in surgical patients, with an incidence rate of 0.20% to 0.36% in subjects treated with LMWH.[58,59]

Final Considerations

Venous thromboembolism is a complication of the treatment of ankle and foot conditions. Although its incidence is lower compared to hip and knee surgeries, robust studies are still required to assess the concomitant risk factors that interact and increase the risk of developing VTE. The assessment of risk factors associated with the type of orthopedic surgery should be individualized to substantiate and direct the focus of the thromboprophylaxis on groups at a higher risk. The current studies lack evidence for a universal thromboprophylaxis recommendation in ankle and foot surgeries.

Once pharmacological thromboprophylaxis is indicated, LMWH (usually enoxaparin) is the anticoagulant agent of choice for VTE prophylaxis in patients submitted to ankle and foot procedures. The use of DAOAs as thromboprophylactic agents in orthopedic surgeries in injuries below the level of the knee still requires further studies. To date, only rivaroxaban has been shown to be effective and safe, and its use has been approved. According to current guidelines, other DAOAs must be used only if the patient refuses heparin and rivaroxaban is unavailable. Thromboprophylaxis must be maintained throughout the period, with no limb support or immobilization, since these are recognized risk factors for the development of VTE.

Future studies should focus on the interaction of other risk factors for the development of VTE concomitantly with ankle and foot orthopedic procedures, as well as on the validation and improvement of risk-assessment tools and their automation. This will enable the identification of patients at the highest risk, resulting in an adequate indication of prophylaxis to reduce the costs and complications.

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Conflicts of Interests

The authors have no conflict of interests to declare.

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Nerve Graft and Nerve Transfer for Improving Elbow Flexion in Children with Obstetric Palsy. A Systematic Review*

Enxerto e transferência de nervo para melhora da flexão do cotovelo em crianças com paralisia obstétrica. Uma revisão sistemática

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Abstract

Obstetric brachial plexus palsy is a rather common injury in newborns, caused by traction to the brachial plexus during labor. In this context, with the present systematic review, we aimed to explore the use of nerve graft and nerve transfer as procedures to improve elbow flexion in children with obstetric palsy. For the present review, we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. We searched the MEDLINE, EMBASE, LILACS, The Cochrane Central Register of Controlled Trials, Web of Science, Wholis and SCOPUS databases. Predetermined criteria defined the following requirements for inclusion of a study: Clinical trials, quasi-experiments, and cohort studies that performed nerve graft and nerve transfer in children ($\leq$ 3 years old) with diagnosis of obstetric palsy. The risk of bias in nonrandomized studies of interventions assessment tool was used for nonrandomized studies. Out of seven studies that used both procedures, three of them compared the procedures of nerve graft with nerve transfer, and the other four combined them as a reconstructive method for children with obstetric palsy. According to the Medical Research Council grading system, both methods improved equally elbow flexion in the children. Overall, our results showed that both techniques of nerve graft and nerve transfer are equally good options for nerve reconstruction in cases of obstetric palsy. More studies approaching nerve reconstruction techniques in obstetric

Keywords

- obstetrical brachial plexus palsy
- nerve transfer
- allogenic grafts

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palsy should be made, preferably randomized clinical trials, to validate the results of the present systematic review.

Resumo

A paralisia obstétrica do plexo braquial é uma lesão bastante comum em neonatos, sendo causada pela tração do plexo braquial durante o trabalho de parto. A presente revisão sistemática tem como objetivo explorar o uso de enxertos e transferências de nervo como procedimentos para melhora da flexão do cotovelo em crianças com paralisia obstétrica. A presente revisão sistemática seguiu as diretrizes Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA, na sigla em inglês) e foi baseada em pesquisa nos bancos de dados MEDLINE, EMBASE, LILACS, The Cochrane Central Register of Controlled Trials, Web of Science, Wholis e SCOPUS. De acordo com os critérios pré-determinados, os artigos incluídos eram ensaios clínicos, quase-experimentos, e estudos de coortes sobre enxertos e transferências de nervos em crianças (de até 3 anos de idade) com diagnóstico de paralisia obstétrica. A ferramenta de avaliação Risk of Bias in Non-Randomized Studies of Interventions foi usada em estudos não randomizados. Sete estudos utilizaram os dois procedimentos; três deles compararam os procedimentos de enxerto e transferência de nervo, enquanto os outros quatro os combinaram como método reconstrutivo em crianças com paralisia obstétrica. Segundo o sistema de classificação do Medical Research Council, os dois métodos melhoraram a flexão do cotovelo das crianças de maneira similar. De modo geral, nossos resultados mostraram que o enxerto de nervo e a transferência de nervo são opções igualmente boas para a reconstrução nervosa em casos de paralisia obstétrica. Mais estudos sobre as técnicas de reconstrução nervosa na paralisia obstétrica devem ser realizados, de preferência ensaios clínicos randomizados, para validação dos resultados dessa revisão sistemática.

Palavras-chave

- paralisia do plexo braquial neonatal
- transferência de nervo
- enxertos alogênicos

Introduction

Obstetric brachial plexus injury (OBPI) or obstetric brachial plexus palsy (OBPP) is a rather common injury in newborns that can have a spontaneous recovery,[1] but it varies from 30% to 90%. This injury is caused by traction to the brachial plexus during labor, and the extent of neural damage can only be assessed by evaluating recovery in the course of time.[2] Its incidence varies between 0.15 and 3 cases per 1.000 live births.[2] The classical injury is a C5, C6 palsy, but all roots can be involved.[1]

Nerve grafting has been performed in neonatal population with brachial plexus palsy for >30 years, and it is recommended for patients who present with postganglionic rupture of the upper nerve roots of the brachial plexus (C5 and C6).[3] On the other hand, nerve transfer surgery is usually indicated in cases of late presentation, failed primary nerve reconstruction, isolated deficit, absence of proximal root for grafting, and multiple nerve root avulsions.[3] Nerve transfer surgery involves taking nerve branches from a neighboring nerve and redirecting them to the distal end of the injured nerve.[4] After the surgery, the body regenerates axons along the new path, and the motor cortex rewires itself to relearn muscle functions.[4]

There are several experimental reports in which allograft nerve has been used as an alternative to nerve autograft to bridge two ends of a nerve together, both in nonhuman and human primates.[5] Allograft tissue would serve as a temporary scaffold in which it enhances neural regeneration by providing the essential structural characteristics of the nerve tissue.[6] Restoration of elbow flexion is of great importance and it is one of the highest priorities of brachial plexus reconstruction,[7] and one of the most commonly grading system to assess this recovery has been the Medical Research Council (MRC) grading system.[8,9] In this context, with the present systematic review, we aimed to explore the use of nerve graft and nerve transfer as procedures to improve elbow flexion in children with OBPP.

Methods

The present systematic review was performed according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA).[10] We searched the MEDLINE, EMBASE, LILACS, The Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Wholis, and SCOPUS databases. In the search, we included terms in English, Spanish and Portuguese using the search equation: *E= (P1 AND P2 NOT (P3 OR P4)) AND I AND O*. The Patient/Population, Intervention, Comparison and Outcomes (PICO) question was: What is the evidence of elbow flexion improvement with the nerve graft or nerve transfer technique in children with OBPP? We did not restrict the search by time (Supplementary material 1).

Selection Criteria

Predetermined criteria defined the following requirements for inclusion of a study: clinical trials, quasi-experiments, and cohort studies that performed nerve graft and nerve transfer in children ($\leq$ 3 years old) with diagnosis of OBPP. For all outcomes, the studies had to have at least 6 months of follow-up. All comparative studies of graft versus transfer reported relevant outcomes regarding the muscle strength measured by the MRC.

Data Extraction

Independent and blinded reviewers extracted data from eligible studies. The variables of abstraction included: author, year of the study, study design, number of patients for either procedure, age at surgery, gender, injuries, follow-up period, and donor nerve for either procedure. The primary outcome was to explore the use of nerve graft and nerve transfer in children with OBPP, and the secondary outcome was the recovery of elbow flexion following both procedures, assessed by strength by the MRC after the procedure. The MRC grading system consists of 5 grades: 0 represents no contraction, 1 represents flicker or trace of contraction, 2 represents active movement with gravity eliminated, 3 represents active movement against gravity, 4 represents active movement against gravity and resistance, and 5 represents normal power.[8] Two researchers reviewed each study found in the databases by title and abstract, selecting the more adequate ones. Subsequently, they reviewed the full texts of previously selected articles and screened them according to the inclusion criteria. With the studies finally selected, we extracted the data. Disagreements were resolved by consensus, and where disagreement could not be solved, one of the two reviewers solved the conflict.

Risk of Bias Assessment

The Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I) assessment tool[11] was used for nonrandomized studies. This tool includes 7 specific bias domains: 1 - confounding; 2 - selection of participants; 3 - classification of intervention; 4 - deviation from interventions; 5 - missing outcome data; 6 - measurement of outcomes; and 7 - selection of reported overall result. Risk of bias was rated as: 0 - no information; 1 - low risk; 2 - moderate risk; 3 - serious risk; and 4 - critical risk. Two authors assessed independently the risk of bias of the included articles. Disagreements were managed by consensus.

Strategy for Data Analysis

The statistical analysis for categorical variables consisted in percentages, frequencies and measures of central tendency.

Results

From our literature search in the different databases, we found 344 records after removal of duplicates. Following the screening of titles and abstracts, 44 studies were eligible for full-text evaluation. Finally, seven studies were included in the systematic review, as presented in the PRISMA Flow Diagram (►**Fig. 1**). Disagreements were managed by consensus.

Study Characteristics

Seven studies were selected, three of which compared the procedures of nerve graft for 59 patients and of nerve transfer for 34 patients, having a total number of 93 patients (►**Table 1**). On the other hand, four of them did not compare procedures, but used them as a reconstructive method for children with OBPP (►**Table 1**). For the studies that compared nerve graft with nerve transfer, the age at surgery ranged from 5.7 to 18 months old, and the follow-up period ranged from 12 to 70 months. Meanwhile, the age at surgery of the studies that combined both procedures ranged from 3.5 to 23 months old, and the follow-up period ranged from 24.3 to 85 months. Only two of the selected studies had all data necessary to compare the elbow flexion outcome evaluated with the MRC after the nerve grafting or nerve transfer surgeries (►**Table 2**).

Risk of Bias Assessment

Risk of bias assessment for the studies was evaluated using the ROBINS-I tool (Supplementary material 2). Only the three studies that compared the procedures of nerve graft with nerve transfer were included in this assessment. In domains 3 and 6, 3 out of 3 studies were rated as low risk; in domain 7, 3 out 3 studies were rated as moderate; in domains 2 and 4, one-third was rated as moderate; in domains 1 and 5, one-third was rated as serious; overall, two studies were rated as presenting moderate, and one as presenting serious risk of bias.

Discussion

Our objective was to explore the use of nerve graft and nerve transfer as procedures to improve elbow flexion in children with OBPP. Here, we found seven studies that used both procedures, three of them compared the procedures of nerve graft and nerve transfer, as the other four combined them as a reconstructive method for children with OBPP. According to the MRC scale, both methods equally improved the elbow flexion in the children, which is coincident with previous studies.[12]

Chang et al.[3] found similar improvement for elbow flexion in abduction and adduction for both groups of infants who underwent Oberlin transfer versus nerve grafting, with no statistical significance. According to the authors, nerve transfer should be considered in cases such as late presentation, failed primary nerve reconstruction, absence of proximal root for grafting, and multiple nerve root avulsions (preganglionic lesion). Likewise, Luszawski et al.[13] reported the results of children with OBPP lesions operated with the nerve graft or nerve transfer technique. The authors do not show the results of all patients after the follow-up period, but 100% of the patients submitted to nerve transfer (only 1 shown) had biceps muscle recovery to an MRC grade $>$ M3. On the other hand, 77% of the patients (10 out of 13 shown) submitted to nerve graft had biceps muscle recovery to an MRC grade $>$ M3. On the other hand, Malessy et al.,[14] in their study, divided patients into Group A and Group B, depending on the procedures performed. In group A, 17 infants received transfer of either the C6 anterior root filaments with direct coaptation in 15 of them, or the entire C6 nerve to C5. Likewise, Group B comprised 17 infants;

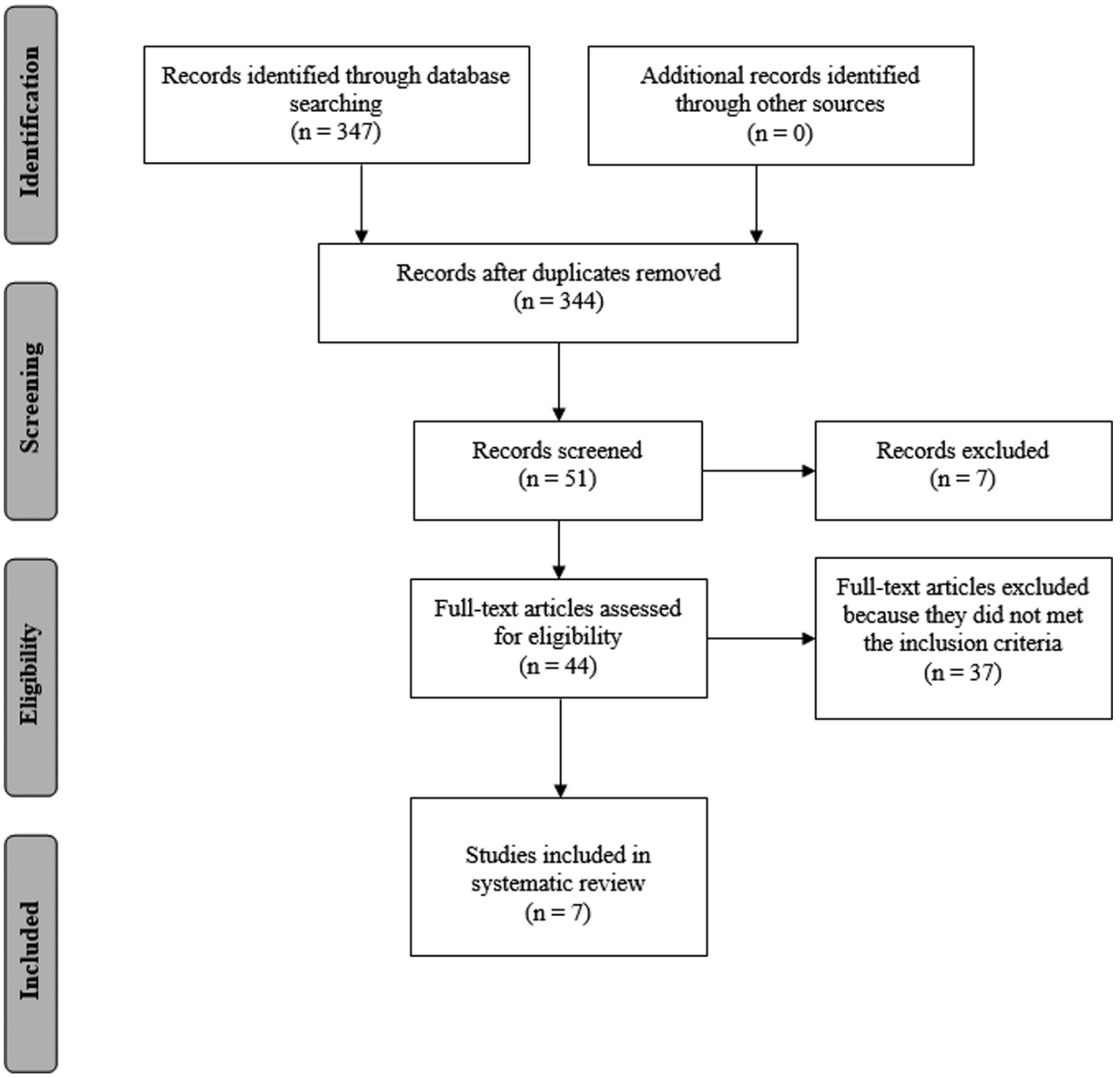


Fig. 1 PRISMA flow diagram of selected studies

in this case, who received grafting from C5 to the anterior division of the superior trunk. According to the authors, all infants, independently of the type of surgery performed, had biceps muscle recovery to a, MRC grade > M4. After this study, another study by Yang et al.[15] also proved the viability of restoring a C5 and C6 avulsion of the brachial plexus with an extradural nerve anastomosis technique.

In the study by Bhandari et al.,[16] the authors used neurolysis and nerve graft combined with nerve transfer as surgical procedures for nerve reconstruction in children with OBPP. Neurolysis was indicated for neuroma-in-continuity,[17] and nerve grafts were used to bridge the nerve defects, once the nonconducting neuromas were resected, and nerve transfers were indicated in avulsion and irreparable nerve root injuries.[18] The patients with total palsy received nerve transfer and nerve graft when the nerve to be transferred was insufficient in length, achieving 70% of biceps recovery. The authors believe that indications for neurolysis in OBPP are very few, and the results are far superior with resection of neuroma followed by nerve grafting in infants aged between 3 and 4 months old. This statement has been widely confirmed by many studies that showed better results of nerve reconstructions in younger children.[14,19] Furthermore, Birch et al.[20] found no statistical difference between a repair of C5 by graft or by nerve transfer. Moreover, Terzis et al.[21] found that, overall, 78% of the extremities that underwent nerve reconstruction surgery achieved good and excellent results (M3 +). According to the authors, late reconstruction (~ 7 months) of the MCN resulted in inferior results, and infants with C5-C6 palsy achieved significantly stronger elbow flexion than those with global palsy. Xu et al.[22] selected patients that had no recovery of biceps contraction by the age of 3 months old. The procedure of nerve transfer and grafting combined was performed in 10 patients with OBPP; excellent and good results in elbow flexion were found in 70% of the patients in the nerve transfer and grafting group. Also, 80% of the infants had biceps muscle

Table 1 Characteristics of the studies included in the systematic review that used nerve graft and nerve transfer

Studies that compared nerve graft versus nerve transfer								
Author, year	**Country**	**Study design**	**(n) Nerve graft**	**(n) Nerve transfer**	**Age at sugery (nerve graft) (months old)**	**Age at sugery (nerve transfer) (months old)**	**Female %**	**Follow-up period (months)**
Chang et al. 2018,[3]	USA	Retrospective cohort study	28	12	6	7	62%	12
Luszawski et al. 2017,[13]	Poland	Retrospective study	14	5	< 18	< 18	NS	> 12
Malessy et al. 2014,[14]	Netherlands	Retrospective study	17	17	5.7	5.7	56%	70
Studies that used nerve graft and nerve transfer combined								
Author, year	**Country**	**Study design**	**(n)**	**Age at sugery (months old)**	**Female %**	**Follow-up period (months)**		
Bhandari et al. 2015[16]	India	Retrospective study	32	3.5 to 23	NS	24.3		
Birch et al. 2005[20]	England	Prospective study	100	7	45%	85		
Terzis et al 2009[21]	USA	Retrospective study	23	14	44%	78		
Xu et al. 2000[22]	China	Retrospective study	10	4.5	40%	44.3		

Abbreviation: NS, not specified.

Table 2 Medical Research Council values of studies that compared nerve graft versus nerve transfer

Author	**Injury**	**MRC nerve transfer PO (%)**	**Injury**	**MRC nerve graft PO (%)**	***p-value***
Chang et al. 2018[3]	C5-C6, C5-C7, C5-T1, C5-T1+ Horner sign	M3 (NS)	C5-C6, C5-C7, C5-T1, C5-T1+ Horner sign	M2 (NS)	0.77
Luszawski et al. 2017[13]	C5-C7	> M3 (100%)	C5-C6, C5-C7, C5-T1	> M3 (77%)	NS
Malessy & Pondaag, 2014[14]	C5-C6 anterior root filament	≥M4 (100%)	C5-anterior division of superior trunk	≥M4 (100%)	NS
	C5-C6	≥M4 (100%)			

Abbreviations: MRC, Medical Research Council grading system; NS, not specified; PO, postoperative.

recovery to an MRC grade of M3 + . According to the authors, the results show that nerve transfer combined with nerve graft is the best option to manage resection of the neuroma and reconstruction of the brachial plexus, that infant nerves have more regeneration capacity,[23] and that a shorter distance for axons to reach the end organ[24] results in a better surgery outcome.

Conclusions

Overall, our results showed that both techniques of nerve graft and nerve transfer are good options for nerve reconstruction in cases of OBPP. The present study has various limitations, one of them being that all included studies were nonrandomized studies. In addition, the injury type, the surgical approach, and the follow-up time were inconsistent in the selected studies. More studies approaching the nerve reconstruction techniques in OBPP should be made, preferably randomized clinical trials to validate the results of the present systematic review.

Authors Contributions

Girón E. V. and Zapata-Copete J. A. contributed substantially to the conception, design of the work, acquisition, analysis, and interpretation of data for the work. Girón E. V. and Zapata-Copete J. A. contributed to the drafting of the work and revised it critically for important intellectual content. Girón E. V. and Zapata-Copete J. A. approved the final version to be published. Girón E. V. and Zapata-Copete J. A. agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or to the integrity of any part of the work are appropriately investigated and resolved.

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Conflict of Interests

The authors have no conflict of interests to declare.

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Translation and Cross-cultural Adaptation of the "Thumb Disability Exam - TDX" questionnaire into Brazilian Portuguese*

Tradução e adaptação cultural do questionário "Thumb Disability Exam – TDX" para o português brasileiro

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Abstract

Objective To perform the translation, cultural adaptation and validation of the Thumb Disability Exam (TDX) questionnaire into Brazilian Portuguese.

Method The questionnaire was translated, with reverse translation. The translations were evaluated and synthesized by a committee, resulting in the THUMB DISABILITY EXAM - BRASIL (TDX-BR). A total of 31 patients diagnosed with rhizarthrosis were selected and answered the questionnaire. Quality parameters were evaluated, such as internal consistency, reproducibility and ceiling and floor effect.

Results The questionnaires were translated and adapted according to defined protocols. Internal consistency, through the Cronbach α coefficient for the TDX-BR, was 0.962. The reliability of the questionnaire, through intraclass correlation coefficient (ICC)also proved to be quite high, with $\kappa = 0.953$ (0.947–0.959). Agreement, measured using the standard error of measurement, remained with standard values $< 5\%$. There was no ceiling and floor effect.

Conclusion Through specific methodology, we consider TDX-BR as translated and valid for the Portuguese language of Brazil.

Keywords

- osteoarthritis
- surveys and questionnaires
- translation
- carpometacarpal joints
- reproducibility of tests

Resumo

Objetivo Realizar a tradução, adaptação cultural e validação do questionário Thumb Disability Exam (TDX) para o português brasileiro.

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Método O questionário foi traduzido, com tradução reversa. As traduções foram avaliadas e sintetizadas por um comitê, chegando ao THUMB DISABILITY EXAM - BRASIL (TDX-BR). Foram selecionados 31 pacientes com diagnóstico de rizartrose que responderam ao questionário. Foram avaliados parâmetros de qualidade, como consistência interna, reprodutibilidade e efeito teto e piso.

Resultados Os questionários foram traduzidos e adaptados conforme protocolos definidos. A consistência interna, através do coeficiente α de Cronbach para o TDX-BR foi de 0,962. A confiabilidade do questionário, através do coeficiente de correlação intraclasse (CCI) também se mostrou bastante elevada, com $\kappa = 0{,}953$ (0,947–0,959). A concordância, medida através do erro padrão de medição manteve-se com valores padronizados $< 5\%$. Não houve efeito teto e piso.

Conclusão Através de metodologia específica, consideramos o TDX-BR como traduzido e válido para a língua portuguesa do Brasil.

Palavras-chave
- osteoartrite
- inquéritos e questionários
- tradução
- articulações carpometacarpais
- reprodutibilidade dos testes

Introduction

Arthrosis of the carpometacarpal joint of the thumb, or rhizarthrosis, is a highly prevalent disease affecting 33% of postmenopausal women and 8 to 12% of the general population. There is a progressive increase in the condition with population aging, reaching a prevalence of 40% in people $>$ 80 years old.[1] It is a potentially limiting disease, which leads to pain in the thumb and reduces the quality of life and independence for work, leisure and daily activities.[2,3]

Diagnosis is based on clinical signs and symptoms associated with radiographic examination.[3,4] This condition consists of swelling at the base of the thumb, angular deviation and crackling associated with progressive pain and limited pinching activities. However, the symptoms are often vague and nonspecific.[3]

Radiographic findings consist of progressive degenerative changes in the carpometacarpal joint of the thumb. Eaton et al. classified this condition through radiographic images of the front and profile of the carpometacarpal joint of the thumb, dividing it into 4 progressive stages.[4] The Eaton et al. classification, although widely used,[5–8] is criticized for its low intraobserver and interobserver reproducibility and for not always corresponding to the symptoms of the patient. Thus, the treatment strategy is often guided subjectively through the perception of limitation by the patient or doctor.[5,9]

Questionnaires are widely used to systematize and score specific characteristics of each disease. These can categorize subjective variables and thus better guide which stage of clinical limitation each patient is in. They are used for diagnosis or evaluation of clinical evolution after medical care.[10] The Disabilities of the Arm, Shoulder and Hand (DASH) score, as an example, has more than six thousand citations, showing the relevance of the instrument mainly in the comparison of outcomes. However, specific questionnaires are rare in the evaluation of rhizarthrosis, and no questionnaires were found in Portuguese.[10,11]

Obviously, adaptation to the language of the country where each questionnaire should be applied is essential. The aim of our work is to translate and carry out the cultural adaptation and validation of the Thumb Disability Examination (TDX) questionnaire for the Portuguese language of Brazil. This method is widely used in the literature, as in the DASH score, translated and adapted in 2005.[12]

Materials and Method

The research project was sent to the research ethics committee, being approved in March 2018 (CAAE - 80666617.4.0000.5505). Our work was authorized by the researchers responsible for the original questionnaire.

Noback et al.[10] proposed a specific questionnaire for rhizarthrosis, the TDX, in order to improve accuracy when comparing therapeutic outcomes.[10,11] The questionnaire evaluates activities performed by patients in the last week and the 20 items are divided into 3 subdivisions, all graded in 5 degrees (following the Likert Scale)[10]:

(I) Function assessment (11 items) - ranging from normal function (1 point), to complete dysfunction (5 points).
(II) Pain level (5 items) - considering the absence of pain (1 point) until continuous pain (5 points).
(III) Satisfaction assessment in global hand and thumb characteristics (4 items) - ranging from a lot of dissatisfaction (1 point) to a lot of satisfaction (5 points).

The results obtained are transformed into a variable between 0 and 100, following the formula: $Score = \left(\frac{N}{Q-B} - 1\right) * 25$, where N is the total sum, Q is the number of total questions and B the number of questions left blank.

The guideline described by Beaton et al. was used[13] as a guide for the entire translation and adaptation process. First, the original questionnaire was translated into Portuguese by two translators who have Portuguese as their native language, and the two translations were compared and synthesized. Then the reverse translation was done by two native English-speaking translators who did not know the original version, and these two new translations were compared with the original versions. Thus, through a committee of experts, composed of an orthopedist, a specialist English teacher, a physiotherapist, in addition to the two main researchers, the discrepancies were resolved, reaching a prefinal version. Thus, validation was performed

with 31 previously selected patients with a previous diagnosis of rhizarthrosis, the understanding of this prefinal version was evaluated and any changes that the committee deemed necessary to improve the understanding of the target audience were made. Lastly, a Portuguese version was created, the TDX-BR.

A test was carried out, and a retest was applied after 2 to 4 weeks, by e-mail or telephone contact. The questionnaire validation process was performed with the calculation of the psychometric variables. The internal consistency, a measure of the homogeneous relationship of the questionnaire items, was calculated using the Cronbach α coefficient of each of the items, with $\alpha \geq 0.70$, as described by Norman et al.[14] Reliability was assessed using the intraclass correlation coefficient (ICC) obtained through testing and retesting. We used the correlation classification scale according to Landis et al.,[15] through the Cohen kappa coefficient, κ, in which there is variation of -1 to 1, with 1 meaning total agreement, -1 meaning total disagreement and zero meaning randomness. Agreement was assessed using the standard error of measurement (SEM), which reflects the intrinsic error of the instrument. Standard error of measurement is calculated as the standard deviation (SD) of the differences between the scores of the 2 test and retest sessions, divided by the square root of 2.[16] The ceiling and floor effect was considered when $> 15\%$ of the interviewees reached the maximum or minimum score.[16]

Results

After the last stage, the final version was configured and the TDX-BR was arranged in two pages, front and back, in a multiple-choice system, with vertical configuration (►**Figures 1** and **2**). It maintained a total of 20 questions, divided into 3 subdivisions.

Of the 31 patients, 83.9% were women, with a mean age of 63 years old. The results of the psychometric variables evaluated are in ►**Table 1**.

Discussion

Rhizarthrosis is a disease of high prevalence and of multidisciplinary interest among rheumatologists, geriatricians, physiotherapists, and orthopedists. It is the most frequently reported form of clinically impacting arthritis in the hand, and the arthritic condition of the upper extremity most frequently treated surgically.[10]

From the description of the Eaton stages, which were later adapted by Eaton et al.,[4] surgeons have been guiding their treatment indications from the radiographic stages. However, we have seen that such a classification often does not reproduce symptoms and limitations, in addition to having weak or moderate reproducibility criteria.[5,7,8,10,17,18]

The diagnosis of the disease is simple, based on a characteristic clinical picture, associated with imaging exams.[4] However, ease of diagnosis is not reflected in therapy. The criteria for deciding between nonsurgical therapies or surgical procedures are quite subjective. Such factors make rhizarthrosis a challenge for hand surgeons.[17,18]

The key issue in the management of any disease is the definition of the best indication for each type of treatment. The questionnaires in clinical practice aim to stratify each case according to the stage of the evolution of the disease, and thus be able to guide the best treatment. A self-administered questionnaire specific to rhizarthrosis is a simple and inexpensive way to, based on the patient's own reports, make it possible to classify the severity of the dysfunction in question and evaluate treatment outcomes in a homogeneous way.[10] Several guidelines are created in order to standardize clinical studies with the primary aim of being able to compare results after conclusions.[19] What we see in the literature is that there is no standardization for rhizarthrosis. Diverse systematic reviews demonstrate inconsistent results that make the authors conclude that there are no differences in outcomes.[2,17,18]

The aim of our work was to provide an efficient method of evaluating outcomes in rhizarthrosis in the Portuguese language. During the literature review, the TDX questionnaire was considered of good methodological quality. Fernandes et al.[20] have already shown that the translation and cultural adaptation of questionnaires is an efficient way for evaluation and comparison for multicenter studies. Translation and adaptation methods are widely described and used in the literature.[12,13,20–22]

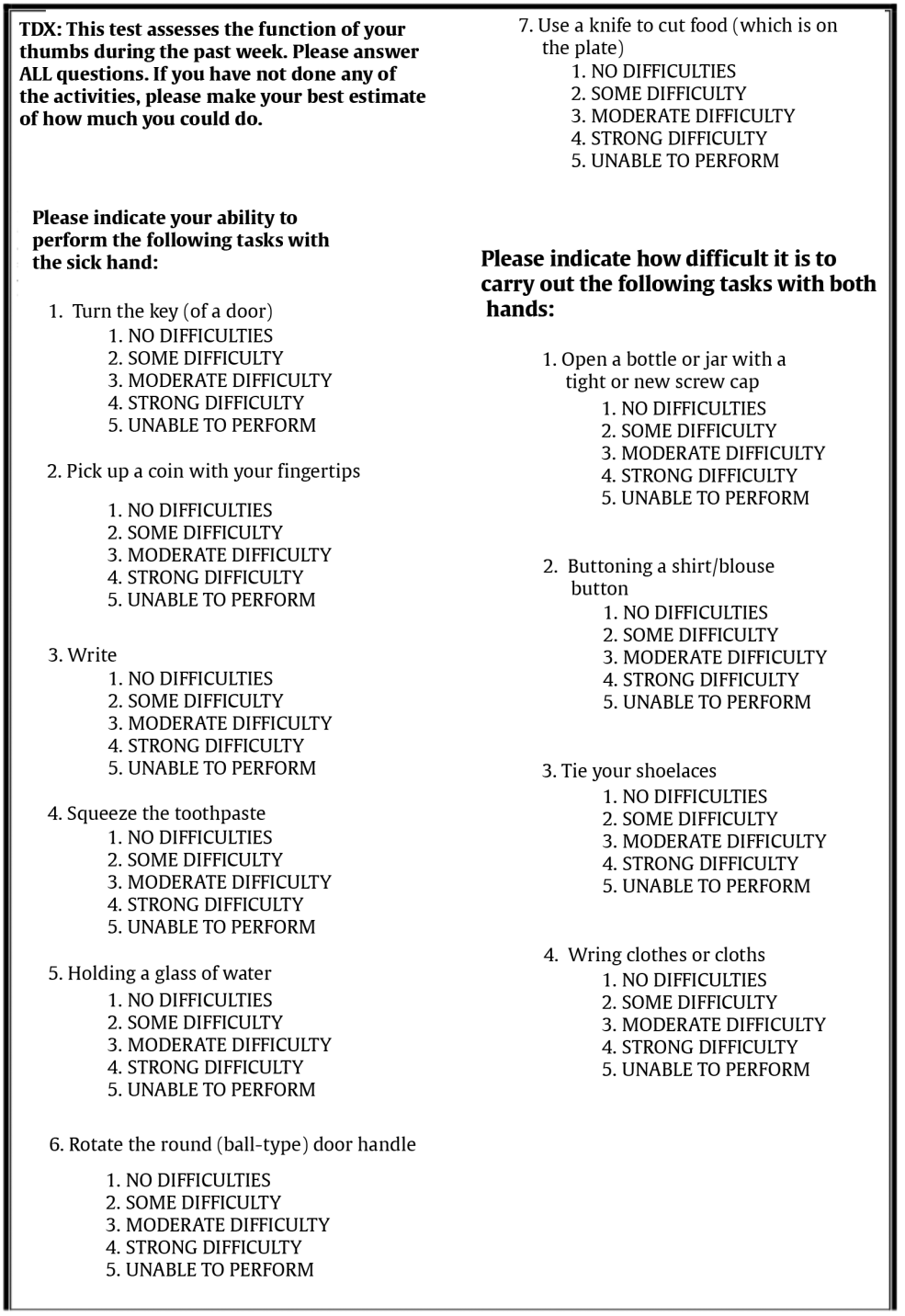
Due to its greater diffusion in the literature, the guideline described by Beaton et al.[13] was used as a guide for the entire process of translation and adaptation, also following the consensus-based standards for the selection of health status measurement instruments (COSMIN) guidelines.[23]

In the original questionnaire, the pagination of the questionnaire was presented in a horizontal model, in which each question corresponded to the answers in a line, in a single table. The multiple-choice longitudinal model for pagination was chosen, as previously proposed by Matsuo et al.[24]

Only three patients reported that they would add or change items in the questionnaires. Thus, after discussion by the expert committee, it was decided not to change the items already described, nor to add or extinguish any of them. All items were considered to have a correlation of interpretation and semantics with the language of the original questionnaires. No patient left > 2 items blank, keeping within the standard tolerated by TDX (up to 10% of the 20 questions). If there was no complete understanding of at least 10% of patients, the prefinal version (PF1) should be changed. As this did not happen, since only 2 patients (6.5%) did not have a complete understanding, we consider the version PF1 as the final version (F1), considering the process of translation and cultural adaptation complete.[23]

The data obtained were then used to perform statistical calculations to validate and assess the reliability of the measurement instrument, translated, and adapted.

Through the Cronbach α coefficient, internal consistency was assessed. The result was considered adequate, with $\alpha = 0.962$. Internal consistency is an important measurement property for questionnaires that intend to measure a single concept using several items, or even assessing it in subdivisions. In our assessment, when separated into subdivisions of "function", "pain level" and "overall satisfaction", all α values



TDX: This test assesses the function of your thumbs during the past week. Please answer ALL questions. If you have not done any of the activities, please make your best estimate of how much you could do.

Please indicate your ability to perform the following tasks with the sick hand:

1. Turn the key (of a door)
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
2. Pick up a coin with your fingertips
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
3. Write
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
4. Squeeze the toothpaste
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
5. Holding a glass of water
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
6. Rotate the round (ball-type) door handle
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
7. Use a knife to cut food (which is on the plate)
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM

Please indicate how difficult it is to carry out the following tasks with both hands:

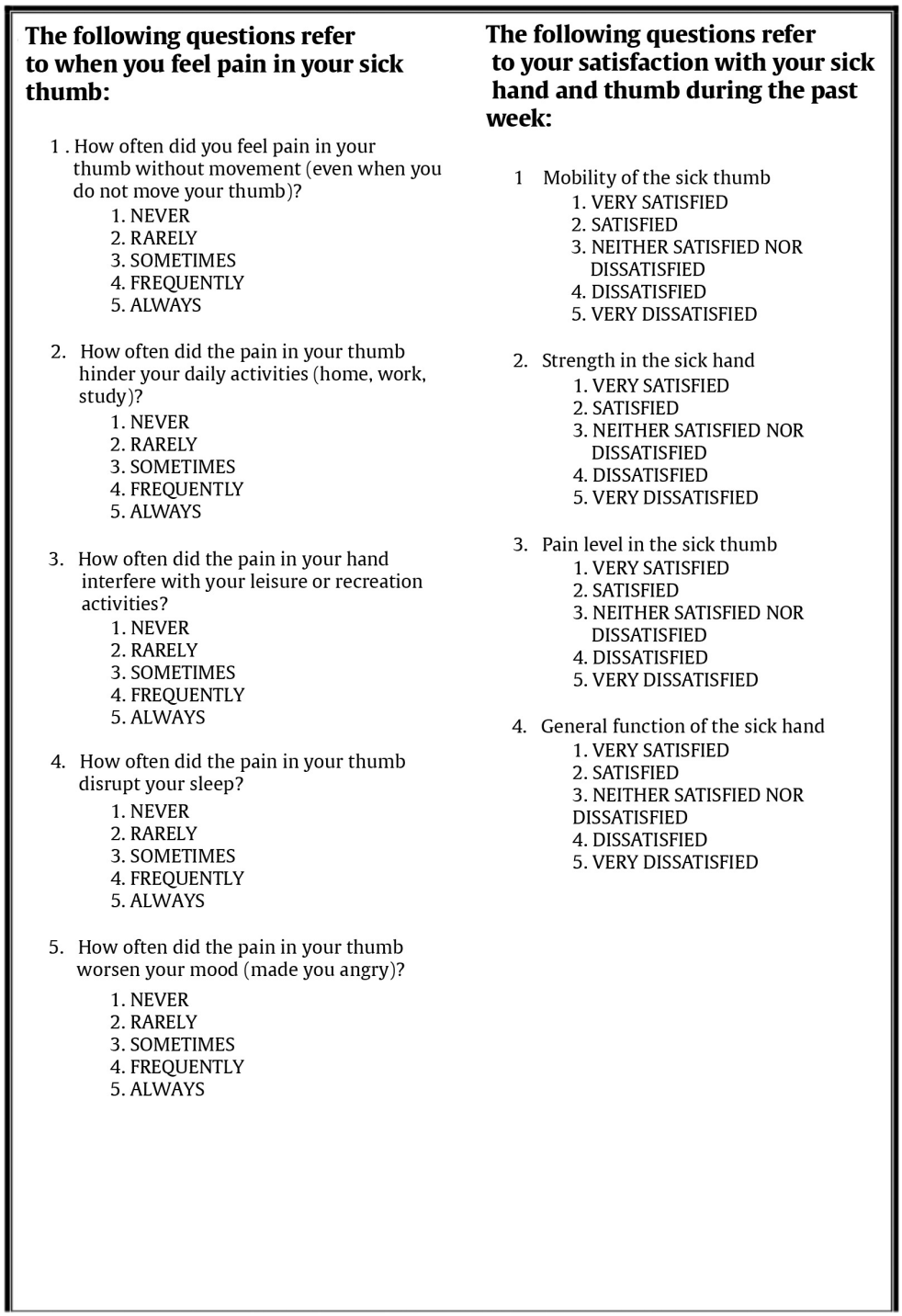
1. Open a bottle or jar with a tight or new screw cap
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
2. Buttoning a shirt/blouse button
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
3. Tie your shoelaces
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM
4. Wring clothes or cloths
   1. NO DIFFICULTIES
   2. SOME DIFFICULTY
   3. MODERATE DIFFICULTY
   4. STRONG DIFFICULTY
   5. UNABLE TO PERFORM

Fig. 1 Translated and adapted TDX-BR questionnaire, part 1.

remained > 0.70. These subdivisions are the most important clinical factors for defining the treatment of rhizarthrosis. The original questionnaire showed value for internal consistency with $\alpha > 0.79$.[10]

No ceiling or floor effect was found in the questionnaire or in the subdivisions. The number of questions and the presence of many alternatives reduce the possibility of this effect. The TDX-BR, with 20 questions and 5 alternatives in each question, leads to many possible answers, considerably reducing this effect. In the original questionnaire, a different parameter than ours was used, with 0-10 (floor) and 90-100 (ceiling) results being considered as ceiling and floor effect. Thus, there was a ceiling effect in only one subdivision, which evaluates patient satisfaction, with 13.2% of patients with scores > 90. However, Terwee et al.[16] consider the ceiling effect as $> 15\%$ of patients resulting in the maximum score.[10,16,25]

The results demonstrated high reproducibility. Values of the ICC > 0.61 are considered as good correlation.[26] In our study, these values varied between $\kappa = 0.940$ and $\kappa = 0.968$. These values denote a high correlation between the test and



The following questions refer to when you feel pain in your sick thumb:

1 . How often did you feel pain in your thumb without movement (even when you do not move your thumb)?
1. NEVER
2. RARELY
3. SOMETIMES
4. FREQUENTLY
5. ALWAYS

2. How often did the pain in your thumb hinder your daily activities (home, work, study)?
1. NEVER
2. RARELY
3. SOMETIMES
4. FREQUENTLY
5. ALWAYS

3. How often did the pain in your hand interfere with your leisure or recreation activities?
1. NEVER
2. RARELY
3. SOMETIMES
4. FREQUENTLY
5. ALWAYS

4. How often did the pain in your thumb disrupt your sleep?
1. NEVER
2. RARELY
3. SOMETIMES
4. FREQUENTLY
5. ALWAYS

5. How often did the pain in your thumb worsen your mood (made you angry)?
1. NEVER
2. RARELY
3. SOMETIMES
4. FREQUENTLY
5. ALWAYS

The following questions refer to your satisfaction with your sick hand and thumb during the past week:

1 Mobility of the sick thumb
1. VERY SATISFIED
2. SATISFIED
3. NEITHER SATISFIED NOR DISSATISFIED
4. DISSATISFIED
5. VERY DISSATISFIED

2. Strength in the sick hand
1. VERY SATISFIED
2. SATISFIED
3. NEITHER SATISFIED NOR DISSATISFIED
4. DISSATISFIED
5. VERY DISSATISFIED

3. Pain level in the sick thumb
1. VERY SATISFIED
2. SATISFIED
3. NEITHER SATISFIED NOR DISSATISFIED
4. DISSATISFIED
5. VERY DISSATISFIED

4. General function of the sick hand
1. VERY SATISFIED
2. SATISFIED
3. NEITHER SATISFIED NOR DISSATISFIED
4. DISSATISFIED
5. VERY DISSATISFIED

Fig. 2 Questionnaire translated and adapted TDX-BR, part 2.

the retest, proving the questionnaire to be reliable in reproducing the symptoms. The interval of 2 to 4 weeks between the test and the retest is considered sufficient, so that there is no change in symptoms or disease progression, and also so that the patient cannot remember the answers he had generated in the previous questionnaire.[25,27] In the original TDX, the ICC values remained between 0.88 and 0.98. Therefore, we got close results.[10,16,27]

The agreement measured through SEM remained with good values, with SEM $< 5\%$ in the TDX and in all its subdivisions. These data demonstrate that the instrument has a low intrinsic error, that is, the "true" scores of each patient do not differ by $> 5\%$ from the measured scores.

As demonstrated in the literature, works related to the translation and validation of questionnaires are widely used and widely cited.[5,10,13,16] In addition, disease-specific

Table 1 Internal consistency (Cronbach α), floor and ceiling effects (percentage ≤ 5 or ≥ 95), reliability (intraclass correlation coefficient) and agreement (standard error of measurement) for the questionnaire TDX-BR, ($n = 31$)

	Cronbach α	Floor/ Ceiling (%)	ICC– κ (CI95%)	(SEM %)
TDX	0.962	6.5% / 0,0%	0.953 (0.947–0.959)	3.68
Function	0.912	2.2% / 0,0%	0.940 (0.929–0.950)	4.64
Pain level	0.922	10.9% / 4.3%	0.968 (0.958–0.975)	3.76
Overall satisfaction	0.919	0.0% / 6.5%	0.963 (0.951–0.973)	4.43

Abbreviations: ICC, intraclass correlation coefficient; SEM, standard error of measurement.

questionnaires have been shown to be more consistent than comprehensive questionnaires.[10]

Conclusion

We consider the TDX questionnaire as translated into the Portuguese language of Brazil. The TDX-BR version is valid. Following a trend in modern literature, we have an objective method, comparable to the original method, which may in the future be used as a standard in research related to rhizarthrosis in Brazil.

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

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Intramedullary Fixation with Headless Screws versus Bouquet in Unstable Metacarpal Neck Fractures in Active Patients: A Randomized Study

Fixação intramedular com parafusos de compressão versus técnica do buquê em fraturas instáveis do colo do metacarpo em pacientes ativos: Ensaio clínico randomizado

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Abstract

Objeticve To compare the range of motion (ROM), return-to-work time, visual analogue score (VAS), disability of the arm, shoulder, and hand (QuickDASH), and radiographic outcomes of two methods of definitive internal fixation in active patients with boxer's fractures, operated in the first week.

Methods This was a prospective, randomized trial, in which 50 patients, with a mean age range of 18 to 40 years old, were randomized and treated to definitive intramedullary fixation using 2 headless screws ($n = 20$) or bouquet (2 or 3 Kirschner wires) ($n = 20$). The patients were assessed on return-to-work time, ROM, patient reported QuickDASH outcome, VAS, and radiographic evaluation at 6 months.

Keywords
- metacarpal bones
- boxer's fracture
- fracture fixation, intramedullary
- minimally invasive surgical procedures
- clinical trials, randomized

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Results At 6 months, there were no differences between the two groups in terms of ROM, postoperative pain (VAS), or QuickDASH score. The overall complication rate was 4.76% in the screw group, compared with 5% in the bouquet-fixation group.

Conclusions In the treatment of the active patients with unstable boxer's fractures, headless screws and bouquet fixation proved to be a safe and reliable treatment. The outcomes were similar in both groups.

Resumo

Objetivo Comparar a amplitude de movimento (ADM), o tempo de retorno de trabalho, a pontuação na escala visual analógica (EVA), o escore no questionário abreviado incapacidade do braço, ombro e mão (QuickDASH) e os resultados radiográficos de dois métodos de fixação interna definitiva em pacientes ativos com fraturas do boxeador, operados na primeira semana.

Métodos Este foi um ensaio prospectivo randomizado, no qual 50 pacientes, com idade mediana na faixa de 18 a 40 anos, foram randomizados e tratados com fixação intramedular definitiva utilizando 2 parafusos sem cabeça ($n = 20$) ou buquê (2 ou 3 fios de Kirschner) ($n = 20$). Os pacientes foram avaliados em relação ao tempo de retorno ao trabalho, à ADM, ao desfecho relatado pelo paciente no questionário QuickDASH, à EVA e à avaliação radiográfica aos 6 meses.

Resultados Aos 6 meses, não houve diferenças entre os 2 grupos em termos de ADM, dor pós-operatória (EVA) ou escore no QuickDASH. A taxa global de complicações foi de 4,76% no grupo de fixação com parafusos, em comparação com 5% no grupo de fixação com a técnica do buquê.

Conclusões Parafusos sem cabeça e fixação com buquês provaram ser tratamentos seguros e confiáveis para pacientes ativos com fraturas instáveis. Os resultados foram semelhantes nos dois grupos.

Palavras-chave

- ossos metacarpais
- fratura de boxer
- fixação intramedular de fraturas
- procedimentos cirúrgicos minimamente invasivos
- ensaios clínicos randomizados

Introduction

Despite the high prevalence (20% of the hand fractures) of unstable neck metacarpals fractures (boxer's fractures), there is still no consensus concerning the preferred method and ideal moment of treatment, especially in active patients[1,2] for whom the time or type of management can have a strong psychological impact on the outcomes.[3,4]

The use of the intramedullary technique (headless screws or bouquet technique fixation) as the definitive treatment of unstable boxer's fractures in active patients in the first week may be a good choice of treatment. This technique is a fast, safe, minimally invasive, and easily performed reproducible method, without addressing the extensor tendon to prevent tendon adhesion and joint stiffness, enabling earlier functional recovery and shortening the return-to-work time of these patients. Choose a reproducible and effective method, which presents a cost / benefit compatible with our reality.[5–7]

The goal of the present study is to compare the return-to-work time, visual analogue scale (VAS) score, disability of the arm, shoulder, and hand (QuickDASH) score, complications rate, and radiographic outcomes of two methods of definitive internal fixation in active patients with boxer's fractures, operated in the first week.

Methods

A double center, parallel group, prospective, randomized clinical trial was conducted at the department of hand surgery of our institution. Two implants were used for fixation in closed reduction of boxer's fractures (►**Fig. 1**): the headless

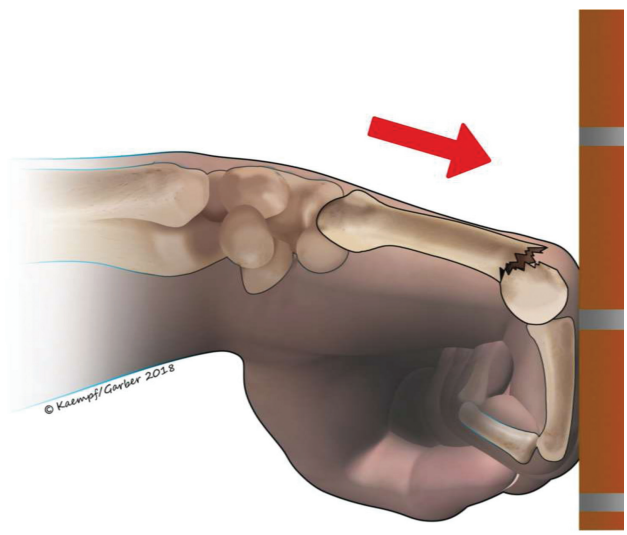


Fig. 1 Boxer's fracture mechanism and anatomic features—schematic drawing.

cannulated screws (Synthes, Davos) and Kirschner wires (k-wires)(bouquet technique) (Synthes, Davos). The protocol was approved by the local research ethics committee (CAAE 127.59813.4.0000.0082). All patients received, signed, and are aware of what was recommended in the informed consent (IC). The inclusion criteria were: presence of an acute (0–7 days), closed, and simple fracture of the metacarpal neck; absence of an ipsilateral injury or deformity; presence of an angulation of over 40 degrees in oblique plane imaging; being adults or $\geq$ 18 years old; having acquired a master's degree or being a student; and being an employee in a social-professional environment with mild physical activities.

Rotational deformity was clinically assessed based on the extension of the axis of the finger toward the scaphoid tubercle during flexion and orientation of the nail of the finger during extension. Angulation of the fracture was evaluated by measuring the angulation in the continuity of the dorsal cortical line of the metacarpal in a 30° oblique X-ray image.

The trial was registered at Clinical Trials. gov No. 32925713.9.0000.0082.

Sample Size Calculation

Patients that received an intervention based on the diagnosis of boxer's fracture between 2016 and 2017 were included in the present study after their consents were obtained. For good results, 70 degrees (standard deviation [SD]: 5) of angulation, as reported in this study, was accepted as the radiological threshold. Accordingly, the power of the study was 80%, with an α value of 0.05, and each group was comprised of 12 subjects.[8]

We Got a Similar Sample

During the study period, January 2016 to December 2017, a total of 45 patients met the inclusion criteria and did not have any of the exclusion criteria (►**Fig. 2**; Consolidated Standards of Reporting Trial [CONSORT] flowchart).[9] Five eligible patients were operated on by orthopedic surgeons

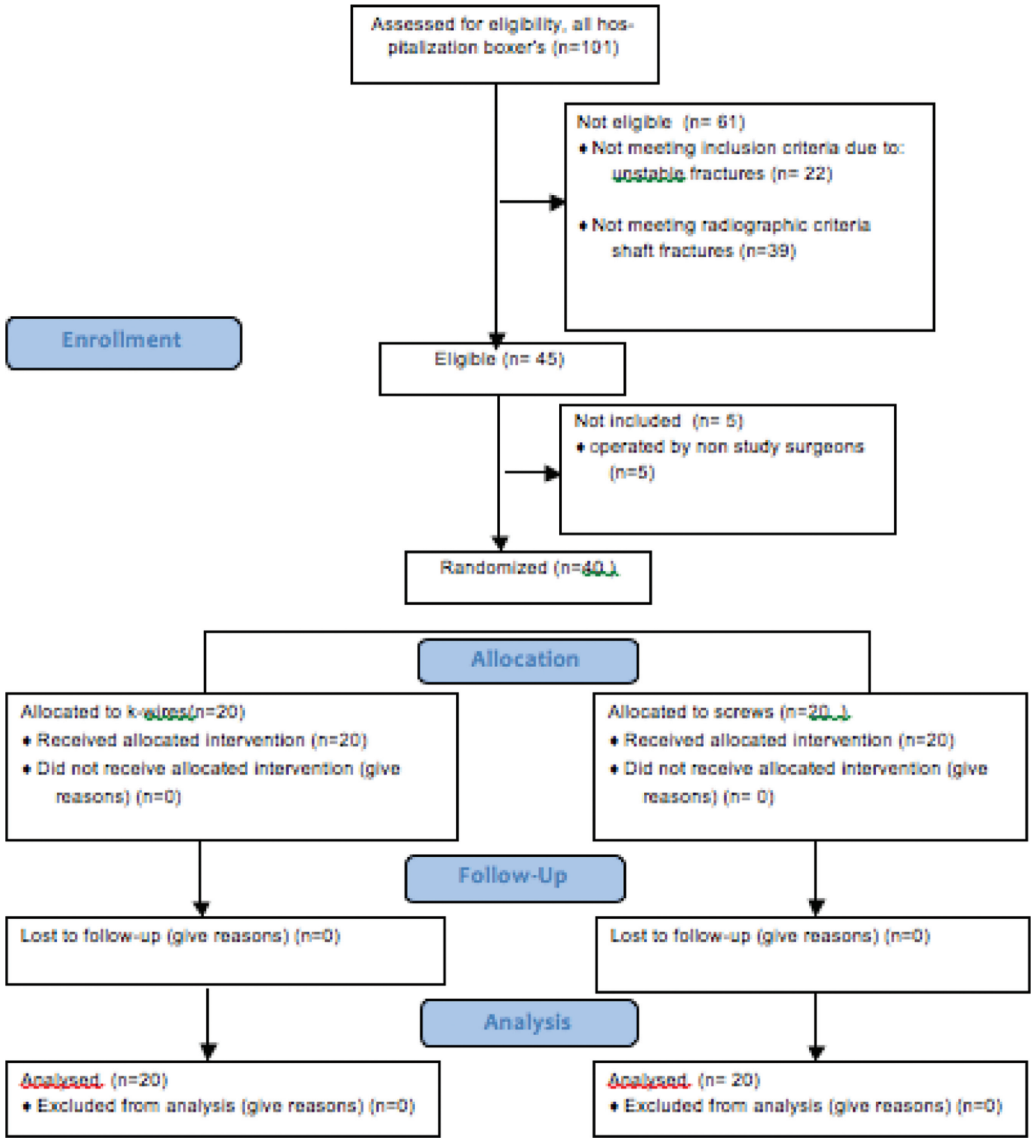


Fig. 2 Consolidated Standards of Reporting Trial (CONSORT) flowchart.

Table 1 Clinical Aspects – A Group

ID	Age	Follow-up	Side	Final ROM %	QuickDASH	Pain VAS	Return to work (days)	Complications	Other surgery
1	25	19	R	100	11.36	1	90	Y	Y
2	23	25	R	100	0	0	60	N	N
3	32	21	L	100	0	0	10	N	N
4	21	17	R	100	2.27	1	30	N	N
5	35	8	R	100	0	0	15	N	N
6	54	13	R	100	4.54	2	30	N	N
7	25	19	L	100	0	0	60	N	N
8	27	25	L	100	0	0	15	N	N
9	28	17	R	100	0	0	30	N	N
10	35	11	R	100	0	0	20	N	N
11	21	16	R	100	2.27	0	20	N	N
12	36	19	R	100	0	0	15	N	N
13	26	7	L	100	2.27	0	30	N	N
14	30	13	R	100	0	0	30	N	N
15	51	8	L	75	0	0	5	N	N
16	27	11	R	100	0	0	20	N	N
17	42	9	L	100	0	1	60	N	N
18	34	13	R	100	0	0	45	N	N
19	21	10	R	100	2.27	0	15	N	N
20	31	11	R	100	0	0	30	N	N

Abbreviations: ID, identification; N, no; Y, yes.

not participating in the study and were not included. Forty eligible patients and 41 fingers were operated in the 1st week. A posthoc analysis showed that the 40 patients included in the study did not differ regarding age, gender, or fracture type compared with the 5 not randomized but eligible patients. Of these, 4 were women and 36 men, with an average of 30.46 years (range 16–54 years).

The patients were randomized by drawing lots (heads = A - treatment with k-wires; tails = B - treatment with headless screws), which were printed and placed in 50 sealed envelopes before the study started. Randomization was blinded to all examiners. Simple randomization was used, and the envelopes were opened in the operating theater, immediately prior to the surgery. Surgical instruments for both procedures were available in a single box. Twenty patients were randomized to each group (►**Tables 1** and **2**).

The groups were similar. Thus, that patients were available for the intention to treat analysis at the 6 months follow-up (minimum) (►**Figs. 3** and **4**) (►**Figs. 5** and **6**)

Surgical Technique Description

In all patients, surgery was performed with the use of general anesthesia. The surgical method of treatment used was closed fracture reduction (the mechanism used was longitudinal traction associated with a Jahss maneuver) and stabilization.

Group A (control): All the patients were operated with an antegrade k-wire stabilization technique. A small incision was performed proximal to the base of the metacarpal; following subcutaneous dissection, a hole was made through the ulnar or radial cortex of the metacarpal, directed distally to open the canal, avoiding perforation of the contralateral cortex; one or two 1.2- mm k-wires were bent at one end to control the direction of introduction. The fracture was then reduced and the k-wires are introduced longitudinally, from the metacarpal base up to the metacarpal head. Hardware positioning was controlled intra operatively with an image intensifier (►**Figs. 3** and **4**).

Group B (tested): A 0.5 cm incision was performed at the level of the metacarpal head, and the extensor tendon was not approached, only avoided and separated, longitudinally to a similar extent. Two 1.0-mm guide wires were inserted along the longitudinal axis of the metacarpal bone under fluoroscopic guidance. The k-wires were over drilled and replaced with either two 2.4 or 3.0-mm cannulated headless compression

Table 2 Clinical Aspects – B Group

ID	Age	Follow-up	Side	Final ROM %	QuickDASH	Pain VAS	Return to work (days)	Complications	Other surgery
1	36	15	L	100	4.54	1	82	N	N
2	28	12	R	100	0	0	13	N	N
3	52	12	R	100	0	1	37	N	N
4	41	11	R	100	2.27	0	43	N	N
5	18	11	R	100	0	0	11	N	N
6	28	11	R	100	2.27	1	71	N	N
7	28	11	R	100	4.54	1	64	N	N
8	27	10	R	100	0	1	44	N	N
9	16	9	R	100	0	0	14	N	N
10	42	8	L	100	0	1	28	N	N
11	38	8	R	100	0	0	11	N	N
12	24	7	R	100	0	1	37	N	N
13	34	6	L	100	2.27	0	51	N	N
14	29	6	R	100	0	0	48	N	N
15	19	6	L	100	0		37	N	N
16	21	6	R	75	15.9	3	54	Y	N
17	29	6	L	100	0	0	10	N	N
18	29	6	R	100	0	0	7	N	N
19	41	6	R	100	0	0	6	N	N
20	23	6	R	100	0	0	13	N	N
21	22	6	R	100	0	0	9	N	N

Abbreviations: ID, Identification; N, No; QuickDASH, abbreviated form of the disabilities of the arm, shoulder, and hand; Y, Yes.

screws, based on preoperative templating. The first screw was inserted until all of the distal screw threads surpassed the fracture site, and after the second screw was placed, also surpassing the fracture site. After hardware positioning was controlled with an image intensifier (►**Figs. 5** and **6**).

All patients were radiographically and clinically assessed at 1, 2, and 8 weeks, and at 6 months. Total joint (metacarpophalangeal + proximal interphalangeal + distal interphalangeal) ROM was evaluated using a standard goniometer. The patient-reported outcome was recorded using the QuickDASH questionnaire (range, 0–100, with 0 as best result),[10,11] VAS (range, 0–10, with 0 as best result) for pain and return-to-work time.

Complications were treated and assessed at 6 months. In addition, shortening, rotation and angulation values were measured on the 30th day follow-up for both groups. Data are presented as mean or median according to type of data and distribution.

Statistical Methods

The Microsoft Excel spreadsheet in its version of MS-Office 2013 (Microsoft Corp., Redmond, WA, USA) for the organization of the data, and the statistical package IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY, USA) for obtaining the results. In the statistical analyses, the level of significance of 5% (0.050) was adopted. The Fisher exact test was used to verify possible differences between both groups in terms of categorical variables.

The Mann-Whitney test was used to verify possible differences between both groups in terms of scalar variables.

Results

Categorical variables regarding side, complications, and other surgeries are found in ►**Table 3**. Scalar variables regarding age, ROM, quickDASH, VAS, and return-to-work time are found in ►**Table 4**.

There are complications: a patient (A group) showed impingement because of the k-wires, and they were removed after 3 months. A patient (B group) showed loss of reduction and he did not undergo another surgery.

Discussion

The treatment of isolated metacarpal fractures with k-wire pinning has a long and proven track record. This treatment is

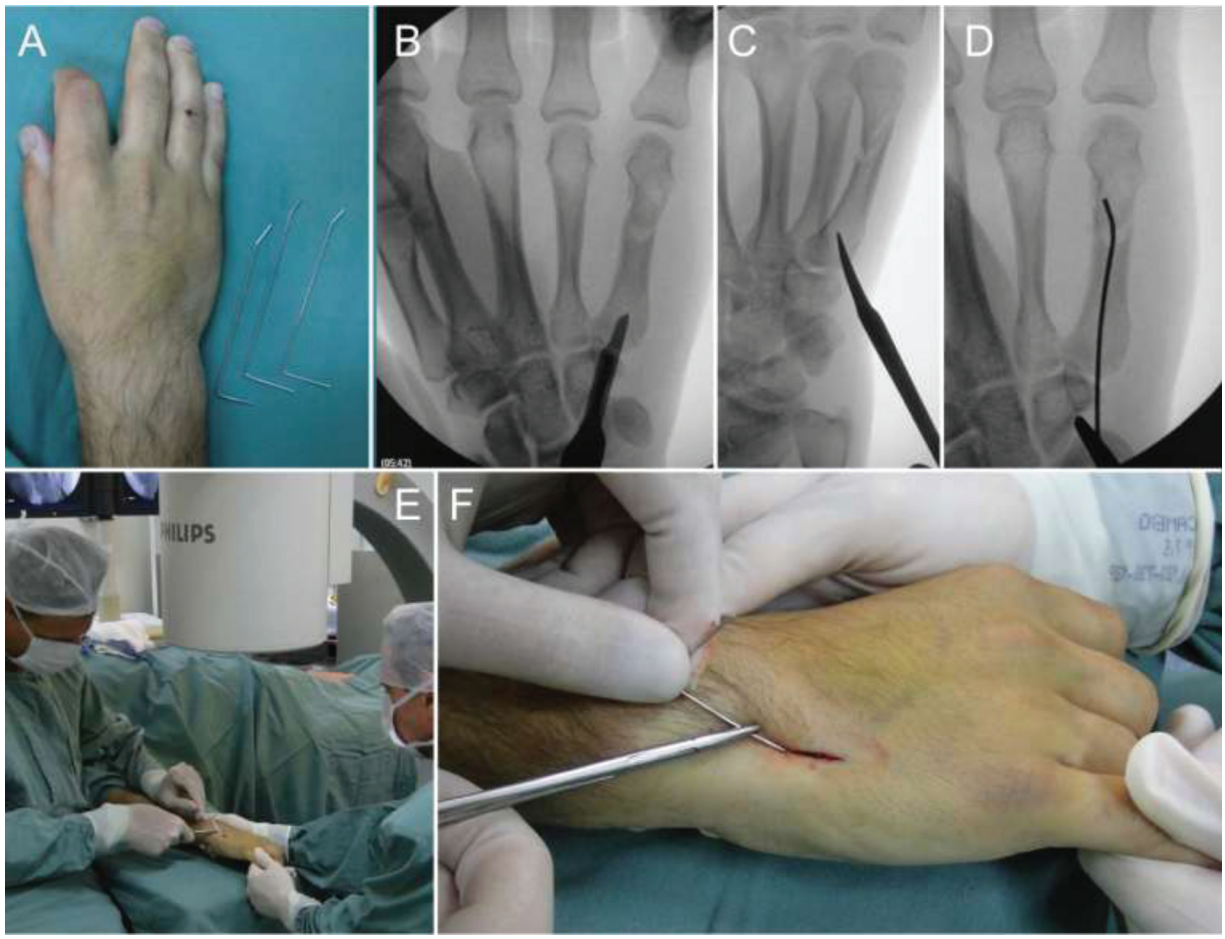


Fig. 3 Kirschner wire (K-wire) antegrade intramedullary "bouquet" fixation technique. (A) Implants and clinical view of operated limb (B) Radioscopic confirmation K-wires entry point (C) Entry point confection (D) Intramedullary K-wire advancement through fracture site. (E) Patient, surgical team, and radioscope positioning (F) Instrumentation of K-wire through subcutaneous entry point. Traction is being applied.

based on the concept of flexible fixation introduced by Foucher,[7] who described the results of the antegrade pinning technique; on their series of 66 patients with 68 fractures, all of their patients returned to their previous activities; 6 patients had a 10° extension lag; and 6 other patients had a 15° extension lag; however, only one patient, an auto mechanic, complained of this decrease in ROM. Intramedullary fixation with headless cannulated screws follows the principles of rigid stable fixation; it allows for early mobilization and decreases the need for postoperative casting. Boulton et al.[12] described the use of the intramedullary headless compression screw technique for the fixation of a fifth metacarpal comminuted neck fracture. The patient's metacarpophalangeal joint flexion at the latest follow-up was 80°; her extension was full.

Our trial included only unstable, simple, or complex fractures of the metacarpal neck (Boxer's fractures), and we had a control group with similar fractures treated with antegrade k-wire pinning versus tested group and patients treated with headless cannulated screws. Del Pinal et al.[6] and Couceiro et al.[13] showed retrospective studies, case series, and patients with shaft metacarpal and proximal phalanx fractures were included in these studies. In the present study, there were no differences between the two in terms of ROM, postoperative pain (VAS), or QuickDASH score.

A criticism of traditional conservative treatment is the inability to use cast immobilization to maintain reduction of the lateral inclination of the metacarpal bone. Ruchelsman et al.[14] and the present study demonstrated that only 2.43% of the patients showed loss of initial reduction. The current study is a prospective, randomized clinical trial, and all patients were operated by two surgeons, upper limb trauma specialists, in a uniform group, and with complete follow-up. There are limitations of the study, the sample size was small for QuickDASH and VAS analysis, but sufficient for statistical analysis for the evaluation of the ROM.

We did not find differences in terms of the mean return-to-work time or time back to their regular activities between the groups. We found no differences in terms of function or patient-related outcomes between the two techniques. We have been unable to conclude that there were any benefits in the application of one particular technique when compared

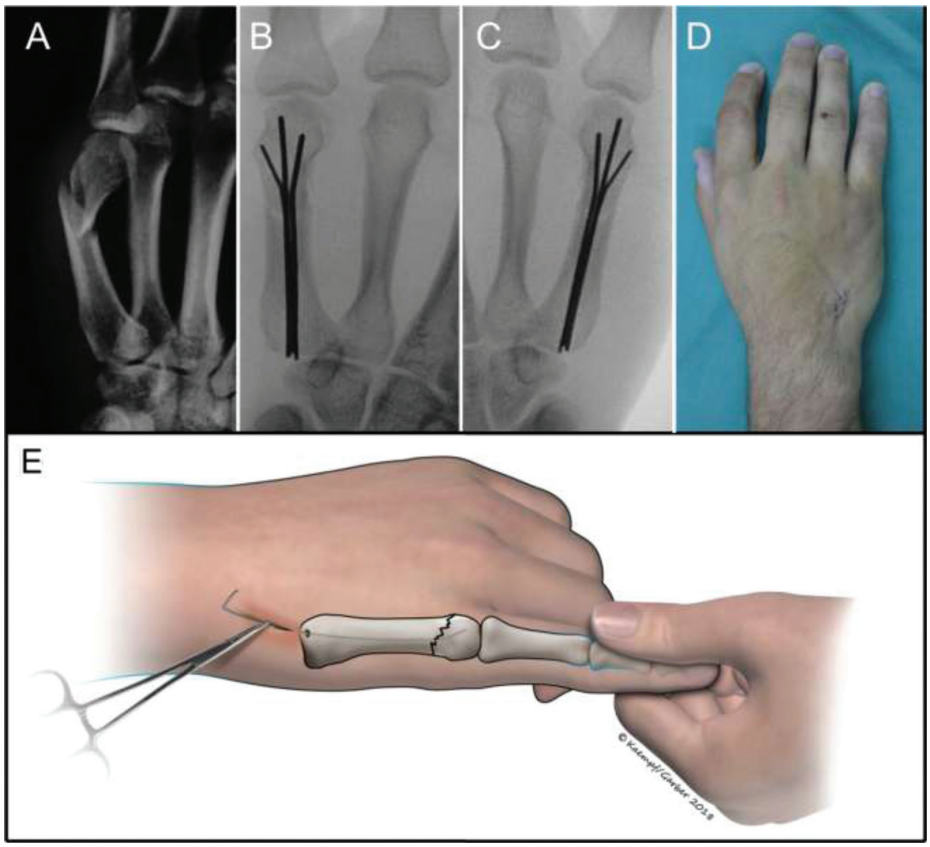


Fig. 4 Kirschner wire antegrade intramedullary "bouquet" fixation technique and radioscopic final images. (A) Boxer's fracture radiographic features. (B and C) Final radioscopic aspect—intramedullary bouquet (D) Final post operatory clinical aspect. (E) Schematic drawing—intramedullary bouquet technique.

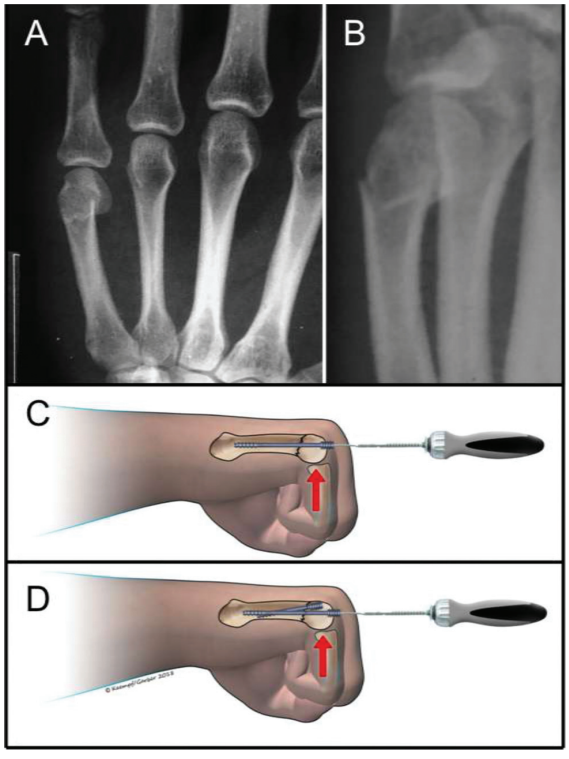


Fig. 5 Percutaneous headless screws intramedullary fixation technique. (A) Radiographic features—Boxer's fracture (B) Radioscopic features—Boxer's fracture (C and D) Headless screws retrograde intramedullary insertion.

with the other. The use of cannulated screws must be carefully weighed by the surgeon. The potential downsides include higher implant costs, the production of an injury to the articular cartilage, and the retention of metallic hardware.[13]

There is a strong trend toward the use of headless cannulated screws in the treatment of boxer's fractures; although the results found were similar, new comparative studies are needed for electing the best method.

Conclusion

In the treatment of active patients with unstable boxer's fractures, headless screws and bouquet fixation proved to be a safe and reliable treatment. The outcomes were similar in both groups, with satisfactory postoperative ROM, Quick-DASH score, VAS results, and with quick return to daily living activities.

Radiographic consolidation was observed in all of the cases.

Note

Work developed at the Department of Hand Surgery, Hospital Universitário da Faculdade de Medicina do ABC, Santo André, SP, Brazil and Hospital Mãe de Deus, Porto Alegre, RS, Brazil.

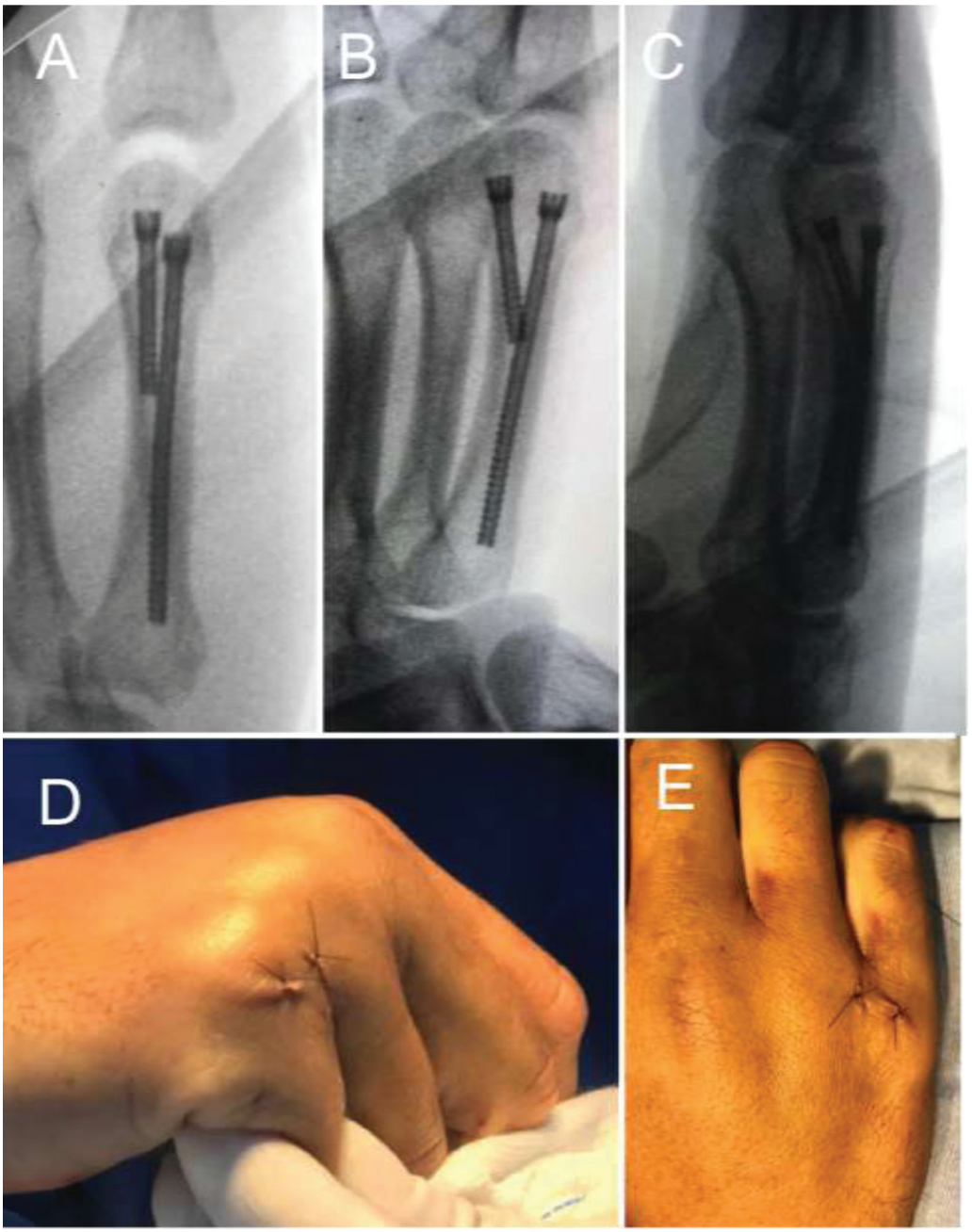


Fig. 6 Percutaneous headless screws intramedullary fixation final clinical and radioscopic images. (A–C) Radioscopic final aspect—headless screws fixation technique. (D and E) Postoperative clinical aspect.

Table 3 Categorical variables

		GROUP				Sig. (p)
		A (K-wire)		B (screw)		
		Freq.	Perc.	Freq.	Perc.	
Side	L R	6 14	30% 70%	5 16	23.8% 76.2%	0.655
Complications	Y N	1 19	5% 95%	1 21	4.76% 95.25%	0.627
Other surgery	Y N	1 19	5% 95%	0 21	0% 100%	0.300

Abbreviations: Freq., frequency; Perc., percentile; Sig., significance.

Table 4 Scalar variables regarding age, range of motion, QuickDASH, visual analog scale, and return to work (days)

Variable	Group	n	Man	Standard deviation	Min	Max	Perc. 25	Perc. 50 (median)	Perc. 75	Sig. (p)
Age (years)	A B Total	20 21 41	31.20 29.76 30.46	9.23 9.22 9.14	21 16 16	54 52 54	25 22.5 23.5	29 28 28	35 37 35.5	0.715
Follow-up (months)	A B Total	20 21 41	14.6 8.52 11.49	5.49 2.77 5.25	7 6 6	25 15 25	10.25 6 7	13 08 11	19 11 14	< 0.001
ROM (% opposite side)	A B Total	20 21 41	98.75 98.81 98.78	5.59 5.46 5.45	75 75 75	100 100 100	100 100 100	100 100 100	100 100 100	0.972
Quick DASH	A B Total	20 21 41	1.25 1.51 1.38	2.71 3.62 3.17	0 0 0	11.36 15.9 15.9	0 0 0	0 0 0	2.27 2.27 2.27	1
VAS	A B Total	20 21 41	0.25 0.52 0.39	0.55 0.75 0.67	0 0 0	2 3 3	0 0 0	0 0 0	0 1 1	0.14
Return to work (days)	A B Total	20 21 41	31.5 32.86 32.20	21.41 23.16 22.05	5 6 5	90 82 90	15 11 13.5	30 37 30	41.25 49.5 46.5	0.865

Abbreviations: Min., minimum; Max., maximum; Perc., percentile; QuickDASH, abbreviated form of the disabilities of the arm, shoulder, and hand; ROM, range of motion; Sig., significance.

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

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Comparative Clinical Evaluation of Two Techniques of Arthroscopic Treatment of Partial Articular Rotator Cuff Tears*

Avaliação clínica comparativa de duas técnicas no tratamento artroscópico das lesões parciais articulares do manguito rotador

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Abstract

Objectives To evaluate the clinical results of patients submitted to arthroscopic treatment of partial lesion of the articular part of the rotator cuff by transtendon suture techniques and after completing the lesion and to compare the postoperative recovery time of the two techniques.

Method Retrospective study based on the identification of all cases with partial lesion of the articular part of the rotator cuff submitted to arthroscopic treatment from October 1999 to December 2016 at the Shoulder and Elbow Group of our institution. Thirty-nine patients were included and divided into two groups: those who underwent the transtendon technique and those in whom the lesion was completed. The two groups were statistically similar. The respective medical records were analyzed as well as the identification of the applied technique, the postoperative results, and the related complications. The functional evaluation was performed using the score of the University of California at Los Angeles (UCLA).

Results There was no statistically relevant difference between the groups, with a mean UCLA score of 32, and no difference in the time required for rehabilitation.

Keywords
- rotator cuff
- arthroscopy
- treatment

* *Study carried out in the Shoulder and Elbow Surgery Group of the Department of Orthopedics and Traumatology of the Faculty of Medical Sciences of Santa Casa de São Paulo, "Pavilhão Fernandinho Simonsen" (DOT - FCMSCSP) (Director: Professor Maria Fernanda Silber Caffaro), São Paulo/SP, Brazil.*

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Conclusion There was no difference between the clinical outcome of the patients, regardless of the technique used to repair the partial lesions of the articular part of the rotator cuff, with satisfactory results in 93% of the cases.

Resumo

Objetivos Avaliar os resultados clínicos dos pacientes submetidos ao tratamento artroscópico da lesão parcial da porção articular do manguito rotador pelas técnicas de sutura transtendão e após completada a lesão e comparar o tempo de recuperação pós-operatório das duas técnicas.

Método Estudo retrospectivo baseado na identificação de todos os casos com lesão parcial da porção articular do manguito rotador submetidos a tratamento artroscópico no período de outubro de 1999 a dezembro de 2016 pelo Grupo de Ombro e Cotovelo da nossa instituição. Foram incluídos 39 pacientes divididos em 2 grupos: os que foram submetidos à técnica transtendão e aqueles nos quais a lesão foi completada. Os dois grupos foram estatisticamente semelhantes. Foi realizada a análise dos respectivos prontuários, da identificação da técnica aplicada, dos resultados pós-operatórios e das complicações relacionadas. A avaliação funcional foi realizada através do escore da University of California at Los Angeles (UCLA).

Resultados Não houve diferença estatisticamente relevante entre os grupos, com escore UCLA médio de 32, não havendo diferença também no tempo necessário para reabilitação.

Conclusão Não houve diferença entre o resultado clínico dos pacientes, independente da técnica empregada para o reparo das lesões parciais da porção articular do manguito rotador com resultados satisfatórios em 93% dos casos.

Palavras-chave
- manguito rotador
- artroscopia
- tratamento

Introduction

Partial rotator cuff injury is recognized as an important cause of shoulder dysfunction and pain.[1] Its incidence is not yet consensus in literature, although there are several studies about it.[2–4] Sher et al.,[3] analyzing 96 asymptomatic shoulders by ultrasound, found 20% of partial lesions. By dissecting 249 shoulders of corpses, Lohr and Uhthoff[2] found 32% of partial injuries, while Fukuda[5] found 13%. These authors described that around 1/3 (27%) of these lesions affect the joint part.

Ellman[6] was the first to propose, based on arthroscopic findings, a partial lesion classification system in relation to its location (A, articular; B, bursal; C, intratendinous) and its extension (grade 1: < 3 mm; grade 2: 3–6 mm; grade 3: > 6 mm).

As for the pathophysiology of partial lesions of the articular part (PLAP) of the rotator cuff, it is believed that they can occur either with intrinsic mechanisms (area of hypovascularization and metabolic alterations related to age) and extrinsic (posterosuperior internal impact, acute traumatic events, and recurrent microtraumas), or even a combination between them.[7] Weinreb et al.,[8] in 2014, published an article showing that there is evidence that intrinsic factors related to the tendon lead to the degeneration of its fibers in the articular face with tapering and disorientation of these, resulting in the anatomical injury of this region. Corroborating this evidence, Ozaki et al.[9] did not find signs of subacromial impact in the articular lesions of the rotator cuff, so they exclude it as a possible cause for these lesions. Another mechanism that leads to PLAP of the rotator cuff is found in pitchers, who can have a posterosuperior internal impact.[4,10]

The initial treatment for PLAP of the rotator cuff is performed with conservative measures, such as physiotherapy and change of habits to prevent the progression of the lesion.[11] Surgical treatment is indicated in the failure of conservative treatment and in cases in which the lesion takes up more than 50% of the tendon thickness, due to a higher risk of progression of the lesion; 40% of the PLAP of the rotator cuff evolve to complete lesions, according to Mall et al.[12] and Stuart et al.[13]

Different arthroscopic surgical techniques have been described to approach this type of lesion, from a simple arthroscopic debridement of the tendon, believing in its healing capacity (since performed in low-grade lesions[14]), to a transtendon repair of the lesion, initially described by Stephen Snyder,[15] or even the disinsertion of the affected tendon area ("completing the lesion") followed by its repair.[16]

The main objective of the present study is to evaluate the clinical results of patients submitted to arthroscopic treatment of PLAP of the rotator cuff by transtendon suture techniques and after the lesion is completed and to compare the postoperative recovery time of the two techniques.

Casuists and Methods

From October 1999 to December 2016, 39 patients with diagnosis of PLAP of the rotator cuff underwent arthroscopic

surgical treatment performed by the Shoulder and Elbow Group of the Department of Orthopedics and Traumatology of our institution.

The patients, all with partial joint lesion of the supraspinal muscle tendon, were divided into two groups: group I, those who underwent transtendon repair, and group II, patients submitted to treatment with repair after turning the partial lesion into complete.

The inclusion criteria were patients diagnosed with PLAP of the rotator cuff, performed by means of magnetic resonance imaging (MRI) in the preoperative period, submitted to arthroscopic treatment, and who had minimal follow-up $\geq$ 2 years.

In group I, there were 19 patients with mean follow-up of 4.61 years. Thirteen of these patients were male (68%) and 6 were female. The mean age was 48 years, ranging from 34 to 70 years. The dominant side was affected in 73% of the cases; 16 patients (84%) practiced sports and 9 patients (47%) reported traumatic event as triggering the condition.

Group II had 20 patients with mean follow-up of 4.35 years. Eleven of these were male (55%) and 9 were female. The mean age was 52 years, ranging from 29 to 75 years. The dominant side was affected in 85% of the cases, 11 patients (55%) practiced sports and only 3 patients reported a traumatic event.

There were no statistically significant differences between the samples in relation to age, gender, and affected limb, and in 78% of the cases, the dominant side was affected. All patients were submitted to the surgical procedure in beach chair position, under general anesthesia associated with anesthetic block of the brachial plexus. Articular arthroscopic inspection was performed, followed by subacromial inspection and partial bursectomy. In group I, seven patients presented SLAP-type lesion, two with arthrosis of the acromioclavicular joint, one with major tubercle fracture, already consolidated and which was treated conservatively, one patient with long biceps head injury and one patient with Bankart injury. In group II, six patients presented SLAP-type lesions, four had rupture of the long head of the biceps, and three had arthrosis of the acromioclavicular joint. From this point, the techniques differ: in group I patients, the wires of the anchors were passed through the transtendon, through the joint space to the bursal surface, following with the repair. When we opted for this type of repair, we increased the pressure of the serum infusion pump to close to 80 mmHg, which causes the joint space to increase and the tendon to lift from its insertion bed and allows intra-articular visualization of the passage of the anchors from subacromial to intra-articular and its correct positioning in the so-called *footprint*. Once the anchor is fixed, a wire is caught with *birdbick* tweezers and passed through the tendon at a point of tissue considered healthy, that is, outside of the lesion area. We return the pump pressure to normal value, to avoid an exaggerated and rapid edema that prevents the rest of the surgery. Then, the optics are positioned again in the subacromial space, and the wires are tied with simple sliding points. The procedure is repeated as many times as deemed necessary (►**Figure 1**). In group II patients, the disinsertion of the bursal fibers, which remained intact, was performed, transforming it into a complete lesion, followed by repair through the passage of

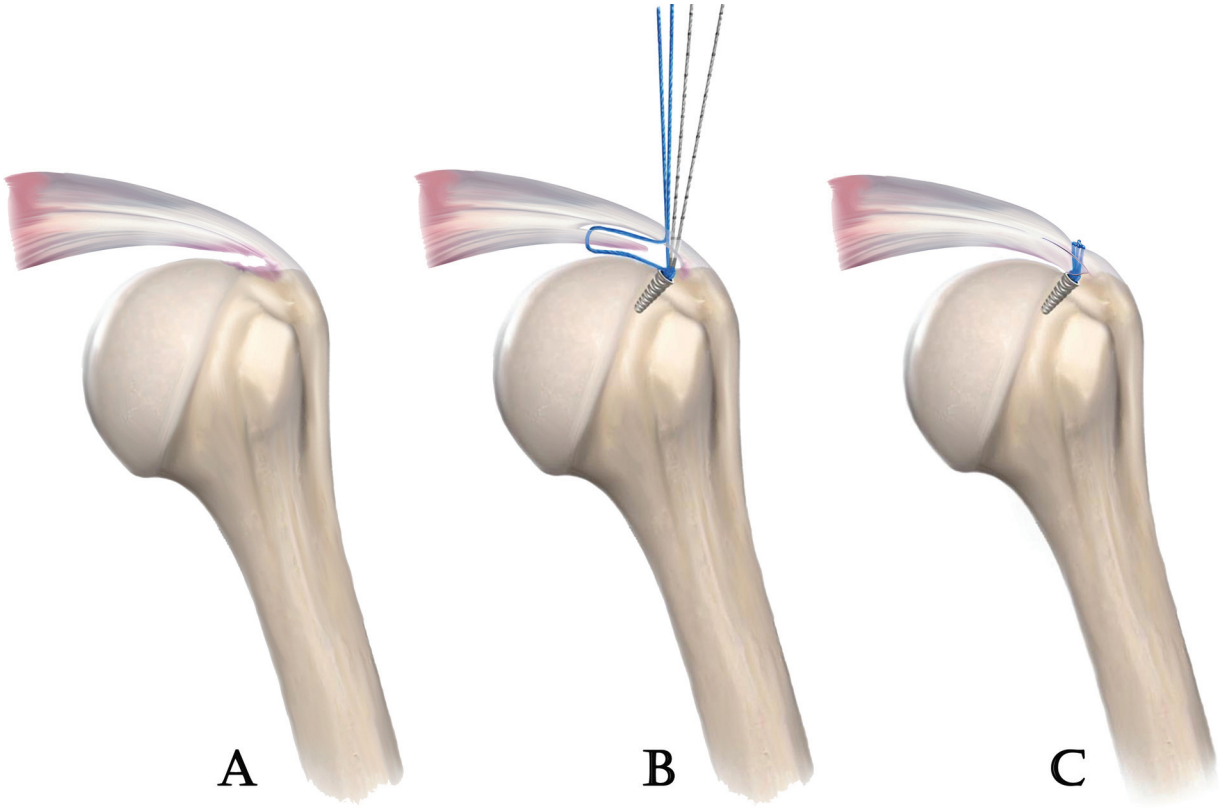


Fig. 1 Transtendon repair of the partial joint lesion of the supraspinal muscle tendon. A - Representation of partial joint injury, B - Way of passage of suture threads according to this technique, C - Sutured lesion.

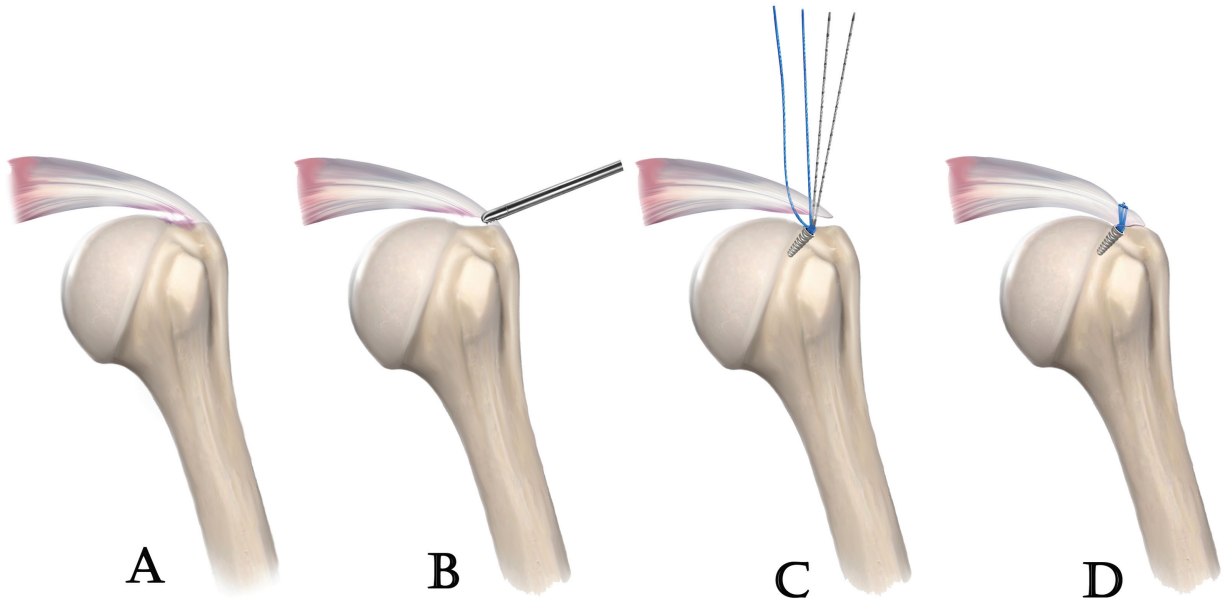


Fig. 2 Repair after transforming the partial lesion into complete in the partial joint lesion of the supraspinal muscle tendon. A - Representation of partial joint injury, B - Partial lesion being completed, C - Way of passage of suture threads in the lesion already completed, D - Sutured lesion.

the suture threads through the bursal face (►**Figure 2**). All of them were repaired by simple points technique via arthroscopy.

In the postoperative period, the patients were immobilized with functional sling between 4 and 6 weeks, continuing rehabilitation.

The amplitude of the range of motion was evaluated by measuring elevation, lateral and medial rotations. Clinical evaluation was performed using the University of California at Los Angeles (UCLA) score.[17] To evaluate the recovery time, we used the comparison of the time that patients in both groups took to reach their "maximum" value of the UCLA score,[17] per specific statistical test listed below.

Initially, a descriptive analysis was performed with calculation of the percentage distribution for each variable. The qualitative variables (gender, dominance, sport, intra and postoperative capsulitis) were analyzed by the chi-Squared independence test, when the hypotheses of independence of the sample were respected, and by Fisher exact test when not respected. The quantitative and qualitative ordinal variables (elevation, medial and lateral rotations, pre- and postoperative, follow-up time, UCLA value and UCLA time) were analyzed by the Mann-Whitney nonparametric test, when the distribution did not adhere to the normal distribution, and by the F-test, when there was adherence to the normal distribution, followed by analysis of the equality of means by Student t-test.

The analyses were performed using the statistical software Minitab (Minitab, LLC, State College, PA, USA), v.17. All hypotheses with descriptive levels (p-value) lower than 0.05 were rejected, which was the level of significance adopted.

The study was submitted to the Research Ethics Committee and approved according to CAAE: 79428617.2.0000.5479.

Results

Using the UCLA score,[17] group I had 9 excellent results (42%), 8 good results (38%), and 2 unsatisfactory results (►**Table 1**). The mean time for rehabilitation was 6 months, postoperative range of motion with an average elevation of 142° (110–160°), lateral rotation of 59° (45–70°), and medial rotation of T8 (T3–L5).

In group II, we had 5 excellent results (25%), 14 good results (70%), and an unsatisfactory result (►**Table 2**). The mean time for rehabilitation was 5.2 months, postoperative range of motion with an average elevation of 146° (130–160°), lateral rotation of 56° (45–70°), and medial rotation of T8 (T5-L2).

As a complication, we had two cases of adhesive capsulitis, one in each group. The patient in group I underwent arthroscopic release after 8 months of repair of the lesion reaching a UCLA[17] score of 33 after 1 year. The patient in group II showed improvement after performing suprascapular nerve blocks and physiotherapy, reaching a UCLA[17] score of 33 7 months postoperatively.[18]

After the statistical analysis, there was no difference between the average UCLA[16] score for both groups, with a result of 32, ranging in group I from 22 to 35, and in group II from 23 to 35. In the analysis of the time required to achieve the result of UCLA,[17] there was a difference of 3 weeks in the mean, but without statistical relevance, with a p-value = 0.336.

Discussion

Surgical treatment for PLAP of the rotator cuff is indicated in the failure of conservative treatment and, commonly, in cases in which the lesion affects more than 50% of the tendon fibers,[13]due to a 40% risk in progression to complete injury, as described by Mall et al.[12] Mazzoca et al.[19] also demonstrated in cases with more than 50% of injury to the tendon fibers, the remaining tendon presents an increase in its tension, which would lead to its eventual complete rupture.

In the operative act, PLAP of the rotator cuff can be approached in two ways in relation to the tendon: either

Table 1 Clinical data of patients undergoing transtendon repair

Nr. of patients	Gender	Age	Dominant side	Δtt	UCLA	Δt	COMPLICATIONS
1	F	50		03 a.	TOTAL:35	4 m	
2	M	70		02 a.	TOTAL: 35	5 m	
3	F	49	+	03 a.	TOTAL: 35	5 m	
4	F	39	+	02 a.	TOTAL: 35	5 m	
5	M	51	+	03 a.	TOTAL: 35	4 m	
6	M	43	+	07 a.	TOTAL: 22	9 m	
7	M	49	+	02 a.	TOTAL: 35	4 m	
8	M	40	+	09 a.	TOTAL: 32	6 m	
9	M	34	+	2 a.	TOTAL: 35	5 m	
10	M	44	+	09 a.	TOTAL: 32	4 m	
11	F	56		09 a.	TOTAL: 31	5 m	
12	M	41	+	12 a.	TOTAL: 34	4 m	
13	F	54	+	02 a.	TOTAL: 32	9 m	
14	M	52	+	09 a.	TOTAL: 31	8 m	
15	M	58		04 a.	TOTAL: 23	10 m	
16	M	59	+	09 a.	TOTAL: 34	5 m	
17	F	53		05 a.	TOTAL: 33	6 m	
18	M	44	+	05 a.	TOTAL: 33	4 m	
19	M	35	+	07 a.	TOTAL: 33	12 m	REVIEW FOR RELEASE WITH 8 MONTHS DUE TO CAPSULITIS

Abbreviations: a: years; F: female; m: months; M: male; Δt: time for rehabilitation; Δtt: postoperative follow-up time; UCLA, University of California at Los Angeles.

by maintaining its integrity in the insertion—a technique known as transtendon fixation of the lesion—or by a second technique in which there is complete disinsertion of the remaining fibers, transforming it into a complete lesion.

Studies such as those by Sethi et al.[20] and Mihata et al.[21] show biomechanical advantages of transtendon repair. In this technique, the bursal (intact and uninjured) and articular (containing the lesion) fibers are sutured separately (►**Figure 1**), which provides less tension at the end of the suture in the bursa fibers, in addition to a larger contact surface in the insertion area. But as observed by Shin,[22] these patients present a more painful postoperative period and a slower recovery of the range of motion, which could be related to lesions with great retraction of the affected joint part, with an unbalance between the fibers repaired and those that were kept intact. In our study, we observed that patients in group I took 1 month longer, on average, to recover and reach the final UCLA[17] than patients in group II, but this difference was not statistically significant.

Shin[22] also mentions that the disinsertion of the entire lateral margin of the rotator cuff, by turning the partial lesion into complete, can lead to the risk of non-anatomical repair, altering the biomechanics and thus resulting in an early degeneration of the tendon. However, in our opinion, as in Shin's,[22] such a maneuver allows a better view and facilitates repair due to greater familiarity with the technique.[11,20] Although good functional result is not a specific factor for knowing whether or not there was anatomical repair of the lesion, we did not suspect any important biomechanical alteration, since patients in group II presented good postoperative evolution, with return of the usual activities, as found in the study by Godinho et al.,[23] who obtained 100% satisfaction and good/excellent results with the technique.

There is no consensus in the literature on the best technique for repairing this type of lesion. The comparative works between the two techniques, such as those of Shin,[22] Ono et al.,[24] and Castagna et al.,[16] do not present statistically significant differences among them, presenting similar results in the postoperative period, with the same healing rate, re-ruptures, and results. Our study demonstrates that both techniques enable good results, without statistical differences when evaluating the UCLA score[17] between the two groups, with a p-value = 0.321, including similar postoperative rehabilitation time, with p-value = 0.336.

Despite the good result obtained with both techniques, we had in our study three cases with unsatisfactory results, two from group I and one from group II. In group I, the 1st patient was 43 years old, a non-professional tennis player with injury affecting the dominant side and with symptoms presenting for about 20 years. With good preoperative mobility (140°, 80°, T3), he evolved with a loss in the postoperative period of 110°, 45° and L5, which remained. It evolved with the patient presenting pain when doing low-intensity work, with the patient being able to perform all

Table 2 Clinical data of patients submitted to repair after the injury was completed

Case	Sex	Age	Dominant side	Δtt	UCLA	Δt	COMPLICATIONS
1	M	58	+	02 a.	TOTAL: 32	6 m	
2	F	63	+	02 a, 10 m	TOTAL: 31	5 m	
3	F	65	+	02 a.	TOTAL: 32	4 m	
4	F	67	+	02 a.	TOTAL: 33	5 m	
5	M	75		03 a.	TOTAL: 34	4 m	
6	F	57		05 a.	TOTAL: 34	6 m	
7	M	39	+	08 a.	TOTAL: 32	6 m	
8	F	73	+	05 a.	TOTAL: 35	5 m	
9	F	59	+	02 a.	TOTAL: 32	5 m	
10	M	43	+	04 a.	TOTAL: 32	7 m	
11	M	38	+	02 a.	TOTAL: 33	7 m	
12	F	29	+	11 a.	TOTAL: 34	4 m	
13	M	44		13 a.	TOTAL: 23	6 m	
14	M	42	+	02 a.	TOTAL: 32	5 m	
15	F	51		08 a.	TOTAL: 33	4 m	
16	M	39	+	06 a.	TOTAL: 32	4 m	
17	M	49	+	02 a.	TOTAL: 33	4 m	
18	M	51	+	03 a.	TOTAL: 32	5 m	
19	M	56	+	03 a.	TOTAL: 33	7 m	CAPSULITIS AFTER 3 MONTHS, PERFORMING BLOCKS AND PHYSIOTHERAPY.
20	F	47	+	02 a.	TOTAL: 35	5 m	

Abbreviations: a: years; F: female; m: months; M: male; Δt: time for rehabilitation; Δtt: postoperative follow-up time; UCLA, University of California at Los Angeles.

domestic activities, but with limitation in movements above the shoulder line (grade IV strength). The second case of group I was a 58-year-old patient, a non-professional swimmer, presenting symptoms in the non-dominant side for 3 years. Good pre and postoperative range of motion, without limitation. He also developed pain to light work, with grade IV loss of strength above the shoulder. After all, the two said they are satisfied with the result. The case of group II was a 44-year-old patient with no history of sports practice, presenting symptoms for 1 year. Preoperative range of motion 160°, 70°, T7. It evolved postoperatively with pain to low-intensity work, and slight decrease in elevation and lateral rotation, without loss of strength. However, he is dissatisfied with the result due to the persistence of pain. What caught our attention in all three cases is that we did not find an objective cause for the maintenance of pain. All patients' imaging showed normal healing of the lesion.

Conclusion

Both the transtendinous suture and suture after completing the lesion led to satisfactory results in 93% of the patients in our series. We did not find a statistically significant difference in rehabilitation time between the two groups.

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

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Evaluation of the Glenoid Track Tomographic Method in Magnetic Resonance Imaging/Arthro-MRI

A avaliação do método tomográfico glenoid track na ressonância magnética/artro RM

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Abstract

Objective To evaluate and compare the glenoid track method in 3D-reconstructed computed tomography (3D-CT) scans with magnetic resonance imaging (MRI) and/or arthro-MRI.

Methods Forty-four shoulders with clinical and radiographic diagnosis of traumatic anterior instability were assessed using 3D-CT, MRI, and/or arthro-MRI scans. Glenoid track (GT), Hill-Sachs interval (HSI), and glenoid bone loss (GBL) were determined by a radiologist using 3D-CT images, and classified as on-track/off-track. Three surgeons, blinded to the radiologist's evaluation, performed the same determinations using MRI/arthro-MRI. Descriptive analysis, variance analysis, results disagreement analysis, and receiver operating characteristic (ROC) curves were performed.

Results Results from the 4 examiners were fully consistent in 61.4% of the cases. Magnetic resonance imaging/arthro-MRI diagnosed off-track injuries with 35 to 65% sensitivity and on-track injuries, with 91.67 to 95.83% specificity. Accuracy ranged from 68.1 to 79.5%. The greatest data divergence occurred for off-track injuries diagnosed by MRI/arthro-MRI. The greatest data variability referred to HSI calculation. Higher HSI and GBL values were associated with greater disagreement among examiners. Hill-Sachs interval values were lower at MRI/arthro-MRI when compared to 3D-CT. Agreement between CT and MRI/arthro-MRI for the GT method was only moderate (kappa value, 0.325–0.579).

Conclusion Magnetic resonance imaging/arthro-MRI showed low accuracy and moderate agreement for the GT method; as such, it should be used with caution by surgeons.

Keywords
- glenoid cavity
- anterior shoulder instability
- shoulder dislocation

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Resumo

Objetivo Comparar a avaliação do método *glenoid-track* (GT) em exames de tomografia computadorizada com reconstrução 3-D (TC-3D) com a avaliação realizada em exames de ressonância magnética (RM) e/ou artro-ressonância magnética (ARM).

Métodos Quarenta e quatro ombros com diagnóstico clínico e radiográfico de instabilidade anterior traumática foram avaliados por meio de exames de TC-3D, RM e/ou ARM. As variáveis GT, intervalo de Hill-Sachs (IHS) e a perda óssea da glenoide (POG) foram realizadas por um médico radiologista, utilizando imagens de TC-3D, e classificadas em *on-track*/*off-track*. Três cirurgiões cegos à avaliação do radiologista realizaram o mesmo método utilizando RM/ARM. O estudo realizou análise descritiva, de variância, de associação da discordância de resultados, de concordância e curva característica de operação do receptor.

Resultados Os resultados dos 4 examinadores foram totalmente concordantes em 61,4%. A RM/ARM diagnosticou lesões *off-track* com a sensibilidade variando de 35 a 65%, e lesões *on-track* com a especificidade variando de 91,67 a 95,83%. A acurácia variou de 68,1 a 79,5%. A maior divergência de dados ocorreu para o diagnóstico por RM/ARM de lesões *off-track*. A maior variabilidade dos dados ocorreu para o cálculo do IHS. Valores maiores de IHS e de POG foram associados a maior discordância entre os examinadores. A RM/ARM apresentou menor medida de valores de IHS quando comparado com a TC-3D. Ocorreu apenas moderada concordância no método GT entre a TC e a RM/ARM (Kappa 0,325–0,579).

Conclusão A RM/ARM apresentou baixa acurácia e moderada concordância para o método GT, devendo ser utilizada com cautela por cirurgiões.

Palavras-chave

- cavidade glenoide
- instabilidade anterior do ombro
- luxação do ombro

Introduction

Proper assessment of patients with traumatic anterior shoulder instability is still a challenge for orthopedists.[1] A precise, detailed study of soft tissue and bone lesions in glenohumeral instability requires three-dimensional-reconstructed computed tomography (3D-CT), magnetic resonance imaging (MRI) or arthro-MRI scans, which can increase propaedeutic costs, delay and bureaucratize treatment.[2]

The dynamic interaction between bone losses at the proximal humerus and the glenoid in traumatic anterior shoulder dislocation, the so-called lesion bipolarity, was described in 3D-CT using the glenoid track (GT) concept. This concept has gained prominence in the scientific community for its prognostic ability and role in guiding the appropriate treatment according to the Hill-Sachs lesion (HSL) classification and the glenoid bone loss (GBL) size.[3]

Considering this method as optimal and in an attempt to reduce costs by the simultaneous evaluation of soft and bone lesions in a single scan, the orthopedic literature tried to replace 3D-CT with MRI/arthro-MRI.[3–5] As such, this study aims to compare the GT method performed by shoulder surgeons using MRI/arthro-MRI with the evaluation performed by a radiologist using 3D-CT. Our hypothesis is that GT measurement by MRI/arthro-MRI can be performed accurately and reliably by surgeons in their clinical practice.

Material

This is a cross-sectional, analytical study with 43 patients and 44 shoulders, selected using a non-probabilistic method (i.e., a convenience sampling), diagnosed with traumatic anterior shoulder instability from March 2015 to September 2018. All patients underwent 3D-CT, MRI, and/or arthro-MRI scans at a single radiology clinic.

Glenoid track, HSI, and GBL calculations, as well as lesion classification as on-track/off-track, were performed in all 3D-CT scans by a single radiologist (R) with more than 10 years of experience in the musculoskeletal system. This analysis was considered the reference standard.

Three shoulder surgeons (C1, C2, and C3) trained in the GT method performed the same calculations in MRI or arthro-MRI scans. All of them were blinded to the results obtained by R or the remaining evaluators. All calculations were performed in a single moment and recorded by 2 4-year residents (R4) in shoulder surgery.

Gender, age, and dominance were not considered. Patients with clinical and radiological diagnosis of traumatic anterior shoulder instability, with complete, documented 3D-CT, MRI, and/or arthro-MRI scans and no previous surgical treatment until the time of data analysis were included. Patients evaluated by another radiologist, whose scans were performed at other radiological facilities, and with incomplete information or associated lesions, such as fractures, rotator cuff injuries or glenohumeral arthrosis, were excluded.

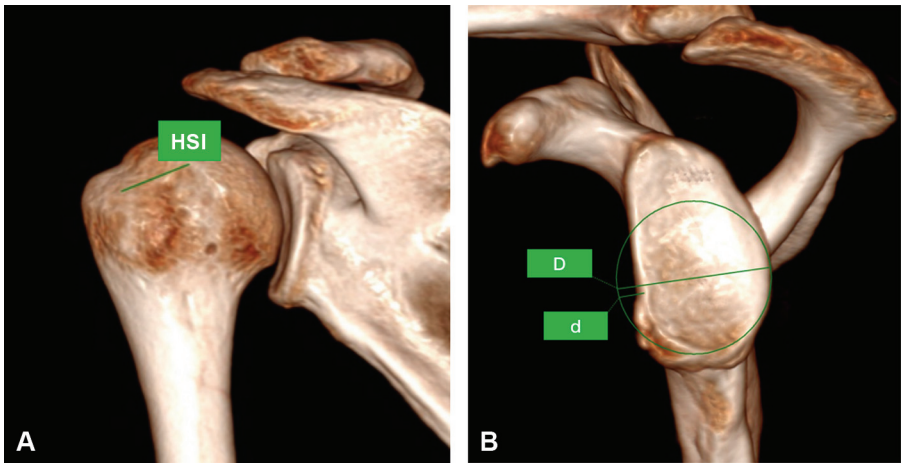


Fig. 1 Three-dimensional computed tomographic images showing the glenoid track (GT) calculation. (1A) The Hill-Sachs interval (HSI) corresponds to the distance between the inner margin of the rotator cuff footprint and the medial border of the bone defect. (1B) A virtual circle drawn in the lower two thirds of the intact glenoid borders shows the potential diameter in the absence of a bone defect (D) and the bone defect width (d). The GT corresponds to 83% of the glenoid diameter minus the bone defect diameter.

Methods

All CT-3D were performed in a 64- or 128-channel scanner, Siemens Somatom Sensation or Siemens Somatom Definition AS, respectively, (Siemens AG, Munich, Germany) in supine position and with limbs in neutral rotation.

Magnetic resonance imaging and arthro-MRI scans (Magnetom Essenza 1.5 T - Siemens Healthcare, Erlangen, Germany) were performed in supine position, with the shoulder in neutral rotation, using T2-weighted sequences with or without fat suppression (TR/TE 2280/42, field of view 160 × 100 mm, matrix 384 × 70, 3-mm thickness) in postprocessed axial, sagittal, and coronal views (Kodak Carestream PACS, Belo Horizonte, Minas Gerais, Brazil).

Glenoid track, HSI, GBL calculations, and on-track/off-track classifications were performed in 3D-CT scans as described by Di Giacomo et al.[3] (►**Figure 1A** and **1B**. The same calculations were performed in MRI/arthro-MRI scans as reported by Guyftpoulos et al.[4] (►**Figure 2A** and **2B**). Glenoid track was determined using the formula GT = 0.83D – d.

Data was analyzed with the IBM SPSS software 23.0. (IBM Corp., Armonk, NY, USA). The level of significance was 5% for the entire study. This study was approved by the institutional research ethics committee.

Results

Descriptive analysis

None of the 44 shoulders from the sample was excluded from the study. All shoulders were submitted to 3D-CT scans; in addition, 19 (43.2%) and 25 (56.8%) of them also underwent MRI and arthro-MRI scans, respectively. Twenty-four shoulders (65.9%) were classified as on-track, and 20 (45.5%) were deemed off-track by examiner R in 3D-CT scans. Results of the four evaluators were completely consistent in 61.4% of the cases (►**Table 1**).

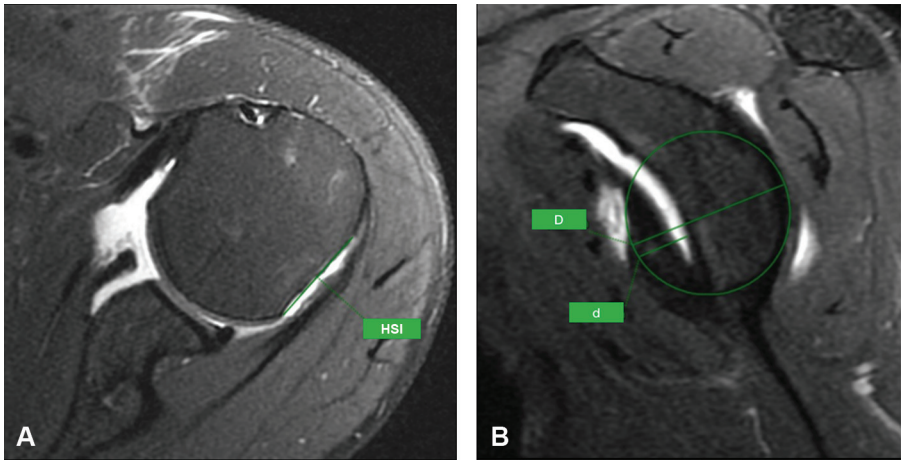


Fig. 2 Arthro-resonance magnetic imaging (arthro-MRI) showing the glenoid track (GT) measurement. The lower glenoid diameter (D) was determined with a circle drawn along it for GT calculation. The length of glenoid bone loss (d) was then measured. The glenoid track was calculated using the formula GT = 0.83D - d. (2A) Hill-Sacks interval (HSI) measurement using a posterior view of the humeral head. (2B) GT calculation similar to the one performed in computed tomography images.

Table 1 Descriptive analysis of qualitative variables: imaging test, on-track/off-track classification, and disagreement among examiners

Variable	Frequency	%
Imaging test		
Computed tomography	44	100.0
MRI	19	43.2
Arthro-MRI	25	56.8
Result – R		
On-track	24	54.5
Off-track	20	45.5
Result – C1		
On-track	29	65.9
Off-track	15	34.1
Result – C2		
On-track	31	70.5
Off-track	13	29.5
Result – C3		
On-track	36	81.8
Off-track	8	18.2
Discordance		
0	27	61.4
1	7	15.9
2	5	11.4
3	5	11.4
Total	44	100.0

Abbreviations: Arthro-MRI, Arthro-resonance magnetic imaging; MRI, magnetic resonance imaging.

Variance analysis

Kolmogorov-Smirnov, Levene, *posthoc* Dunnett, and T3 Dunnett's tests assessed the variation in GT, HSI and GBL results among the four examiners.

There was a statistically significant difference for GT, HSI and GBL values when the results found by the four examiners were compared. The greatest data variability referred to HSI. Mean HSI values were lower at MRI/arthro-MRI when compared to 3D-CT (►**Tables 2** and **3**).

Posthoc tests showed a statistically significant difference in GT values between R and C3 ($p = 0.027$) and C1 and C3 ($p = 0.039$); C3 found significantly higher values than the two other examiners.

For HSI, there was a significant difference between R and C2 ($p = 0.017$) and R and C3 ($p = 0.001$), since R found significantly higher values.

As for GBL, there was a difference between C1 and C3 ($p = 0.027$), since the former found significantly higher values compared to the latter.

Analysis of results disagreement association

A non-parametric correlation analysis was performed to evaluate quantitative variables. To this end, results from R were considered always correct and the number of disagreements with these results was assessed (0–3 disagreements) with the Spearman correlation test.

There was a statistically significant correlation between HSI and GBL, both with a positive coefficient, indicating that higher HSI and GBL values were associated with more disagreements among examiners (►**Table 4**).

The Pearson chi-squared test assessed qualitative variables. Off-track injuries accounted for 88.24% of the disagreements. This finding demonstrates that the greatest difficulty

Table 2 Descriptive analysis of quantitative variables: glenoid track, Hill-Sachs interval and glenoid bone loss according to examiners R, C1, C2 and C3

	n	Mean	Median	Standard deviation	Minimum	Maximum	Interquartile range
Examiner R GT	44	20.30	20.27	2.50	12.98	27.39	3.13
HSI	44	19.64	20.21	3.61	11.32	29.01	4.17
GBL	44	8.68	9.50	7.65	0.00	33.00	14.00
Examiner C1 GT	44	20.00	19.98	3.71	2.46	26.08	3.18
HSI	44	17.36	18.35	5.72	6.35	33.84	8.16
GBL	44	11.63	11.50	7.12	0.00	33.00	7.58
Examiner C2 GT	44	20.60	20.68	2.73	12.08	25.04	4.00
HSI	44	16.62	16.10	5.39	3.78	29.82	5.70
GBL	44	7.83	0.00	9.19	0.00	30.53	15.43
Examiner C3 GT	44	21.95	22.13	2.81	15.49	30.52	3.55
HSI	44	15.69	14.51	5.30	4.79	29.35	6.46
GBL	44	7.21	7.00	7.25	0.00	22.00	13.00

Abbreviations: GBL, glenoid bone loss; GT, glenoid track; HSI, Hill-Sachs interval.

Table 3 Descriptive glenoid track, Hill-Sachs interval, and glenoid bone loss measures for variance analysis according to examiners R, C1, C2 and C3

		n	Mean	Standard deviation	Standard error	95% Confidence interval for the mean		Minimum	Maximum
						Lower limit	Upper limit		
GT	R	44	20.30	2.50	0.38	19.54	21.06	12.98	27.39
	C1	44	20.00	3.71	0.56	18.87	21.13	2.46	26.08
	C2	44	20.60	2.73	0.41	19.76	21.43	12.08	25.04
	C3	44	21.95	2.81	0.42	21.10	22.81	15.49	30.52
	Total	176	20.71	3.04	0.23	20.26	21.17	2.46	30.52
HSI	R	44	19.64	3.61	0.54	18.55	20.74	11.32	29.01
	C1	44	17.36	5.72	0.86	15.62	19.10	6.35	33.84
	C2	44	16.62	5.39	0.81	14.98	18.26	3.78	29.82
	C3	44	15.69	5.30	0.80	14.08	17.30	4.79	29.35
	Total	176	17.33	5.24	0.39	16.55	18.11	3.78	33.84
GBL	R	44	8.68	7.65	1.15	6.36	11.01	0.00	33.00
	C1	44	11.63	7.12	1.07	9.46	13.79	0.00	33.00
	C2	44	7.83	9.19	1.39	5.03	10.62	0.00	30.53
	C3	44	7.21	7.25	1.09	5.01	9.41	0.00	22.00
	Total	176	8.84	7.96	0.60	7.65	10.02	0.00	33.00

Abbreviations: GBL, glenoid bone loss; GT, glenoid track; HSI, Hill-Sachs interval.

Table 4 Correlation analysis for glenoid track, Hill-Sachs interval, glenoid bone loss, and disagreement among examiners

Correlations					
			HSI	GBL	Discordance
Spearman's ρ	GT	Correlation Coefficient	0.154	−0.565	−0.264
		P	0.320	0.000	0.084
		n	44	44	44
	HSI	Correlation Coefficient	1.000	0.177	0.434
		P		0.249	0.003
		n	44	44	44
	GBL	Correlation Coefficient			0.334
		P			0.027
		n			44

Abbreviations: GBL, glenoid bone loss; GT, glenoid track; HSI, Hill-Sachs interval.

occurred in the diagnosis by MRI/arthro-MRI of off-track injuries calculated by 3D-CT.

Concordance analysis

Sensitivity values were not very high, ranging from 35 to 65% (►**Table 5**). The kappa coefficient was statistically significant for all cases. This coefficient describes the agreement between 2 or more tests, with values ranging from 0 to 1. Values close to 0 indicate low agreement, whereas values close to 1 reveal high agreement. The kappa index ranged from 0.325 to 0.579. This means that the GT method using MRI/arthro-MRI images presented only a moderate ability to identify patients with off-track injuries diagnosed at 3D-CT scans.

The positive predictive value (PPV) ranged from 86.67 to 92.31%. The negative predictive value (NPV) ranged from 63.89 to 75.86%. The diagnostic accuracy for off-track injuries ranged from 68.1 to 79.5% among examiners.

Receiver operating characteristic (ROC) curve

The ROC curve revealed that C3 assessment was the only one with no statistical efficiency in off-track injuries diagnosis ($p > 0.05$) (►**Figure 3**). The best classification was performed by C1, which obtained the largest area under the curve. Better test results reflect in an area under the ROC curve closer to 1.

Table 5 Kappa index, sensitivity, specificity, predictive value, likelihood ratio and accuracy of the examining surgeons (C1, C2 and C3) in the diagnosis of on-track/off-track injuries by MRI/arthro-MRI

	C1	C2	C3
Kappa index	0.579	0.575	0.325
Sensitivity (%)	65.00	60.00	35.00
Specificity (%)	91.67	95.83	95.83
Positive predictive value (%)	86.67	92.31	87.50
Negative predictive value (%)	75.86	74.19	63.89
Positive likelihood ratio	7.80	14.39	8.39
Negative likelihood ratio	0.38	0.42	0.68
Accuracy	79.5	79.5	68.1
p-value	< 0.001	< 0.001	0.014

Abbreviations: Arthro-MRI, Arthro-resonance magnetic imaging; MRI, magnetic resonance imaging.

Discussion

Historically, studies on anterior shoulder instability have focused on GBL, which occurs during shoulder dislocation and is also called bony Bankart lesion (BBL).[6,7] It is widely accepted that this structural damage alters glenoid biomechanics by impairing its function as a static stabilizer.[8] Defects greater than 20 to 25% deserve special attention because of their worse prognosis with arthroscopic repair.[6,9]

In an anterior dislocation, the shoulder may suffer an impaction fracture at the posterosuperior and lateral portion of the humeral head. This injury is defined as a Hill-Sachs lesion, and it is observed in up to 70% primary shoulder dislocation cases.[10,11] Studies reveal that bone defects as small as 5/8 of the humeral head radius may result in shoulder instability.[12]

Although the importance of HSL and BBL in shoulder biomechanics was demonstrated, the description of the GT method allowed us to understand the dynamic interaction between these bone injuries.[13] Today, the GT method is part of the routine practice of most orthopedics services due to its prognostic ability in HSL evaluation and its role in guiding the treatment for anterior shoulder instability.[3]

Originally, GT and GBL measurements were described for 3D-CT scans to predict engage-type injuries.[3,13] However, to reduce costs and radiation exposure, the use of MRI/arthro-MRI have been studied for this purpose.[1,4,14]

The engagement concept was proposed initially by Burkhart and De Beer[7] to explain factors related to instability recurrence after an arthroscopic Bankart surgery. Patients bearing these injuries, with the shoulder in abduction and lateral rotation, would be predisposed to the "engagement" of HSL on the anterior edge of the glenoid, leading to joint instability. Engage lesions correspond to off-track injuries per the GT method.[3]

In an attempt to make the glenoid track method feasible for MRI, Gyftopoulos et al.[4] compared GT classification in 75 shoulders with the engagement observed during arthroscopy. They concluded that MRI has 72.2% sensitivity to diagnose engage (off-track) injuries, 87.9% specificity for non-engage injuries (on-track), and a general accuracy of 84.2%. Positive predictive value was 65% and NPV was 91.1%.

In the present study, MRI/arthro-MRI diagnosed off-track injuries with 35 to 65% sensitivity, and on-track injuries with 91.67 to 95.83% specificity. The accuracy for off-track injuries diagnosis ranged from 68.1 to 79.5%. Positive predictive value revealed a chance of identifying truly off-track patients of at least 86.67%, while NPV showed a chance of identifying truly positive on-track injuries of at least 63.89%. The kappa coefficient was significant in all cases. These results are inferior to those demonstrated by Gyftopoulos et al.[4]

Schneider et al.[15] evaluated intra and interobserver variation in GT measurement in 71 patients submitted to 3D-CT scans. They demonstrated that GBL assessment had good intra and interobserver agreement (94% and 96%, respectively). However, the level of reliability among examiners for on-track and off-track classification was only 72%, which was considered low by the authors. They concluded that GBL assessment had better reproducibility and reliability levels compared to HSL.

Our findings demonstrated that the greatest data variability occurred for HSI calculation in MRI/arthro-MRI scans, consistent with the findings of Schnieder et al.[15] with 3D-CT. In addition, we concluded that MRI/arthro-MRI tends to yield lower HSI values when compared to 3D-CT. The proper evaluation of HSL requires several steps and, in our opinion, each one of them presents a potential for error, leading to the low reliability and reproducibility reported in the literature.

Funakoshi et al.[16] assessed the GT classification agreement between 3D-CT scans and intraoperative arthroscopic measurements. Of 16 shoulders classified as on- or off-track, agreement between both methods was achieved in only 10 shoulders (63%, kappa value = 0.16). All cases with disagreement were calculated as on-track by 3D-CT and off-track by arthroscopy. The authors concluded that 3D-CT yields higher GT values compared with arthroscopy, accounting for all discrepancies and the low agreement between methods observed in the study.

Our results revealed a moderate agreement for on-track/-off-track classification between 3D-CT and MRI/arthro-MRI scans (kappa values, 0.325 to 0.579). In our study, most of the discordant results (15 out of 17, or 88.24%) were classified as off-track by 3D-CT and on-track by MRI/arthro-MRI, which may be inadequate to HSL, increasing the risk of instability recurrence. Results from the four examiners were fully consistent in 27 of the 44 shoulders (61.4%) for on-track/off-track classification. Interestingly, higher HSI and GBL values were associated with greater discrepancy among examiners. We believe that this discrepancy can be explained by the evaluators' difficulty in selecting the most representative bone lesions images, especially in MRI/arthro-MRI, which allows image analysis in only two dimensions, unlike CT.

The evaluator C3 obtained the highest average GT and was the only one not to show statistical efficiency according to

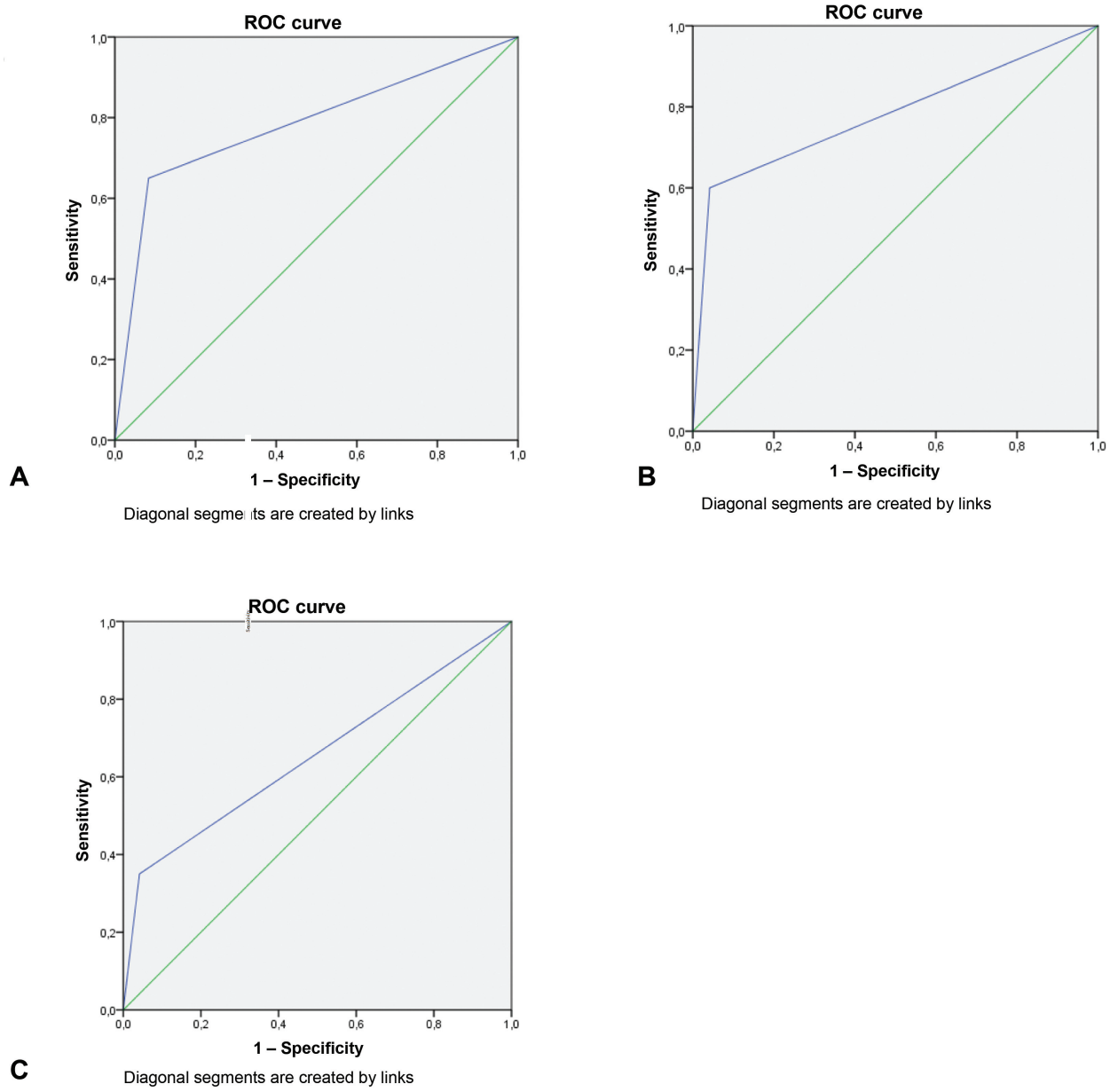


Fig. 3 Receiver operating characteristic (ROC) curves from the three surgeon examiners (C1, C2 and C3) diagnosing on-track/off-track injuries using MRI/arthro-MRI. Areas under the ROC curve and *p*-values were the following: area = 0.783, $p = 0.001$ for examiner C1; area = 0.779, $p = 0.002$ for examiner C2; and area = 0.654, $p = 0.081$ for examiner C3.

the ROC curve. Perhaps, this is why C3 presented the lowest agreement among the examiners (kappa value = 0.325).

To our knowledge, this is the first study to compare the GT method using 3D-CT and MRI/arthro-MRI. Although the available studies use different modalities to compare the GT method, our results are very close to those published in the literature.

Obviously, MRI/arthro-MRI scans for GT classification do not constitute a perfect technique. Our results show that MRI/arthro-MRI tends to yield lower HSI values. In this case, we believe that 3D-CT evaluation overestimates the results because it is unable to identify the exact attachment point of the infraspinatus tendon, used as a reference for measurement. This may explain the difficulty of MRI/arthro-MRI in identifying off-track injuries diagnosed using 3D-CT in our study. This data is highly relevant because, as previously described, these injuries must be addressed using the remplissage technique to reduce the chances of anterior shoulder dislocation recurrence.[3]

The reasons for GT classification diagnostic failure have been discussed in the literature and may be related to inter and intraobserver variations and to the lack of identification of the attachment point of the rotator cuff for HSI calculation, the medial HSL border and the GBL limit. The GT estimate (the most important component of the technique) has been reported as technically difficult and challenging.[4,5]

The limitations of this study include its cross-sectional nature, as well as the limited sampling using a non-probabilistic method, which is attributed mainly to the cost of CT and MRI/arthro-MRI scans. The evaluation performed by surgeons,

and not just radiologists, and the absence of serial evaluations of the same images constitute measurement bias.

Conclusion

The GT method performed in MRI/arthro-MRI revealed low accuracy and moderate agreement to diagnose on-track/off-track injuries when compared with 3D-CT. The medial border of the infraspinatus tendon and the medial border of the HSL must be carefully determined since the greatest data divergences referred to HSI calculation. Magnetic resonance imaging/arthro-MRI scans tend to yield lower HSI values. The greatest difficulty of the study involved the diagnosis by MRI/arthro-MRI of off-track injuries calculated by 3D-CT. Magnetic resonance imaging/arthro-MRI scans should be used cautiously by shoulder surgeons calculating the glenoid track.

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

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To Retain or Resurface the Patella in Primary Total Knee Arthroplasty: A Comparative Study

Preservar ou substituir a patela durante a artroplastia total de joelho: Estudo comparativo

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Abstract

Objective To evaluate and compare clinically and functionally patients undergoing primary total knee arthroplasty (TKA) with preservation or replacement of the patella.

Methods In a cross-sectional study, the functional results were evaluated and compared, using the Western Ontario and McMaster Universities (WOMAC) and Lequesne scores, of 158 patients undergoing primary TKA (162 knees); in 81 knees the patella was submitted to arthroplasty and in 81 the joint surface of the patella was preserved.

Results No significant differences were identified in terms of the Lequesne score ($p = 0.585$), global WOMAC score ($p = 0.169$), nor in terms of its subdivisions regarding stiffness ($p = 0.796$) and functional capacity ($p = 0.190$). There was a significant difference only in terms of the subdivision that evaluates pain in the WOMAC score, being lower in the group undergoing patellar arthroplasty ($p = 0.036$).

Conclusion In the present study, there was no difference in functional assessment in patients who underwent or not patellar replacement during primary knee arthroplasty surgery. However, individuals in whom the patella was preserved reported more pain.

Keywords
- arthroplasty, replacement, knee
- osteoarthritis, knee
- patella

Resumo

Objetivo Avaliar e comparar clínica e funcionalmente pacientes submetidos a artroplastia total primária do joelho (ATJ) com preservação ou substituição da patela.

Métodos Em um estudo transversal, foram avaliados e comparados os resultados funcionais, usando escores de Western Ontario and McMaster Universities (WOMAC, na sigla em inglês) e Lequesne, de 158 pacientes submetidos a artroplastia total primária o

Study developed at the Orthopedics and Traumatology Department, Hospital São Vicente de Paulo, Passo Fundo, RS, Brazil.

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joelho (162 joelhos), sendo que em 81 joelhos a patela foi submetida a artroplastia e em 81 a superfície articular da patela foi preservada.

Resultados Não foram identificadas diferenças significativas quanto ao escore de Lequesne ($p = 0,585$), escore global de WOMAC ($p = 0,169$), nem quanto às subdivisões deste quanto a rigidez ($p = 0,796$) e a capacidade funcional ($p= 0,190$). Evidenciou-se diferença significativa apenas quanto à subdivisão que avalia a dor no escore de WOMAC, sendo menor no grupo submetido a artroplastia patelar ($p = 0,036$).

Conclusão No presente estudo, não houve diferença na avaliação funcional em pacientes submetidos a substituição ou não da patela durante a cirurgia de artroplastia primária do joelho. Entretanto, os indivíduos nos quais a patela foi preservada relataram mais dor.

Palavras-chave
- artroplastia do joelho
- osteoartrite do joelho
- patella

Introduction

Total knee arthroplasty (TKA) is a surgical procedure with proven clinical efficacy[1–4] resulting in a substantial functional and quality of life improvement in patients with gonarthrosis.[5,6]

The first modern total knee prosthesis (TKP) was developed by a Canadian orthopedist, Frank Guston, in 1960; subsequently, it was improved by John Insall in the 1970s, and the patellar component was introduced by Townley and Insall in 1972.[7] The introduction of a patellar component in TKA reduced the occurrence of anterior knee pain, but resulted in new complications, such as component failure, instability, patellar fracture, extensor tendon rupture, patellar avascular necrosis, and other soft tissue injuries.[8] Although such complications were attributed to a poor surgical technique and inadequate implant positioning, the fear of sustaining them hindered the routine adoption of patellar replacement.[8]

Over the years, surgical techniques and implants have improved, significantly reducing the occurrence of complications in patellar arthroplasties, and dividing surgeons regarding their adopted routine procedure.[9] Some authors suggest routine patellar replacement since it improves pain, functional scores, and patient satisfaction, with a lower rate of reintervention due to pain persistence.[10] Others defend patellar retention as routine due to the risk of complications and the potential advantage of patellar bone stock maintenance with similar satisfaction and functional rates.[11–13] Additionally, some still recommend patellar replacement in selected cases, believing that its routine performance is not supported by the literature.[14]

The present study aims to functionally evaluate subjects submitted to primary TKA with patellar joint resurfacing and to compare them with patients in whom the patellar joint surface was retained.

Materials and Methods

A total of 191 patients who underwent primary TKA from January 2012 to December 2014 for primary gonarthrosis were initially selected from our database to participate in the study. All of them had at least 5 years of follow-up, received the same implant (Advance Medial-Pivot Knee System, Microport Orthopaedics, Arlington, TN, USA) and were operated on by two experienced surgeons from an orthopedic reference hospital. After medical records analysis, 33 patients were excluded; 7 were deceased, 2 were unable to participate due to comorbidities not related to TKA, and 24 who were lost to follow-up. No patient met the exclusion criteria regarding complications with major functional impairment. Finally, 158 patients were included in the study. Four patients underwent bilateral TKA in different years: two subjects were submitted to a patellar arthroplasty in one knee, while the other patella was preserved; one patient had both patellae retained; and one patient underwent a bilateral arthroplasty. In these cases, both knees were assessed separately. The final sample consisted of 162 knees, including 81 knees with patellar resurfacing and 81 knees with patellar joint surface retention.

Knees were divided into two groups: those with patellar resurfacing during TKA and those with patellar joint surface retention. Patellar resurfacing was selectively indicated in case of moderate to severe patellofemoral arthrosis detected at a gross assessment during surgery. Only patellae with articular surfaces in good conditions were retained.

All patients were contacted by telephone by one of the authors (de Campos Júnior L. R.) and answered the Lequesne[15] and the Western Ontario and McMaster Universities (WOMAC) and its subdivisions questionnaires.[16] During contact, subjects were invited to participate in the study and, if they agreed, the call was resumed.

Patients who agreed to participate in the study signed an Informed Consent Form (ICF). The study was previously approved by the Research Ethics Committee of the institution.

Statistical Analysis

Quantitative variables were described as mean and standard deviation or median and interquartile range values. Categorical variables were described as absolute and relative frequencies. Mean values were compared using the t-Student test. In case of asymmetry, the Mann-Whitney test was applied. The Pearson chi-squared test was used to compare proportions. The level of significance was set at 5% ($p < 0.05$) and the

analyzes were performed with IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA).

Results

A total of 46 patients were male and 112 were female; the study groups were homogeneous both in gender distribution and in number of knees (►**Table 1**). The ages of the subjects at the time of surgery, questionnaires application, and the interval between them were also homogeneous (►**Table 2**).

The median Lequesne score was 3.5 points for the group with patellar retention and 2.5 points for the group with patellar resurfacing; this difference was not sufficient to generate statistical significance (►**Table 3**).

In the WOMAC score, in all three evaluated areas (pain, stiffness, and difficulty to perform daily/physical activities) and the global score, the only significant difference was observed in pain, with a higher score in the group with patellar retention (►**Table 3** and ►**Figure 1**). There was no significant difference in joint stiffness scores between groups (►**Table 3**). Although there was no significant difference regarding the difficulty in daily/physical activities score ($p = 0.190$) and the global score ($p = 0.169$), median, 25th percentile and 75th percentile values were slightly higher among patients with patellar retention (►**Table 3** and ►**Figures 2** and **3**). Since scores were expressed as natural numbers, some median values were equal to zero because most subjects had the same score in a given subdomain.

Three patients presented complications during the study. Two subjects had surgical wound dehiscence, including one submitted to patellar resurfacing and another with patellar retention. Both underwent surgical debridement and antibiotic therapy with good outcomes. The third patient had an early periprosthetic infection and underwent a new surgical procedure for polyethylene change, washing and debridement, in addition to antibiotic therapy. One patient excluded due to loss at follow-up had a late knee infection and underwent a limb amputation.

Table 1 Knee distribution per patellar retention or resurfacing and gender

	Male	Female	Total
Patellar retention	23	58	81
Patellar resurfacing	24	57	81
	47	115	162

Table 2 Sample characterization per age and follow-up time

Variables	With no patellar resurfacing*	With patellar resurfacing*	*p*-value**
Age at surgery (years old)	71.9 ± 9.5	71.3 ± 6.3	0.614
Age at data collection (years old)	77.9 ± 9.8	77.2 ± 6.4	0.595
Follow-up (years)	5.9 ± 0.7	5.9 ± 0.8	0.918

*Mean ± standard deviation.
**Statistically significant difference considering $p < 0.05$.

Table 3 Scores evaluation per groups

Scores	With no patellar resurfacing*	With patellar resurfacing*	*p*-value**
	median (P25-P75)	median (P25-P75)	
Lequesne WOMAC	3.5 (0.5–7)	2.5 (0.5–7)	0.585
Pain	0 (0–2)	0 (0–1)	0.036**
Rigidity	0 (0–0)	0 (0–0)	0.796
Physical Activity	7 (1–12.5)	5 (0–9)	0.190
Total	8 (2–15)	5 (0.5–11.5)	0.169

Abbreviations: P25, 25th percentile value; P75, 75th percentile value; WOMAC, Western Ontario and McMaster Universities.
*Mean ± standard deviation.
**Statistically significant difference considering $p < 0.05$.

Discussion

Over the years, several studies have evaluated the difference in outcomes between the performance or not of patellar arthroplasty. Recently, Ha et al.[17] performed the first prospective randomized study in which patients had one knee submitted to TKA with patellar resurfacing and the other knee had the patella retained at the same surgical time and using the same implant model. After 5 years of follow-up, 60 patients (120 knees) were reevaluated. The authors found out that knees submitted to patellar resurfacing had less anterior pain ($p < 0.001$) and a lower incidence of patellar crepitation ($p < 0.001$). Although both knees showed functional improvement, it was significantly higher in those submitted to patellar resurfacing ($p < 0.001$). Neither knee presented complications nor required surgical revision. In a satisfaction assessment, 47% of the patients preferred the knee submitted to patellar resurfacing, while 46% were indifferent.[17]

Migliorini et al.[18] performed a meta-analysis of 31 articles, totaling 4,132 knees, while Longo et al.[19] carried out another meta-analysis with 35 articles and a total of 5,535 knees. Both found less anterior knee pain in patients who underwent patellar resurfacing ($p = 0.02$ and $p = 0.00001$, respectively); this same group also presented lower revision rates ($p < 0.0001$ and $p = 0.00001$, respectively). Only the first set of authors observed a statistically significant functional difference, with better function in patients undergoing patellar resurfacing ($p = 0.009$).

Better pain outcomes in patients undergoing patellar resurfacing was a common finding between our study and the literature; we believe that this is a well-defined outcome. Although we did not show any significant difference

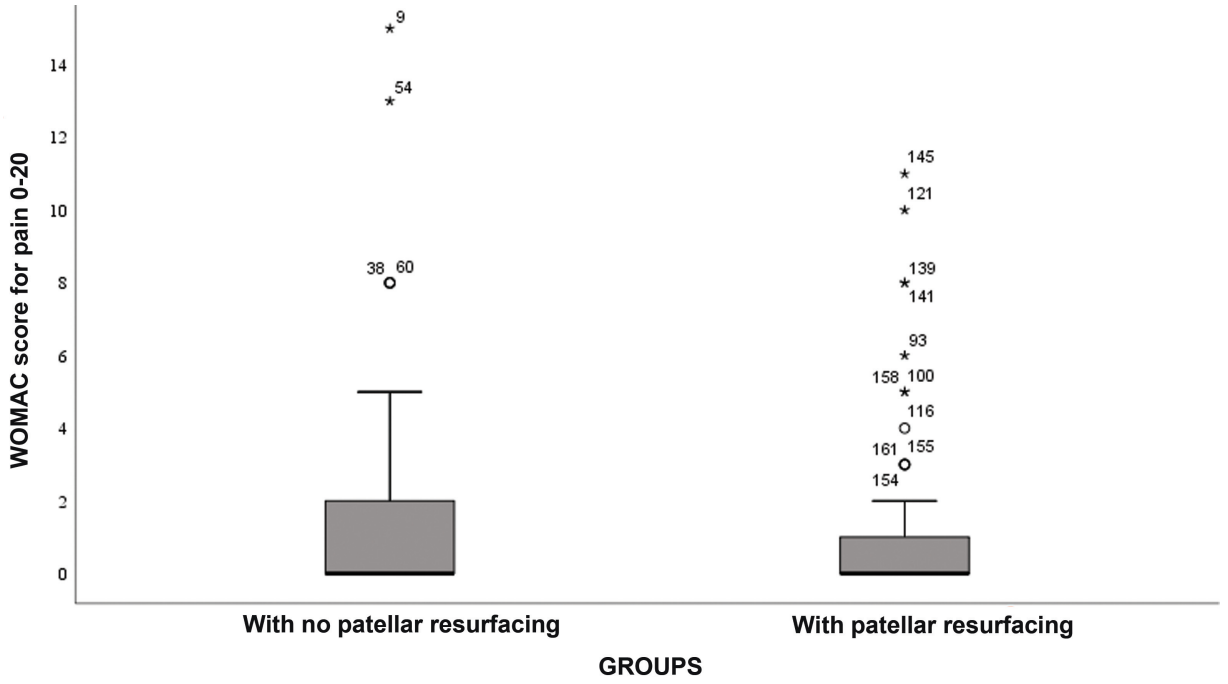


Fig. 1 Western Ontario and McMaster Universities (WOMAC) score for pain.

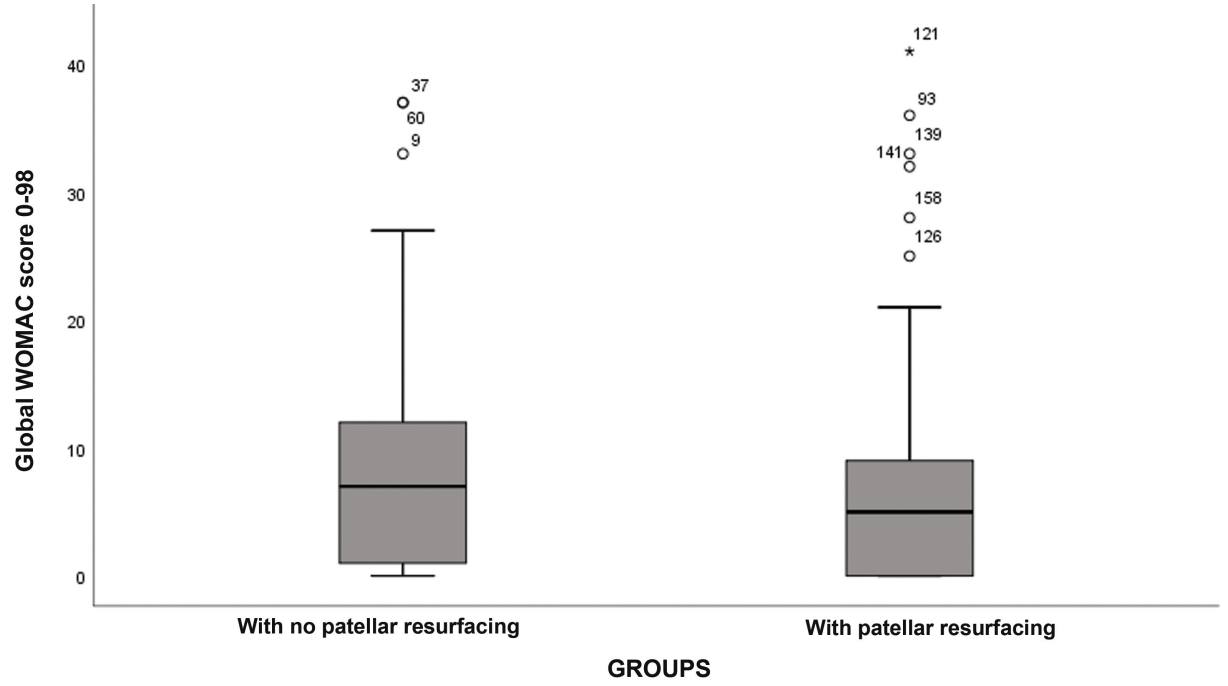


Fig. 2 Western Ontario and McMaster Universities (WOMAC) score for difficulty in daily living activities.

regarding the global WOMAC score and its subdomain for difficulty in daily living/physical activities, higher median values, relatively higher 25th and 75th percentiles and a considerably low *p*-value in the patellar retention group lead us to believe that the difference could become significant if the study population was larger. This hypothesis seems plausible, given the significance evidenced by Migliorini et al.[18] and Ha et al.,[17] and the consistent findings of Longo et al.,[19] who believe there is a trend for better function after patellar resurfacing. Further studies are certainly required for functional comparison between these groups of patients to generate solid evidence.

The three studies showed lower revision rates in the patellar resurfacing group.[17–19] Migliorini et al.[18] believe that this is related to individual dissatisfaction with pain persistence after patellar retention, leading surgeons to reoperate and perform a resurfacing procedure.[18] However, we tried to evaluate only the functional outcomes from two scenarios in ideal situations, excluding patients with complications leading to great functional impairment. We

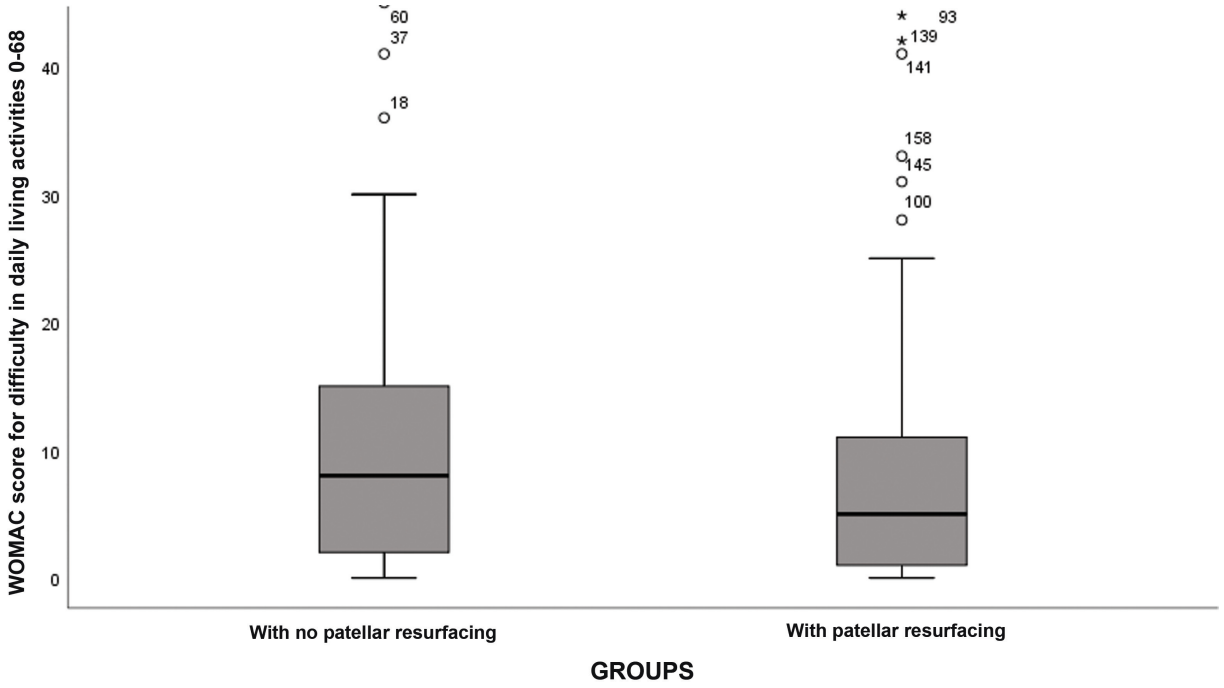


Fig. 3 Global Western Ontario and McMaster Universities (WOMAC) score.

believe that these complications and their analysis would affect group outcomes in a nonrepresentative way. We emphasize that despite this definition, only one patient who was excluded due to loss at follow-up had a serious complication which was not caused by patellar resurfacing. We believe that outcomes related to the incidence of revision must not be considered because there is a greater tendency to indicate revision in symptomatic patients with retained patellae. There are some questionable points in the aforementioned meta-analyzes: lack of description of the surgeons' skills and of the implant model in most studies, heterogeneity among studies,[19] use of different implants and inclusion of studies with 2 years of follow-up.[18]

In a cost-effectiveness study, Zmistowski et al.[20] reviewed 14 prospective randomized studies investigating different outcomes from surgeons who chose selective or nonselective patellar arthroplasty. After nonselective patellar arthroplasty, the persistence of anterior knee pain was 20.9% in the patellar retention group and 13.2% in the patellar resurfacing group ($p < 0.001$), with reoperation rates for patellar conditions of 3.7 and 1.6% ($p < 0.01$), respectively. In studies excluding patellae with arthrosis, the incidence of anterior pain was equivalent between groups, that is, 3.1% in the patellar retention group and 3.2% in the patellar resurfacing group ($p = 0.97$), while the rate of reoperation due to patellar pain persistence dropped to 1.2 and 0% ($p = 0.06$), respectively. After assessing the outcomes, complications and related costs, the study concluded that the routine performance of patella resurfacing does not have the best cost-benefit relationship and that patellar retention is better because it avoids revisions due to persistent pain and minimizes risks inherent to patellar arthroplasty.[20]

Since our service performs selective patellar arthroplasty procedures, we believe that, hypothetically, we exposed the patellar retention group to the best possible perspective in terms of clinical outcomes – after all, by preserving only patellae in good macroscopic conditions, we can state that the higher WOMAC scores for pain in the patellar retention group did not result from moderate or advanced arthrosis. However, even with selective arthroplasty, the difference between groups was significant, in contrast to Zmistowski et al.[20] We believe that the selection may also have been a reason for not identifying a significant difference between groups regarding global WOMAC and difficulty in daily living activities scores due to the probable reduction of the real difference that could have occurred in the absence of selection.

We recognize limitations in our study, such as sample size, lack of assessment of quality of life and mental health scores, and the application of questionnaires over the telephone. It is worth mentioning that all patients received the same prosthesis model and that the procedures were performed by the same group of experienced surgeons. Since we used scores validated for the Brazilian population,[15,16] the clinical and functional evaluation were based only on subjective criteria reported by patients, preventing objective data appraisal by an evaluator. We believe that this results in reliable outcomes – as Epstein et al.[21] states, symptoms referred by the patient are always the most important data. Instruments based on patients' report can provide data that are not achieved by physiological assessments and that may have greater reproducibility on quality of life than clinical, biochemical, and physiological indices.[21]

Conclusion

The present study revealed no significant difference between the group that underwent patellar resurfacing and the group with patellar retention in terms of Lequesne score, global WOMAC score and WOMAC scores for difficulty in daily living/physical activity and stiffness scores. There was a significant difference only in WOMAC score for pain, with a better outcome in the group undergoing patellar resurfacing even in the presence of selective arthroplasty.

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

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Portuguese Translation and Cross-Cultural Adaption of the Banff Patella Instability Instrument*

Tradução e adaptação transcultural para a língua portuguesa do Questionário Banff para Instabilidade Patelar

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Abstract

Objective To translate into Brazilian Portuguese and to cross-culturally adapt the Banff Questionnaire for Patellar Instability.

Methods The translation and cross-cultural adaptation followed the linguistic validation process proposed by international guidelines, which consists of six steps: translation, synthesis, back-translation, review by an expert committee, pretest, and final report presentation to the authors of the original questionnaire. Literate patients with recurrent patellar instability, older than 12 years of age, who signed the informed consent form or had it signed by a legal guardian were included in the study. Patients with neurological or systemic comorbidities were excluded from the study.

Results A total of 62 patients (18 males and 44 females) were included in the study. Discrepancies observed during the processes of translation and harmonization of the back-translations were modified with no need for reformulation. No pretest version replacements were required.

Keywords
- patellar dislocation
- quality of life
- surveys and questionnaires
- transcultural adaptation
- translation

* *Study developed at the Orthopedics and Traumatology Department, Escola Paulista de Medicina, Universidade Federal de São Paulo, São Paulo, SP, Brazil.*

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Conclusion The Banff Questionnaire for Patellar Instability has been successfully translated and cross-culturally adapted into Brazilian Portuguese, so it can be used to assess patients with patellar instability who speak this language.

Resumo

Objetivo Realizar a tradução para a língua portuguesa falada no Brasil e a adaptação transcultural do Questionário Banff para Instabilidade Patelar.

Métodos A tradução e adaptação transcultural seguiu o processo de validação linguístico proposto por diretrizes internacionais, que consiste em seis etapas: tradução, síntese, retrotradução, revisão pelo comitê de especialistas, pré-teste, e apresentação do relatório final aos autores do questionário original. Foram incluídos no estudo pacientes alfabetizados, com diagnóstico de instabilidade patelar recorrente, com mais de 12 anos de idade, que assinaram ou tiveram o termo de consentimento livre e esclarecido assinado por um responsável legal. Foram excluídos do estudo pacientes portadores de comorbidades neurológicas ou sistêmicas.

Resultados Um total de 62 pacientes (18 homens e 44 mulheres) foram incluídos no estudo. Durante os processos de tradução e harmonização das retrotraduções, foram observadas discrepâncias, que foram modificadas sem necessidade de reformulação. Não foram necessárias substituições na versão do pré-teste.

Conclusão O Questionário Banff para Instabilidade Patelar foi traduzido e adaptado transculturalmente para a língua portuguesa falada no Brasil com sucesso, podendo ser utilizado para a avaliação de pacientes portadores de instabilidade patelar falantes desta língua.

Palavras-chave
- luxação patelar
- qualidade de vida
- inquéritos e questionários
- adaptação transcultural
- tradução

Introduction

Patellar instability is an important knee condition not only because of its incidence – in the United States, annual estimates are 29/100 thousand people in the general population,[1] reaching 77/100 thousand people in some risk groups –[2] but also for recurring in most patients,[1] in rates ranging from 17% to 70% in selected groups.[3,4] In addition, it essentially affects the youngest, most active members of society, with a peak incidence between the ages of 15 to 19 years,[3] resulting in an economic impact regardless of the proposed treatment method.[5]

Although common during sports activities,[4] atraumatic mechanisms are reported in individuals with predisposing conditions.[6] Patellar instability is sometimes accompanied by limitations regarding recreational or sports activities, and reduced quality of life.[7,8] Since patellar instability is a multifactorial condition,[1–9] it can be managed with several therapeutic options according to the patient's anatomical features and individual presentation.[10]

The assessment of the therapeutic outcomes using clinical and radiographic criteria alone may underestimate the impact of the disease on the daily life of the patient. The health status should take into consideration the influence of the clinical condition in different daily life, work, recreation, sports and social scenarios.[11,12] The assessment instruments to address the therapeutic effectiveness and impact on the quality of life have been designed to broaden our understanding regarding health care outcomes.[13]

Questionnaires such as the Kujala[14] and International Knee Documentation Committee Subjective Knee Evaluation Form (IDKC)[15] are already established in the literature as tools for this kind of clinical application. While the IKDC assesses a wide variety of knee conditions, the Kujala questionnaire is more specific to patellofemoral joint disorders, since it specifically documents patellofemoral pain. Even so, the daily subjective limitations experienced by these patients might not be fully understood, hindering the evaluation of the clinical interventions.[16,17]

Hiemstra et al.[18] developed the Banff Questionnaire for Patellar Instability[7,18] to assesses the quality of life of these patients in terms of symptoms and functional, social, and economic activities. The present study aimed to translate and cross-culturally adapt the Banff Questionnaire into Brazilian Portuguese.

Methodology

The present study was initiated after approval by the Ethics in Research Committee under number CAAE 70103717.3.0000.5505. Data was collected from the Knee Group outpatient clinic of our institution. Literate patients with recurrent patellar instability, older than 12 years of age, who signed the informed consent form or had it signed by a legal guardian were included in the present study. Patients with neurological or systemic comorbidities were excluded from the study.

Sample size was calculated based on the number of variables analyzed, as recommended in the literature, and set at a minimum of 62 patients, that is, twice the number of questions contained in the Banff instrument.[19]

In total, 62 patients with recurrent patellar instability participated in the present study. The diagnosis was established by a history of at least two episodes of patellar dislocation observed by the patient or third parties, along with the findings of the clinical examination and imaging tests, as described by Brattstroem.[20]

The translation and cross-cultural adaptation of the Banff Questionnaire for Patellar Instability into Brazilian Portuguese followed the internationally accepted linguistic validation process described by Guillemin et al.[21] and modified by Beaton et al.[22,23] Linguistic validation aims to generate a translation that is both equivalent to the original text and comprehensible by the target population. The method used in the present study is described below (►**Figure 1**).

1. Translation: the translation started after obtaining the authorization to use the questionnaire by the authors of the original article, the review of the questionnaire items and organization of the material and the data collection flow, that is, the "Preparation" process. The 32 questions, instructions, answer options and other items from the original questionnaire in English were independently translated into Portuguese by 2 Brazilian orthopedic surgeons fluent in both languages, resulting in 2 translated texts (Banff VT1 and Banff VT2).
2. Synthesis: both versions were compared by an expert committee, resulting in "Banff Version T12" (Banff VT12).
3. Back translation: the Banff VT12" was back translated by two native English speakers who were also fluent in Portuguese, and blinded as to the original questionnaire and with no knowledge of the subject. The aim of this stage was to find conceptual translation errors and gross inconsistencies from the previous steps and to generate two "back-translated versions" (Banff VRT1 and Banff VRT2).
4. Expert committee review: a new meeting including the third and fourth translators and the same expert committee was held to search for inconsistencies and check correspondences between the back-translated texts (Banff VRT1 and Banff VRT2), the initial translation (Banff VT12), and the original questionnaire. The harmonization of discrepancies, seeking semantic, idiomatic, experiential, and conceptual equivalence between the texts, resulted in a "Banff Brazilian Prefinal Version" (in Portuguese, "Banff Versão Brasileira Pré-Final", VBPF). This text consolidated all information produced so far in an easily understandable instrument used at the pretest with the sample from the study.
5. Pretest: this step was carried out at the Knee Group's outpatient clinic at Hospital São Paulo, Orthopedics and Traumatology Department, Escola Paulista de Medicina, Universidade Federal de São Paulo (UNIFESP), using the "Banff VBPF" and a probing technique:[21] after the application of the questionnaire, each patient was individually surveyed for clarity, understanding and acceptability of each item from the instrument. Doubts or suggestions would require an item reformulation to be discussed with the committee; otherwise, we would proceed to the last step.
6. Presentation of the final version to the authors of the original questionnaire: reports prepared during all steps of the process were submitted along with discrepancies and the committee consensus on each Banff VBPF item. The main author of the original questionnaire approved this version with no suggestions or changes. The Banff VBPF was then renamed "Banff Brazilian Final Version" (in Portuguese, "Banff Versão Brasileira Final", VBF).

Results

The pretest occurred from June 2018 to August 2019 at the aforementioned Knee Group's outpatient clinic. The study included a total of 62 patients with a mean age of 29.2 years (standard deviation: 11.6 years), ranging from 12 to 57 years old. Most patients (44 subjects; 70.69%) were female, whereas 18 (29%) were male. The Banff scores are summarized in ►**Table 1**.

During the reconciliation of VT1 and VT2, the expert committee found a total of 22 discrepant items in 32 questions, 19 discrepant items in 32 answers, and 18 discrepant items in 21 information, title or instruction sentences from the original questionnaire. Emphasizing the need to maintain the equivalence, as proposed by Guillemin et al.,[21] each item was individually analyzed by the committee in an attempt to reach a consensus at the synthesis stage and maintain the features from the original version.

The VT12 questionnaire was back translated, resulting in the two English texts shown in ►**Figure 1**, called VRT1 and VRT2. During the harmonization, the semantic, idiomatic, experiential, and conceptual cross-cultural equivalences[22] of each item regarding its original version were analyzed; no reformulation by the committee was required when the concordance index among its 5 members was higher than 80%.[24]

Only one analysis was required by the expert committee. The back-translated versions resulted in 26 discrepant items in 32 questions, 29 discrepant items in 32 answers, and 20 discrepant items in 21 information, title, or instruction sentences. All discrepancies were resolved, resulting in the VBPF. The committee pointed out the need for some adaptations in the VBPF to maintain both the equivalence to the original version and the instrument comprehension by the Brazilian population with no change in the analyzed measures. A summary of this process is exemplified in ►**Table 2**.

There was no record of questions, answers or other items which were not understood by the evaluated patients regarding the linguistic validation during the pretest. Therefore, the VBPF was submitted, with no need for reformulation, to the author of the original questionnaire together with a report of the adaptations made throughout the process. The author of the original questionnaire approved this version with no suggested modifications; as such, the VBF became the Banff Questionnaire for Patellar Instability – Brazilian Version, available in ►**Annex 1**.

Discussion

There is an increased concern in the literature not only to improve patient satisfaction but to develop outcome measures for a specific population or clinical condition.[25] Since patellar instability is a multifactorial condition,[1–10,26–28] it

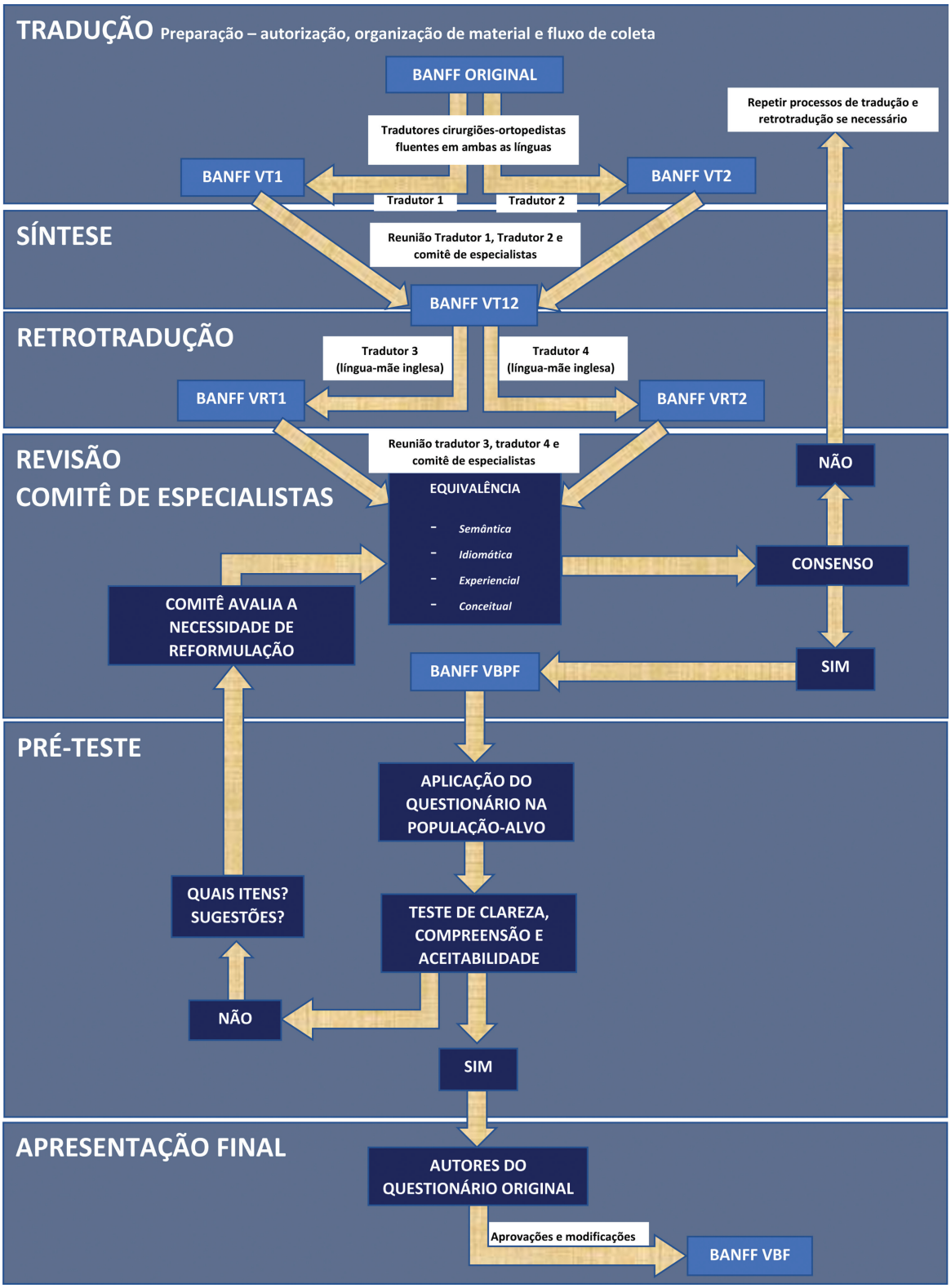


Fig. 1 Flowchart of the linguistic validation of the Brazilian Portuguese version of the Banff questionnaire. Abbreviations: VT1, translated version 1; VT2, translated version 2; VT12, translated version 12; VRT1, back-translated version 1; VRT2, back-translated version 2; VBPF, Brazilian Portuguese prefinal version; VBF, Brazilian Portuguese final version.

requires appropriate tools to compare different treatment strategies. ►**Figure 2** summarizes the instruments for the assessment of patellar instability as reported by Hiemstra et al.[25]

These data reveal that some questionnaires used for many years to assess patellofemoral joint disorders focus on characterizing other knee conditions, often emphasizing items not necessarily observed in this type of injury. In total, 60 of

Table 1 Pretest Banff Score

Banff Score	Mean	Standard deviation	Minimum	Maximum	95% confidence interval
General	30.33	15.7	4.68	86.5	26.71–33.96
Male gender	33.09	19.04			24.65–41.54
Female gender	29.19	14.21			25.27–33.11

Table 2 Cross-cultural adaptation of selected Banff Patella Instability Instrument (BPII) items

Question	Original Text (BPII)	Translation (VT12)	Changes for VBPF	Comment
1a	"...severity of the 'giving way' episodes?"	"...episódios em que a rótula (patela) sai do lugar? (Gravidade)"	"...episódios em que a rótula sai do lugar? Qual a gravidade dos episódios de deslocamento?"	Expression with no idiomatic equivalent in Portuguese. To keep it understandable to the Brazilian population and preserve its conceptual equivalence, the term "dislocation" was avoided, using "kneecap out of place" ("rótula sai do lugar") and "displacement" ("deslocamento")
3	"...stiffness"	"joelho duro"	"joelho duro"	Although the committee believed that the most appropriate semantic equivalence would be "rigidez" (Portuguese for "stiffness"), the expression "joelho duro" ("hard knee") had the same conceptual equivalence but greater understanding. So, it was kept in the VBPF
9	"...sudden twisting and pivoting movements or changes in direction"	"...movimentos de giro/rotação repentinos ou movimentos de mudanças de direção repentinos"	"...movimentos rotacionais ou de mudanças bruscas de direção"	Attempt to simplify the terms from translation VT12, maintaining its conceptual equivalence
14	"...knee 'giving way'"	"...joelho 'sair do lugar'"	"...rótula (patela) sair do lugar"	Expression with no idiomatic equivalence in Portuguese. "Joelho" ("knee") from translation VT12 was replaced by "rótula (patela)" ("patella") because, according to the committee, the translated term suggested the idea of the entire knee dislocating, instead of the patella alone
28	"...to psychologically 'come to grips'?"	"...superar psicologicamente"	"...superar psicologicamente"	Expression with no idiomatic equivalence in Portuguese, translated into an expression of similar conceptual equivalence, which was kept in the VBPF

Abbreviations, BPII, Banff Patella Instability Instrument; VT12, translated version 12; VBPF, Brazilian prefinal version.

the 100 points of the Lysholm score, for instance, which was translated and validated for the Portuguese language,[29] measure pain and instability, making it unsuitable for an estimate of anterior pain.[14] Although widely used in patients with a previous history of patellar dislocation, the Kujala questionnaire, "Scoring of Patellofemoral Disorders", also translated and culturally adapted into Portuguese,[30] has only 1 in 13 questions directed specifically at patellar instability.

The Banff Patella Instability Instrument (BPII) was first published in Canada, in 2013, by Hiemstra et al.,[18] in an attempt to fill the void[31] of the lack of a specific questionnaire to assess patellar instability in the templates of "Patient-Reported Outcome Measures". The 32 questions belonging to 5 different domains were listed by a modified Ebel method, performed by an international group of experts, to identify which specific outcome measures were most relevant for patellar instability.[7]

Since the weight attributed to each answer is similar among different items, the final score consists of the average value of all answers from all five domains, and a higher final score reflects a better quality of life.[25] As such, the Banff

Instrumentos*	Lysholm	Kujala	IKDC modificado	Pedi-IKDC	KOOS	KOOS-Child	NPI
Ano de publicação	1982	1993	2001	2011	1998	2012	2012
Construto avaliado	Instabilidade ligamentar	Dor anterior no joelho	Lesões no joelho	Lesões no joelho	Lesões no joelho; inclui osteoartrite	Lesões no joelho	Instabilidade patelar
População-alvo	Acima de 12 anos e adultos	Adultos	Adultos	10-18 anos	16 anos, adultos e idosos	7-18 anos	Adultos
Número de itens	8	13	18	13	42	39	19
Modelo de resposta	Múltipla escolha	Múltipla escolha	Escala Likert	Escala Likert	Escala Likert	Escala Likert	Escala Likert
Pontuação	Variável de acordo com o item medido	Variável de acordo com o item medido	Itens com peso estabelecido	Itens com peso estabelecido	Domínios avaliados separadamente	Itens com peso estabelecido; domínios avaliados separadamente	Itens com peso estabelecido
Faixa de pontuação	0-100	0-100	0-100	0-100	0-100 para cada domínio	0-100	0-100
Tempo para completar	3 min	4 min	10 min	10 min	10 min	10-20 min	4 min
Idioma original	Sueco e inglês	Finlandês e inglês	Inglês	Inglês	Inglês e sueco	Inglês e sueco	Inglês
Traduções disponíveis	> 5	> 10	> 10	Dinamarquês	> 50	> 5	Alemão

Fig. 2 Instruments evaluating patellofemoral disorders, except for the Banff questionnaire. Abbreviations: IKDC, International Knee Documentation Committee; KOOS, Knee Injury and Osteoarthritis Outcome Score; NPI, Norwich Patellar Instability.

questionnaire can assess the quality of life of patients with patellar instability in a more comprehensive way.[7]

Even though the Norwich Patella Instability Score[32] was introduced because of a similar demand and context to the BPII to analyze outcome measures in patients with patellar instability, it focuses on characterizing physical symptoms generated by the clinical presentation. The weight attributed to its 19 items obeys a complex algorithm: the maximum score for items referring to activities that most commonly generate instability symptoms is lower, whereas activities that do not generate these same symptoms for most patients, except those with more severe instabilities, receive more points. Thus, a high final score indicates greater degrees of instability, and, therefore, worse function.

Only a fraction of the patellar instability questionnaires available in the literature was validated at any of the nine possible spheres as recommended by the Consensus-based Standards for the Selection of Health Status Measurement Instruments (COSMIN).[33,34] The BPII was analyzed per several psychometric properties, including content validity, internal consistency and reliability,[18] and construct and criterion validity.[7]

In 2016, the BPII underwent a factor analysis and item reduction,[34] resulting in the BPII 2.0, with 23 items divided into the same 5 domains as its first version. This reduction was partly due to the fact that many patients did not answer all the questions; in addition, it constitutes an attempt to adapt these questions to the pediatric population. The author of the original questionnaire reported, via e-mail, that the BPII 2.0 is associated with a smaller number of unanswered questions.

Several psychometric properties of the BPII 2.0 were tested and added to its validation process, including a multicenter study of the validation of the BPII 2.0 to the Pedi-IKDC,[35] with moderate correlation, and a cross-cultural validation for the German language targeting the German, Austrian and Swiss populations.[36] In addition, the BPII 2.0 is being validated into Dutch, Spanish, Finnish and French.[25]

Even after establishing a consensus, the committee had doubts in some questions from the final Portuguese translation regarding the acceptability of certain grammatical constructions (such as, "quanto medo", regarding the intensity of fear) by the target population. Nevertheless, all questions were understood by all participants during the pretest, with no suggestions of changes. Another limitation of the present study was to carry out only the translation and cross-cultural adaptation of the Banff Questionnaire for Patellar Instability. Since the validation is a complex, iterative process, further studies are required to increase the representative sample of the Brazilian population, and our group is working on that.

Conclusion

The BPII has been successfully translated and cross-culturally adapted into Brazilian Portuguese, enabling its application to assess the quality of life of patients with patellar instability in Brazil.

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Conflict of Interests
The authors have no conflict of interests to declare.
Dr. Galvão reports a pending patent on "Questionário Banff para Instabilidade Patelar Versão Brasileira".

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QUESTIONÁRIO BANFF PARA INSTABILIDADE PATELAR VERSÃO BRASILEIRA

Escore de qualidade de vida para pacientes com instabilidade patelar

Nome do paciente (nome completo)_____

Data (dia/mês/ano)**:**_____ **Sexo**:_____

Telefone para contato:_____ **E-mail para contato**_____

Qual o joelho responsável pelas suas queixas?

[ ] Direito
[ ] Esquerdo
[ ] Ambos

Esta visita sua é:

[ ] Primeira consulta
[ ] Dia da cirurgia
[ ] Pós-operatório (3 meses)
[ ] Pós-operatório (6 meses)
[ ] Pós-operatório (1 ano)
[ ] Pós-operatório (2 anos)
[ ] Outro:_____

INSTRUÇÕES

Responda as questões abaixo considerando os últimos três meses, a respeito do estado atual, função, atividades do dia-a-dia e sensação de insegurança que o seu joelho proporciona por conta da instabilidade patelar (rótula que sai do lugar). Para cada uma das questões abaixo haverá uma linha contínua de 0 a 100. Por favor, indique com um "risco" ("/") sobre o ponto que mais se aproxima de sua resposta para cada uma das situações solicitadas.

Este é um exemplo:

Este é um bom questionário?

0 _____ **100**

Inútil **Excelente**

Caso você posicione o "/" **no meio da linha**, isto indica que o questionário é de qualidade **moderada**, pois a resposta se encontra no meio do caminho entre "Inútil" e "Excelente". Já se a sua resposta representar o extremo de cada situação, é importante você posicionar o "/"no início ("Inútil") ou no final da linha ("Excelente"), refletindo a sua condição.

Annex 1 Banff Questionnaire for Patellar Instability, Brazilian Version.

SEÇÃO A: SINTOMAS E QUEIXAS FÍSICAS

As primeiras quatro questões estão relacionadas a **SINTOMAS E QUEIXAS FÍSICAS**

1) A respeito da função geral do seu joelho, quão problemáticos são os episódios em que a rótula sai do lugar?

Marque o "/" à direita do final da linha caso você não esteja apresentando nenhum episódio de deslocamento da rótula neste período. Esta pergunta tem duas partes: **(1.a) e (1.b)**

1.a) Qual a gravidade dos episódios de deslocamento?

0 _____ ***100***

Episódios muito graves — ***Episódios pouco graves***

1.b) Qual a frequência dos episódios de deslocamento?

0 _____ ***100***

Sempre acontecem — ***Nunca acontecem***

2) Quanto de desconforto ou dor você sente no joelho durante uma atividade prolongada (por exemplo, acima de 30 minutos)?

0 _____ ***100***

Dor intensa — ***Sem dor***

3) Sobre a função do seu joelho envolvido, quanto você se incomoda com a perda de movimento do joelho ou com ficar com o "joelho duro"?

0 _____ ***100***

Muito incomodado — ***Nada incomodado***

4) Considerando a função do seu joelho e sua relação com a força muscular: quão fraco é o seu joelho?

0 _____ ***100***

Muito fraco — ***Sem fraqueza***

Annex 1 (continued).

SEÇÃO B: QUEIXAS RELACIONADAS AO TRABALHO

As questões abaixo se relacionam à sua profissão ou vocação e se referem à sua funcionalidade no trabalho e qualquer queixa relacionada ao trabalho. Caso você seja um estudante em tempo integral ou trabalhe no seu domicílio, considere esta atividade como a sua profissão. Também pode ser considerado nesta seção qualquer trabalho temporário extra. Leve em conta os últimos três meses para responder as perguntas abaixo.

Se você é **DESEMPREGADO** por outras razões que **NÃO RELACIONADAS AO SEU JOELHO**, marque um "X" nesta linha:_____

5) Quanto de dificuldade você encontra, por conta do seu joelho, para realizar movimentos de mudança de direção ou de rotação do corpo sobre o joelho? (Marque o "/" no início da linha à esquerda se você se encontra incapaz de trabalhar devido ao seu joelho)

0*_____*100

Completamente incapaz ***Não me gera limitações***

6) Quanto de dificuldade você encontra, por conta do seu joelho, para realizar movimentos de agachamento no seu trabalho? (Marque o "/" no início da linha à esquerda se você se encontra incapaz de trabalhar devido ao seu joelho)

0*_____*100

Muita dificuldade ***Sem dificuldade***

7) Quanto você se preocupa em perder dias de trabalho devido a problemas ou novas lesões no joelho? (Marque o "/" no início da linha à esquerda se você se encontra incapaz de trabalhar devido ao seu joelho)

0*_____*100

É um problema extremamente significante ***Não me preocupa***

8) Quanto você se preocupa em perder aulas no colégio, faculdade ou ainda tempo de trabalho devido ao seu tratamento do joelho?

0*_____*100

É um problema extremamente significante ***Não me preocupa***

Annex 1 (continued).

SEÇÃO C: ESPORTES/ATIVIDADES RECREACIONAIS/COMPETITIVAS

As questões abaixo se referem a **ATIVIDADES RECREACIONAIS E PARTICIPAÇÃO EM ESPORTES OU COMPETIÇÕES**. Elas relacionam suas habilidades em participar destas atividades e como estas são influenciadas pelo seu problema do joelho. Considere os últimos três meses para responder estas questões.

9) Quanto de limitação você apresenta para movimentos rotacionais ou de mudanças bruscas de direção?

0 _____ ***100***

Totalmente limitado — ***Sem limitações***

10) Quanto você se preocupa com o fato de que atividades esportivas ou recreacionais possam piorar o estado do seu joelho?

0 _____ ***100***

Muito preocupado — ***Sem preocupações***

11) Qual é o seu nível atual de performance nas atividades recreacionais ou esportivas, comparando com a performance antes da lesão?

0 _____ ***100***

Totalmente limitado — ***Sem limitações***

12) Considerando as atividades ou esportes que você se envolve hoje, quanto as suas expectativas mudaram devido ao estado do seu joelho?

0 _____ ***100***

Diminuíram completamente — ***Não diminuíram nada***

13) Você tem que praticar suas atividades esportivas ou recreacionais com cuidado? (Marque o "/" no início da linha à esquerda se você se encontra incapaz de praticar atividades esportivas ou recreacionais devido ao seu joelho)

0 _____ ***100***

Sempre pratico com cuidado — ***Nunca pratico com cuidado***

14) Quanto de medo você tem de sua rótula (patela) sair do lugar durante atividades esportivas ou recreacionais?

0 _____ ***100***

Muito medo — ***Sem medo***

Annex 1 (continued).

15) Você se preocupa com condições do ambiente, como um campo ou solo molhado, ou ainda uma quadra rápida, ou então com o tipo do piso do ginásio, quando está envolvido com suas atividades esportivas ou recreacionais? (Marque o "/" no início da linha à esquerda se você se encontra incapaz de praticar atividades esportivas ou recreacionais devido ao seu joelho)

0 _____ ***100***
Muito preocupado ***Nada preocupado***

16) Você se frustra quando pensa no seu joelho ao considerar a realização de atividades recreacionais ou esportivas?

0 _____ ***100***
Extremamente frustrado ***Não me sinto frustrado***

17) Qual é o grau de dificuldade para você "dar o máximo de si" nas atividades esportivas ou recreacionais? (Marque o "/" no início da linha à esquerda se você se encontra incapaz de praticar atividades esportivas ou recreacionais devido ao seu joelho)

0 _____ ***100***
Extremamente difícil ***Não sinto dificuldade***

18) Você sente medo ao praticar esportes de contato? (circule o item "N. S. A." - Não Se Aplica – à direita da linha, caso o motivo pelo qual você não pratica esportes de contato não seja o seu joelho)

0 _____ ***100***
Muito medo ***Sem medo*** **N.S.A.**

As questões abaixo se relacionam aos dois principais esportes ou atividades recreacionais que você realiza. Por favor escreva estas duas atividades em ordem de importância.

1._____

2._____

19) Quanto de limitação você encontra quando pratica o esporte ou atividade recreacional listado como número 1? (Posicione o "/" no início da linha à esquerda se você se encontra incapaz de praticar esportes ou atividades recreacionais devido ao seu joelho)

0 _____ ***100***
Extremamente limitado ***Sem limitações***

20) Quanto de limitação você encontra quando pratica o esporte ou atividade recreacional listado como número 2? (Posicione o "/" no início da linha à esquerda se você se encontra incapaz de praticar esportes ou atividades recreacionais devido ao seu joelho)

0 _____ ***100***
Extremamente limitado ***Sem limitações***

Annex 1 (continued).

SEÇÃO D: ESTILO DE VIDA

As questões abaixo lidam com seu estilo de vida em geral e devem ser consideradas fora do ambiente de trabalho e de esportes ou atividades recreacionais. São relacionadas ao seu joelho no que diz respeito a instabilidade patelofemoral (rótula que sai do lugar).

21) Você se preocupa com problemas de segurança em geral (como ao carregar uma criança pequena, jardinagem...) no que diz respeito ao seu joelho com instabilidade patelofemoral?

0 _____ ***100***

Extremamente preocupado — ***Sem preocupações***

22) Quanto da sua habilidade de se exercitar e se manter em forma esteve limitada devido ao seu problema no joelho?

0 _____ ***100***

Completamente limitado — ***Sem limitações***

23) Quanto do seu prazer na sua vida foi limitado pelo seu problema no joelho?

0 _____ ***100***

Completamente limitado — ***Sem limitações***

24) Com que frequência você se dá conta do seu problema no joelho?

0 _____ ***100***

O tempo todo — ***Nunca***

25) Considerando o seu estilo de vida, quanto você se preocupa com o seu joelho em relação às atividades que você e sua família realizam?

0 _____ ***100***

Extremamente preocupado — ***Não me preocupo***

26) Você teve que modificar seu estilo de vida para evitar atividades que pudessem machucar o seu joelho?

0 _____ ***100***

Modifiquei completamente — ***Não modifiquei***

Annex 1 (continued).

SEÇÃO E: SOCIAL E EMOCIONAL

As questões abaixo consideram suas atitudes e sentimentos e a maneira que eles se relacionam com seu joelho com instabilidade patelofemoral (rótula que sai do lugar). Considere os últimos três meses.

27) Quanto você se incomoda com o fato de não ser mais competitivo por conta do seu problema no joelho? (Marque o "/" ao final da linha à direita, para além do 100 se suas necessidades competitivas estão sendo alcançadas. Marque o "/" ao início da linha, sobre o 0 se você não tiver necessidades competitivas)

0 _____ ***100***

Extremamente incomodado — ***Nada incomodado***

28) Você apresentou alguma dificuldade para superar psicologicamente os problemas relacionados ao seu joelho?

0 _____ ***100***

Dificuldade extrema — ***Sem qualquer dificuldade***

29) Com que frequência você se sente apreensivo ou com medo em relação ao seu joelho?

0 _____ ***100***

O tempo todo — ***Em nenhum momento***

30) Quanto você se incomoda por uma falta de confiança no seu joelho?

0 _____ ***100***

Extremamente incomodado — ***Sem nenhum incômodo***

31) Se você pudesse quantificar, quanto de medo você tem de desenvolver uma nova lesão no mesmo joelho envolvido?

0 _____ ***100***

Muito medo — ***Sem medo algum***

Obrigado por completar este questionário.

Annex 1 (continued).

Sensitivity of Laségue Sign and Slump Test in Hernia and Disc Bulging Diagnoses Compared with Magnetic Resonance Imaging*

Sensibilidade das manobras de Laségue e de slump nos diagnósticos de hérnia e abaulamento discal em comparação com ressonância magnética

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Abstract

Objective To show the accuracy of the most used maneuvers in the clinical diagnosis of lumbosciatalgia, the slump test and the Laségue sign.

Methods In order to perform the present study, 101 patients with magnetic resonance imaging (MRI) discopathy (gold standard) were selected and had their medical records reviewed to identify which had the positive maneuvers on the initial physical examination.

Results The sensitivity found for the slump test and the Laségue sign in the diagnosis of disc herniation was 55.3% and 18.1%, respectively. Nonetheless, when they were compared with each other for the diagnosis of disc bulging, the sensitivity obtained was of 85.7% for the slump test and of 28.6% for the Laségue sign.

Conclusion Comparing both clinical exams with MRI, it was found that the slump test presents superior sensitivity compared with the Laségue sign for both the diagnosis of hernia and disc bulging, and should be more present in clinical practice.

Keywords

- sensitivity and specificity
- lower back pain
- disc hernia
- radiculopathy

Resumo

Objetivo Mostrar a acurácia das manobras mais usadas no diagnóstico clínico da lombociatalgia, a manobra de *slump* e a de Laségue.

* *Study carried out by the Orthopedics Group of the Universidade Federal de Pelotas (UFPel) at the Clinic of Orthopedics and Traumatology Dr. José Raymundo, Pelotas, RS, Brazil.*

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Métodos Para a realização do presente estudo, foram selecionados 101 pacientes com discopatia na ressonância magnética (RM) (padrão ouro), sendo posteriormente realizada a revisão dos prontuários para identificar quais tiveram as manobras positivas no exame físico inicial.

Resultados A sensibilidade encontrada para as manobras de *slump* e Laségue no diagnóstico de hérnia discal foi respectivamente 55,3% e 18,1%. Já quando comparamos as manobras para o diagnóstico de abaulamento discal, a sensibilidade obtida foi de 85,7% para a manobra de *slump* e de 28,6% para a manobra de Laségue.

Conclusão Foi constatado que a manobra de *slump* apresenta sensibilidade superior à da manobra de Laségue tanto para o diagnóstico de hérnia quanto para o de abaulamento discal quando comparadas a RM, e deveria estar mais presente na prática clínica.

Palavras-chave
- sensibilidade e especificidade
- dor lombar
- hérnia discal
- radiculopatia

Introduction

Lumbosciatalgia is defined as pain that affects the lumbar spine intermittently and radiates in the path of the sciatic nerve in the lower limb, commonly affecting even the foot.[1]

Low back pain is among the main complaints that lead patients to seek medical attention. Around 70% of adults have low back pain at some point in life, and in 14% of cases, the pain lasts >2 weeks.[2] Patients usually seek care when this pain is recurrent and tends to radiate to one lower limb, more frequently, or to both limbs, with burning sensation, shock or paraesthesia in the specific dermatomes of the sciatic nerve. Among the roots that form the sciatic nerve, the most affected ones are L5 and S1.

Pain assessment and physical examination are fundamental for the diagnosis and treatment of the patient, thus the importance of being familiar with and knowing how to apply the maneuvers that evaluate the roots that make up the sciatic nerve, and the Laségue sign and the slump test are the methods of choice in the evaluation. For a better comprehension of these diagnostic tests, it is essential to understand the axis of motion of vertebral bodies, because this is the only way to understand why both tests are in flexion, since with the spine bent, there is compression in the roots,[3] allowing clinical suspicion. However, for the use of tests on physical examination to corroborate in patient care, it is necessary to know their ability to identify the individuals who truly have herniated nerve root compression or bulging in the levels that make up the sciatic nerve.

Once the pain is characteristic and physical examination suggests root compression, we can continue the investigation with more appropriate imaging. In the case of suspected nerve root compression, magnetic resonance imaging (MRI) is the most indicated test, because the root can be visualized and, thus, it will evidence the correct diagnosis through image visualization.

Considering this, the present study was developed to estimate the sensitivity of the Laségue and slump maneuvers, using magnetic resonance imaging as a comparative gold standard.

Material and Methods

For the present study, 130 medical records of patients undergoing follow-up of low back pain with lower limb irradiation were randomly selected. This pain was defined as pain located in the back in lumbar topography and radiating to either of the lower limbs or to both lower limbs in the dermatomes of the sciatic nerve. The follow-up of patients with this complaint is standardized by the authors in all their routine visits, by the performance of anamnesis and physical examination in every first consultation. This semiological evaluation includes the performance of the slump and Laségue maneuvers, and it is followed by imaging whenever the complaint is consistent with the diagnosis of lumbosciatalgia, with the examination of choice in these cases being MRI of the lumbar spine (gold standard). Of the 130 records initially selected, 29 were excluded during the evaluation because they did not meet the MRI criterion with diagnosis of hernia or bulging, while 101 patients were included because they presented these alterations in the imaging exam.

The present study compares the sensitivity of the slump and Laségue maneuvers in the diagnosis of hernia and bulging of intervertebral discs causing pain in the sciatic nerve path; for this reason, only patients who presented with any of these diagnosis in the MRI report were selected. In order to analyze the medical records retrospectively, the diagnosis presented on the RMI with were compared regarding the presence or not of positivity in each maneuver mentioned.

The slump test was performed with the patient sitting on the stretcher, with his legs hanging and his hands on his thighs; the examiner performed the flexion of the chest on the thighs and flexion of the cervical segment, approaching the chin to the sternum; then, with the other hand, the examiner held the plantar face of one of the feet and performed the knee extension and dorsal flexion of the foot, keeping the other leg pending and, afterwards, performed the same test with the lower contralateral limb.[4]

The Laségue sign, also applied bilaterally, was performed with the patient in the supine position, with the lower limbs extended on the stretcher; the examiner, placing one hand

on one of the heels of the patient, performs flexion of the thigh up to 60°, keeping the knee extended, in one limb at a time.[5,6]

Both maneuvers were considered positive only when, during their performance, the patient referred pain irradiated in the lower limb that manifested itself in the path of the sciatic nerve.

Regarding MRIs, they were all performed at the same site and in the same machine, and all the examinations were analyzed by the same radiologist. The examination reports of all those selected either had hernia or disc bulging.

In reference to the definition of hernia and bulging, a literature review was performed and, after an analysis of several articles, the authors opted for the definitions found in the work of Jensen et al.,[7] in which the authors differentiate hernia from bulging. In this study Jensen et al. differentiated the hernia as protrusion or extrusion of the pulpous nucleus; in the first case, the base of the rupture is smaller than the largest diameter of the outerized pulpous nucleus, while in the second case, the base of the rupture is larger than the largest diameter of the pulpous nucleus externalized out of the fibrous ring. However, in the present study, the authors will consider only the diagnosis of hernia, without differentiating the subtypes of Jensen et al. The definition of bulging is described by Jensen et al. as a distension of the disc in the transverse plane compressing the nerve root.

Results

There were 101 patients included, 62 (61.4%) of them were female and 39 (38.6%) were male, with ages ranging from 18 to 89 years old, with 94 (93.1%) diagnosed with hernia and 7 (6.9%) with bulging in the gold standard exam, suggesting a higher prevalence of diagnoses in patients with hernia (►**Table 1**).

During the review of medical records, it was found that 58 of the 101 patients presented a positive slump test, 40 on the right, 36 on the left, and 18 bilaterally, while 19 presented a positive Laségue maneuver, 13 on the right, 9 on the left, and 3 bilaterally. From this, it was possible to calculate the sensitivity of each maneuver in the diagnosis of intervertebral discs hernia and bulging.

In order to evaluate the sensitivity of the slump test in the diagnosis of disc herniation, the number of disc herniation diagnoses on MRI (94) was compared with the number of patients who had a positive slump test (52); therefore, if 94 is equivalent to 100% of the hernias, the 52 who had a positive maneuver are equivalent to 55.3%, and this is the sensitivity of the slump test in the diagnosis of disc herniation. To evaluate the sensitivity of the Laségue sign, the number of diagnoses of hernia in MRI (94) was compared with the number of patients who had a positive Laségue sign (17); therefore, if 94 is equivalent to 100% of the hernias, the 17 who had a positive maneuver are equivalent to 18.1%, which is the sensitivity of the Laségue sign in the diagnosis of herniated disc (►**Table 2**).

To calculate the sensitivity of the slump test in the disc bulging diagnosis, the number of disc bulging diagnosis in MRI (7) was compared with the number of patients who had a positive slump test (6); therefore, if 7 is equivalent to 100% of the bulging, the 6 who had a positive maneuver are equivalent to 85.7%, and this is the sensitivity of this maneuver in the diagnosis of disc bulging. To calculate the sensitivity of the Laségue sign in disc bulging diagnosis, the number of disc bulging diagnoses in MRIs (7) was compared with the number of patients who had a positive Laségue sign (2); therefore, if 7 is equivalent to 100% of the bulging, the 2 who had the positive sign are equivalent to 28.6%, and this is the sensitivity of this maneuver in disc bulging diagnosis (►**Table 3**).

Table 1 Division by gender of patients with discopathy

Variable	General ($n = 101$)	Female ($n = 62$)	Male ($n = 39$)
Age (years old)	53.2 ± 15.7 (18–86)	53.8 ± 16.3 (18–84)	52.1 ± 14.9 (18–89)
Discopathy			
- Hernia	94 (93.1%)	56 (90.3%)	38 (97.4%)
- Bulging	7 (6.9%)	6 (9.7%)	1 (2.6%)

Results described by means ± standard deviation (minimum - maximum) or by frequency (percentage).

Discussion

In the present study, it was found that the evaluated tests present significant sensitivity difference, and the slump test had a much greater capacity than the Laségue sign to detect patients who truly present hernia or disc bulging when compared with the gold standard test. This result reinforces the findings of Majlesi et al.,[8] who also found a statistical difference in the sensitivity of the maneuvers, also showing the greater efficacy in the slump maneuver when identifying the true positives.

However, it is worth remembering that these maneuvers are physical examination tests and, for this reason, they can vary a little from examiner to examiner and according to the pain threshold of each patient. It is also emphasized that both maneuvers, in this case mainly the slump maneuver, may be falsely positive in patients who have hamstring shortening. Therefore, it is important that the doctor can recognize well the dermatomes of the cyatic nerve, knowing how to differentiate the causes of pain that manifests itself posteriorly in the lower limbs.

Under this scenario it is suggested that both maneuvers be performed in the search for the most accurate diagnosis, and the slump maneuver is valued here, since its applicability brings more security to confirm the suspicion of hernia or disc bulging at the level of the roots of the sciatic nerve. It should also be emphasized that more studies are needed so that the clinical diagnosis, based on anamnesis and physical examination, is increasingly effective, bringing the patient's physician closer to the patient through propaedeutic, which is sometimes forgotten these days.

Table 2 Sensitivity of the slump test and of the Lasége sign in the diagnosis of disc herniation

	Maneuver	Side	Cases with alteration	Sensitivity	95%CI
Total ($n = 94$)	Slump	Right	34	36.2%	26.5%–45.9%
		Left	35	37.2%	27.5%–47%
		Bilateral	17	18.1%	10.3%–25.9%
		Right and/or left	52	55.3%	45.3%–65.4%
	Lasègue	Right	11	11.7%	5.2%–18.2%
		Left	9	9.6%	3.6%–15.5%
		Bilateral	3	3.2%	0%–6.7%
		Right and/or left	17	18.1%	10.3%–25.9%
Female ($n = 56$)	Slump	Right	18	32.1%	19.9%–44.4%
		Left	18	32.1%	19.9%–44.4%
		Bilateral	9	16.1%	6.5%–25.7%
		Right and/or left	27	48.2%	35.1%–61.3%
	Lasègue	Right	6	10.7%	2.6%–18.8%
		Left	5	8.9%	1.5%–16.4%
		Bilateral	2	3.6%	0%–8.4%
		Right and/or left	9	16.1%	6.5%–25.7%
Male ($n = 38$)	Slump	Right	16	42.1%	26.4%–57.8%
		Left	17	44.7%	28.9%–60.5%
		Bilateral	8	21.1%	8.1%–34%
		Right and/or left	25	65.8%	50.7%–80.9%
	Lasègue	Right	5	13.2%	2.4%–23.9%
		Left	4	10.5%	0.8%–20.3%
		Bilateral	1	2.6%	0%–7.7%
		Right and/or left	8	21.1%	8.1%–34%

Abbreviation: CI, confidence interval.

Table 3 Sensitivity of the slump and laségue maneuvers in the diagnosis of disc bulging

	Maneuver	Side	Cases with alteration	Sensitivity
Total ($n = 7$)	Slump	Right	6	85.7%
		Left	1	14.3%
		Bilateral	1	14.3%
		Right and/or left	6	85.7%
	Lasègue	Right	2	28.6%
		Left	0	0%
		Bilateral	0	0%
		Right and/or left	2	28.6%
Female ($n = 6$)	Slump	Right	6	100%
		Left	1	16.7%
		Bilateral	1	16.7%
		Right and/or left	6	100%
	Lasègue	Right	2	33.3%
		Left	0	0%

Table 3 (*Continued*)

	Maneuver	Side	Cases with alteration	Sensitivity
		Bilateral	0	0%
		Right and/or left	2	33.3%
Male (n =1)	Slump	Right	0	
		Left	0	
		Bilateral	0	
		Right and/or left	0	
	Lasègue	Right	0	
		Left	0	
		Bilateral	0	
		Right and/or left	0	

Conclusions

With the present work, we tried to transmit to the scientific community that the physical examination still has great value in the diagnosis, especially when the examiner knows the various maneuvers and understands their value in the suspicion of the pathology.

In the case of the slump test and of the Laségue sign, it was concluded, through a study with approximately 100 patients, that none of them have high sensitivity, but the first has a much greater capacity than the second to suggest the diagnosis of lumbosciatalgia in patients who actually have root compression evidenced as hernia or bulging on MRI.

Statement of Consent

I, José Luiz Pozo Raymundo, authorize the use of the medical records of my clinic to carry out scientific review work without the disclosure of the identity of the patients treated by me.

Conflict of Interests

The authors have no conflict of interests to declare.

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Lumbar Decompression Versus Spinal Fusion in a Private Outpatient Setting: A Retrospective Study with Three Years of Follow-up*

Descompressão lombar versus fusão espinhal em ambiente ambulatorial privado: Um estudo retrospectivo com três anos de acompanhamento

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Abstract

Objective To compare pain, function, quality of life and adverse events of lumbar decompression and spinal fusion in patients with degenerative spinal pathologies who participated in a second opinion program for spinal surgeries with a 36-month follow-up.

Methods The data for this retrospective cohort were withdrawn from a private healthcare system between June 2011 and January 2014. The study sample consisted of 71 patients with a lumbar spine surgical referral. The outcomes for the comparisons between lumbar decompression and spinal fusion were quality of life (evaluated through the EuroQoL 5D), pain (measured by the Numerical Rating Scale) and function (assessed through the Roland Morris Disability Questionnaire) measured at baseline, and at 12 and 36 months after the surgical procedures. The definitions of recovery were established by the minimal clinically important difference (MCID). The baseline differences between the groups were analyzed by non-paired *t*-test, and the differences in instrument scores between time points, by generalized mixed models. The results were presented as mean values adjusted by the models and 95% confidence intervals.

Results Concerning the surgical techniques, 22 patients were submitted to spinal fusion and 49 patients, to lumbar decompression. As for the comparisons of the findings before and after the surgical interventions, the MCID was achieved in all outcomes regarding quality of life, pain and function at both time points when compared to baseline scores Moreover, concerning the complication rates, only lumbar

Keywords
- outcome assessment, health care
- musculoskeletal diseases
- back pain
- spine
- surgical interventions

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decompression presented a surgical rate of 4% ($n = 3$) for recurrence of lumbar disc hernia.

Conclusion Patients with degenerative spinal pathologies present improvements in long-term outcomes of pain, function and quality of life which are clinically significant, no matter the surgical intervention.

Resumo

Objetivo Comparar a dor, a função, a qualidade de vida e os eventos adversos da descompressão lombar e da fusão espinhal em pacientes com patologias degenerativas da coluna vertebral que participaram de um programa de segunda opinião para cirurgias de coluna com acompanhamento de 36 meses.

Métodos Os dados desta coorte retrospectiva foram obtidos de um sistema de saúde privado entre junho de 2011 e janeiro de 2014. A amostra do estudo foi composta por 71 pacientes encaminhados para cirurgia de coluna lombar. Os desfechos para comparações entre a descompressão lombar e a fusão espinhal foram qualidade de vida (avaliada pelo questionário EuroQoL 5D), dor (medida pela Escala Numérica de Classificação de Dor) e função (avaliada pelo Questionário de Incapacidade de Roland Morris) no início do estudo e aos 12 e 36 meses de acompanhamento pós-cirúrgico. As definições de recuperação foram estabelecidas pela diferença mínima clinicamente importante (DMCI). As diferenças basais entre os grupos foram analisadas por teste *t* não pareado, e as diferenças nas pontuações dos instrumentos entre os momentos, por modelos mistos generalizados. Os resultados foram apresentados como valores médios ajustados pelos modelos e intervalos de confiança de 95%.

Resultados No total, 22 pacientes foram submetidos à artrodese, e 49 pacientes, à descompressão lombar. Quanto às comparações de achados antes e depois das intervenções cirúrgicas, a DMCI foi alcançada em todos os desfechos de qualidade de vida, dor e função nos dois pontos de acompanhamento em relação aos escores basais Em relação às complicações, apenas a descompressão lombar apresentou 4% ($n = 3$) de taxa cirúrgica de recidiva da hérnia de disco lombar.

Conclusão Pacientes com patologias espinhais degenerativas apresentam melhoras nos desfechos de dor, função e qualidade de vida em longo prazo que são clinicamente significativas e independentes da intervenção cirúrgica.

Palavras-chave

- avaliação de resultados em cuidados de saúde
- doenças musculoesqueléticas
- dor nas costas
- coluna vertebral
- intervenções cirúrgicas

Introduction

Degenerative joint disease is the leading cause of chronic disability worldwide, and is usually associated with pain, joint blockage, and stiffness.[1] The increase in spinal surgeries nowadays is most frequently associated with degenerative processes of the lumbar spine; in recent years, the rate of lumbar procedures grew ten times faster than that of other orthopedic procedures, such as total hip or knee replacement.[2]

One of the consequences of spinal degeneration was first described by Verbiest in 1954, and is defined by the narrowing of the spinal canal, which causes compression of the spinal cord.[3] According to the author[4], the symptoms of nerve root compression due to hypertrophy of the articular processes occurred when the patient was in the upright position, especially during gait. Further studies have described that the compression of nerve structures is due to other components, such as hypertrophy of the ligamentum flavum, synovial cysts adjacent to the facet, and loss of height of the intervertebral disc.[5]

Symptomatic patients should initially be treated conservatively with physical therapy and medication, but, during patient assessment, it is possible to detect a small proportion of serious spinal pathologies, as well as those with compromised nerve root, and refer these patients to surgery.[6] The second opinion program was proposed to analyze the risks of unnecessary surgical procedures, as well as the costs, promoting a more ethical and beneficial practice for the patients, and a standard service for the treatment of low back pain.[7]

Surgical decompression is indicated in the following situations: when the conservative treatment fails, or when the patient develops cauda equina syndrome or presents progressive motor deficit.[8] On the other hand, lumbar fusion is indicated in cases of instability of the lumbar spine, and it can be performed through posterolateral (PL) fusion, in which the bone graft is placed between the transverse processes, or through the interbody (IB) fusion technique, in which the bone graft is placed between the vertebral bodies.

The use of IB fusion is indicated once the source of the pain is the intervertebral disc; regardless of its current widespread use, there is little evidence confirming its superiority.[9] Despite being technically more demanding, IB fusion provides better support for the anterior spine, indirect

foraminal decompression, lordosis restoration, and better removal of the intervertebral disc, which is an important pain factor.[10] The PL fusion is indicated when the source of the pain is the facet joint.[11] This technique is easier to perform and has a lower rate of complications, but could lead to more pain due to the need for greater exposure and damage to paravertebral muscles.[12] In regard to the outcomes, such as pain and dysfunction, the literature is inconclusive, because it has not been determined whether one approach offers any gains compared with the other.[13,14]

Despite these data, there is a controversy concerning which is the more appropriate intervention: isolated fusion or decompression.[11,15] Therefore, the aim of the present study is to compare pain, function and quality of life after lumbar decompression or spinal fusion in patients with degenerative spinal pathologies who participated in a second opinion program for spinal surgeries with a 36-month follow-up.

Methods

Study Design

Data for this retrospective cohort were withdrawn from a program of second opinion in spinal surgeries conducted in a private healthcare system, which includes patients with health insurance who had received an indication for surgery from a private practice spinal surgeon, and were offered a second opinion by their health insurers in Brazil.

The patients were assessed for eligibility between June 2011 and January 2014, and were followed up for 36 months. The eligibility criteria included: having an indication for spinal surgery due to degenerative lumbar spine conditions, such as intervertebral disc disease, degenerative spondylolisthesis, lumbar canal stenosis, facetary low back pain and lumbar instability; no contraindication to general anesthesia; ability to understand Portuguese; and agreeing to participate in the study. Patients with spinal fractures, scoliosis >20 degrees, congenital deformities, spinal tumors, confirmed or suspected pregnancy, and those who could not complete the follow-up were excluded from the study.

Surgical Interventions

Surgical procedures were performed or supervised by 14 senior surgeons (neurosurgeons or orthopedic surgeons) with more than 15 years of expertise. All patients underwent decompression or fusion. Decisions on which procedure to perform and on which levels were based on clinical practice guidelines, considering the findings on the clinical exam, instability criteria, and spinal stenosis.

Data Collection and Follow-up

Baseline data such as sociodemographic characteristics, general health, and any associated disease were collected at the hospital right before the surgical procedure by a research assistant (blinded to the aim of the study) as well as all outcome measurements. Long-term follow-up data were collected by telephone 12 and 36 months after surgery. The data were checked by two study coordinators, and, in case of any missing data, the databases were crosschecked in order to retrieve the information.

Outcomes

The outcomes for this study were: pain, function and quality of life measured at baseline, and at 12 and 36 months after surgery by specific questionnaires. All instruments have been translated and cross-culturally adapted into Brazilian Portuguese, and have had measurement properties tested.[16–18] Moreover, complications and relapse rates were assessed by the study coordinators through the hospital database and the medical records of the patients.

The participants were asked to classify their average pain over the previous week, and its intensity was measured by the pain Numerical Rating Scale (NRS), an 11-point numerical scale, which ranges from 0 to 10 (with 0 representing "no pain" and 10 representing "the worst pain the patient could ever experience").[19]

Also, self-rated back pain related function was measured by the Roland Morris Disability Questionnaire (RMDQ), in which each question is worth 1 point, and the scores range from 0 (no disability) to 24 (severe disability).[17]

Health-related quality of life was measured by the EuroQoL (EQ-5D), an assessment tool which uses five dimensions (5D: mobility, self-care, usual activities, pain/discomfort and anxiety/depression) to generate a score from 0 to 1 (worst to best).[17]

The minimal clinically important difference (MCID), which assigns a specific value of variation between follow-ups to define a clinically significant change in a patient's outcome (NRS: 2 points; RMDQ: 5 points; EQ-5D: 0.03 points) between the baseline and the follow-up periods is used as a definition of recovery.[20–22]

Sample Size

Since the present study is a retrospective cohort, the sample size is limited to the number of eligible patients who completed the treatment between June 2011 and January 2014.

Based on a previous study,[21] we estimated the mean pain score of 5.8 and the standard deviation of 2.0. Considering the main objective of comparing groups with different treatments regarding the level of pain and assuming that the standard deviation of the pain scale in the present study is similar to that observed in the study by Childs et al.,[21] the sample is sufficient to reach a power $>95\%$ for the detection of a difference of 1 point in the pain scale if we use the repeated measures design with a correlation structure, assuming that the correlation between measurements of the same patient over time is of ,0.5 and the significance level is 5%. The calculations were performed using the Power Analysis and Sample Size 14 (PASS 14, NCSS, LLC, Kaysville, UT, US) software package.

Statistical Analysis

Data were described as absolute and relative frequencies for the categorical variables, and, for the numerical variables, as means and standard deviations (SDs) or medians and

Table 1 Demographic and clinical characteristics of the study sample in values expressed as mean (standard deviation or percentage)

	Spinal fusion ($n = 22$)	Lumbar decompression ($n = 49$)	Total (n = 71)
Gender, male*	11 (50%)	27 (55.1%)	38 (53.5%)
Age, years*	59.14 (15.65)	44.51 (15.15)	62.47 (8.66)
Body mass index, kg/m^{2*}	28.96 (2.97)	27.19 (4.91)	27.7 (4.4)
Smoking, yes*	5 (22.72%)	9 (18.36%)	14 (19.7%)
Commorbities*			
Hypertension, yes	5 (22.72%)	12 (24.48%)	17 (23.9%)
Diabetes, yes	2 (9.09%)	2 (4.08%)	4 (5.6%)
History of cancer, yes	1 (4.54%)	1 (2.04%)	2 (2.8%)
Diagnosis			
Radiculopathy/Disc herniation/Disc protrusion	7 (31.81%)	37 (75.51%)	44 (62.0%)
Lumbar canal stenosis	4 (18.18%)	3 (6.12%)	7 (9.9%)
Mechanical low back pain	3 (13.63%)	2 (4.08%)	5 (7.0%)
Spondylolysis/Spondylolisthesis	3 (13.63%)	1 (2.04%)	4 (5.6%)
Intervertebral disc disease	3 (13.63%)	2 (4.08%)	5 (7.0%)
Unknown	2 (9.09%)	4 (8.16%)	6 (8.5%)
Reoperations	0	3 (4%)	3 (4%)

Note: *$p > 0.05$ for every characteristic analyzed.

quartiles, as well as minimum and maximum values. Generalized mixed models were adjusted to investigate differences in scores between follow-up periods, in order to consider the dependence between evaluations of the same patient. Baseline differences between groups were analyzed by non-paired *t*-test and the differences in instrument scores between the moments of assessment were investigated using generalized mixed models. Differences were found on multiple-comparison tests corrected by the sequential Bonferroni method, evaluating the effects between the baseline and the follow-up periods, as well as the interaction between time points. The results were presented as mean values adjusted by the models and 95% confidence intervals. The analyses were performed using the Statistical Package for the Social Sciences (SPSS, IBM Corp., Armonk, NY, US) software, considering a significance level of 5%.

The present study has been approved by the local Research Ethics Committee (under CAAE 59736016.0.0000.0071). All participants signed a consent form agreeing to participate in the spine program.

Results

The study sample consisted of 71 patients aged $\geq$ 18 years, with an indication of surgery (referred by the health care provider) for the treatment of degenerative diseases of the lumbar spine. All of them participated in the second opinion in spinal surgeries program, conducted at a tertiary hospital with access to supplemental health care, and were treated surgically and followed up for 36 months. The baseline demographics and clinical characteristics of the patients are presented in ►**Table 1**, according to the surgical procedure. Comparing the two types of surgical procedures, we observed significant differences in the demographics, clinical characteristics and diagnosis of the patients in each group ($p > 0.05$). A higher prevalence of lumbar decompression (69%) was observed; moreover, the groups presented statistically significant differeces ($p > 0.05$) in all characteristics analyzed. Concerning the rates of reoperation, only lumbar decompression presented a surgical rate of 4% (n = 3) for lumbar disc herniation.

Regarding the comparisons of the findings before and after the surgical interventions, ►**Table 2** presents outcome measurements of quality of life, pain and function, showing that the MCID was achieved in all outcomes, at both time points, when compared to the baseline scores ($p < 0.001$; ►**Table 2**).

However, when analyzing the postoperative time points without considering the surgical procedure, we did not observe differences or a specific value of variation between follow-ups to define a clinically significant change in a patient's outcome reached between the 12-month and 36-month follow-ups regarding quality of life, pain and function (►**Table 2**).

Discussion

Surgical interventions are frequently considered an option for the treatment low back pain, despite the divergences concerning the choice of technique.[2,3,5] Therefore, the aim of the present study was to compare long-term outcomes of quality of life, pain and function after lumbar decompression

Table 2 Mean adjusted values and 95% confidence intervals for the instrument scores for quality of life, pain and function at baseline and follow-ups according to surgical intervention.

Instruments	Baseline(N = 71)	12-month follow-up (N = 68)	36-month follow-up (N = 67)	*p*-value
EuroQoL-5D				
Spinal fusion	0.39 (0.28–0.49)	0.72 (0.61–0.82)	0.69 (0.58–0.80)	
Lumbar decompression	0.37 (0.30–0.44)	0.77 (0.70–0.84)	0.83 (0.76–0.91)	
Total	0.38 (0.32–0.44)	0.75 (0.69–0.81)	0.79 (0.73–0.85)	< 0.001
Minimal clinically important difference	–	0.37	0.41	0.356†
Numerical Rating Scale				
Spinal fusion	7.8 (6.8–9.0)	4.5 (3.7–5.4)	4.0 (3.2–5.1)	
Lumbar decompression	8.2 (7.5–9.0)	4.5 (3.9–5.1)	4.4 (3.8–5.1)	
Total	8.1 (7.5–8.7)	4.5 (4.0–5.0)	4.3 (3.8–4.8)	< 0.001
Minimal clinically important difference	–	3.6	3.8	0.559†
Roland Morris Disability Questionnaire				
Spinal fusion	14.8 (11.8–18.5)	6.4 (4.5–9.0)	5.9 (4.0–8.6)	
Lumbar decompression	16.4 (14.2–18.9)	5.8 (4.5–7.4)	4.8 (3.7–6.3)	
Total	15.9 (14.1–17.9)	6.0 (4.9–7.3)	5.1 (4.1–6.4)	< 0.001
Minimal clinically important difference		9.9	10.8	0.200†

Note: †*p*-values corrected by the sequential Bonferroni method.

and spinal fusion in patients with degenerative spinal pathologies who participated in a second opinion program for spinal surgeries.

Our results support the current evidence concerning clinically significant improvements after surgery,[23] and highlight the information that the scores did not differ between patients operated by spinal fusion or lumbar decompression, but they changed between time points (p <0.001), since the mean preoperative score was higher than the mean values (p <0.001) of the follow-ups at 12 and 36 months.

On the other hand, it is already known that the positive outcomes, the low rates of complications and reoperation, as well as the cost-effectiveness, are associated to the selection of patients for specific surgical techniques, which is often made based on patient profile and specific comorbidities, such as age and body mass index (BMI).[24] Likewise, recent evidence suggests that fusion provides no additional benefits compared to the traditional decompression surgery.[25] In addition, evidence shows that spine reoperation has an incidence of 5% to 16%, depending on the risk factors,[26,27] which means that the present study showed positive outcomes and a minimal rate of recurrence for lumbar disc hernia (4%), which were only observed on the lumbar decompression group.

Moreover, the patients of the present study are part of a second opinion program which can be considered an alternative to perform a shared decision-making approach to validate or not the decision of having surgery for back pain in the first place.[28] This interaction between the patient and the health care professional has been already proven to improve patient compliance and reduce healing time and functional deficits.[29]

Descriptive and administrative data concerning outcomes have been presented by researchers in an attempt to report population-based procedure rates, surgical safety outcomes, and costs regarding the diagnosis and management of conditions related to back pain.[15,30] Our results contribute to current body of evidence by demonstrating that patients with degenerative spinal pathologies present clinically significant long-term outcomes for pain, function and quality of life, regardless of the surgical intervention.

In addition, given the heterogeneity of symptoms and pathology, it is wise to state that there are no standardized criteria to refer patients to clinically meaningful groups based on surgical indication.[31] The present study points out a higher rate of lumbar decompression in a spinal-surgery program, but this could be linked to many reasons, such as the surgeons' discretionary use of operative techniques, hospital management and shared decision-making approaches.

The surgical treatment is highly controversial, and many techniques have been developed and performed worldwide. Spinal fusion and lumbar decompression are the top-two most performed low back surgeries overall, and have been associated with poor outcomes in 20% to 40% of the patients.[30,31] In the present study, we observed a variety of diagnosis with the same surgical indication, which leads to the urge to conduct further studies in order to sharpen the indication criteria, reduce the reoperation rates, and improve the quality of the health care.

Conclusion

In conclusion, patients with degenerative spinal pathologies present long-term outcomes for pain, function and quality of

life which are clinically significant, regardless of the surgical intervention. However, further studies must be conducted in order to better understand the factors which contributed to these outcomes, as well as also the economic impact associated with each intervention.

Authors' Contributions

All authors conceived the study. IOO chose the study design, and ML, EA and MF helped with the final version of the manuscript. IOO and EA were involved in the statistical analysis. All authors contributed to the refinement of the study and approved the final manuscript.

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Conflict of Interests

The authors have no conflict of interests to declare.

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Evaluation of Intramedullary Methods with Polymethylmethacrylate for Fixation of Bone Lesions of the Extremities*

Avaliação de métodos intramedulares com polimetilmetacrilato para fixação em lesões ósseas de extremidades

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Abstract

Objective To evaluate the better potential and functional results in pain control in the treatment of pathological fractures and prophylactic fixation with an intramedullary nail associated with polymethylmethacrylate, compared with the utilization of an intramedullary nail in long bone tumor lesions.

Methods From January 2012 to September 2017, 38 patients with 42 pathological lesions (fractures or impending fractures according to the Mirels criteria) were treated surgically. Sixteen patients allocated to the control group underwent a locked intramedullary nail fixation, and 22 patients with pathological lesions were allocated to treatment with an intramedullary nail associated with polymethylmethacrylate. Postoperatively, the patients were submitted to the Musculoskeletal Tumor Society (MSTS) rating scale, radiographic assessment, and to the assessment of events and complications related to the treatment.

Results The evaluation using the MSTS questionnaire showed better functional results in the group associated with polymethylmethacrylate, in comparison with the control group, which obtained an average score of 16.375 out of a maximum of 30 points (54.6%). The group studied with association with polymethylmethacrylate obtained a mean of 22.36 points (74.5%). The procedure proved to be safe, with similar complication and severity rates, and with no statistical difference in comparison with the standard treatment.

Keywords
- fractures, spontaneous
- polymethyl methacrylate
- bone neoplasms
- bone cements

* The present study was carried out at the Division of Orthopedic Oncology of the Hospital de Clínicas da Universidade Federal do Paraná and the Hospital do Trabalhador – SESA, Curitiba, PR, Brazil.

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Conclusion Stabilization of tumor lesions with an internal fixation associated with the polymethylmethacrylate demonstrated early rehabilitation and improved the quality of life, allowing rapid functional recovery. The use of polymethylmethacrylate has advantages such as reduced bleeding, tumor necrosis and higher mechanical stability.

Resumo

Objetivo Avaliar o potencial melhor resultado funcional e controle álgico no tratamento de fraturas patológicas e fixações profiláticas tratadas com haste intramedular associada ao polimetilmetacrilato (PMMA) em comparação com o uso de haste intramedular em lesões tumorais em ossos longos.

Métodos De janeiro de 2012 a setembro de 2017, 38 pacientes com 42 lesões patológicas (fraturas ou iminência segundo os critérios de Mirels) foram tratados cirurgicamente. Dezesseis pacientes submetidos a fixação com haste intramedular bloqueada foram alocados ao grupo controle e 22 pacientes com lesões patológicas foram alocados para tratamento com haste intramedular associada ao PMMA. No pós-operatório, foi realizada a submissão dos pacientes ao escore da Musculoskeletal Tumor Society (MSTS, na sigla em inglês) e à avaliação radiográfica do tratamento realizado, assim como à avaliação de intercorrências e complicações relacionadas ao tratamento.

Resultados A avaliação através do questionário MSTS demonstrou melhor resultado funcional do grupo associado com PMMA quando comparado com o grupo controle, o qual obteve uma pontuação média de 16,375 em um máximo de 30 pontos (54,6%), enquanto o grupo em estudo com associação do PMMA obteve uma média de 22,36 pontos (74,5%). O procedimento mostrou-se seguro, taxas de complicações e gravidade semelhantes e sem diferença estatística quando comparado com o tratamento padrão.

Conclusão A estabilização de lesões tumorais com fixação associada ao PMMA demonstrou reabilitação precoce e melhora na qualidade de vida, permitindo rápida recuperação funcional. A utilização do PMMA apresenta vantagens como diminuição do sangramento e da necrose tumoral e maior estabilidade mecânica.

Palavras-chave
- fraturas espontâneas
- polimetilmetacrilato
- neoplasias ósseas
- cimentos para ossos

Introduction

Advances in chemotherapy and radiotherapy treatment have increased the life expectancy of cancer patients, making them more susceptible to metastatic presentation.[1]

Pathological fractures occur in between 11 and 29% of metastatic bone lesions.[2–5] Surgical treatment allows for improved functional capacity, greater emotional acceptance, and care, as well as pain relief; therefore, early treatment provides a far better quality of life.[6]

Benign lesions such as simple and aneurysmal bone cyst, fibrous dysplasia, giant cell tumors, and Paget disease present an increased risk of fracture, especially in the proximal portion of long bones.[7–9]

Among the surgical methods, the foremost used is the intramedullary nail (IMN), due to its biomechanical properties[5,10–13] and greater stability in the face of disease progression, where the stabilization of lesions with the utilization of plates and screws may fail and define the survival of the patient.

The IMN can be introduced through the open or percutaneous technique; therefore, the use of bone cement allows for greater stability and pain control.[14–16] The association of bone cement has already been shown to be efficient in the oncological treatment of the spine and flat bones.[17]

The present study aimed to evaluate the results of the treatment of pathological lesions in long bones with the use of IMN associated or not with polymethylmethacrylate (PMMA).

Materials and methods

Between January 2012 and September 2017, 38 patients with 42 pathological injuries were treated, meeting the objectives of this research, with fractures or bone injuries on the verge of a fracture according to the criteria of Mirels, who underwent surgical procedure, being divided into two groups.

The inclusion criteria were: long bone neoplasm (primary or secondary), meeting the criteria of Mirels with surgical indication, pathological fractures in long bones, intramedullary osteosynthesis associated or not with PMMA, absence of previous treatment of the lesion, acceptance of the written informed consent form (WICF).

Table 1 Epidemiological differentiation between groups

	Control	Intramedullary nail + PMMA
Gender (F:M)	11:5	15:7
Primary Injury		
Breast	6	8
Multiple myeloma	2	2
Prostate	1	4
Uterine	0	2
Pulmonary	0	1
Melanoma	0	1
Colon	1	0
COA	1	0
Lymphoma	1	0
Hepatic	1	0
Renal	1	2
Fibrous dysplasia	1	0
Fracture secondary to osteochondroma resection	1	0
Hyperparathyroidism	0	1
Fracture secondary to radiation	0	1

Abbreviations: F, female; M, male; PMMA, polymethylmethacrylate; COA, aneurysmal bone cist.

The exclusion criteria were: previous fracture in the affected limb, non-intramedullary osteosynthesis, a previous infectious process in the affected limb, non-acceptance of the WICF.

Group 1, with 16 patients, received treatment with IMN. For Group 2, with 22 patients, the treatment was associated with PMMA. The surgical technique had similar surgical steps. After placing the nail and drilling the locking holes close to the insertion of the nail, the material was removed, and a hole was drilled in the metadiaphyseal region opposite to the entrance of the nail. The objective was to reduce intramedullary pressure during cementation and insertion of the intramedullary cement through the nail entry point, with continuous aspiration through the drilling point. Before the complete hardening of the cement, the nail is replaced and locked.

Among the patients allocated to Group 1, 11 females and 5 males, the primary disease is described in ►**Table 1**. The lesion site in eight cases was the proximal femur, five cases with involvement of the diaphyseal humerus, two cases in the diaphyseal portion of the femur, and on case in the distal femur (►**Table 1**).

In Group 2 patients, 15 females and 7 males, the primary disease is described in ►**Table 1**. The lesion site in 10 cases was the proximal femur, in 10 cases the diaphyseal humerus, 4 cases in the diaphyseal portion of the femur, 1 case in the distal femur, and 1 fracture of the diaphyseal tibia. In this group, there was one patient with a bilateral humeral fracture, one patient with bilateral transtrochanteric injury, and one patient with a bilateral femoral diaphyseal fracture and humeral diaphyseal fracture (►**Table 1**).

Table 2 Age evaluation and follow-up, according to the Student t test

	Control	Intramedullary nail + PMMA	
Age (years old)	51.5	64.8	$p = 0.05$
Follow-up (months)	11.7	8.4	$p = 0.48$

Abbreviation: PMMA, polymethylmethacrylate.

The mean follow-up time for the patients in Group 1 was 11.7 months (between 0 and 63 months), and in Group 2 it was 8.4 months (between 0 and 30 months). The functional assessment of the patients was performed through the analysis of the Musculoskeletal Tumor Society (MSTS) score. The postoperative radiographic assessments were carried out in order to verify the union of the fractures.

Results

A total of 38 patients, with a mean age of 59.24 years (between 14 and 85 years old), 26 females and 12 males, met the inclusion criteria. One patient had a bilateral femur fracture and a unilateral humerus fracture, 1 had a bilateral proximal femoral injury, and 1 had a bilateral humerus fracture, comprising 42 treated injuries.

The radiographic evaluation showed adequate alignment of the fractures and, in cases with a follow-up >1 year, no case of pseudarthrosis was evidenced by the radiographs. One patient with a fracture within the proximal femur had apparent cement leakage, but this patient did not wish to undergo to a replacement treatment, as she had sporadic pain.

The mean age in the control group was 51.5 years old (between 14 and 85 years old), whereas in the group treated with PMMA associated with IMN the mean age was 64.8 years old (between 27 and 84 years old). The mean follow-up time in the control group was 11.7 months (between 0 and 63 months), and in the PMMA-associated IMN group, it was 8.4 months (between 0 and 30 months). There was no statistical difference between ages in the groups ($p = 0.05$), as well as no statistical difference in the follow-up ($p = 0.48$) (►**Table 2**).

The functional assessment of patients using the MSTS questionnaire showed the superiority of the group that received the treatment linked to PMMA, with statistical significance ($p = 0.049$). The control group had an average score of 16.375 out of a maximum of 30 points, while the group with the PMMA association had an average score of 22.36 points (►**Fig. 1**).

In a comparative evaluation with new segmentation, this difference was not observed when we compared only the patients with injuries and treatments in the upper limbs, with a mean score of 20 ($n = 5$) in the MSTS questionnaire of patients treated with surgical synthesis material, and a score of 23.125 ($n = 8$) when associated with PMMA ($p = 0.60$). However, when this assessment was carried out comparing patients with injuries in the lower limbs, the control group ($n = 10$) had an average score of 13.6, and the group with

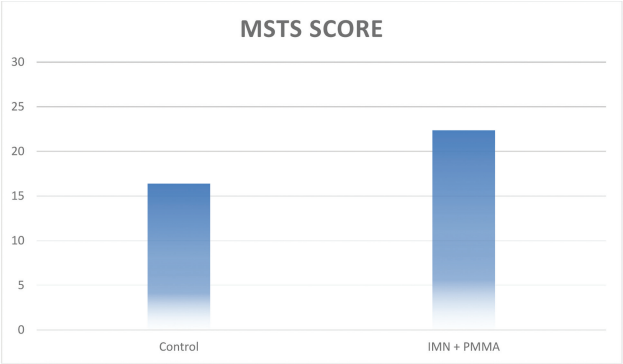


Fig. 1 MSTS rating scale for functional evaluation.

PMMA association ($n = 13$) had an average score of 21.46, with statistical significance ($p = 0.036$).

The comparison between the affected upper and lower limbs shows no difference within the group in the comparison between the control group and the group associated with PMMA. The patients in the control group with injury in the upper limbs, with a mean score of 20 ($n = 5$) versus patients with injuries in the lower limbs of the control group ($n = 10$), with a mean score of 13.6 ($p = 0.21$). In a comparison linked to PMMA, however, no statistical difference was observed: patients with injuries in the upper limbs treated with IMN + PMMA had a score of 23.125 ($n = 8$) versus the group of patients with injuries in the lower limbs ($n = 13$), with a mean score of 21.46 ($p = 0.69$).

Among the complications related to surgical treatment, we did not observe any statistical difference between the series. In the control group, there were three deaths (one after pulmonary thromboembolism [PE]), one deep surgical site infection, one superficial infection, and one case of decompensated heart failure. In the treatment group with association with PMMA, two deaths were observed (one case after PTE associated with stroke, and one after acute renal failure in a polytrauma patient), two cases of bone cement extravasation (one of these cases was examined in the initial surgery, with the removal of extravasated cement), one case of hypokalemia, and two of delirium (►**Figs. 2** and **3**).



Fig. 3 Pathological fracture of the left humerus. Primary lung adenocarcinoma (**A**) pathological fracture; (**B**) fixation with nail and cement; (**C**) bone union 15 weeks.

Discussion

The goal of treating pathological lesions is early mobilization, pain relief, and functional recovery as quickly as possible.[18] The Mirels score proved to be an important tool to identify the precise timing of prophylactic fixation of the tumor lesions.[19–21]

Conservative treatment showed the worst results, with higher morbimortality; thus, surgical treatment is the standard treatment for pathological fractures.[22] Osteosynthesis showed a lower rate of complications when compared with an endoprosthesis, as it allows immediate support.[23] The use of long nails is the most chosen and indicated method, as it prevents future injuries as the disease progresses. The



Fig. 2 Metastatic breast cancer lesion in the proximal femur in a 61-year-old patient with transtrochanteric fracture and impending contralateral fracture. The distal locking screw was not necessary due to stabilization with bone cement.

milling procedure of the medullary canal showed biomechanical advantages. The possibility of tumor cell dissemination has not been demonstrated.[24–27]

The treatment with association with PMMA and IMN has advantages over the standard treatment only with the use of the implant. As the cement occupies the spinal space, bleeding from the lesion is reduced. The cement provides greater mechanical stability to the compound, reducing adjacent bone destruction, and, consequently, pain.[17,28] Reports show that cement would lead to volume reduction and tumor necrosis caused by thermal injury, as well as to reduced blood supply to the tumor.[29,30]

Conclusion

Surgical treatment for long bone injuries, especially in palliative cases, aims at rapid pain control and functional recovery. Thus, the association with the percutaneous method of fixation of long bone fractures, with the use of an intramedullary nail associated with cementation with PMMA, proved to be an efficient technique. It presented complication rates similar to those of the traditional method and better functional results, allowing the patient to recover quickly. These results are more prominent in patients with lower limb involvement when compared with patients with upper limb injuries.

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The authors have no conflict of interests to declare.

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Acromioclavicular, Coracoclavicular and Medial Coracoclavicular Ligaments Assessment in Acromioclavicular Dislocation

Avaliação dos ligamentos acromioclavicular, coracoclaviculares e coracoclavicular medial na luxação acromioclavicular

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Abstract

Objective To study the anatomy of the medial coracoclavicular ligament and assess the contribution of the acromioclavicular, coracoclavicular and medial coracoclavicular ligaments to the stability of the acromioclavicular joint.

Methods Twenty-six shoulders from 16 fresh cadavers were dissected after placement in dorsal recumbency with a 15-cm cushion between the shoulder blades. An extended deltopectoral approach was performed proximally and medially, followed by plane dissection and ligament identification. The acromioclavicular and coracoclavicular distances were measured using points previously marked with a millimeter caliper. Six of these specimens were submitted to a biomechanical study. The acromioclavicular ligament, the coracoclavicular ligament and the medial coracoclavicular ligament were sectioned sequentially, and a cephalic force of 20 N was applied to the lateral clavicle. The acromioclavicular and coracoclavicular distances were measured in each of the ligament section stages.

Results The right medial coracoclavicular ligament presented, on average, 48.9 mm in length and 18.3 mm in width. On the left side, its mean length was 48.65 mm, with a mean width of 17.3 mm. Acromioclavicular, coracoclavicular and medial coracoclavicular ligament section resulted in a statistically significant increase in the coracoclavicular distance and posterior scapular displacement.

Conclusion The medial coracoclavicular ligament is a true ligamentous structure found in all dissected shoulders. Our results showed that the scapular protraction

Keywords
- acromioclavicular joint
- joint dislocations
- anatomy
- dissection

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relaxed the medial coracoclavicular ligament, while scapular retraction tensioned it; in addition, our findings demonstrate that this ligament contributes to the vertical and horizontal stability of the acromioclavicular joint.

Resumo

Objetivo Estudar a anatomia do ligamento coracoclavicular medial e avaliar a contribuição do ligamento acromioclavicular, coracoclaviculares e coracoclavicular medial na estabilidade da articulação acromioclavicular.

Métodos Foram dissecados 26 ombros de 16 cadáveres frescos, posicionados em decúbito dorso-horizontal, com um coxim de 15 cm de altura entre as escápulas. Realizou-se uma via deltopeitoral estendida proximal e medialmente. Realizou-se dissecção por planos e identificação dos ligamentos. Realizou a medida da distância acromio-clavicular e coracoclavicular usando pontos previamente demarcados com paquímetro milimetrado. Em seis dessas amostras foi realizado estudo biomecânico. Seccionando, nesta ordem, o ligamento acromioclavicular, os coracoclaviculares e o ligamento coracoclavicular medial com uma força cefálica de 20N foi aplicada na clavícula lateral. Foi medida a distância acromio-clavicular e coracoclavicular em cada uma das etapas de secção dos ligamentos.

Resultados A média de comprimento do ligamento coracoclavicular medial foi de 48,9mm e a média de largura, de 18,3mm no lado direito. No esquerdo, a média de comprimento foi de 48,65mm e a média da largura, 17,3mm. Após a secção dos ligamentos acromioclaviculares, coracoclaviculares, com a secção do ligamento coracoclavicular medial houve aumento estatisticamente significativo da distância córaco-clavicular e um deslocamento posterior da escápula.

Conclusão O ligamento coracoclavicular medial é uma estrutura ligamentar verdadeira, presente em todos os ombros dissecados. Nossos resultados demonstraram que o ligamento coracoclavicular medial encontra-se relaxado com a escápula em protração e tenso com a escápula em retração e segundo nossos resultados participa tanto da estabilidade vertical quanto da estabilidade horizontal da articulação acromioclavicular.

Palavras-chave
- articulação acromioclavicular
- luxações articulares
- anatomia
- dissecação

Introduction

The literature on the anatomy and ligamentous biomechanics of the acromioclavicular (AC) joint is very rich. Countless studies discuss different types of treatment for traumatic AC joint injuries and the open and arthroscopic surgical approaches to the acromioclavicular and lateral coracoclavicular (conoid and trapezoid) ligaments. However, there are few papers regarding the ligamentous anatomy medial to the coracoid process, notably the medial coracoclavicular ligament (LCCM) and its role in acromioclavicular dislocation, as this anatomical study.

Described as a "bicorne ligament" for presenting two main fascicles by Leopoldo Caldani in 1802,[1] LCCM was once considered a thickened part of the clavipectoral fascia[2] or a coracocostal ligament;[3] its own existence was questioned.[4–8]

LCCM forms a strip of pearly-yellow fibers arising from the medial border of the coracoid process as two fascicles (an anterior and a posterior fascicles) which merge to form the ligamentous body attached to the medial portion of the clavicle.[2,9,10] There are divergences regarding its attachment. Some authors[11–13] divide it into two fascicles (a superior fascicle on the anterior border of the clavicle and a lower fascicle on the sternal border of the first rib).[10] Other authors believe its attachment is at the anterior border of the clavicle and divided into three expansions (superior, inferior, and medial expansions).

Recently, LCCM features have been described in magnetic resonance images.[14]

This work studied LCCM anatomy to assess its function and contribution to the stability of the acromioclavicular joint in cases of injury.

Materials and Methods

This study was approved by the Research Ethics Committee of our institution (CAAE number 12358919.0.00005463) and performed at the coroner's office from São Paulo, SP (Serviço de Verificação de Óbitos, SVO) from Universidade de São Paulo (USP), Brazil.

Twenty-six shoulders from 16 fresh adult cadavers with no scars or previous deformities were dissected. All dissections were performed by the same group of researchers, consisting of orthopedic specialized in shoulder surgery, and carried out in a standardized way, with the cadaver in dorsal recumbency with a 15-cm cushion at the interscapular region. Dissection started with an extended, proximal



Fig. 1 Extended deltopectoral approach.



Fig. 2 Dissection, structures identification and medial coracoclavicular ligament (LCCM) measurement; ACL, coracoacromial ligament; C, coracoid; CT, joint tendon; Pm, pectoralis minor; LCCL, lateral coracoclavicular ligaments; AS, anterosuperior band; PI, posteroinferior band.

deltopectoral approach in "L" shape, following horizontally towards the clavicular sternum joint (►**Figure 1**–Approach).

Dissection was performed in planes. The deltoid and pectoralis major muscles were removed from the anterior aspect of the clavicle, and the LCCM was identified from its attachment to the coracoid process to its attachment to the medial end of the clavicle; its length and width were measured with a millimeter caliper (►**Figures 2** and **3**). Scapular retraction and protraction movements were performed, observing the effect on ligament tension. The acromioclavicular, trapezoid, conoid, and medial coracoclavicular ligaments were sectioned sequentially, and the displacement of the acromioclavicular joint was observed both in cephalic and anteroposterior directions (►**Figure 4**).

At first, an anatomical study was carried out on 20 shoulders of ten cadavers to assess LCCM morphology. Next, a biomechanical study was carried out with six shoulders from six cadavers, which ligaments were sectioned sequentially. The clavicle was submitted to a cephalic traction with a constant force of 20 N, applied at 1 cm from the distal edge and measured with a dynamometer. Newton and kgF units were considered equivalent. Three anatomical points were marked (A, B, C); point A was located 1 cm from the most medial point of the acromion; point B was 1 cm from the most lateral point of the clavicle; and point C was on the lateral edge of the coracoid process. AC joint was dissected, and its intrinsic ligaments were sectioned for the first time, followed by the sequential sectioning of the trapezoid and conoid ligaments and LCCM. At each step, a uniform 20 N traction force was applied to the lateral end of the clavicle. In addition, the vertical and horizontal distance between the acromion and the clavicle (from the upper edge of the acromion to the upper edge of the distal clavicle), the vertical distance between the coracoid process and the clavicle (coracoclavicular space), and the distance between



Fig. 3 Dissection, structures identification and medial coracoclavicular ligament (LCCM) measurement; ACL, coracoacromial ligament; C, coracoid; CT, joint tendon; Pm, pectoralis minor; LCCL, lateral coracoclavicular ligaments; AS, anterosuperior band; PI, posteroinferior band.

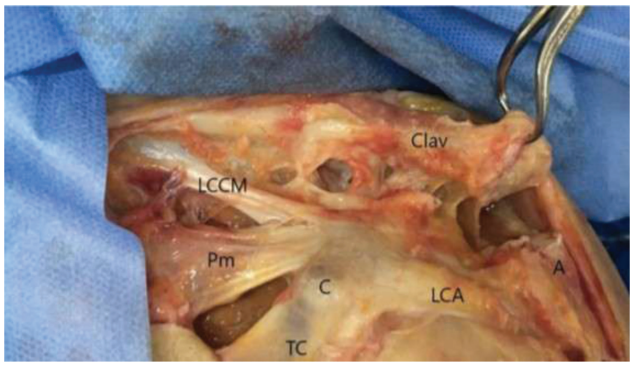


Fig. 4 Dissection and structures identification. Clav, Clavicle; A, acromion; LCCM, medial coracoclavicular ligament; ACL, coracoacromial ligament; C, coracoid; CT, joint tendon; Pm, pectoralis minor.

Table 1 Medial coracoclavicular ligament measurements

	Mean	Standard deviation	Variance
Length, right side	48.90 mm	2.438	5.933
Length, left side	48.65 mm	2.7262	7.432
Width, right side	18.30 mm	0.949	0.900
Width, left side	17.30 mm	0.949	0.900

the acromion and the clavicle was measured after each section, as described by Moya et al.[15]

Data was presented as mean and standard deviation values, and descriptively analyzed. Differences in variances were determined using analysis of variance (ANOVA) with repeated measures. Results were considered statistically significant when p value was less than 0.05 considering alternative two-tailed hypotheses. Collected information formed a database developed in Excel® for Windows and the statistical analysis was performed using SPSS® 16.0 software.

Results

LCCM was identified and measured in all dissected shoulders. On the right shoulder, LCCM presented, on average, 48.9 mm in length (ranging from 46 to 53 mm) and 18.3 mm in width (ranging from 17 to 20 mm). On the left shoulder, LCCM had, an average length of 48.65 mm (ranging from 45.5 to 52.5 mm) and an average width of 17.3 mm (ranging from 16 to 18 mm). ►**Table 1** shows results from the statistical analysis.

LCCM was divided into three segments: origin, body, and attachment. This ligament originates at the medial border of the coracoid process, medial and posterior to the pectoralis minor muscle attachment and distal to the origin of the conoid and trapezoid ligaments. LCCM bifurcates in its origin, forming two fascicles, an anterior and a posterior one, which merge to form the ligamentous body; this ligamentous body has pearly yellow color and fibroelastic consistency, and runs anteriorly to the subclavian muscle. Its attachment is located at the anteroinferior border of the medial clavicle, at a topography that hinders its isolation due to the large amount of aponeurosis.

Scapular protraction relaxed the LCCM, whereas scapular retraction tensioned it.

Six specimens were submitted to the sequential sectioning of the acromioclavicular, trapezoid, conoid and medial coracoclavicular ligaments. An upper displacement of the AC joint and posterior scapula was observed. A 20 N cephalic force was applied to the lateral clavicle using a portable analog dynamometer, and the distance from the AC, the coracoclavicular space and their variations were recorded. The anteroposterior movement of the clavicle following LCCM section was also evaluated. All (100%) cadavers were males. The right side was evaluated in 66.7% of the cases. The mean body mass index (BMI) was 23.8, with a standard deviation of 5.6, ranging from 12.5 to 32.0. Mean age was 67 years old, with a standard deviation of 9.5, ranging from 58 to 84 years old (►**Table 2**).

Superior displacement was assessed using the AB (acromion-clavicle) and BC (coracoid-clavicle) distances; posterior displacement was determined using the posterior AB (acromion-clavicle) distance. When measuring

Table 2 Measures found during assessment

Cadaver	Height	Age	Side	Acromioclavicular Distance				Acromion- Posterior Clavicle Distance				Coracoid-Clavicular Distance			
				1	2	3	4	1	2	3	4	1	2	3	4
1	1.85	68	Right	0.8	1.6	2.5	3.0	2.0	2.9	3.1	3.2	3.4	4.0	5.2	5.7
2	1.75	70	Right	0.6	1.4	3.0	3.4	2.2	2.3	3.8	4.5	3.0	3.5	4.8	5.5
3	1.65	64.	Right	0.9	1.4	2.2	2.7	2.2	2.5	2.7	3.5	3.3	3.8	4.5	5.0
4	1.87	58	Right	0.6	1.7	2.6	2.9	2.8	4.0	4.5	4.6	3.3	4.3	5.3	5.5
5	1.53	59	Left	1.0	2.1	3.2	3.9	1.8	2.5	3.9	4.3	3.5	4.0	5.0	5.8
6	1.70	84	Left	0.2	1.2	2.1	2.2	3.6	5.1	5.1	5.2	2.8	4.0	5.0	5.4

1, No injury; 2, acromioclavicular injury; 3, coracoclavicular injury; 4, medial coracoclavicular ligament injury.

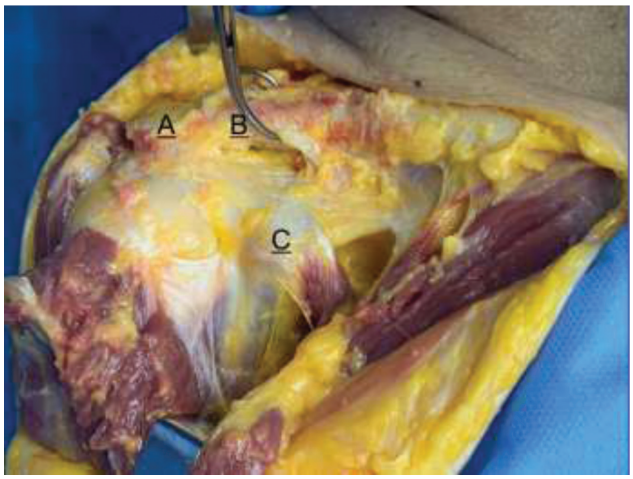


Fig. 5 Points A, B and C.



Fig. 6 Traction (20 N) after ligament section.

clavicular displacement at the superior AB point, posterior AB point and BC point at four different moments (with no injury to the acromioclavicular [AC] and coracoclavicular [CC] ligaments), AC injury, AC + CC injuries, and AC + CC + LCCM injuries (►**Figures 5** and **6**), a statistically significant increase was observed in all points, as shown in ►**Table 3**.

Mean acromion-clavicle (AB) distance went from 0.7 cm with no injury to 3.0 cm after sectioning all ligaments, including LCCM. Mean coracoid-clavicle (BC) distance increased from 3.2 cm with no injury to 5.5 cm after sectioning all ligaments, with $p < 0.001$.

Ligament section resulted in a posterior scapular deviation that was exacerbated after LCCM section.

Discussion

LCCM, also called Henle's anterior coracoclavicular ligament and Soulié's horizontal coracoclavicular ligament[1,10,12–14] is a matter of controversy; some authors even failure to mention it in the coracoid ligament anatomy.[16] Klassen et al.[8] did not find it in their dissections; Rouvière[2], Vallois and Thomas[13] did not consider it a structure of its own, but a thickening of adjacent structures, i.e., a cord from the clavipectoral fascia.[17] For Terra et al.,[18] LCCM is an anatomical variation of the conoid ligament.

Poitevin et al.[10] described the presence of LCCM in 100% of the studied shoulders (15 adults and eight fetuses). These authors reported the LCCM as originating in the coracoid process, divided into two fascicles, and attaching itself at the medial clavicle, where it is divided into three expansions (superior, lower, and medial expansions).

In addition, the LCCM was studied using magnetic resonance imaging and viewed in its complete extension, from its origin at the coracoid process to its attachment to the medial clavicle, and its anatomical features were described.[14]

Stimec et al.[12] described the ligament from the dissection of a 92-year-old female cadaver specimen. The authors resected the ligament for measurement and histological analysis. They confirmed its ligament nature, its structure, and arrangement of collagen fibers, which are paired and surrounded by a thin layer of a richly vascularized connective tissue, similar to the conoid ligament.

Starting our studies in LCCM, we noted that the current literature is scarce, and that Poitevin et al.,[10] Moya et al.[15] and Azulay et al.[14] papers reported recent studies. We tried to use a similar methodology to confront our results, and then discuss them to agree and/or disagree with their conclusions. We described absolute values of ligament lengths which were similar to those found by other authors in their dissections.

Table 3 Mean distance between points and standard deviation

	No Injury	AC Injury	CC Injury	LCCM Injury	p value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
AB Distance	0.7 ± 0.3	1.6 ± 0.3	2.6 ± 0.4	3.0 ± 0.6	<0.001
Posterior AB Distance	2.4 ± 0.7	3.2 ± 1.1	3.9 ± 0.9	4.2 ± 0.7	0.009
BC Distance	3.2 ± 0.3	3.9 ± 0.3	5.0 ± 0.3	5.5 ± 0.3	<0.001

AC, Acromioclavicular; CC, coracoclavicular; LCCM, medial coracoclavicular ligament; SD, standard deviation.

We found the LCCM in all our dissections, bilaterally, as described by other authors. Its attachment to the medial clavicle is located at the anteroinferior portion of the bone, but it is surrounded by aponeuroses that can be confused with ligamentous branches or expansions. In addition, it was observed that the LCCM has intimate contact with the subclavian muscle, a finding that could lead to the conclusion that it would be the result of a scapulothoracic muscle metaplasia, as described by Luk et al.[19] However, we dismiss this hypothesis because this ligament has been described in dissected human fetuses.[10] Moya et al.[15] suggest that the LCCM is a constant structure with mechanical ligamentous features that can act as the last restriction of the coracoclavicular space both in the cephalic and posterior direction, preventing further displacement in the absence of the lateral coracoclavicular ligaments.

Since this study was carried out at SVO on fresh cadavers and not on anatomical pieces as Moya et al.,[15] we opted to position the cadaver in dorsal recumbency with a 15-cm cushion at the interscapular region to free the shoulder and keep it away to the dissection table. This allows for a better evaluation of the involved joints after progressive ligament section.

This study revealed that LCCM is relaxed during ipsilateral scapular protraction and it is tensioned during scapular retraction, raising the hypothesis that LCCM functions as a secondary horizontal stabilizer of the AC joint. This hypothesis reinforces the observation that, after sequential sectioning of AC, trapezoid and conoid ligaments, and keeping the interscapular cushion to suspend the shoulders, LCCM excision at its origin at the coracoid process promotes a statistically significant increase in AC distance.

We also found that, when sectioning all ligaments that join the scapula to the clavicle, the upper limb is totally subject to gravitational forces, i.e., the scapula is inferior to the clavicle, creating an image similar of a patient in orthostasis with Rockwood stage 5 AC dislocation.[16] As such, we assume that LCCM lesion occurs in stages 4 and 5 of the Rockwood classification for AC dislocations.

We understand that the knowledge of the ligament structures medial to the coracoid process can contribute to the understanding of traumatic AC injuries; in addition, it can be of great value to surgical approaches requiring dissection of the soft tissues inserted in the coracoid process, such as muscle transfers, Bristow and Latarjet procedures and decompression in thoracic outlet syndrome.

LCCM existence as an anatomical structure is well established. However, we believe that new biomechanical and imaging studies may further clarify its stabilizing function at the AC joint.

A limitation of our study is the use of cadavers with an elevation of only 15 degrees. It would be ideal to have a greater body flexion for a better evaluation of the AC joint aided by gravitational force and orthostasis. Another limitation is the small number of specimens. However, our findings are important to understand the structures involved in AC dislocation and the role of LCCM in AC joint stability. Further studies are required to clinically assess the importance of this ligament, correlating clinical, radiographic, and magnetic resonance imaging data.

Conclusion

LCCM is a true ligament structure present in all dissected shoulders. It is relaxed with the scapula in protraction and tensioned under scapular retraction. LCCM contributes to the vertical and horizontal stability of the AC joint.

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Conflict of Interests
The authors declare no conflict of interests.

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Influence of Hypovitaminosis D on the Ocurrence of Fractures*

Influência da hipovitaminose D na ocorrência das fraturas

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Abstract

Objective To measure the levels of vitamin D in patients hospitalized for fractures and to evaluate its relationship with fractures.

Methods A primary, analytical, cross-sectional, non-interventional, observational, controlled study was conducted in humans. The serum measurement of: vitamin D, parathyroid hormone (PTH), calcium, phosphorus, magnesium and albumin was performed in 49 patients who were consecutively hospitalized for surgery due to fracture(s) (study group), and in 50 patients without fractures, from the various outpatient clinics, and who underwent routine tests (control group).

Results The mean level of 25-hydroxyvitamin D (25[OH]D) in patients with fractures was of 23.78 ± 8.01 ng/mL (61.22% of patients with fractures had hypovitaminosis D). The mean 25(OH)D of the control group was of 37.52 ± 9.21 ng/mL (10% of the patients had hypovitaminosis D). Most cases of hypovitaminosis (96%) did not course with secondary hyperparathyroidism (mean PTH = 41.80 ± 22.75 pg/mL).

Conclusion Hypovitaminosis D was found in a significant percentage (61.22%) of the patients who suffered fractures. Further studies on the subject are needed to better understand the influence of hypovitaminosis D on the occurrence of fractures, as well as the benefits of vitamin D supplementation in these patients.

Keywords
- vitamin D
- vitamin D deficiency
- osteoporosis
- hip fractures
- fracture healing

* *Work developed at the Department of Orthopedics and Traumatology, Hospital das Clínicas Samuel Libânio, Pouso Alegre, Minas Gerais, MG, Brazil.*

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Resumo

Objetivo Dosar a vitamina D nos pacientes internados por fratura e avaliar sua relação com as fraturas.

Métodos Realizou-se estudo primário, analítico, transversal, não intervencional, observacional, controlado, em seres humanos. Fez-se a dosagem sérica de: vitamina D, paratormônio(PTH), cálcio, fósforo, magnésio e albumina em 49 pacientes que foram internados consecutivamente para cirurgia devido a fratura(s) (grupo de estudo), e em 50 pacientes, dos diversos ambulatórios, sem fraturas, e que realizaram exames de rotina (grupo de controle).

Resultados A média de 25-hidroxivitamina D (25[OH]D) nos pacientes com fraturas foi de 23,78 ± 8,01 ng/mL (61,22% dos pacientes com fraturas apresentaram hipovitaminose D). A média de 25(OH)D do grupo de controle foi de 37,52 ± 9,21 ng/mL (10% dos pacientes apresentaram hipovitaminose D). A maioria dos casos de hipovitaminose (96%) não cursou com hiperparatireoidismo secundário (média do PTH = 41,80 ± 22,75 pg/mL).

Conclusão A hipovitaminose D foi encontrada em um percentual expressivo (61,22%) dos pacientes que sofreram fraturas. Mais estudos sobre o assunto são necessários para se compreender melhor a influência da hipovitaminose D na ocorrência das fraturas e os benefícios da suplementação com vitamina D nesses pacientes.

Palavras-chave

- vitamina D
- deficiência de vitamina D
- osteoporose
- fraturas do quadril
- consolidação da fratura

Introduction

The study of vitamin D (VIT D) and the consequences of its deficiency in the body are relatively new topics, and they became known after the Industrial Revolution, when the rural population migrated to the urban centers.

The main known function of VIT D is to keep calcium and serum phosphorus concentrations within normal physiological limits to maintain most metabolic functions, neuromuscular transmission, and bone mineralization. Most often, the changes due to VIT D deficiency are subclinical.[1]

Hypovitaminosis D (HVD) leads to decreased mineralization of the bone matrix, which can lead to rickets in childhood and osteomalacia in adults, as well as worsening of cases of osteoporosis. Vitamin D plays a fundamental role in the metabolic pathway of calcium, and its supplementation is associated with increased bone mineral mass and the prevention of fractures. Fractures due to osteoporosis result in high costs, with a treatment comparable to those for cardiovascular diseases.[2]

Approximately one third of the world's population has levels of 25-hydroxyvitamin D (25[OH]D) lower than 20 ng/mL, which may not be ideal to maintain good bone health.[3] There is evidence that HVD is the most common nutritional deficiency in the world.[4] Traditionally, Brazil was considered a place where there were no cases of HVD, because it is a tropical, sunny country, with wide exposure of the population to the sun. However, recent studies have demonstrated the lack of VIT D in the most diverse age groups and places in the country.[5–10] Hypovitaminosis D, which plagues the world population and even Brazil may have occurred due to changes in habits such as protection against the sun protection, the use of sunscreen, the season of the year and lower exposure to the sun in cold regions, as well as food shortages.

It is well established in the literature that HVD predisposes to bone fragility and influences postural and dynamic balance, favoring the occurrence of fractures. However, until the beginning of the present study, no studies on the dosage of VIT D in the population of our region (the southern part of the state of Minas Gerais, Brazil) had been found, nor studies on the influence of VIT D on the occurrence of fractures in the Brazilian population. The aim of the present study was to measure the levels of VIT D in fractured patients and evaluate its relationship with fractures.

Methods

A primary, analytical, cross-sectional, non-interventional, observational, controlled study was conducted in humans. We consecutively selected 49 patients with fractures (study group) (1 patient in the study group was excluded due to renal alteration) with surgical indication, and 50 patients without fractures (control group), older than 18 years of age, without any restrictions regarding color or gender, who agreed to participate in the study. The patients in the study group were selected consecutively to their hospitalization in the orthopedics and traumatology ward of our institution; and the tests were collected along with routine preoperative blood tests. The patients in the control group were selected from the outpatient clinics of the various specialties in the same hospital, provided they had any outpatient indication of blood collection. We excluded: patients hospitalized for more than 24 hours; undergoing VIT D replacement; with endocrine, genetic or metabolic diseases capable of altering the normal metabolism of VIT D (osteogenesis imperfecta, Paget disease); with acute or chronic renal failure; with pathological fractures of neoplastic origin or under neoplastic treatment; with malnutrition; with psychiatric eating disorders (bulimia and

anorexia); those undergoing bariatric surgery or bowel resection; those with small bowel diseases, biliary or hepatic tract disease, and intestinal exocrine pancreatic insufficiency that interfere with fat absorption (sprue, amyloidosis, etc.); and patients using medications that hinder the resorption of fat (orlistat, cetilistat and the like).

All patients who spontaneously agreed to participate in the study signed a free and informed consent form. The study was approved by the Ethics Committee under CAAE 94612618.6.0000.5102. The patients were initially submitted to sociodemographic data collection, body weight and height (in meters) measurements, and filled out a questionnaire on habits of protection against the sun and smoking. Next, they were submitted to peripheral venous puncture and blood collection for dosage of 25(OH)D, parathyroid hormone (PTH), total and ionized serum calcium, phosphorus, magnesium and albumin. The 25(OH)D and PTH were dosed by the chemiluminescence method. Hypovitaminosis was characterized according to the current position of the Brazilian Society of Clinical Pathology and Laboratory Medicine (Sociedade Brasileira de Patologia Clínica e Medicina Laboratorial, SBPC/ML, in Portuguese) and the Brazilian Society of Endocrinology and Metabology (Sociedade Brasileira de Endocrinologia e Metabologia, SBEM, in Portuguese).[11] Thus, evels of 25 (OH)D $>$ 20 ng/mL were considered the normal value for a healthy population (aged up to 60 years); between 30 ng/mL and 60 ng/mL, the recommended value for risk groups such as: elderly, pregnant women, osteoporosis patients, those with a history of falls and fractures, and patients with secondary causes of osteoporosis (diseases and medications); levels $>$ 100 ng/mL were considered risk of intoxication.

The data were tabulated in Microsoft Excel 2016 (Microsoft Corp., Redmond, WA, US) spreadsheets and submitted to statistical analysis. Central trend measurements were used for the quantitative variables, and absolute and relative frequencies were used for the categorical variables. The Minitab (Minitab, LLC, State College, PA, US) software, version 18.1, and the Statistical Package for the Social Sciences (SPSS, IBM Corp., Armonk, NY, US) software, version 22.0, were used. The significance level adopted for the statistical tests was of 5% ($p < 0.05$).

Results

The groups were similar in terms of body mass index (BMI), age and gender (►**Tables 1** and **2**). In the study group, there were 15 (30.61%) elderly (aged $>$ 60 years) patients, and 14 of them (93.33%) had VIT D levels $<$ 30 ng/mL. In the control group, there were 18 (36%) elderly people, and 5 of them (27.77%) had VIT D levels $<$ 30 ng/mL.

There was also a similarity between the skin color of the groups, which was predominantly white in more than 80% of the population studied (82% of white subjects in the control group, and 87.75% in the study group).

The groups also resembled each other in degree of skin protection, smoking and exposure to the sun (►**Table 3**).

The mean level of PTH of the control group was of 39 ($\pm$ 23.70) pg/mL, and that of the study group was pf 44.60 ($\pm$ 21.80) pg/mL (VN = 18.5 pg/mL to 88 pg/mL). Evaluating both groups, only two cases of hyperparathyroidism secondary to HVD were observed.

Table 2 Comparison of groups with respect to gender

Group	Male	Female	Total	*p*
Study	31 (63%)	18 (37%)	49 (100%)	0.150
Control	25 (50%)	25 (50%)	50 (100%)	

Note: Fischer exact test.

Table 3 Comparison between the degree of protection against and exposure to the sun and smoking between the groups

Protection against the sun	Control	Study	*p*
No	23	23	
Sunscreen and/or clothing	27	26	1
Only sunscreen	0	0	
Total	50	49	
Smoking			
Yes	10	12	
No	40	37	0.483
Total	50	49	
Exposure to the sun			
Daily	37	32	
Occasional	13	19	1
Total	50	49	

Note *t*-Test.

Table 1 Disribution of the sample considering age and body mass index

	Group	N	Mean	Standard deviation	Minimum	Maximum	*p*
Age	Control	50	50.40	21.3	20	89	
							0.983
	Study	49	50.30	21.5	18	90	
Body mass index	Control	50	26.13	3.69	18.39	35.1	
							0.289
	Study	49	27.10	5.19	18.13	45.49	

Note: *t*-test.

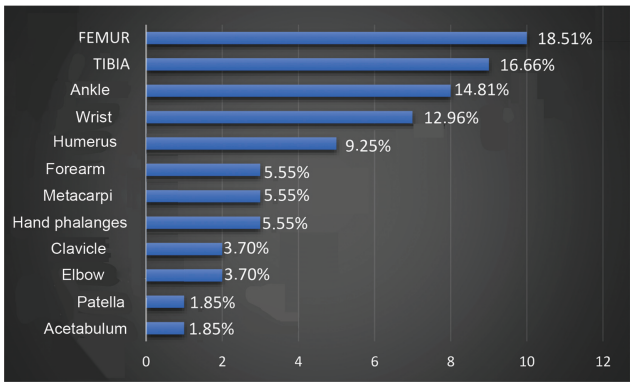


Fig. 1 Distribution of fractures (low- and high-energy traumas).

Table 4 25-hydroxyvitamin D dosage: comparison of the groups by the *t*-test

Groups	N	Mean (ng/mL)	Standard deviation	*p*
Study	49	23.78	8.01	**0.00***
Control	50	37.52	9.21	

Note: *Statistical significance.

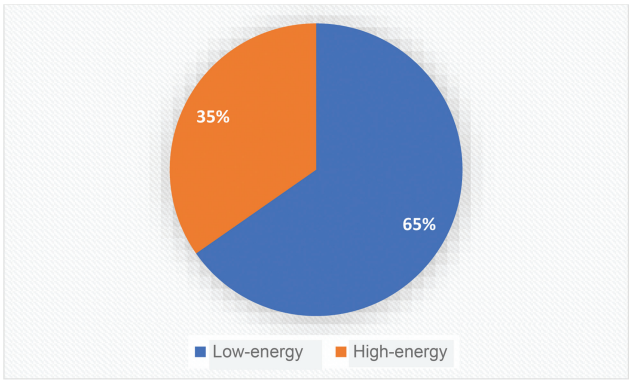


Fig. 2 Distribution of trauma energy (percentage of patients).

FA total of 54 fractures were observed in 49 patients, and 53.68% of them occurred in the lower limbs (►**Figure 1**). The mean level of 25(OH)D of the groups can be observed in Table **4**. In total, HVD was present in 30 (61.22%) patients with fractures (study group), and in 5 (10%) patients in the control group.

The distribution of fractures according to the intensity of the energy of the trauma is demonstrated in ►**Figure 2**, and its relationship with the degree of sufficiency of 25(OH)D is shown in ►**Figure 3**. The correlation between HVD and the occurrence of fractures is found in ►**Table 5**.

Discussion

Studies, including Systematic reviews[12–16] evaluated the dosage of VIT D in fractures and evidenced the importance of HVD in their occurrence (prevalence: between 40% and 100% of the cases).[12–16] In the present study, HVD was

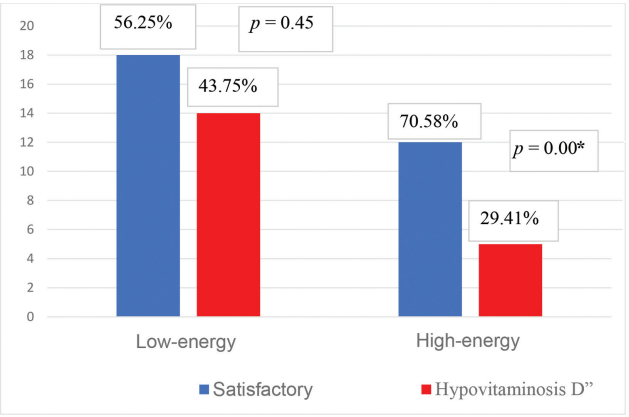


Fig. 3 Distribution of fractures according to trauma intensity and degree of vitamin D sufficiency (Fischer exact test). Note: *Statistical significance.

Table 5 Correlation between fractures and vitamin D by the Spearman coefficient

N (STUDY + CONTROL)	Spearman r	*p*
99	0.668	**0.00***

Note: *Statistical significance.

observed in 30 (61.22%) patients with fractures. There was a statistically significant difference regarding the dosage of VIT D between the groups, which enabled us to speculate that HVD was a facilitating agent for fractures (►**Tables 4** and **5**). Most studies mainly evaluate the elderly and post-menopausal women, who are populations at risk for osteoporosis;[7] therefore, these studies evaluate low-energy fractures, because they represent the highest percentage of fractures.[12,13,16] Fractures resulting from low-energy trauma tend to be spontaneous, due to falls from standing height, or to tortional mechanisms, and they mainly occur in the proximal femur, distal radius and spine,[12,16,17] especially in the elderly, among whom an episode within their own home is frequent. They are commonly unique lesions and are the ones that mostly require surgical treatment.[13] In studies that exclusively evaluated low-energy fractures, a higher frequency of fractures of the proximal femur [12,16] or wrist was found.[15] The present study evaluated all fractures that arrived consecutively in the emergency room, that is, low- and high-energy fractures, which were included in the study as long as they had a surgical indication. On the one hand, this could be a limiting factor of the present study, since fractures without surgical indication were not catalogued; however, it venous punctures that for the exclusive purpose of the present study were avoided. Low-energy fractures were also predominant in the present study (►**Figure 2**), but, unlike other publications[12,15,16], the highest incidence of low energy fractures occurred in the ankles (8 cases; 14.81% of the fractures). This discrepancy may be justified by the fact that, in the present study, unlike other studies[12,13,15,16], the male population composed most of the sample (63% of the

cases), and also because the mean age (50.30 years) was much lower than that found in other studies. Therefore, the sample of the present study was composed of a majority of patients of the male gender and of an age group in which proximal fractures of the femur are less frequent.

High-energy fractures are usually due to accidents that occur outside the home, such as car accidents; they are less evaluated, but these patients also tend to have a very high HVD index.[14] In the fractures caused by high-energy trauma in the present study, there were 29.41% of cases of HVD (►**Figure 3**).

Although the effect of VIT D on a fracture that already occurred is unknown and there is no concrete evidence that VIT D accelerates the consolidation process, its effect of increasing the vascularization of the bone callus,[18]increaseing bone strength and mineral density, as well as increasing the volume of the bone callus, is undeniable.[10,14] In addition, a study reported[19] HVD in 83% of the cases of pseudarthrosis and consolidation delays.[19] In a retrospective study, Gorter et al.[15] evaluated 617 patients with fractures (40% of prevalence of HVD) and observed that fracture consolidation was influenced by the status of VIT D at the time of the fracture.

It is customary that, in the case of fractures, the levels of VIT D fall sharply due to their consumption in the focus of the fracture, especially if the initial level is already low. This fall occurs between oneand three weeks after the fracture.[14] The initial levels of VIT D fall around 20% at the end of the first week.[20] This detail is considered a major factor in studies on HVD prevalence in fractures, but a significant part of the studies[12,13,15,16] does not mention the exact moment the levels of 25(OH)D were assessed. In the prsent study, this assessment occurred within 24 hours of the fracture. This detail also has importance in order to supplement more rigorously the patient with HVD who suffers a fracture.

Falls represent a marker of morbidity and mortality, especially in the elderly, and in about 10% of the times they cause fractures.[21] In Brazil, osteoporosis mainly affects women from metropolitan regions.[22] There is a high prevalence of HVD, especially among the elderly. In the present study, we observed that 93.33% of the elderly with fractures presented HVD. Fractures resulting from falls, especially in the hip, lead to death in about 20% of the cases and, in 50% of the non-fatal cases, they lead the elderly to become dependent.[23] The treatment of HVD in the elderly reduces falls by 20%, and in every 15 patients treated, a fall is prevented.[24] Adequate levels of VIT D reduce the risk of fractures by 20%.[25] It was also observed that the associated use of VIT D and calcium decreased by 15% the chance of developing fractures in general, and decreased hip fractures by 30%.[26]

The orthopedic surgeon should be prepared to recognize HVD and know how to track and treat it, or give the patient a referral.[27] In the daily practice, patients who are hospitalized with fractures to undergo surgical treatment have preoperative tests that usually do not involve the measurement of VIT D. Given the importance of VIT D in muscle strength and balance, and its role in fracture consolidation (although questionable), it is suggested that, whenever possible, the measurement of the levels of VIT D (a relatively expensive examination, not covered by the Brazilian Unified Health System [SUS, in Portuguese]), should be part of the preoperative routine, especially in the elderly or postmenopausal women with fractures, as well as its replacement, if necessary. Hypovitaminosis D is present in all age groups and population groups, especially among the Brazilian elderly, who depend on skin synthesis to obtain sufficiency.[5,6] Although exposure to the sun can increase the levels of VIT D, this organic management for the sufficiency of VIT D has been shown to be unfavorable in view of the potential carcinogenic effects of ultraviolet rays and changes in habits (protection against the sun), and also because the seasons and geographic latitude may prevent appropriate exposure to sunlight. Therefore, dietary supplementation has been the preferred method to manage VIT D levels. A study[24] conducted with healthy young adults showed that the use of VIT D is safe and does not have severe side effects, even in doses that are ten times greater than the recommended dose. The policy of supplementation of foods such as milk, orange juice and butter with VIT D proved to be efficient to increase the plasma concentrations of 25(OH)D in the countries in which it is enforced.[6] Similar policies could also be used in Brazil, with potential benefits for our geriatric population. Given the low cost, safety and demonstrated benefit of higher concentrations of 25(OH)D, VIT D supplementation should be a public health priority.[28] Although VIT D supplementation is considered inexpensive in food, in Brazil it is addded to specific foods that are not part of the routine feeding of the elderly. Until a broader VIT D supplementation becomes a reality in Brazil, traumatologists have a duty to know and correct HVD, especially in the elderly treated with fractures. The events of intoxication by VIT D are rare. It should be considered that, in selected cases, supplementation, although somewhat indiscriminate (it is not always possible to dose VIT D), can bring benefits that would overcome the risks of its deficiency and the high costs related to fractures.

Conclusion

Hypovitaminosis D was found in a significant percentage (61.22%)of the patients who suffered fractures. Further studies on the subject are needed to better understand the influence of HVD on the occurrence of fractures and the benefits of VIT D supplementation in these patients.

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

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Analysis of Intraoperative Exposure to X-rays and Surgical Time in Different Techniques for Fixation of Transtrochanteric Fractures of the Femur*

Análise da exposição intraoperatória ao raio X e do tempo cirúrgico em diferentes técnicas de fixação das fraturas transtrocanterianas do fêmur

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Abstract

Objective The present study aimed to evaluate and compare the total surgical procedure time and intraoperative X-ray exposure during different techniques for fixation of transtrochanteric fractures of the femur in elderly patients, using extramedullary and intramedullary methods based on cephalic traction screws.

Methods The Orthopedics and Traumatology Service from our hospital evaluated 107 patients with transtrochanteric fractures, including 34 males and 73 females, with age ranging from 61 to 101 years old. Fracture fixation was performed with a dynamic hip system (DHS) in 21 patients, a standard proximal femoral nail (PFN) in 55 subjects, and a standard gamma nail in 31 patients. All procedures were performed by the same surgeon and his team of nursing assistants, along with the same radiology technician using the same image intensifier. Total surgery time (in minutes) and X-ray emission (in centigrays [cGy]) were evaluated.

Results Transtrochanteric fracture fixation with PFN provides a significantly shorter surgical time ($p = 0.013$) in comparison to the 2 other techniques. Intraoperative exposure to X-rays was significantly lower when using DHS ($p = 0.015$) as a fixation method when compared with gamma nail and PFN.

Conclusion Although PFN resulted in the shortest surgical time, DHS was associated with the lowest X-ray exposure levels within the studied sample.

Keywords
- cancer
- femoral fractures
- internal fixators
- neoplasms, radiation-induced
- X-rays

* *Study developed at the Orthopedics and Traumatology Service, Hospital São Jose do Avaí, Itaperuna, RJ, Brazil.*

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Resumo

Objetivo Avaliar e comparar o tempo total do procedimento cirúrgico e a exposição ao raio X no intraoperatório em diferentes técnicas de fixação das fraturas transtrocanterianas do fêmur em pacientes idosos, utilizando técnicas extramedulares e intramedulares baseadas em parafuso de tração cefálico.

Métodos Foram avaliados no serviço de ortopedia e traumatologia do nosso hospital 107 pacientes com fraturas transtrocanterianas, sendo 34 do sexo masculino e 73 do sexo feminino, com idade mínima de 61 anos e máxima de 101 anos. As fraturas fixadas, utilizando a técnica com dynamic hip system (DHS, na sigla em inglês) somaram 21 pacientes; em 55 pacientes, foi utilizado o proximal femur nail (PFN, na sigla em inglês) standard; e em 31 idosos, foi optado pelo uso do gama nail standard. Todos os procedimentos foram realizados pelo mesmo cirurgião acompanhado de sua equipe de auxiliares de enfermagem, assim como pelo mesmo técnico de radiologia manuseando o mesmo intensificador de imagens. Foram avaliados o tempo total da cirurgia (em minutos) e a emissão de raios X medida em centigrays.

Resultados A fixação das fraturas transtrocanterianas com PFN proporciona um menor tempo cirúrgico com uma diferença estatística significativa ($p = 0,013$), quando comparada com as demais técnicas utilizadas entre os grupos envolvidos. Foi observada, também, uma menor exposição intraoperatória aos raios X ($p = 0,015$), a qual foi estatisticamente relevante quando utilizado o DHS como método de fixação comparado com o gama nail e o PFN.

Conclusão Apesar do PFN ter o menor tempo de cirurgia, a técnica do DHS se mostrou com menores níveis de exposição dentro da amostra estudada.

Palavras-chave

- câncer
- fraturas do fêmur
- fixadores internos
- neoplasias induzidas por radiação
- raios X

Introduction

Transtrochanteric fractures occur from the base of the femoral neck up to 2.5 cm distally to the lesser trochanter.[1] They are extracapsular injuries. These fractures mostly affect elderly patients who suffer falls from their own height or young people submitted to high-energy traumas.[2,3] The majority of these fractures should be surgically treated. Synthesis can be performed with intramedullary nails (proximal femoral nails [PFNs] and gamma nails) or extramedullary plates (dynamic hip system [DHS]). These three techniques are based on fixation with a sliding cephalic traction screw. Clinical outcomes from these techniques are similar, providing stable fracture fixation, early mobilization, bone consolidation with a low complication rate, and a quick return to usual activities.[1,3–5]

Diagnosis and treatment are contingent to imaging tests, including radiography and computed tomography (CT) scans. These resources increase diagnostic accuracy, leading to more specific treatments for each type of fracture, that is, the selection of the best fixation technique.

The introduction and development of image intensifier technology improved surgical procedures due to a better visualization for fracture reduction and implant positioning. In addition, image intensifier technology decreased surgical times, further improving clinical and functional outcomes.[3,6,7]

However, exposure to ionizing radiation has medium- and long-term negative consequences.[8] The accumulated radioactive load may cause and/or potentiate cancers due to the so-called stochastic effects; for instance, the likelihood of cancer is proportional to the radiation dose received.[9,10]

Transtrochanteric fractures require radiographic images for diagnosis and treatment; as such, patients are exposed to radiation twice. Therefore, the present study compared different surgical treatments for transtrochanteric fractures of the femur, all with similar outcomes,[11] to determine which has the shorter procedural time and lower radiation exposure to all involved personnel,[8] minimizing this harm.

Materials and Methods

This is a qualitative and quantitative study with a sample of 107 patients who underwent surgery for transtrochanteric femoral fractures correction at the Orthopedics and Traumatology Service of our institution from January 1 to December 31, 2017. Data on the type of fracture from each patient were collected using a protocol and classified by the authors of the present research. The sample consisted of 73 (68.2%) females and 34 (31.8%) males, with an average age of 81 years old, maximum age of 101 and minimum age of 61 years old. The type of implant used for fracture fixation, number of x-rays required for fixation, and surgical time were also determined.

Differences between techniques were determined by a nonparametric hypothesis test, the Mood median test. All procedures were performed by the same surgeon, the same

radiology technician, and the same image intensifier (Ziehm Solo Imaging).

In addition, the present study was based on a bibliographic research focused on a narrative literature review, defined as a comprehensive bibliographic research appropriate to describe, approach, and analyze the development of a certain object of study in the literature under a theoretical or contextual bias. Therefore, there is no conflict of interests. This research included textbooks and scientific papers from databases such as SciELO, PubMed, and RBO.

Results

A detailed data analysis was performed to summarize the features from each evaluated surgical technique, as well as their outcomes (►**Figure 1**).

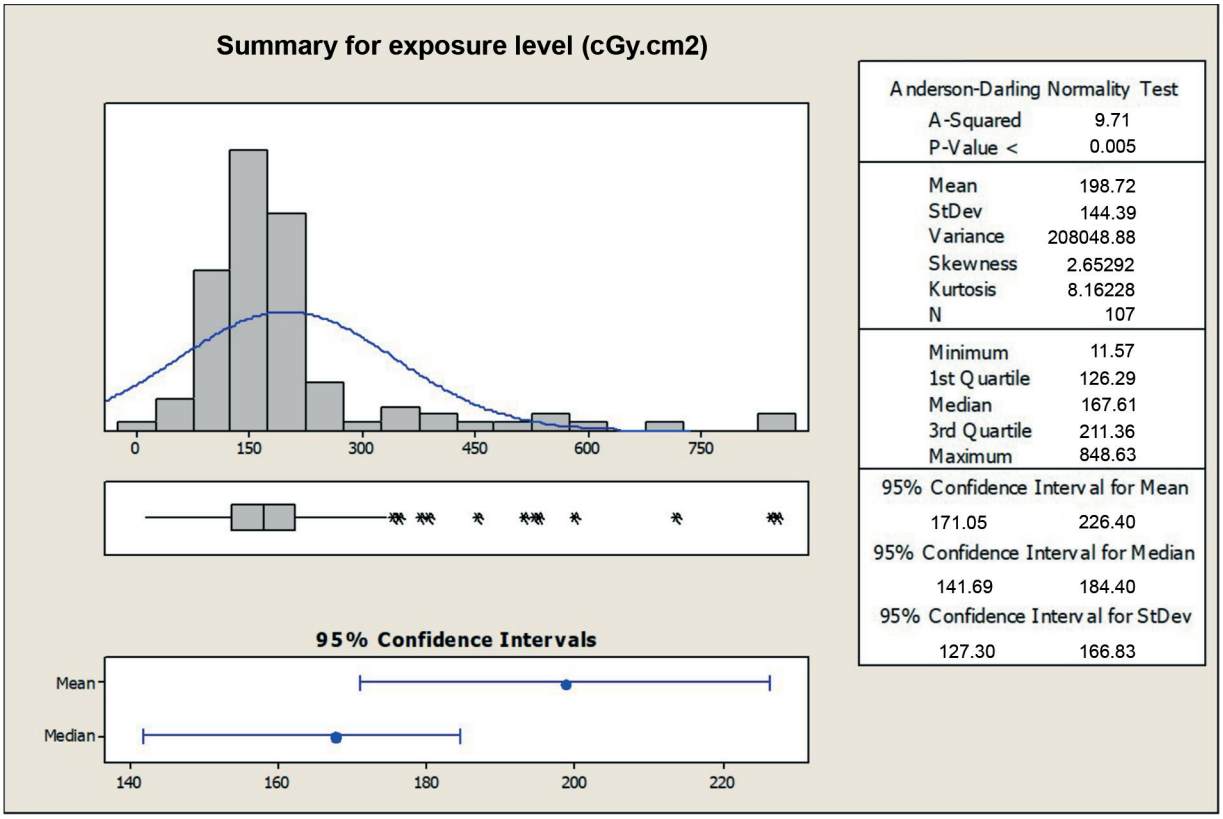


Fig. 1 Data was tested for normality to determine the types of tests that could be applied. When data does not follow normality ($p < 0.05$), the most suitable value for evaluations is median, instead of mean, as usual. The following values are showed here: $p < 0.005$; mean, 198.72; 11.57, minimum value; 848.63, maximum value. The median value (167.61) is the best measure for analysis due to the lack of normal distribution. Source: research data.

Mood Median Test: Nível de Exposição (cGy.cm2) versus Técnica Cirurgica

Mood median test for Nível de Exposição (cGy.cm2)
Chi-Square = 8,38 DF = 2 P = 0,015

Técnica Cirurgica	N<=	N>	Median	Q3-Q1	Individual 95,0% CIs
DHS	16	5	115	133	(--------*------)
GAMA	11	20	187	112	(-----*---)
PFN	27	28	168	84	(--------*----)

105 140 175 210

Overall median = 168

Fig. 2 Descriptive analysis of exposure level features per surgical technique. Source: research data.

General descriptive analysis of X-ray exposure level (cGy.cm2).

Differences between techniques were determined using a nonparametric hypothesis test, the Mood median test. Since our sample does not have a normal distribution (as previously shown), the test was based on median values of exposure levels between groups (►**Figure 2**).

- H0: Median values of exposure levels are equal (conservative hypothesis)
- Ha: At least one median value of the exposure levels from the groups is different from the other two.

The test allows us to affirm, with 95% confidence, that there is a statistically significant difference in at least one of the median values. H0 is rejected and Ha is accepted with a p-value equal to 0.015.

Median values show that gamma nails and PFNs have a higher level of exposure compared with DHS; however, we cannot statistically state that gamma nails are associated to a higher level of exposure than PFN, because their median values are statistically equal (note that their intervals overlap).

We also show boxplots, which are graphs used to visually compare two or more groups. The horizontal line dividing the boxes is the median value, whereas the vertical lines indicate the boundaries of continuous data (►**Figure 3**).

The following boxplots show data distribution as a form of representation. The line connecting the samples indicates the mean value, and the horizontal line at the center of each block is the median value (►**Figures 4** and **5**).

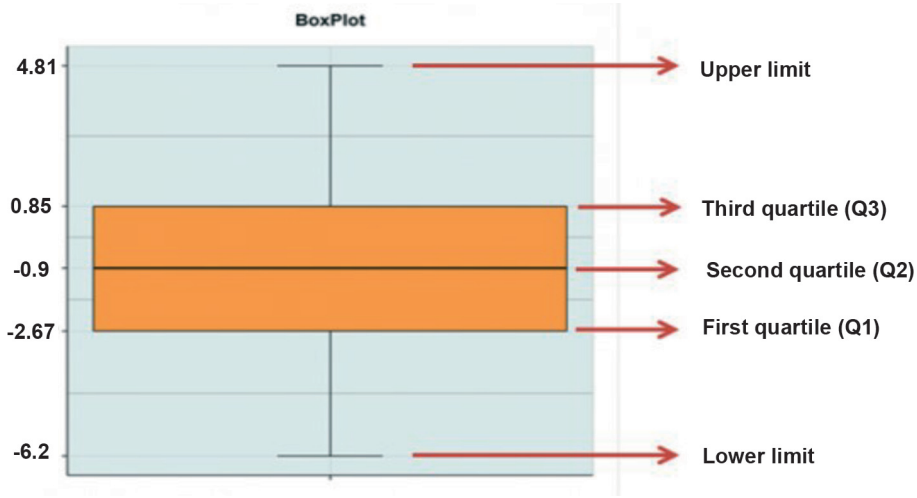


Fig. 3 Explanatory boxplot. Source: research data.

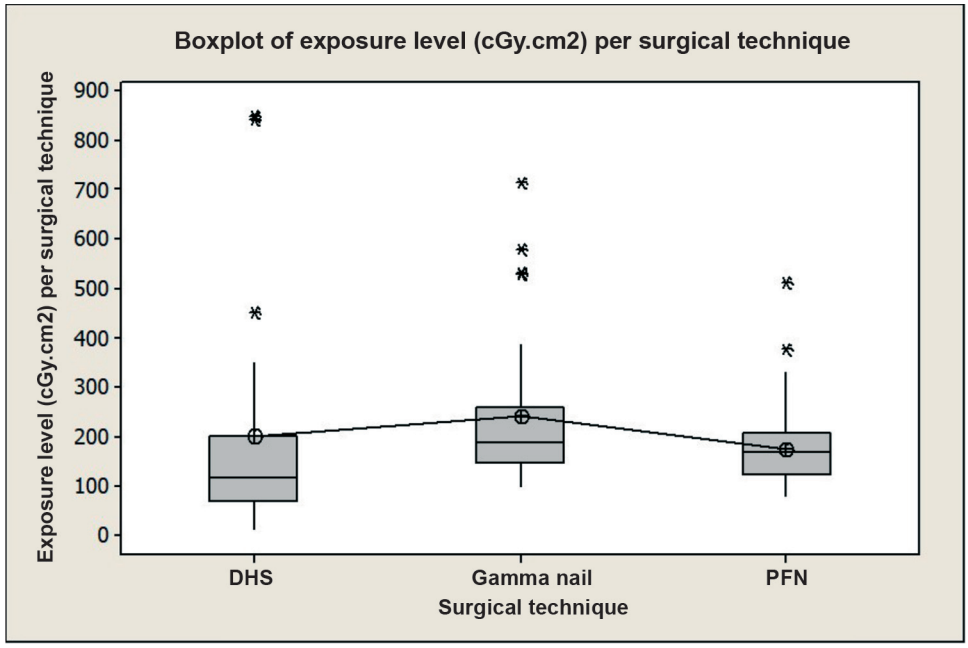


Fig. 4 Boxplot comparing surgical techniques. DHS, Dynamic hip system; PFN, proximal femoral nail. Source: research data.

Mood Median Test: Tempo cirurgia (min) versus Técnica Cirurgica

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Mood median test for Tempo cirurgia (min)
Chi-Square = 8,75    DF = 2    P = 0,013

Técnica                                  Individual 95,0% CIs
Cirurgica  N<=  N>  Median  Q3-Q1  ---------+---------+---------+-------
DHS          6  15    40,0   27,5            (-------*--------------)
GAMA        13  18    35,0   20,0       (-----*-----------)
PFN         35  20    30,0   10,0  (------*)
                                   ---------+---------+---------+-------
                                         32,0      40,0      48,0

Overall median = 30,0
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Fig. 5 Mood median test for surgical time versus surgical technique. Source: research data.

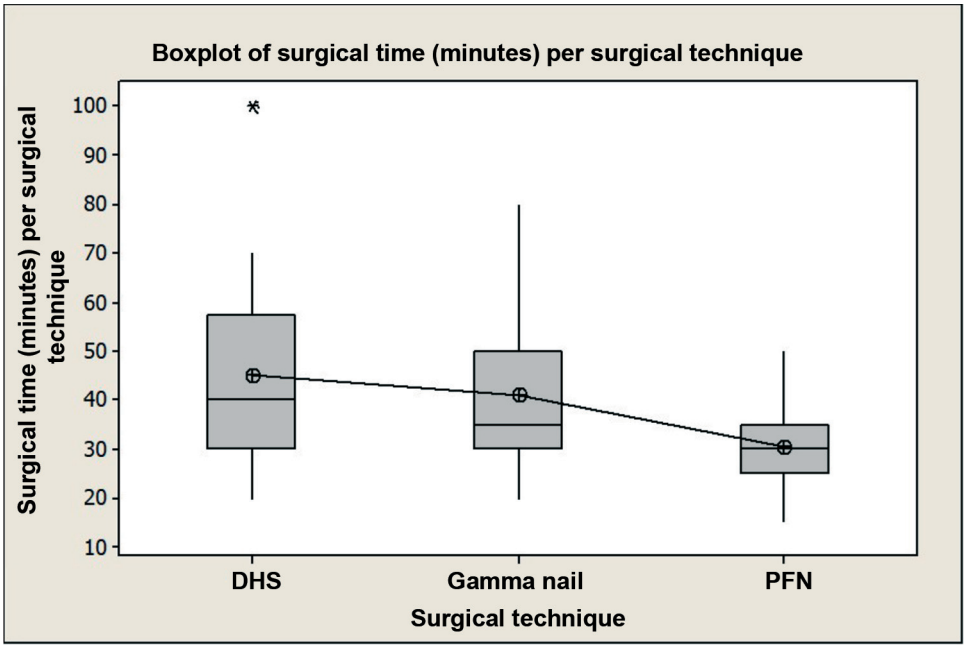


Fig. 6 Time versus technique boxplot. DHS, Dynamic hip system; PFN, proximal femoral nail. Source: research data – based on data from the Orthopedics and Traumatology Service from our institution.

Asterisks above each block are outliers, that is, "points outside the curve" with a very different behavior from the other points.

The test allows us to affirm, with 95% confidence, that there is a statistically significant difference in at least one of the median values. H0 is rejected and Ha is accepted with a p-value equal to 0.013.

Median values indicate that DHS is associated with a longer surgical time compared with PFN; however, we cannot affirm that DHS and gamma nails are statistically different. Similarly, gamma nails and PFNs present statistically equal median values (►**Figure 6**).

Discussion

The increased average life expectancy resulted in an expansion in surgeries for fractures of the proximal third of the femur, along with more studies to determine the best way to perform them. The estimated superiority in surgical time is associated with elevated intra- and postoperative complication rates in elderly patients, who are the most involved in this type of surgery. In contrast, shorter surgical times generate lower bleeding rates, hemodynamic instability, and anesthetic exposure.

In a study conducted at a multidisciplinary Government Hospital in India, Sharma et al.[3] compared clinical and radiological outcomes from patients with stable intertrochanteric fractures treated with PFN or DHS. The authors concluded that PFN provided significantly shorter surgical times ($p < 0.01$), smaller incisions and, consequently, a lower rate of surgical wound-related complications.

Zhang et al.[12] also compared surgical techniques using DHS and PFN to treat transtrochanteric fractures. Both studies concluded that there is a statistically significant difference regarding surgical time, and all statistical analyzes

corroborate that the PFN-type intramedullary nail is statistically associated with a shorter time when compared with DHS, an extramedullary technique.

Since the discovery of x-rays, the use of ionizing radiation for intraoperative assistance has been expanded with image intensifier devices. There is an increasing concern about radiation emissions involved in medical procedures due to their medium- and long-term negative effects. It is known that using appropriate personal protective equipment (PPE) and keeping the maximum possible distance from the x-ray beam represent effective solutions to maintain a reasonably safe level of exposure. The present study also demonstrated that the selected technique reduces radiation exposure in these work environments.

Sharma et al.[3] compared x-ray exposure using DHS (extramedullary technique) and PFN (intramedullary technique). The average exposure was 48.7 mGy/cm^2 with DHS and 71-mGy/cm^2 with PFN, with a significant difference ($p < 0.001$). For Rashid, who also compared these techniques, the average exposure was 668 mGy/cm^2 with DHS and 1,040 mGy/cm^2 with PFN, with a notable difference ($p < 0.001$). These findings are consistent with our study, which found a statistically significant difference ($p = 0.015$) when comparing an average exposure of 115 mGy/cm^2 with DHS versus 168 mGy/cm^2 with PFN, an increase in exposure close to 50% between both surgical techniques in these 2 studies.

Conclusion

Transtrochanteric fractures fixation using PFN had a shorter surgical time. However, DHS provided lower X-ray exposure, which was statistically significant when compared with gamma nails and PFNs, benefiting both the patient and health professionals involved in the procedure.

Therefore, based on this discussion and technical comparisons, the surgeon must decide which technique to use according to skill, experience and, of course, material availability at the institution. The surgeon needs to understand the risks and benefits of each technique, as well as their peculiarities, to make the best possible choice for both the surgical team and, especially, for the patient.

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

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Monitoring the Progress of Treatment in Fracture Non-Union: The Role of Alkaline Phosphatase and Ultrasonography*

Monitoramento da evolução do tratamento da ausência de consolidação da fratura: Papel da fosfatase alcalina e da ultrassonografia

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Abstract

Objective To evaluate the role of serum alkaline phosphatase (ALP) and ultrasonography (USG) in monitoring the progress of treatment in diaphyseal non-unions.

Methods This prospective observational cohort study included adult patients with diaphyseal fractures of major long bones previously treated with internal fixation and eventually resulting in non-union. Following the definitive treatment for non-union, the patients were followed-up periodically for six months, and serial monitoring of the levels of ALP and USG were performed along with radiographs (X-rays) to ascertain the status of the union.

Results After an initial rise at seven weeks, ALP levels declined to normal values in fractures which united, whereas they remained high in cases of persistent non-union. Similarly, after an elevation of the vascular resistive index (RI) at around 12 weeks in all the patients, it decreased in cases progressing to union, while it remained persistently high even at 24 weeks in fractures failing to unite. Cases of persistent non-union continued to show hypoechogenic callus at 24 weeks instead of converting into hyperechogenic callus, as observed in cases which progressed to union.

Conclusion Significant changes suggestive of union appeared simultaneously on the X-rays, USG and ALP levels during the follow-up. However, a serial examination of the ALP levels and USG during the follow-up gave a hint of the direction of progress in the healing process of fracture non-union. Their role in monitoring the outcome of non-union is more complimentary than supplementary to the X-rays.

Keywords
- bony callus
- ultrasonography
- alkaline phosphatase

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Resumo

Objetivo Avaliar o papel da concentração sérica de fosfatase alcalina (FA) e da ultrassonografia no monitoramento do progresso do tratamento da ausência de consolidação em fraturas diafisárias.

Métodos Este estudo de coorte observacional prospectivo incluiu pacientes adultos com fraturas diafisárias dos principais ossos longos previamente submetidas a fixação interna sem consolidação. Após o tratamento definitivo, os pacientes foram avaliados periodicamente por seis meses, com realização seriada de ultrassonografia, determinação da concentração de FA, e radiografias para verificar a presença de consolidação.

Resultados Após um aumento inicial em sete semanas, os níveis de FA voltaram ao valor normal em pacientes com fraturas consolidadas, mas continuaram elevados nos casos de ausência de consolidação. Da mesma forma, após uma elevação do índice de resistência (IR) vascular em cerca de 12 semanas em todos os pacientes, o IR diminuiu nos casos que progrediram para consolidação, mas continuou alto até as 24 semanas em fraturas não consolidadas. Os casos com ausência de consolidação ainda apresentavam calo hipoecogênico às 24 semanas, que não se converteu no calo hiperecogênico observado nos casos que progrediram para consolidação.

Conclusão Alterações significativas sugestivas de consolidação foram simultaneamente observadas nas radiografias, na ultrassonografia e na concentração de FA durante o período de acompanhamento. No entanto, a realização seriada de exames da concentração de FA e de ultrassonografia durante o acompanhamento indicou o progresso da consolidação da fratura. Seu papel no monitoramento da ausência de consolidação é mais complementar do que suplementar à radiografia.

Palavras-chave

- calo ósseo
- ultrassonografia
- fosfatase alcalina

Introduction

Fracture non-union is an outcome difficult to predict, and even though it is an established complication, in the clinical practice, both clinicians and patients deem it a poor outcome.[1] There is variability in the clinical assessment of the status of union in fractures and a lack of consensus on the the reliability of various methods to assess the progress of the union. Clinical appreciation combined with X-rays is used for the assessment of both acute fractures and non-unions, even though other methods to monitor and document bone healing, like computed tomography (CT), magnetic resonance imaging (MRI), bone scintigraphy etc., have been used sparingly in select cases. However, in addition to the concern regarding availability, these advanced investigations represent an added financial burden and/or pose a risk of radiation exposure to the patient. The objective of the present study was to evaluate the role of alternative investigative methods: serum alkaline phosphatase (ALP) and ultrasonography (USG), and compare them with the conventional radiograph (X-ray) in monitoring the progress of treatment in diaphyseal non-unions. In addition to being inexpensive and easily available, USG and the measurementof the levels of ALP were selected to represent physical and biochemical markers of union respectively.

Methodology

This prospective observational study was performed at a state-run tertiary care hospital attached to a postgraduate teaching institute from April 2018 to September 2019, with due permission from the Institutional Ethics Committee. Diaphyseal fractures of major long bones that is, the femur, tibia (with or without the fibula), humerus and the radius and ulna (individually / combined), previously treated with any type of internal fixation in adults ($>$ 18years), and eventually resulting in non-union, were included in the study. Only those patients with normal liver function confirmed by USG and serum biochemical tests were included in the study. The treatment of non-union remained independent of the study. All patients were followed up for six months at six-week intervals. At each follow-up visit, all patients were assessed clinically and by plain radiographs for signs of union. In addition to serial ALP measurements, at each follow-up, the fractures were evaluated by USG for echogenecity and measurement of the vascular resistive index (RI) of the callus. The measurement of the ALP levels was performed spectrophotometrically using the p-nitrophenylphosphate (PNPP) kinetic International Federation of Clinical Chemistry (IFCC) method with a laboratory reference range of 28 IU/L to 111 IU/L. The USG was performed using a Philips (Amsterdam, The Netherlands) iU22 camera equipped with a linear probe with a resolution of 12 MHz to 5 MHz, MSK Superficial program and 3D Power Color Doppler. Whereas the authors evaluated fracture healing using plain radiographs, the USG examination of the fracture was performed by an independent radiologist without the knowledge of the X-ray status. ►**Fig. 1** shows a brief overview of the methodology.

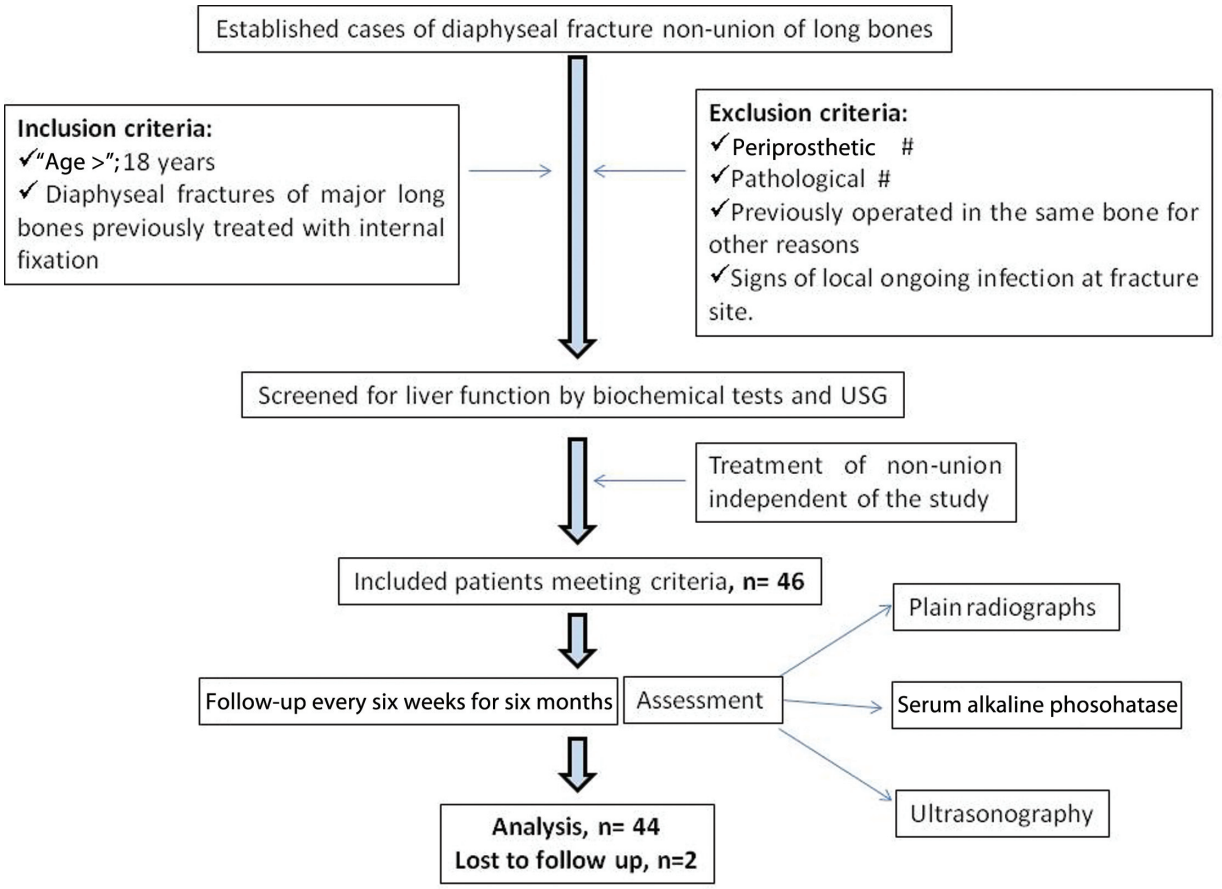


Fig. 1 Flowchart showing the basic methodology applied to the present study.

Observations and Results

The sample for the final follow-up and analysis was composed of 44 patients (36 male, 8 female). These included 20 cases of upper-limb and 24 cases of lower-limb diaphyseal non-unions. Morphologically, there were 24 cases of atrophic, 6 cases of hypertrophic and 14 cases of comminuted non-unions. The average age of the patients was 37 (range: 18 to 75) years. In total, 28 patients underwent cancellous/tricortical/fibular bone grafting, 6 were stabilized by additional fixation, 4 patients were subjected to implant extraction followed by functional bracing, 4 patients were treated by late dynamisation of statically interlocked nail, and the remaining 2 were treated by an Illizarov ring fixator. ►**Table 1** shows a summary of the observations with reference to the outcome of the study. Illustrative cases are shown in ►**Figs. 2**, **3** and **4**.

X-ray

We considered a fracture radiologically united only when the X-rays showed bridging bone across the fracture in both orthogonal views. A total of 30 patients showed signs of union, and 14 patients showed persistent non-union on the X-rays at the final follow-up (►**Figs. 2d**, **3d** and **4d**). During the follow-up, calluses were observed as early as 12 weeks and as late as 24 weeks. The average union time as assessed by the X-rays was of 18.8 (range: 12 to 24) weeks. Bone grafting ($n = 22$) showed more promising results in achieving union.

Serum Alkaline Phosphatase

It has been our observation that patients with established non-union who present within six months of the primary surgery usually have ALP levels > 110 IU/L. The average ALP level as measured when the patients were recruited to the study was of 120 (range: 42 to 202) IU/L. The average peak level reached during the study was of 180 (range: 136 to 216) IU/L. The levels of ALP initially increased in all cases and reached a peak at around 7 weeks. In fractures which progressed toward union, the ALP levels dropped to normal by the end of the study period, whereas, in cases which failed to unite, the ALP levels continued to remain high following the initial spike until the end of the study period (►**Fig. 5**). The average ALP level at the end of the study period in united and persistent non-union cases were of 94 IU/L and 128 IU/L respectively.

Ultrasonography

The assessment of union in fractures by USG was performed qualitatively, by the echogenicity of the callus, and quantitatively, by measuring the vascular RI.[2]

In the sample, there were established cases of non-union. Hence, a hypoechoic structure (fibrous tissue) was observed since the first day of recruitment. However, in contrast to the homogenously hypoechoic signals of a newly-formed hematoma converting to soft callus, in our cases, gray-scale USG at recruitment showed heterogenous-hypoechogenicity due to

Table 1 Summary of the observations regarding the outcomes of the study

Outcome→	Union	Non-union	Total/Gross
Parameters ↓			
Number of cases	30	14	44
Type of non-union			
Atrophic	18	6	24
Hypertrophic	4	2	6
Comminuted	8	6	14
Average level of serum akaline phosphatase (28–111 IU/L)			
At admission	121	118	120
At the final follow-up	94	128	105
Peak value during the study	179	181	180
Average resistive index (ultrasonography)			
At admission	0.28	0.12	0.22
At the final follow-up	0.22	0.9	0.44
Peak value during the study	0.79	1.04	0.87
Follow-up (weeks)			
Peak level of serum akaline phosphatase	7.2	6.9	7.0
Peak value of the resistive index	14.4	21.4	16.6
Hyperechoic callus on ultrasonography	20	Not observed	20
Callus on X-ray (union time)	18.8	Not observed	18.8

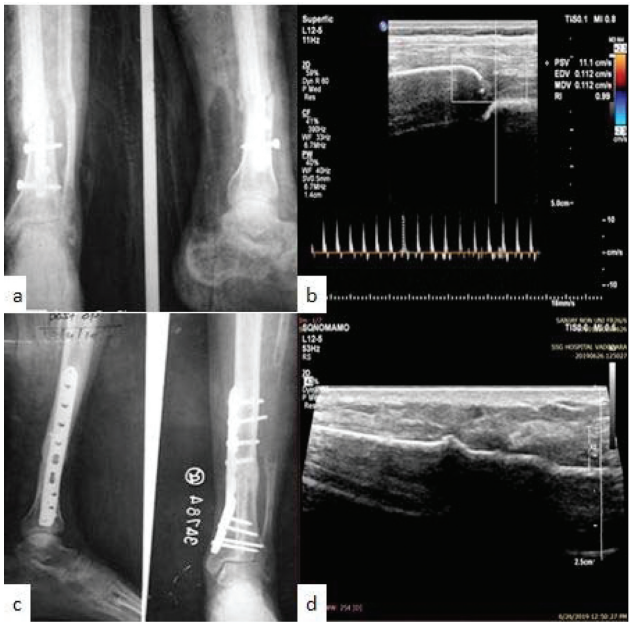


Fig. 2 Illustrative Case1. (**A**) X-ray showing non-union of the distal tibia; (**B**) ultrasonography (USG) showing fracture gap with high resistive index; (**C**) fracture union after bone grafting at 24 weeks; and (**D**) USG at 24 weeks showing hyperechoic signals and absent vascular resistance.



Fig. 3 Illustrative Case2. (**A**) X-ray showing non-union of the proximal tibia; (**B**) USG showing heterogenous hypoechoic signals of non-union; (**C**) fracture union after bone grafting at 18 weeks; and (**D**) USG at 18 weeks showing hyperechoic signals.

the fibrosclerosis that had ensued within the non-union (►**Figs. 2b**, **3b** and **4b**). The average time taken for hyperechoic callus suggestive of mineralization to appear in uniting fractures was of 20 (range: 18 to 24) weeks. In cases which failed to unite, the USG examination continued to show hypoechogenicity at 24 weeks (►**Fig. 4d**).

The average of RI score as measured when the patients were recruited to the study was of 0.22, with 30 patients showing non-recordable levels (due to fibrosclerosis). Irrespective of the outcome, a steady elevation in RI scores was observed in all

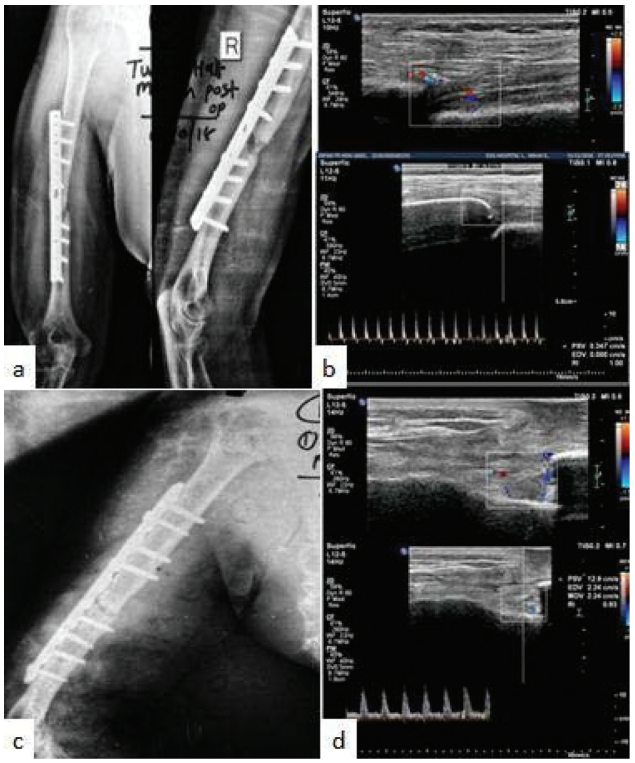


Fig. 4 Illustrative Case3. (**A**) X-ray showing non-union shaft of the humerus; (**B**) USG showing fracture gap with high resistive index; (**C**) persistent fracture non-union after 24 weeks of the revision surgery; and (**D**) USG at 24 weeks showing fracture gap, hypoechoic signals and high vascular resistance.

cases until around 12 to 18 weeks. The RI scores decreased following their elevation in patients progressing to union. In fractures failing to unite, they persistently remained high even at 24 weeks (►**Fig. 6**). The average RI scores at the final follow-up in united and persistent non-union cases were of 0.22 and 0.90 respectively (►**Fig. 2d**, **3d** and **4d**).

A gross analysis of the findings of the study (►**Table 2**) was attempted using the frequency with which all parameters that is, the X-ray, ALP levels, hyperechoic callus and RI scores, showed positive signs of union at different intervals during the follow up. Bridging callus on X-ray, ALP levels within the laboratory reference range, hyperechoic signals on gray-scale USG and a lower RI score as compared with the previous reading on the Doppler USG were considered signs of progress of the union. In the present analysis, the cases of each parameter were mutually inclusive for that follow-up time. The earliest time when the ALP levels and the USG predicted a possible outcome of the treatment (12 to 18 weeks) coincided with the early changes observed on the X-rays.

Discussion

The non-union of diaphyseal fractures to long bones, which otherwise have a lower incidence, represent an uphill task to the treating surgeon. Although much information is available in the literature regarding non-union, to the best of our knowledge, we could not find any perfectly-matching study that described the monitoring of the progress of the treatment in cases of long-bone non-union. A detailed evaluation of studies regarding the value of the laboratory and imaging

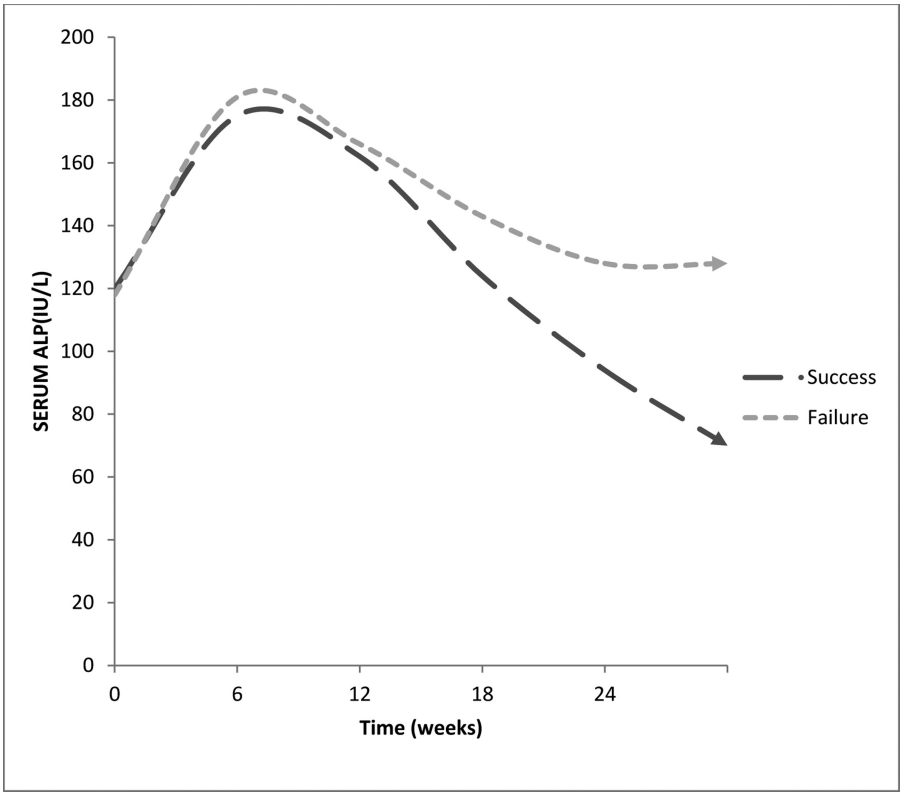


Fig. 5 Trend of average serum alkaline phosphatase levels in cases of union and non-union.

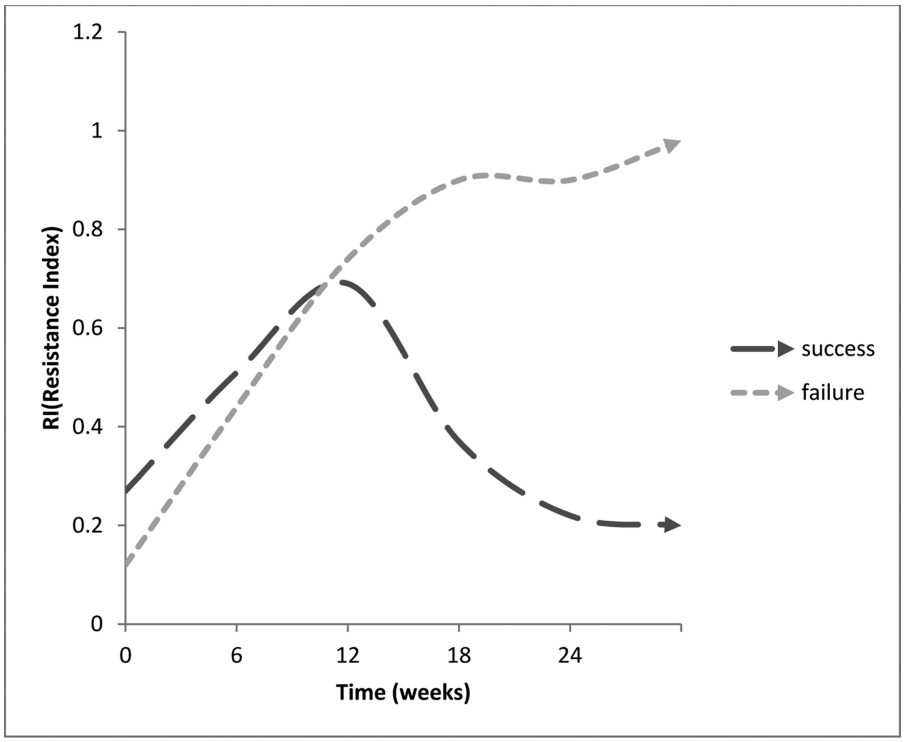


Fig. 6 Trend of average vascular resistive index in cases of union and non-union.

Table 2 Analysis of the findings of the present study

Investigation	Number of patients			
	At 6 weeks	At 12 weeks	At 18 weeks	At 24 weeks
X-ray (bridging callus)	0	4	22	30
Level of serum akaline phosphatase (< 111 IU/L)	0	0	8	30
Ultrasonography (hyperechoic signal+ decreasing resistive index)	0	0	20	30

studies in cases of long-bone non-union in animals was performed by Zimmermann et al.[3] However, most of these studies cannot be properly reproduced in the routine clinical practice. Clinical improvement, such as painless weight bearing, use of the affected extremity, and lack of swelling and tenderness have always comforted both patient and surgeon as a reflection of a fair progress. Supportive radiological evidences such as that of X-rays and CT scans have reinforced such clinical impressions. In the qualitative assessment, the line, margins and gaps of the fracture, the external callus, the callus-to-cortex ratio and the bridging callus are examined. Advanced diagnostic methods, like dual-energy X-ray absorptiometry (DEXA) scans, multidirectional CT and laboratory tests, like the measurment of the levels of done-specific alkaline phosphatase, matrix metalloproteases and specific growth factors[4] etc., have booked a place in theoretical texts, but have yet to find place in the routine clinical practice.

Several studies[5–8] have been published supporting the evidence that the ALP levels can be used as an adjunct biomarker to the clinical and radiological evidences of healing. In clinical trials,[9,10] ALP levels showed a significantly higher baseline and a tendency towards a slow increase during the first two months of healing in acute fractures, and this might help to predict delayed fracture healing. This increase in ALP activity observed is assumed to happen due to the rising concentration of the bone isoenzyme of ALP during the healing process,[11] and it coincides with the beginning of mineralization.[12] In line with the studies related to biological markers in acute fractures, ALP levels temporarily increased after the intervention for up to seven weeks in all patients, followed by normalization in those showing signs of union in the present study. Based on this, we believe that, as observed in acute fractures, serial ALP measurements have significance in monitoring the treatment of fracture non-unions as well.

The evaluation of the callus by USG has been well described in the literature, which reports that the callus can be observed much sooner on the USG than on plain X-rays.[13–16] Significant changes in the mineral composition of the callus during fracture healing changes the speed of the reflected wave (echo) picked up by the transducers. Based on this echo pattern, the callus is labeled either as hypoechoic or hyperechoic.[17] Early (soft) calluses in fresh fractures are seen as homogenous-hypoechoic which, with mineralization, mature

to homogenous-hyperechoic (hard) calluses over time. The presence of a hyperechoic ultrasonographic signal from the fracture site was found to have 100% of correlation with the presence of a hard callus on the biopsy.[14] Fractures which fail to progressively unite show persistence of the hypoechgenic pattern. Fibrous tissue is seen as a heterogenous hypoechoic strutucture in cases of non-union.[12] Chachan et al.[18] compared the efficacy of plain radiography versus USG in monitoring fracture healing, and found the sensitivity and specificity of USG to diagnose fracture union to be of 100% and 80% respectively. In the present study, over the course of up to 16 weeks, all patients showed hypoechoic calluses, which converted to hyperechoic calluses in the patients showing signs of union, and remained hypoechoic in those with persistent non-union. Fibrosclerotic tissue within the non-union site was a significant limiting factor in the qualitative evaluation of the callus by USG in the present study. In our sample consisting exclusively of cases of non-union, the absence of hematoma-induced periosteal reaction and mixed echogenic images due to a standstill in the initial healing process might have been the factors that led to the underestimation of the onset of healing as diagnosed by USG.

The process of fracture healing can be followed with color Doppler imaging and spectral analysis.[19] The USG is able to follow the formation of new vessels at the fracture site and to assess flow characteristics in them during the development of the fracture callus. In addition to following the formation of new vessels at the fracture site, Doppler USG can measure the RI, which reflects the resistance to blood flow caused by a microvascular bed distal to the site of measurement. In patients with normal callus development, the caliber of the afferent vessels progressively increases, and their number decreases. The RI progressively increases, up to values similar to those of nutrient vessels (0.36 to 0.90). Within the second month of the fracture, a muscular tunic develops in the vessel wall, converting to a mature vessel with the progressing mineralization of the cortex, thus causing the RI to progressively decrease and finally disappear.[11] On the other hand, patients with non-union and delayed healing have persistent higher resistance related to a poor formation of neovasculature and increasing peripheral resistance in the residual vessels because of the fibrosclerotic involution of bone healing[11] (►**Fig. 7**). In consistence with the aforesaid description, in the present study, the RI steadily increased until around 12 weeks in all patients; subsequently, at 24 weeks, patients who progressed to union showed low RIs, and those who progressed toward non-union had persistently high RIs.

A gross analysis of the findings of the present study showed that changes in ALP levels, USG and X-rays occurred simultaneously during the follow-up in cases of fracture non-union. None of them proved superior in terms of early prediction of the outcome. Nevertheless, a serial examination of ALP levels and USG during the follow-up gave a hint of the direction of progress in the healing process of the fracture. There is still a great need for scientific research before biological markers like the ALP can be used to make major treatment decisions. Although USG has been established to be a reliable technique for the early diagnosis of healing in acute fractures, its role in outcome evaluation in cases of non-union is yet to be determined. Whereas spot X-rays provide qualitative information regarding the changes during fracture healing, isolated ALP and USG findings have no defined laboratory limits for the period of follow-up after fixation, which can be used to separate individual cases into favorable and unfavorable categories. Furthermore, the USG requires training and

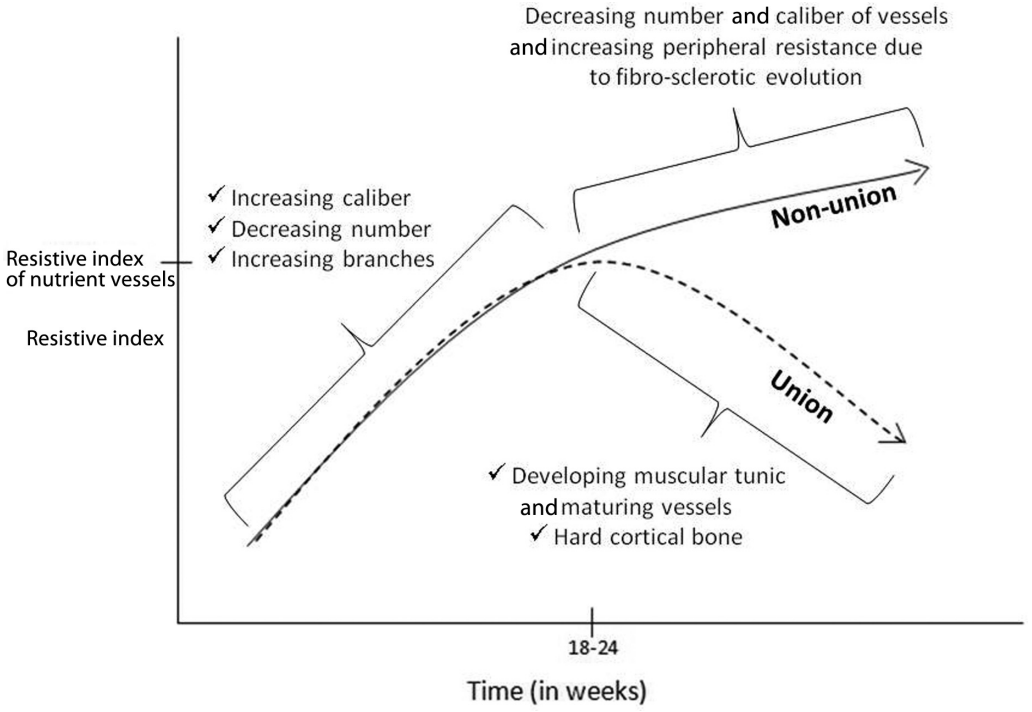


Fig. 7 Vascular changes and their effect on the resistive index in cases of union and non-union.

technical expertise to demonstrate the required results. This could possibly be a limitation to the widespread use of USG for such cases. Although the equipment is easy to procure, not all institutions have on staff professionals trained to evaluate the healing process. Moreover, a study on the cost-effectiveness of USG could further validate the role of USG in monitoring fracture healing. The conventional plain radiograph will surely remain a popular method of assessment because of its long time-tested history, practicality, and lower costs.[1,18]

Conclusion

The limited sample size of the present study ruled out any statistical conclusion. Significant changes suggestive of union were simultaneously observed on X-rays, USG and ALP levels during the follow-up. The earliest period when ALP levels and USG predicted a possible outcome coincided with the early changes observed on the X-rays. However, the serial evaluation of ALP levels and USG definitely gave a hint regarding the direction of the progress of the treatment. At present, their role in monitoring the outcome of non-union is more complimentary than supplementary to the X-rays.

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

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Evaluation of Hormonal Influence in Patients with Fractures Attributed to Osteoporosis*

Avaliação da influência hormonal em pacientes com fraturas atribuídas a osteoporose

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Abstract

Objective The present study aims to evaluate the influence of hormonal levels of vitamin D, calcitonin, testosterone, estradiol, and parathyroid in patients with fractures attributed to osteoporosis when compared with young patients with fractures resulting from high-impact accidents.

Methods Blood samples were collected from 30 elderly patients with osteoporosis-attributed fractures (T-score $\leq$ -2.5) (osteoporotic group), and from 30 young patients with fractures resulting from high-impact accidents (control group). Measurement of 1,25-hydroxyvitamin D (Kit Diasorin, Saluggia, Italy), calcitonin (Kit Siemens, Tarrytown, NY, USA), testosterone, estradiol, and parathyroid hormone (Kit Beckman Couter, Indianapolis, IN, United States) was performed using a chemiluminescence technique. Data were inserted into a Microsoft Excel (Microsoft Corp., Armonk, WA, USA) spreadsheet and analyzed using Statview statistical software. Results showing non-normal distribution were analyzed with nonparametric methods. The Mann-Whitney test was applied for group comparison, and a Spearman test correlated hormonal levels. Statistical significance was set at $p < 0.05$. All analyzes compared gender and subjects with and without osteoporosis.

Results Women with osteoporosis had significantly lower levels of estradiol and vitamin D ($p = 0.047$ and $p = 0.0275$, respectively). Men with osteoporosis presented significantly higher levels of parathyroid hormone ($p = 0.0065$). There was no significant difference in testosterone and calcitonin levels.

Keywords
- osteoporosis
- hormones
- estradiol
- calcitonin
- parathyroid hormone

* *Study developed at the Immunology Laboratory, Department of Biological Sciences, Universidade Federal do Triângulo Mineiro, Uberaba, MG, Brazil.*

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Conclusion Osteoporosis patients presented gender-related hormonal differences. Women had significantly lower levels of estradiol and vitamin D, whereas men had significantly higher parathyroid hormone levels, apparently impacting the disease.

Resumo

Objetivo Avaliar a influência dos níveis hormonais de vitamina D, calcitonina, testosterona, estradiol e paratormônio em pacientes com fratura atribuída a osteoporose, quando comparados com pacientes jovens que tiveram fraturas decorrentes de acidente de alto impacto.

Métodos Foram coletadas amostras de sangue de 30 pacientes idosos com fratura atribuída a osteoporose (T-score $\leq$ -2,5) (grupo com osteoporose) e 30 amostras de sangue de pacientes jovens que sofreram fraturas decorrentes de acidentes de alto impacto (grupo controle). Foram realizadas dosagem de 1,25-hidroxivitamina D (Kit Diasorin, Saluggia, Italy), calcitonina (Kit Siemens, Tarrytown, NY, USA), testosterona, estradiol e paratormônio (Kit Beckman Couter, Indianapolis, IN, United States) pela técnica de quimiluminescência. Os dados foram inseridos em uma planilha de dados no programa Microsoft Excel (Microsoft Corp., Redmond, WA, EUA) e analisados pelo programa de estatística Statview. Os resultados que apresentaram distribuição não normal foram analisados com métodos não paramétricos. Para análise de variáveis comparando-se os dois grupos, aplicou-se o teste Mann-Whitney. Foi utilizado o teste de correlação de Spearman para a correlacionar os níveis hormonais. Um valor-p $>$0.05 foi considerado significante. Todas as análises foram feitas comparando gênero e grupos de pacientes com e sem osteoporose.

Resultados Mulheres com osteoporose apresentam níveis significativamente menores de estradiol e vitamina D ($p = 0.047$ e $p = 0.0275$), respectivamente. Homens com osteoporose demonstraram níveis significativamente maiores de paratormônio ($p = 0.0065$). Não houve diferença significativa nos níveis de testosterona e calcitonina.

Conclusão Existem diferenças hormonais entre os gêneros na osteoporose. Em mulheres, níveis significativamente menores de estradiol e vitamina D e, nos homens, níveis significativamente maiores de paratormônio, parecem influenciar na doença.

Palavras-chave
- osteoporose
- hormônios
- estradiol
- calcitonina
- hormônio paratireóideo

Introduction

Osteoporosis results from an imbalance in normal bone metabolism between osteoblasts and osteoclasts.[1] Osteoclasts seem more active than osteoblasts in bone resorption processes.[2,3] Studies indicate that hormones may play an important role in imbalanced bone formation,[4] since parathyroid hormone apparently induces osteocytes differentiation into osteoclasts.[5] Likewise, hormones such as estradiol and testosterone are supposedly important,[6–8] and testosterone acts by inhibiting osteoblast apoptosis.[9] On the other hand, estrogen seems critical to bone remodeling both in males and females, since it apparently stimulates calcitonin release and activates intestinal vitamin D receptors, resulting in endocrine and immune functions during bone metabolism.[10,11] Calcitonin and vitamin D help to maintain adequate serum concentrations of calcium to allow normal bone mineralization. In addition, vitamin D is required for bone growth and remodeling by osteoblasts and osteoclasts.[12]

The increase in life expectancy resulted in a considerable increase in diseases associated with hormonal changes, including osteoporosis, warranting the focus on studies to clarify these interactions.

The present study aims to evaluate the influence of hormonal serum levels of vitamin D, calcitonin, testosterone, estradiol, and parathyroid hormone in patients with fractures attributed to osteoporosis in comparison with young patients with fractures resulting from high-impact accidents.

Materials and Methods

The present project was approved by the Ethics Committee under protocol number 51827515.4.0000.5145.

Study Group

Blood samples were collected from 30 elderly patients with fractures attributed to osteoporosis (T-score $\leq$ -2.5) (osteoporotic group), and from 30 young patients with fractures resulting from high-impact accidents (control group). Patients with other bone conditions, nonosteoporotic fractures, immunosuppression, malignant neoplasms, or liver disorders were excluded from the study, along with those who did not agree to participate in it. Serum collected from these patients was used for hormone measurement.

Blood Collection

Venous blood collection was always performed in the morning, 1 day after the bone reconstruction surgery indicated by the orthopedist. A blood sample was obtained by venipuncture, using three vacuum collection tubes containing a clot activator and separating gel. Thirty minutes after collection, the samples were centrifuged at 5,000 rotations per minute (rpm) for 10 minutes to obtain serum.

Hormonal Analysis

Serum obtained after blood samples centrifuging was sent for hormonal analysis. Measurement of 1,25-hydroxyvitamin D (Kit Diasorin, Saluggia, Italy), calcitonin (Kit Siemens, Tarrytown, NY, USA), testosterone, estradiol, and parathyroid hormone (Kit Beckman Couter, Indianapolis, IN, United States) was performed using a chemiluminescence technique, a chemical reaction that generates luminous energy. Chemiluminescence reagents are transformed into electrically excited intermediate states and release the absorbed energy as light when becoming less excited.

Statistical Analysis

Data were inserted into a Microsoft Excel (Microsoft Corp., Redmond, WA, USA) spreadsheet and analyzed using Statview statistical software. Results showing non-normal distribution were analyzed with nonparametric methods. The Mann-Whitney test was applied for group comparison, and a Spearman test correlated hormonal levels. Statistical significance was set at $p < 0.05$.

Results

The present study measured hormones in 30 patients with osteoporosis and in 30 control subjects, totaling 60 people.

The mean age of the patients was 58.8 ± 22.61 years old, and all analyzes compared gender and subjects with or without osteoporosis. ►**Table 1** shows the number of patients and the mean age from each group.

In the control group, serum vitamin D levels were significantly higher in females when compared with males (Mann-Whitney test; $p = 0.0169$). Comparing both groups (osteoporosis and control subjects), serum vitamin D levels were significantly higher in women from the control group than in women with osteoporosis ($p = 0.0275$). There was no significant difference between males and females from the osteoporosis group (►**Figure 1A**).

Significantly higher free testosterone levels were observed in males when compared with females in both the control and osteoporotic groups (Mann-Whitney test; $^{*}p = 0.0023$ and $^{**}p = 0.0046$). There was no significant difference in free testosterone levels between males from the control and osteoporotic groups (►**Figure 1B**).

Estradiol levels were significantly lower in women with osteoporosis compared with those of the control group (Mann-Whitney test; $p = 0.047$). There was no significant difference in estradiol levels between men and women from the control group and the osteoporotic group (►**Figure 1C**).

Parathyroid hormone levels were significantly higher in men with osteoporosis when compared with the control group (Mann-Whitney test; $p = 0.0065$). There was no significant difference between women from the control group and women with osteoporosis. No significant difference was observed in parathyroid hormone levels when comparing males and females with or without osteoporosis (►**Figure 1D**).

There was no significant difference in calcitonin levels between the control and osteoporotic groups, regardless of gender. In addition, there was no significant difference when comparing men and women from both groups (►**Figure 1E**).

Discussion

Osteoporosis results from an imbalance of bone remodeling potentially caused by hormonal factors. In addition, more recent studies show that immunological factors also play a role in the pathophysiology of the disease. The present study evaluated hormonal levels in patients with osteoporosis and compared gender-related differences.

Our study revealed significant differences in vitamin D, estradiol, and parathyroid hormone levels. Osteoporotic women and young men had significantly lower levels of vitamin D compared with young women. Studies show that vitamin D deficiency is associated with muscle weakness, bone loss, falls and fractures.[13] In line with the literature, our data suggest that a decrease in vitamin D in older women may contribute to osteoporosis. The present study also showed that reduced estradiol levels are related to the onset of osteoporosis in women > 60 years old, which is consistent with other works, showing that bone health is inversely related to lower estradiol

Table 1 Mean, minimum, and maximum age (in absolute numbers) in female and male subjects with and without osteoporosis

	Mean Age (years old)	Number of Patients (*n*)	Minimal Age (years old)	Maximal Age (years old)
Female control subjects	39.5	08	18	58
Male control subjects	39.6	22	19	58
Women with osteoporosis	80.05	18	64	98
Men with osteoporosis	74.9	12	60	88
Total	58.8	60	18	98

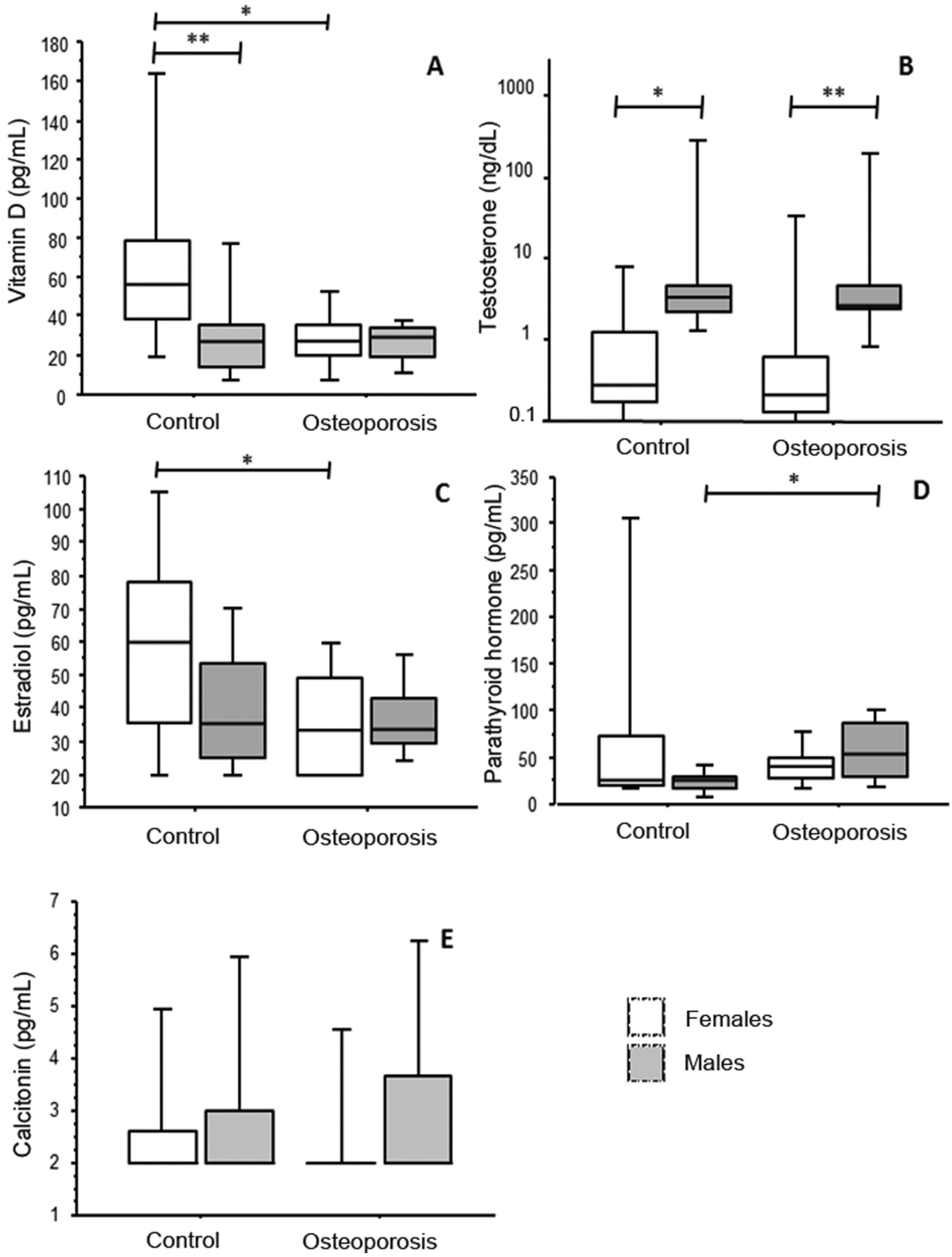


Fig. 1 Hormonal measurement using chemiluminescence in female and male patients diagnosed with osteoporosis and control subjects. (**A**) Vitamin D, $^{*}p = 0.0169$ and $^{**}p = 0.0275$; (**B**) Testosterone, $^{*}p = 0.0023$ and $^{**}p = 0.0046$; (**C**) Estradiol, $p = 0.047$; (**D**) Parathyroid hormone, $p = 0.0065$; (**E**) Calcitonin (Mann-Whitney test).

concentrations.[7,8,14] Estradiol deficiency was also linked to osteoporosis in men > 64 years old,[15] although this association was not observed here.

Bone remodeling is also stimulated by parathyroid hormone. A study with elderly women showed a significant increase in parathyroid hormone levels in women with osteoporosis.[16] In the present study, significantly higher levels of parathyroid hormone were found in men with osteoporosis, showing that it contributes to the onset of the disease in men > 60 years old; in contrast, women present no differences in parathyroid hormone levels.

Testosterone was not a limiting factor for the onset of osteoporosis in our patients. This hormone seems to be more related to differences between males and females. However, a study showed that testosterone deficiency in men > 64 years old is associated with rapid bone loss, leading to osteoporosis.[15] Even though the literature showed that calcitonin acts by inhibiting bone resorption,[17] we found no significant differences in calcitonin levels between groups and genders.

Conclusion

The present study suggests that women with osteoporosis had significantly lower levels of estradiol and vitamin D compared with young women without the disease, whereas men with osteoporosis had significantly higher levels of parathyroid hormone compared with men without the disease. These findings show the importance of hormones and vitamin D in the development of osteoporosis. Although lower testosterone levels are associated with osteoporosis, our study does not show its impact on the disease, except for a significant gender-related difference, regardless of age and of the presence of osteoporosis.

Authors contributions

All authors contributed to the conception and design of the study. The study was designed by Rodrigues V. e Rodrigues D. B. R. Gaia, L. F. P., Sousa F. F. A., Favaro, P. I. and Malheiros-Souza D. collected the material, prepared the database, and performed the statistical analyzes. Malheiros-Souza D. and Rodrigues D. B. R. wrote the manuscript and revised it. Rodrigues V. revised the manuscript.

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Conflict of Interests

The have no conflict of interests to declare.

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Use of 3D Printing in Planning the Reconstruction of Total Hip Arthroplasty: A Teaching Tool*

Uso de prototipagem rápida no planejamento de reconstruções da artroplastia total do quadril: Uma ferramenta para ensino

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Abstract

The present study aims to demonstrate how biomodels can be used as teaching tools for surgical techniques and training in a medical residency service.

A case series was carried out in our orthopedics and traumatology outpatient facility using three-dimensional (3D) printing for surgical planning to contribute to the surgical teaching and training of resident physicians. Two cases were selected as examples in the present article.

Biomodels enable a better understanding of the surgery by the surgical team and residents, reducing the surgical time and the risks for the patients.

These models can be a good teaching method to plan reconstructions of total hip arthroplasties, evaluate and predict surgical difficulties, and optimize procedures.

Keywords

- arthroplasty, replacement, hip
- hip/surgery
- printing, three-dimensional
- models, anatomic

* *Study developed at the Orthopedics and Traumatology Service of Santa Casa de Misericórdia de Porto Alegre and at Universidade Federal de Ciências da Saúde de Porto Alegre, Rio Grande do Sul, with the collaboration of the Bioengineering, Biomechanics and Biomaterials Laboratory of Universidade de Passo Fundo, Rio Grande do Sul, Brazil.*

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Resumo

O objetivo deste trabalho é demonstrar como os biomodelos podem servir como ferramenta de ensino para o esclarecimento de técnicas cirúrgicas e o treinamento em um serviço de residência médica.

Foram realizadas séries de casos em nosso ambulatório de ortopedia e traumatologia nos quais o uso da prototipagem para o planejamento cirúrgico contribuiu para o ensino cirúrgico e treinamento de médicos residentes. Dois casos foram selecionados como exemplo neste artigo.

O uso de biomodelos permite um melhor entendimento da cirurgia pela equipe cirúrgica e pelos residentes, e diminui o tempo e os riscos cirúrgicos aos pacientes.

O uso de biomodelos no planejamento de reconstruções da artroplastia total do quadril pode servir como um bom método de ensino, para a avaliação e previsão das dificuldades no momento da cirurgia, e para otimizar os procedimentos.

Palavras-chave

- artroplastia do quadril
- quadril/cirurgia
- impressão tridimensional
- modelos anatômicos

Introduction

Briefly speaking, fast prototyping is a way to physically reproduce virtual three-dimensional (3D) models using various techniques for the deposition of material layer by layer.[1] This physical deposition in layers enables the creation of a wide range of geometric shapes that would be difficult or even impossible to obtain with conventional industrial techniques, such as machining, which are based on material removal.[2] The technique has proven to be very useful to reproduce living organic structures, including tissues and organs, which do not have perfect shapes (that is, they are regular polyhedra), since their architecture is based on cell growth, an individual process related to several genetic and environmental factors.[3] Because the phenotypic diversity in *Homo sapiens* is very high, competence regarding the medical praxis occurs by intervention/interaction in countless patients who exhibit heterogeneous anatomical characteristics.

The growing search for excellence in the diagnosis and treatment of musculoskeletal disorders has become a major challenge for orthopedists. As such, new technologies in imaging diagnosis and in the planning of advanced therapies, including repair and reconstructive surgery, must be implemented in the medical practice since the beginning of orthopedic training.[3] Mothes et al.[4] used prototyping to study glenohumeral defects when planning shoulder arthroplasties. In his master's dissertation, Marques[5] tested several prototyping models that could be applied in traumatology for implant planning in osteosynthesis.

In the medical field, prototyping biomodels can be obtained from computed tomography (CT) or magnetic resonance imaging (MRI) scans.[4] The technique is widespread in the medical practice and in orthopedic and traumatological surgery, and it has been used to facilitate the understanding of bone deformities and failures.[3] In addition, previous structural knowledge can reduce the surgical time and the risks to the patients.[4]

Technique Description

The present technical note aims to demonstrate how fast prototyping (3D printing) can be used as a tool to understand surgical techniques and improve staff training in a medical residency service.

For the clinical cases herein presented, surgical training with fast prototyping models was held. Two steps were required to build 3D models. Initially, CT scans of the patients were requested, and their images were processed using the free software InVesalius (CTI Renato Archer, Campinas, SP, Brazil) and MeshMixer (Autodesk, Inc., San Rafael, CA, US). The biomodels were built with a 3D Cliever (Cliever Tecnologia, Belo Horizonte, MG, Brazil) printer using polylactic acid (PLA) filament.

Both procedures were performed according to the recommended technique, and then, routinely followed-up by the Orthopedics and Traumatology Service. The surgery was performed using the technique planned during training.

The inclusion criteria were patients with major bone defects and deformities and CT scans suitable for 3D measurements. A 3D printed model was made for each case and then compared with the real situation in loco. The entire procedure was thoroughly described.

In addition, the present study considered medical record data, including pre-, peri- and postoperative parameters, along with an evaluation of the imaging findings and of the printed model. The patients were coded to preserve their anonymity. The present study was submitted and approved by the hospital ethics committee.

Case 1

A 77-year-old female patient with a right-sided cemented hip arthroplasty due to primary coxarthrosis. This initial procedure had been performed 17 years ago at our service. The patient complained of pain in the operated hip for 3 years. The outpatient radiological follow-up revealed periacetabular osteolysis, and failure of the acetabular component with loosening and rotation. The femoral component showed no significant changes in comparison to previous imaging studies (►**Figure 1A, B**).

►**Figure 1C** shows a printed hemipelvis for a better evaluation of the bone defect and for the training of the residents. The diagnostic hypothesis of acetabular failure, probably of aseptic origin, was supported because the patient had no clinical and laboratory signs of infection. As such, revision of the acetabular

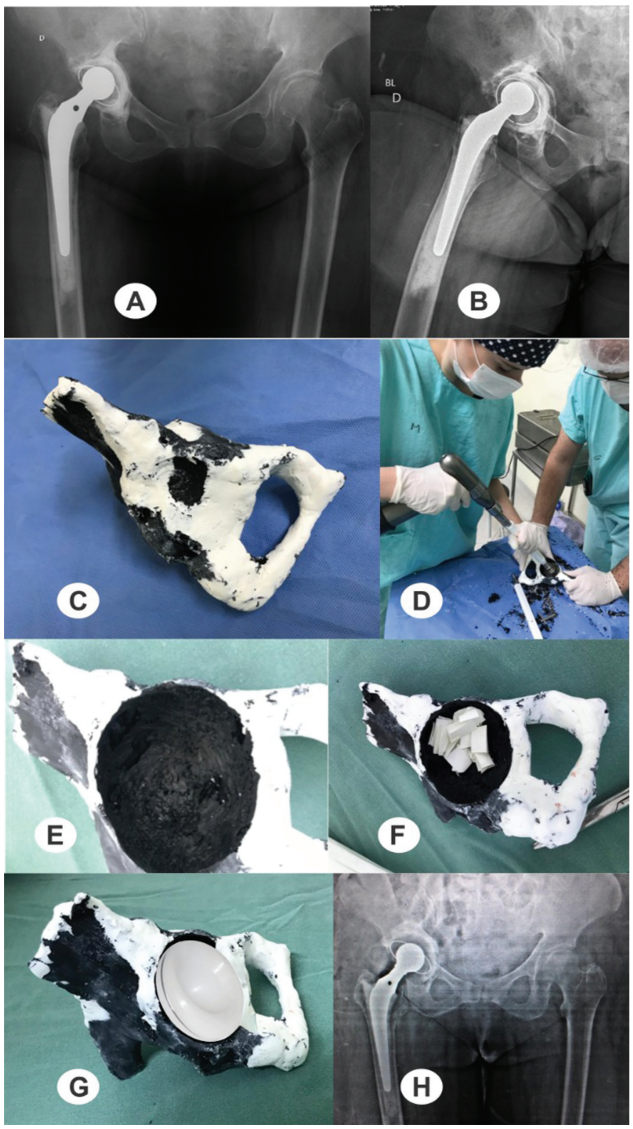


Fig. 1 Preoperative radiographs of the pelvis (**A**) and lateral view of the right hip (**B**) at the time of the review, revealing an important acetabular bone failure with loosening of the components. (**C**) View of the printed prototyping model; (**D**) residents training with prototyping models; (**E**) cavity and (**F**) acetabulum preparation with visualization of the bone defect and its filling with chopped, impacted bone; (**G**) planning of the size and position of the implant; (**H**) postoperative radiograph of the revision of the right total hip arthroplasty.

component was indicated (►**Figures 1D, E, F, G**), using chopped bone graft impacted on the acetabular roof and bottom. ►**Figure 1H** shows a postoperative pelvic radiograph.

Case 2

A 61-year-old male patient with a history of left-hip arthroplasty performed 18 years ago due to acetabular fracture, with subsequent revision 6 years ago. The patient had reported progressive pain in the left hip associated with significant functional loss for at least 5 years. During this period, the patient consulted with several colleagues who advised on expectant behavior or implant removal, claiming there were no more therapeutic options. Preoperative radiographs revealed that the patient had a total cementless hip prosthesis with a loose acetabular component, extensive acetabular erosion, steel mesh ruptures, and screw fractures (►**Figure 2A, B**). There were no significant changes in the femoral component, and the patient did not show clinical or laboratory signs of infection. A CT scan was requested to better assess the bone defect, followed by hip prototyping (►**Figures 2C, D, E**). Considering the extensive bone lesion, we initially considered using bone from the Bone Bank, but this service is not available in our city. Next, residents and staff were trained using assemblies with trabecular metal and interspace bone grafting (►**Figures 2F, G, H, I**). Given the severity of the injury, we initially considered the two acetabula option proposed by Paprosky, but the circumferences of the cups did not fit properly. Then we thought about a new structural option with two cages and an anchoring system with divergent screws, filled with bone graft, on which the new acetabulum was placed and cemented in the appropriate inclination and anteversion. The surgical procedure occurred exactly as planned, saving a lot of time in a major procedure and with little bleeding (►**Figures 2J, K, L, M, N**). The postoperative radiograph was satisfactory (►**Figure 2O**), with perfect graft integration and excellent function at a 3-year follow-up (►**Figure 2P**). Currently, the patient is asymptomatic and satisfied with the procedure.

Discussion

The present research evaluated different cases of revision of total hip arthroplasty involving 3D printing in the surgical planning and training of orthopedics and traumatology residents. Several authors have endorsed the importance of such technology in preoperative planning. Mothes et al.[4] report the role of prototyping for preoperative planning to treat bone deformities in the shoulder and believe that it minimizes the risk of intraoperative complications while attempting to improve outcomes.

The treatment of a CT scan image takes approximately one shift, since it requires correction and removal of potential artifacts, implants, and volume failures. Printing takes about 16 hours depending on the filling (the density of the material). The average cost of printing each biomodel is 56 reais (around 10 US dollars). It is worth mentioning that the hips are sectioned in the software to print only from the pubic symphysis to the near sacroiliac area.

The use of prototyped models can simplify the 3D visualization of different conditions, facilitate the understanding and planning of complex surgical procedures, and expand anatomical, radiological, and surgical knowledge.

Final Considerations

In the present work, we observed the need to modify the surgical technique by training in a prototype, using a new trabeculated metal arrangement. The inclusion of these technologies in the preceptor's repertoire is critical for the differentiation of future specialists in the job market, since medical education must adapt to train professionals able to meet societal demands. Therefore, fast prototyping combines the convenience of preoperative training with the use of technology in orthopedic surgeries, and it must become widespread in the medical teaching environment. We emphasize that the

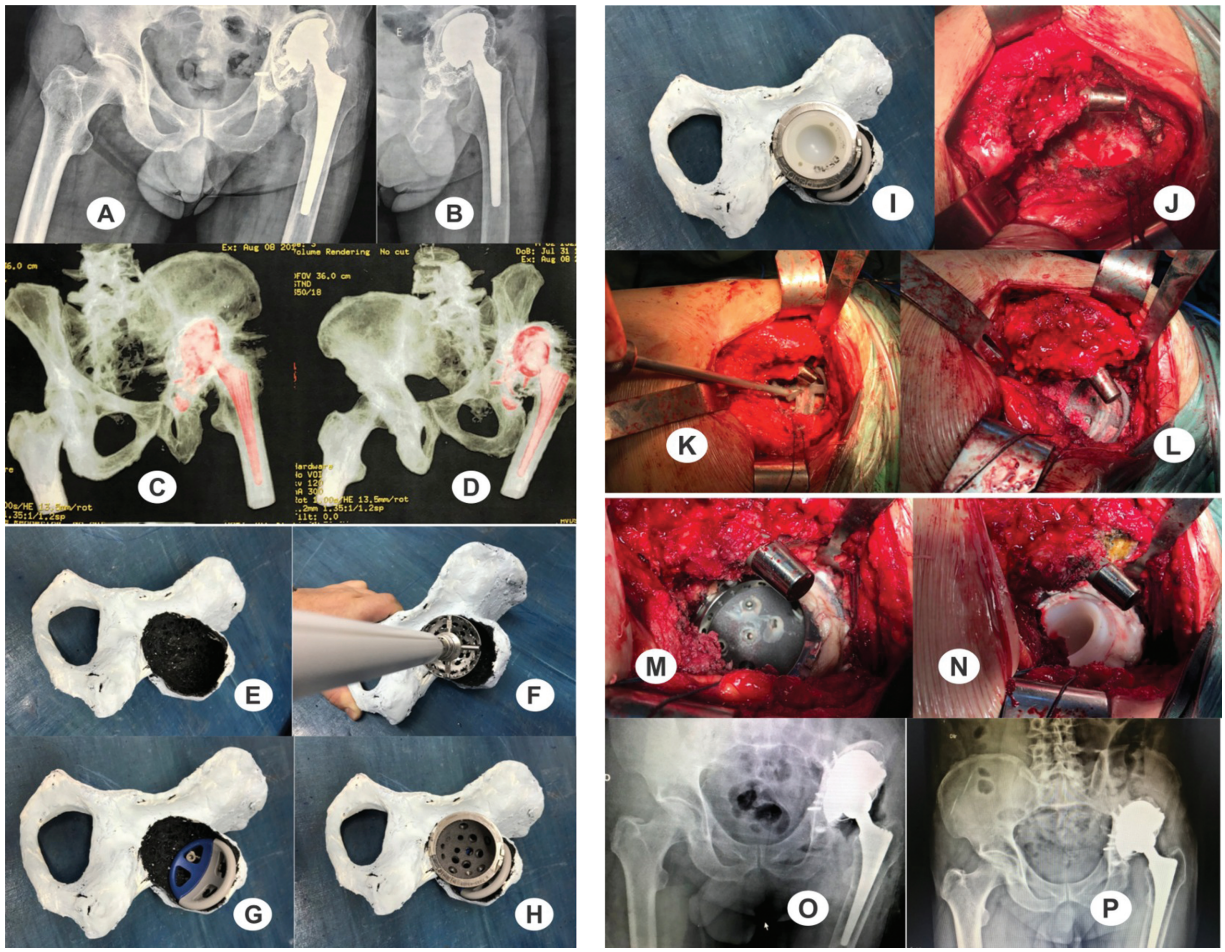


Fig. 2 (**A**, **B**) Preoperative radiographs of the pelvis and lateral view of the left hip; (**C**, **D**) computed tomography scans; (**E**) visualization of the extensive acetabular lesion; (**F**) study of the situation; (**G**) assembly of a new arrangement with trabeculated metal and study of its anchoring; (**H**) placement of the new acetabulum; (**I**) positioning the cemented polyethylene; (**J**) visualization of the intraoperative lesion (note the virtual absence of the acetabular roof and of the anterior and posterior walls); (**K**) assembly of the trabeculated metal structure; (**L**) placement of divergent screws and chopped, impacted bone graft; (**M**) placement of the trabeculated metal cup after deposition of a thin layer of cement between the metal components to avoid metallic contact; (**N**) acetabulum cementation at the proper position; (**O**) immediate postoperative radiograph; and (**P**) radiograph three years after the procedure (note the graft integration).

present study is not only applicable to orthopedics and traumatology, but to all medical areas.

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

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Triathlete with Multiple Stress Fractures in the Lower Limbs: Case Report and Literature Review*

Triatleta com múltiplas fraturas por estresse nos membros inferiores: Relato de um caso e revisão da literatura

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Abstract

Recurrent stress fractures rarely affect the same athlete. We present the case of a female triathlete who suffered multiple stress fractures in both tibias, the right fibula, and the left femoral neck. Conservative treatment was instituted in all episodes, with rest, reduced training load, and physical therapy rehabilitation. The relative energy deficiency in sport syndrome, along with an eating disorder, training overload, and osteopenia, was identified as a risk factor. Although rare, multiple stress fractures can occur in female triathletes. These patients must be screened for risk factors associated with biomechanics, nutrition, and training to develop an effective prevention and treatment program.

Keywords

- fractures, stress
- female athlete triad syndrome
- case reports

Resumo

Fraturas por estresse recorrentes num mesmo atleta são raras. Apresentamos o caso de uma triatleta que sofreu múltiplas fraturas por estresse na tíbia bilateral, na fíbula direita e no colo femoral esquerdo. O tratamento conservador foi instituído em todos

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Palavras-chave
- fraturas de estresse
- síndrome da tríade da mulher atleta
- relatos de casos

os episódios, com repouso, redução da carga de treino e reabilitação fisioterápica. Foi identificada como fator de risco a síndrome da deficiência energética relativa no esporte, com distúrbio alimentar, sobrecarga de treino e osteopenia. Mesmo que seja raro, múltiplas fraturas por estresse podem ocorrer em mulheres triatletas, nas quais é importante avaliar os fatores de risco associados à biomecânica, nutrição e ao treinamento para arquitetar um programa de prevenção e tratamento efetivo.

Introduction

Recurrent stress fractures rarely affect the same athlete. They account alone for 10% of sports injuries.[1] These fractures are considered atypical cases, requiring screening for predisposing factors.[2,3] Female athlete triad syndrome was redefined to a broader spectrum, now called relative energy deficiency in sport (RED-S) syndrome.[3] This syndrome mainly results from metabolic changes due to nutritional imbalances. Athletes with RED-S syndrome are at an increased risk for fractures, as this condition is associated with hormonal dysfunction and reduced bone mineral density (BMD).[3]

The present study describes the case of a female triathlete with RED-S syndrome with multiple stress fractures and

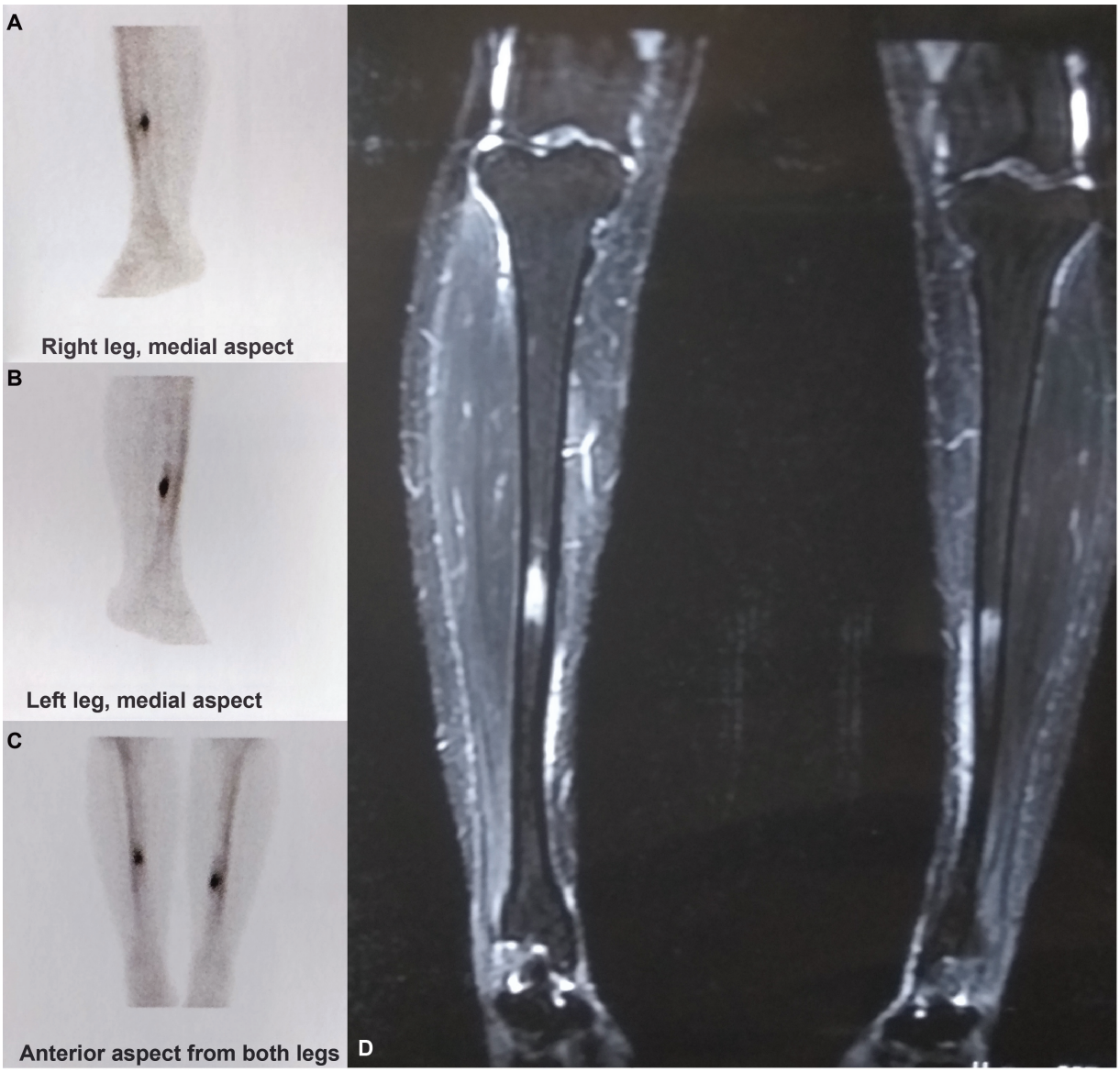


Fig. 1 Test images revealing tibial stress fractures. (**A**, **B** and **C**). Bone scintigraphy scan images, (**D**) T2-weighted magnetic resonance imaging scan.

reviews the associated risk factors. An informed consent form was signed by the patient. This manuscript was written according to the CARE guidelines for case reports[4] and approved by the research ethics committee (CAAE 22982819.8.0000.5133).

Case Report

The patient described in the present report is a 34-year-old female triathlete, with a body mass index (BMI) of 20 kg/cm^2, and a history of polycystic ovary syndrome, bulimia (sic), menstrual irregularity, and anxiety disorder.

Eight years ago, after 6 months of running (4 times a week) supervised by a physical educator, the patient complained of atraumatic, progressive pain in the anterior aspect of the right leg, which worsened, became bilateral, and prevented training. She was evaluated by an orthopedist, who suspected a stress fracture. Bone scintigraphy and magnetic resonance imaging (MRI) scans revealed bilateral damage to the posterior cortex of the tibial diaphysis (►**Figure 1**). At the time, the patient reported that she was voluntarily on a caloric deficit diet for weight loss and presented a bulimic behavior. The treatment was conservative, with no sports practice for 2 months. The patient was referred to a sports dietitian for a dietary energy readjustment but had no specific treatment for bulimia. In addition, the patient visited a gynecologist, who told her that her hormonal tests came back normal (sic). Physical activity was resumed with walking and cycling, progressing under supervision; lack of pain was a criterion for training intensification. The patient resumed running after 8 months, and also practiced swimming and cycling with no complaints. She was followed up by

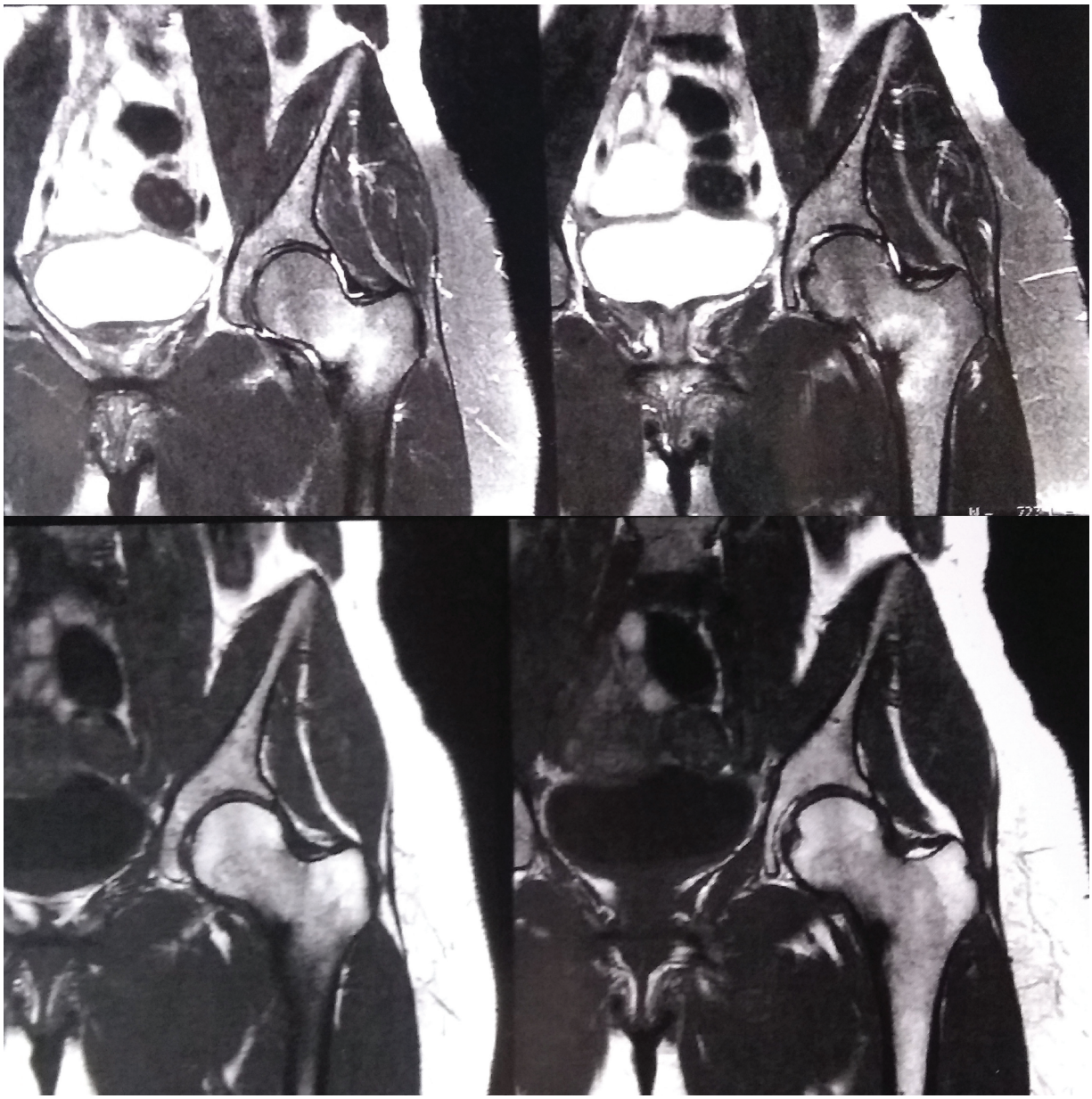


Fig. 2 T2-weighted magnetic resonance imaging scan revealing a hypersignal at the medial cortex of the femoral neck.

a dietitian and reported an adequate energy supply. Although the patient did not seek medical advice for bulimia, she stated that there was no recurrence of these symptoms after nutritional treatment.

Three years later, under a high-intensity daily training for triathlon, the patient complained of insidious pain in the lateral aspect of the right leg when running, preventing the practice. An orthopedic medical evaluation was performed, and an MRI scan showed a stress fracture in the right fibular diaphysis. The patient reported using insoles for pronated feet, which were prescribed by a physical therapist. We advised her to stop running, which lasted for 8 months, and to maintain lower limb muscle strengthening and proprioception with swimming and cycling at a reduced intensity and incremental progressive load supervised by a coach. Upon resuming running, she was instructed not to use the insoles anymore and to wear comfortable sneakers for training and competitions. After 1 year, during a medical visit, the patient reported being asymptomatic; biochemical tests revealed no alterations, and bone density scan showed osteopenia. We prescribed a daily oral supplementation with calcium (500 mg) and vitamin D (1,000 IU).

Two years after the last fracture, with no symptoms and still under nutritional care, during a high-intensity training cycle supervised by a coach, the patient started to feel progressive left hip pain when running; the pain was refractory to a decrease in training volume. A new orthopedic medical evaluation diagnosed a stress fracture in the medial cortex of the left femoral neck (►**Figure 2**). As a treatment, the patient was instructed to restrict load on the limb and to

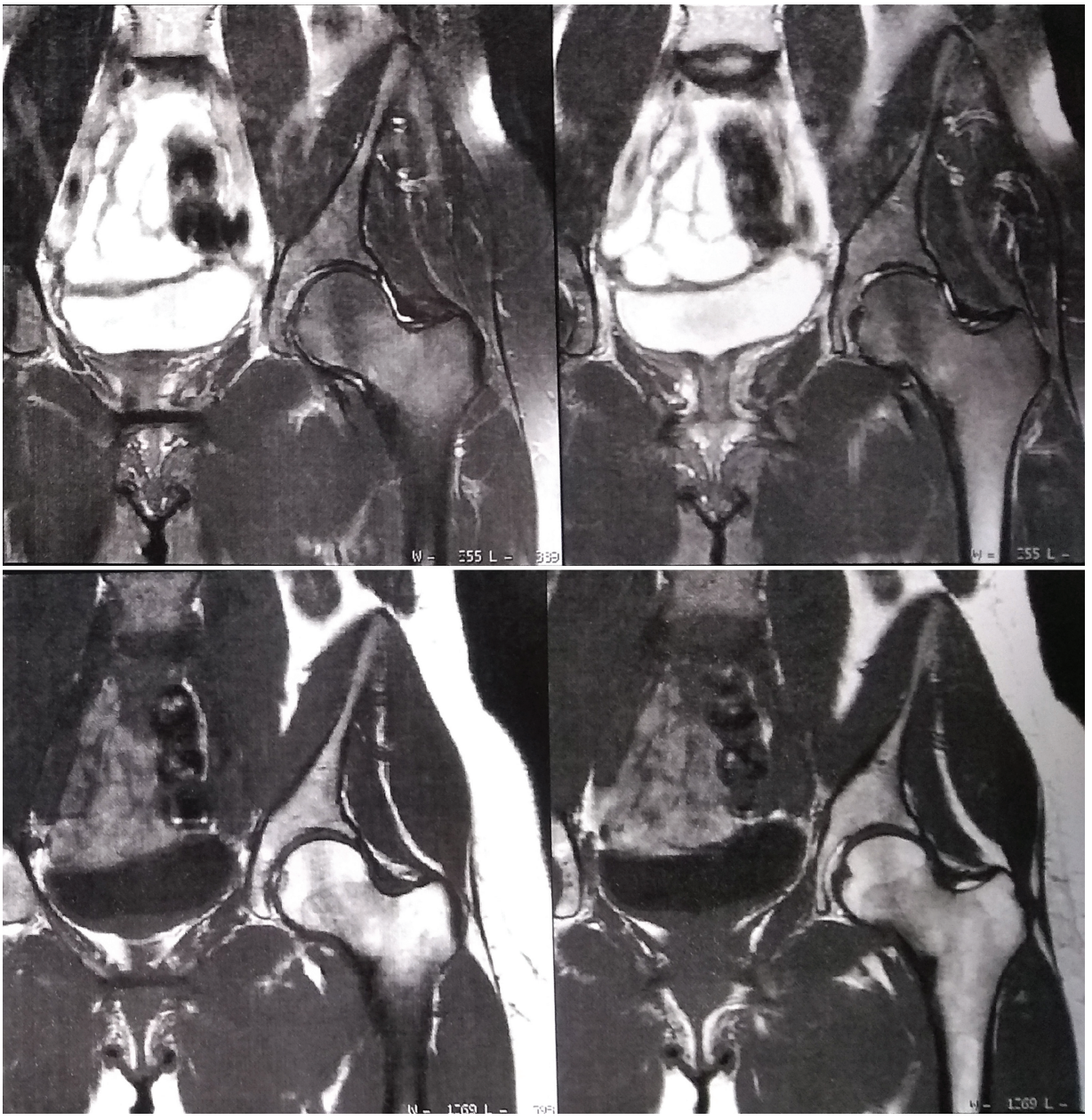


Fig. 3 T2-weighted magnetic resonance imaging scan confirming femoral neck fracture consolidation.

use crutches. After 15 days, she resumed swimming (freestyle), twice a week. After 2 months, she was pain-free and resumed cycling, with slow load and training volume progression. Four months after the diagnosis, at a medical visit, a new MRI scan was requested (►**Figure 3**), which revealed fracture consolidation. Running was resumed, with weekly progression of 10% of the training volume, accompanied by a physical educator. Eight months after the diagnosis of femoral neck fracture, the patient returned to triathlon, participating in two competitions with no complaints (►**Figure 4**).

Discussion

Stress fractures occur in healthy athletes submitted to cyclic physical overload; bone turnover imbalance and osteoclastic activity predominance result in microfractures and, eventually, complete fractures.[5] This case describes an apparently healthy athlete who had four stress fractures. The most common symptom of stress fracture is mechanical pain;[6] the lower limbs are more commonly affected, accounting for almost 90% of cases.[7] In running, stress fractures are associated with training overload, especially when the weekly mileage is high.[6,7] Running was the common training at all occurrences, highlighting it as a risk factor.

Additional risk factors for recurrent fractures include reduced vitamin D levels, eating disorders, anxiety, calorie deficit, menstrual disorders, BMI $< 21\,kg/m^2$, and low BMD.[2,6,7] Together, these conditions result in RED-S syndrome.[3] The imbalance between energy intake and expenditure, associated with exhaustive training and excessive concerns with performance and aesthetics, leads to hormonal dysfunction, with an increased risk for stress fractures.[3,8] We believe that despite the occurrence of other fractures, the sustained good nutrition helped the treatment of the first injury and the follow-up of subsequent events. Biomechanical changes of the plantar arch and footstep types are potential risk factors for stress fractures, but clinical evidence is low.[8] We decided to ask the patient not to use the prescribed insoles, and there was no fibular fracture recurrence.

Biochemical tests, including calcium, 25(OH)D3, and albumin levels, are requested during the investigation for multiple fractures.[9] As for imaging tests, the gold standard is MRI, with 100% sensitivity and 85% specificity.[10] Bone mineral density scan is indicated when RED-S syndrome is suspected.[2,3] In our case, despite the normal findings in biochemical tests, calcium and vitamin D supplementation were instituted due to osteopenia.

Stress fractures are differentiated into "low" and "high" risk of pseudoarthrosis and refracture without surgical treatment.[9] The patient's fractures were classified as "low risk" since cortical strength was not affected. These injuries are conservatively managed,[9] as performed in this case report. To prevent the fracture from becoming complete, patients should rest or reduce load for some time, but no immobilization is required.[9,10] The gradual return to sports occurs after 10 to 14 days with normal radiographic findings and no pain.[2] Physical rehabilitation includes physical conditioning with no impact, and training adapted to the sports gesture, with 25% less training volume and 10% weekly increase at the tolerated load.[2,3] Decreased high-intensity cycles are recommended, along with an adequate energy supply.[3,6] Unrestricted practice is medically authorized only when a new MRI scan shows bone healing.[9,10]

The strengths of this report included the rarity of the case, the occurrence of fractures during the same gesture (running), and the favorable evolution with treatment and secondary prevention. The main limitation of the study was the difficult access to the implemented training program, as its details could demonstrate an association between overload and multiple stress fractures.

Multiple stress fractures in female triathletes are rare. These injuries can be associated with risk factors, such as inadequate nutrition, bulimic behavior, and training

- 2012 = The patient started to run as an amateur.
- 2012 = Left and right tibial stress fractures. Temporary running suspension and slow progression of training volume.
- 2014 = The patient started triathlon.
- 2015 = Right fibular stress fracture. Training load reduction and specific physical therapy.
- 2016 = Osteopenia diagnosis and supplementation start.
- April 2017 = Medial cortical stress fracture at the left femoral neck. Patient is advised to and use crutches, with subsequent return to swimming and physical therapy rehabilitation.
- August 2017 = Bone healing is confirmed and gradual return to running and cycling.

Fig. 4 Timeline.

overload. The identification of these factors is critical to treat such injuries and perform an effective secondary prevention in triathlon.

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Conflict of Interests
The authors declare no conflict of interests.

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Letter to the Editor Regarding the Article: "Radiographic Evaluation of Postoperative Alignment in Total Knee Arthroplasty" – Thomaz LDG, Geist JGB, De Lucena RDL, Schwartsmann CR, Freitas GLS, Spinelli LF. *Rev Bras Ortop* 2021 https://doi.org/10.1055/s-0041-1726061. (e-first)

Carta ao editor sobre o artigo: "Avaliação radiográfica do alinhamento pós-operatório na artroplastia total de joelho" – Thomaz LDG, Geist JGB, De Lucena RDL, Schwartsmann CR, Freitas GLS, Spinelli LF. Rev Bras Ortop 2021 https://doi.org/10.1055/s-0041-1726061. (e-first)

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Dear Editor,

First, we would like to congratulate the authors of the article entitled "Radiographic Evaluation of Postoperative Alignment in Total Knee Arthroplasty"[1] for the interesting article. In addition, we would also like to make some comments about the methodology used in the research.

We believe that the performance of orthostatic radiographs in the immediate postoperative period, still during hospitalization, may have compromised the quality of the imaging examination, considering that the intensity of pain and edema common to the immediate postoperative period often limits the total extension of the knee, especially during orthostatism.

The attitude in flexo and external rotation of the operated limb may have been a bias in relation to the correct positioning of the patient and the obtainment of the images. Radiography in the immediate postoperative period has not been shown to be beneficial,[2] and we believe, in line with Abu-Rajab et al.,[3] that the radiographic evaluation should have been performed in a later postoperative period, at around six weeks.

Another methodological point that we thought was inappropriate was to try to infer the location of the femoral head and the center of the ankle on short radiography. On short radiography, the only reproducible axis to be traced is the anatomical axis of the femur and tibia (tibiofemoral),[4] which

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is a good predictor of long-term alignment after total knee arthroplasty.[4]

We conclude that, methodologically, the panoramic radiographs should have been performed in a later postoperative period to avoid a positioning bias, and that a comparison of long and short radiography analyses could only be made taking into account the tibiofemoral anatomical axis. Attempting to infer the mechanical axis on a short x-ray causes an inference bias regarding the location of the femoral head and the center of the ankle.

Conflict of Interest

The authors have no conflict of interests to declare.

References

1 Thomaz LDG, Geist JGB, De Lucena RDL, Schwartsmann CR, Freitas GLS, Spinelli LF. Avaliação radiográfica do alinhamento pós-operatório na artroplastia total de joelho. [Publicação online: 2021–04–19]. Rev Bras Ortop 2021. Disponível em: *https://www.thieme-connect.de/products/ejournals/abstract/10.1055/s-0041-1726061*

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3 Abu-Rajab RB, Deakin AH, Kandasami M, McGlynn J, Picard F, Kinninmonth AW. Hip-Knee-Ankle Radiographs Are More Appropriate for Assessment of Post-Operative Mechanical Alignment of Total Knee Arthroplasties than Standard AP Knee Radiographs. J Arthroplasty 2015;30(04):695–700

4 Ishii Y, Ohmori G, Bechtold JE, Sherman RE, Gustilo RB. Accuracy of the short radiograph in the measurement of the tibiofemoral angle. Knee 1995;2(02):81–84

Answer to the Letter to the Editor Regarding the Article "Radiological Evaluation of Postoperative Alignment in Total Knee Arthroplasty"

Resposta à carta ao editor referente ao artigo "Avaliação radiográfica do alinhamento pós-operatório na artroplastia total de joelho"

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Rev Bras Ortop 2021;56(6):821–822.

We thank you for the considerations made to our article through a letter to the editor presented by colleagues regarding the article "Radiographic Evaluation of Postoperative Alignment in Total Knee Arthroplasty" – *Rev Bras Ortop* 2021 (https://doi.org/10.1055/s-0041-1726061) (efirst).[1] In our article, we tried to demonstrate the greater accuracy of panoramic radiographs of the lower limbs (long) in relation to short radiographs of the knee in the measurement of the mechanical axis of the lower limb after total knee arthroplasty (TKA). We considered valid the observation about the time of performance of the radiography and the fact that a possible attitude in flexo and external rotation could lead to a positioning bias. The fact that long radiographs are performed in bipodal support when patients are still hospitalized in our hospital occurs at a time when analgesia is adequate, reducing the intensity of the pain. We routinely perform saphenous nerve block in the adductor canal with sonographic control, which enables knee analgesia without motor loss of the quadriceps.[2] Thus, the patients are able to start the support early, which accelerates their postoperative rehabilitation and decreases the possibility of difficulty being in the position of orthostasis and, therefore, performing the examination.

It is worth mentioning that all short radiographs used in the evaluation were obtained directly from the panoramic radiography itself, as stated in the section of materials and methods of our article, precisely to avoid the influence of possible rotations in the performance of new radiographs.[3] Thus, the comparative analysis performed decreased the chance of bias in relation to positioning, even if it did not totally exclude it. In addition, we consider the suggestion of colleagues to be valid to be investigated in a future study, comparing the analysis of long radiographs in the immediate postoperative period and six weeks later, in order to evaluate possible interferences of immediate postoperative situations. We remember that Abu-Rajab et al.[3] do not

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recommend x-rays in six weeks, but do perform them as a routine currently. So, the study proposal is valid.

Although the anatomical axis is the only axis that is actually reproducible on short radiography, Felson et al.[4] showed that the agreement between the measurement of the anatomical axis on short knee radiography and the measurement of the mechanical axis on long radiography is only moderate. In another study, by the Muticenter Osteoarthritis Group,[5] the authors concluded that there are significant limitations to the use of the anatomical axis to predict the alignment of the lower limbs, especially when an accurate measurement of the mechanical alignment is necessary. We used as reference other published studies that applied this methodology to try to predict the measurement points of the mechanical axis.[3] Thus, it was possible to compare their results with those obtained by our group. Then, we reproduce a methodology already widely presented in the literature and used in several studies.

We consider that the suggestion about the postoperative time to perform panoramic radiography may be the object of a future study, as a way of comparing the results obtained by different observers in the highlighted period. Regarding the use of the tibiofemoral anatomical axis in the postoperative period of TKA, we recall that the literature is conflicting in relation to the use of this measure; therefore, we chose to follow the methodology of studies previously performed in order to obtain comparative results.

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

References

1 Thomaz LDG, Geist JGB, De Lucena RDL, Schwartsmann CR, Freitas GLS, Spinelli LF. Avaliação radiográfica do alinhamento pós-operatório na artroplastia total de joelho. [Publicação online: 2021–04–19]. Rev Bras Ortop 2021. Disponível em: https://www.thieme-connect.de/products/ejournals/abstract/10.1055/s-0041-1726061
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3 Abu-Rajab RB, Deakin AH, Kandasami M, McGlynn J, Picard F, Kinninmonth AW. Hip-Knee-Ankle Radiographs Are More Appropriate for Assessment of Post-Operative Mechanical Alignment of Total Knee Arthroplasties than Standard AP Knee Radiographs. J Arthroplasty 2015;30(04):695–700
4 Felson DT, Cooke TD, Niu J, et al; OAI Investigators Group. Can anatomic alignment measured from a knee radiograph substitute for mechanical alignment from full limb films? Osteoarthritis Cartilage 2009;17(11):1448–1452
5 Sheehy L, Felson D, Zhang Y, et al. Does measurement of the anatomic axis consistently predict hip-knee-ankle angle (HKA) for knee alignment studies in osteoarthritis? Analysis of long limb radiographs from the multicenter osteoarthritis (MOST) study. Osteoarthritis Cartilage 2011; 19(01):58–64

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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.
- Do not submit art created in Microsoft Excel, Word, or PowerPoint. These files cannot be used by the typesetter.
- 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.
- It is preferable for figures to be cropped to their final size (approximately 3½ inches for a single column and up to 7 inches for a double column), or larger, and in the correct orientation. If art is submitted smaller and then has to be enlarged, its resolution (dpi) and clarity will decrease.

  Note: Lower resolutions (less than 300 dpi) and JPEG format (.jpg extension) for grayscale and color artwork are strongly discouraged due to the poor quality they yield in printing, which requires 300 dpi resolution for sharp, clear, detailed images. JPEG format, by definition, is a lower resolution (compressed) format designed for quick upload on computer screens.

Black-and-White Art

- Black-and-white artwork can be halftone (or grayscale) photographs, radiographs, drawings, line art, graphs, and flowcharts. Thieme will only accept digital artwork.
- 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.

- Use 1-point (or thicker) rules and leader lines.
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- Where there are alternate terms or spellings for a named structure, use the most common one and make sure it is consistent with what is used in the text.
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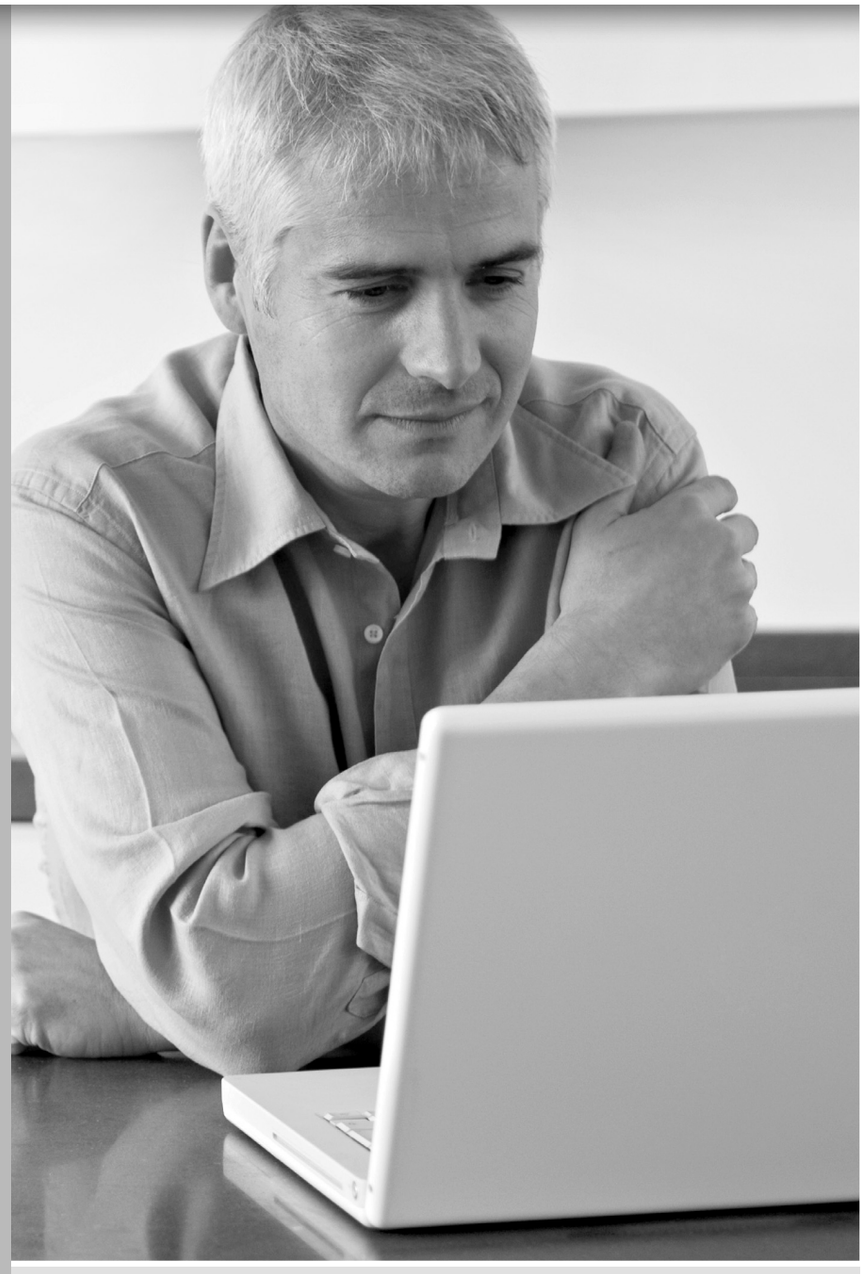
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