

ISSN 1413-7852

# 1 stand JCR wound Citation Reports Acta Ortopédica Brasileira

Volume 31 – Number 4 – Year 2023

Acta Ortopédica Brasileira



Department of Orthopedics and Traumatology, Faculdade de Medicina da Universidade de São Paulo (DOT/FMUSP), São Paulo, SP, Brazil

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(Reviewed April 2022)

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#### Levels of Evidence for Primary Research Question<sup>a</sup>

(This chart was adapted from material published by the Centre for Evidence-Based Medicine, Oxford, UK. For more information, please visit www.cebm.net.)

Types of study							
Level	Therapeutic Studies Investigating the Results of Treatment	Prognostic Studies – Investigating the Effect of a Patient Characteristic on the Outcome of Disease	Diagnostic Studies – Investigating a Diagnostic Test	Economic and Decision Analyses – Developing an Economic or Decision Model			
I	High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	High quality prospective study <sup>d</sup> (all patients were enrolled at the same point in their disease with ≥80% of enrolled patients)	Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses			
	Systematic review <sup>b</sup> of Level RCTs (and study results were homogenous <sup>c</sup> )	Systematic review <sup>b</sup> of Level I studies	Systematic review <sup>b</sup> of Level I studies	Systematic review <sup>b</sup> of Level I studies			
II	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective' study	Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)	Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses			
	Prospective <sup>d</sup> comparative study <sup>e</sup>	Untreated controls from an RCT	Systematic review <sup>b</sup> of Level II studies	Systematic review <sup>b</sup> of Level II studies			
	Systematic review <sup>b</sup> of Level II studies or Level I studies with inconsis tent results	Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% followup)					
		Systematic review <sup>b</sup> of Level II studies					
	Case control study <sup>g</sup>	Case control study <sup>g</sup>	Study of non consecutive patients; without consistently applied reference "gold" standard	Analyses based on limited alternatives and costs; and poor estimates			
ш	Retrospective <sup>f</sup> comparative study <sup>e</sup>		Systematic review <sup>b</sup> of Level III studies	Systematic review <sup>b</sup> of Level III studies			
	Systematic review <sup>b</sup> of Level III studies		Case-control study				
			Poor reference standard				
IV	Case series <sup>h</sup>	Case series		Analyses with no sensitivity analyses			
v	Expert opinion	Expert opinion	Expert opinion	Expert opinion			

<sup>a</sup> A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

<sup>b</sup> A combination of results from two or more prior studies

<sup>c</sup> Studies provided consistent results.

<sup>d</sup> Study was started before the first patient enrolled.

e Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip

arthroplasty) at the same institution

<sup>f</sup> The study was started after the first patient enrolled.

<sup>9</sup> Patients identified for the study based on their outcome, called "cases" eg, failed total arthroplasty, are compared with patients who

did not have outcome, called "controls" eg, successful total hip arthroplasty.

h Patients treated one way with no comparison group of patients treated in another way

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Diogo Lino Moura, Josué Pereira Gabriel DOI: http://dx.doi.org/10.1590/1413-785220233104e262943

## MODIFIED MUBARAK TECHNIQUE FOR FLEXIBLE FLATFOOT CORRECTION IN CHILDREN AND ADOLESCENTS

## TÉCNICA DE MUBARAK MODIFICADO PARA CORREÇÃO DO PÉ PLANO FLEXÍVEL DE CRIANÇAS E ADOLESCENTES

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#### ABSTRACT

Objective: To describe the technique, analyze possible radiographic correction and evaluate the clinical result of medial and plantar calcaneal displacement osteotomy associated with opening wedge cuboid osteotomy for flexible flatfoot correction. Methods: 23 patients (30 feet) diagnosed with flexible flat foot treated with plantar and medial calcaneal displacement osteotomy associated with opening wedge cuboid osteotomy were evaluated retrospectively. In the lateral radiographs calcaneal pitch and Meary's angle were the radiographic parameters evaluated; while the talonavicular coverage angle was evaluated in the anteroposterior radiographs. To assess the clinical outcome of the surgical procedure, the American Orthopedic Foot and Ankle Society Score (AOFAS) for the ankle and hindfoot was adopted. Results: The mean values of the evaluated angles and AOFAS score for ankle and hindfoot significantly improved when comparing pre- and postoperative values. Conclusion: Plantar and medial calcaneal displacement osteotomy associated with an opening wedge cuboid osteotomy is able to improve radiological and clinical parameters of child patients with flexible flatfoot. Level of Evidence III, Retrospective Comparative Study.

#### RESUMO

Objetivo: Descrever a técnica, analisar possíveis correções radiográficas e avaliar o resultado clínico da osteotomia de deslocamento medial e plantar do calcâneo associada à osteotomia em cunha de adição do cuboide para correção do pé plano flexível de crianças. Métodos: Foram avaliados retrospectivamente 23 pacientes (30 pés) com diagnóstico de pé plano flexível tratadas com osteotomia de deslocamento plantar e medial do calcâneo associada à osteotomia em cunha de adição do cuboide. Os parâmetros radiográficos avaliados nas imagens em perfil foram o pitch do calcâneo e o ângulo de Meary, enquanto nas radiografías anteroposteriores o ângulo de cobertura do tálus. Para avaliar o resultado clínico do procedimento cirúrgico, foi adotado o escore da American Orthopaedic Foot and Ankle Society (AOFAS) para tornozelo e retropé. Resultados: Os valores médios dos ângulos avaliados e do escore AOFAS para tornozelo e retropé melhoraram significativamente na comparação dos resultados pré e pós-operatórios. Conclusão: A osteotomia de deslocamento plantar e medial do calcâneo associada à osteotomia em cunha de adição do cuboide é capaz de melhorar os parâmetros radiológicos e clínicos de crianças com pé plano flexível. Nível de Evidência III, Estudo Comparativo Restrospectivo.

Keywords: Flatfoot. Tarsal Bones. Osteotomy.

Descritores: Pé Chato. Ossos do Tarso. Osteotomia.

**Citation:** Silva BAM, Silva NA, Vasconcelos JB. Modified Mubarak technique for flexible flatfoot correction in children and adolescents. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 4. Available from URL: http://www.scielo.br/aob.

#### **INTRODUCTION**

Flexible flatfoot is defined by the loss of the longitudinal arch of the foot and hindfoot valgus, in addition to abductus and a certain degree of supination of the forefoot relative to the midfoot. The deformity is assessed with the tip toe test or the Jack test.<sup>1</sup> If the patient does not respond to conservative treatment, surgery is indicated. Recently, many surgical procedures have been described, among which osteotomies have been the treatment of choice for children with flexible flat feet since it does not sacrifice foot mobility.<sup>2</sup> In 1893, Gleich described medialization calcaneal osteotomy to correct hindfoot valgus,<sup>3</sup> which was later popularized by Koutsogiannis in the treatment of flexible flatfoot.<sup>4</sup> However, it cannot restore the longitudinal arch of the foot.<sup>4</sup>

The concept of correcting valgus flat foot with lateral column lengthening osteotomy was achieved by Evans. In 1975, Evans described that, when the lateral wall of the calcaneus was elongated, the navicular moved medially, improving both talar coverage and the longitudinal arch of the foot.<sup>5</sup>

A few years later, Mubarak described calcaneal-cuboid-cuneiform osteotomy to correct a child's planovalgus foot. The calcaneal osteotomy corrects hindfoot valgus, the opening wedge in the

All authors declare no potential conflict of interest related to this article.

The study was conducted at Instituto Ortopedico de Goiania.

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Article received on 06/17/2022, approved on 10/19/2022.



cuboid lengthens the lateral column realigning the talonavicular joint, while the cuneiform osteotomy allows forefoot plantar flexion.<sup>6</sup> It was with Mubarak's concept that we associated the opening wedge cuboid osteotomy and modified the calcaneal osteotomy by displacing it both medially and plantarly.

Based on Mubarak's concept, a plantar and medial calcaneal displacement osteotomy associated with an opening wedge cuboid was proposed for treating flexible flat foot in children.

Our hypothesis is that the plantar and medial calcaneal displacement is sufficient to correct the plantar arch and hindfoot valgus and that the opening wedge cuboid can correct forefoot abductus. Cuneiform osteotomy would not be necessary.

This study aims to describe the technique, analyze possible radiographic correction and evaluate the clinical result.

#### **METHODS**

The research project was evaluated by the Research Ethics Committee of the institution and approved under opinion number 2,160,581 and registered on Plataforma Brasil, protocol CAAE number: 68282217.2.0000.5078.

We retrospectively evaluated 23 patients (30 feet) diagnosed with flexible flat foot treated with plantar and medial calcaneal displacement osteotomy associated with opening wedge cuboid osteotomy. The surgery was performed by a single surgeon from 2013 to 2016, with at least two years of follow-up.

Inclusion criteria were patients with symptomatic flexible flat foot, aged 10–18 years with follow-up of at least two years. Patients with tarsal coalition, rigid flat foot, posterior tibial dysfunction, and patients undergoing other foot bone surgeries were excluded. The flexible flat foot diagnosis was based on loss of the longitudinal plantar arch and hindfoot valgus with the patient in orthostatism. Flexibility was defined as the reconstitution of the longitudinal plantar arch of the foot and calcaneus varus with the patient on tiptoe.

Initially, conservative treatment was attempted by changing shoes, using insole, and muscle stretching of the posterior chain muscles of the leg. Surgical treatment was indicated to patients who remained in pain after 6 months of conservative measures.

Patients underwent radiographic examination of the feet in the preoperative period, 6 weeks after surgery, and at the last office visit. The parameters evaluated in the lateral radiographs were the calcaneal pitch and the Meary's angle; whereas in the anteroposterior radiographs, the talonavicular coverage angle was evaluated, following Davids, Gibson, and Pugh.<sup>7</sup> The measurements were taken by the senior author (B.A.M), using the WTT-Dicom Viewer version 0.5.326 program.

To assess the clinical outcome of the surgical procedure, the American Orthopedic Foot and Ankle Society Score (AOFAS) for the ankle and hindfoot was adopted. The scores measured were considered excellent if ranging 90–100, good if ranging 80–89, fair if ranging 70–79, and poor if it had less than 70 points.<sup>8</sup>

Data were tabulated in a spreadsheet using Excel program (Office 2013) and later analyzed using the statistical package Statistical Package of Social Sciences (SPSS 24.0). Data normality was verified using the Shapiro-Wilk test. The comparison of AP – COB TALUS, P – PITCH and P – MEARY values before and after treatment was performed using the paired t-test. In all analyses, a 5% significance level (p < 0.05) was adopted.

#### Surgical technique

The procedures were performed with the patient under spinal anesthesia and a 300 mmHg tourniquet at the thigh level. A 1.5 cm access from the distal tip of the fibula is made obliquely

A 1.5 cm access from the distal tip of the fibula is made obliquely (45° with the ground) starting from the upper edge of the calcaneus to the lower edge of the distal part of the calcaneus (Figure 1).

The sural nerve is moved dorsally. A calcaneal osteotomy is then performed, respecting the 45° angle with the ground. Initially, an oscillatory saw is used, and the medial wall of the calcaneus is cut with an osteotome.

The posterior fragment of the calcaneus is medialized until its medial border is aligned with the talar sustentaculum, a displacement of approximately 5–10 mm. Additionally, a plantar deviation of this same fragment is made around 5–10 mm. The calcaneal osteotomy is then fixed with 02 k-wire (Figure 2).

Once the calcaneus is fixed, a lateral access is made over the cuboid, plantarly to the extensor digitorum brevis (EDB) in alignment with the IV metatarsal (Figure 3).

The EDB is moved dorsally and then an opening wedge cuboid osteotomy is performed equidistant from the calcaneal-cuboid and cuboid-metatarsal joints. A spreader is placed on the osteotomy to make room for placement of a structured bone graft taken from the iliac crest, approximately 10 mm thick (Figure 4).

No fixation is used for this osteotomy. Once the procedure is over, it is possible to see the formation of the longitudinal plantar arch (Figure 5)



Figure 1. Calcaneal osteotomy approach.



Figure 2. Calcaneal osteotomy.



Figure 3. Cuboid approach

## << SUMÁRIO



Figure 4. Opening wedge cuboid osteotomy.



Figure 5. Final aspect of foot.

#### Post operative management

The patient usually stays at the hospital the day after surgery. Knee walking boot is recommended to protect the osteotomies, and patients were kept non-weight bearing for 6 weeks. A radiological evaluation is performed after six weeks and, according to the result, K pins are removed. Weight-bearing is then allowed with boot on for 2 weeks. The patient is released to wear shoes eight weeks after surgery and once physical therapy rehabilitation is started. A new radiographic evaluation is performed after 12 weeks of surgery (Figure 6A and 6B).



Figure 6. A: Anteroposterior post-op radiograph; B: Lateral radiograph.

#### RESULTS

Of the 27 selected patients (36 feet) operated during the chosen period, 4 cases were excluded from the study: 2 patients with tarsal coalition, 1 patient with cerebral palsy (2 feet), 1 case of review of failure of previous surgical treatment, and 1 case without radiography. The total number of patients included in this study was 23 (30 feet). We evaluated the 23 (13 boys and 10 girls) patients, diagnosed with flexible flat foot in childhood, using medial and plantar calcaneal

displacement osteotomy associated with opening wedge cuboid osteotomy at our referral center from 2013 to 2016. The mean age of girls at the time of surgery was 12.7  $\pm$  2.3 years, and the boys were 10.5  $\pm$  1.8 years. The mean follow-up time of patients after surgery was 37  $\pm$  4.8 months (Table 1).

All osteotomies consolidated in eight weeks. No loss of correction was observed in any patient during follow-up (26–60 months). The mean values of the evaluated angles and AOFAS score for ankle and hindfoot significantly improve when comparing pre and postoperative values (Table 2).

The postoperative complications observed were superficial infection (one patient), suture dehiscence (one patient) and k-wire path infection (two patients). No subluxation of the calcaneal-cuboid joint or lateral foot pain was observed.

<b>Table 1.</b> Baseline data of all patients ( $N = 23$ ).					
Characteristic	N (%)				
Total patients	23				
Boys	13 (56.5)				
Girls	10 (43.5)				
Mean age					
Boys	10.5				
Girls	12.7				

#### Table 2. Preoperative and postoperative measures.

· · ·	(Mean ± Standa	***	
	Pre	Post	p.
Talonavicular coverage angle	38.83 ± 13.40	22.49 ± 13.35	< 0.001
Calcaneal pitch	12.25 ± 4.07	23.75 ± 4.05	< 0.001
Meary's angle	18.90 ± 7.76	8.41 ± 6.16	< 0.001
AOFAS score	62 ± 11.1	89.8 ± 3.7	< 0.001

\* Student's t-test.

#### DISCUSSION

Surgical treatment for flexible flat foot in children is indicated after a failed attempt with conservative treatment. Surgery aims to relief pain in the medial plantar surface of the midfoot and/or in the sinus tarsus, which interferes with the patient's day-to-day activities. Among surgical interventions, osteotomies have become the first choice due to the possibility of realigning the foot without sacrificing its movements.<sup>2</sup>

Rathjen and Mubarak described sliding and medial closing wedge osteotomy of the calcaneus associated with osteotomy of plantar closing wedge of the cuneiform and lateral opening wedge in the cuboid (triple "C"). This technique proved to be capable of correcting the deformities found in the flexible flat foot of children, with good functional results and a low complication rate.<sup>6</sup>

When comparing the technique proposed by Mubarak and the isolated lengthening of the external column of the foot (Evans modified by Mosca), it was observed that the osteotomy of lengthening the lateral column has greater power to correct the talar coverage and the talus-first metatarsal angle on anteroposterior radiograph of the foot. Confirming a better correction of the foot abductus with the Evans technique modified by Mosca.<sup>2</sup>

However, lengthening the lateral column presents a greater chance of subluxation of the calcaneal-cuboid joint (possibly increasing chances of arthrosis), a higher complication rate (18.2%  $\times$  10%), pain at the lateral edge of the foot, a chance of migration of the bone graft and possible injury to the calcaneal joint surface.<sup>8</sup>





Figure 7. Effect calcaneus osteotomy on Meary's angle.

The association of plantar closing wedge osteotomy of the medial cuneiform with the aforementioned intervention aims to restore the longitudinal arch of the foot.<sup>6</sup> Although this association has proven capable of restoring radiological parameters, it increases surgical time, implies additional surgical incision and leads to a shortening of the medial column of the foot.

Our work showed that it is possible to correct the deformities found in the flexible flat foot of children, including the restoration of the longitudinal plantar arch of the foot without plantar closing wedge osteotomy of the medial cuneiform. Plantar and medial calcaneal displacement osteotomy associated with opening wedge cuboid osteotomy was able to improve talonavicular coverage, calcaneal pitch, and Meary's angle.

When we compared the triple "C" technique with medial and plantar calcaneal displacement associated with opening wedge cuboid osteotomy, we noticed similar radiological results. In the work by Mubarak et al.,<sup>2</sup> the talus-first metatarsal angle changed from  $21.8 \pm 9.3$  to  $15.5 \pm 11.1$ . talonavicular coverage angle changed from 41  $\pm$  9.2 to 28  $\pm$  14.7, and Meary's angle changed from 25.3  $\pm$  12.2 to 16.1  $\pm$  10.25. All three parameters mentioned showed a statistically significant improvement (p < 0.05). In the surgical technique described by our group, we found that the same aforementioned parameters showed a statistically significant improvement.

Like Mubarak, we performed the lengthening of the external column of the foot through the opening wedge cuboid osteotomy, however we were able to improve Meary's angle without the medial cuneiform osteotomy. The improvement in this angle can be explained by the tendency of the 1st ray to flex plantarly as a result of the medial and plantar calcaneal displacement osteotomy (Figure 7).

The medial and plantar calcaneal displacement osteotomy associated with cuboid opening wedge proved to be able to improve patients' clinical condition. Patients showed an improvement in the AOFAS scale from poor to good, corroborating the outcomes of other studies related to "triple C" osteotomy.8-10

Our work has some limitations: the small number of patients, a short follow-up time without a control group, and the retrospective study model. A prospective and randomized study with a control group and longer follow-up is necessary. Moreover, it is necessary to prove the effect of plantar and medial calcaneal displacement on the first ray, possibly with weight-bearing tomography.

#### CONCLUSION

Our work showed that the plantar and medial calcaneal displacement osteotomy associated with opening wedge cuboid osteotomy can improve radiological and clinical parameters of flexible flat feet in children.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. BAMS: article writing on authorship, study design, analysis and interpretation of data, writing, and final approval of the article version; NAS: paper writing, data acquisition, and study design; JBV: acquisition, analysis, and interpretation of data.

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## COMPARATIVE EVALUATION OF SKIN SUTURE IN RATS WITH POLYGLYCAPRONE 25 AND NYLON

## AVALIAÇÃO COMPARATIVA DA SUTURA DE PELE COM POLIGLICAPRONE 25 E NYLON EM RATOS

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#### ABSTRACT

Currently, the market offers a wide variety of suture threads, made of materials with different structural and chemical properties. Among many other characteristics, they vary in origin, absorption or degradation, and structure. From this variety, the clinical doubt arises as to which material provides the patient with the best healing quality. Objective: This study aims to comparatively evaluate two different types of suture threads-Monocryl<sup>®</sup> (polyglycaprone 25) and Ethilon<sup>®</sup> (nylon)—regarding their ability to aid in tissue regeneration by a histological and immunohistochemical analysis of the skin of rats sutured with the aforementioned materials. Methods: This basic experimental study used 12 adult Wistar rats, randomly divided into three groups with four animals each and subjected to four longitudinal incisions under anesthesia. Each group corresponded to a postsurgical evaluation date (one, seven, and 14 days). Results: At 14 postoperative days, the studied groups had no histological difference. However, the use of nylon thread showed greater evidence of earlier fibrotic union. Conclusion: This study found no histological difference in healing 14 days after surgery among the techniques and the types of suture threads. Level of Evidence II, Therapeutic Studies.

Keywords: Skin. Wound Healing. Sutures. Inflammation. Metalloproteinases. Tissue Inhibitor of Metalloproteinases.

#### RESUMO

Atualmente, encontra-se disponível no mercado uma grande variedade de fios de sutura, compostos de materiais com diferentes propriedades estruturais e químicas, que variam quanto à origem, absorção ou degradação e estrutura, entre outras características. A partir dessa disponibilidade, emerge a dúvida clínica quanto ao material que propicia a melhor qualidade de cicatrização ao paciente. Objetivo: Avaliar comparativamente dois tipos de fios – Monocryl® (poliglicaprone 25) e Ethilon<sup>®</sup> (nylon) – quanto à sua capacidade de auxílio na regeneração tecidual, por meio da análise histológica e imuno-histoquímica da pele de ratos submetidos a suturas com esses materiais. Métodos: Neste estudo básico experimental, foram utilizados 12 ratos adultos da linhagem Wistar, randomicamente divididos em três grupos com quatros animais cada, que foram submetidos a quatro incisões longitudinais sob anestesia. Cada grupo correspondeu a uma data de avaliação pós-cirúrgica (1, 7 e 14 dias). Resultados: Passados 14 dias após a operação, não houve diferença histológica em relação aos grupos estudados. No entanto, o uso de fio de nylon apresentou evidência de união fibrótica mais precoce. Conclusão: Não há diferença histológica de cicatrização após 14 dias pós-operatórios entre as técnicas e os tipos de fio de sutura. Nível de Evidência II, Estudos Terapêuticos.

**Descritores:** Pele. Cicatrização. Suturas. Inflamação. Metaloproteinases. Inibidores Teciduais de Metaloproteinases.

**Citation:** Alves RS, Tanaka LY, Carvalho VB, Lopes LC, Santos SB, Dsouki NA, et al. Comparative evaluation of skin suture in rats with polyglycaprone 25 and nylon. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 4. Available from URL: http://www.scielo.br/aob.

#### INTRODUCTION

Synthesis is the last step of a surgical procedure and, compared with other methods used at this stage, such as adhesives, suturing is the most frequent, which makes suture materials the most common exogenous implants found in human organisms.<sup>1</sup> The main functions of the suture include promoting closure and

healing of the wound or surgical incision, and helping reduce possible infections by restoring continuity between the edges and layers separated in the dieresis.<sup>2</sup>

Each material has a distinct set of structural and chemical properties, which interferes with its ability to prevent infection, minimize inflammation, and aid in the healing process. Among the aforementioned factors, inflammation is an inherent response

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The study was conducted at the vivarium of the Centro Universitario Faculdade de Medicina do ABC. Correspondence: Victor Bignatto Carvalho. Avenida Lauro Gomes, 2001, Santo Andre, SP, Brazil, 09060870. victor\_bignatto@hotmail.com

Article received on 08/04/2022, approved on 10/26/2022.



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of the body to the implantation of threads, which are interpreted as foreign bodies. Normally, sutures of animal origin have greater inflammatory tissue reactions.

The use of materials with greater tensile strength and suture firmness also implies the search for materials with less inflammatory response, such as monofilaments.<sup>3-5</sup> Nylon, in its monofilament form, causes little tissue reaction and can be used and well tolerated in infected tissues. Similarly, another monofilament suture, Monocryl (absorbable, epsilon-caprolactone, and glycolide copolymer), is easy to handle and has minimal resistance during tissue passage and adequate tension. The absorption time is completed about 120 days after implantation in the tissue, with minimal tissue reaction.<sup>6</sup>

The suture technique applied is also important in the progress of wound closure and healing. In 2014, Gurusamy et al.,<sup>7</sup> in a review comparing five studies on continuous sutures with interrupted skin sutures for 730 participants undergoing nonobstetric operations, found no significant difference in the proportion of participants who developed superficial site infection between the continuous suture and interrupted suture groups. A total of 23 participants (23/625; 3.7%) developed superficial wound dehiscence. Among the 23, 22 participants were part of the interrupted suture groups. The proportion of participants who developed superficiantly lower in the continuous skin suture group than in the interrupted skin suture group (RR 0.08; 95%CI 0.02–0.35).<sup>7</sup>

Considering the wide variety of suture materials regarding structural and chemical properties, the need for studies to guide the clinical choice of threads is undeniable, to provide the best possible tissue healing and recovery using quantitative and qualitative histological evidence. Therefore, in this study, we compare materials with different degradation—absorbable polyglycaprone 25 and nonabsorbable nylon—regarding their behavior in animal tissues sutured with both threads.

This study aims to comparatively evaluate Monocryl<sup>®</sup> (polyglycaprone 25) and Ethilon<sup>®</sup> (nylon) suture threads regarding the quality of healing favored by histological and immunohistochemical analysis of the scar tissue of rats subjected to sutures with both materials.

#### **METHODS**

#### Animals

In total, 12 adult Wistar rats, weighing about 320 g, from the vivarium of the Faculdade de Medicina do ABC (FMABC) were used. They were kept with food and water *ad libitum* in individual polypropylene boxes. The 12:12-hour light-dark cycle of the FMABC vivarium was also controlled. The humidity in the vivarium was about 70% and the room temperature about 23°C.

The rats were randomly divided into three groups of four animals each. Each group corresponded to a postsurgical evaluation date (one, seven, and 14 days):

Group 1 (one day after surgery):

• Four rats subjected to four dorsal incisions and sutured with the following four types of threads;

Group 2 (seven days after surgery):

- Four rats subjected to four dorsal incisions and sutured with the following four types of threads; Group 3 (14 days after surgery):
- Four rats subjected to four dorsal incisions and sutured with the
- following four types of threads. The rats were anesthetized with ketamine (50 mg/kg i.p.) and xylazine

(10 mg/kg i.m.), and then their backs were shaved. To demarcate the skin to be removed, a specially made metal punch with a cutting blade on its lower edge, similar to the tool used in plastic surgeries, was used. With this instrument, four 3-cm longitudinal incisions were made on the dorsal skin, with a distance of 2 cm between them, reaching the subcutaneous space. The incisions were made in the dorsal region of the rats so that they would not access the incision with their mouths. The rats received tramadol (10 mg/kg) intramuscularly immediately after the end of the surgery and every 12 hours for the first 24 hours after surgery to obtain analgesia. Due to the nature of the study, anti-inflammatory medications were not used. The rats received 0.2 mL of antibiotic (Veterinary Pentabiotic for Small Animals – Fort Dodge 2000 IU/mL) intramuscularly as a prophylactic measure in a single dose to prevent infection. Hemostasis was performed by digital compression, using sterile

Hemostasis was performed by digital compression, using sterile gauze. Each rat was randomly subjected to one of the following types of suture (Figure 1):



**Figure 1.** A: Representation of the single suture technique; B: Representation of the intradermal suture technique.

- I) Single suture<sup>3,8,9</sup> with Ethilon<sup>®</sup> nylon;
- II) Single suture with Monocryl<sup>®</sup>;
- III) Interrupted intradermal suture<sup>3,8,9</sup> with Monocryl<sup>®</sup>;

IV) Continuous intradermal suture with Ethilon<sup>®</sup> nylon.

Immediately after surgery, the rats were placed in individual polypropylene boxes, receiving water and food *ad libitum* and analgesia with tramadol (10 mg/kg i.m.)—immediately after surgery and every 12 hours for the first 24 hours after surgery. All rats were examined daily for mobility and a macroscopic evaluation of the surgical wound was performed to assess the presence or absence of secretion, crusts, or necrosis. Data were evaluated and recorded on a specific, individual form for each rat.

The incisions were photographed by digital camera at pre-established periods (first, seventh, 14th, and 28th days) with protocol records for later comparison by digital planimetry (healing assessment by measuring the wound area) using the Image Tool software (University of Health Center, USA).

On the pre-established day for euthanasia (first, seventh, 14th, and 28th days), two rats from each group were weighed and received an overdose of sodium thiopental (100 mg/kg i.p.). Then, after confirmation of cardiopulmonary arrest and lack of reflexes, they were fixed on the operating table for tissue collection for morphological and molecular analysis. The wound was excised with a margin of 1 cm of intact skin around the incision, in depth to the muscle fascia. Each piece was individually identified, fixed in Styrofoam, and placed in a 10% formalin solution for slide preparation and histological evaluation.

Tissues were embedded in paraffin for histological sections  $20 \,\mu m$  thick on a microtome.

The histological sections of the wound were stained using the hematoxylin-eosin and Picrosirius methods.

Hematoxylin-eosin staining of histological sections

Initially, the histological sections of the wound were deparaffinized and hydrated. Then, hematoxylin staining was performed (15 to



20 minutes), followed by washing in running water for 10 minutes. The sections were then placed in 1% HCl alcoholic solution (1 mL of HCl in 99 mL of 70% alcohol) until the desired intensity was reached. The sections were quickly washed in running water, after differentiation, and then stained with eosin for two minutes and washed in running water until the water was clear. They were dehydrated, quickly in 70% alcohol, followed by 95% alcohol, 100% alcohol, and xylene, and, finally, the slides were covered with ERV-MOUNT to place a coverslip.

#### Picrosirius staining of histological sections

After deparaffinization and hydration, the sections were stained in 0.1% Sirius red solution dissolved in saturated aqueous picric acid for one hour. Then, they were washed in running water (five minutes), counterstained with Ehrlich's hematoxylin (two minutes), and washed again in running water (five minutes). After this process, the sections were dehydrated in an ethanol gradient, cleared in xylene, and mounted in Entellan<sup>®</sup>. The use of this stain, besides identifying collagen (which acquires an intense red color under conventional light), allows a qualitative assessment of the degree of collagen aggregation when analyzed under polarized light, according to Junqueira, Bignolas, and Brentani.<sup>10</sup>

#### Verhoeff's stain

After deparaffinization and hydration, the sections were stained with Verhoeff's solution for 30 seconds. Then, they were carefully washed in distilled water. The sections were covered with wound chloride solution for 15 seconds and washed with distilled water, and the slides were covered with Van Gieson's stain for three minutes. After this process, the sections were dehydrated in an ethanol gradient, cleared in xylene, and mounted in Entellan<sup>®</sup>. Verhoeff's stain highlights the collagen fibers with a red or orange color and the presence of elastin with a black or blue color.

#### Immunohistochemistry

The tissue fixed in 10% formalin, sectioned on the microtome, and 20- $\mu$ m sections were separated for immunohistochemistry with specific antibodies to metalloproteinases 1, 2, and 9 and TIMP-1. The sections were initially washed with PBS (0.01 M; pH 7.4) for 15 minutes. Antigen exposure was performed in 10/1 mM Tris/EDTA buffer (pH 9.0) for five minutes, followed by heating in an oven at 70°C for 30 minutes in 10 mM sodium citrate buffer (pH 6.0). After washing with PBS for 15 minutes, endogenous tissue peroxidases were blocked with 1% hydrogen peroxide in PBS for 10 minutes. After washing again for 15 minutes, nonspecific binding sites were blocked for 60 minutes with a solution of normal goat serum and Triton X-100 (nonionic detergent) diluted in PBS. Then, without washing, but removing excess blocking solution, the sections were incubated for 24 hours at  $4^\circ C$  with their respective primary antibodies anti-metalloproteinases 1, 2, and 9 and TIMP-1 (Santa Cruz Biotechnology). Negative controls, omitting primary antibodies, were included in the processing of sections to avoid nonspecific labeling. The sections were then incubated with their respective peroxidase-coupled secondary antibodies and mounted on gelatinized slides, dried, and covered with coverslips using appropriate mounting medium for immunohistochemistry.

The research project was approved by the Animal Research Ethics Committee of the Faculdade de Medicina do ABC (CEUA-FMABC) on November 19, 2020, registration number 12/2020.

#### RESULTS

The results from the first group of rats showed some open wounds, probably due to self-made scratches, and cellular evidence of an early healing/closing process of organized tissue.

Regarding the second group, all associations showed compatible granulation tissue. However, the single suture-nylon association caused a greater inflammatory reaction. In the intradermal suturepoliglycaprone association, we observed a more advanced fibrotic union. The intradermal suture-nylon association presented a better healing aspect (Figure 2).



**Figure 2.** I: Simple suture and poliglycaprone 25 seven days after surgery; II: Simple suture with nylon seven days after surgery; III: intradermal suture with poliglycaprone 25 14 days after surgery; IV: intradermal suture with nylon 14 days after surgery.

D: dermis; E: epidermis.

At 14 days postoperatively, all associations in all rats showed compatible healing and no evident difference in the histological pattern of each healing.

#### DISCUSSION

Several materials can be used for skin closure, with different techniques, in order to minimize complications such as scar pain, dehiscence, and infection, reduce surgical time, and improve aesthetics. Sutures with absorbable and nonabsorbable threads are the most widespread methods, as they are the simplest and least expensive techniques. In the literature, many studies compare different techniques and materials. However, the results are not unanimous.<sup>11</sup> The results obtained in this study showed that:

- At the first day postoperatively (G1), the different suture techniques and materials showed no difference;
- At seven days postoperatively (G2), the rats subjected to nylon suture were at a more advanced stage of healing and the intradermal suture showed greater fibrotic union;
- At 14 days postoperatively (G3), we observed no evident difference in the histological pattern of each healing.

Normally, when a wound is closed with absorbable suture, the decrease in tensile strength in the first few weeks is gradual and linear. During this period, a leukocyte cellular response mounts to remove cellular debris and physical suture material, and this process overlaps with the second stage. Hydrolysis produces a lesser degree of tissue reaction compared with the enzymatic degradation process. In contrast, the in vivo tissue response around the nondegradable material involves fibroblasts encapsulating the suture to form a fibrous capsule. Adjacent macrophages and foreign body giant cells respond in a process known as frustrated phagocytosis, in which they attempt to enzymatically degrade the nondegradable suture.<sup>12</sup>

Our results are similar to the findings of Ribeiro et al.<sup>13</sup> in 2005, in a clinical and histopathological analysis of the tissue reaction of nylon and polyglycaprone 25 monofilament threads in internal and external sutures in 40 rats. In their study, fibrosis formation was higher in external



and internal sutures with polyglycaprone 25 from the seventh to the 21th day after surgery. The formation of granulation tissue, along with the presence of giant cells, was greater in external and internal sutures with nylon from the seventh day after surgery, since this material causes a greater inflammatory reaction, resulting in epithelialization of the suture path through the tissues with invagination of the wound edges.<sup>13</sup>

#### CONCLUSION

We observed satisfactory wound healing with all associations. However, we highlight the considerably inflammatory reaction caused by the use of simple suture with nylon and the advanced wound healing seven days after surgery with the use of intradermal suture with poliglycaprone 25.

#### ACKNOWLEDGEMENTS

We thank the Centro Universitario Faculdade de Medicina do ABC, the Núcleo de Estudos Pesquisa e Assessoria à Saúde (NEPAS), and the Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP) for the support and assistance in the development of this study.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. RSA: elaborated the study hypothesis, developed the experiments, discussed the information obtained, and wrote the manuscript; LYT, VBC, LCL, SBS: elaborated the study hypothesis, discussed the information obtained, and wrote the experiments; MAS: guaranteed financial support.

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## STUDY OF THE MEDIAN AND ULNAR NERVOUS BRANKS TO KAPLAN'S LINE

## ESTUDO ENTRE OS RAMOS DOS NERVOS MEDIANO E ULNAR COM A LINHA DE KAPLAN

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#### ABSTRACT

Objective: This study aims to present lines A1 and A2 in association with Kaplan's cardinal line (LCK), and relate them to the thenar motor branch of the median nerve (RMTNM) and to the deep branch of the ulnar nerve (RPNU). Methods: Ten hands of five adult cadavers were dissected. Results: The RMTNM origin was positioned proximal to the LCK in all limbs. In two, the RMTNM was positioned exactly on the A1 line; in seven, it was on the ulnar side in relation to A1. In one, it was on the radial side relative to the A1. The origin of the RPNU was identified between the pisiform and the LCK in nine limbs; in one, the RPNU was positioned from the ulnar nerve in relation to A2; and in two, the A2 passed exactly at the point of division of the ulnar nerve into superficial branches and deep. We did not identify the positioning of the RPNU on the radial side of the A2 line. Conclusion: The impact of this study was to identify the anatomical trajectory of these nerves by detaching A1 and A2 along with the KCL, avoiding iatrogenic lesions during surgical procedures. Level of Evidence IV, Case Series.

Keywords: Median Nerve; Ulnar Nerve; Nerve Transfer; Hand.

RESUMO

Objetivo: Apresentar as linhas A1 e A2 em associação com a linha cardinal de Kaplan (LCK) e relacioná-las ao ramo motor tenar do nervo mediano (RMTNM) e ao ramo profundo do nervo ulnar (RPNU). Métodos: Foram dissecadas dez mãos de 5 cadáveres adultos. Resultados: Em todos os membros, a origem do RMTNM posicionou proximal a LCK. Em dois, o RMTNM foi posicionado exatamente na linha A1, em sete foi no lado ulnar em relação à A1. Em um, foi no lado radial em relação à A1. A origem do RPNU foi identificada entre o pisiforme e o LCK em 9 membros, em um, o RPNU foi posicionado a partir do nervo ulnar em relação à A2, em dois, a A2 passou exatamente no ponto de divisão do nervo ulnar em ramos superficial e profundo. Não identificamos o posicionamento do RPNU no lado radial da linha A2. Conclusão: O impacto deste trabalho é que, ao destacar A1 e A2 juntamente com o LCK, conseguimos identificar a trajetória anatômica desses nervos e, evitar lesões iatrogênicas durante os procedimentos cirúrgicos. Nível de Evidência IV; Série de Casos.

**Descritores:** Nervo Mediano; Nervo Ulnar; Transferência de Nervo; Mãos.

**Citation:** Tozello VNN, Volpiani TS, Mansur Silva VL, Amaral Junior SA, Vieira LA, study of the median and ulnar nervous branks to kaplan's line. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 4. Available from URL: http://www.scielo.br/aob.

#### INTRODUCTION

There are reference lines on the palmar surface of the hand, which are used to help locate deep structures. The thenar motor branch of the median nerve (TMBMN) and the deep branch of the ulnar nerve (DBUN) are deep structures that can be injured when performing surgical procedures. The TMBMN is responsible for innervating the muscles in the thenar region that provide the thumb opposition, which is the most important function of the hand. All other intrinsic muscles of the hand are innervated by the DBUN.

In 1953 Kaplan<sup>1</sup> described a line starting at the apex of the interdigital fold between the thumb and index finger towards the

ulnar side of the hand, parallel to the middle palmar fold and called it the cardinal line, which allows establishing the relationship with deep structures such as vessels and nerves of the hand. In 1968, Kaplan himself started to consider the cardinal line as being drawn from the junction of the line which starts at the apex of the interdigital fold between the thumb and index finger, following in the direction of the ulnar border of the hand to a point 2 cm distal to the pisiform bone<sup>2</sup> (Figure 1). The KCL has often been used as a reference for surgical incisions and to identify deep structures, guide surgical incisions and prevent injuries<sup>2-5</sup>. The intersection of the KCL with a line following the radial border of

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Article received on 06/29/2022, approved on 10/13/2022.





Figure 1. Kaplan's cardinal line.

the middle finger has been used to locate TMBMN<sup>1,3-5</sup>. This point of intersection has been described as the location of the origin of the nerve (TMBMN)<sup>3-5</sup>, or the site where the nerve enters the thenar muscle mass<sup>1</sup>. The intersection of the KCL with a line that follows the ulnar border of the ring finger has been used to locate the annulus of the hamate and the DBUN<sup>1,6</sup>. In addition, the path of the KCL has been used to identify the deep branch of the ulnar nerve<sup>1</sup>, the superficial palmar arch,<sup>1,3,5</sup> and the distal margin of the transverse carpal ligament<sup>4</sup>. Other investigators have used the KCL to describe the location of surgical incisions for procedures such as open carpal tunnel release<sup>4,5,7</sup>, endoscopic carpal tunnel release<sup>7</sup> and Dupuytren's fasciectomy<sup>8</sup>.

The aim of this study is to introduce the new lines A1 and A2 in association with the Kaplan's cardinal line (KCL) and relate those to the thenar motor branch of median nerve (TMBMN) and deep branch of the ulnar nerve (DBUN). By highlighting these new lines along with KCL, we are able to identify the anatomical path of these nerves and furthermore orient surgeons during medical procedures.

#### MATERIAL AND METHODS

We dissected 10 hands from 5 adult male cadavers, aged 27 to 66 years old, available at the Anatomy Department of PUC-Sorocaba. The dissected hands had no lesions, deformities or scars. The dissections were performed with the aid of a magnifying glass (magnification of 2.5X). The dissection technique was started by an incision proximal to the wrist crease, in the interval between the flexor carpi radialis and palmaris longus muscles, extending distally in the palm of the hand. The median nerve was identified proximally to the transverse carpal ligament, the ligament was sectioned longitudinally on its ulnar side, and its branches were dissected distally. The ulnar nerve was also identified in the wrist, proximal to Guyon's canal, its deep motor branch was followed distally. Line A1 was drawn from the second interdigital commissure, in a proximal direction following the axis of the hand, which corresponds to the line drawn from the radial border of the middle finger. Similarly, line A2 was drawn from the third commissure, following the axis of the hand and parallel to line A1. Lines A1 and A2 cross the KCL (Figures 2, 3 and 4). The distance between the TMBMN and the DBUN was measured with the KCL. Schematic drawings of the parts were made and systematically photographed. All available specimens adhered to the ethical principles of the institution and the project was evaluated by the Ethics in Research Committee and registered in the Plataforma Brasil, under CAAE No. 14643419.5.0000.5373.



Figure 2. Kaplan's cardinal line passing directly over the Thenar Motor Branch of the Median Nerve.

 $\mathsf{DBUN}$  = deep branch of the ulnar nerve.  $\mathsf{MN}$  = median nerve.  $\mathsf{PB}$  = psiform bone.  $\mathsf{TMBMN}$  = thenar motor branch of median nerve.  $\mathsf{UN}$  = ulnar nerve.



**Figure 3.** Kaplan's Cardinal Line positioning itself on the ulnar side in relation to the Thenar Motor Branch of the Median Nerve. DBUN = deep branch of the ulnar nerve. KCL = Kaplan's cardinal line MN = median nerve. PB = psiform bone. TMBMN = thenar motor branch of median nerve. UN = ulnar nerve.



**Figure 4.** Kaplan's Cardinal Line positioning itself on the radial side in relation to the Thenar Motor Branch of the Median Nerve. DBUN = deep branch of the ulnar nerve. KCL = Kaplan's cardinal line MN = median nerve. PB = psiform bone. TMBMN = thenar motor branch of median nerve. UN = ulnar nerve.

## << SUMÁRIO

#### RESULTS

We identified that the origin of the TMBMN positioned proximal to the KLC with a distance ranging from 0.3 to 2.5, mean 1.4 cm. In 2 limbs, the TMBMN was positioned exactly on line A1 (Figure 2), in 7 limbs, the TMBMN was positioned on the ulnar side in relation to line A1 (Figure 3) with a distance ranging from 0.2 to 0.6 cm, mean 0.4 cm. In one limb it was positioned 0.3cm from the radial side in relation to line A1 (Figure 4). In all limbs the TMBMN originated from the antero-radial aspect of the median nerve.

The origin of the DBUN, was identified between the psiphorme bone and the KCL in 9 limbs. With distance ranging from 0.4 to 0.9, with an average of 0.7 cm proximal to the KCL. In 1 limb the DBUN originated 2.5 cm proximal to the piriform bone (Figure 3). We did not identify the DBUN originating distal to the KCL. In 8 limbs the UPRNB was positioned on the ulnar side in relation to line A2, (Figure 2), in 2 limbs the line A2 passed exactly at the point of division of the ulnar nerve into superficial and deep branches (Figure 4). We did not identify the DBUN positioned on the radial side of line A2.

#### DISCUSSION

Analyzing the literature, we observed that there is no consensus regarding the definition of KCL, four different descriptions were found<sup>1,2,9,10</sup>. Vella et al<sup>9</sup> reported that their research showed that most surgeons who participated in their research used KCL as a reference in the surgical act. In the present study, we considered the KCL definition of<sup>9</sup>, i.e. the trace of the junction starting at the apex of the interdigital fold between the thumb and index finger, following towards the ulnar border of the hand, up to a point 2 cm distal to the pisiform bone<sup>2</sup>.

Kaplan's cardinal line has been used as a surface marker in several clinical and anatomical studies. In this study, we identified that the origin of the TMBMN was positioned proximal to the KCL with a distance ranging from 0.3 to 2.5 averaging 1.4 cm. In 2 limbs, the line A1 passed exactly over the TMBMN, in 7 it was positioned on the ulnar side in relation to the line A1 with distance varying from 0,2 to 0,6 cm, mean of 0,4 cm, in another limb it was positioned 0,3 cm on the radial side in relation to the line A1 (Figure 4). In all limbs the TMBMN originated from the antero-radial aspect of the median nerve. Eskandari et al<sup>10</sup>, performed a study on 37 hands of 34 patients undergoing carpal tunnel release procedure. A radiological marking technique was used to determine the location of the TMBMN, in relation to the KCL and also in relation to the line accompanying the radial margin of the middle finger, which corresponds to line A1 in our study. They concluded that the RMT had a mean ulnar displacement of 12.6 mm (range 4.0 to 19.7 mm) from the radial lateral line of the middle finger and was located 4.4 mm (range 0 to 9.5 mm) proximal to the cardinal line. Our findings agree with those of Eskandari et al<sup>10</sup>, regarding the KCL because in all limbs the TMBMN was positioned proximal to the KCL. In relation to the radial-ulnar impingement, we registered slightly different results. According to Eskandari el al<sup>10</sup>, in all cases the TMBMN was positioned on the ulnar side in relation to the line following the radial margin of the middle finger. In this study we identified in 7 limbs, the TMBMN was positioned on the ulnar side in relation to line A1, agreeing with these authors. In another limb it was positioned on the radial side (Figure 3), in two limbs the line A1 passed exactly over the TMBMN. The origin of the DBUN was identified between the psiform and the KCL in 9 limbs. With distance ranging from 0.4 to 0.9, average of 0.7 cm proximal to the KCL. In 1 limb the DBUN originated 2,5 cm proximal to the piriformis. We did not identify the DBUN originating distal to the KCL. In 8 limbs the DBUN was positioned from the ulnar lobe in relation to line A2, in 2 limbs the line A2 passed exactly in the point of division of the ulnar nerve in superficial and deep branches. We did not identify the DBUN positioned on the radial side of line A2. We did not find in the literature any work that directly relates the DBUN to the KCL. Bini and Leclercq<sup>11</sup> studied the DBUN in 21 hands of recently deceased cadavers, with the purpose of analyzing its branches to the intrinsic muscles of the hand. They used three anatomical points as reference: the biestiloid line, the radial flexor tendon of the carpus, and the pisiform bone; they did not inform why they did not also use the KCL as reference. Dashe and Jones<sup>12</sup> presented a method for safe exposure and removal of the hamate annulus in cases of pseudoarthrosis with pain symptoms. They used the KCL and the line accompanying the ulnar margin of the ring finger as a reference for the access route, to avoid damage to the DBUN. Choi and Yoon<sup>13</sup> evaluated the DBUN in 60 wrists of 30 healthy adult patients using high-resolution ultrasonography. The course of the RMNU was evaluated using the hamate annulus and skin depth as reference. They did not report why Kaplan's line was not used as a reference.

Some authors have related the KCL to the arterial arches of the palmar surface of the hand. Panchal and Trzeciak<sup>14</sup> performed an anatomical study in 30 cadavers, dissecting 60 hands, to describe the relationship between Kaplan's cardinal line and the superficial palmar arterial arch. They stated that from a clinical point of view, Kaplan's cardinal line is the most predictable marker to identify the superficial palmar arch. McLean et al<sup>15</sup> performed an anatomical study on 48 cadaveric hands in specimens between 50 and 75 years old, with the purpose of assessing the distance of the superficial palmar arch and the KCL. Similarly, Anand and Trzeciak<sup>16</sup> anatomically correlated the relationship of Kaplan's cardinal line with the superficial and deep palmar arterial arches. Kwiatkowska et al<sup>17</sup> dissected 20 upper limbs from cadavers. They related the deep palm structures to the palmar folds, and concluded that the palmar folds vary considerably between people and that genetics has an influence on the formation of the folds. They considered that the middle palmar crease was parallel to the KCL.

We are aware of the limitations in the present study, such as the limited number of cases and the non-living tissue conditions. Although we could not examine in vivo conditions, cadaver preparation does not alter the positioning of the anatomical structures. The highlight of this work is that we found no anatomical studies in the literature that relate the KCL to the TMBMN and DBUN.

#### CONCLUSION

In this study we propose new reference lines, named A1 and A2, to guide hand surgeries. In all members the TMBMN and DBUN were positioned close to the KCL. The TMBMN was positioned on the ulnar side in relation to the A1 line in 7 limbs; on one of the radial side; in two passed over the TMBMN. The DBUN was positioned on the ulnar side in relation to the A2 line, between the psiform bone and the KCL in 9 limbs in 1 proximal to the psiform bone. The impact of this work is that by highlighting lines A1 and A2 together with the KCL, we are able to identify the anatomic trajectory of these nerves and consequently avoid iatrogenic injures during surgical procedures.

AUTHORS' CONTRIBUTION: Each author has significantly contributed to this article. EC e LV: writing of the manuscript, statistical analysis of the data, and intellectual concept of the manuscript and development of the research project; VT, TV e VS: data collection, data analysis, manuscript writing and revision; VL: data collection and analysis. SAJ: revision of the manuscript and intellectual concept; EC: critical analysis of the intellectual concept and final approval of the manuscript version to be published.



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## SIMULTANEOUS RUPTURE OF THE PATELLAR AND CONTRALATERAL QUADRICEPS TENDONS IN A NEPHROPATHY PATIENT

## RUPTURA SIMULTÂNEA DE TENDÃO PATELAR E QUADRICIPITAL CONTRALATERAL EM PACIENTE NEFROPATA

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#### ABSTRACT

Simultaneous rupture of the patellar and contralateral quadriceps tendons in patients with chronic renal failure is an extremely rare condition, with few cases described in the medical literature. Several systemic pathological conditions that lead to a decline in kidney function can predispose individuals to spontaneous tendon rupture, such as rheumatological and endocrine diseases, and even gestational conditions, such as eclampsia. Objective: In this case report, we describe the case of a 39-year-old woman with chronic renal failure on dialysis due to a previous history of eclampsia that caused the simultaneous rupture of the patellar and contralateral guadriceps tendons. Methods: Data were collected by interviews, direct observation, and medical examinations, and include information about the case history, the patient's characteristics, the former interventions, and the results obtained. Results: The surgery to repair the patellar and contralateral quadriceps tendons was performed by transosseous tunnels and the Krackow technique with nonabsorbable sutures was used. The semitendinosus tendon was removed and used as reinforcement. Conclusion: Patient under follow-up with good functional results in both knees. Level of Evidence V, Expert Opinion.

**Keywords:** Rupture. Patellar Ligament. Renal Insufficiency. Preeclampsia.

#### RESUMO

A ruptura simultânea de tendão patelar e tendão quadricipital contralateral em paciente com insuficiência renal crônica é uma condição extremamente rara, havendo poucos casos descritos na literatura médica. Diversas condições patológicas sistêmicas que levam ao declínio das funções renais podem predispor à ruptura tendinosa espontânea, como doenças reumatológicas e endócrinas, até mesmo condições gestacionais, como a eclâmpsia. Objetivo: Neste relato de caso, descrevemos o caso de uma mulher de 39 anos com insuficiência renal crônica dialítica decorrente de quadro pregresso de eclâmpsia que culminou na ruptura simultânea de tendão patelar e tendão guadricipital contralateral. Métodos: Estudo realizado com dados coletados por meio de entrevista, observação direta e exames médicos. Os dados incluem informações sobre o histórico do caso, as características do paciente, as intervenções realizadas e os resultados obtidos. Resultados: A cirurgia para reparo da lesão de tendão patelar contralateral e tendão quadricipital foi realizada por túneis transosseos e a rafia foi feita com pontos Krakow utilizando fios não absorvíveis. Além disso, o tendão semitendinoso foi retirado e usado como reforço. Conclusão: A paciente apresentou bons resultados funcionais em ambos os joelhos operados. Nível de Evidência V, Opinião do Especialista.

**Descritores:** Ruptura. Ligamento Patelar. Insuficiência Renal. Pré-Eclâmpsia.

**Citation:** Branco FRT, Gonçalves WA. Simultaneous rupture of the patellar and contralateral quadriceps tendons in a nephropathy patient. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 4. Available from URL: http://www.scielo.br/aob.

#### INTRODUCTION

Quadriceps tendon rupture is a condition with a higher incidence in older patients, aged around the 60th and 70th decades of life, due to degenerative conditions in the tendon caused or aggravated by falls and low-impact trauma.<sup>1,2</sup> Patellar tendon rupture usually occurs in patients aged under 40 years due to intra- and periarticular applications of corticosteroids as a result of previous patellar tendinitis and/or sports practices that increase the risk of this type of injury.<sup>3</sup> Simultaneous rupture of the patellar and contralateral quadriceps tendons in patients with chronic renal failure is an extremely rare condition, with few cases described in the medical literature.<sup>4</sup> In this case report, we describe the case of a 39-year-old woman with chronic renal failure on dialysis due to a previous history of eclampsia that caused the simultaneous rupture of the patellar and contralateral quadriceps tendons.

#### **CASE REPORT**

A 39-year-old female patient was admitted to our service with bilateral functional disability in the knees and mild pain on

#### All authors declare no potential conflict of interest related to this article.

The study was conducted at Universidade Estadual do Oeste do Parana, Faculdade de Medicina, Hospital Universitario do Oeste do Parana, Serviço de Residencia de Ortopedia e Traumatologia. Correspondence: Wallysson Arraes Gonçalves. Avenida Tancredo Neves, 3224, Cascavel, PR, Brazil, 85806470. wallysson.arraes@gmail.com

Article received on 09/09/2022, approved on 09/17/2022.



palpation, referring to a sudden onset of weakness when walking, which led to a fall from her standing height. On physical examination, during inspection, she had significant swelling in both knees, with areas of ecchymosis over the patella in the right knee and in the peripatellar region in the left knee. In the dynamic inspection, we observed inability to actively extend the knees bilaterally. During palpation, we found a gap in the suprapatellar region on the right and an infrapatellar gap on the left, with patella alta (Figure 1).

During anamnesis, the patient reported a history of chronic renal failure on dialysis resulting from a previous history of eclampsia nine years ago, when she was pregnant with her last child. Laboratory tests showed altered creatinine levels (5.9 mg/dL) and increased urea (79 mg/dL) and mild anemia (hemoglobin 8.1 g/dL).

Radiological examination of the knees showed no fractures, but patella alta on the left side and patella baja on the right side (Figure 2). Ultrasound examination confirmed quadriceps tendon rupture in the right upper pole and patellar tendon rupture in the left knee (Figure 3).

As a result of the condition, the patient was admitted and hospitalized, and seven days elapsed from injury to surgery. Intraoperatively, we confirmed injury to the right quadriceps tendon and left patellar tendon. As a synthesis method, we performed transosseous tunnels and raffia using the Krackow technique with nonabsorbable sutures.<sup>5,6</sup> Moreover, the semitendinosus tendon was removed and used to reinforce the left patellar tendon. (Figure 4) Postoperative imaging studies showed a bilateral return of patellar height to normal parameters (Figure 5).

As a post-surgical indication, we prescribed the use of a long knee immobilizer brace for 60 days. After three weeks, the patient started isometric exercises and early mobilization bilaterally. After six weeks, we recommended partial load using Canadian crutches associated with active mobilization. Three months after surgery, the patient started walking with full weight bearing, but still using crutches.



**Figure 1.** Preoperative image. Severe swelling in both knees with areas of ecchymosis over the patella in the right knee and in the peripatellar region in the left knee. The arrows show the location of the 'gaps' palpated during physical examination.



**Figure 2.** Ultrasound examination of the knees. Left: signs of total quadriceps tendon rupture with a gap measuring approximately 20 mm and signs of associated hematoma. Right: rupture of the proximal insertion of the patellar tendon with an associated patellar bone fragment, a large hematoma on the left, and a large cranial deviation of the patella.



**Figure 3.** Radiographs showing patella baja on the right knee, with a Caton-Deschamps index of 2.1, and patella alta on the left knee, with a Caton-Deschamps index of 0.5.

## << SUMÁRIO



**Figure 4.** Intraoperative images. Transosseous tunnels and raffia performed using the Krackow technique with nonabsorbable sutures. The semitendinosus tendon was removed and used to reinforce the left patellar tendon.

#### DISCUSSION

Several systemic pathological conditions that lead to a rapid decline in kidney function<sup>7</sup> can predispose individuals to spontaneous tendon rupture, such as rheumatological and endocrine diseases, medications, and even gestational conditions, such as eclampsia.<sup>8-10</sup> Simultaneous rupture of the patellar and contralateral quadriceps tendons in patients with chronic renal failure is an extremely rare condition, with few cases described in the medical literature.<sup>4</sup> We could not find any cases identical to the one described in this article, related to chronic renal failure due to a previous history of eclampsia. However, we found cases resulting from chronic renal failure<sup>4,5</sup> and other pathological conditions: amyloidosis;<sup>10</sup> rheumatological diseases, such as lupus;<sup>9</sup> endocrinological diseases, such as hyperparathyroidism;<sup>11</sup> and uremia. We also found cases related to the use of medications, such as intra-articular corticosteroids and



**Figure 5.** Postoperative radiographs showing the return of patellar height to normal parameters, with a Caton-Deschamps index of 1.0 on the right side and 0.9 on the left side.

quinolones. On the other hand, the literature also includes few reports of this type of injury in healthy patients without systemic diseases.<sup>1,3</sup> Some explanations suggest that spontaneous tendon rupture in dialysis patients results from several complications, such as renal osteodystrophy and amyloidosis.<sup>12,13</sup> This is associated with the hemodialysis process, which promotes, among dysfunctions, musculoskeletal manifestations, such as flexor tenosynovitis in the hands and carpal tunnel syndrome. In turn, osteodystrophy is as a condition secondary to hyperparathyroidism that can lead to osteoporosis, weakness of the osteotendinous junctions, and increased subperiosteal resorption.<sup>14</sup>

#### CONCLUSION

Osteotendinous complaints in patients with chronic kidney disease deserve careful evaluation and investigation. Early diagnosis and treatment of the underlying condition can prevent osteotendinous pathologies and injuries, ensuring a better quality of life.

Patients with blood pressure disorders during pregnancy should be monitored periodically and have adequate management of renal function. The authors understand that prevention and early diagnosis can reduce morbidity and future complications in the knees, as well as in other segments of the body.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. FRTB: analysis, discussion of the results, revision, and approval of the final version; WAG: writing and revision of the article, and analysis and discussion of the results.



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## ANTEROMEDIAL OR CENTRAL ANATOMIC ACL RECONSTRUCTION? A CADAVERIC HIP-TO-TOE STUDY

## RECONSTRUÇÃO ANATÔMICA ANTEROMEDIAL OU CENTRAL DO LCA? ESTUDO EM CADÁVER COMPLETO

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#### ABSTRACT

Objective: To compare anatomic anterior cruciate ligament (ACL) reconstruction between two tunnel positions in knees with isolated ligament tears. Methods: Anatomic ACL reconstruction was performed, from hip-to-toe, on 15 fresh cadaveric specimens. No associated lesions were created to enhance knee instability. The protocol was conducted in three states: (1) complete isolated ACL deficiency; (2) anatomic femoral and tibial anteromedial ACL reconstruction (AM REC); and (3) anatomic femoral and tibial central ACL reconstruction (Central REC). The reconstruction protocols were randomly assigned. The continuous mechanized pivot-shift test was recorded dynamically with a tracking system. Results: The Central REC group showed a smaller degree of internal rotation  $(0.6^{\circ} \pm 0.3^{\circ} \text{ vs. } 1.8^{\circ} \pm 0.3^{\circ}$ , respectively, P < 0.05) and no difference in anterior translation (4.7 mm  $\pm$  0.4 mm vs. 4.5 mm  $\pm$  0.4 mm, respectively, P > 0.05) in the pivot-shift test, compared with the AM REC group. Conclusion: The central anatomic ACL reconstruction resulted in greater restriction of internal rotation than the anteromedial anatomic ACL reconstruction. Experimental Study on Cadaver.

**Keywords:** Anterior Cruciate Ligament. Anterior Cruciate Ligament Reconstruction. Cadaver.

#### RESUMO

Objetivo: Comparar a reconstrução anatômica do ligamento cruzado anterior (LCA) entre duas posições de túnel em joelhos com lesões isoladas do ligamento. Métodos: A reconstrução anatômica do LCA foi realizada, do quadril aos pés, em 15 pecas anatômicas de cadáveres frescos. Não foram criadas lesões associadas para intensificar a instabilidade do joelho. O protocolo foi realizado em três estados: (1) deficiência isolada completa do LCA; (2) reconstrução anatômica femoral e anteromedial tibial do LCA (AM REC); e (3) reconstrução anatômica femoral e central tibial do LCA (Central REC). Os protocolos de reconstrução foram atribuídos aleatoriamente. O teste de pivot-shift mecanizado contínuo foi registrado dinamicamente com um sistema de rastreamento. Resultados: O grupo Central REC apresentou menor grau de rotacão interna  $(0.6^{\circ} \pm 0.3^{\circ} \text{ vs. } 1.8^{\circ} \pm 0.3^{\circ}, \text{ respectivamente, } p < 0.05)$ e nenhuma diferença na translação anterior (4,7 mm  $\pm$  0,4 mm vs. 4,5 mm  $\pm$  0,4 mm, respectivamente, p > 0,05) no teste de pivot--shift, comparado ao grupo AM REC. Conclusão: A reconstrução anatômica central tibial do LCA resultou em maior restrição da rotação interna do que a reconstrução anteromedial tibial do LCA. Estudo em Cadáver Experimental.

**Descritores:** Ligamento Cruzado Anterior. Reconstrução do Ligamento Cruzado Anterior. Cadáver.

Citation: Fernandes TL, Souza MO, Albuquerque Neto C, Araujo PH, Pedrinelli A, Hernandez AJ. Anteromedial or central anatomic ACL reconstruction? A cadaveric hip-to-toe study. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 5. Available from URL: http://www.scielo.br/aob.

#### INTRODUCTION

The pivot-shift test is the focus of basic and clinical research in the evaluation of knee ligament surgeries.<sup>1,2</sup> Knee kinematics during the pivot-shift test may represent the most clinically relevant biomechanical outcome when comparing surgical techniques for reconstruction of anterior cruciate ligament (ACL).<sup>3</sup>

The concept of ACL reconstruction is constantly changing and there is no consensus on the best anatomical position of the tunnel.<sup>4</sup>

This study mainly aimed to compare knee stability in ACL reconstruction between two different anatomical positions of the tibial tunnel (anteromedial and central) in anatomical pieces of cadavers from hip to foot after an isolated ACL rupture.

It was hypothesized that the anatomical reconstruction of the ACL performed in the middle of the original impressions of the femoral and tibial ACL should be more effective in controlling the kinematics of the internal rotation of the knee

All authors declare no potential conflict of interest related to this article.

The study was conducted at Universidade de Sao Paulo, Faculdade de Medicina, Hospital das Clinicas, Departamento de Ortopedia e Traumatologia, Bioengineering Laboratory, Department of Orthopedic Surgery and Massachusetts General Hospital.

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Article received on 09/26/2022, approved on 02/17/2023.



than that performed in the anatomical impression of the anteromedial bundle.

#### METHODS

#### Protocol

A total of 15 anatomical pieces of lower extremities of fresh male cadavers, from hip to foot, aged  $65.3 \pm 9.8$  years (mean  $\pm$  standard deviation) were used. The set of tests described was performed on each of the 15 knees in three states, including (1) without the ACL (ACL-absent); (2) ACL reconstruction with femoral and central anatomical tunnel in the tibia (Central REC), and (3) ACL reconstruction with femoral and anteromedial anatomical tunnel in the tibia (AM REC). The AM REC and Central REC were performed in random order to reduce the risk of lateral condyle wall rupture bias. The fresh samples were kept in a refrigerator at 4 °C and the procedures were performed at 16 °C (room temperature). Each specimen was placed in dorsal decubitus and the pelvis was fixed on the operating table to allow external load and free and unrestricted range of motion of the hip and knee.

Each measurement was performed at least three times to ensure high repeatability of the pivot-shift pattern, and the first measurement was used for analysis and comparisons.

Our institutional review board approved this study, and permission was obtained from the Research Ethics Committee of the University of São Paulo (CEP No. 436/11).

No soft tissue was cut or removed from the area around the knee or adjacent joints, which would amplify knee instability.

In total, 30 ACL reconstruction procedures were performed under anatomical conditions and were randomized to AM or central tunnel positioning surgery using a randomization plan generator.

Individuals without any significant deformity and surgical intervention were selected and examined manually. A standard anteromedial arthrotomy was performed to verify the ligamentous integrity of the joint and the presence of meniscal and gross lesions of the articular cartilage, bone abnormalities, and osteoarthritis. Knees with any of these signs were excluded from the study.

#### Surgical technique

The same surgeon performed all ACL reconstructions. A fivecentimeter medial parapatellar arthrotomy was created in each knee. The remnants of the ACL footprint on the femoral and tibial sides were used to indicate the tunnel positions. The AM REC was performed by passing the graft through the anatomical femoral tunnels and at the site of the anteromedial band of the ACL in the tibia, and the Central REC was performed by passing the graft through the anatomical femoral tunnels and in the middle of the ACL bands in the tibia (central).

The anterior tibial tendon was removed from the ankle of the opposite limb. The loop of the tendon created a doublestranded graft, and an 8 mm diameter graft was standardized for all surgical procedures.

The femoral and tibial tunnels were drilled into the anatomical footprint using an outside-in technique, depending on randomization. Femoral and tibial fixations were performed with a radiolucent and bioabsorbable screw (9 mm  $\times$  28 mm, Biosteon<sup>®</sup> HA/PLLA, Stryker, USA), and the impact of the intercondylar notch in full extension was verified before tibial fixation. Notchplasty was not performed (Figure 1).

Before fixation, each limb was preconditioned with 10 flexionextension cycles from 0° to 130°. The graft was manually tensioned and fixed to the tibia in the knee extension position with an interference screw while a manual posterior tibial load was applied. After fixation, 10 flexion-extension cycles were performed to accommodate the graft.



**Figure 1.** Rendered 3D computed tomography of the anatomical reconstruction of the anterior cruciate ligament. A1 and B1: representative position of the anteromedial tunnel (upper white dot) and central tunnel (lower white dot) in the femur and tibia, respectively; A2 and A3: anteromedial and central tunnels in the femur, respectively; B2 and B3: anteromedial and central tunnels in the tibia, respectively.

After biomechanical examinations and computed tomography (CT) for the first ACL reconstruction, the screws and tendon graft were removed. Donor bone plugs that were 1 mm larger than the tunnel size were harvested from the extra-articular side of the medial condyle using a 10 mm osteochondral donor plug collector (Arthrex, Naples, FL) and pressure adjustment to completely fill the previously used tunnels.<sup>3</sup> The second ACL tunnel was then drilled randomly as described earlier. The walls of the new tunnels were probed before and after the tests to ensure their integrity. No cortical fractures or ruptures of the lateral condyle were observed.

The same undamaged tendon grafts were used for the second reconstruction, and each reconstruction used the same fixation methods.

The graft was passed, tensioned, and fixed following the same procedure as the first reconstruction. The test protocol described previously was performed.

#### **Mechanized Pivot-Shift**

An instrumented pivot-shift test was performed using a continuous passive motion (CPM) machine (Carci, Ortomed 4060, ANVISA: 10314290029) that has been fixed to the operating table. A custom-made foot support was attached to allow the application of an internal rotation moment in the knee and axial load.<sup>5</sup>

This machine was developed at the Biomechanics Laboratory of the Institute of Orthopedics and Traumatology (IOT HCFMSUP) and was compatible with a device described by Musahl et al. $^6$ 

The pivot-shift examination technique followed the description of Galway and MacIntosh.<sup>7</sup> The leg was flexed from a fully extended position with an axial load while a valgus and internal rotation moment was applied to the leg.

A cable and pulley system was used to perform a valgus and internal torque moment with a 45° inclination in relation to the operating table. This was consistent with the procedure described by Musahl et al.,<sup>6</sup> in which the tibia was subluxated anteriorly in relation to the femur (Figure 2).

A 20 Nm torque was applied to a 15 cm Steinmann pin that was fixed vertically to the tibial tuberosity.

The thigh supports were removed, and the femur was completely loosened to allow free movement of the hip and knee. The tibia was fixed in its position on the foot support.<sup>6</sup>

The CPM machine moved the knee from full extension to 55° of flexion dynamically and in a multidirectional motion,<sup>8</sup> a navigation system simultaneously recorded the kinematics of the knee frame by frame (15 Hz).



**Figure 2.** A: Mechanized pivot-shift with cable and pulley system for valgus and internal rotation moments. Note the foot support with internal rotation of 15° (CPM, Carci, Ortomed 4060); B: Reflective markers on the tibia and femur for the optical tracking system.

#### **Tracking system**

A computer-aided navigation system was used to evaluate the knee kinematics and allowed the decomposition of the pivot-shift and Lachman tests.

Two Steinmann pins (2.5 mm) were placed in the anterior cortical of the distal femur and proximal tibia, where the rigid bodies were fixed approximately 10 cm away from the joint line. Each rigid body had a distinct configuration of reflective markers that could be tracked by an optical locator (Figure 2).

A bifocal tracking camera (MicronTracker 2; model H40; Toronto, Canada; 15 Hz; manufacturer's accuracy of 0.2 mm) was used to track the optical markers on the rigid bodies. A routine (Basic SQL) was created to recognize and save 3D data (X, Y, Z) in real time (15 Hz, 0.2 mm accuracy).<sup>9</sup>

Data acquisition involved calibration, rigid body recording, and a movement sequence to create accurate dynamic models of knee movement with  $6^{\circ}$  of freedom (calculated relative standard error = 0.82% from 350 to 800 mm).

Radiopaque markers in the same position were scanned using CT and were used to align and merge the optical tracking and three-dimensional CT systems. The anterior translation of the tibia and the internal rotation were expressed in millimeters and degrees, respectively.<sup>9</sup>

#### **Coordinate system**

The 3D models of bone scans (axial thickness of 1 mm; CT Emotion 2010; 16 channels; Siemens; PISA Project) were digitized and processed according to the descriptions provided by Chen et al.<sup>10</sup> and Van de Velde et al.<sup>11</sup>

The condyle geometric axis was used to create the femoral coordinate system. The tibial coordinate system was defined by the mechanical axis and centroids of the ellipses embedded in the medial and lateral tibial plateaus (Rhinoceros<sup>®</sup>, McNeel, Seattle, WA).<sup>10,11</sup>

Internal and external rotation were measured according to the classic study by Grood and Suntay,<sup>12</sup> and anteroposterior motion

was defined as the displacement of the center of the femoral coordinate system in relation to the tibial coordinate system in the anterior direction.<sup>10,11,13</sup>

#### Evaluation of the position of the ACL tunnel

Postoperative tunnel positions were evaluated using a rendered 3D CT protocol.

For the femur, tunnel positioning was measured according to the method of Bernard et al.,<sup>14</sup> who described the position of the center of the tunnel as a percentage of the distance along the Blumensaat line (from proximal and posterior to distal and anterior) and as a percentage of the distance along a line perpendicular to the Blumensaat line (from proximal and anterior to distal and posterior). The positioning of the tunnel in the tibia was measured according to the method of Lorenz et al.<sup>15</sup> and consisted of a percentage of the height of the tibial plateau (vertical axis) and length (horizontal axis).

#### Statistical analysis

The sample size was calculated based on the first five experiments for the primary outcome, internal tibial rotation (mechanized pivotshift between the AM REC and the Central REC). The minimum difference in the mean was  $1.92^{\circ}$  and the standard deviation was  $1.42^{\circ}$ . The sample size was 15 (groups = 4, alpha = 0.05, power = 0.80, sample size for ANOVA, SigmaPlot 12.5).

Kinematic data based on the results of pivot-shift loading tests were analyzed using 2-way RM-ANOVA and a post hoc multiple comparison test. Significance was set at P < 0.05 (SigmaPlot 12.5). The statistical power of the study was calculated based on the final data for four groups of 15 subjects with alpha equal to 0.05. The minimum difference in the mean was 1.5° and the standard deviation was 1.1°. The statistical power of the study was equal to 85.5% (Power for ANOVA, SigmaPlot 12.5).

#### RESULTS

Figure 3A shows the mean and standard deviation of femoral tunnel positioning for anatomical AM (length:  $20.8\% \pm 5.7\%$ ; height:  $27.0\% \pm 11.6\%$ ) and central (length:  $39.5\% \pm 5.1\%$ ; height:  $52.4\% \pm 9.6\%$ ) ACL reconstructions according to the quadrant method of Bernard et al.<sup>14</sup> A baseline analysis showed that the AM and central tunnel positions differed significantly (P < 0.001). Figure 3B the mean and standard deviation of tibial tunnel positioning for anatomical AM (length:  $56.4\% \pm 4.1\%$ ; height:  $30.6\% \pm 4.3\%$ ) and central (length:  $51.4\% \pm 2.4\%$ ; height:  $43.2\% \pm 5.7\%$ ) ACL reconstructions according to the method of Lorenz et al.<sup>15</sup> A baseline analysis showed that the AM and central tunnel positions differed significantly (P < 0.001).

Figure 4 shows the results of the instrumented pivot-shift test.



**Figure 3.** A: the method of Bernard et al.<sup>14</sup> to measure the position of the femoral tunnel of the anterior cruciate ligament for anteromedial (upper point) and central anatomical (lower point) reconstructions of the anterior cruciate ligament; B: the method of Lorenz et al.<sup>15</sup> to measure the position of the tibial tunnel of the anterior cruciate ligament for anteromedial (upper point) and central anatomical (lower point) reconstructions.

L: length of the tibial plateau, H: height of the tibial plateau (Rhinoceros®, McNeel, Seattle, WA).



**Figure 4.** The comparisons of the pivot-shift test of the knee kinematics between the groups absence of anterior cruciate ligament (red), femoral and anteromedial tibial anatomical reconstruction of the anterior cruciate ligament (gray), and femoral and central tibial anatomical reconstruction of the anterior cruciate ligament (yellow).

AM REC: anteromedial anatomical reconstruction of the ACL; Central REC: central anatomical reconstruction of the ACL.

Two-way RM-ANOVA, \* P < 0.05.

#### DISCUSSION

The most important finding of this study was that the Central REC produced a lower degree of internal rotation than the anatomical AM REC based on the mechanized pivot-shift test, which partially confirmed our initial hypothesis.

Diermann et al.<sup>1</sup> stated that an ACL deficiency leads to increased internal rotation of the tibia in a simulated pivot-shift test and that the anatomical reconstruction of the single-bundle ACL significantly reduces internal tibial rotation in a simulated pivot-shift test when compared with an absent ACL.

Our study found that a simulated pivot-shift test resulted in more significant anterior translation of the tibia, but not internal rotation in the group with ACL absence.

These results are in line with other studies that have used a robotic test system.<sup>1,7</sup>

All secondary stabilizers were preserved. We used an anatomical piece with lower limb from hip to foot. A possible explanation for the difference obtained by Diermann et al.<sup>1</sup> regarding internal rotation in the group with ACL injury is that soft tissue resection and the use of small pieces of bone may have increased knee instability. The resulting anterior tibial translation and internal rotation were evaluated for the first time by using a simulated pivot-shift test in a complete cadaver model from hip to foot without associated injuries to amplify knee instability. Regarding the use of intentionally associated injuries to increase knee instability, Cross et al.<sup>16</sup> stated that meniscus resection undoubtedly influenced knee kinematics after ACL reconstruction when compared with a reconstructed knee with intact meniscus. Our study used a mechanized device, and the magnitude of the pivot was large enough to detect statistically significant differences between the groups without meniscal resecting.

Differences in the magnitude of mean values between statistically different groups may be a weak point in this study. Although the differences were small between the groups, this study was well designed and properly conducted, increasing internal validity.<sup>3,6,16,17</sup> The effect size was in agreement with other published biomechanical studies and the power of the study was adequate (85%) to calculate small differences for the primary outcome, which reduced the potential bias of a type II error.<sup>3,6,16,17</sup>

The device used in this study is simpler than robotic systems and can achieve consistent and observer-independent results.

The results of our study show that the pivot-shift device accurately collected data and replicated the physiological movements of the knee pivot-shift, as discussed by Driscoll et al.<sup>17</sup>

Pearle et al.<sup>18</sup> validated this model as a reliable tool to quantify knee stability by comparing it with a robotic force-moment test system and sensor.

According to some studies, the subluxation/reduction event occurs at approximately 20 to 35° of flexion.<sup>6,19,20</sup> Bedi et al.<sup>3</sup> state that the maximum displacement occurs at a flexion angle of 10 to 20°. Our study identified similar values for a reduction of subluxation at 30°.

#### Limitations

This experiment suffered the disadvantages of using anatomical parts of older adults cadavers *in vitro*, which were much older than the average age at which ACL injuries occur. In addition, the analysis refers to a zero-time condition, and laxity was not influenced by *in vivo* graft relaxation and remodeling.

#### CONCLUSION

The main conclusion is that ACL central anatomical reconstruction results in greater restriction of internal rotation than ACL anteromedial reconstruction.

#### ACKNOWLEDGMENTS

This study was supported by a grant from the Coordination for the Improvement of Higher Education Personnel, CAPES, Brazil (BEX 4251/14-8).

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. TLF: conception, work design, article review, data analysis, and surgery; MOS: writing work and article review; CAN, PHA: data analysis and article review; AP, AJH: article review and intellectual concept.

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## ROLE OF INCISIONAL VACUUM THERAPY IN ENDOPROSTHETIC BONE RECONSTRUCTION SURGERY

## PAPEL DA TERAPIA A VÁCUO INCISIONAL EM CIRURGIA DE RECONSTRUÇÃO ÓSSEA COM ENDOPRÓTESE

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#### ABSTRACT

Reconstructive surgery with endoprostheses is the chosen method for treating bone malignancies. Postoperative infections are frequent complications, and their treatment involves prolonged hospital stays and antibiotic therapy. Among the advancements aimed at reducing the rate of postoperative infection, the use of incisional negative pressure therapy (iNPT) has shown promising results, with no reports in the literature regarding its use in patients with such conditions. Objective: To evaluate the effectiveness of iNPT in reducing postoperative complications in surgeries for resection of bone tumors associated with modular endoprosthesis reconstruction. Methods: Retrospective case series of 16 patients diagnosed with osteosarcoma, who underwent resection and reconstruction with endoprosthesis associated with iNPT during the postoperative period. Follow-up was performed for a period of six months, and the evaluated outcomes were the incidence of postoperative infection and complications of the surgical wound. Results: The use of iNPT for a postoperative period of seven days resulted in only three (18.7%) cases of postoperative infection. No cases of wound dehiscence, seroma formation, or hematoma at the surgical site were observed. Conclusion: The rate of surgical wound complications in our case series is lower than that reported in most of the literature, and iNPT appears to be an efficient way to reduce the rate of local complications in reconstructive surgeries with endoprosthesis after resection of bone malignancies. Level of Evidence III, Retrospective Study.

**Keywords:** Negative Pressure Wound Therapy. Prostheses and Implants. Osteosarcoma.

#### RESUMO

A cirurgia reconstrutiva com endopróteses é o método escolhido no tratamento de malignidades ósseas. As infecções pós-operatórias são complicações frequentes, e seu tratamento envolve internações e antibioticoterapia prolongadas. Entre os avanços que visam reduzir a taxa de infecção pós-operatória, o uso da terapia com pressão negativa incisional (TPNi) vem mostrando resultados promissores, não havendo relatos na literatura de seu emprego em pacientes com tal quadro. Objetivo: Avaliar a eficácia da TPNi em reduzir complicações pós-operatórias em cirurgias de ressecção de tumores ósseos associadas à reconstrução com endopróteses modulares. Métodos: Série de casos retrospectiva de 16 pacientes diagnosticados com osteossarcoma, submetidos à ressecção e reconstrução com endoprótese associada à TPNi durante o pós-operatório. Foi realizado seguimento por um período de seis meses e os desfechos avaliados foram incidência de infecção pós-operatória e complicações da ferida operatória. Resultados: O uso da TPNi por um período pós-operatório de sete dias resultou em apenas três (18,7%) casos de infecção pós-operatória. Não foram observados casos em que ocorreu deiscência da ferida operatória, formação de seromas ou hematomas no sítio cirúrgico. Conclusão: A taxa de complicações de ferida operatória em nossa série de casos é menor que a da maior parte da literatura, e a TPNi parece ser uma forma eficiente de reduzir a taxa de complicações locais em cirurgias reconstrutivas com endoprótese após ressecção de malignidades ósseas. Nível de Evidência III, Estudo Retrospectivo.

**Descritores:** Tratamento de Ferimentos com Pressão Negativa. Próteses e Implantes. Osteossarcoma.

**Citation:** Baptista AM, Camargo AFF, Caiero MT, Torres Filho JSCS, Narciso JH, Silva MRD. Role of incisional vacuum therapy in endoprosthetic bone reconstruction surgery. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 3. Available from URL: http://www.scielo.br/aob.

#### INTRODUCTION

Osteosarcomas are rare primary malignant neoplasms of the bone tissue. Currently, the main form of treatment for these tumors consists of resection of the lesion and reconstructive surgery using endoprostheses.<sup>1</sup> The primary advantages of this method include

limb preservation, rapid function restoration with early rehabilitation, good long-term functional outcomes, and wide availability in specialized services for the treatment of musculoskeletal neoplasms.<sup>2</sup> Disadvantages include material wear, which leads to aseptic loosening, fractures, and periprosthetic infections.<sup>3</sup>

#### All authors declare no potential conflict or interest related to this article.

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Article received on 01/24/2022, approved on 03/31/2022.



Due to the increased overall survival rate among patients with orthopedic tumors, implant failure has become one of the primary complications in treating bone sarcomas, with implant-related infection being the most frequent.<sup>4</sup> Surgical site infections are associated with significant morbidity and cost during their follow-up.<sup>5</sup> Considering the impact on the patient's quality of life and the financial burden on the healthcare system,<sup>6.7</sup> the reduction of postoperative infections has been the focus of numerous studies. As a result of advancements in material quality, reduced surgical time, improved surgical techniques, periodic glove changes, and other enhancements, postoperative infection rates associated with the use of endoprostheses have decreased.<sup>4</sup>

However, some studies still report periprosthetic infection rates of 15 to 20% in the early years of postoperative period.<sup>8</sup> It is known that persistent incisional drainage occurs in 1 to 3% of patients undergoing arthroplasty surgeries, resulting in an increased infection risk of 29 to 42% for each day the condition persists. In this context, there is a significant focus on optimizing care for the surgical wound and the use of negative pressure therapy (NPT).<sup>9</sup>

The application of NPT originated centuries ago in traditional Chinese medicine, and its use in Western traditional medicine was approved by the Food and Drug Administration only in 1995 for the treatment of wounds deemed incurable. Today, its application has been extended to include the management of chronic wounds, acute wounds, subacute wounds, traumatic wounds, burns, dehiscence, coverage failures, diabetic foot ulcers, pressure ulcers, among others.<sup>10,11</sup>

One of the modalities of interest and worth delving into for this study is incisional negative pressure therapy (iNPT), which is used in surgical wounds undergoing primary closure. This therapy is applied directly to the incision site using polyurethane or polyvinyl alcohol foam, a gas-permeable adhesive tape, a "TRAC pad," a connecting tube, and a vacuum device that maintains a continuous negative pressure of 125 mmHg.<sup>11</sup> The benefits of iNPT include acting as a barrier to the external environment and protecting the incision from contaminants, reducing tension forces on the surgical wound, minimizing stress on the suture line, optimizing tissue perfusion, and reducing the formation of hematomas and seromas.<sup>9</sup> The effect on bacterial bioburden has shown conflicting findings in the literature, with more recent studies demonstrating an increase in bioburden without affecting wound healing.<sup>12</sup> The main drawback of the method is its high cost.

Although widely studied, there are few studies on iNPT in the field of orthopedic oncology. This study aims to describe the treatment outcomes of patients undergoing oncologic resection and reconstruction with knee and hip endoprostheses, along with the use of iNPT, at the Orthopedics and Traumatology Institute of the Hospital das Clínicas, Faculty of Medicine, University of São Paulo (IOT – HCFMUSP).

#### **METHODS**

This study is a retrospective case series aimed at reporting the results obtained by the Department of Orthopedic Oncology at IOT-HCFMUSP using Incisional Negative Pressure Therapy following oncologic resection surgery and reconstruction with endoprostheses in patients treated from January 2018 to December 2020 at the quaternary healthcare center. This study has been approved by the hospital's Ethics and Research Committee under protocol number 1.529/22.279.

The study included patients who had reached skeletal maturity, were literate, diagnosed with osteosarcomas, underwent resection and reconstruction with endoprostheses, and received postoperative iNPT. The exclusion criteria were as follows: clinical and radiographic follow-up of less than six months, use of iNPT for less than five days, insufficient data in medical records, and refusal to sign an informed consent form.

All surgeries were performed by the authors (CMT, BAM, and/or CAFF), and the data – including age, gender, tumor type and location, surgical treatment specifics, duration of iNPT use, length of hospital stay, surgical wound complications, overall postoperative complications, as well as subsequent necessary treatments – were collected from the electronic medical record system and available imaging exams of the participating patients in the study. The primary analyzed outcome was the occurrence of postoperative infection, which was determined based on the presence of inflammatory changes with or without secretion, along with laboratory alterations such as increased inflammatory markers and/or positive culture from deep surgical site material. As secondary outcomes, other local complications of the surgical wound such as dehiscence and fluid collections were evaluated.

The results will be presented descriptively using distribution measures such as mean, standard deviation, and percentage, calculated using the PASW Statistics 18.0 software (SPSS Inc.). Chicago, USA) in a number of cases.

#### RESULTS

Incisional negative pressure therapy (iNPT) was used in a total of 16 patients over the course of these two years, including 5 women and 11 men, with a mean age of 44 years. All patients underwent iNPT for a total of seven days (Table 1). Only two patients had diseases other than neoplastic.

Among the performed reconstructions, there were two (12.5%) hip endoprostheses, five (31.2%) total femur endoprostheses, eight (50%) knee endoprostheses, and one (6.2%) proximal tibia endoprosthesis. Out of these, ten were primary reconstructive procedures, and six were revision surgeries. After a 6-month outpatient follow-up, only three (18.7%) patients presented postoperative infection, with no occurrence of other surgical wound complications such as dehiscence, and hematoma or seroma formation. In most patients – 10 (62.5%) – at least one surgical procedure had already been performed in the location of the osteosarcoma. The above information is presented in Table 2, among the patients who presented or not with postoperative infection.

 Table 1. Mean age, gender, length of hospital stay, time of incisional negative pressure therapy.

Number of patients	Age Mean (SD)	Length of hospital stay* <i>Mean (SD)</i>	Time of iNPT* <i>Mean (SD</i> )	Gender n (%)	
16	44.1 (16.8)	12.1 (6.5)	19.3 (14.5)	Women = 5 (31.2) Men = 11 (68.8)	

\*Measured in days.

n: number; SD: standard deviation; iNPT: incisional negative pressure therapy.

 Table 2. Presence of comorbidities, previous infections, and previous surgeries.

	Comorbidities n (%)	Previous infections n (%)	Previous surgeries on tumor topography <i>n</i> (%)	Revision of the primary endoprosthesis n (%)
No postoperative infection (n = 13)	1 (7.6)	1 (7.6)	8 (61.5)	4 (30.7)
Postoperative infection (n = 3)	1 (33.3)	2 (66.6)	2 (66.6)	2 (66.6)

n: number



#### DISCUSSÃO

In our case series, we observed a predominance of men, similar to the studies conducted by Theil et al.,<sup>3</sup> but with a significantly higher mean age of 44, which is considerably higher compared to the aforementioned study with mean age of 21.

In the systematic review conducted by Thornley et al.,<sup>13</sup> osteosarcoma was identified as the most frequent primary malignancy among patients, excluding cases of metastasis. The study also reported a high rate of surgical re-intervention following tumor resection and primary reconstructive surgery. In these cases, it was observed that only 5% of the reoperations occurred due to tumor recurrence, whereas the remaining 95% were due to postoperative local complications. Mechanical causes such as periprosthetic fracture, implant failure, and aseptic loosening were more frequent, followed by infectious causes.<sup>13</sup>

In general, we found an infection rate of 18.7%, slightly lower than the 22% presented by Theil et al.<sup>3</sup> for cases of primary approach. When comparing these rates to revision surgeries, we observed a value of 37%, which is slightly lower than the 39% reported in the aforementioned study. Regarding non-infectious complications of surgical wounds, no cases of dehiscence or other complications were found, contrasting with an approximate incidence of 17% reported in the previous study.<sup>3</sup>

To our knowledge, no studies have compared the outcomes of using iNPT in reconstructive surgeries following tumor resection. Studies on primary arthroplasties have shown that iNPT can reduce the risk of infection by up to four times. Similar findings have also been reported in patients with orthopedic trauma, which are also high-risk cases for surgical wound complications. In these cases, the use of iNPT resulted in a reduction of more than five times in the risk of infection, from 28% to 5.4%.<sup>9</sup>

A meta-analysis conducted by Hyldig et al.,<sup>14</sup> which included various studies on orthopedic surgeries in trauma and reconstruction,

supports the findings that the use of iNPT reduces the risk of surgical site infection, dehiscence, seroma formation, and other complications. However, the number needed to treat (NNT) reached up to 25, considering that the cost associated with it is more than 10 times that of a simple dressing, which would not justify the routine use of this therapy.<sup>14</sup> It is worth noting that several studies included in this meta-analysis presented methodological issues and a short follow-up period, limiting the analysis of the quality of evidence and extrapolations regarding cost-effectiveness.

The study conducted by Cooper et al.<sup>15</sup> defends the routine use of iNPT in high-risk patients for postoperative wound complications since the rates of endoprosthesis preservation in cases of deep surgical site infection are low, and the cost of reoperation and continuing care in these patients is high. The cost-effectiveness analysis conducted by Nherera et al.<sup>16</sup> demonstrated cost savings of \$10,293.00 to \$11,296.00 per treated patient, resulting from the savings in the treatment of local complications and their repercussions.

#### CONCLUSION

In this case series, we observed a lower rate of surgical site infection than expected when compared with the findings in the literature for reconstructive surgeries with endoprosthesis after resection of malignant bone tumors, as well as the absence of other complications such as dehiscence and fluid collections. Despite the high cost of incisional negative pressure therapy, the use of this therapeutic strategy in high-risk wounds seems to be justified. Considering the low sample size of this study, further prospective and randomized studies are necessary to corroborate with our hypotheses. However, our data indicate that iNPT can reduce the risks of infection and complications associated with bone resection and reconstruction with endoprosthesis.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. AMB, AFFC, MTC: study design, surgery and article review; JSCSTF, JHN, MRDS: surgery, medical records survey and writing of the article.

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## EARLY COMPLICATIONS OF SURGICAL TREATMENT OF CERVICAL SPONDYLOTIC MYELOPATHY

## COMPLICAÇÕES PRECOCES DO TRATAMENTO CIRÚRGICO DE MIELOPATIA CERVICAL ESPONDILÓTICA

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#### ABSTRACT

Objective: To evaluate the early postoperative complications associated with the surgical approach of the cervical spine of patients with cervical spondylotic myelopathy (CSM), comparing the anterior surgical, the posterior surgical, and the combined approaches. Methods: This is a retrospective study based on a database with 169 patients. Demographic data, such as gender and age, and surgical data, such as surgical approach, number of segments with arthrodesis, surgical time, and complications, were evaluated. Complications were divided into major (deep surgical wound infection, intercurrence with the implant, early new compression, and heart failure) and minor (dysphagia, superficial infection, pain, urinary intercurrence, neuropraxia of the C5 root, acute confusional state, and surgical wound hematoma). Results: This included 169 patients, 57 women (33.7%) and 112 men (66.2%). Age ranged from 21 to 87 years, with a mean of 56.48  $(\pm 11)$  years. Of these, 52 (30.8%) underwent the anterior approach; 111 (65.7%), the posterior approach; and 6 (3.5%), the combined approach. Conclusion: As in the literature, we evinced dysphagia, pain, and superficial infection of the surgical wound as the most frequent postoperative complications. However, it was impossible to establish a statistical relationship between the incidence of complications and surgical time, access route, and number of fixed segments. Level of Evidence III, Retrospective Comparative Study.

## RESUMO

Objetivo: Avaliar as complicações pós-operatórias precoces associadas à abordagem cirúrgica da coluna cervical de pacientes portadores de mielopatia cervical espondilótica (MCE), comparando a abordagem cirúrgica anterior, a abordagem cirúrgica posterior e a abordagem combinada. Métodos: Estudo retrospectivo baseado em um banco de dados com 169 pacientes. Foram avaliados dados demográficos, como gênero e idade, e dados cirúrgicos, como abordagem cirúrgica realizada, número de segmentos artrodesados, tempo cirúrgico e complicações. As complicações foram divididas em maiores (infecção profunda da ferida operatória, intercorrência com o implante, nova compressão precoce, insuficiência cardíaca) e menores (disfagia, infecção superficial, dor, intercorrência urinária, neuropraxia da raiz de C5, estado confusional agudo, hematoma de ferida operatória). Resultados: Foram incluídos 169 pacientes, sendo 57 do sexo feminino (33,7%) e 112 do masculino (66,2%). A idade variou de 21 a 87 anos, com média de 56,48 anos (± 11). Destes, 52 (30,8%) foram submetidos à abordagem anterior, 111 (65,7%) à abordagem posterior e 6 (3,5%) à abordagem combinada. Conclusão: Assim como na literatura, evidenciamos a disfagia, a dor e a infecção superficial da ferida operatória como as complicações pós-operatórias mais frequentes. No entanto, não foi possível estabelecer uma relação estatística da incidência de complicações com o tempo cirúrgico, a via de acesso e o número de segmentos fixados. Nível de Evidência III, Estudo Retrospectivo Comparativo.

Keywords: Cervical Cord. Spondylosis. Spinal Cord Compression.

**Descritores:** Medula Cervical. Espondilose. Compressão da Medula Espinal.

**Citation:** Saheb RLC, Soeira TP, Moratelli L, Pontes MDS, Herrero CFPS. Early complications of surgical treatment of cervical spondylotic myelopathy. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 5. Available from URL: http://www.scielo.br/aob.

#### INTRODUCTION

Cervical spondylotic myelopathy (CSM) is a general term to characterize an age-related degenerative process that corresponds to a set of changes involving vertebrae, intervertebral discs, facet joints, and associated ligaments.<sup>1</sup> A striking feature of this evolution

is the formation of osteophytes, which develop from vertebral bodies in an attempt to add stability to areas with disc degeneration and hypermobility.<sup>2</sup> Moreover, they often occur concomitantly with disc protrusion, hypertrophy of uncovertebral and facet joints, and thickening or hypertrophy of the flavum. Such factors associated

#### All authors declare no potential conflict of interest related to this article.

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Article received on 01/26/2022, approved on 05/30/2022.



with the degenerative process contribute to narrowing the vertebral canal and potentially the spinal  $cord.^3$ 

Cervical spondylosis typically affects several vertebral segments and estimates suggest it affects from 70% to 95% of individuals over 60 years of age asymptomatically;<sup>4</sup> configuring an important cause of neurological dysfunction and the primary source of spinal cord dysfunction in individuals over 55 years of age.<sup>5</sup>

Surgical treatment is indicated in moderate to severe neurological symptoms or cases with worsened neurological deficits. It involves decompressing the compromised neural structures (which may be followed by surgical stabilization of the involved vertebral segments).<sup>2</sup> Available approaches for surgical treatment consist of the anterior, posterior, or combined approaches (the latter involves both the anterior and posterior approaches).<sup>6</sup> However, controversy remains about the best approach to surgically treat patients with cervical spondylotic myelopathy.<sup>7</sup>

Previous studies have shown the advantages and disadvantages of different approaches to the cervical spine and compared surgical complications related to each approach.<sup>8</sup> Nevertheless, studies have investigated the clinical outcomes of several diseases that led to the surgical treatment of the cervical spine.<sup>9</sup> Thus, this study aimed to identify the early postoperative complications associated with the surgical approach to the cervical spine in patients with CSM, comparing the anterior, posterior, and combined surgical approaches.

#### **METHODS**

A retrospective study was conducted based on electronic clinical records of patients who underwent surgical procedures to treat CSM at the Ribeirao Preto Medical School Clinics Hospital of University of Sao Paulo (HCFMRP-USP), from 2008 to 2015. This study was approved by the Institutional Ethics Board (Ribeirao Preto Medical School Clinics Hospital of the University of Sao Paulo) under Registration number 1.575.506 (CAAE: 56419516.1.0000.5440), and all patients signed informed consent forms.

We assessed patients' demographic data (gender, age) and surgeryrelated data (surgical approach, operated spine levels, duration of surgery). Male and female patients aged above 18 years with complete registration data — including gender, age, comorbidities, type of surgical procedure, and early complications — were included. Patients with incomplete registration data and previous surgery were excluded. The procedure performed in patients undergoing the anterior approach involved performing a discectomy or corpectomy associated with the placement of an intersomatic device and fixation with a plate for decompression and arthrodesis, whereas in patients undergoing the posterior approach, the surgical procedure comprised laminectomy associated with fixation with screws of lateral mass and bars.

Complications were divided into major and minor. We included all adverse events, and complications were defined as major when the adverse event led to permanent sequelae or required additional surgical intervention. On the other hand, complications were considered minor when the adverse event neither deteriorated the clinical picture neither required additional surgical intervention. The time considered for evaluating the adverse event was 30 days from the date of surgery.

We described the data by measures of central tendency, dispersion, and frequencies. The assessment of normality of the continuous variable was obtained by the Shapiro-Wilk test. Inferential analyses were performed using Pearson's correlation and Fisher's exact tests to assess correlations between categorical variables and the Student's T-test of independent samples to assess difference in means. Multivariate analysis was obtained by multinomial logistic regression. SPSS, version 24, for Windows (Armonk, NY, USA) was used for statistical analyses, assuming a significance level of 5%.

#### RESULTS

This study included 169 patients, 57 of which were women (33.7%) and 112 men (66.2%). Their age ranged from 21 to 87 years, with a mean of 56.48 years ( $\pm$  11). Figure 1 shows the distribution of patients according to gender and age group.

Of the 169 patients included in this study who underwent surgical procedures, 52 (30.8%) underwent the anterior approach; 111 (65.7%), the posterior approach; and 6 (3.5%), the combined approach (anterior and later), as shown in Figure 2.



Figure 1. Distribution of patients according to gender and age group.



Figure 2. Distribution of patients according to the used approach.

In patients who underwent the anterior approach, the number of fused segments ranged from 1 two 4, with 19 patients (36.53%) undergoing fixation of 1 segment; 19 patients (36.53%), of 2 segments; 11 patients (21.15%), of 3 segments; and 3 patients, (5.7%) of 4 segments. In patients who underwent the posterior approach, the number of fused segments ranged from 2 to 9 segments, with 2 patients (1.8%) undergoing fixation of 2 segments; 20 patients (18.01%), of 3 segments; 39 patients (35.13%), of 4 segments; 38 patients (34.23%), of 5 segments; 10 patients (9%), of 6 segments; 1 patient (0.9%), of 7 segments; and 1 patient (0.9%), of 9 segments. The combined approach involved fusion of 2 to 6 segments, with 2 patients (33.33%) undergoing fixation of 2 segments; 1 patient (16.66%), of 3 segments; 1 patient (16.66%), of 5 segments; 1 patient (16.66%), of 5 segments; and 1 patient (16.66%), of 6 segments.

The mean surgical time of the procedures performed by the anterior approach was 179 minutes, with a standard deviation of 53.5 minutes (ranging from 95 to 440 minutes). The surgical time of the procedures performed by the posterior approach had a mean of 224 minutes and a standard deviation of 62 minutes (ranging from 102 to 480 minutes); and the surgical time of procedures performed by the combined anterior/ posterior approach had a mean of 333 minutes, with a standard deviation of 108 minutes (ranging from 138 to 463 minutes).



From a total of 169 operated patients, we found 64 complications (37.9%). Of these, 21 (12.4%) represented major complications and 43 (25.5%), minor complications. Of the major complications, 11 referred to deep surgical wound infections; five, to cardiovascular complications; four, to complications with implants, and 1 case with new early root compression. Minor complications involved12 cases of pain, nine of dysphagia, seven of superficial infection, five surgical wound hematomas, five of C5 root neuropraxia, four4 of urinary complications, and four 4 which evolved into acute confusional state. When comparing complications regarding the number of fused levels, one group consisting of patients with up to 2 levels of fixation and another, of patients undergoing three or more levels of fixation, dysphagia was the only complication associated with the number of fused levels with statistical significance (p = 0.005) (Table 1).

When we separately evaluated complications regarding the number of fused levels in the different approaches, we found no statistically significant difference in the anterior, posterior, and combined approaches (Tables 2, 3, and 4).

By correlating surgical time with the presence or absence of complications, we found a statistically significant difference in patients with superficial surgical wound infections (p = 0.014), complications with implants (p = 0), and between total complications (p = 0.005) (Table 5).

Table	1.0	Compl	icat	ions accorc	ling to	the num	ber of	fused	levels	3 (N	l = 1	169).	

Complication	N	Compl. depe number of I	n valuo	
Complication	(N = 169)	Up to 2 levels	3 or more	p-value
		(n = 45)	(n = 124)	
Dysphagia	9 (5.3%)	6 (13.3%)	3 (2.4%)	0.005
Superficial infection	7 (4.1%)	3 (6.7%)	4 (3.2%)	0.321
Urinary Intercur.	4 (2.4%)	0 (0%)	4 (3.2%)	0.223
Pain	12 (7.1%)	6 (13.3%)	6 (4.8%)	0.057
Confusional state	4 (2.4%)	1 (2.2%)	3 (2.4%)	0.941
Hematoma	5 (3.0%)	2 (4.4%)	3 (2.4%)	0.492
C5 neuropraxia	5 (3.0%)	0 (0%)	5 (4.0%)	0.171
Deep infection*	11 (6.5%)	1 (2.2%)	10 (8.1%)	0.174
Implant intercur.*	4 (2.4%)	0 (0%)	4 (3.2%)	0.223
New compression*	1 (0.6%)	1 (2.2%)	0 (0%)	0.096
Cardiac intercur.*	5 (3.0%)	2 (4.4%)	3 (2.4%)	0.492
Death*	2 (1.2%)	0 (0%)	2 (1.6%)	0.391
*Major complic.	21 (12.4%)	4 (8.9%)	17 (13.7%)	0.401
Total complic.	64 (37.9%)	22 (48.9%)	42 (33.9%)	0.075

\* Major complications.

**Table 2.** Complications regarding the number of fused levels in the different approaches: anterior approach.

Complication	N	Compl. depe number of l	n voluo**	
Complication	(N = 52)	Up to 2 levels (n = 40)	3 or more (n = 12)	p-value
Dysphagia	9 (17.3%)	6 (15.0%)	3 (25.0%)	0.340
Superficial infection	2 (3.8%)	1 (2.5%)	1 (8.3%)	0.412
Pain	4 (7.7%)	4 (10.0%)	0 (0.0%)	0.338
Confusional state	2 (3.8%)	1 (2.5%)	1 (8.3%)	0.412
Hematoma	2 (3.8%)	2 (5.0%)	0 (0.0%)	0.588
Deep infection*	1 (1.9%)	1 (2.5%)	0 (0.0%)	0.769
Cardiac intercur.*	2 (3.8%)	2 (5.0%)	0 (0.0%)	0.588
Major complic.	3 (5.8%)	3 (7.5%)	0 (0.0%)	0.447
Total complic.	21 (40.4%)	17 (42.5%)	4 (33.3%)	0.413

\* Major complications; \*\*Fisher's exact test.

**Table 3.** Complications regarding the number of fused levels in the different approaches: posterior approach.

Complication	N	Compl. depe number of I	n volue**	
Complication	(N = 110)	Up to 2 levels (n = 2)	3 or more (n = 108)	p-value**
Superficial infection	4 (3.6%)	1 (50.0%)	3 (2.8%)	0.072
Urinary Intercur.	4 (3.6%)	0 (0.0%)	4 (3.7%)	0.928
Pain	7 (6.4%)	1 (50.0%)	6 (5.6%)	0.124
Confusional state	2 (1.8%)	0 (0.0%)	2 (1.9%)	0.964
Hematoma	3 (2.7%)	0 (0.0%)	3 (2.8%)	0.946
C5 neuropraxia	4 (3.6%)	0 (0.0%)	4 (3.7%)	0.928
Deep infection*	10 (9.1%)	0 (0.0%)	10 (9.3%)	0.826
Implant intercur.*	3 (2.7%)	0 (0.0%)	3 (2.8%)	0.946
Cardiac intercur.*	3 (2.7%)	0 (0.0%)	3 (2.8%)	0.946
Death*	2 (1.8%)	0 (0.0%)	2 (1.9%)	0.964
Major complic.	16 (14.5%)	0 (0.0%)	16 (14.8%)	0.729
Total complic.	38 (34.5%)	2 (100%)	36 (33.3%)	0.117

\* Major complications; \*\*Fisher's exact test.

**Table 4.** Complications regarding the number of fused levels in the different approaches: combined approach.

Complication	N	Compl. depe number of l		
Complication	(N = 7)	Up to 2 levels (n = 3)	3 or more (n = 4)	p-value""
Superficial infection	1 (14.3%)	1 (33.3%)	0 (0.0%)	0.429
Pain	1 (14.3%)	1 (33.3%)	0 (0.0%)	0.429
C5 neuropraxia	1 (14.3%)	0 (0.0%)	1 (25.0%)	0.571
Implant intercur.*	1 (14.3%)	0 (0.0%)	1 (25.0%)	0.571
New compression*	1 (14.3%)	1 (33.3%)	0 (0.0%)	0.429
Major complic.	2 (28.6%)	1 (33.3%)	1 (25.0%)	0.714
Total complic.	5 (71.4%)	3 (100%)	2 (50.0%)	0.286

\* Major complications; \*\*Fisher's exact test.

Table 5. Duration of the proce	edure according to the occurrence of
complications ( $N = 169$ ).	

	Occurr compli	ence of cations	Mean difference		
Complication	Yes Mean ± SD	No Mean $\pm$ SD	± Standard error of the diff.	p-value	
Dysphagia	$187.7\pm43.2$	$217.6\pm71.0$	$-29.9\pm24.0$	0.214	
Superficial infection	$279.3\pm89.6$	$\textbf{213.2} \pm \textbf{68.1}$	$66.0\pm26.6$	0.014	
Urinary Intercur.	$257.8\pm56.3$	$215.0\pm70.2$	$42.8\pm35.4$	0.229	
Pain	$270.4\pm102.3$	211.8 ± 65.6	$\textbf{58.6} \pm \textbf{30.0}$	0.075	
Confusional state	$221.0\pm85.6$	$215.9\pm70.0$	$\textbf{5.1} \pm \textbf{35.6}$	0.885	
Hematoma	$207.0\pm54.5$	$216.3\pm70.6$	$-9.3\pm31.9$	0.772	
C5 neuropraxia	$248.0\pm92.6$	$215.0\pm69.4$	$\textbf{33.0} \pm \textbf{31.8}$	0.301	
Deep infection*	$196.6\pm45.4$	217.3 ± 71.4	$-20.8\pm21.9$	0.343	
Implant intercur.*	$345.0\pm91.5$	$212.9\pm66.8$	$132.1 \pm 34.1$	0.000	
New compression*	138.0 ± 0.0	$216.45\pm70.0$	$-78.5\pm70.2$	0.266	
Cardiac intercur.*	$209.6\pm24.5$	216.2 ± 71.0	$-6.6\pm31.9$	0.837	
Death*	$197.5\pm24.8$	$216.2\pm70.4$	$-18.7\pm50.0$	0.709	
Major complic.	$225.1\pm78.5$	214.7 ± 69.0	$10.5\pm16.4$	0.524	
Total complic.	235.4 ± 82.0	204.1 ± 59.0	31.3 ± 10.9	0.005	

\* Major complications



When we separately evaluated surgical time according to complications in the different approaches, we found no statistically significant difference in the anterior approach. (Table 6) Regarding patients who underwent the posterior approach, we observed a statistically highermean duration of surgery in cases with pain (p = 0.000) and complications with implants (p = 0.016) (Table 7). And regarding patients who had undergone surgery by the combined approach, we found a statistical difference when we evaluated one major complication: early compression (p = 0.014) (Table 8).

Table 6. Duration of the procedure depending on the occurrence of
complications stratified by surgical approach: anterior approach.

	Occurr compli	ence of cations	Mean difference		
Complication	Yes         No           Mean ± SD         Mean ± SD		± Standard error of the diff.	p-value	
Dysphagia	$187.7\pm43.2$	$181.2\pm57.1$	$\textbf{6.4} \pm \textbf{20.2}$	0.751	
Superficial infection	$315.0\pm177.0$	$177.0\pm41.5$	$138.0\pm125.1$	0.468	
Pain	$172.5\pm15.0$	$\textbf{183.2} \pm \textbf{56.7}$	$-10.7\pm28.7$	0.711	
Confusional state	$165.0\pm21.2$	$183.0\pm55.5$	$-18.0\pm39.7$	0.651	
Hematoma	$165.0\pm63.4$	$183.0\pm54.9$	$-18.0\pm39.7$	0.651	
Deep infection*	$100.0\pm0.0$	$184.0\pm53.9$	$-84.0\pm54.4$	0.129	
Cardiac intercur.*	$210.0\pm42.4$	$181.2\pm55.1$	$\textbf{28.8} \pm \textbf{39.6}$	0.471	
Major complic.	$173.3\pm70.2$	$182.9\pm54.4$	$-9.6\pm32.8$	0.772	
Total complic.	$190.9\pm69.6$	$176.5\pm41.9$	$14.4\pm15.5$	0.357	

\* Major complications.

**Table 7.** Duration of the procedure depending on the occurrence of complications stratified by surgical approach: posterior approach.

i	Occurr compli	ence of cations	Mean difference		
Complication	$\begin{array}{c} \text{Yes} \\ \text{Mean} \pm \text{SD} \end{array}$	No Mean $\pm$ SD	± Standard error of the diff.	p-value	
Superficial infection	$252.5\pm58.5$	$\textbf{222.2} \pm \textbf{61.2}$	$\textbf{30.3} \pm \textbf{31.1}$	0.885	
Urinary Intercur.	$257.8\pm56.3$	$\textbf{222.0} \pm \textbf{61.1}$	35.8 ± 31.1	0.252	
Pain	$\textbf{316.4} \pm \textbf{97.0}$	$\textbf{216.9} \pm \textbf{52.9}$	$99.5\pm22.0$	0.000	
Confusional state	$\textbf{277.0} \pm \textbf{94.8}$	$\textbf{222.3} \pm \textbf{60.5}$	$54.7\pm43.5$	0.211	
Hematoma	$235.0\pm31.2$	$\textbf{222.9} \pm \textbf{61.7}$	$12.1 \pm 35.9$	0.737	
C5 neuropraxia	$220.0\pm78.7$	$\textbf{223.4} \pm \textbf{60.8}$	$-3.4 \pm 31.2$	0.914	
Deep infection*	$206.2\pm33.9$	$225.0\pm63.0$	$-18.8 \pm 20.3$	0.357	
Implant intercur.*	306.7 ± 61.1	$220.9\pm59.7$	85.8 ± 35.0	0.016	
Cardiac intercur.*	209.3 ± 17.2	$223.6\pm61.8$	$-14.3 \pm 35.9$	0.691	
Death*	197.5 ± 24.7	$223.7\pm61.5$	$-26.2 \pm 43.7$	0.550	
Major complic.	$225.6\pm53.3$	$\textbf{222.9} \pm \textbf{62.5}$	$\textbf{2.8} \pm \textbf{16.6}$	0.868	
Total complic.	$248.6\pm70.8$	$209.9\pm50.9$	38.7 ± 13.0	0.004	

\* Major complications.

Table 8. Duration of the procedure depending on the occurrence of
complications stratified by surgical approach: combined approach.

	Occurr compli	ence of cations	Mean difference		
Complication	Yes No Mean ± SD Mean ± SD		± Standard error of the diff.	p-value	
Superficial infection	$315.0\pm0.0$	$357.8 \pm 119.1$	$-42.8\pm128.7$	0.753	
Pain	$340.0 \pm 0.0$	$353.7 \pm 120.3$	$-13.7 \pm 129.9$	0.920	
C5 neuropraxia	$\textbf{360.0} \pm \textbf{0.0}$	$350.3 \pm 120.4$	$9.7\pm130.0$	0.944	
Implant intercur.*	$460.0\pm0.0$	$333.7 \pm 108.5$	$126.3\pm117.2$	0.330	
New compression*	138.0 ± 0.0	$\textbf{387.3} \pm \textbf{62.0}$	$-246.3\pm67.0$	0.014	
Major complic.	$299 \pm 227.7$	$\textbf{372.8} \pm \textbf{56.8}$	$\textbf{73.8} \pm \textbf{163.0}$	0.726	
Total complic.	322.6±117.0	$424.5 \pm 54.4$	101.9 ± 89.9	0.308	

\* Major complications.

#### DISCUSSION

Surgical decompression is considered the gold standard procedure for treating and preventing neurological deficits in cervical spondylotic myelopathy (CSM).<sup>10</sup> Nevertheless, a discussion still remains about the surgical approach for each case, considering the number of addressed segments. Thus, this study aimed to evaluate the early postoperative complications associated with surgical approaches to the cervical spine of individuals with CSM, comparing the anterior surgical, the posterior surgical, and the combined approaches, evaluating the relation between complications and the used approach, number of segments involved in the procedure, and surgical time. Thus, we conducted a retrospective study based on a database obtained from electronic medical records and imaging exams. All 169 selected patients had undergone a surgical procedure to treat CSM by the same surgical team from 2008 to 2015 in a tertiary hospital. Retrospective studies on databases can lead to information collection errors since we established no previous research protocol. To minimize this bias, we collected data by a complete evaluation of patients' medical records and nursing staff and the physiotherapy team's notes.

Several previous studies have evaluated complications resulting from surgery to treat cervical spine conditions.<sup>11-18</sup> However, most studies regarding surgical approaches to the cervical spine included patients with different types of diseases, such as tumors, traumatic injuries, herniated disc-associated radiculopathy, spondylodiscitis, and (less commonly) vascular malformations and deformities.<sup>6</sup> Thus, we believe that selecting a sample of patients with the same disease may reduce the risk of selection bias since the indication for surgical treatment was CSM in all cases.

Likewise, the literature has no consensus regarding the definitions of postoperative complications. Thus, we agree with Campbell et al.<sup>7</sup> and Fehlings et al.<sup>19</sup> and follow the same standards as these authors regarding the definition of early complications as an adverse event that occurs within the first 30 days after surgery, ruling out complications after this period (which we considered late complications). Furthermore, even after several previous studies,<sup>20-23</sup> controversy remains regarding the severity of complications, making it difficult to use a pre-established pattern. Thus, we once again follow the model used by Campbell et al.<sup>7</sup> and chose to assess early complications as minor and major, the difference being the need for new surgical intervention or permanent sequelae.

According to Montano et al.,<sup>24</sup> prolonged operative times and increased blood loss are individually associated with an increase in the overall complication rate regardless of whether the approach is anterior, posterior, or combined.<sup>25</sup> Our results showed no statistically significant difference between the mean surgical time of anterior approach surgeries when we separated patients with complications from cases without them. However, when we evaluated the mean surgical time of procedures performed by the posterior approach, the occurrence of total complications and, specifically, pain and complications with the implant were statistically significant in longer surgeries. In the total research sample, superficial infections (p = 0.014), complications with implants (p = 0.000), and total complications (p = 0.005) were more prevalent in cases of longer surgery.

The anterior approach, involving decompression, followed by arthrodesis, is widely indicated in cases with an anterior compressive component and associated kyphosis. Moreover, it is considered a safe and effective procedure to treat CSM.<sup>26</sup> The complication with the highest incidence in this approach is dysphagia and one of the most severe complications is airway obstruction, which can have several causes, such as edema in the upper airways and postoperative hematoma.<sup>25</sup> In our study, the rate of dysphagia in patients who underwent the anterior approach totaled 17.3%. Dysphagia is believed to be related to the extension and duration of

esophageal withdrawal or retraction during the surgical procedure due to compromised blood flow to the mucosa.<sup>25</sup> An information that may explain the higher rate of dysphagia in our study, compared with previous studies, was the use of notes from the nursing and physiotherapy team to obtain the data.

Regarding the posterior surgical approach, Shammassian and Hart<sup>25</sup> reported a wound infection rate of 4.7% and attributed postoperative immobilization, pressure on the wound, changes in vascular supply, and tension in wound closure as probable causes for this complication. We found a 3.6% rate of superficial infection in cases operated by the posterior approach in our sample. However, this result showed no statistically significant difference (p = 0.072) when we compared the group of patients undergoing surgical treatment in up to two segments with patients undergoing surgical treatment involving three or more spinal segments. On the other hand, we found a statistically significant correlation (p = 0.014) between superficial infection and longer surgical time.

Another aspect we considered significant and previous studies failed to do so<sup>6,7</sup> was the occurrence of pain in the early postoperative period. We found this minor complication in 7.7% of the patients who underwent the anterior approach and in 6.4% of patients treated using the posterior approach, corresponding to 7.1% of all complications in this study. We believe that many authors have chosen to disregard pain in their assessments of early complications since differentiating the pain symptom expected in the early postoperative period from a pain symptom resulting from a complication is difficult. We defined pain as a complication when the symptom was worse than in the preoperative period to minimize this risk.

This study has some limitations. First, the study design is a retrospective analysis of a database. However, knowing this potential bias in the collection of information, we used the notes of the medical team and those of the nursing and the physiotherapy teams. This fact allowed us to detect complications that we think are more effective. The second limitation was the lack of standardization of a previously established definition of early complications. Thus, we chose to use the definition models used by Campbell et al.,<sup>7</sup> which enabled us to define with some ease what would be an early complication and differentiate major complications from minor ones.

However, our study managed to include patients with the same disease (CSM), making our sample more homogeneous. Moreover, the same team performed all surgical procedures, reducing the bias inherent to surgeons' experience.

#### CONCLUSION

Our results agree with findings reported in the literature by showing that dysphagia, pain, and superficial surgical wound infection were the most frequent postoperative complications. However, establishing a statistical relationship between the incidence of complications and the surgical time, surgical approach, and number of fused segments was impossible.

**AUTHORS' CONTRIBUTIONS:** Each author contributed individually and significantly to the development of this article. RLCS: data analysis, writing and reviewing of the article; TPS: writing and reviewing the article; LM: data analysis and statistical analysis; MDSP: data analysis and article review; CFPSH: writing of the article, statistical analysis, intellectual concept of the article, and preparation of the entire research project.

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## COMPARATIVE ANALYSIS OF OPEN AND CLOSED FLOATING KNEE INJURIES

ANÁLISE COMPARATIVA DE LESÃO DE JOELHO FLUTUANTE ABERTA E FECHADA

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#### ABSTRACT

Objective: To compare the functional outcomes between floating knee injuries with open femur and tibia fractures and closed floating knee injuries. Methods: Floating knee injuries (followed up and treated in our clinic) were retrospectively analyzed. Patients were divided into two groups: floating knee injuries with open femur and tibia fractures (Group 1) and floating knee injuries with closed femur and tibia fractures (Group 2). Patients were compared according to their demographic characteristics and clinical and functional outcomes. Results: Of 52 study patients, 28 had Group 1 injuries and 24, Group 2 injuries. We found a statistically significant difference in length of hospital stay between the two groups (p = 0.01) and a statistically significant difference in Karlström-Olerud functional scores between the groups (p = 0.02). We found osteomyelitis in five (17%) patients in Group 1 and in one (4%) patient in Group 2. Conclusion: Patients with floating knee injuries and open fractures showed poorer outcomes than those with closed fractures. Those with open floating knee injuries show complications more often and longer hospital stays. Level of Evidence III, Therapeutic Studies Investigating the Results of Treatment.

#### RESUMO

Objetivo: Comparar os resultados funcionais entre lesões do tipo joelho flutuante com fraturas expostas de fêmur e tíbia e lesões de joelho flutuante fechadas. Métodos: As lesões de joelho flutuante acompanhadas e tratadas em nossa clínica foram analisadas retrospectivamente. Os pacientes foram divididos em dois grupos: lesões de joelho flutuante com fraturas expostas de fêmur e tíbia (Grupo 1) e lesões de joelho flutuante com fraturas fechadas de fêmur e tíbia (Grupo 2). Os pacientes foram comparados de acordo com as características demográficas e os desfechos clínicos e funcionais. Resultados: Entre os 52 pacientes do estudo, 28 tiveram lesões do Grupo 1 e 24 do Grupo 2. A diferenca no tempo de internação entre os dois grupos foi estatisticamente significativa (p = 0,01). Também houve diferença estatisticamente significativa nos escores funcionais de Karlström e Olerud entre os grupos (p = 0,02). Osteomielite foi identificada em 5 (17%) pacientes do Grupo 1 e em 1 (4%) paciente do Grupo 2. Conclusão: Comparados aos pacientes com lesões de joelho flutuante com fraturas fechadas, aqueles com fraturas expostas têm piores resultados, uma vez que as complicações são mais comuns e a permanência hospitalar é mais longa nestes casos. Nível de Evidência III, Estudos Terapêuticos – Investigação dos Resultados do Tratamento.

Keywords: Knee Injuries. Femur. Tibia. Fractures, Bone.

Descritores: Traumatismos do Joelho. Fêmur. Tíbia. Fraturas Ósseas.

**Citation:** Bozgeyik B, Büyükbebeci O, Güner S, Mert A. Comparative analysis of open and closed floating knee injuries. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 3. Available from URL: http://www.scielo.br/aob

#### INTRODUCTION

The term floating knee, first described by Blake and McBryde,<sup>1</sup> includes traumatic ipsilateral fractures of the femur and tibia. These injuries result from high-energy traumas and are usually associated with high rates of mortality and morbidity.<sup>2,3</sup> Fraser classified floating knee injuries in 1978 to guide their treatment.<sup>4</sup> This classification sorts fractures based on their location in patients' femur and tibia. Since floating knee injuries are high-energy injuries, patients may have additional injuries, which may include additional problems

such as abdominal and thoracic injuries.<sup>5</sup> Vascular injuries may also accompany these traumas, showing a rate of around 7%.<sup>6</sup> The formation of fractures by high-energy mechanisms also damages the soft tissues surrounding the fractures. Therefore, many patients show open fractures. Treatment of patients with open injuries can be more complicated. A literature review shows several studies on the outcomes of floating knee injuries.<sup>7,8</sup> However, no study has evaluated both femoral and tibial fractures due to open injuries and compared open fractures with isolated closed ones.

All authors declare no potential conflict of interest related to this article.

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Article received on 04/05/2022, approved on 11/22/2022.



This study aimed to compare the functional outcomes between adult-type open floating knee injuries and closed floating knee injuries.

#### **METHODS**

Following the approval of the local ethics committee (numbered 2021/220), 52 patients with floating knee injury from 2013 to 2019 were retrospectively reviewed and included in this study. Among 52 study patients, 28 had open floating knee injuries (Group 1) and 24 (Group 2), closed fractures. Patients with open injuries were categorized by the Gustilo-Anderson classification. Fraser's classification was used to classify both groups. Patients' age, gender, neurovascular damage, follow-up length, union presence, fixation method, osteomyelitis development, hospital stay length, type of fracture fixation, and complications were recorded. All patients were evaluated by X-ray at follow-ups after 3, 6, 9, and 12 months. Functional outcomes in both groups were assessed by the Karlström-Olerud criteria. Children; pregnant women; patients with pathological fractures and isolated open femur or tibia fracture, and those who missed regular followups were excluded. Adults with closed femur and tibia fractures (Group 2) and open femur and tibia fractures (Group 1) were included in this study. Patients with open fractures were administered firstgeneration cephalosporin and metronidazole during their hospital stay. Antibiotics were changed according to the culture results in eligible patients. The closed fracture group was preoperatively administered prophylactic first-generation cephalosporin.

#### **Statistical analysis**

The descriptive statistics of the analyzed variables in this study were expressed as mean  $\pm$  standard deviation and median (minimummaximum) and nominal variables as n (%) in appropriate charts. The statistical significance of nominal variables between groups was tested using the chi-squared test and that of continuous variables, by the Mann–Whitney U test. In all statistical analyses, the level of significance was set at p < 0.05. IBM SPSS, version 22.0, (IBM Corp, Armonk, NY, USA) was used for data analysis.

#### RESULTS

This study included 52 patients with floating knee injuries, 28 of which had open floating knee injuries and 24, closed fractures. Group 1 had 26 (92%) men and 2 (2%) women, whereas Group 2, 20 (83%) men and 4 (17%) women. Group 1 and 2 showed a 33.96 (18–59) and 32.7 (16–68) mean age (in years), respectively.

According to Fraser's classification, 15 (28%) patients had Type I fractures; 12 (23%), Type IIa; 14 (27%), Type IIb; and 11 (21%), Type IIc. According to the Gustilo-Anderson classification, three patients in the open floating knee injury group had Type I fractures; seven, Type II; and 18, Type III femoral fractures (Table 1).

Patients' follow-ups averaged 28 (14–70) months. Our comparison of hospital stay length between showed a mean length of 13.17 (7–18) days in Group 1 and of 9.75 (5–14) days in Group 2. Length of stay showed a statistically significant difference between groups (p = 0.01). The Karlström-Olerud criteria categorized Group 1 patients' functional and radiological outcomes as poor in 14 patients, acceptable in five, good in eight, and excellent in one, and as poor in two, acceptable in four, good in 10, and excellent in eight Group 2 patients. We found a statistically significant difference in Karlström-Olerud functional scores between our two groups (p = 0.02) (Table 2).

Of the 28 patients in Group 1, nine (with femoral shaft fractures) underwent intramedullary nailing and five (with Gustilo-Anderson type III-b-c fractures), intramedullary nailing following a damage control surgery using external fixation. In total, 12 of 14 patients with fractures involving the articular surface of the distal femur underwent a combination of plate and cannulated screws, whereas

two patients with Gustilo-Anderson type III-b-c fractures preferred plate fixation after external fixation. Of the 24 patients with closed femur and tibia fractures, 13 patients with femoral shaft fractures underwent primary fixation with intramedullary nailing and 11, with a combination of plate and cannulated screws. Moreover, 13 patients with tibial shaft fractures underwent intramedullary nailing and 11, a combination of plate and cannulated screws for their fractures involving the articular surface of their proximal tibiae.

In total, two patients with type III-c open fractures underwent vascular repair. Their subsequent insufficient circulation required amputation. Moreover, four patients in the open fracture group underwent dualplating knee arthrodesis due to the development of osteoarthritis at follow-up. We found that six patients showed femoral fracture nonunion, four of which had open fractures and two, closed ones. Moreover, two patients developed tibia nonunion, one in the open group and the other in the closed group. We diagnosed osteomyelitis in five (17%) patients in Group 1 and in one (4%) patient in Group 2 (Table 3).

Table 1. Fraser and Gustilo-Anderson classifications by Fraser subty	pes.
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			Fraser Cl	assification	
		Type I (n = 15)	Type IIa (n = 12)	Type IIb (n = 14)	Type llc (n = 11)
Femur	Closed	7	6	6	5
	Type I	2	0	0	1
Open fracture	Type II	3	0	3	1
Gustilo-Anderson	Type IIIa	1	3	4	3
classification	Type IIIb	1	2	0	0
	Type IIIc	1	1	1	1
Tibia	Closed	7	6	6	5
	Type I	0	0	0	0
Open fracture	Type II	2	1	2	2
Gustilo-Anderson	Type Illa	1	2	2	3
classification	Type IIIb	2	2	2	0
	Type IIIc	3	1	2	1
Age		28.06 (16–49)	33.08 (18–47)	35.07 (21–65)	38.81 (18–68)
Length of hospital	stay (days)	7 (5–11)	12 (9–15)	13.71 (10–18)	14.72 (12–18)

**Table 2.** Relation between KOOS and length of hospital stay by group.

Char	acteristic	Group 1	Group 2	p-value
Length of he	ospital stay (day)	13.17 (7–18)	9.75 (5–14)	0.01
	Poor	14	2	
Karlström-	Acceptable	5	4	0.01
Olerud	Good	8	10	0.01
	Excellent	1	8	

Table 3. Complications and their distribution.

Table el complicatione ana troir e		
Complications	Group 1	Group 2
Amputation	2 (7%)	0
Knee arthrodesis	4 (14%)	0
Femoral nonunion	4 (14%)	2 (8%)
Tibial nonunion	1 (3%)	1 (4%)
Osteomyelitis	5 (17%)	1 (4%)
Superficial infection	1 (3%)	1 (4%)

#### DISCUSSION

This study functionally compared patients who had floating knee injuries with open femoral and tibial fractures and those who had

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floating knee injuries with closed femoral and tibial fractures. No study in the literature has compared open and closed fractures. Previous studies suggest early final fixation of floating knee injuries as advantageous<sup>9,10</sup> in orthopedic surgeries as it reduces hospital stay length.<sup>11</sup> Open fractures, however, have been considered disadvantageous in this regard. Although we aimed at early fixation for both patient groups, the transition to internal fixation after infection control with external fixators in the open fracture group prolonged those patients' hospital stay.

Our comparison of Karlström-Olerud functional outcomes between aroups showed better outcomes in the closed fracture group (p = 0.02). Similar studies support the good outcomes of closed fractures.<sup>12</sup> Kulkarni et al.<sup>13</sup> found that floating knee injuries suffer the influence of open or closed fractures, segmental nature, additional injuries, and intraarticular surfaces. Our study ignored floating knee injuries with segmental fractures. We found no statistically significant difference in fracture types between groups. This facilitated our evaluation of patients with open and closed fractures, rendering it more objectively and independent of other factors. Chouhan et al.<sup>14</sup> compared Fraser subtypes considering that fracture types would affect outcomes, showing that IIA fractures had better functional outcomes than IIB and IIC ones. From this point of view (and considering that Fraser subtypes would affect the outcomes), our study compared Fraser subtypes between groups and found no significant difference between them, making our study comparable regarding open-closed fractures.

Floating knee injuries also show complications due to their highenergy nature. Rollo et al.<sup>15</sup> found compartment syndrome in eight patients, open fractures in 60, and partial amputation in 24, having to perform total amputation on three patients. We amputated two patients in the open floating injury group due to insufficient circulation after vascular repair. Floating knee injuries can seriously damage bones and soft tissues and may even progress to amputation in patients with open fractures.

It would be inaccurate to consider floating knee injuries as isolated bone lesions as these traumas can also injure the soft tissues around and inside the knee. A study investigating concomitant ligamentous and meniscal tissue injuries reported that they co-occurred by meniscus, anterior cruciate ligament, and posterior cruciate ligament injuries, which required treatment after a careful physical examination.<sup>16</sup> This study ignored additional ligamentous injuries. Further additional and complex traumas in patients may hinder the determination of subgroups in the floating knee classification.<sup>17</sup>

Other system and organ injuries often follow floating knee injuries. Although our study excluded patients with additional injuries, two patients in the open fracture group showed vascular injuries. The literature has reported poor prognostic outcomes for patients with vascular injuries,<sup>18</sup> agreeing with our results.

Fixation methods also vary in floating knee injuries, provoking discussions on which fracture should be fixed first and by which implant. Dwyer et al.<sup>9</sup> reported that treating femur fractures by external fixation reduced knee range of motion due to quadriceps muscle dysfunction, but their method for fixating tibial fractures had no effect on outcomes. Our study ignored comparing groups by implant types and fixation methods as they scarcely affect outcomes due to similar fracture types.

Our study diagnosed osteomyelitis in 20% of patients in the open fracture group and in 4% in the closed fracture group. The case series in Chouhan et al.<sup>14</sup> included 27 patients, finding infections and osteomyelitis in 25% and 11% of them, respectively. Shahzad et al.,<sup>19</sup> on the other hand, found femoral and tibial infections in 16.9% and 20% of their 65 patients, respectively. Our study results and literature data have shown that floating knee injuries increase the risk of osteomyelitis due to its high-energy nature and surgical procedures, a process triggered by the open fracture pattern since open fracture management is closely related to both negatives in the process of fracture union and infections.<sup>20</sup>

Our study has a number of limitations, including its retrospective setting and no examination of the effects of ligamentous injuries on outcomes. Moreover, how fixation methods and length of transition from external to internal fixation affect outcomes remains unknown.

#### CONCLUSION

Floating knee injuries involving the femur and tibia configure rare injuries. In conclusion, floating knee injuries with open femur and tibia fractures show poorer functional outcomes than those with isolated closed fractures.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. BB, OB: writing, study design, and critical revision of the manuscript; SG, AM: study design and data collection.

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## EVALUATION OF THE EPIDEMIOLOGY OF EXPOSED FRACTURES BEFORE AND DURING THE COVID-19 PANDEMIC

## AVALIAÇÃO DA EPIDEMIOLOGIA DAS FRATURAS EXPOSTAS ANTES E DURANTE A PANDEMIA DE COVID-19

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#### ABSTRACT

Objective: To assess the impact of the COVID-19 pandemic on the epidemiology and clinical outcomes of open fractures considering the periods before and during the pandemic. Methods: An observational and retrospective study, which included patients aged over 18 years, admitted to the Orthopedics and Traumatology Ward of Hospital São Paulo, of the Federal University of São Paulo (UNIFESP). Data was collected in two moments: pre-pandemic (March 1, 2019, to February 29, 2020) and during the pandemic (March 1, 2020, to February 28, 2021). Results: In total, 183 patients were evaluated with a mean age of 36 years  $\pm$  14 years. In the pre-pandemic period, 94 patients underwent surgery, 81 men (85.37%) and 13 women (14.2%), with a mean age of  $36 \pm 3$  years. During the pandemic period, 89 patients were subjected to surgery, 77 men (86.6%) and 12 women (13.4%), with a mean age of  $38 \pm 3$  years. Conclusion: During the pandemic, open fractures were still more common in men. Regarding hospital indicators, the prevalence of infections in the surgical wound and the length of stay of patients with open fractures increased, however, with little significance. Fractures classified as Gustilo IIIA were the most common, while the most common according to the AO classification were 33, 34, 42, 43, 2R3, and 2R3 + 2U2. The frequency of run overs during the pandemic decreased. However, firearm projectile injuries and falls and occupational injuries increased. Level of Evidence III, Retrospective Comparative Study.

**Keywords:** Epidemiology. Trauma Centers. Wounds and Injuries. Multiple Trauma. Fractures, Bone. COVID-19.

#### RESUMO

Objetivo: Avaliar o impacto da COVID-19 na epidemiologia e nos desfechos clínicos das fraturas expostas considerando os períodos antes e durante a pandemia. Métodos: Estudo observacional e retrospectivo que incluiu pacientes maiores de 18 anos, internados na Enfermaria de Ortopedia e Traumatologia do Hospital São Paulo, da Universidade Federal de São Paulo. Os dados foram coletados em dois momentos – antes (março de 2019 a fevereiro de 2020) e durante a pandemia (março de 2020 a fevereiro de 2021) -, por meio da análise de prontuários eletrônicos de todos os registros hospitalares dessa instituição. Resultados: No total, foram avaliados 183 pacientes com média de idade de 36 ± 14 anos. No período pré-pandêmico, foram operados 94 pacientes, sendo 81 homens (85,37%) e 13 mulheres (14,2%), com média de idade de  $36 \pm 3$  anos. Já ao longo do período pandêmico, foram operados 89 pacientes, sendo 77 homens (86,6%) e 12 mulheres (13,4%), com média de idade de 38 ± 3 anos. Conclusão: Durante a pandemia, a ocorrência de fraturas expostas se manteve com maior frequência em indivíduos do sexo masculino. Quanto aos indicadores hospitalares, houve aumento da prevalência de infecções na ferida operatória, assim como do tempo de internação dos pacientes, todavia, com pouca significância. Foram mais frequentes as fraturas classificadas como Gustilo IIIA e, pela classificação AO, as fraturas 33, 34, 42, 43, 2R3 e 2R3 + 2U2. Notamos redução da frequência de atropelamentos durante a pandemia e aumento dos casos de ferimentos por projétil de arma de fogo, quedas e acidentes ocupacionais. Nível de Evidência III, Estudo Retrospectivo Comparativo.

**Descritores:** Epidemiologia. Centros de Traumatologia. Ferimentos e Lesões. Traumatismo Múltiplo. Fraturas Ósseas. COVID-19.

**Citation:** Franco VP, Gonçalves GM, Fração OC, Sungaila HYF, Cocco LF, Dobashi ET. Evaluation of the epidemiology of exposed fractures before and during the COVID-19 pandemic. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 6. Available from URL: http://www.scielo.br/aob.

#### INTRODUCTION

According to a World Health Organization study, COVID-19 has affected over 216 countries, with 194,080,019 confirmed cases and 4,162,304 deaths as of the termination of this

study.<sup>1</sup> The transmission of the SARS-cov-2 disease can easily occur by airways infection and can lead to many clinical situations, ranging from a common cold to more severe respiratory syndromes.<sup>2</sup>

#### All authors declare no potential conflict of interest related to this article.

The study was conducted at Universidade Federal de Sao Paulo, Escola Paulista de Medicina, Hospital Sao Paulo, Serviço de Ortopedia e Traumatologia. Correspondence: Vinicius Pagliaro Franco. Rua 3 de Maio, 61, Sao Paulo, SP, Brazil, 04044020. vinicius\_franco11@hotmail.com

Article received on 09/29/2022, approved on 02/17/2023



The new scenario set by the COVID-19 pandemic has created enormous pressure on health systems worldwide. This scenario deeply impacted the management of fractures on the locomotor system, which are the main circumstances responsible for admissions to emergency rooms.<sup>3</sup> Thus, the continuous provision of care in trauma services are a great challenge.<sup>4</sup> Many orthopedic surgeons have been instructed to postpone or cancel elective surgeries without urgency to delay the transmission of the disease and conserve health resources.<sup>5</sup>

The new standard of living during the pandemic has had a significant impact on epidemiology and prevalence, especially in cases of orthopedic trauma, including fractures.<sup>6</sup> The increase in social isolation due to the pandemic and the length of stay at home have affected the number of hospital visits and the distribution of patients with fractures who are admitted to the emergency room.<sup>3</sup> Recent studies such as those by Murphy, Akehurst, and Mutimer<sup>7</sup> and by Lima et al.<sup>8</sup> reported a reduction in the number of cases of fractures at the beginning of the pandemic, which probably occurred due to the decrease in patient demand for health services justified by the fear of contamination and the possibility of sequelae from COVID-19 infection.<sup>7,8</sup> However, we also found studies showing an increase in mortality rates<sup>9-11</sup> and complications<sup>12,13</sup> in patients with fractures treated during the pandemic.

Mortality rates are considerably higher in patients with fractures and seropositive for COVID-19, compared to patients without fractures and seropositive for COVID-19. Regarding the mortality rate in patients with fractures and carriers of COVID-19, a recent systematic review showed an average rate of 34%, and 91.7% mortality rate when considering hip fractures.

Mortality rate was also related to older patients with hip fractures, which is one of the main predictors of death in these patients.<sup>14</sup> Furthermore, other studies described the consequences of the pandemic in the surgical treatment of different types of fractures, mostly of the hip,<sup>5,14</sup> lower limbs,<sup>4</sup> and ankle.<sup>15</sup> However, only few studies evaluated the impact of the COVID-19 pandemic considering epidemiological data, waiting time for hospitalization, pre- and post-operative follow-up time, treatment options, clinical outcome of patients with open fractures before and during the pandemic. Therefore, information on these aspects is scarce, especially at the national level.

Although many advances in the treatment of open fractures have been achieved over the years, these injuries are still a great challenge, mainly due to the possibility of complications such as infection and non-consolidation, as well as the inherent difficulty of dealing with high-energy injuries with significant impairment of bones and soft tissues.<sup>16</sup>

Furthermore, the COVID-19 pandemic has changed the population's standards of health care and mobility and has seriously impacted the epidemiology and prevalence of fractures.<sup>8</sup> Thus, it is essential to understand the impact of the pandemic on the reduction or increase in the prevalence of hospital visits, waiting time for hospitalizations, treatment options, and clinical outcomes of patients with open fractures treated before and during the pandemic, providing information that may improve patient management.

In this way, our research group decided to carry out this study. Therefore, this study aimed to evaluate the impact of the pandemic on patients with fractures considering the epidemiological elements. Moreover, we aimed to analyze the clinical outcome of open fractures in the periods before and during the COVID-19 pandemic.

#### **METHODS**

This study was submitted to evaluation and approved by the Research Ethics Committee of the Federal University of São Paulo (UNIFESP) according to opinion No. 5,609,990 of August 29, 2022,

for meeting the guidelines provided for in Resolution 466 of 2012 of the National Health Council regarding the ethical and legal aspects related to studies involving human beings.

This is an observational and retrospective study of patients who were admitted to the Orthopedics and Traumatology Ward of the Hospital São Paulo of UNIFESP. Data were collected before (March 1, 2019, to March 29, 2019) and during the pandemic (March 1, 2020, to February 29, 2021). Patients older than 18 years of both sexes who underwent surgical procedures for fractures were included in the study. Those who had a diagnosis of infection such as pyoarthritis, abscesses, thrombosis, and who did not undergo orthopedic surgeries were excluded from the sample.

Patient data were obtained by consulting the electronic medical record (EMR) of Hospital São Paulo, which has all hospital records (HR) of patients. The information collected included: age, sex, trauma mechanism, anatomical site of fractures classified by the radiographic alphanumeric system AO, preoperative time, length of hospital stay, postoperative time, type of surgery, clinical outcome, cause of fracture, affected side, type of surgery, and functional status. Furthermore, patients' comorbidities, including smoking, diabetes, hypertension, chronic obstructive pulmonary disease, heart failure, and the need for dialysis were recorded.

Postoperative complications of patients were recorded, including death, coma, use of mechanical ventilator, unplanned intubation, stroke, thromboembolic event (deep vein thrombosis or pulmonary embolism), cardiac arrest, acute myocardial infarction, kidney failure, sepsis, septic shock, return to the operating room, wound dehiscence, deep surgical site infection, and peripheral nerve lesions.

Therefore, our sample included 183 patients with a mean age of 36 years  $\pm$  14 years. Before the pandemic, 94 patients were operated, 81 (85.37%) men and 13 (14.2%) women, with a mean age of 36  $\pm$  3 years. During the pandemic, 89 patients were operated, 77 (86.6%) men and 12 (13.4%) women, with a mean age of 38  $\pm$  3 years.

The analyses used the tests of percentage comparisons between the two groups as statistical sufficiency, associating the profile of hospital indicators with the incidence rates and diversity of fractures, as well as the risk factors that involved them. All analyses were performed using STATA program version 16 (2019), with a 5% alpha as the adherence parameter.

Measures of central tendency to determine the parametricity of the values were assessed based on the normal distribution of the mean and its respective standard deviation. Categorical variables were presented by their absolute and relative frequencies to the total sample size.

Statistical significance was considered when p-values were equal to or lower than 0.05, both for the results from the *t*-test, and for those from the proportional difference tests, allowing to verify the existence of significant differences between the parameters before and during the COVID-19 pandemic. P-values higher than 0.05 indicate that the period is insignificant for the measures analyzed.

#### RESULTS

Table 1 shows data regarding hospital indicators, length of hospital stay, ICU admission, number of surgical procedures, and Gustilo classification.

Table 2 shows the results based on the test of difference of proportions, involving the qualitative variables related to the surgical processes in both periods evaluated.

Table 3 shows the diversity of fracture classifications, their frequencies, and proportional comparisons.

Table 4 shows the data on the incidence of complications, as well as their proportional differences.



Table 1. Comparison of hospital indicators in the two periods (before
and during the COVID-19 pandemic).

0		/			
Characteristic	Before the	pandemic	During the	<i>p</i> value	
	Mean and Confidence Interval		Mean and Confidence Interval		
Length of hospital stay (days)	8 (2-	–14)	9 (1	-23)	< 0.05*
Surgical time	AF	RF	AF	RF	
T1	48	51%	49	55%	0.06
T 2	46	49%	40	45%	
ICU	AF	RF	AF	RF	
No	92	98%	83	93%	> 0.07
Yes	2	2.1%	6	7%	
Death	AF	RF	AF	RF	
No	93	99%	87	97%	> 0.07
Yes	1	1%	2	3%	
Gustilo classification	AF	RF	AF	RF	0.05
1	4	4%	8	9%	> 0.05
II	13	14%	6	6.7%	> 0.03
III A	74	78%	72	80%	> 0.05
III B	3	3%	1	1.2%	-
III C	-	-	2	1.2%	-

\*Statistically significant difference between periods.

AF: Absolute frequency; FR: Relative frequency.

 
 Table 2. Proportional comparison of variables involved in surgeries before and during the COVID-19 pandemic.

Trauma mechanism	Before the pandemic		During the pandemic		p value
Running over	AF	RF	AF	RF	
	15	16%	9	10.1%	< 0.03*
Car $\times$ guard rail accident	1	1.2%	-	-	-
Bicycle Accident	3	3.7%	4	4.5%	> 0.06
Motorcycle × guard rail accident	2	2.5%	2	2.2%	-
Motorcycle × automobile accident	36	38%	37	41.5%	> 0.08
Motorcycle fall	7	7.4%	7	7.8%	> 0.09
Sprains	2	2.5%	1	1.1%	< 0.04*
Crushing	5	5.3%	1	1.1%	< 0.02*
Assaults	1	1.2%	-	-	-
HGI	2	2%	4	4.5%	< 0.01*
Animal bite	-	-	1	1.1%	-
Fall up to 2 meters	13	14%	10	11.2%	< 0.05*
Fall greater than 2 meters	5	5.3%	3	3.3%	< 0.05*
Chainsaw	2	2%	3	3.3%	< 0.04*
Caved in	-	-	2	2.2%	-
Diverse	-	-	2	2.2%	-

\*Statistically significant difference between periods.

AF: Absolute frequency; FR: Relative frequency.

**Table 3.** Proportional differences between the incidences and classifications of fractures before and during the COVID-19 pandemic.

AO Fracture Classification	Before the pandemic		During the pandemic		<i>p</i> value
3	AF 1	RF 1.06%	AF -	RF -	-
11	AF 1	RF 1.06%	AF	RF	-
12	AF 1	RF 1.06%	AF 1	RF 1.12%	> 0.06

AO Fracture Classification	Before the	pandemic	During the	pandemic	<i>p</i> value
13	AF 1	RF 1.06%	AF 1	RF 1.12%	> 0.06
21	AF 1	RF 1.06%	AF 1	RF 1.12%	> 0.06
23	AF 3	RF 3.2%	AF -	RF -	-
31	AF 1	RF 1.06%	AF -	RF -	-
32	AF 6	RF 6.3%	AF -	RF -	-
33	AF 5	RF 5.3%	AF 2	RF 2.2%	< 0.04*
34	AF 1	RF 1.06%	AF 6	RF 6.7%	< 0.03*
41	AF 1	RF 1.06%	AF -	RF -	-
42	AF 28	RF 29%	AF 14	RF 15.7%	< 0.02*
43	AF 9	RF 9.5%	AF 4	RF 4.4%	< 0.04*
44	AF 6	RF 6.3%	AF 4	RF 4.4%	> 0.06
54	AF 2	RF 2%	AF 1	RF 1.12%	> 0.05
61	AF -	RF -	AF 1	RF 1.12%	-
70	AF 7	RF 7.4%	AF -	RF -	-
75	AF -	RF -	AF 1	RF 1.12%	-
77	AF 1	RF 1.06%	AF 3	RF 3.3%	< 0.05*
78	AF 3	RF 3.2%	AF 4	RF 4.4%	> 0.05
80	AF 1	RF 1.06%	AF -	RF -	-
81	AF 1	RF 1.06%	AF -	RF -	-
82	AF -	RF -	AF 2	RF 2.2%	-
85	AF -	RF -	AF 1	RF 1.12%	-
88	AF -	RF -	AF 3	RF 3.3%	-
89	AF -	RF -	AF 1	RF 1.12%	-
2R1	AF 1	RF 1.06%	AF -	RF -	-
2R2	AF 1	RF 1.06%	AF -	RF -	-
2R3	AF 1	RF 1.06%	AF 3	RF 3.3%	< 0.03*

**Table 3.** Proportional differences between the incidences and classifications

 of fractures before and during the COVID-19 pandemic.



AO Fracture Classification	Before the	pandemic	During the	pandemic	<i>p</i> value
2R3 + 2U2	AF 2	RF 2.1%	AF 7	RF 7.8%	< 0.02*
2R2 + 2U2 2R3	AF -	RF -	AF 2	RF 2.2%	-
2R3 + 2U3	AF -	RF -	AF 2	RF 2.2%	-
2R3 + 2U3 + 42	AF -	RF -	AF 1	RF 1.12%	-
2U1	AF -	RF -	AF 1	RF 1.12%	-
2U2	AF -	RF -	AF 2	RF 2.2%	-
2U2 + 78	AF -	RF -	AF 2	RF 2.2%	-
22U	AF 1	RF 1.06%	AF -	RF -	-
32 + 41 + 77	AF -	RF -	AF 2	RF 2.2%	-
32 + 43	AF -	RF -	AF 2	RF 2.2%	-
33 + 43	AF 1	RF 1.06%	AF -	RF -	-
41 + 34	AF 1	RF 1.06%	AF -	RF -	-
42 + 41	AF 1	RF 1.06%	AF -	RF -	-
42 + 80	AF 1	RF 1.06%	AF -	RF -	-
42 + 4F2	AF -	RF -	AF 9	RF 11%	-
42 + 80	AF 1	RF 1.06%	AF -	RF -	-
42 + 87	AF -	RF -	AF 1	RF 1.12%	-
42 + 88	AF -	RF -	AF 1	RF 1.12%	-
4F2	AF -	RF -	AF 1	RF 1.12%	-
77 + 78	AF -	RF -	AF 2	RF 2.2%	-
81 + 21	AF 1	RF 1.06%	AF -	RF -	-
78 + 85 + 87	AF 1	RF 1.06%	AF -	RF -	-

**Table 3.** Proportional differences between the incidences and classifications
 of fractures before and during the COVID-19 pandemic

Table 4. Proportional differences between the incidence of surgical complications before and during the COVID-19 pandemic.

-						
8 + 2U2	AF 2	RF 2.1%	AF 7	RF 7.8%	< 0.02*	Consolida
2 + 2U2 2R3	AF -	RF -	AF 2	RF 2.2%	-	Fat en
s + 2U3	AF -	RF -	AF 2	RF 2.2%	-	Infectio
2U3 + 42	AF	RF	AF 1	RF	-	Synthesi
2U1	AF	RF	AF	RF		Skin
	-	-	1	1.12%	-	Radial ne
2U2	AF -	RF -	AF 2	RF 2.2%	-	Poor re
2 + 78	AF -	RF -	AF 2	RF 2.2%	-	De
22U	AF 1	RF	AF	RF	-	Osteo
41 . 77		1.00 %	-			Loss of
41 + //	- -	-	2	2.2%	-	Loss of S
2 + 43	AF -	RF -	AF 2	RF 2.2%	-	Pseuda
8 + 43	AF 1	RF 1.06%	AF	RF -	-	Joint s
+ 34	AF	RF	AF	RF		Surgica
	1	1.06%	-	-		Loss
2 + 41	AF 1	RF 1.06%	AF -	RF -	-	Comp
2 + 80	AF 1	RF 1.06%	AF -	RF -	-	No com
+ 4F2	AF -	RF -	AF 9	RF 11%	-	*Statistically AF: Absolute
2 + 80	AF 1	RF 1.06%	AF -	RF -	-	There wa
2 + 87	AF -	RF -	AF 1	RF 1.12%	-	in age gr Regardir
2 + 88	AF	RF -	AF 1	RF 1.12%	-	difference the class
4F2	AF -	RF -	AF 1	RF 1.12%	-	of run ove injuries (f
' + 78	AF -	RF -	AF 2	RF 2.2%	-	situations pandemic
+ 21	AF 1	RF 1.06%	AF -	RF -	-	motor veh statistical
	<u> </u>					When ver

\*Statistically significant difference between periods.

AF: Absolute frequency; FR: Relative frequency.

## << SUMÁRIO

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Complication	Before the	pandemic	During the	pandemic	<i>p</i> value
Amputation	AF	RF	AF	RF	. 0.05*
	1	1.06%	2	2.89%	< 0.05
Consolidation delay	AF	RF	AF	RF	
	-	-	1	1.1%	-
Fat embolism	AF	RF	AF	RF	
	1	1.06%	-	-	-
Infection of OSW	AF	RF	AF	RF	- 0.04*
	11	11.7%	8	9%	< 0.04
Synthesis infection	AF	RF	AF	RF	
	4	4.2%	-	-	-
Skin injury	AF	RF	AF	RF	
	1	1.06%	1	1.1%	> 0.10
Radial nerve injury	AF	RF	AF	RF	
	-	-	1	1.1%	-
Poor reduction	AF	RF	AF	RF	
	-	-	1	1.1%	-
Deaths	AF	RF	AF	RF	
	-	-	2	2.89%	-
Osteomyelitis	AF	RF	AF	RF	> 0.10
	2	2.12%	2	2.89%	> 0.10
Loss of reduction	AF	RF	AF	RF	
	-	-	2	2.89%	-
Loss of Substance	AF	RF	AF	RF	
	2	2.12%	-	-	-
Pseudarthrosis	AF	RF	AF	RF	< 0.06
	2	2.12%	3	3.4%	/ 0.00
Joint stiffness	AF	RF	AF	RF	
	1	1.06%	-	-	
Surgical revision	AF	RF	AF	RF	
	-	-	1	1.1%	
Loss of limbs	AF	RF	AF	RF	
	-	-	1	1.1%	
Compartment	AF	RF	AF	RF	
Syndrome	1	1.06%	-	-	
No complications	AF	RF	AF	RF	< 0.06
	60	63%	61	68%	

significant difference between periods.

frequency; FR: Relative frequency; OSW: obstetric surgical wound.

as a statistically significant difference in the prevalence of oth periods (p < 0.02). However, we found no difference roups between the periods analyzed (p > 0.07).

ng hospital indicators, we found a slight statistical e in the length of stay during the pandemic, as well as in sifications of Gustilo I, II, and IIIA (Table 1).

luation of risk factors, we highlight the reduction in the frequency ers during the pandemic, the increase in firearm projectile FPI) and falls and occupational injuries, epidemiological s involved with measures to restrict activities during the c. Amputations slightly increased, however, at levels very tatistical insignificance. On the other hand, accidents involving nicles, such as motorcycles and automobiles, did not present ly significant differences between the periods.

rifying the incidences and classifications of fractures, not all of them could be compared due to the differences of incidence. Those that occurred simultaneously between the groups and that showed statistically significant differences between the periods were 33, 34, 42, 43, 2R3, and 2R3 + 2U2.

Post-surgical complications were the same before and during the pandemic, except for surgical wound infection. Notably, the absence of post-surgical complications maintained stable percentages and without differences between the two periods evaluated.

#### DISCUSSION

Both public and private healthcare services have needed significant adaptations to handle the large influx of patients during the COVID-19 pandemic. There has been a new level of redeployment of surgical and anesthetic teams of all grades to manage the vast workload related to the pandemic, which has greatly impacted service delivery, with the complete suspension of elective orthopedic surgeries and significant changes in the way trauma care is provided.<sup>17</sup>

Considering the risks to which patients and medical staff were exposed in the pandemic, the Department of Orthopedics and Traumatology of the Federal University of São Paulo (UNIFESP) created three protocols in the service that were applied during the pandemic. Thus, the application of these protocols aimed to reduce the risk of infection of patients and healthcare professionals and adapt work, academic, and scientific activities, and orthopedic treatment in the face of the pandemic.<sup>8</sup>

The impact on trauma services was especially related to the need to balance optimal treatment of patients' injuries with safety and clinical resources. The need to reduce hospitalizations and elective surgeries was reinforced, as well as accepting that conventional surgical decision-making would have to change, with an increase in cases of late reconstruction. However, major orthopedic injuries, including open fractures, had to continue their treatment in emergency cases. Open fractures are complex injuries associated with high rates of complications, including infection and neurological and vascular impairment.<sup>17</sup>

Thus, this study aimed to understand the impact of the pandemic on the reduction or increase in the prevalence of hospital visits, the waiting time for hospitalizations, treatment options, and clinical outcomes of patients with open fractures, comparing the rates obtained in our service before and during the COVID-19 pandemic, to provide information that can improve patient management. Our results showed a higher prevalence of fractures in men for both periods. This finding is similar to that observed by Tian et al.,<sup>18</sup> who evaluated 111 studies involving 41,429 individuals by a systematic review of the literature, to identify factors involved with the occurrence and resolution of fractures, including those involved with the formation of pseudarthrosis in tibial fractures. According to the authors, many factors significantly influenced the outcomes, including being aged over 60 years old and being a man, occurrence of open fracture, IIIB or IIIC fractures according to the Gustilo classification, among others.<sup>18</sup> These results are very similar to those identified in this survey.

We observed fewer run overs and more firearm projectile injury and domestic accidents during the COVID-19 pandemic. According to Sephton et al.,<sup>19</sup> the confinement led to a decrease in emergency orthopedic emergency referrals and the number of procedures, as well as resulting in a shift in the injury mechanisms, which became characterized by domestic accidents and some situations of violence, justifying the change in the profile of the trauma mechanism observed in this study.

During the pandemic, the prevalence of surgical wound infections increased. Moreover, the length of stay of patients with open fractures was slightly longer during the pandemic.

Although our findings were significant, we had some limitations since this is single-center study and the sample size is relatively small. However, all patients treated at our tertiary health care institution were compiled for the analyses.

#### CONCLUSION

During the pandemic, open fractures maintained their occurrence, which had a higher frequency in men. Regarding hospital indicators, the prevalence of infections in the surgical wound and the length of stay of patients with open fractures increased, however, they were not significant. The fractures classified as Gustilo IIIA were the most prevalent and, according to the AO classification, the most common types were 33, 34, 42, 43, 2R3, and 2R3 + 2U2. Furthermore, during the pandemic, the frequency of run overs decreased, however, FPI and falls and occupational injuries increased.

**AUTHORS' CONTRIBUTIONS:** Each author contributed individually and significantly to the development of this study. VPF, GMG, OCF, HYFS, LFC, ETD: study conception and design, analysis and interpretation of the data, writing of manuscript and critical review of its intellectual content, and final approval of the final version of the manuscript.

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## **EXPANDABLE INTRAVERTEBRAL IMPLANTS IN POST-TRAUMATIC VERTEBRAL NECROSIS – NEW CLASSIFICATION SUGGESTION**

**IMPLANTES INTRAVERTEBRAIS EXPANSÍVEIS NO** TRATAMENTO DE NECROSE VERTEBRAL PÓS-TRAUMÁTICA – PROPOSTA DE NOVA CLASSIFICAÇÃO

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#### ABSTRACT

The progressive evolution of post-traumatic vertebral necrosis and consequent loss of structural integrity of the vertebral body along with neurological risk, makes it one of the most feared and unpredictable pathologies in spine traumatology. Several studies have addressed the role of vertebroplasty, kyphoplasty, and corpectomy in its treatment; however, it remains a controversial concept without a defined therapeutic algorithm. The recent emergence of expandable intravertebral implants, which allow, by a percutaneous transpedicular application, the capacity for intrasomatic filling and maintenance of the height of the vertebral body, makes them a viable option, not only in the treatment of acute vertebral fractures, but also in non-union cases. In this study, we present a review of the current evidence on the application of expandable intravertebral implants in cases of post-traumatic vertebral necrosis. Based on the available scientific literature, including previous classifications of post-traumatic necrosis, and on the mechanical characteristics of the main expandable intravertebral implants currently available, we propose a simplified classification of this pathology, considering parameters that influence surgical therapeutic guidance, the morphology and the dynamics of the necrotic vertebra's mobility. According to its stages and based on authors' experience and on the scarce literature, we propose an initial therapeutic algorithm and suggest preventive strategies for this disease, considering its main risk factors, that is, fracture comminution and impairment of vertebral vascularity. Therefore, expandable intravertebral implants have a promising role in this condition; however, large prospective studies are needed to confirm their efficacy, to clarify the indications of each of these devices, and to validate the algorithm suggestion regarding treatment and prevention of post-traumatic vertebral necrosis. Level of Evidence III, Systematic Review/Actualization.

#### RESUMO

A evolução progressiva da necrose vertebral pós-traumática e consequente perda da integridade estrutural do corpo vertebral, juntamente com o risco neurológico, a torna uma das patologias mais temidas e imprevisíveis na traumatologia da coluna. Vários estudos têm abordado o papel da vertebroplastia, cifoplastia e corpectomia no tratamento da necrose vertebral, no entanto, o tratamento ainda é controverso sem um algoritmo terapêutico definido. O recente surgimento dos implantes intravertebrais expansíveis, que permitem através duma aplicacao transpedicular percutânea a capacidade de preenchimento intrassomático e de manutenção da altura do corpo vertebral, torna-os uma opção viável não số no tratamento das fraturas vertebrais agudas, mas também em situações de não consolidação óssea. Neste estudo, apresentamos uma revisão das evidências atuais sobre a aplicação de implantes intravertebrais expansíveis em casos de necrose vertebral pós-traumática. Com base na literatura científica disponível, incluindo classificações prévias de necrose vertebral pós-traumática, e nas características mecânicas dos principais implantes intravertebrais expansíveis disponíveis, propomos uma classificação simplificada desta patologia, considerando parâmetros que influenciam a orientação terapêutica cirúrgica, a morfologia e a dinâmica da mobilidade da vértebra. De acordo com seus estágios e com base na experiência dos autores e na escassa literatura, propomos um algoritmo terapêutico inicial e sugerimos estratégias preventivas para esta doença, considerando seus principais fatores de risco, ou seja, cominução da fratura e lesão da vascularização vertebral. Portanto, os implantes intravertebrais expansíveis têm um papel promissor nessa condição; no entanto, estudos prospectivos de grande dimensão são necessários para confirmar sua eficácia, esclarecer as indicações de cada um desses dispositivos e validar a presente proposta do algoritmo de tratamento e prevenção da necrose vertebral pós-traumática. Nível de Evidência III, Revisão Sistemática/Atualização.

Keywords: Necrosis. Pseudarthrosis. Spinal Fractures. Spine. Bone.

Descritores: Necrose. Pseudoartrose. Fraturas da Coluna Vertebral. Osso.

Citation: Moura DL, Gabriel JP. Expandable intravertebral implants in post-traumatic vertebral necrosis - new classification suggestion. Acta Ortop Bras. [online]. 2023;31(4): Page 1 of 10. Available from URL: http://www.scielo.br/aob.

#### All authors declare no potential conflict of interest related to this article.

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Article received on 04/09/2022, approved on 11/22/2022.



#### **INTRODUCTION**

Post-traumatic osteonecrosis of the vertebral body was first reported in 1891 by Hermann Kummell, initially describing it as a vertebra collapse symptom that appears from weeks to months after a minor trauma, indicating the vertebral body's nutritional insufficiency as the etiological hypothesis.<sup>1,2</sup> Initially, it was considered a rare condition; however, its diagnosis has been increasing, probably due to population aging, being more commonly found in the thoracolumbar transition and in older adults with osteoporosis.<sup>3-7</sup> It is estimated that post-traumatic vertebral necrosis is underdiagnosed and that its real incidence is significant. Reports indicate a prevalence ranging from 7% to 37% of vertebral compression fractures, particularly affecting those with a more comminuted fracture pattern, greater flattening, and those occurring in less vascularized regions of the vertebral body, which are all known risk factors for the development of pseudarthrosis. A type of extrinsic interference has been described, consisting of an excessive load on a weakened fractured vertebra without enough stability to heal. Effectively, the vertebral fracture evolution to non-union bone, with progressive osteonecrosis of the vertebral body and the consequent loss of its structural integrity and neurological risk, is currently one of the most concerning and unpredictable challenges in spine traumatology. Currently accepted diagnostic criteria are patients who persist symptomatic from six weeks to three months after a vertebral fracture and patients who exhibit imaging signs of vertebral necrosis on computed tomography and magnetic resonance, with or without progressive flattening and collapse, or the development of intrasomatic clefts.<sup>1,2,8-11</sup>

Post-traumatic vertebral necrosis represents a failure in vertebral bone healing. Thus, it makes sense that the treatment aims to interrupt this disease evolution and negative consequences. This way, patients with

symptomatic vertebral necrosis (axial pain and functional limitation), with or without nerve compression symptoms, are candidates for surgical intervention. Atrophic type pseudarthrosis in general fractures is usually treated with bone resection, repairing bony ends to restore blood and growth factors for the site; local application of bone graft, stimulating the process of bone healing; and fixation. However, in spine, cementoplasty techniques (vertebroplasty and kyphoplasty) have been used to treat this disease, immediately stabilizing the vertebral body without waiting for bone healing.<sup>5-9</sup>

Expandable intravertebral implants are self-expanding devices applied percutaneously with posterior transpedicular access. They are introduced inside the vertebral body and their expansion allows for restoring their height, integrity, and stability, when filled with bone cement or graft. The application of expandable intravertebral implants, sometimes referred to as armed kyphoplasty, in addition to allowing the immediate analgesia and stabilization benefits of vertebroplasty and kyphoplasty, can also creates a vertebral body metallic endoskeleton which ensures a greater strength and resistance and a long-term maintenance of restored vertebral height. This happens because vertebral endplates, after reduction, are mechanically supported by the expanded devices, decreasing or preventing vertebral flattening after its expansion and also lowering the risk of post-traumatic local and segmental kyphosis, in addition to ensuring very stable anterior support for the vertebral body.<sup>12-26</sup> In Table 1, we present the characteristics of the two most commonly applied expandable intravertebral implants currently available: Vertebral Body Stenting (VBS®) and SpineJack® systems.<sup>12-26</sup> The evolution of the indications for these recent devices has also shown promising results in vertebral fractures which turn into chronic and symptomatic non-union situations.18,27

Implant designation	Vertebral Body Stenting <sup>®</sup>	SpineJack®
Illustration		
	http://synthes.vo.llnwd.net/o16/LLNWMB8/INT%20Mobile/Synthes%20 International/SGT-EMEA-Agile/SE_818940AA/SE_818940AAeng.pdf	https://www.stryker.com/us/en/interventional- spine/products/spinejack-system.html
Morphology	Cylinder-shaped mesh (stent), two implants by transpedicular access	Similar to a car jack, with superior and inferior lamellas, and two implants by transpedicular access
Material	Chromium-cobalt	Titanium
Expansion direction	Centrifugal circumferential in the coronal plane (craniocaudal + lateral)	Bidirectional in craniocaudal or vertical direction
Expansion mechanism	Hydraulic mechanism, via a kyphoplasty balloon (controlled pressure and volume)	Mechanical mechanism
Expansion power	Maximum pressure = 30 Atm; Maximum expansion volumes: #small stent = 4 mL; #medium stent = 4.5 mL; #large stent = 5 mL	Expansion force = 500 Newtons; maximum expansion heights: #small implant 4.2 = 12.5 mm; #medium implant 5.0 = 17 mm; #large implant 5.8 = 20 mm

 Table 1. Biomechanical characteristics of the two most commonly applied expansive intravertebral implants currently available, the Vertebral Body Stenting<sup>®</sup> and the SpineJack<sup>®</sup>.<sup>12-26</sup>



Table 1. Biomechanical characteristics of the two most commonly applied expansive intravertebral implants currently available, the Vertebral Body Stenting<sup>®</sup> and the SpineJack<sup>®</sup> <sup>12-26</sup>

Implant designation	Vertebral Body Stenting®	SpineJack®
Objective	Vertebra reduction and space occupation	Vertebra reduction, preservation of unfractured trabeculae
Rationale	VBS <sup>®</sup> is a reducing and space-occupying implant since it presents a multidirectional expansion (vertical and lateral). It is indicated for reconstruction or replacement of the vertebral body without the intention to wait for vertebral fracture natural healing. Stents are implants that, due to their expansion and impaction of the surrounding bone trabeculae, form two cavities inside the vertebral body, which are covered by an envelope of impacted trabeculae. These implants form cavities that, after being filled with bone cement or graft, replace a large part of the vertebral body, filling and stabilizing it. In addition, they minimize cement leakage by recreating the vertebral body walls by impacting bone trabeculae, thereby containing the cement inside	SpineJack <sup>®</sup> is a more powerful reduction implant and preserver of unfractured native trabeculae. This implant is not as space occupant since it only expands vertically. In these cases, the goal is to reduce the fracture and wait for its healing, rather than replacing the vertebral body. This implant only reduces and supports the vertebral body, as it does not have a cavity shape or lateral expansion. Therefore, it does not destroy intact lateral trabeculae and does not create significant empty space within the vertebral body. Thus, this implant is useful in cases that demand fracture reduction and bone healing while preserving bone health. We consider that this implant is not ideal for replacing the comminuted, lytic, or porotic vertebral bodies with unstable interior content. Such cases require intrasomatic filling in addition to fracture reduction
Cement Distribution Pattern	Cavitary in the interior of the stents and trabecular at periphery	Trabecular, often joining the two implants in a horizontal pattern

#### **METHODS**

This study was based on a literature search in September 2021 on the MEDLINE/PubMed platform, with combination of terms concerning diagnosis and surgical procedure. The search terms for diagnostic words were "chronic vertebral fracture," "kummel disease," "vertebral osteonecrosis," "vertebral pseudoarthrosis," "vertebral nonunion," and "osteonecroticcleft," whereas search terms for surgical intervention were "armed kyphoplasty," "expandable intravertebral implant," "VBS stent," "stentoplasty," and "Spinejack". A total of 47 results papers were found, of which, after reviewing titles and abstracts, only two were selected since they focused on the role of expandable intravertebral implants on post-traumatic necrosis or chronic fractures of thoracolumbar spine fractures (PRISMA chart in Figure 1).<sup>18,27</sup>



**Figure 1.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.<sup>28</sup>

#### RESULTS

Application of expandable intravertebral implants in posttraumatic vertebral necrosis – literature review

We selected an article on SpineJack<sup>®</sup> expandable implants and another article on VBS<sup>®</sup> stents, which are summarized in Table 2. Premat et al.<sup>27</sup> analyzed the application of expandable intravertebral implants in chronic fractures, prospectively studying 19 consecutive adult patients who had undergone reduction and stabilization with SpineJack® in Magerl A3 burst fractures, with the intervention occurring after a mean delay of 5.8  $\pm$  2.9 months from the initial fracture. All consecutive adult patients with symptomatic osteoporotic vertebral compression fractures (OVCFs) who underwent vertebral augmentation with the SpineJack® were prospectively included. Patients were considered eligible for inclusion if they met the following criteria: OVCFs involving the lower thoracic and/or lumbar vertebrae, considered unstable (grade A3 according to Magerl's classification), kyphosis of at least 20° at the vertebra's level, fractures older than six weeks, intractable back pain, with a visual analogue scale (VAS) of at least four. Preoperative evaluation included clinical examination and an imaging workup, including a computed tomography (CT) and a spine magnetic resonance imaging (MRI). All patients had postoperative spine and chest control X-rays in the operating room followed by a spine CT scan focused on the treated site. A systematic clinical follow-up was performed at one and six months after intervention. This way, they identified significant improvements between the preoperative visual analogue pain scale (median 7) and after six months postoperatively (median 2). The improvement in the mean local kyphosis was significant in 94.7% of the cases, going from  $24.4 \pm 4.1$  to  $11.7^{\circ} \pm 6.7$ . The mean Beck index increased significantly, from 0.43 to 0.66. Additionally, the anterior (11.2 mm  $\pm$  3.1 to 16.3 mm  $\pm$  2.7) and middle (11.5 mm  $\pm$  3.3 to 17.2 mm  $\pm$  2.7) vertebral heights also had significant improvements, with a smaller increase in posterior height (23.4 mm  $\pm$  3.4 to 24.2 mm  $\pm$  3.5). There was no worsening of posterior wall protrusions. The mean of injected cement was  $5.9 \pm 1.4$  mL. By using computerized tomography (CT), the authors identified that 36.8% of patients presented discal extravasations, 15.4% presented venous extravasations, and one (5.3%) presented pulmonary embolism with cement, all asymptomatic. There were 21.1% of adjacent vertebral fractures, with a significant higher prevalence in cases with more accentuated corrections of the



local kyphosis, which leads to the recommendation of prophylactic vertebroplasties at the adjacent levels in cases of chronic fractures with severe kyphosis.

Table 2. Current studies regarding the application of intravertebral implants
in the context of chronic compression vertebral fractures 14-27

Article	Premat et al.27	Distefano et al. <sup>18</sup>
Nature	Case series, prospective	Case series, retrospective
Fracture type	A3 compression chronic fracture (older than six weeks)	80 severe osteoporotic vertebral compression fractures – advanced collapse (Genant grade 3), high degree of osseous fragmentation (McCormack grade 2 and 3), burst morphology, pediculo-somatic junction fracture, and/or large osteonecrotic cleft.
Number of fractured vertebrae	19	Vertebrae with large osteonecrotic clefts in 56/80 levels (70%) of the sample
Intervention	Armed kyphoplasty with SpineJack <sup>®</sup> implants	internal fixation (SAIF)
Mean follow-up	Six months	Six months
Symptoms (VAS)	Median VAS: $7 \rightarrow 2$ (p < 0.01)	VAS median 8 at preoperative $\rightarrow$ 3 at one month $\rightarrow$ 2 at six months (p < 0.05)
Function	57.9% of patients presented improvements in mobility, with nine patients (47.9%) able to fully ambulate without any help	PGIC Scale: 5.6 $\pm$ 0.9 at one month; 6.1 $\pm$ 0.9 at six months
Imaging	Parameters comparison from preoperative to postoperative: Mean kyphotic angulation: $24.4^{\circ}\pm 4.1 \rightarrow 11.7^{\circ}\pm 6.7$ (p < 0.01); Mean vertebral heights: anterior aspect $11.2 \text{ mm} \pm 3.1 \rightarrow$ 16.3 mm $\pm 2.7(\text{p} < 0.01)$ ; middle aspect $11.5 \text{ mm} \pm 3.3 \rightarrow$ 17.2 mm $\pm 2.7(\text{p} < 0.01)$ ; posterior aspect $23.4 \text{ mm} \pm 3.4 \rightarrow$ 24.2 mm $\pm 3.5(\text{p} = 0.48)$ ; Modified Beck index $0.43 \rightarrow 0.66 (\text{p} < 0.01)$	Vertebral body reconstruction was evaluated by two external persons and considered satisfactory in 98.8% of levels, based on scores regarding correct placement and expansion of the implants, cement filling, and vertebral body height restoration.
Complications	21.1% of patients presented secondary adjacent level fractures correlated with kyphosis reduction; and 15.79% of patients presented minor PMMA	17.5% of patients presented painful adjacent vertebral fractures; 10% presented cement leakage detected on CT, with an epidural or foraminal location in 3.8%, all asymptomatic; 20.5% presented osseous subsidence around the VBS-cement complex, with mild to moderate secondary vertebral body height loss
Conclusion	Successful augmentation and reduction are reachable with SpineJack <sup>®</sup> in chronic vertebral body fractures.	SAIF is a minimally invasive, safe, and effective treatment for severe osteoporotic vertebral compression fracture, including clefted vertebral bodies. VBS recreates the internal structure of the vertebral body, and favors a predictable and uniform cement distribution within the stents

VAS: Visual Analogue Scale; OSW: Oswestry disability score; PMMA: polymethylmethacrylate; Modified Beck index: minimal vertebral height/maximum vertebral height; PGIC Scale: Patient's Global Impression of Change Scale; CT: computed tomography. In the second included paper, Distefano et al. applied the stent-screw-assisted internal fixation (SAIF) technique, previously described by the same group, to treat 56 vertebrae with osteonecrotic intravertebral clefts.<sup>18,29</sup> The SAIF aims to complement the reduction and reconstruction of the vertebral body using VBS® stents with pedicle screws, which anchor the stents-cement complex to the posterior elements. This method prevents their migration and acts as a bridge across the middle column, allowing union between the anterior and posterior portions of the vertebra, ensuring its integrity and preventing collapse and splitting.<sup>29</sup> In another study by the same author, severe vertebral compression fractures were characterized by advanced collapse (Genant grade 3), a high degree of osseous fragmentation (McCormack grade 2 and 3), burst morphology with middlecolumn injury, pediculo-somatic junction fracture, and/or large osteonecrotic cleft, with several patients presenting more than one of these conditions.<sup>18</sup> All patients underwent preprocedural spinal CT and/or MRI at the target level to accurately define the fracture morphology. Vertebral body reconstruction was assessed with post procedure radiographs and CT scan. Patients were followed-up at one and six months, with a clinical examination and upright plain radiographs. One of the problems involving the analysis of this article was the impossibility to isolate the results of vertebrae with necrotic clefts, since the authors do not separate the data by pathology groups; therefore, the study outcomes include acute comminuted fractures. Despite this, we consider that 70% of the sample with intravertebral clefts is a very relevant slice; thus, most cases correspond to situations of non-union or vertebral pseudarthrosis, so we present their results. Visual analog scale (VAS) scores improved with statistically significant difference from median 8 in preoperative to 3 at 1-month follow-up and to 2 at six months. The PGIC scale (Final Patients' Global Impression of Change) was 5.6  $\pm$  0.9 at one month and 6.1  $\pm$  0.9 at six months, which indicates a positive subjective evaluation of their clinical improvement. There was a 17.5% rate of adjacent vertebral fractures, most of which were treated with vertebroplasty or SAIF. Cement leakage was detected in 10% of cases on post-procedure CT, with an epidural or foraminal location in 3.8% without any symptoms. Vertebral body reconstruction was evaluated by two external experts and considered satisfactory in 98.8% of levels, based on scores regarding correct placement and expansion of the implants, cement filling, and vertebral body height restoration. The authors highlight the importance of the SAIF technique in the stable reconstruction of the vertebra as a whole. They report that often in traditional vertebroplasty or kyphoplasty, only the anterior two thirds of the vertebral body are augmented for safety reasons to avoid intracanal cement leakage, turning the Denis's middle column into a fragile 'bare area.' These areas favor bone reabsorption and refracture, cleavage, and splitting between the augmented anterior column and the middle column, with risk of posterior wall protrusion, focal kyphosis, instability, and neurologic injury.<sup>18,29</sup> Thus, they consider that, especially in unstable necrotic vertebrae-that is, with considerable intravertebral clefts, where the middle column is almost always affected-,traditional vertebroplasty and kyphoplasty may be insufficient since they do not strengthen this Denis column, which increases the risk of progressive bone resorption and vertebral collapse. The SAIF technique allows a 360° non-fusion interior vertebra reconstruction, in which stents restore the anterior column, whereas pedicle screws allow its anchorage to the posterior elements through the reinforcement of the middle column.<sup>18,29</sup> In short, both studies consider armed kyphoplasty with expandable intravertebral implants a successful minimally



invasive option for the interior reconstruction of the vertebral body in non-union situations, obtaining excellent clinical and functional outcomes. Despite excellent outcomes, the first paper does not clarify what is the morphology and dynamics of the treated necrotic vertebra, whereas the second paper states that necrotic vertebrae were mobile, presenting large clefts. We think posttraumatic vertebral necrosis treatment and results should be analyzed separately according to a clear previous definition of the affected vertebra, clarifying vertebral necrosis presentation and stage and the performed treatment, mostly because the surgical options, its difficulties, and also their outcomes, are certainly distinct; therefore, as an example, the authors should refer to the following section of this study. Furthermore, about 20% of secondary adjacent level fractures seems to be a significant number and it is present in both studies; however, it is unclear whether it is a complication or a natural progression of osteoporotic spinal disease. Finally, the authors did not consider the severity of osteoporosis of each patient and the degree of correction of vertebral height that could justify prophylactic vertebroplasties at the adjacent levels.

#### DISCUSSION

Suggestion of therapeutic and preventive algorithm for post--traumatic vertebral necrosis

Based on the scarce scientific literature available and on authors' experience with expandable intravertebral implants, we propose an simplified classification for post-traumatic vertebral necrosis. This classification is based on parameters that directly influence the surgical therapeutic approach (Figure 2), namely the morphology and mobility dynamics of the necrotic vertebra (Figure 2). Furthermore, to aid in the management of this condition, we also propose a therapeutic and preventive algorithm for this disease (Figure 3).<sup>30-35</sup> Therefore, we distinguish *two types of vertebral morphology: vertebra non-plana* and *vertebra plana; two types of mobility:* vertebrae with mobile deformity or in pseudarthrosis, characterized by intrasomatic clefts in the mobile region; and vertebrae with

immobile deformity, that is, without evident intravertebral cleft. All these types of morphology and mobility can be combined in four stages, according to Figure 2. The determination of vertebral morphology and mobility in the context of post-traumatic necrosis must be performed by the combination of radiographs, including dynamic radiographs in hyperextension and orthostatism, computed tomography, and magnetic resonance imaging, also allowing to evaluate the amount of remaining bone tissue. The type of vertebral morphology and of the necrotic vertebra's mobility will determine the surgical therapeutic option based on the possibility or not to preserve the vertebral body.<sup>1-10,36</sup>

The authors define vertebra non-plana morphology as a vertebral body with a height that is equal to or greater than one third of the height of the original body along its entire length. We consider necrosis with vertebra non-plana to be a vertebral body still with sufficient bone tissue, namely with preserved bone cover (cortical ring and endplates), which allows for containing the application of expandable intravertebral implants, permitting a vertebral body interior reconstruction instead of its total replacement. Therefore, in these cases, we recommend armed kyphoplasty, in which empty spaces within the vertebral body are created by expandable intravertebral implants, which are surrounded by bone trabeculae impacted by the devices. Afterwards, the body is filled with bone cement or graft, which provides it with interior consistency and stability. In mobile vertebrae (pseudarthrosis), that is, with intravertebral clefts, regardless of their non-plana or plana morphology, it is possible to restore almost the entire height of the vertebral body by the positioning of the spine in hyperextension, which causes the separation of the upper and lower halves of the pseudarthrosis, increasing the cleft size and restoring the vertebral body height, which is filled internally. Thus, armed kyphoplasty is also indicated in these cases. The complete filling of the intrasomatic cleft is essential to stabilize the vertebral body, eliminating pathological intravertebral mobility. In turn, in vertebrae with immobile deformity, the goal is not to gain height, but only to fill the necrotic body, stabilizing it and preventing its progressive flattening by necrosis and bone resorption.<sup>1-10,36</sup>



**Figure 2.** Suggested post-traumatic vertebral necrosis evolution stages: Stage 0 – Initial fracture without necrosis; Stage 1i – Immobile (i) necrotic vertebra non-plana; Stage 1m – Mobile (m) necrotic vertebra non-plana; Stage 2i – Immobile necrotic vertebra plana; Stage 2m – Mobile necrotic vertebra plana; Highlighting the presence of intravertebral cleft only in the mobile vertebrae. Immobile vertebrae do not present intravertebral cleft. On the right side, note the vertebral body pseudarthrosis or mobile necrotic vertebra morphology and biomechanics.





**Figure 3.** Suggested therapeutic and preventive algorithms for post-traumatic vertebral necrosis: Therapeutic algorithm for post-traumatic vertebral necrosis. Mobile vertebrae non-plana and plana – Armed kyphoplasty with VBS<sup>®</sup>. After removal of pseudarthrosis region (the same as the intravertebral cleft) and proper intravertebral cleaning, the implants are expanded and filled with bone cement or graft; Immobile vertebra non-plana – Armed kyphoplasty with SpineJack<sup>®</sup>. After proper intravertebral drilling, the implants are expanded and then bone cement or graft are applied around them; Immobile vertebra plana – the recommended treatment for young and active patients involves corpectomy and intersomatic fusion using a spacer (synthetic cage or structural allograft), along with fixation using a plate and pedicle instrumentation at adjacent levels. However, in older patients or cases where corpectomy is contraindicated, adjacent pedicular fixation with cemented screws and vertebroplasties at adjacent levels are indicated. Preventive algorithm for post-traumatic vertebral necrosis: 1 – For osteoporotic comminuted compression fractures, we recommend armed kyphoplasty with VBS<sup>®</sup> filled with bone cement. In these patients the goal is interior replacement and reconstruction of the fragile vertebral body, fracture healing is not expected; 2 – For traumatic comminuted compression fractures (A4 from AOSpine classification), we recommend initial indirect reduction via adjacent pedicle instrumentation, followed by additional direct reduction and interior reconstruction of the vertebral body with VBS<sup>®</sup> filled with cancellous bone graft. Highlighting the direct vertebral reduction that allows height restauration by elevation of the central depression of the upper vertebral endplate after expansion of VBS<sup>®</sup> implants and their final filling with bone graft (yellow/brown final image representing the bone graft inside the stents).

Given the lack of evidence in the current scientific literature on which expandable intravertebral implants to apply according to vertebral necrosis types and stages, the authors suggest, based mainly on clinical experience with the use of these devices and on treating this condition, in addition to current scientific evidence, an algorithm that considers vertebral morphology and mobility at each stage, as well as on the characteristics of each expandable device (Figure 3, Table 1). The present algorithm is not validated since literature is insufficient, so it should be seen as an initial suggestion of the role of expandable intravertebral implants in vertebral necrosis



based on disease stage and progression, device characteristics, and personal experience of the authors. In vertebrae non-plana and in mobile vertebra plana, situations susceptible to armed kyphoplasty, we usually choose VBS® implants in vertebrae with mobile deformity and SpineJack® implants in those with immobile deformity (Figure 3). The VBS<sup>®</sup> is an implant with a high capacity for space occupation, allowing the creation of large intrasomatic cavities with the cover made of the metallic mesh of the device and impacted bone trabeculae, which allows the application of a greater amount of bone cement or graft and, simultaneously, creates less pressure and more containment to minimize cement leakage. The cement filling in the VBS® primarily follows a cavity pattern inside the stents. However, it also exhibits a trabecular pattern due to peripheral interdigitation, which establishes contact with an interior network of trabeculae-which penetrate the holes of the stent's mesh upon expansion—and with the stent metallic network itself (Table 1). It is essential, in vertebral necrosis, for the cement agglomerate to be peripherally immobilized by the interdigitation in surrounding healthy bone trabeculae, which can only be achieved if there is an adequate previous removal of the fibrocartilaginous membrane and residues of pseudarthrosis, and of the peripheral sclerosis, minimizing the risk of cement and implant migration. Proper cleaning of the pseudarthrosis region, keeping only the bone cover of the vertebral body, is also essential when applying bone graft inside the stents, seeking to bring blood inside the vertebra. Thus, the necessary mediators are allowed to provide invasion by vessels of the bone graft matrix and osseointegration without interference from interposed necrotic tissues and fibrocartilaginous membrane, which characterizes the false joint and internally lines the intravertebral cleft, making local blood access difficult.1-10,13-18,37,38 However, considering important sclerotic regions present in the vertebral body of the immobile deformity type and the hydraulic and pressure-dependent expansion mechanism of the VBS<sup>®</sup>, there is a risk that the resistance of the sclerotic bone is greater than the expandable capacity of these implants, and these may not expand or expand insufficiently, not creating the intrasomatic cavities of the desired size. Furthermore, in necrotic vertebrae with immobile deformity (without intravertebral cleft), vertebral expansion is not possible by positioning the spine in hyperextension; therefore, the creation of intrasomatic spaces is totally dependent on the action of intravertebral implants. Thus, in immobile vertebrae non-plana, we recommend SpineJack® implants, which, despite not being space-occupying implants, have a more powerful and mechanical expansion capacity, that is not directly dependent on pressure, managing to create intrasomatic spaces even in vertebrae with immobile deformity, which will be filled with bone cement or graft (Figure 3). The filling pattern of cement with SpineJack® implants is mainly trabecular, as this implant only creates small cavities corresponding to its vertical expansion, so the cement, after occupying these small cavities, interdigitates in the surrounding trabecular space and often connects both implants in a horizontal pattern (Table 1). As previously mentioned, since SpineJack® implants, unlike VBS®, do not create intrasomatic cavities that will contain the cement inside, their use in the context of vertebral necrosis-given the alternation of sclerotic with necrotic bone and the unpredictability of the vertebral body's cortical ring-should imply a rigorous intraoperative fluoroscopic control when introducing bone cement to prevent its extravasation.<sup>1,19-26</sup> From a technical point of view, we highlight the probable difficulty in drilling and opening the interior of the vertebral body with immobile deformity, as it often alternates areas of very resistant sclerotic bone with fragile regions of necrotic bone, being necessary to be cautious in this gesture to avoid going beyond cortical walls and cause serious neurological and vascular damage.

The application of bone cement aims to fill and stabilize the interior of the vertebral body in an inert way, solving the problem of bone regeneration inability without waiting for bone healing. However, in post-traumatic vertebral necrosis in patients with young age and healthy bone, the authors defend that, instead of bone cement, the intrasomatic application of cancellous bone graft associated with expandable implants, seeking to obtain bone matrix colonization by osteoprogenitor cells, its vascular invasion and osseointegration, with the objective of achieving a vertebra that is biomechanically and physiologically more similar to the original in terms of loads distribution towards an active patient with a high functional demand in the future (Figure 4). We recommend the use of autologous cancellous graft extracted from the patient's iliac bone for intrasomatic filling and, if the case demands more quantity, it is possible to mix the autograft with cancellous allograft from bone bank. In the same way of the treatment of general bone pseudarthrosis, in vertebral necrosis we sought to use a type of bone graft combining all the properties of osteoconduction, osteoinduction, osteointegration, and osteogenesis that are favorable to bone healing.<sup>38-46</sup> The application of the bone graft combined with expandable intravertebral implants not only ensures the maintenance of vertebral height in time but also protects the bone graft from excessive loads, minimizing its damage and resorption until its osseointegration is achieved, allowing to obtain a totally bony vertebra with a metallic endoskeleton. The limited histological evidence conducted in cases without the use of intravertebral implants, has demonstrated, in some patients, the absence of intrasomatic graft integration, with frequent microscopic findings of partial graft necrosis even in the presence of clinical and imaging evidence of bone healing. This suggests a likely excessive load on the not yet osseointegrated graft (not protected by the intravertebral implant) and a weak histology-clinical correlation. Other studies have demonstrated the efficacy and revascularization of bone grafts applied in the context of vertebral pseudarthrosis.<sup>38,46-53</sup> However, long-term prospective studies are needed to demonstrate the advantage of intrasomatic application of bone graft associated with intravertebral implants in this context. As such, considering that functional age is more important than chronological age and that each patient must be considered individually, we empirically admit that, in individuals under 60 years of age, intrasomatic cancellous bone grafting should be preferred to bone cement. Over that age, the potential benefits of cancellous bone graft compared to bone cement filling become less evident, as such, in individuals older than 60 years of age, bone cement is usually applied. In short, the use of bilaterally expandable intravertebral implants and their symmetrical expansion allows a balanced filling of the vertebral body, providing the strength from the metal associated with the bone cement (simulates the concept of reinforced concrete from civil construction) and ensuring structural and protective support for its platforms until the intrasomatic bone graft is osseointegrated, restoring the body to its function of stable anterior support of loads and preventing its future flattening.5,8,9,13-26,38,46-53

In turn, situations concerning the morphology of immobile vertebra plana, defined as those with a vertebral body with a height that is less than one third of the original on, in which there is no intravertebral cleft and the vertebral body bone tissue was practically completly reabsorbed, it is impossible to apply expandable intravertebral implants, as there is not enough somatic bone cover to allow a stable implant containment within vertebral bone tissue (Figures 2 and 3). Attempting to place expandable intravertebral implants in this type of vertebrae involves high risks and may have serious consequences, from migration of the implants, because they are not stable within bone tissue, with major neurological and vascular tissues injury risks, to important extravasation of cement or even inability to



apply cement in the vertebra. As such, in cases of vertebra plana with immobile deformity, if the patient has conditions and functional expectations that justify it, the solution is the total replacement (exterior and interior) of the vertebral body through corpectomy and its replacement using a spacer (synthetic cage or structural allograft) with lateral plate fixation to adjacent vertebral bodies and pedicular instrumentation (Figure 3). However, these patients are often older adults, over 80 years old, presenting vertebrae with severe osteoporosis and various comorbidities. The patient's own physiological condition may, by itself, contraindicate the invasiveness of the anterior approaches to abdominal or thoracic cavities, or an extensive posterior approach, needed for the corpectomy. The presence of porotic vertebrae increases the risk of adjacent vertebral fractures and loss of fixation in the intersomatic spacer after corpectomy. Therefore, in these cases, we recommend adjacent percutaneous pedicle fixation with cemented screws two levels above and below the level of the vertebra plana, to which we associate prophylactic vertebroplasties at the two adjacent upper and lower levels to the instrumentation, to minimize its overload and reduce junctional kyphosis and adjacent fracture (Figure 3). This treatment aims, by a less invasive treatment than corpectomy, to ensure for older patients a quick pain relief, as well as allowing early rise and walking. In sporadic cases of severe kyphosis in these osteoporotic patients with sagittal imbalance, Ponte osteotomies may be performed at some levels to minimize this deformity.<sup>37,42,45,47,54-58</sup>

Considering this algorithm, it is easily understood that we should early intervene in situations of post-traumatic vertebral necrosis, ideally in vertebrae non-plana stages (stages 1i and 1m – Figure 2), so that there is still enough bone tissue in the vertebral body to allow for the less invasive treatment, with percutaneous access and faster convalescence, the armed kyphoplasty. The most common evolution of vertebral necrosis is the progressive resorption of bone tissue; thus, we should not delay the indication of treatment with armed kyphoplasty. A late diagnosis or an unnecessary postponement of surgical intervention causes bone necrosis and resorption to progress, leading to situations of vertebra plana (stage 2) and increasing the risk of developing neurological damage due to posterior wall retropulsion and collapse of the vertebral body, which requires more aggressive surgical solutions.

Although there is no clear scientific evidence, the most probable and accepted cause of evolution of a vertebral fracture to nonunion is the injury of intraosseous blood vessels during the fracture, compromising the vertebral body bone tissue blood supply, which prevents bone healing and favor progression to necrosis and pseudoarthrosis.<sup>1-11</sup> However, up to the present day, there is no exam that allows to determine, in biological and vascular terms, that a given vertebra fracture pattern caused disruption of major intraosseous blood vessels and led to pseudarthrosis. As such, the authors consider that, in vertebral body comminuted fractures—those that

reach the entire bone extension of the vertebral body, including both endplates and the posterior wall, which may be of traumatic origin (type A4 of the AOSpine classification<sup>59</sup>) or osteoporotic—, there is a high probability that the intraosseous vascularization of the vertebral body is compromised and will be insufficient to guarantee adequate bone healing. Thus, while the scientific literature has not evolved in determining the vascular biological importance within the treatment of thoracolumbar fractures, we exercise caution and, in fractures with high comminution (type A4 of the AOSpine classification<sup>59</sup>), we empirically consider that intraosseous vascularization is compromised, performing, as the fracture's initial treatment, an immediate interior replacement of the vertebral body by an armed kyphoplasty with VBS® expandable intravertebral implant filled with bone cement in osteoporotic fractures or with bone graft in traumatic fractures in individuals with healthy bone and under 60 years old (Figure 3). In type A4 traumatic fractures, we initially perform indirect reduction of the cortical ring and segment by ligamentotaxis and annulotaxis by maneuvers with pedicle screws in the adjacent vertebrae. Then, we perform additional direct reduction with VBS® implants by multidirectional interior impaction of bone trabeculae, namely elevation of the central portion of the vertebral endplates, which guarantees anatomical reduction and its maintenance over time, as interior metallic supports (Figure 3). As for most osteoporotic compression fractures, usually without significant segmental kyphosis, isolated armed kyphoplasty is sufficient, without the need for adjacent pedicle instrumentation (Figure 3).

#### CONCLUSION

This article reviews the promising role of expandable intravertebral implants in the treatment of post-traumatic vertebral necrosis and in its prevention in acute fractures with a high risk of non-union since these devices allow interior replacement of the vertebral body and stable anterior support of the spine by a percutaneous transpedicular approach. The authors propose a simplified classification of posttraumatic vertebral necrosis and a therapeutic algorithm based on the role of expandable intravertebral implants, reserving corpectomy or multilevel pedicle fixation only for immobile vertebrae plana. Currently, scientific evidence on the treatment of post-traumatic vertebral necrosis is limited, despite more studies have been addressing vertebroplasty and kyphoplasty more frequently, only a few focus on the application of intravertebral expansive implants in this context. Moreover, there is little scientific literature regarding the ability to identify high risk acute vertebral fractures that will evolve into non-union, thus enabling early action to prevent this dangerous disease. Large prospective studies are needed to clarify the indications for each of the expandable intravertebral implants in the treatment and prevention of post-traumatic vertebral necrosis and to consolidate their effectiveness.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. DLM, JPG: substantial contribution to the conception, design, acquisition, analysis, and interpretation of data for the work; drafting and critically revising its intellectual content; final approval of the manuscript version to be published; and agreeing to be accountable for all aspects of the work, ensuring that any issues related to the integrity or accuracy of any part of it are properly investigated and resolved.

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