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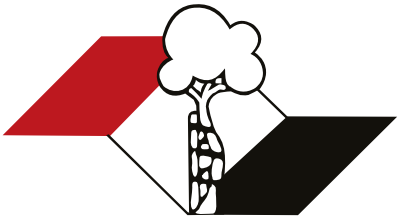

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ACKNOWLEDGEMENTS

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

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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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FACE-TO-FACE EXERCISES ARE NOT SUPERIOR TO TELE-REHABILITATION IN RECENT POST-OPERATIVE TOTAL HIP ARTHROPLASTY: A RANDOMIZED CLINICAL TRIAL

EXERCÍCIOS FACE-TO-FACE NÃO SÃO SUPERIORES À TELEREABILITAÇÃO NO PÓS-OPERATÓRIO RECENTE DE ARTROPLASTIA TOTAL DE QUADRIL: ENSAIO CLÍNICO RANDOMIZADO

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2. Hospital de Clínicas de Porto Alegre (HCPA), Porto Alegre, RS, Brazil.

ABSTRACT

Objective: compare a face-to-face exercise program (face-to-face group [FG]) to telerehabilitation (telerehabilitation group [TG]), in patients undergoing total hip arthroplasty (THA). Methodology: randomized clinical trial with 24 participants: 14 in the FG, which held weekly exercise sessions with face-to-face supervision in the clinic; and 10 in the TG, which performed exercises at home, with guidance from the booklet and weekly calls from the researchers. All participants underwent 6 weeks of intervention and were evaluated, by a blinded evaluator, in the pre- and post-intervention moments for: pain; kinesiophobia; functional; joint range of motion (ROM); and peak muscle torque (PT). Results: post-intervention only the TG ($p = 0.018$; $d = 1,744$) showed improvement in the results of the TUG, however both TG ($p = 0.043$; $d = 1,876$) and FG ($p = 0.002$; $d = 1,854$) showed improvement in the HHS results. Conclusion: telerehabilitation proved to be as effective as face-to-face rehabilitation in improving PT, ROM and functional capacity of patients in the initial stage of THA rehabilitation. It can be considered a low-cost and easy access alternative in this post-operative phase. ***Level of Evidence I, Randomized control trial.***

Keywords: Rehabilitation. Muscle strength. Osteoarthritis. Hip prosthesis.

RESUMO

Objetivo: comparar um programa de exercícios face-to-face (GF) à telerreabilitação (GT), em pacientes submetidos à artroplastia total de quadril (ATQ). Metodologia: ensaio clínico randomizado com 24 participantes: 14 no GF, que realizou sessões semanais de exercícios com supervisão presencial na clínica; e 10 no GT, que realizou exercícios em casa, com orientação de cartilha e ligações semanais dos pesquisadores. Protocolo de 6 semanas de intervenção, foram avaliados pré e pós-intervenção para: dor (END); cinesiofobia (Escala de Tampa); capacidade funcional (HHS e TUG); amplitude de movimento articular e picos de torque muscular. Resultados: pós-intervenção somente o GT ($p = 0.018$; $d = 1.744$) apresentou melhora nos resultados do TUG, porém tanto GT ($p = 0.043$; $d = 1.876$) como GF ($p = 0.002$; $d = 1.854$) apresentaram melhora nos resultados do HHS. Houve aumento na ADM pós-intervenção, no GF, de 9 graus ($p = 0.013$; $d = 1.028$) na abdução e de 5 graus na extensão ($p = 0.037$; $d = 0.949$) do membro inferior operado (MIO), e no GT, de 18 graus ($p = 0.028$; $d = 1.571$) na flexão do MIO. Conclusão: a telerreabilitação mostraram-se tão eficaz quanto a reabilitação face-to-face na melhora dos PT, da ADM e da capacidade funcional de pacientes em fase inicial de reabilitação de ATQ. ***Nível de evidência I, Estudo clínico randomizado.***

Descritores: *Reabilitação. Força Muscular. Osteoartrite. Prótese de Quadril.*

Citation: Brazeiro MC, Mueller KF, Rohde CS, Lopes BM, Silva MF. Face-to-face exercises are not superior to tele-rehabilitation in the recent post-operative total hip arthroplasty: randomized clinical trial. Acta Ortop Bras. [online]. 2024;32(2) Esp.: Page 1 of 8. Available from URL: http://www.scielo.br/aob.

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

The study was conducted at the laboratory of physical therapy of Universidade Federal de Ciencias da Saude de Porto Alegre.
Correspondence: Bruna de Moraes Lopes. Rua Sarmento Leite, 245 - Centro Histórico, Porto Alegre, RS, Brasil. CEP: 90050-170. E-mail: blopes.fisio@gmail.com.

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INTRODUCTION

The number of THAs performed globally has been growing annually, with estimations pointing to a worldwide increase of 219% in THAs by 2046, indicating a higher cost for the health system. Despite the high quality of life indices (84-97%) reported, evidence suggests that individuals undergoing THA surgery may exhibit functional alterations, movement restrictions, and deficits in muscle strength postoperative for one or two years.[1-2]

Scientific literature shows great variation in intervention: home-based programs (orientations or booklets)[3] or exercises with face-to-face supervision;[3-6] exercises with[6] or without load;[4-7,9] frequency;[9] protocol duration and postoperative period—ranging from right after hospital discharge.[5-8]

Some studies[8,9,10] investigated the delivery of home-based exercise protocols (supervised or not) performed immediate or late postoperative, which were able to improve muscle strength, functionality and gait speed in THA patients.[8-10]

Hence, this study compared the effects of a face-to-face supervised exercise protocol, performed in the clinical setting, with a home-based program (tele-rehabilitation), followed via remote monitoring, in patients undergoing THA surgery.

METHODS

Study design

A randomized clinical trial was conducted following the CONSORT Statement guidelines after approval by the Research Ethics Committee of the University (protocol 3.049.371) and was registered on ClinicalTrials (NCT3208829). Before starting the procedures, all participants red, agreed and signed the informed consent form.

Participants

Sample size calculation was based on a mean difference of 10.84Nm regarding the peak torque of the hip abductors[4], assuming a standard deviation of 11 points for group 1 and 10, for group 2, an alpha level of 0.05 and a power of 80%. A minimum total of 56 patients was obtained, 28 in each group.

Both groups consisted of patients (men and women) over 45 years of age attended at three hospitals in Porto Alegre city, Brazil, for primary THA surgery (10-30 days postoperative). Exclusion criteria included individuals with postoperative complications (infections, deep vein thrombosis, prosthesis dislocation, periprosthetic fractures, and neural lesions), who underwent a surgical procedure on the lower limbs less than 6 months ago, with muscle injuries for less than 3 months in the lower limbs, who had cardiovascular diseases with the presence of disability (severe heart failure) and neurological diseases (stroke with sequelae, Parkinson's disease, neurodegenerative diseases), and those who were already undergoing physiotherapy.

Outcomes

Participants underwent two assessments: initial (pre-intervention), performed before randomization; and post-intervention, within 7 days after the end of the 6-week follow-up. Both evaluations were conducted by a blinded researcher.

Pain and kinesiophobia

Pain intensity on the operated hip was measured by the Pain Numerical Scale (PNS) which consists of 11 points numbered from 0 to 10. Presence of kinesiophobia was assessed by the Tampa Kinesiophobia Scale translated, adapted and validated in Brazil.

Self-reported functional capacity

Self-reported functional capacity was measured by the Harris Hip Score (HHS) questionnaire[11].

Objectively measured functional capacity

Objectively measured functional capacity was assessed through the Test Timed Up and Go (TUG), which has excellent validity and reliability.[11-12]

Range of Motion

Active range of motion (ROM) was assessed in both hips by a single evaluator using a fleximeter (model FL6010, Sanny, Brazil), which showed excellent intra-rater reliability in three measurements (ICC = 0.935-0.994; $p < 0.05$). Movements were evaluated in the following positions: hip flexion, hip extension and abduction, internal and external hip rotation.[13] Participants performed each movement three times, and were interrupted if compensatory movements were observed in the pelvis or trunk. Analysis used the means of the three measurements of each movement.

Muscle strength

Muscle strength was evaluated by measuring the isometric peak torque (TP) in both lower limbs using a portable dynamometer (model HHD 01165, Laffayete, United States), which showed excellent intra-rater reliability over three measurements (ICC = 0.939-0.980; $p < 0.05$). For each muscle group, three maximal isometric contractions were performed lasting 5 seconds with a 30-second interval for rest.[14] Assessment measured the strength of the following muscle groups: hip abductors, hip extensors, hip flexors, internal and external hip rotators.[14] The means of the three measurements were used for analysis, and the PT values were normalized by body mass according to the equation PT = peak torque (Nm)/body mass (kg)x100.

Limb order was previously randomized using a mobile application (*Randomizers - www.random.org*).

Randomization and allocation

After initial assessment, the participants were randomized into two physiotherapy treatment groups: Face-to-face (FG) and Tele-rehabilitation (TG). An assistant researcher, who was not involved in the data collection or the follow-up, was responsible for generating a numerical sequence using random.org and hide this information in opaque envelopes numbered in sequence. The assistant researcher responsible for the training protocols opened these envelopes at the end of the pre-intervention evaluation to allocate each individual to one of the two treatment groups.

Protocols

Inpatient phase

All patients were operated by orthopedic hip surgeons, with over 10 years of experience, using a posterolateral approach and with early support release of the operated lower limb. During hospitalization, all patients received daily physiotherapy sessions.

Post-hospital discharge phase

Two 6-week protocols consisting of exercises to be performed bilaterally (operated and non-operated lower limbs), twice a week, respecting the care and restrictions recommended for THA postoperative were delivered.

Both protocols included the same exercises: bridge (elevation of the pelvis in supine position); knee and hip flexion in supine position; seated knee extension; sit down and stand up; orthostatic planting; knee flexion in orthostasis. Three sets of 12 repetitions were performed for each exercise.

After randomization, TG members received an illustrated booklet and general guidelines, as well as explanations and demonstrations of all the exercises to be performed at home, whereas the FG group performed the exercises under supervision of the researchers. TG

was monitored through weekly calls from the researchers to resolve possible doubts.

Statistical analysis

Data distribution was analyzed by the Shapiro-Wilk test. Despite the normal distribution found, we decided to adopt non-parametric tests due to sample size. Reliability and reproducibility of the peak torque measurements were analyzed by intraclass correlation coefficient (ICC). Comparison between groups used the Mann-Whitney test. Effect of the interventions was represented by relative variation, calculated using the equation: $(Value_{post} - Value_{pre})/Value_{pre} \times 100$, in which $Value_{pre}$ is the median of the pre-intervention measure and $Value_{post}$ is the median of the post-intervention measure. Intra-group analysis used the Wilcoxon test and effect size (ES) through Cohen's *d* [effect size = $(M_{post} - M_{pre})/DP_{Grouped}$, in which M_{post} is the mean of the post-intervention measure, M_{pre} is the mean of the pre-intervention measure, and $SD_{Grouped}$ is the pooled standard deviation of the pre- and post-intervention measures. Effects were considered to be: insignificant ($d < 0.19$); small ($d = 0.20$-0.49); medium ($d = 0.50$-0.79); large ($d > 0.80$). Descriptive analysis used central tendency (median) measures of the data and of the 25th and 75th percentiles. Significance level (α) was set at 5%. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) for Windows (version 18.0).

RESULTS

From May 2018 to March 2020, we contacted 80 potential participants, of which 26 refused participation, 12 met exclusion criteria, 14 were already undergoing physical therapy, and 4 failed to attend initial assessment. Of the remaining patients, 24 met the inclusion criteria and were randomized into FG (n = 14) and TG (n = 10). Over the 6-week treatment, we had three dropouts (1 in the FG and 2 in the TG) and one patient (TG) developed deep vein thrombosis, and exercising is contraindicated, totaling four losses (Figure 1). FG and TG showed no significant differences ($p > 0.05$) in the initial assessment regarding age, body mass index (BMI), disease duration, and postoperative time. Table 1 summarizes sample characterization.

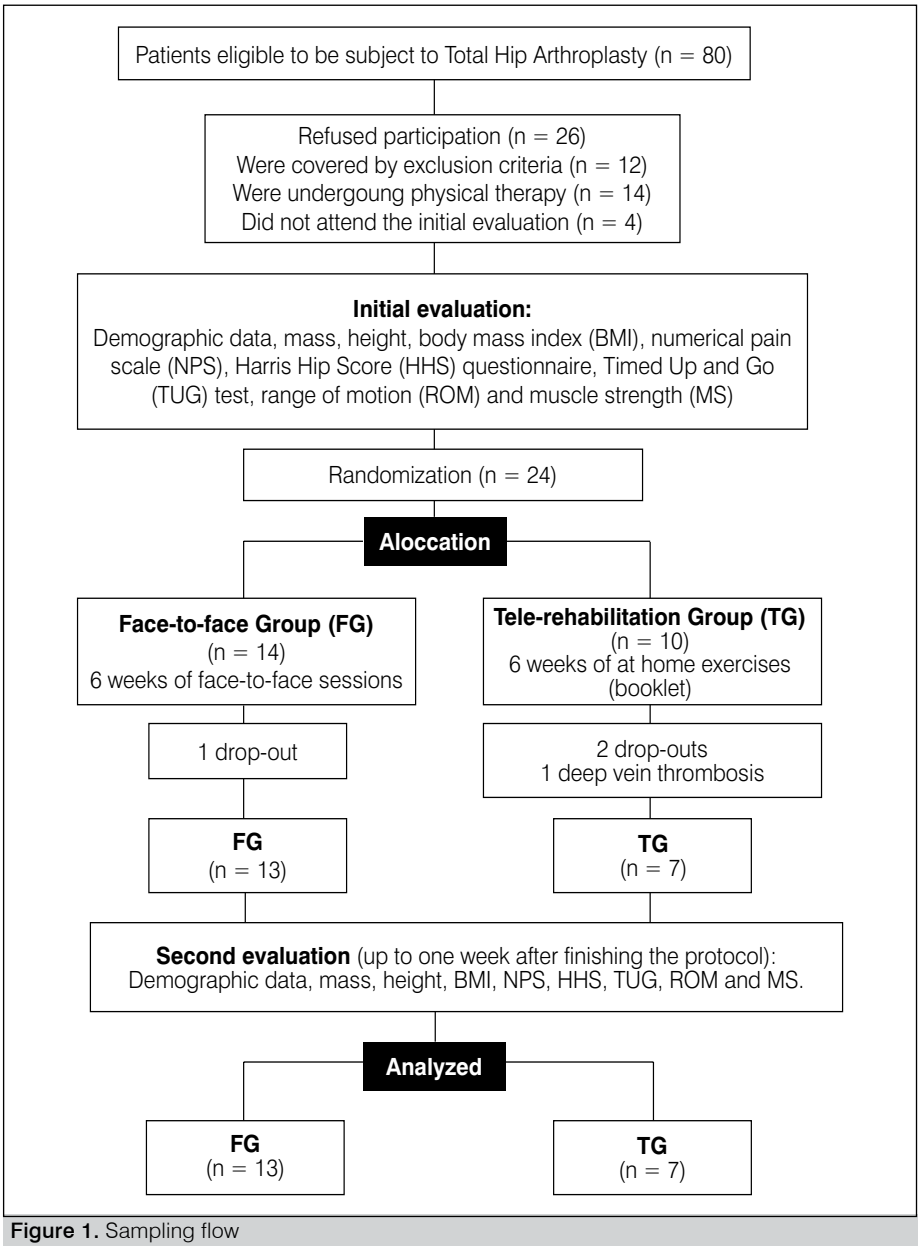

Figure 1. Sampling flow

FG and TG showed no significant differences ($p > 0.05$) in the initial assessment regarding age, body mass index (BMI), disease duration, and postoperative time. Table 1 summarizes sample characterization.

Table 1. Sample characterization of the Tele-rehabilitation and Face-to-face groups.

Variables	Tele-rehabilitation Group (n = 7)	Face-to-face group (n = 13)	p
Age (years)	60.50 (47.00;69.00)	61.00 (59.00;67.75)	0.206
BMI (kg/m)	28.80 (26.90;33.30)	30.10 (26.60;33.70)	0.968
Gender			
Male	2 (20%)	10 (71.42%)	
Female	8 (80%)	4 (28.58%)	
Disease duration (years)	5.00 (2.37;15.25)	6.00 (1.54;14.25)	0.837
P.O. time (days)	24.00 (19.00;30.00)	25.00 (19.00;30.00)	0.556
Type of prosthesis			
Cemented	3 (30%)	4 (28.60%)	
Non-cemented/hybrid	7 (70%)	10 (71.40%)	
Contralateral THA			
Yes	1 (10%)	3 (21.43%)	
No	9 (90%)	11 (78.57%)	
LL operated			
Dominant	4 (40%)	8 (57.14%)	
Non-dominant	6 (60%)	6 (42.86%)	

THA: total hip arthroplasty; BMI: body mass index; LL: lower limb; PO: postoperative. Data presented as median (P25;P75) or n (%).

Source: prepared by the authors.

Pain and Kinesiophobia

Both TG and FG exhibited low levels of pain according to the Numerical Pain Scale scores in pre and post-intervention evaluations, with no statistically significant differences between (pre-intervention $p = 0.698$; post-intervention $p = 0.967$) or intra-group (TG $p = 0.443$; FG $p = 0.090$). Regarding the kinesiophobia scores measured by the Tampa Scale, no significant differences were found when comparing pre- and post-intervention evaluations (TG $p = 0.271$; FG $p = 0.461$), or between groups (pre-intervention $p = 0.905$; post-intervention $p = 0.266$) (Table 2).

Table 2. Pain (numerical pain scale), kinesiophobia (Tampa Scale) and functional capacity (Harris Hip Score and Timed Up and Go) in the Tele-rehabilitation and Face-to-face groups.

		Tele-rehabilitation (n = 7)	Face-to-face (n = 13)	p	intergroup d
NPS	Pre	1.00 (2.00;5.00)	3.00 (1.00;6.00)	*0.698*	
	Post	1.00 (0.00;4.00)	1.00 (0.00;3.00)	*0.967*	*0.043*
	intragroup p	*0.443*	*0.090*		
	intragroup d	*0.477*	*0.662*		
Tampa	Pre	33.00 (31.00; 44.00)	37.00 (30.00;41.00)	*0.905*	
	Post	28.00 (27.00;41.00)	34.00 (30.00;38.00)	*0.266*	*0.315*
	intragroup p	*0.271*	*0.461*		
	intragroup d	*0.659*	*0.308*		
TUG(s)	Pre	44.40 (31.10;66.00)	24.10 (18.00;36.40)	*0.036**	
	Post	17.50 (13.40;21.90)	16.30 (11.10;19.70)	*0.501*	*0.015*
	intragroup p	*0.018**	*0.064*		
	intragroup d	*1.744*	*0.718*		
HHS	Pre	56.00 (40.80;61.70)	58.40 (49.60;68.80)	*0.285*	
	Post	81.50 (76.80;86.50)	78.20 (71.50;90.00)	*0.843*	*0.066*
	intragroup p	*0.043**	*0.002**		
	intragroup d	*1.876*	*1.854*		

NPS: Numerical pain scale; HHS: Harris Hip Score; TUG: Timed Up and Go. Data presented as median (P25;P75) or n (%); size of the effect represented by Cohen's *d*; **p*<0.05.
Source: prepared by the authors.

<< SUMÁRIO

Self-Reported and Objectively Measured Functional Capacity

Regarding self-reported functionality, patients had significantly higher HHS scores post-intervention compared with pre-intervention, with a large effect size both in the TG (d = 1.876) and FG (d = 1.854) groups (Table 2).

As for objectively measured functionality, we observed a significant difference (p = 0.036) between the groups pre-intervention, in which TG individuals needed more time to perform the TUG test. Both groups showed a reduction in the time taken to perform TUG in the post-intervention evaluation (TG = 26.9 seconds; FG = 7.8 seconds), but only the differences found for TG were significant (p = 0.018; d = 1.744). No significant differences were found (p = 0.501) between groups in the post-intervention evaluation (Table 2).

Range of Motion

Participants showed a significant increase, with a large effect size, in the range of motion of the lower limbs post-intervention (Table 3). FG presented a statistically significant increase in abduction (p = 0.013; d = 1.028) and extension (p = 0.037; d = 0.949) in the operated lower limb, whereas TG showed a statistically significant increase in flexion (p = 0.028; d = 1.571) on the operated lower limb and in extension (p = 0.027; d = 1.298) on the non-operated lower limb (Table 3)

Table 3. Hip range of motion (ROM) pre- and post-intervention in the Tele-rehabilitation and Face-to-face groups, expressed in degrees.

		Operated Lower Limb			Non-Operated Lower Limb		
ROM		Tele-rehabilitation (n = 7)	Face-to-face (n = 13)	p	Tele-rehabilitation (n = 7)	Face-to-face (n = 13)	p
Abduction	Pre	13.00 (11.00;24.00)	15.00 (14.00;17.50)	*0.520*	25.00 (17.00;30.00)	22.00 (18.00;24.50)	*0.381*
	Post	23.00 (20.00;30.00)	24.00 (17.00;33.00)	*0.662*	29.00 (24.00;35.00)	25.00 (20.00;30.00)	*0.379*
	intragroup p	*0.075*	*0.013**		*0.150*	*0.064*	
	intragroup d	*1.028*	*1.042*		*0.611*	*0.441*	
Extension	Pre	15.00 (15.00;19.00)	20.00 (15.00;24.00)	*0.166*	13.00 (12.00;24.00)	20.00 (15.00;29.00)	*0.102*
	Post	24.00 (14.00;30.00)	25.00 (19.50;29.00)	*0.577*	25.00 (20.00;30.00)	25.00 (18.00;27.50)	*0.905*
	intragroup p	*0.075*	*0.037**		*0.027**	*0.286*	
	intragroup d	*0.949*	*0.931*		*1.298*	*0.292*	
Flection	Pre	35.00 (24.00;43.00)	45.00 (34.00;51.00)	*0.218*	54.00 (35.00;79.00)	60.00 (43.00;63.50)	*0.905*
	Post	53.00 (49.00;58.00)	48.00 (40.00;62.50)	*0.605*	62.00 (51.00;66.00)	55.00 (39.50;65.50)	*0.427*
	intragroup p	*0.028**	*0.136*		*0.672*	*1.000*	
	intragroup d	*1.571*	*0.723*		*0.252*	*0.025*	
Medial Rotation	Pre	15.00 (10.00;19.00)	14.00 (10.00;20.00)	*0.905*	20.00 (19.00;27.00)	16.00 (10.00;20.00)	*0.163*
	Post	15.00 (12.00;25.00)	15.00 (14.00;21.00)	*0.935*	23.00 (15.00;27.00)	22.00 (12.50;28.50)	*0.751*
	intragroup p	*0.612*	*0.381*		*0.752*	*0.123*	
	intragroup d	*0.411*	*0.276*		*0.161*	*0.022*	
Lateral Rotation	Pre	10.00 (6.00;11.00)	10.00 (5.50;14.50)	*0.874*	20.00 (15.00;30.00)	16.00 (12.50;21.50)	*0.190*
	Post	11.00 (10.00;12.00)	12.00 (10.00;15.00)	*0.354*	21.00 (15.00;25.00)	15.00 (11.00;18.50)	*0.095*
	intragroup p	*0.528*	*0.333*		*0.733*	*0.969*	
	intragroup d	*1.929*	*0.476*		*0.244*	*0.696*	

Data presented as median (P25;P75) or n (%); size of the effect represented by Cohen's *d;* *p<0.05

Source: prepared by the authors.

Muscle strength

TG and FG participants showed significant differences in torque peaks of the abductors and external rotators in the operated lower limb when comparing pre- and post-intervention evaluations. We observe an increase in TP of the abductors in TG (p= 0.028; d = 2.409) and FG (p= 0.023; d= 1.003), as well as an increase in TP of the rotators in TG (p= 0.018; d= 0.862) and FG (p= 0.016; d= 1.386) (Table 4).

Table 5 presents the treatment effect (pre- and post-intervention difference) on pain, kinesiophobia, self-reported and objectively measured functional capacity, ROM and muscle strength. According to the relative variation results, the effect of the interventions was similar in both groups.

Table 4. Pre- and post-intervention torque peaks in the Tele-rehabilitation and Face-to-face groups, expressed in Nm/kgx10.

		Operated Lower Limb			Non-Operated Lower Limb		
Torque Peaks		**Tele-rehabilitation (n = 7)**	**Face-to-face (n = 13)**	**p**	**Tele-rehabilitation (n = 7)**	**Face-to-face (n = 13)**	**P**
Abductors	Pre	58.46 (40.41;63.64)	85.66 (51.28;132.34)	*0.104*	123.65 (72.33;152.24)	114.20 (71.92;205.09)	*0.721*
	Post	128.04 (99.70;149.30)	148.26 (124.46;196.93)	*0.251*	148.49 (121.16;204.48)	159.07 (103.57;216.89)	*0.721*
	intragroup p	*0.028**	*0.023**		*0.091*	*0.345*	
	intragroup d	*2.409*	*1.003*		*0.772*	*0.206*	
Extensors	Pre	53.05 (47.24;115.01)	83.81 (65.53;156.66)	*0.166*	97.42 (57.48;135.51)	108.69 (88.28;187.45)	*0.219*
	Post	123.62 (52.08;157.09)	157.27 (75.37;184.61)	*0.501*	131.52 (60.07;196.35)	164.70 (94.47;230.05)	*0.322*
	intragroup p	*0.128*	*0.173*		*0.176*	*0.345*	
	intragroup d	*1.081*	*0.479*		*0.600*	*0.384*	
Flexors	Pre	86.14 (73.52;92.92)	173.16 (104.86;199.16)	*0.008**	135.26 (105.82;204.62)	190.65 (148.55;231.71)	*0.088*
	Post	130.59 (114.59;169.65)	189.74 (148.86;231.92)	*0.036*	159.38 (99.47;202.45)	201.76 (132.47;263.53)	*0.251*
	intragroup p	*0.128*	*0.249*		*0.612*	*0.552*	
	intragroup d	*1.157*	*0.418*		*0.194*	*0.086*	
Internal Rotators	Pre	51.32 (38.43;63.48)	88.96 (52.79;109.97)	*0.036**	78.77 (62.24;91.22)	100.73 (57.28;145.84)	*0.405*
	Post	74.24 (50.48;107.96)	71.91 (62.52;113.83)	*0.606*	102.04 (64.13;126.74)	103.56 (60.56;143.41)	*0.968*
	intragroup p	*0.310*	*0.917*		*0.499*	*0.861*	
	intragroup d	*0.861*	*0.031*		*0.055*	*0.029*	
External Rotators	Pre	41.71 (38.37;49.10)	43.26 (34.56;77.47)	*0.968*	98.40 (69.91;123.67)	108.56 (66.18;129.11)	*0.721*
	Post	80.17 (66.30;93.33)	99.78 (80.38;121.43)	*0.104*	113.02 (63.28;131.85)	123.93 (67.36;145.37)	*0.501*
	intragroup p	*0.018**	*0.016**		*0.866*	*0.279*	
	intragroup d	*0.862*	*1.386*		*0.445*	*0.292*	

Data presented as median (P25;P75) or n (%); size of the effect represented by Cohen's *d;* *p<0.05

Source: prepared by the authors.

Table 5. Effect of the intervention on the Tele-rehabilitation and Face-to-face, represented by relative change (Δ).

	Δ Tele-rehabilitation (n = 7)	**Δ Face-to-face (n = 13)**	**p**
NPS	-80.00 (-95.00; 200.00)	-60.00 (-95.00; 00.00)	*1.000*
TAMPA	-25.80 (-36.40; 24.20)	-05.70 (-16.20; 19.40)	*0.405*
TUG (s)	-61.20 (-66.80; -59.00)	-33.70 (-64.20; -01.00)	*0.122*
HHS	50.00 (27.70; 112.00)	36.00 (21.80; 49.40)	*0.362*
Range of Motion			
Operated Lower Limb			
Abduction	66.70 (-19.20; 109.10)	60.00 (-07.70; 113.30)	*0.874*
Extension	60.00 (-18.80; 66.70)	25.00 (00.00; 66.70)	*0.721*
Flection	38.90 (14.00; 120.80)	25.00 (03.80; 41.30)	*0.322*
Medial Rotation	20.00 (-25.00; 133.30)	15.40 (-19.00; 60.00)	*1.000*
Lateral Rotation	10.00 (-09.10; 100.00)	00.00 (-14.30; 66.70)	*0.721*
Non-Operated Lower Limb			
Abduction	16.00 (-10.00; 50;00)	13.60 (07.10; 25.00)	*0.905*
Extension	25.00 (11.10; 92.30)	08.30 (00.00; 66.70)	*0.250*
Flection	20.40 (-16.50; 45.70)	00.00 (-21.40; 40.00)	*0.663*
Medial Rotation	26.30 (-34.30; 70.00)	35.00 (-06.30; 116.70)	*0.721*
Lateral Rotation	-20.00 (-30.00; 71.40)	06.70 (-15.00; 17.60)	*0.968*
Torque Peaks			
Operated Lower Limb			
Abduction	134.60 (38.10; 252.20)	80.90 (-14.70; 278.50)	*0.663*

Extension	105.30 (04.20; 239.10)	98.70 (-11.20; 134.20)	*0.552*
Flection	51.80 (28.70; 115.90)	16.30 (05.70; 70.80)	*0.362*
Medial Rotation	72.00 (38.80; 123.80)	151.90 (07.60; 226.70)	*0.606*
Lateral Rotation	01.20 (-01.90; 93.20)	15.70 (-45.30; 85.40)	*0.452*
Non-Operated Lower Limb			
Abduction	25.90 (04.90; 110.30)	19.10 (-13.30; 83.40)	*0.663*
Extension	35.00 (-16.70; 53.60)	23.90 (-12.70; 94.30)	*0.968*
Flection	18.90 (-16.20; 50.60)	02.10 (-17.80; 46.10)	*0.968*
Medial Rotation	-04.10 (-27.40; 25.30)	22.20 (-18.00; 51.30)	*0.606*
Lateral Rotation	13.30 (-29.70; 74.00)	-00.40 (-15.20; 21.80)	*0.843*

Data presented as median (P25;P75); $p < 0.05$

Source: prepared by the authors.

DISCUSSION

After the 6-week application of two rehabilitation protocols, we found no significant differences between the groups (face-to-face and home) regarding the outcomes analyzed (pain, kinesiophobia, functional capacity, ROM and muscle strength). To our knowledge, this was the first randomized controlled and blinded clinical trial to compare two distinct forms of rehabilitation—a supervised face-to-face exercise protocol performed in the clinical setting, and a home-based exercise program with remote monitoring—in patients undergoing THA surgery.

Both showed improved functional capacity after physical therapy follow-up. Galea et al.[10] findings corroborate ours, showing no differences between the groups in self-reported functional capacity. In their study, however, the supervised face-to-face exercise group performed significantly better on the TUG test.[10] A population-based study showed that differences greater than 2.4 seconds on the TUG test can be considered clinically relevant.[18] We can therefore consider that even without statistically significant differences, there was a clinically relevant improvement in the objectively measured functional capacity in both groups after the interventions, since the individuals showed reductions between 7.80 and 26.90 seconds on the TUG test.[18] Notably, in the study by Galea et al.[10], the home group did not receive calls or follow-up during the intervention period, and the evaluators were not blinded to the participant allocation.

Both protocols were able to increase the torque peaks of the operated lower limb's abductors and external rotators. Even though FG used shin guards, we observed no significant differences in the torque peaks between groups, suggesting that in this phase of rehabilitation the use of an external load increment seems not to add benefits to the treatment. Considering that evidence points to hip abductor weakness as one of the main deficits found in THA patients[16,17], and given its fundamental role in maintaining posture stability, trunk control and gait performance, rehabilitation protocols that facilitate its rapid recovery are of paramount importance.[19] Contrary to our results, Unlu et al.[4] observed higher hip muscle strength values in the group that performed supervised face-to-face exercises. However, the groups showed a significant difference in torque peaks in the pre-intervention evaluation, which may have influenced the study results.[4]

No studies with a methodology similar to ours that evaluated the ROM of THA patients were found in the literature. Although punctual improvements were observed in ROM, from a clinical perspective both groups persist with important limitations. According to Polkowski et al.[20], a typical individual needs between 67-124 degrees of flexion, 18-33 degrees of abduction, and 15-26 degrees of external hip rotation to perform functional activities like tying shoes, going up and down stairs, sit down and get up from a chair.

Study limitations include the absence of a longer follow-up period and a possible response bias in relation to the exercising records of the TG participants, since this information was self-reported.

Given the difficulties in accessing traditional physical therapy treatment, the results of the present study, in agreement with previous studies on home-based treatment and/or tele-rehabilitation in patients with lower limb arthroplasty[7,10,15], point to home exercises associated with remote monitoring as an alternative in the physical therapy treatment of THA patients.

CONCLUSION

Our findings indicate no differences between a supervised face-to-face exercise protocol and a tele-rehabilitation program among patients in the recent THA postoperative period for the outcomes of pain, kinesiophobia, functional capacity, ROM and muscle strength. Both forms of rehabilitation were able to improve the functional capacity, range of motion and muscle strength in postoperative individuals, and proved to be safe and easy to reproduce.

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TROCHANTERIC FRACTURES: ARE THE CLASSIFICATIONS RELIABLE?

FRATURAS TROCANTÉRICAS: AS CLASSIFICAÇÕES SÃO CONFIÁVEIS?

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ABSTRACT

Objective: To evaluate classification use based on the assessment of agreement in trochanteric fractures between different observers through a simple proposal of bimodal classification. Methodology: A total of 50 radiographic images of femur trochanteric fractures were selected and classified by 22 evaluators, 10 traumatologists and 12 residents, as STABLE or UNSTABLE. The assessment of reproducibility was done using the kappa statistical index. After the evaluation, the groups were isolated and submitted to the ANOVA test with Bonferroni correction to evaluate the statistical differences between them. Results: When evaluated by the kappa index, the results of the 50 fractures assessed by the 22 evaluators were k = 0.272. The reproducibility of the classification proposal was considered statistically weak. Conclusion: Based on this study, it is recommended that the classifications be extensively tested and reach a minimum level of interobserver reproducibility (kappa > 0.8). It is suggested that classifications that do not achieve this result be improved or abandoned. ***Level of evidence II, Prospective study.***

Keywords: Trochanteric fracture. Classification. Reliability. Interobserver agreement.

RESUMO

Objetivo: Avaliar a utilização das classificações a partir da avaliação de concordância nas fraturas trocantéricas entre diferentes observadores através de uma proposta simples de classificação bimodal. Métodos: Foram selecionadas 50 imagens radiográficas de fraturas trocantéricas do fêmur e classificadas por 22 avaliadores, sendo 10 traumatologistas e 12 residentes que definiram as fraturas como ESTÁVEIS ou INSTÁVEIS. A avaliação da reprodutibilidade foi dada pelo índice estatístico Kappa. Após a avaliação, os grupos foram isolados e submetidos ao teste ANOVA com correção Bonferroni para avaliar as diferenças estatísticas entre eles. Resultados: Quando submetidos a avaliação pelo índice Kappa os resultados das 50 fraturas avaliadas pelos 22 avaliadores foi de k = 0,272. A reprodutibilidade da proposta de classificação foi considerada estatisticamente fraca. Conclusão: A partir deste estudo recomenda-se que as classificações sejam extensamente testadas e atinjam um nível mínimo de reprodutibilidade (Kappa > 0,8) interobservadores. Sugere-se que as classificações que não atinjam este resultado sejam aprimoradas ou abandonadas. ***Nível de evidencia II, Estudo prospectivo.***

Descritores: *Fratura Trocantérica. Classificação. Confiabilidade. Concordância Interobservadores.*

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This study was conducted at the Santa Casa de Misericórdia Medical Center, Porto Alegre, RS, Brazil.
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INTRODUCTION

Classifications are a part of orthopedists' routines since their training. Based on them, it is possible to classify fractures, degrees of arthrosis, and other injuries, facilitating the diagnosis, stratification, treatment, and prognosis. It is assumed that classifications are an important tool in our arsenal and that they are used homogeneously by all evaluators, therefore, being useful in daily practice. Does this really happen?

In the literature, there is a vast number of studies verifying the interobserver agreement of orthopedic classifications. In this study, we isolated those that treat trochanteric fractures and evaluated the reproducibility of a fictitious classification for trochanteric fractures, which is extremely simplified: STABLE and UNSTABLE.

Like in other studies, we used the kappa index or coefficient, first presented in 1960 by Cohen, as an indicator of reliability; this index is a way to evaluate intra and interobserver agreement by adjusting for random agreement. The index of agreement between observers is measured using a scale from -1 to 1. The closer the index gets to one, the greater the agreement, and the lower the number, the lower the agreement.[1-4]

The objective of this study is to evaluate the interobserver agreement of 50 radiographic images of trochanteric fractures among 22 traumatologist and resident observers.

MATERIALS AND METHODOLOGY

A total of 50 radiographic images of femur trochanteric fractures without patient identification were randomly selected from our residence database (Figure 1). All radiographies were anteroposterior (AP), performed without traction prior to the reduction maneuver.

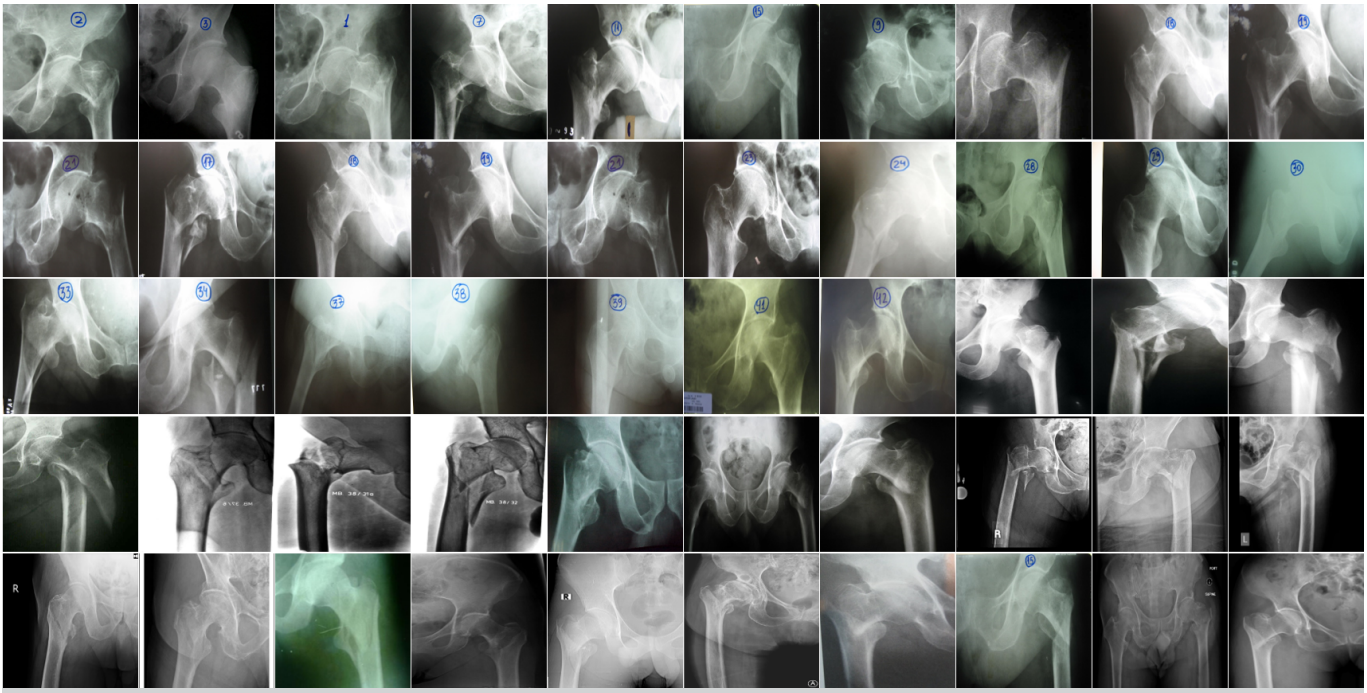


Figure 1. Image of the 50 radiographs used for the assessment.

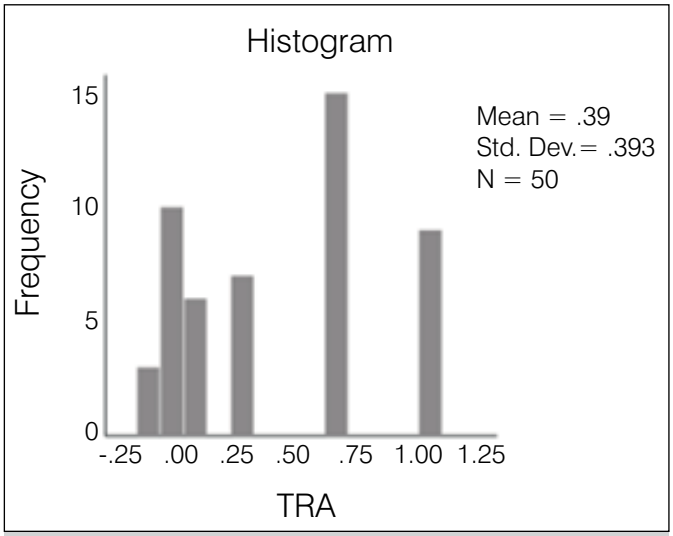
The radiographies were evaluated by 22 observers, 10 traumatologists and 12 residents (three 3rd year, four 2nd year, and four of 1st year students). An explanation about fracture classification was previously carried out, and the observers were asked to classify one fracture as STABLE or UNSTABLE. A stable fracture was one in which the muscular forces involved in the focus keep the fragments in the anatomical position, without secondary deviations. Unstable fractures are those in which the muscle forces involved in the fracture focus tend to displace the fragments.

The images were individually projected and numbered in a sequence from 1 to 50. Each image was projected for 30 seconds, and the protocol was completed individually by each observer.

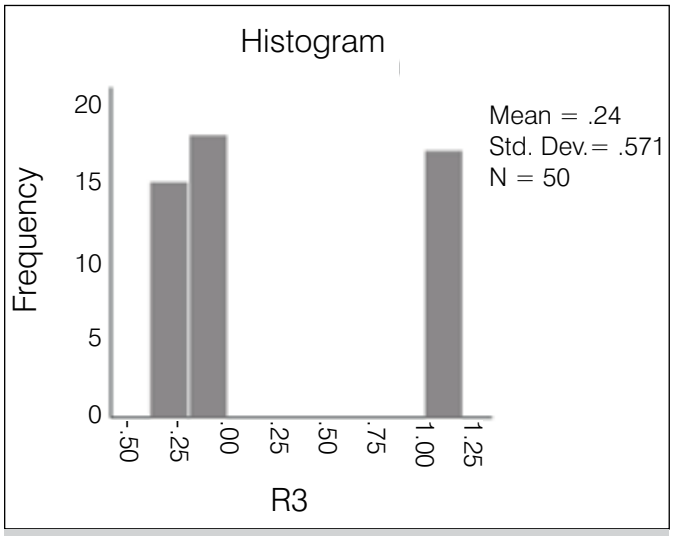
The data were analyzed and interpreted by a statistician using the kappa agreement test. Subsequently, the results were analyzed using the ANOVA variance analysis with Bonferroni correction.

RESULTS

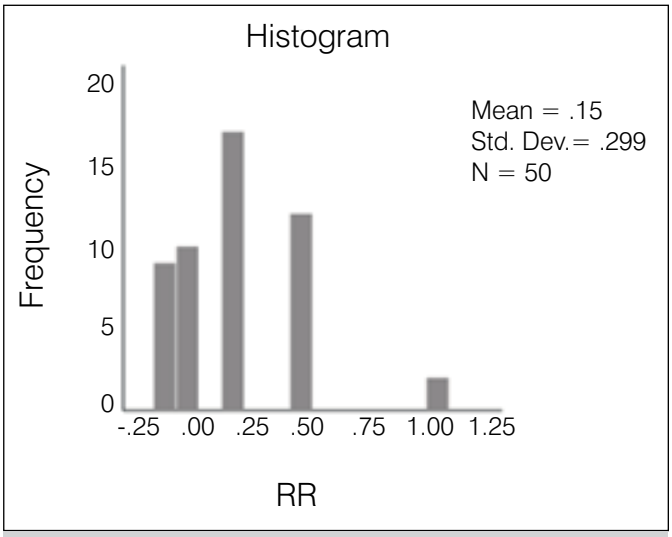
Results were grouped into 4 sets according to the evaluator's professional experience. Traumatologists were in the first group, last-year residents were in the second group, the rest of the residents were in the third group, and the fourth group was comprised of all observers. The kappa agreement index was used in the statistical evaluation of the results. The evaluation of the 10 traumatologists had an index of 0.388—weak agreement (Graph 1); 3rd year residents had an index of 0.235—weak agreement (Graph 2); 1st and second year residents had an index of 0.147—slight agreement (Graph 3); the overall result with all groups was 0.272—weak agreement (Graph 4). It was demonstrated that the more experienced the group of evaluators, the higher the agreement index, with a statistically significant difference ($p < 0,05$) as is shown in Table 1. When comparing means and dispersions (with a 95% confidence interval) between the groups, we can see in Graph 5 that the dispersion among residents was also greater than among traumatologists.



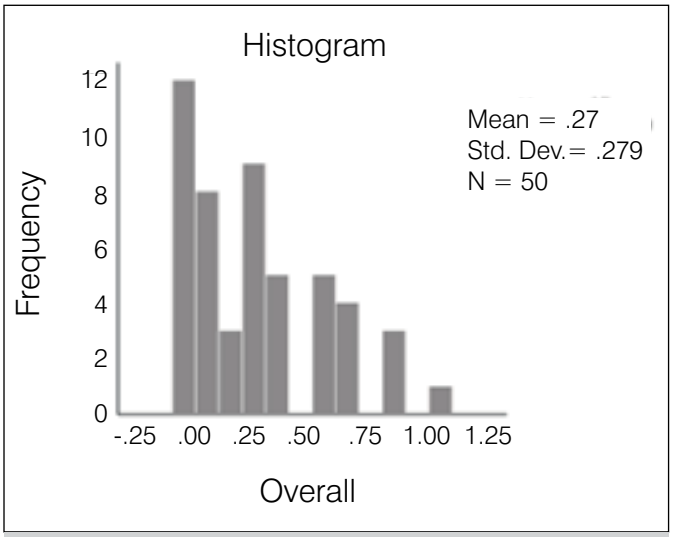
Graph 1. Histogram of the variation and concentration of kappa indices among traumatologists



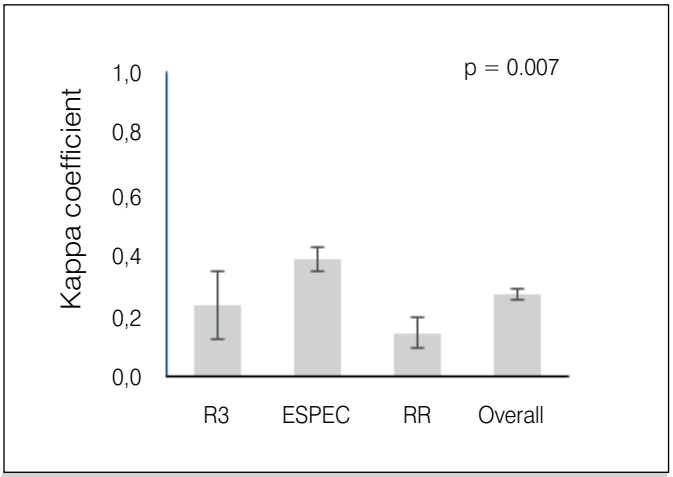
Graph 2. Histogram of the variation and concentration of kappa indices among R3



Graph 3. Histogram of the variation and concentration of kappa indices among R1 + R2



Graph 4. Histogram of the variation and concentration of kappa indices among all observers



Graph 5. Graph presenting each group's kappa coefficient with 95% CI, demonstrating that the traumatologists group had a statistically significant difference in relation to the other groups (p = 0.007)

Table 1. Comparison of the covering index using the ANOVA test with Bonferroni correction.

Group	Kappa	SD	95% CI
Tra	0.388	0.39	0.347 – 0.43
R3	0.235	0.57	0.122 – 0.348
R1 + R2	0.147	0.3	0.094 – 0.199
Overall	0.271	0.28	0.252 – 0.289

Kappa p-value: 0.7
Tra: Traumatologists
SD: Standard deviation
CI: Confidence index

DISCUSSION

This study highlighted the low agreement among observers in the classification of trochanteric fractures divided into stable and unstable. The simple assessment of agreement made by organizing the number of cases in the same category has an intrinsic error — it cannot distinguish real agreement from random agreement. This subject has already been discussed by several authors who point out the need to incorporate random agreement in the evaluation to improve the reliability of the evaluation.[2,3]

To correct for random agreement, in 1960 Cohen *et al* formulated the kappa coefficient. This measure evaluates the agreement between two observers and two objects adjusting for the possibility of random agreement. In 1971, Fleiss, based on the kappa coefficient, introduced the Fleiss kappa, which could evaluate agreement by correcting for random agreement between a larger number of fixed observers and more item classification options, as well as a greater number of items.[1,4,6]

This coefficient varies between -1 (complete disagreement) and +1 (complete agreement). There is no precise definition of an acceptable level of agreement. The variables between these denominators can be stratified more simply into: poor (< 5) and excellent (< 0.75).[5] According to Landis *et al*., another way to evaluate the result would be: poor (below 0), mild (0 – 0.2), weak (0.21 to 0.4), moderate (0.41 to 0.6), substantial (0.61 to 0.8) and almost perfect (0.81 to 1).[7]

The literature reveals several studies that aim to evaluate the reproducibility of diverse classifications related to orthopedics. Limiting the search to classifications related to trochanteric fractures and interobserver evaluation, we found the following results: Schwartzmann *et al* evaluated the AO classification and found a 0.34 kappa with subgroups and 0.6 without subgroups; Oliveira *et al* evaluated Tronzo's rating and found a 0.44 kappa; Mattos *et al* evaluated the Tronzo and simplified AO classifications and found kappa of 0.36 and 0.53, respectively; Schipper *et al* evaluated the AO classification finding a 0.33 kappa with subgroups and 0.67 in the simplified one; Pervez *et al* evaluated Jansen's classification by finding a 0.34 kappa; van Embeden *et al* evaluated Jansen and AO classifications by finding kappa of 0.48 and 0.4, respectively; Jim *et al* evaluated AO classifications with and without subgroups, Evans and Boyd by observers with more than 10 years of experience, finding kappa of 0.75, 0.41, 0.44 and 0.38, respectively; Yin *et al* evaluated the Evans, Jansen, AO, and Tang ratings and found kappa of 0.54, 0.53, 0.46, and 0.63, respectively. Cavaignac *et al* conducted a study using radiographies and tomographies with and without 3D reconstruction using Evans and AO classifications. This study found kappa of 0.28 and 0.50 in radiographies in AO and Evans classifications; AO simple tomography and Evans kappa of 0.33, 0.35, respectively; tomography with AO 3D reconstruction and Evans kappa of 0.28 and 0.47, respectively.[8-16]

The analysis of these studies reveals, at most, substantial results (0.61 – 0.8) in four articles when using the simplified AO classification in three groups and in one article using the Tang classification. We observed that more complex classifications, such as AO with its nine subgroups and Tronzo, always perform poorly (0.21 – 0.4). Evans and Jansen had a moderate agreement score (0.41 – 0.6).[8,11,12,14,15]

In this study, we proposed that the evaluators classify fractures in two ways: stable or unstable. Even with this extreme simplification, the kappa agreement index was 0.271, which is considered weak (0.21-0.4), when accounting for all observers.

It is observed, as in other studies, that the observers' level of professional experience influenced the result.[10] When comparing the result obtained by isolating 1st and 2nd year residents (k = 0.147), 3rd year residents (k = 0.235), and traumatologists (k = 0.388), a statistically significant difference was found. Although traumatologists reached a better agreement value, it is still very low, which makes this simple classification ineffective.

Considering that the use of classifications aims at discrimination, prognosis, and adequate treatment, we conclude that classifications with low reproducibility indexes that present high variability lose their clinical usefulness.

The December 1993 editorial of the Journal of Bone and Joint Surgery (JBJS) questioned the functionality and usefulness of the classifications. It presented the idea that classifications are tools that should always work in the same way and produce the same results. This tool should first prove to be functional and later prove to be useful in clinical practice. Considering these points, the JBJS is reluctant to accept studies that correlate classification with results.[17]

In light of this, we consider that classifications play an important role in clinical practice in orthopedics, but we must use them with the necessary level of criticism. It is evident from this study that the results analyzed in general are not reproducible with an acceptable level of agreement, even when making extreme simplifications. To be effective as work tools, kappa index classifications with rates lower than or equal to 0.8 should be improved or abandoned.

CONCLUSION

This study showed a low interobserver agreement with a kappa of 0.272 in the classification of trochanteric fractures divided into STABLE and UNSTABLE. Based on this study, it is recommended that the classifications be extensively tested and reach a minimum level of interobserver reproducibility (kappa > 0.8). It is suggested that classifications that do not achieve this result be improved or abandoned.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. LHZW: statistical analysis, writing and data collection; OM: statistical analysis and writing; EPC: statistical analysis and review; IS: statistical analysis and review; CRS: intellectual concept of the article, writing and review; FCK: review, writing and statistical analysis.

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ORIGINAL ARTICLE

ORTHOPEDIC ONCOLOGY

EPIDEMOLOGICAL, RADIOGRAPHIC AND PROGNOSTIC EVALUATION OF CHONDROBLASTOMA

AVALIAÇÃO EPIDEMIOLÓGICA, RADIOGRÁFICA E PROGNÓSTICA DO CONDROBLASTOMA

Bernardo Lopes Crisostomo[1], *Julia Pozzetti Daou*[1], *Jairo Greco Garcia*[1], *Marcelo de Toledo Petrilli*[1], *Dan Carai Maia Viola*[1], *Reynaldo Jesus Garcia Filho*[1,2]

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ABSTRACT

Objective: To describe the clinical and imaging characteristics of chondroblastoma and identify possible factors related to joint complications. Method: This retrospective cohort study was carried out with data from the medical records of 23 patients diagnosed with chondroblastoma, subjecting them to statistical analyses. Result: In total, 19 patients were included, 12 (63.2%) of which were mean with a mean age of 13.6±3.5 year. The relation with the local dimension equaled 57.9%, higher in the apophysis of the greater trochanter: 95.2% (p<0.001). Based on imaging, 15.8% patients had an open physis; 55.6%, no damaged physeal line; 42.1%, cortical rupture; 21.1%, secondary aneurysmal bone cyst; 26.7%, violated cartilage; and all cases, medullary edema. 15.8% of cases showed local recurrence and no metastasis. Moreover, 46.7% of patients had relevant secondary osteoarthritis related to the aggressiveness of the tumor according to the Enneking classification (p= 0.041). Conclusion: The clinical outcome of chondroblastoma show no relation to age, sex, location, physeal status, or presence of calcifications or secondary aneurysmal bone cyst. Progression to secondary osteoarthritis configured the most frequent non-oncological complication and showed a direct relation with the severity of the chondroblastoma. ***Level of Evidence IV, Case Series.***

Keywords: Chondroblastoma, Bone Neoplasms, Risk Factors, Artrosis, Recurrence.

RESUMO

Objetivo: Descrever as características clinicas e imaginológicas do condroblastoma e identificar possíveis fatores relacionados a complicações articulares. Método: Estudo de coorte retrospectiva realizado utilizando-se dados de prontuários de 23 pacientes com diagnóstico de condroblastoma, submetidos a análise estatística. Resultado: Foram incluídos 19 pacientes, 12 (63,2%) do gênero masculino, idade média 13,6±3,5. A relação com a dimensão local foi de 57,9%, maior na apófise do grande trocanter com 95,2% (p<0,001). Do ponto de vista imaginológico, tiveram status fisário aberto 15,8%; 55,6% não violavam a linha fisária; rotura cortical em 42,1%, cisto ósseo aneurismático secundário em 21,1%, cartilagem violada em 26,7% e todos casos apresentaram edema medular. 15,8% dos casos apresentaram recidiva local e nenhuma metástase. 46,7% dos pacientes tiveram artrose secundaria relevante, com relação com a gravidade do tumor pela classificação de Enneking (p= 0,041). Conclusão: O desfecho clínico do condroblastoma não apresentou relação com idade, sexo, localização, status fisário, presença de calcificações ou cisto ósseo aneurismático secundário. A evolução para artrose secundaria foi a complicação não oncológica mais frequente, e mostrou relação direta com a gravidade do condroblastoma. ***Nível de Evidência IV, Série de Casos.***

Descritores: *Condroblastoma; Neoplasias Ósseas; Fatores de risco; Artrose; Recidiva.*

Citation: Brazeiro MC, Mueller KF, Rohde CS, Lopes BM, Silva MF. Face-to-face exercises are not superior to tele-rehabilitation in the recent post-operative total hip arthroplasty: randomized clinical trial. Acta Ortop Bras. [online]. 2024;32(2) Esp.: Page 1 of 8. Available from URL: http://www.scielo.br/aob.

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

This study was developed at Universidade Federal de São Paulo, Orthopedic Oncology, Department of Orthopedics and Traumatology.
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ETHICS APPROVAL
This research was approved by the Research Ethics Committee at Universidade Federal de São Paulo (CEP-UNIFESP) and is registered on Plataforma Brasil under CAAE 75502323.1.0000.5505.

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<< SUMÁRIO

INTRODUCTION

Epiphyseal chondroblastoma was first described in 1931[1] as an "epiphyseal chondromatous giant cell tumor." Later, Jaffe and Lichtenstein recognized it as an independent entity[2].

Also known as Codman's tumor[1], this benign cartilaginous tumor usually includes an aggressive presentation, comprising 1-2% of all bone tumors and 9% of benign tumors[3]. It slightly predilects men in their second decade of life. However, up to 52% of cases often show closed growth physis[3-4].

Clinically, chondroblastoma is associated with local pain (the main symptom), in common combination with synovitis and limitation of the range of motion, which has an important correlation with the typically epiphyseal location of the tumor[3]. Such location renders giant cell tumor, aneurysmal bone cyst, and osteomyelitis as the most frequent differential diagnoses[4]. Chondroblastoma also tends toward apophyseal presentations, such as in the greater tubercle of the humerus and the greater trochanter of the femur. In general, it most commonly occurs in the proximal tibia epiphysis (PTE)[3,5].

Radiographically, it manifests itself as an eccentric radioluscent image in the epiphyses of long bones, typically with well-defined margins but no halo of sclerosis. Calcifications occur often, as does aggressiveness or even pathological fractures, happening in 6.5% of manifestations. Magnetic resonance imaging studies show significant spinal cord edema in most cases[4-6].

As a progressive bone tumor, most cases undergo surgical treatment, with extended curettage configuring the treatment of choice[3-6]. No consensus exists on the best adjuvant methods (such as argon scalpel, cryoablation, phenol, absolute alcohol, or mechanical techniques). Other methods are possible, such as radioablation for some cases and en bloc resection, which obtains a lower recurrence rate and the undesired functional worsening[7].

The main complication consists of tumor recurrence, varying from 13.6 to 14.7% of the cases treated with curettage and a local adjuvant (according to the used surgical technique). Lung metastasis occur rarely[6]. The risk of joint degeneration, subchondral cartilage injury, and deformities stand out among the non-oncological complications due to the epiphyseal location, although few studies have observed it[4,8].

Due to its infrequency, relative few studies have evaluated it, some of which have described their radiographic findings and the joint complications of chondroblastoma. Moreover, this research found no prospective study on this neoplasm.

This study aims to describe the clinical and imaging characteristics of chondroblastoma to find possible factors related to local joint complications.

METHODS

This retrospective cohort study was carried out by the Bone Tumors Group at GRAACC-IOP Hospital (Support Group for Adolescents and Children with Cancer – Institute of Pediatric Oncology); a reference service in pediatric cancer treatment to evaluate patients with chondroblastoma regarding their epidemiological and imaging profile and prognosis. The "STROBE" guideline was followed for retrospective studies to stratify the sample (Figure 1)[9].

From 08/01/2009 to 12/31/2023, 23 patients diagnosed with chondroblastoma were treated at the service. During the retrospective analysis of medical records and anatomopathological reports, two patients (8.7%) failed to show the minimum data necessary for analysis, and two others (8.7%) had a minimum follow-up time shorter than 12 months. Thus, data of 19 patients were evaluated, corresponding to the series in this study.

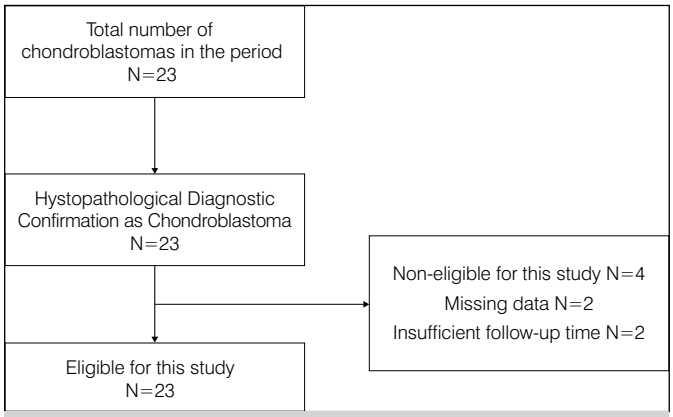

Figure 1. Series Stratification

Source: Prepared by the authors.

The anatomopathological analysis of all patients was performed by the same pathologist. The imaging data of all patients were performed by the same orthopedic oncologist and a radiologist. The following variables of interest were analyzed: gender, age, follow-up time, anatomical location of the tumor, tumor dimensions, physeal plate status, presence of a sclerosis halo, calcifications, cortical rupture, spinal cord edema, edema in the adjacent joint, presence of secondary aneurysmal bone cyst, the Enneking classification[10], presence of metastasis, presence of recurrence, treatment modality, presence of signs of joint degeneration, deformity, and the Kellgren-Lawrence classification[11].

An analysis was carried out to determine which risk factors may be related to joint degeneration and deformities of the epiphyseal chondroblastomas. The Fisher's exact test was used to describe the associations between categorical variables and the Student's t-test, to compare the means of the groups of the continuous variables. The null hypothesis of this study postulated no difference between the means of the groups, in which values equal to $p<0.05$ were deemed statically significant ($p = 0.05$).

RESULTS

Our series included 19 patients with chondroblastoma, 63.2% of which were men and 36.8% women (a ratio of 1.7:1). The mean age at diagnosis totaled 13.6 years (ranging from four to 21 years) (Figure 2). Injuries occurred in the lower limbs in 78.9% of patients and in their upper limbs, in 21.1% of them (4/19). The femur (10 patients, 50.0% at the distal portion and 50.0% in the proximal one), tibia (four patients, 50% at the distal portion and 50% the proximal one), and humerus suffered the most, with all three lesions affecting the proximal portion of the bone. The most affected topographies include the distal femoral epiphysis (DFE) (26.3%) (Figure 3), the greater trochanter apophysis (GTA) (21.1%), the proximal humeral epiphysis (PHE) (15.8%), and the PTE (10.5%). Figure 4 summarizes the location of the tumors.

The chondroblastomas had a medium size, measured radiographically in the anteroposterior view to total 2.87 x 3.07 mm in their laterolateral and cephalocaudal dimensions, respectively. The DFE (2.18 x 2.54 cm) and GTA (2.23 x 2.30 cm) lesions had the smallest sizes. When compared with the size of the epiphysis or the affected apophysis, the lesions occupied an average of 57.9% of the largest local diameter (24.2% in DFE, and 95.2% in GTA, with statistical significance) ($p< 0.001$).

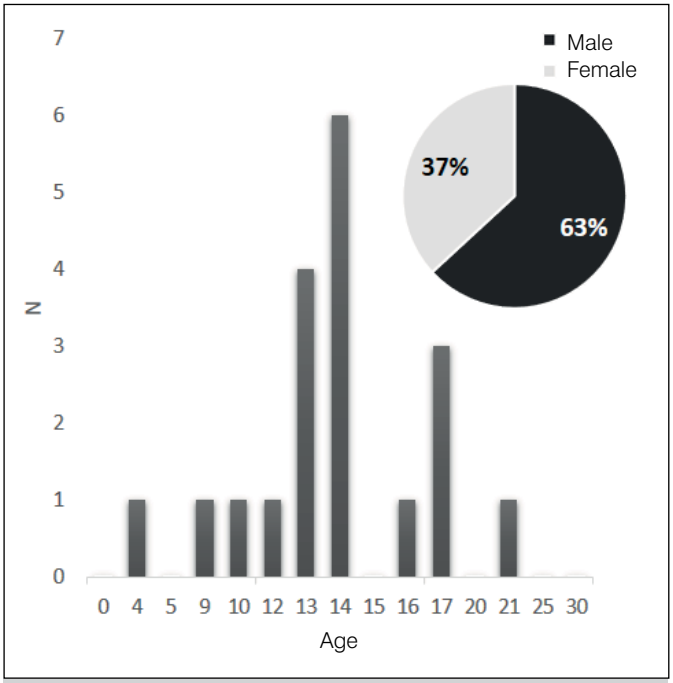

Figure 2. Age and gender distribution of patients suffering with chondroblastomas (n=19). The male:female gender ratio totaled 1.7:1, whereas the mean age and standard deviation, 13.6 ± 3.5 (four to 21) years.

Source: Prepared by the authors.

Figure 3. Radiography and magnetic resonance imaging of the right knee of a patient with chondroblastoma

Caption A: Radiograph of the right knee of a 16-year-old boy with a history of moderate pain for six months. The bone lesion lies in the distal epiphysis of the femur, measuring 2.6 cm, totaling 16.7% of the total epiphysis size, showing an eccentric shape, in a closed physis and without a sclerosis halo or calcifications. B and C: Contrast-weighted magnetic resonance imaging with coronal and axial T2-weighted images showed heterogeneous signals, perilesional spinal cord edema, and cortical rupture in the region of the intercondyle in the axial section.

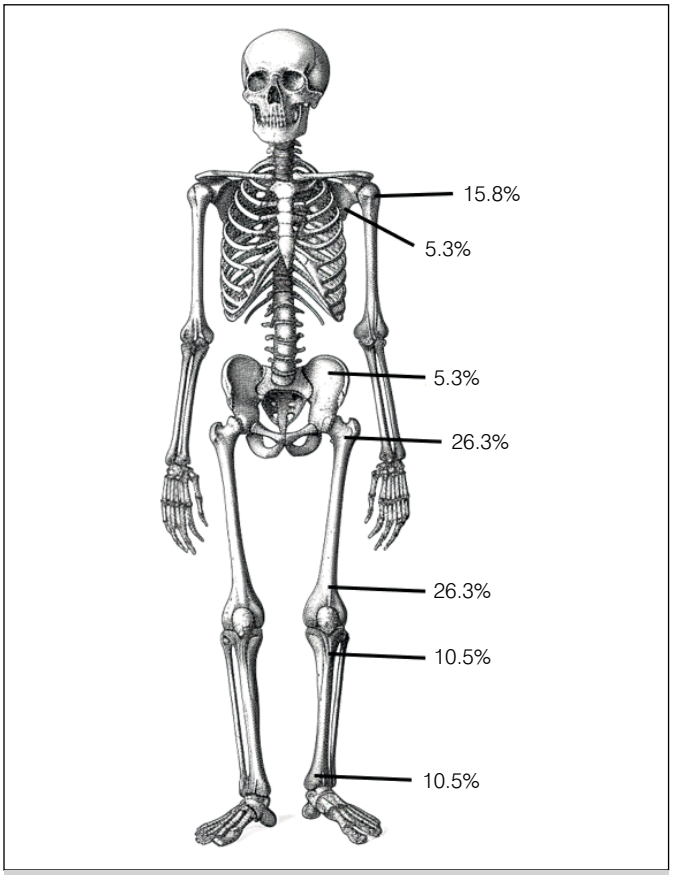

Figure 4. Illustration showing the distribution of the 19 cases of chondroblastoma

Source: prepared by the authors.

Of the radiographic characteristics of the lesions, 36.8% showed a centric shape and 63.2%, an eccentric one. This study considered patients' physis status open in 3/19 of patients (15.8%), and 55.6% of the lesions failed to exceed the physeal line, whereas cortical rupture occurred in eight patients (42.1%). In total, 21.1% (4/19) of patients had secondary aneurysmal bone cysts. All lesions in the series had spinal cord edema (Figure 5). Considering the 15 epiphyseal lesions, 93.3% had associated synovitis after magnetic resonance imaging, whereas 4/15 patients (26.7%) had their damaged articular cartilage. Table 1 summarizes the imaging characteristics.

Table 1. Imaging characteristics of patients with chondroblastoma

Findings (%)	n=19
Centric lesion	36.8
Eccentric lesion	63.2
Open physis	15.8
Partially closed physis	31.6
Closed physis	52.6
Halo of sclerosis	42.1
Calcifications	57.9
Cortical rupture	42.1
Aneurysmal bone cyst	21.1
Bone marrow edema	100
Associated synovitis	93.3
Damaged cartilage	26.7

Source: prepared by the authors.

Figure 5. Magnetic resonance imaging of the left knee of a patient with chondroblastoma

Caption A and B: Contrast-weighted magnetic resonance imaging on T2-weighted (A and C) and T1-weighted (B) sequences of the left knee of a 17-year-old boy with a history of severe pain for four months. The bone lesion lies in the proximal epiphysis of the tibia, measuring 4.0 cm, occupying 47.9% of the epiphysis and showing an eccentric shape. The coronal and sagittal sections show heterogeneous signals, perilesional spinal cord edema, synovitis in the adjacent joint, and a proximal tibial cartilage lesion. C: axial section showing rupture of the medial cortical fluid, which confirmed the secondary aneurysmal bone cyst in the anatomopathological analysis.

All cases received surgical treatment, one (5.3%) by en bloc resection and 18/19 (94.7%) by intralesional resection with extended curettage. Of these, 15/18 (83.3%) received autografts; one (5.5%), an allograft, and two (11.1%) (with an affected glenoid and GTA), received no filling. Local recurrence occurred in 15.8% of cases (3/19), all of which occurred within 12 postoperative months and caused aggressive lesions according to the Enneking classification in the glenoid, PHE, and DFE. The survival time free of local recurrence at one and two years totaled 84.2%. No cases showed metastasis.

In total, eight patients had non-oncological local complications. The most frequent complication referred to secondary arthrosis (46.7%), classified by Kellgreen-Lawrence as type 3 or 4, which occurred in only 1/5 (20%) DFE lesions. Considering only epiphyseal lesions, 5/15 (33.3%) had signs of deformity, occurring more often in the PHE (66.7%) (Figure 6).

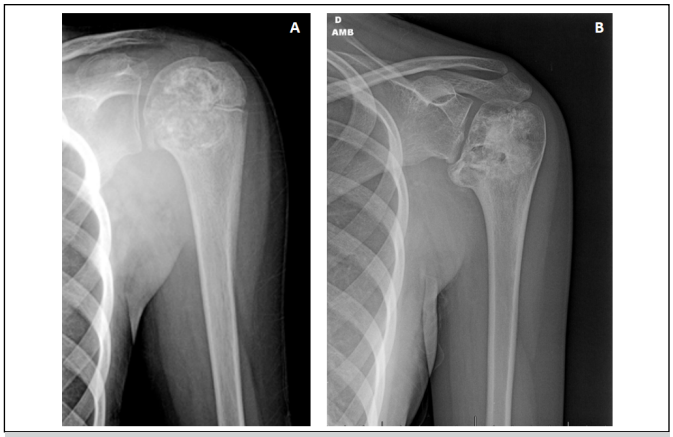

Figure 6. Shoulder X-ray of a patient with chondroblastoma

Caption: A: Anteroposterior radiograph of the left shoulder of a 13-year-old girl with a history of moderate pain for a year, severe limitation of range of motion, with flexion and abduction of 30º. The bone lesion lies in the epiphysis of the proximal humerus, measuring 3.8 cm, occupying 74.0% of the epiphysis, and showing an eccentric shape, calcifications, and damaged partially closed physis. Surgical treatment was performed with curettage with a mechanical and thermal adjuvant and filling with an autologous graft of the iliac crest. B: Anteroposterior radiograph of the left shoulder four years after surgery. This study observed an important deformity of the humeral head, associated with deformity of the inferior surface of the glenoid, classified as Kellgreen-Lawrence 4.

Table 2. Characteristics of patients with chondroblastoma with evolution to relevant arthrosis

K/L	Age	Gender	Location	Enneking	Ratio %	2º ABC	Damaged Cartilage	Cortical Rupture	Recurrence
3	17	M	Proximal Tibia	3	47.9	Yes	Yes	Yes	No
3	14	F	Distal Femur	3	26.7	No	Yes	Yes	No
3	16	F	Scapula-Glenoid	3	60.2	No	Yes	Yes	Yes
4	13	F	Proximal Humerus	3	74.0	No	No	Yes	Yes
4	14	M	Distal Tibia	3	53.2	No	No	Yes	No
4	9	M	Proximal Femur	2	52.3	No	No	No	No
4	4	M	Iliac	3	95.2	Yes	No	Yes	No

[1]Kellgren–Lawrence classification. [2] 2º ABC: Secondary Aneurysmal Bone Cyst.

DISCUSSION

Chondroblastoma configures a rare benign tumor that can show aggressive features, including bone and lung metastasis[3,5,12-14]. Few studies have evaluated large series, and this research reports the largest series of cases observing epidemiological, imaging, and prognostic characteristics in a single Brazilian institution to date.

Results showed a prevalence of boys with a mean age of 13.6 years. The literature shows that this relation between genders always points to a higher frequency in men, despite a wide variation. Studies evince a ratio from 1.6 to 3.0, which also occurs with mean age, ranging from 11 to 25 years. However, some studies report cases of patients aged from 51 to 55 years[12-15]. Thus, we observed a greater tendency toward polarization of the male sex the older the sample, as in Angelini et al[13], which considered only thane adult population with a 25-year mean age and a 3.0 gender ratio, whereas series that only considered the pediatric population showed a ratio from 1.6 to 1.8 with a mean age from 11 to 12.5 years, as in this study[14,15].

In this series, the most common locations refer to the proximal femur, DFE, PHE, and PTE, in agreement with much of the literature [4,5,12,14,16]. Tumors measures a mean 3.07 cm and a 58.0% lesion-epiphysis ratio, in accordance with the literature[5,12,17]. A Harvard Medical School study observed that lesions larger than 5.3 cm would have a higher rate of local recurrence[12], whereas dimensions below 2.5 cm have been the cutoff point for indicating radiofrequency radioablation as a method to treat chondroblastomas with low associated recurrence[7,17].

The positioning of the lesion is an important characteristic to define diagnostic hypotheses in bone tumors, in which lesions such as fibrous dysplasia, bone cysts (which typically occur centrally); and giant cell tumors (which usually manifest eccentrically) configure the classic differential diagnoses of chondroblastoma[18-19]. Reference textbooks for orthopedic residents show divergences, such as Campbell's Orthopedic Surgery, which characterizes chondroblastoma as predominantly centric, and the Pediatric Orthopedics of Tachdjian, which describes chondroblastoma as eccentric[18,19]. The sample of this study agrees with most of the literature, considering the lesion to be predominantly eccentric[3,5,7,13,16,17].

Formation of a sclerosis halo, presence of calcifications, cortical rupture, and cartilage violation are widely studied characteristics that, with the presence of secondary aneurysmal bone cysts, occurred from 6 to 32% of the cases in the literature, as in this study, showing no relation with the chondroblastoma prognosis [3,13-17].

As this a lesion typically occurs in adolescents and young adults, patients' physes were predominantly closed, a finding similar to Xu et al.[6] who found 52.1% of patients with closed physes, as did Liu et al.[17] (47.2%) and Lehner et al.[4] (41.6%). However, the lesion

may contribute to physeal closure, despite its weak relation with anisomelia and relevant angular deformities [3,7,16].

The presence of edema on the magnetic resonance imaging shows a relevant characteristic in differentiating chondroblastomas from other diagnoses. It occurred in all cases in this study. This finding may explain the activity of the disease in our series and the fact that no lesion was classified as latent according to the Enneking classification[11]. Moreover, the resolution of perilesional edema in the follow-up of patients holds value for treatment effectiveness and clinical success[17,18].

Because it is a potentially aggressive lesion, the main oncological complication of chondroblastoma refers to recurrence. This occurred in a significant proportion of the cases, in agreement with other studies that considered curettage and filling as the main method of choice [5,13,20]. Relapse occurs infrequently after the first year, and few studies have shown cases after two years[13,16]. No recurrent lesion occurred in the apophyseal location or showed a sclerosis halo, secondary aneurysmal bone cyst, or completely open physis. Few studies have defined any prognostic relation between recurrence and another variable[6,12,14-16]. Wang et al. found a worse prognosis for epiphyseal versus apophyseal locations and reported that curettage of sites such as GTA showed minimal levels of technical difficulties, whereas the femoral epiphysis head showed the greatest difficulties[16]. PHE and the proximal femoral epiphysis showed the highest risk of recurrence[6,15]. These findings were replicated in neither other studies nor in ours, which may stem from differing epidemiological profiles and sample sizes[3-5, 20]. All recurring lesions in this study occurred in aggressive lesions according to the Enneking classification.

Secondary arthrosis and deformities configured possible non-oncological local complications of chondroblastoma[8,17,20]. Farfalli et al. observed that 38% of the cases showed arthrosis, whereas Outani et al. found only 16.7%[8,20]. Our study showed a prognostic relation between tumors classified as aggressive by Enneking and cases that evolved with relevant secondary arthrosis type 3 or 4 according to the Kellgreen-Lawrence classification ($p = 0.041$). Other studies have compared the same classification with anatomical location, finding better results for the DFE and worse for the proximal femoral epiphysis, PHE, and the subtalar region[8,20]. We also observed a lower tendency of the PHE to develop joint degeneration, probably because they show smaller dimensions and joint involvement, whereas 66.7% of the lesions in the PHE evolved into arthrosis.

The main limitation of this study refers to its sample size and retrospective design, which is related to the low prevalence of chondroblastoma. Thus, its statistical analyses aim to support the findings and enable comparison of the found numbers without intending to bring a definitive answer and exhaust the subject.

CONCLUSION

In patients with chondroblastoma, the development of secondary arthrosis showed a direct relation between the aggressiveness of the tumor according to the Enneking classification and the emergence of this complication.

Aggressiveness and clinical outcome in patients with chondroblastoma showed no causal relation when analyzed for age, sex, physeal status, or presence of calcifications or secondary aneurysmal bone cysts.

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SURVIVAL AND COMPLICATIONS ASSOCIATED WITH UNCONVENTIONAL ENDOPROSTHESIS RECONSTRUCTIONS FOR PRIMARY BONE TUMORS AND BONE METASTASES

SOBREVIDA E COMPLICAÇÕES ASSOCIADAS ÀS RECONSTRUÇÕES COM ENDOPRÓTESES NÃO CONVENCIONAIS PARA TUMORES ÓSSEOS PRIMÁRIOS E METÁSTASES ÓSSEAS

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ABSTRACT

Objective: To evaluate the survival and complications associated with unconventional stent reconstructions for bone and soft tissue tumors. Methods: We retrospectively extracted data from the ICESP (Instituto do Cancer do Estado de São Paulo) registry system to evaluate postoperative complications, including thrombosis, amputation, infection, tumor recurrence, and death. We also assessed time until complications and reoperations, as well as survival. Results: We evaluated 108 patients who underwent unconventional stent reconstruction surgeries for bone tumors. There were significant associations between smoking and tumor recurrence, and between type of cancer, patient functionality, hypertension, and the occurrence of postoperative complications, presence of comorbidities, and death after surgery. Patients with soft tissue tumors and those unable to perform normal activities were at risk of earlier complications. Conclusion: Type of cancer, patient functionality, presence of comorbidities, stent location, and exposure to chemotherapy or radiotherapy are important risk factors associated with complications and survival after unconventional stent reconstruction surgeries. ***Level of Evidence IV, case series, retrospective study.***

Keywords: Bone Neoplasms. Joint Prosthesis. Limb Salvage.

RESUMO

Objetivo: Nosso objetivo foi avaliar a sobrevida e as complicações associadas às reconstruções com endopróteses não convencionais para tumores ósseos e de tecidos moles. Métodos: Extraímos dados retrospectivos do sistema de registro do ICESP (Instituto do Câncer do Estado de São Paulo). Avaliamos complicações pós operatórias, incluindo trombose, amputação, infecção, recidiva tumoral e óbito. Também avaliamos o tempo até complicações e reoperações, bem como a sobrevida. Resultados: Avaliamos 108 pacientes submetidos a cirurgias de reconstruções com endopróteses não convencionais para tumores ósseos. Houve associações significativas entre tabagismo e recidiva tumoral, bem como entre tipo tumoral, função do paciente, hipertensão e ocorrência de complicações em pós-operatórias, presença de comorbidades e óbito após a cirurgia. Foi observado que os pacientes com tumores de tecidos moles e aqueles incapazes de exercer atividades normais apresentavam risco de complicações mais cedo. Conclusão: O tipo de tumor, a função do paciente, a presença de comorbidades, a localização das próteses e a exposição à quimioterapia ou radioterapia são importantes fatores de risco associados a complicações e à sobrevida após cirurgias de reconstruções com endopróteses não convencionais. ***Nível de Evidência IV, série de casos, estudo retrospectivo.***

Descritores: *Neoplasias de Tecido Ósseo. Prótese Articular. Salvamento de Membro.*

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INTRODUCTION

Bone reconstruction after surgical resection of long bones is a challenging procedure for orthopedic oncology specialists. Reconstruction methods include autografts, allografts, and non-conventional stents, aiming to relieve pain, achieve tumor control, and preserve functionality by restoring the ability to walk or perform usual activities. Ideally, reconstruction should provide immediate stability, preservation and early movement of adjacent joints, and survival throughout the patient's life.[1]
The use of non-conventional stents in orthopedic oncology represents a significant advancement in treating malignant bone tumors and metastatic lesions. Among the available treatment methods, non-conventional stents have been shown to be a reliable technique that reduces pain, allows early weight bearing and has fewer adverse effects.[2]
Main complications experienced by patients undergoing limb reconstruction with non-conventional stents include surgical complications (infection and healing problems), implant-related complications (wear and loosening, adverse reactions to the material), and specific oncological complications (tumor invasion and bone metastases).[3]
Studies investigating the functional outcome, survival rates, and complications after bone reconstruction with non-conventional stents are essential for improving this surgical treatment technique. To date, the literature on the subject includes retrospective surveys conducted in single centers or with a small sample size.[4-6]
Our objective was to evaluate the survival and complications associated with reconstructions with non-conventional stents for bone and soft tissue tumors.

METHODS

Study design

An observational study was conducted to evaluate the survival and complications associated with reconstructions using non-conventional stents for bone and soft tissue tumors. Its description follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[7]

Ethics

The Human Research Ethics Committee of the School of Medicine at University of São Paulo approved this study (CEP-FMUSP).

Context

Data were obtained from the Electronic Health Record system held by ICESP (Cancer Institute of the State of São Paulo, University of São Paulo). All patient record data were stored on the Philips Tasy system server. After organizing the data, regular expression algorithms and human review maximized the amount of information extracted from the unstructured text (e.g., surgical and discharge notes).

Participants

ICESP patients who underwent surgical procedures for bone and soft tissue tumors involving reconstructions with non-conventional stents were included. Patients with incomplete records and those with a non-tumor diagnosis were excluded.

Results

Our outcomes of interest included complications after reoperation, including thrombosis, amputation, infection, tumor recurrence, and death. We also assessed time until complications and reoperations, as well as survival.

Predictors

Predictors included sociodemographic characteristics (age, gender, occupation), weight, height, smoking, alcohol use, stent location, type of cancer, comorbidities, functionality, and whether the patient underwent chemotherapy and radiotherapy.

Statistical methods

Our exploratory analysis began with a visual exploration of all variables to assess frequency, percentage, and near-zero variance for categorical variables (e.g., gender, occupation, complications, smoking, alcohol use, stent location, type of cancer, comorbidities, functionality, chemotherapy, and radiation therapy). Near-zero variance is found when a categorical variable has a small percentage of a given category, which is addressed by combining different categorizations of variables. We assessed the distribution of numerical variables (including age, weight, height, time until reoperation, and time until complications) and patterns of missing values.[8] Since time until complication and time until reoperation had a non-normal distribution, they were categorized as 30, 90, 180, and 365 days. Differences between groups were assessed using standardized mean differences (SMD). We considered the following guidelines in interpreting the SMD magnitudes: SMD = 0.2 corresponds to a small effect; SMD = 0.5 corresponds to a medium effect; and SMD = 0.8 corresponds to a large effect.[9]
We also present p-values for t-tests (for numerical variables) and Chi-square tests (for categorical variables). A p-value < 0.05 was adopted as statistically significant.
We applied multiple linear and logistic regression models to assess associations between outcomes and predictors. We report the odds ratio with 95% confidence intervals for categorical variables (e.g., complications) and the categorized time until reoperation and time until complications. Results were statistically significant when the confidence intervals did not exceed the value of 1.0.
Survival models investigated predictors contributing to the duration of complications and survival using Cox proportional hazards models.[1] We report the hazard ratios with 95% confidence intervals. Results were significant when the confidence intervals did not exceed the value of 1.0. Numbers > 1.0 indicate an increased risk of complications, whereas < 1.0 reduce the risk of complications at a specific time. We also generated Kaplan-Meier survival curves to describe the likelihood of complications after surgical procedures involving non-conventional stents for bone and soft tissue tumors. Finally, we used regression trees (recursive partitioning) with the same set of results and predictors described above. Regression trees represent the best cut-off points for predictor values in the context of a given variable after considering previous predictors.

RESULTS

Complications after surgery included reoperation, infection, thrombosis, amputation, tumor recurrence, or death. Our sample had a mean age of 50.7 years (±17.4), mean weight of 68.2 (±11.7), mean height of 168 (±9.56) and mean BMI of 24.3 (±3.86). Most patients were male (56.5%), retired or unemployed (14.8%), nonsmokers (50%), did not consume alcohol (47.2%), and did not undergo chemotherapy or radiotherapy (77.8%). Stents were more frequently placed in the proximal femur (33.3%) and the most common type of cancer was "other" (not in bone, articular, mesothelial cartilage or soft tissues, 66.7%). A total of 36.1% of patients presented at least one comorbidity, 26.9% had hypertension, and 8.33% had diabetes. KPS showed that most patients had normal functionality or mild signs of disease (21.3%). Our results indicate no significant differences between patients who had complications and those who did not.
Evaluation of the overall frequency of different complications found that a total of 12 (11.1%) patients had thrombosis, 6 (5.56%) underwent amputation, 13 (12%) experienced infections, 26 (24.1%) exhibited tumor recurrence, and 24 (22.22%) died after surgery (Figure 1).

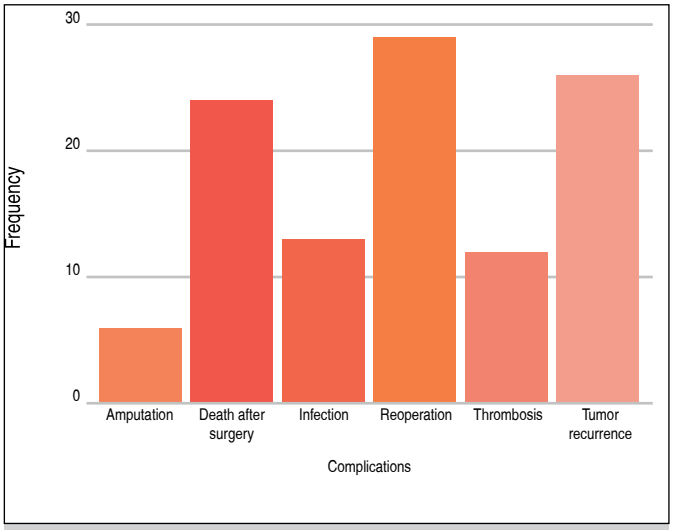

Figure 1. Frequency of complications. Source: prepared by the authors.

We assessed the association between these outcomes and smoking, alcohol consumption, exposure to chemotherapy or radiotherapy, type of cancer, gender, functionality, and comorbidities. Our results indicated a significant association between nonsmokers and tumor recurrence but found no statistically significant associations between alcohol consumption and death after surgery, thrombosis, infections, tumor recurrence, reoperations at 365 days, and complications at 180 and 265 days.

We found no statistically significant association between gender and death after surgery, thrombosis, amputation, infection, tumor recurrence, complications at 30, 90, 180, or 365 days, and reoperation at 30, 90, 180, or 365 days.

Results indicate no statistically significant associations between exposure to chemotherapy or radiotherapy and death after surgery, thrombosis, infections, tumor recurrence, complications at 30, 90, 180 or 365 days, and reoperations at 30, 90, 180 or 365 days. Given the low percentage of patients who had amputations and underwent chemotherapy or radiotherapy, we were unable to assess the association between exposure to chemo or radiotherapy and this outcome.

Table 1 presents the odds ratio for the association between type of cancer and each outcome. We found a significant association between mesothelial and soft tissue cancer and complications at 90, 180, and 365 days. Associations between types of cancer and amputation, complications at 30 days, and reoperations at 30, 90, or 180 days were not evaluated due to the low frequency of patients in each of these outcomes who had mesothelial and soft tissue cancer.

Table 2 presents the odds ratio for the association between functionality and each outcome. Our results indicate a significant association between patients requiring assistance or disability and complications at 180 or 365 days. Associations between functionality and thrombosis, infection, amputation, complications at 30 days, and reoperations at 30, 90, or 180 days were not evaluated due to the low frequency of patients in each of these outcomes with different functionality levels.

Table 3 presents the odds ratio for the association between comorbidities and each outcome. Our results indicate a statistically significant association between the presence of comorbidities and death after surgery.

Table 4 presents the odds ratio for the association between hypertension and each outcome. Results indicate a significant association between the absence of hypertension and complications after 365 days.

Table 1. Association between outcomes and types of cancer

	Bone or articular cartilage cancer	Mesothelial soft tissue cancer	Other types of cancer
Death after surgery	1 [Reference]	1.39 (0.036; 37.8) [p = 0.844]	0.549 (0.048; 5.16) [p = 0.603]
Thrombosis	1 [Reference]	5.18 (0.095, 357) [p = 0.397]	0.731 (0.02, 27) [p = 0.852]
Infection	1 [Reference]	4.18 (0.316, 130) [p = 0.313]	0.067 (0.002, 1.15) [p = 0.094]
Tumor recurrence	1 [Reference]	0.968 (0.029; 20.4) [p = 0.984]	0.38 (0.034; 3.54) [p = 0.4]
Complication at 90 days	1 [Reference]	27.7 (1.5; 1,553) [p = 0.047]	3.22 (0.279, 81) [p = 0.383]
Complication at 180 days	1 [Reference]	24.1 (1.26; 1,345) [p = 0.061]	1.42 (0.155; 15.4) [p = 0.756]
Complication at 365 days	1 [Reference]	25.3 (1.2, 1,543) [p = 0.065]	1.78 (0.21; 18.7) [p = 0.602]
Complication after 365 days	1 [Reference]	0.72 (0.029; 9.02) [p = 0.808]	0.207 (0.009; 2.03) [p = 0.219]
Reoperation at 365 days	1 [Reference]	12 (0.564, 591) [p = 0.135]	1.88 (0.045; 70.5) [p = 0.721]

Source: ICESP Archive.

Table 2. Association between outcomes and functionality

	Normal or minor signs of illness	Normal activity with exertion	Able to take care of oneself, but unable to perform usual activities	Requires occasional assistance	Requires assistance or invalid
Death after surgery	1 [Reference]	2.03 (0.177; 28.3) [p = 0.57]	0.395 (0.013; 7.97) [p = 0.556]	0.521 (0.043; 5.2) [p = 0.581]	0.021 (0.001, 0.319) [p = 0.015]
Tumor recurrence	1 [Reference]	1.33 (0.088; 21.9) [p = 0.834]	0.781 (0.061; 8.78) [p = 0.839]	0.632 (0.057; 5.97) [p = 0.689]	3.08 (0.425; 26.6) [p = 0.276]
Complication at 90 days	1 [Reference]	0.955 (0.062; 15.7) [p = 0.973]	2.24 (0.146; 36.8) [p = 0.552]	0.976 (0.071; 12.9) [p = 0.985]	8.08 (0.877, 123) [p = 0.087]
Complication at 180 days	1 [Reference]	3.13 (0.215; 56.8) [p = 0.409]	6.72 (0.613, 107) [p = 0.136]	3.61 (0.396; 43.2) [p = 0.269]	16.3 (1.79, 257) [p = 0.024]
Complication at 365 days	1 [Reference]	0.647 (0.048; 7.23) [p = 0.726]	4.41 (0.473, 55) [p = 0.208]	3.41 (0.37; 40.6) [p = 0.295]	9.08 (1.01, 129) [p = 0.068]

Source: ICESP Archive.

Table 3. Association between outcomes and comorbidities

	No comorbidity	Comorbidity
Death after surgery	1 [Reference]	6.4 (1.46; 36.1) [p = 0.02]
Thrombosis	1 [Reference]	1.66 (0.214; 14.6) [p = 0.623]
Amputation	1 [Reference]	1.16 (0.039, 23) [p = 0.92]
Infection	1 [Reference]	0.608 (0.106; 2.94) [p = 0.545]
Tumor recurrence	1 [Reference]	0.783 (0.191; 2.98) [p = 0.723]
Complication at 90 days	1 [Reference]	0.514 (0.117; 2.04) [p = 0.354]
Complication at 180 days	1 [Reference]	0.98 (0.261; 3.61) [p = 0.976]
Complication at 365 days	1 [Reference]	0.64 (0.168; 2.31) [p = 0.499]
Complication after 365 days	1 [Reference]	2.72 (0.636, 13) [p = 0.185]
Reoperation at 30 days	1 [Reference]	4.79 (0.371; 90.7) [p = 0.236]
Reoperation at 90 days	1 [Reference]	4.79 (0.371; 90.7) [p = 0.236]
Reoperation at 180 days	1 [Reference]	2.15 (0.208; 23.1) [p = 0.504]
Reoperation at 365 days	1 [Reference]	2.32 (0.287, 21) [p = 0.424]
Reoperation after 365 days	1 [Reference]	1.76 (0.256; 12.6) [p = 0.558]

Source: ICESP Archive.

Table 4. Association between outcomes and hypertension

	No hypertension	**Hypertension**
Death after surgery	1 [Reference]	3.15 (0.697; 15.4) [p = 0.138]
Thrombosis	1 [Reference]	1.77 (0.161; 20.9) [p = 0.63]
Amputation	1 [Reference]	0.558 (0.007; 13.2) [p = 0.742]
Infection	1 [Reference]	0.609 (0.073; 3.61) [p = 0.602]
Tumor recurrence	1 [Reference]	2.31 (0.564; 9.83) [p = 0.243]
Complication at 90 days	1 [Reference]	0.39 (0.068; 1.81) [p = 0.247]
Complication at 180 days	1 [Reference]	0.98 (0.237, 4) [p = 0.977]
Complication at 365 days	1 [Reference]	0.725 (0.168; 3.01) [p = 0.656]
Complication after 365 days	1 [Reference]	5.57 (1.05; 38.9) [p = 0.055]
Reoperation at 30 days	1 [Reference]	9.76 (0.566, 382) [p = 0.136]
Reoperation at 90 days	1 [Reference]	9.76 (0.566, 382) [p = 0.136]
Reoperation at 180 days	1 [Reference]	4.65 (0.352; 77.6) [p = 0.236]
Reoperation at 365 days	1 [Reference]	2.04 (0.181; 22.9) [p = 0.538]
Reoperation after 365 days	1 [Reference]	1.62 (0.205; 12.6) [p = 0.633]

Source: ICESP Archive.

Survival analysis

A Cox proportional hazards model[1] assessed predictors that contribute to time until complication and survival (time until death). Results of the survival analysis for time until complications indicate that patients with mesothelial soft tissue cancer [6.93 (1.25, 38.5), p = 0.027] and those who were unable to perform normal activities [4.1 (1.6, 10.6), p = 0.003] were at risk of earlier complications, i.e., had higher risk ratios. Conversely, patients who had consumed alcohol in the past [0.191 (0.053; 0.685), p = 0.011] had significantly lower risk ratios (Table 5).

Table 5. Time until complications after surgery for reconstruction with non-conventional stents

	Complication
Nonsmoker	1 [Reference]
Former smoker	0.974 (0.296; 3.21) [p = 0.966]
Smoker	0.435 (0.112; 1.7) [p = 0.23]
No alcohol use	1 [Reference]
Past alcohol use	0.191 (0.053; 0.685) [p = 0.011]
Current alcohol use	2.43 (0.456, 13) [p = 0.298]
No chemotherapy or radiation therapy	1 [Reference]
Chemotherapy or radiation therapy	0.452 (0.178; 1.15) [p = 0.095]
Bone and articular cartilage cancer	1 [Reference]
Mesothelial soft tissue cancer	6.93 (1.25; 38.5) [p = 0.027]
Other types of cancer	4.45 (0.892; 22.2) [p = 0.069]

Female	1 [Reference]
Male	0.476 (0.222; 1.02) [p = 0.057]
Able to perform usual activities (KPS)	1 [Reference]
Unable to perform usual activities (KPS)	4.1 (1.6, 10.6) [p = 0.003]
No comorbidity	1 [Reference]
Comorbidity	0.557 (0.273; 1.14) [p = 0.108]
No hypertension	1 [Reference]
Hypertension	0.526 (0.247; 1.12) [p = 0.094]

Source: ICESP Archive.

Figure 2 illustrates the Kaplan-Meier plots for the risk of early complications after surgery for reconstructions with non-conventional stents. Our results indicate a higher risk of earlier complications for patients who were currently consuming alcohol than for those with past alcohol use (0.014). The analysis also pointed to a higher risk of earlier complications for patients who had mesothelial soft tissue tumors, and those who were unable to perform normal activities. These results corroborate those obtained from the Cox proportional hazards model.

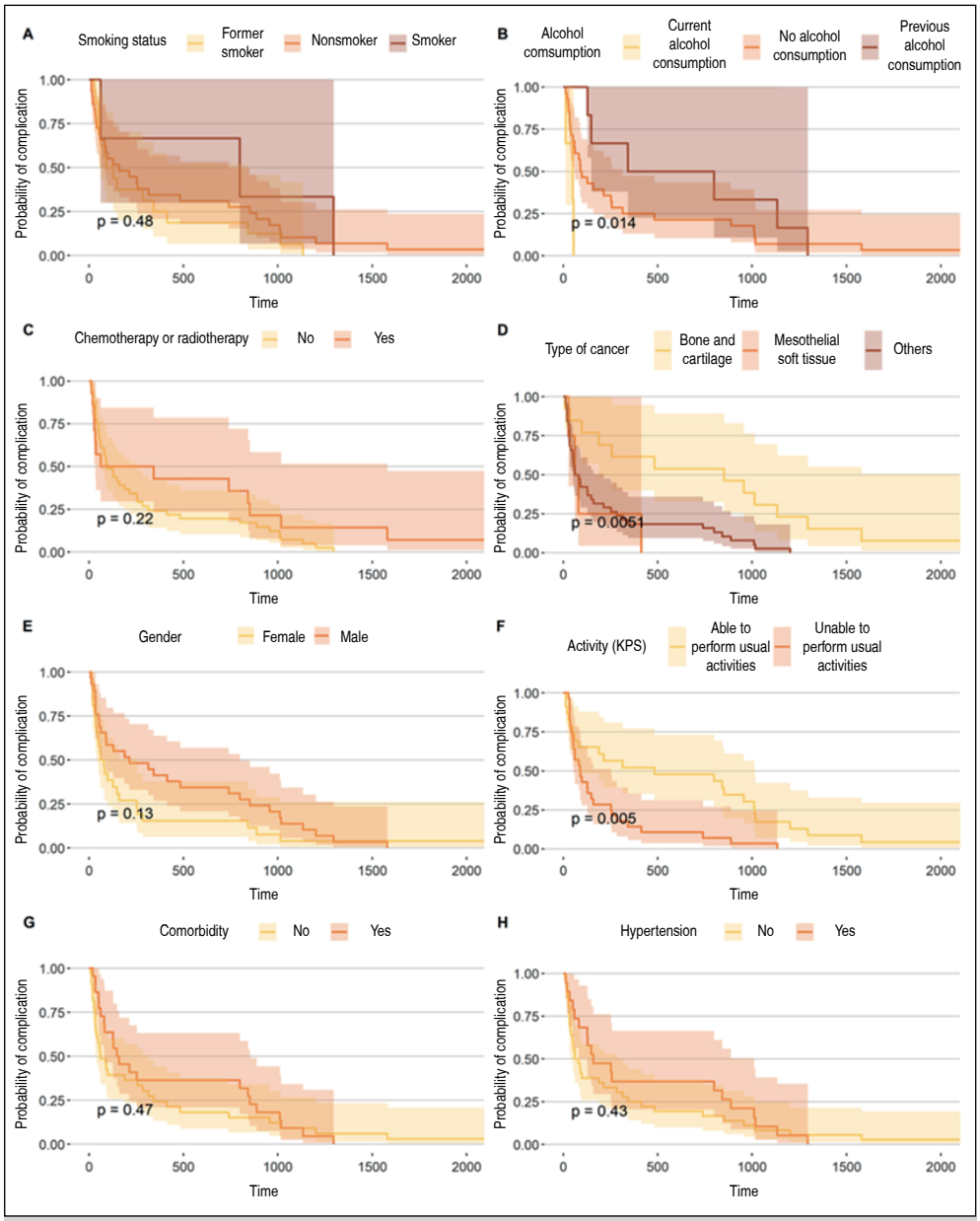

Figure 2. Risk of complications after surgery for reconstructions with non-conventional stents. Source: prepared by the authors.

Survival analysis for time until death found that patients who were unable to perform normal activities [12 (1.86; 77.4), p = 0.009] had a risk of earlier death. Patients undergoing chemotherapy or radiotherapy had significantly lower risk rates, i.e., longer survival time (Table 6).

Table 6. Time until death (survival) after reconstructive surgery with non-conventional stents

	Time until death
Non-smoker	1 [Reference]
Former smoker	5.57 (0.53; 58.5) [p = 0.152]
Smoker	0.655 (0.048; 9.03) [p = 0.752]
No alcohol use	1 [Reference]
Past alcohol use	0.746 (0.147; 3.79) [p = 0.724]
Current alcohol use	0.484 (0.048; 4.89) [p = 0.538]
No chemotherapy or radiation therapy	1 [Reference]
Chemotherapy or radiation therapy	0.113 (0.015, 0.838) [p = 0.033]
Women	1 [Reference]
Men	0.579 (0.165; 2.02) [p = 0.392]
Able to perform normal activities (KPS)	1 [Reference]
Unable to perform normal activities (KPS)	12 (1.86; 77.4) [p = 0.009]
No comorbidity	1 [Reference]
Comorbidity	3.4 (0.426; 27.1) [p = 0.248]
No hypertension	1 [Reference]
Hypertension	0.595 (0.086; 4.14) [p = 0.6]

Source: ICESP Archive

DISCUSSION

Limb reconstruction with non-conventional stents has been described in the literature as a safe approach, capable of improving the survival of patients with bone tumors.[9] As such, studies focused on investigating the prognosis and complications of this type of surgical treatment are increasingly pertinent.

Thomley's systematic review[10] highlights a high overall percentage of complications (47%) in stent reconstructions, with an average loss to follow-up of 21% among the included studies. The research reveals that most patients (63%) with reconstructions using primary non-conventional stents have a mean survival of 79 months. Main complications included infections, which required reoperation after 24 months, and tumor recurrence after 36 months postoperative. According to the authors, the loss of follow-up in studies (average of 21%) may underestimate the complication rate, emphasizing the need to create prospective databases to reduce data inconsistency between studies.

Most patients analyzed in our study presented a good functional status, as indicated by KPS, with normal functionality or mild signs of disease in 21.3% of the cases. Survival analysis indicated that patients with mesothelial soft tissue cancer and those unable to perform normal activities were at risk of earlier complications. This highlights the importance of considering the histological type in postoperative planning and prognosis. The association between patient functionality and postoperative complications highlights the need for preoperative functional assessment with at least one validated instrument.

A large-sample, multicenter study of patients with bone tumors who underwent stent reconstruction of the lower extremity reported significant functional improvement after 1 year, with approximately two-thirds of the sample achieving excellent functionality. Older patients, those with a history of poor preoperative functional outcomes, and patients with soft tissue sarcomas were less likely to report excellent functionality at 1 year.[11]

Analysis of patients' lifestyle habits, such as smoking and alcohol consumption, showed significant associations with certain outcomes. Our results highlighted a significant association between nonsmokers and tumor recurrence. Despite no statistically significant associations between alcohol consumption and various complications, we observed a significant association between past alcohol consumption and lower complication rates. A higher risk of earlier complications was found for current alcohol users compared with past users.

Tree regression models identified the stent location as the main predictor of complications, emphasizing the importance of appropriately selecting the implantation site of non-conventional stents. Other studies also found a higher frequency of complications in reconstructions with non-conventional stents in the proximal region of the femur.[13-14]

Chemotherapy or radiotherapy were associated with lower rates of risk of complication, indicating longer survival. This finding differs from that described by Guzik,[14] who suggests that radiotherapy and preoperative chemotherapy weaken tissues and increase the risk of infections due to tissue damage and necrosis, caused by the former, and the immunosuppression induced by chemotherapy.

One of the limitations in the present study was the retrospective design adopted. We suggest conducting prospective studies with previous sample size calculations and a larger number of participants to validate the present results, since some analyses were limited by sample size.

Due to the short-term follow-up (365 days), results regarding complication rates should be interpreted with caution since many of these potential complications – such as tumor recurrence and denture loosening – can only be observed in the long term. Thus, our results should only guide the prediction of complications after stent grafts in the short term (1 year).

Nonetheless, our study had a significant sample and considered oncological and functionality data of patients with bone and soft tissue tumors. Additionally, the statistical models applied can offer valuable insights for early identification of patients at risk, enabling a more assertive approach to postoperative care and follow-up.

CONCLUSION

This study provides a comprehensive overview of the complications associated with reconstructions using non-conventional stent grafts in patients with bone or soft tissue tumors, highlighting the importance of considering factors such as cancer, functionality, and stent location for a more personalized approach in managing these cases. Additionally, preoperative functional assessment and a multidisciplinary approach should be prioritized to optimize surgical outcomes and patient survival.

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EVALUATION OF THE PERFORMANCE OF CHATGPT/ARTIFICIAL INTELLIGENCE IN THE MULTIPLE-CHOICE TEST TO OBTAIN THE TITLE OF SPECIALIST IN ORTHOPEDICS AND TRAUMATOLOGY

AVALIAÇÃO DO DESEMPENHO DO CHATGPT/ INTELIGÊNCIA ARTIFICIAL NA PROVA DE MÚLTIPLAS ESCOLHAS PARA OBTENÇÃO DO TÍTULO DE ESPECIALISTA EM ORTOPEDIA E TRAUMATOLOGIA

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ABSTRACT

Introduction: ChatGPT, an advanced Artificial Intelligence model specialized in natural language processing, shows remarkable abilities, achieving high scores in certification exams in various specialties. This study aims to evaluate ChatGPT's performance in multiple-choice tests applied to obtain specialist certification in Orthopedics and Traumatology. Methods: We used ChatGPT 4.0 to answer 100 questions from the first phase of the *Título de Especialista em Ortopedia e Traumatologia* 2022 (TEOT) (Specialist in Orthopedics and Traumatology Test). We excluded non-text-based questions. Each question was entered individually into ChatGPT, with a new session initiated for each question. Performance was evaluated regarding number of words and questions' taxonomic classification. Results: Of the 95 questions analyzed, ChatGPT answered 61.05% correctly and 38.95% incorrectly. There was no statistically significant difference regarding number of words, and ChatGPT's performance did not vary according to taxonomic level. Conclusion: ChatGPT demonstrated vast knowledge in Orthopedics, with acceptable performance in the TEOT exam. Results suggest ChatGPT's an educational and clinical resource in Orthopedics, but needs future progress and human supervision for its effective application. ***Level of evidence IV, Case series.***

Keywords: Artificial Intelligence. Orthopedics. Medical Education.

RESUMO

O ChatGPT, um avançado modelo de Inteligência Artificial especializado em processamento de linguagem natural, tem mostrado habilidades notáveis, alcançando pontuações altas em exames de certificação em várias especialidades. Este estudo foi conduzido com o objetivo de avaliar o desempenho do ChatGPT no teste de múltipla escolha aplicado para se obter a certificação de especialista em Ortopedia e Traumatologia. Métodos: Utilizamos o ChatGPT 4.0 para responder 100 perguntas da primeira fase do TEOT 2022. Excluímos perguntas não baseadas em texto. Cada questão foi inserida individualmente no ChatGPT, com uma nova sessão iniciada para cada questão. A performance foi avaliada em relação ao número de palavras e à classificação taxonômica das questões. Resultados: Das 95 questões analisadas, o ChatGPT respondeu corretamente 61.05% e incorretamente 38.95%. Não houve diferença estatística significativa em relação ao número de palavras das questões e o ChatGPT não apresentou variação de desempenho conforme o nível taxonômico. Conclusão: O ChatGPT demonstrou vasto conhecimento em ortopedia, com um desempenho aceitável no exame TEOT, resultado que sugere o potencial do ChatGPT como recurso educacional e clínico em ortopedia, porém com a necessidade de progressos futuros e supervisão humana para sua aplicação efetiva. ***Nível de evidência IV, Série de casos.***

Palavras-chave: *Inteligência Artificial. Ortopedia. Educação Médica.*

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This study was conducted at Universidade Estadual Paulista, Departamento de Cirurgia e Ortopedia, SP, Brazil.
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INTRODUCTION

Over the last ten years, Artificial Intelligence (AI) revolutionized the way we perform tasks in different fields, ranging from medical sciences to finance and administration.[1-4] In this context, ChatGPT, developed by OpenAI, stands out in the scope of advanced natural language processing. It is part of the Large Language Model (LLM) and based on data, generating natural language responses and adapting them to conversational contexts. Confined to a server environment, ChatGPT works with pre-existing information, without the ability to search for new data or perform up to date research. Its ability to develop answers comes from an abstract analysis of connections between words in its neural network, a different technique than those employed by conventional chatbots, which access online databases and have additional informational resources.[5,6] AI emerged as a tool in medical education and quick access to data, ranging from computer models to virtual reality simulators and adaptive learning platforms.[7-9] In Brazil, Orthopedics is one of the fields that most require certification from the Brazilian Society of Orthopedics and Traumatology. The certification process includes theoretical and practical exams, analysis of clinical cases and other criteria. The multiple-choice test is challenging and requires extensive knowledge in Orthopedics.[10]

This study's main goal is to evaluate what percentage of questions in the first phase of the *Título de Especialista em Ortopedia e Traumatologia* (TEOT) (Specialist in Orthopedics and Traumatology) exam can be answered correctly by ChatGPT. Secondary goals include investigating the influence of number of words on ChatGPT's accuracy and a correlation between questions' taxonomic classification and accuracy of responses provided by ChatGPT.

METHODS

This was an experimental study using a commercial LLM (ChatGPT 4.0). [5] The multiple-choice test from the first phase of TEOT 2022, with 100 publicly available questions, was selected. Questions containing non-text-based data were excluded. The provided answers were compared with the official template, also publicly available.[10] All questions were individually entered into ChatGPT's text box as originally written, including answer options. To reduce memory retention bias, a new session was initiated for each question (Figure 1).

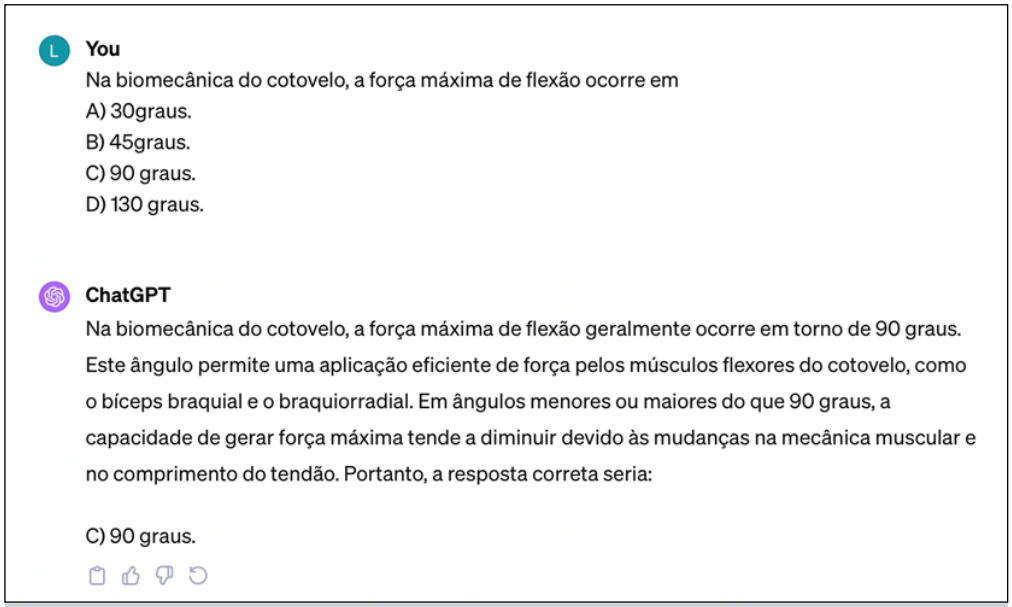

Figure 1. Example of ChatGPT's answers.

If ChatGPT did not select an answer or expressed more than one correct answer, the question was re-entered with the command "select the best answer." If ChatGPT did not select an answer by the second request, the question was listed as "did not answer" and the next question was provided.

ChatGPT's performance according to number of words in the questions

For each question, the number of words was provided by the Pages app (Apple) with the word counting tool, excluding the question number and punctuation marks.

ChatGPT's performance according to question taxonomy

To verify ChatGPT's performance concerning increasingly challenging levels of question taxonomy, two board-certified orthopedists classified the questions according to Buckwalter's taxonomic scheme.[11] Questions were divided into three groups: type 1 tests recognition and recall only, type 2 assesses comprehension and interpretation, and type 3 asks about application of knowledge.

Statistical Analysis

Questions' data were compared through quantitative statistical analysis to determine main differences in terms of number of words. The Shapiro-Wilk test was used for all data, and the Wilcoxon test was used when normality was rejected. Pearson's chi-squared test verified whether the percentage of ChatGPT's correct and incorrect answers varied according to questions' taxonomic classification. Statistical tests were performed using the R software (version 4.0.3) with a significance level of 5%.

RESULTS

Percentage of questions answered correctly

A total of 95 questions were analyzed, excluding five questions due to images, and ChatGPT was able to answer all questions,

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regardless of assertiveness. ChatGPT answered 61.05% correctly (58/95 questions) and 38.95% incorrectly (37/95 questions).

ChatGPT's performance regarding number of words

Among questions answered incorrectly, the mean word count was 18.42, ranging from 8 to 28, with a standard deviation of 5.22. Among questions answered correctly, the average word count was 17.93, ranging from 8 to 37, with a standard deviation of 5.47. There was no statistical difference in number of words between questions answered correctly or incorrectly (p = 0.660, 95%CI). (Table 1).

Table 1. Word Count x Assertiveness

Word Count	Average	Min - Max	Standard deviation	P
Correct Answers	17.94	8 - 37	5.47	0,6411
Incorrect Answers	18.45	8 - 28	5.29	

ChatGPT's performance regarding questions' taxonomic complexity

Of the 95 questions evaluated, 56 were classified as type 1, 39 were classified as type 2 and none were classified as type 3. ChatGPT's performance did not change regarding questions' taxonomic level, correctly answering 34 of the 56 type-1 questions (60.71%) and 24 of the 39 type-2 questions (61.53%), with no statistically significant difference (p = 0.9354, 95%CI) (Table 2).

Table 2. Taxonomic Classification vs Assertiveness

Taxonomic Classification	Correct Answers	Incorrect Answers	P
Type 1	34	22	0.9354
Type 2	24	15	

DISCUSSION

ChatGPT, a state-of-the-art language model developed by OpenAI, showed remarkable achievements in various domains. [1,12] Although a higher standard should be set for it to gain credibility as an educational or clinical decision-making tool, its current performance and rapid improvement suggest this standard may be viable in due course.[13] We sought to determine whether ChatGPT could be used similarly for orthopedic residents by determining its competence in the field using TEOT.

In our study, we evaluated ChatGPT's performance in the first phase of TEOT 2022 and it performed well enough to pass the multiple-choice phase, with assertiveness above the 60% mark, regardless of number of words or taxonomic classification of questions.

Many studies analyzed ChatGPT's performance in training and certification tests in medical specialties. ChatGPT achieved a performance equivalent to a first-year resident on the UK Plastic Surgery Examination, answering about 55% of questions correctly. [14-15]

In Orthopedics, Lum and colleagues examined ChatGPT's performance on Orthobullets (Lineage Medical) practical questions, noting the system answered 47% of questions correctly. They noticed a variation in accuracy, which decreased as taxonomic complexity of questions increased. [6] Kung and collaborators [16] evaluated the performance of ChatGPT 4.0 on the Orthopedic In-Training Examination between 2020 and 2022, finding an average of 73.6% correct answers, which matches the average performance of a fifth-year resident and exceeds the corresponding passing score for the American Board of Orthopaedic Surgery Part I.

We have not identified studies correlating number of words with ChatGPT's assertiveness. However, OpenAI claims their artificial intelligence model can process up to 25,000 words with accuracy and contextualization.[5]

After analyzing ChatGPT's incorrect answers, we identified possible conflicting information sources on different topics. This can hinder ChatGPT's ability to answer questions correctly. In addition, ChatGPT 4.0 is only trained with information up to April 2023, so new information used in medical tests may not be available. Specifically in Medicine, there can be multiple potentially correct answers to a question with only one best answer, which can be challenging for AI if there is correct information supporting each answer. A potential solution would be to train an AI model with only peer-reviewed medical literature, such as PubMed.[14]

Despite these results, there are several limitations to our study. First, the current version of ChatGPT cannot analyze images, making it difficult to evaluate an essential skill for orthopedic surgeons. However, given the rapid progress in AI learning, we anticipate future models will incorporate image analysis. We also observed cases where ChatGPT provided a verifiable source of information, but still gave an incorrect answer, citing articles that were outdated or showed little evidence, or drew incorrect conclusions based on certain sentences that did not represent their conclusions. These logical errors based on false or incomplete facts are worrying and were even defined as the "hallucination effect," to which ChatGPT is susceptible. [16] Finally, our study did not present questions with level-3 taxonomy, which require a higher degree of interpretation and application of data that could affect ChatGPT's assertiveness.

CONCLUSION

Due to the evolution of standards established by AI, it is important that orthopedic professionals actively incorporate this technology, steering it towards its application in providing patient care. ChatGPT, in its current configuration, shows vast knowledge in Orthopedics, and with progress, under human supervision, it will play a relevant role in medical training, patient instruction and clinical decisions.

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ORIGINAL ARTICLE

ORTHOPEDIC TRAUMA

TECHNIQUES AND MATERIALS TO TREAT SHOULDER PATHOLOGIES BY ARTHROSCOPY: A SURVEY IN MEMBERS OF THE BRAZILIAN SOCIETY OF SHOULDER AND ELBOW SURGERY

TÉCNICAS E MATERIAIS NO TRATAMENTO DAS PATOLOGIAS DO OMBRO POR ARTROSCOPIA: UM *SURVEY* ENTRE OS MEMBROS DA SOCIEDADE BRASILEIRA DE CIRURGIA DO OMBRO E COTOVELO

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ABSTRACT

Objective: To evaluate the preferences of shoulder and elbow surgeons from the Brazilian Society of Shoulder and Elbow Surgery to treat rotator cuff injuries, glenohumeral instability, and acromioclavicular dislocations considering a current and an ideal scenarios. Methods: A nationwide survey included 314 specialists who answered a 20-question questionnaire on treating shoulder pathologies. Results: This study included 314 specialists. Most (96%) perform rotator cuff repair arthroscopically and 74% use metallic anchors as a fixation method. In open surgery, most specialists reported using anchors (75%) instead of transosseous sutures. In treating glenohumeral instability via arthroscopic Bankart repair, 86% used three or more fixation anchors and 87%, bioabsorbable anchors. In Latarjet cases, 57% used cannulated screws. In treating acute acromioclavicular dislocations, 88% used the open route. Regarding fixation, 70% chose high-resistance wires; 65%, anchors; and 61%, Kirschner wires. Conclusion: The current Brazilian scenario has limited availability of ideal instruments and materials so specialists can treat shoulder pathologies. However, specialists' preferences agree with the latest medical literature. ***Level of evidence V, Expert opinion.***

Keywords: Rotator Cuff Injuries; Shoulder Dislocation; Acromioclavicular Joint; Arthroscopy; Bankart Lesions.

RESUMO

Objetivo: Avaliar as preferências dos cirurgiões de ombro e cotovelo da Sociedade Brasileira de Cirurgia do Ombro e Cotovelo em relação ao tratamento das lesões do manguito rotador, instabilidade glenoumeral e luxação acromioclavicular, considerando os cenários atual e ideal. Métodos: Uma pesquisa nacional envolveu 314 especialistas que responderam a um questionário com 20 perguntas sobre o tratamento de patologias do ombro. Resultados: Este estudo incluiu 314 especialistas. A maioria dos especialistas (96%) realizam o reparo do manguito rotador pela via artroscópica e 74% utilizam âncoras metálicas como método de fixação. Na cirurgia aberta, a maioria relatou utilização das âncoras (75%) ao invés de suturas transósseas. No tratamento da instabilidade glenoumeral através do reparo artroscópico de Bankart, 86% utilizaram 3 ou mais âncoras de fixação, com 87% utilizando âncoras bioabsorvíveis. Nos casos de Latarjet, 57% utilizaram parafusos canulados. No tratamento da luxação acromioclavicular aguda, 88% realizaram o procedimento pela via aberta. Para a fixação 70% escolheram os fios de alta resistência, 65% as âncoras e 61% os fios de Kirschne. Conclusão: No cenário brasileiro atual, há limitações na disponibilidade de instrumentais e materiais ideais para o tratamento de patologias do ombro pelos especialistas. No entanto, as preferências dos especialistas estão alinhadas com a literatura médica mais recente. ***Nível de evidência V, Opinião do especialista.***

Palavras-chave: *Lesões do Manguito Rotador; Luxação Glenoumeral; Articulação Acromioclavicular; Artroscopia; Rupturas de Bankart.*

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INTRODUCTION

The Brazilian Society of Shoulder and Elbow Surgery (SBCOC) currently has about 1200 members throughout Brazil. The country, with continental dimensions and very different socioeconomic realities, offers surgeons many choices regarding the technique and materials to surgically treat the main shoulder pathologies.

Rotator cuff injuries feature among the most common upper-limb orthopedic conditions, showing a prevalence of 10% in older adults aged over 60 years.[1]

A study carried out in the United States showed the growth in the number of rotator cuff repairs from 2007 to 2016 in the age group ranging between 50 and 64 years.[2]

The medical literature indicates that the surgical treatment of rotator cuff injuries offers a high rate of good and excellent results.[3] In 1987, Ellman et al. introduced arthroscopy as a treatment method that provides greater knowledge of intra-articular lesions and lower morbidity. In 2006, 60% of North American surgeons performed repair arthroscopically, a number that rose to 83% a decade later.[2] Arthroscopic rotator cuff repair constitutes the current standard to treat these injuries in major medical centers around the world.[4]

As with rotator cuff injuries, anterior arthroscopic procedures have also been adopted in place of open ones to treat labral injuries. In 1923, Bankart described labral injuries as the leading cause of recurrent anterior glenohumeral instability of the shoulder, and open repair remained for decades the gold standard to treat this injury, with a recurrence rate below 10%.

Arthroscopic Bankart repair was first described in 1993. The improvement of instruments and surgical techniques has significantly increased the number of surgeries performed by the arthroscopic route, totaling 87.7% of all Bankart repairs performed in the United States in 2008.[5]

Another indicated procedure to treat shoulder instability refers to the Latarjet procedure, which has gained notoriety with the increase in knowledge of the injuries associated with recurrent anterior glenohumeral dislocation and patients' individual characteristics. Latarjet surgery plays an important role especially in cases of Bankart repair failure and in those patients with significant bone lesions.

However, some shoulder pathologies have no gold standard treatment defined. For example, acromioclavicular dislocations have more than 150 treatment options, leaving surgeons to choose the best technique.[6] Adequate treatment of such dislocations in their acute phase is critical due to a greater healing potential of the acromioclavicular ligaments.[7]

Rockwood[8] states that treating acromioclavicular dislocations according to severity into two fundamental options: conservative treatment for Rockwood grade I and II lesions (the greatest controversy occurs for grade III lesions, when each case is evaluated according to patient's characteristics) and surgical treatment for grade IV, V, and VI lesions.[7]

This study aims to show how SBCOC surgeons currently treat these shoulder pathologies and how they would address them in an ideal scenario.

MATERIAL AND METHODS

This study was approved by the Research Ethics Committee of the Pedro Ernesto University Hospital/UERJ on June 16, 2021, under number 4,783,761.

A single intersectional survey was carried out in which 314 orthopedists who were SBCOC members and specialized in shoulder and elbow surgery were interviewed via online questionnaire created using a Google form.

The complete survey consisted of two blocks (current scenario and ideal scenario) with 20 questions each. In the current scenario, surgeons answered how they perform the procedures and what materials they use in their daily routine in Brazil. In the ideal scenario, participants answered what they consider to be the best treatment despite the availability of the instruments and material to be used in each procedure. Respondents could mark more than one answer for each topic.

The questionnaire addressed the surgical materials used by SBCOC members to treat the main shoulder pathologies, such as rotator cuff injuries, anterior glenohumeral instability, and acromioclavicular dislocations. The specialists who consented to participate in this study were anonymized for their gender, age, and area of activity. All comparisons between groups were evaluated as univariate analyses. Differences in the distribution of categorical variables were evaluated by the McNemar's test. A significance level was defined for this study (a p-value, i.e., the statistical error admitted in the analyses, equal to 0.05). Statistical analysis was performed on R, version 4.2.3.

RESULT

This study divided its questionnaire into two scenarios with the same questions, the first referring to specialists' current reality routine and the second, to the ideal scenario, i.e., that with unlimited surgical materials.

Among the participants, 96% had repaired rotator cuffs arthroscopically in their daily practice (Table 1). Regarding material, metallic anchors are the most used as the method to fixate rotator cuffs (74%) (Table 2).

Table 1. Treatment options for rotator cuff repair

	Current (n = 314)	Ideal (n = 314)	p-value
Arthroscopic, n (%)	300 (96%)	301 (97%)	<0.001
Open, n (%)	41 (13%)	20 (6.5%)	<0.001
No answer, n	3	4	

Source: prepared by the authors.

Table 2. Treatment options in arthroscopic rotator cuff repair.

	Current (n = 314)	Idea (n = 314)	p-value
Metallic anchors, n (%)	232 (74%)	131 (42%)	0.012
Bioabsorbable anchor, n (%)	138 (44%)	217 (70%)	0.005
Transosseous suture, n (%)	29 (9.2%)	23 (7.4%)	< 0.001
No answer, n	0	3	

Source: prepared by the authors.

In the ideal scenario, most participants also considered arthroscopy the best method (97%), preferring bioabsorbable anchors to repair rotator cuffs. (70%) (p = 0.005).

In the case of open rotator cuff repairs, surgeons prefer to use anchors instead of transosseous sutures in the current (75%) and ideal (79%) scenarios (p< 0.001) (Table 3).

Table 3. Treatment options in open rotator cuff repair.

	Current (n = 314)	Ideal (n = 314)	p-value
Anchors, n (%)	212 (75%)	225 (79%)	<0.001
Transosseous Suture, n (%)	111 (39%)	95 (34%)	<0.001
No answer, n	30	30	

Source: prepared by the authors.

In the arthroscopic treatment of glenohumeral instability, most surgeons (87%) chose bioabsorbable anchors in their routine (p< 0.001), as in the ideal scenario, in which 96% of them also deem bioabsorbable anchors as the best fixation method (p < 0.001) (Table 4).

Table 4. Material options in the Latarjet procedure.

	Current (n = 314)	Ideal (n = 314)	p-value
Cannulated screw, n (%)	175 (57%)	207 (68%)	<0.001
Non-cannulated screw, n (%)	143 (47%)	109 (36%)	0.005
Cortical screw, n (%)	1 (0.3%)	0 (0%)	<0.001
Cancellous screw, n (%)	1 (0.3%)	1 (0.3%)	<0.001
No answer, n	9	9	

Source: prepared by the authors.

This research also evaluated the number of used anchors, finding similar answers for both scenarios. In daily practice, most members of our Society use three or more anchors (86%) for labral repairs. In the ideal scenario, the preference for three or more anchors increased to 94% of interviewees (p< 0.001) (Table 5).

Regarding the treatment for anterior shoulder instability by the Latarjet procedure, SBCOC members prefer cannulated screws (57%) over non-cannulated ones (47%) to fixate the graft to the glenoid in the current scenario. In an ideal scenario, 68% of these professionals would use cannulated screws for graft fixation (Table 6).

This study found that 88% of interviewees treat acromioclavicular dislocations in an open conventional manner in their daily practice (Table 7). Currently, high-strength wires are the most chosen materials (70%), followed by anchors (65%) and Kirschner wires (61%). In the ideal scenario, the open technique remains the best option among specialists (77%), but they also included the endobutton fixation system in their options for surgical materials (54%). Participants chose high-strength wires the most in the ideal scenario, totaling 70% (Table 8).

Table 5. Material options in arthroscopic Bankart repair.

	Current (n = 314)	Ideal (n = 314)	p-value
Bioabsorbable anchor, n (%)	271 (87%)	298 (96%)	<0.001
Metallic anchor, n (%)	58 (19%)	17 (5.5%)	<0.001
No answer, n	1	4	

Source: prepared by the authors.

Table 6. Number of anchors in arthroscopic Bankart repair.

	Current	Ideal	p-value
1-2 Anchors, n (%)	39 (14%)	18 (6.4%)	<0.001
3-4 Anchors, n (%)	249 (86%)	264 (94%)	<0.001
No answer, n	26	32	

Source: prepared by the authors.

Table 7. Arthroscopic repair for acromioclavicular dislocation: yes or no.

	Current, N= 314	Ideal, N= 314	p-value
Arthroscopic, n (%)	38 (12%)	70 (23%)	<0.001
No answer, n	4	9	

Source: prepared by the authors.

Table 8. Material options in the treatment of acromioclavicular dislocation.

	Current, (n = 314)	Ideal, (n = 314)	p-value
Anchors, n (%)	199 (65%)	171 (56%)	<0.001
Endobutton, n (%)	81 (27%)	164 (54%)	<0.001
Kirschner wires, n (%)	186 (61%)	151 (50%)	0.093
High-strength wires, n (%)	213 (70%)	215 (70%)	<0.001
No answer, n	9	9	

Source: prepared by the authors.

DISCUSSION

Rotator cuff

Rotator cuff repair has significantly evolved over the past decade due to the advent of less invasive techniques. A study carried out in the United States observed a 600% increase in the number of performed arthroscopies from 1996 to 2006.[9] This increase in video-assisted surgeries may be related to clinical outcomes similar to open repair and is associated with lower morbidity.

Most SBCOC members also arthroscopically repair rotator cuffs (96%). A comparative study of the two techniques found better short-term recovery in arthroscopic repairs and equivalent long-term outcomes. An analysis of 1,962 cases showed that the single most important factor in the clinical outcome of rotator cuff repair referred to the initial size of the lesion,[10] finding no significant differences after analyzing the incidence of complications such as tendon re-rupture and comparing the two techniques.[11]

A biomechanical study on the pullout force of fixation devices considering device types (metal or bioabsorbable anchors), fixation method (transosseous suture or anchors), and use of high-strength threads showed that transosseous sutures have lower pullout resistance than anchors. Comparisons of metallic and bioabsorbable anchors showed similar pullout forces. The use of high-strength sutures instead of conventional ones show no better results in transosseous suturing due to failures in the bone bridge, unlike with anchors, in which high-strength sutures have been shown to increase the strength of the set.[12]

Most participants reported using metallic anchors in their daily practice as they guarantee a secure and long-term fixation.[13] However, this device increases the technical difficulty in revision surgery[14] and hinders the interpretation of postoperative MRI, if necessary.[15]

On the other hand, bioabsorbable anchors avoid the potential risks and future difficulties of metallic anchors, which explains the preference for this type of implant. However, they also have disadvantages such as unwanted biological responses, shorter fixation time, and higher cost.[16]

Bioabsorbable implants showed excellent clinical results, resembling those obtained with non-absorbable devices.[17]

Instability

Glenohumeral instability offers a challenge due to the variety of associated injuries and possible treatments to stabilize the joint. The ISIS score has been developed to help shoulder surgeons define treatment for each case.[18] A recent multicenter study shows a high reliability rate when using an ISIS score at a cutoff point < 3 (which would indicate arthroscopic repairs).

Bankart open repair has a high success rate, failing only 2% of the time.[19] With the emergence of arthroscopy, the possibility of performing less invasive procedures has changed the way most shoulder surgeons approach glenohumeral instability, reaching a rate of 90% of repairs performed arthroscopically in 2012.[20]

The reasons for the high adherence of arthroscopy in treating this pathology include its ability to evaluate and treat concomitant lesions that may put Bankart repair at risk alone.[21] In labral lesions without significant bone lesions, the objective is to fix the capsulolabral complex in its original anatomical position to restore the static restrictor function of the anterior band of the inferior glenohumeral ligament. Bankart repair should consider the number of anchors to be used. A systematic review on the recurrence rate of instability showed a 15% average recurrence with the use of less than three anchors and one below 10% using three or more anchors.[22] Comparing these findings with the data in this research, in which the use of one or two anchors represented only 14% of experts' responses, shows that participants' choices agree with the literature.

This same review by Brown et al. found no significant difference between the recurrence rate of instability in relation to the type of used anchor (metallic or bioabsorbable).[22] This study found a more prominent use of bioabsorbable anchors than metallic ones (87% vs. 19%), probably because this intra-articular lesion offers a high risk of complications in case of poor positioning of the metallic anchor.

Labral lesions with significant bone loss (ISIS score above three) require the concomitance of other procedures such as the Remplissage technique or a bone block using the Latarjet technique.[23]

The Latarjet technique is a safe procedure with a low recurrence rate of instability.[24] A cadaveric biomechanical study evaluated the main methods of fixation of the coracoid graft in the glenoid: unicortical or bicortical, use of cannulated or solid screws, with partial or total thread. It observed no statistical difference in fixation failure between the tested devices.[25] In Brazil, the members of the SBCOC reported using mostly cannulated screws (57%).

Acromioclavicular Dislocation

The literature has described about 151 techniques, including the primary repair of acromioclavicular ligaments, reinforcement with autologous grafts, reinforcement with absorbable or non-absorbable sutures, and coracoclavicular stabilization with metal screws.[26]

Historically, metallic devices to fixate the acromioclavicular joint have fallen into disuse due to their greater number of complications and the greater morbidity of the procedure.[27] More anatomical and less invasive methods have become more popular.

These more anatomical procedures include suspensory techniques, which can use autologous grafts or allografts (usually with a semitendinosus tendon) or high-strength wires fixating the clavicle to the coracoid process by anchors or endobuttons.[28] The latter cause lower morbidity by requiring neither donor site (in the case of autologous grafts) nor tissue bank availability (as in the case of allografts).

A biomechanical study comparing native coracoclavicular ligaments with TightRope (Arthrex, Naples, Florida) showed that reconstruction with this device obtained a resistance equal or superior to that of native ligaments, evincing a safe fixation method.[29]

A randomized comparative study analyzed clinical outcomes between open and arthroscopic surgeries in treating acute acromioclavicular dislocation, obtaining good results in both procedures.[30] This study observed that 88% of its specialists prefer open surgeries than arthroscopic ones, and the high-strength wires (70%) as the fixation method.

CONCLUSIONS

The current Brazilian scenario has a limited availability of instruments and materials SBCOC specialists would prefer in an ideal scenario to treat various shoulder pathologies.

The most recent medical literature corroborates the options SBCOC members chose more often.

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PROXIMAL FEMUR FRACTURE IN OLDER ADULTS: CORRELATION BETWEEN SURGICAL TREATMENT TIME AND MORTALITY

FRATURA PROXIMAL DE FÊMUR EM IDOSOS: CORRELAÇÃO ENTRE TEMPO DE TRATAMENTO CIRÚRGICO E MORTALIDADE

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ABSTRACT

Introduction: Osteoporosis impacts public health because of its high morbidity and mortality in older adults and high costs to public funds. Objectives: Analysis of the epidemiological profile, temporal distribution, deaths, and period from low-impact proximal femoral neck fracture to management in older adults people treated at a Tertiary Hospital. Methods: Cross-sectional, descriptive and retrospective study that analyzed 133 medical records involving fractures of the proximal femoral neck due to low-energy trauma from 2017 to 2020. Statistical analysis using the chi-square test, Student's t-test and Fisher's exact test. Results: Of the 133 medical records, there was a predominance of females ($p < 0.01$) with 93 (69.92%). As for age, the average is 79.87±8.23, median 81 years and range from 61-99 years. The months of May, June, and August were dominant ($p > 0.05$), 15 (11.28%), 10 (7.52%), and 21 (15.79%), respectively. The most common spot ($p < 0.001$) was the transtrochanteric region 105 (78.95%). In four years, the number of deaths was: 5(20.83%) in 2017, 4(23.53%) in 2018, 8(33.33%) in 2019, 7(10.29%) in 2020,with no significant changes regarding sex ($p > 0.05$). Conclusion: Most data were consistent with the literature. However, two differ, the transtrochanteric fracture and mortality in 2020. The decrease in deaths in 2020 is mainly due to the new surgery protocol within 48 hours of the fracture. **Level Of Evidence IV, Case Series.**

Keywords: Osteoporosis. Femur fractures. Hip fractures.

RESUMO

Introdução: A osteoporose impacta a saúde pública pela alta morbimortalidade em idosos e pelos altos custos aos cofres públicos. Objetivos: Análise do perfil epidemiológico, distribuição temporal, óbitos e período da fratura colo de fêmur proximal em baixo impacto, até a conduta em idosos atendidos no Hospital Terciário. Métodos: Estudo transversal, descritivo e retrospectivo que analisou 133 prontuários envolvendo fraturas de colo de fêmur proximal por trauma de baixa energia de 2017 a 2020. Análise estatística pelo teste qui-quadrado, T Student e Exato de Fisher. Resultados: Dos 133 prontuários houve predomínio do sexo feminino ($p < 0,01$) com 93(69,92%). Quanto a idade, média é 79,87±8,23, mediana 81 anos e variação de 61-99 anos. Predominou-se ($p > 0,05$) o mês de maio, junho e agosto 15(11,28%), 10(7,52%) e 21(15,79%), respectivamente. O local mais comum ($p < 0,001$) foi a região transtrocanteriana 105(78,95%). Nos quatro anos os óbitos foram: 5(20,83%) em 2017, 4(23,53%) em 2018, 8(33,33%) em 2019, 7(10,29%) em 2020 e não havendo alterações significativas quanto ao sexo ($p > 0,05$). Conclusão: A maioria dos dados foram condizentes com a literatura. Todavia, dois se destoam, a fratura transtrocantérica e mortalidade em 2020. A queda de óbitos em 2020 deve-se principalmente ao novo protocolo de cirurgia em 48 horas da fratura. **Nível de evidência IV, Série de Casos.**

Palavras-chaves: *Osteoporose. Fraturas do Fêmur. Fraturas do Quadril.*

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INTRODUCTION

Osteoporosis is a systemic skeletal disease that reduces bone mass and deteriorates its microarchitecture. Consequently, bone fragility and susceptibility to fractures increase[1]. After 50 years, the probability of a man suffering a fracture due to osteoporosis is approximately 20%, but for women this number is higher, affecting around 50% of the population[2]. This pathology is very discrete, and can be asymptomatic until the first fracture occurs, and the diagnosis is made by analyzing the patient's history, complaints of low-impact fractures, laboratory tests, imaging tests, and, especially, bone densitometry[3], as low mineral density in the bone of the femoral neck is an important predictor[4].

Fractures of the lower limbs, most common of which are of the proximal femur, are the main cause of functional loss in the older adults[5]. The main cause in these patients is the fall from one's own height and the treatment of most fractures is surgical, while conservative treatment is more indicated for cases of incomplete fractures or without displacement[6]. Besides previous comorbidities, prolonged time of immobility in bed and hospitalization tend to rapidly worsen the patient's clinical conditions. In older patients, the risk of death increases when the period between fracture and surgery is longer than 48 hours. For each day waiting for surgery about 4% of death possibility of the older adult with hip fracture increases[7].

In this scenario, the trend of significant expansion of the Brazilian older adults' population by 2050 stands out[9]. The number of people over 60 years old in 1991 was 10.7 million people, whereas in 2011 this group expanded to 23.5 million[10]. Thus, there is an emerging need for planning and public policies to meet the demands of the older adults, since this group is increasingly affected and prone to suffer from this pathology that has a great power of incapacitation and lethality.

In an attempt to reduce postoperative complications and mortality in this population group, the hospital where this study was conducted implemented the "Surgical treatment of fractures in older patients" protocol, which consists of surgical treatment in patients aged 60 years or older, who present femoral fractures, especially proximal ones (femoral head, femoral neck, transtrochanteric, intertrochanteric, subtrochanteric), evidenced by radiography, tomography or magnetic resonance imaging. Studies have shown that early corrective surgery was associated with better functional outcomes and shorter hospital stays, including reducing mortality by up to 20% in the 12 months after the fracture in individuals over 60 years old[9].

This study aimed to analyze the epidemiological profile, temporal distribution, deaths, and period between the occurrence of fracture in older patients with proximal femoral fractures, due to low-energy trauma, between 2017 and 2020 operated by the Orthopedics and Traumatology service of a Tertiary Hospital.

MATERIALS AND METHODS

This is a descriptive, cross-sectional, retrospective, and comparative study conducted at the Tertiary Hospital, approved by the Research Ethics Committee (13390519.6.0000.5481). Patients under 60 years and with fractures from high-energy trauma were excluded. Sex, age, month, seasons, day of the week, period of the day, period between fracture and conduct, and deaths were evaluated.

Data collected from the medical records were arranged in an Excel spreadsheet and the pivot table tool was used to gather the results and facilitate statistical analysis. Quantitative variables were expressed as mean and standard deviation, and qualitative variables as frequencies and percentages. The statistical tests were performed with a significance level of $\alpha = 0.05$ and, therefore, 95% confidence. The chi-square test was used to evaluate the distribution of cases by sex, age group, month, season of the year, day of the week, period of the day, and time between fracture and management and deaths. To compare sex and period before or after the protocol with mean age, Student's t-test was applied. The verification of the existence of an association between the variables: fracture spot and mortality with sex. The mortality period before or after the implementation of the protocol was performed using Pearson's chi-square test and Fisher's Exact test.

RESULTS

The study was composed of a sample of 133 medical records distributed over four years with 24 (18.05%) in 2017, 17 (12.78%) in 2018, 24 (18.05%) in 2019 and 68 (51.13%) in 2020, showing an increase of almost three times in the number of patients in 2020. **Table 1** and **Table 2** show that there was a relevant predominance ($p < 0.01$) of females (n = 93; 69.92%) over males (n = 40; 30.08%). Figure 1 shows that regarding age, the mean is 79.87±823, the median age is 81 years (ranging from 61 to 99 years), and the age group presents a significant bias ($p < 0.001$) for the prevalence of the 80-90 years interval. When sex was associated with the age of the patients, it was noticed that women were significantly older than men ($p < 0.01$), with a mean of 79.87±8.23 years.

Table 1. Epidemiological characteristics of older patients with femoral fractures

Characteristics of victims	2020		
	n	%	p-value*
Sex			p < 0.01
Male	40	30.08	
Female	93	69.92	
Age			p < 0.001
60-69 years	18	14	
70-79 years	41	31	
80-89 years	58	44	

(*) p-value by chi-square test using the homogeneity of the distributions each year as null hypothesis; **Source:** author's own elaboration.

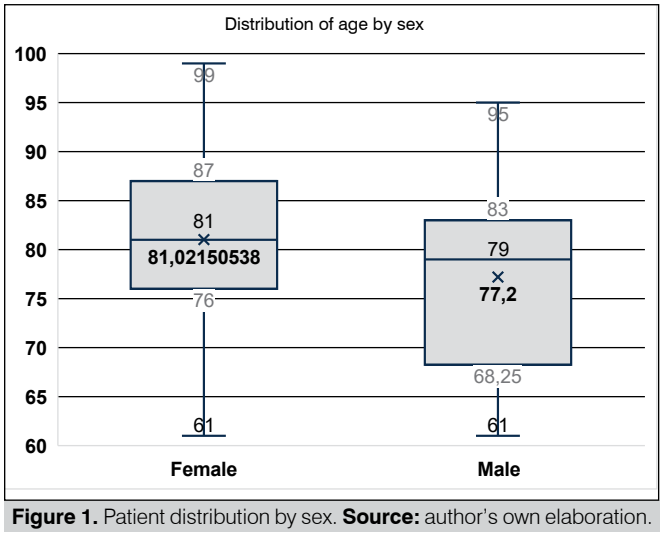

Figure 1. Patient distribution by sex. **Source:** author's own elaboration.

Figure 2 shows that there was a difference in the number of cases according to the month of the year ($p < 0.05$) being predominant in May (n = 15; 11.28%), June (n = 10; 7.52%), and August (n = 21; 15.79%). When analyzing the data assembled according to the seasons, the p-value < 0.01 helps to conclude that the cases are scattered in a heterogeneous way, being higher in winter (n = 48; 36.09%) and fall (n = 39; 29.32%).

<< SUMÁRIO

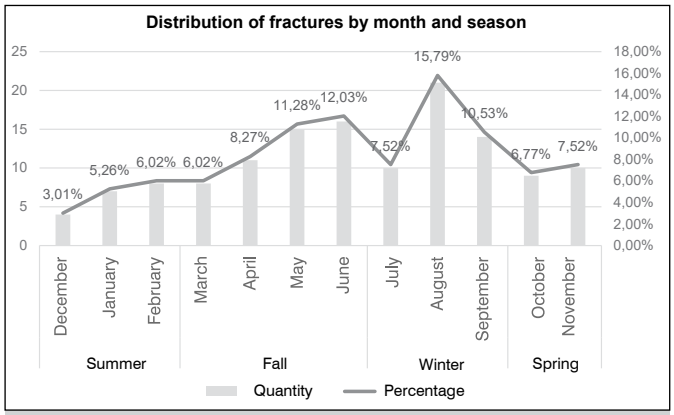

Figure 2. Distribution of fractures by month and season. **Source:** author's own elaboration.

P > 0.05 for the analysis of the distribution of fractures throughout the week indicates we cannot exclude the hypothesis that the cases occurred homogeneously, and it is not possible to affirm that any day of the week concentrated a greater number of cases. When analyzing the period of the day when the fractures occurred, data from the medical records that did not present this information were excluded from the calculation of the p-value, as named on **Table 1** as NI (n = 52; 39.10%), resulting in p < 0.01. P-value shows a statistically relevant bias for the heterogeneous distribution of cases, with a predominance of morning (n = 32; 24.06%) and afternoon (n = 21; 15.79%).

Table 2 shows a statistically significant difference (p < 0.001) regarding the fracture spots preferring unstable pertrochanteric femoral fractures (n = 105; 78.95%). There was no significant difference (p > 0.05) when correlating sex with the fracture spot.

Table 2. Mean age, fracture spot, and mortality

	Female (n = 93)			Male (n = 40)		
	n	%	p-value*	n	%	p-value*
Mean age	81.027.64		< 0.01	77.209		< 0.01
Type of fracture			< 0.001			> 0.05
Cervix	10	7.52		5	3.76	
Subtrochanteric	11	8.27		2	1.50	
Transtrochanteric	72	54.14		33	24.81	
Mortality						> 0.05
Deaths	15	11.28		9	6.77	
Non-deaths	78	58.65		31	23.31	

(*) p-value by chi-square test using the homogeneity of the distributions each year as null hypothesis
Source: author's own elaboration.

In **Table 3** there was a significant reduction (p < 0.01) of the mean waiting time between the occurrence of the fracture and the surgical procedure increased from 6.69±8.85 days for the group evaluated before implementing the protocol (2017, 2018, and 2019) and 3.39±3.46 days for patients admitted after the protocol came into effect (2020). Of the total sample in the four years, 24 (18.05%) patients died within one year after the surgical intervention (between zero and eight months), which corresponds to 17 (26.15%) of the group analyzed before and seven (10.29%) of the group analyzed after the implementation of the surgery protocol within 48 hours after the occurrence of fracture in older adults. Note that there was a statistically significant decrease in mortality (p < 0.05) between both groups. There was no statistical correlation between sex and death (p > 0.05).

Table 3. Mean age, fracture spot, and mortality.

	Before the protocol	After the protocol	p-value
N	65	68	0.003*
MeanDP	6.698.85	3.393.46	
Median	5	2	
Maximum value	66	20	
Minimum value	0	0	
CI95%	2.19	0.83	
Mortality			< 0.05**
Non-mortality	48 (73.85%)	61 (89.71%)	
Death	17 (26.15%)	7 (10.29%)	

(*) T-test: two samples with unequal variances
(**) p-value by the chi-square test using the homogeneity of the distributions of each variable as a null hypothesis.
Source: author's own elaboration.

CONCLUSION

Osteoporosis is a global health problem due to the aging process of the population and has been characterized by WHO as the "Silent Epidemic of the Century"10. In Brazil, the number of people who have the disease reaches 10 million and it is estimated that treatment and care costs in the Unified Health System (SUS) with patients with osteoporosis and victims of falls and fractures will be around BRL 160 million in 2050[11]. This pathology has a high prevalence and predisposes the individual to falls and fractures that can lead to decreased functional capacity or even death[12]. Proximal femoral fractures have some special attention because they present a high risk for the older adults, it is estimated that mortality up to one year after the injury is around 20-30% and that only 15% fully recover the previous functional capacity, and 40% remain with severe disability[13].

Most of our study samples agreed with results found in the literature. A statistically relevant predominance of fractures was observed in females (p < 0.01) in a 2.3:1 ratio, and mean age of 79.87±8.23 (between 61 and 99). Bittar et al.[14] found in this same service a predominance of women in a 4:1 ratio and a mean of 83.2 years (1999/2000). Rocha et al.[16] found 3.3:1 and a mean of 78.5 years. Hungary et al.[15] had a score of 2:1 and a mean of 78.2 years. Note that although similar studies show a higher incidence in the female population, there is no consensus on the ratio between the sexes and the mean age. Although osteoporosis affects both sexes equally, complications such as fractures tend to be more prevalent in women due to lower muscle strength, longer life expectancy, besides the climacteric and other comorbidities that are risk factors for this pathology. However, when a general analysis of fractures is performed, not focusing only on the proximal region of the femur, it is observed that men are the most affected, involving in most cases high-impact fractures, mainly related to traffic and work accidents[18]. A correlation was observed, with a significant bias (p < 0.01), between sex and mean of age and it was observed that women's mean (81.02±7.64) is higher than men's (77.20±9). Bittar et al.[14] found 80.03 in women and 80.25 in men. Hungary et al.[12] had 79.6 in women and 75.5 in men. Rocha et al.[16] found 72.41 in women and 62.16 in men. Bagur et al.[17] had 80 in women and 70 in men. In general, the studies show a higher prevalence of fractures in older women, when comparing our study's results with the data in literature, the mean ages of both males and females are above

the other studies quoted. The highest concentration of cases in the female population is due to the physiological loss of bone mass that begins after the age of 35 years and is more pronounced in females (1%/year) than in males (0.3%/year). Such reduction can be up to 10 times greater when a woman enters menopause[9].

Regarding the temporal disposition of the 133 cases over the years, we have 24 (18.05%) in 2017, 17 (12.78%) in 2018, 24 (18.05%) in 2019, and 68 (51.13%) in 2020, showing an increase of almost three times in the number of patients in 2020. The significant increase in the number of cases is related to the fact that the hospital has become a reference institution for the care of traumas and other non-Covid pathologies in the city, as of April 2020[19].

The distribution of cases per month is heterogeneous ($p < 0.05$) showing a higher concentration in May with 15 (11.28%), followed by June with 10 (7.52), and August with 21 (15.79%). When assembling the months by seasons, there was a predominance ($p < 0.01$) in winter 48 (36.09%) and fall 39 (29.32%), agreeing with various studies[13-15], but there are studies that did not find this seasonal variation[13]. The reasons for the higher occurrence of winter fractures are uncertain, Chiu et al.[20] try to explain this event with the hypothesis that the greater number of layers of clothing worn during the cold ends up compromising the mobility of the older adults and increasing the fractures incidence.

This study analyzed the occurrence of fractures throughout the week and, as well as the findings in literature, it did not show a relevant correlation ($p > 0.05$) to exclude the null hypothesis that the cases are arranged homogeneously, so it is not possible to affirm that any day of the week has concentrated a greater number of fractures[21].

When evaluating the distribution by the period of the day, it showed significance ($p < 0.01$), with a higher frequency during the day, morning with 32 (24.06%) and afternoon with 21 (15.79%). However, this conclusion should be made with reservations due to the removal of the medical records that did not contain these data. The higher prevalence of fractures during the day is related to the performance of basic and instrumental activities of daily life. However, there are studies that obtained a higher prevalence at night, influenced by psychotropic medications[22].

The fracture spot is associated with the anatomical region and with the aid of imaging tests. Thus, femoral neck fracture is related to injuries to the femoral neck, transtrochanteric is related to damage to the intertrochanteric line, and subtrochanteric injury occurs below the smaller trochanter[23]. There is no agreement among the studies on the ratio between the affected spots, but the literature presents the femoral neck as the region that suffers the most fractures. Ramalho et al.[24] reported 49.3% of trochanteric fractures and 50.7% of femoral neck, whereas Bentler et al.[25] found 45% of trochanteric fractures and 55% of femoral necks. Our study showed results that differed, with 88.72% of the trochanteric fractures (78.95% transtrochanteric and 9.77% subtrochanteric) and 15% were of the femoral neck. However, such results agree with Bittar et al.[14] who performed the research at the same service (1999/2000) and obtained 80% of the trochanteric fractures (75% transtrochanteric and 5% subtrochanteric) and 20% of the femoral neck.

The hospital implemented the protocol for the care of older adults with proximal femoral fractures, which consists of surgical intervention up to a maximum of 48 hours after their hospitalization. Thereby, a significant decrease ($p < 0.01$) of the mean time of surgical treatment can be seen, from 6.69 ± 8.85 to 3.39 ± 3.46 days after protocol implementation. Such decrease had a positive impact on the mortality analysis, with a significant reduction ($p < 0.05$), decreasing from 26.15% to 10.29% after the protocol. Our results agree with the literature, Siegmeth et al.[26-27] who concluded an increase in mortality of patients over 60 years old when the surgical procedure is performed after 48 hours. Therefore, it showed a tendency to reduce the length of hospital stay and mortality by 6 months when surgery for the treatment of proximal femoral fractures in older adults is performed within 48 hours of hospital stay.

CONCLUSION

Osteoporosis is considered a global health problem due to the aging process of the population. Most data were consistent with the literature. However, two are at odds, the transtrochanteric fracture and mortality in 2020. The main hypothesis that justifies the drop in deaths in 2020 was the implementation of the protocol "Surgical treatment of fracture in older patients", which consists of surgical treatment in patients over 60 years of age within 48 hours after the fracture. The research emphasizes the importance of greater attention from hospital services in the care of older adults with fractures, as early treatment can modify and reduce morbidity and mortality rates, with reduced waiting times between fracture and surgery, and consequently reduce the length of hospital stay and the incidence of infections.

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LOCAL INJECTION OF HUMAN DENTAL PULP STEM CELLS FOR TREATMENT OF JUVENILE AVASCULAR NECROSIS OF THE FEMORAL HEAD: PRELIMINARY RESULTS IN IMMATURE PIGS

INJEÇÃO LOCAL DE CÉLULAS TRONCO DE POLPA DENTÁRIA HUMANA PARA TRATAMENTO DA NECROSE AVASCULAR JUVENIL DA CABEÇA FEMORAL: RESULTADOS PRELIMINARES EM PORCOS IMATUROS

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ABSTRACT

Introduction: Legg-Calvé-Perthes disease is a major cause of hip joint deformities in children. Currently, experimental research is directed at investigating biological therapies, including the use of human dental pulp stem cells (hDPSC), which have not yet been studied for this purpose in swine models. This study aimed to evaluate whether local injection of hDPSC induces bone mineralization in the proximal femoral epiphysis in an experimental model of avascular necrosis of the femoral head in immature pigs. Methods: Ten immature pigs underwent surgery to induce osteonecrosis of the proximal femoral epiphysis on the right side. In the intervention group (IG), hDPSC injections were performed immediately after osteonecrosis induction, and in the control group (CG), no additional procedure was performed. Left hips were used as controls. After 8 weeks, all animals were euthanized, and macroscopic, radiographic, and histological evaluations were performed. Results: Bone mineralization was greater in the right hips of the IG compared to the CG ($p = 0.0356$), with an average mineralization index increase of 77.78% after hDPSC injection. Radiographic evaluation of the epiphyseal index showed a greater collapse in the right IG hips compared to the right CG hips ($p < 0.001$) and macroscopic evaluation showed a higher chance of the femoral head being flat ($p = 0,049$). Conclusion: The injection of hDPSC into the proximal femoral epiphysis with induced osteonecrosis increases bone mineralization in immature pigs, but these treated hips show more deformity compared to the untreated hips. ***Level of Evidence IV, Case Series***.

Keywords: Legg-Calvé-Perthes Disease. Ischemia. Models, Animal. Swine. Dental Pulp. Stem Cells. Biological Treatment.

RESUMO

Introdução: A doença de Legg-Calvé-Perthes é uma das principais causas de deformidades do quadril na infância. Pesquisas atuais exploram terapias biológicas, incluindo células-tronco da polpa dentária humana (CTPDh), cujos efeitos ainda não foram estudados em modelos suínos. Este estudo avalia se injeções locais de CTPDh promovem a mineralização óssea em um modelo experimental de necrose avascular da cabeça femoral no porco imaturo. Métodos: Dez porcos imaturos foram submetidos à osteonecrose induzida cirurgicamente na epífise femoral proximal do lado direito. O grupo de intervenção (GI) recebeu injeções de CTPDh, enquanto o grupo controle (GC) não recebeu tratamento adicional. Os quadris esquerdos serviram como controles. Após oito semanas, todos os animais foram submetidos à eutanásia e foram realizadas avaliações macroscópicas, radiográficas e histológicas. Resultados: A mineralização óssea foi maior no GI do que no GC ($p = 0,0356$), com aumento da mineralização de 77,78% após a injeção de CTPDh. O GI apresentou maior colapso da cabeça femoral ($p < 0,001$) e maior chance de a cabeça apresentar um formato plano ($p = 0,049$). Conclusão: As injeções de CTPDh aumentam a mineralização óssea nos quadris de porcos

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This study was developed at the Institute of Orthopedics and Traumatology at Hospital das Clínicas at Universidade de São Paulo
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<< SUMÁRIO

imaturos submetidos a osteonecrose isquêmica, mas levam a maior deformidade da cabeça femoral. ***Nível de evidência IV, Série de Casos.***

Palavras-chave: *Doença De Legg-Calvé Perthes. Isquemia. Modelos Animais. Suínos. Polpa Dentária. Células-Tronco. Tratamento Biológico.*

INTRODUCTION

Idiopathic avascular necrosis of the proximal femoral epiphysis configures a major cause of permanent hip joint deformities in children[1–3]. Clinical practice has found that Legg-Calvé-Perthes Disease (LCPD), which can affect patients aged from two to 14 years, occurs more often in boys. It is considered the most common form of pediatric patients' femoral head osteonecrosis, showing an overall annual prevalence from 5.1 to 16.9 per 100,000[4–6].

Treatment involves reducing the deformity of the femoral head and minimizing its complications[7]. Numerous forms of treatment have been proposed for LCPD[7]. However, the few cases to produce randomized clinical trials entails the scarce concrete evidence about the best treatment for the disease. Experimental studies in animal models have been carried out since the 1970s to try to find answers on the approach to the disease[8–10]. Several studies with animal models have shown important points regarding treatment options, such as non-weight bearing in affected limbs[1] and biologic therapies to increase bone mineralization and decrease necrotic femoral head deformity[11–17].

Human dental pulp stem cells (hDPSC) have an excellent potential for osteogenic differentiation[18–24]. However, the use of hDPSC to treat hip osteonecrosis is yet to be studied in immature swine models. Research in mature sheep has shown faster bone regeneration after locally implanting hDPSC in osteonecrosis-induced proximal femoral epiphyses[24]. Due to the feasibility of acquiring this type of biological material, which can be cultivated from a sample of temporary teeth from children, its study may offer an effective treatment for patients with LCPD in the future.

The primary objective of this pilot study was to evaluate whether locally injecting hDPSC induces bone mineralization in the proximal femoral epiphyses in an experimental model of avascular necrosis of the femoral head in immature pigs.

METHODS

This comparative experimental clinical trial was approved by the Scientific Committee of the Institute of Orthopedics and Traumatology at Hospital das Clínicas at the School of Medicine at Universidade de São Paulo (IOT-HCFMUSP) under protocol IOT 1149 and by the Ethics Committee on the Use of Animals (CEUA) at FMUSP under protocol no. 141/15. The animals were kept at the Vivarium of the School of Medicine at Universidade de São Paulo (a suitable place to maintain the species) with a local caretaker. Cleaning, adequate disposal of waste following local sanitary standards, and suitable water and feed were offered to the animals.

PRODUCTION OF THERMOSENSITIVE HYDROGEL

For this study, a bioabsorbable injectable bone substitute with bioactive properties was developed, which was composed of chitosan-xanthan-methylcellulose polymers and calcium phosphate granules in their hydroxyapatite phase.

First, the base production of the hydrogel was carried out in a mass ratio of 1:1 of chitosan and xanthan. The chitosan solution at 1% w/v (Sigma-Aldrich, 83% deacetylation) was prepared in a solution composed of 2% v/v lactic acid (Merck) dissolved in ultrapure water (Milli-Q Direct Q 8/16 System) and homogenized in a mechanical agitator (Tecnal, nautical impeller) at a 1000-rpm rotation. In addition to the chitosan-xanthan polyelectrolyte complex, the methylcellulose polymer was used at a concentration of 10%. The manufacturer (Sigma-Aldrich) and the literature state that the sol-gel transition occurs from 30 to 34 ^{o}C for such concentration. The following steps were performed to add the methylcellulose: dispersion of the methylcellulose powder in 1/3 of the volume of solvent heated to 80 ^{o}C; addition of another 1/3 of the volume of solvent at a temperature from 2 to 8 ^{o}C in agitation; and addition of the remaining 1/3 of solvent to adjust the concentration and liquid behavior at low temperatures.

The calcium phosphate granules were obtained after synthesizing hydroxyapatite by a chemical precipitation in aqueous medium[25,26]. The precipitated dust was then filtered with filter paper (Qualy, J.Prolab – 80 grams, 18.5 cm) in a vacuum system (DVP, model ZA 60S) at 400 mbar. The retained powder was washed with ultrapure water to remove its potassium ions until a pH of seven was obtained in the filtered liquid. The obtained powder was dried at 70 ^{o}C for 12 hours to produce the hydroxyapatite granules. The powder was macerated by a grail and agate pistil and transferred to a particle size sieve from 150 to 300 μm (A bronzinox, 100 mesh and 5" x 2" stainless steel frame). The final step to produce the chitosan-xanthan-methylcellulose hydrogel with hydroxyapatite particles consisted of mixing the products described above with a spatula at a temperature below 8 ^{o}C until complete homogenization.

ADVANCED THERAPY PRODUCT

To deliver the advanced therapy product, the cells were associated to the hydrogel in two stages:

- **Cell Preparation:** HDPSC (DPSC - PT5025, LONZA) were thawed and resuspended in 1× DPBS (Thermo Fisher Scientific). Cells were counted by Countess™ equipment, and a concentration of 1.0 x 10^6 cells was centrifuged at 300 × g for six minutes. The supernatant was discarded, and the cell pellet was resuspended in 600 μL of 0.9% sodium chloride saline solution.
- **Hydrogel Cell Association:** A volume of 1.4mL of the sterilized hydrogel was homogenized with 600 μL of cells resuspended in a saline solution. The final 2 mL of the mixture were aspirated into a 5-mL syringe, ensuring an even distribution of the cells in the hydrogel. This process facilitates the manipulation of the material for extrusion and promotes an environment conducive to cell adherence and proliferation that are essential for bone regeneration.

CELL VIABILITY TESTING

Triplicate samples were seeded in a 12-well culture plate for the viability test based on the MTT assay[27,28] (3-[4,5-dimethyl-thiazole-2-yl]-2,5-diphenyltetrazolium bromide) (Sigma-Aldrich, St. Louis, MO) in the groups referring to two samples of the hydrogel. After adding hDPSC to the hydrogel samples, they were cultured for 48 hours for cell adherence in the hydrogel with the basal culture medium (DMEM F12 + 15% fetal bovine serum). After this period, the samples were washed with 3 ml of PBS to remove the excess basal medium, then 500μl of 0.05mg/ml of MTT were added to the culture wells. All plates were properly wrapped in aluminum foil to keep them away from light for four hours in an incubator (Thermo Fisher Scientific,Waltham, Massachusetts, USA) at 37°C with 5% CO^2. After incubation, 500μl of DMSO (Dimethyl sulfoxide; (CH3)2SO - Sigma-Aldrich, St. Louis, MO) were placed in each cultured well, and all plates were stirred in a horizontal stirrer for five minutes to homogenize the solution. Then, the contents were transferred to a 96-well reading plate and read in a spectrophotometer (TECAN, infinity 200 PRO, Switzerland) with a reading in a 570nm absorbance filter. The values were processed on Magellan 3. The absorbance of the solubilized product is directly proportional to the number of viable cells[29,30].

STUDY DESIGN

Overall, 10 immature pigs aged from 70 to 165 days and weighing from 8 to 13 kg were used. Avascular necrosis of the right proximal femoral epiphysis was surgically induced in all animals. Their left hips were used as controls. The protocol to induce avascular necrosis was based on previously described models[31–36].

The surgical procedure to induce necrosis consisted of performing two intracapsular ligatures around the neck of the right femur of the animals with absorbable Vicryl 2-0 sutures (Ethicon INc., Somerville, NJ) and the section of the ligamentum teres (Figure 1). The procedure aims to interrupt blood flow to the proximal femoral epiphysis. . After necrosis was inducted, hip reduction and wound closure in a standard fashion were performed in layers in the control group. In the intervention group, after necrosis induction, the hDPSC were injected into the proximal femoral epiphysis.

The injection of hDPSC into the proximal femoral epiphysis was performed directly (Figure 2). A 1.5-mm Kirschner wire was used to perforate the articular cartilage of the femoral head, pointing to the center of the epiphysis. After the articular cartilage is passed, using a 5-ml syringe with a 1.2x25-mm needle filled with hDPSC added to Hydrogel, 2ml of the solution containing 1 x 10^6 cells were injected into the femoral head, taking care to avoid extravasated material into the joint. After the needle was removed from the femoral epiphysis, the hole was occluded with bone wax and the hip was reduced at the joint. The wound was closed in a standard fashion.

The animals in both groups were observed for eight weeks from the day of ischemia induction, when they were euthanized to evaluate the results. The animals were allowed full weight-bearing as tolerated.

Figure 1. Photograph of the surgical procedure showing the intracapsular ligatures in the femoral neck with absorbable sutures after the ligamentum teres was sectioned.

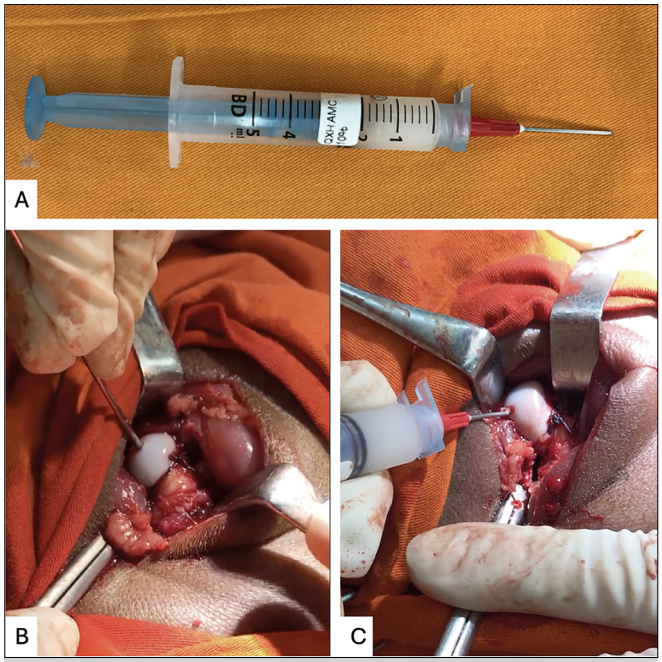

Figure 2. Photographs of the surgical procedure showing the direct injection of hDPSC into the proximal femoral epiphysis. A: syringe containing hDPSC and hydrogel. B: perforation of the proximal femoral epiphysis with 1.5-mm Kirschner wire. C: Injection of hDPSC and hydrogel into the proximal femoral epiphysis, taking care to avoid leaking the material.

ANATOMOPATHOLOGICAL AND HISTOLOGICAL EVALUATION

The right and left hips of the animals were carefully dissected. The samples were macroscopically and microscopically examined. In the macroscopic examination, the sphericity of the femoral head was evaluated based on the Stulberg classification, modified by Huhnstock et al.[37] (flat, ovoid, and spherical).

For the microscopic evaluation, 3-mm thick cuts were made on the femoral heads and necks with a saw in the coronal plane. Each sample was analyzed macroscopically and microscopically. Each sample was fixed in 10% formalin, soaked in paraffin, and cut into 6-μm slices. The sections were stained with hematoxylin-eosin and von-Kossa staining and examined under ordinary light microscopy. Histomorphometric evaluations were performed by a specialist in bone pathology who was blinded to the groups.

RADIOGRAPHIC EVALUATION

All hips underwent radiographic evaluation. Radiographic examinations of the right and left hips were performed in anteroposterior projection. The exams were carried out shortly after the euthanasia. The hips of the animals were dissected, and radiographs were performed only in the proximal region of the femurs, avoiding image overlapping artifacts.

The degree of femoral epiphysis deformation was measured by the epiphyseal index, which is defined as the maximum height divided by the maximum diameter of the proximal femoral epiphysis on an anteroposterior radiograph[38]. Flattening of the femoral epiphysis tends to decrease its height and increase its diameter, reducing the epiphyseal index. Measurements were performed on the picture archiving and communication system software at IOT-HCFMUSP.

STATISTICAL ANALYSIS

Analysis aimed to test the effect of induction of avascular necrosis in the femoral head of pigs and to evaluate the effect of treatment with hDPSC injection on the femoral epiphysis after necrosis. This purpose was addressed in an experimental plan designed to independently test the factors. Thus, the inference of the effect of osteonecrosis was based on the comparison between the right joint (induced to avascular osteonecrosis) and the contralateral side spared from the lesion in the same animal, considering that neither side received treatment with hDPSC. Given the paired nature of this comparison, the assumption of independence between the measurements of both sides in the same individual becomes implausible, and the respective correlation is represented by the longitudinal character of the statistical model. Thus, the inference of the possible effect of inducing avascular osteonecrosis was based on the representation of its relationship with the outcomes of interest by parametric modeling in the scope of the generalized mixed linear models, the distribution of which was assumed, in each situation, according to the nature of the response and the function of linking the median of the response to the linear combination of the defined predictors to optimize fit. In all cases, the mixed component of the model, as defined by carrying out the experiment, consisted of the random effect of the individual, represented by an independent intercept for each animal.

In turn, the analysis of the effect of treatment with hPDSC injection was restricted to the subset of right-sided joints induced by avascular osteonecrosis, and only some of them were treated with pluripotent cell implants. In this unpaired context, the manifestation of treatment under the necrotic limb is compared with the state of the joints that are also injured but from different animals. Thus, the relations between treatment and the outcomes of interest were represented by generalized linear models so that the distribution assumed for the response was consistent with its nature and data and the connection of the mean response to the linear combination of predictors met the need for quality of fit. In the face of ordinal answers, cumulative link models, as generalizations of logistic regression under the assumptions of proportional odds (i.e., the odds ratio for an increase in the ordinal scale ignores the level of that scale) and flexible thresholds were used.

In any case, all inference was initially guided by a previous exploratory analysis, indicating possible relation patterns to support plausible models. After adjusting the data, the models were selected and validated to support valid inferences. Naturally, the validation methods were defined according to the class of the model and availability of the developed and deployed tools. In the case of the generalized mixed linear models, data representation by the model was validated by diagnostic measures based on the residuals of each model. In turn, the validation of a cumulative link model was supported by the Akaike information criteria, Bayesian information criteria, and the Hessian conditional matrix. Due to the small sample size, the evaluation of the statistical significance of each coefficient of a model (thus, of the effect represented by it) was carried out by maximum likelihood ratio test given its favorable convergence properties. Moreover, the statistical significance of any effect (or association) was set at a significance level $\alpha = 0.05$. Finally, all analyses, graphs, and tables were generated on RStudio.

RESULTS

Cell Viability Assay

The normalized results below include the absorbance values for the negative control. Culture on both hydrogel samples showed the loss of about half of the cells. The comparison between hydrogel types showed no difference in viability regardless of the number of cells (Table 1).

Table 1. Cell viability assay in two hydrogel samples. The samples evaluated showed no difference in cell viability. The T-test obtained the p values.

		MTT ViabilityTest				Triple Average	Standard Deviation	p
HYDROGEL I	Positive Control	Cells	0.352	0.346	0.3663	0.355	0.01	
		Cells + Hydrogel I – 10^5 cels/ml*	0.1979	0.1591	0.1622	0.173	0.02	
		Cells + Hydrogel I – 10^4 cels/ml **	0.1589	0.1579	0.1625	0.160	0.00	
	Negative Control	Hydrogel I	0.0741	0.0627	0.0612	0.066	0.01	

HYDROGEL II	Positive Control	Cells	0.3453	0.3655	0.3772	0.363	0.02	
		Cells + Hydrogel II – 10^5 cels/ml*	0.18568	0.18339	0.1845	0.185	0.00	0.394*
		Cells + Hydrogel II – 10^4 cels/ml **	0.14632	0.14752	0.1664	0.153	0.01	0.41**
	Negative Control	Hydrogel II	0.0453	0.0447	0.0445	0.045	0.00	

Source: Prepared by the authors.

Mineralization

The statistical significance of the effect of treatment with hDPSC injection on necrotic femoral head mineralization followed the selection and validation of the statistical model (Table 2) ($p = 0.0356$). In this case, estimates suggest that the mean mineralization index increases by 77.78% after hDPSC injection in comparison to osteonecrosis-induced femoral heads without the application of the treatment (Figures 3 and 4).

Table 2. Effect of the treatment with hDPSC injection on the mineralization of the necrotic femoral head

Mixed linear model range with logarithmic binding for mineralization					
			Likelihood ratio		
	Estimate	Standard Error	Lambda	DF	p
Location / mean					
(Intercept)	1.30933	0.11889			
Treatment: treated x necrosis	0.575365	0.251607	4.414781	1	0.035629
Scale / Dispersion					
(Intercept)	2.649667	0.625142			
Treatment: treated x necrosis	1.24665	0.872256	1.908586	1	0.16712

Source: Prepared by the authors.

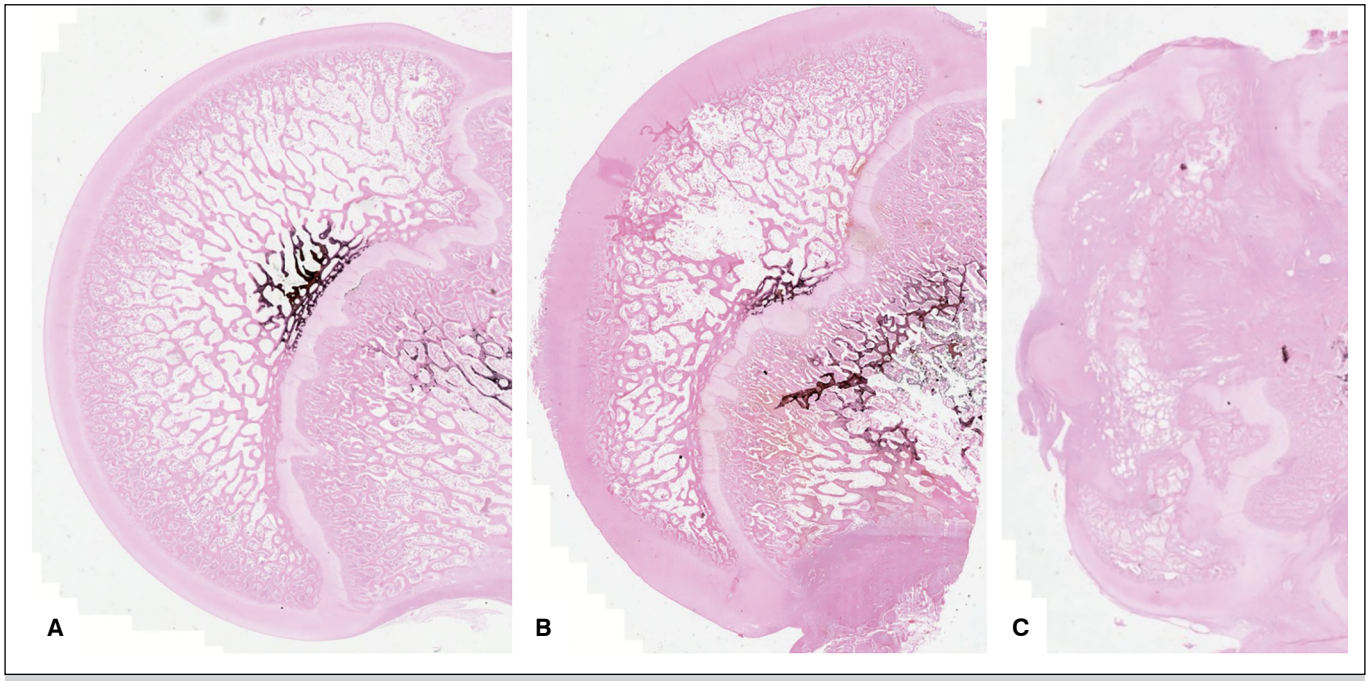

Figure 3. Microscopic images of histological sections stained by von Kossa staining (0.5x). A: Left hip of the control group. The femoral epiphysis has a normal trabecular distribution and spherical shape. B: Right hip from the control group. The femoral epiphysis has a heterogeneous and decreased trabecular distribution, loss of epiphyseal height, and a spherical shape. C: Right hip from the intervention group. The femoral epiphysis, despite greater collapse, shows greater trabecular bone density than the hips in Figures A and B.

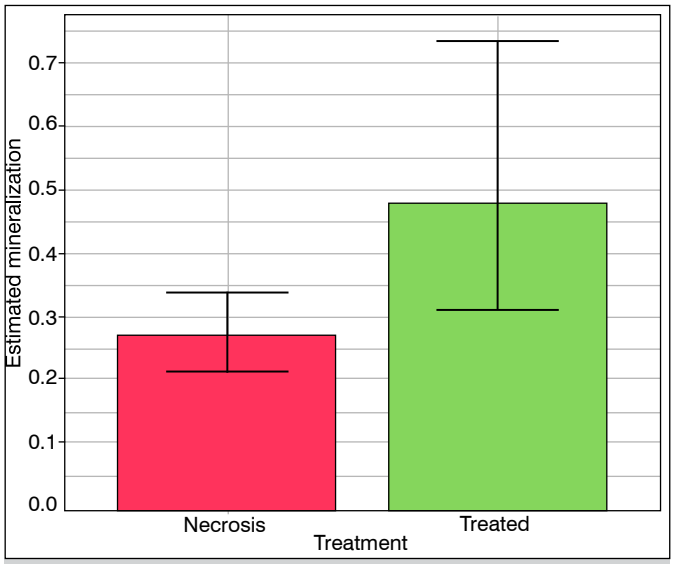

Figure 4. Effect of the treatment on the mineralization of the proximal femoral epiphysis. Columns indicate the values predicted by the model according to the treatment. In turn, the vertical bars illustrate the 95% confidence intervals for the respective estimated average value.

Femoral Head Sphericity

In individuals who received no hDPSC treatment, 80% of the femoral heads spared from necrosis induction (controls) had a spherical appearance, and the remaining 20% evinced a single observation, whose femoral head was ovoid. In turn, the induction of necrosis in the ipsilateral limb of these same animals resulted in an ovoid appearance in 80% of cases and only a flat shape in the remaining ones. On the other hand, applying hDPSC seems to be associated with greater necrosis-induced deformation of the femoral heads since the proportion of cases with flat shape increased to 80%, followed by a reduced incidence of ovoid appearance in a single case. In other words, most femoral heads spared from manipulation had a spherical shape, whereas the limbs subjected to necrosis were predominantly ovoid when untreated with hDPSC injections. Treatment with hDPSC seems to have further affected the femoral head sphericity after necrosis since most cases showed a flat femoral head (Figure 5).

Treatment statistically and significantly affected the femoral head toward flatness ($p = 0.0496$). Implanting pluripotent cells may reduce the chance of the femoral head being ovoid by 93.75% when compared to heads that are only necrotic.

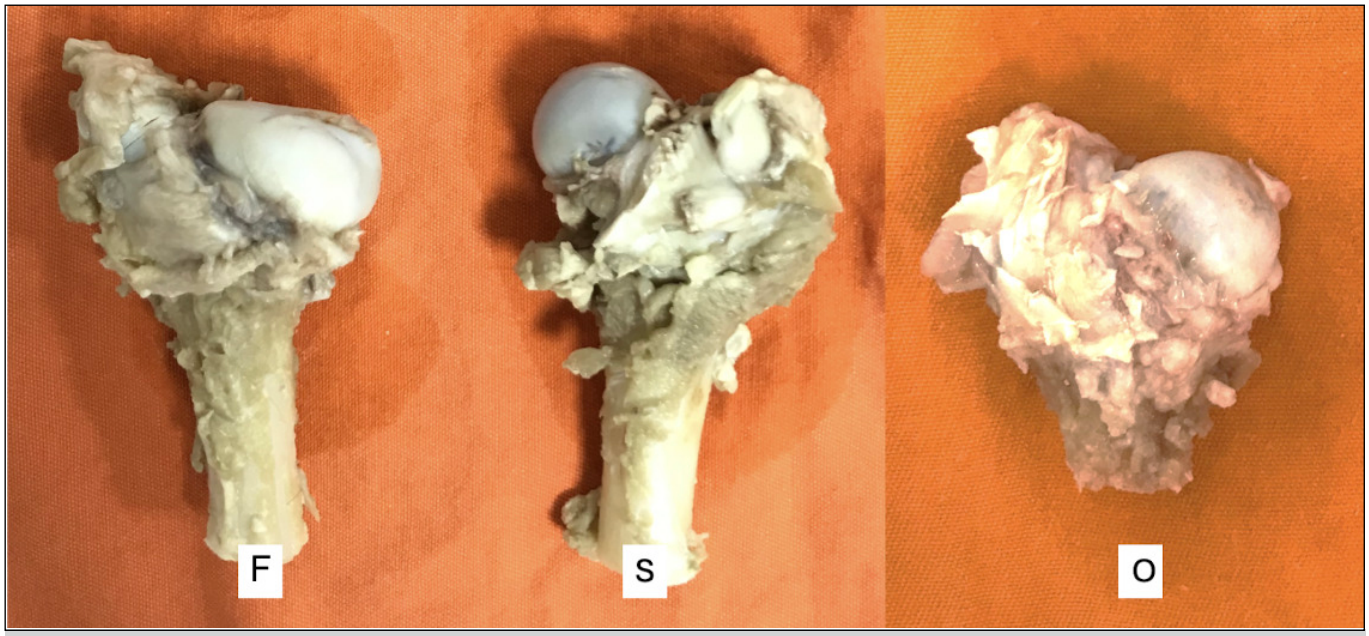

Figure 5. Macroscopic qualitative evaluation of the shape of the femoral head. F: Flat femoral head. S: Spherical femoral head. O: Ovoid femoral head.

Radiographic Epiphyseal Index

The inferential context confirmed the statistical significance of the effect of avascular osteonecrosis induction on the epiphyseal index ($p = 0.0032$). In this case, the epiphyseal index of the joints subjected to necrosis decreased, on average, by 7.1189 when compared to the limbs without avascular lesions. In addition to affecting the mean response, inducing osteonecrosis was also statistically significantly associated with an increased variability of radiographic epiphyseal index values ($p = 0.0231$).

This study also confirmed the statistical significance of the effect of hDPSC injection on the epiphyseal index of the limb previously induced to avascular osteonecrosis ($p < 0.001$). Thus, the robustness of the evidence can estimate that treatment reduces 49.22% of the mean epiphyseal index of a joint induced to avascular osteonecrosis in comparison with limbs with the same lesion without cell treatment (Figures 6 and 7).

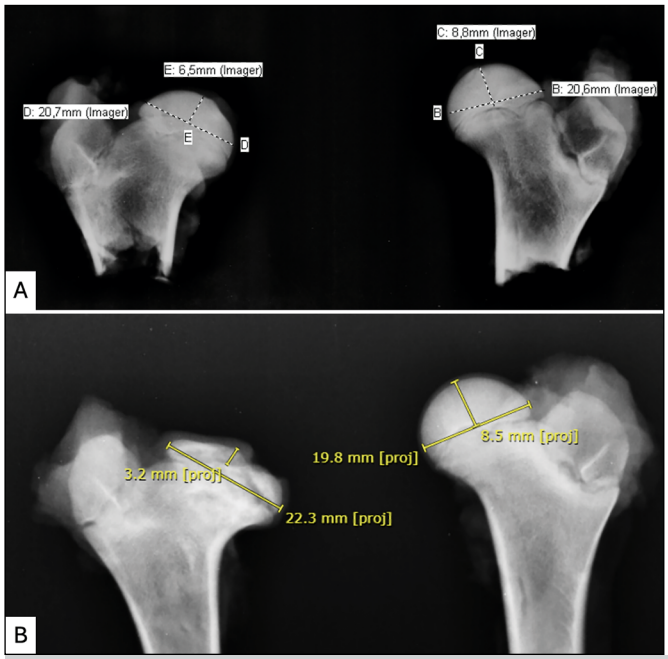

Figure 6. Example of the measurement of the radiographic epiphyseal index in the groups. A: Measurement image on a control group specimen. The epiphyseal index of the right hip equals 6.5/20.7 = 0.31, and that of the left hip, 8.8/20.6 = 0.42. B: measurement image on an intervention group specimen. The epiphyseal index of the right hip equals 3.2/22.3 = 0.14, and that of the left hip, 8.5/19.8 = 0.42.

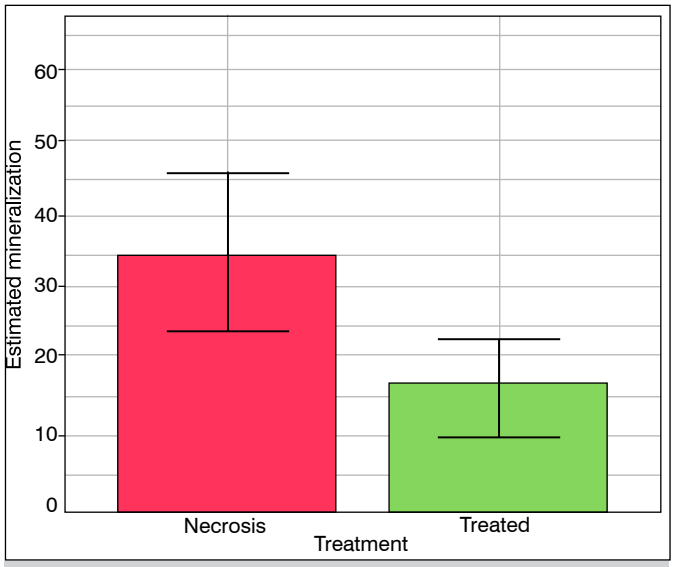

Figure 7. Effect of treatment on the epiphyseal index by comparing the right hips of the control (necrosis) and intervention groups (treated). Columns indicate the values the model predicted according to treatment. The vertical bars illustrate the 95% confidence intervals for the respective estimated average values.

Treatment Safety

No specimen in this analyses showed heterotopic ossification or malignant transformation.

DISCUSSION

The main motivation of this study involved testing the hypothesis that injecting hDPSC into the proximal femoral epiphysis of immature pigs induced to avascular necrosis would increase the bone mineralization of their epiphyses, generating greater support and preserving the morphology of the femoral head when compared to controls subjected to osteonecrosis alone. The primary outcome of this study (femoral epiphysis mineralization) showed a positive and statistically significant result that favored the main formulated hypothesis. However, the secondary outcome (maintenance of femoral head sphericity) was unfavorable to the tested hypothesis since the hips treated with hDPSC showed greater deformity than the hips only subjected to avascular necrosis.

Over the more than 100 years since the discovery of LCPD, numerous studies have been published on mechanical treatment options to the prevent deformation of the affected proximal femoral epiphysis based on the principle of femoral head containment[7,39]. Surgical treatment options such as femoral osteotomies, acetabular osteotomies, and hip arthrodiastasis with external fixators configure the most common current options to treat the disease[7,40]. Regarding conservative treatment, non-weight bearing has gained prominence in recent publications[41–43]. However, few studies have evaluated biological treatments for the disease in humans[44–46]. Herrera-Soto and Price have reported good results in the femoral epiphysis decompression in six adolescents with LCPD by a perforation with a cannulated drill and/or eight to 10-mm trephines and autologous bone grafting and synthetic bone substitutes[44]. The best results in this series occurred in patients who underwent operation during early fragmentation[47]. These authors published a review that recommended early decompression and shelf acetabular arthroplasty so these patients could obtain better results[46]. Sivakumar et al.[45] published a report of two cases subjected to epiphyseal injection of 2mg zoledronic acid in patients diagnosed with LCPD. The authors claimed satisfactory results. No prospective or retrospective comparative studies in humans evaluating the efficacy of any biologic therapy for LCPD have been published to date.

Studies applying interventions in experimental animal models have shown good results, increasing the bone density of the femoral epiphysis and preserving femoral head sphericity [11–13,15–17,24,35,48–50]. Cheng et al.[35] most closely resembles this study as they applied the interventions at the same time as they induced avascular necrosis. These authors concluded that the sucrose acetate isobutyrate offers an efficient means to carry bone morphogenetic protein 2 (BMP-2) to the proximal femoral epiphysis. They also showed that injecting recombinant human BMP-2 without bisphosphonate failed to prevent femoral epiphysis deformity. However, it maintained the shape of the femoral head well when injected with bisphosphonate.

Most experimental models that evaluated biological interventions applied them one or two weeks after osteonecrosis induction[11–13,48–50]. Regarding studies that used BMP-2 as their main agent, Kim et al.[11] experimented in 18 immature pigs, in which six animals received locally applied BMP-2; six, directly and locally applied BMP-2 associated with ibandronate; and six, no local biological therapy. The injections occurred from one to two weeks after osteonecrosis induction. Aruwajoye et al.[48] also studied the injection of BMP-2 and ibandronate one week after osteonecrosis induction. The authors concluded that the treatment with BMP-2 or with it and ibandronate maintained the material properties of the femoral epiphysis similar to those of normal bone. Both studies concluded that associating BMP-2 with a bisphosphonate better preserve femoral head sphericity and bone mineralization. Our investigation did not use a resorptive agent, which may have contributed to femoral head sphericity loss in the treated group.

Aruwajoye et al.[13], Wang et al.[49], and Gong et al[12] tested transphyseal perforations as a biological treatment. Aruwajoye et al.[13] compared multiple transphyseal perforations with single transphyseal tunneling in immature pigs subjected to classic induction of avascular osteonecrosis. The pigs underwent amputation of the right limb to simulate non-weight bearing. The interventions occurred one week after necrosis induction. Both interventions caused no growth defect in the proximal physis of the femur, and the multiple perforations stimulated greater bone formation than tunneling. Wang et al.[49] associated a single transphyseal perforation with a 1.2-mm diameter metallic wire with the injection of BMP-2 and rabbit adipose tissue-derived stem cells in an experiment with 45 immature rabbits. The intervention occurred two weeks after osteonecrosis induction. The authors concluded that the transphyseal injection of BMP-2 and tissue-derived stem cells induced greater bone formation and less deformation of the femoral head than in the control group or the group that only underwent perforation without inoculations. Gong et al.[12] performed three transphyseal perforations with 1.57-mm Kirschner wires in the left hips three weeks after medial necrosis induction. The authors found a higher percentage of hip revascularization in multiple perforations, which seems to produce no bony bars in the physis. However, the perforations neither prevented the collapse of the femoral head nor promoted bone reformation. Our study injected hDPSC directly into the femoral head, which may have contributed to greater deformation of the proximal femoral epiphysis than in the control group. Since Wang et al. and Gong et al. observed that the perforations were unable to prevent the collapse of the femoral epiphysis, a single perforation with a thin wire would very likely fail to increase bone formation in the epiphysis by itself. Therefore, the effect of the increased mineralization in our study can be attributed to hDPSC inoculation rather than to drilling.

Another biological treatment option refers to the systemic use of tocilizumab, a substance that inhibits interleukin 6, which is elevated in the synovial fluid of patients with LCPD and is produced by chondrocytes[14]. Kamiya et al.[50] induced osteonecrosis in six-week-old immature rats by surgically cauterizing the four veins that supply the right proximal femoral epiphysis. The study compared them with a control group (for which that study found such veins but refrained from cauterizing them). The animals were treated with tocilizumab injections since the third day after osteonecrosis induction every week for six weeks (totaling six doses). The authors concluded that the drug increases bone volume in the injected epiphyses. Kuroyanagi et al.[17] and Ren et al.[15] have come to the same conclusion.

Our study has several limitations. Due to issues related to the supply of hDPSC and the inability to operate and maintain more than five animals concomitantly in our physical structure, this study ignored randomization. However, the described methodology of osteonecrosis induction and postoperative care were exactly the same between the groups, and the same team and the same surgeon performed all the experiments on all animals. Another limitation of this study refers to the absence of a third comparative group that would only undergo perforation of the femoral epiphysis without hDPSC injection. Although studies have evaluated the effect of single perforations in the femoral epiphysis with a control group — such as Wang et al.[49] — to date, beneficial or harmful effects are yet to be shown on outcomes related to single fine-needle drilling in the femoral epiphysis. Studies such as Kim et al.[11] considered a model to investigate the biological treatment of avascular necrosis of the hip in immature pigs also ignored a control group with isolated perforation. Thus, we believe that perforation failed to affect the results of our experiment. On the other hand, we stress that the association of directly perforating the femoral epiphysis without protecting loads may have influenced the decrease in the epiphyseal index in the intervention group.

Regarding the effect of hDPSC inoculation, this study was limited by the absence of cell labeling and evaluation of the results from immunohistochemical analyses. Wang et al.[49] labeled adipose-derived stem cells in their experiment with bromodeoxyuridine. The authors concluded that the location of the cells gradually changed from the mesenchymal area of the femoral epiphysis to the trabecular bone from the fourth to the eighth week. They also observed that the intensity of the marking signal decreased up to the eighth week, probably suggesting that cell modulation on the cells of the own animals played an important role in increasing bone volume in their proximal femoral epiphyses. Therefore, we conclude that injecting hDPSC into the femoral epiphysis increased bone mineralization, although it is impossible to state whether the effect stemmed from the cellular modulation due to the implanted cells or from these cells directly increasing bone volume in the femoral head of the treated animals.

This study has several strengths. This pioneering study evaluated the use of hDPSC to treat induced osteonecrosis in a porcine animal model of Legg-Calvé-Perthes disease. Numerous studies have investigated biological therapies to increase bone mineralization and decrease the deformity of the femoral epiphysis due to avascular necrosis induction[11–13,15–17,24,35,48–50]. Adipose-derived stem cells, BMP-2, bisphosphonates, and systemic therapies such as tocilizumab injection showed benefits in models with pigs, rats, and rabbits. However, only one[24] offered an option for a graft that induces bone formation that could be collected and cultured from temporary baby teeth, avoiding the need for a treatment with allografts or synthetic options that remain unavailable in several countries, such as BMP-2. The clinical feasibility of obtaining hDPSC in patients with LCPD is timely since patients who need intervention are usually aged from six to 10 years, the age at which the exchange of temporary and permanent teeth occurs naturally[7]. This would make the graft extraction method less invasive and morbid for patients. The clinical use of this type of graft to stimulate bone formation in patients diagnosed with cleft palate, for example, has been studied and its safety proven[51–53]. This study found neither side effects related to heterotopic ossification in the hip joint of the treated animals — as in Kim et al.[11] by injecting BMP-2 and ibandronate — nor any evidence of cellular malignancy in the evaluated femoral epiphyses. The osteogenic potential of hDPSC has been extensively studied[18], and this study adds another possible application of the use of this type of cell graft to possibly benefit patients with LCPD in the future.

Finally, injecting hDPSC into the proximal femoral epiphysis of immature pigs induced to avascular necrosis increases bone mineralization when compared to epiphyses induced only to avascular necrosis. Still, collapse and deformity of the femoral head occurred consistently in the treated epiphyses. Therefore, our future studies aim to associate transphyseal injections of hDPSC with the removal of limb support by transfemoral amputation to investigate whether it will be possible to preserve the sphericity of the epiphysis in association with increased bone mineralization. A future translational study is required to evaluate the possibility of testing treatment in humans in case of promising results regarding the maintenance of head sphericity.

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COMPLEX FRACTURES OF THE DISTAL RADIUS: ANALYSIS OF OSTEOSYNTHESIS USING SPANNING PLATES

FRATURAS COMPLEXAS DO RÁDIO DISTAL: ANÁLISE DA OSTEOSSÍNTESE COM O USO DE PLACAS DE DISTRAÇÃO

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ABSTRACT

Objective: To radiographically evaluate the postoperative results of AO 2R3C3 type distal radius fractures treated using the spanning plate technique, associated or not with other fixation methods. Methods: Retrospective observational study that evaluated 14 patients, aged 29 to 80 years, who underwent osteosynthesis, from November 2021 to June 2022. For radiographic measurement, the following parameters were defined: ulnar variance, volar inclination, radial inclination and step articulate. Results: The mean value of radial inclination was 13.70 degrees, volar inclination was 0.85 degrees, ulnar variance was 0.60mm and joint step was 0.78mm. Conclusion: Fixation using spanning plate is an excellent alternative in the management of complex fractures of the distal radius. ***Level of Evidence IV, Case Series.***

Keywords: Analysis. Internal Fracture Fixation. Radius Fractures. Bone Plates.

RESUMO

Objetivo: Avaliar radiograficamente os resultados pós-operatórios de fraturas do rádio distal do tipo AO 2R3C3 tratados pela técnica de placa distração associada ou não a outros métodos de fixação. Métodos: Estudo observacional retrospectivo que avaliou 14 pacientes, de 29 a 80 anos, submetidos à osteossíntese, no período de novembro de 2021 a junho de 2022. Para mensuração radiográfica, foram definidos como parâmetros: variância ulnar, inclinação volar, inclinação radial e degrau articular. Resultados: O valor médio da inclinação radial foi de 13,70 graus, da inclinação volar foi de 0,85 graus, da variância ulnar de 0,60mm e do degrau articular foi de 0,78mm. Conclusão: A fixação com o uso de placas de distração dorsal é uma excelente alternativa no manejo de fraturas complexas do rádio distal. ***Nível de evidência IV, Série de Casos.***

Descritores: *Análise. Fixação Interna de Fraturas. Fraturas do Rádio. Placas Ósseas.*

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INTRODUCTION

Distal radius fractures are serious injuries with an unclear prognosis, regardless of the treatment applied, and the presence of associated injuries makes the outcome even more unpredictable. Although distal third radius fractures are among the most frequent in orthopedic emergency care, being the most common fracture of the upper limb, treating them remains a challenge even with many fixation methods available, and the search for more appropriate solutions is constant.

In the case of complex fractures, this challenge is even greater. It affects adults of varying ages, younger ones generally being victims of high-energy traumas, while older ones have fractures even in low kinetic energy accidents. Given their regularity, difficulty of treatment, wide age range affected, complications reflecting on work capacity and high social/economic cost, these fractures are reasons to constantly search for effective solutions.

Most fractures are extra-articular, classified, according to the AO group, as type A. There are also the so-called partial joint fractures (AO type B) and complete joint fractures (AO type C).[2] About 4.5% of complete joint fractures are complex, represented by the AO 2R3C3 subtype[3] (Figure 1). Complex articular distal radius fractures will be the object of this study.

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

The study was conducted at Fundação Hospitalar São Francisco de Assis, MG, Brazil.
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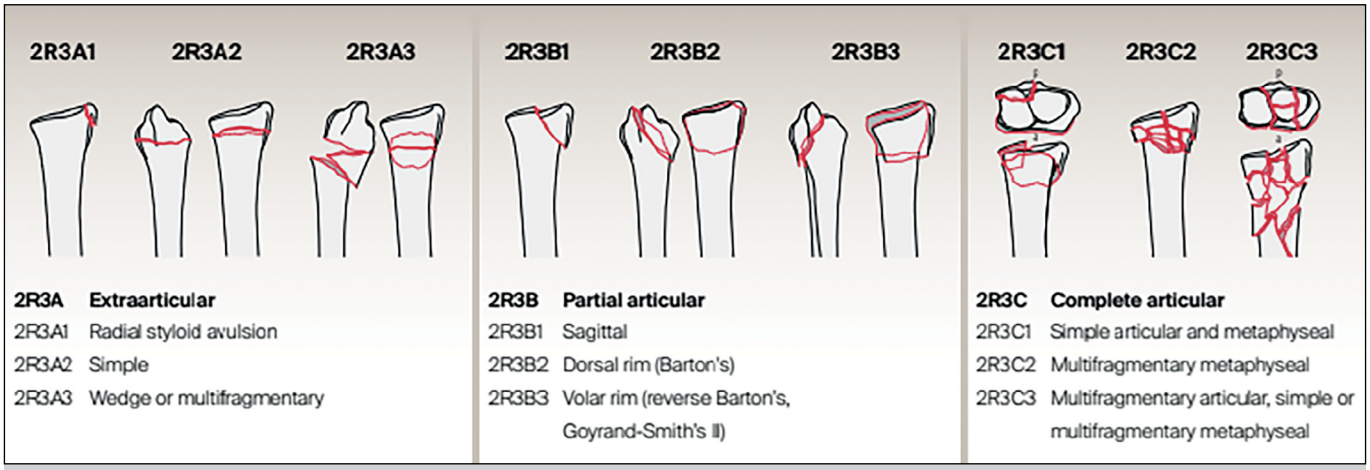

Figure 1. AO classification for distal radius fractures. Source: AO/OTA Fracture and Dislocation Classification Long-bone Fractures - Poster.

There is a variety of proposed treatments in literature, with no consensus around obtained results.[4] The goal is to restore the normal anatomy of the distal radius as precisely as possible, offering sufficient stability to allow wrist consolidation and maintenance of physiological biomechanics.[3-5]

Fractures that show instability do not present good results with conservative treatment. Therefore, surgical treatment should be favored and selected individually according to the fractures' particularities.[5-7]

Complex joint fractures with multiple fragments are usually treated with internal fixation, using locked plates or external fixators with or without Kirschner wires. Locked plates offer great stability, but, due to their low availability, are not a solution for all cases. External fixators show satisfactory results but show a considerable number of infections in the pin path, loss of reduction, stiff fingers and discomfort with the material.[3,6,7,9]

Spanning plates were first described by Burke and Singer in 1998, representing a method of relative stability, in which indirect reduction of the fracture is performed by ligamentotaxis and dorsal support, with a lower risk of infection and greater material tolerance, also allowing early partial weight support.[6-9]

The objective of this study is to radiographically evaluate the use of spanning plates, associated or not with other fixation methods, as a viable alternative to external fixators when treating complex articular distal radius fractures, in departments where locked plates are unavailable.

MATERIALS AND METHODS

We performed a retrospective observational study at the São Francisco de Assis Hospital, in Belo Horizonte, Minas Gerais, Brazil, based on medical records and pre and postoperative radiographs of patients admitted to the Hand Surgery department who underwent surgery for complex distal radius fractures, between November 2021 and June 2022, using a spanning plate, associated or not with other synthesis materials.

The following exclusion criteria were used: patients with an immature skeleton, patients who did not undergo the proposed postoperative follow-up, patients with fractures of the ipsilateral upper limb (shoulder or elbow) and patients who had open fractures with extensive associated soft tissue injuries.

The patients' basic sociodemographic data were obtained and recorded, such as: age, gender, mechanism and date of trauma, date of surgery, affected side and dominant hand.

Fractures were categorized before surgery, based on radiographs in anteroposterior (AP) and lateral views, according to the AO classification. There was a total of 14 fractures, all of them being type C3. In addition to instability criteria originally described by La Fontaine et al.,[5] new parameters from recent studies were used to prescribe surgery, such as: dorsal angulation greater than 20 degrees, dorsal comminution, shortening of the radius greater than 9 mm, involvement of the radiocarpal joint and the distal radioulnar joint, associated fracture of the ulna, deviation greater than 2 mm and age greater than 60 years old.[1,2]

All surgeries were performed in the department by the same team of hand surgery specialists. Postoperative follow-up consisted of periodic consultations in the first, second, fourth, and eighth postoperative weeks, when plaque removal was scheduled.

In the eighth postoperative week, AP and lateral radiographs were used to measure ulnar variance, radial inclination, and volar tilt (Figure 2), as well as the articular step. Measurements were taken by two of the four authors, and the average was, then, recorded. The postoperative outcome was evaluated according to radiographic parameters of reduction present in literature.[10]

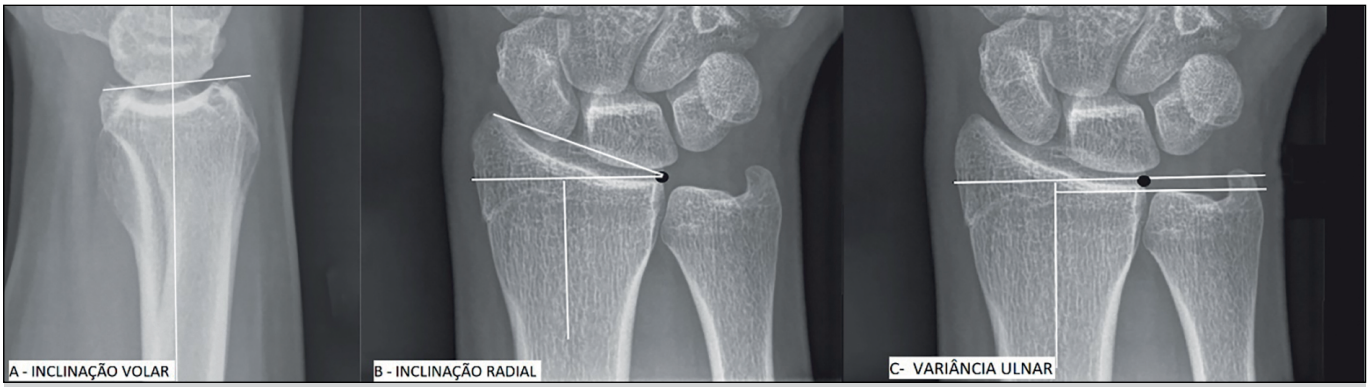

Figure 2. Measurements of radiographic parameters of the distal radius. A - Volar tilt. B - Radial inclination. C - Ulnar variance[2].

SURGICAL TECHNIQUE

The patient is positioned in the horizontal dorsal decubitus position, under brachial plexus block. A radiolucent auxiliary table is used to support the limb, and a pneumatic arm tourniquet is placed on it. After asepsis and antisepsis of the limb, the tourniquet is inflated 100 mmHg above the patient's systolic pressure.

A 12-hole 3.5 mm acetabular reconstruction plate is selected and placed directly on the back of the wrist. Fluoroscopy is used to identify the proximal and distal incision sites. The first incision is made on the dorsal aspect of the third metacarpal, approximately 4 cm long, dissecting until the periosteum is exposed, carefully removing the extensor tendon and other structures. A second longitudinal incision is made on the dorsal aspect of the distal metaphysis of the radius, of about 4 cm, guided by the plate's length and positioning. The radial extensor tendons are identified, and blunt dissection is performed in the interval between them and the periosteum of the radius[6,8,11,12] (Figure 3). A third, intermediate incision of 3 cm, slightly ulnar to Lister's tubercle, is made to open the third extensor compartment and subsequently remove the long extensor tendon of the thumb (Figure 4). The extensor tendons in the fourth compartment are then elevated ulnarly, allowing the plate to be placed on the floor of that compartment. The plate is then carefully passed from distal to proximal, ensuring there is no extensor tendon clamping[6,7,9,13] (Figure 5).

Figure 3. Surgical accesses: distal, intermediate, and proximal. Source: Authors' personal archive, 2021

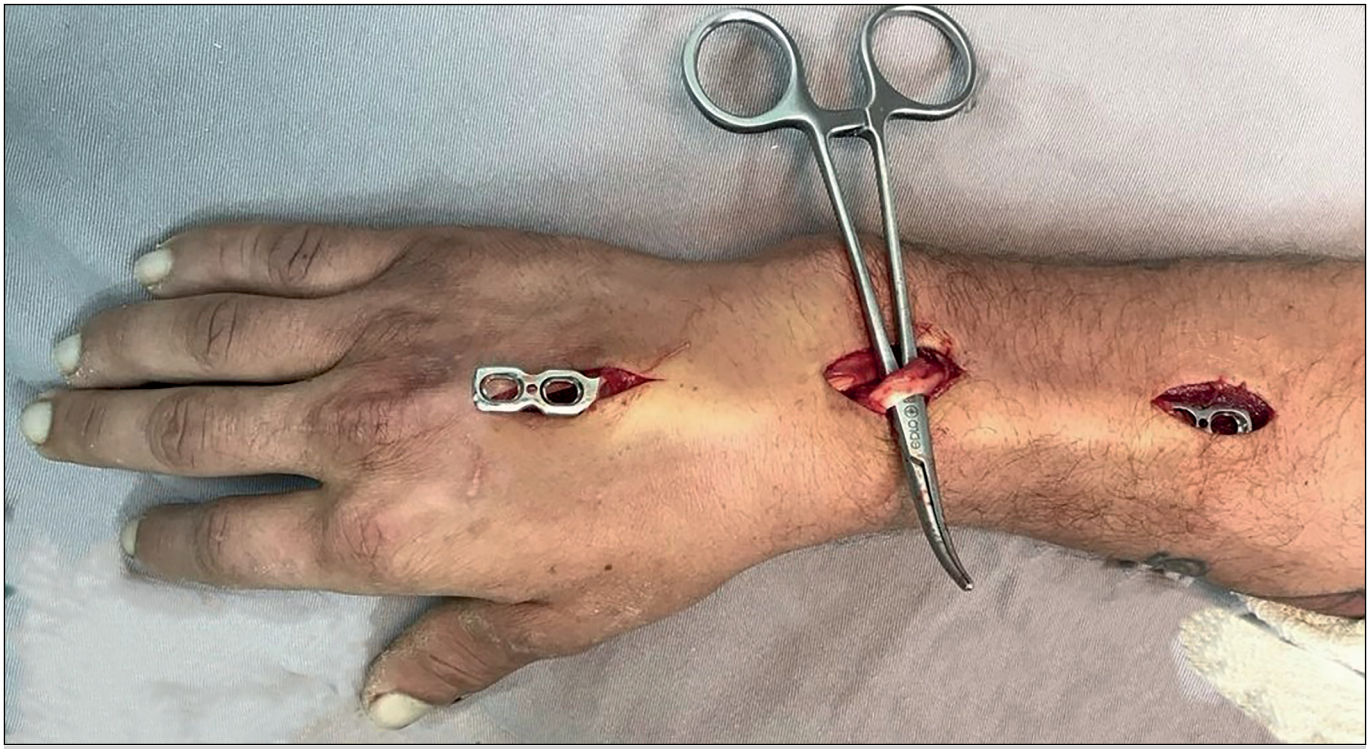

Figure 4. Release and clearance of the extensor pollicis longus (ELP) in the intermediate access. Source: Authors' personal archive, 2021.

Figure 5. Final aspect of surgical wounds after fixation with the plate, the ELP tendon free. Source: Authors' personal archive, 2021.

The most distal screw of the metacarpal is then passed. The hand and forearm are kept in a neutral position, performing traction through the third finger. After traction, the proximal screw of the radius is fixated. Next, fixation is complemented with at least three bicortical screws in the third metacarpal and three bicortical screws in the radius. After fluoroscopy evaluation, the need for additional fixation with Kirschner wires or volar plate of small fragments is verified (Figure 6).

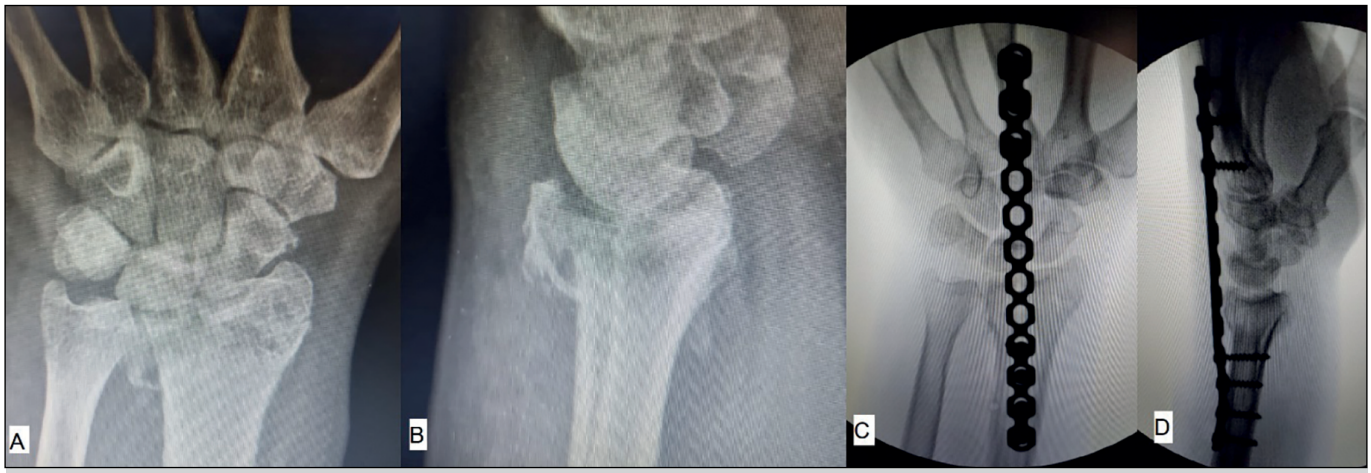

Figure 6. Preoperative radiographic images (A and B). Intraoperative fluoroscopic images after reduction and fixation (C and D). Source: Authors' personal archive, 2021.

Immediately after surgery, a forearm plaster splint is applied in case Kirschner wires were used and is maintained until they are removed. In the absence of adjuvant fixation materials, immobilization is not used. The patient is stimulated and released to move their fingers, forearm and elbow extensively to avoid tendon adhesions and stiffness. Percutaneous pins, when used, are removed after six weeks. The plate is removed after eight weeks and, simultaneously with the surgery, the joint is manipulated to reestablish motion range and break possible fibrosis and adhesions. Physical therapy rehabilitation begins immediately after the synthesis is removed (Figure 7).

Possible complications include superficial and deep infections, loosening of the extensor mechanism (especially the third finger), irritation or even rupture of the extensor tendons, pseudoarthrosis, loosening of the synthesis material (plates and screws), loss of reduction. Complication rate in literature is low.[2]

Figure 7. Radiographic images in AP (A) and lateral (B), two months postoperatively, after removing the spanning plate. Source: Authors' personal archive, 2021.

RESULTS

The study group consisted of 14 patients, five women (35.7%) and nine men (64.3%), with a mean age of 60.8 years, ranging from 29 to 80. Twelve of these were right-handed (85.7%) and two were left-handed (14.3%). Considering the total of fractures, thirteen were on the left wrist (92.85%) and only one was on the right wrist (7.15%). The most common injury mechanism was falls from one's own height, eight patients (57.15%), and the other six (42.85%) were victims of traffic accidents.

All fractures were consolidated during the study. Radiographic results were obtained by measuring the angles of volar tilt and radial inclination, ulnar variance and articular step. For the measurement, wrist radiographs in AP and lateral radiographs were used, in the eighth postoperative week. Measurements were taken by two of the four authors, and the average among them was registered. Radial inclination had a mean of 13.70 º, ranging from 5 º to 22 º, representing a variance of 20.06 and a standard deviation of 4.48. Volar tilt had a mean of 0.85 º, ranging from 10 º to -3 º (3 degrees of dorsal tilt), configuring a variance of 8.26 and a standard deviation of 2.87. Ulnar variance had a mean of 0.60 mm, ranging from -1 mm to 4 mm, indicating a variance of 2.11 and a standard deviation of 1.45. Articular step had a mean of 0.78 mm, ranging from 0 to 3 mm, showing a variance of 1.16 and a standard deviation of 1.081. Table 1 shows the results.

Table 1. Recording of the averages obtained from radiographic parameters of each patient.

PATIENT	AGE	VOLAR TILT (DEGREES)	RADIAL INCLINATION (DEGREES)	ULNAR VARIANCE (MM)	ARTICULAR STEP (MM)
1	76	1	14	0	0
2	67	0	10	1	1
3	54	0	10	1	0
4	64	3	18	0	1
5	64	1	10	-1	2

6	63	1	10	0,5	0
7	58	0	5	0,5	0
8	54	0	15	3	3
9	51	0	18	0	3
10	49	-2	12	4	0
11	29	10	14	-1	0
12	73	-3	22	2	0
13	69	1	20	-1	1
14	80	0	14	-0,5	0

Source: Prepared by the authors.

Table 2. Acceptable radiographic parameters after fracture reduction.

PARAMETER	MEASURE
DORSAL TILT	UP TO 10 º
RADIAL INCLINATION	GREATER THAN OR EQUAL TO 10 º
ULNAR VARIANCE	UP TO 5 MM

Source: Prepared by the authors.

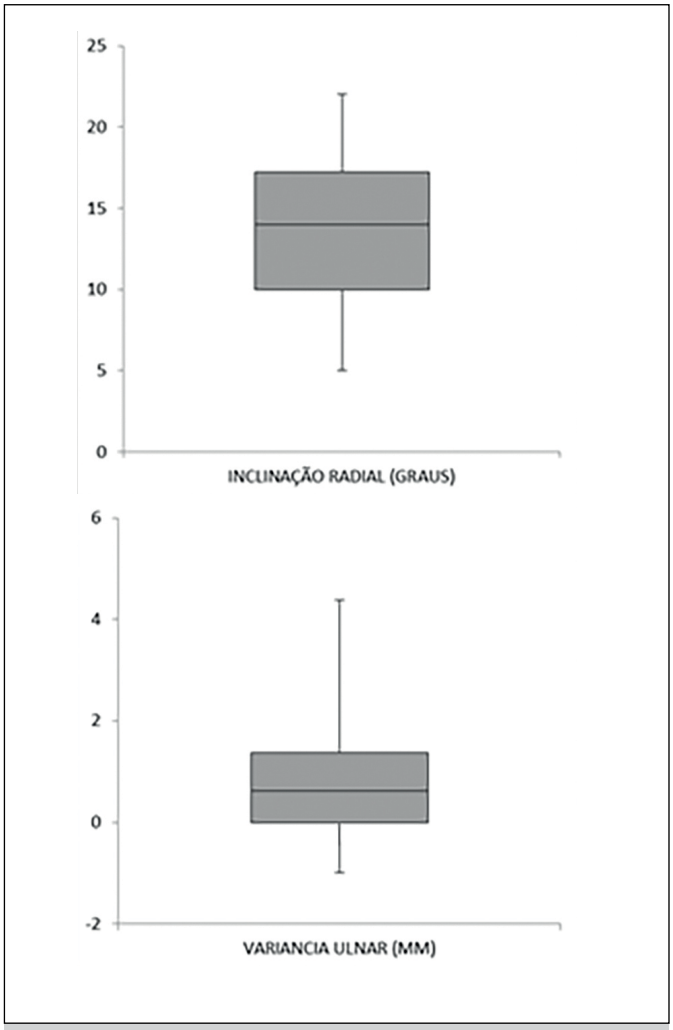

Figure 8. Box plot representations of obtained results for radial inclination and ulnar variance after treatment with spanning plates in the patients observed. Midlines represent medians, boxes represent standard errors, and vertical lines represent standard deviations.

DISCUSSION

We present a solution for a problem (complex unstable fractures of the distal radius) many procedures and techniques tried to solve. Currently, there are blocked plates, which show good results, but are not available in all departments. Maintaining stability is as important as reducing the fracture, since extreme comminution leaves them prone to collapse and malunion can lead to numerous complications, mainly post-traumatic osteoarthritis.[7,15]

Spanning plates, in addition to reducing the fracture, keep it stable, maintaining radius length and allowing the articular surface to consolidate without collapsing. A disadvantage is the plate needs to be removed after a new procedure, which can cause material fatigue and breakage if the plate is maintained for more than six months.[7,8]

Compared to external fixators, spanning plates do not keep open wounds on the skin or a bulky external device, reducing complications and facilitating patient management both in and outside the hospital.[8] Furthermore, Wolf et al.[16], via a biomechanical test, showed greater rigidity and stability when using spanning plates, compared to external fixators, as long as three proximal screws and three distal screws were used.

Two recent anatomical studies examined the risk of iatrogenic damage to the radial sensory nerve when using a spanning plate. Lewis et al.[17], after dissecting six cadavers, totaling 12 wrists, created unstable distal radius fractures, which were treated with a dorsal spanning plate in the second or third metacarpals. Compression of the radial sensory was not identified in none of them, but nerve branches were visualized when accessing fixation in the second metacarpal. Similarly, Dahl et al.[18] dissected 12 frozen cadavers and found branches of the radial sensory nerve were at risk when the second metacarpal was exposed and came into contact with the plate, which did not occur when the third ray was fixated.

Lauder et al.[19] reported almost total recovery of grip and extension strength after removing the spanning plate, especially in patients with wrist fractures on the dominant side.

The present study showed fixation of complex distal radius fractures using spanning plates reached solid results in terms of radiographic parameters. A satisfactory reduction was obtained in 11 of 14 patients, representing 78.5% of the total sample. Some study limitations can be indicated, such as small sample size, lack of direct comparison with another fixation method, and lack of patients' functional evaluation.

CONCLUSION

Distal radius fractures are a relevant injury in our daily lives, and their incidence increases every year. Overall, literature shows good functional results and reduced complication rates with the studied when compared to others, such as the external fixator.

Fixation using dorsal distraction plates is an excellent alternative when managing complex distal radius fractures in departments where blocked plates are unavailable. It is an effective and low-cost method, showing satisfactory results, especially regarding postoperative radiographic parameters. Therefore, it is a useful technique and should be present in the arsenal of hand surgeons and orthopedists.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. TFCR: writing and performing surgeries; ADF: review and final approval; JACV: critical review and data analysis and interpretation; JCOR: data acquisition and critical review; RMC: design and final approval.

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PREVENTION OF SYMPTOMATIC NEUROMA BY USING SYNTHETIC CONDUITS IN FINGER AMPUTATION STUMPS

PREVENÇÃO DE NEUROMA SINTOMÁTICO PELO USO DE CONDUÍTES SINTÉTICOS EM COTOS DE AMPUTAÇÃO DE DEDOS

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ABSTRACT

Objective: Compare the formation of symptomatic neuromas in patients submitted to digital amputations, with and without nerve conduits (Neurolac®), and sensitivity return. Methods: Prospective, case-control study, including 14 patients with digital amputations (total of 17 fingers) whose conduits were used on the ulnar or radial side, while the contralateral side was used in the same patients as control. The Tinel test, Semmes-Weinstein monofilament, and two-point discrimination tests were evaluated at one week, two weeks, one month, three months, and six months postoperatively. Results: Using nerve conduits (Neurolac®) *in* digital nerve amputation stumps had statistical significance (p = 0.04) in preventing pain due to symptomatic neuroma at the end of six months after digital regularization. Conclusion: There is a favorable trend towards using conduits as prophylaxis of symptomatic neuroma formation since the nerves in which they were used showed fewer clinical signs of neuroma formation six months after surgery. ***Level of evidence II, Prospective comparative study.***

Keywords: Amputation. Traumatic. Fingers. Neuroma. Nerve Conduit. Sensory Recovery.

RESUMO

Objetivo: Comparar a formação de neuroma sintomático em pacientes submetidos a amputações digitais com e sem uso de neurotubo (Neurolac®) e avaliar retorno de sensibilidade. Métodos: Estudo prospectivo, caso- controle. Amostra de 14 pacientes com amputações digitais (total de 17 dedos) onde foram utilizados conduítes no lado ulnar ou radial, enquanto o contralateral no mesmo paciente foi usado como controle. Avaliados quanto ao teste de Tinel, monofilamenteo de Semmes-Weinstein e discriminação de 2 pontos com 1 semana, 2 semanas, 1 mês, 3 meses e 6 meses de pós-operatório. Resultados: o uso de conduíte neural (Neurolac®) em cotos de amputação de nervo digital apresentou significância estatística (p = 0,04) na prevenção de dor decorrente de neuroma sintomático ao final de 6 meses da regularização digital. Conclusão: Há tendência favorável ao uso de conduíte como profilaxia à formação de neuroma sintomático, já que, os nervos em que foram utilizados, apresentaram menos sinais clínicos de formação de neuroma após 6 meses da cirurgia. ***Nível de evidência II, Estudo prospectivo comparativo.***

Descritores: *Amputação traumática. Dedos. Neuroma. Conduite de Nervo. Recuperação Sensorial.*

Citation: Wataya EY, Lopes DB, Takazono DK, Pessa MMN, Rusig RP, Sorrenti L, Torres LR, Wei TH, Rezende MR, Mattar Junior, R. Prevention of symptomatic neuroma for using synthetic conduits in digital amputation stumps. Acta Ortop Bras. [online]. 2024;32(Spe.2): Page 1 of 6. Available from URL: http://www.scielo.br/aob

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

The study was conducted at Universidade de São Paulo, School of Medicine, Institute of Orthopedics and Traumatology.
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ETHICS APPROVAL
This study was approved by the Ethics Committee under No. 4,707,488.

Article received on 02/11/2024, approved on 04/15/2024

INTRODUCTION

Traumatic digital amputations are frequent injuries, especially in manual workers, due to the use of circular saws, and can cause a high rate of functional disabilities.[1]

In the event of impossibility or failure of replantation, the approach to traumatic amputation of fingers is to regularize the stump to a lower bone level that allows primary closure, or the use of flaps that allow better coverage of the injury, without the need for shortening.

The most common procedure regarding radial and ulnar digital nerve stumps is neurectomy of each nerve under traction, made in a single section, and with a cold blade. This would prevent the formation of neuromas near the surgical scar, which can generate neuropathic pain and discomfort for manual functions.[2-4]

In some cases, even after an appropriate traction neurectomy symptomatic neuromas appear, which cause functional impairment to the patient.

New techniques for the reconstruction of a complex neurological injury, in which there is segmental loss, or distance between the nerve stumps, enable the use of nerve conduits as an alternative to autografts.[5]

Nerve conduits, or nerve tubes, are tubes usually made of synthetic silicone or polysaccharides, absorbable or not, which can serve as a guide for nerve regeneration in cases of injury with a distance between the stumps.[6] They create an appropriate microenvironment for axonal growth, which can generate good functional results[7-8], and do not bring morbidity to the donor area, such as autogenous grafts.[9-10] However, its use is restricted to cases in which there is a small distance between the nerve stumps.[11-12]

They can also be used in the treatment of post-traumatic neuroma as a support to contain the neuroma inside a cul-de-sac, which reduces neuropathy pain due to friction with the scar, with satisfactory results.[13-15] Koch (2011) had satisfactory results in the prevention of post-traumatic neuroma by transposing the nerve stump into a vein segment.[16]

However, in cases of digital amputations, injuries with great potential to generate neuroma, it is still uncertain whether the technique of restraining the nerve within the synthetic nerve conduit would better prevent symptomatic neuroma formation, compared to traction neurectomy alone.

Self-absorbing synthetic caprolactone conduit (Neurolac®) is an option for injury reconstruction with spacing between stumps, with good results and without risk of immunogenic reaction.[17-20]

The study aims to compare the formation of symptomatic neuroma in patients undergoing digital amputations with and without the use of neurotube (Neurolac®) and to evaluate return sensitivity using the Semmes-Weinstein monofilament test and the two-point discrimination test in nerves with and without conduit.

METHODS

This study was conducted at the IOT – HC – FMUSP and the sample consisted of patients coming from the emergency room or hospitalized. The study was approved by the Research Ethics Committee in Human Beings (IOT-HC-FMUSP) under Protocol No. 4,707,488. This was a prospective, randomized, double-blind, case-control study.

Inclusion criteria

- Patients with injuries in Verdan Flexor Zones one or two (distal to pulley zone A1).
- Patients with single or multi acute digital amputations with no indication for reimplantation.
- Patients who evolved with loss of reimplantation of one or more digits and regularization need.
- Application of a free informed consent form.

Exclusion criteria

- Loss of patient follow-up.
- Digital nerves not found in the stump.
- Complex, segmental, multi-level injuries.
- Patients with inclusion criteria for the study were randomized, by an observer out of the study, to apply the conduit to the radial or the ulnar digital nerve. Informed consent form was applied for the surgical procedure.

Epidemiological, injury descriptive, and trauma mechanism were collected from the patient data and placed in an Excel table.

- Patient data: Name, age, RGHC, comorbidities, occupation, dominant hand.
- Injury data: Trauma mechanism, injured digital, regularization level, injury zone (one or two Verdan), conduit use (in radial or ulnar digital nerve).

The outcome analyzed was formation or absence of symptomatic neuroma in digital amputation stumps after placement or not of nerve conduit.

Surgical technique

After bone regularization and before primary or via locoregional flaps closure, the ulnar and radial digital nerves will be dissected proximately to the ideal point for neurectomy, approximately 1.0 centimeters below the bone level (Figure 1).

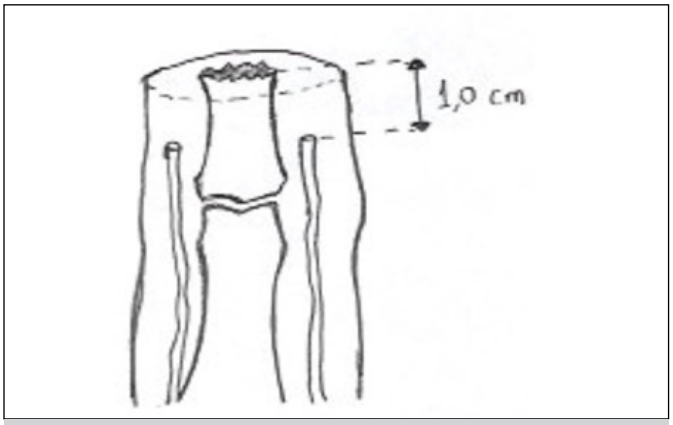

Figure 1. Amputation stump after bone regularization and cold neurectomy

The neurectomy will be done with a 15-scalpel blade, through a single cut.

Then, one of the radial or ulnar digital nerves will be capped with the conduit, with about 0.5 centimeters of distance between the nerve stump ending and the conduit ending (Figure 2).

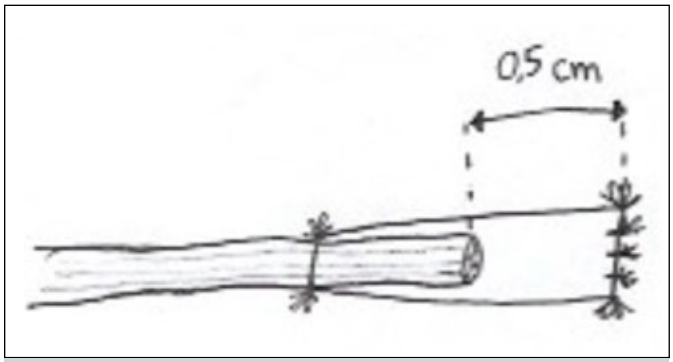

Figure 2. Nerve ending sutured with conduit in cul-de-sac.

<< SUMÁRIO

The conduit will be sutured to the nerve epineurium with two stitches at 180 degrees, with 8.0 Nylon suture thread (Figure 3). The conduit ending will also be sutured with 8.0 Nylon thread to restrain the nerve ending in cul-de-sac.

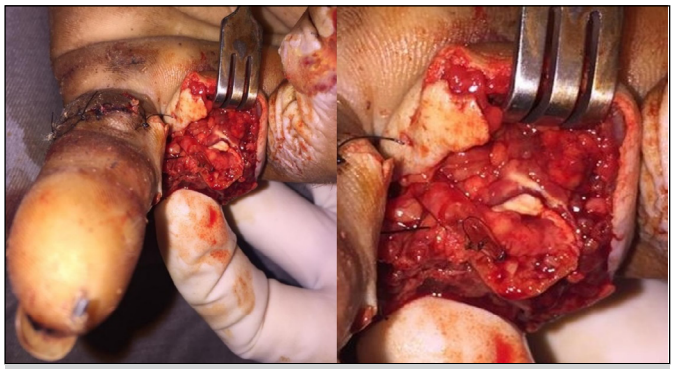

Figure 3. Clinical image demonstrating neurotube in the digital nerve.

Then, primary or via locoregional flaps closure will be performed, as indicated in each case.

Postoperative

The patients were discharged in the first postoperative period, with simple dressings, without the need for immobilization.
They used prophylactic antibiotics for at least one week.
The first return visit occurred after one week for surgical wound evaluation, in which there was already a referral to occupational therapy for evaluations.
Return in the second week for a new evaluation and stitches removal.
From then on, clinical evaluations were performed at one, three, and six months postoperative and involved:

- Search of symptomatic neuroma via pain presence in shock by the Tinel test, both to ulnar and radial sides of the amputation stump.
- Search for sensitivity feedback via Semmes-Weinstein monofilament test, and two-point discrimination, also for the radial and ulnar sides of the stump.

Statistical analysis

Descriptive statistics were used to describe the sample. The normality of the numerical variables (age, number of errors in the two-point discrimination test, and thickness of the Semmes-Weinstein monofilaments) was tested using the Shapiro-Wilk test, which did not indicate normality for all the variables analyzed. Therefore, the median, minimum (min) and maximum (max) values were used to describe the numerical variables.
Absolute (n) and relative (%) frequencies were used to describe categorical variables (Verdan's zone, surgical procedures, injury mechanisms, Tinel sign).
The differences in the Tinel sign occurrence (Yes vs. No) were tested for each follow-up period and for the last valid data of each patient via the McNemar test. The positive Tinel occurrence was considered as a positive outcome in cases in which Tinel sign was present equal to or greater than the contralateral nerve sign (Table 1).

Table 1. Evaluation of Tinel sign occurrence.

Outcome	Description	Example
Negative	Tinel sign lower than in contralateral nerve	Tinel sign of the case group lower than the control group
Positive	Tinel sign equal to or greater than in contralateral nerve	Equal positive Tinel sign between case and control

The Wilcoxon test was used to compare the thickness of the Semmes-Weinstein monofilament and the number of errors in the two-point discrimination test in each follow-up period and for the last valid data of each patient.
The $p < 0.05$ value was used as statistical significance for all comparisons. All analyses were performed using the statistical software Stata 14 (StataCorp, College Station, TX, EUA).

RESULTS

The study had an initial sample of 14 patients with a median age of 33.0 years (minimum eight and maximum 67 years). All patients had the right hand as dominant and three of them injured more than one finger, totaling 17 observations at the baseline of the study. Most injuries occurred in Verdan zone two (82.3%). At the end of follow-up, only four patients presented valid data, totaling a follow-up loss of 76.5%.
Table 2 shows the surgical procedures performed on the patients. Regularization of the second finger in FP was the most prevalent procedure in the sample studied (23.3%), followed by thumb regularization in IF (11.8%), third finger regularization in FM (11.8%), and fourth finger regularization in FM (11.8%).

Table 2. Types of surgical procedures performed (n = 17).

Procedure	Occurrence	%
Thumb regularization in IF	2	11.8%
Thumb regularization in FP	1	5.9%
Thumb regularization in MCF	1	5.9%
Regularization of the second finger in FD	1	5.9%
Regularization of the second finger in FP	4	23.3%
Regularization of the second finger in IFP	1	5.9%
Regularization of the second finger in IFP	2	11.8%
Regularization of the second finger in FP	1	5.9%
Regularization of the fourth finger in FM	2	11.8%
Regularization of the fourth finger in IFP	1	5.9%
Regularization of the fifth finger in IFP	1	5.9%

FP: proximal phalanx; FM: middle phalanx; FD: distal phalanx; MCF: metacarpal phalangeal joint; IFP: proximal interphalangeal joint; IFD: distal interphalangeal joint; IF: interphalangeal joint of the thumb.

Figure 4 shows the injury mechanisms reported by the patients. Most injuries (52.9%) were caused by circular saw handling, followed by injuries by industrial machinery (11.8%).

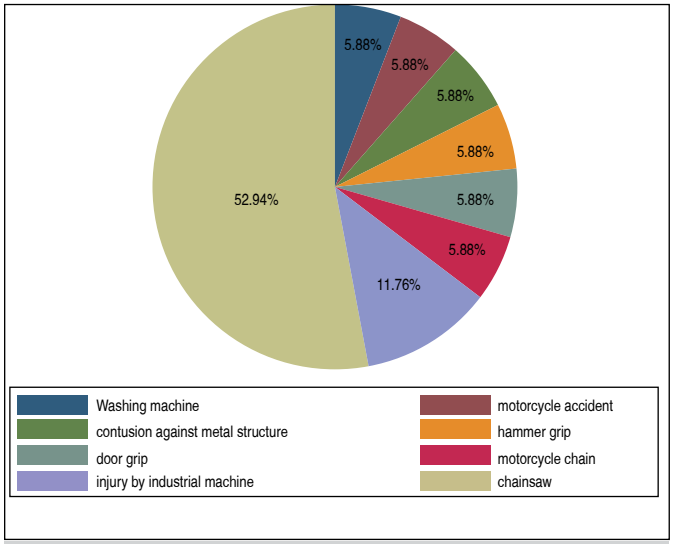

Figure 4. Injury mechanism

Of the 17 observations, nine had the use of conduit on the ulnar digital nerve and eight on the radial digital nerve. Follow-up of the patients occurred after one and two weeks and one, three and six months after the surgical procedure. Table 3 shows the occurrence of Tinel for each conduit using group over the follow-up period and using the last valid data from each patient.

Table 3. Tinel occurrence for each conduit using group during the six months of follow-up.

	Follow-up period										Last valid data (n = 34)	
	1 week (n = 28)		2 weeks (n = 24)		1 month (n = 18)		3 months (n = 16)		6 months (n = 8)			
Conduit use	**n (%)**	**p***	**n (%)**	**p***	**n (%)**	**p***	**n (%)**	**p***	**n (%)**	**p***	**n (%)**	**p***
Yes	14 (100%)	0.31	10 (83.3%)	0.15	5 (55.5%)	0.18	6 (75.0%)	1.00	**0 (0%)**	**0.04**	12 (70.6%)	0.25
No	13 (92.9%)		12 (100%)		8 (88.9%)		6 (75.0%)		**4 (100%)**		15 (88.2%)	

***** = p value for McNemar's accurate test; **n** = number of observations mixing the Case and Control groups.

Meaningful differences were observed only in the six-month follow-up period, with Tinel positive occurring only on the side without conduit use (p = 0.04). Table 4 shows the descriptive data and the comparison of the use of Semmes-Weinstein monofilaments between the groups in each of the follow-up periods and for the last valid data of each patient. The comparisons identified no important difference between the conduit using groups.

Table 5 shows the median, minimum, and maximum values of errors obtained in the two-point discrimination test for each conduit using group in the one, three, and six-month follow-up periods and for the last valid data of each patient. No difference was seen between the conduit using groups.

Table 4. Thickness of the Semmes-Weinstein monofilaments used in each conduit using group in the follow-up periods and for the last valid data of each patient.

	Follow-up period						Last valid data	
	1 month		3 months		6 months			
Conduit use	**Median (min - max)**	**p***	**Median (min - max)**	**p***	**Median (min - max)**	**p***	**Median (min - max)**	**p***
Yes	0.20 (0.05 – 0.20)	0.63	0.20 (0.05 – 0.20)	0.54	0.20 (0.05 – 0.20)	0.31	0.05 (0.05 – 0.2)	0.19
No	0.20 (0.05 – 4.0)		0.05 0.05		0.05 (0.05 – 0.05)		0.05 (0.05 – 4.0)	

***** = p value for the Wilcoxon test for differences between the conduit using groups.

Table 5. Number of errors obtained in the two-point discrimination test for each conduit using group in the follow-up periods and for the last valid data of each patient.

	Follow-up period						Last valid data	
	1 month (n = 14)		3 months (n = 7)		6 months (n = 4)			
Conduit use	**Median (min-max)**	**p***	**Median (min-max)**	**p***	**Median (min-max)**	**p***	**Median (min-max)**	**p***
Yes	4.5 (0 – 9.0)	0.94	5.0 (1.0 – 9.0)	0.93	3.5 (1.0 – 8.0)	0.84	4.0 (0 – 10)	0.93
No	6.0 (0 – 10.0)		3.0 (0 – 9.0)		2.5 2.0		3.0 (0 – 9.0)	

***** = p value for the Wilcoxon test for differences between the conduit using groups.

DISCUSSION

The formation of symptomatic digital neuroma is frequent and can cause limitations. Van der Avoort et al. (2013), in a retrospective cohort study, concluded the incidence of people with symptomatic neuroma after traumatic digital amputation is higher than people undergoing primary neurorrhaphy.[21] Also, patients with symptomatic neuroma have higher rates of reoperation than those with asymptomatic neuroma.

Vlot et al. (2018), also in a retrospective study, analyzed 1083 patients who underwent review of digital amputation stumps aiming to evaluate painful neuroma.[22] He concluded that about one in 15 patients will develop symptomatic neuroma after amputation and approximately 50% will require surgical review. Because of that, the development of methods that prevent the formation of neuroma that generates pain, or limitation of function after digital amputations, would reduce the risk of reoperations and functional impairment to the patient.

In the face of a traumatic digital amputation, some techniques are described in nerve stump management and in the prevention of symptomatic neuroma appearance. Swanson et al. (1977), Thomsen et al. (2010), and Gould et al. (2013) described good results in the prevention of symptomatic neuroma with nerve restriction within neurotubes.[13-15]

Thomsen et al. (2010) retrospectively evaluated the formation of symptomatic neuroma in digital nerves and common digital nerves after digital amputations in 10 patients, using collagen conduit.[14] After an average period of 18 months, it showed good results in 50% of cases in relation to the two-point discrimination. There was a decrease in sensitivity to light touch and protective sensitivity in about 80% of the cases and no cases of pain recurrence.

Gould et al. (2013) also evaluated the use of synthetic conduits in nerve stumps at the ankle and foot level.[15] In a retrospective study, out of a total of 69 nerves evaluated, 43% showed total improvement in pain after the use of the neurotube.

Lans et al. (2020), in a retrospective study, evaluated 33 symptomatic digital neuromas surgically treated through repair (39%), and simple excision with (30%) or without (30%) implantation of the stumps.[23] Cases in which repair or reconstruction was performed had better results in terms of pain improvement.

All these studies had good results, favorable to the use of some type of conduit that would prevent the onset of neuroma, but they were retrospective studies.

The use of synthetic nerve conduits, in addition to the good results in reestablishing neural connection and restraining the neuroma, thus improving symptoms, also has a low immunogenic response.[17-20]

Shin et al. (2009) functionally and histologically compared the use of autograft with several other types of nerve conduits in rat nerve gaps.[18] The neurotube consisting of caprolactone was like the autograft in the functional return in 10mm segmental defects of the sciatic nerve. Luis et al. (2007) was also favorable to caprolactone as a component of conduits regarding functional return responses and axonal regeneration rate.[24]

Bertleff et al. (2005) used the caprolactone substitute as a guide for nerve regeneration in segmental injuries compared to other neural reconstruction techniques, also presenting favorable results for the use of conduit in transects of nerves in the hand.[20]

In a series of 12 cases, Costa Serrão de Araújo et al. (2017) demonstrated that caprolactone conduits are also favorable in reestablishing sensory response in segmental nerve injuries of up to 25mm.[17]

This study aimed to prospectively analyze whether the use of caprolactone conduit (Neurolac®) can alleviate or prevent the formation of symptomatic neuroma in nerve stumps of digital amputations.

The sample of this study consisted of young adults, with a median age of 33 years, and the right hand affected. The amputations were mainly caused by a circular saw (52.9%), mainly affecting Verdan zone 2 (82.3%) of the index finger (23.3%). These data confirm the age group most likely to suffer severe trauma or amputations in the upper limb caused by circular saws in the national context and reinforce the need for correct and safe use during manual work.

Facing a single digital amputation in Verdan zone two, the success of reimplantation is questionable, due to the high chance of generating stiffness of the finger to be reimplanted, due to the high number of structures to be rebuilt in this region. This may be one of the reasons why the number of regularizations at this level was higher.

The presence of Tinel sign, which causes excruciating pain to nerve percussion, indicating the presence of neuroma, was positive in most observations of the first week after surgery, regardless of the group. Only one patient had a larger Tinel sign on the conduit side compared to the control; however no statistical difference was seen ($p = 0.31$).

In the second week and first month, the positive Tinel sign was more prevalent on the control side, and in the third month, the occurrence of Tinel was similar between both groups. Despite this higher prevalence of Tinel sign in the control group in the second week and first month, no statistical difference was seen ($p > 0.05$).

Only in the sixth postoperative month this comparison was statistically important, and in this period, in all cases in which conduits were not used, the Tinel sign was present.

The last valid data per patient in relation to Tinel sign showed that it was positive in 88.2% of the nerves without the conduit; versus 70.6% of nerves with conduit.

Regarding the sensitivity evaluation by the Semmes-Weinstein monofilament test, there was a favorable trend for nerves without conduit at three and six months. However, there was no statistical importance in any period. And, in the last valid data per patient, the nerves with and without conduit presented equal medians.

In the two-point discrimination test, patients had a lower rate of errors on the conduit side only in the first month. At three and six months after surgery, the median number of errors favored the side without the conduit. On the other hand, there was a higher rate of correct answers over time, which indicates an improvement in the return of sensitivity on both sides. No statistical importance was observed.

This study presented some limitations. The low number of patients and the small number of fingers evaluated negatively favored the analysis, interfering with the results.

Loss to patient's follow-up was also a limiting factor that interfered with data analysis. Some determining factors were, because these are injuring whose treatment is definitive and that presents rapid improvement, providing an early return to routine activities, the patients often missed the return for evaluations. The global COVID-19 pandemic may also be a negative factor that has contributed to the loss to several patients' follow-up.

Based on epidemiological data of the study, it is possible to ratify the importance of proper handling of circular saws and occupational safety measures for manual workers to avoid injuries, often mutilating.

An important difference with $p = 0.04$, favorable to the use of conduit, occurred at the end of the six-month follow-up in the Tinel test evaluation. However, the number of patients who maintained follow-up during this period was low.

The group analysis of the last valid data per patient favored the conduit use in the Tinel test; similar on the sides with and without conduit in the monofilament test; and favored the non-conduit side in the two-point discrimination test.

Even in the absence of statistical importance in most analyses, this study points to a favorable trend towards the use of conduit as a prophylaxis for the formation of symptomatic neuroma, since the nerves in which they were used showed fewer clinical signs of neuroma formation. A study with greater inclusion of patients and a lower rate of follow-up loss may elucidate the issue in favor or not of the use of conduit for nerve stumps after digital amputation.

CONCLUSION

The use of nerve conduit (Neurolac®) in digital nerve amputation stumps showed statistical importance in the prevention of pain resulting from symptomatic neuroma at the end of six months of digital regularization. However, there was no statistical difference in the sensitivity analysis at the end of the period.

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