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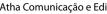
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(Reviewed January 2016)

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Levels of Evidence for Primary Research Question^a

(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				
ı	High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals	High quality prospective study ^d (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 ^b of Level RCTs (and study results were homogenous ^c)	Systematic review ^b of Level I studies	Systematic review ^b of Level I studies	Systematic review ^b of Level I studies				
	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective ^r 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 ^d comparative study ^e	Untreated controls from an RCT	Systematic review ^b of Level II studies	Systematic review ^b of Level II studies				
II	Systematic review ^b 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 ^b of Level II studies						
	Case control study ^d	Case control study ^g	Study of non consecutive patients; without consistently applied reference "gold" standard	Analyses based on limited alternatives and costs; and poor estimates				
Ш	Retrospective ^f comparative study ^e		Systematic review ^b of Level III studies	Systematic review ^b of Level III studies				
	Systematic review ^b of Level III studies		Case-control study					
			Poor reference standard					
IV	Case series ^h	Case series		Analyses with no sensitivity analyses				
V	Expert opinion	Expert opinion	Expert opinion	Expert opinion				

^a A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

^b A combination of results from two or more prior studies.

^c Studies provided consistent results.

^d 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.

^f The study was started after the first patient enrolled.

^g 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.

SUMMARY

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Original Articles
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COMPARING OUTCOMES OF THE ANKLE ARTHRODESIS BY USING TWO DIFFERENT MATERIALS VIA A TRANSFIBULAR APPROACH

COMPARAÇÃO DOS RESULTADOS DA ARTRODESE DO TORNOZELO USANDO DOIS DIFERENTES MATERIAIS ATRAVÉS DE UMA ABORDAGEM TRANSFIBULAR

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ABSTRACT

Objective: To compare clinical and radiologic results and complications of patients who underwent arthrodesis using a transfibular approach with either a cannulated screw or an anterior fusion plate. Methods: Patients who underwent ankle arthrodesis were divided into two groups according to the used materials: 6.5 mm cannulated screw (A) and anterior fusion plate (B). The clinical scores were compared between groups. The radiologic results were then assessed by union time. The results were statistically analyzed using SPSS 20. Results: There was no significant difference between both groups in the American Orthopedic Foot & Ankle Society (AOFAS) score (p = 0.75), and in the visual analog scale (p = 0.42). In group B, two cases included wound infection at the surgical site. In group A, the mean union time was 10.5 \pm 2.3 weeks. In group B, it was 7.8 \pm 1.3. There was a statistically significant difference (p = 0.007) between union time in both groups. Conclusion: Anterior fusion plate is an effective method for shorter union time, but the surgeon should be careful with the surgical wound at the skin incision site in the lesion of the distal tibia. Level of Evidence III, Retrospective comparative study.

Keywords: Ankle Joint. Osteoarthritis. Arthrodesis.

RESUMO

Objetivo: Comparar os resultados clínicos e radiológicos assim como as complicações de pacientes sujeitos a artrodese de abordagem transfibular com o uso de parafuso canulado ou placa óssea anterior. Métodos: Pacientes sujeitos a artrodese do tornozelo foram divididos em dois grupos de acordo com os materiais usados: parafuso canulado de 6,5 mm (A) e placa óssea anterior (B). Os escores clínicos de ambos os grupos foram comparados e os resultados radiológicos foram avaliados de acordo com o tempo de união óssea. Os resultados foram analisados estatisticamente usando SPSS 20. Resultados: Não houve diferença significativa entre os grupos quanto ao escore American Orthopedic Foot & Ankle Society (AOFAS) (p = 0,75) e a escala visual analógica (p = 0,42). No grupo B, ocorreu infecção na área da cirurgia em dois casos. No grupo A, a média de tempo de união foi de 10,5 \pm 2,3 semanas. No grupo B, este foi de 7,8 \pm 1,3. Constatou-se diferença estatisticamente significante (p = 0.007) quanto ao tempo de união em ambos os grupos. Conclusão: Os autores concluíram que a placa óssea anterior é um método eficiente para tempos de união curtos, porém o cirurgião deve ficar atento à ferida cirúrgica na área de incisão da pele em casos de lesão na tíbia distal. Nível de Evidência III, Estudo retrospectivo comparativo.

Descritores: Articulação do Tornozelo. Osteoartrite. Artrodese.

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INTRODUCTION

Ankle arthrodesis in end-stage ankle osteoarthritis is still a treatment of choice for this condition due to its short learning curve, short-term follow-up, and fewer complications compared to other treatments, such as failure of implants.¹⁻⁴

There are many reports about the approach and the fixation method for the arthrodesis,¹ including arthroscopic and open arthrodesis.

The required time for the arthroscopic ankle arthrodesis may be longer than that for the open arthrodesis depending on the surgeon's proficiency. ^{5,6} In addition, arthroscopic ankle arthrodesis has a disadvantage, because it cannot be performed when there is more than 5 varus or valgus deformities or in the case of a severe bone defect. ⁷ Because of such advantages, open arthrodesis is commonly used.

Open approaches include anterior, transfibular, and posterior methods. Among them, the transfibular approach is widely used because it provides enough operation field of view with the advantage of avoiding anterior neurovascular injuries or injury of the posterior deep flexor tendon.⁴ The fixation materials for arthrodesis are the following: cannulated screw, cancellous screw, or plate. Cannulated screw fixation is the most commonly used one to apply a compression force to the fusion site.⁸ Arthrodesis with anterior fusion plate has been reported recently.⁹⁻¹¹ Although there are many studies reporting results for each fixation material,^{1,4} studies that compare these materials are insufficient. This study aims to compare clinical and radiologic results, complications of patients who underwent an arthrodesis using a 6.5 mm cannulated screw, and those who underwent arthrodesis using the same approach with an anterior fusion plate.

MATERIALS AND METHODS

Patient population

The study plan and the patient's data analysis were approved by the Institutional Review Board (IRB number: DSH-인-19-14) of Sun Medical Center. All participants signed an informed consent form. From August 2011 to August 2017, 24 patients (24 cases) underwent arthrodesis due to end-stage osteoarthritis of ankle joints with more than 5° of varus or valgus ankle joint deformity (Figure 1). All cases were performed with the transfibular approach. In group A, 12 cases underwent arthrodesis with three 6.5 mm cannulated screw (Biomet Trauma, IN, USA) (Figure 2), and 12 cases in group B, with anterior fusion plate (Arthrex Inc. FL. USA) (Figure 3). After choosing the fixation materials from the two groups, screws were used in group A in February 2017, in Korea, before the introduction of the anterior fusion plate in group B, which was then performed. The mean patients' age at the time of surgery for group A was 56.9 years (ranging from 33 to 69 years old) and 64.1 years for group B (ranging from 53 to 81 years old). The mean follow-up period was 15.4 months for group A (ranging from 13 to 27 months) and 14.8 months for group B (ranging from 12 to 18 months). There were no statistically significant differences in sex, body mass index (BMI), mean age, diabetes mellitus (DM), smoking, surgical side, durations of symptom, and mean follow-up period between the two groups (Table 1).



Figure 1. Plain radiographs showing end-stage arthritis in the ankle joint through anteroposterior (AP) view (A) and lateral view (B).



Figure 2. Plain radiographs showing an arthrodesis from group A using the 6.5 mm cannulated screw (Biomet Trauma, Indiana, USA) and complete fused ankle joint on AP view (A) and lateral view (B).



Figure 3. Plain radiographs showing an arthrodesis from group B with anterior fusion plate (Arthrex Inc, Florida, USA) and complete fused ankle joint on AP view (A) and lateral view (B).

Table 1. A statistical description of the case series $(N = 24)$.							
	Group A (n = 12)	Group B (n = 12)	P*				
Sex (M:F)	8:4	7:5	0.347				
Mean age (years)	56 (33 to 69)	64 (53 to 81)	0.235				
BMI (kg/m²)	23.1 3.0	25.2 4.5	0.786				
Surgical Side (Left:Right)	5:7	3:9	0.413				
DM	2 (16%)	4 (33%)	0.566				
Smoking	4 (34%)	3 (25%)	0.651				
Follow-up period (months)	15.4 5.1	14.8 2.0	0.786				
VAS score at final follow-up	2.3 0.6	2.4 0.5	0.487				
AOFAS Ankle- Hindfoot score	64.4 6.1	65.3 5.5	0.525				
Union time (weeks)	10.5 2.3	7.8 1.3	0.007				
Complications							
Skin necrosis	0 (0%)	2 (16%)	NA				

The values are given as mean ± standard deviation.

P': p-value, Mann-Whitney test comparing group A and B; p-value < 0.05 indicates statistical significance; BMI: body mass index (kg/m²); DMI: Diabetes Mellitus; Smoking: more than 10 packs/ years; VAS: visual analog scale; AOFAS Ankle-Hindfoot score; American Orthopedic Foot and Ankle Society Ankle-Hindfoot score; NA: not applicable.

Surgical technique & postoperative management

The patients on the operating table underwent spinal or general anesthesia using a typical tourniquet in the supine position. For the transfibular approach, an incision was made over the posterior half of the fibular, starting from 8 to 10 cm proximal to the tip of the fibula (Figure 4A). If more skin incision was needed, another incision was made curving anteriorly and distally over the sinus tarsi for another 2 to 4 cm toward the base of the fourth metatarsal. The approach used the internervous plane between the sural nerve posteriorly and the superficial peroneal nerve anteriorly. When performing the dissection at the level of the fibula, full-thickness flaps were created and a subperiosteal dissection was performed to minimize soft tissue

tension. A fibular osteotomy was performed from 3 to 5 cm proximal to the level of the ankle joint. An oblique osteotomy from proximal lateral to distal medial was preferred. The cut edge was beveled to avoid creating bony prominence. Using a micro sagittal saw in the sagittal plane, the medial third of the fibula was removed, morselized, saved as bone graft, and then it was trimmed as a structural and bone chip type.

Fibular bone graft was performed in all cases, because this study speculated that it could reduce the risk of shortening the limb length and that it maintained the stable fusion construct. Although there were many methods of autogenic bone graft, the study used only the fibular structural bone harvest via a transfibular approach, because it could achieve an appropriately structural bone graft and had no additional incisions for the harvest.

A joint distractor or laminar spreader was used to fully expose the tibial plafond and the dome of the talus. Tibial plafond and talar dome preparations were performed with transverse flat cuts. The residual articular cartilage was removed with an osteotome, a curette, and a high-speed burr, exposing the subchondral bone. The medial side of the ankle joint was exposed by the anterior approach between the extensor hallucis longus and the tibialis anterior. The medial cartilage of the talus and tibia was then removed. When a plate was used for arthrodesis, the anterior skin incision was extended over the proximal portion to the distal tibia. The skin incision was carefully made at that time. The anterior skin incision should be sufficiently spaced (more than 5 cm) from the lateral skin incision (Figure 4B). The skin incision interval aimed to prevent skin necrosis at the incision site. The cartilage was removed, and the ankle alignment was adjusted to a neutral extension, 5° of valgus, 5° of external rotation, and hindfoot posteriorly. A 6.5 mm cannulated screw or anterior fusion plate was used for the arthrodesis with an autogenous bone graft from a fibular bone. In screw fixation methods, three cannulated compression screws were applied at 45 degrees on the long axis of the tibia; two of them were into the medial side of the tibia from the lateral side of the talus, and one was into the anterior neck of the talus from posterior surface of the tibia, which is called 'home run screw.'

In the anterior plate method, the ankle was temporarily fixed in a proper position by the Kirschner wire. After the plate was applied, the locking screw was used through the distal talar holes. The compression force in the ankle joint was obtained by placing a nonlocking screw eccentrically in the oblong compression hole on the tibial portion of the plate, and the fixation was continued in the anatomic lag screw hole and in the remained proximal plate holes.

In all cases, the suture was removed postoperatively after two weeks. Short leg cast immobilization and non-weight-bearing were performed for 6 weeks. At 6 weeks, partial-weight-bearing was allowed using walking cast or cam walker boot. Only at 8 weeks the full-weight-bearing was allowed using a cam boot.



Figure 4. Pictures showing the preparation of skin incision for the approach. We prepared the skin incision for transfibular approach (A). And then, the designed skin incision over the posterior half of the fibular, starting from 8 to 10 cm proximal to the tip of the fibula. Interval between the transfibular approach (asterisk) and the anterior approach (arrow) at more than 5 cm (B).

Clinical and radiologic assessment

The clinical assessment used "the American Orthopedic Foot and Ankle Society Ankle-Hindfoot" Score ("AOFAS hindfoot-ankle" score)^{12,13} and the Visual Analog Score (VAS) before and after the surgery. Postoperative complications, such as wound infection and metal failure, were recorded. The radiologic assessment was performed at 2, 3, 6, 9, and 12 months postoperatively. Plain radiographs were taken at standing posture to confirm the fixation and the fusion status.

The fusion of joints was judged to be united when more than 50% of the ankle joint surface was connected on the anteroposterior and on the lateral plain radiographs. The delayed union was defined as a symptom of pain with the absence of union evidence for more than 6 months on radiographs and nonunion lasting for more than 12 months.⁸

Clinical scores, radiographic assessment, and period of the union were recorded for all cases and the statistical comparison was made between the two groups. The statistical tests were performed using the Kolmogorov-Smirnov test, the Leven's test, the Multiple linear regression analysis, the Mann-Whitney test, and the Wilcoxon signed rank test using SPSS 20 (IBM, Inc, New York, NY, USA). This study defined statistical significance level at 5% (p \leq .05).

RESULTS

Clinical results

"AOFAS hindfoot-ankle" score in group A was significantly increased (p=0.003) from 43.3 \pm 4.3 preoperatively to 64.4 \pm 6.1 after the surgery. In group B, it was also significantly increased (p=0.002) from 44.3 \pm 4.3 preoperatively to 65.3 \pm 5.5 after the surgery. However, there was no significant difference in this score between the two groups (p=0.525) (Table 2).

In group A, the mean preoperative VAS was 7.3 \pm 1.0, significantly improved ($\rho=0.003$) to 2.3 \pm 0.6 after the surgery. In group B, the mean preoperative VAS was 7.5 \pm 0.9 and also significantly improved ($\rho=0.002$) to 2.4 \pm 0.5 after the surgery. There was no statistically significant difference ($\rho=0.487$) in the VAS between the two groups (Table 2).

Nonunion was not observed in both groups. In group B, two cases had wound infection at the surgical site (Figure 5A), and the patients were being treated for diabetes mellitus. One of them underwent skin grafting surgery with full-thickness skin flap of the ipsilateral thigh (Figure 5B), while the other one underwent simple dressing and wound healing (Figure 5C). Neither case progressed to deep infection. The infection did not affect the bone union.

Table 2. Preoperative and Postoperative VAS and AOFAS scores in the Groups, A and B

	Outcomes	Preoperative	Postoperative	p-value
Group A	VAS	7.3 1.0	2.3 0.6	0.003
(6.5 mm cannulated screw)	AOFAS Ankle hindfoot score	43.3 4.3	64.4 6.1	0.003
Group B	VAS	7.5 0.9	2.4 0.5	0.002
(Anterior fusion plate)	AOFAS Ankle hindfoot score	44.3 4.3	65.3 5.5	0.002

Wilcoxon signed rank test comparing preoperative and postoperative in both groups p-value < 0.05 indicates statistical significance; VAS: visual analog scale; AOFAS Ankle-Hindfoot score: American Orthopedic Foot and Ankle Society Ankle-Hindfoot score.



Figure 5. Pictures showing wound problems and the healing process. Surgical site infection occurred in Group B (A). The skin graft was done at infected surgical site (B). The wound was healed at infected surgical site after simple dressing (C).

Radiological results

All cases obtained fusion status in group A. The mean union time was 10.5 \pm 2.3 weeks. In group B, fusion was achieved for all 12 cases. The mean union time was 7.8 \pm 1.3. A statistically significant difference (p=0.007) was observed in the mean union time between the two groups.

Statistical analysis

The Kolmogorov-Smirnov test was used to confirm the normal distribution of the data in each group. The Levin's test was used to determine the equilibrium distribution of data between the two groups. The Mann-Whitney test and the Wilcoxon signed rank test were used to compare the results. Multiple linear regression analysis revealed that sex, age, DM, smoking, duration of symptom and BMI were not associated with clinical or radiological results.

DISCUSSION

Ankle arthrodesis is the most commonly used surgical procedure for the treatment of end-stage ankle osteoarthritis. Many approaches (medial, lateral, anterior, and posterior) and fixed materials have been introduced since the first report of the anterior approach by Albert. In general, the anterior and lateral approach are widely used. The lateral approach is also called the transfibular approach, and useful when it is necessary to do additional fibular osteotomy. In

The anterior approach can reach all ankle joint surface. However, it has limited access to the medial and lateral malleolus. It is an attentive approach that can injury the anterior vasculature.

However, the transfibular approach is in general easier to expose than the anterior approach. Due to the use of a full-thickness flap, there is less possibility of skin problems and fewer complications.¹⁶

In this study, all cases were performed by a transfibular approach. The most common method of arthrodesis is cannulated screw fixation that can exert a compressive force on the union site. Many studies about union rate, long-term follow-up results, and subsequent complications were performed.¹⁷ Recently, several methods using an anterior fusion plate have been introduced.⁹⁻¹¹ However, there are few comparative studies of plate fixation and cannulated screw fixation.

This study compared 12 cases of cannulated screw fixation and 12 cases of anterior fusion plate fixation via a transfibular lateral approach. As a result, clinical scores in each group were significantly improved after surgery, similar to those reported in previous studies.⁸⁻¹⁰ However, these scores were not significantly different between the two groups. Bone union time was measured at 10.5 weeks for group A and 7.8 weeks for group B. Group B showed significantly faster bone union (p = 0.007) than the group A.

Guo et al. has reported anterior fusion plate fixation performed in 10 cases of end-stage ankle arthritis. In 9 cases with mean 15 weeks follow-up, screw loosening after screw fixation resulted in a union period of 12 weeks in one anterior plate fixation. Although shorter union time was observed in this study, a simple comparison is not possible for those factors that affect the bone union.

According to Park et al.⁸, the union period of cannulated screw fixation was between 6 weeks and 40 weeks, with an average of 9 weeks. The results of their study were similar to those of the screw fixation group in this study. However, their study did not consider all factors affecting the bone union either. With both methods, the results of the union period were not significantly different.

Common complications of ankle arthrodesis are nonunion, malunion, wound infection, deep soft tissue infection, and arthritis of adjacent joints after a long-term follow-up.¹⁷ Mark et al.¹⁰ has reported that nonunion rates are high when arthrodesis of post-traumatic arthritis is performed and that nonunion tends to be due to smoking, history of diabetes, alcohol and illicit drug use, and psychiatric history. According to Zwipp H et al.¹⁶, screw fixation performed in a neutral posture of the ankle has a high fusion rate and low complication rate, with satisfactory functional results at mid-term follow-up.

Many long-term follow-up results have reported an incidence of osteoarthritis in adjacent joints, a typical complication of the non-union. However, additional arthrodesis and surgical treatment about these complications remain controversial.

With an anterior approach using an anterior AO-T plate, 31 (94%) of a total of 33 cases achieved fusion. The incidence of complications was relatively low, and the technique was reported to be simple and stable. In addition, Mark A et al. 10 has compared nonunion rates of patients who underwent anterior locking fusion plate fixation and screw fixation. One case (2.1%) of patients with an anterior plate (47 cases) reported nonunion in the Mark A et al. study, and the patients using screw fixation reported 4 cases (11.1%). Therefore, the nonunion rate did not differ between the two groups.

In this study, there were no nonunions in both groups (n = 24) and two cases of wound infection (16%, 2/12) occurred in the anterior part of the distal tibia in group B. However, nonunions were not observed in these two cases.

In 2 cases, which had wound problem, had no DM, smoking, and other underlying disease.

A possible cause of the wound problem might be the tightness of the sutured wound.

This study has some limitations.

First, there are few cases studied. This study considered that the validity of the statistical analysis could be lower. Second, there were short term results. Long-term follow-up results are needed to observe more complications, such as an incidence of arthritis in the adjacent joint. To confirm the findings of this study, more prospective analysis and comparison with other approaches are

needed, along with more cases and long-term follow-up results for wound infection of the anterior skin of the distal tibia.

CONCLUSION

In conclusion, the anterior fusion plate in the treatment of end-stage ankle osteoarthritis was superior to a cannulated screw in bone

union time. However, complications, such as wound problems, were more common than with the screw method.

The authors concluded the anterior fusion plate is an effective method for the shorter union time, but the surgeon should be careful because of the wound at the skin incision site in the distal tibia lesion.

AUTHORS' CONTRIBUTIONS: Each author individually and significantly contributed to the development of this article. JBK: writing, reviewing, and performing surgeries; BJL: data analysis and writing; DJ: statistical analysis and review; UJ: data analysis and review; CA: writing and statistical analysis.

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ORIGINAL ARTICLE

PRE-PLANNING ANKLE ARTHRODESIS USING 3D RECONSTRUCTED TOMOGRAPHIES

DESENVOLVIMENTO DA ARTRODESE DO TORNOZELO BASEADA NA TOMOGRAFIA COM RECONSTRUÇÃO 3D

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ABSTRACT

Objective: To implement one analysis method of the ankle bone contour that could make a more precise ankle arthrodesis. Methods: Twenty tomographies were submitted to 3D reconstruction. Seven points of anatomic interest for ankle arthrodesis with the three screws technique were marked with a triplannar marker. The median of the position of markers was estimated, and the union of the seven median points allow the construction of one median ankle for that population. Using this median ankle, sizes and angles for the screws position were determined. Results: Two median ankles were reconstructed, left and right. The position of the screw passage were determined considering the anatomical parameters. In the right ankle the lateral to medial screw should enter 4.56 cm and 0.79 above and posterior to lateral malleolus, with one inclination of 17.34° in relation to tibial longitudinal axis; and 0° in relation to tibial axial plane. The position for the other two screws is also described. Conclusion: Our article is the first to presents one precise guide for ankle arthrodesis based on a populational assessment. Level of evidence II, Diagnostic Studies.

Keywords: Foot. Ankle. Arthrodesis. Pre-Planning. 3D-Reconstruction. Joint Diseases.

RESUMO

Objetivo: Implementar método de análise do contorno e alinhamento ósseos no tornozelo de uma população normal, possibilitando uma artrodese tibiotársica mais precisa. Métodos: Tomografias de vinte tornozelos foram submetidas à reconstrução 3D. Nesses exames, 7 pontos anatômicos de interesse para a técnica de fixação com 3 parafusos foram identificados e marcados com indicadores da posição triplanar. As médias das localizações de cada ponto foram calculadas. A união dessas médias permitiu a reconstrução de um tornozelo padrão daquela população. Nesses tornozelos médios estudou-se os comprimentos e ângulos para a passagem dos parafusos. Resultados: Dois tornozelos, direito e esquerdo, foram reconstruídos. A posição para a passagem dos parafusos em relação a parâmetros anatômicos foi determinada. Para o tornozelo direito, a passagem do parafuso de lateral para medial deve ocorrer com o ponto de entrada 4,56 cm acima e 0,79 cm posterior à ponta do maléolo lateral, com inclinação de 17,34° em relação ao eixo longitudinal e 0° em relação ao eixo axial da tíbia. As posições dos outros dois parafusos também estão descritas. Conclusão: Esse é o primeiro trabalho que apresenta um guia preciso para realização da artrodese do tornozelo, baseado em um estudo populacional. Nível de evidência II, Estudos Diagnósticos.

Descritores: Artropatias. Pé. Tornozelo. Artrodese. Pré-Planejamento. Reconstrução 3D.

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INTRODUCTION

Ankle arthrodesis (AA) is a procedure for salvation in advanced ankle arthrosis. Despite the new techniques such as ankle arthroplasty, it is the only possible procedure in the case of young patients or bone defects. In addition, many studies have shown similar complication scans and quality of life between procedures.¹⁻³

Many studies have compared different forms of fixation.^{4,5} Screw fixation is the most traditional method, usually made with two crossed screws, one with medial entry and the other with entry.^{3,6,7} A third screw was generally added to the anteroposterior axis due to the high incidence of non-consolidations, usually with posterolateral entry into the tibia towards the neck of the talus, known as "home-run" screw (Figures 1 and 2).⁷⁻¹⁰

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

This study was developed at Universidade Federal do Ceará, Department of Surgery.

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Figure 1. Fixing technique with 3 screws.



Figure 2. Fixing technique with 3 screws.

The screw is positioned to confront the strong deformation force of the Achilles tendon. 11-13 The stability of arthrodesis made only with the screws seems to be sufficient. 5,11 But plates are often used to neutralize rotation forces along the screws. 9,14,15 Additional stability increased consolidation rates; 8 however, plates cannot be used in some cases as in arthroscopic arthrodesis.

Most parameters used to determine surgery with good alignment and good position of screws use postoperative radiographs with load. As this type of examination is not likely to be performed intra-operatively, the surgeon may have difficulty in positioning and passing the screws.¹⁶

Thus, the best form of guiding the surgeon are the anatomical references. Although several studies show the functional results of the fixation technique with three screws^{5,6,17,18}, we did not find studies on the anatomical population variation of the ankle and reference points that could be used by the surgeon for screw fixation and bone positioning.

Our study showed a cheap and simple method of study with a group of individuals without anatomical anomalies to create a practical guide for positioning and fixation in ankle arthrodesis, using 3D reconstruction of scans.

METHODS

This is a retrospective study with access to the archive of tomographic images of the General Hospital of Fortaleza approved by the Ethics Committee of the Institution under the opinion number: 2.889.433, wherein the signing of an informed consent form was not necessary. We selected 20 tomographies of 13 patients, 8 men and 5 women, aged between 18 and 70 years (10 left and 10 right ankles) to study the ideal positioning between the ankle bones and the best points of passage of the screws in the ankle arthrodesis.

We used the tripod fixation technique with two crossed screws, one entry and one of medial entry In addition to entry screw known as "home run screw," as described by Schuberth et al.¹⁹, the tests were performed on a platform that kept the foot at 90°, positioned relative to the tibia. The images were obtained from the medical archive after approval by the ethics committee of the General Hospital of Fortaleza. Only ankles without bone misalignment or deformities were included according to evaluation of a radiologist and an orthopedist for each ankle.

The device used was the multislice tomography (Toshiba Medical System Corporation) with cuts of 1 mm. Using the Horos program (GNU Lesser Genera Public License®), the 104 tomographies were reconstructed three-dimensionally adjusting the density parameters for the best possible bone contour definition. Initially, we scored a standard zero point on all images and from these points we scored 8 points (Figure 3):

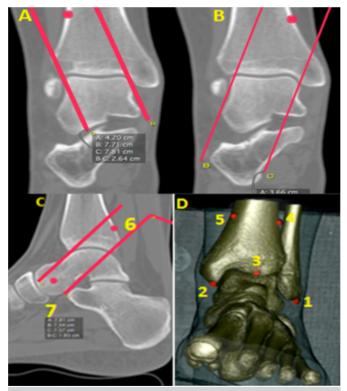


Figure 3. Marking of the entry points of the screws and anatomical reference points. A: determination of the lateral entry point in the middle distance of two parallel lines within the limits of the talus in the anteroposterior incidence and justa anterior point of the fibula in the profile; B: medial entry point, half distance of two parallel lines within the limits of the talus at the most central point of the tibia in the profile; C: posterior entry point determined by two parallel lines within the limits of the talus in the profile and the center point of the talus head determined as the center of a circumference between the upper point of the talus head and the lower point; D: 3D reconstruction image.

- 1. lateral malleolus (more distal point of fibula)
- 2. medial malleolus (most distal point of tibia)
- 3. most anterior point of tibial pestle
- 4. Entry point of the medial screw
- 5. Entry point of the medial screw
- 6. Entry point of the posterior screw
- 7. Upper talus point
- 8. lower point of the talus (we defined the center of the circumference made between these last two points as the center of the talus)

The program generated the reference in the X, Y, and Z planes for each point from the given zero point. We estimated the mean compiling the data and confidence interval (CI) by simple inferential analysis for each plane of each point. Each midpoint was marked in the AutoCAD graphic design program[®], generating the average ankle of the study population (Figure 4). The relationship between the points was analyzed and a guide for the passage of the screws and intraoperative positioning of the ankle was generated.

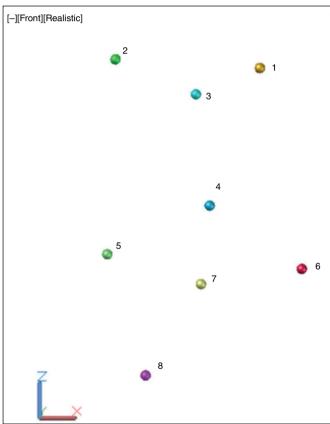


Figure 4. The estimated means for each point plotted in drawing program, the distances and angles between these points can be used to quide the passage of the screws.

RESULTS

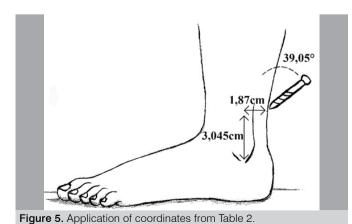
We could not unify the data for the left and right ankles due to the topographic evaluation of the points. Thus, a guide was created for each laterality. Table 1 shows the means obtained for the positioning of each point with the confidence interval. Table 2 shows the result of the relationship between the points plotted in the drawing (Figure 3), generating the guide to perform the surgery, with expected length of the screws, distance between the points of entry of the screws and the reference points and the angles of attack of the screws. Figures 5, 6 and 7 exemplify the use of the Table 2 guide.

Table 1. The means obtained for the positioning of each point with the confidence interval.

Plane X Right Ankle	Mean	CI
Lateral Entry Point	34.78 mm	(29.97 - 39.58)
Medial Entry Point	61.46 mm	(56.25 – 66.66)
Posterior Entry Point	45.57 mm	(39.15 – 52.00)
Anterior Tibia Point	46.03 mm	(41.47 – 50.60)
Medial Malleolus Point	70.26 mm	(65.45 – 75.07)
Lateral Malleolus Point	26.80 mm	(17.15 – 36.45)
Talus Upper Point	47.98 mm	(42.98 – 53.01)
Talus Upper Point	56.309	56.309
Plane Y Right Ankle	Mean	CI
Lateral Entry Point	13.25 mm	(8.01 – 18.49)
Medial Entry Point	8.82 mm	(4.90 – 12.75)
Posterior Entry Point	19.39 mm	(1.51 – 37.28)
Anterior Tibia Point	-0.06 mm	(-3.48 – 3.35)
Medial Malleolus Point	4.46 mm	(-1.32 – 10.61)
Lateral Malleolus Point	25.81 mm	(20.42 - 31.20)
Talus Upper Point	-15.76 mm	(-18.87 – -12.64)
Talus Upper Point	-3.85 mm	3.85
Plane Z Right Ankle	Mean	CI
Lateral Entry Point	1143.86 mm	(1141.29 – 1146.42)
Medial Entry Point	1146.83 mm	(1145.42 – 1148.23)
Posterior Entry Point	1128.67 mm	(1108.43 – 1148.90)
Anterior Tibia Point	1117.26 mm	(1114.59 – 1119.92)
Medial Malleolus Point	1109.98 mm	(1106.71 – 1113.24)
Lateral Malleolus Point	1098.22 mm	(1095.95 – 1100.49)
Talus Upper Point	1102.61 mm	(1100.52 – 1104.69)
Talus Upper Point	1083.8 mm	1083.8 mm
Plane Z Right Ankle	Mean	CI
Lateral Entry Point	77.96 mm	(69.76-86.17)
Medial Entry Point	50.79 mm	(41.39 – 60.19)
Posterior Entry Point	65.88 mm	(57.68 – 74.07)
Anterior Tibia Point	68.47 mm	(63.10 - 73.84)
Medial Malleolus Point	49.14 mm	(28.81 - 69.47)
Lateral Malleolus Point	85.88 mm	(77.11 – 94.64)
Talus Upper Point	66.85 mm	(59.85 – 73.85)
Talus Upper Point	56.309 mm	56.309 mm
Plano Y Left Ankle	Mean	CI
Lateral Entry Point	14.58 mm	(7.46 – 21.71)
Medial Entry Point	5.77 mm	(2.53 – 9.00)
Posterior Entry Point	27.19 mm	(22.15 – 32.22)
Anterior Tibia Point	2.44 mm	(-1.09 – 5.98)
Medial Malleolus Point	1.77 mm	(-0.9 – 4.47)
Lateral Malleolus Point	29.22 mm	(19.71 – 38.73)
Talus Upper Point	-12.26 mm	(-17.15 – -7.37)
Talus Upper Point	3.85	3.85
Plano Z Left Ankle	Mean	CI
Lateral Entry Point	1141.95 mm	(1134.99 – 1148.91)
Medial Entry Point	1143.59 mm	(1139.39 – 1147.80)
Posterior Entry Point	1136.99 mm	(1135.05 – 1138.92)
Anterior Tibia Point	1115.93 mm	(1111.35 – 1120.51)
Medial Malleolus Point	1106.72 mm	(1104.19 – 1109.24)
Lateral Malleolus Point	1103.96 mm	(1084.03 – 1123.90)
Talus Upper Point	1101.08 mm	(1099.50 – 1102.66)
Talus Upper Point	1083.8	1083.8

Table 2. Surgical guide obtained by the analysis of the correlation between the midpoints of the right ankle.

Right Ankles							
Entry Point	Superior to Medial Malleolus	4.56 cm					
Lateral	Posterior to Medial Malleolus	0.79 cm					
Entry Point	Superior to Medial Malleolus	3.68 cm					
Medial	Posterior to Medial Malleolus	0.88 cm					
Posterior Entry Point	Superior to Medial Malleolus	3.045 cm					
Posterior Entry Point	Posterior to Medial Malleolus	1.87 cm					
Entry angle in relation to the longitudinal axis of the Tibia	17.34 degrees (for lateral and medial screws)						
Entry angle in relation to tibia axial axis	zero for lateral and medial screws						
Entry angle in relation to the longitudinal axis of the Tibia	39.05 degrees (for the posterior screw)						
Entry angle in relation to tibia axial axis	59.26 degrees (for the posterior screw)						
Length of lateral screw	4.62 cm						
Length of medial screw	4.34 cm						
Length of posterior screw	4.57 cm						
Entry Point	Superior to Medial Malleolus	3.79 cm					
Lateral	Posterior to Medial Malleolus	0.79 cm					
Entry Point	Superior to Medial Malleolus	3.68 cm					
Medial	Posterior to Medial Malleolus	0.15 cm					
Posterior Entry Point	Superior to Medial Malleolus	3.303 cm					
	Posterior to Medial Malleolus	2 cm					
Entry angle in relation to the longitudinal axis of the Tibia	17.34 degrees (for lateral and medial screws)						
Entry angle in relation to tibia axial axis	zero for lateral and medial screws						
Entry angle in relation to the longitudinal axis of the Tibia	38.35 degrees (for the poserior screw)						
Entry angle in relation to tibia axial axis	57.29 degrees (for the poserior screw)						
Length of lateral screw	4.33 cm						
Length of medial screw	4.48 cm						
Length of posterior screw	6.2 cm						



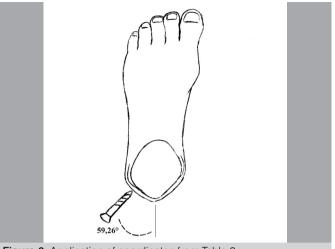


Figure 6. Application of coordinates from Table 2.

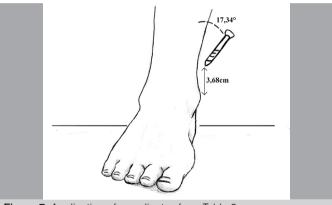


Figure 7. Application of coordinates from Table 2.

DISCUSSION

Although ankle arthrodesis is a widely performed procedure, especially because it is the only possible procedure in many cases, we could not find a description of each step based on an anatomical study.

High non-consolidation rates reported in all types of fixation make this an important issue.^{7,8,15} Many studies focus on the biomechanical stability of different fixation methods¹¹; however, they do not mention how to find the best entry point and the entry angle for the screw, which increases the need for experience and skill of the surgeon, increasing the chance of error.

The best positioning and the quantity of screws are still controversial. The two screws of the crossed coronal plane can compress at the arthrodesis site, failing, however, to stabilize the strong traction in the sagittal plane of the Achilles tendon or the dorsiflexor force made by the forefoot in the soil, which generated the need to add a third screw in the sagittal plane. 11.20

Despite the evidences showing that the screw of the sagittal plane should be passed from anterior to posterior¹³, we have chosen to study the method as a posterolateral "home-run" screw to the center of the talus head because it seems to be the most used method by surgeons.¹⁰

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The confidence interval was very wide in most of the points analyzed, often greater than 10 cm, which is above the tolerable considering that the ankle is a small joint. Thus, our study can work as an initial orientation for surgeons. Initial statistical analysis showed that we will need 357 ct scans to develop an accurate guide to be used with all the population. This study has been developed by our group.

Despite the small sample, the two groups generated, right and left, showed similar results (angles of entry of the lateral and medial screws were 17.34° for the right and 18° to the left, for example). This suggests that the applied method is simple and reproducible. Moreover, it uses widely available computer tests and programs, generating the possibility of evaluating larger populations.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article: RSA: project design, development of the ct analysis technique, data compilation, writing of the article. MPBC: data compilation and tabulation, marking of points of interest in tomography. JRL: selection of appropriate tomographic cuts, adjustment of images for analysis. MPBC: data compilation and tabulation, marking of points of interest in tomography. MJDT: coordination of the project, statistical analysis and review of the article. JADL: project coordination, statistical analysis and review of the article.

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RELATIONSHIP BETWEEN QUALITY OF LIFE AND RADIOLOGICAL PARAMETERS AFTER HALLUX VALGUS CORRECTION

RELAÇÃO ENTRE A QUALIDADE DE VIDA E PARÂMETROS RADIOGRÁFICOS APÓS CORREÇÃO DO HÁLUX VALGO

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ABSTRACT

Objective: To evaluate the correlation between postoperative quality of life and the severity of hallux valgus deformity. Methods: A total of 23 patients underwent moderate (n = 14) and severe (n = 9) hallux valgus (HV) surgical correction with the Scarf technique between January 2010 and December 2012. The mean follow-up time was 60 months. Participants answered the SF-36 quality of life assessment questionnaire and their radiographs were evaluated at three different moments (preoperative, 1 and 5 years after surgery). Statistical analysis was performed with a maximum 5% significance level. Results: The sample consisted of two men and 21 women, aged 58.7.SF-36 mean value was 75.73 and the metatarsophalangeal and interphalangeal angles improved significantly at the three moments (p < 0.05). SF-36 showed no statistical difference between patients with moderate or severe HV (p > 0.05). No correlations were found between quality of life and pre and postoperative radiographic angles. Conclusion: Patients with moderate and severe hallux valgus submitted to surgical correction had a very good quality of life and a significant improvement in radiographic parameters. However, these variables were not correlated. Level of Evidence II, Retrospective study.

Keywords: Hallux Valgus. Osteotomy. Quality of Life.

RESUMO

Objetivo: Avaliar a correlação entre qualidade de vida pós--operatória e a gravidade da deformidade do hálux valgo. Métodos: 23 pacientes foram submetidos à correção cirúrgica do hálux valgo (HV) moderado (n = 14) e grave (n = 9) pela técnica de Scarf, entre janeiro de 2010 e dezembro de 2012. O tempo mínimo de acompanhamento foi de 60 meses. Os participantes responderam ao questionário de avaliação de qualidade de vida SF-36 e foram avaliadas suas radiografias em três momentos distintos (pré-operatório, 1 e 5 anos de pós-operatório). A análise estatística foi realizada com nível de significância máximo de 5%. Resultados: A amostra contou com 2 homens e 21 mulheres, com média de idade 58,7 anos. O valor médio do SF-36 foi 75,73 e os ângulos metatarsofalangiano e interfalangiano apresentaram melhora significativa nos momentos avaliados (p < 0,05). O SF-36 não mostrou diferença estatística entre os pacientes com HV moderado ou grave (p > 0,05). Não houve correlações entre a qualidade de vida e os ângulos radiográficos pré e pós-operatórios. Conclusão: Os pacientes com hálux valgo moderado e grave submetidos à correção cirúrgica apresentaram qualidade de vida considerada muito boa e tiveram significativa melhora dos parâmetros radiográficos. Contudo, não houve associação entre essas variáveis. Nível de Evidência II, Estudo retrospectivo.

Descritores: Hallux Valgus. Osteotomia. Qualidade de Vida.

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INTRODUCTION

Hallux valgus (HV) is a deformity prevalent in 23% of the adult population aged between 18 and 65 and in 35.7% of those above 65, especially women. In addition to aesthetic deformity, most patients experience pain in the first metatarsophalangeal joint, and for 30% of them, wearing footwear is difficult, which leads to worse quality of life.1-4

Several surgical techniques are described to correct the various degrees of deformity, allowing the performance of soft tissue balancing procedures to surgeries involving osteotomies and arthrodeses. 4-6 Burutaran and Zygmunt originally described the Scarf technique, and Weil and Barouk later popularized it. It is a Z osteotomy to realign the first metatarsal bone, widely used to correct different degrees of HV deformity.7-11

Most articles published on the topic compare the results between the different surgical techniques, evaluating the degree of radiographic correction, relapse rates and complications. Data such as pain and range of motion of the first metatarsalopharlangean

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

The study was conducted at the Department of Foot and Ankle Surgery of Instituto Nacional de Traumatologia e Ortopedia. Correspondence: Henrique Mansur. Área Militar do Aeroporto Internacional de Brasília, Lago Sul, Brasília, DF, 71607-900. henrimansur@globo.com

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joint are commonly used by surgeons to evaluate the postoperative outcome. ^{10,12} However, surgeon and patient diverge on their perception. Often, although with a residual deformity, patients are highly satisfied. SF-36 score, when evaluating the psychometric properties of the patient's quality of life, allows a broader analysis of the postoperative outcome of bunion correction surgery from the patient's point of view. ¹³⁻¹⁶

Studies evaluating the quality of life of patients with hallux valgus and, mainly, relating quality of life to the degree of radiological correction are scarce. ^{13,14} Thus, this work aims to evaluate the correlation between quality of life and radiographic parameters obtained after hallux valgus surgical correction using the Scarf technique. Our hypothesis is that even patients with residual radiographic deformities improve their quality of life after surgery. To know this correlation endorses the importance of the deformity clinical correction rather than of the radiographic aspect.

METHODS

This study was approved by the Institution Research Ethics Committee. A study was conducted with all patients submitted to moderate and severe HV surgical correction by Scarf technique associated with soft tissue release between January 2010 and December 2012 to obtain a cohort of patients with a minimum follow-up of five years. Different specialists from the foot and ankle surgery group of the institution performed the surgeries and all patients followed the same postoperative protocol and signed the informed consent form.

Patients without all necessary imaging tests, patients with mild deformities, those submitted to deformity correction with other techniques, revision surgeries or bilateral correction were excluded. Besides, patients who disagreed to participate in the study were removed.

Patients who met the inclusion and exclusion criteria were invited to participate in the study. The characteristics recorded were sex, age at the time of surgery and operated foot. Quality of life was quantified applying the Medical Outcomes Study 36–Item Short-Form (SF-36). The questionnaire has 36 items, divided into eight scales (physical functioning, role limitations due to physical health, pain, general health, energy/fatigue, social functioning, emotional well-being, and role limitations due to emotional problems), with scores ranging from zero (worst general health status) and 100 (best health status). The form involves aspects related to disease consequences, it has already been validated for the Portuguese language in Brazil and proved to be reliable to evaluate the results of hallux valgus correction surgery. All participants were evaluated by the lead researcher, who did not participate in the surgery of any of them.

Radiographic analysis

Foot radiographs in orthostasis at dorsoplantar incidences and profile were performed by the patients before surgery, about one and five years after surgical correction. The radiographic parameters evaluated and compared in the three moments were the following:

- metatarsophalangeal angle (MPA)²¹: angle formed by the lines that bisect the diaphysis of the first metatarsal and of the hallux proximal phalanx;
- Intermetatarsal angle (IMA)²¹: angle formed by the lines that bisect the diaphyses of the first and second metatarsals.

Each angle was measured twice by the same examiner, with a one–week interval between the evaluations, and calculated in degrees with the angular measurement tool of the Dicom Viewer software, version 3.0.0®, in the dorsoplantar incidence with load.

The patients were separated into two groups according to radiographic parameters. The moderate hallux valgus group included patients with intermetatarsal angle between 11° and 16° or metatarsophalangeal between 20° and 40°; and the severe hallux valgus group included those with intermetatarsal angle higher than 16° or metatarsophalangeal higher than 40°, according to Couglin's criteria. 21,22 Demographic characteristics, final values of SF-36 score, and radiographic parameters were compared between the two subpopulations.

Statistical analysis

Continuous variables were reported as mean ± standard deviation and were compared between moderate and severe HV groups and between different pre and postoperative moments. When repeated measurements of the same variable were normal. we compared two of them using the paired Student t-test and then three measurements with the ANOVA test for repeated measurements, with the post-hoc corrections of Bonferroni and Tukey to compare means. When they did not follow normal distribution, we compared two measurements with the Wilcoxon nonparametric test and three repeated measurements using the Kruskal-Wallis test. The assumption of normality for continuous variables was evaluated with the Kolmogorov-Smirnov (KS) and Shapiro–Wilk (SW) tests. The correlational research between two quantitative variables was performed by calculating the Spearman's rank-order correlation coefficient or Pearson Test. Based on the collected data, a database was built in a spreadsheet to analyze them with the IBM SPSS (Statistical Package for the Social Science) program, version 21.0, and with Microsoft Excel. All discussions considered a 5% (0.05) maximum significance level.

RESULTS

A total of 23 patients met the inclusion and exclusion criteria. Nine patients (39.1%) had severe HV and 14 (60.9%), moderate HV. Of the patients with severe HV, six had MPA > 40° and three had IMA higher than 16°. The patients' mean age at the time of surgery was 58.7 \pm 8.99 (39–76 year–olds), 57.4 in the severe group, and 59.5 in the moderate group. This result showed no statistical difference (p > 0.05) (Table 1).

 Mean
 Max
 Min
 SD
 Moderate HV
 Severe HV

	Mean	мах	Min	SD	Moderate HV	Severe HV
Sample	total (n = 23)				n = 14	n = 9
Sex	13W 11M				16W 0M	7W 2M
Side	12R 12L				10R 4L	5R 4L
Age	58.7	76	39	8.99	59.5	57.4
SF-36	75.7	91	33.4	15.77	73.3	79.5

HV: hallux valgus; SD: standard deviation; W: women; M: men; R: right; L: left.

After a 60-month minimum follow-up time, the total sample SF-36 was 75.7 (SD \pm 15.77) and per subgroup it was 79.5 and 73.3, respectively for severe and moderate HV. This difference had no statistical significance (p > 0.05).

The values found when measuring the metatarsophalangeal angle in the preoperative phase, one and five years after surgery, showed significant improvement (p < 0.05) in all three moments. Regarding the intermetatarsal angle, the initial values improved considerably one year after surgery and these values also improved after five years (p < 0.05). However, the difference between the initial values and after five years was insignificant (p > 0.05) (Table 2 and Figure 1).

Table 2. Variation of radiographic parameters in the pre and postoperative period of patients submitted to HV correction with the Scarf technique.

	Mean	Max	Min	SD	Moderate HV	Severe HV
MPA	33.9	50	20	8.62	28.5	42.4
MPA1	13.9	26	2	6.19	12	16.9
MPA5	18.5	41	2	8.90	17.4	20.2
IMA	14.8	19	6	3.00	13.4	17.1
IMA1, 2011	7.7	14	2	2.95	6.8	9.1
IMA5	8.8	14	2	3.27	8.4	9.4

Caption: HV: hallux valgus; SD: standard deviation; MPA: metatarsal angle; MPA1: one year after surgery; MPA5: five years after surgery; IMA: intermetatarsal angle.

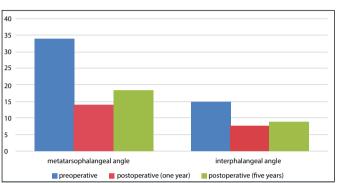


Figure 1. Pre and postoperative radiographic parameters to HV correction with the Scarf technique.

The quality of life (SF-36) of patients five years after surgery and the values of radiographic parameters (MPA and IMA) preoperatively, one and five years after surgery (p > 0.05) were not correlated. Similarly, SF-36 and the patients' age at the time of surgery were not correlated (p > 0.05).

DISCUSSION

This study aimed to determine the correlation between quality of life (QoL) and radiographic parameters after Scarf surgery for HV correction. Our initial hypothesis has been confirmed. We found no correlation between the SF-36 values and the radiographic parameters measured in the late postoperative period. In addition, no differences in QoL were found between patients who had moderate and severe deformities. Our findings serve for surgeons to care more about clinical criteria than radiographic when evaluating their postoperative results.

Scarf technique is widely used especially for moderate to severe deformities, presenting great correction power.^{7,10,23,24} Our patients' metatarsophalangeal and interphalangeal angles improved

significantly. MPA was significantly lower (p < 0.05) than the preoperative period at all postoperative moments; IMA has improved significantly after one year (p < 0.05), which remained improving after five years, but without relevance (p > 0.05). Accordingly, Choi et al. 23 evaluated 53 feet operated with the technique and all radiographic changes showed statistically significant improvement. The difference is that these authors had a 24–month mean follow-up, while in this study it was 60 months.

The SF-36 score sum in our work showed a mean value of 75.7 points, with no statistical difference (p > 0.05) between the groups of patients with moderate and severe hallux valgus. According to the Spanish version of SF-36, adapted by Caporicci and Neto, 25 the final score was divided into: 0 = Bad; from 0 to 25 = Regular; from 26 to 61 = Good; from 62 to 84 = Very Good, and from 85 to 100 = Excellent. Thus, we can consider that after the mean time of five years, the operated patients' quality of life was very good. 17, 21 Menz et al¹⁹ evaluated patients with hallux valgus and compared clinical deformity and QoL with SF-36. They found a reduction in QoL when deformity worsened. Lopez et al.²⁶, after evaluating 100 women with HV, confirmed a relationship between QoL and the bunion deformity. However, these authors used the Manchester scale to measure foot deformity, while our study used objective angular parameters measured on radiographs. In accordance with our results, other authors^{27,28} found no relationship between the degree of radiographic deformity and the score obtained in the SF-36, proving the relevance of SF-36 to evaluate the results of hallux valgus surgeries. We can see a correlation between worse quality of life and HV deformity when it is clinically analyzed. It is different when we consider radiographic parameters; however, literature has no consensus. Lazarides et al.²⁹, preoperatively evaluating radiographs of 22 patients together with SF-36, attested the more severe the deformity, the worse the QoL.

Our study has some limitations, such as sample size, although it is compatible with the number of patients in other studies. In addition, the SF-36 evaluation at one single moment limited us in identifying changes in the patients' quality of life in an evolutionary way. The studies on the subject show hallux valgus cripples QoL when clinical criteria based on patients' impressions are analyzed. On the other hand, articles that use angular measurement in their methodology report no relationship between deformity and QoL. Although this was not the objective of our work, we infer that sometimes HV hypocorrection aiming at a better aesthetic result, especially in more severe cases, can bring more satisfactory results to the patient.

CONCLUSION

The quality of life of patients submitted to the Scarf technique for moderate and severe hallux valgus correction has no correlation with postoperative radiographic parameters after five years of surgery.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. HM: writing and review of the article and approval of the final version; VC: idealization and planning of the activities that led to the study, writing of the article and approval of the final version; TN: writing and review of the article and approval of the final version; IC: text review and approval of the final version.

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MEASUREMENT OF PELVIC RETROVERSION DURING HIP FLEXION: EVALUATION WITH ACCELEROMETERS

MENSURAÇÃO DE RETROVERSÃO PÉLVICA DURANTE FLEXÃO DO QUADRIL: AVALIAÇÃO COM ACELERÔMETROS

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ABSTRACT

Objective: To quantify pelvic retroversion during clinical evaluation of hip flexion with accelerometers and to verify the reliability of these sensors to measure hip flexion. Methods: An accelerometer was positioned laterally in the pelvis to measure pelvic retroversion. Another accelerometer was positioned anteriorly on the thigh to evaluate hip flexion amplitude. The evaluations were performed with volunteers in supine position by three raters. For evaluation of pelvic retroversion, the mean \pm SD (minimum-maximum) was calculated. Reliability of the accelerometer between raters was determined by intraclass correlation coefficients (ICC). The linear correlation coefficient between hip flexion was determined by using goniometer and accelerometer. Results: The mean pelvic retroversion was $7.3^{\circ} \pm 0.93^{\circ}$ (6°-11°) in the clinical limit of the hip range of motion, which was 106.25° ± 10.46° (93°-130°). The ICC between two raters were 0.60, 0.71 and 0.74 (goniometer) and 0.46, 0.71 and 0.83 (accelerometer). The linear correlation between hip flexion measurements with goniometer and accelerometer was 0.87. Conclusion: During clinical evaluation of the final range of hip flexion, there was an associated pelvic movement of approximately 7.3°. Accelerometers have proven to be reliable for measurement of hip flexion. Level of Evidence III, Study of nonconsecutive patients with no gold reference standard applied uniformly.

Keywords: Pelvis. Hip. Articular Arthrometry. Accelerometer.

RESUMO

Objetivo: Quantificar a retroversão pélvica durante avaliação clínica da flexão do quadril com acelerômetros e verificar a confiabilidade destes sensores para mensurar flexão do quadril. Métodos: Posicionou-se um acelerômetro lateralmente na pelve para mensurar retroversão pélvica. Outro foi posicionado anteriormente sobre a coxa para avaliar flexão do quadril. As avaliações foram realizadas com voluntários, em decúbito dorsal, por três avaliadores. Para avaliação da retroversão pélvica, determinou-se a média ± DP (mínimo-máximo). Avaliou-se a confiabilidade dos acelerômetros entre avaliadores pelo coeficiente de correlação intraclasse (CCI). Determinou-se o coeficiente de correlação linear entre as mensurações de flexão do quadril com goniômetro e acelerômetro. Resultados: A retroversão pélvica média \check{f} oi de 7,3 $^\circ$ \pm 0,93 $^\circ$ (6 $^\circ$ -11 $^\circ$), mensurada no limite clínico da flexão do quadril, que foi de $106,25^{\circ} \pm 10,46^{\circ}$ (93°-130°), ambos com acelerômetro. Os CCI entre dois avaliadores diferentes nas avaliações de flexão do quadril foram de 0,60, 0,71 e 0,74 (goniômetro) e 0,46, 0,71 e 0,83 (acelerômetro). A correlação linear entre as mensurações de flexão do quadril com goniômetro e acelerômetro foi de 0,87. Conclusão: Durante avaliação clínica da amplitude final de flexão do quadril, houve movimentação associada da pelve aproximadamente de 7,3°. Acelerômetros mostraram-se confiáveis para mensuração da flexão do quadril. Nível de evidência III, Estudo de pacientes não consecutivos sem padrão de referência "ouro" aplicado uniformemente.

Descritores: Pelve. Quadril. Goniometria articular. Acelerômetro.

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INTRODUCTION

The assessment of hip flexion is essential in semiology for diagnosis, rehabilitation and evolutionary follow-up of joint diseases. ^{1,2} The hip flexion, osteoarthrosis limitations³, femoroacetabular impingement (FAI)² and degenerative diseases of the lumbar spine are directly related. ⁴

It is essential that hip flexion assessment are reliable for joint motion to ensure specific treatments, according to the biomechanical conditions of each patient.⁵

Pelvic retroversion occurs during hip flexion⁶, which can start with only 8° of hip flexion.⁷ If the retroversion of the pelvis is not properly measured, the flexion movement may be overestimated.⁸ Studies that

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

The study was developed at Hospital das Clínicas of Ribeirão Preto Medical School of the Universidade de São Paulo.

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passively evaluated healthy hip mobility present variations of up to 24% in flexion results, but pelvic movement was not analyzed alone. 9,10 Hip movement assessments in the sagittal plane are complex due to biases related to pelvis control.¹¹ Recently, an evaluative study on hip flexion with 100 healthy adults showed that pelvic retroversion of 15° occurs within the clinical limit of hip flexion amplitude.5

The universal goniometer (UG) is often used in hip flexion evaluation¹². but there may be difficulties during the stabilization of the anatomical segment due to the use of both hands in the handling of the goniometer arms. Furthermore, the alignment of the arms is visual and subjective. 13,14 New tools have been used in the assessment of joint range of motion to make the process simpler and more accurate, such as: inclinometers^{15,16}, smartphone apps¹⁷, photogrammetry¹⁸, image tests¹⁹ and the Inertial Movement Unit (IMU).²⁰ Recent studies on the assessment of human gait have shown that IMU - motion sensor typically composed of acceleration transducers (accelerometers), rotation (gyroscopes) and magnetic orientation (magnetometers) -, present accurate results in kinematic knee and hip evaluations.²¹ IMU dispense external references. ²⁰ In this case, after positioning the sensors, the rater's hands are free, which could enable a more accurate evaluation, including the pelvis monitoring. Quantitative data on pelvis retroversion during hip flexion evaluations are uncommon in the literature, as well as possible effects on the clinical implications of hip flexion oversizing. This study proposes the use of accelerometers to measure pelvic retroversion during clinical evaluations of hip flexion and to evaluate the reliability of these sensors to measure hip flexion movements.

MATERIAL AND METHODS

This study was approved by the Research Ethics Committee of the Institution with the consent form signed by each volunteer. A total of twenty-three hips (11 right and 12 left) of 12 volunteers (5 men and 7 women) with a mean age of 30 \pm 8 years and body mass index with a median of 23.7 Kg/m² (22-27.8) were evaluated. Volunteers were healthy people with no complaints of pain, no diagnosis of disease nor hip surgery, except for a volunteer who complained of right hip pain without a defined diagnosis. He was evaluated only on the left side. Measurements were performed by three different raters – an orthopedic surgeon with 12 years of experience in hip preserving surgery, a physical therapist trained in hip physical evaluation with 10 years of experience, and an engineer involved in the development of the system with accelerometers, who received specific training for hip goniometry. A training session between raters was performed before the collection, to standardize the evaluation and the positioning of the sensors. Volunteers were asked to wear adequate clothing and to provide no resistance to performing movements. Initially, the hip flexion amplitude was evaluated in supine horizontal position by digital goniometry^{22,23}, it was followed by the evaluation of hip flexion amplitude and pelvis retroversion by the system with accelerometers. Each rater examined the hips independently, without knowing the results of the other raters. The amplitude of passive flexion was measured until the rater's perception of pelvic motion onset. Goniometry was performed with a digital device of two long arms

(Brand: Vktech; Model: X15-33) (Figure 1).



Figure 1. Digital goniometer of long arms.

The system of electronic evaluation by accelerometers was based on the Arduino platform (system with low-cost data acquisition and free software) and it was composed of two IMU (Movement Proccessing Unit [MPU] 6050 from Invensense), Arduino UNO acquisition plate and secondary components for connections and sampling of the data (Figure 2).

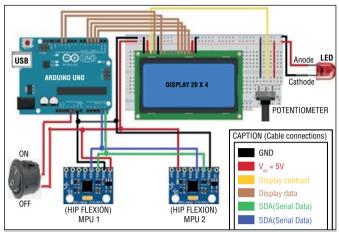


Figure 2. Electronic system for hip flexion and pelvic retroversion

The MPUs-6050 were placed inside acrylic casings (parallelepiped format). The sensor circuit was electrically and mechanically isolated and it caused no discomfort to volunteers. Each MPU-6050 has a triaxial accelerometer (responsible for measurements), whose axes (x, y, z) were fixed parallel to the faces of the casing, with external identification of the respective orientations (Figure 3). The system worked with electrical voltages up to 5 volts, which did not provide risk of electric shocks.



Figure 3. Casing of the hip flexion accelerometer estimator (similar to pelvic retroversion estimator) with identification of the orientations of the accelerometer axes for guidance during positioning. The batteries are for dimensional references.

The accelerometer responsible for measuring hip flexion was positioned with elastic and Velcro-like in the distal third of the thigh. The accelerometer - adjusted to measure the pelvic retroversion – was fixed laterally at the level of the anterior superior iliac spines, on the skin and under elastic firmly tied up around the pelvis (Figure 4). Both measured movements occur in the sagittal anatomical plane, with accelerometers configured to measure the variations in the gravitational acceleration (g). The three piezoelectric "membranes," spatial and orthogonally arranged among each other in triaxial accelerometers, varying their deformations and responses according to the vector "g" (module, direction and gravitational acceleration direction).23



Figure 4. Positioning of pelvic accelerometers (pelvic retroversion estimator) and thigh accelerometer (hip flexion estimator).

The thigh accelerometer was placed with the "x"axis aligned to the craniocaudal axis, "y" axis on the transversal axis and the "z" axis on the anterior posterior axis, then "x," "y," and "z" axes are orthogonal to each other. The axes "x" and "z" vary their inclination in the sagittal plane and in relation to the vector "g," during hip flexion movements (Figure 5). The linearity of the sensor response (proportionality relationship between deformation of piezoelectric material and measured angle) is desirable in this application and it occurs as more aligned (parallel) the axis responsible for measurement is to the vector "g." As the flexion amplitudes usually range between 90° and 120°,24 the "z" axis was more appropriate. At 90°, for example, the accelerometer will measure the maximum value, because the piezoelectric material will present the greatest deformation. In the initial position (extended hip), the "z" axis has direction opposite to the vector "g." The result is negative (deformation in the opposite direction to the "z" axis) for angles less than 90° and the result is positive (deformation and vector "g" in the same direction) for angles greater than 90° (Figure 6).

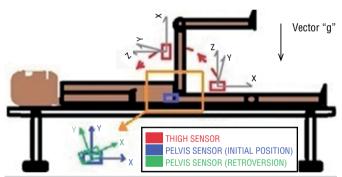


Figure 5. Lateral view of the estimator axes positioning of the pelvis and hip accelerometers. Orange rectangle: magnification of the "x" and "y" axes of the pelvis sensor in the initial position.

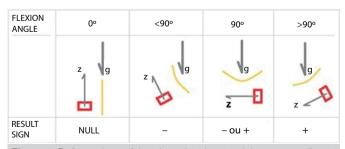


Figure 6. Deformations of the piezoelectric material corresponding to the variation of the vector "g" position.

The determination of the axis responsible for measuring pelvic retroversion was based on the same criteria used to choose the "z" axis of the thigh accelerometer, but with positioning of the "x" and "y"

axes dependent on the inclination in the sagittal plane related to the vector "a." The "x" axis was chosen as responsible for the retroversion measurements, because as the inclination of the axes presents small variations during this movement, the "y" axis always remains close to the parallel position in relation to the "g" vector, where the results are outside the linear accelerometer response range. The "z" (hip) and "x" (pelvis) axes chosen presents average standard error for angular measurement of 1.26° and 0.11°, respectively. The standard error was determined through the quotient of the standard deviation by the square root of the sample size. The estimator axes evaluated only inclination variations in the sagittal plane. During hip flexion evaluations, simultaneous movements (abduction or induction and internal or external rotation) of small amplitude may occur, which do not affect measurements in the sagittal plane. The results of the evaluations using the goniometer and accelerometers were noted in a specific form. The statistical analysis of the data was assisted by the software RCran (R Development Core Team, R: A Language and Environment for Statistical Computing). The mean \pm standard deviation (minimum and maximum value) of the results related to pelvic retroversion measurements by the three raters (69 samples) were determined. Fixed hip flexion angles (flexing angle of the pelvic retroversion subtracted of the hip angle) were estimated. The behavior of hip flexion angles was observed by a box plot graph, before (with goniometer) and after deductions from pelvis movements (with accelerometers), for the complete sample (data from the three raters). The inter-rater ICCs (for the three possible combinations of two raters) were calculated for goniometer and accelerometer to compare the measurements among raters. Pearson's linear correlation coefficient (r) was determined between hip flexion measurements with goniometer

RESULTS

The values (mean \pm standard deviation [minimum-maximum]) of hip flexion (goniometer), hip flexion (accelerometer), pelvic retroversion (accelerometer) and hip flexion with deduction of pelvic retroversion (accelerometers) were, respectively: $106.83^{\circ} \pm 8.91^{\circ}$ ($92^{\circ}-129^{\circ}$), $106.25^{\circ} \pm 10.45^{\circ}$ ($93^{\circ}-130^{\circ}$), $7.30^{\circ} \pm 0.93^{\circ}$ ($6^{\circ}-11^{\circ}$) and $98.94^{\circ} \pm 10.27^{\circ}$ ($87^{\circ}-122^{\circ}$). Boxplot graphs compared the behavior between hip flexion measured with goniometer and the hip flexion with deduction of pelvic retroversion measured by accelerometers (Figure 7).

and accelerometer (without pelvic retroversion deductions).

The ICC estimated between two raters presented better results between physical therapist and orthopedist, for both measurement tools (Table 1). The linear correlation coefficient (r) between hip flexion measurements with goniometer and accelerometer was 87% (CI = 95% and p < 0.0001) (Figure 8).

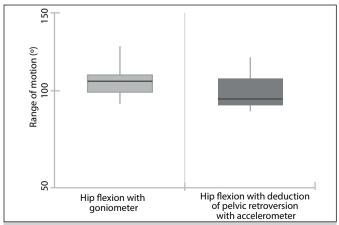


Figure 7. Box plot to compare hip flexion before (with goniometer) and after pelvic retroversion deduction (with accelerometers).

Table 1. Correlation coefficients between two different raters.

	ICC _{goniometer}	95% = CI	ICC _{accelerometer}	95% = CI
Rater 1 vs. Rater 2	0.598	-0.313–0.865	0.461	-0.299–0.78
Rater 1 vs. Rater 3	0.714	0.024-0.898	0.711	0.091-0.892
Rater 2 vs. Rater 3	0.738	0.392-0.888	0.825	0.577-0.926

Rater 1: engineer; Rater 2: hip specialist; Rater 3: Physical therapist; ICC: intraclass correlation coefficient; CI: confidence interval.

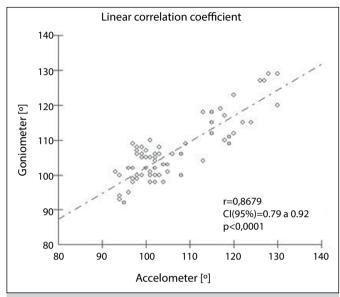


Figure 8. Graph of the linear correlation between hip flexion measurements with goniometer and accelerometer (no deductions from pelvic movements).

DISCUSSION

Hip flexion assessment is part of the classical semiology for arthrosis diagnostic², femoroacetabular impingement³, and lumbar dysfunctions⁴, in addition to specific research protocols. The more reliable the clinical interpretation of joint mobility, the more specific and effective will be the performance of the health professional. In hip flexion assessments, it is suggested the use of one hand under the pelvis to stabilize and to monitor the onset of the pelvic movement.²⁵ However, the gonjometer requires both hands of the rater to be used, which hinders pelvis monitoring, a factor that implies probable overestimation of hip flexion amplitude. 21-28 This study presented hip flexion of approximately 107° with goniometer and 106° with accelerometer. Although the UG is considered a gold standard in evaluations of joint range of motion, it presents significant differences for hip flexion (113°-141°). 10,16-19 New measurement instruments such as accelerometers, which do not rely on external references, would enable hip assessments with pelvic monitoring in a simple way. This study measured pelvis retroversion during hip flexion evaluations by accelerometers and obtained an average result near to 7.3°, in the sample evaluated. Hip flexion measurements performed with accelerometer and goniometer showed a strong linear correlation (r = 0.87). The accelerometers were reliable in the measurements of hip flexion (combined: hip plus pelvis). In most analyses, the results showed substantial or optimal inter-rater agreement (ICC > 0.60).²⁶ The use of accelerometers in both measurements (flexion and retroversion) proved to be simple and fast. The results regarding the pelvis retroversion increase information to the health professional, supporting the correct interpretations about the mobility of the hip joint. Clinical evaluations of hip flexion amplitude with accelerometers have the potential advantage of deducing pelvic retroversion.

Studies correlating the measurements of joint range of motion between goniometer and other instrument (inclinometers^{15,16}, smartphones¹⁷, imaging exams¹⁹, and IMU²⁰) have shown good results. With increasing technological advances in electronic and computer instrumentation, new devices and techniques are continuously available, with a tendency to improve the accuracy and versatility of the new procedures. In 2015, a study obtained excellent results in hip flexion amplitude evaluations in 20 volunteers, when it compared the measurements performed by inclinometer (ICC = 0.94) and smartphone (ICC = 0.92) with 3DMA (Three Dimensional Motion Analysis). 11 The high versatility and low cost of accelerometers have supported its progressive use in human gait assessments, energy expenditure monitoring and various applications in many sports. 20,21 The good results of our research corroborate with recent studies assessing the reliability of accelerometers in human movements. 20,21 The results presented better agreements among the raters of the field of health, especially the lower limits of the confidence interval (Table 1). A possible interpretation of this episode is due to the small experience of the first examiner (engineer) in executing the movement. Pelvic retroversion begins with approximately 8° of hip flexion and this movement is extremely complex to monitor and to quantify without technological assistance.7 If the retroversion of the pelvis is not considered, hip flexion can be overestimated, making the clinical interpretation inconsistent with the real mobility of the joint. In patients with FAI, during the impingement test (combination of flexion, adduction and internal rotation of the hip), the range of motions are visually assessed and vary with the combination of pelvic movements. Without deduction of pelvic movements, patients who present normal evaluation for hip flexion may receive the FAI characteristic by lumbar compensation, which may be associated with degenerative changes in the spine.⁴ Pelvic retroversion measured in this study may be clinically important in these cases (FAI and lumbar problems) and extremely useful in decision-threshold circumstances about total hip arthroplasty and positioning guidelines of surgical prostheses. The pair of box plot graphs (Figure 7) showed reductions in median, quartiles, maximum and minimum values of the amplitudes of results of the hip flexion with deduction of pelvic retroversion (accelerometers) in relation to hip flexion without retroversion deduction (goniometer) The same graph (Figure 7) showed greater dispersion (variability) of hip flexion after deduction of pelvic movements. Several studies radiographically evaluated the spinopelvic alignment and inclination of the pelvis in the sagittal plane, with a strong linear correlation between the dimensions evaluated of the obturator foramen and the spinopelvic alignment. However, few studies quantified pelvic movements by the method.²⁷ A study composed of 101 preoperative patients of total hip arthroplasty measured – by computed tomography through the obturator foramen – the pelvic inclination in the sagittal plane and obtained 5° (degrees) of pelvic anteversion in the supine position, 3° in the upright vertical position and 29° pelvic retroversion with the patients seated.²⁸ In the aforementioned study, most patients had advanced arthrosis²⁸, which makes it impossible to use the results as parameters in researches with healthy people. Other studies have used the palpation method to identify anterior and posterior reference points of the pelvis for inclinometer fixation and pelvic anteversion measurement, whose values varied (3° to 10.3°). 27,29

In 2018, a study with a purpose similar to our research, measured with inclinometer the retroversion of the pelvis (15° on average) during hip flexion. At first, this evaluation occurred with patients in upright vertical position to measure pelvic anteversion (hip in neutral position). Then, in a supine position, for pelvic retroversion evaluation (at the physiological limit of flexion movement). The sum of the two results composed the total pelvic retroversion.⁵ Pelvic retroversion amplitude found in our study is lower (7.3°). compared to those found with inclinometer in 2018 (15°)⁵, justifiable differences due to the different evaluation protocols, instruments and experience of raters, especially in relation to pelvic monitoring. The hip flexion values found were also greater in the inclinometer study (116°), greater in 10° compared with this study (106°). Part of this difference probably occurred due to the different criteria regarding the final limits of movement, or variations between the populations studied. The closer to the clinical limits of flexion, the greater the tendency to occur retroversion of the pelvis, possibly as a response to the ligament and musculotendinous limits as well as to the proximity of the proximal region of the femur with the acetabular notch.

This study presented several limitations. One of the main limitations refers to the possibility of relative movement of the accelerometer positioned in the pelvis in relation to the skin and the pelvis. This factor could imply errors in the measurements. No study was found

evaluating the relative movement between pelvis and accelerometer. Another limitation refers to the lack of imaging exams, which would enable comparative evaluations, raising the reliability of the study and minimizing the hypothesis of possible evaluations in hips with pathological limitations, which could not be separated in the results. Furthermore, during the study sampling biases occurred, reducing the representativeness of the study: (a) small sample size, which did not enable to correlate variables such as sex and age group; (b) selection of volunteers for convenience. Despite the biases presented, the accelerometer has shown itself as a functional and reliable tool for semiology measurements of hip flexion and according to the positioning methodology presented, the accelerometer has the potential to measure the movements of pelvic retroversion.

CONCLUSION

The pelvic retroversion range in this study presented an approximate mean value of 7.3° . In the sample assessed, the accelerometers were reliable in hip flexion evaluations.

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ORIGINAL ARTICLE

ASSESSMENT OF THE USE OF TRANEXAMIC ACID AFTER TOTAL KNEE ARTHROPLASTY

AVALIAÇÃO DO USO DO ÁCIDO TRANEXÂMICO DURANTE A ARTROPLASTIA TOTAL DO JOELHO

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ABSTRACT

Objective: To evaluate the profile of blood loss and blood transfusions after the introduction of Tranexamic acid (TXA) in a tertiary university hospital in Brazil. Methods: 173 patients were retrospectively divided into two groups: the ones who received TXA and the control group. Hemoglobin levels (Hb), drain output, transfusion rates, and thromboembolic events were measured. Results: Among the patients included in this study, 82 cases received TXA. Blood transfusion occurred in 3 cases of the TXA group (3.7%), and in 27 control group cases (29.7%; p < 0.001). The average Hb decrease was 2.7 g/dl (\pm 1.39) and the median drain output was 270 mL in the TXA group. In the control group, the values were 3.41 g/dl (\pm 1.34; p < 0.001) and 460 mL (p < 0.001), respectively. Thromboembolic events occurred in 2 TXA group cases (2.4%) and in 3 control group cases (3.3%; p > 0.999). Conclusion: TXA was effective in reducing blood transfusion rates, Hb decrease, and drain output on the 1st postoperative day without increasing thromboembolic events. Level of evidence III, Retrospective comparative study.

Keywords: Tranexamic Acid. Blood Transfusion. Knee Replacement Arthroplasty.

RESUMO

Objetivo: Avaliar o perfil de perda sanguínea e hemotransfusões após a introdução da prática do uso de ácido tranexâmico (ATX) em um serviço terciário universitário brasileiro. Métodos: 173 pacientes foram separados retrospectivamente em dois grupos: uso do ATX e controle. Foram analisados valores da hemoglobina (Hb), débito do dreno, necessidade transfusional e complicações tromboembólicas. Resultados: Dentre os pacientes admitidos no estudo, 82 fizeram uso do ATX. Hemotransfusão ocorreu em 3 casos do grupo ATX (3,7%) e em 27 controles (29,7%, p < 0,001). A gueda de Hb teve média de 2.7 g/dl (± 1.39) e o débito do dreno, mediana de 270 ml no grupo ATX. No grupo controle, os valores foram de 3,41 g/dl $(\pm 1.34; p < 0.001)$ e de 460 ml (p < 0.001), respectivamente. Eventos tromboembólicos ocorreram em 2 casos (2,4%) no grupo ATX e em 3 no controle (3,3%, p > 0.999). Conclusão: o uso do ATX foi efetivo em reduzir hemotransfusões, queda de Hb e débito drenado no 1° dia pós-operatório, sem aumentar eventos tromboembólicos. Nível de evidência III, Estudo retrospectivo comparativo.

Descritores: Ácido Tranexâmico. Transfusão de Sangue. Artroplastia do Joelho.

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INTRODUCTION

Total knee arthroplasty (TKA) is currently one of the most cost-effective treatments in the management of osteoarthrosis in more advanced stages. Patients undergoing TKA are in risk for blood losses over 1500 ml, being submitted to allogenic blood transfusion in 10%-38% of the cases. Allogenic blood transfusion is not a benign procedure and is associated with complications, such as transmission of infectious diseases, transfusion reactions, fluid overload, and periprosthetic infection. In addition, it can lead to

prolonged hospital stay, thromboembolic events, and increased in-hospital mortality. Different strategies have been used to reduce blood loss after TKA, such as autologous transfusion, cell saver, pneumatic tourniquet, and the use of tranexamic acid (TXA). The fibrinolytic process is a major cause of intraoperative bleeding. By acting with the inhibition of hyperfibrinolysis, TXA stabilizes the fibrin clot and reduces blood losses. Mechanistically, it is a competitive inhibitor of plasminogen-activating enzymes, preventing its proteolytic activity to avoid the formation of plasmin and the

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This study was developed at the Institute of Orthopedics and Traumatology, Hospital das Clínicas, Medical School, Universidade de São Paulo.

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consequent degradation of fibrin.^{1,6} Several systematic reviews and meta-analyses have demonstrated the TXA role, in cases of TKA, in reducing blood loss and transfusion needs, without increasing the risk of thromboembolic events.⁶⁻⁸

TXA is usually indicated to prevent and treat different causes of bleeding, including large surgical procedures, such as orthopedic, cardiac, and liver transplantation surgeries. In this regard, TXA reduces the need for blood transfusion improving the patient's outcome, therefore its use in polytraumatized patients may decrease mortality by preventing the excessive bleeding.⁹

In recent years, the use of TXA has increased progressively in the TKA worldwide centers . On the other hand, the impact of TXA after TKA is still poorly documented in Brazil. Our service started to use this medication in 2013, introducing the administration of TXA routinely by the end of 2014. Therefore, we could gather a significant amount of experience.

This study aims to evaluate the impact of the TXA routine use, reducing blood loss related to the primary TKA procedure. The study aims to evaluate the hematimetric parameters, the number of transfusions, and the drain output in a retrospective cohort of patients admitted in a tertiary university hospital in Brazil.

MATERIALS AND METHODS

The study was approved by our ethics committee (CAPPesq number 15754619.7.0000.0068). All patients signed an informed consent form. A retrospective cohort study was carried out with patients undergoing TKA between 2013 and 2017 admitted in our service. Patients were not included in the study if they had:

- any hematological diseases, renal insufficiency, hepatic insufficiency, previous cardiovascular and/or thromboembolic events;
- preoperative use of anticoagulant or other medications that alter coagulation;
- alteration in coagulation exams prior to the surgical procedure;
- intraoperative fracture that required the use of intramedullary nails and revision components.

Based on that, 220 patients were selected. Of those, 47 were excluded due to the lack of medical records information. Totally, 173 cases were included in the study.

The cases were separated based on the TXA use. The clinical protocol allowed the administration of the highest TXA dose between 1 g or 10 mg/kg during anesthetic induction, with or without a dose replication just before the tourniquet deflation.

Demographic data were collected. In addition, information regarding the administered TXA dose, the levels of preoperative hemoglobin (Hb), the hemoglobin on the 3rd postoperative day, and the drain output on the 1st postoperative day were evaluated. The need for transfusion was indicated intraoperatively by the anesthesiologist according to subjective criteria, or by the clinician postoperatively, when Hb < 7 g/dl or Hb > 7 g/dl with clinical repercussions. Thromboembolic complications or hematoma formation requiring joint aspiration, and the total hospital/ICU length of stay were analyzed. As an exploratory analysis, this study also compared the patients' subgroup that received or not blood transfusion, regarding the need for hospitalization in the ICU, and the total hospital and ICU length of stay.

Statistical analysis

Numerical variables were described as mean and standard deviation when normal distribution in groups, or as median and interquartile range (IR) when non-normal distribution, according to Shapiro-Wilk test and Histogram analysis. Categorical variables were described by the absolute number and percentage within the group. In the univariate analyses, for numerical variables between groups, the Student's t-test or the Mann-Whitney U test was used, according to the variable's

normality. In the categorical variables the Fisher's test in the respective contingency tables was used. To evaluate the determinants of the need for transfusion with control of possible confounding variables, multivariate binomial logistic regression was performed, including the following variables: sex, age, use of tranexamic acid, and drain use. Statistical significance was considered when $\rho < 0.05$.

RESULTS

Demographic characteristics

From 2013 to 2017, a total of 220 patients undergoing primary TKA surgery in our service had their data adequately recorded. Of this total, 173 patients were included based on the eligibility criteria of this study. Demographic characteristics showed no significant difference between groups (Table 1). Forty-seven (57.3%) patients received two doses of TXA.

Table 1. Patient demographics. Age is shown in years \pm *standard deviation*; sex and diagnosis are described as n (%).

,			(·)	
	TXA Group (n = 82)	Control group (n = 91)	TOTAL (n = 173)	p*
Age	66.5 11.4	65.4 10.4	65.9 10.9	0.525
Sex				0.318
Male	18 (22)	26 (28.6)	44 (25.4)	
Female	64 (78)	65 (71.4)	129 (74.6)	
Diagnosis				0.864
Primary Osteoarthritis	64 (78)	72 (79.1)	136 (78.6)	
Others	18 (22)	19 (20.9)	37 (21.4)	

*Fisher's Test

Blood loss

Table 2 shows the parameters associated to blood loss, such as Hb levels, drain output, and need for transfusion.

Table 2. Values related to blood loss. The values are shown as mean \pm standard deviation or as median/IR. In the case of blood transfusion, the values are expressed in n (%).

		TXA group	Control group	р
	Hb preoperative	13.57 1.32	13.54 1.26	0.8671
	Hb postoperative (PO)	10.87 1.66	10.13 1.42	0.0021
	Hb decrease	2.70 1.39	3.41 1.34	< 0.001 ¹
	1st PO drain output	270/290	460/575	< 0.001 ²
_	Blood transfusion	3 (10)	27 (90)	< 0.001 ¹

1: Student's t-test; 2: Mann-Whitney U test.

The mean preoperative Hb was 13.5 g/dl (\pm 1.32) in the TXA group and 13.5 g/dl (\pm 1.26) in the control group (ρ = 0.867). On the 3rd postoperative day, the Hb levels were significantly higher in the TXA group in comparison with the control group (10.87 g/dl \pm 1.66 vs 10.13 g/dl \pm 1.42, respectively). TXA-treated patients had a smaller Hb decrease than the control group (2.7 g/dl \pm 1.39 vs 3.41 g/dl \pm 1.34; ρ < 0.001). Moreover, the median drain output on the 1st postoperative day was significantly reduced in the TXA group when compared with the control group.

Hemotransfusion was performed in 30 patients. Most transfusion cases were from the control group (90%), while a small proportion of the TXA-treated patients (10%) needed transfusion.

Length of stays and need for ICU

The mean length of stay in hospital was 5.17 days for the TXA group and 7.70 for the control one. Regarding the need for ICU,

62 (35.8%) patients required intensive postoperative support, 28 (34.1%) in the TXA group and 34 (37.4%) in the control group. The mean ICU length stay was 0.41 (\pm 0.68) days for the TXA group and 1.86 (\pm 7.66) for the control group.

As an exploratory analysis, this study correlated blood transfusion with the total hospital and ICU length of stay. For patients undergoing transfusion, the mean total hospitalization stay was 13.83 days, compared with 4.97 days of non-transfused patients (p = 0.002). Similarly, the mean ICU stay was 5.17 days for those who received blood and 0.34 days for those who did not receive blood transfusion (p < 0.001).

Moreover, the relationship between transfusion events and the need for ICU admission also showed statistical significance. Of the 30 patients receiving transfusion, 19 (63.3%) were referred to the ICU, while 11 (36.7%) did not require intensive care (p = 0.001).

Complications

Thromboembolic events and hematoma formation were evaluated as complications of TKA and accounted for 8.67% of the participants. Thromboembolic events occurred in 5 cases and hematoma formation that required joint aspiration occurred in 10 cases. No statistically significant difference was found between the groups (Table 3).

Table 3. Complications. The values are shown in n (%)

	TXA group	Control group	TOTAL	p*	
Thromboembolic events	2 (2.4)	3 (3.3)	5 (2.9)	> 0.999	
Hematoma	4 (4.9)	6 (6.6)	10 (5.8)	0.750	

^{*}Fisher's Test.

The multivariate evaluation by logistic regression was performed and included the following variables: sex, age, use of tranexamic acid, and drain output. Among the variables, only the use of TXA was correlated to the need for blood transfusion (odds ratio [OR], 0.097 {95% confidence interval [CI]}; 0.027-0.344, $\rho=0.001$). This suggests the TXA afforded a protection from the need for transfusion of approximately 10 times.

DISCUSSION

In this study, we showed the effective use of TXA in decreasing the perioperative transfusion requirement. In addition, it reduced the hemoglobin decrease and the drain output on the 1st postoperative day. These results are similar to those found in the literature. Many studies show a favorable correlation between the use of TXA and the decrease in intra and postoperative bleeding during the TKA surgery. 10,11 Its efficacy and safety has been well studied recently.¹² A Cochrane review conducted by Henry et al. (2011) showed that TXA efficiently decreased blood loss during and after orthopedic procedures, reducing it in approximately 446.19 ml (95%CI 554.61-337.78 ml).13 In this regard, Yang et al.7, in a meta-analysis study, showed a significantly lower value in blood transfusion rates in patients who used TXA compared with the placebo group (OR 0.16, 95%Cl 0.10-0.25; p < 0.001) (7). Similarly, the systematic review and meta-analysis conducted by Alshryda et al. (2011) show the use of TXA significantly reduced perioperative blood loss in over 591 ml (95%Cl 536-647; p < 0.001) and the need for blood transfusion (RR 2.56, 95% Cl 2.1-3.1; ρ < 0.001), without increasing the risk of adverse events, regardless of the via of administration (oral, topical, or intravenous).14

Besides the growing interest in TXA studies, there is no absolute conclusion of the best administration *via* (intravenous, intra-articular, topical, or oral)¹⁵, dose, and the number of required

applications for the best results. The review performed by Melvin et al. Indicates that the effective dose has ranged from 1 g to 10-20 mg/kg of TXA, applied intravenously or topical, without significant different outcome. Although it is proposed that the number of doses may influence the reduction of blood loss Indicated in the number of doses may influence the reduction of blood loss Indicated is no consensus about the best administration regimen. In this study, the TXA was administered intravenously using the highest dose between 1 g or 10 mg/kg during anesthetic induction. Some of the cases had the treatment replicated immediately before the pneumatic tourniquet disinflation. Given the retrospective analysis of this study, there was no dose standardization, which is a limitation of the study.

Despite the good obtained results, the TXA also presents theoretical risks, such as deep vein thrombosis (DVT) and pulmonary thromboembolism (PE). Based on its mechanism of action, TXA might activate coagulation cascade and increase the tendency of thrombus formation. However, Alshryda et al. 14 showed no increase in the risk of these complications after the use of the TXA. Moreover, Sabbag et al. 18 conducted a retrospective study of patients with thromboembolic events history prior to TKA. They concluded that the recurrence of these events is uncommon after surgery, with no significant increase in incidence related to the use of TXA compared with the placebo group (2.3% versus 1.9% respectively; $\rho=0599$). 18

The incidence of DVT and pulmonary embolism after TKA surgery without an adequate prophylaxis was estimated to be 41%-85% and 1.5%-10%, respectively. Adequate prophylaxis reduces this incidence to approximately 1% during hospitalization. In this study, prophylaxis was made with Enoxaparin 40 mg/day for 14 days. The study found 5 thromboembolism events, 2 (2.4%) of those in TXA group and 3 (3.3%) in the control group, without significant association regarding the use of TXA (ρ > 0999). The perioperative blood transfusion itself could also increase the risk of DVT after arthroplasty surgeries, by increasing blood viscosity, causing erythrocytes and platelets aggregation with subsequent thrombus formation. Thus, decreasing the number of blood transfusions would improve the occurrence of these events.

As stated in this study with exploratory analysis, patients undergoing blood transfusion have a greater need for postoperative intensive care. Likewise, there was a positive correlation between the blood transfusion and the hospital and ICU length of stay. The use of TXA, by reducing the need for blood transfusion, would also be beneficial in decreasing the need for postoperative ICU, and the hospital and ICU length of stay. Randomized controlled trials are required to improve the understanding of this correlation.

The study had several limitations. Because it is a retrospective study, the patients may have different demographic characteristics. Moreover, as mentioned before, there was no standardization in the number of TXA applications (one or two doses). It was not possible to define the dose influence that in fact decreases perioperative bleeding. Additional studies would be useful to clarify these variables. Another limitation is the lack of real blood loss measurement, which was made by indirect methods, such as drain output and Hb decrease. Of note, there is a small difference in postoperative Hb between the groups, despite the statistically significant result (averages of 2.7 g/dl (\pm 1.39) in the TXA group and 3.41 g/dl (\pm 1.34) in the control group. This value refers to the 3rd postoperative day and, therefore, after blood transfusions. Since the control group was subjected to a more expressive number of transfusions, the Hb could be underestimated in these cases.

In this study, the primary outcome was the reduction of blood transfusions required after the TKA. The study considered this as one of the most faithful clinical expressions of blood loss. It is important

to emphasize that the indication for postoperative transfusion was made by a clinical team, which was unaware of the TXA use.

Despite the limitations, this study is one of the few in the national literature to compare the use of TXA with a control group. Furthermore, the study shows the successful use of TXA in reducing the transfusion requirement, the postoperative Hb decrease, and the drain output in a pragmatic situation of an uncontrolled study.

CONCLUSION

In conclusion, the use of TXA had a positive role after TKA in our service. It significantly reduced the blood transfusion rates, being a potent tool in the therapeutic arsenal, aiming to improve the clinical and surgical conditions related to the TKA procedure and the perioperative period.

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FACTORS AFFECTING THE FUNCTIONAL OUTCOME OF OXFORD PHASE 3 UNICOMPARTMENTAL KNEE ARTHROPLASTY

FATORES QUE AFETAM O RESULTADO FUNCIONAL DA ARTROPLASTIA UNICOMPARTIMENTAL DO JOELHO OXFORD PHASE 3

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ABSTRACT

Objective: To determine the factors that affect the functional outcome of Oxford Phase 3 unicompartmental knee arthroplasty (UKA). Methods: We assessed a total of 52 UKA knees of 49 patients with a minimum follow-up of 2 years (24-72 months). We recorded the results for Range of motion (ROM) and body mass index (BMI) and the presence o patello-femoral arthrosis (PFA). In the radiological evaluation, we measured the posterior tibial slope (PTS), the tibial plateau angle (TPA) and the femorotibial angle, in addition to an assement using the Oxford radiological criteria. Patients were grouped by age, follow-up time, BMI, radiological criteria, PFA presence, occurance of complications and revision surgery. The clinical and functional results of these groups were compared statistically. Results: A total of 40 women and 9 men participated in the study, with an average age of 60 years, and a mean BMI of 34.6. No significant differences were found among the age and PFA groups. Postop VAS scores were high and knee evaluation scores were significantly lower in the morbidly obese group and in the groups with postop TPA <85° and >90°. The revision ratio was 11.5%. Conclusion: Postop TPA, PTS and morbid obesity are the most significant factors that can lead to revision surgery. Level of Evidence IV, Case series.

Keywords: Osteoarthritis. Arthroplasty. Replacement. Knee. Pain.

RESUMO

Objetivo: Determinar os fatores que afetam o resultado funcional da artroplastia unicompartimental do joelho Oxford Phase 3 (AUJ). Métodos: Foram incluídos 52 joelhos AUJ de 49 pacientes com um período mínimo de 2 anos (24-72 meses) de acompanhamento. Foram registrados: amplitude de movimento (ADM), índice de massa corporal (IMC) e presença de artrose femoropatelar (AFP). Na avaliação radiológica, medimos o declive tibial posterior (DTP), o ângulo do planalto tibial (APT) e o ângulo femorotibial, além de usarmos os critérios radiológicos de Oxford. Os pacientes foram agrupados de por idade, tempo de acompanhamento, IMC, critérios radiológicos, presença de AFP e ocorrência de complicações e cirurgias de revisão. Os resultados clínicos e funcionais desses grupos foram comparados estatisticamente. Resultados: Participaram do estudo 40 pacientes do gênero feminino e 9 do gênero masculino, com idade média de 60 anos, IMC de 34,6. Não foram encontradas diferenças significativas entre os grupos formados por idade e presença de AFP. As marcações da EVA pós-operatória foram altas e as marcações do joelho foram significativamente baixas no grupo com obesidade mórbida e nos grupos com APT pós-operatória <85º e >90º. A taxa de revisão foi de 11,5%. Conclusão: APT e DTP pós-operatório e obesidade mórbida são os fatores mais significativos que podem levar à cirurgia de revisão. Nível de Evidência IV, Série de casos.

Descritores: Osteoartrite. Artroplastia do Joelho. Dor.

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INTRODUCTION

Osteoarthritis is the most common joint disease in the world and the most frequent cause of chronic musculoskeletal pain.¹ In 80-90% of the cases, osteoarthritis begins in the medial compartment and tends to remain unicompartmental.² There are different types of surgical treatment for single compartment osteoarthritis, including Total Knee Arthroplasty (TKA), High Tibial Osteotomy or Unicompartmental Knee Arthroplasty (UKA), when conservative treatments are not responsive. Oxford Phase 3 UKA, was introduced in 1998 by Murray and Goodfellow et al.3 Many advantages of the UKA are mentioned in the literature, including: minimally invasive incision, preservation of the anterior and posterior cruciate ligaments, fewer bone cuts, less postoperative blood loss and pain, better functional outcomes. reduced hospitalization time, lower costs and faster and earlier rehabilitation.^{4,5} Its disadvantages include surgical technical difficulties and experience requirements.⁴⁻⁷ Additionally, higher revision rates have been reported for UKA compared to total knee arthroplasty (TKA).8 Improper patient selection and implant malpositioning may be responsible for this high rate. 5,7,9

With the development of implants, component materials, surgical fixation techniques, and the definition of correct indications and correct patient selection criteria, positive results have been recorded for UKA in the last 20 years. ^{6,10,11}

All surgeons must analyse the pitfalls and underlying clinical and radiological reasons for early failure of UKA before performing this procedure. However, as the surgeons' experience increases, their surgical technique improves, ensuring a more accurate implant positioning. We aimed to evaluate radiological and clinical results and determine the factors that affect the functional outcome of Oxford Phase 3 unicompartmental knee arthroplasty cases. This study also intends to be a helpful tool for surgeons, identifying the causes of early failure of UKA.

MATERIAL AND METHODS

Participants

In this retrospective study, we analysed 52 knees of 49 patients who underwent Oxford Phase 3 unicompartmental knee arthroplasties (Oxford Partial Knee, Biomet Orthopaedics, Bridgend, UK) for anteromedial osteoarthritis. These surgeries were performed by the last author (TT) or under his control, in the Orthopaedics and Traumatology Clinic of the Istanbul Training and Resarch Hospital, between 2011 and 2016. The inclusion criteria were: presenting non-inflammatory arthritis with an intact anterior cruciate ligament, passively correctable angular deformity under 10° varus and 5° valgus, flexion deformity under 15° and no lateral compartment involvement. Patients with a minimum follow-up of 2 years were included. This study was approved by the Research Ethics Committee (ID:47 date:07/06/2016). All patients who took part in this study signed forms of informed consent, agreeing to its publishing.

Clinical and radiological evaluation

As part of the preoperative radiological evaluation, we assessed weight-bearing anteroposterior and flexed lateral knee X-rays, patella tangential X-rays, varus-valgus stress X-rays and orthoroentgenograms. Preoperatively, all 52 knees underwent MRI examinations. The groups divided according to the presence of patellofemoral arthrosis (PFA) were based on its grading shown in the Magnetic resonance imaging (MRI). Postoperatively, we performed orthoroentgenograms, weight-bearing anteroposterior and flexed lateral knee X-ray imaging.

For the evaluation of the patients, pre and postoperatively, we used the Knee Society Score (KSS) and functional Knee Society Score (fKSS), the Oxford Knee Score (OKS) and the visual analogue scale (VAS). The range of motion (ROM) was also recorded for each patient pre and postoperatively. Additionally, the body mass index (BMI) and the presence of patellofemoral arthrosis (PFA) were documented. In the radiological evaluation, we assessed the posterior tibial slope (PTS), the tibial plateau angle (TPA) and the femorotibial angle (FTA), besides using the Oxford radiological criteria (Table 1) (Figure 1). Preop and postop FTA are measured by the angle between the two lines drawn from the centers of the femur and tibia, which start 10 cm above and below the joint line. Preop and postop PTS are defined by the angle between the tibial anatomical axis and the line drawn tangentially to the medial tibial plateau on the lateral radiographs. The preop TPA is the angle between the tibial plateau and the tibial anatomic axis, whereas the postop TPA is measured between the tibia anatomic axis and the tangential line of the medial plateau implant cuts. Two authors (AEP and TG) assessed all images and measured all angles independently. The images were blinded, and their order was randomized. When there was a disagreement between the examiners, re-evaluations were made until a consensus was reached. Patients were grouped according to their ages, follow-up time, BMI, varus-valgus and flexion-extension positions of the femoral component, FTA, PTS, TPA, PFA presence in MRI, occurrence of complications and revision surgeries. The clinical and postoperative ROM results of these groups were statistically compared.

Table 1. Oxford radiological criteria.								
	Description	Criterion						
Femoral component								
A/A	Varus/valgus angle	< 10° varus to < 10° valgus						
B/B	Flexion/extension angle	< 5° flexion to < 5° extension						
C/C	Medial/lateral placement	Central						
D	Posterior fit	Flush/ < 2 mm overhang						
Tibial component								
E/E	Varus/valgus angle	< 10° varus to < 5° valgus						
F/F	Posteroinferior tilt	7° ± 5°						
G	Medial fit	Flush or < 2 mm overhang						
Н	Posterior fit	Flush or < 2 mm overhang						
J	Anterior fit	Flush or < 3 mm overhang						
K	Lateral fit	Flush, no gap						

Source: Oxford Phase 3 unicompartmental knee prosthesis user's manual.

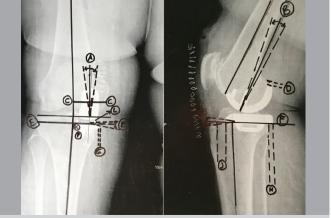


Figure 1. Postoperative correct positioning of unicompartmental knee arthroplasty according to Oxford radiological criteria.

Statistical analysis

For the statistical analysis, we used the SPSS 15.0 software for Windows. The ratio of categorical variables in the groups was tested by Chi-square analysis. The Monte Carlo simulation was applied when the conditions were not met. Because the numerical variables presented no normal distribution, two independent group comparisons were made using the Mann-Whitney U test and the Kruskal Wallis test in all groups. Subgroup analysis was done using Mann-Whitney U test and interpreted by Bonferroni correction. The relationships between numerical variables were examined by Spearman correlation analysis, since the parametric test conditions were not provided. The Cox Regression Analysis Forward Method was used in the model, based on the factors that could affect the revision rates. Statistical significance level alpha was accepted as p < 0.05.

RESULTS

In total, 40 patients (81.6%) were women and 9 (18.4%) were men. Their mean age was 60 years (in a range of 49-80), and their mean BMI was 34.6 (in a range of 22-56.9). Two (3.8%) of the patients had normal weight (BMI below 25 kg/m²), 11 (21.2%) were overweight (BMI, 25-29.9 kg/m²), 31 (59.6%) were obese (BMI, 30-34.9 kg/m²) and 8 (15.4%) were morbidly obese (BMI \geq 35 kg/m²). The left knees of 21 patients, the right knees of 28 patients and both knees of 3 patients underwent UKA. The mean follow-up period of the patients was 48 months (ranging between 24 and 72 months). The average OKS. KSS and fKSS scores improved significantly, from 12.7, 43.3 and 34.8 in preoperative measurements to 37.8, 85.7 and 82 in postoperative measurements, respectively, and the mean VAS scores decreased from 9 to 2.6. Additionally, ROM improved from 111° to 123° (Table 2). According to the Oxford radiological criteria, component replacement error was found in 19 (36.5%) patients. The most common error was a defective central placement of the femoral component. However, the most frequent problems in the revised knees were errors in the lateral placement of the tibial component - more than 10° varus or valgus of the tibial component, or more than 10° varus or valgus of the femoral component - and posterior tibial slope defects. All three patients with PTS misplacement underwent revision surgery (Table 3).

ROM		111.2 ± 12.6 (90-130)	123.6 ± 14.6 (75-135)	< 0.001
KSS		43.3 ± 9.7 (17-69)	85.7 ± 19.9 (31-100)	< 0.001
	Excellent	_	40 (76.9)	
- (0/)	Good	_	5 (9.6)	
n (%)	Fair	2 (3.8)	2 (3.8)	
	Poor	50 (96.2)	5 (9.6)	
fKSS		34.8 ± 19.0 (0-90)	82.0 ± 24.4 (0-100)	< 0.001
	Excellent	1 (1.9)	38 (73.1)	
- (0/)	Good	1 (1.9)	7 (13.5)	
n (%)	Fair	2 (3.8)	2 (3.8)	
	Poor	48 (92.3)	5 (9.6)	
OKS		12.7 ± 7.8 (0-32)	37.8 ± 10.4 (7-48)	< 0.001
	Severe	43 (82.7)	6 (11.5)	
- (0/)	Moderate	6 (11.5)	2 (3.8)	
n (%)	Mild	2 (5 0)	6 (11 5)	

Preoperative

Postoperative

6 (11.5)

 $\frac{38 (73,1)}{2.6 \pm 2.9 (0-10)}$

OKS: Oxford Knee Score; KSS: Knee Society Score; fKSS: functional Knee Society Score; ROM: range of motion; VAS: visual analogue scale.

Values are shown as mean ± SD (range) unless otherwise indicated.

3 (5.8)

 $9.0 \pm 1.1 (6-10)$

Mild

Normal

Table 2. Pre and postoperative scores.

Table 3. Defects and revision percentages according to Oxford radiological criteria.

Criterion	Defects	Revisions	
A. Femoral component > 10° varus-valgus positioning defect	3 (5.7)	2 (66.6)	
B. Femoral component > 5° of flexion-extension positioning defect	4(7.69)	_	
C. Femoral component central positioning defect at coronal plane	12 (23)	2 (16.6)	
D. Femoral component posterior fit defect	_	_	
E. Tibial component > 10° varus-valgus positioning defect	2 (3.8)	2 (100)	
F. Posterior tibial tilt defect	3 (5.7)	3 (100)	
G. Tibial component more than 2 mm medial flush	1 (1.9)	1 (100)	
H. Tibial component posterior fit defect	_	_	
J. Tibial component anterior fit defect	1 (1.9)	_	
K. Tibial component lateral fit defect	4 (7.69)	3 (75)	
L. Insert positioning	_	_	

Values are shown as n (%).

Patients were grouped according to the following postoperative measured angles: PTS (87° – 79° is normal), FTA (over 175° is varus, 170° – 175° is normal, under 170° is valgus) and TPA (over 90° is valgus, 90° normal, 89° – 85° is minor varus, under 85° is varus). KSS, fKSS, OKS, VAS and ROM were compared postoperatively in these groups (Tables 4 and 5).

Table 4. Preoperative and postoperative mean values.										
		Preoperative	Postoperative	р						
PTS		82.9 ± 1.9 (78-87)	84.0 ± 4.0 (76-102)	0.074						
n (%)	> 87	_	5 (9.6)							
	87-79	51 (98.1)	41 (78,8)							
	< 79	1 (1.9)	6 (11.5)							
FTA		179.4 ± 3.0 (174-190)	174.9 ± 4.6 (162-185)	< 0.001						
n (%)	> 175	47 (90.4)	20 (38.5)							
	175-170	5 (9.6)	28 (53.8)							
< 170		_	4 (7.7)							
TPA		84.8 ± 2.7 (80-90)	88.7 ± 3.7 (72-98)	< 0.001						
n (%)	> 90	_	2 (3.8)							
	90 (normal)	4 (7.7)	34 (65.4)							
85-89		25 (48.1)	11 (21.2)							
	< 85	23 (44.2)	5 (9.6)							

PTS: posterior tibial slope; FTA: femorotibial angle; TPA: tibial plateau angle. Values are shown as mean \pm SD (range) unless otherwise indicated.

Table 5. Comparison of postoperative clinical scores in the postoperative tibial plateau angle groups

	Tibial plateau angle								
	> 9	90*	90 (no	rmal)	85-89		< 85		
	Ort.	SD	Ort. SD		Ort.	SD	Ort.	SD	Р
ROM postop	112.5	31.8	124.9	14.1	127.7	8.2	110	17.7	0.933
KSS postop	54.0	32.5	88.5	17.0	94.7	6.6	59.4	25.2	0.010
fKSS postop	45.0	63.6	84.4	19.3	92.3	11.7	58.0	37.7	0.048
OKS postop	21.0	12.7	38.8	9.6	42.9	3.3	26.4	12.4	0.014
VAS postop	6.00	4.24	2.24	2.74	1.45	1.92	6.00	2.92	0.020
ROM: range of motion: KSS: Knee Society Score: fKSS: functional score: OKS: Oxford Knee									

ROM: range of motion; KSS: Knee Society Score; fKSS: functional score; OKS: Oxford Knee Score; VAS: visual analogue scale.

The patients, whose mean age was60 years, were divided into three age groups: those younger than 55 years, those between 55 and 65 years, and those older than 65 years. There were no statistically significant differences among these groups. Furthermore, there were no statistically significant differences among the patients grouped according to the presence of PFA, identified by MRI. In the morbidly obese group, the postop clinical scores were significantly lower and the VAS scores, significantly higher, while clinical scores were excellent in the other BMI groups.

Complications developed in five patients (9.6%). Three of the complications were intra-operative eminence fractures and two of them were insert dislocations. The eminence fractures occurred in the first UKA surgery experiences, while the surgeon was making a horizontal tibial cut, and were fixed intra-operatively with two headless cannulated screws (Figure 2). In the subsequent surgeries, a sagittal saw was used to avoid this complication. Two of these patients underwent revision surgeries, 7 months and 45 months after the UKA operation. The eminence fracture healed completely with the revision. Both these patients also had implant misplacement. The other patient with an eminence fracture did not have any implant placement defects and their postoperative functional outcomes were good. Two patients were referred to the authors' clinic because of ROM limitations, and insert dislocations were diagnosed at 3 and 10 months after the operation. Both patients had a history of knee distortion. Radiologic evaluations of the patients with insert dislocation did not reveal any misplacement at implantation, except for the central placement of the femoral component (placed 4 mm or 3 mm laterally). Furthermore, two of the five patients who developed complications were morbidly obese and three of them were obese.



Figure 2. Eminence fracture fixed intra-operatively with two headless cannulated screws.

Six (11.5%) of the patients required revision (Table 6). The UKA revision rate in the authors' clinic was 11.5%, while the TKA revision rate for the same period was 8%; UKAs performed between 2011-2016 accounted for 4.6% of the knee replacement surgeries conducted during that period.

Using the Cox Regression Analysis, Forward Method, we assessed the age, sex, BMI, presence of PFA, postop TPA, postop FTA, postop PTS, varus and valgus alignment of femoral component and follow-up times, composing a model of the factors that could lead to the need of revision. In this analysis, the postop tibial plateau angle (Figure 3), the postop posterior tibial slope (Figure 4) and morbid obesity were determined as the most significant factors that could lead to revision.

Tal	Table 6. Summary of findings on revision patients.													
	PTS\F	FTA	TPA\E	Fem component VARUSVALGUS	С	G	J	K	ВМІ	Complication	Revision Cause	Revision time	Age	Revision implant
1	102	183	78 VAR	N	N	N	4 mm Posterior	1 mm	38.7	None	T. loosening + collapse	52nd m.	53	Constrain
2	90	N	84 VAR	N	N	N	N	N	33	Eminence fracture	T.+F. loosening	45th m.	65	Primer
3	N	183	N	12 VAR	2 mm Med	N	N	1 mm	41.6	Eminence fracture	T. loosening + collapse	7th m.	58	Primer
4	N	N	N	N	N	N	N	N	47	None	T.+F. loosening	7th m.	51	Primer
5	N	183	98 VAL	N	3 mm Med	3 mm Med	N	2 mm	50	None	T. loosening + collapse	12nd m.	53	Constrain
6	76	185	72 VAR	12 VAR	3 mm Med	N	N	N	49	None	T.+F. loosening	12nd m.	56	Primer

BMI: body mass index; C: femoral component central positioning; FTA: femorotibial angle; G: tibial component more than 2 mm medial flush; J: tibial component anterior fit defect; K: tibial component lateral fit defect; m: month; N: normal; PTS\F: posterior tibial slope or F: posterior tibial tilt; T: tibial; F: femoral; TPA\E: tibial plateau angle or E: tibial component varus-valgus; VAR: varus. VAL: valgus; Med: media: mm: milimeter



Figure 3. 4th year postoperatively, anteroposterior/lateral X-ray view of unicompartmental knee arthroplasty with tibial plateau angle 8° valgus.



Figure 4. 3rd year postoperatively, anteroposterior/lateral X-ray view of unicompartmental knee arthroplasty with PTS 78°.

DISCUSSION

Although the patient selection process has been shown to be one of the most important factors for obtaining successful outcomes in UKA surgery, there are still some controversial indication criteria. 9,12,13 Kozin et al. were the first to identify the traditional criteria for such indications. They were limited to the patients with medial osteoarthritis over 60 years old, with a body weight under 82 kg, no anterior knee pain and no arthrosis, except for minimal erosive changes in the patellofemoral region.¹² The indications were then expanded by Berend and Lambordi. 13 According to these authors, to be eligible for UKA it is sufficient to have posteriorly preserved anterior full-thickness medial cartilage loss, fully correctable varus deformity, full-thickness preserved on the lateral cartilage and a solid anterior cruciate ligament. 13 The indication criteria of the Oxford Group include knees with medial arthrosis (except inflammatory diseases), a solid anterior cruciate ligament (ACL), flexion contractures under 15 degrees, full-thickness on the lateral cartilage and fully correctable intra-articular varus deformities.9 In the present study, the parameters of the Oxford Group were preferred when determining the indications.

The presence of PFA is controversial in the indication criteria. It was a contraindication in previous studies, ¹⁴ but in recent publications this is no longer accepted. ⁹ In accordance with the current literature, this study shows that PFA does not affect early and mid-term functional outcome of UKA.

Price et al. reported that the 10-year cumulative survival rate in 52 Oxford UKA patients under 60 years of age was not significantly different from that of patients older than 60 years. In this study, no statistically significant differences were found among age groups. We believe that the UKA is a suitable method for patients of all ages, provided that the indications are met.

In 2013, Murray et al. demonstrated, with multicenter trials, that there is no reduction in survival rates in patients with high BMI values (such as 45-50).¹⁵ In this study, while the functional outcomes of patients who were obese, overweight and had normal weight were excellent, those of morbidly obese patients were significantly lower. We believe that it is not appropriate to perform UKA on morbidly obese patients, although it is possible to achieve excellent results in obese and overweight patients with effective planning and correct surgical techniques.

Most authors believe that valgus overcorrection of the varus deformity is the main cause for lateral arthrosis¹⁶ and some surgeons recommend that the implants should be placed in the minimal varus position, in order to avoid lateral arthrosis.¹⁷ Perkins et al. reported that FTA angles greater than 3° varus and 7° valgus decreased the functional results and increased the revision rate.¹⁸ Consonantly with the literature, in this study the implant placement detected postoperative was 1.5° minor varus. The results were worse in patients whose tibial component position had an angle smaller

than 85° (varus) or bigger than 90° (valgus), while the 85° – 90° TPA groups (normal and minor varus) had excellent results. Furthermore, four out of six patients requiring revision presented TPA disturbances. Bruni et al. found an increase in the PTS in the revised knees of 84 UKA patients, due to spontaneous osteonecrosis, so they recommend the avoidance of PTS overcorrection. All three patients who were diagnosed with PTS misplacement had been submitted to revision. Shakespeare et al. reported that femoral component malalignment did not lead to disorientation in the lower extremity, but many publications state that this angular deformity could lead to polyethylene wear. In this study, the group with the femoral component placed more than 10° varus had lower rKSS, with a statistically significant difference, and their VAS was significantly higher.

In the Swedish Knee Arthroplasty Register of 2004, which reported a wider number of cases, the most common cause of failure was aseptic loosening of components. 4 In this study, six (11.5%) patients required revision. For three of them, the reason was the loosening collapse of the tibial and femoral components, while in the other three, it was the tibial loosening and collapse. In five of these cases, what caused the need for revision was incorrect implant positioning, in the case of the other patient, it was caused by morbid obesity (Table 5). Moreover, it was seen that BMI, postoperative TPA and postoperative PTS were the most significant factors that could motivate revision. We found no statistically significant difference between the clinical and radiological outcomes of UKA surgeries performed in the first two years and those of the two subsequent years. However, 60% of the complications and all the revisions occurred during the first two years of UKA surgical experience. This shows the importance of surgical experience.

We understand that the retrospective nature of this study is a limitation. It could be a guide for new surgeons starting to perform UKA surgeries, demonstrating the complications caused by intra-operative eminence fractures, which are not mentioned in the literature. Another factor that attests the value of this study is the insufficient information in the literature about the effect of the PTS angle on implant survival. Multicenter studies should be conducted so that more meaningful results can be obtained, investigating more case series.

CONCLUSION

As the results indicate, implant positioning is a critical factor in the functional outcome and survival rates of UKA. Tibial plateau angle and posterior tibial slope are the radiological parameters that should be particularly considered. In terms of patient selection, UKA is not a suitable option for morbidly obese patients. It may be possible to reduce significantly the revision rates through appropriate patient selection, correct surgical technique and increased surgical experience. If these conditions are met, UKA is a method that can provide excellent results for anteromedial arthrosis in patients of middle and advanced ages.

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LATARJET PROCEDURE ON ANTERIOR SHOULDER INSTABILITY IN PROFESSIONAL SOCCER PLAYERS

CIRURGIA DE LATARJET NA INSTABILIDADE ANTERIOR DO OMBRO EM JOGADORES PROFISSIONAIS DE FUTEBOL

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ABSTRACT

Anterior glenohumeral instability is a frequent cause of professional soccer players' removal, reduced performance, and prolonged recovery. Players are subjected to intense physical contact and high performance, thus demanding lower rates of recurrence after surgical correction so they can return to sport quickly. Objective: To assess professional soccer players treated by the Lartajet technique considering the rate and time of return to sports activities, complications or failures. Methods: Analysis held between 2010 and 2018 of professional soccer players diagnosed with anterior shoulder instability operated by the open procedure of Lartaiet in our service. Results: The mean return to professional sports was 93.5 days. The mean time of surgery in relation to the first dislocation was 12.4 months. Each athlete had 4.3 shoulder dislocations until the procedure was performed. The rate of recurrence was zero and subluxation was not observed. Conclusion: The Latarjet procedure allowed all professional athletes to return to competitive activities quickly, without dislocations and subluxation, negative seizure and without complications during follow-up. Level of evidence IV, Case series.

Keywords: Anterior Shoulder Instability. Soccer. Shoulder Dislocation.

RESUMO

A instabilidade glenoumeral anterior é uma frequente causa de afastamento dos jogadores de futebol profissional, redução do desempenho e recuperação prolongada. Os jogadores são submetidos ao contato físico intenso e ao alto desempenho, sendo assim necessário atingir menores taxas de recidiva após a correção cirúrgica e retorno ao esporte de forma mais rápida. Objetivo: Avaliar jogadores de futebol profissionais tratados pela técnica de Lartajet com análise da taxa e tempo de retorno às atividades esportivas, complicações ou falhas. Métodos: Análise entre 2010 a 2018 de dez jogadores de futebol que estão atuando em clubes profissionais, diagnosticados por instabilidade anterior do ombro operados pelo procedimento aberto de Lartajet em nosso serviço. Resultados: A média de retorno ao esporte profissional foi de 93,5 dias. A média de tempo da cirurgia em relação ao primeiro episódio de luxação foi de 12,4 meses. Cada atleta teve 4,3 luxações de ombro até o procedimento ser realizado. A taxa de recidivas foi zero e não foi observada subluxação. Conclusão: O procedimento Latarjet propiciou que todos os atletas profissionais de futebol retornassem às atividades competitivas de maneira rápida, sem recidivas das luxações e subluxações e sem complicações durante o acompanhamento realizado. Nível de evidência IV, Séries de casos.

Descritores: Instabilidade Anterior do Ombro. Futebol. Luxação do Ombro.

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INTRODUCTION

Professional soccer athletes present high risk for traumatic shoulder dislocations. Injuries have become a growing problem recently; the physical demands of the game, the higher speed of athletes and muscle strength are reasons that explain the increase in trauma and its associated energy.¹ About 2% of sports injuries in professionals from European teams were linked to the shoulder from 2001 to 2008, but recent studies have shown a total increase of 3.3% and from 35% in the 2006/2007 season to 89% in 2009/2010.²

Anterior glenohumeral instability is a frequent cause of professionals' removal from work, reduced performance and prolonged recovery.³ Several techniques have been proposed to restore stability, function and prevent the development of glenohumeral instability, especially when it comes to athletes with high demand and professionals.⁴ The arthroscopic Bankart repair is a therapeutic option with excellent results in non-athletes but higher failure rates in practitioners of professional contact sports athletes.⁵ Thus, the Lartajet procedure is a viable option for arthroscopic repair failure, in bipolar lesions and when there is a high probability of recurrence.⁶

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

The study was developed at Universidade Federal de São Paulo (UNIFESP), Department of Orthopedics and Traumatology, Sports Traumatology Center (CETE), São Paulo, SP, Brazil. Correspondence: Guilherme Augusto Stirma. Rua Arruda Alvim, 297, Apartamento 205, São Paulo, SP, Brazil, 05410020. guilhermeaugusto89@hotmail.com



The results of open procedures are higher when compared with the arthroscopic ones in high-risk sports athletes⁷; however, few studies show bone block results related to athletic activity, in this case, soccer. The objective of this study was to assess professional soccer players treated by the Lartajet technique, analyzing the rate and time of return to sports activities, complications or failures.

METHODS

After a retrospective analysis of medical records between 2010 and 2018, professional soccer players diagnosed and followed by anterior shoulder instability who were operated by Lartajet open procedure were evaluated in our service. All patients signed the free and informed consent form, with the number 09628919.2.0000,5505 of the approval by the ethics committee.

The analysis included sex, age, field position, follow-up time, previous surgical procedure on the same shoulder, number of dislocations, time from the first dislocation to surgery, recurrence, complications and time of return to sport.

Patients with multidirectional instability, reparable and irreparable rotator cuff rupture, SLAP, biceps tendon pathology or acromioclavicular joint involvement requiring surgical intervention were not included. The inclusion criteria were: preoperative positive seizure, bipolar injuries, history of dislocations and professional soccer contract.

The surgical Lartajet technique was chosen because of a lower rate of recurrence comparatively with the arthroscopic one in contact sports athletes^{8,9}, patients' profession, bipolar injuries, the surgeon's greater experience and treatment of recurrences by the Bankart repair technique.

The surgery is performed with the patient in a beach chair, access of 6 cm below the coracoid by the axillary line, identification and removal of the cephalic vein, exposure and osteotomy of the coracoid at its base, preparation of the graft with debridement of soft tissues. Horizontal access through the subscapularis and longitudinal muscle of the capsule joint. The debridement and removal of the anteroinferior labrum is performed. The graft is then fixed to the glenoid with two spongy screws of 3.5mm, partial thread with washers (Figures 1 and 2). The subscapularis suture is always lateral to the entry of the conjoint tendon to avoid reduction in lateral rotation.



Figure 1. Postoperative (AP incidence)



Figure 2. Postoperative (scapular profile).

The patients use sling for two weeks. Physical therapy was performed at the institution, going from passive movements to active movements after one month. They performed Isometric rotator cuff exercises from the fourth to the sixth week and global isotonics from the fourth-sixth week on, as well as the strengthening of the scapula stabilizers, avoiding carrying weights and lateral rotation with 90°/90° abduction until the eighth week. The evolution is expected to occur from the 4th week up to the 12th week with wide and painless range of motion (ROM). After achieving wide and painless ROM, V strength grade of all intrinsic and extrinsic shoulder muscles, the patient returns to work.

RESULTS

Ten male professional players with a mean age of 22.9 years (ranging from 16 to 28 years) were observed. In three cases (30%) the indication of Latarjet surgery was due to failure in arthroscopic treatment (Bankart repair). The mean of return to sports was 93.5 days, ranging from 60 to 120 days. No acute and chronic complications were observed. No case evolved with positive seizure test in the postoperative period.

The rate of recurrence was zero and subluxation was not observed. In relation to the first dislocation, the mean time of surgery was 12.4 months. Each athlete had 4.3 shoulder dislocations until the procedure was performed. During the follow-up, all patients' motion arc with elevation, abduction, lateral and medial rotation reached the same amplitude. Four (40%) players were strikers, two (20%) were full-backs, two (20%) were defensive midfielders, one (10%) was central-midfielder and one (10%) was defender. The mean follow-up time was 1,251 days. There were no cases of glenohumeral arthrosis (Table 1).

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Table 1. Data of the professional athletes.									
Sex	Age	Position	Follow-Up	Complications	Return to Sport	Failure	Previous Arthroscopy	First Dislocation-Surgery	Dislocations until Surgery
М	28	Defensive Midfielder	70 months	None	3 months None No 24 months		24 months	10	
М	25	Defender	12 months	None	2 months and 5 days	None	No	1 month	2
М	24	Defensive Midfielder	10 months	None	2 months and 10 days	None	No	2 months	2
М	25	Striker	13 months	None	2 months and 14 days	None	No	6 months	4
М	16	Striker	3 months	None	2 months	None No 4 months		6	
М	26	Central-Midfielder	72 months	None	3 months	3 months None Yes 24 months		3	
М	17	Full-Back	38 months	None	3 months and 10 days	nd 10 days None Yes 8 months		8 months	4
М	27	Striker	58 months	None	3 months and 28 days	months and 28 days None No 7 months		7 months	4
М	22	Striker	52 months	None	4 months	None No 36 months		36 months	6
М	19	Full-Back	72 months	None	4 months and 28 days	None	Yes	12 months	2

DISCUSSION

The current literature shows that professional athletes present a high recurrence after arthroscopic treatment of anterior shoulder instability in contact sports. ¹⁰ In our sample, 30% of the patients underwent capsuloplasty, Bankart repair in another service and evolved with failure. Bacilla et al. ¹¹ found 10% of the new dislocations with only 18 months of follow-up; however, they were football athletes, and the arthroscopic procedures were performed by the author himself.

The values found for non-athletes cannot be compared with and analyzed for athletes. In initial studies on non-athletes, authors showed high numbers in the failure of arthroscopic Bankart repair, Flinkkila et al.¹⁰ 19%, Voo et al.¹² 18%. However, after the advance of the arthroscopic procedure, some recent cases found similar and even lower values for failure rate. Milchteim et al.¹³ showed 6.4% in contact sports athletes with a return of 82.5% with the same performance level.

For an athlete, being away from sports practice in addition to reduced performance and prolonged recovery can cause devastating effects on their career. Hovelius et al.8 analyzed, in a comparative study (Lartajet versus Bankart repair), 185 shoulders in which Lartajet presented better postoperative stability and lower complication rates. An et al.9, in meta-analysis, described that Lartajet still has lower failure rates and better lateral rotation compared with the Bankart repair.9 Although the arthroscopic Bankart repair shows similar comparative values of reluxations in some case series, Lartajet still contains better clinical results and lower dislocation and subluxation rates after long-term follow-up, and it offers greater safety for athletes to resume their activities. 4,3,13,14 For strikers, central-midfielders, defenders and full-backs, the instability can cause major problems for their careers. The residual pain, ROM loss and positive seizure are factors that can lead to fear of new dislocations due to falls and physical contact, reduced professional performance and inefficiency in throw-ins. Ekstrand et al. 15 reported that shoulder dislocation represents the most serious upper limb injury in soccer, with an average leave time of 41 days. They have shown that the absence of training and games is twice higher for goalkeepers than for field players due to throw-ins, direct and indirect shoulder traumas for falls and defenses. The injuries in the upper limb in goalkeepers can reach frequent values up to 5x more, compared with other soccer positions.1

Although this study is unique and the results differ from those of Cerciello et al.³ who studied 28 professional goalkeepers treated surgically and observed a 12.5% rate of recurrence, other analyses were verified with contact athletes, in which case series respect and match our low failure rate after the open Lartajet

procedure.^{11,15} Privitera et al.⁵ described 8% and 14% of patients with postoperative instability perception (positive seizure), but without dislocation; however, from the cases analyzed, only six (8%) were soccer players.

Neyton et al. in a 12-year follow-up after the surgical procedure in Rugby players did not find subluxation or anterior glenohumeral dislocation.¹⁶

In relation to the first dislocation, the mean time of surgery was 12.4 months. Each athlete had 4.3 shoulder dislocations until the procedure was performed. Cerciello et al.³ showed that the goalkeepers waited 2.2 dislocations, since they rely more on their shoulder than strikers, mid-fielders, defenders and full-backs present in our study and cannot wait to undergo surgery after the soccer season.

Positive seizure in the postoperative clinical evaluation was not obtained. Neyton et al. found 14% in rugby players through the Lartajet procedure. 16

The mean time of return to sport was 93.5 days, with 100% return of players. Hart and Funk¹⁷ after the treatment of 25 soccer players by arthroscopic technique and five by Latarjet surgery returned to the fields after 81.9 days, on average, with no significant difference between goalkeepers and field players and without recurrences after 91 weeks of follow-up. Cerciello et al.³ reported excellent results for bone block (Latarjet) in a sample of 26 soccer players (28 shoulders). Only one player did not return to soccer. The mean return time was longer than in our study, 150 days. Eighteen players (20 shoulders, 71% of cases) returned to the same level. A goalkeeper suffered a recurrence 74 months after surgery.³

In comparison with other sports, we obtained a superior percentage of return to sports. Neyton et al.¹⁶ showed that Rugby players reached 67%, Bonnevialle et al.¹⁶, 97%, and Larrain et al.¹⁸, 84%. Privitera et al.⁵ obtained 72% return to activities, 63% at the same previous competitive level; however, the sample of the study consisted of higher-risk sports (football, hockey, skiing, snowboarding, martial arts, wrestling, boxing).

It is of paramount importance to highlight the success of the Lartajet procedure in high-performance athletes, not only due to early functional improvement, lower chance of postoperative seizure, but because they are submitted to early return to professional activities, small rest time between games, intense physical contact, need to return early to high performance level and due to lower rates of recurrence.

This study has some limitations, because it is a retrospective analysis, a unique surgical technique. Only 10 patients were studied, but it is noteworthy that they are professional athletes with long follow-up time.

CONCLUSION

This study showed that the Latarjet procedure in the treatment of recurrent anterior instability in professional soccer players is effective. The Latarjet procedure allowed all professional athletes to return to sports quickly, without dislocations and subluxation, negative seizure and no complications during the follow-up.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. GAS: authorship, writing, review, intellectual concept of the article and preparation of the entire research project. EBSL: authorship, writing, review and intellectual concept of the article; DHC: authorship, writing, review and intellectual concept of the article; PSB: authorship and review of the article; CVA: authorship, writing, review and intellectual concept of the article; BE: authorship, writing, review and intellectual concept of the article.

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ORIGINAL ARTICLE

TREATMENT OF MIDSHAFT CLAVICLE FRACTURE WITH SUPERIOR PLATE PLACEMENT

TRATAMENTO PARA FRATURA DA DIÁFISE DA CLAVÍCULA COM INSERÇÃO DE PLACA ÓSSEA SUPERIOR

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ABSTRACT

Objective: To evaluate the late clinical and radiological results of patients had locking plate anatomically compatible from superior surface and muscle cover on plate due to clavicle mid-region. Materials and Methods: Forty patients were included retrospectively. Patients had a routine right shoulder anterior posterior graph after examination. The results were assessed by returning to the patient's daily activities, Constant score, the Disability of the Arm, and Shoulder and Hand scoring, followed by radiological and clinical examination. Results: Fourteen (35%) patients were female and 26 (65%) were male. The mean age was 36.2 years. Twenty-six patients had right clavicle fracture and 14 patients had left. Twenty-three fractures were type 2B1 and 17 fractures were type 2B2. Mean follow-up time was 36.4 months. Radiologic union was at a mean of 9.1 \pm 1.3 weeks. All patients had excellent results. The mean Constant score was 97.2 \pm 1.8, the mean Disability of the Arm, and Shoulder and Hand score was 3.8 \pm 2.4. Conclusion: It is possible to obtain complete union with high patient satisfaction by avoiding the complications and difficulties of the conservative treatment with the use of the anatomically compatible locking plates in superior fixation and our surgical dissection. Level of Evidence III, Retrospective Case controlled study.

Keywords: Clavicle. Midshaft Clavicle Fracture. Osteosynthesis. Plate Fixation. Superior Placement.

RESUMO

Objetivo: Avaliar os resultados clínicos e radiológicos tardios dos pacientes com placa óssea de trava anatomicamente compatível com a superfície superior e a cobertura muscular na placa devido à região média da clavícula. Materiais e Métodos: Quarenta pacientes foram incluídos retrospectivamente. Os pacientes apresentaram um gráfico ântero-posterior de rotina do ombro direito após o exame. Os resultados foram avaliados retornando às atividades diárias do paciente, escore de Constant, incapacidade do braço e escores de ombro e mão, seguidos de exame clínico e radiológico. Resultados: Quatorze (35%) pacientes eram do sexo feminino e 26 (65%) do sexo masculino. A idade média foi de 36,2 anos. Vinte e seis pacientes tiveram fratura da clavícula direita e 14 pacientes saíram. Vinte e três fraturas foram do tipo 2B1 e 17 fraturas do tipo 2B2. O tempo médio de acompanhamento foi de 36,4 meses. A união radiológica foi em média de 9,1 \pm 1,3 semanas. Todos os pacientes tiveram excelentes resultados. A pontuação média constante foi de 97.2 ± 1.8. a média de incapacidade do braço e a pontuação do ombro e da mão foi de 3,8 ± 2,4. Conclusão: É possível obter união completa com alta satisfação do paciente, evitando as complicações e dificuldades do tratamento conservador com o uso das placas ósseas de trava anatomicamente compatíveis na fixação superior e na nossa dissecção cirúrgica. **Nível de** evidência III, Estudo retrospectivo controlado por caso.

Descritores: Clavícula. Fratura de Clavícula de Eixo Intermediário. Fixação de Placas Ósseas. Colocação Superior.

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INTRODUCTION

Clavicle fracture is a common fracture and constitutes approximately 4% of all fractures in adults.1 The location of the clavicle fracture is approximately 75% clavicular and 1/3 middle part due to its thin form and direct contact with the skin. Clavicular injuries can lead to abnormal biomechanical stresses and long-term disability along the pectoral girdle.^{2,3}

Conservative treatment and open reduction and plate fixation are used in the treatment of the currently displaced midshaft clavicle fractures. Conservative treatment was reported to have a higher union rate than open reduction and plate fixation.4 However, patients treated with open reduction and plate fixation have a better outcome than conservative treatments according to functional scores. 5 Despite the reduced pain and improved

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functional recovery in patients with displaced midclavicular fractures treated with open reduction and plate fixation, ^{6,7} infection due to the graft of a large soft tissue can lead to complications such as numbness on the skin, nonunion, delayed union, and enlarged scar tissue.⁸⁻¹⁰

Treatment of these fractures with open reduction and internal fixation preserves from nonunion, symptomatic malunion, shortening and deformity. Studies have shown that the superior plate is biomechanically better than the anterior plate and that the locked screws are better than the unlocked ones.¹¹⁻¹³ But superior resident plates are usually palpable under the skin and can cause skin irritation.¹⁴⁻¹⁹

In this study, we sought to evaluate the late clinical and radiological results of patients who underwent locking plate fixation anatomically compatible in the superior surface and muscle cover on plate due to the mid-region of the clavicle.

METHODS

Forty patients who underwent surgery between May 2009 and September 2016 with mid-diaphyseal clavicle fracture were included retrospectively in our study. All patients participating in the study signed an informed consent form. The study was conducted in agreement with the Declaration of Helsinki. Approval for our study was obtained from the institutional review board. Our study is in line with the STROCSS criteria. Displacement or shortness of more than 20 mm in patients with segmental fractures with multiple fractures or disintegration, as well as conservative treatment intolerance were indicated for surgical treatment. The study included only patients with isolated mid-diaphyseal clavicle fractures.²⁰ Patients with pathologic fractures, open fractures, those with neurovascular injuries and/ or 2-week fractures were excluded. All patients had chest radiography to exclude possible cote and scapular injury. After diagnosis, patients were prepared for surgery by applying a shoulder-arm sling.

All patients were assessed with a routine right-shoulder anterior-posterior graph after a detailed physical examination. During the follow-up period, the results were clinically assessed by the patient's return to daily activities, Constant score, the Disability of the Arm, and Shoulder and Hand scoring, followed by radiological and clinical examination of the fracture union.

Surgical Technique

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Patients were prepared for operation in beach-chair position under general or regional anesthesia. Skin incision was made approximately 1 cm below the clavicle lower level (infraclavicular incision). The subcutaneous tissue was prepared without dissecting, and the preparation of skin-subcutaneous and platysma muscle together in a flap style, clavicle anterior and superior sides were elevated by approaching to proximal. Thus, the clavipectoral fascia was scrapped over the clavicle to the extent that was required and the fraction was reduced by avoiding an aggressive dissection. Temporary detection with K-wires was performed when necessary. In the case of the butterfly fragment, these fragments were temporarily attached to the main part with absorbable sutures (Vicryl no: 0). Rigid fixation by applying a 3.5 mm locking screw (LCP Superior Anterior Clavicle Plate) and a preformed clavicle plate with a low contact surface were performed for the all patients. At the end of the operation, clavipectoral fascia was repaired to cover the plate. Flap prepared initially from skin-subcutaneous and muscle, was completely closed on the plate in such a way that it was completely muscular (Figure 1).

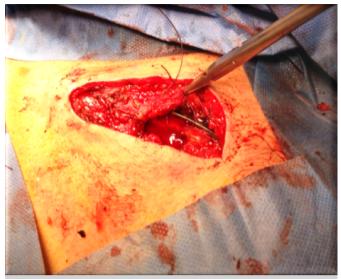


Figure 1. Muscular flap.

Post-operative protocol

Shoulder pendular exercises were started for patients on the first day after the surgery. Antibiotic prophylaxis continued for 2 days after the operation. Surgical wound was checked on the 3rd day, and the patients were discharged with arm sling. Patients were called for control at 4, 8 and 12 weeks postoperatively. In the fourth week, exercises of the shoulder joint movement were started when the use of the arm sling were interrupted. The radiologic examinations required to evaluate the postoperative fracture were examined by an orthopedic surgeon and a radiologist blinded for the study. Radiographically, more than 50% of the fracture lines were classified as complete union. Union was assessed by bone bridge formation between fracture fragments, sensitivity on the fracture line and clinical examination of the shoulder joint movements. The delayed union was determined by the initial radiologic callus formation that was seen after 24 weeks, and the nonunion was determined by the absence of callus and pathological movement after 24 weeks.²¹ Shoulder strengthening exercises have been initiated for patients that had union symptoms. Contact sports were allowed three months after the surgery.

NCSS 2007 version software (Number Cruncher Statistical System—Kaysville, Utah, USA) was used for the statistical analysis. While evaluating the data from the study, apart from using descriptive statistical methods (Mean, Standard Deviation, Median, Frequency, Rate, Minimum, Maximum), Mann Whitney U test was used for the two group comparison for the parameters with abnormal distribution. Fisher-Freeman-Halton test, Fisher's Exact test and Yates' Continuity Correction test (Yates' correction chi square) were used to compare qualitative data. Wilcoxon Signed Ranks test was used for intra-group comparisons of abnormal parameters. Significance was evaluated considering $\rho < 0.05$.

RESULTS

In total, 14 patients (35%) were women and 26 were men (65%). The mean age of the patients participating in the study was 36.2 (range: 22-59). Twenty-six patients had clavicle fracture on the right side and 14 patients, on the left side. According to Robinson's classification, 23 fractures were type 2B1 and 17 fractures were type 2B2. Mean

follow-up time was 36.4 months (range: 24-95). Fractures occurred in 20 patients due to traffic accidents, in 11 patients due to falls and in 9 patients due to sports injuries, as shown in Table 1.

Table 1. Information on patients and fractures.						
Characteristic	Total	%				
Sex						
Women	14	35				
Men	26	65				
Age	36.2					
Side						
Right	26	65				
Left	14	35				
Fracture type						
Type 2B1	23	57.5				
Type 2B2	17	42.5				
Injury mechanism						
Traffic Accident	20	50				
Fall	11	27.5				
Sports Injury	9	22.5				

Radiologic complete union was achieved in all patients at a mean of 9.1 \pm 1.3 weeks, (range: 8-13 weeks). No callus formation was observed in the fracture area of any patient. No complications such as infection or detection failure were found in the early or late period. In total, two patients described the feeling of irritation due to the plate and 7 patients were cosmetically disturbed by the incision scar. None of the patients had major complications such as infection, plate rupture or neurovascular injury. All patients reported excellent results in terms of shoulder functions. At the end of the follow-up period, the mean Constant score was found to be 97.2 \pm 1.8 (range: 95-100), mean Disability of the Arm, Shoulder and Hand score was 3.8 \pm 2.4 (range: 0-10), as shown in Table 2. The mean duration of the surgery was 52.2 minutes.

Table 2. Functional score results.						
Outcome score	Post-operative					
Constant score	97.2					
Disability of the Arm, Shoulder and Hand scoring	3.8					

DISCUSSION

Numerous studies seeking an optimal treatment in the treatment of mid-diaphyseal clavicle fractures have been increasingly conducted. Mid-diaphyseal clavicle fractures were traditionally treated conservatively; however, recent studies show that nonunion, malunion, and poor shoulder functions are seen together with conservative treatment of displaced mid-diaphyseal fractures. In a comparative study between plate-treated and conservatively treated displaced mid-diaphyseal fractures, high functional outcomes, low nonunion and malunion results were found in patients treated surgically.²² Patients treated with plate fixation recovered faster and returned to their previous activity levels, and a risk of developing a symptomatic malunion was reported in conservatively-treated patients. Many other studies also suggest open reduction and fixation in the treatment of displaced mid-diaphyseal fractures, particularly those with 20 mm shortening, 100% displacement and bone defect. 23-25 Despite the good stability, compression and mechanical fixation with plate fixation, complications such as infection and formation of scar tissue were found. Although the clavicle fixation as an

intramedullary is cosmetically acceptable, complications rates of up to 75% were reported, namely lack of rotational control, the need for a second surgical procedure to remove the implant, skin problems, and implant migration. ^{6,26-28}

Optimal plate fixation for the treatment of mid-diaphyseal clavicle fracture is still controversial. Some studies suggest that anteroinferior plate fixation techniques are better, suggesting that plate prominence is felt less often. However, more soft tissue dissection is required for this plate fixation. In the same study, the authors suggested that the lateral bearing of the plate fixation point and the lateral screws could cause a pull-out in the placement of the superiorly positioned plate in fragmented fractures.²⁹ This is the reason why the fixation due to an unsuccessful reduction was reported as a posterior slide of the support point and a significant force to the lateral load, causing the pull-out of the screws. The sternoclavicular joint created a tension band effect and the support point remained at the fracture fixation point in simple transverse fractures. 30 In our study, 17 patients with Robinson type B2 (partial fracture) had no complications due to plate placement, which can be considered a result of the suitability of the reduction, plate fixation and fixation method for the stabilization rules, as shown in Figure 2.

In an anatomical study, the subclavian artery in the medial half of the clavicle was the closest to the posterior cortex. 31,32 This is the reason why anteroinferior plate fixation can pose a great risk for neurovascular structures in the medial clavicular area. This may be considered a safe fixation method due to the reduction in the risk of a neurovascular injury caused by superior plate detection. Neurovascular injury or other major complications were not detected in any of our patients in our study when super anatomical plate detection was used in surgical treatment.

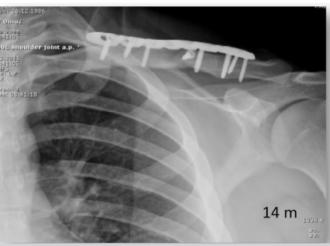


Figure 1. Muscular flap.

A previous study showed that the use of locked plate-screw in fragmented clavicle fractures increased the angular stability and decreased the effect on the bio-alloying of small fractures. ^{21,33} Clinically, plate prominence inferiority due to low profile of anatomically compatible plate in mid-diaphyseal clavicle fractures is low. ³⁴ We also think that the use of preformed anatomically compatible plates in our study reduces the duration of surgery and plate tiredness risk. At the same time, without applying subcutaneous dissection after surgical incision, the approach that we provide as flap with the plate scar can provide a good cover after plate fixation and reduce plate prominence risk.

In a study conducted biomechanically, the anterior, antero-superior, and superior plating types were found to be the most important

method for detecting axial fracture of superior plate in the detection of midshaft clavicle fractures. In the same study, no difference was found between torsional forces and resistance among all three types of plate fixation.³⁵

Our study has some limitations. First, the study retrospective design was the main limitation, and we also included patients with wide range of age distribution. However, we included similar type of fracture and treated our patients with the same method. Our study may guide further studies on the evaluation of the superior plating treatment due to the clinical outcomes found.

We believe we have achieved excellent results with our study on the fixation of the fracture with our superior plate fixation technique and with an early rehabilitation program applied to all patients. Furthermore, we think that we can minimize the plate prominence risk by providing the muscle flap and plate covering that we used during the surgical approach and adapt the patients to the rehabilitation period, minimizing the complaints of skin irritation in later periods.

CONCLUSION

Complications such as shortening and excessive callus formation can be observed as a result of disintegrated or multi-part midshaft clavicle fractures. It is possible to obtain complete union with high patient satisfaction by avoiding the complications with anatomically compatible locking plates in superior fixation and our surgical dissection.

AUTHORS' CONTRIBUTIONS: Each author made significant individual contributions to this manuscript. BEK: substantial contributions to the conception and design of the study; YO: data acquisition, analysis, and interpretation; REE: final approval of the version to be published and accountability for all aspects of the study, ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

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ORIGINAL ARTICLE

CHANGES IN THE LUMBAR VERTEBRAL SEGMENT RELATED TO THE CAGE POSITION IN TLIF TECHNIQUE

ALTERAÇÕES DO SEGMENTO VERTEBRAL LOMBAR RELACIONADAS À POSIÇÃO DO CAGE NO TLIF

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ABSTRACT

Objective: To evaluate the morphological changes on the intervertebral foramen and segmental lordosis related to the transforaminal lumbar interbody fusion (TLIF) positioning. Methods: PEEK cages were placed in the disc space (L1-S1) of a polyurethane anatomical model. Cages of different heights (8 mm, 10 mm, 12 mm and 14 mm) were positioned in the posterior, medial or anterior part of the vertebral body surface, and the intervertebral foramen and segmental lordosis heights were measured after their insertion. Results: The vertebral foramen height decreased in all positions and heights of the cages in relation to the control. The cage posterior positioning induced a smaller reduction in the vertebral foramen height. Vertebral lordosis tended to increase in relation to the control, and the greatest increase occurred with the cage posterior positioning. Conclusion: Cage positioning induces changes in the intervertebral foramen height and in the vertebral segment lordosis. Cage posterior positioning induces a smaller reduction of the intervertebral foramen height and increases the vertebral segment lordosis. Level of evidence III, Therapeutic study.

Keywords: Spine. Arthrodesis. Biomechanical Phenomena.

RESUMO

Objetivo: Avaliar as alterações morfológicas do forâmen intervertebral e da lordose segmentar relacionadas ao posicionamento do espaçador intersomático na artrodese lombar intersomática transforaminal (TLIF). Métodos: Cages de PEEK foram colocados no espaço discal (L1-S1) de modelo antômico de poliuretana. Os cages de diferentes alturas (8 mm, 10 mm, 12 mm e 14 mm) foram posicionados na parte posterior, média ou anterior da superfície do corpo vertebral e a altura do forame intervertebral e lordose segmentar mensuradas após a sua inserção. Resultados: Foi observado redução da altura do forame vertebral em todos os posicionamentos e alturas dos cages em relação ao controle. O posicionamento posterior do Cage induziu à menor redução da altura do forame vertebral. A lordose do semento vertebral apresentou tendência de aumento em relação ao controle, tendo sido observado a maior tendência com o posicionamento posterior do Cage. Conclusão: O posicionamento do Cage induz a alterações da altura do forame intervertebral e lordose do segmento vertebral. O posicionamento posterior do Cage induz a menor redução da altura do forame intervertebral e aumento da lordose do segmento vertebral. Nível de evidência III, Estudo terapêutico.

Descritores: Coluna Vertebral. Artrodese. Fenômenos Biomecânicos.

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INTRODUCTION

Transforaminal lumbar interbody fusion (TLIF) has been widely used for the treatment of diseases affecting the lumbar spine, especially degenerative diseases. ¹⁻³ Restoration or maintenance of the vertebral segment lordosis has guided surgical treatment due to its influence on clinical outcomes. ³⁻⁶ Design and positioning

of the vertebral spacers used in TLIF influence the operated vertebral segment lordosis. Cages with lordotic angulation can maintain or restore lordosis due to its geometric shape. ⁷ Cages that lack angulation also influence the vertebral segment lordosis depending on their position on the vertebra body surface (anterior, medial or posterior). ⁸⁻¹⁰

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

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Although Cage positioning in the vertebral segment lordosis is recognizably important^{11,12}, there is no consensus on the spacer proper positioning on the body surface. According to Kwon et al.¹³, a spacer should be used in the anterior part of the vertebral endplate, achieving greater segment stability and increasing the lordosis of the vertebral segment operated. However, Faundez et al.⁸ found that the spacer positioning did not cause a difference in lumbar lordosis, result corroborated by Ould-Slimane et al.¹⁰

Cage positioning also influences intervertebral foramen.⁹ The contralateral foramen stenosis after performing open TLIF has been related to segmental lordosis hypercorrection.^{14,15} The incidence of contralateral radiculopathy, secondary to the reduction of vertebral foramen dimensions after TLIF, is 5.9%.¹⁴ Contralateral radiculopathy after TLIF has been reported after the open or percutaneous approach.¹⁴⁻¹⁶ The precise compression mechanism of contralateral vertebral

The precise compression mechanism of contralateral vertebral foramen is not completely clear and might be related to increased segmental lordosis during surgery. 9,14 However, indirect decompression by increasing the intervertebral foramen height can be obtained by restoring the intervertebral disc height using Cage. 9 Although clinical reports describe morphological changes in lumbar intervertebral foramens and the influence of the spacers position on the segmental lordosis after TLIF 9,11,12, literature lacks reports of bench tests on the influence of vertebral spacers on the height of the intervertebral foramen and on lordosis of the vertebral segment operated.

This study aimed to evaluate height change of intervertebral foramen and of segmental lordosis related to Cage positioning after transforaminal lumbar interbody fusion (TLIF).

METHODS

In the study, an anatomical model of lumbar spine with vertebrae made with solid foam of low–density polyurethane and polyethylene intervertebral disc (Nacional Ossos®) was used. Experiments used PEEK (polyether ether ketone) spacers Fusimax TLP® model (Víncula, Brazil), 8 mm wide, 29 mm long, 8 mm, 10 mm, 12 mm and 14 mm high, and non-angulated, used for transforaminal lumbar interbody fusion (TLIF) (Figure 1).



Figure 1. Photo of Cage in height ascending order (8 mm, 10 mm, 12 mm and 14 mm)

The experimental model consisted in removing the intervertebral disc, performing bilateral cataract surgery, positioning the intervertebral spacer, applying compression in the vertebral segment, and bilaterally measuring lordosis and craniocaudal diameter of the intervertebral foramen. Spacers 8 mm, 10 mm, 12 mm and 14 mm high were inserted in all disc spaces, except for L1-L2, which could not use the 14 mm spacer because of their height. The study variables were: the positioning of intervertebral spacers (at the posterior, medial or anterior part of the vertebral body upper surface) (Figure 2), and the intervertebral spacers height (8 mm, 10 mm, 12 mm and 14 mm) (Figure 1). Compression of the vertebral segment was performed with compression clamps, and the compression limit was the bone contact of the posterior elements, which was a mechanical obstacle to additionally apply compression in the vertebral segment.

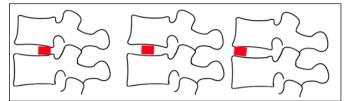


Figure 2. Illustration of the spacer positioning on the vertebral body upper surface (posterior, medial and anterior).

The vertebral segment lordosis was evaluated by measuring the angle formed by the threaded Steinmann pins put inside the vertebral pedicles. The angle was measured before removing the intervertebral disc and after placing the intervertebral spacer and applying compression in the vertebral segment (Figure 3). The craniocaudal diameter of the intervertebral foramen was evaluated by direct measurement with caliper, defined as foramen height. It was bilaterally measured before removing the intervertebral disc and after placing the spacer and applying compression in the vertebral segment. This study was not submitted to the Ethics and Research Committee as it is an experimental study that did not involve human beings at any stage of its realization. For this reason, the Term of Free and Informed Consent was not applied.

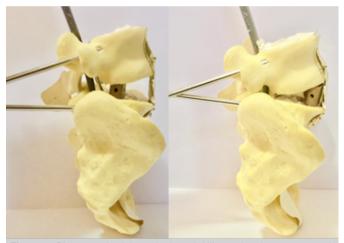


Figure 3. Photograph of the spinal model illustrating the spacer positioning on the posterior (left) and anterior (right) parts of the vertebral body surface.

STATISTICAL ANALYSIS

Statistical analysis was performed using the Kolmogorov–Smirnov test to determine the normality of each group sample. Mood's median test, a nonparametric test, was used to evaluate the influence of intervertebral spacers positioning and height on the intervertebral segment lordosis and intervertebral foramen height, with significance level $p < 0.05. \ SAS Institute Inc., SAS/STAT® User's Guide, Version 9.4, Cary, NC: SAS Institute Inc., 2012 was used to perform statistical analysis.$

RESULTS

The intervertebral foramen height reduced in relation to the values of the control group in all the tests (Mood's test p < 0.05). The intervertebral foramen height reduced regardless of the spacers position and height on the vertebra surface (Table 1 and Figure 4). The intervertebral foramen height tended to reduce as the spacer shifted to the anterior position of the vertebral body surface, but without statistical difference (Figures 4-5).

Table 1. Height values of the foramen and vertebral lordosis in the different experimental groups

		Foramen Height (mm)	Lordosis in Degrees		
Cage	Group	Mean (standard deviation)	Mean (standard deviation)		
	Anterior	11.70 1.75*	9.80 2.28		
8	Medial	11.80 1.75*	11.80 2.49		
	Posterior	13.60 1.78*	13.40 4.88		
	Anterior	12.88 2.17*	10.80 3.27		
10	Medial	13.20 1.92*	13.00 5.39		
	Posterior	14.90 1.56*	13.60 5.41		
	Anterior	13.50 2.12*	13.00 6.28		
12	Medial	13.60 2.19*	15.00 6.48		
	Posterior	16.30 1.48*	16.20 6.87		
	Anterior	15.25 2.90*	17.00 6.16		
14	Medial	17.00 2.61*	17.75 7.68		
	Posterior	19.00 1.47*	18.75 7.63		

^{*:} Statistical difference (p < 0.05) in relation to the control group.

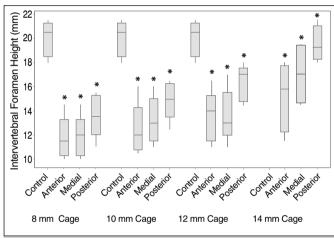


Figure 4. Height values of the vertebral foramen in the different spacers and positioning. Asterisk indicates statistical difference in relation to the control.

In the posterior positioning of the vertebral body surface, the 14 mm high spacer reduced less the intervertebral foramen height with statistical significance (Mood's test p < 0.05) when compared with the other spacers with smaller height in the same position.

The vertebral segment lordosis increased in relation to the control in all the variables (spacer positioning in relation to the body surface and spacer height). The spacer posterior positioning on the vertebral body surface and the use of a spacer with increased height tended to obtain higher values of the segment lordosis in which the TLIF was performed. (Table 1 and Figure 5)

The analysis of the results, considering only the use of the vertebral spacer of height close to the intervertebral disc height (spacer height 1 mm lower than disc height), is represented in Table 2.

The use of spacer of height close to the intervertebral disc height showed that the highest value of the vertebral segment lordosis was observed with the spacer posterior positioning. The spacer posterior positioning in this situation was the one that least reduced the intervertebral foramen height.

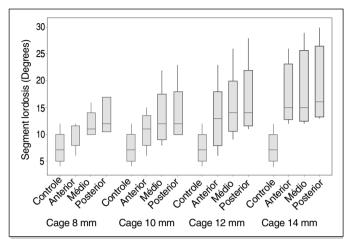


Figure 5. Segmental lordosis values with the use of the different spacers in the different positions.

Table 2. Height values of intervertebral foramen and of segmental lordosis with the use of the vertebral spacer at height close to the intervertebral disc height.

			Foramen Height (mm)			Lo	rdosis	in Deg	rees	
Segment	DH	SH	Post.	Med.	Ant.	Cont.	Post.	Med.	Ant.	Cont.
L1/L2	13	12	17	13	14	18	11	9	6	4
L2/L3	15	14	19	15	17	20.5	13	12	12	6
L3/L4	15	14	18	14.5	14.5	21	16	14	15	8
L4/L5	15	14	19.5	19.5	18	21.5	16	16	15	7
L5/S1	15	14	21.5	19	11.5	19	30	29	26	12

DH: Disc height; SH: Spacer height (mm); Post.: Posterior; Med.: Medial; Ant.: Anterior; Cont.: Control.

The experiment results were validated using trigonometric principles, in which the highest angular value of the vertebral segment was observed with the spacers posterior positioning (Figure 6). We considered "A" as the height of the anterior spacer, "P" the height of the posterior spacer, "d" the distance from the posterior edge of the vertebral body (in the media line) to the posterior edge of the spacer (in the media line), and angle "L" as angle of the segmental lordosis presented. Thus, the formula $A = P + (d \times Sin L)$ allows to demonstrate that the same degree of segmental lordosis was obtained with spacers of different heights positioned in the anterior or posterior part of the vertebral body. For example, the 11.22 mm high anterior spacer and the 8 mm high posterior spacer would produce the same segmental lordosis.

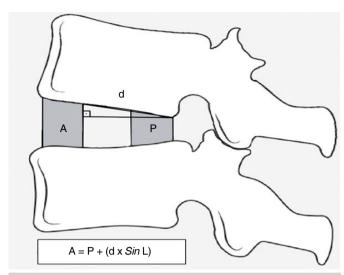


Figure 6. Formula illustration. A: Anterior Cage; P: Posterior Cage; D: Distance from the posterior limit of the posterior cage to the posterior limit of the anterior cage; L: Segment lordosis angle; Sin: Sine.

DISCUSSION

The position of kidney-type spacers in TLIF procedures induces morphological changes in intervertebral foramen and in the lordosis of the operated segment. Contralateral radiculopathy after TLIF is reported ranging from 2% to 8.5% after TLIF-MIS^{16,17} and 1.9% to 5.9% after open TLIF¹⁴⁻¹⁶ and drew attention to changes in intervertebral foramen after this procedure. Contralateral foraminal stenosis is the most frequent cause of contralateral radiculopathy after the use of a unilateral TLIF. Other factors such as poor screw positioning, disc herniation and hematoma were also reported.¹⁴ In our study, intervertebral foramen height reduction with statistical significance was observed in all the spacers. However, it should be considered that most of the spacers was smaller than the control disc. The original disc height could not be restored with smaller spacers, but the spacers positioning influenced the reduction of the intervertebral foramen height (Table 2). The spacer posterior positioning induced the lower reduction in the intervertebral foramen height in different sizes of spacers. Iwata et al.9 also found this result and showed a significant increase in the foramen height with the posterior positioning. The analysis of the results considering only the values corresponding to the spacer height according to the control disc height also showed a tendency of more correction of the segmental lordosis and less reduction in the intervertebral foramen height. The use of the spacer with height close to the intervertebral disc height is similar to the clinical use of spacers, which avoids spacers with superior or inferior height than the intervertebral disc height. Although no statistical difference was seen between the spacer positions on the intervertebral foramen height, the observed tendency is for its lower reduction with posterior positioning. The lower reduction in the intervertebral foramen height with posterior positioning is clinically relevant, because contralateral radiculopathy can be a result of failure to obtain indirect decompression. 14-16 According to our findings, restoring the disc height should be enough to allow the contralateral foramen indirect decompression with the appropriate spacer height and its posterior position. Contralateral foramen indirect decompression in TLIF depends on the spacer height and position.

Originally, the TLIF technique was described to use two titanium spacers in the mid or posterior third of the intervertebral space and fill with bone graft anteriorly behind the anterior longitudinal ligament. Spacers must provide initial distraction and segmental stability, as well as the support of axial loads.¹ Biomechanics studies suggested anteriorly positioning spacers would result in better load sharing and increase stability.^{8,18} Although spacers anterior positioning can improve the instrumentation stiffness of the vertebral segment, it reduces the intervertebral foramen height, causing contralateral intervertebral foramen stenosis. *In vitro* mechanical studies presented a different conclusion, recommending the posterolateral positioning of spacers used in the TLIF to obtain better mechanical stability and high fusion consolidation rates.¹9

The ideal alignment of the lumbar spine sagittal plane is still unknown. However, the positive correlation between reconstruction or maintenance of lumbar lordosis and clinical outcomes has been widely reported.^{5,20} To avoid "flatback syndrome", segmental lordoses must be maintained or reconstructed.

The increase in lordosis in relation to control values occurred with the use of spacers of different heights, as well as in their location. Spacers located in the posterior position on the vertebral endplate tended to obtain greater lordosis. Production of segmental lordosis is associated with decreased intervertebral foramen height. A negative correlation is visible between increased segmental lordotic angle and changes in foraminal morphology and in transverse area of intervertebral foramen. The increase in lordosis during TLIF may affect the contralateral foramen. The segmental lordotic angle is significantly higher in symptomatic patients with contralateral radiculopathy when compared with asymptomatic patients. The segmental patients.

The analysis of the results must consider that the model has different characteristics from those biological and biomechanical lumbar spine characteristics. Ligaments and other structures, part of the lumbar spine biomechanical properties, are absent in the artificial model. The results reflect only the geometric changes in the model after inserting the Cage in the different positions. However, they open the perspective for a critical analysis of changes induced by intervertebral spacers, as well as the motivation to study these changes using human vertebrae for more accurate observation of changes induced by vertebral spacers.

The spacer must be able to restore the intervertebral disc height and maintain or restore the segmental lordosis. According to the results of our study, spacers should be placed in the posterior part of the spine to reach the objectives.

CONCLUSIONS

The results indicate that the posterior positioning of the vertebral spacer induces a lower reduction in the intervertebral foramen height and increased vertebral segment lordosis.

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EPIDEMIOLOGICAL PROFILE OF MOTORCYCLE ACCIDENT VICTIMS IN UNIVERSITY HOSPITAL

PERFIL EPIDEMIOLÓGICO DE VÍTIMAS DE ACIDENTES DE MOTO EM HOSPITAL UNIVERSITÁRIO

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ABSTRACT

Objective: To evaluate the epidemiological profile of motorcycle accident victims in a metropolis with more than one million inhabitants attended in a university hospital of reference in 2017. Methods: a retrospective study through the analysis of medical records of 105 motorcycle accident victims in Campinas (SP) attended in a university hospital of reference and who needed surgical procedure in 2017. Results: 87 patients (82.9%) were men. Multiple fractures were observed in 61 patients (58.1%) and polytrauma was found in 14 patients (13.3%). Tibial fracture was the most frequent, present in 65 cases (61.9%). Exposed fractures occurred in 68 patients (64.7%). Among the polytrauma victims. the most frequent injury was traumatic brain injury (TBI), present in seven patients (6.6%). The mean age was 29.8 years (range 6-63 years). The average length of hospital stay was 14 days (1-87). Conclusion: It is essential to investigate and evaluate the victims' epidemiological profile, as well as the resulting injuries. in order to provide adequate support for the implementation of measures aimed at primary prevention and awareness of the most affected groups. Level of Evidence II, Prognostic studies -Investigating the effect of a patient characteristic on the outcome of disease.

Keywords: Accidents, Traffic. Health Profile. Multiple Trauma. Craniocerebral Trauma.

RESUMO

Objetivo: Avaliar o perfil epidemiológico das vítimas de acidentes motociclísticos ocorridos em uma metrópole com mais de 1 milhão de habitantes atendidas em um hospital universitário de referência no ano de 2017. Métodos: Estudo retrospectivo através da análise de prontuários de 105 vítimas de acidentes motociclísticos ocorridos em Campinas, SP. Brasil, no ano de 2017 atendidas em um hospital universitário de referência que necessitaram de procedimento cirúrgico. Resultados: Oitenta e sete pacientes (82,9%) eram do sexo masculino. Foram verificadas polifraturas em 61 pacientes (58,1%) e politraumatismo em quatorze (13,3%). A fratura de tíbia foi a mais frequente, presente em 65 casos (61,9%). Fraturas expostas ocorreram em 68 pacientes (64,7%). Entre as vítimas de politraumatismo, a lesão mais recorrente foi o traumatismo cranioencefálico (TCE), presente em sete pacientes (6,6%). A média de idade foi 29.8 anos (variando de 6-63 anos). O tempo de internação médio foi 14 dias (1-87). Conclusão: É fundamental investigar e avaliar o perfil epidemiológico das vítimas, assim como os agravos resultantes, de modo a propiciar subsídio adequado para implementação de medidas de prevenção primária e conscientização, especialmente direcionadas para os grupos mais acometidos. Nível de Evidência II, Estudos prognósticos - Investigação do efeito de característica de um paciente sobre o desfecho da doença.

Descritores: Acidentes de Trânsito. Perfil de Saúde. Traumatismo Múltiplo. Traumatismos Craniocerebrais.

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INTRODUCTION

Traffic accidents are considered a major problem for public health in the world, being one of the main causes of morbidity and mortality. According to the World Health Organization (WHO), about 1.2 million people die each year from traffic accidents worldwide, of which

90% are concentrated in low- or medium-development countries.¹ In Brazil, it is estimated more than 980,000 deaths following traffic trauma between 1980 and 2011.²

From 1998 to 2010, the motorcycle fleet growth in Brazil was 490%, jumping from 2,800,000 to 16,500,000, supported by government

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The study conducted at the Pontificia Universidade Católica de Campinas, Centro de Ciências da Vida, Faculdade de Medicina, Campus II.

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policies that stimulated manufacturing, reduced the cost, and enabled the financing of these vehicles. It is important to highlight that, in the same period, the automobiles general fleet growth was 160%, which indicates a growth three times higher in the number of motorcycles.¹

Motorcyclists are one of the most susceptible and likely groups to engage in traffic accidents. When compared with other means of locomotion, having a motorcycle has its benefits, such as easy travel capacity on congested roads, low purchase price and maintenance cost, and fuel economy, in addition to its increasing use in the labor market (motorcycle taxi and deliveries). Therefore, the motorcycle use in Brazil has been increasing significantly.^{1,3}

Associated with this significant increase in motorcycles in circulation, the mortality involving motorcyclists in Brazil grew by 700% from 1998 to 2008, thus being responsible for a substantial increase in the number of hospitalizations in public services. In 2000, 16,692 hospitalizations were recorded. In 2005, this number grew to 30,562 (83%). Thus, the need for new public policies in order to reduce traffic accidents is evident.

Regarding the epidemiological profile of motorcycle accidents, many studies indicate the young male population is the most vulnerable, and head and lower limb injuries are the most prevalent. In addition, obese motorcyclists have longer length of hospital stay and different body injuries when compared with normal weight motorcyclists.⁴⁻⁶ Thus, safety measures, such as the use of appropriate helmets and clothing are extremely important for injury protection, reduced length of hospital stay, prevention of physical disability, and for the economy of social costs, reducing the need for institutional care. 7,8 Therefore, in order to reduce the number of victims involved in motorcycle accidents, traffic accidents should be treated as a health promotion issue, with the development of intersectoral projects to stimulate the participation of the entire population and the adoption of more supportive behaviors, which aim both at traffic education and information on the physical consequences of motorcycle accidents.9 Furthermore, improving the infrastructure of streets and roads is crucial for the proper movement of motor vehicles. This study aims to evaluate the epidemiological profile of motorcycle accident victims that occurred in a metropolis with more than one million inhabitants attended in a university hospital of reference in 2017.

METHODS

This is a retrospective cross-sectional study conducted at the PUC-Campinas Hospital, filed by the Research Ethics Committee with registration on *Plataforma Brasil* under the number 88812818.3.0000.5481, in which the analysis of medical records of 105 patients, who were motorcycle accident victims in Campinas, São Paulo, Brazil, were performed in 2017 (from January to December 2017). The patients were treated primarily in the emergency room of a university hospital of reference and required surgical procedure.

The following characteristics were evaluated: sex, age, length of hospital stay, type and frequency of injuries (fractures, multiple fractures, and polytraumas), and infection occurrence.

Data were analyzed from medical records listed in the Orthopedics and Traumatology service of the PUC-Campinas Hospital. All study participants signed an informed consent form.

RESULTS

Among the 105 analyzed patients, 87 (82.9%) were men and 18 (17.1%) were women. The mean age was 29.8 years (range 6-63 years). Among all victims, 61 (58.1%) had multiple fractures and 14 (13.3%) presented polytrauma. Tibia fracture was the most common,

present in 65 cases (61.9%), followed by femur and fibula fractures, with 30 cases each (28.5%), and radio and humerus fracture, with six cases (11.4%). Exposed fractures occurred in 68 patients (64.7%). Among the polytrauma victims, the most frequent injury was traumatic brain injury (TBI), present in seven patients (6.6%); followed by pulmonary injuries, with six cases (5.7%); urinary tract injury, with four cases (3.8%); and liver, splenic, and testicular injuries, with one case each (1%). Besides, among the polytraumatized patients, 12 of them (11.4%) also suffered multiple fractures. Infections were observed in 49 patients (46.6%). The mean length of hospital stay was 14 days, with a minimum stay of one day and a maximum of 87 days.

DISCUSSION

Data from the literature indicate a predominance of motorcycle accidents involving men, ranging from 79% to 96%. ¹⁰ This study confirmed these data, with a prevalence of 82.9% male patients. The greater involvement of male motorcyclists is related to risky driving behavior and disrespect for the traffic laws, since data indicate most accidents occur due to motorcyclists' carelessness. ^{10,11} Regarding the age group, 63.8% of the patients were aged between 11 and 35 years. In a study conducted in Piauí, 74.4% of those injured were aged 10 to 39 years. ¹¹ Other studies indicate that the predominant victims involved in fatal motorcycle accidents are young people from the age group of 15 to 29 years. ⁴

The higher occurrence of accidents among young people and adolescents is related to relevant socioeconomic factors. First, motorcycles represent an alternative of lower cost, greater agility, and independence for young people when compared with public transportation.4 Associated with this, young people generally present risky driving behavior and have less experience and driving skills.¹⁰ Another relevant point in this study is the presence of underage individuals involved in motorcycle accidents. There were 10 victims aged between 14 and 17 years, and the minimum age determined by Brazilian legislation for drivers' qualification is 18 years old. Data on the position of the victims regarding the accident (driver or passenger) were not collected, but it is believed that among those patients mentioned above, not all were passengers. This fact shows the need for better investigation regarding motorcycle riding by unqualified individuals and its impact on traffic accidents. In a study conducted in the municipality of Campinas, 4 we found that the number of traffic accidents with victims increased after 2004, mainly due to the significant motorcycle fleet growth. Likewise, a mortality growth involving motorcyclists was also observed.

Regarding the injuries found, the most frequent ones were those of the lower limbs, mainly represented by tibia fractures, which were observed in 65 patients (61.9%). Koizumi found that the lower limbs are the most affected in motorcycle accidents, representing about 29.8% of them, followed by head injuries (21.5%).¹² The highest incidence of injuries in the lower limbs is directly related to lower protection and greater exposure of these body areas in motorcyclists as opposed to the head, which is protected by helmet.¹³

However, Koizumi points out that the frequency of injuries by body region changes in patients who died, being more observed in patients who suffered head lesions, followed by abdominal, lower limb, and pelvic lesions.¹²

It is noteworthy that no data were collected regarding patients who died. However, we observed that seven patients (6.6%) were victims of TBI, which is among the most frequent fatal injuries, with high severity, in addition to a high degree of disability. 10,12,14 The importance of wearing helmets for TBI prevention stands out, with studies showing the significantly higher occurrence of this condition in individuals who do not use any safety equipment. 12

In this study, multiple fractures occurred in 61 (58.1%) victims. These data directly focused on the length of hospital stay, on average 14 days, with a minimum of one day and a maximum of 87 days, since orthopedic patients are among those who contribute the most to increasing the length of hospital stay. Koizumi established 15.8 days of average hospitalization.¹²

Long length of hospital stay is directly associated with greater trauma severity and with the occurrence of infectious complications. In this study, 49 patients (46.6%) presented infection during the hospitalization. Araújo and Whitaker point out that patients who suffered motorcycle accidents and evolved with complications have longer hospitalization time, mainly because of infectious situations, such as surgical site infection, and pressure ulcer.¹⁵

This study has a limitation regarding the methodology applied, as it was a retrospective analysis, dependent on medical records

information. Therefore, it was impossible to confirm any information not completed in the patient records.

The identification of the epidemiological profile of patients involved in motorcycle accidents and the development of preventive measures are of outstanding importance, given the seriousness of the resulting injuries, with high morbidity and mortality, and the demand to health services.

CONCLUSIONS

Given the significant motorcycle fleet growth, the high incidence of traffic accidents involving these vehicles, especially among young male individuals, and the resulting high morbidity and mortality rates, it is essential to investigate and evaluate the victims' epidemiological profile, as well as their resulting injuries, in order to provide adequate support for the implementation of measures aimed at primary prevention and awareness of the most affected group.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. CKB: study design, review, and approval of the final version; ACJ: study design, review, and approval of the final version; VSDAC: data collection, analysis and interpretation, and writing; ACFP: data collection, analysis and interpretation; RLR: data collection, analysis and interpretation.

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