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ACTA ORTOPÉDICA BRASILEIRA

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(Reviewed April 2022)

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ACKNOWLEDGEMENTS

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LEVELS OF EVIDENCE FOR PRIMARY RESEARCH QUESTION: Access the following link.

The sending of manuscripts

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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**
I	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
II	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective[f] 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
	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		
III	Case control study[g]	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
	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 Article

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GENERAL

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CEFAZOLIN PROPHYLACTIC EFFICACY ON PROSTHETIC JOINT INFECTION AFTER PRIMARY HIP ARTHROPLASTY

EFICÁCIA PROFILÁTICA DA CEFAZOLINA SOBRE A INFECÇÃO PROTÉTICA ARTICULAR APÓS ARTROPLASTIA PRIMÁRIA DE QUADRIL

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ABSTRACT

Objective: Perioperative deep prosthetic joint infection (PJI) is a serious postoperative complication of total hip arthroplasty (THA). We aimed to compare the efficacy of cefazolin administered within 24 and 48 h of primary THA for PJI prophylaxis. Methods: In this retrospective study, 720 patients were divided into two groups depending on whether cefazolin was administered as a single injection of 2 g twice daily within 24 (24-h group) or 48 h of surgery and the following day (48-h group). Sex, age at surgery, body mass index, co-existing diseases, blood test data, and PJI risk factors were evaluated. Results: The 24- and 48-h groups included 364 and 356 patients, respectively. Diabetes mellitus was the most common risk factor for PJI in both groups. The corresponding incidence of perioperative deep PJI following primary THA was 0.55% and 0.28% in the 24- and 48-h groups, respectively. There was no significant difference in patient background characteristics between the groups. Conclusions: Cefazolin administration within 24 h of primary THA may be appropriate for perioperative deep PJI. ***Level of Evidence II; Retrospective study.***

Keywords: Cefazolin. Surgical Wound Infection. Arthroplasty, Replacement, Hip. Antibiotic Prophylaxis.

RESUMO

*Objetivo: A infecção de prótese articular (IPA) perioperatória profunda é uma grave complicação pós-operatória da artroplastia total de quadril (ATQ). Este estudo buscou comparar a eficácia da cefazolina administrada dentro de 24 e 48 horas após ATQ para profilaxia de IPA. Métodos: Neste estudo retrospectivo, 720 pacientes foram divididos em dois grupos, que receberam cefazolina em uma injeção de 2g duas vezes por dia nas primeiras 24 e 48 horas (grupos de 24 e 48 horas), respectivamente. Foram avaliados sexo, idade na data da cirurgia, índice de massa corporal, comorbidades, testes sanguíneos e fatores de risco para IPA. Resultados: Os grupos de 24 e 48 horas incluíram, respectivamente, 364 e 356 pacientes. O fator de risco para IPA mais comum nos dois grupos foi o diabetes mellitus. A incidência de IPA perioperatória profunda após ATQ foi, respectivamente, de 0,55% e 0,28% nos grupos de 24 e 48 horas. Não houve diferença significativa nas características gerais dos pacientes entre os dois grupos. Conclusão: A administração de cefazolina dentro de 24 horas após ATQ primária pode ser adequada para IPA perioperatória profunda. **Nível de Evidência II; Estudo retrospectivo.***

Descritores: *Cefazolina. Infecção da Ferida Cirúrgica. Artroplastia de Quadril. Antibioticoprofilaxia.*

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INTRODUCTION

Prosthetic joint infection (PJI) is one of the most serious post-operative complications of total hip arthroplasty (THA), with an estimated incidence of 1.1% or less.[1] Cefazolin, a first-generation cephalosporin, is a first-line drug for PJI prophylaxis following THA.[2] In 2017, the United States Center for Disease Control and Prevention (CDC) recommended a single antibiotic dose to prevent postoperative infection.[3] However, the American Association of Hip and Knee Surgeons disagrees with this recommendation owing to a lack of evidence of a protective effect with a single antibiotic dose against PJI in case of artificial joint replacements. The current recommendation is prophylactic antibiotic dosing at 24 h postoperatively.[4] Thus, further research is needed to determine the most appropriate time for cefazolin administration and procure a more direct evidence of its effects. Therefore, we investigated the incidence of perioperative deep PJI in patients who underwent primary THA followed by cefazolin prophylaxis administration within 24 and 48 h.

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

The study was conducted at the Nissan Tamagawa Hospital, Tokyo, Japan.
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PATIENTS AND METHODS

This retrospective study involved patients who received a single cefazolin injection (2 g) twice daily, for deep PJI prevention following primary THA, within 48 h of surgery and on the following day (48-h group) from August 2018 to June 2019, and within 24 h of surgery (24-h group) from July 2019 to January 2020. Furthermore, it was approved by our institutional ethics committee. For the 48-h group, rapid administration was performed 30 min preoperatively to maximize the drug tissue concentration during the operation. The second administration was performed 2 h after the surgery (3 h after starting the surgery in case of bilateral hip arthroplasty), and in the morning and afternoon on the second day. Body exhaust system surgical suits were worn during the surgery. All surgeons wore double gloves to ensure aseptic operation. The affected limb was thoroughly wiped with 70% alcohol containing chlorhexidine, and then with 10% iodine solution. The operative field was covered with an iodine drape and opened. Cases of revision THA and THA with concurrent surgery were excluded.

The following data were analyzed: sex, age, body mass index, surgical site, PJI risk factors (such as diabetes mellitus),[5] and preoperative blood test values. PJI was defined based on the criteria established by Parvizi et al.[6] and evaluated along with magnetic resonance imaging (MRI) findings. The investigation period was 90 days after the surgery.[7] Cases of late infection (>90 days) were excluded. Statistical analysis was performed using Excel Statistics ver. 3.2 (Bell Curve). Nominal and continuous variables were compared using Fisher's exact test and Mann–Whitney *U* test, respectively. Results were considered statistically significant at P-value < 0.05. The ethics committee of Nissan-Kouseikai Institute of Medicine approved this study (approved number 2019-027).

RESULTS

There were 364 and 356 patients in the 24- and 48-h groups, respectively. The proportion of women was higher in both groups; the median ages were 66 and 65 years in the 24- and 48-h groups, respectively. There was no significant difference in the distribution of body weight or surgical sites, with more surgeries performed for the right hip joint than for the left and both hip joints. Diabetes mellitus was the most common risk factor in both groups. Intergroup differences in the other baseline patient characteristics were statistically insignificant. (Table 1)

The incidence rates of perioperative deep PJI following primary THA were 0.55% (2/364) and 0.28% (1/356) in the 24- and 48-h groups, respectively; the intergroup differences were statistically insignificant. The clinical background and courses of the three PJI cases are shown in Table 2. MRI showed a high-intensity area, akin to that associated with pus accumulation (Figure 1). The age range of the patients with PJI was 65–85 years; there were no other risk factors. However, the infection onset date was postoperative days 9–21. These three cases of PJI were treated with debridement; the patients were administered several antibiotics orally and parenterally and were discharged on postoperative days 37–57.

Table 1. Characteristics of patients in the two groups.

	Cefazolin at 24 h after surgery (n = 364)	Cefazolin at 48 h after surgery (n = 356)	P-value
Male/Female, n (%)	42/322 (11.5/88.5)	54/302 (15.2/84.8)	0.0929
Age (years), median (range)	66 (21–91)	65 (42–92)	0.5709
Body weight (kg), n (%)			
<60	244 (67.0)	221 (62.1)	0.0948
60–120	120 (33.0)	135 (37.9)	0.0948
BMI (kg/m^2), median (range)	22.7 (16.4–41.4)	23.0 (16.0–38.8)	0.2448
Surgical site, n (%)			
Right hip	173 (47.5)	157 (44.1)	0.1983
Left hip	116 (31.9)	133 (37.4)	0.3058
Both hip	75 (20.6)	66 (18.5)	0.2730
Diabetes mellitus, n (%)	27 (7.4)	22 (6.2)	0.3049
Blood tests, median (range)			
WBC (/μL)	5,300 (2,300–11,100)	5,300 (2,700–10,500)	0.6281
Lymp (%)	27.5 (5.4–49.0)	27.2 (5.6–47.7)	0.5413
AST (IU/L)	20.0 (10.0–71.0)	20.0 (10.0–116.0)	0.8801
ALT (IU/L)	15.0 (4.0–129.0)	16.0 (5.0–143.0)	0.4793
sCr (mg/dL)	0.7 (0.4–1.3)	0.7 (0.4–1.4)	0.6543
eGFR (mL/min/1.73 m^2)	70.9 (33.8–143.4)	71.4 (38.9–126.7)	0.1128

Abbreviations: BMI: body mass index; WBC: white blood cell; Lymp: lymphocyte; AST: aspartate aminotransferase; ALT: alanine aminotransferase; sCr: serum creatinine; eGFR: estimated glomerular filtration rate.

DISCUSSION

This study suggests that a suitable cefazolin prophylaxis period for preventing perioperative deep PJI following primary THA is within 24 h of surgery. The overall incidence of PJI in this study was 0.42% (3/720), which was within the range reported previously.[1] In this study, the detected coagulase-negative staphylococci (CNS) strain was methicillin-resistant; moreover, the strains detected in the three cases have been previously reported.[8,9] The main advantages of shortening the antibiotic administration period are suppression of the emergence of resistant bacteria; prevention of needle stick infections; and reduction of drug-induced adverse events, medical costs, and work burdens.

In this study, cefazolin was administered at a dose of 2 g intravenously to all patients; this is the recommended standard adult perioperative dose.[10] However, the current guidelines recommend a weight-based dosing protocol of 1, 2, and 3 g once for patients weighing <60, 60–120, and >120 kg, respectively.[11,12] None of the patients weighed >120 kg in the present study, and it seems that there was no case of cefazolin underdosing.

PJI incidence has been reported to be significantly higher in patients with artificial joint replacements who have diabetes mellitus than in those without diabetes.[5] In this study, the hemoglobin A1c level in the 24- and 48-h groups was 6.6% (6.0%–7.5%) and 6.7% (5.9%–7.8%) in patients with diabetes mellitus, respectively, with intergroup differences being statistically insignificant. There were 67 and 50 patients aged ≥75 years in the 24- and 48-h groups, respectively; the corresponding PJI incidence rates were 1.5% and 2.0%, which did not differ significantly. As the three PJI patients were aged between 65 and 85 years, PJI may have to be monitored more closely in elderly patients than in young patients.

The limitations of this study are that it was conducted in a single facility as a retrospective survey with a small sample number of patients. Furthermore, the year of cefazolin administration was different between the groups. However, this study revealed the appropriate time of cefazolin administration for perioperative deep PJI prophylaxis following primary THA.

CONCLUSION

Cefazolin administration within 24 h of primary THA may be appropriate for the prophylaxis of perioperative deep PJI.

Table 2. Clinical background of and courses followed in the three cases with deep PJI.

Patient no.	Cefazolin	Age/body weight	Sex	Surgical site	Infection onset date/symptoms	Bacterium detection date/bacterium (Specimen)	Readmission date	Treatment	Discharge date
1	24 h	65/89.2 kg	Female	Both hip	POD9 Exudate from the right wound	POD16 /Staphylococcus epidermidis MRCNS (Pus)	Continued hospitalization	Debridement Levofloxacin Vancomycin Clindamycin Minomycin Sulfamethoxazole-Trimethoprim	POD37
2	24 h	85/55.5 kg	Male	Right hip	POD21 Fever, redness	POD25 /Staphylococcus aureus (Excise tissue, pus)	POD23	Debridement Linezolid Rifampicin Sulfamethoxazole-Trimethoprim Tedizolid Clindamycin	POD57
3	48 h	75/47.9 kg	Female	Right hip	POD18 Fever, pain	POD19 /MRSA (Excise tissue, synovial fluid)	POD19	Debridement Levofloxacin Rifampicin Linezolid Clindamycin	POD38

Abbreviations: PJI: prosthetic joint infection; MRCNS: methicillin-resistant coagulase-negative staphylococci; MRSA: methicillin-resistant *Staphylococcus aureus*; POD: postoperative day.

Figure 1. Magnetic resonance imaging findings in the three cases with deep prosthetic joint infection (PJI). Arrows indicate parts with deep PJI. Case 1: T2 coronal image, Case 2: fat-suppressed coronal image, Case 3: (left) T2 axial image, (right) T2 coronal image.

AUTHORS' CONTRIBUTION: This manuscript, which is a multi-institutional study has six authors. Each author contributed individually and significantly to the development of the manuscript: KS: Substantial contribution to the conception and design of the study, and acquisition, analysis, interpretation of the study data. Writing of the work and final approval of the version of the manuscript to be published; YT, ST, TO, AK and MM: Writing of the work and final approval of the version of the manuscript to be published.

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RADIOGRAPHIC EVALUATION OF IMMEDIATE LOADING SAFETY AFTER SURGICAL REDUCTION IN ACETABULAR FRACTURES: A COMPARATIVE-RETROSPECTIVE STUDY

AVALIAÇÃO RADIOGRÁFICA DA SEGURANÇA NA CARGA IMEDIATA APÓS REDUÇÃO CIRÚRGICA EM FRATURAS ACETABULARES: ESTUDO COMPARATIVO-RETROSPECTIVO

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ABSTRACT

Objective: Radiographically evaluate the quality of reduction over six weeks of follow-up in patients with surgically treated deviated acetabular fractures who underwent rehabilitation with immediate loading as tolerated and compare this with the results of the unloaded protocol. Methods: We retrospectively evaluated the records of 137 patients with deviated acetabular fractures treated with open reduction and internal fixation. Sixty-six (48.2%) patients underwent postoperative rehabilitation with immediate loading as tolerated, while 71 (51.8%) patients completed rehabilitation using a no-load protocol. The quality of the reduction was assessed radiographically by measuring the fracturing step and gap on radiographs taken immediately after surgery and three and six weeks after surgery. Results: Comparing the joint step, group 1 had an average of 0.44 ± 1.4 mm, 0.47 ± 1.5 mm, and 0.51 ± 1.6 mm immediately, three and six weeks after surgery, respectively. Group 2 had a mean step of 0.24 ± 0.8 mm, 0.27 ± 0.9 mm, and 0.37 ± 1.2 mm immediately, three, and six weeks after surgery. No statistically significant differences were observed between the groups. With a joint gap, group 1 had a mean of 1.89 ± 1.7 mm, 2.12 ± 1.8 mm, and 2.36 ± 2.1 mm; and group 2 had a mean of 2.16 ± 2.4 mm, 2.47 ± 2.6 mm, and 2.67 ± 2.8 mm in the immediate postoperative period, three, and six weeks, respectively. There was also no statistical difference between groups in these measurements. Conclusion: Immediate loading after surgical treatment of deviated acetabular fracture had no negative impact on radiographic reduction parameters and had similar results to the protocol without weight bearing. ***Level of evidence III; Therapeutic Retrospective Cohort Study.***

Keywords: Fractures, Bone. Acetabulum. Weight-Bearing. Rehabilitation. Fracture Fixation, Internal.

RESUMO

Objetivo: Avaliar radiograficamente a qualidade da redução ao longo de 6 semanas de acompanhamento em pacientes com fratura desviada do acetábulo tratados cirurgicamente e submetidos à reabilitação com carga imediata conforme tolerado e comparar com os resultados do protocolo sem carga. Métodos: Avaliamos retrospectivamente os prontuários de 137 pacientes com fraturas desviadas do acetábulo que foram tratadas com redução aberta e fixação interna. Sessenta e seis (48,2%) pacientes foram submetidos à reabilitação pós-operatória com carga imediata conforme tolerado, enquanto 71 (51,8%) pacientes completaram a reabilitação utilizando um protocolo sem carga. A qualidade da redução foi avaliada radiograficamente pela medição do degrau da fratura e do gap nas radiografias feitas imediatamente após a cirurgia e três e seis semanas após a cirurgia. Resultados: Comparando o degrau articular, o grupo 1 teve uma média de 0,44 ± 1,4 mm, 0,47 ± 1,5 mm e 0,51 ± 1,6 mm imediatamente, três e seis semanas após a cirurgia, respectivamente. O grupo 2 teve um degrau médio de 0,24 ± 0,8 mm, 0,27 ± 0,9 mm e 0,37 ± 1,2 mm imediatamente, três e seis semanas após a cirurgia. Não foram observadas diferenças estatísticas significantes entre os grupos. Com gap articular, o grupo 1 teve uma média de 1,89 ± 1,7 mm, 2,12 ± 1,8 mm e 2,36 ± 2,1 mm; e o grupo 2 de 2,16 ± 2,4 mm, 2,47 ± 2,6 mm e 2,67 ± 2,8 mm nos pós-operatório imediato, três e seis semanas, respectivamente. Também não houve diferença estatística entre os grupos nessas medidas. Conclusão: A carga imediata após o tratamento cirúrgico da fratura do acetábulo desviada não teve impacto negativo nos parâmetros de redução radiográfica e teve resultados semelhantes em comparação com o protocolo sem descarga de peso. ***Nível De Evidência III; Estudo Terapêutico de Coorte Retrospectivo.***

Descritores: *Fraturas Ósseas. Acetábulo. Suporte de Carga. Reabilitação. Fixação Interna de Fraturas.*

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<< SUMÁRIO

INTRODUCTION

Acetabular fractures usually occur after high-energy trauma and are related to permanent motor impairment and high morbimortality rates.[1] Conservative treatment was the main method of management until Judet et al. published a study in 1964 that demonstrated superior outcomes after open reduction and internal fixation surgery, leading to the reduced incidence of post-traumatic osteoarthritis and higher rates of hip preservation.[2]

In other joints of the lower limb, stable internal fixation allows early weight-bearing, which improves functional rehabilitation, reduces time off work, and reduces the risk of the complications that relate to long periods of immobility.[3] In patients with acetabular fractures, even in those with stable internal fixation, there is no consensus on the weight-bearing protocol used during rehabilitation. Current protocols vary from non-weight-bearing, toe-touch, to partial weight-bearing.[4]

Until 2015, the postoperative protocol in our hospital for patients that underwent internal fixation of the acetabular fracture was 6 weeks of non-weight bearing rehabilitation. As of 2016, rehabilitation with immediate weight-bearing as tolerated was implemented. All other aspects of the treatment were similar.

The aim of this study was to evaluate the quality of reduction retrospectively radiographically over the 6 weeks of follow-up in patients that underwent rehabilitation with immediate weight-bearing as tolerated, and to compare these findings with the results of the non-weight bearing rehabilitation group. We hypothesized that immediate weight-bearing had no negative effect on the reduction and was comparable to that of the non-weight-bearing protocol.

PATIENTS AND METHODS

This therapeutic retrospective cohort study examined patients with displaced acetabular fractures that underwent open reduction and internal fixation surgery between January 2011 and December 2018. Two distinct weight-bearing protocols in the postoperative period were compared: non-weight-bearing and immediate weight-bearing as tolerated. This study was approved by the Research and Ethics Committee of the University (number: 3.212.380) and was carried out in accordance with the Declaration of Helsinki.

From the patients' records, we collected the baseline demographics (age, sex, fracture classification, associated injuries, time to surgery, and time to initiation of weight-bearing). All surgeries were performed by two of the authors (KEK and/or MCL).

The inclusion criteria were patients with a displaced acetabular fracture that underwent open reduction and internal fixation surgery, a mature skeleton, and six weeks of radiographic follow-up.

Patients were excluded if they underwent conservative treatment, has a follow-up shorter than six weeks, had inadequate radiographic exams, were treated with immediate total hip arthroplasty, had another fracture (bilateral, associated with pelvis injury), non-displaced, pathological, had an immature skeleton, fracture with more than 3 weeks, had a local infection, or were non-adherent to the weight-bearing protocol.

The non-weight-bearing group (group 1) consisted of patients who underwent the operation between 2011 and 2015; who were not allowed to bear weight for six weeks, while patients who underwent the operation between 2016 and 2018 formed the immediate weight-bearing group (group 2); who were allowed to bear weight as tolerated on the operated limb, with the support of two crutches, immediately after the surgical procedure.

Radiographs of the affected hip were taken immediately after the surgery and on postoperative weeks three and six of all patients. The quality of reduction was quantified by analysis of the radiographic images in the alar and obturator oblique views. The reduction was evaluated based on the measurement of the articular step and gap, in accordance with the method described by Borrelli et al.[5] The intact weight-bearing dome (WBD) was identified using the 45° method described by Matta,[6] and a digital circular template matching the arc of curvature of the intact WBD was drawn. The subchondral fracture margin of the intact portion of the acetabulum was marked as A, and the subchondral fracture margin of the displaced fragment was marked as C. A straight line between the center of the circle and point C was drawn, and the point of intersection with the circle was labeled point B. The distance between points A and B represented the gap deformity, while the distance between points B and C was the articular step. (Figure 1) The articular step and gap were measured in both views, taking into consideration the necessary adjustments that needed to be made to correct for the radiographic amplification.

To decrease bias, the measurements were performed by three authors who were not involved in the surgeries (BMM, BSK, DSP), and the median value of the three different measurements was used for the analysis.

The reduction was considered satisfactory if the articular step and gap was $\leq$ 1 mm and $\leq$ 5 mm, respectively, which allows for maximized sensitivity and specificity when considering conversion to total hip arthroplasty as reported by Verbeek et al.[7] An increase of $>$ 2 mm in either of the measurements at the three- or six-week follow-up was noted as a loss of reduction.

Statistical analyses were performed using SigmaPlot 11.0 software (SPSS, Richmond, CA, USA). Fracture patterns and associated fracture prevalence were compared using the Z-test to establish if there was any selection bias. Quantitative results were compared between equivalent time points after surgery between the two groups, and between time points within each group. Non-parametric distribution was determined using a normality test. Ergo, quantitative comparison was performed with the Mann-Whitney U test and Wilcoxon signed rank test in non-paired and paired evaluations, respectively. For qualitative comparison, we utilized Fischer's exact test and McNemar's test for non-paired and paired analyses, respectively. A p-value that was less than 0.05 was considered as statically significant.

RESULTS

Between 2011 and 2018, there were a total of 187 patients who underwent treatment for acetabular fracture, and 137 met the criteria for inclusion in our study. Of these patients (Table 1), 115 (83.9%)

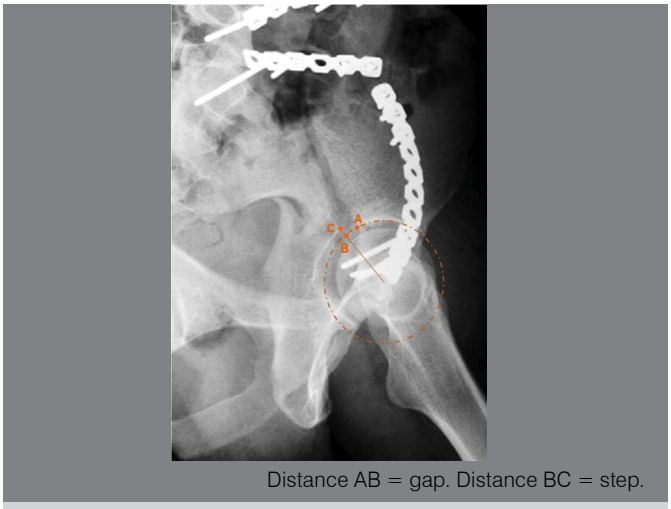

Figure 1. Measurement of the step and gap after internal fixation of a left acetabular fracture.

<< SUMÁRIO

were men and 22 (16.1%) were women, and the mean age was 34.1 years (range, 16 - 74 years).
Of the 137 patients, 71 (51.8%) were treated between 2011 and 2015 and underwent rehabilitation with the non-weight-bearing protocol. The remaining 66 (48.2%) patients were treated between 2016 and 2018 and underwent rehabilitation with immediate weight-bearing as tolerated. (Table 1)
Associated fractures were more common in the lower extremity (34.3%) and were not different between the two groups. (Table 2)
The most common acetabular fractures were posterior wall fractures (22.6%), followed by associated both column fractures (15.3%). Overall, associated fractures were more frequent than elementary fractures. There was no difference in the incidence of fracture patterns between the two groups (Table 3).
The average articular step in the non-weight-bearing group on the day immediately after surgery was 0.40 ± 1.4 mm and increased to 0.47 ± 1.5 mm and 0.51 ± 1.6 mm in the third- and sixth-week post-surgery, respectively. In the immediate weight-bearing group, the articular step immediately post-surgery was 0.24 ± 0.8 mm. At the three- and six-week evaluations, the measurements were 0.27 ± 0.9 mm and 0.37 ± 1.2 mm, respectively. Both groups showed a statistically significant difference between the immediate and six-week postoperative time points (p = 0.001; Graph 1). Comparison of the articular step measurements between groups 1 and 2 using Mann-Whitney U test revealed no statistical difference immediately after surgery (p = 0.300), after 3 weeks (p = 0.310), or after 6 weeks (p = 0.453).
In the non-weight-bearing group, the mean articular gap measurement immediately after the surgery was 1.89 ± 1.7 mm. At the three- and six-weeks post-surgery, the gap were 2.12 ± 1.8 mm and 2.36 ± 2.1 mm, respectively. In the immediate weight-bearing group, the articular gap in the day immediately after the surgery was 2.26 ± 2.4 mm; and 2.47 ± 2.6 mm and 2.67 ± 2.8 mm in the third- and six-week examinations, respectively. Similar to the results obtained from the analysis of the articular step, a significant difference was observed between the immediate and six-week postoperative time points in both groups (p = 0.001; Graph 2). Analysis of the articular gap measurements using the Mann-Whitney U test revealed no statistical differences between both groups an any time point (immediate post-surgery, p = 0.933; three weeks post-surgery, p = 0.902; six weeks post-surgery, p = 0.995).
Based on the analysis of the changes in the articular step, satisfactory reduction was observed in 63 (88.8%) and 61 (92.4%) patients in the non-weight-bearing and immediate weight-bearing groups, respectively (p = 0.487). In the final evaluation at six weeks, the number of patients with satisfactory reduction in group 1 was 61 (86.0%), and 59 (89.4%) in group 2 (p = 1.000) (Table 2). From the analysis of the changes in the articular gap measurements, 67 (94.4%) and 57 (86.3%) of the patients in group 1 and group 2, respectively, had a satisfactory reduction (p = 1.000). In the sixth week, the number of patients with a satisfactory gap reduction in group 1 and group 2 was 61 (86.0%) and 51 (77.2%) patients, respectively (p = 0.671;). (Table 3)
As we classified that an increase of > 2 mm in either the articular step or gap as loss of reduction, a total of 5 (7.0%) cases in group 1 and 7 (10.6%) cases in group 2 were considered to fall into this category. Loss of reduction due to early weight-bearing presented a relative risk of 1.506 (CI: 0.503-4.514), although there was no significant difference in the number of cases between groups (p = 0.664) when compared using Fischer's exact test.

Table 1. Mean age, time to surgery and gender.

	Age Mean (SD)	Time to surgery Mean (SD)	Gender n (%)
Non-weight bearing (n=71)	32.9 (12.0)	13.4 (8.5)	Women = 9 (12.7) Men = 62 (87.3)
Immediate weight-bearing (n=66)	35.5 (14.1)	18.5 (21.0)	Women = 13 (19.7) Men = 53 (80.3)

n = number; SD = standard deviation.

Table 2. Associated injuries.

	Immediate weight-bearing n (%)	Non-weight bearing n (%)	Total n	p*
Lower limbs	19 (28,8%)	28 (39,4%)	47	0,260
Vertebral column	4 (6,0%)	6 (8,4%)	10	0,832
Upper limbs	3 (4,5%)	2 (2,8%)	5	0,941

*Z test "p" value.

Table 3. Fracture pattern.

Fracture pattern	Immediate weight-bearing n (%)	Non-weight bearing n (%)	Total n	p*
Posterior wall	19 (28,7%)	12 (16,9%)	31	0,148
Both column	8 (12,1%)	13 (18,3%)	21	0,422
Transverse posterior wall	6 (9,1%)	12 (16,9%)	18	0,273
T-shaped	8 (12,1%)	8 (11,2%)	16	0,918
Transverse	5 (7,5%)	10 (14,0%)	15	0,344
Posterior wall posterior column	11 (16,6%)	4 (5,63%)	15	0,073
Anterior column posterior hemitransverse	4 (6,06%)	5 (7,0%)	9	0,913
Anterior column	5 (7,5%)	1 (1,4%)	6	0,183
Anterior wall	0	2 (2,8%)	2	0,513
Posterior column	0	1 (1,4%)	1	0,966
Non classifiable	0	3 (4,2%)	3	0,272

*Z test "p" value.

DISCUSSION

Following lower limb fracture fixation surgery, early weight-bearing is advantageous as it rapidly improves functional outcome, allowing a faster return to work and minimizing the economic impact of the injury. However, allowing the patients to bear weight may lead to loss of reduction or fixation failure, thereby compromising patient outcomes.[9]
In diaphyseal fractures, the likelihood of complications with early weight-bearing is very low.[10-12] In articular fractures, such as those in the tibial plateau and the ankle, there is evidence that early weight-bearing is safe because it does not cause fracture displacement, and there is no loss of fixation, leading to positive functional outcomes.[13]
In postoperative rehabilitation after operative fixation of an acetabular fracture, the weight-bearing protocol varies from non-weight-bearing for 4 to 10 weeks, toe-touch weight-bearing within the first 6 to 12 weeks, or partial weight-bearing for 6 to 12 weeks.[4] The potential consequences of weight-bearing leading to fixation failure and subsequent loss of reduction may explain the restriction of weight-bearing after acetabular surgery.
With respect to a posterior wall fracture, a systematic review by Heare et al. compared the outcomes following early (unrestricted weight-bearing before 12 weeks) and late weight-bearing (restricted weight-bearing for 12 weeks). They found no significant difference in the Merle dÁubigné functional score and no difference in heterotopic ossification, avascular necrosis, infection, or osteoarthritis.[14]
For associated fracture patterns, existing studies only examined percutaneous fixation of non-displaced or minimally displaced fractures

(< 2 mm). Mouhsine et al.[15] studied the impact of weight-bearing as tolerated after fixation of non-displaced and minimally displaced transverse, T-type, or associated both column fractures subjected to percutaneous fixation, and found that fixation failure did not occur and that the functional results were satisfactory. Kazemi and Archdeacon[16] showed that in anterior column and anterior column posterior-hemitransverse fractures that were fixed percutaneously, rehabilitation with immediate full weight-bearing resulted in radiographic union in all cases and good functional outcomes in 87% of cases.

The literature on the comparison of weight-bearing protocols after fixation of displaced fractures of the acetabulum is limited. To our knowledge, this is the first study to compare immediate weight-bearing as tolerated and non-weight-bearing after surgical fixation of displaced acetabular fractures, while also taking into consideration both elementary and associated fractures.

The mean age of our patients was lower than the mean age reported by Kelly et al. in their literature review (34.1 vs. 43.8).[4] However, we believe that this difference is not significant because the population of patients in both studies are young and have good bone quality. Regarding gender, the majority of our participants were men (83.9%). In our patients, the elementary fracture pattern accounted for 40.1% of the cases, with associated fracture patterns making up 59.9%, with no statistically significant difference between the two groups ($p > 0.05$; Table 3).

The time interval between the fracture and the surgical treatment was 13.4 days, which could have been an issue, as the delay may affect the ability to achieve a successful reduction. Indeed, the average interval in the study completed by Kelly et al.[4] was 6.6 days. However, even with a delay in the surgery, a satisfactory reduction of articular step and gap was achieved in most patients (88.8% for step and 94.4% for gap), similar to the results to the reported by Kelly et al.[4] (87.3%).

Importantly, in group 2, there was no loss of reduction in articular step (Table 4) or gap (Table 5) when patients underwent rehabilitation with immediate weight-bearing protocol at the third- and six-week evaluation, demonstrated by the stable level of reduction that was comparable to the non-weight-bearing group. Both sets of data show that there is no negative radiographic impact of the immediate weight-bearing protocol on the degree of reduction after 6 weeks, indicating that the fixation was sufficient to withstand the physiological load of the weight-bearing as tolerated.

Reduction loss due to early weight bearing presented a relative risk of 1.506 (CI: 0.503 to 4.514), but no significant difference in the total number of cases was apparent when comparing between the groups ($p = 0.664$), indicating that immediate weight-bearing rehabilitation protocol implemented after surgical reduction and fixation of displaced acetabular fractures have no negative repercussions when compared to non-weight-bearing protocol.

While articular step and gap distances were significantly increased in the weight-bearing group after 6 weeks compared to the measurements on the day immediately after surgery ($p = 0.001$), such a difference was also found in the non-weight-bearing group ($p = 0.001$). Although statistically significant, Graphs 1 and 2 reveal a small quantitative variation in both groups. For instance, the mean step and gap increase in the former group was 0.30 mm and 0.12 mm, respectively. The question remains whether such values would have any impact on functional outcomes. We are currently conducting another study to evaluate the functional results in group 2 to further clarify the answer to this question.

As the goal of the study was to analyze de quality of reduction, no functional evaluation was performed. However, it has been shown that there is a correlation between the quality of the reduction, the patient outcomes, and the development of arthritis.[8-17] Therefore, we can infer that as the immediate weight-bearing group achieved and maintained a satisfactory reduction over the 6 weeks, the patients are likely to have a positive functional outcome.

Our study may have been limited by small number of patients, which in turn limited the power of the study. Therefor we may have not detected differences that would otherwise be statistically relevant. The intrinsic limitations to the methodology of retrospective cohort studies should also be considered. Furthermore, we inferred the outcome based on radiographic findings alone, and did not directly assess the functional scores of the patients. Finally, intrinsic difficulties exist when making radiographic measurements, as subjective errors can be introduced by surgeons, or by the malposition of the patient during the X-ray.

CONCLUSION

In conclusion, we found that rehabilitation with immediate weight-bearing after displaced acetabular fracture surgical treatment did not negatively impact the radiographic reduction parameters, and the outcomes were like that of the non-weight-bearing rehabilitation protocol.

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Table 4. Articular step qualitative analyzes.

	Postoperative		3 weeks		6 weeks	
	Satisfactory n (%)	Unsatisfactory n (%)	Satisfactory n (%)	Unsatisfactory n (%)	Satisfactory n (%)	Unsatisfactory n (%)
Group 1 (n=71)	63 (88.8%)	8 (11.2%)	63 (88.8%)	8 (11.2%)	61 (86.0%)	10 (14.0%)
Group 2 (n=66)	61 (92.4%)	5 (7.6%)	60 (90.0%)	6 (10.0%)	59 (89.4%)	7 (10.6%)
	*p = 0.487		*p = 0.555		*p = 1.000	

*Fisher Exact test "p" value.

Table 5. Gap qualitative analyzes.

	Postoperative		3 weeks		6 weeks	
	Satisfactory n (%)	Unsatisfactory n (%)	Satisfactory n (%)	Unsatisfactory n (%)	Satisfactory n (%)	Unsatisfactory n (%)
Group 1 (n=71)	67 (94.4%)	4 (5.6%)	64 (90.2%)	7 (9.8%)	61 (86.0%)	10 (14.0%)
Group 2 (n=66)	57 (86.3%)	9 (13.7%)	54 (81.8%)	12 (18.2%)	51 (77.2%)	15 (22.8%)
	*p = 1.000		*p = 0.582		*p = 0.671	

*Fisher Exact test "p" value.

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3D PRINTING APPLICATION IN BONE DEFECT AREA MEASUREMENT ON PATIENTS WITH DEVELOPMENTAL DYSPLASIA OF THE HIP

APLICAÇÃO DE IMPRESSÃO 3D NA MENSURAÇÃO DA ÁREA DE DEFEITOS ÓSSEOS EM PACIENTES COM DISPLASIA DO DESENVOLVIMENTO DO QUADRIL

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ABSTRACT

Objectives: Evaluate the application value of 3D printing technology in measuring acetabular bone defect area in adult patients diagnosed with developmental dysplasia of the hip (DDH). Methods: 23 cases of DDH requiring total hip replacement surgery were enrolled in this study. Preoperative examination confirmed the standard pelvic plain films Crowe, including 3 cases of Crowe I, 7 Crowe II, and 13 Crowe III. The 3D printing technology was used to print the hip model before the operation. Based on the pre-printed model, pre-operative planning and surgical procedures were established. The area of the acetabular bone defects was measured, the selected size prosthesis was recorded, and the surgery was performed (group A). The actual acetabular bone defect area and the prosthesis size were also recorded (group B). Results: The comparative results indicated that the actual acetabular defect area measured intraoperatively and the area measured using the 3D printing technology did not significantly differ for all participants (all P>0.05). Conclusion: Preoperative model can accurately measure the acetabular bone defect area for DDH. It is significant to develop individualized implants for DDH patients treated with the 3D printing technique. ***Level of Evidence IV: Case series.***

Keywords: Developmental Dysplasia of the Hip. 3 D Printing. Arthroplasty, Replacement, Hip.

RESUMO

Objetivos: Avaliar o potencial da aplicação da tecnologia de impressão 3D na medição da área de defeito ósseo acetabular em pacientes adultos diagnosticados com displasia do desenvolvimento do quadril (DDH). Métodos: 23 casos de DDH que requereram cirurgia de substituição total do quadril foram incluídos neste estudo. O exame pré-operatório confirmou os filmes pélvicos padrão Crowe, incluindo 3 casos de Crowe I, 7 Crowe II, e 13 Crowe III. A tecnologia de impressão 3D foi utilizada para imprimir o modelo de quadril antes da operação. Com base no modelo pré-impresso, o planejamento pré-operatório e os procedimentos cirúrgicos foram estabelecidos. A área dos defeitos ósseos acetabulares foi medida, a prótese de tamanho selecionado foi registrada, e a cirurgia foi realizada (grupo A). A área do defeito ósseo acetabular real e o tamanho da prótese também foram registrados (grupo B). Resultados: Os resultados comparativos indicaram que a área real do defeito acetabular medida intraoperativamente e a área medida usando a tecnologia de impressão 3D não diferiu significativamente para todos os participantes (todos P>0,05). Conclusão: O modelo pré-operatório pode medir com precisão a área de defeito ósseo acetabular para DDH. É relevante desenvolver implantes individualizados para pacientes com DDH tratados com a técnica de impressão 3D. ***Nível de Evidência IV: Série de casos.***

Descritores: *Displasia do Desenvolvimento do Quadril. Impressão em 3D. Artroplastia de Quadril.*

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INTRODUCTION

The pathological changes underlying the developmental dysplasia of the hip (DDH) are mainly the reduction of femoral head acetabular coverage, which leads to unstable femoral head and anterolateral displacement and changes in the joint load status. Total hip arthroplasty (THA) is primarily performed for adults with DDH end-stage osteoarthritis and who will face three major challenges in acetabular reconstruction and soft tissue balance of the hip joint and femoral medullary cavity intraoperatively.[1] Given the considerable changes in the anatomy of the acetabulum, especially in adult DDH patients with Crowe □, type IV patients have poorly developed mortar and are affected by the loss of

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femoral head. The outer wall often has defects. Coverage on the upper edge of the acetabulum is lacking when the prosthesis is placed on a mortar and is loose with insufficient support.[2] Preoperative condition of patients with acetabular bone defect area must be understood to guide the operation. Bone grafting method and prosthesis choice are of great significance when printing out the ipsilateral acetabulum of the patient using 3D printing technology. The acetabular bone defect area can be quantitatively measured through the print model. 3D printing technology is the use of metal or plastic powder and other special materials applied with laser beam or hot melt nozzle and other methods in the 2D X-Y plane bonded to a cross-sectional shape and in the Z coordinate layer overlay. In contrast to the traditional four "cut-and-remove" material approaches, 3D printing uses a "layer-by-layer" approach to making 3D solids.[3] In this investigation, whether or not 3D printing can accurately measure the area of acetabular bone defects in adults with DDH and contributes to guiding the surgery was investigated.

MATERIALS AND METHODS

Hard- and soft-ware

Hardwares and softwares mainly consisted of 3D Reconstruction Software Mimics 10.01 (Materialize, Belgium), 3D Printer, OS: Windows 7 Home Basic 64 bit, Photoshop CS6 (Adobe, USA) and SPSS19.0 Statistical Software (SPSS Inc., Chicago, U.S.).

Inclusion criteria

Those suffering from pain severely affecting daily life; workers aged 40–75 years; those untreated after conservative therapy; those requiring total hip arthroplasty of all types of adult DDH end-stage osteoarthritis; those with no medical history of hip orthopedic surgery; those with no medical history of hip injuries; those able to tolerate surgery and with some knowledge of the procedures. All surgical procedures were performed by the same highly-qualified surgeon using the same surgical approach.

Exclusion criteria

Those complicated with alternative severe diseases; those fail to tolerate the surgery; those who are allergic to the implant; those suffering from mild pain whichdoes not affect their normal quality of life; those refused the surgery and the pregnant or lactating female patients.

Preoperative examination

All patients underwent preoperative physical examinations, routine blood test, coagulation, immunity and other laboratory tests. Shooting pelvic plain film, full-length double-leg films, and hip CT scan + 3D reconstruction were also conducted. Scanned data were obtained as output in a recordable DVD disc to preclude the risk of surgical contraindications. (Figure 1)

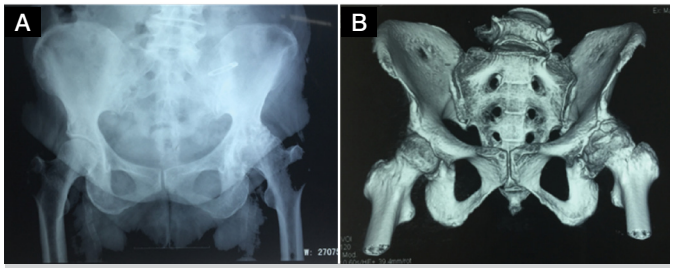

Figure 1. Preoperative pelvic X-ray (A); preoperative CT scan+3D reconstruction (B).

3D print modeling

Twenty-three patients underwent acetabular CT scan in DICOM format. The data were imported into Mimics 10.01 for 3D reconstruction. A series of initial settings, threshold adjustment, noise removal, segmentation and region growth, and slice data integration was completed. 3D reconstruction of mortar was conducted in a STL format output file, which was coded into the main program of the 3D printer computer. Plastic powder was used in the Z coordinate layer overlay to obtain the required acetabular model. Based on the related imaging data, the operation on the acetabular model was simulated. Acetabular grinding with a suitable depth was used to determine the acetabular center of rotation. The suitable acetabular mortar was placed in the acetabulum, which was covered with cement in the defect area. Once the cement is fixed, it is removed, and the cement model of the desired acetabular bone defect was obtained. (Figure 2) This study was approved by the ethic committee of First Affiliated Hospital of Bengbu Medical College, written consent was obtained from the patients.

Acquisition of intraoperative acetabular bone defect area

After successfully implementing anesthesia in patients in lateral position, conventional disinfection, shop towels, and surgery in the lateral approach were performed. Assuming the greater trochanter site as the center, the skin layer was cut until the subcutaneous fascia. Shun gluteus maximus muscle fibers were exposed, and the flap was cut before and after surgery. The left lower limb flexion adduction was revealed, and the outer swollen muscle group was cut off. Most of the joint capsule was excised to reveal the femoral head and neck. Pendulum saw perpendicular to the trochanter was cut off the femoral neck, and the diseased femoral stump was removed to reveal the acetabulum. The hyperplastic tissue above the osteophyte was removed, acetabular anterior tilt 15°, 40° outreach direction step by step to expand the soft tissue and cartilage surface. The appropriate acetabular mold placed in the acetabulum was selected with bone wax covering the defect area. After fixation, the bone wax was removed and the bone wax model of the actual acetabular bone defects was obtained. (Figure 3)

Data measurement

In group A, a cement model in which acetabular defects were obtained from a 3D printed model. Bone wax model of the actual acetabular defects was intraoperatively located in group B. The bone

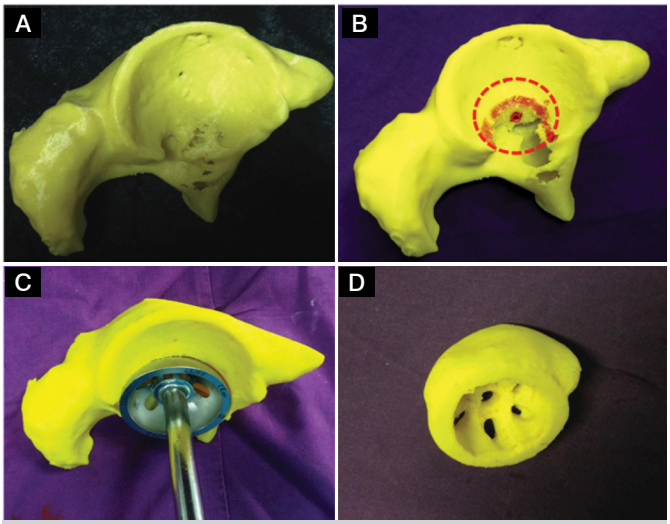

Figure 2. 3D printed acetabular model (A); acetabular cup polished in the acetabular model (B); appropriate acetabular abrasive (C); Covering the area of the defects (in red color) with cement (D).

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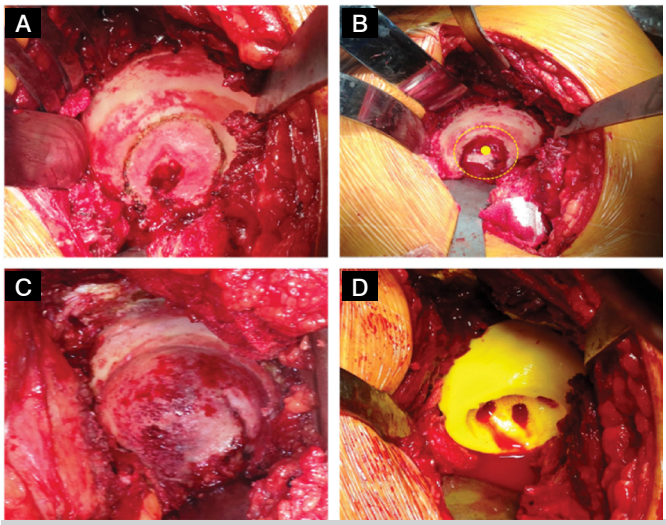

Figure 3. Surgery on the affected hip acetabulum (A); Surgery revealed the polished acetabulum (B); Selecting the appropriate mold placed in the acetabulum department (C); Removing the acetabular bone surgery at the wax model (D).

cement model was obtained by 3D printing, whereas the actual bone model was obtained during the operation. The acetabular defect area was an irregular 3D smooth surface. The 3D surface was first transformed into a figure on a 2D plane for convenient calculation. Steel rulers perpendicular to each other were used as a reference for vertical shooting to keep the steel ruler and the calculated area in the same plane. The shots were imported into Photoshop software, and the pixels in the blue selected area were divided by the pixels in the steel ruler area (5545/263283). The actual area of the area enclosed by the steel straightedge was multiplied to obtain the required acetabular bone defect area.

Statistical analysis

All experimental data were statistically analyzed by using SPSS19.0 statistical software (SPSS Inc., Chicago, U.S.). The obtained were statistically compared between two groups by using the paired t-test. A P value of less than 0.05 was considered as statistical significance.

RESULTS

Twenty-three adult patients diagnosed with DDH in the First Affiliated Hospital of Bengbu Medical College were enrolled in this study. Among them, 6 cases were male and 17 female. Prior to surgery, all patients were subject to Crowe classification including type I in 3 cases, type II in 7 cases and type III in 13 cases. All enrolled patients were aged 41–72 years with an average age of 59.2 years. Patients possessed limited activity and experienced preoperative hip pain, which seriously affected their quality of life. Physical examination and imaging analysis prompted the surgical indications. For each of the 23 patients, the actual acetabular defect area and the area measured based upon the 3D printing model were measured and statistically compared. The comparative results indicated that the actual acetabular defect area measured intraoperatively and the area measured using the 3D printing technology did not significantly differ for all participants (all $P>0.05$). The detailed data were illustrated in Table 1.

Table 1. Comparison of acetabular bone defect area between group A and group B.

Case No.	Area in group A (cm^2)	Area in group B (cm^2)
1	7.29	7.13
2	3.16	3.25
3	5.14	5.21
4	6.81	6.71
5	4.40	4.62
6	6.69	6.56
7	3.97	3.77
8	4.94	4.82
9	5.36	5.31
10	4.47	4.42
11	3.62	3.51
12	4.52	4.46
13	3.17	3.25
14	7.12	7.11
15	3.56	3.44
16	5.35	5.56
17	6.42	6.52
18	4.72	4.62

DISCUSSION

3D printing technology has been widely applied in multiple fields of orthopedics. For DDH patients, 3D printing technology can aid in preoperative planning, improve the success rate of operation and reduce the intraoperative blood loss and postoperative complications by preoperatively measuring the size and direction of the implants. Zhang et al.[4] demonstrated that the operation time was 118.6 min and the bleeding loss was 410.9 mL in the control group (140.2 minutes, 480.6 mL, controllable abduction angle, and anteversion tilt angle of $(1.2\pm0.9)^\circ$ and $(2.1\pm1.2)^\circ$ were significantly better than those in the conventional surgery group $(5.4\pm3.2)^\circ$ and $(4.1\pm2.8)^\circ$. In addition, Chinese scholars have also proposed that 3D printing technology play a vital role in adult patients with DDH and total hip arthroplasty. Guan et al.[5] performed total hip arthroplasty in eight patients with dysplasia of the hip. Preoperative 3D printing model and surgical planning were adopted to identify the acetabular defects and sclerosis and the size of the defect site. Intraoperative acetabular prosthesis polished range, intraoperative acetabular center position, and 3D printing prosthesis model were exactly the same. The operation time and bleeding volume were significantly reduced over the traditional surgery. Preoperative selection of the size of the prosthesis is consistent with that used in surgery, for the postoperative functional improvement of joint function.

Given the proximal femoral deformity of patients with DDH, narrow marrow cavity, soft tissue contracture, and the common femoral stem prosthesis often do not match the femoral canal and thus complicate the surgery. With the development of 3D printing technology, the optimal matching of the femoral canal cavity can be designed, and the stress can be transmitted uniformly, thus greatly reducing the operation difficulty. Sixty patients with individualized prosthesis were followed up by Martini et al.[6] who found that bone mineral density around the prosthesis were significantly increased compared with those in patients with other types of prosthesis, and the prosthesis and medullary cavity were well fitted.

DDH is a common disease that causes secondary osteoarthritis of the hip.[7] Patients with the development of end-stage osteoarthritis often require total hip arthroplasty. Intraoperative acetabular reconstruction is one of the most difficult parts. The principle of acetabular reconstruction is to reconstruct the rotational center of the acetabulum, provide adequate osseous coverage for the acetabulum, and maintain the integrity of the acetabulum. We can establish a 3D printing model of the patient's affected acetabulum preoperatively. Accurately calculating the area of acetabular defects through the printed model is important to provide adequate osseous

coverage. 3D printing is more intuitive than previous imaging data and simulates surgical procedures on the model. The depth of grinding, bone graft method, and bone mass must be determined. Contradictions exist between standardized acetabular components and differentiated individuals. The 3D printing technology can be used according to each patient's different designs of different mortar to improve its mechanical properties. Perticarini et al.[8] used a 3D printed titanium cup for 134 total hip arthroplasty. Postoperative 60–86 months of follow-up showed no surgical complications, and 99.3% of acetabular components were radiographically stable. No osteolysis occurred around the acetabular component. Qu et al[9] used large-scale acetabular bone defects in 26 patients (26 hips) to design individualized cages using 3D printing technology. After an average follow-up of 67 months, the Harris score improved from 36 to 82 on average, and no imaging artifact shift was found. The accuracy of the acetabular defect area may be affected by the location and orientation of the acetabular mold implants and the depth of acetabular abrading. Therefore, the location of the need for acetabular implantation should be maintained at the lower edge of the tear level and the upper edge of the closed hole. To date, the techniques of orientation of acetabular components mainly include the following four methods: manual method, anatomical marker positioning method, instrument orientation method and computer-assisted orientation method. All acetabular bone defect area models in this study were obtained by "unarmed" methods. The direction of implantation was based on Lewinnek et al.,[10] who reported that the abduction angle (40 ± 10) ° and anteversion angle (15 ± 10)° are the "safe areas" for the acetabular component implantation. On the contrary, the depth of acetabular grinding affects the size of acetabular bone defects. This experiment was based on the study of Zhou Jiansheng et al.,[11] who restored the Harris nest to determine the depth of acetabular grinding. The rotation center can be reconstructed accurately, and the coverage of the acetabular component and the clamping of the prosthesis by the acetabular anterior and posterior wall can be maximized. In addition, Minoda et al.[12] suggested the posterior lateral approach. Considering the intraoperative pelvic 14 ° forward tilt, the posterior superior iliac spine must be touched to determine the pelvic tilt angle. The operating table must be adjusted simultaneously to ensure that the pelvis and the ground are completely vertical. The acetabular model was then placed, and all the surgeries in this study were performed by the same senior physician to control the different levels of operation of doctors on the experimental results. The 2D bone defect model of bone wax was photographed to ensure that the ruler and the calculated area were perpendicular in a plane. The image of the calculated area must be at the center of the field of view. Given the different shooting angles, the area calculated into Photoshop is different; hence, the shooting angle and the calculated area of the image must be vertical.

CONCLUSION

3D printing has advantages over other conventional imaging examination. It can capture a virtual image preprocessed by a series of image processing softwares and then print a 3:1 solid model with a 3D printer. Based upon this model, we can intuitively observe the patient's hip joint situation, simulate the operation of the model and foresee the difficulties encountered in actual surgery. Based on a series of data, 3D printing technology can accurately calculate the acetabular bone defect area to help understand the patient's hip defect before surgery. 3D printing plays a unique role in guiding the intraoperative bone graft, the way of using the bone graft, the difficulty in reducing the operation and the reduction of complications.

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THE OUTCOMES OF POSTERIOR CRUCIATE LIGAMENT TIBIAL AVULSION FIXATION WITH A SCREW USING A DUAL POSTEROMEDIAL PORTAL TECHNIQUE

DESFECHOS DA TÉCNICA DE PORTAL PÓSTERO-MEDIAL DUPLO PARA FIXAÇÕES DE FRATURA EM AVULSÃO TIBIAL DO LIGAMENTO CRUZADO POSTERIOR

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ABSTRACT

Objectives: Our purpose was to evaluate the clinical results of PCL tibial avulsion fracture fixation performed with 4 mm cancellous screws using a dual posteromedial (PM) portal technique. Methods: In a prospective study, we followed 12 patients submitted to PCL tibial insertion avulsion arthroscopic fixation using dual PM portals with cancellous screws from March 2014 to Jan 2020. The proximal higher PM portal served as an instrument portal and provided an optimal trajectory for arthroscopic screw fixation of larger PCL avulsion fractures. The lower PM portal was used as a viewing portal. Results: Significant improvements were found between the preoperative and postoperative mean Lysholm scores at six months. The preoperative IKDC score mean of 10.13 increased to 89.3 at the end of six months. Minor adverse results with this technique were: grade I on posterior sag in five knees (41.6%), temporary stiffness in two cases (16.7 %), delayed union in one patient (8.3 %), and difficulty squatting at the end of six months in one patient (8.3%). Temporary extension lag was present in two individuals (16.7%), and fixed subtle flexion deficit of 3-5 degrees occurred in one individual (8.3 %). Conclusion: The outcomes obtained with the proposed technique were similar to those obtained with open techniques, although mild flexion deficits and discreet posterior sag may be present in a significant number of cases. ***Level of Evidence II; Prospective Cohort Study.***

Keywords: Posterior Cruciate Ligament. Fractures, Avulsion. Surgical Procedures, Arthroscopic.

RESUMO

Objetivos: O objetivo foi avaliar os resultados clínicos da fixação da fratura da avulsão tibial PCL realizada com parafusos esponjosos de 4 mm, utilizando uma técnica de portal postero-medial (PM) duplo. Métodos: Em um estudo prospectivo, acompanhamos 12 pacientes submetidos à fixação da avulsão tibial de inserção PCL por via artroscópica utilizando portais duplos PM com parafusos esponjosos de março de 2014 a janeiro de 2020. O portal PM proximal superior serviu como um portal de instrumentos e forneceu uma trajetória ideal para a fixação artroscópica com parafusos de fixação de fraturas avulsas PCL maiores. O portal PM inferior foi usado como um portal de visualização. Resultados: Foram encontradas melhorias significativas entre o pré-operatório e o pós-operatório, com pontuação média de Lysholm aos seis meses. A pontuação média do IKDC pré-operatório de 10,13 aumentou para 89,3 no final dos seis meses. Os resultados adversos menores com esta técnica foram: grau I na flacidez posterior de cinco joelhos (41,6%), rigidez temporária em dois casos (16,7%), união tardia em um paciente (8,3%) e dificuldade de agachamento ao final de seis meses em um paciente (8,3%). O atraso temporário da extensão estava presente em dois indivíduos (16,7%) e o déficit de flexão sutil fixo de 3-5 graus ocorreu em um indivíduo (8,3%). Conclusão: Os resultados obtidos com a técnica proposta foram similares aos obtidos com técnicas abertas, embora déficits leves de flexão e discreta flacidez posterior possam estar presentes em um número significativo de casos. ***Nível de Evidência II; Estudo de Coorte Prospectivo.***

Descritores: *Ligamento cruzado posterior. Fratura Avulsão. Procedimentos Cirúrgicos Artroscópicos.*

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The study was conducted at the multiple institutes where the primary surgeon is associated.
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INTRODUCTION

Isolated posterior cruciate ligament (PCL) tibial avulsion fractures account for 20 % of the total knee ligament injuries.[1] The PCL is the central pivot of the knee and predominantly resists the posterior translation of the tibia in all knee positions.[2] The mode of injury in PCL is commonly classified as dashboard, hyperextension, fall on the flexed knee with the foot in plantar flexion, and hyperflexion injuries.[3] Trivial domestic PCL injuries form a less sizeable group. Contact, athletic sports and road traffic high energy injuries form the majority of cases.[4]

Multiple biomechanical studies have shown that PCL deficiency if untreated may lead to increased risk of meniscal tears, medial compartment, and patellofemoral osteoarthritis.[4,5] PCL avulsion fracture fixation was advocated by Griffith et al. to avoid the above complications including nonunion and late degenerative osteoarthritis.[6] Dhillon et al. have suggested that poor outcome is common if the PCL avulsion fractures are treated beyond 16 weeks of its occurrence.[7] Ohishi et al. recommend surgical reinsertion and fixation of displaced PCL avulsion fractures.[8]

Posterior compartment arthroscopy is essential during PCL reconstruction, PCL avulsion fracture fixation, subtotal synovectomies, posterior loose bodies removal, longitudinal tears involving the peripheral attachment of the medial meniscus' posterior horn (ramp lesions) repairs and even meniscal transplants. [9,10]

The transseptal portal is used by some surgeons during PCL related surgeries.[8,11] The addition of this portal increases the visualization and aids in the direct passage of instruments for reduction. But the transseptal portal is specifically risky during PCL avulsion fracture fixations. The most dangerous risk is injury to the popliteal vessels.[11,12] The neurovascular bundle is at risk not only during transseptal portal creation during PCL surgery steps, but also during negligent posterolateral (PL) portals. The PL compartment is smaller than posteromedial (PM) compartment by more than 1.5 times.[8] The popliteal artery has been found closer to posterior septum and may be a deterrent for creating transseptal portal from medial to lateral side. Kim et al. suggested that the transseptal has to be made from lateral to medial side to obviate any small chance of popliteal neurovascular injury. The PL portal needs to be created from outside-in technique therefore and it may be difficult to enter the smaller PL compartment.[13]

The PCL can be viewed entirety via PM portal. The previous literature suggests use of a single PM portal or the addition of a transseptal portal during PCL surgeries.[11,13,14] We propose use of dual PM portals to prevent the additional risk when creating transseptal and PL portals. The high PM portal serves as instruments working portal and the other PM portal as a viewing portal. The cadaveric study done by Pace and Wahl [12] suggested a safe zone in relation to the saphenous vein. They suggested knee flexion to 90 degrees as a mandatory position during the PM portal creation.[15] The injury to the saphenous nerve and vein was documented by multiple studies but the occurrence is uncommon.[15,16]

PCL avulsion fracture may be fixed with 4 mm cancellous using two PM portals[15-17] placed in the safe zone with consideration of the capsular folds for PCL tibial avulsion fixation with screw. Fixation method of PCL avulsion fracture is usually dictated by the size of the fragment. The smaller fragments are fixed using suture techniques. The 4mm cancellous cannulated with washers are utilized for larger fragments.[18,19] Posterior approach[20] and Burk Schaffer's approach including its modification[21] may be used for this purpose, too.

In the arthroscopic PCL tibial avulsion fixation transseptal or posterolateral portals may be used, and they may increase the risk to the knee posterior neurovascular anatomical structures. Zhao et al. fixed PCL tibial avulsion by two PM portals with polyester sutures fixed on a titanium tibial button,[22] Gui et al. also utilized two PM portals for avulsion fragment fixation with PDS sutures tied over a screw into the tibia[23] and Gwinner et al. used additional PM portals to perform PCL avulsion fracture using Tight Rope® device.[24]

This study aimed to evaluate the clinical outcomes of PCL tibial avulsion fracture fixation using dual PM portal technique, to avoid neurovascular anatomical structures injuries that may happen with PL portal, and done with screws, in order to provide a more rigid fixation.

MATERIALS AND METHODS

Ethical committee approval was taken prior to the study protocol introduction. In a prospective study, we followed 12 patients submitted to PCL tibial insertion avulsion arthroscopic fixation from March 2014 to Jan 2020. The inclusion criteria were isolated PCL avulsion fractures evaluated by clinical evaluation and confirmed with CT or MRI, and closed physes. Exclusion criteria were tibial avulsion fragment less than 1 cm, pre-existing knee arthrosis, any ligaments insufficiency which may need additional procedures, multiligamentous knee dislocations, any extension of fracture on the tibial plateau either medially or laterally, any avulsion fracture beyond 12 weeks, polytrauma patients with medical comorbidities and history of knee surgery in past.

All 12 patients were meticulously followed for a minimum of six months post-surgery. None of patients were lost to follow-up. Acute patients were considered those whose treatment was performed within three weeks of fracture occurrence, those whose treatment was performed between three and six weeks were classified as subacute and those treated between six and 12 weeks were considered chronic.

There were nine (75%) men and three (25%) women. Their mean age was 39.9 years (range from 29 to 50). There were five patients (41.7%) with road traffic injuries, four patients (33.3%) with hyperflexion knee injury mechanism, two patients (16.6%) caused by hyperextension and in one patient the mechanism was unknown. Seventy-five % (nine cases) were acute, one (8.3%) subacute and two (16.6%) were chronic.

The history was followed by a complete clinical examination to evaluate the posterior sag secondary to PCL tibial avulsion fracture. The mechanism of injury was documented as well. The knee was specifically evaluated of any additional ligament injury or neurovascular involvement. The MRI in addition to the basic X-ray enables the fixation method to be chosen and also aids in excluding the extension in the tibial plateau which can be missed on plain X-rays. When the fragment size was critical to the screw used for fixation we analyzed the CT scans, too. We fixed tibial avulsion fragments equal or greater to 1 cm to prevent splintering of the fragment while screw insertion. The patient was explained about the procedure along with the rehabilitation protocol and standard consent is taken. The follow-up X-ray was done at six and 12 weeks as per study protocol.

Surgical Technique and Rehabilitation

All 12 patients were operated under spinal anesthesia and tourniquet control. Leg hanging position was utilized with legs hanging within a thigh holder and unhindered flexion was checked. The thighs were abducted to increase the space between the two thighs to increase the working space which has to accommodate the arthroscope as well as multiple instruments including drill bits for screws passage. The anteromedial and anterolateral arthroscopic portals were created close to the patellar tendon and just a little above the joint line as the maximum work in through the intercondylar notch.

The meniscal pathologies were tackled initially. The arthroscope was then pushed in the PM compartment and the two portals were created by outside-in technique under direct visualization in the safe zone based on synovial folds of medial head of gastrocnemius and semimembranosus as described by McGinnis et al.[17] The needles

<< SUMÁRIO

and instruments were always directed from posterior to anterior angulation to avoid any neurovascular injury. The low portal was termed the viewing portal and the high PM portal was considered the instrument or working portal. Two arthroscopic cannulas were used to facilitate the introduction of arthroscope and instruments. (Figure 1) The arthroscope was placed in the lower PM portal. The higher PM was created to get adequate optimal trajectory for the suture instruments and drills to pass in the PCL facet on the tibia. The fragment was secured by guide wire followed by sequential drilling and 4mm cancellous cannulated screw insertion over washer. (Figure 2) There were certain tricks with the reduction. Many times a small serrated punch was used to push the PCL avulsion fracture towards the PCL facet. Alternatively, we had used a cannulated drill bit with serrations to reduce the fragment directly and then passed the guide wire from within to secure the fragment. Also, in one case, we used a PCL zig to firmly pull the fragment back as the wire was passed. Another way of reducing fragment was passing a suture from a scorpion biter and then passing a temporary suture through the substance of PCL and then push that suture along with the fragment towards the PCL facet with a knot pusher. Many times just passing the guide wire or drill rotated the fragment to a certain extent but then passing two wires settled that issue.

The screw trajectory had an angle that is directed from posteromedially to anterolaterally. The patients were given compressive crepe bandage dressing with knee immobilizer postoperatively. Pre and postoperative X-rays are showed at Figure 3.

Physiotherapy and bedside mobilization was advised immediately. Restricted or protected weight bearing was permitted after three weeks although range of motion was advised from day one. The patients were allowed to graduate from partial weight bearing starting from three weeks to full weight bearing by six weeks. The physiotherapy focused on regaining quadriceps strength and complete knee extension. The patients returned to their activities of daily living after three months. Bike, cycle was utilized during the postoperative phase after six weeks. Running, deep squatting was allowed only after complete range of motion and radiological union confirmation after three months.

The follow-up was done at two weeks, for portal stitch removal. The patients were asked to do an X-ray at six weeks and three months. Clinical evaluation of results was done using Lysholm and International Knee Documentation Committee (IKDC) score at three and six months' post-surgery.

Statistical Analysis

The Lysholm and International Knee Documentation Committee (IKDC) scores were evaluated statistically using SPSS (statistical package for social sciences) 25 version. The parametric paired Student's t-test was utilized for statistical calculations. The significance (α) was fixed at p=0.05.

RESULTS

All X-rays showed fracture union by six weeks except one case (8.3%) which showed delayed union but consolidated at 16 weeks. There were no complications directly related to the surgical procedure itself, such as failure of fixation, thrombophlebitis, neurovascular injuries, superficial or deep infections.

The following minor adverse results occurred in our cohort study: grade I on posterior sag was present in five knees (41.6%) as compared to contralateral side, although none had objective symptoms due to patellofemoral issues; temporary stiffness in two cases (16.7 %); temporary extension lag in two individuals (16.7%) delayed union in one patient (8.3 %); one patient (8.3%) had difficulty squatting at the end of six months; and fixed subtle flexion deficit of 3-5 degrees in one individual (8.3 %) occurred in a chronic case operated beyond six weeks post-injury and minor swelling persisting for three weeks post-surgery. (Table 1)

The follow-up at three months showed quadriceps wasting objectively with difference in thigh girth, difficulty to squat and fixed subtle flexion deficit of 3-5 degree in one (8.3 %) chronic case. The patient

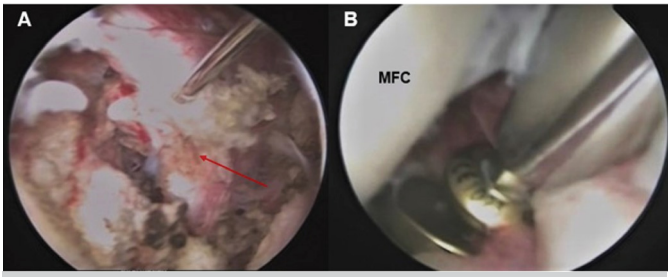

Figure 2. Arthroscopic view of the posterior left knee showing the fractured fragment reduced with a guide wire (red arrow) (A), the fragment fixation with one screw and the medial femoral condyle (MFC) (B).

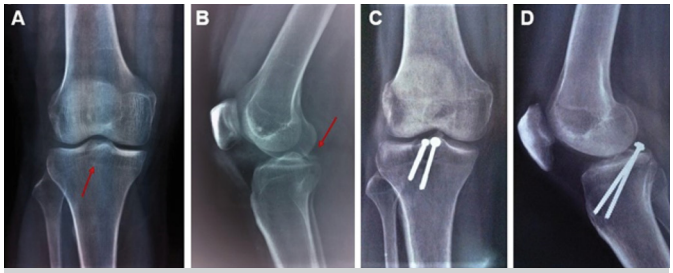

Figure 3. Preoperative AP X-ray of a right knee showing the fracture line (red arrow) (A), preoperative lateral X-ray showing the avulsioned fragment line (red arrow) (B), the reduction and fixation of the fractured fragment at the AP X-ray (C) and lateral X-ray (D).

Figure 1. Arthroscopic view of the posteromedial left knee corner showing one needle (red arrow) introduced from posterior to anterior and the medial femoral condyle (MFC) (A) the higher portal with one cannula (B) and two cannulas inside higher and lower portals (C).

was aggressively subjected to physiotherapy and at six months' quadriceps wasting recovered but difficulty in squatting persisted. Despite that adverse results the preoperative Lysholm score mean was 28.2 which increased to 75.4 at six months. Student's t-test yielded a P=0.000 which proves that the difference was statistically significant. The preoperative IKDC score mean of 10.1 increased to 89.3 at the end of six months and was statistically significance (p=0.000). (Table 1)

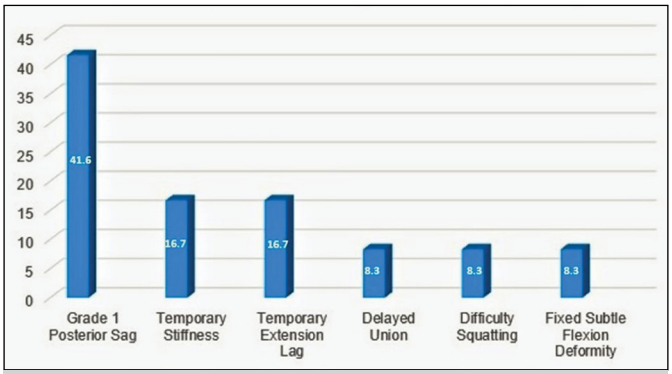

Figure 4. Adverse results after surgical treatment, in percentage.

Table 1. Comparative scores before and after the surgical procedure.

	Preoperatively	Postoperatively	p value
Mean Lysholm Score	28.2	75.4	0.000
Mean IKDC Score	10.1	89.3	0.000

DISCUSSION

The most important finding of our study was that transseptal and PL portals may be unnecessary for PCL tibial avulsion fixation if one more proximal PM portal is added for arthroscopic passage of the cancellous screw since it provides an optimal screw trajectory and this technique's outcomes were similar to those obtained with an open one.

In our study 75% of the patients were males and maximum patients were falling in the age group between 29-50 years with mean age being 39.9 years. Road traffic accident type (41.7%) was the main cause to produce upper pretibial contusion and PCL avulsion fractures in our population as we had an age group of people who got involved in vehicular type incidents with dashboard as the predominant mechanism. Data from literature are varied: in most articles, there is a predominance of males, ranging from 66.6 to 90 %,[6,18,22-27] patient's mean age diversified from 30 to 42.9 years,[6,18,22,23,24,26,27] and predominant mode of injury of PCL avulsion fractures was traffic accidents (57-90%).[18,22,23,26,27] According to Pache et al. dashboard trauma is the more common vehicular accidents whereas non-contact mechanism like hyperflexion and hyperextension are less common.[28]

All of our patients with PCL tibial avulsion were treated with arthroscopic fixation of the fragment by screws using two PM portals, but some authors did it through an open posterior approach.[18,26,29] Griffith et al. attached their PCL avulsion fractures either by arthroscopy or open surgery,[6] Chen et al. did arthroscopic suture fixation of the fragment using PM and PL portals[27] and Gwinner et al. created PM portals as needed in order to improve visualization of the PCL avulsion fracture and used Tight Rope® suture to fix the fragment.[24] Zhao et al. utilized two PM portals to fix PCL tibial avulsion with polyester sutures secured on a tibial button,[22] and Gui et al. created two PM portals for arthroscopic fixation of the PCL avulsed fragment tied over a screw in the tibia with PDS sutures.[23] Theoretically fracture fragment could have a more rigid fixation with screws.

The screw trajectory for PCL avulsion fixation was directed from posteromedially to anterolaterally and it is governed by the high instrument PM portal. It is not perpendicular to the fracture plane and their placement cannot be bicortical, as further advancement of the screw may injure the peroneal nerve if the angle of screw placement is extremely oblique and it ventures near the tibia-fibular side, also. Such an angle is only possible if the PM instrument portal is very low and anterior.

It was not possible to define a normal angle interval for the screw trajectory since we had a small number of patients. This angle which may injure the common peroneal nerve can only be validated by cadaveric studies. And to our knowledge, there are no papers in literature with arthroscopic screw fixations for PCL avulsion fractures as reference, and consequently there are no issues with concerning to the union in spite of screw obliquity, too.

All fracture healing occurred by six weeks except one chronic case (8.3%) which showed delayed union but had united at 12 weeks. This was the reason why it was unnecessary to repeat X-Rays after this period of time. One factor that had led to good union at six weeks in 11 cases might be that we have chosen avulsion fractures which had a size of 1 cm or greater wherein screw could be inserted without further splintering the fragment, and compression with screw with or without washer was achieved as well. Data from literature reports complete osseous healing of the bony avulsion in all cases[23,24,26,27,30] but Abdallah et al. reported one failure of fixation in a on-compliant patient.[25]

Regarding posterior instability, asymptomatic grade I posterior sag persisted in five knees (41.6%) of our population, possibly due to intrasubstance elongation[18,19], although none had any objective symptoms due to patellofemoral issues in our the short term follow-up.

Some authors reported the results of the PCL avulsed fragment arthroscopic fixation. For Chen et al. in 94.4% of patients the anterior-posterior translation was 0 to 2 mm and in 3 to 5 mm, in 5.6% of them.[27] Gwinner et al. patients had 2.8mm mean posterior tibial translation.[24] For Zhao et al. one of their 29 patients had 1+ positive posterior drawer test and it was negative in other patients.[22] Finally for Gui et al. the side-to-side difference was 0 to 2 mm in 23 patients and 3 mm in one patient.[23]

Other authors reported the results of open fixation of the PCL avulsion. Nicandri et al. reported that 80% of their patients had grade I laxity, and 20% demonstrated laxity grade II.[26] For Abdallah et al. the posterior drawer test returned to normal in 22 patients (81.5%), and it was grade I and II in 14.8% and 3.7% of the patients, respectively.[23] Piedade et al. reported that there was a residual draw of + (0.5 cm) to ++ (1 cm) in 95% of the cases. These authors believe that clinical outcomes suggest that PCL avulsion fracture should be interpreted as a bone-ligament injury,[16] although Inoue et al. didn't find any significant differences between normal and occult PCL mid-substance injury outcomes in primary repair of its avulsion fracture.[19]

Relating to motion deficit we had temporary stiffness in two cases (16.7%) and fixed subtle flexion deficit of 3-5 degrees in one chronic case (8.3 %) operated beyond six weeks.The PCL avulsed fragment arthroscopic fixation results were reported by some authors. In Zhao et al. series there was no extension limitation and flexion limitation in 6.8 % of the patients.[22] Gui et al. reported normal range of motion in 83.3% of the knees and terminal flexion limitations in 16.6 of them.[23] Chen et al. published that 27.7% of their patients had an extension deficit exceeding 10° and 8.3% of them showed flexion deficits between 16° and 25°.[27] On the other hand, Nicandri et al. using an open access for PCL avulsion fixation published that any of their 10 patients showed flexion difference greater than 10 degrees and extension difference greater than two degrees. In addition to the review of medical records of six patients lost to follow-up demonstrated that all had regained a functional range of motion, characterized as loss of extension <5 and flexion > 115°.[26]

<< SUMÁRIO

Regarding subjective evaluation, our mean Lysholm and IKDC scores at the end of six months were 75.4 and 89.3, respectively. Some authors also reported the results of subjective evaluation of arthroscopically treated patients. In Zhao et al. series the postoperative Lysholm score was 97.4 and the IKDC score was 97.1.[22] Chen et al. in his series of 36 patients the mean postoperative Lysholm score was 95,[27] and Gwinner et al. reported a mean Lysholm score of 82 and a mean IKDC was 72.6[24]. One publication whose authors used open approach fixation reported good and excellent postoperative Lysholm score in 43% and 57% of cases, respectively[16] and another paper, where the authors also used open access reported an average Lysholm score of 91.[29] Table 2 shows a comparative description of general outcomes. It's possible to realize that it may be difficult to compare the results of the residual posterior instabilities among the authors because they used different ways to describe them. On the other hand we noticed that flexion deficits are more common among the outcomes of authors who used arthroscopic treatment of PCL avulsion although these deficits have not been described by authors who used open surgery treatment or small deficits were considered normal.[26] Regarding the Lysholm and IKDA scores, they are subjective and may vary from one studied population to another.

Although a review of PCL avulsion fractures and the available treatment options,[31] two systematic studies[32,33] and one paper[30] reported similar outcomes for both open and arthroscopic PCL avulsion fractures fixation, the immediate postoperative recovery may be faster and less painful with arthroscopic approach.[24] Hooper et al. suggested that arthroscopic approach may gives a chance to treat intra-articular pathologies which can have a bearing in outcome when only open approaches were used, and that the arthroscopic procedure may have higher subjective and objective results scores, and slightly higher rate of arthrofibrosis.[33]

Our study has some limitations: the first one is the small number of cases, the absence of a control group and short follow-up, although we found some published papesr with fewer patients than in our study.[24,26,29]

Table 3. Summary Description of General Outcomes.

	Residual Posterior Instability	Motion Deficit	Lysholm Score	IKDC Score
Zhao et al. AS - 2006	3.4% PDT 1+	6.8% FD	97.4	97.1
Gui et al. AS - 2009	88.4% 0-2 mm PTT	16.6% FD	NA	NA
Chen et al. AS - 2012	94.4% 0-2mm PTT	27.7% ED >10º	95	NA
Gwinner et al. AS - 2016	2.8 mm mean PTT	NA	82	72.6
Piedade et al. OS - 2007	95% RD 1+ or 2+	NA	43% Good 57% Excellent	NA
Nicandri et al. OS - 2008	80% Grade I Laxity	Any Patient FD>10º, ED >2º	NA	NA
Chiarapattanakom et al. OS - 2009	NA	NA	91	NA
Abdallah et al. OS - 2017	14.8% Grade I 3.7% Grade II PDT	NA	NA	NA
Our Results AS	41.6% Grade I TPS	8.3% 3-5º FD	75.4	89.3

AS = Arthroscopic Surgery, OS = Open Surgery, PTT = Posterior Tibial Translation, PDT = Posterior Drawer Test, RD = Residual Draw, ED = Extension Deficit, FD = Flexion Deficit, TPS = Tibial Posterior Sag, NA = Not Available.

CONCLUSION

The PCL avulsion screw fixation by dual PM portal technique's outcomes was similar to those obtained with open approach. Nevertheless, mild flexion deficits and discreet posterior sag may be present in a significant number of cases, and this may lead to patellofemoral degenerative changes in the long term.

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ORTHOPEDIC TRAUMA

DISTAL FEMORAL FRACTURES FROM HIGH-ENERGY TRAUMA: A RETROSPECTIVE REVIEW OF COMPLICATION RATE AND RISK FACTORS

FRATURAS DISTAIS DO FÊMUR POR TRAUMA DE ALTA ENERGIA: UMA REVISÃO RETROSPECTIVA DA TAXA DE COMPLICAÇÕES E FATORES DE RISCO

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ABSTRACT

Objective: Determine complications' incidence and risk factors in high-energy distal femur fractures fixed with a lateral locked plate. Methods: Forty-seven patients were included; 87.2% were male, and the average age was 38.9. The main radiographic parameters collected were distal lateral femoral angle (DFA), distal posterior femoral angle (DPLF), comminution length, plate length, screw working length, bone loss, and medial contact after reduction and plate-bone contact, location of callus formation, and implant failure. The complications recorded were nonunion, implant failure, and infection. Results: Complex C2 and C3 fractures accounted for 85.1% of cases. Open fractures accounted for 63.8% of cases. The mean AFDL and AFDP were 79.8 4.0 and 79.3 6.0, respectively. The average total proximal and distal working lengths were 133.3 42.7, 60.4 33.4, and 29.5 21.8 mm, respectively. The infection rate was 29.8%, and the only risk factor was open fracture ($p = 0.005$). The nonunion rate was 19.1%, with longer working length ($p = 0.035$) and higher PDFA ($p = 0.001$) as risk factors. The site of callus formation also influenced pseudoarthrosis ($p = 0.034$). Conclusion: High-energy distal femoral fractures have a higher incidence of pseudoarthrosis and infection. Nonunion has greater working length, greater AFDL, and absence of callus formation on the medial and posterior sides as risk factors. The risk factor for infection was an open fracture. ***Level of Evidence III; Retrospective Cohort Study.***

Keywords: Femoral Fractures. Shock, Traumatic. Femoracetabular Impingement. Pseudarthrosis.

RESUMO

Objetivos: Determinar a incidência e os fatores de risco de complicações nas fraturas de alta energia das fraturas distais do fêmur fixadas com placa bloqueada lateral. Métodos: Foram incluídos 47 pacientes, sendo 87,2% homens e idade média de 38,9 anos. Os principais parâmetros radiográficos coletados foram o ângulo femoral distal lateral (AFDL), ângulo femoral distal posterior (AFDP), comprimento da cominuição, comprimento da placa, comprimento de trabalho dos parafusos, perda óssea, contato medial após a redução e contato placa-osso, localização da formação do calo e falha do implante. As complicações registradas foram não união, falha do implante e infecção. Resultados: Fraturas complexas C2 e C3 representaram 85,1% dos casos. As fraturas expostas corresponderam a 63,8% dos casos. O AFDL e AFDP médios foram 79,8° ± 4,0° e 79,3°± 6,0°, respectivamente. Os comprimentos de trabalho total, proximal e distal médios foram 133,3 ± 42,7, 60,4 ± 33,4 e 29,5 ± 21,8 mm, respectivamente. A taxa de infecção foi de 29,8% e o único fator de risco foi a fratura exposta ($p = 0,005$). A taxa de não união foi de 19,1%, com maior comprimento de trabalho ($p = 0,035$) e maior PDFA ($p = 0,001$) como fatores de risco. O local de formação do calo também influenciou na pseudoartrose ($p = 0,034$). Conclusões: Fraturas distais do fˆmur de alta energia apresentam maior incidência de pseudoartrose e infecção. A não união tem como fatores de risco maior comprimento de trabalho, maior AFDL e ausência de formação de calo nos lados medial e posterior. O fator de risco para infecção foi a fratura exposta. ***Nível de evidência III; Estudo de Coorte Retrospectivo.***

Descritores: *Fraturas do Fêmur. Choque Traumático. Impacto Femoroacetabular. Pseudoartrose.*

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INTRODUCTION

Distal femur fractures are common orthopedic problems affecting individuals across varied age groups, ranging from young patients with high-energy trauma to elderly patients with an injury associated with osteoporosis and a lower energy mechanism of trauma such as simple falls. For both groups, surgical fixation is the treatment of choice.[1] Lateral locking plate (LLP) has become the standard method of fixation because of its biomechanical property to resist varus collapse, multiple fixation points in the short distal fragment, and technical ease implant.[2,3] As this technique has been used in various fracture patterns, ranging from low-energy fractures to high-energy fractures, moderate nonunion, infection, and implant failure rates have been reported.[4,5]

The risk factors for complications after LLP include patient-related factors (such as age, sex, habits, and comorbidities), fracture characteristics (such as type of fracture, comminution, bone loss, and soft tissue injury), and fixation-related factors (such as reduction, plate length, working length, and number of screws).[6] Factors associated with complications and failures should be determined separately according to the mechanism of trauma. Both patients and fractures are different in low-energy and high-energy trauma, and most likely, the complication rates and risk factors may also be different between them.

The goals of this study were to examine a population of patients with high-energy distal femur fractures treated with LLP to determine the incidence and risk factors of complications.

MATERIAL AND METHODS

This retrospective study was performed at the Instituto de Ortopedia e Traumatologia da Faculdade de Medicina da Universidade de São Paulo, an urban university-based level 1 trauma center, between 2012 and 2018. Data were collected through a retrospective chart review and review of existing radiographs. Ethical approval was provided by the Scientific and Ethical Committee of the University under the protocol 2.827.192. Written informed consent was obtained from all patients.

The inclusion criteria were as follows: type A and type C distal femur fractures, open reduction and internal fixation with LLP, age > 18 years, victims of high-energy trauma, no previous procedures in the knee, a minimum of 9 months of follow-up, complete radiographic examination, and signed informed consent.

The exclusion criteria included low-energy fractures, periprosthetic fractures, type B distal femur fracture, intramedullary fixation, dual plating fixation, contraindication for surgery or anesthesia, would infection prior to internal fixation, pathologic fractures, and associated neurovascular injury.

Demographic data on the following were collected: age, sex, mechanism of trauma, associated injuries, OTA/AO classification,[7] and Gustilo classification[8] for open fractures.

The surgical technique followed established recommendations provided in the literature.[9,10] All patients were fixed with a stainless-steel LLP (De Puy Synthes, USA). Weight-bearing as tolerated was allowed during the postoperative rehabilitation.

The radiographic parameters evaluated were the quality of articular reduction, lateral distal femoral angle (LDFA), posterior distal femoral angle (PDFA), length of comminution, length of the plate, screw working length, number of screws proximal and distal, bone loss, medial contact after reduction and plate bone contact, location of callus formation, and implant failure. (Figure 1)

The quality of reduction was classified binarily as anatomical or nonanatomical reduction.

The coronal plane alignment was measured using the LDFA. AP radiographs were used to measure the angle on the lateral side between the anatomical axis of the femoral shaft and the articular line. The PDFA measured the sagittal alignment on the lateral view with the angle between the femoral shaft and the line parallel to the articular line with the Blumensaat line as a reference. (Figure 1)

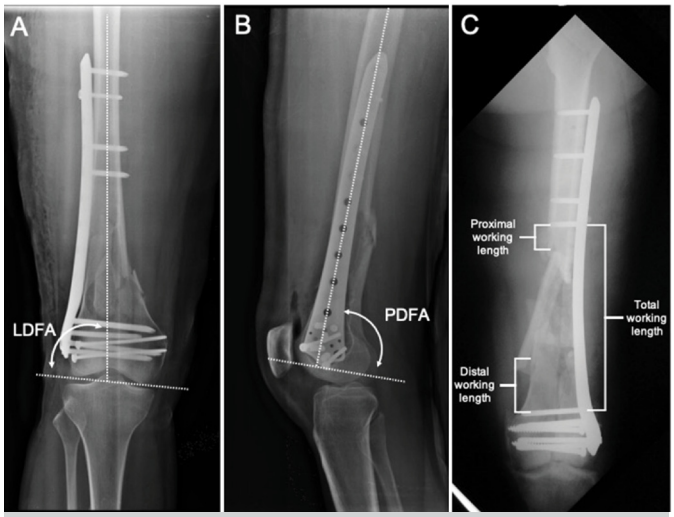

Figure 1. Radiographic measurements. - A- Lateral distal femoral angle (LDFA), B- Posterior distal femoral angle (PDFA), C- Total working length, proximal and distal working length.

The length of the plate was defined by the number of holes proximal to the articular cluster, and the total working length was defined as the distance spanning the fracture site between the two screws on each side closest to the fracture.[11] The proximal working length was defined as the distance between the fracture and the immediate proximal screw, and the distal working length as the distance between the fracture and the immediate distal screw. (Figure 1)

According to its location (anterior, posterior, medial and lateral) the location of the callus formation was noted. Union was defined as the presence of a minimum of three of four bridging cortices on AP and lateral X-rays at 6 months.[12] Failure to meet the minimum requirement of the bridging cortices was recorded as nonunion.

The following complications were recorded: implant failure, deep infection, nonunion, and reoperation. Mechanical implant failure was defined as any failure of the implant, including plate break, screw breakage, plate loosening, bending of the plate, and screw disengagement.[13] Infection was defined according to the fracture-related infection criteria published by Metzemakers et al in 2018.[14]

Descriptive statistics included means and standard deviations for continuous variables and counts (percentages) for categorical variables. Statistical analysis of infection and nonunion was performed using the chi-square test or Fisher's exact test. Comparative analysis was performed according to the outcome and compared using Student's t-test. Odds ratios were estimated with the respective 95% confidence intercal and adjusted with the model of multiple logistic regression with the variables that presented with a descriptive level of bivariable analysis less than 0.10 ($p<0.10$). Statistical analysis was performed using IBM SPSS software for Windows version 22.0, with a significant level of 5%.

RESULTS

During the observation period (2012-2018), a total of 56 patients with high-energy distal femur fracture were treated with LLP. Nine patients were excluded from the study due to incomplete follow-up or radiographic control. Among the 47 included patients, 41 (87.2%) were men and six (12.8%) were women, with an overall average age of 38.9 ± 12.9 years.

The most frequent trauma mechanism was motorbike accidents in 27 (57.4%) cases, followed by motor vehicle accidents in nine (19.!1%) cases, and falls from height and run over by a car in four (8.5%) cases each. Associated injuries occurred in 31 (65.9%) cases. (Table 1)

According to the OTA/AO classification, 24 (51.1%) fractures were type 33C3, 16 (34.0%) were type 33C2, and the remaining seven (14.9%) were type A (Table 1). The average length of comminution was 50.1 ± 31.3 mm.

Thirty (63.8%) fractures were open, of which 28 (80.0%) were Gustilo type 3A and two (6.7%) were Gustilo 3B (Table 1).

Articular anatomical reduction was achieved in 35 (74.5%) patients. The plate length was 13 holes in 34 (72.3%) patients, 11 holes in two (4.3%) and nine holes in 11 (23.4%) patients. The coronal alignment measured by the LDFA average was 79.8°± 4.0° and that by the sagittal plane PDFA was 79.3°± 6.0°. The average total working length was 133.3 ± 42.7 mm. The proximal working length was 60.4 ± 33.4 mm, and the distal working length 29.5 ± 21.8 mm. More details can be seen by comparing radiographical parameters and nonunion in Tables 2 and 3.

The overall deep infection rate was 29.8% (14 fractures). Of the 17 closed fractures, only one developed a postoperative deep infection, and of the 30 open fractures, 43.4% (13 fractures) developed deep infection. Open fracture was a statistically significant factor for infection (p=0.005) (Table 4). The presence of associated injuries almost reached a statistically significant risk factor (p=0.055). None of the other patient characteristics had a positive effect on the postoperative infection rate (p>0.05).

Nonunion was noted in nine (19.1%) cases. Statistical analysis revealed a strong correlation between nonunion and a longer total working length (p=0.035) and higher values of PDFA (p=0.001). The likelihood of nonunion increased by 31% for each unit with a higher PDFA (Table 5). The location of the callus formation was also correlated with the development of nonunion (p=0.034). The least influenced nonunion development location was medial callus formation, followed by posterior callus formation. (Table 4)

Some results emphasized the lack of correlation between nonunion and length of comminution (p=0.165), bone loss (p=0.071), and medial contact after reduction (p=0.138).

Infection did not correlate with the development of nonunion (p>0.05).

Table 1. Demographic characteristics of the patients.

Variable	Description (n = 47)
Age (years)	
Mean ± SD	38.9 ± 12.9
Median (min.; max.)	39 (18; 69)
Gender, n (%)	
Female	6 (12.8)
Male	41 (87.2)
Mechanism of injury, n (%)	
Motorbike accident	27 (57.4)
Motor vehicle accident	9 (19.1)
Fall from height	4 (8.5)
Run over by car	4 (8.5)
Other	3 (6.5)
Associated injuries, n (%)	
No	16 (34.1)
Yes	31 (65.9)
AO/OTA classification, n (%)	
A1	1 (2.1)
A2	2 (4.2)
A3	4 (8.5)
C2	16 (34.1)
C3	24 (51.1)
Open fractures, n (%)	
No	17 (36.2)
Yes	30 (63.8)

DISCUSSION

Distal femoral fractures have a bimodal distribution - high-energy trauma in young patients and low-energy trauma in elderly patients.[15] The systemic condition of the patients and the characteristics of the fracture are completely different between the two groups, In young patients multiorgan injury (polytrauma) is the main systemic concern, followed by other associated orthopedic injuries. In contrast, in elderly patients, the frail systemic condition, comorbidities, and polypharmacy are the main concerns.

In young patients with high-energy injuries, fractures tend to be intra-articular, have more displacement and comminution, and more severe soft tissue compromise. In contrast, in elderly patients, fractures tend to be simple, non-comminutes, and extra-articular and the main concern in fixation is bone quality.[16,17]

Despite occurring in the same anatomical area, high- and low-energy fractures are two completely different types of fractures. In our view, studies to analyze the risk of complications should separate the risk of high-energy fractures from that of low-energy fractures. This is because the risks and consequences of both are different. This may explain the wide range of incidence of complications, such as nonunion varying from 6%[18] to 38%[19] and infection from 3%[20] to 15%.[17]

To our knowledge, this is the first study to include only high-energy fractures with a significant number of patients (n=47) to determine the incidence and risk factors of complications. In a review by Ebraheim et al.,[19] among the 19 studies, the number of patients varied from 1 to 31.

Similar to that reported in the literature, in our study, the average age was 38.9%, most patients were young, and there was a male predominance (87.2%). In contrast to the predominant cause of injury (motor vehicle accident) reported in the literature, due to the characteristics of the traffic in the city, the main cause of injury was motorbike accidents (57.4%) in our study.

In contrast to low-energy trauma, where an isolated injury is more common, associated injuries were reported in 65.9% patients in our study. Another characteristic of high-energy trauma is the type of fracture with more complex, comminuted, and articular involvement. In our series, 85.2% fractures were C2 and C3 types.

The nonunion rate was 19.1% (9/47 patients). The incidence of non-union was highly correlated with a longer working length (p=0.035) and higher PDFA (0.001).

Two factors influence the total working length - the extension of the comminution and the decision of the surgeon to insert the screws closest to the fracture. Longer comminutions lead to longer working length; however, with the use of long plates, the surgeon can increase the proximal working length and position the screw distant from the fracture. We did not observe the influence of extension of comminution on the nonunion rate (p=0.165). However, the proximal working length was almost double the distal working length (63.8 mm vs. 29.6 mm), causing an imbalance in the total working length. One may consider decreasing the total working length by inserting the proximal screw closer to the fracture, thus decreasing the proximal working length. This aligns with what Peschiera et al.[21] called in their article as unbalanced fixation as risk factor for nonunion. In a study conducted by Ricci et al.,[11] longer working length was

Table 2. Description of the non-union according to the radiographic measurements and the statistical analysis.

Variable	Non-union		OR	IC (95%)		p
	No	Yes		Inferior	Superior	
LDFA (79 - 83)			**0.86**	**0.71**	**1.04**	**0.104****
mean ± SD	80.5 ± 4	78 ± 4.2				
median (min.; max.)	80 (72; 88)	80 (70; 82)				
PDFA (79 - 87)			**1.23**	**1.03**	**1.48**	**0.001***
mean ± SD	78.4 ± 6.1	83.8 ± 3.3				
median (min.; max.)	78 (66;90)	84 (78; 88)				
Length of comminution (mm)			**1.02**	**0.99**	**1.04**	**0.165****
mean ± SD	74.4 ± 29.8	63.5 ± 33.9				
median (min.; max.)	43 (8; 127)	79 (12; 100)				
Total working length (mm)			**1.02**	**1.00**	**1.04**	**0.035****
mean ± SD	126.6 ± 40.5	159.1 ± 40.7				
median (min.; max.)	118 (41; 221)	149 (113; 253)				
Proximal working length (mm)			**1.00**	**0.98**	**1.03**	**0.767****
mean ± SD	60.1 ± 32.9	63.8 ± 36.6				
median (min.; max.)	51 (11; 182)	59 (22; 127)				
Distal working length (mm)			**1.00**	**0.97**	**1.03**	**0.982****
mean ± SD	29.4 ± 23.2	29.6 ± 16.5				
median (min.; max.)	28 (3; 148)	26 (13; 67)				
Plate length (holes)			**1.26**	**0.77**	**2.04**	**0.287****
mean ± SD	11,7 ± 1.9	12.3 ± 1.4				
median (min.; max.)	13 (9; 13)	13 (9; 13)				
Bone-plate contact, n (%)						**> 0.999***
No	11 (23.4)	2 (14.3)	1.00			
Yes	27 (76.6)	7 (20.6)	1.56	0.28	8.62	
Proximal screws			**1.50**	**0.43**	**5.28**	**0.536****
mean ± SD	4.0 ± 0.6	4.1 ± 0.3				
median (min.; max.)	4 (2; 6)	4 (4; 5)				
Distal screws			**1.37**	**0.54**	**3.48**	**0.522****
mean ± SD	5.4 ± 0.8	5.6 ± 0.7				
median (min.; max.)	5 (4; 7)	6 (4; 6)				
Bone loss, n (%)						**0.071***
No	35 (85.4)	6 (14.6)	1.00			
Yes	3 (50.0)	3 (50.0)	6.00	0.97	36.99	

** Fischer exact test, * Student t test.

Table 3. Description of the non-union according to the radiographic measurements and the statistical analysis.

Variable	Non-union		OR	IC (95%)		p
	No	Yes		Inferior	Superior	
Medial contact after reduction, n (%)						**0.138**
No	10 (66.6)	5 (33.3)	1.00			
Yes	28 (87.5)	4 (12.5)	0.31	0.07	1.39	
Callus formation, n (%)						**0.034**
Anterior	3 (100)	0 (0)	1.00			
Medial	17 (100)	0 (0)	&			
Posterior	11 (64.7)	6 (35.3)	&			
Lateral	2 (66.7)	1 (33.3)	0.55	0.03	10.37	
Postero-medial	2 (66.7)	1 (33.3)	0.55	0.02	19.56	
Implant failure, n (%)						**0.188**
No	38 (82.6)	8 (17.3)	1.00			
Yes	0 (0)	1 (100)	&			

** Fischer exact test, * Student t test.

Table 4. Description of the infection according to demographical characteristics and the statistical analysis.

Variable	Infection		OR	IC (95%)		p
	No	Yes		Inferior	Superior	
Age (years)			**0.98**	**0.93**	**1.03**	**0.416****
mean SD	40.6 13.5	37 13.9				
median (min.; max.)	40 (18; 61)	38.5 (19; 69)				
Gender, n (%)						**0.656***
Female	5 (83.3)	1 (16.7)	1.00			
Male	28 (68.3)	13 (31.7)	2.24	0.24	21.15	
Associated injuries, n (%)						**0.055***
No	8 (50.0)	8 (50.0)	1.00			
Yes	25 (80.6)	6 (19.4)	0.27	0.07	1.00	
AO/OTA classification, n (%)						**0.183****
A1	1 (100)	0 (0)	1.00			
A2	2 (100)	0 (0)	&			
A3	4 (100)	0 (0)	&			
C2	10 (62.5)	6 (37.5)	&			
C3	16 (66.7)	8 (33.3)	&			
Open fracture, n (%)						**0.005**
No	16 (94.1)	1 (5.9)	1.00			
Yes	17 (56.7)	13 (43.3)	13.00	1.53	110.73	

** Fischer exact test, * Student t test.

Table 5. Result of regression analysis to explain non-union.

Variable	OR	IC (95%)		p
		Inferior	Superior	
PDFA (79 - 87)	1.31	1.03	1.65	0.025
Total working length	1.03	1.00	1.06	0.053

Multiple logistic regression analysis (full model).

an independent risk factor for nonunion. Based on the results reported by Kiyono et al.,[22] leaving one hole empty on either side of the fracture may decrease the incidence of nonunion in both simple and comminuted fractures.

A higher PDFA also had a positive correlation with nonunion (p=0.001). Each increase in the angle increased the risk of non-union (p=0.025). A high PDFA indicates a lack of reduction of the extension deformity caused by the gastrocnemius muscle. The result is the creation of a gap in the posterior side of the femur. The callus formation results showed that the two most important locations for callus formation to avoid nonunion were medial and posterior. During surgery, it is important to pay attention to the reduction in the sagittal plane, which is occasionally difficult because of the external guide of the plate that interferes with the C-arm image.

In contrast to the findings reported by Karam et al.[23] and Ebraheim et al.,[19] the presence of comminution or extension of comminution was not a risk factor for nonunion (p=0.165) in our study.

There was no correlation between bone loss and nonunion (p=0.071), but analysis of the absolute numbers showed that 50% cases with bone loss developed nonunion (3/6). In addition, there was also no correlation with medial contact after reduction (p=0.138), but analysis of absolute numbers showed that almost 50% cases with nonunion did not have medial contact.

Individual analysis of the nine cases of nonunion showed that they all had a hypotrophic type of nonunion with little callus formation on the medial and posterior side.

The low implant failure, regardless of the 19.1% nonunion rate, may be explained with the use of long plates (11- and 13-holes plates in 95.7%). The long plates and the long lever arm prevented plate pullout. This is in line with the recommendation of many authors to use long plates to avoid failure.[11,15,22] Long plates allow for longer working lengths, but care should be taken even in long plates to keep the working length short.[23]

The deep infection rate was 29.8% (14/47 patients), and the only predictive factor was open fracture (p=0.005). In this study including only high-energy fractures, the incidence of open fracture was 63.8% (30/47), and among these cases, 43.3% (13/30) developed deep infection. Regardless of initial care with abundant lavage and debridement and staged treatment with external fixation, the incidence of infection was high. The combination of severe soft tissue injury and the comminution of the fracture puts this injury at a high risk of infection when caused by high-energy trauma.

Bai et al.[20] studied the incidence of infection in 665 distal femur fractures and found an infection rate of 3.6%. The low number of infections can be explained by the inclusion of low-energy fractures, representing 30% cases and representing < 20% of the infected cases. Looking at only the high-energy cases, they represented 83.3% of the infections and also had open fractures as risk factor.

This study has several limitations. This study was retrospective, therefore, the final decision about the implant and its application was made by the operating surgeon and could not be controlled experimentally. A low number of patients may have influenced the results. Several patients who initially met the inclusion criteria were unable to complete the 9-month follow-up. Any radiographic measurement may be inconsistent because of the magnification of the image and imprecise measurement.

In conclusion, the incidence of complications is higher in high-energy distal femur fractures than in low-energy fractures. We found a strong correlation between nonunion and the total working length of the fixation and the increase in the PDFA. Callus formation on the medial and posterior sides had a negative influence on the nonunion rate. The only risk factor for infection was open fracture.

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ORTHOPEDIC TRAUMA

FUNCTIONAL OUTCOME OF TREATMENT OF DEVIATED OLECRANON FRACTURE (MAYO 2A) BY AN INTRAMEDULLARY SCREW WITH TENSION BAND COMPARED TO CLASSIC TENSION BAND - A PROSPECTIVE RANDOMIZED STUDY

RESULTADO FUNCIONAL DO TRATAMENTO DA FRATURA DO OLÉCRANO DESVIADA (MAYO 2A) COM PARAFUSO INTRAMEDULAR COM BANDA DE TENSÃO COMPARADO À BANDA DE TENSÃO CLÁSSICA - ESTUDO PROSPECTIVO RANDOMIZADO

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ABSTRACT

Objective: evaluate the functional treatment outcome of deviated transverse olecranon fractures (Mayo 2A) after treatment with tension-banded intramedullary screw (PIBT) compared to classical tension band (BTC). Methods: Prospectively collect all deviated transverse olecranon fractures from 2012 to 2016 and randomize them into PIBT and BTC groups. Range of motion (ROM) was measured after 2 and 5 weeks, 3 and 6 months, and 1 and 2 years. Functional assessments (DASH, Oxford Elbow Score, and Mayo Elbow Performance Index) were performed after 3 and 6 months and 1 and 2 years. Complications were collected up to 2 years of follow-up. Results: 22 patients were included, 11 in each group. The mean age was 47.9 years, and the left side was injured in 13 (59.0%) patients. All patients completed the 2-year follow-up. There was no ROM difference at any time between the two groups (p> 0.005). Flexion and extension gain was maximum at three months and remained unchanged until two years. Neither flexion nor extension returned to normal, missing around 10°. Pronation and supination returned to normal. All three functional scores showed almost complete recovery of elbow function after three months postoperatively, with no difference between the groups. No group had complications, no reoperation, and no implant removal. Conclusion: PIBT had similar results in ROM and functional score compared to BTC. Both had low complication rates and no need for implant removal. ***Level of evidence I; Randomized Trial.***

Keywords: Olecranon Process. Fracture Fixation, Internal. Treatment Outcome.

RESUMO

Objetivo: Avaliar o resultado funcional do tratamento das fraturas transversas desviadas do olécrano (Mayo 2A) após o tratamento com parafuso intramedular com banda de tensão (PIBT) em comparação com a banda de tensão clássica (BTC). Métodos: Foram coletados prospectivamente todas as fraturas transversas do olécrano desviadas de 2012 a 2016 e randomizá-las em dois grupos: PIBT e BTC. A amplitude de movimento (ADM) foi medida após 2 e 5 semanas, 3 e 6 meses e 1 e 2 anos. As avaliações funcionais (DASH, Oxford Elbow Score e Mayo Elbow Performance Index) foram realizadas após 3 e 6 meses e 1 e 2 anos. As complicações foram coletadas até 2 anos de acompanhamento. Resultados: Foram incluídos 22 pacientes, 11 em cada grupo. A idade média foi de 47,9 anos, e o lado esquerdo foi lesado em 13 (59,0%) pacientes. Todos os pacientes completaram o acompanhamento de 2 anos. Não houve diferença na ADM em nenhum momento entre os dois grupos (p> 0,005). O ganho de flexão e extensão foi máximo aos 3 meses e permaneceu inalterado até 2 anos. Nem a flexão nem a extensão voltaram ao normal, faltando em torno de 10º. A pronação e a supinação voltaram ao normal. Todos os três escores funcionais mostraram uma recuperação quase completa da função do cotovelo após 3 meses de pós-operatório, sem diferença entre os grupos. Nenhum grupo apresentou complicações, nem reoperação ou retirada do implante. Conclusão: O PIBT teve resultados semelhantes na ADM e pontuação funcional em comparação com o BTC. Ambos tiveram baixas taxas de complicações e não há necessidade de remover implantes. ***Nível de evidência I; Estudo clínico randomizado.***

Descritores: *Olécrano. Fixação Interna de Fraturas. Resultado do Tratamento.*

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INTRODUCTION

Olecranon fractures commonly occur from falls from ground-level height or more high energy trauma in young patients.[1] They account for 10% of upper extremity injuries and simple type transverse fractures account for approximately 85% of all adult olecranon fractures.[2,3]

Except for undisplaced fractures, most of the olecranon fractures require open reduction and internal fixation with primary aim to restore articular congruity with anatomical reduction, restoration of the extensor mechanism and a stable fixation to allow early range of motion.[4]

For intra-articular simple transverse fractures (Mayo IIA) the tension band wiring remains the AO recommended first-line treatment, as it allows early mobilization, it is relatively simple technique and is of low cost.[5]

Because some biomechanical studies questioned the thought that the tension band wiring converts tensile forces in compressive forces at the joint surface[6,7] and complications like painful hardware prominence, heterotopic ossification, non-union and ulnar nerve neurapraxia are commonly reported,[8,9] other different methods of fixation started to be used.

Amongst different types of fixation options, the 6.5 mm intramedullary cancellous screw with tension band wiring is a reliable option because it provides a rigid fixation with the combination of interfragmentary compression given by the lag screw and the tension band effect given by the cerclage wire.[10] Ahmed et al. showed good clinal results and low re-operation rates with this technique.[11]

The aim of this study is to compare the functional results and complications of displaced simple olecranon fractures using intramedullary screw combined with tension band and the classic AO tension band wiring.

CASUISTICS AND METHODS

This is a prospective randomized study looking at simple transverse olecranon fractures (Mayo 2A), in a tertiary teaching hospital from 2012 to 2016. The study was approved by the Scientific and Ethic Commission of the University under the number 164.130. The CONSORT guidelines were used to ensure comprehensive reporting of this study.[12]

The inclusion criteria were simple transverse fracture of the olecranon, displaced, Mayo 2A, mature skeleton, closed fracture, be able to comply with the functional evaluation, signed term of consent and agreement to complete 2-year follow-up.

The exclusion criteria were pathologic fractures, multifragmentary fractures, open fractures, associated injury in the ipsilateral upper extremity, polytraumatized patients, not able to comply to the functional evaluation, previous elbow stiffness and incomplete follow-up.

The demographic data collected from the enrolled patients were age, gender, injury side, dominance, and mechanism of trauma.

The patients were randomly divided into two groups: 1 - AO tension band wiring (TBW) and 2 - intramedullary screw with tension band (ISTB), following a list generated in Microsoft Excel file, in groups of five. To decrease bias the randomization was done immediately before the surgery and the surgeons didn't have access to the randomization list.

The TBW followed the classic technique with insertion of two parallel 1.6 mm Kirschner wires, placed antegrade across the fracture, penetrating the anterior cortex. A 1.0 mm stainless steel wire was passed through a pre-drilled hole perpendicular to the ulnar shaft and then passed in a figure of eight and tensioned symmetrically under gentle traction (Figure 1).[13]

The ISTB involved the intramedullary insertion of a partially threaded 6.5 mm cancellous screw with a washer through the tip of the olecranon crossing the fracture site and a 1.0 mm stainless steel wire passed and tightened (Figure 1).[14]

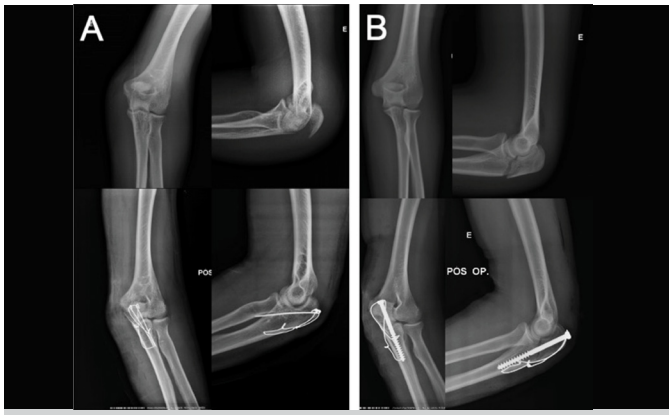


Figure 1. Cases representing: A- tension band wiring (TBW), and B- intramedullary screw with tension band.

All patients were put in a back slab for seven days, and then gentle active exercises were gradually started, with flexion-extension and prono-supination exercises done four times a day.

Check X-rays (anteroposterior and lateral views) were obtained after 2, 6, 12 weeks, 6 months, 1 and 2 years.

The range of motion (flexion, extension, supination and pronation) was evaluated with a goniometer after 2 and 6 weeks, 3 and 6 months, and 1 and 2 years. The assessor was blinded regarding the surgical procedure performed in the patient.

The functional evaluation was done at 3, 6, 12 and 24 months. The assessments were done with the DASH score, Oxford Elbow Score and Mayo Elbow Performance Index.

Complications that were collected included implant loosening, loss of reduction, non-union, infection and re-operation.

For binary and ordinal variables proportions and percentage were presented. For continuous variables the descriptive statistics were presented in counts, mean and standard deviation. Comparison among two groups for each continuous dependent variable were done using non-parametric Wilcoxon Rank Sum test. For comparison between independent groups of variables the Mann-Whitney test was used. The level of significance was 5%. The software used for the analysis was the SPSS v.18 for Windows.

RESULTS

A total of 22 patients were included in the study, 11 in the TBW group and 11 in the ISTB group. In total 9 (40.9%) patients were male and 13 (59.1%) female. The average age in TBW was 48.7 ± 15.6 years and in ISTB was 47.1 ± 14.6 years ($p = 0.7414$). There was a slight predominance of injury on the left side, 13 (59.0%) patients. The dominant side was injured in 15 (68.1%) patients (Table 1). The groups were comparable in the characteristics of the patients.

The main mechanism of trauma was fall from ground-level height in 12 (54.5%) patients, followed by motorbike accident in 5 (22.7%). All patients completed 2 years follow-up with radiographic and functional evaluations.

The results of the evolution of the active flexion and extension measurements in 2 and 6 weeks, 3 and 6 months and 1 and 2 years are shown in Figure 2 and 3, respectively. In the 3-month evaluation ISTB had a slight better active flexion, but it was not statistically significant ($p = 0.168$). For the active extension, overall, it was greater in the ISTB group, but it was also not statistically significant ($p > 0.05$).

Figure 4 and 5 show the results of active pronation and supination. There was no statistical difference between the groups at any point in

Table 1. Characteristics of study participants.

Characteristics	$n_{missing}$		n = 22	n (%)
Gender	0	Male	9 (40,9)	
		Famale	13 (59,1)	
Race/ color	1	White	12 (57,1)	
		Black	1 (4,8)	
		Brown	7 (33,3)	
		Yellow	1 (4,8)	
Body mass index (kg/m^2)		Mean (SD)		24,7 (3,0)
		Median (min-max)		24 (19,0-29,4)
Dominance	9	Right	12 (92,3)	
		Left	1 (7,7)	
Occupation	9	Retired	1 (7,7)	
		Cleaning assistant	1 (7,7)	
		Realtor	1 (7,7)	
		Dentist	1 (7,7)	
		From home	2 (15,4)	
		Bank clerk	1 (7,7)	
		Student	3 (23,1)	
		Photographs	1 (7,7)	
		Teacher	1 (7,7)	
		Saleswoman	1 (7,7)	
Smoking	8	No	12 (85,7)	
		Yes	2 (14,3)	
Associated diseases	8	No	8 (57,1)	
		Yes	6 (42,9)	
Continuous use medication	8	No	7 (50,0)	
		Non-steroidal anti-inflammatory drugs	1 (7,1)	
		Antihypertensives	2 (14,3)	
		Antihypertensives+ antidiabetics	1 (7,1)	
		Antihypertensives+ anticoagulants	1 (7,1)	
		Antihypertensives+ anticoagulants+other	1 (7,1)	
		Other	1 (7,1)	
ASA	8	1	8 (57,1)	
		2	6 (42,9)	
Physical activity	9	No	5 (38,5)	
		Bodybuilding	1 (7,7)	
		Other activity	7 (53,8)	
Labor dispute	13	No	7 (77,8)	
		Yes	2 (22,2)	

SD: standard deviation; min: minimum value; max: maximum value.

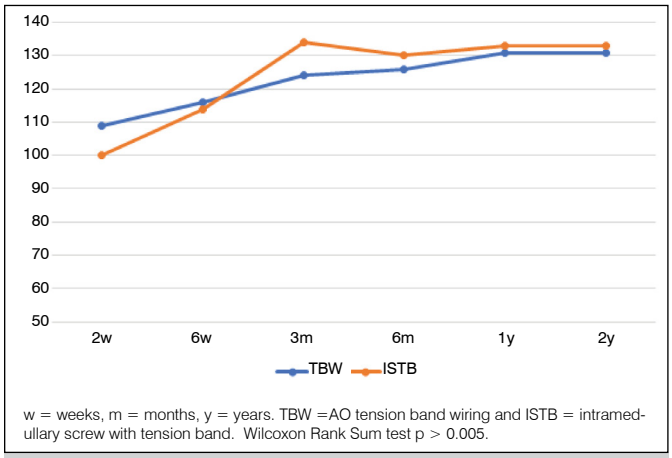
time (p = 0.05), both achieving the maximum range of motion. What can be seem is the faster recovery of the supination over the pronation. Figure 6 shows the assessment with the DASH score, Figure 7 with the Oxford Elbow Score and Figure 8 with Mayo Elbow Performance Index. None of the functional score showed any difference between the functional results between TBW and ISTB in any point in time (p > 0.005). There was no complication noted in any of the groups.

DISCUSSION

We were able to include same number of patients in each group, with a predominance of the fracture in women (59.0%), but with the same distribution between the two groups.

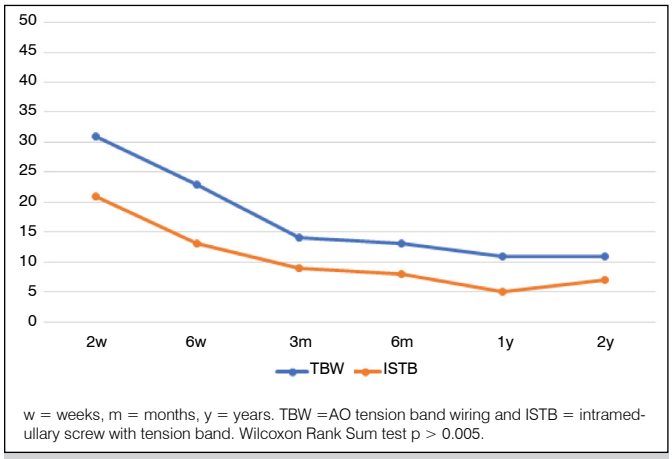
In the non-displaced olecranon fractures, the conservative treatment with immobilization and serial radiographs to monitor for displacement is the treatment of choice.[15] For the displaced fractures multiple surgical treatment have been described, including tension band wiring (TBW), plate fixation (PF), intramedullary screw fixation (IMS), intramedullary screw with tension band (ISTB) and fracture excision with triceps advancement.[15,16]

The PF has better results over the TBW in olecranon fractures with articular comminution, fractures extending distal to the semilunar



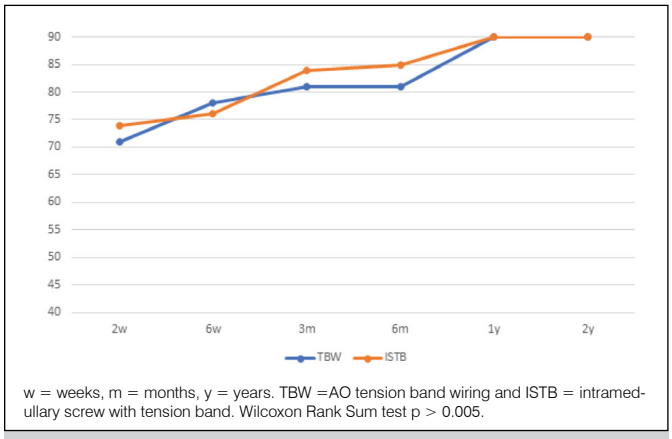
w = weeks, m = months, y = years. TBW =AO tension band wiring and ISTB = intramedullary screw with tension band. Wilcoxon Rank Sum test p > 0.005.

Figure 2. Active elbow flexion. Comparison between TBW and ISTB techniques.



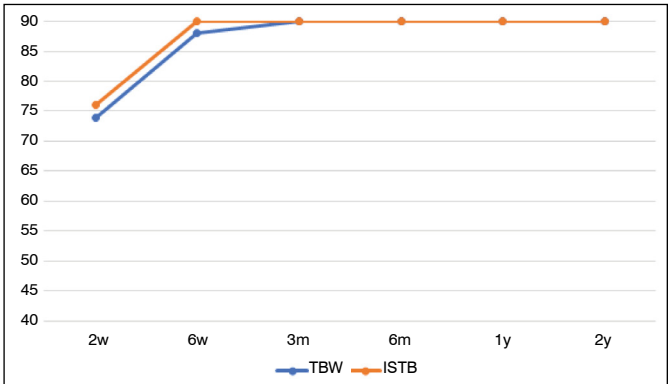
w = weeks, m = months, y = years. TBW =AO tension band wiring and ISTB = intramedullary screw with tension band. Wilcoxon Rank Sum test p > 0.005.

Figure 3. Active elbow extension. Comparison between TBW and ISTB techniques.



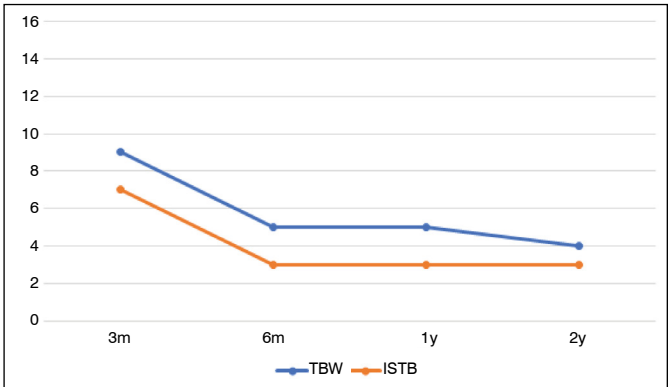
w = weeks, m = months, y = years. TBW =AO tension band wiring and ISTB = intramedullary screw with tension band. Wilcoxon Rank Sum test p > 0.005.

Figure 4. Active elbow pronation. Comparison between TBW and ISTB techniques.



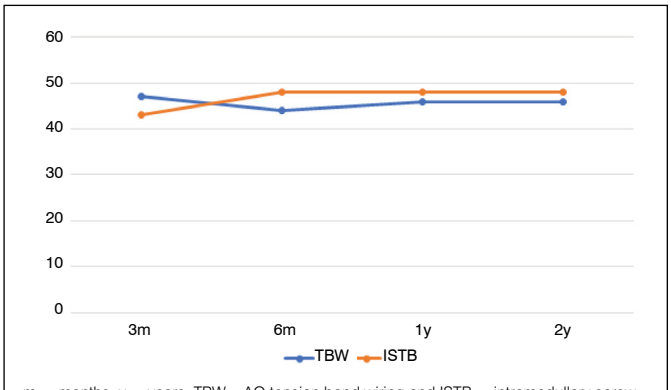
w = weeks, m = months, y = years. TBW =AO tension band wiring and ISTB = intramedullary screw with tension band. Wilcoxon Rank Sum test p > 0.005.

Figure 5. Active elbow supination. Comparison between TBW and ISTB techniques.



m = months, y = years. TBW =AO tension band wiring and ISTB = intramedullary screw with tension band. Wilcoxon Rank Sum test p > 0.005.

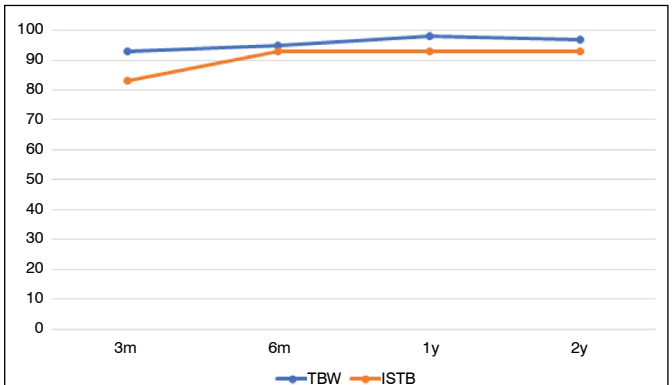
Figure 6. DASH score. Comparison between TBW and ISTB techniques.



m = months, y = years. TBW =AO tension band wiring and ISTB = intramedullary screw with tension band.Wilcoxon Rank Sum test p > 0.005.

Figure 7. Oxford Elbow Score. Comparison between TBW and ISTB techniques.

notch, and olecranon fracture dislocation (Mayo III).[17] For transverse olecranon fractures (Mayo IIA) several studies showed similar functional results, but PF constructs are more costly, requires more extensive dissection, and often fail to match the anatomic proximal ulna dorsal angulation, which may lead to mal-reduction.[18-20] In the other hand, the TBW had a higher rate of symptomatic hardware and implant failure.[17,20]



m = months, y = years. TBW =AO tension band wiring and ISTB = intramedullary screw with tension band. Wilcoxon Rank Sum test p > 0.005.

Figure 8. Mayo Elbow Performance Index. Comparison between TBW and ISTB.

An alternative construct for the simple transverse fracture is the intramedullary screw with tension band (ISTB).[11,21] This construct is infrequently used by orthopedic surgeons, but maybe a good option to the traditional TBW.

In this study only transverse fractures of the olecranon were included, because in simple but oblique fractures the shearing force may lead the TBW to fail and have worse results.[22]

There was no difference between the two groups in the flexion and extension in any point in time ($p > 0.005$). In both groups the final flexion/extension was achieved after 3 months, maintaining stable until 2 years. Neither the flexion nor the extension went back totally to normal. The flexion gap was in average 10° and the extension gap was 7° for the ISTB and 13° for the TBW ($p = 0.433$). This is consistent to what was achieved by Ahmed et al.[11] who studied prospectively 30 patients including both transverse and oblique fractures.

Both pronation and supination went back to the normal amplitude (90°), with no difference between the two groups. What called our attention is that the supination went back to normal in 6 weeks, but the pronation took between 6 months to 1 year to recover full range of motion.

The functional evaluation with the DASH score, Oxford Elbow Score and Mayo Elbow Performance Index showed the same trend, with almost full recovery of the elbow function after 3 months post-operatively, and few improve after 6 months, 1 or 2 years.

Post-operative loss of reduction or implant failure did not occur in any of the patients of the two groups. In the literature it's described displacement of more than 2 mm in up to 20% of the cases.[23] One possible explanation for this is that we only included simple transverse fractures, which are intrinsically stable after reduction and the compression given by the fixation, either TBW or ISTB, creates an absolute stability with no movement in the fracture site.

One could expect that the intramedullary screw fixation with a washer could have a higher rate of soft tissue irritation leading to a higher rate of implant removal, but it did not happen. None of the patients had complains about the implant and did not ask for implant removal. The zero incidence of post-operative infection may also be explained by the inclusion criteria, where the complex fractures and more severe soft tissue injury were not included.

The limitation of the study is the low number of patients, 11 per group. Another limitation is that the joint range of motion was measured manually and there is possibility of error. In addition, the scores for functional evaluations were filled in according to patient's statements and may thus show subjective results.

The final result of this study showed similar range of motion and functional results for the ISTB compared to TBW.

CONCLUSION

Both TBW and ISTB showed to be an efficient method for the treatment of the displaced transverse olecranon fracture (Mayo 2A), with recovery of the range of motion and excellent functional results. None of them presented any complication after 2 years follow-up.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article: FCF and Fernando BAS: Surgeons responsible for the procedures; Writing and preparation of the model and method in which the study was developed; Data collect. FFE: Development of discussion and theoretical basis. Survey of articles and incorporation into the work. JAH: Development of discussion and theoretical basis. Survey of articles and incorporation into the work. JSS: Supervision, review and contribution to the discussion and conclusion of the article. KK: Text writing, supervision, review and contribution to the discussion and conclusion of the article.

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ORTHOPEDIC TRAUMA

RADIOGRAPHIC EVALUATION OF OSSEOINTEGRATION OF UNCEMENTED TARGOS® STEMS. A 5-YEAR FOLLOW-UP

AVALIAÇÃO RADIOGRÁFICA DA OSSEOINTEGRAÇÃO DE HASTES NÃO CIMENTADAS TARGOS®. UM SEGUIMENTO DE 5 ANOS

HELDER DE SOUZA MIYAHARA[1], JORGE HENRIQUE NARCISO[1], JOSÉ GUILHERME LOLLO CORREA[1], JOSÉ RICARDO NEGREIROS VICENTE[1], LEANDRO EJNISMAN[1], BRUNO ALVES RUDELLI[1], HENRIQUE DE MELO CAMPOS GURGEL[1], ALBERTO TESCONI CROCI[1]

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ABSTRACT

Introduction: Total hip arthroplasty is a widespread treatment and is considered the gold standard in cases of hip osteoarthritis, with high rates of success in improving pain and function when well performed. After five years of follow-up, this study evaluates the osseointegration of uncemented Targos® collared stems in arthroplasties. Methods: Observational study of 182 total hip arthroplasties performed in 2014 with Targos® cementless collared femoral stems (Lepine). Bone quality was assessed according to the Dorr scale and osseointegration according to the Engh score. Results: The overall mean age was 56.5 years, consisting of 104 men (57.1%) and 103 women (56.6%). The osseointegration rate of the stems (total Engh>0) was 100%. There was no statistical difference between groups concerning age (p=0.262), gender (p=0.463), primary diagnosis (p=0.585), affected side (p=0.459), and degree of Dorr (p=0.857). Conclusion: Targos® cementless collared femoral stems showed excellent osseointegration in all patients evaluated, regardless of age, gender, and preoperative bone quality. Moreover, spot welds observed on preoperative radiographs have the best association with implant osseointegration. ***Level of evidence IV, case series.***

Keywords: Hip Arthroplasty. Osseointegration. Femur. Osteoarthritis, Hip.

RESUMO

*Introdução: A artroplastia total do quadril é um tratamento amplamente difundido, sendo considerado padrão ouro nos casos de osteoartrose do quadril, com altos índices de sucesso na melhora da dor e função, quando bem realizada. Este estudo avalia a presença de osseointegração de hastes com colar não cimentadas Targos® em artroplastias após cinco anos de seguimento. Métodos: Estudo observacional com 182 artroplastias totais de quadril realizadas em 2014 com com hastes femorais com colar não cimentadas Targos® (Lepine). A qualidade óssea foi avaliada de acordo com a escala de Dorr e a osseointegração de acordo com o escore de Engh. Resultados: A média geral de idade foi de 56,5 anos, sendo 104 homens (57,1%) e 103 mulheres (56,6%). A taxa de osseointegração das hastes (Engh total>0) foi de 100%. Não houve diferença estatística nos grupos quanto à idade (p=0,262), sexo (p=0,463), diagnóstico primário (p=0,585), lado acometido (p=0,459) e grau de Dorr (p=0,857). Conclusão: As hastes femorais com colar não cimentadas Targos® apresentaram excelente osseointegração em todos os pacientes avaliados, independentemente da idade, sexo e qualidade óssea pré-operatória. Além disso, a presença de "spot welds" observados nas radiografias pré-operatórias tem a melhor associação com a osseointegração do implante. **Nível de evidência IV, case series.***

Descritores: *Artroplastia de Quadril. Osseointegração. Fêmur. Osteoartrite do Quadril.*

Citation: Miyahara HS, Narciso JH, Correa JGL, Vicente JRN, Ejnisman L, Rudelli BA, Gurgel HMC, Croci AT. Radiographic evaluation of osseointegration of uncemented Targos® stems. A 5-year follow-up. Acta Ortop Bras. [online]. 2022;30(2)Esp.: Page 1 of 4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

The total hip arthroplasty is a widely widespread treatment, being considered gold standard in cases of hip osteoarthrosis, with high levels of success in pain and function improvement.

With the ageing of the population, associated to the global obesity epidemic, degenerative diseases has become increasingly prevalent.[1] In advanced cases, the hip osteoarthrosis can be manifested with important pain and function limitation, impacting the individual quality of life. Furthermore, the loss years of work and the resources employed to treat this condition result in high costs to the national health system.[2]

In last years, both surgical technique and implants have evolved, bring less morbidity and a better functional outcome. After increasing number of procedures and improving in cement implantation

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

The study was conducted at Universidade de São Paulo, Faculty of Medicine, Hospital das Clínicas, Institute of Orthopedics and Traumatology, São Paulo, SP, Brasil.
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process, with development of centralizers and distal restrictors, several studies with excellent cemented implants survival have been published.[3,4] At the same time, bone cement implantation syndrome (BCIS) cases has been notified. This syndrome involves several cardiovascular alterations that might occurs during cement introduction in bone medullar canal, ranging from hypotension to acute cardiac insufficiency.[5] As an alternative to the cemented steams and a way to avoid the BCIS, the cementless femoral stems was developed, based on fixation by osseointegration, obtained through microporosities in the implant and the guarantee of immediate stability ("press fit").[6]

Classically, the cemented stems was indicated for patients with worse bone quality (Dorr C), since the initial implant stability can be deficient in this cases, predisposing the micromovement of the stem and consequent loosening of the femoral implant. However, there are studies that emphasize the presence of osseointegration in cementless femoral stems used in patients with worse bone quality after several years of fallow-up (Dorr C).[7]

OBJECTIVES

The primary objective of this study is evaluate the presence of cementless femoral with collar stems osseointegration (Targos®, Groupe Lépine, Genay) in patients submitted to total hip arthroplasty in 2014 by the hip surgery team from an orthopedic hospital. The secondary objective is correlate the individual bone quality, age, gender, and preoperative diagnosis with possible complications related to that implant.

METHODS

This is a transversal observational study with 182 patients submitted to total hip arthroplasty using a cementless femoral with collar steam (Targos® - Lepine) performed in the year of 2014 by the hip surgery team from an orthopedic hospital.

All patients submitted to total hip arthroplasty in the year of 2014 who used the cementless femoral with collar steam (Targos®) collar and were in good clinical condition at the time of the evaluation (walking without support and without limitation for usual activities) were included. The patients with a preoperative complication that difficult the "press fit" evaluation or these that fail to perform the rehab protocol was excluded. These that refuse to sign the participation term also has been excluded. The epidemiologic evaluation has been done by medical records analysis with data on age, gender, follow up period, operated side and initial diagnosis being recorded.

The bone quality evaluation was done by the classic Dorr scale, that considers the bone quality through evaluation of anteroposterior and lateral radiographs of the femur, ranging between a good bone quality (Dorr A), which the patient presents thick cortices in both incidences, intermediate bone quality (Dorr B), which is possible to observe thinning of the posterior cortex and, finally, worse bone quality (Dorr C), which the cortex present thinning, both in anteroposterior and lateral radiographs.

The evaluation of osseointegration was done based on the scale proposed by Engh (Table 1)[8] which radiographic signs are evaluated in anteroposterior images of the hip, predicting the degree of osteointegration of the porous femoral stems. These signs are: the presence of radiolucency in the porous area, the presence of "spot welds", the presence of radiolucency in the smooth area, the presence of pedestal, the calcar modelling, the stem migration and the particle shedding. Each of these aspects receives a specific value and the final score can vary from -28.5 to +24.5. (Table 1)

The stratification of patients in the original article is done in four groups, in which values bigger than +10, indicate the presence of osseointegration. Values between 0 and +10 suggest osseointegration and indicate stable implant. Values between – 10 and 0 indicate failure of osseointegration, however with stem fibrous stabilization, and values less than -10, indicate unstable stem. (Table 1) The patients have been separated in two groups accords to the value obtained by Engh's score, which are: Integration (Engh >10), Suspected Osseointegration (0<Engh≤10) and Non-integration (Engh<0).

Table 1. Engh's score.

Variables	Category	Score
	Presence >50%	-5
Presence of radiolucency in the porous area (ENGH 1)	Absence	5
	Presence <50%	0
	Presence	5
Presence of "spot welds" (ENGH 2)	Absence	-2,5
	Presence	0
	Presence >50%	-3,5
Presence of radiolucency in the smooth area (ENGH 3)	Absence	5
	Presence <50%	0
	Unstable	-3,5
Presence of pedestal (ENGH 4)	Absence	2
	Stable	0
	Hypertrofic	-4
Calcar modelling (ENGH 5)		
	Atrophic	3
	Presence	-5
Stem migration (ENGH 6)	Absence	3
	Indefinite	0
	Presence	-5
Particle shedding (ENGH 7)		
	Absence	1

All patients were submitted to the same institutional protocol of physical therapy analgesia: orthostasis and gait training with partial load protected by a walker, since the first day of post-op, maintaining progressive partial load until the sixth week of post-op and full load after this time. Activities without jumps or running were aloud from the third week of post-op, according to the patients tolerance. The ways of surgical access were the Hardinge's side way and Moore's posterior way.

The assumptions of normal data distribution and homogeneity of variances were checked for continual variables by Kolmogorov-Smirnov test and Levene test. The comparison between the groups that presented *Integration* (Score ENGH >10), *Suspected Integration* (Score ENGH ≤ 10) and *Non-integration* (Engh<0), were done by T Test of Student or U Test of Mann Whitney, for continual variables and Chi-square test, for categorical variables. The significant differences related to the comparisons between proportions were identified on contingency charts through the analysis of standardized residuals (under -2 or more than 2).[9]

The variables that presented significant differences between *Integration* and *Suspected Integration* groups were analyzed by models of Binary Logistic Regression to test the influence of the patients characterization parameters and ENGH's score subitems, about bone integration. Categorical variable with more than two levels of comparison, were treated as dummy variable in these models. The effect of each variable for the prediction of bone integration were presented through the odds ratios (OR) and breaks with 95% of trust (IC 95%). All the analyses were conducted in the PASW software statistics 18.0 (SPSS Inc., Chicago, USA), adopting significance level of 5% ($p< 0.05$).

This study was approved by the hospital ethics committee.

<< SUMÁRIO

RESULTS

Two hundred total hip arthroplasties which used cementless femoral with collar stem (Targos® - Lepine) were initially selected. Among the 200 selected cases, 18 patients were excluded because a perioperative complication that could difficult the implant "press fit" evaluation or the accomplishment of the rehab protocol (15 intraoperative femur fractures, 2 nerve injuries, 1 perioperative dislocation). A total of 182 patients were considered for analysis.
The mean age found was 56.5 years, with a male majority (57.1%). The primary osteoarthrosis was the most prevalent diagnosis in the sample (56.6%), followed by secondary causes of osteoarthrosis. None of the cases have negative value in Engh's score. There was no statistical difference between bone *Integration* and *Suspected Integration* groups about age, gender, diagnosis, affected member and Door's rating (p> 0.05). (Table 2) The integration index of the implants was 100% (Engh total>0).
When we considered each criteria of the Engh score (Table 3), we could observe that *Integration* group presented bigger proportion of patients with absence of radiolucency in stem porous area (ENGH 1) in comparison to bone *Suspected Integration* group (52.6% vs. 25.5% - p = 0.001). About the "spot welds" (ENGH 2), *Integration* group presented less proportion of patients with absence of this signal in comparison to *Suspected Integration* group (3.0% vs. 40.4%, standard waste = 5.4 – p < 0.001).
The ENGH 3 criteria (radiolucency in stem flat area) was adapted to our stem model, once that the Targos® stem doesn't present flat area. Therefore, we evaluated radiolucency in its diaphyseal area. It has been observed bigger absence of radiolucency in *Integration* group (39.3% vs. 10.6% - p< 0.001, standard waste = -2.6).
No statistical difference between bone *Integration* and *Suspected Integration* groups about radiographic finding of pedestal (ENGH 4) and the presence of metallic particles (ENGH 7) was observed. Finally, the *Integration* group presented a lower calcar hypertrophy proportion (ENGH 5) and stem migration (ENGH 6) in comparison to *Suspected Integration* group (1.5% vs. 14.9%, p = 0.001, standard waste = 3.1 and 0.7% vs. 10.6%, p = 0.003, standard waste = 2.8).
The binary logistic regression model 1 was capable to predict correctly *Integration* or *Suspected Integration* in 87.2% and 89.1% of the patients, from the presence of "spot welds" (ENGH 2). Patients that obtained maximum score in this criteria, presented 55.9 times more chances of bone integration in comparison to patients that recorded the lower score. From the obtained record by ENGH 2, it was possible to explain 59.2% (r2 -Nagelkerke), from the variance related to the patients rating in *Integration* or *Suspected Integration* groups. (Table 4)

Table 2. Patients characteristics.

Variables	Integration (n = 135)		Suspected Integration (n = 47)		p-value
Age [average (standard deviation)] (years)	55	11	58	12	0.262
Gender					
Woman	60	(44.4)	18	(38.3)	0.463
Man	75	(55.6)	29	(61.7)	
Diagnosis [No. (%)]					
Primary osteoarthrosis	78	(57.8)	25	(53.2)	0.585
Other	57	(42.2)	22	(46.8)	
Affected member [No. (%)]					
Right	72	(53.3)	28	(59.6)	0.459
Left	63	(46.7)	19	(40.4)	
DORR's rating [No. (%)]					
A	95	(70.4)	33	(70.2)	0.857
B	34	(25.2)	11	(23.4)	
C	6	(4.4)	3	(6.4)	

DISCUSSION

Comparing our studies with the studies found in literature, the average age, more prevalent gender and initial diagnosis, most of studies show male prevalence, with average age around 60 years old, having primary osteoarthrosis as main diagnosis.[10-14] However, it is also possible to observe studies with female prevalence with initial diagnosis of dysplasia and lower average age (50 years old).[15-17]
Among the evaluated groups, there was no statistical difference of femoral stem osseointegration about the age (p=0.262), gender (p=0.463), initial diagnosis (p=0.585) and Dorr's rating (p=0.857). All the analyzed patients obtained >0 score in Engh's rating, which can be interpreted as absence of osseointegration radiologic failure

Table 3. Partial and total score ENGH.

Items	Integration (n = 182)		Suspected Integration (n = 18)		P-value
ENGH 1 [No. (%)]					
-5	0	(0)	0	(0)	0.001
0	64	(47.4)	35	(74.5)	
5	71	(52.6)	12	(25.5)	
ENGH 2 [No. (%)]					
-2,5	4	(3.0)	19	(40.4)	< 0.001
0	14	(10.4)	23	(48.9)	
5	117	(86.7)	5	(10.6)	
ENGH 3 [No. (%)]					
-3,5	14	(10.4)	0	(0)	< 0.001
0	68	(50.4)	42	(89.4)	
5	53	(39.3)	5	(10.6)	
ENGH 4 [No. (%)]					
-3,5	1	(0.7)	3	(6.4)	0.069
0	65	(48.1)	23	(48.9)	
2,5	69	(51.1)	21	(44.7)	
ENGH 5 [No. (%)]					
-4	2	(1.5)	7	(14.9)	0.001
3	133	(98.5)	40	(85.1)	
ENGH 6 [No. (%)]					
-5	1	(0.7)	1	(2.1)	0.003
0	1	(0.7)	5	(10.6)	
5	133	(98.5)	41	(87.2)	
ENGH 7 [No. (%)]					
1	135	(100)	47	(100)	-----
5	0	(0)	0	(0)	
ENGH Total [average (interquartile range)] (score)	15	(12 a 22)	9	(7 a 10)	< 0.001

Table 4. Model of logistic regression for prediction of bone integration.

Variables	B	P-Value	OR	IC 95% (OR)	r^2
Model 1					
ENGH 2 (score 5)[a]	4.0	< 0.001	56.0	19.4 a 161.3	0.592
Constant	-3.1	< 0.001		----------	

[a] Reference to obtaining a score 5 in ENGH 2. B = angular coeficient. OR = Odds ratio that indicates the likelihood of bone Integration from the occurrence of the reference predictor. IC 95% = range with 95% of trust. r^2 = Variance explained according to Nagelkerke.

of the implants. It is important to notice, that there was no statistical difference between groups about the individual's previous bone quality, evaluated by Dorr's scale. Therefore, the individual's previous bone quality did not interfere in a statistically significant way with the osteointegration of cementless femoral stems with Targos® collar, considering that, in this study, the failure tax of the implants osseointegration was 0%. This conclusion is in agreement with a large part of the literature, which confirms that most of the cementless femoral implants, integrate with the bone and that the individual's previous bone quality doesn't have a direct relationship with the failure in this process, although some studies have been done in specific populations, such as individuals with dysplasia sequelae or with rheumatoid arthritis, or differentiated implants.[18-22]
Other authors have investigated the capacity of osseointegration of cementless femoral stems and obtained similar outcome. Casper et al.[23] observed that review tax of Accolade® type femoral component, conical and with total proximal porosity, in an average follow-up of 7.6 years, it was only 0.6%, considering aseptic loosening. Froimson et al.[24] reported that all the 96 arthroplasties done with Corail® type stem, conical and with metaphyseal micro porosity, presented radiographic signs of osseointegration after follow-up of 10 years. Finally, McLaughlin and Lee[25] reported that after an average follow-up of 20 years, 99% of 65 arthroplasties done with Taperloc® type femoral component, conical and with proximal porosity, presented osseointegration.
It was possible to observe that the presence of radiolucency in the stem porous and diaphyseal areas and the presence of "spot welds" were the most important relate to the score of Integration and Suspected Integration group', what we understand as the most important criteria to be observed in radiographs. In a similar way, as expected, it was observed that the Integration group obtained a lower proportion of individuals with negative score in ENGH 5 and ENGH 6 rating, which means that the integrated stems don't present bone foot remodeling and had no subsidence.
Those outcomes confirm the applicability of Engh's score to predict the presence of radiological osseointegration of cementless femoral implants. The isolated evaluation of "spot welds" presence, allow us to infer that this criterion, when present, it the most reliable to evaluate an appropriate osseointegration, among the other Engh's criteria. For the detachment of metallic particles, both groups present all patients with maximum positive score. This finding can be explained by the stem type used in this study, that has a peculiar porous structure, with extremely small porosities and all over the surface, preventing particles loosing.
It must be pointed that the patients don't present any difference about Integration and Suspected Integration subgroups, since patients were selected without complaints of pain in the lame femoral joint and who don't have functional limitations for their daily activities.

CONCLUSION

Our study allows to conclude that the non-cemented femoral stems with Targos® have a excellent outcome in a follow-up of 5 years, regardless of age, gender, initial diagnosis and bone quality, with 100% survival rate. It is also possible to affirm that the presence of "spot welds" in a postoperative control radiography suggests osseointegration in more than 85% of the cases. Long term studies are needed to confirm this implant survival.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of the manuscript. HSM and JGLC were the main contributors in writing the manuscript. LE, BAR and HMCG performed the surgery, followed the patients and gathered clinical data. JHN evaluated the data from the statistical analysis. ATC performed the bibliographic research, revised the manuscript and contributed to the intellectual concept of the study.

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EVALUATION OF SCAPULAR DYSKINESIS IN CROSSFIT®-PRACTICING ATHLETES

AVALIAÇÃO DA DISCINESE ESCAPULAR EM ATLETAS PRATICANTES DE CROSSFIT®

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ABSTRACT

Objective: Evaluate the scapular movement of Crossfit® practitioners and identify whether they present an increased incidence of scapular dyskinesis (SD) compared to non-practitioners. Method: A transversal study was evaluated quantitatively and dynamically, using retro-reflective spherical markers, the scapular movements of ten volunteers composing the control group, and 11 Crossfit® practitioners. The control group's results were used as a normality parameter and compared to those of the Crossfit® practitioner's group. Results: It was identified that the superior scapular rotation in the ascending phase is inferior in the group of Crossfit® practitioners ($p = 0.02$). Conclusion: The regular practice of Crossfit® causes scapular dyskinesis (SD), with alteration in the scapular superior rotation movement. ***Level of Evidence III: Retrospective comparative.***

Keywords: Scapula. Sports Medicine. Shoulder.

RESUMO

Objetivo: Avaliar o movimento escapular de praticantes de Crossfit® e identificar se apresentam incidência aumentada de discinese escapular (DE) quando comparados a não praticantes. Método: Estudo transversal que avaliou de forma quantitativa e dinâmica, utilizando marcadores retro-refletivos esféricos, os movimentos escapulares de dez voluntários, compondo o grupo controle, e 11 praticantes de Crossfit®. Os resultados do grupo controle foram utilizados como parâmetro de normalidade e comparados aos do grupo de praticantes de Crossfit®. Resultados: Identificou-se que a rotação superior escapular na fase ascendente é inferior no grupo de praticantes de Crossfit® ($p = 0,02$). Conclusão: A prática regular de Crossfit® causa discinese escapular (DE), com alteração no movimento de rotação superior da escápula. ***Nível de Evidência III: Retrospectivo comparativo.***

Descritores: *Escápula. Medicina Esportiva. Ombro.*

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INTRODUCTION

Crossfit® is a training and fitness program that has been gaining more recognition and interest from the physically active population. This program was initially developed for military training and gradually spread to the general population.[1] Such a program is based on a complex set of exercises that include running, weightlifting, Olympic gymnastics, and ballistic training.[1] Exercises are usually a combination of high-intensity workouts to be performed quickly, repeatedly, and with little or no time to recover between sets.[2]

In Brazil, there are about 440 registered Crossfit® gyms, thus resulting in a total of approximately 40 thousand athletes.[2] This total number of practitioners of an activity with an intense overload onto the upper limb leads to injuries, whether symptomatic or not.[3] Among those is scapular dyskinesis, which is a condition commonly found in athletes with upper-limb overload.[4]

Scapular dyskinesis (SD) consists of dynamic changes in the position of the scapula in relation to the rib cage, resulting in an imbalance of the thoracic-scapular-humeral rhythm. In general, it occurs secondary to fatigue, neurological dysfunction, intra-articular or subacromial disorders. This imbalance can be present in up to 67-100% of athletes with shoulder injuries and are also often found in asymptomatic individuals.

It is debated in the literature that SD is not just a consequence of shoulder injuries, but can rather act as a cause thereof due to an overload on the muscles of the scapular girdle and limitation in both shoulder strength and range of motion, predisposing it to tendinitis of the rotator cuff, subacromial impingement syndrome, and glenohumeral instability.[4]

The current study's hypothesis is that there is a higher incidence of SD among Crossfit® practitioners than in the non-practicing population.

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

The study was conducted at the Shoulder and Elbow Surgery Group at the Department of Orthopedics and Traumatology, Santa Casa de São Paulo School of Medical Sciences and Institute of Physical Activity and Sport Sciences (ICAFE – Instituto de Ciências da Atividade Física e Esporte) at Universidade Cruzeiro do Sul.
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<< SUMÁRIO

This pioneering study in Brazil aimed to test the hypothesis above by comparing the dynamic and quantitative results from assessing scapular movement in two paired populations: practitioners and non-practitioners of Crossfit®.

SAMPLING AND METHODS

This was a cross-sectional study, in which we divided the participants into a control group and a group of Crossfit® practitioners. The inclusion criteria for the control group were: the individuals had to be adults, without any symptoms, changes or previous surgical procedures on their shoulders. It was comprised of ten participants (20 shoulders). In this group, six males and four females were evaluated, and had a mean age of 28.5 years, ranging between 21 and 54 years. All ten patients were right-handed, with a Body Mass Index (BMI) averaging 24.9 kg/m^2 and ranging between 18.65 and 30.68 kg/m^2.

Eleven Crossfit® athletes were evaluated. The Inclusion criteria were that individuals needed to have been Crossfit® practitioners for at least six months prior, at a minimum frequency of three times per week – thus characterizing regular practitioners.[2,5] The exclusion criteria were: practice times shorter than 6 months, training frequency less than three times per week, and/or having already undergone any surgical procedure on either shoulder. Among those evaluated, there were seven males and four females, whose average age was 31 years, ranging from 26 to 36 years, and having a an average Body Mass Index (BMI) of 26.7 kg/m^2, ranging from 20.20 to 32.91 kg/m^2.

In comparing the physical characteristics between the two groups, no statistically significant difference was found for the mean weight ($p=0.378$), height ($p=0.724$), and BMI ($p=0.304$). It became evident, however, that the group of Crossfit® practitioners had a greater mean age than that of the control group ($p=0.028$).

After having been included in the study, all participants were inquired about the presence of any ongoing or recent pain or functional complaints with regard to their shoulders with the following question: "Do you have or did you had over the last 6 months any pain and/or difficulty moving your shoulders that lasted more than a day?". All participants gave negative responses.

Following the method of Salvia et al.,[6] scapular movement assessment was performed using spherical retro-reflective markers, which were fixed with appropriate adhesive tape onto specific anatomical landmarks on the trunk and upper limbs, bilaterally, following the recommendations of the International Biomechanics Society.[7] More specifically, these markers were fixed onto the skin over the spinous process of the seventh cervical vertebra (C7), the spinous process of the eighth thoracic vertebra (T8), the inferior-most point of the jugular notch and the xiphoid process, in order to define the trunk segment. To define the scapula, in turn, the markers were fixed onto the skin over the scapular spine trigone, lower angle of the scapula, acromial angle, and the most ventral portion of the coracoid process. To define the arm and forearm segments, the markers were fixed onto the skin on the lateral epicondyle and medial epicondyle of the humerus, and styloid processes of the radius and ulna. In addition to these markers, rigid sets with retro-reflective markers were also attached onto the skin on the flatter region of the acromion, manubrium-sternum angle, and proximal lateral region of the humerus. (Figure 1)

The three-dimensional recording of all markers was performed by eight special cameras (Vicon Bonita 10 Motion Capture Cameras®) controlled by a specific unit (Giganet Lab Unit, Vicon, Inc.®) that allows synchronization of these cameras and sending the acquired signals to a computer via a specific computer software program (Vicon Nexus®). Initially, data were collected from participants in an orthostatic, neutral, and static position in order to register a reference position. Subsequently, the participants underwent the dynamic part of the evaluation and were asked to perform unilateral circling movements to estimate the articular center of the shoulders. Then, with the upper limbs close to the body, following a verbal command, they were instructed to perform six repetitions of maximum elevation and return to a starting position at comfortable time intervals, ranging from three to five seconds. The first elevation performed by each patient was disregarded and only the last five of them were considered. The posterior inclination, upward rotation, and medial rotation of the scapulae (Figure 2) at 60°, 90°, and 120° elevation angles were evaluated, both in the ascending and descending phases.

The data acquired during the evaluations were reconstructed with the Nexus software program (Vicon®) and the trajectories of each spherical retro-reflective marker were stored for later analysis in The Motion Monitor (Innovative Sports Training, Inc.®) and Matlab (Math Works, Inc.®).[8] Scapular rotations in the three planes of movement of the right and left scapulothoracic joints were calculated by means of representing the Euler angles and following the convection recommended by Wu et al. and Van Der Helm.[7,9]

Statistical data processing was performed using multivariate analysis of variance (MANOVA) in search for possible differences between the dominant and non-dominant sides within each group. As there was no statistically significant difference between them, multivariate analysis of variance (MANOVA) was then used again for comparing only the participants' dominant side in the control group with the participants' dominant side in the Crossfit® group. The level of significance was calculated using the Statistical Package for the

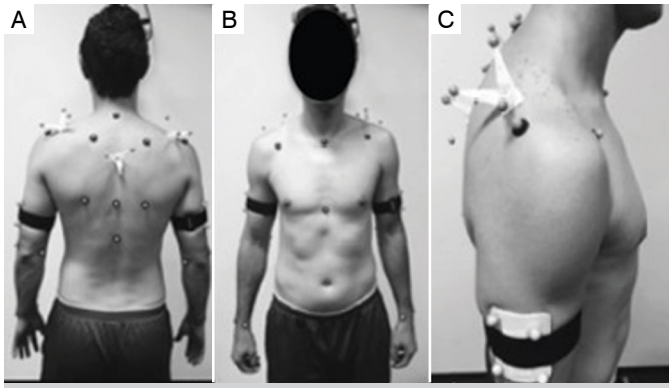

Figure 1. Arrangement of spherical retro-reflective markers. A, posterior view; B, anterior view; C, side view.

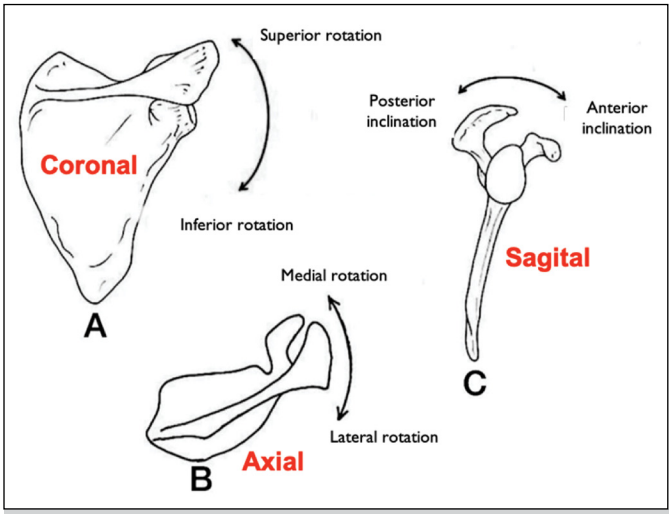

Figure 2. Scapular movements in the three planes. A, coronal plane; B, axial plane; C, sagittal plane.

<< SUMÁRIO

Social Sciences® program software, version 18.0 (SPSS Inc, IBM Company, Chicago, IL, USA).
The study was approved by the Institution's Research Ethics Committee (document number: 80591817.4.0000.5479) and has no conflict of interest. The devices used in this study were funded by the researchers.

RESULTS

The mean, confidence interval, and standard deviation for inclination, upward rotation, and medial rotation of the scapula in relation to the trunk during the ascending and descending phases of the shoulder elevation movement for the dominant hemibody both in the control group (CG) and the group of Crossfit® practitioners (XFG) are documented in Table 1 and Figure 3.
We found that there was a statistically significant difference between the two groups regarding the upward rotation movement of the scapula in the ascending phase (p = 0.02). Participants in both groups showed an increase in upward rotation of the scapula as they raised their shoulders, but the mean value in the CG was greater than that in the XFG. There was no statistically significant difference between the groups in the descending phase (p=0.06) and both exhibited a decrease in the upward rotation of the scapula as the shoulder descended, as shown in Figure 3.
In relation to the scapular inclination movement, the difference between the groups' mean values was not statistically significant either in the ascending phase (p=0.38) or in the descending phase (p=0.25). Paired comparisons indicated that in both groups there was a decrease in the posterior scapular inclination as the shoulder was raised and vice versa.
For medial rotation of the scapula in the ascending and descending phases, there was no difference between the groups in either phase (p=0.92 and p=0.93, respectively). As with the other movements, in all cases there was an increase in medial rotation of the scapula as the shoulder was raised and vice versa.

Table 1. Mean values (± standard deviation) and confidence interval (CI) for inclination, upward rotation, and medial rotation of the scapula in relation to the trunk during the ascending and descending phases of the shoulder upward movement for the dominant hemibody both in the control group (CG) and group of Crossfit® practitioners (XFG) are documented in Table 1 and Figure 3.

Scapular movement	95% CI	
	CG	XFG
Ascending phase		
Inclination		
60 degrees	-15 - -8	-16 - -10
90 degrees	-12 - -4	-15 - -6
120 degrees	-8 - 4	-11 - -1
Upward rotation		
60 degrees	10 - 17	5 - 12
90 degrees	21 - 30	14 -23
120 degrees	32 - 42	25 - 34
Medial rotation		
60 degrees	-38 - -24	-38 - -25
90 degrees	-39 - -24	-37 - -23
120 degrees	-34 - -17	-33 - -17
Ascending phase		
Inclination		
120 degrees	-6 - 5	-8 -1
90 degrees	-11 - -2	-15 - -7
60 degrees	-16 - -9	-18 - -12
Upward rotation		
120 degrees	33 - 44	27 - 36
90 degrees	22 - 31	16 - 24
60 degrees	8 - 16	4 - 12
Medial rotation		
120 degrees	-31 - -15	-30 - -15
90 degrees	-35 - -22	-34 - -22
60 degrees	-36 - -24	-35 - -24

Note: for the inclination movement, positive values indicate anterior inclination and negative values indicate posterior inclination.

DISCUSSION

The evaluation of SD is still one of the greatest difficulties found in the study of scapular kinetics. Some studies have sought to perform reproducible tests, but in all of them, poor reproducibility was found.[10,11] The most frequently used test in the literature is the one described by Kibler et al.,[12] a qualitative method based on visual observation and therefore prone to subjective interpretations and dependent on the examiner's level of experience.[4]
Considering that we sought greater specificity and sensitivity, we used in our study a quantitative method, since it allows for the objective assessment of scapular movement in three planes and is neither invasive or painful to the participant, relying on specific anatomical parameters, establishing an accurate reproducibility evaluation protocol, in addition to yielding accurate numerical data.[6] Such methodology has been increasingly used for understanding the dynamics of the shoulder as a whole in sports practitioners, especially the scapula.[13-15]
The resulting mean values for scapular kinetics herein presented showed a statistically significant difference between the control group and the athletes evaluated, as made evident by the reduction in the upward scapular rotation.
This finding is similar to the findings reported by Struyf et al. and Thomas et al.,[16,17] who, by means of inclinometers, showed the presence of reduced scapular upward rotation in athletes in different modalities that require raising the upper limb (pitchers, swimmers, tennis players, and volleyball players) with shoulder pain in relation to those who were asymptomatic and also in university baseball athletes when compared to school baseball athletes, respectively. This finding is also related to the subacromial impact in baseball and swimming athletes and glenohumeral instability in pitchers.[18-20]
It is worth mentioning that the participants in the Crossfit® group were asked about occasional pain or functional complaints in their shoulders only after having been included in the study to avoid selection bias. However, as everyone denied having any pain or functional complaints, it was impossible to correlate our findings with any symptoms according to the studies above.
We stress the importance of this work in demonstrating the use of a new, non-invasive dynamic method for evaluating SD in athletes practicing Crossfit®, a sport that currently has been having an important increase in the number of its practitioners. However, we emphasize that the quantitative method used has some deficiencies: a need for technical experience, sophisticated equipment, a lack of predetermined control values, and positioning of the markers onto the skin, with the latter being attributable to a possible superficial reflex of the scapular movement, rather than to the bone structure itself. For this reason, reproducibility in obese patients is more difficult, as the thickness of the adipose layer can hinder the evaluation of the bone movement being analyzed. In our study, there was no statistically significant difference in the mean body mass index (BMI) between the control group and Crossfit® practitioners, making it impossible to correlate BMI with scapular kinematic changes. New studies with a larger sample should allow the identification of this influence with a margin of statistical significance.

CONCLUSION

The regular practice of Crossfit® causes scapular dyskinesis (SD), with changes to the upward rotation movement of the scapula.

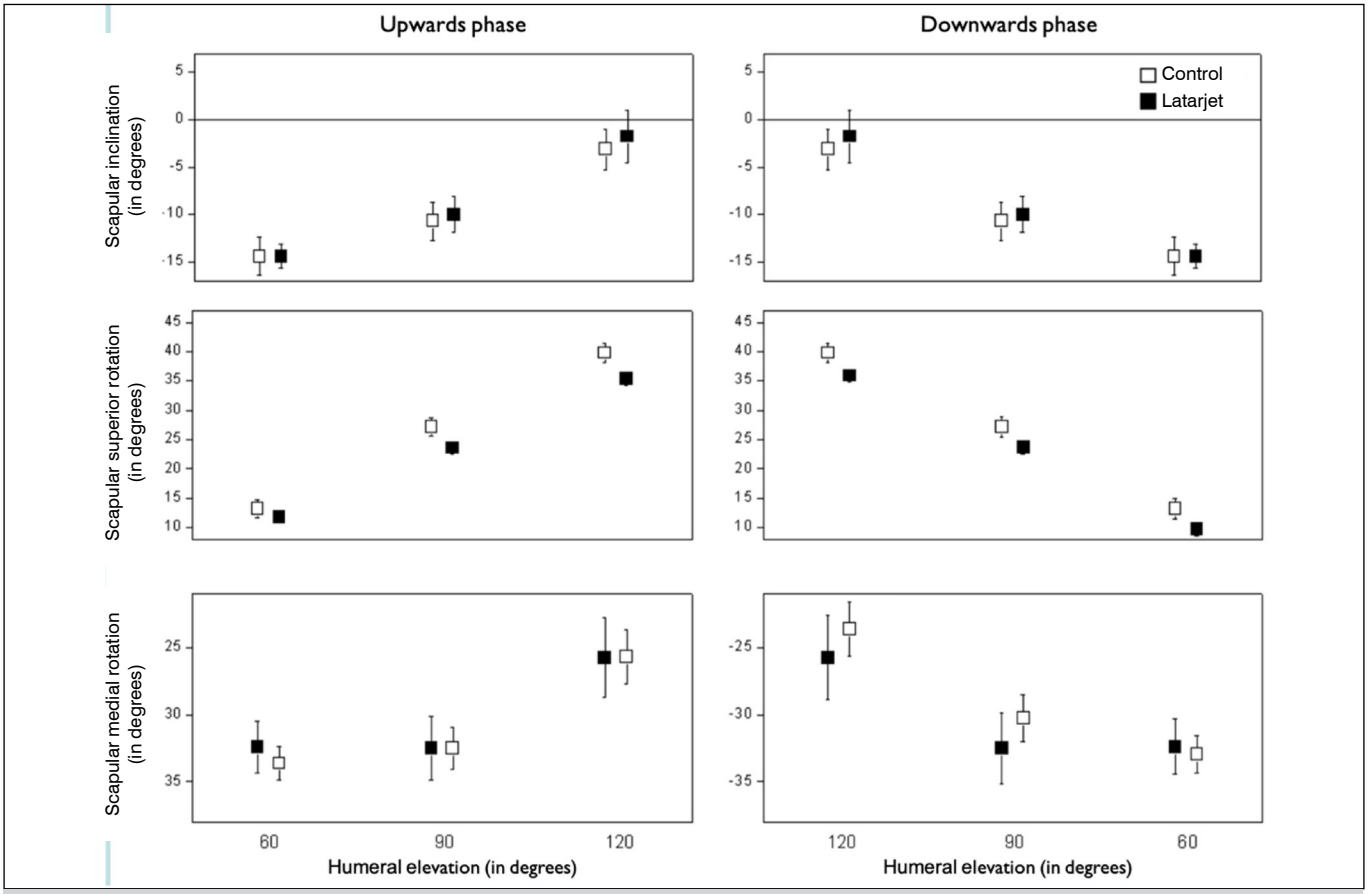

Figure 3. Mean values (± standard deviation) for inclination, upward rotation, and medial rotation of the scapula (in degrees) in relation to the trunk during the ascending (on the left side) and descending (on the right side) phases of the shoulder upward movement for the dominant hemibody in the control group (white squares) and group of Crossfit® practitioners (black sqaures). Note: for the inclination movement, positive values indicate anterior inclination and negative values indicate posterior inclination, as shown in Figure 2.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this paper. GVG and LHGC: writing of the manuscript and statistical analysis; CSC: data analysis and reviewing of the manuscript; LAS: reviewing and intellectual concept of the manuscript, approval of the final version of manuscript to be published. DSS and AMFB: Data collection and analysis at the Movement Laboratory.

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SPINE

COSTS ANALYSIS OF SPINAL COLUMN METASTASES SURGICAL TREATMENT

ANÁLISE DOS CUSTOS DO TRATAMENTO CIRÚRGICO DAS METÁSTASES DA COLUNA VERTEBRAL

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ABSTRACT

Introduction: End-of-life cancer treatment is associated with substantial healthcare costs. Objective: This study aimed to analyze the surgical treatment cost of spinal metastasis and epidural compression patients undergoing surgical treatment. Methods: A retrospective cost analysis of 81 patients with spinal metastasis and epidural compression undergoing surgical treatment. Cost evaluation was defined in the following categories: medications, laboratory and imaging tests, nursery, recovery room, intensive care unit, surgical procedure, and consigned material. The cost of pain improvement, functional activity, and survival was also evaluated. Results: The total cost of surgical treatment for 81 patients was $3,604,334.26, and the average value for each patient was $44,497.95. The highest costs were related to implants (41.1%), followed by hospitalization (27.3%) and surgical procedure (19.7%). Conclusion: The cost of surgical treatment for spinal metastases is one of the most expensive bone complications in cancer patients. The cost of treatment related to outcomes showed differences according to the outcome analyzed. Hospital stay, tests, drugs, and intensive care play an important role in some of the costs related to the specific outcome. ***Level of Evidence II, Retrospective Study***.

Keywords: Palliative care. Spinal Cord Compression. Hospital Costs. Costs and Cost Analysis.

RESUMO

Introdução: O tratamento do câncer em fim de vida está associado a custos substanciais em saúde. Objetivo: O objetivo do estudo foi analisar o custo do tratamento cirúrgico de pacientes com metástase espinhal e compressão peridural submetidos ao tratamento cirúrgico. Métodos: Uma análise retrospectiva de custos de 81 pacientes com metástase espinhal e compressão peridural submetidos a tratamento cirúrgico. A avaliação de custos foi definida nas seguintes categorias: medicamentos, exames laboratoriais e de imagem, enfermaria, sala de recuperação, unidade de terapia intensiva, procedimento cirúrgico e material consignado. O custo relacionado à melhora da dor, atividade funcional e sobrevida também foi avaliado. Resultados: O custo total do tratamento cirúrgico de 81 pacientes foi de R $ 3.604.334,26 e o valor médio de cada paciente foi de R $ 44.497,95. Os maiores gastos foram relacionados com implantes (41,1%), seguidos de internação (27,3%) e procedimento cirúrgico (19,7%). Conclusão: O custo do tratamento cirúrgico para metástases espinhais é um dos mais caros entre as complicações ósseas em pacientes com câncer. O custo do tratamento relacionado aos desfechos apresentou diferença de acordo com o desfecho analisado e a permanência hospitalar, exames, medicamentos e terapia intensiva tem papel importante em alguns dos custos relacionados ao desfecho específico. ***Nível de Evidência II, Estudo retrospectivo***.

Descritores: *Cuidados Paliativos. Compressão da Medula Espinal. Custos Hospitalares. Custos e Análise de Custo.*

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INTRODUCTION

The spine is the most common site of bone metastasis and, 70% of all bone metastasis are in spine,[1,2] being that epidural or vertebral metastasis is presented in 94.5% of patients, on the other hand, intradural extramedular (5-6%) or intramedullary metastasis (0.5%) are rare.[2] Spinal cord compression (SCC) is the most serious complication, affecting 20% of patients.[3] The (sites) organs with tumors most likely to cause bone metastasis are in order of incidence: prostate, breast, kidney, lung and thyroid cancer,[4,5] so, there is a large impact on healthcare resources from spinal metastasis and their complications.[6-8]

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

The study was conducted at the Universidade de São Paulo, Ribeirão Preto Medical School, Department of Orthopedics and Anesthesiology.
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<< SUMÁRIO

Surgical treatment of spinal metastasis received acceptance and began to be widely used after the report of a controlled trial by Patchell et al.,[9] showing that surgery followed by radiotherapy provided better outcome compared to radiotherapy alone in patients with a life expectancy superior to three months. This study influenced the indication for surgical treatment of spinal metastasis and adopted the threshold of life expectancy that has also influenced the decision for surgical indication. The goal of surgical treatment of spinal metastasis is pain relief, restoration or preservation of the neurological function, stabilization of spinal segment, and improvement of health-related quality of life. Surgical strategies are diverse and can include simple decompression and stabilization or spinal reconstruction that can be accomplished via anterior or posterior approach.[1,2,9]

The widespread availability of advanced imaging and the improvement of survival with the use of target therapies has contributed to increase the magnitude of the problem related to spinal metastasis.[2,10] It is expected the number of survivors that will undergo surgery will increase.[11] Surgical treatment of spinal metastasis is the most expensive procedure among skeletal events in oncologic patients, whose cost is estimated at 83,000 US$ per patient.[12] It was reported that around 27% of total cost were spent with surgery with a mean cost of 16,888 pounds per patient.[13]

Our University Hospital is a reference center for Oncology, the number of referred patients with spinal metastasis has historically grown. Thus, the motivation of the study was to perform a critical retrospective evaluation of the cost related to patients with spinal metastasis with epidural compression that underwent surgical treatment, so, the aim of the study was to evaluate the cost of surgical treatment of patients with spinal metastasis with epidural compression and the correlation of the cost with some outcomes.

METHODS

This is a cross-sectional study, approved by local HCRP – no. 8120/2017. We carried out a retrospective review of the data of 81 patients with spinal metastasis and epidural compression who underwent surgical treatment between March 2009 and August 2015 in the Department of Orthopedics and Anesthesiology from Ribeirão Preto Medical School - University of São Paulo, Brazil.

The inclusion criteria were patient's 18 years and older with a diagnosis of spinal metastasis and epidural metastasis of solid malignant tumor who underwent surgical treatment. Patient who underwent previous surgery, diagnosis of hematological malignancy and individuals with solid metastatic neoplastic disease, whose spinal compression was not confirmed after anatomopathological evaluation of the surgical material were not enrolled in the study.

To compare data of categorical variables, the chi-square test with or without correction was used, while for the comparison of central tendency measures, Student's t test for independent samples was used for means, or the test from Mann-Whitney for independent samples, to medians. In all analyzes, a significance level of 5% was considered.

The cost data were collected retrospectively using the electronic data system of University Hospital of Ribeirão Preto Medical School-USP, between March 2009 and August 2015, and took into account consumption material, equipment and human resources. The cost evaluation followed the methods proposed by Drummond et al (2005)[14] including real direct monetary costs health care, defined in the following categories: 1) medicines, 2) laboratory and imaging exams, 3) ward, 4) surgical procedure, 5) surgical material (consigned or not), 6) post-surgical recovery room and, 7) intensive care unit.

The cost were those registered in the hospital system on the day of its use by the patient and considering the real amount paid by the hospital through public bidding process. Laboratory and imaging exams: the cost of each exam performed by the patient during hospitalization period. Ward, recovery room and intensive care unit: all direct and indirect cost such as water, energy, telephone and support services (cleaning, physiotherapy, psychology) make up the value average cost of the patient day. Surgical procedure: value of the surgical hour added to the cost of anesthesia. Surgical material (consigned or not): implants for surgical procedure reimbursed by the health system (SUS). For cost corrections, Inflationary adjustments: estimated cost were expressed in Brazilian Real (BRL) from December to August 2015 and adjusted for June 2018 through the Consumer Price Index (IPCA). The discount rates were not used in the study since the costs analyzed are related to a period less than one year in all patient.[14]

Univariate sensitivity analysis was used to evaluate the most influential input parameter with the exact delimitation of the minimum and maximum values. This method is used to prove the degree of stability of the results found in the study.[14]

RESULTS

Complete required information was obtained from 81 patients, with forty-nine male (60.5%), being that the age of the patients at the time of spinal decompression surgery ranged from 18 to 91 years old (mean 56.3 years; SD 15.9); 58.24 (16.22) for male and 53.31 (15.92) for women ($p > 0.05$). The Table 1 is illustrating the distribution of primary tumors by gender and descending order. The two most frequent tumors were malignant breast cancer (28.4%) and prostate cancer (20.99%). The primary tumor site was unable to be identified in six patients (7.41%).

The performed surgical treatment in the enrolled patients was open posterior fixation using pedicle screw based system associated with decompressive laminectomy, while corpectomy was performed in patients who the anterior column reconstruction was required.

The total cost of surgical treatment of 81 patients was R$ 3,604,334.26 and the mean value for each patient was R$ 44,497.95. The cost

Table 1. Distribution (in descending order and gender) of primary tumors among the selected patients.

	Gender		Total
	Male	Female	
	n (%)	n (%)	n (%)
Primary tumor			
Breast	0 (0%)	23 (71.88%)	23 (28.4%)
Prostate	17 (34.69%)	-	17 (20.99%)
Sarcoma	5 (10.2%)	1 (3.13%)	6 (7.41%)
Occult primary tumor	5 (10.2%)	1 (3.13%)	6 (7.41%)
Rectum	3 (6.12%)	1 (3.13%)	4 (4.94%)
Oral cavity	2 (4.08%)	1 (3.13%)	3 (3.7%)
Lung	3 (6.12%)	0 (0%)	3 (3.7%)
Kidney	3 (6.12%)	0 (0%)	3 (3.7%)
Thyroid	2 (4.08%)	1 (3.13%)	3 (3.7%)
Bladder	2 (4.08%)	0 (0%)	2 (2.47%)
Cervix	0 (0%)	2 (6.25%)	2 (2.47%)
Colon	1 (2.04%)	1 (3.13%)	2 (2.47%)
Testis	2 (4.08%)	0 (0%)	2 (2.47%)
Esophagus	1 (2.04%)	0 (0%)	1 (1.23%)
Choroid plexusmelanoma	1 (2.04%)	0 (0%)	1 (1.23%)
Nasopharynx	1 (2.04%)	0 (0%)	1 (1.23%)
Sinus maxillary	1 (2.04%)	0 (0%)	1 (1.23%)
Gallbladder	0 (0%)	1 (3.13%)	1 (1.23%)
Total	49 (100%)	32 (100%)	81 (100%)

items and respective values are shown in Table 2. The largest expense was related to consigned material (implants) with a total cost of R$ 1,491,008.13 (41.1%) and mean cost of R$1,407.50 for each patient.

The distribution of the number of patients by KPS (Figure 1) level and Frankel Scale (Figure 2), with respective costs per item, is shown in Table 3 below. There was a tendency for higher cost in patients with lower KPS values, but without statistical significance ($p>0.05$). The cost of surgical treatment according to neurological deficit was lower in patients with severe neurological deficit (Frankel A and B)[15] but without statistical significance ($p>0.05$).

Sensitivity analysis showed a large range between the minimum and maximum values. (Figure 3) The total cost was more sensitive to the cost variation in the hospital ward. The variation of consigned material was 87.1%, 52.89% for intensive care unit, 24.06% for laboratory exams, 17.67% for surgical procedure, 15.51% for medicines and 5.21% for recovery room.

The cost of surgical treatment of the five most common tumor is represented on Table 4. The treatment of unknown primary tumor was the highest mainly due to the cost of the ward, that account for 36% of the total cost.

As can be seen, the average cost (R$ 73,493.31) of surgery in patients with a hidden primary site was higher when compared to the other four cancer sites.

Table 2. Distribution of costs (mean and total) with respective values of all items used in the surgery of the selected patients.

Variables	Mean Costs (R$)	Total (R$)	%
Consigned materials	18,407.51	1,491,008.13	41.4
Nursery	12,146.41	983,859.09	27.3
Surgery procedure	8,782.94	711,417.90	19.7
Exams	2,959.31	239,704.45	6.7
Intensive Care Unit	1,138.36	92,207.00	2.6
Medicines	819.22	66,356.54	1.8
Recovery room	244,21	19,781.15	0.5
Total	44,497.95	3,604,334.26	100.0

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disable; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

Figure 1. Karnofsky Performance Scale.

Frankel grade	Definition
A	Complete injury, no motor or sensory function below the level of injury
B	Incomplete injury, no motor function
C	Incomplete injury, motor function useless, sensory incomplete
D	Incomplete injury, motor function useful, sensory incomplete
E	Incomplete injury, motor function normal, sensory normal

Figure 2. Frankel Classification of Spinal Cord Injury.

The cost of treatment considering the outcome related to pain improvement was higher (R$ 45,736.35) in the group of patients who showed postoperative pain improvement compared to patients with postoperative pain (R$ 44,550.84). All cost components were higher in postoperative pain improvement group except the cost of intensive care and, The cost for patients who maintained or improved functional activity (Frankel D or E) was slightly smaller than patients with impaired function (Frankel A,B and C). The difference in cost was related to hospital stay, medicines and recovery room. (Table 5)

The cost of patients with less than three months of survival was higher (R$ 13,844.54) *versus* (R$ 13,801.32) compared to patients who had longer survival (R$ 11,061.94) *versus* (R$ 7,126.41). The cost of hospital stay including ward, intensive care and medication were responsible for this difference. (Table 6)

DISCUSSION

The mean cost of surgical treatment for patients with spinal metastasis that underwent surgical treatment was R$ 44,497.95 for each patient. The largest expenses was related to implants (41.1%), followed by hospital stay (27.3%), and surgical procedure (19.7%). The other costs were smaller compared to the mentioned cost. The total cost for treatment of 81 patients was R$ 3,604,334.26. Cost estimates were obtained using micro-costing to obtain a more accurate information.

Several reports have presented the cost of surgery for spinal metastasis with epidural compression. Although there are some differences in the final value of the cost, there is an agreement that it's the most expensive treatment for skeletal event in those patients.[6,8,16,17]

The rough comparison of the cost of surgical treatment for patients in our group was lower than the value reported in other studies,[6,15] that mentioned it as the most expensive treatment among the skeletal event in patients with cancer. Hospitalization cost range widely secondary to the variability in the procedures performed, pathologies treated, and different countries.[6,15,18]

The highest percentage of the cost in our patient was related to the cost of implants, whereas in other reports the hospital stay was in charge for the highest percentage. DuBois and Donceel (2010) reported that hospital stay was 39% and it was in charge for the highest percentage of the treatment cost.[7] The costs of surgery for spinal tumor range widely and depend on a variety of factors. The identification of factors that can be modified is critical for decreasing the cost of treatment. Analysis of the cost of treatment related to outcomes showed interesting data that should be considered in treatment guidelines in order improve treatment, and resources allocation.

The cost of consignated and implants was in charge for a large amount of the total cost of the treatment considering all the group. When the cost is analyzed considering the outcomes, the

Table 3. Distribution of the number of patients by KPS level and Frankel Scale, with respective costs (mean) per item, between 2009 – 2015.

Resources	Mean Costs(R$) by KPS level						
	50 (n=8)	60 (n=26)	70 (n=30)	80 (n=12)	90 (n=3)	100 (n=1)	P Value
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (DP)	
Nursery	17.141,04 (7187,05)	11.208,61 (7126,69)	11147,97 (13922,5)	12530,44 (7905,87)	12679,2 (14962,19)	3953,98 (-)	0,05
Intensive Care Unit	1.920,22 (4462,27)	546,75 (2438,22)	1966,18 (6018,9)	154,68 (535,84)	596,08 (1032,44)	0 (-)	0,67
Medicines	1135,11 (1013,08)	577,71 (567,34)	819,87 (1486,74)	963,99 (1405,8)	1845,06 (2792)	107,77 (-)	0,38
Surgery procedure	8641,33 (1727,8)	8757,96 (2861,57)	8350,59 (3132,85)	9896,81 (2198,16)	8801,29 (5408,5)	8670,25 (-)	0,52
Recovery room	646,81 (840,82)	127,42 (338,79)	132,38 (306,42)	495,67 (780,87)	458,12 (229,17)	0 (-)	0,05
Exams	3908,06 (2118,36)	3199,32 (2279,11)	2795,47 (2604,27)	2866,63 (2423,58)	1998,5 (602,55)	641,33 (-)	0,34
Consignedmaterials	15528,88 (3587,85)	19428,58 (12363,14)	19195,72 (9972,2)	15004,37 (3869,59)	19378,58 (17497,18)	24749,42 (-)	0,64
Total	48921,45 (12376,19)	43846,34 (16143,94)	44408,19 (20570,72)	41912,59 (12754,09)	45756,82 (19058,13)	38122,75 (-)	0,84

Recursos	Mean Costs (R$) by Frankel Scale				
	A (n=12)	B (n=11)	C (n=19)	D (n=11)	E (n=28)
	média (DP)	média (DP)	média (DP)	média (DP)	média (DP)
Nursery	13.751,89 (8011,05)	9.483,56 (6925,58)	13.771,18 (8867,44)	12.678,74 (12405,18)	11.192,81 (13123,63)
IntensiveCare Unit	1.209,45 (3662,76)	2.266,92 (6690,98)	748,68 (2845,85)	156,91 (520,4)	1.314,52 (4797,15)
Medicines	1.134,67 (1532,21)	1.113,61 (1637,26)	721,85 (659,9)	537,61 (598,47)	745,07 (1435,33)
Surgery procedure	7.813,3 (2966,82)	7.804,85 (2846,55)	8.472,78 (2776,78)	9.466,92 (2848,02)	9.524,5 (2740,2)
Recovery room	333,19 (515,63)	112,61 (213,84)	427,54 (722,64)	248,9 (469,91)	131,53 (390,91)
Exams	3.354,78 (2072,01)	3.051,1 (1033,25)	3.839,9 (2684,49)	1.667,74 (1044,96)	2.663,64 (2800,63)
Consignedmaterials	14.534,17 (4430,22)	18.692,2 (9979,45)	18.314,78 (10070,88)	20.792,42 (14382,18)	19.081,66 (9667,67)
Total	42.131,43 (14111,55)	42.524,85 (13093,73)	46.296,7 (13848,25)	45.549,24 (18542,97)	44.653,74 (21089,07)

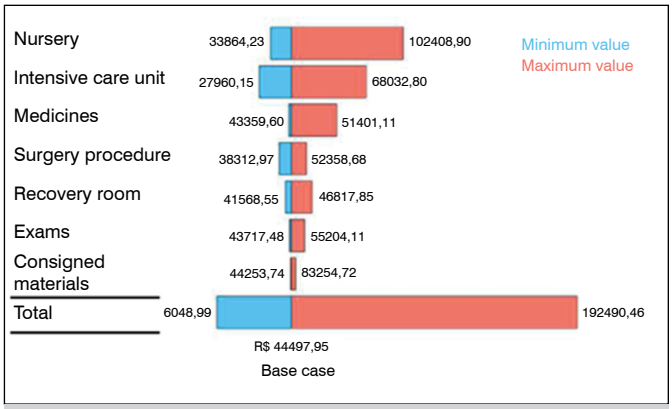

Figure 3. Sensitivity analysis showed a large range between the minimum and maximum.

consignates and implants do not have a large role as in the total cost. Considering the cost and outcome related to neurological deficit, the cost of implants was lower in patients more severe neurological deficits (Frankel A and B). This would be explained by more palliate surgery in patients with severe neurological deficit compared to patients with partial neurological deficit or normal patients that underwent more sophisticated treatment and reconstruction. Cost of consignated and implants concerning the other outcomes as pain, function, survival showed was similar and other factors as hospital stay, intensive unit care, exams was in charge for the difference in costs.

The reported cost by Barlev (2010)[6] of patients with spinal metastasis due to prostate, breast and multiple myeloma similar to our cost and showed that treatment of spinal metastasis with or without epidural compression is the most expensive event related to skeletal.[6] Hagiwara, Delea and Chung (2014)[19] also reported that surgical treatment of spinal metastasis with epidural compression was the most expensive event. Felix et al. (2011)[20] reported the mean cost of EUR 13,203.00 for patient with prostate or breast cancer and spinal cord compression in the National Health Service of Portugal.[20] Jaysekera et al. (2014) reported the cost of U$82,868.00 for patients with prostate cancer in EUA that underwent surgical treatment for spinal metastasis with epidural compression. Only 4% of the patients required surgery among 52% that had epidural metastasis.[12]

The cost of unknown primary tumors was higher compared to others metastatic tumor, mainly due hospital stay, intensive care unit, medicines and exams and, would be related to difficult and attempts to find the primary tumor site. The primary site of histologically documented carcinoma cannot be identified in 3.0 to 13.0% of patients. In epidural neoplastic metastasis, the primary tumor is unknown in 15.0 to 25.0% of patients.[21]

The cost of patients with shorter survival was higher and related to the cost with hospital stay and intensive unit care. It should also be considered that postoperative complications are concentrated in the group of patients with lower survival. This observation reinforces the need to identify the patient with a good prognosis in order to avoid a surgical procedure with lower survival expectancy and that can also increase the total cost of the treatment.

The morbidity and cost of spinal metastasis shown that early diagnosis could avoid the risks and high costs related to surgical treatment. Screening of spinal metastasis using new available imaging technology would improve quality of life of patients with spinal metastasis and reduce the overall cost avoiding surgery. It should also be considered that postoperative complications are concentrated in the group of patients with lower survival.

The evaluation of the cost of treatment allowed identification of the different components that act in the cascade of cost. The results allows to better understand flow of the cost and how we can better allocate the resources or reduce the overall cost. Considering the high cost of surgical treatment and benefits of early diagnosis that reduces cost and morbidity, protocols for early diagnosis of spinal metastasis should be stimulated. Early diagnosis and target treatment might reduce or delay serious and expensive outcomes.

<< SUMÁRIO

Table 4. Means of cost of surgical treatment of the five most common tumor among the selected patients.

Resources	Mean Costs (R$)					
	Breast (n=23)	Prostate (n=17)	Sarcoma (n=6)	Occult primary Tumor (n=6)	Rectum (n=4)	Lung (n=3)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Nursery	8,802.16 (6,751.85)	14,636.08 (9,388.04)	11,857.46 (5,150.85)	26,209.10 (23,943.17)	7.416,03 (4,892.92)	9.696,1 (4,522.08)
Intensive Care Unit	370.55 (1425.9)	256.62 (742.09)	3,716.59 (9,103.74)	6,233.06 (10,369.09)	905.02 (1,810.05)	0 (0)
Medicines	472.21 (526.53)	704.68 (657.29)	853.30 (1,110.74)	3,315.46 (2,687.48)	443.44 (381.15)	735.91 (442.65)
Surgery procedure	8,021.70 (2,780.35)	8,108.18 (2,324.40)	8,828.27 (4,286.67)	9,766.38 (2,089.18)	10,577.42 (2.120.63)	9,548 (1,401.16)
Recovery room	232.63 (469.27)	455.40 (690.86)	122.01 (174.76)	114.02 (231.80)	198.28 (174.79)	0 (0)
Exams	2,305.48 (1,719.42)	3,628.24 (2,796.64)	2,575.93 (1,063.43)	6,506.64 (4,023.95)	1,440.17 (1,466.58)	3,472.19 (570.96)
Consigned materials	19,880.78 (10,010.88)	18,284.85 (12,115.92)	21,406.65 (16,597.71)	21,348.66 (11,034.17)	18,015.10 (5,373.75)	18,058.90 (2,273.84)
Total	40,085.52 (12,454.57)	46,074.06 (16,394.62)	49,360.20 (19,176.88)	73,493.31 (28,488.30)	38,995.47 (8,383.85)	41,511.10 (5,901.17)

Table 5. The cost distribution according to postoperative pain outcome and functional activity outcome.

Resources	MeanCosts (R$)	
	Pain improvement	Persistant pain
	Mean (SD)	Mean (SD)
Nursery	13,072.34 (12,379.03)	12,694.51 (9,721.62)
IntensiveCare Unit	480.05 (2,282.52)	1,028.71 (3,987.35)
Medicines	906.71 (1,611.65)	762.94 (936.28)
Surgery procedure	9,219.05 (3,205.74)	8,487.95 (2,529.14)
Recovery room	244.42 (526.35)	281.08 (534.15)
Exams	3,287.22 (2,974.13)	2,786.70 (1,895.63)
Consigned materials	18,526.56 (10,090.63)	18,508.95 (10,131.71)
Total	45,736.35 (19,459.00)	44,550.84 (15,981.18)
Resources	**MeanCosts (R$)**	
	Improves deambulation	**Not able to walk**
	Mean (SD)	**Mean (SD)**
Nursery	12,025.02 (11,736.63)	14,600.98 (8,696.96)
IntensiveCare Unit	1,055.15 (3,973.04)	745.65 (2,690.82)
Medicines	697.14 (1,156.13)	1,093.24 (1,483.43)
Surgery procedure	8,839.17 (2,931.33)	8,400.93 (2,735.23)
Recovery room	232.91 (549.03)	323.90 (484.46)
Exams	2,908.86 (2,700.31)	3,318.16 (1,762.71)
Consigned materials	18,767.43 (11,330.24)	17,614.30 (7,048.87)
Total	44,525.67 (19,544.81)	46,097.16 (12,375.63)

Table 6. Costs distribution according to survival greater than or less than 3 months.

Recursos	Mean Costs (R$)	
	<3 months	≥3 months
	Mean (SD)	Mean (SD)
Nursery	13,844.54 (13,801.32)	11,061.94 (7,126.41)
Intensive Care Unit	2,453.35 (6,121.35)	140.88 (541.77)
Medicines	1,142.18 (1,572.08)	585.37 (856.53)
Surgery procedure	9,333.99 (2,847.32)	8,428.16 (2,786.71)
Recovery room	232.81 (446.40)	258.51 (554.87)
Exams	3,185.05 (2,532.89)	2,832.93 (2,247.65)
Consigned materials	18,995.79 (10,689.28)	18,028.20 (9,498.72)
Total	49,187.7 (20,121.19)	41,335.98 (13,077.85)

CONCLUSION

The mean cost of surgical treatment for patients with spinal metastasis that underwent surgical treatment was R$44,497.95 for each patient. The largest expenses was related to implants (41.1%), followed by hospital stay (27.3%), and surgical procedure (19.7%). The cost of unknown primary tumors was higher compared to others metastatic tumor as well as the cost of patients with shorter survival.

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SPORTS MEDICINE

EFFECT OF AEROBIC AND ANAEROBIC TRAINING ON DIFFERENT ERGOMETERS IN RAT MUSCLE AND HEART TISSUES

EFEITO DOS TREINAMENTOS AERÓBIO E ANAERÓBIO EM DIFERENTES ERGÔMETROS NOS TECIDOS MUSCULAR E CARDÍACO DE RATOS

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ABSTRACT

Objective: Analyze the effects of aerobic and anaerobic training on different ergometers on muscle and cardiac hypertrophy in rats. Methods: The animals were separated into the following groups: Control (C), Aerobic Training in Water (ATW), Resistance Training in Water (RTW), Aerobic Training on Treadmill (ATT), and Resistance Training in Climbing (RTC). All training protocols were carried out for 4 weeks, 3 times/week. The cross-sectional area (CSA) of the gastrocnemius muscle cells and the areas of the cardiomyocytes were measured. Results: In the fast-twitch fibers, there was an increase in CSA in the RTW and RTC groups compared to the ATW ($p<0.01$ and $p<0.01$) and ATT groups ($p<0.01$ and $p<0.01$). In the slow-twitch fibers, the ATW and ATT groups demonstrated a lower CSA compared to the RTW ($p=0.03$ and $p<0.00$) and RTC groups ($p<0.01$ and $p<0.01$). In the cardiomyocytes, there was an increase in the area of the RTW and RTC groups compared to groups C ($p<0.01$; $p<0.01$), ATW ($p=0.02$; $p<0.01$), and ATT ($p<0.01$; $p<0.01$). Conclusion: The anaerobic training effectively promotes hypertrophy in the fast-twitch fibers and the cardiomyocytes. ***Level of Evidence V; Animal experimental study.***

Keywords: Resistance training. Myocytes, Cardiac. Muscle Fibers, Skeletal. Physical Endurance.

RESUMO

Objetivo: Analisar os efeitos dos treinamentos aeróbios e anaeróbios em diferentes ergômetros na hipertrofia muscular e cardíaca de ratos. Métodos: Os animais foram separados nos grupos controle (C), treinamento aeróbio em natação (ATW), treinamento resistido em meio aquático (RTW), treinamento aeróbio em esteira rolante (ATT) e treinamento resistido em escalada (RTC). Os protocolos de treinamento foram realizados por 4 semanas, 3 x/semana. Foram mensurados a área de secção transversa (CSA) das células do músculo gastrocnêmio e as áreas dos cardiomiócitos. Resultados: Nas fibras de contração rápida houve aumento da CSA dos grupos RTW e RTC em relação aos grupos ATW ($p<0,01$ e $p<0,01$) e ATT ($p<0,01$ e $p<0,01$). Nas fibras de contração lenta os grupos ATW e ATT demonstraram menor CSA comparado aos grupos RTW ($p=0,03$ e $p<0,00$) e RTC ($p<0,01$ e $p<0,01$). Nos cardiomiócitos houve aumento da área dos grupos RTW e RTC em comparação com os grupos C ($p<0,01$ e $p<0,01$), ATW ($p=0,02$ e $p<0,01$) e ATT ($p<0,01$ e $p<0,01$). Conclusão: Os treinamentos anaeróbios promoveram hipertrofia nas fibras de contração rápida e nos cardiomiócitos. ***Nível de Evidência V; Estudo experimental em animais.***

Descritores: *Treinamento de Resistência. Miócitos Cardíacos. Fibras Musculares Esqueléticas. Resistência Física.*

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INTRODUCTION

Physical training is essential for maintaining quality of life, promoting improvement in the skeletal and cardiac muscular system, which results in better cardiovascular capacity and improvement in the individual's functional capacity, in addition to avoiding the harmful effects of sedentarism.[1–3] However, the adaptations generated are dependent on the training modality used.[3,4]

Training models can be grouped into aerobic and anaerobic training. The first group includes training modalities composed of exercises

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The study was conducted at the Laboratory of Biomaterials in Orthopedics (UNICAMP), in partnership with the Laboratory of Histology and Histochemistry of São Paulo State University "Júlio de Mesquita Filho" (FCT/UNESP), where all experimental procedures were performed.
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<< SUMÁRIO

of low and moderate intensity and higher volume. The second group includes exercises with high intensity and lower volume.[3,5,6] Anaerobic training presents greater stimulus for muscle hypertrophy, since it can promote synthesis of contractile elements, which consequently increases the contraction force.[3,5,6] Aerobic training presents greater stimulus for resistance to fatigue, with greater oxidative capacity, an increased number of mitochondria, and improved blood perfusion.[6,7]

In cardiac muscle tissue, aerobic training is known to promote physiological hypertrophy and improve parameters such as ejection volume and reduced peripheral resistance. Anaerobic training is seen as a valuable tool to promote adaptations in the cardiovascular system, such as hypertrophy of cardiomyocytes and increased thickness of the left ventricle.[8,9]

Muscle hypertrophy occurs in both skeletal muscle and cardiac muscle, and is an important factor for improving contraction strength and improving functional capacity in both tissues.[1,2] Thus, evaluating the effects of different models of aerobic and anaerobic exercises is relevant so that health professionals can develop specific treatment programs to meet the therapeutic objective and improve physical capacities.

Therefore, the current research aimed to analyze the effects of aerobic and anaerobic training using different ergometers on skeletal and cardiac muscle hypertrophy.

MATERIAL AND METHODS

Animals

In total, 40 male Wistar rats, 150 days old, were used. The animals were kept in collective cages with five animals, under controlled conditions of temperature (22 ± 2°C), humidity (50 ± 10%), and a 12-hour light/dark cycle (7-19h), with water and feed provided ad libitum.

The study was previously approved by the Ethics Committee for the use of animals– CEUA of the São Paulo State University (FCT/UNESP), São Paulo, Brazil (protocol number 03/2014).

Experimental Groups

The animals were divided into five groups according to the independent variables:

• Control (C, n=12): The animals remained in the cages and were euthanized in a paired way with the other experimental groups.

• Aerobic Training in Water (ATW, n=7): The animals were subjected to the critical load test to determine the training load, then underwent aerobic training in water for 30 minutes, three times a week, with an intensity corresponding to 70% of the anaerobic threshold and water temperature of 30° C (±1).

• Resistance Training in Water (RTW, n=7): The animals were submitted to the test of 10 Maximum Repetitions (10RM) to determine the training intensity, then performed jump training in water, three times a week, composed of 4 series of 10 jumps with overload corresponding to the intensity of 80% of 10 RM test and water temperature of 30° C (±1).

• Aerobic Training on Treadmill (ATT, n=7): The animals were submitted to the critical speed test on a treadmill, and then underwent training for 30 minutes, three times a week, with an intensity of 70% of the anaerobic threshold.

• Resistance Training in Climbing (RTC, n=7): The animals were subjected to a maximum workload test to determine the training intensity. Subsequently, the animals performed training consisting of 4 series of climbing, three times a week, with an intensity corresponding to 80% of 1RM.

One week before starting the tests, to determine the training load, the animals, except group C, performed adaptation to the ergometers. In the ATW group the animals performed 10-20 minute efforts, without load; in the ATT group the animals performed 10-20 minute efforts with a speed of 10-15 m/min; in the RTW group the animals performed 1x of 10 jumps with 50 % of body weight; and the RTC group performed 3 climbs with a load of 50% of the body weight. Adaptation is important for animals to become familiar with the exercise, without physiological adaptations to training.[4,10]

Critical Load Test to determine the Anaerobic Threshold (Lan)

The Critical Load (CL) test was performed to determine the anaerobic threshold of animals in the ATW group, and the Critical Speed (CS) test for animals in the ATT group. For the first, a tank with cylindrical tubes 25 cm in diameter was used, with water at a depth of 70 cm. For the CS test, a treadmill with individual lanes was used.

The tests were performed using 4 different intensities: 7, 9, 11, and 13% of body weight for the CL and 0.9, 1.2, 1.5, and 1.8 km/h for the CS. The intensities were randomized and one performed each day, with an interval of 24 hours between each session, in order to avoid interference from the previous session. Thus, the exercise time of each animal until fatigue was obtained for each intensity. Subsequently, the data were multiplied by the inverse of the time limit and plotted on a scatter plot. Finally, a trend line (linear) was added, from which the anaerobic threshold was defined.[7,10]

Maximum load test

Maximum strength tests were performed in the RTW and RTC groups, in order to define the work intensity of each animal. The animals in the RTC group were submitted to efforts on the stairs (1.1 x 0.18 m, 2 cm space between the steps, 80° inclination), with a load corresponding to 75% of the body weight of each animal, adding 30g to each successful climbing attempt. The test was stopped when the animal failed to climb after three attempts.[11]

In the RTW group, the same test model was performed, with the animals submitted to aquatic jumps in PVC tubes (30 cm in diameter and 50 cm in height, and 38 cm deep). The load was tied to the animal by means of a vest in the region of the torso. The same equipment was also used during training.[12]

The animals in the RTW group were subjected to the maximum load test, for which an initial load of 80% of the animals' body weight was used, with 10% of the body weight being added in each new series, until the animal was unable to perform the test. Failure to perform the test was determined when the animal could not complete 10 jumps (10 RM). The final completed intensity was assumed as an intensity of 10 RM. This test was adapted from the previously proposed climbing model.[11]

The training started 72 hours after the tests, using the same ergometer. The training was performed 3 times a week; in aerobic training the intensity used was 70% of the threshold, and the anaerobic training was performed at 80% of the maximum intensity.

Sample collection and preparation

Forty-eight hours after the final exercise session, the animals were euthanized by anesthetic overdose of ketamine hydrochloride and xylazine hydrochloride via the intraperitoneal route.[13] The right gastrocnemius muscles of the animals were collected.

Histological Processing of the Gastrocnemius Muscle

The muscle tissue was immersed in n-hexane solution and cooled in liquid nitrogen (-190) by the method of freezing unfixed tissues, and later stored in an ultra-low temperature freezer (-75° C). The 5 μm sections were produced in a cryostat microtome at -20° C, collected on slides, and then histochemical staining of nicotinamide adenine dinucleotide tetrazolium reductase (NADH-TR) was used, which indicates the presence of oxidative activity, for analysis of type I and type II muscle fibers.[14,15]

Histological Processing of the Cardiac Muscle

Samples of cardiac muscle tissue were fixed in a 10% buffered formaldehyde solution for a period of 48 hours. After fixation, the tissue was embedded in paraffin blocks, before obtention of histological sections of 4 micrometers. These histological sections were stained on a slide with Hematoxylin-Eosin (HE) solution to measure sectional areas of cardiomyocytes.

Microscopic Analysis

The slides of skeletal and cardiac muscle tissue were photographed using a Nikon® microscope, model 50i, attached to an Infinity 1 camera. Analyses were performed from the images: in the skeletal muscle, the cross-sectional areas of 100 muscle fibers of each type (type I and type II) were analyzed; and in the heart, areas of 50 cardiomyocytes of the left ventricles were analyzed. All analyses were performed using NIS-Elements D3.0 2 software- SP7 - Nikon®.

Statistical analysis

The results were initially analyzed by the Shapiro-Wilk test to verify the Gaussian distribution of the data. The values of the cross-sectional morphometry of the muscle fibers and the area of the cardiomyocytes did not demonstrate normality, so we proceeded with the Kruskal-Wallis test and Dunn's post hoc, to assess the differences between the groups. The analyses were performed using IBM-SPSS v.22 software, with a significance level of 5%.

RESULTS

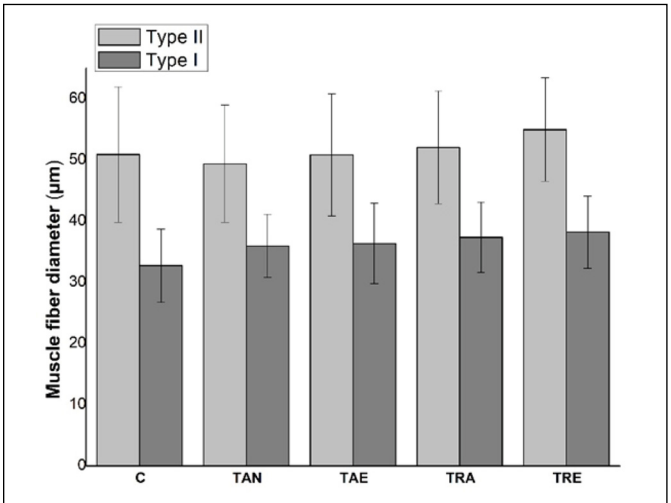
In the gastrocnemius muscle, statistical analysis showed an increase in the diameter of type II muscle fibers in the RTW group (117.59 μm ± 0.70) compared to groups C (109.85 μm ± 0.03; p<0.01), ATW (107.96 μm ± 0.79; p<0.01), and ATT (110.68 μm ± 0.64; p<0.01); the RTC group (119.75 μm ± 0.70) also presented greater muscle fibers in relation to the ATW (p<0.01) and ATT groups (p<0.01). In addition, the ATW group presented a significant decrease with group C (109.85 μm ± 0.77; p = 0.03). (Figure 1)

In type I fibers, the ATW group (69.99 μm ± 0.48) presented a smaller fiber diameter compared to the RTW (72.09 μm ± 0.49; p = 0.03) and RTC groups (72.71 μm ± 0.48; p <0.01); the ATT group (69.31 μm ± 0.40) presented a smaller fiber diameter compared to the RTW (p <0.01) and RTC groups (p <0.01). In addition, group C (78.39 μm ± 0.44) presented a larger diameter compared to the ATW (p = 0.03), ATT groups (p <0.01), RTW (p <0.01) and RTC (p <0.01). (Figure 1)

In the morphometry of the cardiomyocyte area, group C (486.68μm2 ± 8.54) presented a lower value compared to the RTW (550.95 ± 11.07; p <0.01) and RTC groups (591.97 ± 9.48; p <0.01). The RTW group showed a greater area of cardiomyocytes in relation to the ATW (498.12 ± 8.03; p = 0.02) and ATT groups (489.54 ± 10.30; p <0.01). In addition, the RTC group also presented greater area of cardiomyocytes compared to the ATW (p <0.01) and ATT groups (p <0.01). (Figure 2)

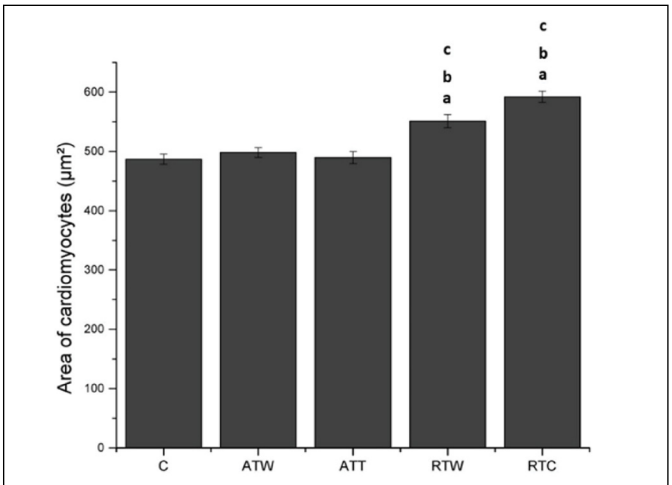
DISCUSSION

The results demonstrated that resistance training in both water jumping (RTW) and climbing (RTC), were more effective for gaining muscle volume in skeletal muscle in type II fibers. However, the cross section of type I muscle fibers was greater in group C. Regarding cardiomyocytes, only the RTW and RTC groups demonstrated hypertrophy. During the anaerobic exercise, the animals performed vigorous muscle contraction. This type of exercise mainly uses fast-twitch muscle fibers (type II), and in the aerobic exercise they performed less vigorous contractions for a longer period, which preferentially uses slow-twitch muscle fibers (type I). As type I fibers preferentially use the oxidative pathway, and type II fibers preferentially use the glycolytic pathway, the adaptations resulting from exercise may be different in the fast-twitch and slow-twitch fibers.[5,16,17]



C= Control; ATW= Aerobic Training in Water; ATT= Aerobic Training on Treadmill; RTW= Resistance Training in Water; RTC= Resistance Training in Climbing. a Significant difference in relation to the C group; b Significant difference in relation to the ATW group; c Significant difference in relation to the ATT group.

Figure 1. Values of mean and standard error of the cross section of the fast-twitch fibers (type II) and slow-twitch fibers (type I) of the gastrocnemius muscle.



C= Control Group; ATW= Aerobic Training in Water; ATT= Aerobic Training on Treadmill; RTW= Resistance Training in Water; RTC= Resistance Training in Climbing. a Significant difference in relation to the C group; b Significant difference in relation to the ATW group; c Significant difference in relation to the ATT group.

Figure 2. Values of mean and standard error of the cardiomyocyte area.

Several authors have demonstrated an increase in the cross-sectional area of muscle fibers from high-intensity, low-volume training.[5,7,18,19] The greater the intensity of the exercise, the greater the stimulus for hypertrophy, promoting greater stimulus to the protein synthesis of the contractile elements responsible for muscle contraction, generating an increase in the volume of muscle fiber.[5,6,17]

The muscle hypertrophy process is modulated by the mechanical stimulus to which the muscle tissue is submitted, so an exercise with greater overload will promote greater stimulus for muscle hypertrophy.[20] In addition, a study carried out with exercise on a stationary exercise bike[21] that the stimulus for the hypertrophy pathway, and increase in the glucose transporter (GLUT4), occurred with greater magnitude in type II muscle fibers, than in type I muscle

fibers, a fact that could explain the hypertrophy observed only in type II fibers in the current study.

In the slow-twitch fibers there was no increase in the cross section of muscle fibers, so the effects of training seem to have occurred only in the fast-twitch fibers. This finding corroborates a previous study that also did not observe hypertrophy in slow-twitch muscle fibers after 4 weeks of training.[18] Aerobic exercise is best known for promoting improvement in oxidative capacity, increased blood perfusion, and the number of mitochondria, generating greater resistance to fatigue.[3,6]

A review study looked at the effectiveness of aerobic training for gaining muscle hypertrophy, and found that there is hypertrophy when the exercise is performed over the long term (9 to 12 weeks).[22] In the current study, only 4 weeks of training were performed, so the training time may have been decisive for the non-adaptation of the slow-twitch muscles to exercise. In addition, the strength gain also depends on neuromuscular adaptation, so the non-increase in the cross section does not mean that there were no adaptations in this tissue.[3,23]

Regarding the cardiac muscle, an increase in cardiomyocytes was observed in the RTW and RTC groups compared to the control group. Although aerobic exercise has the ability to promote cardiomyocyte hypertrophy,[24–26] some authors did not find hypertrophy of cardiac cells after training.[27,28] In addition, strength exercise also demonstrates effectiveness in increasing the ventricle wall and the contraction force of the heart.[8,29]

In the current study, only anaerobic training showed higher values of cardiomyocyte area when compared to aerobic training and group C. This type of training promotes an overload to the cardiovascular system, which through this stimulus remodels itself with alterations such as cellular hypertrophy and an increase in the left ventricular wall, promoting greater ventricular ejection capacity, less peripheral resistance to blood flow through the vessels, and greater efficiency in contraction.[30,31] Thus, anaerobic training may have induced a greater adaptation to exercise through the larger effort required during the execution of this type of exercise.

It should be noted that the current research was carried out with healthy animals; therefore, caution should be exercised when extrapolating these results to humans and to cardiac patients. Research with humans is necessary to verify the effectiveness of this training model and the safe parameters of exercise in these conditions.

The current study collaborates with the literature by investigating the effects of different forms of training on the striated cardiac and striated skeletal muscles of Wistar rats. However, as limitations of the present research we can mention the lack of a performance test at the end of the experimental period, which could demonstrate whether there were adaptations beyond hypertrophy, and the lack of measurement of the left ventricular wall.

CONCLUSION

It was concluded that anaerobic training was effective in promoting hypertrophy in the fast-twitch fibers and in the cardiomyocytes. Furthermore, there was no hypertrophy in the slow-twitch fibers in any of the training protocols. Thus, the adaptation proved to be sensitive to the exercise model, aerobic or anaerobic, and not to the ergometer model used.

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WRIST AND HAND

AN ALTERNATIVE MODEL FOR TEACHING TENDON REPAIR AND SURGICAL TECHNIQUE IN HAND SURGERY

UM MODELO ALTERNATIVO PARA O ENSINO DE REPARO TENDÍNEO E A TÉCNICA CIRÚRGICA EM CIRURGIA DA MÃO

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ABSTRACT

Introduction: At the beginning of the medical career, the orthopedic surgeon in academic training needs valid methodologies for training complex surgeries in tissues that simulate real situations. With training in animal tissue, adapted to approach human tissue, it is possible to simulate procedures and decisions that will be necessary in real situations. Objective: This study consists in presenting a simple and reproducible simulation model for surgical repair of tendons by training on fresh tendons fixed on a wooden frame. Methodology: The model construction consists of a flat piece of Medium Density Fiberboard (MDF) and two threaded hooks were used on the board, to which Nylon threads are attached to tie the tendon, allowing a satisfactory simulation of a human tendon. Conclusion: This is a simple, inexpensive, and effective method for tendon suturing training, through which the trainee can develop repair techniques and basic surgical principles, such as instrument handling, safety, and sharps disposal. This approach aims to improve the trainee's skills and dexterity when placed in live surgery. The surgical techniques developed include the modified Kessler and Bunnel sutures. ***Level of Evidence IV, Descriptive Study.***

Keywords: Tendons. Suture Techniques. Hand Injuries.

RESUMO

Introdução: No início da carreira médica, o ortopedista em formação acadêmica necessita de metodologias válidas para o treinamento de cirurgias complexas em tecidos que simulem situações reais. Com o treinamento em tecido animal, adaptado para abordar o tecido humano, é possível simular procedimentos e decisões que serão necessários em situações reais. Objetivo: Este estudo consiste na apresentação de um modelo de simulação simples e reprodutível para reparo cirúrgico de tendões por meio do treinamento em tendões frescos fixados em estrutura de madeira. Metodologia: A construção do modelo consiste em uma peça plana de Fibra de Média Densidade (MDF) e foram utilizados dois ganchos roscados na prancha, aos quais são fixados fios de Nylon para amarrar o tendão, permitindo uma simulação satisfatória de um tendão humano. Conslusão: É um método simples, barato e eficaz para o treinamento de suturas tendíneas, por meio do qual o trainee poderá desenvolver técnicas de reparo e princípios cirúrgicos básicos, como manuseio de instrumentos, segurança e descarte de objetos cortantes. Este método visa melhorar as habilidades e destreza do trainee quando colocado em cirurgias ao vivo. As técnicas cirúrgicas desenvolvidas incluem as suturas Kessler e Bunnel modificadas. ***Nível de Evidência IV, Estudo Descritivo****.*

Descritores: *Tendões.Técnicas de Sutura. Traumatismos da Mão.*

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INTRODUCTION

Hand flexor tendon repair is a technically demanding procedure with a narrow margin of error in its acceptability for a satisfactory result. The repair must be strong enough to allow early mobilization and, at the same time, it must be simple, sparsely bulky and atraumatic to allow smooth sliding of the tendon into the flexor sheath during postoperative active mobilization.[1-4] The greatest advance in the basic science of flexor tendon repair is the understanding of the multiple factors that can affect repair strength. The tension of the central suture, the size of the suture fixation area, the curvature of the tendon slip, and the presence of intact main pulleys (A2 and A4) affect the repair strength.[5]

Training in tissue of animal origin, adapted to approach human tissue allows the possibility to simulate procedures and decisions that will be necessary in real situations. This study consists in using a simple and reproducible model for simulating the surgical repair of tendons. The construction of the model was made with a flat piece of medium density fiberboard (MDF) and two threaded hooks on the plate, to which Nylon threads are tied to fix a fresh bovine tendon, allowing a satisfactory performance simulation of

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a human tendon. It is a simple, low cost and effective method for training tendon sutures, through which orthopedists in academic formation who use the simulator can develop repair techniques and basic surgical principles, such as instrument handling, safety and disposal of sharp instruments. The types of sutures to be practiced include modified Kessler and Bunnel sutures.[6-8]

In one year, approximately 18,000 primary tendon repairs are performed in England, most of them by orthopedists in academic formation.[7,8] Associated with serious complications intrinsic to the procedure, such as tendon rupture and adhesion formation, we also have those that can be triggered or aggravated by inadequate surgical techniques and the surgeon's inexperience.[9] In addition, the success of surgical repair of the injured tendon is limited by its diminished ability to recover.[8]

Training and practice for a hand surgeon in this technique is essential to reduce patient morbidity, associated with improving the learning curve. Therefore, professionals need realistic simulation and effective practice models to develop their skills and abilities. This skill is best taught in the anatomy lab and refined in the operating room (OR). The simulator provides a safe environment for orthopedists in academic formation and physicians to practice suture techniques, while surgical approaches and instrument handling skills are more appreciated in the OR. In suturing the tendon, placing the central stitch at an adequate distance from the edges and configuring the proper tie are the main components for the success of the procedure.[6-8]

Teaching the orthopedists in academic formation how to repair a flexor tendon is particularly difficult, as surgical skill is technically demanding and function recovery is directly proportional to it. Developing fine motor skills needed to repair a tendon through simulation, removing tension from the operating room, is ideal and should increase the training orthopedist's ability to concentrate and increase his chances of success when in the operating room.[5-8]

In line with this, realistic and low cost models allow residents to develop their repair skills before perform them *in vivo*.[9] There for, the orthopedist in academic training would also have the possibility of simulating, under test conditions, situations that are likely to occur in the real practice.[2] Regarding simulation, we can say that animal models are more commonly used because they are cheap, easily available and offer a realistic texture of the tissue. While commercial training kits are expensive and of variable designs.[8]

With this specific competence in mind, we designed a training model that consists of simulating a tendon injury and subsequently repairing it, using the modified Kessler and Bunnel suture techniques, working with two and four passes, respectively, which have progressive degrees of difficulty.[7]

The present study aim to propose a simple, realistic and low cost model that can allow surgeons in training to practice flexor tendon repair in an environment without clinical risks to patients.

METHODOLOGY

The proposed simulation initially requires the creation of a model that reproduces tendon injuries. For this purpose, an instrument that promotes tension in the tendon was developed, consisting of: a flat piece of wood in MDF, dimensions of 2cm x 29,7cm x 42cm, two threaded hooks for support and Nylon 1-0 threads tied to the hooks and to the ends of the pieces of bovine tendon. Other materials that make up the experimental model are: bovine tendon, 4-0 Nylon suture thread, surgical instruments (needle holder, tweezers and straight scissors), scalpel blade, procedure gloves and sharps disposal box. (Figure 1)

The procedure consists of using a model per student to teach two different tendon suture techniques: modified Kessler and Bunnel. Each student injuries the tendon of their model and then performs the repair, reproducing the techniques as they are taught by the guiding physician.

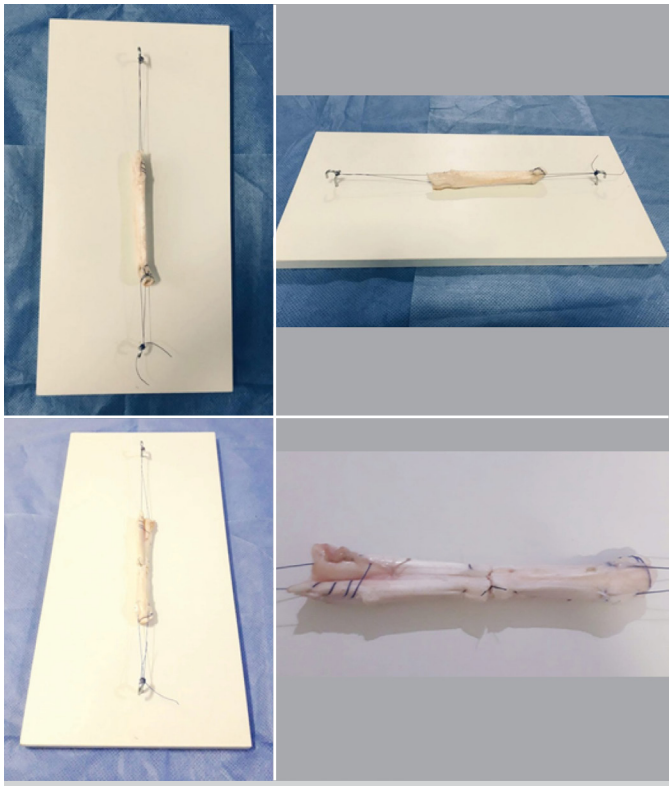

Figure 1. Final appearance of the simulator with the tendon before and after the suture.

This project has no conflict of interest, and has been aproved by the institution etic´s comitee (CAAE 45309421.0.0000.5373) and there was no need of aplication of conscentiment forms, according to the etic´s comitee resolution.

RESULTS

The elaborated model described presented a satisfactory simulation of the procedure for repairing tendon structures. Both the texture of the selected biological material and the tension developed by the model were within the expected range for training the surgical procedure. The students were able to elaborate the modified Kessler and Bunell suture techniques according to the guidelines described by the guiding physician.

DISCUSSION

Surgeon resident training presents the challenge of teaching tendon repair psychomotor skills to real patients. The early part of the learning curve is fraught with errors, which can have functional morbidity consequences. Ensuring that the interface between surgeon-in-training and patient occurs safely is one of the biggest challenges for assistant surgeons. What makes it clear that simulation models are a necessary educational tool, allowing the surgeon in training to develop their technical skills without pressure or risk of having to improve their technique directly on the patient.

CONCLUSION

The bovine tendon is easily obtainable and readily available for practice, when divided and fixed to a surface it can simulate the texture and structure of a human tendon, both are mostly made up of type I collagen and proteoglycans. The ability to practice on this model prepares students and orthopedic in academic formation in the development of their surgical skills before performing tendon repair *in vivo*.

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GENERAL

ETHICAL AND LEGAL ASPECTS OF TELEMEDICINE APPLIED IN ORTHOPEDICS

ASPECTOS ÉTICOS E LEGAIS DA TELEMEDICINA APLICADA À ORTOPEDIA

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ABSTRACT

Due to the pandemic of COVID-19, many outpatient services were suspended, affecting hundreds of patients. As a result, several countries were forced to seek strategies to readapt their health systems, one of which was the expansion of telemedicine. Currently, telemedicine is used for several specialties, facilitating the treatment and follow-up of patients who have difficulty accessing it. Tele-orthopedics, telemedicine applied to the orthopedic specialty, allows orthopedic care to be offered to patients regardless of distance. By reducing travel time, waiting time, and costs, tele-orthopedics presents high patient satisfaction, allowing greater rehabilitation effectiveness after surgery and treatment compliance. There is much information in the current literature about telemedicine's legal and ethical aspects, but it is fragmented. This article aims to present a general explanation of these legal and ethical aspects, emphasizing tele-orthopedics. The ethical principles of autonomy, beneficence, non-maleficence and justice must be respected, as well the privacy and confidentiality during a teleconsultation. In this respect, orthopedic surgeons should be governed by traditional moral and ethical precepts. Still, they must also adapt to the new norms and laws regulating telemedicine use. **Level of Evidence V: Expert Opinion.**

Descriptors: Telemedicine. Medical Ethics. Jurisprudence. Orthopedics.

RESUMO

Com a pandemia da COVID-19, muitos atendimentos ambulatoriais foram suspensos, afetando centenas de pacientes. Isso forçou diversos países a buscarem estratégias para readaptar seus sistemas de saúde e, uma delas, foi a expansão da telemedicina. Atualmente, a telemedicina está sendo utilizada para diversas especialidades, facilitando o tratamento e o acompanhamento de pacientes que possuem dificuldade de acesso. A tele-ortopedia, telemedicina aplicada à especialidade ortopédica, permite a oferta dos cuidados ortopédicos a pacientes independente da distância. Por reduzir tempo de viagem, tempo de espera e custos, a tele-ortopedia, apresenta alta satisfação por parte pacientes, o que permite maior efetividade na reabilitação após cirurgias e adesão ao tratamento. Há na literatura atual diversas informações acerca dos aspectos legais e éticos da telemedicina, contudo são informações fragmentadas. Este artigo visa proporcionar uma explanação geral sobre esses aspectos éticos e legais, com ênfase na tele-ortopedia. Os princípios éticos da autonomia, beneficência, não-maleficiência e justiça devem ser respeitados, da mesma forma a privacidade e confidencialidade durante uma teleconsulta. Com isso, os ortopedistas devem ser regidos pelos tradicionais preceitos morais e éticos, mas também, devem se adequar as novas normas e leis que regulamentam o uso da telemedicina. ***Nível de evidência V: Opinião do especialista****.*

Descritores: *Telemedicina. Ética Médica. Jurisprudência. Ortopedia.*

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INTRODUCTION

Telemedicine and telehealth are both remote ways to offer medical care, but have different meanings. Telemedicine involves a real-time virtual interactivity between patient and physician. Otherwise, telehealth has a broad meaning and consists of use of communication technology to promote health care, medical education and health care center administration.[1]

The first report of telemedicine was in the end of XIX century when electrocardiographic data was transmitted by telephone line. In 1927, the first video consultation occurred between patient and doctor.[2] The COVID-19 pandemic caused most ambulatory consultations to be cancelled, affecting thousands of patients around the world and forcing many countries to search for new strategies, such as telemedicine.[3] Many studies show that patients have high satisfaction

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with telemedicine because it is easy to access, saves time, and reduces expenses - particularly among patients that need to travel long distances or participate in labor.[4-6]

In developed countries, telemedicine is consolidated with remote monitoring services of patients with chronic and acute diseases with large investments. In 2016, when the world did not even imagine a pandemic, the global telemedicine market was estimated to grow to US$ 19.2 billion in 2014,35.1 billion in 2018, and 43.4 billion in 2019. The European market alone was expected to triple to 12.6 billion U.S. dollars in 2019. However, with the advent of the pandemic, the amounts invested in telemedicine vastly surpassed these previous estimations.[7,8]

On the other hand, developing countries have less effort and investment in this area, likely due to lack of resources, return on investments, and technological infrastructure. However, telemedicine is an important ally to expand access to basic health services and bring the needy population closer to specialized centers located in large cities in developing countries.[6,8]

Brazil is a continental country with many difficult access areas and has heterogeneous distribution of medical resources.[7] At the beginning of the COVID-19 pandemic, the Brazilian ministry of Health regulated telemedicine actions to offer remote care and allowed basic unit of health to perform teleconsultations since ambulatory consultations had been cancelled.[9]

According to the World Health Organization (WHO), one of the major changes that will occur in the 21st century is the availability of high-quality healthcare for all. To achieve this, the WHO recommends that countries use telemedicine as a health planning strategy. However, despite the increased use of telemedicine, there are a large number of ethical and legal problems, which hinders the expansion of this modality of care.[10]

There is in current literature some information about the legal and ethical aspects of telemedicine, however the data is fragmented. This article aims to provide a general explanation about the ethical and legal aspects of telemedicine, with emphasis on telemedicine applied to orthopedics, known as tele orthopedic.

Telemedicine applied to orthopedic specialty

A study published in 1997 analyzed 410 virtual orthopedic consultations for 2 years with 43% of orthopedic consultations were fracture, 35 % ligamentous injury, joint swelling and infection and 18 % postoperative evaluation. No adverse effects were observed, and the authors concluded that tele orthopedic is an excellent option for performing diagnosis and follow-up examinations on orthopedic patients.[11]

In 2017, an Australian publication evaluated 9 tele-orthopedics services and observed that was good to diagnose and follow-up fracture cases and performed successfully perioperative consultations.[12]

Laskowsli et al, described musculoskeletal examination by telemedicine and showed that many physical tests are feasible by tele orthopedics, taking another step towards this form of teleconsultation becoming a reality.[13] Jaenisch M et al. evaluated viability of virtual physical examinations of hip joints. They compared presential and virtual examinations and showed that there is good concordance in the inspection and follow-up on orthopedic surgical wounds.[14]

Polinski et al published a satisfaction survey in which 95 % of all patients were very satisfied with teleconsultation and be considered telemedicine equal or better than in-person consultation. Publications suggest that tele orthopedic is safe, cost-effective and high rates of satisfaction among patients.[15] Pastora-Bernal JM et al showed that tele-rehabilitation had good results in patients after knee and hip arthroplasty.[16]

Altogether, these results indicate that orthopedic specialty works, via telemedicine, in several ways such as diagnosis, treatment and rehabilitation. In addition to reducing costs, it is safe and increases the engagement of patients in treatment with potential to be explored.[17]

Ethical aspects of teleorthopedia

Despite of technology development and new models of care, the ethical foundations in the practice of medicine remains unchanged. Unlike traditional interaction, tele-orthopedics raises concerns about the risks to privacy and confidentiality, limitation of physical examination and the possible breakdown of the doctor-patient relationship.[1,2]

Telemedicine respects the ethical principles of universality, equity, and integrality, since it allows all patients access to the health system and enables consultations with highly specialized medical centers located in urban areas.[4,18]

With the use of telemedicine, some doubts have arisen and one of them is what would be the effect of telecommunication problems on the patient. In other words, if issues such as connection problems, delay, poor image and audio quality and disconnection occur, anxiety and vulnerability in the patient may be caused or, perhaps, even damage.[19] However, in general, the advantages of telemedicine clearly outweigh the disadvantages.[1,20]

In October 1999, the 51st General Assembly of the World Medical Association, held in Tel Aviv, Israel, published the "Tel Aviv Declaration on Responsibilities and Ethical Norms in the Use of Telemedicine." The statement says, "Regardless of the telemedicine system under which the physician is operating, the principles of medical ethics which are globally binding upon the medical profession must never be compromised." The Tel Aviv Declaration emphasizes that because of the risks of information leakage inherent to some types of electronic communication, the physician has an active obligation to ensure that all established standards of security measures have been followed to protect the patient's confidentiality.

The absence of physical interaction between physician and patient may be a problem. Besides, quality level of telemedicine is difficult to define because of lack of regulations. Regarding the ethical aspects to maintain privacy and confidentiality, autonomy, beneficence, nonmaleficence, justice and equity must be respected in telemedicine and teleorthopedics.[19,20]

Autonomy: The patient has the right to receive all information about the recommended treatment, both via tele orthopedic and by face-to-face consultation. Autonomy begins even before the consultation, explaining that the two modalities of care are available and clarifying that the patient has full autonomy to switch at any time, unless it violates the patient's safety or the physician's awareness.

Patient privacy and confidentiality should be respected in the same way as in face-to-face consultation and should not be shared without patient authorization. In addition, during tele orthopedic consultations, all people together with patient in the consultation should be identified and, likewise, all individuals with the physician should also be identified and remain in the consultation with the patient's permission.[1,2,21] Despite the creation of protocols of care and orthopedic physical examination, such as the publications of Tanaka and Laskowsli, the patient needs to be informed about the limitation of tele orthopedics, such as the physical examination[13,22] and advised, if necessary, that the physician could request his face-to-face evaluation.

Beneficence: The principle of beneficence is the ethical obligation to maximize benefit and minimize injury to the patient. As such, the medical professional must have the greatest technical information possible to ensure a beneficial medical act to the patient.

In tele orthopedics this principle occurs through medical education. It is not plausible to believe that physicians move from face-to-face to virtual care without prior training. Recent studies show that 75% of physicians feel uncomfortable in performing virtual consultations

without previous experience in telemedicine and 95% in performing diagnosis and deciding treatment without physical evaluation.[23] Currently in Brazil, several orthopedics centers have huge queues of patients waiting for joint replacement. Many of these patients live far away from hospitals or have limitations of transportation. Tele orthopedics allows the care of these and other patients, avoiding long trips and waiting time, besides avoiding contagion by the new coronavirus.[4, 24]

Nonmaleficience: It is the medical action of causing the least harm or no harm to the patient's health. It is associated with the maximum hippocratic *primum non nocere*, *i.e.,* first not harm. Telemedicine has several benefits, such as time savings, costs and environmental pollution.[24] However, telemedicine can present threats, such as the breakdown of patient autonomy, by imposing virtual care without the possibility of choice. Another situation is the choice of inadequate treatment, because of physician's inexperience with telemedicine or the low accuracy of the virtual physical examination. In order to avoid that, the physician should evaluate patient face-to-face in case of doubt diagnoses or any alarm signal.[4, 21] In addition, recommendations for the use of electronic medical records and digital platforms in order to protect the privacy and confidentiality of the patient must be followed.

Justice and equity: The principle of justice has equity as its fundamental condition and treats each patient according to what is morally appropriate, providing to each individual what is due to them. Physicians should be impartial, and resources should be distributed fairly. Orthopedics, because it treats disorders of the musculoskeletal system, has patients with osteoarticular pain and movement restrictions. Thus, patients with difficulty in locomotion have the possibility of access to orthopedic services, via tele orthopedics, on par with face-to-face care.[4]

Table1 - Pros and cons of tele-orthopedics regarding to ethical aspects. (Table 1)

Legal aspects of tele orthopedic

Currently, telemedicine is being applied to several medical specialties, facilitating the treatment and follow-up of patients with access limitation. Tele orthopedics allows the provision of orthopedic care to patients regardless of distance. Besides, it has high patient satisfaction and allows greater effectiveness in rehabilitation after surgeries, as it reduces travelling time, waiting time and transport expenses.[1, 25] Although the care is virtual, the legal aspects of telemedicine remain the same as in-person care.

Table 1. Pros and cons of tele-orthopedics regarding to ethical aspects.

Ethical principles	Pros	Cons
autonomy	Autonomy to choose care modality / Patient participates in decision making	Limitation of physical examination/Risks privacy and confidentiality
Beneficence	Reduce travelling and waiting time, absenteeism on work, transportation expanses/ Consultation even in the COVID-19 pandemic	Internet access and technological equipment limitation
Nonmaleficience	Autonomy/ Reduces travelling and waiting time, absenteeism on work, transportation expanses / Avoiding hospitals	Risk privacy and confidentiality /Interference and change of medical conduct
Justice and equity	Allow access to patients with disability / Orthopedic care to risk group in the COVID-19 pandemic	Internet access and technological equipment limitation / Minimum patient's education degree

Silva et al., studied 30 years of telemedicine policy in the SUS and identified 79 federal laws related to telemedicine and 31 resolutions of councils.[26] In 2002, 19 years ago, the Federal Council of Medicine published resolution n°.1,643/2002 that defines telemedicine as the exercise of medicine through audiovisual communication and data transmission, with the objective of health care, education, and research.

In 2017, the Federal Council of Medicine (FCM) report n°.14/2017 regulated the use of WhatsApp in a hospital environment, for communication between doctors and their patients, as well as between physicians.

In 2019, FCM resolution n°.2,227/2018 of February 6, 2019, defined telemedicine as a form of technology-mediated medical services. However, FCM resolution n°.2,228/2019 of March 6, 2019, revoked FCM resolution n°. 2,227/2018 and reestablished FCM resolution n°.1,643/2002. This fact occurred due to high number of proposals submitted by Brazilian physicians to change the terms of FCM resolution n°. 2.227/2018, since this resolution required prior establishment of a face-to-face consultation and, for a long time or chronic diseases, in-person consultation was recommended at intervals not exceeding 120 days.

On March 19, 2020, officio of FCM n°.1,756/2020 recognized that "as exceptionality and for as long as the battle to combat contagion of COVID-19 lasts, recognizing the possibility and effectiveness of the use of telemedicine, besides of the provisions in FCM resolution n°.1,643 of August 26, 2002". On April 15, 2020, law n°.13,989/2020 was published, which has authorized telemedicine during Coronavirus pandemic. In article 3, the practice is defined as "the exercise of medicine mediated by technologies for the purposes of care, research, disease and health promotion". Article 4 says "the physician must inform the patient of all limitations inherent in the use of telemedicine" and Article 5 " telemedicine service will follow rules and ethical aspects of face-to-face care".[27]

Telemedicine and tele orthopedic must follow the rules of Civil Framework of the Internet [28] and law n°.13,709 of August 14, 2018 - General Law for the Protection of Personal Data (GLPPD). In Article 1 of GLPPD, regards the processing of personal data, including in digital media, by a natural person or by a legal entity under public or private law, with the aim of protecting the fundamental rights of freedom and privacy and the free development of the personality of the natural person.[29]

Regarding the legal aspects of medical practice in tele orthopedic, the informed consent form, medical license, digital platforms and prescription are important points to be discussed.

Informed consent: Following the principle of autonomy, the patient has the right to accept or not the consultation via tele orthopedic after explanation about the benefits and risks. The inform consent form is necessary because there is a medical intervention mediated by a technological resource. The absence of an informed consent form characterizes an infringement of medical ethics, except in confirmed situations of imminent danger of life. This consent should be prepared according to the changes in the doctor-patient relationship resulting from the intermediate of high-tech devices.

In addition, the Superior Court of Justice (SCJ) understands that the signing of the consent form removes the responsibility of the medical professional, if it is demonstrated that the eventual damages were due to factors unrelated to their performance, but the lack of the consent form leads the professional not to comply with the duty of information.

Medical license: According to the Code of Medical Ethics, for the practice of medicine, registration is required in the Regional Council of the respective state. On May 18, 2020, Regional Council of Medicine of Rio Grande do Sul published resolution n°.10 that says, "medical care via remote means provided directly to patients

located in another state or country can only be performed if the physician has enrollment in the Regional Council of Medicine of the state in which the patient is located as a way to ensure the continuity of care in person".

FCM, in order COJUR n°.383/2020, does not dispense secondary enrollment when there is the provision of services in states other than where the doctor has primary enrollment, even if through telemedicine.

Therefore, to attend to the patient from another state virtually, it is necessary to have the license in that state for the practice of medicine to be considered legal.

Digital platforms: The electronic medical records must have security guarantee level 2 (SGL2) established in the Certification Manual for Electronic Health Registration Systems of the Brazilian Society of Health Informatics - Federal Council of Medicine (SBIS-CFM), digital certificate, computer with microphone, webcam and internet access and an audio and video platform that is compatible with Health Insurance *Portability and Accountability Act* (HIPAA).[30]

Prescription and digital certificates: The one proven by law n°.13.989/2020, the medical prescription and medical certificate can be sent in digital format by e-mail or by application of message to the patient. For this, it is necessary use of electronic signature through certificates and keys issued by the Brazilian Public Key Infrastructure- ICP-Brazil. The Pharmacy Council clarified that the prescriptions must contain a digital signature with ICP-Brazil certificate, i.e., digitalized copies of manually issued prescriptions, as photos or scanned files are not recognized by Anvisa.

Medical responsibility: The physician who performs care, via telemedicine, has the same responsibilities over the patient as the physician in face-to-face care. Currently, there is little discussion about the alterations and the result of doctor-patient relationship by telemedicine.[1,20,31]

Even with the patient's informed consent, physicians who provide care through tele orthopedic are responsible for possible harm to the patient. There is concern regarding the fact that the misdiagnosis and mistreatment are associated with the absence of presential physical examination, as article 37 of the Code of Medical Ethics states that: "Prescribe treatment and other procedures without direct examination of the patient, except in cases of urgency or emergency and proven impossibility of performing it, in which case, should do so immediately after the end of the impediment, as well as consult, diagnose or prescribe by any way of mass communication". Thus, as stated in Art. 4 of law n°. 13.989/2020: "The physician must inform the patient of all the limitations inherent to the use of telemedicine, since of the impossibility of performing physical examination during the consultation". In addition to ethical norms, the physician is also subject to civil and legal sanctions, as is law n°.13,989/2020 in article 5: "the provision of the telemedicine service will follow the common normative and ethical standards of face-to-face care".[27]

Patient responsibility: In tele orthopedic, as in telemedicine, the patient also has responsibilities, especially regarding sending exams, clinical information and data transmission. For example, in case of failure of connection by the patient during important guidance on treatment or if incomplete or erroneous information about the clinical condition is provided.[1, 23] (Table 2)

Table 2. FCM and Federal Government relevant issues to telemedicine since 2002.

Issues	Entity	Contents
Resolution No. 1,643/2002	FCM	Define and discipline provision of services via Telemedicine
Resolution No. 1890/2009	FCM	Define tele-radiology
Ordinance No. 35/2007	Fed. Government	National Program of Tele health
Ordinance No. 402/2010	Fed. Government	Tele health in Family Health Strategy - SUS and repeal ordinance 35/2007
Ordinance No. 2,546/2011	Fed. Government	Redefine and expand Brazil Tele health Program and repeal ordinance 402/2010
Opinion No 09/12	FCM	Videoconference in administrative legal consultation
Order SEJUR nº 194/2013	FCM	Guidance on how to proceed to enable legal consultation by videoconference
Resolution No. 2,107/2014	FCM	Define tele-radiology and repeal Res. FCM No. 1,890/09
Law No. 12,965/2014	Fed. Government	Internet civil landmark
Resolution No. 2,178/2017	FCM	Regulate medical apps
Opinion No 14/2017	FCM	WhatsApp regulamentation
Opinion No 17/2018	CFM	O aconselhamento genético por telemedicina.
Resolução nº 2.227/2018	FCM	Define and discipline telemedicine. Repeals Res.CFM No. 1643/2002
Law No. 13,709/2018	Fed. Government	General Law for the Protection of Personal Data
Resolution No. 2,264/2019	FCM	Discipline to telepathology
Resolution No. 2,228/2019	FCM	Discipline telemedicine, reestablishe Res.CFM no. 1,643/2002
Opinion No 3/2020	FCM	Prohibit legal consultation without in-person examination
Opinion No 8/2020	FCM	Prohibit occupational examinations without direct clinical examination on the worker
Opinion No 10/2020	FCM	Prohibit legal consultation without examination of the patient
Order COJUR Nº 383 /2020	FCM	Not authorize the waiver of secondary enrollment in another state, even via telemedicine
Offício Nº 1756/2020	FCM	Recognize telemedicine for as long as the pandemic lasts
Law 13.989/2020	Fed. Government	Allow telemedicine for the duration of the pandemic

FINAL CONSIDERATIONS

The emergence of the COVID-19 pandemic expanded the use of telemedicine, which generated discussion of ethical and legal aspects on this subject. Telemedicine care differs from face-to-face care and requires physicians to be trained to perform this type of care. As medical graduation has poor contact with telemedicine, physicians feel uncomfortable in performing a teleconsultation. In addition, the lack of a public policy in Brazil hinders the implementation of telemedicine and guidance of health professionals. However, regardless of the modality, the ethical principles of autonomy, beneficence, nonmaleficience and justice must be respected in the same way as privacy and confidentiality of patient data. Moreover, the requirement for regulation of telemedicine in a short period of time did not allow time for adequate discussions on the matter, generating numerous publications of resolutions and laws, some of which were divergent and outdated.

Currently, telemedicine is regulated by law n°.13.989/2020 that authorizes telemedicine for the duration of the Coronavirus pandemic. However, this modality of care is already consolidated and, even with the increase in vaccination around the world, it will tend to be increasingly used, both for care and for research.

Telemedicine applied to orthopedics, known as tele orthopedic, has an extensive field of activity from diagnosis to rehabilitation,

with low risk, high patient satisfaction and is an expanding area with potential to be studied. The continuous implementation of tele orthopedic is changing the form of care and has numerous advantages. However, like any intervention, there are risks that should be calculated and made available to the patient. In addition, medical training and development of protocols in telemedicine contributes to a better care.

Thus, orthopedists during tele orthopedic should be guided by the traditional moral and ethical precepts of in-person care but must also adapt to the legal bases of telemedicine.

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