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(Reviewed March 2021)

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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
	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective ¹ 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
11	Systematic review ^b of Level II studies or Level I studies with inconsis tent results	Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% followup)		
		Systematic review ^b of Level II studies		
	Case control study ^g	Case control study ^g	Study of non consecutive patients; without consistently applied reference "gold" standard	Analyses based on limited alternatives and costs; and poc estimates
ш	Retrospective ¹ 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

° 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.

⁹ 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.

ORIGINAL ARTICLE

GENERAL

EFFECT OF TRANEXAMIC ACID ON FRACTURE HEALING IN RATS

EFEITO DO ÁCIDO TRANEXÂMICO NA CURA DE FRATURA EM RATOS Erhan Bayram, Mehmet Yunlu, Deniz Gulabi, Ergun Bozdag, Murat Yilmaz,Dogan Atlihan DOI: http://dx.doi.org/10.1590/1413-785220223001e245670

ORTHOPAEDIC TELEMEDICINE SERVICES DURING THE CURRENT NOVEL CORONAVIRUS PANDEMIC

SERVIÇO DE TELEMEDICINA EM ORTOPEDIA DURANTE A ATUAL PANDEMIA DO CORONAVÍRUS Paulo Henrique Schmidt Lara, Carolinne Nascimento de Oliveira, Vinícius Tiburtino Chaves Oliveira, Thaisa Assad Araújo, Victor Otávio Moraes de Oliveira, Gustavo Gonçalves Arliani DOI: http://dx.doi.org/10.1590/1413-785220223001e252138

HAND

RADIOCARPAL FRACTURE DISLOCATIONS: A NEW CLASSIFICATION AND TREATMENT PROPOSAL

FRATURA-LUXAÇÃO RADIOCÁRPICA: NOVA CLASSIFICAÇÃO E PROPOSTA DE TRATAMENTO Emygdio José Leomil de Paula, Edgard de Novaes França Bisneto, Renata Gregório Paulos, Rames Mattar Junior DOI: http://dx.doi.org/10.1590/1413-785220223001e248404

KNEE

THE RESULTS OF A COMPARISON OF A BRAZILIAN AND AN IMPORTED KNEE PROSTHESIS - 5 YEARS OF FOLLOW-UP

OS RESULTADOS DE UMA COMPARAÇÃO DE UMA PRÓTESE DE JOELHO BRASILEIRA E UMA IMPORTADA - CINCO ANOS DE ACOMPANHAMENTO

Joao Henrique Costa Calegari, Thiago Cavalcante Coelho Marqueze, Omar Sharid Teixeira El Kadri, Eike Jefferson Galdino Pereira, Alexandre Oliveira Queiroz, Paulo Roberto Bignardi, Marcus Vinicius Danieli, João Paulo Fernandes Guerreiro DOI: http://dx.doi.org/10.1590/1413-785220223001e253870

PEDIATRICS

DOES ULNA FIXATION ALTER THE OUTCOME FOR DISTAL-THIRD FOREARM FRACTURES IN CHILDREN?

A FIXAÇÃO DA ULNA ALTERA O DESFECHO DAS FRATURAS DO TERÇO DISTAL DO ANTEBRAÇO? Jonatas Brito de Alencar Neto, Amanda Progênio dos Santos, Guthierrez Victor de Abreu Bezerra, Luiz Holanda Pinto Neto, Maria Luzete Costa Cavalcante DOI: http://dx.doi.org/10.1590/1413-785220223001e250848

THE ROUND LIGAMENT IN DEVELOPMENTAL HIP DYSPLASIA: ARE ITS MECHANICAL AND HISTOLOGICAL PROPERTIES PRESERVED?

O LIGAMENTO REDONDO NA DISPLASIA DO DESENVOLVIMENTO DO QUADRIL: SUAS PROPRIEDADES MECÂNICAS E HISTOLÓGICAS SÃO PRESERVADAS?

Alexandre Zuccon, Hamilton da Rosa Pereira, Sérgio Alexandre Alcântara dos Santos, Sérgio Luís Felisbino, Luís Antônio Justulin Junior, Daniele Cristina Cataneo

DOI: http://dx.doi.org/10.1590/1413-785220223001e235808

SHOULDER

A NEW ANATOMICAL PLATE FOR EXTRA-ARTICULAR DISTAL HUMERAL FRACTURES: BIOMECHANICAL STUDY

UMA NOVA PLACA ANATÔMICA PARA FRATURAS EXTRA-ARTICULARES DISTAIS DO ÚMERO: ESTUDO BIOMECÂNICO Harun Mutlu, Abdulkadir Polat, Mehmet Ümit Çetin, Serhat Mutlu, Teyfik Demir, Atilla Sancar Parmaksizoğlu DOI: http://dx.doi.org/10.1590/1413-785220223001e248473

HYLAN G-F 20 VERSUS TRIAMCINOLONE IN THE TREATMENT OF PRIMARY SHOULDER OSTEOARTHRITIS. RANDOMIZED TRIAL

HILANO G-F 20 VERSUS TRIANCINOLONA NO TRATAMENTO DA OSTEOARTRITE PRIMÁRIA DO OMBRO. ESTUDO RANDOMIZADO

Simone Tortato, Alberto de Castro Pochini, Carlos Vicente Andreoli, Carina Cohen, Paulo Henrique Schmidt Lara, Paulo Santoro Belangero, Benno Ejnisman

DOI: http://dx.doi.org/10.1590/1413-785220223001e244410

THE POLYMORPHISM OF METALLOPROTEINASES 1 AND 13 AND POSTTRAUMATIC ELBOW STIFFNESS

O POLIMORFISMO DAS METALOPROTEINASES 1 E 13 E A RIGIDEZ ARTICULAR PÓS-TRAUMÁTICA DO COTOVELO Gustavo de Mello Ribeiro Pinto, Jorge Henrique Assunção, Maria Cristina Leme Godoy dos Santos, Alexandre Leme Godoy-Santos, Mauro Emilio Conforto Gracitelli, Eduardo Angeli Malavolta, Fernando Brandão de Andrade e Silva, Arnaldo Amado Ferreira Neto DOI: http://dx.doi.org/10.1590/1413-785220223001e253503

SPINE

PERCUTANEOUS ENDOSCOPIC LUMBAR INTERBODY FUSION: RESULTS OVER 47 MONTHS OF FOLLOW-UP

ARTRODESE LOMBAR INTERSOMÁTICA ENDOSCÓPICA PERCUTÂNEA: RESULTADOS DEPOIS DE 47 MESES DE ACOMPANHAMENTO

Anibal Correia Silva, Tabata de Alcantara, Monica Paschoal Nogueira DOI: http://dx.doi.org/10.1590/1413-785220223001e249489

SPORT MED

PELVIC INCIDENCE AND OSTEITIS PUBIS IN PROFESSIONAL SOCCER PLAYERS

INCIDÊNCIA PÉLVICA E OSTEÍTE PÚBICA EM JOGADORES PROFISSIONAIS DE FUTEBOL

Fernando Mansano Rodrigues, Atul Kumar Taneja, Erica Narahashi, Flavio Duarte Silva, Artur Rocha Corrêa Fernandes, Guilherme G. Falotico,

André Fukunishi Yamada

DOI: http://dx.doi.org/10.1590/1413-785220223001e244380

TRAUMA

A NEW FLUOROSCOPY TECHNIQUE FOR SUPRACONDYLAR HUMERUS FRACTURES

UMA NOVA TÉCNICA DE FLUOROSCOPIA PARA FRATURA SUPRACONDILAR DO ÚMERO

Mirza Zafer Dagtas, Omer Kays Unal DOI: http://dx.doi.org/10.1590/1413-785220223001e246231

COMPARISON OF SINGLE- AND DOUBLE-PLATE FIXATION TECHNIQUES IN THE TREATMENT OF NONUNIONS OF THE HUMERAL SHAFT

COMPARAÇÃO DE TÉCNICAS DE FIXAÇÃO DE PLACA SIMPLES E DUPLA NO TRATAMENTO DE PSEUDOARTROSE DO CORPO DO ÚMERO

Mehmet Akdemir, Çağdaş Biçen, Mustafa Özkan

DOI: http://dx.doi.org/10.1590/1413-785220223001e240181

ISOLATED CAPITELLAR FRACTURE FIXATION WITH HEADLESS SCREWS IN DIFFERENT CONFIGURATIONS

FIXAÇÃO DE FRATURA ISOLADA DO CAPÍTULO DO ÚMERO COM PARAFUSOS SEM CABEÇA EM DIFERENTES CONFIGURAÇÕES Mehmet Baydar, Serkan Aykut, Muhammed Mert, M.Vakit Keskinbiçki, H.Emre Akdeniz, Kahraman Öztürk DOI: http://dx.doi.org/10.1590/1413-785220223001e244357

REVIEW ARTICLE

PEDIATRICS

COVID-19 AND UPPER LIMB ANOMALIES IN NEWBORNS: A REASON FOR CONCERN?

COVID-19 E ANOMALIAS DO MEMBRO SUPERIOR EM RECÉM-NASCIDOS: UM MOTIVO DE PREOCUPAÇÃO? Carlos Henrique Fernandes, Rodrigo Guerra Sabongi, João Baptista Gomes Dos Santos DOI: http://dx.doi.org/10.1590/1413-785220223001e252308

Systematic Review Article

HAND

SURGICAL TREATMENT FOR RHIZARTHROSIS: A SYSTEMATIC REVIEW OF THE LAST 10 YEARS

TRATAMENTO CIRÚRGICO DE RIZARTROSE: UMA REVISÃO SISTEMÁTICA DOS ÚLTIMOS DEZ ANOS Ricardo Lucca Cabarite Saheb, Breno Alves De Sousa Vaz, Thabata Pasquini Soeira, Filipe Jun Shimaoka, Carlos Fernando Pereira da Silva Herrero, Nilton Mazzer DOI: http://dx.doi.org/10.1590/1413-785220223001e246704

EFFECT OF TRANEXAMIC ACID ON FRACTURE HEALING IN RATS

EFEITO DO ÁCIDO TRANEXÂMICO NA CURA DE FRATURA EM RATOS

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ABSTRACT

Introduction: In this study we investigated the effect of tranexamic acid (TXA) on fracture healing in an established animal model, when used to stop bleeding in orthopedic trauma surgery. Materials and Methods: This study was a randomized, controlled, laboratory study. Eighteen Sprague-Dawley rats were randomly assigned to three groups, either receiving TXA intravenously (Group 1), TXA topically (Group 2), or isotonic TXA intravenously and TXA topically in the same amounts for the control group (Group 3). First, a Kirschner wire was inserted retrogradely into the femoral intramedullary canal. Then the femurs were fractured at the midshaft region with blunt guillotine. After 4 weeks, the rats were sacrified and the femurs harvested. Cortical bone volume, callus volume, and bone mineral density were calculated using computer tomography scans. Torsion tests were performed. Groups were compared by maximum torgue to failure and callus stiffness. Results: There were no statistical differences in torque to failure and stiffness between the 3 groups. There were no differences in mean total bone volume, callus volume, percent bone volume, or callus density between the groups. Conclusions: A single dose of topical or intravenous TXA has no negative effect on fracture healing when used in traumatic femur fracture surgery in an animal model. Evidence level II; Randomized controlled experimental study.

RESUMO

Introdução: Neste estudo, investigamos o efeito do ácido tranexâmico (TXA) sobre a consolidação de fraturas em um modelo animal estabelecido, quando é usado para estancar o sangramento em cirurgias de trauma ortopédico. Materiais e Métodos: Trata-se de estudo de laboratório randomizado e controlado. Dezoito ratos Sprague-Dawley foram atribuídos randomicamente em três grupos, que receberam TXA por via intravenosa (Grupo 1), TXA tópico (Grupo 2) ou isotônico por via intravenosa e tópico na mesma quantidade como grupo controle (Grupo 3). Primeiro, foi inserido um fio de Kirschner por via retrógrada no canal intramedular femoral. Em seguida, o fêmur dos animais foi fraturado na região média do corpo do fêmur com guilhotina romba. Depois de quatro semanas, os ratos foram sacrificados e os fêmures foram retirados. O volume do osso cortical, o volume do calo e a densidade mineral óssea foram calculados por meio de tomografia computadorizada e foram realizados testes de torção. Os grupos foram comparados de acordo com o torque máximo até a falha e a rigidez do calo. Resultados: Não houve diferença estatística no torque até a falha e rigidez entre os três grupos nem diferenças entre os grupos quanto ao volume médio total do osso, volume e densidade do calo e percentual de volume ósseo. Conclusões: Uma dose única de TXA tópico ou intravenoso não tem efeito negativo sobre a consolidação da fratura quando usada em cirurgia de fratura traumática de fêmur em modelo animal. Nível de evidência II; Estudo experimental controlado randomizado.

Keywords: Fracture. Orthopedic surgery. Tranexamic acid.

Descritores: Fratura. Cirurgia ortopédica. Ácido tranexâmico.

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INTRODUCTION

Uncontrolled bleeding and subsequent high blood loss is still one of the main causes for mortality and morbidity after severe multiple trauma. Life threatening blood loss has also been managed with relatively liberal use of allogeneic blood transfusions. Blood transfusions are associated with an increased risk of bacterial and viral infection and increased length of hospital stay^{1,2}. Previous studies have also showed allogeneic blood transfusion to be associated with a significantly increased risk of postoperative infection².

Tranexamic acid (TXA), a synthetic derivative of the amino acid lysine, is an antifibrinolytic agent that acts by binding to plasminogen and blocking the interaction of plasminogen with fibrin, thereby preventing dissolution of the fibrin clot³. TXA has demonstrated efficacy in reducing transfusion rates without increasing complications in patients undergoing elective orthopedic surgery, including arthroplasty and spine surgery^{4,5}. TXA also inhibits plasmin, which is known to induce proinflammatory effects by activation of monocytes, neutrophils, platelets, and endothelial cells; and by

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

The study was conducted at Istanbul University, Aziz Sancar Deneysel Tıp Araştırma Enstitüsü, and Istanbul Technical University Biomechanics Laboratory. Correspondence: Erhan Bayram, Ugur Mumcu Mah., Belediye Sok. No:7, Haseki Training and Research Hospital, Sultangazi, Istanbul, Turkey. bayerhan@yahoo.com

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inducing lipid mediators, cytokines, and proinflammatory genes ⁶. TXA acts like anti-inflammatory drugs, which have been associated with nonunion of fractures ⁷.

The aim of the current study was to investigate the effect of TXA on fracture healing in an established animal model, when used to stop bleeding in orthopedic trauma surgery. It was hypothesized that TXA would not reduce healing potential. This would provide valuable information regarding the potential clinical utility of TXA during orthopedic fracture fixation surgery.

MATERIAL AND METHOD

This study was approved by the Istanbul University Ethic Committee for Animal Experiments (2018/06) and all the procedures were in accordance with the 1995 Helsinki Declaration and the Ethics in Experimentation Animals. A total of 18 four-month-old male Sprague - Dawley rats, each weighting 400 g (380-420), were obtained from the central animal unit of Istanbul University and randomly assigned to three groups, either receiving TXA (30 mg/kg) intravenously (Group 1); TXA 30 mg/kg topical (Group 2); or a matched volume of 0.9% NaCl solution intravenously (Group 3). TXA dosage was calculated as Roy et al.⁸ described in their animal study. The animals were kept under standardized conditions regarding temperature ($22 \degree C \pm 1 \degree C$), humidity (55% - 5%), and 12-h/12-h light-dark cycles, and were fed ad libitum (Ssniff-Spezialdiäten, Soest, Germany) with free access to water and were not fasted before the experiments. At the postoperative period we used systemic analgesic (buprenorphine 0.01 mg/kg) for pain control. Kokubu et al. showed that they achieved hard callus and bridging callus formation at 4 weeks. So, we choosed timeframe as 4 weeks 9. At the end of week 4, all rats sacrified with injection of sodium pentobarbital (250 mg/kg). All femurs disarticulated and all soft tissue removed. After BT anaylses all bones wrepped in saline soaked gauze and frozen at -40 °C.

Femur Fracture Model

The skin was cleaned with alternating chlorhexidine and 70% ethanol scrubs. After a preoperative subcutaneous dose of buprenorphine hydrochloride analgesia (0.03-0.05 mg/kg), surgical anesthesia was achieved with a mixture of ketamine (80-120 mg/kg) and xylazine (12-16 mg/kg) introduced intraperitoneally. We introduced 0.12 ml TXA (30 mg/kg) for group 1 and 0.12 ml saline for group 2 and 3 parenteraly.⁸ With a sterile technique, a 20-mm longitudinal incision was made over the medial knee joint. The medial structures stabilizing the patella were divided and the patella manually dislocated laterally. A 1.2-mm-diameter Kirschner wire (TST, Istanbul, Turkey) was inserted retrograde into the femoral intramedullary canal beginning between the femoral condyles. The pin was cut as close as possible to the knee articular cartilage so that the tip was flush with the cartilage. The patella was relocated and stabilized with absorbable sutures, and the skin incision closed using suture clips. The femur was fractured at the midshaft using a three-point bending force generated by a blunt guillotine technique, as previously described ¹⁰. After this a 10-mm lateral incision was made at midshaft region of femur. Through an intramusculer approach fracture site visualised. 0.12 ml txa injected to fracture site for group 2 and the same amount of saline injected to fracture site for goup 1 and 3 and the skin incision closed using suture clips.

Biomechanical Analyses

The bones were thawed at room temperature in a saline bath 24 hours before mechanical testing. Torsion tests were performed until failure with a constant angular speed of 3°/second (MTS, İstanbul Technical University). The torque - angular displacement curve was obtained and used to determine callus stiffness. Maximum torque to failure was obtained from the same data.

Radiologic Analyses

Kirschner wires were removed before CT analyses. Scans were obtained for a 10-mm midshaft region of each bone, with the fracture line in the middle. Ten axial slices each 1mm thickness were obtained from each scan. In all sections the image of callus and cortical bone segmented manually after adjustment window. A three-dimensional reconstruction was made (Figure 1). Cortical bone volume and callus volume and bone mineral density were calculated by computer (Philips Extended Brilliance Workspace V4.5.6.52040). Total bone volume and callus volume was calculated as mm², and Callus Bone Density was calculated as mg/cm².

Sample Size

Sample size was calculated with G*Power Version 3.1.6 program (Faul F, Erdfelder E, Buchner A, Lang AG. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. Behavior Research Methods, 41, 1149-1160.). It was determined that biomechanical testing for 6 rats per group was adequate to detect a medium effect size (effect size = 1) with a statistical power of 0.95 and p<0.05.

Statistical Analyses

All data are reported as the mean and standard deviation. The statistical differences between groups were evaluated with a paired t-test and significance was set at p<0.05. Moment and stiffness differences between groups were assessed using the Kruskal-Wallis non-parametric test. Statistical analyses were performed using SPSS version 16.0 (SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. Chicago, SPSS Inc.).

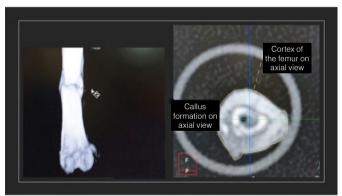


Figure 1. 3- dimensional reconstruciton of the femur and cortical bone - callus formation on axial

RESULTS

No animals were excluded because of operative or post-operative complications.

Torque to failure and stiffness were used as predictors for fracture healing. Torque to failure in groups 1, 2, and 3 were 164.95 ± 35.05 , 132.73 ± 48.54 , and 233.04 ± 120.45 Nmm, respectively. The torque load before fracture was slightly higher in the control group but this difference was not significant (p=0.12). There was no significant difference in stiffness between the 3 groups (32.75 ± 16.25 , 42.83 ± 17.46 , and $51.28\pm28\pm43$ Nmm/deg for groups 1, 2, and 3, respectively, p=0.491) (Table 1).

Radiologic Analyses

We analyzed the total volume, callus volume and density of the new bone with CT scans. Total bone volume was $29.32 \pm 7.70 \text{ mm}^2$ for group 1, 29.23 ± 5.02 for group 2, $24.83 \pm 9.54 \text{ mm}^2$ for group 3, callus volume was $17.60 \pm 9.27 \text{ mm}^2$ for group 1, $19.25 \pm 4.2 \text{ mm}^2$



for group 2 and 16.20 \pm 9.50 mm² for group 3.Callus bone density was 654.71 \pm 95.36 mg/cm² for group 1, 603.14 \pm 62.90 mg/cm² for group 2, and 583.57 \pm 85.61 mg/cm² for group 3. There were no differences between the groups in mean total bone volume, callus volume, percent bone volume, or callus density. The results are shown in Table 2.

Table 1. Biomechanical test results.					
Group 1 Group 2 Group 3 p-va					
Torque (Nmm)	164.95 ± 35.05	132.73 ± 48.54	233.04 ± 120.45	p = 0.12	
Stiffness (Nmm/deg)	32.75 ± 16.25	42.83 ± 17.46	51.28 ± 28.43	p = 0.491	

Table 2. Radiologic analyses

	Group1	Group 2	Group 3	p-value
Total Bone Volume (mm)	29.32 ± 7.70	29.23 ± 5.02	24.83 ± 9.54	p = 0.4
CallusVolume (mm)	17.60 ± 9.27	19.25 ± 4.20	16.20 ± 9.50	p = 0.713
Bone Volume (%)	56.30	65.47	61.21	p = 0.285
Callus Bone Density (mg/cm)	654.71 ± 95.36	603.14 ± 62.90	583.57 ± 85.61	p = 0.648

DISCUSSION

This prospective, randomized study investigated the effect of TXA on fracture healing when used to stop bleeding during fracture surgery. The main findings of the present study were that biomechanical and radiological assessments confirmed that topical or systemic TXA did not have adverse effects on fracture healing in the animal model. There were many studies published in the literature on adverse or positive effect of treatment modalities on fracture healing ¹¹⁻¹⁴. TXA was widely used nowadays especially in arthroplasty and spinal surgery to decrease the blood loss and mortality and morbidities related to the bleeding and allogenic blood tranfusions. Because of the anti-inflammatory effects of TXA, we researched its effect on fracture healing. In a recent study Cevik et al. showed that topical application of TXA during orthopedic fracture surgery may accelerate fracture healing and systemic use may delay healing according to histological and radiological findings¹⁵. Our animal model demonstrated that a single dose application via systemic or topical will not affect statistically significant callus formation, volume,

or density whereas total bone and callus volume. Although we could not confirm this findings with histopathological analysis, we believed that TXA could be used in fracture treatment after verifing our findings in prospective designed study including histopatological analysis. There is significant mortality and morbidity from traumatic fractures, which is associated with perioperative hemorrhage. The increased amount of blood loss can lead to complications including anemia. TXA is commonly used in knee and hip arthroplasty, and its positive effects in reducing blood loss, hemoglobin decreases, and allogenic blood transfusion rates have been reported in previous studies ^{4,16}. However, TXA is rarely used in traumatic fracture surgery, possibly due to the expectation of negative effects on fracture healing because of its anti-inflammatory properties ^{17,18}. The findings of the present study lend support to the safety of single-dose TXA use in traumatic fracture surgery.

There are some limitations in the present study. Firstly, this study investigates indirect diaphyseal femur fracture healing in a rat model, we need further researchs to learn the effect of TXA on human bone healing. Secondly, the fractures were stabilized with a non-locked Kirschner wire in the rat intramedullary canal, which helped to reduce but not eliminate micromotion.Thirdly, immunohistochemical and histopathological examinations were not conducted. Larger, well-designed, randomized controlled studies will help clarify any potential association between TXA and thromboembolic events, and more research is needed to determine the optimal dose and timing for TXA in orthopedic trauma patients.

CONCLUSION

The present study substantiate that a single dose of TXA has no negative effect on fracture healing when it is used in traumatic femur fracture surgery in an animal model. Further studies including histopathological assessments may demonstrate the safety of TXA in traumatic fracture surgery.

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AUTHORS' CONTRIBUTION: BE: design and writing of the work; YM: design of the work, performing surgeries; GD: data analysis, critical review; BE: design of the work, performed biomechanic tests; YM: review of the article and intellectual concept of the article; AD: critical review and final approval of the version of the manuscript.

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ORTHOPAEDIC TELEMEDICINE SERVICES DURING THE CURRENT NOVEL CORONAVIRUS PANDEMIC

SERVIÇO DE TELEMEDICINA EM ORTOPEDIA DURANTE A ATUAL PANDEMIA DO CORONAVÍRUS

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ABSTRACT

Introduction: To evaluate the use of telemedicine by physicians specializing in orthopaedics and traumatology at the authors' institution, and to assess the rates of satisfaction and resolution for this type of care. The current global coronavirus disease 2019 (COVID-19) pandemic has resulted in the expansion of telemedicine services. However, quality measures and barriers for physicians dealing with the rapid increase in patients have not been well described. Materials and Methods: This study included 255 patients with orthopaedic complaints. Between 24 and 48 hours after the appointment, independent physicians, who did not participate in the initial appointment. contacted one another to assess the degree of satisfaction with the appointment, and whether there was a solution to the orthopaedic complaint. Results: There was a need for referral for face-to-face consultation in only 13.8% of cases. When asked about the probability of recommending telemedicine to a friend/family member, the answer was 90.3%. The satisfaction rate with the service was 91.1% and 93.69% of patients would return for a telemedicine consultation. Telemedicine consultations solved the problem in 82.74% of cases. Conclusions: Telemedicine care in orthopaedics proved to be a service modality with a high rate of satisfaction among the patients evaluated. Level of evidence III, Retrospective cohort study.

Keywords: Orthopedics. Pandemics. Telemedicine.

RESUMO

Introdução: O estudo avaliou o uso da telemedicina por especialistas em ortopedia e traumatologia da instituição dos autores e avaliou os índices de satisfação e resolução desse tipo de atendimento. A atual pandemia causada pelo coronavírus 2019 (COVID-19) resultou na expansão dos serviços de telemedicina. Contudo, as medidas de gualidade e barreiras para médicos que lidam com o rápido aumento não foram bem descritas. Material e Método: Este estudo incluiu 255 pacientes com queixas ortopédicas. Entre 24 e 48 horas depois da consulta, médicos independentes, que não participaram da primeira consulta, entraram em contato para avaliar o grau de satisfação com o atendimento e se houve solução da queixa ortopédica. Resultados: Houve necessidade de encaminhamento para consultas presenciais em apenas 13,8% dos casos. Quando questionados sobre a probabilidade de recomendar a telemedicina para um amigo/familiar, a resposta dos participantes foi 90,3%. A taxa de satisfação com o serviço foi de 91,1% e 93,6% de pacientes que retornariam para consulta por telemedicina. As consultas de telemedicina resolveram o problema em 82,74% dos casos. Conclusões: O atendimento por telemedicina em ortopedia mostrou ser uma modalidade de serviço com alto índice de satisfação entre os pacientes avaliados. Nível de evidência III, Estudo de coorte retrospectivo.

Descritores: Ortopedia. Pandemia. Telemedicina.

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INTRODUCTION

Shortly after the outbreak and rapid spread of coronavirus disease 2019 (COVID-19), the World Health Organization declared it a pandemic on March 11, 2020¹. Governments around the world are quickly realising the impact of COVID-19 on healthcare services and the economy. Amid reports regarding the spread of the causative agent-severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-there is also recognition that online tools, such as telemedicine, can play a critical role in the global response to this crisis. Telemedicine is ideal for the management of communicable diseases. A key factor in delaying the transmission of a virus is "social distancing" ²⁻⁵, which is aimed at decreasing interpersonal contact. For patients with COVID-19, or those concerned about the possibility of being infected with SARS-CoV-2, telemedicine can help with remote assessment (screening) and the provision of initial care. For individuals not infected with SARS-CoV-2, especially those most at risk for being affected (e.g., elderly individuals with co-morbid or pre-existing medical conditions), telemedicine can

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The study was conducted at the Instituto de Ortopedia Prevent Senior.

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provide convenient and remote access to routine care without the risk for exposure to hospital environments or waiting rooms in physicians' offices and outpatient clinics⁶⁻¹⁰.

However, for telemedicine to be effective during the current COVID-19 pandemic and similar future events, we must ensure that the tool is properly integrated into existing health services. The purpose of this study was to evaluate the use of telemedicine in orthopaedics and traumatology consultations at our institution, and to assess the rate of satisfaction with and resolvability in this type of service.

METHODOLOGY

This prospective, observational study included 300 patients with orthopaedic complaints, who were treated by physicians specialising in orthopaedics and trauma from the authors' institution, using the institution's telemedicine platform. After initial consultation, the physicians completed a questionnaire addressing items such as diagnostic hypothesis, examinations requested, and proposed treatment, whether there was a need for referral for face-to-face consultation, and total consultation time. In the period from 24 to 48 h after the appointment, independent physicians, who did not participate in the initial appointment, contacted one another to assess the degree of satisfaction with the appointment and completed a questionnaire with questions including: age; what is the probability of indicating the telemedicine for a friend/family member: how satisfied you were with the service: if you would have a telemedicine consultation again; and if the consultation solved your problem. When the physicians get in touch to evaluate the care, the consent form is sent by e-mail or cell phone message, and if the patient agrees to participate, he/she will accept by e-mail or cell phone.

Inclusion criteria

Patients undergoing orthopeadic consultation using telemedicine during the study period.

Exclusion criteria

Patients who did not wish to or were not contacted for evaluation after care.

RESULTS

Of the 300 patients initially recruited, 255 were contacted. The mean age of the patients was 64.75 years (range, 15-95 years). The average consultation time was 22.65 min (range, 4-45 min). Summaries of the diagnostic hypotheses, requested examinations, and proposed treatment are presented in Tables 1 to 3, respectively.

Table 1. Distribution of diagnostic hypotheses.			
Diagnostic hypotheses			
Backacke	76,4%		
Rotator Cuff Syndrome	49,01%		
Gonarthrosis	37,2%		
Coxarthrosis	36,8%		
Neck pain	22,74%		
Lumbociatalgia	22,35%		
Carpal tunnel syndrome	11,3%		
Trigger finger	9,8%		
Back pain	9,01%		
Epicondylitis	6,27%		
Gluteal tendinopathy	5,88%		
Plantar fasciitis	5,09%		
Remaining	<5%		

Table 2. Distribution of requested exams.		
Requested exams		
None	43,89%	
Xrays	18,77%	
Ultrasound	10,32%	
Nuclear magnetic resonance	3,82%	
Computed tomography	2,88%	
Eletroneuromiography	0,93%	

Table 3. Distribution of treatments performed

Treatment	
Analgesic	87%
Physiotherapy	75%
Opioids	66%
Anti-inflamatories	65%
Acupuncture	51%
Chondroprotectors	25%
Orientation	20%
Shockwave therapy	3,5%

There was a need for face-to-face referral consultation in only 13.8% of cases. When asked about the probability of recommending telemedicine to a friend/family member, the response was "yes" in 90.3%, and the satisfaction rate with the service was 91.1%. A total of 93.69% of patients would return for a telemedicine consultation. Of the 15 patients who did not return, the reasons were as follows: they would not participate in telemedicine consultation in the orthopaedics specialty (n = 7); only if there was no face-to-face consultation (n = 5); only in cases of return (n = 2); and because physicians requested too many examinations in this type of care (n = 1). The consultation performed by telemedicine solved the problem in 82.74% of cases.

DISCUSSION

Due to the challenges imposed by the current coronavirus pandemic (i.e., COVID-19), we observed an increase in the use of telemedicine in orthopaedics. Current studies have reported that satisfaction rates with the use of telemedicine are comparable to those of face-to-face consultations, and patients who experience virtual consultation are more likely to seek this type of care in the future¹¹⁻¹⁷. In our study, we obtained similar results, with a high rate of satisfaction, as well as a high percentage of patients who would return to use this type of care.

Buvik et al.¹¹ conducted a randomised clinical trial involving 389 patients, of whom 86% preferred consultation by telemedicine in orthopaedics over personal consultation, and 99% indicated that they were satisfied or very satisfied with consultation by telephone. Sinha et al.¹⁶ conducted a non-randomised study in which they compared paediatric follow-up after fracture performed by telemedicine and in person. Although the satisfaction levels of the two groups were similar, telemedicine reduced the costs and time associated with consultation. In addition, only 8 of the 101 patients who were treated with telemedicine preferred the next consultation to be in person.

Bertani et al.¹⁷ performed a prospective evaluation of paediatric orthopaedic consultations between 2009 and 2011, and found that consultation by telemedicine resolved 90% of diagnostic doubts, although the clinical outcome was reported to be "good" or "very good" in only 81% of patients. Haukipuro et al.¹⁸ conducted a randomised clinical trial of orthopaedic services and found that the level of patient satisfaction was similar in the telemedicine (n = 76) and face-to-face (n = 69) consultation groups.



In a study by Hurley et al.¹⁹, 268 orthopaedists were interviewed about the use of telemedicine, in which 84.8% of surgeons were currently using telemedicine, but only 20.5% of surgeons used it before the COVID-19 pandemic. The satisfaction rate with the use of telemedicine ranged from 20.9% to 70.3%. Among those who used telemedicine, 75% used it for new patients, 86.6% for routine monitoring, and 80.8% for postoperative patients.

Orthopaedists were more easily able to perform the physical examination in patients who were already accompanied or who were in the postoperative period than in those who were undergoing the first consultation. Thus, they reported that after the COVID-19 pandemic, they tended to maintain telemedicine in these patients. A very important point is which patients experience the greatest benefit from using telemedicine. In our study, 15 patients reported that they would not return to consultations by telemedicine in orthopaedics. Of these, 46% reported that they would not participate in the orthopaedics specialty, 33.3% only if there was no face-to-face consultation, 13.3% only in return visits, and 0.06% stated that they would not participate the telemedicine consultation again because physicians ordered too many exams.

To our knowledge, this was the first study to investigate the use of telemedicine in orthopaedics in our country to enable the assessment of the perception(s) of patients who are subjected to this type of care. A limitation of this study was that there was no comparison with face-to-face consultations, not only to compare satisfaction and resolution rates, but also cost(s). An important question is whether orthopaedists actually request a greater number of tests in telemedicine services, given the limitations to physical examinations that may exist. Because our study was performed during the COVID-19 pandemic, we did not perform a comparison with the face-to-face consultation; however, we aim to do so in the near future. In addition, due to the characteristics of the beneficiaries of the health plan in our study, the average age was high. Among elderly patients, it may be more difficult to use telemedicine. However, there was a high rate of satisfaction among the patients who participated in our study, suggesting that advanced age is not necessarily a limiting factor for the use of this type of care.

CONCLUSION

Telemedicine care in orthopaedics proved to be a service modality with a high rate of satisfaction among the patients evaluated, and a high proportion returning to this type of care. Telemedicine demonstrated a high rate of resolvability without the need for referral for face-to-face consultation.

AUTHORS' CONTRIBUTION: Each author helped substantially to the development of this study. PHSL: Data analysis, critical review, study text and final approval. CNO, VTCO and TAA: Data acquisition. VOMO and GGA: Critical review and final approval.

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RADIOCARPAL FRACTURE DISLOCATIONS: A NEW CLASSIFICATION AND TREATMENT PROPOSAL

FRATURA-LUXAÇÃO RADIOCÁRPICA: NOVA CLASSIFICAÇÃO E PROPOSTA DE TRATAMENTO

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ABSTRACT

Introduction: The radiographic and surgical findings, and treatment of radiocarpal fracture dislocations, were analyzed retrospectively in 40 patients. Materials and Methods: All patients were classified according to Dumontier's radiological classification and compared with the surgical findings. Based on this analysis, a new classification and treatment are proposed. Results: From 1995 to 2018, 40 patients with radiocarpal fracture dislocation underwent surgery. Thirty-six were males and four were females. The mean age was twenty-four years (range: 18-45). Three dislocations were volar dislocations and 37 were displaced dorsally. Initially, 8 (20%) patients were classified as group I, 29 (72.5%) as group II, and 3 (7.5%) remained unclassified. The main variations occurred in group II. Seven fractures were stable after radial styloid fixation and 6 remained unstable. Sixteen fractures presented articular fragments or an interposed capsule, which prevented anatomical reduction using conservative maneuvers. Conclusion: Based in our intraoperative observations and surgical results, we believe that a more detailed classification should be adopted. Level of Evidence IV; Therapeutic Studies; Case Series.

Keywords: Carpal bones. Joint dislocations. Joint instability. Ligaments, articular. Radius fractures. Wrist injuries.

RESUMO

Introdução: Os achados radiográficos, cirúrgicos e o tratamento das fraturas-luxações radiocárpicas foram analisados retrospectivamente em 40 pacientes. Materiais e Métodos: Todos os pacientes foram classificados de acordo com a classificação radiológica de Dumontier e comparados com os achados cirúrgicos. Com base nessa análise, uma nova classificação e tratamento são propostos. Resultados: De 1995 a 2018, 40 pacientes com fratura-luxação radiocárpica foram submetidos à cirurgia. Trinta e seis eram homens e quatro mulheres. A média de idade foi de vinte e quatro anos (variação de 18 a 45). Três luxações eram volares e 37 dorsais. Inicialmente, 8 (20%) pacientes foram classificados como Grupo I, 29 (72,5%), como Grupo II e 3 (7,5%), permaneceram sem classificação. As variações principais ocorreram no Grupo II. Sete fraturas permaneceram estáveis depois da fixação da estiloide radial e 6 permaneceram instáveis. Dezesseis fraturas apresentaram fragmentos articulares ou cápsula interposta que impediu a redução anatômica por manobras conservadoras. Conclusões: Com base em nossas observações intraoperatórias e nos resultados cirúrgicos, acreditamos que uma classificação mais detalhada deva ser adotada. Nível de evidência IV; Estudos Terapêuticos; Série de casos.

Descritores: Ossos do carpo. Luxações. Instabilidade articular. Ligamentos articulares. Fraturas do rádio. Lesões do punho.

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INTRODUCTION

Radiocarpal fracture-dislocation is a complex injury characterized by dislocation of the radiocarpal joint, associated with avulsion of the dorsal or palmar cortical margin of the distal radius. Fractures of the radial and ulnar styloids are common. Reports in the literature vary widely from approximately 1 in 500 to 1 in 25 dislocations involving the wrist.^{1,2} This injury must, however, be differentiated from a shearing or rim fracture of the distal radius, in which the articular fracture is substantial and remains in contact with the carpus (Figure 1).³ Dorsal radiocarpal dislocations are more common than volar dislocations and account for 60% of cases.⁴ Historically, the prognosis of radiocarpal dislocation depends on the presence of intercarpal dislocations, and consequently, Moneim et al.⁵ proposed a classification based on it.

In a type I dislocation, the carpus remains intact, but tears of the radiocarpal ligaments cause the carpal bones to dislocate as one unit on the distal radius. In a type II dislocation, the ligaments connecting the carpal bones to one another are injured and therefore associated intercarpal dislocations are present (Table 1).

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The study was conducted at the Instituto de Ortopedia e Traumatologia, Hospital das Clínicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo, São Paulo, SP, Brazil. Correspondence: Emygdio José Leomil de Paula. Ovídio Pires de Campos St., 333. Cerqueira César, São Paulo, SP, Brazil, 05403-010. leomildepaula@uol.com.br

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Lately, Dumontier et al.⁶ reviewed 27 radiocarpal dislocations and proposed a new classification. Group I dislocations include all patients with radiocarpal dislocations and possibly fractures of the tip of the radial styloid process. Group II dislocations include fractures of the radial styloid process that involve more than one-third the width of the radial scaphoid fossa (Table 2). The basis for the distinction is that in the first group the volar radiocarpal ligaments are torn from the radius and need to be surgically repaired to avoid ulnar/volar translation and in the Group II, this is not necessary. Also, this classification, does not discern between radiocarpal dislocations that also have associated interposed fragments and /or intercarpal dislocations.^{7,8} We performed a retrospective study of our cases and based on our observations, some modifications on Dumontier's Classification are proposed.



Figure 1. A) Radiocarpal Dislocation B) Shearing or rim fracture of the distal radius.

Table 1. Moneim's classification.			
Туре	Description		
Type I	Radiocarpal fracture dislocation with fracture of the radial or ulnar styloid or both		
Type II	Radiocarpal fracture dislocation with fracture of the radial or ulnar styloid or both, with associated ligamentary lesion.		

Table 2. Dumontier's classification.

Туре	Description
Type I	Pure radiocarpal dislocation or with only a fracture of the tip of the radial styloid process.
Type II	Radiocarpal dislocation and an associated fracture of the radial styloid process that involved more than
71-	one-third of the width of the scaphoid fossa.

MATERIALS AND METHODS

A retrospective study of all radiocarpal fracture-dislocations referred to our service was performed. Age, gender and associated injuries were noted at the time of dislocation. Diagnosis of a radiocarpal fracture-dislocation was made on plain film injury radiographs and complementary CT scans when available. We postulated that type II lesions, according to Dumontier's classification, presents severe volar ligament injury that must be repaired. All patients underwent surgery, and the operative findings were analyzed and compared with pre-operative images. Ethical approval for this study was obtained from Hospital das clínicas HCFMUSP, Faculdade de Medicina, Universidade de Sao Paulo, São Paulo, Sao Paulo, Brazil (approval number 4.283.317).

RESULTS

Forty patients presented with radiocarpal fracture dislocations were treated between 1995 and 2018. There were 36 male and four females. The mean age was 24 years (range 18-45). Twenty-seven were right wrists and thirteen left wrists. None had open injury. All patients were involved with a high energy trauma: 26 motorcycle accidents, 10 falls from heights, and 4 a car accident. Due to the

violence of the event, we were not able to precise the mechanism of trauma and 26 patients presented associated injuries. The carpus was volary displaced in 3 patients.

Eight patients were graded as Group I (20%); 29 as group II (72.5%) and 3 unclassified (7.5%). However, in the group II, only in seven patients (24%), radiocarpal articulation remained stable after Radial styloid fixation and in 6 (21%), presented instability even after fixation of the Radial Styloid. In this cases, extensive capsular rent was observed, and anterior repair was performed (Figure 2).

In 12 (41%), interposed fragment of the anterior lip of the Radius, that were reduced and fixed with screws and four (14%) anterior lip avulsion and dorsal compression fracture, that were reduced and fixed with screws or support plates dorsally (Figures 3 and 4). Three patients, with radiocarpal fracture- dislocation, with fracture of carpal bone and or intrinsic ligamentary lesion were observed (Figure 5).

DISCUSSION

Isolated radiocarpal dislocations are very rare; besides radiocarpal fracture dislocations are much more frequent, although both are uncommon injuries.¹ In fact, this may be due to the low incidence

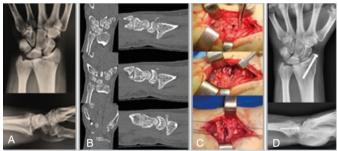


Figure 2. A) Dumontier's Type II, B) CT scans showing dorsal dislocations, C) Severe lesion of volar extrinsic ligaments and it's repair, D) Final radiographs.

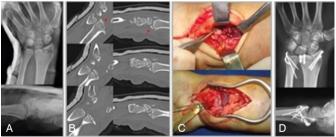


Figure 3. A) Dumontier's Type II, B) CT scans showing dorsal dislocations and large interposed volar fragment, C) volar rim of the radio rotated 1800 and it's temporary fixation after reduction, D) Final radiographs.



Figure 4. A) Dumontier's Type II, B) CT scans showing dorsal dislocations with major commitment of the dorsal rim of the radio, C) Severe lesion of volar extrinsic ligaments and fixation of the dorsal rim after reduction, D) Final radiographs.

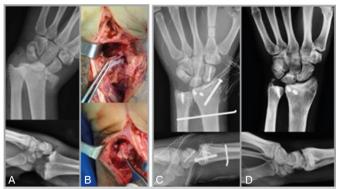


Figure 5. A) Unclassified radiocarpal dislocation, B) severe anterior capsular rent with associated FCT lesion, C) Immediate post reduction, D) Final radiographs.

of these lesions or because some authors include the radiocarpal fracture dislocations as a complex fracture in distal radius classifications.^{2,3,9} All patients in our series were involved in high energy trauma and associated lesions were frequent (65%).

Regarding the mechanism of this injury, an association of hyperextension, ulnar deviation and hiperpronation. This rotational movement should be the cause of frequent commitment of the distal radioulnar joint presented in the acute phase or as sequelae.^{3,6,8}

Graham¹⁰ described the pathomechanism of this injury in terms of transition forces that occur from lateral to medial aspect of the radius surface. He stated that pure ligamentary disruption seldom occurs, and these injuries are often associated by fracture of the radial styloid or at dorsal or volar margins. Two types of fracture patterns were described: a large fragment type and a small fragment type. The large radial styloid fracture runs obliquely from the area of the physeal scar near the crest separating the scaphoid and lunate fossa. This pattern, that in our understanding means a "traction fracture" was observed in 32 fractures of our patients. The small fragment type represents either avulsion by the stout extrinsic volar ligaments or impaction from the sub luxating carpus against the dorsal or volar margin of the radius.^{11,12} This study also suggested that the presence of ulnar-sided lesion is an indicative of more severe trauma. In our cases, despite absence of data, we didn't observe any case of pronation-supination impairment.

According with the adopted classification, in the group II, fixation of the Radial Styloid would be enough to stabilize the joint, because the volar ligaments remained attached in the radial styloid.⁸ However, in our data, in the 29 patients considered group II, only 7 (24%) wrists remained stable after Radial Styloid fixation. The remaining, presented a great variance of presentation, when compared with intraoperative findings, ranging from anterior extensive capsule injuries to anterior marginal interposed avulsion radius fractures. Only in 4 dislocations, with major commitment of dorsal margin at lunate fossae were observed. These most common pattern, the ligamentary lesion or fracture at the anterior lunate fossae, explains the late ulnar translocation of the carpus, observed in many cases classified as group II by Girard et al.¹³ and Lahtaoui et al.¹⁴

Lozano-Calderón et al.¹⁵ include the radiocarpal fracture dislocations in a spectrum of what they call "dorsal articular margin of the distal part of the radius with dorsal radiocarpal subluxation" with four main characteristics: 1) Impaction of the majority of articular surface with relatively intact volar metaphyseal fracture line; 2) True radiocarpal fracture dislocation: lesion of radiolunate ligaments; 3) Radiocarpal fracture-dislocation with fracture of the volar portion of the Lunate facet where the radio-lunate ligaments originate; and 4) central articular impaction with relative sparing of the radial styloid and the volar most portion of Lunate facet. We did not observe in any of our cases impaction of the majority of articular surface or central impaction with sparing of radial styloid. The main characteristic of our cases was the occurrence of a volar lip fracture avulsion of the radius, generally at lunate fossa, in 12 patients (41%). This characteristic has been mentioned, but not considered to determine another group, in the adopted classification or by other authors.¹⁶⁻¹⁸ In our understanding, the recognition and repair of the volar avulsion lip fracture is fundamental to maintain the stability of entire carpus and prevent any disability at distal radioulnar joint. The radiolunate and radioscapholunate ligaments are inserted at this site and this volar fragment, frequently, is also a part of distal radioulnar joint, that in our hands, it was impossible to achieve and maintain an anatomical reduction by close maneuvers or with isolated repair of the radial and ulnar styloids as cited by Mugdal et al.¹⁷ It's our opinion that in anterior lip fractures, surgical anterior fixation or ligaments reinsertion (with screws or bone anchors), prevents a chronic volar subluxation of the carpus and therefore, has a formal indication for anterior approach. As described by Bilos et al.¹⁹ and Schoenecker et al.²⁰ the dorsal approach is necessary to reduce, under direct vision, the radial styloid or elevate impacted fragments that were dorsally dislocated. The posterior approach was our initial exposure in 3 patients to reduce carpal fractures or in patients with dorsally impacted fractures.

Based on these observations and our results, we propose a modification on Dumontier's classification, specifying the more common standards of the Radiocarpal dislocation and fracture dislocations. The group I, pure ligamentary lesion and associated with volar lip of the Radius. In this case the anterior approach extended to the carpal tunnel, allows a very good exposure of the entire anterior capsule retracting the Flexors mass and Median Nerve radially and ulnary thus enabling, an attack angle for screws fixation if it is necessary (Figure 6). In group II, Stable after reduction of the Radial Styloid. In this situation, the fixation of the radial styloid is enough. If it remains unstable or translated, anterior approach is indicated because the anterior lesion is extensive at the radioulnar joint. Anterior lip avulsion fracture, reduction and fixation of it predate reduction and fixation of the radial styloid. In our experience, after this, reduction the Radial styloid is very simple and easy. When dorsal compression fracture is associated, dorsal approach is needed first, to stabilize the radiocarpal articulation and then, anterior approach is performed to repair the volar lesion. In all this situations, definitive fixation of the Radial Styloid is performed by last. In cases that carpal commitment is present, dorsal approach is also performed first to reduce or repair fracture or ligamentary lesion (Table 3).

CONCLUSION

We believe that a good understanding based on a rationale classification could lead to a better treatment with an anatomical repair with stable fixation assuring satisfactory functional results.

Table 3. Proposed classification.		
Type I: Radiocarpal Fracture dislocation without or a little commitment of the Radial and ulnar Styloid		
A. Extrinsic Ligament lesion (Dumontier's Group I)		
B. Anterior Lip avulsion fracture		
Type II: Associated with Transversal styloid radial fracture with volar or dorsal deviation		
A. Extrinsic ligament lesion, stable after reduction (Dumontier's Group II)		
B. Unstable anterior lip avulsion fracture		
C. Anterior lip avulsion.		
D. Anterior lip avulsion fracture with dorsal compression fracture		
Type III: Associated carpal lesion		
Carpal bone Fracture / Intrinsic Ligament lesion		



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THE RESULTS OF A COMPARISON OF A BRAZILIAN AND AN IMPORTED KNEE PROSTHESIS - 5 YEARS OF FOLLOW-UP

OS RESULTADOS DE UMA COMPARAÇÃO DE UMA PRÓTESE DE JOELHO BRASILEIRA E UMA IMPORTADA -CINCO ANOS DE ACOMPANHAMENTO

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ABSTRACT

Introduction: To compare the functional results, satisfaction rates, and revisions of total knee arthroplasties performed by the same surgical team using either Brazilian or imported implants, with a minimum follow-up of 5 years after surgery. Materials and Methods: A retrospective cohort study analyzing the medical records and interviews of patients who underwent total knee arthroplasty with Brazilian or imported implants with a minimum of 5 years after surgery. Results: One hundred and fifty patients were evaluated (164 knees). In the functional questionnaire, 71% of patients had favorable answers in the group of patients who underwent surgery using the Brazilian prosthesis and 74.8% in the group with imported implants (p=0.634). There was no statistical difference in satisfaction between the groups, with 78.4% of patients satisfied or very satisfied in the Brazilian implant group and 90.7% in the imported implant group (p=0.053). Loosening of the implants was reported in 5.3% versus 4.7% (p>0.999). Conclusion: The total knee arthroplasties performed by the same surgical team with a minimum follow-up period of 5 years showed similar levels of satisfaction, function, and complications with both the Brazilian and imported implants. Level of Evidence III, cohort study.

Keywords: Arthroplasty. Replacement. Knee. Knee prosthesis.

RESUMO

Introdução: Comparar resultados funcionais, índices de satisfação e revisões de artroplastias totais de ioelho realizadas pela mesma equipe cirúrgica usando implantes brasileiros ou importados, com acompanhamento mínimo de cinco anos após a cirurgia. Material e Método: Estudo de coorte retrospectivo com análise de prontuários e entrevistas de pacientes submetidos à artroplastia total do joelho com implantes brasileiros e importados com no mínimo cinco anos de pós-operatório. Resultados: Foram avaliados 150 pacientes (164 joelhos). No questionário funcional, encontramos 71% dos pacientes com respostas favoráveis no grupo de pacientes submetidos à cirurgia com uso de próteses brasileiras e 74,8% no grupo com implantes importados (p = 0,634). Em relação à satisfação, não houve diferença estatística entre os grupos com 78,4% dos pacientes satisfeitos ou muito satisfeitos no grupo com implante brasileiro e 90,7% no grupo com implante importado (p = 0.053). A ocorrência de soltura dos implantes foi relatada em 5,3% versus 4,7% (p > 0,999). Conclusões: As artroplastias totais de joelho realizadas pela mesma equipe cirúrgica com acompanhamento mínimo de cinco anos apresentaram níveis semelhantes de satisfação, função e complicações com os implantes brasileiros e importados. Nível de evidência III, estudo de coorte.

Descritores: Artroplastia. Substituição. Joelho. Prótese de joelho.

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INTRODUCTION

Degenerative osteoarthritis affects 4% of the Brazilian population¹. The best solution found to treat advanced knee osteoarthrosis is total arthroplasty and, in developed countries, the increase in arthroplasties already produces relevant social and economic impacts¹. A large proportion of total knee arthroplasties in our country

is performed with imported implants which, thanks to the exchange rate discrepancy, transportation, taxes and import costs, can cost twice the price of the material manufactured in Brazil². Imported implants are widely used abroad, many cases are monitored and have durability rates that reach up to 82% in 25 years³. Some Brazilian implants have shown good durability in biomechanical

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The study was conducted at the Hospital de Ortopedia Uniort.e and the Hospital Evangélico de Londrina. Correspondence: João Paulo Fernandes Guerreiro, Av. Higienópolis, 2.600, Londrina, PR, Brazil, 86050170. drjoaopauloguerreiro@gmail.com

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tests⁴, but we do not have large clinical studies with a long follow-up period proving the same durability and results. Some national case series have already demonstrated good results and low revision rate with some Brazilian implants in a medium-term follow-up⁵⁻⁶. The choice of implant impacts health care costs and generates a lot of conflicts between surgeons and health managers⁷⁻⁸.

Our objective was to evaluate whether there are differences in functional results, satisfaction rates and revisions between Brazilian and imported implants used by the same surgical team and with a minimum follow-up of 5 years after surgery.

Our hypothesis was that there is no difference in satisfaction, function, and revision rates between imported and Brazilian implants used by the same surgical team with a minimum follow-up time of 5 years.

MATERIALS AND METHODS

A retrospective cohort study was carried out with analysis of medical records of 377 patients who underwent total knee arthroplasty using Brazilian and imported implants. All patients were operated on by the same team, which included three knee surgeons, between 2010 and 2015. The data collection took place between August 2020 and June 2021 after approval by the Research Ethics Committee. The preoperative inclusion criteria were patients with primary osteoarthritis, Ahlbäck classification⁹ of arthrosis type 3, 4 and 5. The postoperative inclusion criteria were a minimum follow-up of 5 years and complete medical records. The preoperative exclusion criteria were valgus deformity, osteoarthritis secondary to inflammatory diseases and fracture sequelae. The postoperative exclusion criteria were patellar replacement, use of an implant with preservation of the posterior cruciate ligament, the impossibility of phone contact for interview and patients who did not agree to participate in the phone interview after reading the informed consent form.

The selected cases were subdivided into two groups: "national" when undergoing surgery with the Brazilian implant (MB®, Meta Bio Ltd., Rio Claro, São Paulo, Brazil) and "imported" when undergoing with the imported implant (NexGen®, Zimmer, Warsaw, IN, USA). The two models of prosthesis used have a similar design (Figure 1) and compatible surgical instruments. The choice of the type of implant for each patient was based on the option of the surgeon, the patient, and the health plan at the time of surgery.

In medical records, we searched for the following information: name, gender, date of birth, date of surgery, type of implant used and whether the patient underwent a new surgery (arthrofibrosis release, cleaning without exchange material, osteosynthesis due to



Figure 1. A and B: Brazilian Implant; C and D: Imported Implant.

peri-prosthesis fracture or revision surgery), if the patient underwent revision surgery, what was the cause (stiffness, infection, aseptic loosening, peri-prosthetic fracture or anterior pain requiring patellar replacement). In the interview with the patient, we searched for new information about treatments or the need for new surgeries not reported in the medical record and asked about the degree of satisfaction with the procedure (very dissatisfied, a little dissatisfied, a little satisfied, satisfied or very satisfied), if he would underwent the surgery again (if yes or no), and if there were symptoms at that moment related to the operated knee (yes or no), what symptoms were present: any difficulty to walk (yes or no), if he could support his body weight on the operated leg (yes or no), if he had any difficulty using stairs (yes or no), any difficulty to squat (yes or no), the presence of knee swelling (yes or no), if he could bend the knee to 90 degrees of flexion (yes or no), if he felt any disturb such as crackles or "noise" when moving the knee (yes or no).

For the analysis of qualitative variables, the Chi-square test or Fisher's Exact test was used. For quantitative variables, the Shapiro-Wilk test was first applied to verify normality, then the Mann-Whitney test was used for non-normal data and t test for variables with Gaussian distribution. The results were analyzed using the Statistical Package for Social Sciences program (SPSS Inc., Chicago, IL, USA) - 18.0, with a confidence level of 5% being established for all applied tests.

RESULTS

We selected 125 patients (143 knees) that met the inclusion and exclusion criteria. There were 57 patients in national group and 86 in the imported group. The two groups matched in age, sex, and follow up (Table 1).

Regarding the answers to the functional guestionnaire that we created, we found 71% of patients with favorable responses in the group of patients submitted to the Brazilian prosthesis and 74.8% in the group with imported implants, with no statistical difference between the groups (Figure 2). Regarding satisfaction, there was also no statistical difference between the groups with 78.4% of satisfied or very satisfied patients in the group with Brazilian implants and 90.7% in the group of patients with imported prosthesis (Figure 3). Evaluating new surgeries, aseptic loosening and other causes, we found similar rates between the implants (Table 2).

Table 1. Demographic data.					
	National	Imported	P Value		
Age (years)	76,1 ± 6.5	74,8 ± 7,7	0.294		
Gender (F/M)	43/14	67/21	0.698		
Follow-up (years)	6,85 (5,2 - 9,64)*	6,56 (5,18 - 9,96)*	0.292		

*Average (IQR).

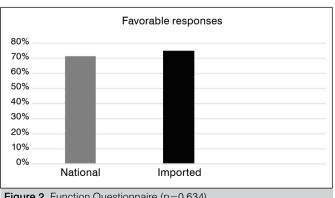


Figure 2. Function Questionnaire (p=0.634)

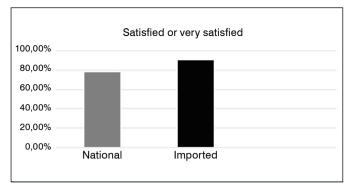


Figure 3. Satisfaction Index (p=0.053).

Table 2. Complications.

	National	Imported	P Value
New surgery	11/57 (19,3%)	12/86 (14,0%)	0.725
Infection	3/57 (5,3%)	4/86 (4,7%)	>0,999
Aseptic loosening	3/57 (5,3%)	4/86 (4,7%)	>0,999
Arthrofibrosis	2/57 (3,5%)	2/86 (2,3%)	>0,999
Fracture	0/57 (0%)	1/86 (1,2%)	>0,999
Haematoma	3/57 (5,3%)	1/86 (1,2%)	0,301

DISCUSSION

This study shows that, in a medium-term follow up, the results of surgeries with Brazilian and imported implants performed by the same medical team had statistically similar results regarding satisfaction rate, functional results and complications.

Our results of satisfaction and functional questionnaire were comparable to the national and international literature and regardless the type of implant used^{5-6,10-12}. Kahlenberg et al.¹² shows, in a retrospective cohort, similar results of improvement in function and satisfaction among 4069 patients undergoing five of the most common different international brands of implant.

Aseptic loosening rate in this study was 4.8% in the evaluated patients. In a literature review, Labek et al.¹³ found a 12% rate of revisions in 10 years in the largest international series. We found good results regarding aseptic loosening in two case series with Brazilian implants with a mean follow-up of 5 years⁵⁻⁶ and in another national case series that used the imported implant¹⁰ with similar follow-up. Barreto et al.⁵ presents in his series 58 knees and no revision due to aseptic loosening. He reports only 3 cases of asymptomatic patients with radiolucents on radiographs. Vasconcelos et al.⁶ presents the results of 53 knees and does not report loosening or revisions. Fuchs et al.¹⁰ with imported implants presents 68 knees and 2 cases (2,9%) of aseptic loosening. One case with loosening due to wear of the patellar component and another case in a patient with rheumatoid arthritis. This study has several limitations. First, the mean follow-up time was 6.6 years, while we predict a durability of more than 15 years in most cases. Second, the number of patients is limited for a retrospective cohort on this topic. Third, we didn't do any objective functional tests on the patients, just a simplified questionnaire about function, so the patient could understand and answer on the phone. This can make it difficult to compare our results with other studies. Due to the fact that we evaluated a population of patients from the same center and operated by the same team, we believe there was an advantage in making these comparison. We know that the implant is just one of the factors that lead to a successful procedure⁷⁻⁸. There are several other factors that hinder the analysis of the results of arthroplasties in our country, such as: the heterogeneous characteristics of the services that perform arthroplasties: the lack of documentation of results: the low adherence of patients to long-term follow-ups (especially in cases with good results); cultural, structural, and socioeconomic issues that limits the access to medical services^{1,14}. Our study showed, as well as the few previous case series using Brazilian implants⁵⁻⁶ that the Brazilian implant has results comparable to the imported. A better investment in registries and in follow-up of patients using these implants can lead to an increase in the reliability of the Brazilian implant. This can contribute to cost reduction and economic improvement for our healthcare system.

CONCLUSION

Total knee arthroplasty performed by the same surgical team in a minimum follow-up period of 5 years showed similar levels of satisfaction, function, and complications between the Brazilian and imported implants used.

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DOES ULNA FIXATION ALTER THE OUTCOME FOR DISTAL-THIRD FOREARM FRACTURES IN CHILDREN?

A FIXAÇÃO DA ULNA ALTERA O DESFECHO DAS FRATURAS DO TERÇO DISTAL DO ANTEBRAÇO?

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ABSTRACT

Introduction: Fractures of the distal third of the forearm are common in the pediatric population. Conservative treatment of an ipsilateral fracture of the distal ulna metaphysis is one of the risk factors for loss of reduction. Percutaneous fixation of the fracture with K-wires is recommended. This study aims to evaluate the outcome of percutaneous fixation of both bones performed as the primary treatment. Materials and Methods: A randomized, open, prospective, clinical trial was conducted, including skeletally immature patients who underwent surgery for fractures of the distal radius and ulna. They were randomized into two groups, one with fixation only of the radius fracture and the other with fixation of both the radius and the ulna fractures, and they were followed clinically and radiologically for up to 12 weeks postoperatively. Results: Sixteen children were selected. In the intraoperative period, fluoroscopy was activated for a longer time when fixing the ulna (p = 0.011) and the surgical time was longer in this group (p = 0.014). In the postoperative evaluations, the group whose surgery involved the fixation of both bones had a lower postoperative pain score (p <0.001) and less time away from school (p <0.001). Conclusions: In this study, postoperative pain and absence from school were both less when fixation of the radius and ulna was performed. Evidence Level II; Randomized Controlled Study.

Keywords: Bone fractures. Forearm. Bone wires.

RESUMO

Introdução: As fraturas do terço distal do antebraço são comuns na população pediátrica. O tratamento conservador da fratura ipsilateral da metáfise distal da ulna é um dos fatores de risco para a perda da redução. Recomenda-se a fixação percutânea da fratura com fios K. Este estudo tem como objetivo avaliar o resultado da fixação percutânea de ambos os ossos realizada como tratamento primário. Materiais e Métodos: Foi realizado um estudo clínico randomizado, aberto e prospectivo, que incluiu pacientes com esqueleto imaturo que foram submetidos à cirurgia para fraturas da parte distal do rádio e a ulna. Os participantes foram randomizados em dois grupos. um com fixação apenas da fratura do rádio e outro com fixação das fraturas do rádio e da ulna, e foram acompanhados clínica e radiologicamente por até 12 semanas de pós-operatório. Resultados: Dezesseis crianças foram selecionadas. No intraoperatório, a fluoroscopia foi ativada por mais tempo na fixação da ulna (p = 0,011) e o tempo cirúrgico foi maior nesse grupo (p = 0,014). Nas avaliações pós-operatórias, o grupo cuja cirurgia envolveu a fixação de ambos os ossos teve escore de dor menor depois da cirurgia (p < 0,001) e menos tempo de afastamento da escola (p < 0,001). Conclusões: Neste estudo, a dor pós-operatória e o afastamento da escola foram menores guando se realizou fixação do rádio e da ulna. Nível de Evidência II; Estudo randomizado controlado.

Descritores: Fraturas ósseas. Antebraço. Fios ortopédicos.

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INTRODUCTION

Fractures of the distal third of the forearm correspond to approximately 21% of all fractures in the pediatric population.¹ Conservative treatment is the generally preferred in the long-term follow-up of children with metaphyseal fracture of the distal radius, consisting of closed reduction and immobilization with plaster.² However, unacceptable displacement of reduction after this treatment method can occur in up to 39% of patients.³ Zamzam and Khoshhal observed that the initial displacement of the fragments is the most important risk factor for loss of fracture reduction.⁴ In completely displacement fractures, even after anatomical reduction, there is a high risk of loss of reduction, therefore percutaneous fixation with Kirschnner wires (K-wires) is recommended to maintain alignment.⁵

The ipsilateral fracture of the distal ulna metaphysis is also a risk factor for loss of reduction.⁶ Ozcan M, et al cite the presence

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of ulna fracture associated with a distal radius fracture as an indication of percutaneous fracture fixation with K-wires to prevent loss of reduction. $^{\rm 5}$

Studies on the theme commonly do not differentiate the results of isolated fractures of the distal third of the radius from those that occur associated with fracture of the distal third of the ulna.¹ Furthermore, fixation of the ulna when fixing the radius is also not a consensus in the literature.

This study aims to evaluate the clinical and radiological outcome of patients with fracture of the distal third of the forearm bones of children and adolescents when subjected to fixation with K-wires of both bones as the primary treatment. Secondarily, it seeks to identify the impact of the fixation of the two bones in the intraoperative period.

METHODS

A study carried out from June 12, 2019 to June 1, 2020, at a tertiary referral hospital in childhood traumatology.

This study included patients with an immature skeleton on radiography (that is, those whose growth plate is still open) and aged up to a maximum of 16 years, 11 months and 30 days,⁷ of both sexes, with fracture of the distal metaphyseal region of the forearm bones for surgical indication - considered when there is at least one fracture instability criterion, such as initial angle of fracture greater than 30 degrees, association with complete fracture or plastic deformity of theulna, initial displacement of fragments greater than 50%⁸ and were operated on at the Hospital of the study in the period from June 12, 2019 to June 1, 2020 by a single surgeon with expertise in child orthopedic trauma.

The study excluded patients who voluntarily did not return for post-operative consultations, those who had a fracture of only one forearm bone, those whose patients did not sign the Informed Consent Form or those legally responsible did not sign the Term Informed Consent Form.

A clinical, randomized, open and prospective study was carried out. The patients were divided into two groups: group A formed by the patients in which the radius and ulna were fixed and group B formed by the patients in which only the radius was fixed. The sample size was defined based on the study by Ozcan et al⁵ being estimated at 40 patients in total to obtain statistical relevance.

During the study period, 16 patients were operated who met the inclusion and exclusion criteria, with six participants allocated to group A - fixed radius and ulna - and ten participants to group B - only the radius was fixed. All operated patients were followed up until the end of the study. (Figure 1)

Randomization was performed using Microsoft Excel® (Microsoft Corporation, Redmond, WA) to randomly select from a sample space of 40 numbers 20 participants in each group. The 40 numbers were then allocated in opaque envelopes to be opened only in the operating room to define which group the patient would belong to. All data obtained in the study were allocated in a spreadsheet using Microsoft Excel® (Microsoft Corporation, Redmond, WA).

After a patient of the study profile was admitted to the hospital, during hospitalization in the pediatric ward awaiting surgical treatment, he was invited to participate in the study by one of the researchers, and after consenting, preoperative information was filled in, which is identification, epidemiological and trauma-related data - mechanism, date and time - and fracture - deviation, percentage of contact between the fragments, angulation, shortening and presence of bone exposure. Until the surgical intervention was performed, the patient waited immobilized with an axillopalmar plastered splint.

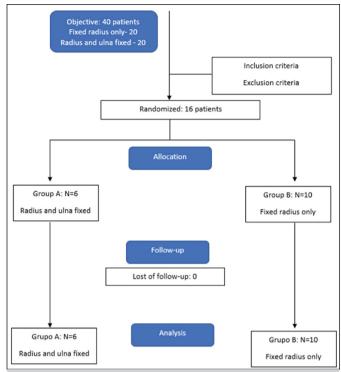


Figure 1. Patient enrollment as shown through a Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram.

Surgical technique

The surgical procedure was performed with the patient in horizontal supine position under regional anesthesia using brachial plexus block via supraclavicular and axillary guided by - model GE Healthcare Venue [™] 40 - and peripheral nerve stimulator Stimuplex® DIG RC (B. Braun, Melsung, Germany) and Levobupivacaine 0.2 - 0.25% associated with sedation with fentanyl 50 - 100mcg and midazolam 2-3mg(9). A single closed reduction attempt was made before degermation (retirar?),¹⁰ which was checked under fluoroscopy. When the fracture reduction was satisfactory, the radius was fixed percutaneously using two 1.5mm kirschnner wires and a 1.5mm kirschnner wire for ulnar fixation if it was assigned to the patient in guestion and immobilized with an axillopalmar plaster splint. The quality of the obtained reduction was classified as anatomical reduction (anatomical restoration). good (<10° angulation or <2mm translation) and reasonable (10-20° angulation or translation 2-5mm).

Fluoroscopy was activated during surgery to check the reduction and fixation at the surgeon's discretion. The fluoroscopy equipment used is a Philips BV Pulsera CE 0344 (Koninklijke Philips Electronics N.V., Holland), which makes it possible to check how many times the fluoroscopy was activated and the time of radiation exposure information used in the study as well as the total surgical time.¹¹ For this study, it was decided to adjust the device to 57 kV and 1.5 mA. After the procedure, the patient was followed up at the hospital's pediatric ward, receiving hospital discharge after 48 hours. All surgeries were performed by the same surgeon, who has expertise in child orthopedic trauma.

Postoperative

In order to assess pain in this study, the Visual Analogue Scale (VAS) was used, which consists of a score for measuring the intensity of pain by the patient shown on a straight line where at one end there is the marking "no pain" (0) advancing in towards the other end with indications of progressive increase in pain - mild



pain (1 - 2), moderate pain (3 - 7), severe pain (8 - 9) - until the other end is marked "worst possible pain".¹⁰ VAS also has colors and images that help patients to define the intensity of pain. Patients were assessed for pain on the first and second postoperative days by one of the researchers and on each outpatient return by the surgeon. To assess the range of motion of the elbow and wrist in outpatient returns, a goniometer was used, with 0 - 145 ° elbow flexion, 145 - 0 ° elbow extension, Radioulnar pronation and supination of 0 - 90 °, flexion were considered normal. 90 ° wrist and 0 - 70 ° wrist extension.

Functionality assessment was carried out by asking the patient and companion about the need for help with dressing, the need for help in bathing, the need for help with food, the need for help with personal hygiene when going to the bathroom and the absence of the ability to use the fractured limb to aid feeding. When the answer was "yes" to at least four of the questions, the patient was considered as "without difficulties", when it was "yes" to two or three questions was considered to have difficulty but did not need constant help and when the answer was " yes "to only one of the questions or none of them was considered to have difficulties and to need constant help to carry out the activities.

After discharge, the returns to the Traumatology Outpatient Clinic of the study hospital occurred at one, two, four, eight and twelve weeks after the operation, being evaluated on each return in addition to pain, the time of absence from school, the quality of the reduction presented, range of motion and presence of any complications.

Statistical analysis

In the statistical analysis, number of cases and percentages were used to describe the non-quantitative variables and mean and standard deviation (SD) or median (minimum - maximum) to describe quantitative variables. To verify normal distribution, the Shapiro-Wilk test was used, for comparisons between groups in relation to quantitative variables, the Student's t test was used for variables with normal distribution and the Mann-Whitney test for those who did not have this. distribution and Fisher's exact test for non-quantitative variables. The calculations were performed using R Version 3.4.4 (2018-03-15). A 95% confidence interval was considered.

The project was approved by the Research Ethics Committeein accordance with Resolution 466/2012 of the National Health Council (Guidelines and Regulatory Norms for Research Involving Humans) under registration 29142720.1.0000.5047. This study was funded by the researchers themselves.

RESULTS

Of the total participants, 14 (87.5%) are male and 2 (12.5%) female (p = 0.500) aged between six and 14 years (p = 0.476), with 8 years old most prevalent (31.25%). As for laterality, 50% of patients fractured the right side and 50% the left side (p = 0.608), and when related to the patient's dominance, 56.25%⁹ injured the dominant side and in 43.75%⁷ the injury was on the non-dominant side (p = 0.518). All fractures showed dorsal deviation, with 87.5% associated with radial displacement and 12.5% associated with ulnar deviation. (Table 1) The time elapsed between the accident and the attendance at the study institution it averaged 24.64 hours, ranging from 30 minutes to 102.5 hours, and the time between attendance and hospitalization until surgery was an average of 4.2 days, with a minimum of 1.5 hours and a maximum of 11 days.

Regarding the trauma mechanism, all referred to low-energy traumas described as falling to the ground (7), falling from a skateboard (1), falling from a horse (1), falling during a soccer game (1), falling from a ladder (1), drop of approximately 0.5 meters (1) and 1 meter (2) and drop of rede (2), which is a regional household appliance used for sleeping.

In the intraoperative period in group A, fluoroscopy was activated on average approximately 79 times (27-136) with an average radiation exposure time of 15.6 seconds (5.4 - 27.2 sec.) And the duration of surgery was from 15 to 47 minutes (average of 36 minutes). In group B, fluoroscopy was activated on average approximately 27 times (minimum 13 - maximum 46) [p = 0.011] with an average radiation exposure time of 5.2 seconds (2.6 - 9.2 seconds) and the duration of the surgery was 10 to 25 minutes (average of approximately 19 minutes) [p = 0.014]. In the immediate postoperative period, anatomical reductions were obtained in 11 (68.8%) patients, good in three (18.7%) patients and reasonable in two (12.5%) patients. (Table 2)

In the postoperative period, group A classified pain according to the Visual Analogue Scale (VAS) on the first postoperative day on average 1.8 (1 - 3) and on the second postoperative day approximately 67% did not complain of pain. In group B, the pain on the first postoperative day was an average of 4.7 VAS (0 - 6) [p = 0.003] and on the second postoperative day, the mean was VAS 1.5 (0 - 2) [p = 0.009]. (Table 3)

	Radiusand ulna fixedFixedradiusonly(N = 6)(N = 10)				
	Average/n	SD/%	Average /n	SD/%	р
Sex					0,500 ²
Female	0	0,0	2	100,0	
Male	6	42,9	8	57,1	
Age (years)	9,0	2,61	10,0	2,67	0,476
Laterality					0,608 ²
Right	4	50,0	4	50,0	
Left	2	25,0	6	75,0	
Dominance					0,518 ²
Right	4	30,8	9	69,2	
Left	2	66,7	1	33,3	
Exposedfracture					0,125 ²
Yes	2	100,0	0	0,0	
No	4	28,6	10	71,4	

(1 – Test t de student; 2 - Test exato de Fisher).

Table 2. Intraoperative data.							
	Radiusand ulna fixedFixedradiusonly(N = 6)(N = 10)				_		
	Average ou Median	SD (Mín - Máx)	Average Median	SD (Mín - Máx)	р		
In-opfluoroscopy (activations)	78,7	45,3	26,6	11,5	0,011 ³		
Surgical time in minutes	36,8	11,8	19,3	4,4	0,014 ¹		

(1 - Test t de student; 3 - Test de Mann-Whitney).

Table 3. Postoperative follow-up. Radiusand ulna fixed **Fixedradiusonly** (N = 6)(N = 10)р SD SD Average Average (Mín - Máx) (Mín - Máx) VAS 1º PO 0,003 1 2 (1 - 3)5 (0 - 6) VAS 2º PO 0 (0 - 1)2 (0 - 2)0,009³ VAS 1 week 2 <0,001 ³ 0 (0 - 0)(1 - 5)VAS 8 week 0 (0 - 1)1 (0 - 2) 0,114³ (3 - 4)(8 - 14) <0.001 1 Schoolleave in days 4 10

. (1 – Teste t de student 3 - Teste de Mann-Whitney); VAS - Visual Analogue Scale; PO - post operative. In the first reassessment 7 days after surgery, all patients in group A denied pain and had already returned to school activities. In group B, all of them complained of pain at some intensity, on average VAS 2 (1 - 5) and no patient had returned to school activities. (p < 0.001)

Radiologically, with 7 days postoperatively, in Group A, two patients presented radial deviation, one patient presented ulnar displacement and in none of the cases there was a shortening of the radius fracture. Regarding fracture of the ulna in Group A, one patient had a radial displacement and one patient progressed with a 1 mm shortening. In Group B, two patients had radial deviation, one patient had ulnar displacement and in none of the cases did the radius fracture shorten. Regarding fracture of the ulna in Group B, five patients had ulnar deviation, three patients had a shortening of two millimeters and one patient had a shortening of three millimeters. (Table 4)

In the reassessment performed 8 weeks after surgery, the radiological aspects were maintained in most patients, except for one patient in group B who presented slight loss of reduction, increasing the ulnar angulation of the radial fracture from 8 ° to 10°. Upon examination of the range of motion, two patients in Group B presented alterations (one with loss of 5 ° of supination of the wrist and one with loss of 5 ° of wrist extension). No range of motion limitations were identified for patients in Group A. (Table 5) In relation to Activity of daily living with 8 weeks, in Group A one patient was classified as having no difficulties to perform basic activities of daily living, three had difficulty but did not need help and two had difficulty and needed help to carry out the activities. In Group B, two patients were classified as having no difficulties to perform basic activities of daily living, two had difficulties but did not need help and six had difficulty and needed help to perform the activities. There was no statistically significant difference in functionality.

On the outpatient return of 12 weeks postoperatively, no patient had range of motion restrictions or functional limitation. Total school leave in group A ranged from three to four days (mean 3.6

Tab	Table 4. Radiological aspects 1 week after surgery.								
N٥	Ulna fixation	Radial Fracture, angulation	Radial Fracture, Shortening (mm)	Ulnar Fracture, angulation	Ulnar Fracture, Shortening (mm)				
1	Yes	-	-	-	-				
2	No	Radial(12°)	-	-	-				
3	No	Ulnar (8°)	-	Ulnar (26°) / dorsal (10°)	3				
4	No	Radial (6°)	-	-	-				
5	Yes	Radial (4°)	-	-	-				
6	No	-	-	Ulnar (13º)/ Dorsal (4º)	2				
7	Yes	Ulnar (4º)/ Dorsal (12º)	-	-	-				
8	No	-	-	Ulnar (10°)	-				
9	No	-	-	-	-				
10	No	-	-	-	-				
11	Yes	Radial(8°) / Dorsal (16°)	-	Radial (10°)/ Dorsal(8°)	1				
12	No	-	-	Ulnar(4°)/ Volar(12°)	2				
13	No	-	-	Ulnar(4°) / Dorsal(8°)	2				
14	No	-	-	-	-				
15	Yes	-	-	-	-				
16	Yes	-	-	-	-				

days) and in group B it ranged from nine to 14 days (mean 10.4 days) [p <0.001]. (Table 6)

Regarding complications during the follow-up, three patients in group B had superficial K-wire infection, being treated with local measures, without using antibiotic therapy. Fracture healing was achieved in all patients ranging from six to nine weeks (three consolidated at six weeks, seven at seven weeks, four consolidated at eight weeks and two at nine weeks).

Table 5. Radiological aspects 8 week after surgery.							
N°	Ulna fixation	Radial Fracture, angulation	Radial Fracture, Shortening (mm)	Ulnar Fracture, angulation	Ulnar Fracture, Shortening (mm)	complications	
1	Yes	-	-	-	-	-	
2	No	Radial(12°)	-	-	-	Superficial infection	
3	No	Ulnar (10°)	-	Ulnar (26°) Dorsal(10°)	3	Slightreductionloss	
4	No	-	-	-	-	-	
5	Yes	Radial (4°)	-	-	-	-	
6	No	-	-	Ulnar(13°) Dorsal (4°)	2	Superficial infection	
7	Yes	Ulnar (4°) Dorsal(12°)	-	-	-	-	
8	No	-	-	Ulnar (10°)	-	-	
9	No	-	-	-	-	-	
10	No	-	-	-	-	-	
11	Yes	Radial(8°) / Dorsal (16°)	-	Radial(10°) Dorsal(8°)	1	-	
12	No	-	-	Ulnar(4°) Volar(12°)	2	-	
13	No	-	-	Ulnar(4°) Dorsal(8°)	2	-	
14	No	-	-	-	-	-	
15	Yes	-	-	-	-	-	
16	Yes	-	-	-	-	-	

 Table 6. Clinical and Functional Evaluation 8 weeks after surgery.

		Grupo A: Radiusand ulna fixed N = 6	Grupo B: Fixedradiusonly N = 10	р
	No difficulty	1	2	
Independence for basic activities	Difficulty, but no help needed	3	2	0,165 ²
of daily living	Difficulty and need help	2	6	
	Elbow	-	-	
Arcof motion	Wrist (flexion and extension)	-	lossof 5° extension (1)	
	Wrist (prone- supination)	-	lossof 5° supination (1)	

(2 - Test exato de Fisher).

DISCUSSION

Fractures of the distal third of the radius correspond to 20 - 35% of all childhood fractures and 80% of pediatric fractures that occur in the forearm.¹² The indirect costs of this injury are incalculable in terms of medical costs, absent period in school activities and future potential working.¹

Loss of reduction is the most common complication of conservative treatment, so that more than a third of patients will progress with



this complication¹³. Associated ulna fracture is cited in several studies as a risk factor for loss of reduction,^{4,5,14} configuring as a relative indication of fracture fixation with Kirschnner wires.⁶ but indications regarding fixing the ulna together with fixing the radius are not well defined and what is the impact of this additional fixation for the patient. Percutaneous fixation with Kirschnner wires is generally preferred when distal radius fractures in the pediatric population require surgical stabilization.¹⁵ There are variations in the fixation configuration, with several techniques described. The wires can be introduced proximal to the physis in order to cross each other to provide stability,^{16,17} the wires can be pre-concealed for arching in the internal cortex¹⁵ transepiphyseal¹⁸ in the case of slightly more proximal fractures. Kapandji's technique¹⁹ is also widely used in metaphyseal fractures with the need for greater attention to veins, tendons and nerves at risk in this approach.¹⁸ When the ulna is fixed, it is performed using a cross-wire technique¹⁶, intramedullary by anterograde approach¹⁸ or retrograde.

Most complications occur due to inadequate indication or poorly performed surgical technique.²⁰ In this study, the Kapandji technique was used to fix the radius in all patients and the ulna fixation was performed by retrograde or anterograde intramedullary route, with no inherent complications identified surgical technique.

Factors associated with loss of reduction are considered to be low technical quality in the making of plastered immobilization, associated fracture of the ulna, and initial angular greater than 30° .¹² Other associated factors are age greater than 10 years, bayonet fracture, fracture line oblique and failure to achieve anatomical reduction in primary treatment.²¹ Initial angular greater than 30 ° and initial translation greater than 50% are described as relative indication of fixation with K wires.¹²

Ozcan et al retrospectively evaluated 40 children with distal radius fracture, dividing them into two groups, one with conservative treatment and the other with fixation with K wires, with loss of reduction being observed in 10% of patients with fixation with wires and in 50 % of patients with only closed reduction.⁵ Satish et al treated 52 children with distal radius fractures using the Kapandji technique, with no cases of loss of reduction being identified in any of the patients.²¹ Parikh et al in a retrospective case-control study compared the evolution of 10 children treated with the kapandji technique with 26 treated with cross-wire fixation and concluded that the Kapandji technique was superior in maintaining the reduction.²² In this study, the loss of reduction occurred in only one patient, who had no indication for a new intervention because the reduction remained within acceptable criteria, confirming previous studies where the Kapandji technique was effective in maintaining the reduction of the fracture. and corroborating the systematic review carried out by Khandekar, Tolessa and Jones who concluded that fixation with k wires implies a minimal incidence of loss of reduction.¹⁷ Ozcan et al performed a functional assessment of 40 patients in their study only at the end of the follow-up, which was 20 months, finding no differences between groups.⁵ Biju, likewise, prospectively evaluated 31 patients treated conservatively or with percutaneous fixation, finding no functional difference at the end of the 24-week follow-up.²³

No long-term functional difference was found by Syurahbil et al when retrospectively evaluating 57 patients treated with percutaneous or conservative fixation.²⁴ The results of this study corroborate with the literature because at the end of the follow-up, no patient had functional limitation, however the group whose ulna was also fixed evolved faster for functional recovery, returning first to school activities, and obtained lower scores in relation to pain in the post operative.

Mclauchlan et al identified that the amount of radiographs taken in conservative treatment - due to the need for more frequent returns and radiographs at each reevaluation - is greater than with the fixation by K wire.²⁵ Jin et al compared intraoperative fixation of distal radius fractures with wires associated or not with ulna fixation, presenting a longer surgical time and exposure to fluoroscopy in those whose ulna fixation was performed.¹⁶ The results obtained in this study corroborate with Jin et al because longer surgical time and fluoroscopic activations were found in patients whose ulna was fixed.

The limitations of this study are found in the small number of cases evaluated, follow-up times of less than 12 months and lack of standardization regarding the time elapsed between the fracture and surgical treatment. However, it was possible to observe statistical relevance in the results and in the last evaluation there were no functional or consolidation differences between the groups. In addition, no fractures with signs of advanced consolidation were treated and there were no statistical differences regarding the quality of the reduction between the groups, regardless of the fracture time.

Further studies are needed to assess fractures of the distal third of the radius when they are associated with ipsilateral fracture of the ulna with an emphasis on the impact of ulna fixation on the patient's functional and radiological evolution. Randomized clinical studies with a larger number of patients will be important to define more clearly the best treatment for these patients.

CONCLUSION

From this study it can be concluded that patients with distal radius fracture associated with ipsilateral fracture of the distal ulna have faster functional recovery and less postoperative pain when the ulna is also fixed with K wires. However, the surgical time and the amount of intraoperative fluoroscopic activations increases when compared to isolated radius fixation.

The functional and radiological result at the end of the treatment proved to be the same regardless of the fixation of the ulna. In addition, the Kapandji technique was efficient in maintaining the reduction after fixation of the radius.

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THE ROUND LIGAMENT IN DEVELOPMENTAL HIP DYSPLASIA: ARE ITS MECHANICAL AND HISTOLOGICAL PROPERTIES PRESERVED?

O LIGAMENTO REDONDO NA DISPLASIA DO DESENVOLVIMENTO DO QUADRIL: SUAS PROPRIEDADES MECÂNICAS E HISTOLÓGICAS SÃO PRESERVADAS?

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ABSTRACT

Introduction: During open surgical dislocated hip reduction, several anatomical structures, such as the round ligament, are approached. However, there is controversy over both the possibility of preserving the ligament and its functional importance. Materials and Methods: This experimental study used skeletally immature rabbits as a model for congenital hip dislocation. Thirty-six rabbits comprised the sample that was submitted to the round ligament analysis. The sample was stratified for analysis (biomechanics, zymography, histology, and immunohistochemistry). Statistical analysis compared the unstable side to the control side of each rabbit. Results: Biomechanical assays showed that the mean maximal strength of the round ligament on the unstable side was similar to that of the control side (p = 0.594), which was also the case with maximum deformation (p = 0.328). Histologically, there was a statistically significant increase in cellularity on the unstable side (p < 0.001). Additionally, there was significantly greater collagen occupancy on the control side (p < 0.001). Zymography revealed no significant difference in the amount of active metalloproteinase 2 (MMP-2) (p = 0.068). Conclusions: Although histological analysis found evidence of significant changes in the RL in unstable hips, there were no significant differences in zymography, and no changes were observed in biomechanical tests. Evidence Level V; Experimental study.

Keywords: Collagen. Hip dislocation. Round ligaments. Models, animal. Rabbits.

RESUMO

Introdução: Durante a redução cirúrgica aberta de luxação de quadril, várias estruturas anatômicas são abordadas, entre elas, o ligamento redondo. No entanto, há controvérsias quanto à possibilidade de preservação desse ligamento, bem como sua importância funcional. Materiais e Métodos: Este estudo experimental usou coelhos esqueleticamente imaturos como modelo de luxação congênita do quadril. Trinta e seis coelhos compuseram a amostra que foi submetida à análise do ligamento redondo. A amostra foi estratificada para análise (biomecânica, zimografia, histologia e imuno-histoquímica). A análise estatística comparou o lado instável com o lado controle de cada coelho. Resultados: Os ensaios biomecânicos mostraram que a força máxima média do ligamento redondo no lado instável era semelhante ao lado controle (p = 0,594), o que também ocorreu com a deformação máxima (p = 0,328). Em termos histológicos, houve um aumento estatisticamente significante da celularidade no lado instável (p < 0,001). Além disso, houve maior ocupação de colágeno no lado controle (p < 0,001). A zimografia não mostrou diferença significativa da quantidade de metaloproteinase 2 ativa (MMP-2) (p = 0,068). Conclusões: Embora a análise histológica tenha encontrado evidências de alterações significativas do LR nos quadris instáveis, não houve diferenças significativas na zimografia e não foram observadas alterações nos testes biomecânicos. Nível de evidência V; Estudo experimental.

Descritores: Colágeno. Luxação do quadril. Ligamentos redondos. Modelos animais. Coelhos.

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INTRODUCTION

Nontraumatic instability of the hip in children may be related to several pathological conditions, and developmental dysplasia of the hip (DDH) is one of the main causes.¹

When surgical treatment is performed through an open reduction, several structures are approached, including the round ligament (RL). The RL is thickened, and since it is considered a factor that may hinder hip reduction, it is traditionally removed.^{2,3}

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

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Wenger et al. (2008), Bache et al. (2008) and more recently, Youssef (2017) reported their results preserving the RL on DDH surgical correction through an open reduction. In these studies, the authors emphasize how maintaining the round ligament can contribute to hip stability after surgery.⁴⁻⁶

Although the RL is a structure that has already been investigated in other studies, there is no clear definition of its histological and biomechanical properties in a dislocated hip. In such cases, it would be worthwhile to know if RL structure and biomechanical function undergo relevant changes that might compromise its preservation in the surgical correction of hip dislocation.

Our hypothesis is that if there are relevant histological and biochemical changes in the RL of dislocated hips, then biomechanical involvement would also occur and compromise RL function.

METHODS

This experimental study involved 88 rabbits at 35 days of life (Norfolk breed). An experimental model of DDH⁷⁻⁸ was used in which knee stabilization was performed with one 1.5 mm Kirschner wire (KW) in one of the hind limbs with the knee in extension (Figure 1). The ipsilateral hip of the limb with the fixed knee was subjected to postural changes and to muscular imbalance that generated articular instability (Figure 2). The contralateral hip served as a control, so each rabbit evaluated with an unstable hip served as its own control.

The experimental protocol was performed according to the Guide to Procedures and Use of Laboratory Animals published by the U.S. National Institute of Health and approved by the institution's Ethics Committee on Animal Use (CEUA) (protocol number: 1012/2013). The animals underwent general anesthesia using 30 mg/kg ketamine, 5 mg/kg xylazine, and 5 mg/kg acepromazine intramuscular infusions. Antibiotic prophylaxis was administered subcutaneously



Figure 1. Stabilization with K-wire of the rabbit's knee in complete extension.



Figure 2. Radiographic image demonstrating left hip dislocation (white arrow) after 6 weeks of ipsilateral knee stabilization.

by infusion of enrofloxacin 10 mg / kg during the anesthetic act. After 24 hours, a new infusion was performed. Analgesia was performed by subcutaneous infusion of tramadol 5 mg / kg during surgery and every 12 hours for the 3 days following surgery.

Six weeks after the knee fixation, the rabbits underwent euthanasia and radiographic examination was performed to identify unstable hips. Rabbits that did not present with at least 50% subluxation (defined by the lateral migration of the femoral head⁹) were excluded from the study (Figure 3).

Nineteen rabbits died before 6 weeks, 28 did not present instability (50% subluxation) and/or developed complications and were excluded. In 5 rabbits with unstable hips, it was not possible to identify the RL for the analysis, therefore they were also excluded. The final sample was 36 rabbits, as depicted in the following flowchart (Figure 4).

Sample size calculation was performed using the RL length values of the first 11 rabbits available for the evaluations comparing the unstable and control sides. After taking values for ligament length on the unstable side ($\bar{x} = 7.51$ mm; $\sigma = 1.12$) and control side ($\bar{x} = 4.29$ mm, $\sigma = 0.76$) into account and adopting a statistical error (alpha) of

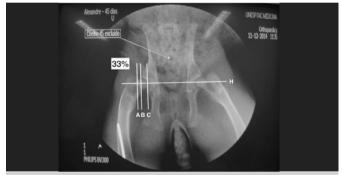
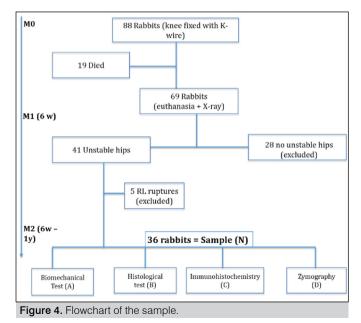


Figure 3. Radiographic image of the right hip presenting 33% of subluxation (excluded from the study). The H-line passes through the triradiated cartilages of the hips (similar to the Hilgenreiner line), line B is drawn perpendicular to line H and on the acetabular ridge (similar to the Perkins line), Line C determines the medial limit of the femoral head and line A determines the lateral limit of the same. The percentage of migration was calculated as distance AB/AC x 100 = % of femur head migration (similar to that performed and described by Reimers, 1980).



5.0%, and test power of 80%, the sample was defined as 8 rabbits for each test (e.g., histological, biomechanical and biochemical).

The quantitative measures included cellularity and quantification of collagen (histological tests), guantification of metalloproteinases 2 and 9 (zymography), and biomechanical tests. In addition to quantitative measurements, immuno-histochemistry was performed as a qualitative test to identify the presence of fibroblasts.

The sample was analyzed comparing migration percentage and ligament length between sides (control and unstable). The ligament length was not evaluated on rabbits in Group A because it could interfere with the biomechanical test, since some measurements required a small bone resection.

Group randomization was performed to allocate the sample among different quantitative tests.

Twelve rabbits were grouped for biomechanical analysis (Group A) through a load-elongation curve test. Data on maximum strength and maximum deformation were collected from both sides (control and unstable). One rabbit was excluded at this stage because the biomechanical test machine was inadvertently started.

Fourteen rabbits were allocated for histological analysis (Group B). The ligament samples of animals from the different experimental sides (n = 14 / group = unstable x control) were prepared and collected on silanized slides stained by hematoxylin-eosin for a general analysis of ligament structure and stained by Picrosirius for automatic detection of collagen fibers. The analyses were carried out in 70 microscopic fields (5 fields per animal of 14 animals / group = unstable x control) in a Leica ™ DMLB 80 microscope coupled to the digital camera and image analysis software (Leica™ DC300FX). Cellular (Figure 5) and collagen quantification were completed on both sides.

Group C was composed of 2 rabbits in which an immunohistochemical test was performed in regards to cell specificity (qualitative analysis) through vimentin (Abcam, ab92547, UK) a marker of mesenchymal cells such as fibroblasts.

In Group D, the round ligaments of 8 rabbits of the unstable and control sides were removed and analyzed by zymography for quantification of the metalloproteinases (MMP-2 and MMP-9), as described by Justulin et al.10

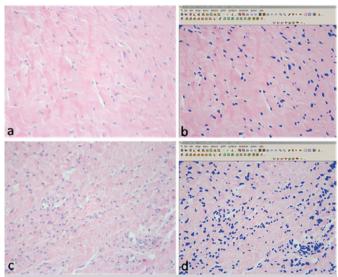


Figure 5. Representative photomicrographs of ligament sections submitted to Hematoxylin and Eosin staining of the control (a) and unstable (c) sides. These images were used for automatic detection of the percentage of area occupied by hematoxylin-stained cell nuclei in control (b) and unstable (d).

Regarding statistical analyses, Wilcoxon tests were performed to evaluate biomechanical tests using a significance level of 5% and 95% confidence intervals. For the other analyses, paired Student's t-tests were used, and a significant difference was considered when p < 0.05. Statistical analyses were performed in the Prisma software (Version 5, GraphPad, Inc., San Diego, CA, USA)

RESULTS

The mean femoral head lateral migration on the control side was 1.44% (SD: 3.85%) while the mean on the unstable side was 75.19% (SD:16.6%). The difference between the evaluated sides was statistically significant (p<0.001) (Table 1).

The mean length of the RL on the unstable side was significantly higher than the mean on the control side (p < 0.001) (Figure 6). Forty-six ligaments were used in this comparison (23 rabbits). Only ligament length data from rabbit 72 was not measured.

There was no significant difference between sides (unstable x control) in both the maximal strength of the RL before the rupture (p = 0.594), and in the maximum deformation of the ligaments (p = 0.328) (Figure 7; Tables 2 and 3).

The cellularity was significantly higher on the unstable side with an average of 6.83% (SD: 3.47%) cells per field (p<0.001; Table 4). The control side showed 3.87% (SD: 2.13%).

Immunohistochemistry has shown that the cells verified in histological tests were consistent with fibroblasts.

The amount of collagen was higher on the control side with 84.5% (SD: 9.5%) of occupancy detection, while on the unstable side there was 74.3% (SD: 10.5%) (p<0.001).

On zymography, there was no MMP-9 activity identified on either side. MMP-2 (active form) appeared to be more active on the unstable side, but the difference was not statistically significant (p = 0.068) (Table 5).

DISCUSSION

The RL has been studied since the 19th century, and its structure and functionality have long been a source of controversy.¹¹

Table 1. Comparison between control and unstable sides for the per-

Percentage	Control Unstable				
Average	1,44%	75,19%			
Median	0%	72,50%			
SD*	3,85	16,6			
Min	0%	50%			
Max¥	15%	100%			
N**	36	36			
P-value	<0	,001			

Standard Deviation. † Minimum value. ¥ Maximum value. ** Sample (number of rabbits)

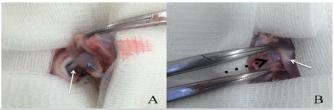


Figure 6. A) Picture of the dislocated hip. The head of the femur (blue arrow) outside the acetabular cavity and thickened elongated ligament (white arrow). B) Picture of the contralateral hip (control) of the same rabbit. Note the head of the femur (dotted black arrow) centered in the acetabulum (white arrow). The ligament on the unstable side was significantly higher.

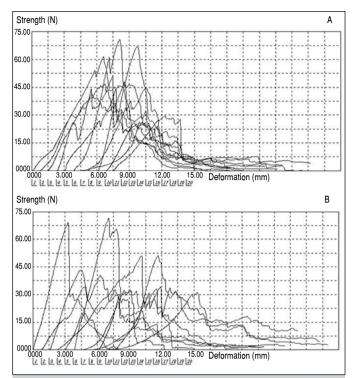


Figure 7. Chart of the biomechanical test showing "strength x deformation" curve on the control side (A) and unstable side (B). Strength was measured in Newtons (N), and deformation was measured in millimeters (mm).

 Table 2. Comparison between control and unstable sides for maximum strength (Smax) in Newtons.

Strength	Control	Unstable
Average	46.62	43.25
Median	46.85	40.6
Standard Deviation	15.56	16.25
Q1*	35.48	32.16
Q3*	56.36	51.16
N**	11	11
P-value	0.5	594

*Interquartile value. **number of rabbits

 Table 3. Comparison between unstable and control sides for maximum deformation in millimeters (mm).

Deformation	Control	Unstable
Average	4.558	3.943
Median	4.574	3.712
Standard Deviation	1.194	1.888
Q1*	4.033	2.872
Q3*	4.960	4.906
N**	11	11
P-value	0.0	328

*Interquartile value. **number of rabbits

There are some experimental studies on RL function in hip stability. Smith et al. (1963)¹² compared the hips of dogs that underwent resection of the RL alone with 2 other groups. One group underwent capsular resection and the other had resection of both the RL and the capsule. The authors reported a higher number of dislocation in the hips among those with the RL resection, which highlighted the possible importance of the RL in joint stability.

Wenger et al. (2007)¹³ conducted an experimental study of the resistance of the RL to maximum tensile strength in pigs. Ultimately,

Table 4. Comparison of cellularity between the Control and Unstable sides through the parameters: mean, median, standard deviation, minimum value (Min), maximum value (Max), number of microscopic fields evaluated (N) and P value.

Cellularity	Control	Unstable
Average	3.87%	6.83%
Median	3.46%	6.27%
Standard Deviation	2.13%	3.47%
Min	1.36%	1.51%
Max	11.05%	15.32%
N	70	70
P-value	<0,001	

Table 5. The mean values of MMP-2 (intermediate and active forms) were compared between the unstable and control sides using the following parameters in arbitrary units (AU): mean, standard deviation, coefficient of variation (CV), minimum value (Min), maximum value (Max), number of rabbits (N) and P value.

Zymogra (per thous		Mean	Standard Deviation	cv	Min	Max	N	P-value
Intermediate	Control	6.453	873	14%	5.155	8.069	8	0.979
(MMP-2)	Unstable	6.472	1.900	29%	3.102	9.088	8	0.979
	Control	294.4	78	26%	254	484	8	0.000
Active (MMP-2)	Unstable	481.8	228	47%	247	872	8	0.068

it was concluded that the biomechanical behavior of this ligament is similar to the anterior cruciate ligament of the knee. Once again, this highlighted the function of the RL as a hip stabilizer, and the authors went even further by discussing the maintenance of the ligament in surgeries for open reduction of hips with dysplasia in children. Wenger et al. (2008)¹⁴ published a series of cases involving 21 patients with hip dislocation associated with both DDH and cerebral palsy, myelomeningocele, and congenital deficiency of the femur. They performed open reduction of the dislocation and used an RL suture to increase the stability of the hips. Afterone year follow-up, they reported no cases of redislocation and concluded that the procedure is safe while acknowledging the need for a longer follow-up. Bache et al. (2008)⁵ studied children with DDH and reported good results in 97% of the 109 hips that underwent open reduction using a medial approach with RL suture in the transverse ligament. The authors hypothesized that the RL suture added stability to the joint. More recently, Youssef (2017)⁶ assessed medial open reduction of hips with DDH associated with partial resection and suture of the RL in 40 hips of 32 children and found that results were 97.5% good and excellent. The author pointed out that there were no cases of redislocation and attributed the positive results to the suture of the RL.

Sarban et al. (2007)¹⁵ studied the morphological characteristics of RL in cases of DDH and identified mechanoreceptors. This finding suggested a possible role for proprioception and joint stability. Considerations were also made about the possible histological changes that may occur in the ligament as a result of hip instability. Muratli et al. (2004)¹⁶ did not identify mechanoreceptors when analyzing the RL and joint capsule of patients with DDH undergoing surgical treatment. These authors did not agree about the possible biomechanical ligament function.

Ligaments are composed of a cellular component and an extracellular matrix. The predominant cell type in ligaments is the fibroblast which is primarily responsible for the production of collagen and is known to respond to biomechanical load changes that tissues



are subjected to. Collagen fibers are responsible for the structural mechanical strength of the tissue (Goh et al., 2003)¹⁷.

Collagen degradation is carried out through a family of zinc dependent enzymes known as metalloproteinases (MMPs). The control of metalloproteinase activity is performed by the tissue inhibitors of metalloproteinases (de Melo et al., 2009)¹⁸.

Considering the possible changes in strength that the RL of unstable hips are subjected to and the subsequent structural changes that occur in that ligament, this study was designed to examine the biomechanical, histological and biochemistry properties of the RL. Some studies^{5,14,15} have suggested a modification in one of the steps of the surgical correction of dislocated hips in children: the maintenance of the RL. However, there is no evidence to date that the RL in an unstable hip maintains its normal properties.

On the unstable side, a higher number of fibroblasts, higher MMP-2 activity (although not statistically significant) and a lower amount of collagen were observed. From these results, it can be concluded that there must be greater strength acting on the RL on the unstable side that results in greater activity both of collagen production and degradation. This activity is important for RL properties.

In cases of more relevant lesions, there is evidence of greater inflammatory activity in the tissue, which may weaken the ligament, since it changes its histological properties in a consistent way as reported in the study of Provenzano et al. (2005).¹⁹

In the present study, no significant functional change was observed in the RL with respect to either maximum strength or maximum deformation. The histological and biochemical alterations noted were probably insufficient to change the functional properties of the RL. However, it is important to note that in 5 hips, round ligaments were not found, probably due to their rupture. It is possible that more consistent metabolic changes occurred in these cases, which impacted the resistance of these ligaments. There are reported cases of RL absence in hips which underwent an open reduction in children with DDH (Li et al., 2015)²⁰. In this study, the authors identified the severity of the dislocation as a risk factor for the absence of the ligament.

The deformation that occurred in the ligaments during the biomechanical test was not significantly different between sides, but this analysis was performed with absolute values. If it is assumed that the average length of the RL on the unstable side was initially 7.80 mm (SD: 1.17) and on the control side was 4.08 mm (SD: 0.62), a proportionally greater deformation on the control side can be identified. This may indicate a loss of the viscoelastic properties of the unstable hip ligament.

Considering the histological, biochemical and biomechanical characteristics of the round ligaments of the unstable hips, it is recognized that they do not maintain their properties as a normal ligament. However, they appear to retain their tensile strength, since the mean maximum strength did not differ significantly between sides.

Therefore, since its viscoelastic properties are abnormal, if the RL is preserved to aid in hip stabilization in the surgical correction of hip dislocation, the ligament may eventually help to prevent redislocation due to a more primitive biomechanical mechanism that decreases the ligament's capability to improve joint proprioception.

Another important consideration is whether the hip has a more severe dislocation in which case there is higher possibility of more changes in the properties of the RL. In addition, the likelihood of RL absence should be remembered in such cases. Therefore, although there are some studies favoring the maintenance of RL in the open reduction of dislocated hips in children^{5,14,15}, more clinical studies with a better level of evidence need to be conducted.

A limitation of this study is its experimental design, which is a limiting factor when making suggestions for clinical practice. However, since the study is focused on comparing the properties of RL in dislocated and normal hips, it might not be possible to perform the study in any other way.

Another limitation was our inability to proportionately assess changes in deformation in the ligaments following the biomechanical test. Additionally, analyzing ligaments in long-standing dislocations might perhaps add information about the behavior of the ligament in more chronic cases.

Finally, a stratified analysis of the hips of the dislocated group could perhaps provide further information on which ligaments present with the most morphological and functional changes. Due to the small sample size in our study, this analysis was not possible.

CONCLUSION

Significant histological changes were observed in the RL of unstable hips, but no changes were observed with respect to biochemical and biomechanical tests.

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A NEW ANATOMICAL PLATE FOR EXTRA-ARTICULAR DISTAL **HUMERAL FRACTURES: BIOMECHANICAL STUDY**

UMA NOVA PLACA ANATÔMICA PARA FRATURAS EXTRA-ARTICULARES DISTAIS DO ÚMERO: ESTUDO BIOMECÂNICO

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ABSTRACT

Introduction: We compared the mechanical properties of two fixation techniques for the treatment of extra-articular distal third humeral fractures. Materials and Methods: Two groups were created from twenty-four humeri. Group 1 was instrumented using a new, precontoured, 8-hole (3.5-mm-diameter) locking compression plate (LCP) placed anterolaterally. Group 2 was instrumented using an 8-hole (3.5-mm-diameter) precontoured posterolateral LCP plate placed on the distal humerus. Fourpoint bending tests and torsion tests were performed until the specimens broke. Results: The four-point bending stiffness test showed that the stiffness of anterolaterally fixed humeri was significantly higher than that of posterolaterally fixed humeri (p<0.05). Torsion testing revealed that posterolateral fixation was associated with better yield strength (p < 0.05), but the torsional stiffness did not differ significantly between the two plates (p > 0.05). Conclusions: The anterolateral plate exhibited higher bending stiffness and torsional yield strength than the posterolateral plate. Anterolateral plate fixation can thus be used to manage extra-articular distal humeral fractures. Multiaxial locking screws ensure rigid fixation, allow early elbow motion without olecranon fossa impingement, and prevent iatrogenic injury of the triceps muscle. Level of Evidence I, Therapeutic Studies Investigating the Results of Treatment.

Keywords: Fracture Fixation, Humeral Fractures, Fracture Fixation,Internal.

RESUMO

Introdução: Comparamos as propriedades mecânicas de duas técnicas de fixação para o tratamento de fraturas extra-articulares do terço distal do úmero. Materiais e Métodos: Dois grupos foram criados a partir de vinte e quatro úmeros. O Grupo 1 foi instrumentado com uma nova placa de compressão com travamento (LCP) pré-contornada e com oito orifícios (3,5 mm de diâmetro) posicionados anterolateralmente. O Grupo 2 foi instrumentado com uma placa LCP pré-contornada posterolateral com oito orifícios (3,5 mm de diâmetro) colocada na parte distal do úmero. Testes de flexão e testes de torção a quatro pontos foram realizados até que os corpos de prova quebrassem. Resultados: O teste de rigidez à flexão de guatro pontos mostrou que a rigidez dos úmeros fixados anterolateralmente foi significativamente maior do que os úmeros fixados posterolateralmente (p <0,05). O teste de torção revelou que a fixação posterolateral foi associada a melhor força de rendimento (p < 0.05). mas a rigidez à torção não diferiu significativamente entre as duas placas (p > 0.05). Conclusões: A placa anterolateral apresentou maior rigidez à flexão e resistência à tração do que a placa posterolateral. A fixação anterolateral da placa pode, portanto, ser usada para tratar fraturas extra-articulares da parte distal do úmero. Os parafusos de travamento multiaxiais garantem uma fixação rígida, permitem o movimento precoce do cotovelo sem causar impacto à fossa do olécrano e previnem lesão iatrogênica do músculo tríceps. Nível de evidência I, Estudos terapêuticos - Investigação dos resultados do tratamento.

Descritores: Fixação de Fratura. Fraturas do úmero. Fixação interna de fratura.

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INTRODUCTION

The goal when treating distal humeral fractures is anatomic alignment and constant fixation, to gain early motion to the elbow.¹ Distal third of the humerus has complex deforming forces due to the elbow joint and muscle anatomy.² Single-plate fixation is inadequate, particularly for low-lying fractures, given the limited space of distal humerus anatomy. This issue is often addressed either by placing a precontoured 3.5-mm locking compression plate

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The study was conducted at the Gaziosmanpaşa Taksim Training and Research Hospital.

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(LCP) via a posterior approach, or by placing a second plate to treat more distal fractures. The use of two plates requires extensive soft tissue dissection and exposure of the radial nerve, and may disturb the blood supply, thus causing non-union. However, when placing the plate posteriorly, fixing both columns of distal humerus is difficult via screw insertion into the small distal fragment impinging on the olecranon fossa.^{3,4} To address these issues, a helical 3.5-mm LCP plate was recently introduced. The plate is modelled on a distal tibial metaphyseal plate, and extends from the lateral to the anterior surface of the humerus. The precontoured helical structure is congruent with the areal anatomy and allows insertion of up to 12 screws with minimal exposure.⁵ We hypothesized that the helical plate would be more rigid than a posterolateral precontoured LCP plate.

MATERIALS AND METHODS

Plate

Plate selection and application depends on the fracture pattern.⁴ To ensure rigid (two- column) rotational fixation, finite element analysis was used to design a new anterolateral anatomical plate (Figure 1).⁶ We devised a prototype with an appropriate screw configuration (Figure 2).

Study groups

We tested 24 fourth-generation composite humeri (model #3404; Pacific Research Laboratories, Inc., Vashon, WA, USA), all of which were left-sided and exhibited distal extra-articular oblique fractures located 60 mm from the lateral trochlear centre and 40 mm from

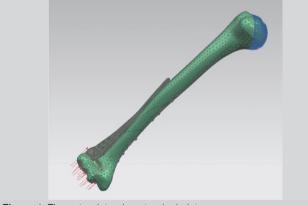


Figure 1. The anterolateral anatomical plate.

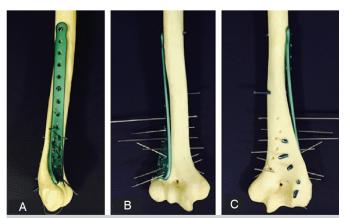


Figure 2. The locking screw configuration used to fix the double column with K-wires. A: Anterolateral plate placement, B: Anterior view, C: Posterior view.

the medial side. In Group 1, all fractures were fixed using a new anterolateral, anatomical, 8-hole (3.5-mm-diameter) LCP (Ilerimed, Istanbul, Turkey) (Figure 3). In Group 2, an 8-hole 3.5 mm precontoured posterolateral distal humeral LCP (Ilerimed) was employed (Figure 4). After plate fixation, redundant humeral bone was removed. In both groups, six specimens were used for the four-point bending tests, and six for torsion testing.

Our study did not include any human or animal test subjects; therefore, no ethics committee approval was required.

Biomechanical testing

We followed the Standard Specification and Test Method for Metallic Bone Plates (ASTM F382-14); the contact points of the loading rollers and plates were located between pairs of screw holes. Similarly, the support rollers and posterior surfaces were arranged to prohibit interaction between screws and support rollers. The distance between the supporting and loading rollers, and between the posterolateral and anterolateral plates, was 112 and 24 mm, respectively. To determine plate yield strength, four-point bending tests were conducted on six specimens of each type of plate. When placing the humeral bones, the anterior surfaces of composite models were in contact with the supporting rollers and posterior surfaces were in contact with the loading rollers. The support points were centred to ensure plate symmetry. The four-point bending test was performed using a tabletop biaxial servohydraulic test system (3369; Instron Corp., Canton, MA, USA) (Figure 5). During the tests, a constant load was applied to all specimens at a rate of 5 mm/min. All tests proceeded until fracture.^{7,8} To prepare specimens for torsion testing, some humeral bone was removed from the distal ends and the specimens were potted in polyurethane resin (Unate; Unicom

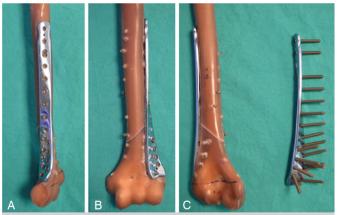


Figure 3. Anterolateral plating. A: Lateral view, B: Anterior view, C: Posterior view screw configuration.

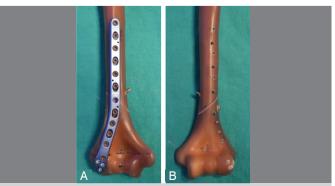


Figure 4. Posterolateral plating. 4a: Posterior view, 4b: Anterior view.

Corp., Istanbul, Turkey) (Figure 6). To ensure accuracy, the distal ends were centred to reflect the biomechanical alignment of the humerus along its longitudinal axis. We then drilled a pinhole in the resin to hold the fixed torsion shaft. We used a steel device to grasp the proximal end of each humerus; to prevent humeral dislocation, all specimens were compressed between the fixed and moving ends. We were careful to ensure that all specimens were placed along the torsional rotation axis. A 55MT device was used for torsional testing (Instron, Norwood, MA, USA). Torsional testing method includes preliminary loading with the rate of 0.5°/ sec until specimen is loaded with 0.3 Nm. When this load level was obtained, tests were proceeded with the constant rate of 2°/ sec rotation until fracture.^{9,10}

Statistical analysis

The SPSS statistical software package for Windows (version 11.5; SPSS Inc., Chicago, IL, United States) was used for the statistical analyses. The Shapiro-Wilk test was used to determine if the distributions of continuous variables were normal. The non-parametric Mann-Whitney U test was used to determine which group differed from the other groups significantly according to P value, with the threshold for significance set at 0.05.

RESULTS

The four-point bending stiffness values were $2,815.97 \pm 225.68$ and $1,374.82 \pm 72.51$ N/mm for the anterolateral and posterolateral plates, respectively. The average loads at the yield points are listed

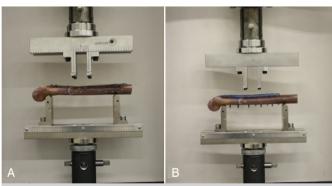


Figure 5. Experimental setup for the four-point bending test. The distance between the rollers was set to avoid contact between the screw holes and the rollers. A: Anterolateral group, B: Posterolateral group.

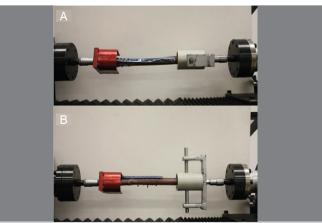


Figure 6. Experimental setup for torsion testing of humeral specimens. Potting of humeral bone models in polyurethane resin. A: Anterolateral group, B: Posterolateral group.

in Table 1. The bending stiffness of the anterolateral plate was significantly greater (p<0.05) than that of the posterolateral plate. The average peak torques are listed in Table 1. The torsional stiffness values were 1.37 ± 0.10 and 1.37 ± 0.19 Nm/° for the anterolateral and posterolateral plates, respectively; the former plate exhibited a higher torsional yield strength than the latter (p<0.05), but torsional stiffness did not differ significantly (p>0.05).

Variable		Group 1 (Anterolateral)		Group 2 (Posterolateral)		P-value
		Mean	SD	Mean	SD	
	Load at yield (N)	3,867	175.12	1,768	200.62	<0.0001
Four- point bending test	Displacement at yield (mm)	1.38	0.16	1.28	0.09	<0.005
	Stiffness (N/mm)	2815.97	225.68	1374.82	72.51	<0.001
	Torque at yield (N.m)	32.67	3.01	23.33	1.63	<0.0001
Torsional test	Displacement at yield (^o)	23.83	1.47	17.17	1.72	<0.005
	Stiffness (Nm/º)	1.37	0.10	1.37	0.19	>0.05

DISCUSSION

The new, precontoured, anterolateral helical plate exhibited superior biomechanical properties based on the four-point bending and torsional tests. The advantages of the helical plate include the anatomical design, bone fixation in different planes, and the need for only minimally invasive surgery.¹¹ Manual contouring is not recommended, because it is associated with excessive screw-hole deformation that leads to plate fatigue failure.¹² The plate was precontoured to the distal anterolateral humeral surface. Two columns may be fixed using up to 10 screws placed into the distal fragment, without any impingement of the olecranon fossa. Parmaksizoglu et al.⁵ used titanium cobra head plates (originally manufactured for the distal end of the tibia) to treat humeral fractures, and observed complete healing of all 23 studied patients. This prompted us to redesign an existing helical plate to repair the distal end of the humerus. For comparison, we choose a posterolateral plate rather than a single 3.5-mm LCP, because Scolaro et al.⁴ recently reported that the average bending and torsional stiffness values of a posterolateral plate were significantly higher than those of an LCP. Conservative treatment for distal humeral fractures is not always successful. The most common reason for surgery is failure to achieve or maintain acceptable reduction. Jawa et al.¹³ compared the outcomes of conservative treatment and surgey; fracture alignment and the functional results were better after surgery.

Anterolateral distal screws do not approach the joint, but the posterolateral plate passes over the joint line and it is hard to put the distal four screws into the lateral epicondyle; surface of the joint is damaged if the screws are too long. Also, the arterial supply to the distal humerus is at posterior region of the lateral epicondyle; iatrogenic injury, scarring, or osteonecrosis may develop with use of a posterolateral approach.14 Prasarn et al.¹⁵ described dual plating for more rigid fixation of distal humerus fractures via a posterior approach. They stated the importance and difficulty of both column fixation for early elbow motion. Yin et al.¹⁶ compared the posterior and lateral approaches for management of extra-articular distal humeral fractures. The posterior group exhibited significantly more complications, including iatrogenic radial nerve palsy, implant irritation and triceps rupture. We think that the use of two plates may disturb bone circulation, and that anterolateral helical plating allows for stable osteosynthesis after rigid fixation of both columns. A limitation of our study was that the specimens were not cadaveric bones, being rather fourth-generation composite bone models



designed for biomechanical studies and lacking soft tissue. An advantage of using composite bone models is the homogeneity of specimens in comparing the two groups, making the plates themselves and the techniques of their insertions the sole different variables between groups. Cadaver bones may differ among size, porosity, tisddue stiffness and other variables. The main strength of our study was that we presented a strong fixation technique using a new plate. Prospective randomised clinical trials are required to validate our results.

CONCLUSION

The anterolateral plate exhibited higher bending stiffness and torsional yield strength than the posterolateral plate. Anterolateral plate fixation can be used to manage extra-articular distal humeral fractures. Multiaxial locking screws allow for rigid fixation and early elbow motion without impingement of the olecranon, and pose no risk of iatrogenic triceps muscle injury.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. HM: writing of the article, data analysis and interpretation, article review and approval of the final version of the manuscript ; AP: biomechanical work and data collection; MÜÇ: conceptualization, data analysis and article review; TD: biomechanical work, conceptualization and article review; ASP: statistical analysis, study supervision and article review.

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HYLAN G-F 20 VERSUS TRIAMCINOLONE IN THE TREATMENT OF PRIMARY SHOULDER OSTEOARTHRITIS. RANDOMIZED TRIAL

HILANO G-F 20 VERSUS TRIANCINOLONA NO TRATAMENTO DA OSTEOARTRITE PRIMÁRIA DO OMBRO. ESTUDO RANDOMIZADO

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ABSTRACT

Introduction: The aim of this study was to evaluate the effect of using an intra-articular injection of hylan G-F 20 (HA group) on primary shoulder osteoarthritis compared with an intra-articular triamcinolone injection (T group). Materials and Methods: The patients were randomized into 2 groups: in the HA group a single dose of intra-articular hylan G-F 20 was administered and in the T control group a dose of triamcinolone 20 mg was administered. The participants were evaluated at 1 week, 1, 3, and 6 months after the procedure. The patients were evaluated for pain, range of motion. Constant score, modified UCLA score, and SPADI. Results: Seventy patients met the inclusion criteria and were randomized to the HA (38) and T (32) groups. Improvements in range of motion were significant (p > 0.05). We observed decreases in the general visual analog scale (VAS) for pain in both groups, especially in the cases of mild and moderate arthritis that received hyaluronic acid (mean values from 8.1 initially to 4.9 after 6 months) (p = 0). Conclusions: Both injections led to a decrease in pain and an increase in patient satisfaction. The results tend to be better and longer lasting in patients receiving hyaluronic acid. Level of evidence II b; Cohort study.

Keywords: Shoulder. Osteoarthritis. Viscosupplementation. Hyaluronic acid. Injections, intra-articular. Corticosteroids.

RESUMO

Introdução: O objetivo deste estudo foi avaliar o efeito do uso de uma injeção intra-articular de Hilano G-F 20 (Grupo HA) na osteoartrite primária do ombro em comparação com injeção intra-articular de triancinolona (Grupo T). Material e Método: Os pacientes foram randomizados em dois grupos: no Grupo HA foi administrada uma dose única de Hilano G-F 20 intra-articular e no Grupo controle T foi administrada uma dose de 20 mg de triancinolona. Os participantes foram avaliados 1 semana, 1, 3 e 6 meses depois do procedimento. Os pacientes foram avaliados guanto à dor, amplitude de movimento, escore de Constant, escore UCLA modificado e índice SPADI, Resultados: Setenta pacientes satisfizeram os critérios de inclusão e foram randomizados para os Grupos HA (38) e T (32). As melhoras da amplitude de movimento foram significativas (p > 0.05). Observamos diminuições na escala visual analógica (EVA) geral para dor em ambos os grupos, principalmente nos casos de artrite leve e moderada que receberam ácido hialurônico (valores médios de 8,1 inicialmente a 4,9 depois de 6 meses) (p = 0). Conclusões: Ambas as injeções reduziram a dor e aumentaram a satisfação do paciente. Os resultados tendem a ser melhores e mais duradouros em pacientes que recebem ácido hialurônico. Nível de evidência II b; Estudo de Coorte.

Descritores: Ombro. Osteoartrite. Viscossuplementação. Ácido hialurônico. Injeções intra-articulares. Corticosteroides.

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INTRODUCTION

Osteoarthritis (OA) is the most common joint disease worldwide and affects more than 25 million people in the United States alone. The glenohumeral joint (GUJ) is the third most affected joint, after the knee and hip.¹

Although the actual prevalence of shoulder OA is difficult to determine, population studies have shown that approximately 20% of Japanese adults over 65 have radiographic evidence of glenohumeral OA.²

Unfortunately, there are still no known interventions that have been shown to delay the natural history of early OA. Eventually, these patients present worsening of pain and joint stiffness, generating functional limitations and decreasing quality of life.

The first step in treating primary glenohumeral OA is, with very few exceptions, conservative treatment, similar to that of other joints. Intra-articular injections (IA) are commonly used, more precisely represented by corticosteroids and hyaluronic acid (HA).³ Normally, surgical treatment is reserved after failed conservative treatment.

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

The study was conducted at the Universidade Federal de São Paulo (UNIFESP), Escola Paulista de Medicina (EPM), Sports trauma Center, São Paulo, Brazil. Correspondence: Paulo Henrique Schmidt Lara. R. Estado de Israel, 636 - Vila Clementino, São Paulo, SP, 04022-001. phslara@gmail.com

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There are no randomized controlled trials in the literature comparing the effects of viscosupplementation (VS) with IA corticosteroid injection in the treatment of glenohumeral OA. The few published controlled studies always used IA injection of saline solution in the control group.^{4,5}

The aim of this study was to evaluate the effect of using intra-articular injection of hylan G-F 20 on primary shoulder osteoarthritis compared with intra-articular triamcinolone injection.

MATERIALS AND METHOD

This is a prospective randomized clinical trial, whose research project was approved by the Research Ethics Committee (CAAE 89081818.5.0000.5505) and was registered through the Brazilian Registry of Clinical Trials (ReBEC).

Between July 2017 and April 2018, 86 patients with primary glenohumeral OA were treated at the shoulder ambulatory clinic of the Sports Traumatology Center of our institution and at the private clinic of the main author, and of these, seventy-seven met the inclusion criteria.

The inclusion criteria for the study were as follows: primary glenohumeral OA, visual analogue scale (VAS) of pain greater than 3, failure of prior conservative treatment for at least 3 months, availability for outpatient follow-up for 6 months after the procedure and completion of the Informed Consent Form.

The exclusion criteria were as follows: previous surgery on the affected shoulder, previous viscosupplementation on the affected shoulder, presence of complete rotator cuff injury, presence of neurological injury to the affected limb, use of corticosteroid regardless of route of administration in the last 2 months, current use of immunosuppressive or anticoagulant therapy and cognitive deficit that compromised the interpretation of the questionnaires. Radiographic evaluation of true anteroposterior shoulder (AP) incidence was performed by the Samilson and Prieto classification⁶. Magnetic resonance imaging of the shoulder was performed to evaluate rotator cuff pathology. Associated injuries such as peri-articular calcifications and intra-articular free bodies were also noted when present in imaging studies. All exams were performed before intervention.

Regarding the rotator cuff findings from the MRI examination, in the HA group, twenty-one patients (56%) presented partial lesion of at least one of the rotator cuff tendons, and 17 (44%) presented only tendinopathy of the rotator cuff. In the T group, twenty-one patients (67%) presented partial lesion of at least one of the rotator cuff tendons, and 11 (33%) presented only tendinopathy.

For pain measurement, the visual analogue scale (VAS) was used, with which the patient scored, on a scale from 0 to 10, the intensity of his pain. The patients were asked about pain in four aspects: general pain in the affected shoulder, movement pain and nocturnal pain.⁷ Three functional questionnaires were applied to assess upper limb function: Constant⁸, modified UCLA⁹ and SPADI¹⁰.

The patients participating in the study knew they would undergo the procedure but were blinded to their medication. All infiltrations were performed by the same doctor in an outpatient setting, as well as all subsequent evaluations. The infiltrations and evaluations were not blinded by the attending physician. In the public ambulatory the medication was paid by the main author and at the private ambulatory the medication was paid by the patient.

The HA group received a single-dose IA injection of hylan G-F 20 48 mg 6 ml (Synvisc One®), while the T group received a single-dose IA injection of triamcinolone hexacetonide (Triancil®) 20 mg 1 ml diluted in 5 ml saline.

The procedure was performed in an outpatient setting, with the patient sitting on a stretcher, with his back to the doctor. Shoulder antisepsis and local anesthesia with 2% lidocaine 5 ml volume with

a 25-mm needle were performed. All infiltrations were performed through a posterior approach, at the same site used for the arthroscopic posterior portal, known as the soft spot of the shoulder, located 2 cm inferior and 2 cm medial to the posterolateral angle of the acromion. The needle is directed anteriorly towards the coracoid process.¹¹

All procedures were guided by ultrasound, a Xario 200 Platinum Toshiba device with a broadband linear transducer at a frequency of 5 to 12 MHz. Routinely, the posterior infraspinatus tendon was first identified, with the patient sitting on the stretcher with an adduced shoulder. With dynamic maneuvers of medial and lateral rotations of the shoulder, the humeral head and the posterosuperior portion of the glenoid cavity were identified (Figure 1).

All patients were instructed not to use NSAIDs during the 6-month follow-up period, and in case of pain, were instructed to use acetaminophen 750 mg every 6 hours. Concomitant use of adjuvant therapies such as physical therapy and acupuncture was not considered in the evaluations. The patients were allowed to do such activities but there was not a protocol and it was not considered in our evaluation. Follow-up visits were as follows: visit 1 (when the initial assessment and procedure were performed), visit 2 (1 week after the procedure), visit 3 (1 month after the procedure), visit 4 (3 months after the procedure) and visit 5 (6 months after the procedure). In all visits, the 3 questionnaires were applied (Constant, modified UCLA and SPADI), as well as pain (VAS) and physical examination to measure range of motion (ROM). The patients were also asked about the occurrence of adverse effects.

Statistical methods

Statistical analysis of all information collected in this research was initially made descriptively through the mean, median, between minimum and maximum values, standard deviations and absolute and relative frequencies (percentages).

Patients who were classified according to Samielson and Prieto⁶ as mild and moderate arthrosis were considered in the same group to perform the analyses; this group was referred to as "nonsevere". In all conclusions obtained through inferential analyses, an alpha significance level equal to 5% was used.



Figure 1. Left: technique for visualization of the posterior aspect of the right shoulder in coronal section. Right: ultrasound image: A) infraspinatus tendon, B) posterosuperior portion of the glenoid cavity, C) humeral head.

RESULTS

The sample selected in this study consisted of 77 patients (77 shoulders). With randomization, the HA group consisted of 41 patients, and the T group consisted of 36 patients. During follow-up, three patients from the HA group were excluded. In the T group, there was a loss of 4 cases. As the final study population, the HA group consisted of 38 patients, and the T group consisted of 32 patients. The mean age of patients in the HA group was 72.7 years, ranging from 57 to 87 years. The average age of patients in the T group was 72.2 years, ranging from 53 to 88 years. Regarding gender, thirty-six (95%) were female in the HA group, and 31 (97%) were female in the T group.



The initial anterior elevation in the HA group was 115 degrees and in the final follow-up (6 months) was 122 degrees. In the T group it was initially 112 degrees and at the final follow-up was 112 degrees. The initial lateral rotation in the HA group was 21 degrees and in the final follow-up (6 months) was 25 degrees. In the T group it was initially 19,5 degrees and at the final follow-up was 20 degrees. The initial abdution in the HA group was 88 degrees and in the final follow-up (6 months) was 95 degrees. In the T group it was initially 95 degrees and at the final follow-up was 85 degrees. There was not statistical difference regarding range of motion.

According to the Samilson and Prieto Classification⁶, in the HA group, nine cases (24%) were classified as mild arthrosis, fourteen (37%) were classified as moderate arthrosis and 15 (39%) as severe arthrosis. In the T group, four (12.5%) were classified as mild arthrosis, twelve (37.5%) were classified as moderate arthrosis and 16 (50%) as severe arthrosis. Although the groups were homogeneous in relation to severity, for statistical analysis, cases of mild and moderate arthrosis were grouped and called "nonsevere", and the remaining severe cases were called "severe". Thus, in the HA group, twenty-three cases (61%) were classified as "nonsevere" and 15 cases (39%) as "severe". In the T group, sixteen cases (50%) were classified as "nonsevere" and 16 (50%) as "severe".

Statistically, there was no significant difference regarding range of motion between the 5 visits performed in either the HA or the T group. Patients classified as having "nonsevere" arthrosis in the HA group presented ROM improvement only 6 months after the procedure while the same patients in the T group presented ROM improvement 1 week after the procedure. However, with the Kruskal-Wallis test, it was not possible to observe a statistically significant difference at a 95% confidence level.

Table 1 shows the average overall pain (VAS) at each visit according to the degree of arthrosis.

We observed that 76% of the patients who received HA injection showed pain improvement after 1 month, and 71% had improvement after 6 months. Patients classified as "nonsevere" had better results than those classified as "severe". Both results without statistical difference. In the group that received the triamcinolone injection, we observed that 82% of the patients had pain improvement in the first week after the procedure, 76% had pain improvement after 1 month, 53% had improvement after 3 months and 32% showed improvement after 6 months compared to the initial assessment. In this group, the cases classified as "nonsevere" also obtained the best results. Table 2 shows the average per VAS evolution from movement pain to each visit by group.

We observed that 76% of patients who received HA injection showed improvement in pain after 1 month and that 63% showed improvement after 6 months compared with the initial assessment. The patients classified as "nonsevere" arthrosis had better results than those classified as "severe".

Table 3 shows the average VAS evolution of night pain at each visit and by groups.

We observed that 73% of the patients who received HA injection showed improvement in nocturnal pain after 1 month and that 66% improved after 6 months compared with the initial assessment.

 Table 1. Mean VAS evolution of overall pain at each visit, by groups and degree of osteoarthrosis (OA).

0		()					
Degree		VAS overall pain					
Group	of OA	1st visit	1 week	1 month	3 months	6 months	
HA	Severe	8,6	8	7,5	7,4	7,25	
Т		9,1	6,5	6	7	8,9	
HA	Nonsevere	8,1	7	5	5	4,9	
Т		8,3	4,8	4,1	6,2	7,8	

Patients classified as "nonsevere" had better results than those classified as "severe", but without statistical difference.

To verify in which visits the difference was observed, a Nemmenyi test was performed. For the HA group, there were improvements in visits at 1 month, 3 months and 6 months after the procedure, compared to the initial visit, for cases classified as "nonsevere". For cases classified as "nonsevere" in the T group, improvement was observed at only 1 week and 1 month after the procedure compared to the first visit.

Table 4 shows the evolution of the average obtained from the Constant questionnaire at each visit and by group.

With the Kruskal-Wallis test for comparison, in relation to the Constant questionnaire, in the HA group, the patients classified as "severe" arthrosis had a gradual improvement (p=0,031), while the same patients in the T group showed more evident improvement in the first week after the treatment (p=0,007).

Table 5 shows the mean evolution of the modified UCLA questionnaire at each visit and by group.

With the Kruskal-Wallis test for comparing the UCLA questionnaire between group visits, it is possible to see that in the HA group patients had a gradual improvement (p=0,007), while the patients in the T group showed more evident improvement in the first month after the treatment (p=0,007).

Table 6 shows the average evolution of the SPADI questionnaire results at each visit and by groups.

With the Kruskal-Wallis test to compare the SPADI questionnaire between the group visits, it can be noted that in the HA group patients had a gradual improvement (p=0,007), while the patients in the T group showed more evident improvement in the first month after the treatment (p=0,007).

No serious adverse effects has been reported. Six patients (8.6%) reported severe pain immediately after injection, 4 (10.5%) from the HA group and 2 (6.2%) from the T group. We had no cases of infection.

Table 2. Mean VNS evolution of movement pain at each visit, by groups
and by degree of osteoarthrosis (OA).

Group	Degree	VNS movement pain				
Group	of OA	1st visit	1 week	1 month	3 months	6 months
HA	Source	8,9	8,4	7,5	7	6,9
Т	Severe	7,9	6	5,9	6,3	8,7
HA	Nonsevere	8,4	6,9	5,3	5,1	5,3
Т		8,6	5	4,6	6,2	7,9

Table 3. Mean VAS evolution of night pain at each visit, by groups and degree of osteoarthrosis (OA).

Group	Degree		in			
Group	of OA	1st visit	1 week	1 month	3 months	6 months
HA	Course	8,4	7,6	6,6	6,9	7,4
Т	Severe	7,6	5,6	5,4	6,4	8
HA	Nonsevere	7,3	5,7	4,1	3,9	4,1
Т		8,5	4,4	4,4	6,5	8,1

 Table 4. Average of the Constant questionnaire at each visit, by group and by degree of osteoarthrosis (OA).

Degree		Constant score					
Group	of OA	1st visit	1 week	1 month	3 months	6 months	
HA	Course	37,4	41,6	47,9	50,4	51,3	
Т	Severe	44,4	58	53,8	49,8	42,2	
HA	Nanaoyoro	56	62	71,3	73,2	77,2	
Т	Nonsevere	53,7	67,6	68,8	63	51,2	

of osteoart	of osteoarthrosis (UA).							
O manum	Degree		l	UCLA score	e			
Group	of OA	1st visit	1 week	1 month	3 months	6 months		
HA	Courses	10,1	12,5	14,7	15,6	14,8		
Т	Severe	10,6	16,7	16,3	14,1	11,7		
HA	Nanaoyoro	13,1	17,6	21,5	22	24,1		

21,4

22

19

15,3

15,4

Nonsevere

Table 5. Average UCLA questionnaire at each visit, by group and by degree

Table 6. Average SPADI questionnaire results at each visit, by groups and by degree of osteoarthrosis

Group	Degree		e			
Group	of OA	1st visit	1 week	1 month	3 months	6 months
HA	Source	77,8	69,1	65,1	65,5	67,3
Т	Severe	81,6	70,3	72,3	76,7	84,4
HA	Nonsevere	73,3	65,3	51	48,3	42,4
Т		72,8	53,8	51	60,6	73,8

DISCUSSION

Painful glenohumeral OA is often profoundly disabling and difficult to treat.¹² Shoulder arthroplasty is effective in both pain reduction and function improvement, but its use is limited by concerns regarding implant longevity, difficulties associated with possible revision surgery, and limited outcomes in individuals with degenerative rotator cuff injuries.¹³ IA injections of corticosteroids are very effective in reducing pain and inflammation in patients with painful OA, particularly during periods of clinical exacerbation.^{14,15} However, their relative short-term effect (1 to 3 weeks) may lead to the need for more frequent injections, which are associated with adverse effects on joint structures, including acceleration of soft tissue damage and hyaline cartilage.¹⁶

Regarding range of motion, even in cases where there was a statistically significant improvement in pain and / or functional guestionnaires scores, the range of motion improvement was very subtle or did not occur, similar to previous study.¹⁷

The evaluation of the questionnaire scores also showed a gradual and longer-lasting improvement in those patients who received HA injection compared to those who received triamcinolone.

Brander et al.¹⁸ in a pilot study in the USA, evaluated 36 subjects with moderate and severe glenohumeral OA with the purpose of determining the safety and efficacy of two fluoroscopy-guided IA injections of hylan G-F 20. They observed improvement in pain after 6 weeks, 3 months and 6 months.

Kwon et al.⁵ evaluated the results of 3 doses of IA injections of high PM hyaluronic acid with a control group that received saline. Only patients with shoulder OA and no concomitant intrinsic shoulder disease treated with IA HA injections showed statistically significant improvements in pain.

Similarly, Porcellini et al.¹⁹, in their prospective study, showed that HA treatment for glenohumeral OA significantly decreased pain and improved shoulder function for at least six months from the first injection.

In a recent systematic review and published meta-analysis of VS in glenohumeral OA, Zhang et al.¹⁷ determined that HA injection IA is safe and improves pain in patients with shoulder OA.

Several studies address the difficulty of accurately administering glenohumeral IA injections. Hegedus et al.²⁰ evaluated 103 IA shoulder injections performed by their team physicians through 3 access routes, all not guided by the imaging method: anterior, posterior and anterosuperior (or Nevaiser). They concluded that only 52.4% of the injections were successful, and the highest rates of extra-articular injection were identified in the posterior and Nevaiser accessions.

Thus, we believe that the best technique for intra-articular GU injection is the one through which the physician has the most affinity-guided ultrasound approach whenever possible. In our study, the posterior approach was chosen, mainly because of the arthroscopic portal experience already used in routine surgical practice. Because it is an outpatient procedure, we believe that the approach used in the present study is efficient and easily applicable to physicians and surgeons, provided they are familiar with the posterior access route of the shoulder and the handling of the ultrasound device. But other studies have different approaches¹⁷ like the study of Brander et al.¹⁸ that used a anterior approach with fluoroscopic guidance.

The current study has some limitations. One is the fact that there was not a physiotherapy program. Another point is that the physician was not blind about the medication. A third point is that the follow-up was short considering the natural course of the osteoarthritis.

CONCLUSION

Viscosupplementation with a dose of hylan G-F 20, as well as intra-articular injection of triamcinolone, lead to decreased pain and increased satisfaction in patients with glenohumeral OA in the absence of complete rotator cuff injury. The results tend to be better and longer-lasting in patients receiving hyaluronic acid, as well as in patients with mild and moderate degrees of arthrosis regarding pain but with no statistical difference in functional scores.

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THE POLYMORPHISM OF METALLOPROTEINASES 1 AND 13 AND POSTTRAUMATIC ELBOW STIFFNESS

O POLIMORFISMO DAS METALOPROTEINASES 1 E 13 E A RIGIDEZ ARTICULAR PÓS-TRAUMÁTICA DO COTOVELO

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ABSTRACT

Introduction: To evaluate the relationship between the genetic polymorphism of matrix metalloproteinases 1 and 13 and posttraumatic elbow stiffness, as well as the association of other risk factors with this condition. Materials and methods: We evaluated 20 patients with posttraumatic elbow stiffness and 12 controls with traumatic elbow disorders without contracture. Deoxyribonucleic acid (DNA) was obtained from buccal mucosa epithelial cells of the volunteers. The MMP-1 and MMP-13 genotypes were determined using PCR-restriction fragment length polymorphism assays. Results: We did not find any significant differences in the frequency of genotypes and alleles between the test and control groups for the polymorphism of metalloproteinases 1 and 13. We observed that genotypes 1G/2G and 2G/2G of MMP-1 were present in 65% (13/20) of patients with articular stiffness and 50% (6/12) of controls (p = 0.599). Genotypes A/A and A/G of MMP-13 were obtained in 95% (19/20) of patients and 91.6% (11/12) of controls (p = 0.491). Among the prognostic factors for elbow stiffness, only immobilization time correlated positively. The mean immobilization time for cases and controls were 16 \pm 10 days and 7 \pm 7 days, respectively (p = 0.017). Conclusion: The genetic polymorphism of MMP-1 at position -1607 and MMP-13 at position -77 was not associated with post-traumatic elbow stiffness. Level of Evidence III; Prognosis Study; Case-Control Study.

Keywords: Articular rigidity. Elbow. Capsule contracture. Trauma. Metalloproteinases. Genetic polymorphism.

RESUMO

Introdução: Avaliar a relação entre o polimorfismo genético das metaloproteinases 1 e 13 da matriz e a rigidez pós-traumática do cotovelo, assim como a associação de outros fatores de risco com essa condição. Material e método: Foram avaliados 20 pacientes com rigidez pós-traumática do cotovelo e 12 controles com distúrbios traumáticos do cotovelo sem contratura. O ácido desoxirribonucleico (DNA) de voluntários foi obtido a partir de células epiteliais da mucosa bucal. Os genótipos MMP-1 e MMP-13 foram determinados usando ensaios de polimorfismo de comprimento de fragmento de restrição de PCR. Resultados: Não encontramos diferença significativa na frequência de genótipos e alelos entre os grupos teste e controle para o polimorfismo das metaloproteinases 1 e 13. Observamos que os genótipos 1G/2G e 2G/2G de MMP-1 estavam presentes em 65% (13/20) dos pacientes com rigidez articular e 50% (6/12) dos controles (p = 0,599). Os genótipos A/A e A/G da MMP-13 foram obtidos em 95% (19/20) dos pacientes e 91,6% (11/12) dos controles (p = 0,491). Dentre os fatores prognósticos para rigidez de cotovelo, apenas o tempo de imobilização se correlacionou positivamente. O tempo médio de imobilização para casos e controles foi de 16 \pm 10 dias e 7 \pm 7 dias, respectivamente (p = 0,017). Conclusões: O polimorfismo genético de MMP-1 na posição -1607 e MMP-13 na posição -77 não foi associado à rigidez pós-traumática do cotovelo. Nível de Evidência III; Estudos Prognósticos; Estudo de Caso-Controle.

Descritores: Rigidez articular. Cotovelo. Contratura capsular. Trauma. Metaloproteinases. Polimorfismo genético.

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INTRODUCTION

Elbow joint stiffness after trauma is a challenging complication in orthopedic practice and it is believed that soft tissue contracture, especially of the joint capsule, is the main source of stiffness. The inflammatory process initiated after the trauma may cause the contraction of elbow capsule due to an action of myofibroblasts and metalloproteinases of matrix 1 and 13 (MMP-1 and MMP-13).¹ MMPs are a family of zinc-dependent endopeptidases, capable of degrading almost all elements of the extracellular matrix. The expression of these proteases is regulated at different levels,

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<< SUMÁRIO

including genetic transcription. Some genetic single nucleotide polymorphisms (SNPs) in the gene promoting region of MMPs are correlated with an increase in the activity and production of these enzymes.² Recently, MMP-1 and -13 SNPs have been associated with diseases that cause joint stiffness, such as Dupuytren's disease³ and adhesive capsulitis.⁴ However, to date, we have not found any study evaluating the influence of genetic polymorphisms on posttraumatic elbow stiffness.

Our primary objective was to evaluate the relationship of genetic polymorphism in the promoter region of the genes of matrix metalloproteinases 1 and 13 with posttraumatic joint stiffness of the elbow. The secondary objective of our study was to assess other risk factors that could be associated with the development of this disease.

MATERIALS AND METHODS

Study design, participants and eligibility

We performed a case-control study. Patients with traumatic elbow disorders were selected during treatment follow-up between July 2017 and December 2018 in a single center. The study was approved by the local ethics committee.

The study patients had all the following inclusion criteria: skeletal maturity; interval greater than 6 months between the initial trauma and the evaluation for eligibility in the study; previous elbow fracture (including the distal humerus, proximal ulna, radial head) or reduced elbow dislocation, treated both surgically and non-surgically; physiotherapy treatment to gain range of motion for 4 months or more. Patients with umeroulnar joint incongruity, intra-articular screw penetration, heterotopic ossification, moderate or severe elbow osteoarthritis (Type II and III according to Rettig and Hastings classification)⁵ were not included. In addition, we did not include patients with previous or active infection in the elbow, fracture nonunion, with a history of traumatic brain injury, neurological injury in the affected limb, associated ipsilateral upper limb fracture, previous elbow surgery, autoimmune systemic diseases, refusal or difficulty to understand the terms of the study and use of immobilization on the elbow for longer than 1 month.

The case group consisted of patients with range of motion - flexion-extension <100°, and control group consisted of those with a functional range of motion (greater than 30° to 130°). Measurement of patients' range of motion was performed with a goniometer by the research assistant.

Variables

The following patient data were collected using a standardized form by the main author: age, sex, ethnicity, dominant side, affected side; clinical comorbidities, trauma type (low or high energy, elbow immobilization time, type of treatment performed (surgical or non-surgical), time of physical therapy treatment and fracture type (simple or comminuted).

DNA extraction and obtaining the genotype

DNA from epithelial buccal cells was extracted using the procedure described by Aidar and Line⁶ DNA concentration was estimated

by optical density measurements 260/280 nm. The researchers group who did the genetic analysis of the collected material, was blinded to which group the patient was included.

The MMP genotypes were determined using the PCR-random fragment length polymorphism assays (Table 1). PCR primers were done in a total volume of 15 μ L containing 100 ng of genomic DNA, 8 μ L Taq Green (Amersham Pharmacia-Biotech, Uppsala, Sweden), and 200 nmol of each primer. An 8 μ L aliquot of PCR products then was digested with 1 unit of specific enzyme overnight.

The total amount of aliquot of the digest was electrophoresed on 5% agarose at 20 mA. The gel was stained by GelRed[™] (Biotium Inc, Fremont, CA, USA).

The SNPs were identified previously and included in the database of the National Center for Biotechnology Information (http://www. ncbi.nlm.nih.gov/SNP/) with minor allele frequencies greater than 0.2. The MMP-1 polymorphism at position -1607 (rs1799750) is characterized by the insertion a base guanine (G), which results in two alleles: 1G and 2G. The allele 2G is represented by the DNA of 118 base pairs and the allele 1G is represented by the DNA of so as pairs. The heterozygous genotype has a combination of both alleles. The 2G allele is associated with increased transcriptional activity of this gene and degradation of the extracellular matrix.⁷

The MMP-13 polymorphism at position -77 (rs2252070) is characterized by an exchange of adenine (A) for guanine (G) creating two different alleles (A or G). Allele A is represented by a band of DNA with 445 base pairs and the allele G by two bands of DNA with 248 and 197 base pairs. The heterozygous genotype has a combination of both alleles. This polymorphism was associated with an alteration in transcription activity: the A allele has approximately twice the transcription activity, than the G allele.⁸

Sample size

The sample size calculation used a level of significance of 5% and power of 80%. At the time this research protocol was elaborated, there were no studies, to our knowledge, regarding the association between the genetic polymorphism of MMPs and posttraumatic elbow stiffness. Using a rate of 25% of the allele 2G of MMP-1 in the control group, an expected difference of 53% between groups based on study by Godoy et al.,⁷ 32 individuals were required in the study.⁸

Statistical Analysis

We submitted continuous variables to the assessment of normality, using the Kolmogorov-Smirnov test, and homogeneity, using the Levene test. Continuous variables are presented by means and standard deviation, while categorical variables are in absolute and percentage values. The comparison between cases and controls, with respect to the different variables, was performed using Chi-square or Fisher's exact tests, in the categorical variables. In continuous variables, using the Wilcoxon test. The difference in the frequency of alleles and genotypes of MMP-1 and 13 in individuals with post-traumatic elbow stiffness and controls was evaluated using the Chi-square test.

The software ARLEQUIN Version 2.0 (Laurent Excoffier CMPG, Institute of Ecology and Evolution, University of Bern, Bern, Switzerland)⁹ was used for the analysis of Hardy-Weinberg equilibrium

SNP	Primers (5'-3')	Anealling	RFLP	pb PCR-RFLP
MMP-1	F: TCGTGAGAATGTCTTCCCATT	55°C	Xmnl	118 (Allele 2G)
(rs1799750)	R: TCTTGGATTGATTTGAGATAAGTGAAATC	30 s	37°C	89 + 29 (Allele 1G)
MMP-13	F: GATACGTTCTTACAGAAGGC	53°C	Bsrl	445 (Allele A)
(rs2252070)	R: ACAAATCATCTTCATCACC	1 min	65°C	248 + 197 (Allele G)

PCR-RFLP = polymerase chain reaction-restriction fragment length polymorphism; MMP = matrix metalloprotease; SNP = single nucleotide polymorphism; F = primer forward; R = primer reverse; bp = base pairs.

<< SUMÁRIO

in the population studied. The distribution of genotypes of the study subjects was in the Hardy-Weinberg equilibrium. For the data analysis, we used SPSS® Version 21.0 (IBM Corp, Armonk, NY, USA) with a level of significance of 5%.

RESULTS

We evaluated 32 patients, 20 with posttraumatic elbow stiffness and 12 without stiffness (Table 2). There was no loss of samples during DNA extraction and genotyping, and the distribution of the study participants' genotypes was in Hardy-Weinberg equilibrium. The cases and controls groups had a mean age of 39.3 ± 11 and 47.4 ± 12.6, respectively (p = 0.068). Of the patients who had elbow stiffness, 14 (70%) were males, and of the control group, 6 (50%) were males (p = 0.258).

The groups did not differ regarding ethnicity, dominant side affected and clinical comorbidities (p > 0.999, p = 0.647 and p = 0.695, respectively). The mean of immobilization time was 15.7 ± 10.7 days in the case group and 6.9 ± 7 days in the control group (p = 0.017). We observed that the 1G allele of the MMP-1 genetic polymorphism (rs1799750) was more frequent in the case and control groups with a frequency of 79% and 65%, respectively (p = 0.477). Regarding the genotypes, we observed that the genotypes 1G / 1G and 1G / 2G were present in 95% of the patients in the elbow stiffness group and 92% of the patients without stiffness (p = 0.599). Also, we found no significant difference in the frequency of the genotypes and alleles of the MMP-13 genetic polymorphism (rs2252070) between the case and control groups (Tables 3 and 4).

DISCUSSION

Joint stiffness is a frequent complication of elbow trauma, and about 10 to 15% of patients will need some type of surgery during the treatment, once a 50° reduction in elbow mobility can result in

	Cases	Controls	р
Age (years)	39.3 11	47.4 12.6	0.068
Sex			
Male	14 (70%)	6 (50%)	0.258
Female	6 (30%)	6 (50%)	
Ethnicity			
White	10 (50%)	6 (50%)	0.999
Nonwhite	10 (50%)	6 (50%)	
Dominant side affected			
Yes	10 (50%)	7 (58%)	0.647
No	10 (50%)	5 (42%)	
Clinical comorbidities			
Yes	5 (25%)	4 (33%)	0.695
No	15 (75%)	8 (67%)	
Trauma type			
Low energy	8 (40%)	8 (67%)	0.273
High energy	12 (60%)	4 (33%)	
Treatment type			
Surgical	11 (55%)	8 (67%)	0.713
Non-surgical	9 (45%)	4 (33%)	
Orthopedic injury type			
Simple fracture	9 (45%)	8 (66%)	0.398
Comminuted fracture	6 (30%)	3 (25%)	
Dislocation	5 (25%)	1 (8%)	
Elbow immobilization time(days)	15.7 10.7	6.9 7	0.015
Time of physical therapy treatment (weeks)	38.8 32.6	16 21	0.040

 Table 3. Distribution of the MMP-1 and MMP-13 allele in case and control groups.

	Cases	Controls	р
MMP-1			
1G	26 (65%)	19 (79%)	0.497
2G	14 (35%)	7 (21%)	
MMP-13			
Α	30 (75%)	15 (63%)	0.289
G	10 (25%)	9 (37%)	

 Table 4. Distribution of the MMP-1 and MMP-13 genotype in case and control groups.

	Cases	Controls	р
MMP-1			
1G/1G	7 (35%)	6 (50%)	0.599
1G/2G	12 (60%)	5 (42%)	
2G/2G	1 (5%)	1 (8%)	
MMP-13			
A/A	11 (55%)	4 (33%) 0	
A/G	8 (40%)	7 (58%)	
G/G	1 (5%)	1 (8%)	

up to 80% of functional loss.¹⁰ The most common cause of elbow stiffness is the contraction of soft tissues after the initial injury, which worsens with the use of prolonged immobilization.¹¹ The elbow capsule becomes thick and there is an increase in the amount of type I, III and V collagen fibers, proteoglycans and MMP-1 and 13, as well as the formation of myofibroblasts in a posttraumatic elbow stiffness.^{1,12}

In our study, the genetic polymorphism of metalloproteinases 1 (rs1799750) and 13 (rs2252070) was not associated with posttraumatic elbow stiffness. It was not possible to find a statistically significant difference in the frequency of alleles and genotypes in the group of cases and controls of the two metalloproteinases studied. Genetic polymorphism is a variation in the sequence of DNA nucleotides and is present in over 1% of the population. Among these variations, the most common is the SNPs.¹³ Some SNPs in the promoter region of MMP genes are correlated with an increase in the activity and production of these enzymes^{2,14} As we did not find a direct association between the genetic polymorphism of MMP-1 and 13 with posttraumatic elbow stiffness, we believe that the increase in levels of metalloproteinases in these patients is related to other biological causes resulting from the trauma, and not to the genetic influence. The role of several external factors that affect both transcriptional and post-transcriptional activation of MMPs has been demonstrated, which include inflammatory cytokines, hormones and growth factors (TGF-β, EGFR, TNF-α, IL-1β).¹⁵

The genetic polymorphisms of MPPs are associated with several orthopedic diseases, such as posterior tibial tendinopathy, rotator cuff tear, stiffness after rotator cuff repair, adhesive capsulitis and Dupuytren's disease.^{3,4,7,16,17} The balance of the Extracellular matrix (ECM) of the articular capsule, tendons and ligaments is guaranteed by equal rates of deposition and removal of collagen fibers, the latter activity mediated by MMPs. An imbalance can lead, when withdrawal predominates, to tendinopathies and tears, such as that of the posterior tibial tendon⁷ and rotator cuff.¹⁶ When deposition predominates, we can observe fibrotic processes such as Dupuytren's disease³ and adhesive capsulitis of the shoulder.⁴

In contrast, we found association between prolonged immobilization and posttraumatic stiffness. Patients with posttraumatic elbow stiffness remained immobilized for 16 days on average during treatment,



whereas patients without stiffness were immobilized for only 7 days (p = 0.017). Monument et al.¹⁸ have shown that prolonged joint immobilization results in numerous physical and biochemical disorders in and around joint structures, including erosions of the articular cartilage, decreased articular proteoglycan content, changes in collagen fibers and synovial adhesions. Others authors such as Schollmeier et al.,¹⁹ showed that immobilization favored contracture of the capsule and reduced the volumetric capacity of the joint. The ideal immobilization time for healing, and the correct time to start the range of motion gain are critical points in the treatment of elbow injuries.

Our study has some limitations. The number of study participants is small for a genetic study. However, elbow stiffness is an uncommon condition and we noticed that patients who evolved without stiffness stopped having follow-up. The power of the study was 21.2% for the evaluation of MMP-1 polymorphism and 18.8% for MMP-13. With these low values, we cannot completely refute the hypothesis that these polymorphisms may influence the development of elbow stiffness. Functional genomics studies carried out to date in orthopedic diseases have been small or modest in scale and they are restricted in terms of power, although necessary to demonstrate experimental feasibility and provide first insights into disease biology.²⁰ In addition, we selected a very heterogeneous

group of patients with regard to age, type of fracture and types of treatment. The disadvantage in this is the lack of pairing between patients in the groups, which increases the possibility of confusion bias. However, the external validity of the study has increased. We could highlight that this study is the first approaching the association of the genetic polymorphism of matrix metalloproteinases with posttraumatic elbow stiffness. Genetic polymorphism of MMPs were associated with increased risk of post-operative stiffness susceptibility and severity in patients after rotator cuff repair.¹⁷ We understand that a larger scale investigation is necessary, trying to decipher if there is really a genetic influence in this disease. The identification of patients most susceptible to elbow stiffness, may in the future lead to alternative forms of treatment and increase knowledge of pathophysiology and the factors involved in the development of posttraumatic elbow stiffness.

CONCLUSION

The genetic polymorphisms of MMP-1 at position -1607 (rs1799750) and MMP-13 at position -77 (rs2252070) were not associated with posttraumatic elbow stiffness. However, among the risk factors evaluated, prolonged immobilization was correlated with stiffness of the joint elbow after trauma.

AUTHORS' CONTRIBUTION: GMRP: conceived and planned the activities that led to the study, wrote the Original Draft and participated in the review process of the manuscript; JHA: conceived and planned the activities that led to the study, development the design of methodology, interpreted the results of the study, participated in the review process of the manuscript; MCLGS: provided study material and scientific support; ALGS: development the design of methodology, provided study material and scientific support; MECG: participated in the review process of the manuscript; FBAS: participated in the review process of the manuscript; AAFN: supervision of the study, participated in the review process of the manuscript. All authors have read and approved the final article, and also authorized its publication.

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PERCUTANEOUS ENDOSCOPIC LUMBAR INTERBODY FUSION: RESULTS OVER 47 MONTHS OF FOLLOW-UP

ARTRODESE LOMBAR INTERSOMÁTICA ENDOSCÓPICA PERCUTÂNEA: RESULTADOS DEPOIS DE 47 MESES DE ACOMPANHAMENTO

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ABSTRACT

Introduction: This study aims to investigate the clinical-functional results of a new surgical technique, Percutaneous Endoscopic Lumbar Interbody Fusion (PELIF), in patients with a clinical diagnosis of low back or sciatic pain and segmental instability who were submitted to surgery using this technique assisted by the attending physician. Materials and methods: Patients completed a consent form and were clinically and radiographically re-assessed by independent evaluators using the visual analog scale (VAS) for pain, the Oswestry Disability Index (ODI), and the SF-36 Quality of Life Score in the pre- and postoperative periods. Their medical records were also reviewed for surgical time, length of hospital stay, need for blood transfusion, return to work, and radiographic fusion evaluation. Results: In the group of 19 patients with 33 levels operated, VAS and ODI decreased from 10.0 and 64% to 2.0 and 28%, respectively. The SF-36 showed significantly higher scores in 5 of its 7 domains at the end of the follow-up as compared to the preoperative period scores. Only 1 case of pseudoarthrosis was diagnosed radiographically. Conclusions: Percutaneous Endoscopic Lumbar Interbody Fusion (PELIF) has been shown to be a safe and efficient technique for the treatment of patients with segmental instability associated with low back or sciatic pain. Level of Evidence VI; Therapeutic Study; Case Series.

RESUMO

Introdução: Este estudo tem como objetivo investigar os resultados clínico-funcionais de uma nova técnica cirúrgica, artrodese lombar endoscópica percutânea (PELIF) em pacientes com diagnóstico clínico de dor lombar ou ciática e instabilidade segmentar, submetidos à referida técnica pelo médico responsável. Materiais e métodos: Os pacientes preencheram um termo de consentimento livre e esclarecido e foram reavaliados clínica e radiograficamente por avaliadores independentes que usaram a Escala Visual Analógica (EVA) para dor, Índice de Incapacidade de Oswestry (ODI) e o Short Form Health Questionnaire SF-36 nos períodos pré e pós--operatório. Foram também pesquisados nos prontuários médicos tempo de cirurgia, tempo de internação hospitalar, necessidade de transfusão de sangue, retorno ao trabalho e avaliação radiográfica da fusão. Resultados: Na amostra final de 19 pacientes com 33 níveis operados, EVA e ODI diminuíram de 10,0% e 64% para 2,0% e 28%, respectivamente. O SF-36 mostrou escores significativamente maiores em 5 de seus 7 domínios no final do acompanhamento, em comparação com o período pré-operatório. Somente 1 caso de pseudoartrose foi diagnosticado por radiografia. Conclusões: A artrodese lombar endoscópica percutânea (PELIF) tem se mostrado uma técnica segura e eficiente para o tratamento dos pacientes com instabilidade segmentar associada a lombalgia ou ciatalgia. Nível de Evidência IV; Estudos Terapêuticos; Série de Casos.

Keywords: Spine/surgery. Arthrodesis. Endoscopy.

Descritores: Coluna vertebral/cirurgia. Artrodese. Endoscopia.

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INTRODUCTION

Low back pain is a major cause of incapacity for work in the western world, with difficult resolution and ineffective responses. Modern techniques have provided better results, but with an increase in costs.¹ The first disc resection was done by Mixter & Barr, in 1934.² Using an arthroscope, Hijikata et al.,³ achieved intervertebral disc resection, being enhanced by Kambin & Gellman⁴, with the description of "Safety Triangle", between the exiting and descending roots, the basis of foraminal accesses.⁵ The introduction of pedicular screws, associated with transforaminal lumbar interbody fusion (TLIF),⁶ with less dissection and neural retraction, a well-established surgical technique for many vertebral lesions.⁷ Fusion is the "gold standard" in the invasive treatment of low back pain and can be achieved by different approaches, however, they are invasive, with blood loss, muscle damage and resections many structures, generating the so-called "fusion disease".⁸

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

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These comorbidities, such as epidural fibrosis, leading to the search for minimally invasive techniques, such as MIS-TLIF. 8

Modern endoscopes have avoids these approaches'complications, allowing views of disc space and spinal canal, direct neural structure'access and showing evidence compared with established techniques.⁹

The advent of percutaneous fixation and tubular dilators, for less aggressive fusion showed, however, some limitations.¹⁰ But, the video decompression, associated with percutaneous fixation, provided the Percutaneous Endoscopic Lumbar Interbody Fusion (PELIF),¹¹ with the same classical surgery objectives, but lower morbidity. However, would the surgical results be the same? This study investigates whether the PELIF technique achieves the same objectives as conventional arthrodesis, and with good clinical-functional results.

MATERIALS AND METHODS

The inclusion criteria were chronic low back or sciatic pain, with segmental instability (vertebral translation of 3.0 to 3.5 mm, or intervertebral angulation greater than 10° on dynamic radiographs), resultant in pain or neurologic symptoms¹² and unresponsive to effective clinical treatment for at least 06 (six) weeks, presenting the classic indications for conventional fusion but underwent PELIF.

Study group

They were attended, by the author, from April 2009 to July 2015, and the diagnosed of tumor, infection, previous surgery and those undergoing PELIF but re-operated in other services were excluded. Patients were clinically and radiologically assessed by independent evaluators using the Visual Analogue Scale (VAS) of pain,¹³ Oswestry Disability Index (ODI)¹⁴ and SF-36 Quality of Life Score,¹⁵ on pre- and postoperative period. Surgical data (surgery time, length of hospital stay, need for blood transfusion) and demographics were obtained from medical charts. Radiographic fusion was confirmed by computed tomography (CT) showing bone trabeculae between vertebral bodies.⁸ The patients were informed about the objectives of the study and signed the written informed consent form. This study was approved by the Ethics Committee (protocol number 2.546.754).

Surgical technique

The PELIF, described by Morgenstern,¹¹ uses percutaneous access through a sequential tube system and direct visualization by the endoscope.

The preoperative images show the interest area and the entry point puncture, avoiding neural manipulation. The general anaesthesia, in prone position, with puncture by 18G needle guided and image enhancer, accessing the disc through transforaminal approach. Discography is performed with iodinated contrast and dye, followed by the placement of a guidewire in the disc center. (Figure 1)

The needle is removed, with dilators passing over the guidewire, ending with a working cannula and dilators removal, followed by endoscopic optics (4.1 mm working channel) entrance. Visualization of the disc space and adjacent neural structures. Haemostasis is performed by radiofrequency probe. The superior articular process is partially resected by drill, with foraminal enlargement (Figure 2) and avoiding postoperative instability or perineural fibrosis. This allow the entry of 04 (four) new larger diameter tubular dilators, with the latter having a working channel of 15.5 mm.

The simultaneous endoscopic and radioscopic guidance, avoiding neural interposition and enabling passage to disc reamers and curettes with larger diameter, to faster and more efficient material removal and debridement of the vertebral end plate. (Figure 3)

After this, the anterior intersomatic space is filled with 10 grams of heterologous bone graft (hydroxyapatite) and, with previous measurement tests, we introduced the polyetheretherketone (PEEK) intersomatic CAGES. Two CAGES are placed according to each patient's biotype, parallels and in the anterior third of the intersomatic space. The 15 mm cannula allows direct CAGES and bone graft visualization in the intersomatic space. (Figure 4) The Spinal fixation is followed by the use of a percutaneous pedicle screw system.¹⁶

Statistical Analysis

The collected data were submitted to statistical analysis, with categorical data in absolute (n) and relative (%) values and continuous data verified by the Shapiro-Wilk test. Variables with normal distribution were described as mean and standard deviation and those without normal distribution were described as medians and quartiles 25 and 75. The student t test was used to compare variables with normal distribution and Wilcoxon rank test to compare variables without distribution. We compared pain perception at three stages of the study evaluation (before, one week and three years after surgery)



Figure 1. Discography with guidewire placement in the center of the disc.

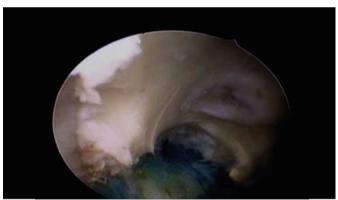


Figure 2. Superior facet partially resected by endoscopic drill.



Figure 3. 15.5 mm working channel, with a series of larger diameter reamers and curettes for debridement of the vertebral end plate.

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with the Friedman test and the binary correlation between continuous variables made by Spearman's product-moment coefficient. The statistical significance level used for all analyzes was p < 0.05, using the 25.0 SPSS version statistical package (IBM®, Chicago, IL, USA).

RESULTS

For an initial sample of 24 patients, we had 05 losses (04 reoperations in other services and one death from urban violence), leaving 19 patients, 17 men and 02 women, with a mean age of $36.1 \pm$ 1.2 years. The mean follow-up time was 47.0 (29.0 - 70.0) months. Thirty-three levels were operated, with 73.7% of cases operating two levels, always between L2 and S1. CAGES of 08 mm and 10 mm were used, according to pre-introduction tests.

The mean surgical time was 355.0 (275.0 - 420.00) minutes, with patients hospital discharged in 3.0 (2.0 - 4.0) days. The mean blood loss was 215.8 ± 76.5 ml and there was no blood transfusion. Among the 19 patients, only one had lower back pain after surgery and 11 had leg pain. Return to work after surgery was 31.6%.

The patients' results related to the surgical procedure and epidemiological data are presented in Table 1.



Figure 4. Final endoscopic cage view between vertebral plateaus.

Table 1. Surgical procedure characteristics and patients clinical status before and after surgery. (n = 19).

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Characteristic	n (%)	Mean SD or Mean (Q25 and Q75)
Operated level		
1	5 (26.3)	-
2	14 (73.7)	-
Operated side		
Right	10 (52.6)	-
Left	9 (47.4)	-
Surgery duration (min)	-	355.0 (275.0 - 420.00)
Hemoglobin concentration before (g / dl)	-	15.2 ± 1.1
Hematocrit concentration before (%)	-	45.2 ± 2.6
Hemoglobin concentration after (g / dl)	-	11.4 ± 1.8
Hematocrit concentration after (%)	-	34.5 ± 4.0
Total Bleeding (mL)	-	215.8 ± 76.5
Length of hospital stay (days)	-	3.0 (2.0 - 4.0)
Postoperative pain perception (u.a.)	-	1.0 (0.0 - 3.0)
Post-surgery pain site		
Free from pain	7 (36.8)	-
Lumbar	1 (5.3)	-
Leg	11 (57.9)	-
Return to work		
Not	13 (68.4)	-
Yes	6 (31.6)	-

The median pain intensity before surgery was 10.0 (9.0 - 10.0) u.a. on VAS, decreasing to 1.0 (0.0 - 3.0) u.a. on postoperative. There was no statistically significant difference in pain intensity between one week 1.0 (0.0 - 3.0) u.a. and at the end of follow-up 2.0 (0.0 - 4.0) [x^{2} (2) = 29.288, p <0.001]. (Figure 5)

Control MRIs showed preservation of the paravertebral muscles, eliminating the high rate of fat replacement, showing that transforaminal percutaneous access reduces soft tissue lesions. (Figure 6) Comparison of Owestry score functionality showed decrease before surgery and at the end of follow-up [64.0 (52.0 to 70.0) vs. 28.0 (20.0 to 36.0)%; z = -3.503, p < 0.001]. (Figure 7)

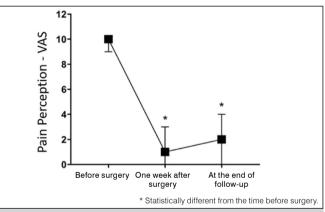
Comparison of quality of life by SF-36, preoperative and at the end of follow-up, showed improvement in functional capacity scores (z = -3.509; p < 0.001), physical aspects limitations (z = 3.535; p < 0.001), pain (z = 3.624; p < 0.001), general SF-36 status (z = 3.333; p = 0.001) and vitality (z = 3.247; p = 0.001). The social aspects (z = -0.700; p = 0.484) and mental health (z = -1.479; p = 0.139) domains were similar before surgery and at the end of follow-up. (Table 2)

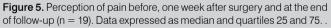
We had four complications with reinterventions: a cage migration, a subsidence with cage removal, an infection and a medially positioned screw. None of the cases required conversion to open surgery, with all complications being corrected by the same technique and only 01 of 19 patients had pseudarthrosis.

DISCUSSION

The surgical lombar procedures show good results in the longterm. However, the postoperative period has limitations like pain, instability and epidural fibrosis.¹

We had five losses in 19 patients. Jacquot and Gastambide,¹⁷ reported 32 losses in 57 endoscopic fusions. The follow-up time





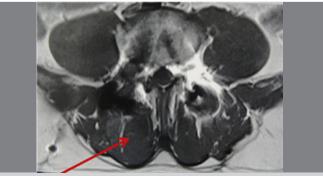


Figure 6. MRI image of 12 months postoperative showing broad muscle preservation (see arrow).

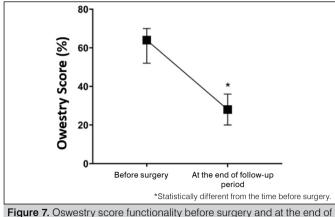


Figure 7. Oswestry score functionality before surgery and at the end of follow-up. Data expressed as medians and quartiles 25 and 75.

Table 2. Quality of life by SF-36 before surgery and at the end of follow-up (n = 19).

(
SF-36 Domain	Before	At the end of follow-up	p-value
Physical capacity	10 (0 - 25)	90 (50 - 100)	<0.001
Physical aspects limitations	0 (0 - 0)	100 (25 –100)	<0.001
Pain	0 (12 - 22)	62 (51 - 100)	<0.001
General health status	25 (5 - 35)	82 (57 - 100)	0.001
Vitality	25 (10 - 40)	80 (50 - 100)	0.001

Data expressed as mean \pm standard deviation or median and (quartiles 25 - 75). P-value in bold equals statistically significant differences.

was 47.0 (70.0 - 29.0) months. Lee et al.¹⁸ had 46 (12–123) months of follow-up time.

The limitations in the CAGES introduction were clear, with 12 patients received 08 mm size CAGES and just 07 received 10 mm CAGES, in a total of 19 cases, according to the tests used. Jacquot and Gastambide¹⁷ had similar difficulty, even using bilateral pathways, inserting only one cage in three of 57 patients. The expandable CAGES did not solve the problem, with five broke implants, one reintervention by implant migration and 02 pseudarthrosis in 18 patients.

Lee et al.,¹⁸ did not use posterior fixation and, with a sample similar to ours (18 patients), had twice as much pseudarthrosis (02 cases). The expandable CAGES provided postoperative dysesthesias too, with 14 cases in 24 patients, and "minimal subsidence" in 7 cases, with significant subsidence in two, both requiring reintervention.¹ We had one subsidence, being corrected by the PELIF technique itself. Other publications with both CAGES models, found no differences between the two groups, suggesting that the type of cage does not interfere with the final outcome.¹¹

Our mean surgical time was 355.0 (275.0 - 420.00) minutes. Wang and Grossman⁽⁵⁾ had a mean operative time of 113.5 \pm 6.3 minutes (range 105 to 120 minutes), showing an initial learning curve, but with a hospital discharge in 3.0 (2.0 - 4.0) days, compared to the same study which had a discharge time of 1.4 \pm 1,3 nights,⁵ showing that the surgery time did not affect the patients' postoperative.

The blood loss was 215.8 \pm 76.5ml, similar to others with 238 mL (140-350)^{16} and there was no blood transfusion.

We had only one postoperative lombar pain in 19 patients. The PELIF uses successive dilators, with minimal incisions and few soft tissue lesions (Figure 6), reducing postoperative pain and long-term complications.¹⁹ Our final working cannula (15.5 mm) (Figure 3), is similar to others with a 12 mm¹¹ and compatible with anatomical studies showing an average size of 15.5 mm at the working triangle because, other authors, have found an average from 18.5 to 26.6 mm.⁵ These limits are more than sufficient for the access of our dilators (15.5 mm).

Transforaminal endoscopic access prevents scar tissue, epidural adhesions and reduces soft tissue lesions, eliminating fat paravertebral muscles replacement¹⁸ similar to found in our PELIF. (Figure 6) However, we had 11 leg pain patients in the immediate postoperative period (Table 1) and, although transitory and low-intensity (u.a.): 1.0 (0.0 - 3.0), is similar to others, and considered as "inevitable".⁹ The final 15.5 mm working fusion cannula, when compared to traditional endoscope, increases postoperative dysesthesia, but provides direct neural visualization in CAGE introduction.

There was improvement in all clinical parameters (VAS, Oswestry Scale and SF-36) on postoperative, when we compare them before, one week after surgery and at the end of follow-up time, showing an immediate pain improvement and mainly, same after three years of follow-up, remaining with low scores. (Figure 5) The good results in minimally invasive procedures, especially in VAS measurement, is widely demonstrated in the literature.¹

The Owestry score was lower at the end of follow-up compared to the time before surgery [64.0 (52.0 to 70.0) vs. 28.0 (20.0 to 36.0) %; z = -3.503, p < 0.001], with an improvement over 100%. Other studies have shown average scores from 69.9 ± 14.3 (range, 44.4–92) to 22.3 ± 17.1 (range, 4–71.1) with 69% improvement (p < 0.001) (18).

The SF-36 data are useful for assessing patients' overall health status.¹⁵ Our findings showed the domains functional capacity (z = -3.509; p < 0.001), physical aspects limitation (z = 3.535; p < 0.001), pain (z = 3.624; p < 0.001), general health status (z = 3.333; P = 0.001) and vitality (z = 3.247; p = 0.001) were higher at the end of follow-up compared to preoperative period, with p-values showing a statistically significant difference, especially in the limitation and pain domains.

Our fusion rate was high, with only one patient presenting pseudarthrosis, verified by computed tomography with the presence of bone trabeculae between vertebral bodies. This patient was also the only one who, due to subsidence, had his CAGES removed and, because of the lesion on the upper vertebral plateau, we could not place a new device.

Other authors found a low subsidence rate of PEEK-like CAG-ES too, because the access route and surgical aggression in this technique are very small. They correlated the subsidence at the L5-S1 level and the anterior cage positioning.^{19,20} Our case (level L4-L5), coincided only the anterior position of the cage.

Our complications are similar to literature,¹⁸ with only four cases requiring reintervention. One cage migration, one subsidence, one case of infection, and one medially positioned screw. The authors Jacquot and Gastambide¹⁷ had 13 of 57 patients with CAGES migration (22.8%), requiring conventional reoperations, because just eleven had a simultaneous posterior fixation at the first procedure, which may be the cause of high rate cage migration. In our sample, no patient required conversion to open surgery, with all complications being corrected by PELIF, including the only case with cage migration.

These found, similar to others,¹⁸ the percutaneous endoscopic lumbar interbody fusion (PELIF) has achieved the expected goal (fusion) and is a safe and effective option for minimally invasive neural decompression.

This is an original technique and although it presents results comparable to similar others,^{1,11,16,18} it has particularities that differ substantially from them.

CONCLUSION

The present study provides evidence that Percutaneous Endoscopic Lumbar Interbody Fusion (PELIF) is a safe option for interbody fusion and patients have good clinical-functional outcomes with a minimum of 29 months of follow-up.



AUTHORS' CONTRIBUTION: Each author made significant individual contributions to this manuscript. ACS: Conceptualization, Writing - Original Draft. TA: Methodology, Investigation, Resources, Writing - Review & Editing. MPN: Methodology, Validation, Formal analysis, Writing - Review & Editing, Supervision.

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PELVIC INCIDENCE AND OSTEITIS PUBIS IN PROFESSIONAL **SOCCER PLAYERS**

INCIDÊNCIA PÉLVICA E OSTEÍTE PÚBICA EM JOGADORES **PROFISSIONAIS DE FUTEBOL**

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ABSTRACT

Introduction. Osteitis pubis is a common inflammatory disease of the pubic symphysis, defined as a chronic pain syndrome caused by repetitive microtrauma. Since adaptative changes are necessary in the pelvis to adjust the equilibrium of the myotendinous structures, the aim of this study was to evaluate the correlation between pelvic incidence and osteitis pubis among professional soccer players. Materials and Methods. An observational, crosssectional study was performed with professional soccer players from five teams during pre-season. Athletes with previous congenital pelvic abnormalities or a history of surgery were excluded. Radiographs of the pelvis were analyzed by two radiologists and assessed for findings consistent with osteitis pubis, and the following parameters were measured: pelvic incidence (PI), sacral inclination (SI), and pelvic version (PV). Results. A total of 107 subjects were included in the study, with a mean age of 25.6 \pm 3.1 years. Findings compatible with osteitis pubis were present in 74.8% of the subjects (80/107). There was no statistical correlation between osteitis pubis and PI (52.3°±12.7° vs. 48.4°±10.8°; p=0.156), SI (43.1°±9.8° vs. 39.9°±10.1°; p=0.146), or PV (9.2°± 6.3° vs $8.6^{\circ} \pm 7.5^{\circ}$; p=0.649). Agreement between readers was excellent (p<0.0001). Conclusion. There was no significant correlation between pelvic parameters and radiographic diagnosis of osteitis pubis. Leve of Evidence II; Diagnostic study.

Keywords: Sports medicine. Pubic symphysis. Pelvis. Soccer.

RESUMO

Introdução. A osteíte púbica é uma doença inflamatória comum da sínfise púbica, definida como síndrome de dor crônica causada por microtraumas de repetição. Uma vez que são necessárias mudanças adaptativas na pelve para adequar o equilíbrio das estruturas miotendíneas, o objetivo deste estudo foi avaliar a correlação entre e a incidência pélvica e a osteíte púbica em jogadores profissionais de futebol. Materiais e Métodos. Estudo transversal, observacional, conduzido com jogadores profissionais de futebol de cinco times profissionais durante a pré-temporada. Foram excluídos do estudo atletas com anormalidades congênitas prévias ou com história de cirurgia. As radiografias de pelve foram avaliadas por dois médicos radiologistas quanto aos achados compatíveis com osteíte púbica, e os seguintes parâmetros foram medidos: incidência pélvica (PI), inclinação sacral (SI) e versão pélvica (PV). Resultados. Foram incluídos 107 participantes, com média de idade de $25,6 \pm 3,1$ anos. Achados compatíveis com osteíte púbica estavam presentes em 74,8% dos indivíduos (80/107). Não houve correlação estatística entre osteíte púbica e PI (52,3°± 12,7° vs. 48,4° ± 10,8°; p = 0,156), SI $(43,1^{\circ} \pm 9,8^{\circ} \text{ vs. } 39,9^{\circ} \pm 10,1^{\circ}; p = 0,146) \text{ ou PV} (9,2^{\circ} \pm 6,3^{\circ} \text{ vs. } 8,6^{\circ}$ \pm 7,5°; p = 0,649). A concordância entre os médicos radiologistas foi excelente (p < 0,0001). Conclusões. Não houve correlação significativa entre os parâmetros pélvicos e o diagnóstico radiográfico de osteíte púbica. Nível de Evidência II; Estudo diagnóstico.

Descritores: Medicina esportiva. Sínfise pubiana. Pelve. Futebol.

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INTRODUCTION

In the current sportive scenario, pubic symphysis is a joint that has gained lot of attention in recent years. Part of the pelvic girdle, pubic symphysis became target of a considerable frequent but difficult to diagnose entity: osteitis pubis.1

Currently, osteitis pubis is considered the most common inflammatory disease of the pubic symphysis and it is defined as a chronic pain syndrome caused by repetitive microtrauma.^{2,3} Osteitis pubis is especially prevalent in sports with "kicking" movement, as soccer, and is frequently associated with aponeurotic, tendinous or muscular

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<< SUMÁRIO

malfunction³. Both adductors and rectus abdominis muscles are inserted at the symphysis pubis, but they act antagonistically, creating increased mechanical traction and repetitive microtraumas that can predispose to a symphyseal imbalance and ultimately to osteitis pubis.^{4–6}

Osteitis pubis represents a complex entity and the wide spectrum of changes seen in osteitis pubis are related with one of the most important principles of physiology of exercise: the adaptability, and also with the balance between the pelvis and the gravity center. There is no consensus about normal sagittal balance values, since there is a great variability between individuals.^{6–8} Even though. one can define a normal spinopelvic sagittal balance as that most frequently observed in asymptomatic subjects, meaning a harmonic balance of the axial body segment to the bicoxofemoral axis (defined by a line crossing the head of both femoral heads) with minimum muscular energy expenditure. Such balance has the aim to position the gravity line of upper body segment (head, trunk and upper extremities) during orthostasis, in low torque situation than bicoxofemoral axis itself and the global gravity line in a strict zone of support. This posture means that osteoarticular and myofascial elements will work in synchrony avoiding early degenerative and malfunction changes.8

Many authors that established radiological parameters to assess sagittal balance reinforced the importance of the pelvic position in vertebral statics.^{1,3,8–11} The literature has defined the mean pelvic incidence angle as 50° in the adult asymptomatic population.¹²

The objective of this study is to evaluate the correlation between pelvic incidence and osteitis pubis among professional soccer players. Since adaptative changes are necessary to the pelvis in order to adequate myotendinous structures equilibrium, we sought to investigate if alterations to athletes' sagittal balance and pelvic parameters are related to osteitis pubis.

MATERIALS AND METHODS

An observational and cross-sectional study was conducted after approval by the Research Ethics Committee (CEP) from our institution. Subjects were recruited from five professional soccer teams during pre-season evaluation, from Jan 2016 to April 2016, by the Sports Medicine Section from Orthopedics and Traumatology Department of our institution.

Inclusion criteria consisted in male athletes and active soccer players. Exclusion criteria were history of congenital pelvic abnormalities, previous pelvic surgeries, or absence of pelvic and spine radiographs from childhood.

Imaging studies

All parameters were evaluated using *Surgimap®* software by two independent readers: a third-year radiology resident and a board-certified orthopedic surgeon. Findings consistent with osteitis pubis were assessed using pelvic radiographs in anteroposterior view. Osteitis pubis was considered in the presence of sclerosis and/ or lytic abnormalities, and osseous protuberances. The following pelvic parameters were measured using lateral views:⁸

• Pelvic incidence (PI) was defined as the angle formed by the crossing of a perpendicular line drawn from the middle point of the superior sacral plateau towards the sacral end and a line that unites both femoral heads centers, also known as bicoxofemoral axis (Figure 1).

• Pelvic version (PV) was defined as the angle formed at the femoral head by crossing a vertical line and a line that unites the middle point of the superior sacral plateau to the femoral head center (Figure 2).

• Sacral inclination (SI) was defined as the angle formed by crossing a horizontal line and a line passing through the superior sacral plateau (Figure 3).

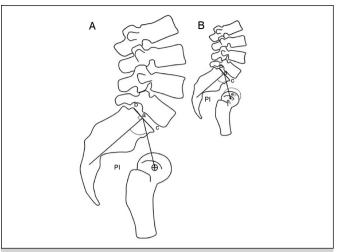
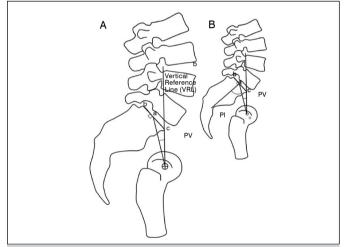
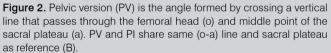


Figure 1. Pelvic incidence (PI) is the angle formed between a line crossing the femoral head to middle point of sacral plateau (o-a) and a perpendicular line from sacral plateau (b-c) to sacral end (a).





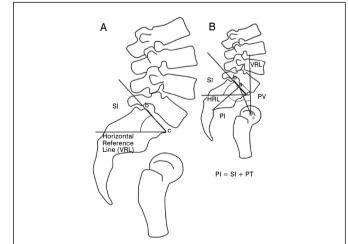


Figure 3. Sacral inclination (SI) is defined as the angle formed by crossing a horizontal reference line (HRL) and the anterior tip of the sacral plateau (b-c). SI, PI and PV share same (b-c) line throughout the sacral plateau (B).

Data collected and statistical analyses

Statistical analyses from all data collected in this study was initially performed in a descriptive manner. Quantitative parameters (numerical) such as age, PI, SI, PV and time since turning professional soccer player, were calculated as summary measures: mean, minimum, maximum and standard-deviation. Qualitative parameters (categorical) were analyzed using absolute and relative (%) frequencies. Agreement between readers for pelvic parameters measurements was performed by *Bland-Altman* graphs and intraclass correlation coefficient (ICC).ICC values interpretation followed levels proposed by Altman (1990), being classified as poor (<0.2), fair (0.2–0.4), moderate (0.4–0.6); good (0.6–0.8) and excellent (>0.8). *Student t-test* for independent samples was used to assess correlation between pelvic measurements and radiographic signs of osteitis pubis, while *Fisher's exact test* was used to assess correlation between osteitis pubis and player's position in soccer field.

Statistical Package for the Social Sciences (SPSS) software version 16 was used to run all analyses, with significance level set to 5%.

RESULTS

Our study group comprised a total of 107 professional soccer players, all male, with a mean age of 25.6 ± 3.1 years old. Three subjects were excluded due to the absence of pelvic radiographs from their childhood (Table 1).

Regarding reproducibility of pelvic measurements, we can see in Bland-Altman graphs the behavior of the differences between means from both readers (Figure 4). The line in red represents difference between means, and lines in green a 95% confidence interval. Overall, in all three parameters, readers achieved very similar values (mean difference varying from -0.6° to 1.0°), demonstrating an excellent agreement (Table 2).

Although PI, SI and PV angles were higher in players with osteitis pubis, there was no statistical correlation between these parameters (Table 3). PV angles in left-footed kickers were significantly greater when compared to right-footed kickers (Table4). There was no correlation between the presence of osteitis pubis and player position in the field (Table 5).

Table 1. Demographic, clinical and Imaging characteris	tics.
Parameters	Results
Age (years), mean \pm standard-deviation (SD)	25.6 ± 3.1
Time since becoming professional (years), mean \pm SD	5.6 ± 2.0
Dominant leg, n (%)	
Right	93 (86.9)
Left	14 (13.1)
Field position, n (%)	
Striker	24 (22.4)
Goalkeeper	7 (6.5)
Right forward	9 (8.4)
Left forward	4 (3.7)
Midfielder	36 (33.6)
Forward	3 (2.8)
Defender	24 (22.4)
Pain symptoms (pelvis, spine or hips), n (%)	2 (1.9)
Pelvic parameters (°), mean ± SD	
Pelvic incidence (PI)	51.1 ± 11.9
Sacral inclination (SI)	41.8 ± 9.3
Pelvic version (PV)	9.3 ± 6.9
Imaging findings, n (%)	
Listhesis	6 (5.6)
Spondylolysis	6 (5.6)
Osteitis pubis	80 (74.8)

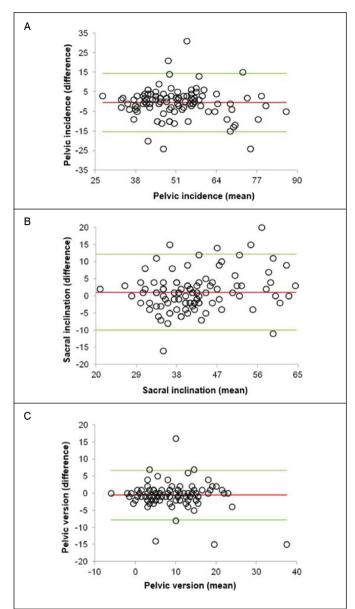


Figure 4. Distribution of pelvic parameters measurements from both readers (degrees). Mean difference between readings was $0.5^{\circ}\pm7.5^{\circ}$ for PI (A), $1.0^{\circ}\pm5.5^{\circ}$ for SI (B) and $-0.6^{\circ}\pm3.6^{\circ}$ for PV (C).Red line: mean difference. Red lines: 95% CI.

Table 2. Agreement bewteen readers.							
Pelvic parameters	Agreement	р					
Pelvic incidence	0.892 [0.841-0.926]	Excellent	< 0,0001				
Sacral inclination	0.901 [0.854-0.933]	Excellent	< 0,0001				
Pelvic version	0.924 [0.888-0.948]	Excellent	< 0,0001				

DISCUSSION

Our results indicate that PI angles were greater in Professional soccer players presenting with osteitis pubis, especially in midfielders, although such correlation did not present statistical significance. We believe that these results might be different if bigger samples were tested. On the other hand, reproducibility of measurements from both readers was excellent for all three parameters, which was also reported by *Lafage et al.*¹³



Pelvic parameters	Osteitis Pubis					
	Present (n=80)	Absent (n=27)	t-test (p)			
Pelvic incidence	52.3° ± 12.7°	48.4° ± 10.8°	0.156			
Sacral inclination	43.1° ± 9.8°	39.9° ± 10.1°	0.146			
Pelvic version	9.2° ± 6.3°	8.6° ± 7.5°	0.649			

Table 3. Correlation between pelvic parameters and osteitis pubis.

 Table 4. Correlation between pelvic parameters and dominant leg.

Pelvic parameters	Dominant leg					
	Right (n=93)	Left (n=14)	t-test (p)			
Pelvic incidence	50.7° ± 11.3°	56.0° ± 17.3°	0.281			
Sacral inclination	42.3° ± 9.1°	42.3° ± 14.7°	0.997			
Pelvic version	8.4° ± 5.9°	13.7° ± 8.6°	0.04			

Table 5. Correlation between osteitis pubis and player position in the field.

Position	Oste	Osteitis pubis			
	Yes (%)	No	Total		
Stricker	18 (75)	6	24	1.000	
Goalkeeper	3 (42)	4	7	0.066	
Right forward	7 (77)	2	9	1.000	
Left forward	3 (75)	1	4	1.000	
Midfielder	30 (83)	6	36	0.166	
Forward	2 (67)	1	3	1.000	
Defender	17 (70)	7	24	0.603	
Total	80 (74)	27	107		

Soccer is a sport modality that involves high-intensity motor actions and sudden modifications, especially during fundamentals movements, promoting a particular biodynamic profile. In this setting, the current study aimed to identify the relationship between presence of osteitis pubis and pelvic parameters, especially PI, since such measure is specific and constant for each individual by the end of osseous growth and skeletal maturity, regardless of the radiographic view, either extension, flexion or neutral position of the hips.^{3,6,8,10,11}

Although a relationship between PI and osteitis pubis might be possible, as seen in the current study, there is no data on literature that corroborates isolated relation of cause-effect between them. Nonetheless, the results obtained suggest greater PI values in subjects presenting with osteitis pubis. In Figure 5 we can see an example of a subject with findings of osteitis pubis (sclerosis and superior symphysis margin fragmentation) but low PI angle (38°). On the other hand, subjects with increased PI angles may not present degenerative changes in pubic symphysis, as exemplified in Figure 6 ($PI = 81^{\circ}$). Since PI is defined by the sum of the two other components to maintain the sagittal balance (SI and PV), during the active period of the soccer player, his field position and specific biomechanics, this balance may change with compensatory adaptative changes in SI and PV. However, such changes, even though they preserve a constant PI value, they come along with ancillary forces restructuration that contributes to maintain the balance, such as myotendinous and aponeurotic forces. Anterior abdominal



Figure 5. Radiographs of the pelvis showing osteitis pubis (AP view, left image) with Pl of 38° (lateral view, right image).

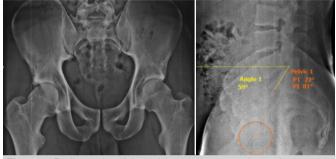


Figure 6. Radiographs of the pelvis showing normal symphysis pubis (AP view, left image) with PI of 81° (lateral view, right image).

hyperextension and hip hyperabduction, frequent movements in professional soccer activity (sudden acceleration, lateral movement and fast changes in direction and kicking) generate chronic overuse over the pubic symphysis.^{6,8,9,14}

Considering that PI is a strong determinant of the special orientation of the pelvis in orthostatic position, we question if abnormalities in these values can determine a specific dynamic in myotendinous and aponeurotic structures forces during movement. Since we believe that osteitis pubis is multifactorial, we included other possible risk factors in our analyses, such as: time since becoming professional player, field position and dominant leg. The union of these factors may lead to higher or lower degree of overload to the pubic symphysis.^{2,5,8,15}

Radiographic evaluation of these subjects must include lateral views of the femoral heads to measure pelvic parameters and, thus, the sagittal balance. Along with ancillary components to maintain the balance, they can aid to customize each athlete training plan to avoid future lesions.^{5,6,8,15}

Our study has been limited to simple radiographs of the pubic symphysis, a method in which findings are not always positive in relation to the symptoms (pubalgia), opposite to magnetic resonance that allows evaluate edema in acute phase, as well as myotendinous and aponeurotic structures of rectus abdominis and adductors, bringing increased correlation of imaging findings to clinical symptoms of the athlete during the evaluation.^{1,3,9}

In conclusion, our data shows that evaluation of pelvic parameters is highly reproducible, presenting excellent inter-observer agreement. There was no correlation between pelvic incidence angles measurements and the presence of osteitis pubis in professional soccer players.

AUTHORS' CONTRIBUTION: Each author made significant individual contributions to this manuscript.. Rodrigues FM: conceptualization, execution, and writing, Taneja AK: writing and critical review, Narahashi E and Silva FD: reading of the cases and data tabulation, Fernandes ARC: critical review and supervision, Falotico GG: clinical evaluation of the patients and orthopedic consultation, Yamada AF: conceptualization, supervision, and guidance.



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A NEW FLUOROSCOPY TECHNIQUE FOR SUPRACONDYLAR **HUMERUS FRACTURES**

UMA NOVA TÉCNICA DE FLUOROSCOPIA PARA FRATURA SUPRACONDILAR DO ÚMFRO

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ABSTRACT

Introduction: To compare two different intraoperative fluoroscopy techniques used for closed reduction and percutaneous pinning (CRPP) in pediatric patients with supracondylar humerus fractures (SHF). Materials and Methods: Thirty-six patients who underwent SHF surgery from May 2011 to June 2019 were included in the study. During surgery, the classical fluoroscopy method (CFM) was used in 21 patients and the new fluoroscopy method (NFM) was used in the remaining 15 patients. Results: The mean age was 5.14±1.13 years in the NFM group and 5.38±1.36 years in the CFM group. Mean operative time was 38.14±5.92 minutes in the CFM group and 21.54±3.48 minutes in the NFM group (p=0.001), while mean fluoroscopy times were 25.65 ± 3.91 seconds and 39.84±7.50 seconds in the NFM and CFM groups, respectively (p=0.001). The NFM and CFM groups demonstrated similar functional capacity as measured by the Mayo Elbow Score (p=0.168). Direct radiographs obtained to measure Baumann's angle also showed that the two groups had similar results (p=0.848). Conclusions: The NFM is a reliable and successful technique as it leads to shorter operative and fluoroscopy times, as well as providing improvement in functional scores and radiological outcomes in short-term follow-up. Level of Evidence III, Therapeutic Studies-Investigating the Results Level of Treatment.

RESUMO

Introdução. Visamos comparar duas técnicas de fluoroscopia intraoperatória usadas para redução fechada e fixação percutânea com pino (CRPP) em pacientes pediátricos com fratura supracondilar do úmero (SHF). Materiais e Métodos: Trinta e seis pacientes submetidos à cirurgia de SHF de maio de 2011 a junho de 2019 foram incluídos no estudo. Durante a cirurgia, o método clássico de fluoroscopia (CFM) foi usado em 21 pacientes e o novo método de fluoroscopia (NFM) foi usado nos 15 pacientes restantes. Resultados: A média de idade foi de 5,14 \pm 1,13 anos no grupo NFM e 5,38 \pm 1,36 anos no grupo CFM. O tempo operatório médio foi de 38,14 ± 5,92 minutos no grupo CFM e 21,54 \pm 3,48 minutos no grupo NFM (p = 0,001), enquanto os tempos médios de fluoroscopia foram 25,65 \pm 3,91 segundos e $39,84 \pm 7,50$ segundos nos grupos NFM e CFM, respectivamente (p = 0,001). Os grupos NFM e CFM demonstraram capacidade funcional semelhante medida pelo Mayo Elbow Score (p = 0,168). As radiografias diretas obtidas para medir o ângulo de Baumann também mostraram que os dois grupos tiveram resultados semelhantes (p = 0,848). Conclusões: O NFM é uma técnica confiável e bem-sucedida, pois reduz o tempo operatório e de fluoroscopia, além de proporcionar melhora nos escores funcionais e resultados radiológicos no acompanhamento de curto prazo. Nível de Evidência III, Estudos terapêuticos - Investigação dos resultados do tratamento.

Keywords: Pediatrics. Humeral fracture. Fluoroscopy.

Palavras-chave: Pediatria. Fratura do úmero. Fluoroscopia.

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INTRODUCTION

Supracondylar humerus fracture (SHF) is the most common type of fracture in the elbow region. It has a high frequency in the pediatric age group (3% of all pediatric fractures), and is especially frequent between 3-7 years of age.¹ Although the majority of subjects are treated through a non-operative approach (since most present with non-displaced fractures), SHF accounts for the majority of pediatric fractures that require surgical treatment.² Unless treated

properly, these fractures may result in severe movement disorders and also deformities in the hand, wrist and forearm, which may have considerable impact on quality of life.³ Therefore, appropriate treatment is essential for the prevention of cosmetic and functional morbidities that may occur in the future.⁴

Depending on the mechanism of injury, SHFs are observed as flexion or extension types, with the former being very rare (<5%).⁵ The common mechanism of injury in extension type SHF is almost always a

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<< SUMÁRIO

fall onto an outstretched hand while the elbow is in extension (forced hyperextension). In recent years, various management concepts have been utilized in pediatric SHFs, including closed or open reduction techniques. Open reduction is associated with a higher incidence of infection and joint stiffness,^{3,6} and since closed reduction can be reliably used in most patients with displaced fractures, the most commonly used method has become the closed reduction and percutaneous pinning (CRPP) with a Kirschner (K) wire method; a method that has been reported as the gold standard.⁷ Although various techniques for CRPP exist, which differ based on the application/number of pins to be used and the opportunity for certain approaches during surgery, it is well-established that all techniques necessitate accurate analysis via fluoroscopy.¹ It is also important to consider the risk for ulnar nerve injury in up to 10% of patients depending on the specific approach.⁸ Some surgeons recommend the use of more than 2 K wires, whereas others support a lateral approach when applying K wires to protect the ulnar nerve.⁹ During the procedure, fluoroscopy is used to ensure proper reduction. The narrow supracondylar surgery site in children may result in reduction loss, inability to guide the K wire to the required position, iatrogenic nerve injury, longer operative time and chondral damage.⁶

This study aimed to investigate the differences in operative time between the traditional method and fluoroscopy-guided closed reduction for treating SHFs, regardless of the medial or lateral pinning position used for fixation.

METHODS

Study population

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Clinical Research Ethics Committee of Maltepe University (No:2020/900/32, Date: 03.08.2020). Parents/guardians of all patients included in the study provided informed consent.

Clinical, radiological and functional evaluations were retrospectively performed for 48 patients aged between 1 and 13 who underwent closed reduction followed by fixation with K wires for the treatment of SHF. from May 2011 to June 2019. Exclusion criteria were as follows: presence of an open fracture or a secondary ipsilateral fracture, being aged younger than 1 or older than 13 years, and having any type of systemic disease or neurovascular injury before the operation. Accordingly, the study included 36 out of 48 patients in total. While all patients underwent SHF fixation with the CRPP method, the classical fluoroscopy method (CFM) was used in 21 patients and the new fluoroscopy method (NFM) was used in the remaining 15 patients. Demographic data, age, operative time, fluoroscopy time, pinning time, time until K wire removal and complications were assessed in all patients. The Mayo Elbow Score was used for the functional evaluation of the affected elbow. Postoperative follow-up studies included imaging and clinical evaluations. All elbows were examined by a single observer.

Fluoroscopy and surgical procedure

The patients were placed in the supine position and operated under general anesthesia within the first 24 hours after trauma. 10% povidone-iodine was used to disinfect the surgical area and then a sterile surgical site was prepared. This was followed by placing the elbows in the fluoroscope to enable imaging. The fluorescent screen was facing the surgeon who performed reduction (across the patient) in order to ensure that the surgeon was able to clearly observe the stages of reduction. Longitudinal traction was maintained while in extension and fluoroscopy was used to avoid varus and valous positions. The thumb was placed on the olecranon and other fingers on the proximal aspect of the fracture line in order to apply opposite forces while the elbow was in flexion and the forearm was pronated. The final state of reduction was reassessed and the lateral and anteroposterior (AP) radiography images were obtained. The fluoroscope was positioned parallel to the patient in the region of reduction and the humeral long axis was first imaged in the full AP plane. If the reduction was acceptable in the AP plane, the fluoroscope was rotated 90 degrees in order to obtain the lateral view without moving the patient's elbow. After reduction was found to be satisfying in both planes, 2 K wires of 1.8-2.0 mm were used for fracture fixation in oblique configuration. The first K wire was inserted through the lateral condyle and guided towards the proximal medial cortex of the fracture line, and the other K wire was inserted through the medial condyle and guided beyond the proximal lateral cortex of the fracture line away from the ulnar tunnel. Joint range of motion was evaluated and the surgery was terminated by long arm splinting with the elbow at pronation and 80-90 degrees flexion.

Postoperative follow-up

During postoperative follow-up, the long arm splint was removed on day 20, after which the passive-active exercises were initiated. The K wires were scheduled for removal between the 4th and 6th postoperative weeks, when periosteal callus formation was observed and the fracture line was blurred. It was deemed necessary to keep the K wire in place for one or two more weeks in cases where callus formation around the fracture line was not sufficient. The final follow-up visit which included functional assessment was performed on postoperative day 90.

Radiological evaluation

Radiological evaluation was performed on postoperative days 1, 15 and 30 from the AP and lateral elbow radiographs of the operated side in all patients. Findings related to union at the fracture line were confirmed with radiological evaluations during follow-up. The radiological evaluation was finalized by measuring the Baumann's angle on AP elbow radiographs of both the affected and contralateral sides (for the purpose of comparison) during the final follow-up visit on day 90.

Statistical analysis

All data was analyzed with SPSS v25. Normality check was performed with the Shapiro Wilk test. Continuous variables were expressed as mean \pm standard deviation. The Student t-test was used to compare the means. Chi square tests were used for the comparison of the distribution of categorical variables. Statistical significance was accepted as p < 0.05.

RESULTS

The study included 36 patients who underwent CRPP and met the inclusion criteria. Mean age was 5.26 \pm 1.24 (range, 1-13) years, 58% (21) were male and 42% (15) were female. The mean ages of the patients included in the NFM and CFM groups were 5.14 \pm 1.13 and 5.38 \pm 1.36 years, respectively (Table 1).

Mean operative time was 38.14 \pm 5.92 minutes in the CFM group and 21.54 \pm 3.48 minutes in the NFM group (p = 0.001). The mean fluoroscopy times were 39.84 \pm 7.50 seconds and 25.65 \pm 3.91 seconds in the CFM and NFM groups, respectively (p = 0.001). There was no significant difference between the CFM and NFM groups in terms of Mayo Elbow Score (p = 0.168).

Direct radiographs obtained on postoperative day 90 showed that there was no significant difference between the two groups in terms of Baumann's angle (p = 0.848). When the operated and contralateral



sides of patients were compared, there was again no significant difference in Baumann's angle values in either group (p = 0.972). The time until pin removal of the NFM group (31.14 ± 4.19 days) was significantly shorter compared to the CFM group (34.71 ± 4.42 days) (p = 0.020). The time until removal of K wires was 38.74 ± 4.45 days in the NFM group and 42.05 ± 4.71 days in the CFM group, demonstrating a significantly shorter duration with the use of NFM (p = 0.040) (Table 2). No complications were recorded in any of the patients included in the study.

Table 1. The age and gender distribution of the patients.						
	New Method (n=15)	P value				
Age	5,14 ± 1,13	5,38 ± 1,36	0,568			
Gender						
Male	9 (60.0%)	12 (57.1%)	0.004			
Female	6 (40.0%)	9 (42.9%)	0.864			

 Table 2. The comparison of surgical features and outcomes.

	New Method (n=15)	Classical Method (n=21)	P value
Operation time (minutes)	21,54 ± 3,48	38,14 ± 5,92	0.001
Scopy time (seconds)	25,65 ± 3,91	39,84 ± 7,50	0.001
Mayo Elbow Score	82,34 ± 10,15	77,62 ± 9,70	0.168
Bauman angle (90 th day)	71,27 ± 2,69	$71,57 \pm 5,65$	0.848
Bauman Angle (contralateral elbow)	$76,67 \pm 2,32$	$76,90 \pm 2,23$	0.758
Difference of Bauman Angle	5.40 4.34	5.33 6.41	0.972
Fracture reduction time (days)	31,14 ± 4,19	34,71 ± 4,42	0.020
Removal of K-wire (days)	$38,74 \pm 4,45$	$42,05 \pm 4,71$	0.040

DISCUSSION

The most important finding obtained in this study was that the use of a new method for fluoroscopy in CRPP led to a significant reduction in operative time and intraoperative fluoroscopy time as compared to the classical method of fluoroscopy.

It has been reported that around 16% of SHF fractures in children require surgical treatment.¹⁰ The main goal of treatment is to re-establish normal elbow structure/function and to prevent neurovascular complications, while also ensuring normal cosmetic appearance of the elbow.¹¹ Prolonged operative time leads to a higher risk of reduction loss and complications. Therefore, completing the surgery successfully also depends on intraoperative time, making procedure duration a factor of interest in the surgical treatment of SHF.¹² In a study by Naik et al., mean operative times were reported to be 28.3 \pm 1.6 and 30 \pm 3.6 minutes with two different CRPP techniques.¹³ Striano et al. reported mean operative times ranging from 20.4 minutes to 46.6 minutes in patients undergoing CRPP for different types of fractures.¹⁴ In the present study, the utilization of NFM for intraoperative evaluation led to a significantly shorter operative time compared to CFM, as well as in comparison to the majority of results reported in the literature, regardless of surgical technique.

In a study by Kraus et al., different methods used in the surgical treatment of SHF were compared in terms of intraoperative fluoroscopy exposure and it was underlined that proper selection of surgical technique was essential to avoid unnecessary fluoroscopy exposure (for the surgical team, patient and other medical staff), and that surgeons should not insist on inappropriate surgical techniques which prolonged intraoperative fluoroscopy time.¹⁵ In another study, Eismann et al. demonstrated that fluoroscopy time was highly variable during the CRPP procedures performed for SHFs, and the operative time was also prolonged depending on C-arm orientation (standard and inverted).¹⁶ In the present study, the NFM led to a significantly shorter fluoroscopy time as compared to the CFM, which would provide considerably lower radiation exposure and protect the wellbeing of the surgeon, patient and other medical staff.

According to the literature, the results were significantly improved in patients who were evaluated with the Mayo Elbow Score following CRPP performed for SHF.¹⁷ Although we observed somewhat better Mayo Elbow Scores in the NFM group compared to the CFM group, statistical significance was not present (p = 0.168). Nevertheless, we attributed the beneficial change to accelerated recovery and shorter operative time resulting from the use of NFM. Considering the lack of significance and the limited number of individuals in this study, it is evident that further studies must be performed to elucidate whether alterations in the conduct of fluoroscopy benefit surgical duration and outcomes.

In a study by Mehlman et al., two different fluoroscopy methods were used in 115 patients with SHF who underwent surgery with the CRPP method. Postoperative radiological evaluation showed that the Baumann's angle was within the normal range in 83% of the patients and that functional results were also satisfactory.¹⁸ According to another study by Li et al. which compared the conventional fluoroscopy and mini-fluoroscopy systems in patients undergoing CRPP for SHF, mini-fluoroscopy guidance employed during surgery led to prolonged operative and fluoroscopy times and an increase in the number of fluoroscopy procedures -with the added fact that Baumann's angles were similar in the two methods.¹⁹ In the present study, both of the fluoroscopy methods led to an improvement in Baumann's angle without any significant superiority to one another, which is similar to the results provided in the literature. Evidence from prior research on SHF dictates that the removal of K wires following CRPP should be performed during the 3rd to 4th postoperative weeks.²⁰ However, it is also known that some surgeons do not remove the K wires until weeks 4, 5 or 6.21 This can be attributed to the fact that surgeons generally prefer to remove K wires when they feel it is safe to do so, instead of considering radiographic evidence of fracture healing as the primary factor. Bearing in mind the possible bias caused by this approach, the time until removal of K wires was slightly longer in the NFM group as compared to the literature, but it was also shorter than the removal time in the CFM group. Although this may indicate another advantage, it is also possible that this was caused by confirmation bias in favor of the new method. We also believe that the mentioned time will come closer to the values reported in the literature as we expand our experience.

The limitations of this study were as follows: limited number of patients, the fact that the standard surgical method (lateral or cross-pinning) was not preferred for CRPP and that Flynn's criteria, which are frequently employed in the literature, were not used to evaluate functional recovery.

CONCLUSION

Among the fluoroscopy methods used during CRPP performed for SHF, the NFM, as we described here, appears to have successful outcomes in the short-term. The NFM is a reliable technique especially since it provides shorter operative time and fluoroscopy time, while also increasing functional scores and improving radiological outcomes.



AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. MZD: conception and design of the study, data acquisition, analysis and interpretation, drafting the article and approval of the final version; OKU: conception and design of the study, drafting the article, revising it critically for important intellectual content and approval of the final version.

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COMPARISON OF SINGLE- AND DOUBLE-PLATE FIXATION TECHNIQUES IN THE TREATMENT OF NONUNIONS OF THE HUMERAL SHAFT

COMPARAÇÃO DE TÉCNICAS DE FIXAÇÃO DE PLACA SIMPLES E DUPLA NO TRATAMENTO DE PSEUDOARTROSE DO CORPO DO ÚMERO

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ABSTRACT

Introduction: Humerus shaft fractures may be treated conservatively or surgically. In 2.5% to 13% of cases, nonunion is observed, and it leads to severe pain and morbidity. Plate osteosynthesis has become popular in the treatment of nonunion of the humeral shaft. In this study, we compared the clinical outcomes of patients with humerus shaft nonunion whom we treated with single- or double-plate fixation. Materials and Methods: Fifty-three patients diagnosed with aseptic humeral shaft nonunion and treated with plate fixation were included in the study. Patients were evaluated according to the number of plates (single vs. double plates). The two groups were subjected to statistical evaluation according to their clinical and radiographical results. Results: The average age of the patients was 53 years (range: 1-86); 28 (52.8%) were female and 25 (47.2%) were male. The union rate was 90.32% for single plate and 90.91% for double plate fixation. There was no statistically significant difference between single and double plates in the clinical and radiographical results (union time, union rate, Q-DASH score) (p > 0.05). There was a significant correlation between age and union times / Q-DASH scores according to the Spearman correlation test (p < 0.05). Transient radial nerve neuropraxia developed in 2 patients and 1 patient suffered from an infection that was treated with debridement and antibiotic therapy. Conclusion: In our study, similar good results were obtained with single and double plates. In treatment of humeral shaft nonunions, a second plate is not needed if enough stability is provided with single plate fixation. Level of evidence III, Retrospective comparative study.

RESUMO

Introdução: As fraturas do corpo do úmero podem ser tratadas de modo conservador ou cirúrgico. Em 2,5% a 13% dos casos, observa-se pseudoartrose, que causa dor intensa e morbidade. A osteossíntese com placas tornou-se popular para tratamento da não união da diáfise do úmero. Neste estudo, comparamos os resultados clínicos de pacientes com pseudoartrose do corpo do úmero que tratamos com fixação de placa simples ou dupla. Materiais e Métodos: Cinquenta e três pacientes com diagnóstico de pseudoartrose asséptica do corpo do úmero tratados com placa de fixação foram incluídos no estudo. Os pacientes foram avaliados de acordo com o número de placas (placa simples vs. dupla). Os dois grupos foram submetidos à avaliação estatística de acordo com seus resultados clínicos e radiográficos. Resultados: A média de idade dos pacientes foi de 53 anos (variação: 1 a 86); 28 (52,8%) eram do sexo feminino e 25 (47,2%) do sexo masculino. A taxa de união foi de 90,32% para placa simples e 90,91% para placa dupla. Não houve diferença estatisticamente significante entre a osteossíntese com placas simples ou duplas nos resultados clínicos e radiográficos (tempo de união, taxa de consolidação e escores do Q-DASH) (p > 0,05). Houve correlação significativa entre idade e tempo de união/escores do Q-DASH, de acordo com o teste de correlação de Spearman (p < p0,05). A neuropraxia transitória do nervo radial desenvolveu-se em dois pacientes e um paciente teve infecção tratada com desbridamento e antibioticoterapia. Conclusões: Em nosso estudo, resultados igualmente bons foram obtidos tanto com placas simples quanto duplas. No tratamento de pseudoartroses do corpo do úmero, uma segunda placa não é necessária se houver estabilidade suficiente com a fixação com placa única. Nível de evidência III, Estudo comparativo retrospectivo.

Keywords: Humerus. Fracture. Diaphysis.

Descritores: Úmero. Fratura. Diáfise.

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<< SUMÁRIO

INTRODUCTION

Humeral shaft fractures constitute 3-5% of all fractures and conservative treatment results are generally good.^{1,2,3} The nonunion rate after humeral fracture ranges from 2.5% to 13%.^{4,5} When nonunion is not treated, daily life is severely restricted due to pain and the patient's inability to use the affected limb. Nonunion must be treated surgically in cases of humeral shaft fractures.^{6,7}

Several methods have been described in the treatment of humeral shaft fracture nonunion such as plate fixation, intramedullary nailing or external fixation.^{8,9} Today, plate fixation is more commonly preferred in the treatment of aseptic nonunion.^{9,10} Grafting and fixation are recommended with a narrow dynamic compression plate with at least seven screws with 4.0-4.5 mm diameter.^{11,12} However, fixation with double plates can be performed in patients who are elderly, have osteoporosis, have undergone multiple surgeries, or have fractures in the proximal or distal shaft that cannot be fixed with a total of seven screws.^{13,14}

In this study, we compared demographic data of the patients with humeral shaft nonunion who were treated surgically in our hospital. We also wanted to evaluate the union rates and clinical scores of shoulders of patients treated for humeral shaft nonunion with single or double plates. The aim of this study, was to evaluate the need for an additional plate and advantages or disadvantages of a second plate for humerus shaft nonunions.

Patients and methods

The humerus diaphyseal region was defined as the area between the pectoralis major attachment point and the epicondylar line. Patients who did not achieve union within six months with conservative or surgical methods and who were followed for at least one year after surgery were included in the study. Pathological fractures, infected cases of nonunion, type 3b or 3c open fractures, patients whose skeletal maturity was not yet complete, and patients with intraarticular extension fractures were excluded from the study. Clinical evaluation of the patients was performed according to the Quick DASH (Disabilities of Arm, Shoulder, and Hand) (Q-DASH) score. Bone union was evaluated radiologically with bone callus formation and bone bridges in at least three cortices and clinically regression of pain in the fracture site.

Patients treated with plates with the diagnosis of humeral shaft nonunion were identified from the hospital records. This examination identified 57 patients who had plate osteosynthesis due to nonunion of humeral shaft fractures. Four patients were excluded from the study because their radiological and clinical records were incomplete. Thus, 53 patients were included in the study.

All of the patients were operated on in our clinic by three orthopedic surgeons. The surgeries were performed with a single plate for 31 patients and with double plates for 22 patients.

The fracture site of the patients was proximal in 9 cases, middle in 30 cases, and the distal shaft in 14 cases. Seven patients had hypertrophic and 46 patients had atrophic nonunion. Nonunion developed in 14 patients after conservative treatment, in 34 patients who had one surgery (plate in 18 cases, intramedullary nailing in 12 cases and external fixator in 4 cases), and in five patients who had multiple surgeries. The average time from the fracture to the last surgery was 19.49 months (range: 6-108).

For single-plate fixation, narrow plates and screws with 4.5 mm diameter were used. Plates were applied through a lateral incision to the anterolateral aspect of the bone. (Figure 1) In double-plate fixation, plates of 3.5 mm were applied to the anterolateral and lateral sides with a lateral incision. (Figure 2) An iliac crest autograft was applied in both groups. The radial nerve was exposed in all patients and interposed in the soft tissue at the end of the surgery. (Figure 3) Patients used a long arm splint for two weeks postoperatively, and



Figure 1. A) X ray of a 50 year old female patient with left humerus fracture due to falling. B) Open reduction and fixation with 4.5mm DCP plate. C) Nonunion on the ninth month. D) Grafting and fixation with a single plate in treatment of nonunion.



Figure 2. A) AP humerus view showing nonunion of a 54-year-old female patient, whose humerus diaphysial fracture was treated with intramedullary fixation B) Lateral humerus view showing nonunion C) AP humerus view of the patient on early postoperative period nonunion treated by fixation with double plates. D) Lateral humerus view of the patient on early postoperative period E) AP humerus view showing union on postoperative sixth month.

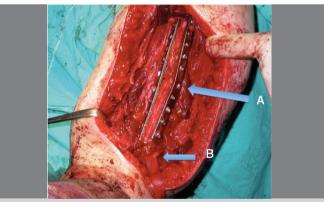


Figure 3. A) Intraoperative image of the patient treated with grafting and fixation with double plates. Second plate was bended in order to compress the graft. B) The radial nerve was exposed and protected.

after the stitches were removed and soft tissue edema decreased, the splint was removed and physical therapy was started. For statistical evaluation, the data were uploaded to Microsoft Excel, and SPSS 17 was used for data analysis. The patients were divided into groups as those treated with a single plate or double plates. The Shapiro-Wilk normality test was applied to decide which tests should be used to compare the numerical data between these groups. According to normality test results, numerical data (age, Q-DASH score, union time, interval from fracture occurrence to time



of last surgery, follow-up time) were compared between the two groups employing nonparametric Mann-Whitney "U" test. Cross tables were created for analysis of categorical data (gender, side, presence of union, nonunion type). For the analysis of categorical data Pearson's chi-square test was used. When the expected frequency was less than five in at least one cell of the cross table, Fisher's exact test was applied. Correlations between age, Q-DASH scores, and union times were checked by Spearman's correlation test. For all tests, p < 0.05 was accepted as statistically significant.

RESULTS

The mean age of all patients was 53.09 (range: 21-86) years, and 52.8% (n = 28) of the patients were female while 47.2% (n = 25) were male. In 45.3% (n = 24) of the patients, nonunion was present in the right humerus and in 54.7% (n = 24) nonunion had occurred in the left.

When patients treated with single plates and double plates were compared, there was no statistically significant difference between the mean ages of the two groups according to the Mann-Whitney U test (p = 0.162, p > 0.05). There was no significant difference between gender and side distribution between the two groups according to Pearson's chi-square test (p = 0.442 and p = 0.561, p > 0.05). (Table 1)

There was no statistically significant difference in types of nonunion (atrophic vs. hypertrophic) between the two groups according to Fisher's exact test (p = 0.431, p > 0.05). The intervals from fracture occurrence to time of last surgery were compared with the Mann-Whitney U test and no statistically significant difference was found (p = 0.136, p > 0.05). (Table 1)

The patients were followed for an average of 39.24 months (range: 12-133). The mean Q-DASH score of the patients was 19.45 (range: 0-81.18). In 5 patients we could not achieve union (9.43%). Thus, the union rate was 90.57%. Union was achieved in an average of 5.10 (range: 3-12) months. Comparisons of follow-up times, Q-DASH scores, and union time averages between groups were performed by Mann-Whitney U test. In statistical evaluation, no significant difference was found between the groups (p = 0.130, p = 0.792, and p = 0.525). The difference between the union rates of the two groups was evaluated with Fisher's exact test and no statistically significant difference was found (p = 0.662, p > 0.05). (Tables 1 and 2)

A statistically significant correlation was found between the Q-DASH scores and union times according to age of the patients by Spearman's correlation analysis (p = 0.037, p = 0.000, p < 0.05).

			Single plate		Single plate Double plate p		p value
Age (years)		50.52 +/-17.27		56.73 +/- 15.85		0.162*	
Gender	Male	16	%51.61	9	%40.91	0.442**	
Gender	Female	15	%48.39	13	%59.09	0.442	
Side	Right	13	%41.94	11	%50.00	0.561 **	
Side	Left	18	%58.06	11	%50.00	0.001	
	Proximal	6	%19.35	3	%13.64		
Region	Middle	20	%64.52	10	%45.45	0.131**	

%16.13

%90.32

%9.68

41.05 +/- 20.02

23.23 +/- 24.73

9

18

4

%40.91

%81.82

%18.18

37.97+/- 31.94

16.84 +/- 17.04

Table 1. Comparison of	fannoral	domographico	of the nationte
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*:Mann-Whitney				

Table 2. Comparison of clinical and radiological results of the patients.					
	p value				
Q – DASH score	0.792*				
Q - DASH Score	D.P.	20.68 +/- 25.03		0.792	
	S.P.	4.96 +/- 2.027		0.505*	
Union time (months)	D.P.	5.25 +/- 2.049		0.525*	
	S.P.	%90.32(+)	%9.68 (-)	0.000**	
Union status	D.P.	%90.91(+) %9.09(-)		0.662**	
IS D. (aincle plate) D.D. (double plate)] *: Mapp Whiteout Liteot. **: Fisher's event test					

[S.P. (single plate), D.P. (double plate)]. *: Mann-Whitney U test. **: Fisher's exact test.

Postoperative radial nerve neuropraxia developed in two patients with single plates and one patient with double plates. At the end of the 6th month, spontaneous regression was seen in all three patients. In a patient treated with a single plate, infective drainage occurred in the postoperative first month. Culturing was performed and methicillin-resistant *Staphylococcus aureus* was isolated. The infection regressed after debridement and antibiotic treatment. Healing occurred in this patient without the need for plate removal.

DISCUSSION

In the treatment of nonunion of humeral shaft fractures, intramedullary nails, plate fixation, and external fixation options are available.^{8,9} Intramedullary fixation is not recommended in the treatment of complex nonunion of the humeral shaft.¹⁵ External fixation is mostly preferred in cases of infected nonunion due to the difficulty of patient compliance.^{16,17}

Today, the refreshing of fracture ends, plate fixation, and bone grafting have become gold standards in the treatment of nonunion of the humeral shaft.^{9,18,19} Fixation with a plate and at least 7 screws with 4.0-4.5 mm diameter is advised, providing both biomechanically stable fixation and good compression.^{6,11} The reason for this is that the most important cause of surgical failure in humeral shaft nonunion is inadequate fixation.¹¹

In a biomechanical study, the humerus was fixed in four different ways: 1) a single plate, 2) a single plate and an additional interfragmentary screw, 3) double plates, and 4) double plates and an additional interfragmentary screw. The most stable fixation was found in the 4th group.¹³ However, it was observed that there was no stability difference between the 1st and 3rd groups. This biomechanical study showed that a well-made single plate can be as stable as double plates. In another biomechanical study, it was emphasized that a single plate cannot provide good stability in patients with a short humerus and a second plate may be needed in such cases.²⁰

In the literature, regarding the treatment of humeral shaft nonunion, there are few studies comparing the results of patients with single and double plates. Double-plate fixation was first performed by Murray et al. in 1964.²¹ In a study in which the results of union with double plates were evaluated, 100% union and an average union time of 4.6 months were obtained.²² In their clinical and biomechanical study, Rubel et al. did not detect any differences between single-plate fixation and double-plate fixation. They achieved union in an average of 4.8 months in 92% of their patients.¹³ Similarly, in our study, the union rate was 90.32% and the average union time was 4.96 months in patients treated with single plate and the rate of union was 90.91% and the union time was 5.25 months in patients treated with double plates.

In their case series, Feng et al. treated 3 of 6 long-term humerus nonunion patients with double plates and the other 3 with single plates and they achieved good clinical results.²³ The authors suggested using a second plate if necessary in the treatment of long-term humeral shaft nonunion. In our study, the interval from fracture to the final surgery of the patients treated with double

Distal

Atrophic

Hypertrophic

Follow up time (months)

Duration of nonunion

(months)

Nonunion

type

5

28

3



0.431***

0.130*

0.136*

plates was 23.23 months on average, and this interval was 16.84 months among that patients with single plates. Although there was no statistically significant difference between the two groups (p = 0.136, p > 0.05), patients treated with double plates had on average a longer nonunion time.

Age is also an important factor in long-bone nonunion treatment.²⁴ The complication rate is expected to be high in these patients due to both bone quality deterioration and concomitant diseases.²⁵ Therefore, applying two plates may provide better stabilization in cases of nonunion in the elderly or osteoporotic patients.^{1,13,26} In a biomechanical study, one plate with 8 holes was applied to the lateral aspect of the humerus and one plate with a different number of screws was applied to the anterior one. The authors suggested a combination of 8-4 screws in young patients and 8-8 in elderly osteoporotic patients.¹⁴ In two clinical studies focusing on elderly and osteoporotic humeral shaft nonunion, the union rates of the patients were found to be over 90%. ^{5,27} Nonunion treatments were mostly performed with a single plate, but special plates (blade plates, wave plates) and double plates were also applied. In both studies, it was stated that the results were good when more stable fixation was obtained in osteoporotic and elderly patients.

There are also studies suggesting strengthening the bone and increasing stability.^{7,28,29} Those researchers aimed at increasing

the stability of the bone quality by extramedullary or intramedullary strut grafts and were generally successful.

The limitations of our study are its retrospective design and the relatively small number of patients. Prospective randomized studies on the treatment of humeral nonunion should be conducted with higher numbers of patients. On the other hand, at the literature most of the studies on humeral shaft nonunions are case series. In our study two different methods of plate fixation is compared statistically.

CONCLUSION

The importance of stabilization has been understood in the treatment of humeral shaft nonunion. When good stabilization is achieved with a single plate, it gives clinical results that are as good as those ones of double plates. Presence of additional plate doesn't have a significant effect on clinical and radiological outcomes. In cases in which stabilization cannot be achieved with a single plate, such as in osteoporotic and elderly patients, in patients with fractures close to the proximal or distal shaft ends, or in patients with a short humerus, additional stabilization with a second plate may be an alternative. Disadvantage of a second plate can be thought as; extended approach and extra cost of the plate. We think that additional plate is not needed in treatment of humeral shaft nonunions.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. Akdemir M: writing, intellectual concept of the article and performing surgeries; Biçen Ç: designing and review of the article and data analysis; Özkan M: data analysis and performing surgeries.

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ISOLATED CAPITELLAR FRACTURE FIXATION WITH HEADLESS SCREWS IN DIFFERENT CONFIGURATIONS

FIXAÇÃO DE FRATURA ISOLADA DO CAPÍTULO DO ÚMERO COM PARAFUSOS SEM CABEÇA EM DIFERENTES CONFIGURAÇÕES

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ABSTRACT

Introduction: We evaluated the clinical and radiological outcomes of capitellar fractures treated with modified screw insertion (inserting the first fixation screw anteroposteriorly and the second screw posteroanteriorly), a technique that can be applied with a minimally invasive lateral elbow approach. Materials and Methods: Twenty-one isolated capitellum fractures that were surgically treated were included in the study. Fixation was achieved with two headless cannulated compression screws placed in anteroposterior and posteroanterior order using the modified lateral elbow approach. The Broberg-Morrey rating system was used to assess the post-operative functional status of the patients. Results: According to the Broberg-Morrey criteria, the mean score was 92.7 (77-100) and 13 cases had excellent, 7 had good, and 1 had fair results. None of the patients developed avascular necrosis or heterotopic ossification. According to the Broberg-Morrey arthrosis score, two cases had Grade 1 and one had Grade 2 arthrosis. One patient had a superficial wound site infection that was treated with antibiotics, and in one case a 60° extension loss was observed in the elbow. Conclusion: Treatment of isolated capitellar fractures with 2 headless screws placed anteroposteriorly and posteroanteriorly can provide stable fixation and is less traumatic for the elbow joint. Level of Evidence IV; Therapeutic Studies -Investigating the results of treatment.

Keywords: Fracture fixation, internal. Humeral fractures. Intra-articular fractures.

RESUMO

Introdução: Avaliamos os resultados clínicos e radiológicos das fraturas do capítulo do úmero tratadas com a técnica de inserção de parafuso modificada (inserção do primeiro parafuso de fixação anteroposterior e do segundo parafuso posteroanterior), que pode ser aplicada com acesso lateral minimamente invasivo do cotovelo. Material e Método: Foram incluídas no estudo 21 fraturas isoladas do capítulo que foram tratadas cirurgicamente. A fixação foi obtida com dois parafusos de compressão canulados sem cabeça colocados em ordem anteroposterior e posteroanterior, usando acesso lateral modificado do cotovelo. O sistema de classificação Broberg-Morrey foi usado para avaliar o estado funcional pós-operatório dos pacientes. Resultados: De acordo com os critérios de Broberg-Morrey, o escore médio foi de 92,7 (77-100) e 13 casos foram excelentes, 7 bons e 1 regular. Nenhum paciente desenvolveu necrose avascular ou ossificação heterotópica. De acordo com o escore de artrose de Broberg-Morrey, dois casos tinham Grau 1 e um tinha artrose de Grau 2. Um paciente tinha infecção superficial da ferida, que foi tratada com antibióticos, e em um caso observou-se perda de 60° da extensão do cotovelo. Conclusão: O tratamento de fraturas isoladas do capítulo do úmero com 2 parafusos sem cabeça colocados anteroposterior e posteroanteriormente pode proporcionar fixação estável e é menos traumático para a articulação do cotovelo. Nível de evidência IV; Estudos terapêuticos - Investigação dos resultados do tratamento.

Descritores: Fixação interna de fratura. Fraturas do úmero. Fraturas intraarticulares.

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INTRODUCTION

Fractures of the capitellum comprise 1% of the fractures around the elbow.¹⁻⁶ The mechanism of formation of these fractures is the shearing force exerted by the radial head on the capitellum due to fall while the elbow is in flexion and the hand is stretched.^{1,3,4,5-9}

Due to its intraarticular nature and the tendency of the fractured fragment to form a mechanical block in the elbow by displacing toward the superior, these fractures generally require surgical treatment.^{2,3} For internal fixation of capitellum fractures, lateral or anterolateral exposure to the elbow is preferred.¹⁰ Kirschner wires

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<< SUMÁRIO

(K-wires), partially threaded cannulated screws, headless cannulated compression screws and 3.5 mm lag screws may be used for fixation. The most reported and the most preferred method for fixation of capitellum fractures is fixation with anteroposterior directed or posteroanterior directed headless cannulated screws.^{6,8,9,11,12,13} In addition, a minimally invasive fixation method with cannulated screws under the guidance of elbow arthroscopy has been defined.¹⁴ Excision of the fragment is preferred in small and unfixable osteochondral fractures, while a prosthetic replacement is a less favored method.^{3,5} As the fracture is an intraarticular one, the head of the fixation component should not be left outside and inserted adequately under the articular surface. For this reason, headless cannulated compression screws is a good option, providing the above requirements and an effective compression.^{1,4,8,15}

The treatment of capitellum fractures is made with two screws to resist fracture fragment rotation and shearing forces over the fracture line. However, if the placement direction of these screws is posteroanterior, the screw on the medial side is difficult to insert because there is not enough space, it increases the risk of neurovascular injury and is often not sent perpendicular to the fracture line. When these screws are sent from the posterior to anterior direction, sufficient compression cannot be obtained in the fracture line and the need for soft tissue dissection in the posterior of the lateral epicondyle increases. We placed one screw (first screw) in the anteroposterior direction from the lateral part of the fragment, and one screw (second screw) in the posteroanterior direction from the epicondyle to fix the medial of the fragment. Thus, we avoided the difficulty of inserting the medial screw, the risk of neurovascular injury in the anterior, and the risk of insufficient compression in the fracture line. In our study, we aimed to describe the modified version of the conventional Kocher lateral approach to elbow to fixate capitellar fracture and to give details of the screw placement technique. As a secondary outcome, we evaluated the clinical and radiological outcomes of patients with capitellar fractures treated with describe technique.

MATERIALS AND METHODS

Clinical data of the patients treated for capitellum fracture between January 2012 and December 2015 were retrospectively evaluated after having approval from the Institutional Ethical Committe&Review Board (document number: 2016-44). Informed consent was obtained from all patients, including for the use of clinical data for scientific purposes. We included patients with a minimum follow-up period of 12 months. Those with open fractures or concurrent unilateral fractures were excluded (two cases). The fractures were classified according to the Dubberley classification. ¹⁶ Anteroposterior and lateral radiographs were used for diagnosis (Figure 1 A, B). Also, all patients were asked to undergo computed tomography to evaluate the fracture displacement and comminution better, detect any possible trochlear fracture extension or accompanying injuries, and for surgical planning (Figure 1 C, D).

Surgical Technique

Infraclavicular block anaesthesia was administered to all patients. The operation was commenced under tourniquet with the patient in the supine position. Elbow ligament injury and instability were sought and compared to the uninjured side. A shorter incision than the usual extended Kocher lateral approach was performed on the lateral elbow.¹⁷ The incision centering the lateral epicondyle was extended 3 cm to the proximal and 2 cm to the distal. In contrary to the classical approach, the extensor origin muscles were partially elevated (Figure 2A, B). In one case with Type 3A fracture, the incision was extended as in the classical approach, and the extensor origin was elevated as a whole. Proximally, the interval between the



Figure 1. Preoperative AP and Lateral elbow X-ray images of 42-year-old female patient (A-B); Preoperative CT (C-D).

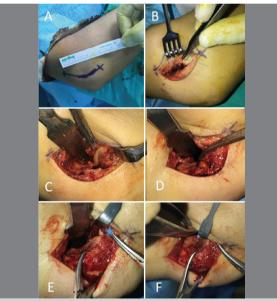


Figure 2. Perioperative pictures showing A: Length of insicion, B: Partial elevation of common extensor muscles from lateral epicondyle (shown with blue line) C: Capitellar fracture that deplaced anterosuperiorly D: After reduction, E: Intact annular ligament (blue asterix) F: Capitellum medial is also anatomically reduced (blue arrow head).

triceps and brachioradialis, and between the extensor carpi ulnaris muscle (ECU) and anconeus muscle at the distal was used to reach the lateral epicondyle. The fracture line was reached after the joint capsule was opened. The capsule was opened from the anterior distally without damaging the annular ligament. In all cases, surgical exposure was performed without cutting the annular ligament, and the fracture line could be reached (Figure 2 D). Besides, soft tissues and capsule were not elevated from the posterior surface of the lateral epicondyle to preserve the blood supply of condyle. Hematoma, blood clots, crushed bone and cartilage fragments, and the interposed soft tissue debris on the fracture line were removed. The joint was irrigated and debrided with saline solution. Then, the joint was checked for any accompanying injuries. The fractured fragment had migrated toward the anterosuperior in all cases (Figure 2 C). The anterosuperior displaced capitellum was reduced, and the continuity of the joint surface at the medial and lateral side was checked. Medial joint surface continuity was controlled while



the elbow is flexed and lateral cortex fracture line continuity with the posterior cortex while the elbow is extended (Figure 2 E). When the anatomical reduction was achieved, the reduction was maintained with C-clamps in the anteroposterior direction (Figure 2 D). To efficiently reduce the elbow was relaxed by flexion and pronation maneuverer. Two screws over K-wires were used for fixation of the fracture line (Figure 3 A, B, C, D). The first screw was used laterally from the anterior to the posterior direction to get compression, and the second screw was placed at the medial of the fragment from the posterior to the anterior direction to get rotational control and more stability. The position of the second screw head, which was placed from the posterior to the anterior direction, was made with fluoroscopic control without soft tissue dissection. Both screws were sent vertically to the fracture line. Moreover, during the insertion of the second screw, the neurovascular structures in the anterior were protected by a retractor. The integrity of the reduction and the fracture line was checked under fluoroscopy (Figure 3 B, D). In sequence, a screw, 2 mm shorter than what was measured with the guidewires, was selected. The screws were advanced over the guidewire, and attention was paid to keep the screw tips beneath the joint (Figure 3 E, F). In multi-fragmented fractures and large fractures with medial extension, additional screws can be placed in the anteroposterior or posteroanterior direction, depending on the ease of insertion, in addition to screw 1 and 2. We used Acutrak 2 Mini System screws with 3.5 mm tip and 3.6 mm tail thickness. The C-arm fluoroscope was once more used to check the final reduction and position. Joint stability and arc of motion were assessed. Haemostasis was achieved, and the partially elevated extensor origin was reattached to its original position with transosseous sutures. Hemovac drains were inserted, and the layers were closed in an anatomic manner.

Postoperative Follow-up Protocol

Posterior elbow plaster splint was applied to all patients for postoperative pain and edema control in an elbow position of neutral rotation and 90° flexion in the first week of operation. Drains were withdrawn within two days after surgery. No medical treatment was given for Myositis Ossificans prophylaxis. At the 1st week, passive exercises in the range of 30-130 degrees were given within the varus-valgus stabilised hinged elbow brace. Active motion was permitted after the 6th week of operation. Clinical follow-up of the patients were performed at first, second, sixth week, and third month postoperatively. Then, annual clinical control was performed. In the early post-operative period, local wound problems and any fracture-related complications were noted. The Broberg-Morrey rating system was used to assess the post-operative functional status of patients. We also categorized the patients according to The Broberg-Morrey score. Elbow and forearm range of motion of the injured and uninjured side measured and compared. Additionally, we examined patients for any elbow instability. Anteroposterior (AP) and lateral radiographs of the elbow were evaluated for union, osteonecrosis, heterotopic ossification, and posttraumatic arthrosis at final control (Figure 4 A, B, C, D). Arthrotic findings in the joint were assessed with the Broberg and Morrey arthrosis classification.¹⁸

Statistics

Mean, standard deviation, lowest and highest frequency, and ratio were used to describe the data. The chi-square test was used to evaluate the relationships between categorical variables. For comparison of continuous variables, Mann–Whitney U test was used. A p value <0.05 was considered to indicate a statistically significant result. SPSS IBM Statistics 22 (IBM, Armonk, New York, USA) was used for all statistical analyses.

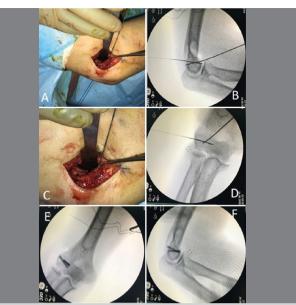


Figure 3. Perioperative pictures and scopy views showing: A-D: K-wire placements, one anteroposterior and one posteroanteriorlly E: After placement of headless compression screw AP scopy view F: After placement of headless compression screw lateral scopy view.



Figure 4. Post-operative AP and lateral radiographs (A-B); and images from final follow-up (twenty-six months) examination demonstrating the ranges of motion of the joint (C-D).

RESULTS

Twenty-one patients (9 males, 12 females) operated in our clinic between 2012 and 2015 due to isolated displaced fractures of the capitellum included in the study. Demographic data of patients were represented in (Table-1). Capitellum fractures occurred after a fall in 14 patients, as a result of a traffic accident in 5 patients, and as a result of sports injuries in 2 patients. Eight of the fractures were on the right side and 13 were on the left side. The mean age of the patients at the time of fracture was 34.8 (16-62) years. The mean follow-up period of our patients was 47.3 (26-63) months. According to Dubberley classification system, 12 cases were classified as 1A, 5 cases as 1B, 3 cases as 2A, and 1 case as 3A. The average time to surgery after trauma was 2.9 (0-7) days. Union in the fracture line was achieved in all patients during our follow-up. The mean time to union was 6 (4-8) weeks. According to the Broberg and Morrey criteria, the mean functional score was 92.7 (77-100). Thirteen cases had excellent, seven had good, and one had fair results. There were



Patient No	Age	Gender	Fracture Side	Fracture Classification	Time to surgery (D)	Time to Union (W)	Follow-up (M)		xt/Flex Sup	Final B-M Rating Score
1	50	М	R	1A	1	6	63	130/0	85/90	86
2	32	М	R	1A	7	6	62	130/0	85/80	86
3	32	М	L	2A	4	5	61	125/-10	70/85	77
4	42	F	R	1B	3	5	56	135/0	95/80	95
5	62	F	L	1B	2	8	52	145/0	85/80	100
6	49	М	R	ЗA	7	7	46	120/-10	85/80	82
7	33	F	L	1A	7	7	55	145/0	90/90	100
8	19	F	L	2A	1	4	38	135/0	85/85	98
9	21	М	L	1A	5	4	37	135/0	90/90	100
10	44	F	L	1A	1	5	26	135/0	90/85	100
11	32	F	L	1A	0	6	32	135/0	85/85	95
12	16	М	L	2A	4	5	30	145/0	85/80	95
13	40	F	L	1A	1	6	29	145/0	85/85	96
14	19	F	R	1A	1	6	26	135/-10	90/90	90
15	36	F	R	1B	0	7	27	145/0	80/80	95
16	40	F	L	1B	2	6	42	135/-10	85/85	90
17	28	F	L	1A	4	5	50	130/0	80/90	90
18	34	М	R	1B	3	6	34	145/0	90/80	96
19	20	М	R	1A	5	5	33	145/0	80/85	95
20	44	F	L	1A	1	6	47	135/-10	85/85	86
21	38	М	L	1A	2	6	46	135/0	85/85	95

Table 1. Pre-operative demographic data of patients and post-operative functional evaluation.

R; right, L; Left, D; Day, W; Week, M; Month, Ext; Extention, Flx; Flextion, Pro; Pronation, Sup; Supination, B-M; Broberg-Morrey Rating System

statistically significant differences between the mean elbow range of motions values of the injured side compared to the uninjured side (Table 2). Radiographic findings confirmed that none of the patients developed avascular necrosis. According to the Broberg and Morrey's arthrosis score, two cases had Grade 1, and one had Grade 2 arthrosis. None of our patients developed heterotopic ossification. One patient had a wound site infection which healed with close follow-up and antibiotics treatment. In one case, 60 ° extension loss was observed in the elbow during follow-up. Since the extension loss did not improve despite the rehabilitation, an anterior capsulectomy with lateral exposure was performed in the 7th month after surgery. The total range of motion of 125° was achieved postoperatively.

DISCUSSION

We fixed the capitellar fractures with a less invasive method than the standard approach, using one anteroposterior and one posteroanterior directed headless cannulated screws with the capability of compression and getting a safe room to placing a medial screw. We faced no radiological reduction loss and screw migration. All patients had excellent and good functional results based on the Broberg and Morrey criteria except one. None of our patients developed the usual complications of avascular necrosis or heterotopic ossification. Joint stiffness was observed in only one of our patients. There are several methods of treatment for capitellar fractures. These include closed reduction and cast treatment, ¹⁹ fragment excision, 20,21 arthroscopic guided reduction and internal fixation, 9,14,22 and the most preferred method today, open reduction and internal fixation.^{1,4,8,11,13,15,19,23,24} Excision of the capitellar fragment might be recommended as an easy procedure, however, as it leads to joint stiffness in the long term, this method should be employed only when the fractured fragment is too small to fix.^{20,21} Although debates continue about optimal surgical exposure and fixation in capitellum fractures, the most important criteria for ideal treatment are stability and anatomical reduction.⁶ Since the blood supply of the capitellum is from the posterolateral capsular attachment, the extensile posterior approach is not preferred and the extensive lateral approach is generally preferred. It is suggested that especially

 Table 2. Comparison of range of motions of operated and non-operated elbows.

	Operated	Non-operated	p value
Flexion	114 ± 15	135,9 ± 6	0.000
Extension	6,6 ± 7	0 ± 3	0.007
Pronation	81,6 ± 7	88,8 ± 4	0.002
Supination	78,8 ± 5	85,2 ± 7	0.001

the medial aspect of the trochlea is involved for capitellar coronal fractures, the anterolateral approach should be preferred over the lateral approach.¹⁰ Likewise, discussions continue on the selection of the implant to be used for fixation. An insertion of the screw from anterior can cause injury to the cartilage surface and can lead to collapsing of fragment.^{12,25,26} In the treatment of large capitellar fragments anterior to posterior cannulated headless compression screws may be useful, which have been shown to be biomechanically superior to postero-anterior cannulated lag screws or Herbert screws.^{5,13,27} However, with postero-anterior placement of lag screws or Herbert screws than after anteroposterior placement we can get better motion and functional scores.²⁸ Reasonable outcomes have also been got with use of threaded K-wires cut at the same level with the joint surface.¹⁸ For communited fractures at the posterior wall bone grafting with posterolateral column plating may be choosen.²⁹ For severely comminuted fractures hinged external fixation to allow early range of motion seems to be a choice.³⁰ Capitellum fracture fixation under arthroscopic guidance may hold promise. In addition, it may be advantageous to remove small fragments that cannot be fixed by arthroscopy.^{14,22} Although there are very limited publications in the form of case reports in the literature on this subject, the classical advantages of arthroscopy are minimally invasive, low infection rate, and most importantly, avoiding open surgery, especially protecting the ligaments around the elbow and eliminating the need for dissection, which is the cause of bone avascular necrosis.

One of the significant post-operative problems is the limited ROM and stiffness in the elbow after surgical treatment of capitellar fracture. For this reason, extensive dissections should be avoided,



and bleeding control should be performed. Also, since the origin of the main arterial circulation is the perforating arteries in the posterior elbow, the posterior dissection of the capitellum should be avoided. Vaishya et al.¹ used the less preferred anterolateral approach in the treatment of capitellar fractures and reported that the extensor origin was kept intact and the fracture line could be accessed directly. However, the necessity of performing an extensive dissection and preserving the neurovascular structures despite this dissection is the disadvantage of this approach. We employed the classical lateral approach with a smaller incision, partially elevated the extensor origin anterior to the lateral epicondyle and had access to the fracture line. Thus, we were able to keep the extensor origin and lateral ligament complex intact. Only one of our patients had limited ROM, and none of our patients developed heterotopic ossification.

The screws can be inserted in different configurations when fixing the fracture.^{1,8,15,23} Elkowitz et al.¹³ compared the stability of fixations with two cancellous screws, one sent anteroposterior and the other posteroanteriorly, with posteroanteriorly placed two headless cannulated compression screws and found that the headless cannulated compression screw provided the least stable fixation. The authors achieved a more stable fixation with the posteroanteriorly placed screws in both groups fixed with cancellous screws. As placing two posteroanterior screws will not provide a stable fixation in case the subchondral bone is inadequate, Carrol et al. pointed out to the necessity of anteroposterior fixation in such cases.² Another problem in sending two posteroanterior screws is the technical challenge when a more medial point is intended for screw insertion. We chose to insert an anteroposterior screw from the lateral and a posteroanterior screw from the medial of the fracture site in order to overcome this challenge and obtain a more stable fixation. In this manner, the fixation takes less time to perform and is less traumatic for the soft tissues around the elbow joint. We believe this method can also reduce the duration of surgery significantly, and due to less surgical trauma in the elbow, it avoids complications like joint stiffness.

The limitations of our study are its retrospective design and lack of a comparison or control group. However, we believe that sharing the results of our new modified technique performed on a decent sized patient population with adequate follow-up will be of use for the literature. Further comparative case series studies on capitellar fractures are required to increase the level of evidence.

CONCLUSION

Fixation with headless cannulated compression screws is considered a safe method that provides a stable fixation and allows for early motion. As an alternative to the currently used surgical approaches and fixation methods, we believe performing a small incision and inserting an anteroposterior and a posteroanterior screw is an easily applicable method that provides a stable and safe fixation.

AUTHORS' CONTRIBUTION: MB: contributed to the intellectual concept of the study, wrote and reviewed the article and performed some of the surgeries. SA: analysed the data and wrote the article. MM: performed statistical analysis, participated at the surgeries. MVK: performed statistical analysis and contributed to the intellectual concept of the study. HEA: analysed the figures and tables and reviewed the article, participated at the surgeries. KÖ: performed surgeries, reviewed the article.

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COVID-19 AND UPPER LIMB ANOMALIES IN NEWBORNS: A REASON FOR CONCERN?

COVID-19 E ANOMALIAS DO MEMBRO SUPERIOR EM RECÉM-NASCIDOS: UM MOTIVO DE PREOCUPAÇÃO?

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ABSTRACT

The relationship between viral infection in pregnancy and congenital anomalies is reported in the medical literature. The risks for the SARS-CoV-2 virus interfering with implantation, growth, and fetal development are not yet known. Many drugs with potential teratogenic risk are being used for treatment. The studies with the vaccine excluded pregnant women from clinical trials, currently preventing high-quality evidence. We present a review of the most common anomalies in the upper extremities caused by congenital viral infection and the risks of anti-COVID-19 therapy and vaccine during pregnancy. We aim to alert orthopedic and hand surgeons to the possibility of these conditions in the future. *Level of evidence V; Narrative review.*

Keywords: COVID-19. Infections. Viruses. Musculoskeletal abnormalities. Pregnancy. Newborn.

RESUMO

A relação entre infecção viral na gravidez e anomalias congênitas é relatada na literatura médica. Os riscos de o vírus SARS-CoV-2 interferir na implantação, crescimento e desenvolvimento fetal ainda não são totalmente conhecidos. Muitos medicamentos com potencial de risco teratogênico estão sendo usados para o tratamento. Os estudos clínicos com a vacina excluíram gestantes, o que tem impedido obter evidências de alta qualidade atualmente. Apresentamos uma revisão das anomalias mais comuns nos membros superiores causadas por infecção viral congênita e os riscos da terapia anti-COVID-19 e da vacina durante a gravidez. Nosso objetivo é alertar os cirurgiões ortopédicos e de mão para a possibilidade desses problemas no futuro. **Nível de evidência V; Revisão narrativa.**

Descritores: COVID-19. Infecções. Vírus. Anormalidades musculoesqueléticas. Gravidez. Recém-nascido.

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INTRODUCTION

The World Health Organization (WHO) declared coronavirus disease (COVID-19) as a pandemic on March 11th, 2020. Around the world, the first peak of infection occurred during May and August 2020. Since then, numerous cases of mild to severe complications have been reported in an impactful way.

The relationship between virus infection in pregnancy and congenital anomalies are reported in the medical literature.¹⁻²⁶ Congenital infections can be transmitted from mother to child via the transplacental route, delivery, or peripartum. Asymptomatic infection of COVID-19 in pregnancy appears to be expected and presents an additional challenge to the medical community worldwide. On the other hand, pregnant women with COVID-19 may have a significantly increased risk of severe symptoms.^{27,28}

For the treatment of COVID-19 or its symptoms, many drugs are being used, with potential teratogenic risks, including combined therapy with hydroxychloroquine and azithromycin. However, it is unclear to what extent these drugs can affect or interfere with the newborn's physiological functions' proper functioning and development.²⁹ Our concern is related to the possibility of the SARS-CoV-2 virus, interfering with implantation, growth, and fetal development, in addition to the use of drugs for the treatment of COVID-19, or even vaccines, affecting the health of the newborn. In upper limbs, two clinical causes of congenital anomalies can be observed: 1) changes caused during the formation/differentiation process; or 2) changes induced in the central nervous system.³⁰ We aimed to alert orthopedic and hand surgeons to such future possible conditions and remind them by a brief review, the anomalies in the upper extremity caused by congenital infection virus more common, the risks of anti-COVID-19 therapies and vaccines.

Congenital virus infection associated with upper limb anomalies The upper limb anomalies that occur in the most common congenital viral infections.

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

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Cytomegalovirus (CMV)

It is the most common cause of intrauterine infection and occurs in approximately 1% of all births. CMV is thought to enter the body by contacting infected secretions such as saliva, urine, blood, or genital secretions. Details of the mechanism by which CMV is transmitted to the human fetus remain unknown.

It affects the central nervous system and causes microcephaly, hydrocephalus, severe mental and motor losses, chorioretinitis, and finger anomalies. Computed tomographic scanning of the brain can demonstrate intracranial calcification. In the CMV infection, the virus may be detected in the urine for five years or longer or in saliva for 2 to 4 years.¹

Congenital CMV infection has been associated with a wide range of finger anomalies. The previous reports were presented as isolated brachydactyly² and short phalanges with rudimentary fingernails.³ The description of clasped thumb flexion deformity is probably due to the associated hydrocephalus.⁴

Herpes simplex virus (HSV)

Infection with the neonatal herpes simplex virus (NHSV), although rare, has a wide overlap of symptoms with other neonatal diseases. It usually manifests with skin lesions, eye damage, and brain abnormalities. However, limb hypoplasia is classically described in congenital varicella syndrome. Carola et al. described upper limb hypoplasia in an NHSV.⁵ Wine-Davie et al. reported hypoplasia of the left hand without nails, severe skin flaking on the left side of the body, and occasional blisters.⁶ Researchers believe that hypoplasia is a consequence of viral damage to the nerve supply to the limb.^{5,7}

Varicella Virus

Chickenpox is an acute disease caused by the varicella-zoster virus. It commonly presents as a benign childhood exanthema. Varicella-zoster virus (VZV) is a teratogen that can cross the placenta if the infection occurs during the first 20 weeks of pregnancy. The congenital malformations and dysfunctions are diverse, with anomalies of the skin, cicatrix in the limbs associated with deformities, ocular abnormalities, brain abnormalities, and mental retardation. Approximately 30% of these children died during the first months of life. Higa et al. believe that the mechanism of congenital varicella syndrome (CVS) malformations can be due not to fetal varicella but the development of herpes zoster in utero and to encephalitis associated with herpes zoster.⁸

In 1987, Alkalay et al. studied 22 children aged between one day and 15 years who had congenital anomalies associated with maternal Chickenpox or zoster-like infection during the first two trimesters of pregnancy. Skeletal abnormalities involved a decrease in the size of an upper or lower extremity in 80% of patients, in addition to bone and muscle hypoplasia. Hypoplasia involved the fingers and toes in 33% of the cases and scapula and clavicle in 13% of the patients.⁹ Sauerbrei and Wutzler related hypoplasia of limbs and other skeletal anomalies in 49% of patients.¹⁰

Savage et al. reported the evidence of denervation of limbs based on electromyography and nerve conduction studies.¹¹ Alkalay et al. found limb paresis in 65% and phrenic nerve palsy in 12% of the patients.⁹ Gupta et al. described a neonate who presented diaphragmatic palsy and brachial palsy associated with bilateral congenital talipes equinovarus.¹²

Neonatal Chickenpox may result from an affected infant's exposure to the virus shortly after birth or if the mother initially contracted Chickenpox more than a week before giving birth. Gangrenous complications occur in 0.05% to 0.16% of patients with varicella infections.

Varicella gangrenous resulted from a postnatal disease. The necrotic area is confined to the region of a previous vesicle. Extensive extremity involvement is rare, and it is believed the gangrene of the limbs occurs due to arterial thrombosis or bacterial superinfection. The treatment consists of surgical debridement and amputation when is necessary.¹³ Ehrbar et al. described a newborn girl with a mummified and hypoplastic arm that died shortly after birth.¹⁴

Influenza Virus

There are four types of influenza viruses: A, B, C, and D. Influenza A viruses are the only ones known to cause influenza. Fever caused by influenza during early pregnancy is associated with an increased risk of congenital disabilities. On the other hand, fever can also serve as a marker of more severe infections.¹⁵

Significant increases in the incidence of some types of defects in children have been reported after influenza A2 epidemics. Defects limited to the thumbs and radius showed a rise, although not statistically, after epidemics in Birmingham, England. Finger-reducing deformities were prevalent among deliveries after the 1963 outbreak in the United States of America.¹⁶ With meta-analysis, limb reductions were associated with influenza exposure in the first trimester.¹⁷

In a recent meta-analysis, maternal influenza vaccination was not associated with an increased risk of congenital malformations. However, observational studies indicate that it is not possible to exclude adverse effects. Also, additional analyzes are needed for more accurate estimates for results of genetic abnormalities.¹⁸

Rubella Virus

Rubella virus (RV) causes a mild rash disease often accompanied by adenopathy and occasional arthralgia. Congenital rubella represents the most important viral cause of fetal harm. During the first trimester of pregnancy, an infection can lead to severe birth abnormalities known as congenital rubella syndrome (CRS). Placental infection occurs during maternal viremia, leading to the spread of the virus throughout the fetus. Spontaneous abortion and fetal death were reported in 40% of the cases analyzed.¹⁹ The involvement of multiple organ systems and common abnormalities include growth restriction, hepatomegaly, hydrocephalus, ventricular septal defect, intracranial calcifications. Anomalies of the musculoskeletal system include weakness in the upper and lower limbs, congenital dislocations, congenital osteogenesis imperfecta, and muscular dystrophies.²⁰ In a Chinese study to determine the incidence and types of disease in rubella infection, the authors described that 2.09% of children presented limb defects.²¹

Zika Virus

Initially isolated in 1947, the Zika virus is an arbovirus in the family Flaviviridae. The first documented human outbreak in the Americas occurred in May 2015. Typically, transmission occurs through infected mosquito bites, blood transfusions, and sexual contact and from the mother to the fetus during pregnancy.

In infection during pregnancy, the Zika virus infects the brain cells of the fetus. Most babies die shortly after birth. At birth, congenital Zika syndrome (CZS) was characterized by microcephaly and cerebral calcifications, craniofacial and ocular abnormalities, and defects in the upper and lower limbs congenital joint contracture as contractures consistent with multiple congenital arthrogryposes and hypertonia.²² In an observational study, eighteen children (21%) had malformations such as arthrogryposis involving> 1 joint contractures. Besides, 3 of the 18 babies had unilateral diaphragmatic paralysis.

Unilateral diaphragmatic paralysis has been described after an infection caused by other viruses such as herpes zoster, poliovirus, West Nile virus, human immunodeficiency virus, and dengue.²³ In a meta-analysis, musculoskeletal disorders, such as arthrogryposis, have been reported as typical. Other reports included clubfoot and hip dysplasia.²⁴ Matos et al. described that the



treatment of orthopedic sequelae of Zika virus infection could be similar to treating orthopedic sequelae of cerebral palsy.²⁵ Based on the characteristics of 47 patients, the authors described three groups: Type I - non-spastic, Type II - spastic, and Type III - arthrogrypotic. Unfortunately, the authors did not describe the results of orthopedic treatment for these patients.

Serpa et al.²⁶ described the arthrogrypotic alterations in 17 infants diagnosed with CZS. It was noted that the upper limbs' proximal segments were less affected, with a compromised concentration in the distal region of the upper limbs. Hand and wrist bilateral deformities were evident. Severe camptodactyly deformities were commonly found in the long and ring fingers (64.70%), a position similar to the horn hand gesture used by heavy metal fans. Joint contracture in flexion associated or not with wrist ulnar deviation was observed in 35.29% of infants. The authors believe that the patients presented a pattern of impairment particular to congenital Zika virus infection.

SARS-CoV-2 virus

Thromboembolic events can be multifactorial and of unclear etiology a lot of times. The COVID-19 infection may be associated with increased risk of limb or digital ischemia in adults⁽³¹⁾. A study showed an increased rates of placental histopathologic abnormalities, particularly fetal vascular malperfusion and villitis of unknown etiology in asymptomatic women delivering at term.³² The question is if the fetuses may be at theoretical risk for intrauterine thrombotic events or any other events induced by maternal infection with COVID-19. Pervenn et al. reported a congenital ischemic limb in a neonate born to a COVID-19 mother. The newborn had present purpuric plaques and hemorrhagic bullae of the left forearm, wrist and hand who soon progressed to necrotic plagues and necrosis of all digits on the left hand. Forearm amputation at level of 4 cm distal to the olecranon tip was performed at 19 days of age.³³ The summary of the limb anomalies observed in congenital virus infection can be seen in Table 1.

Anti-COVID-19 Therapies

Pregnancy is considered a risk factor for COVID-19 severe disease.²⁷ In a meta-analysis, Diriba et al. stated that none of the studies reported transmission of Coronavirus from the mother to the fetus in the womb during the study period (1,316 pregnant women with symptoms [SARS-CoV-2, MERS-CoV and SARS-CoV]).³⁰ On the other hand, Khan et al. believe that COVID-19 can result in long-term congenital anomalies due to infection or therapeutic maneuver.³⁴ Further on, Louchet et al. suggest that there are still many deficiencies in studies on drug efficiency and safety for pregnant women in treating infectious diseases.³⁵

Some drugs used in patients during the pandemic already have safety data for pregnant women, although their safety in the context of COVID-19 may be different from conventional use. There are safety data for pregnancy and placental transfer for colchicine, steroids, oseltamivir, and some monoclonal antibodies.³⁵ A research for study of risk factors for prenatal limb defects in high-risk pregnant women described that 2.1% women took glucocorticoid.³⁶

 Table 1. Virus infections that cause upper limb anomalies following exposures during pregnancy.

Infection	Anomalie
Cytomegalovirus (CMV)	brachydactyly, short phalanges with rudimentary fingernails, clasped thumb
Varicella (Chickenpox)	Upper Limb hypoplasia Limb gangrenous Limb paresis
Herpes simplex virus 2 (HSV-2)	Upper Limb hypoplasia
Influenza Virus	Reduction deformities of the fingers
Rubella (German measles)	Upper limb anomalies
Zika virus	wrist flexion with or not ulnar deviation flexion contracture, camptodactyly.
SARS-CoV-2 virus (COVID-19)	Limb gangrenous

Lopinavir/ritonavir has low placental transfer. Some drugs are banned in pregnancy because of the known teratogenicity like thalidomide or fetal toxicities like blockers of the renin-angiotensin system. Other medications do not have sufficient data on pregnancy outcomes as tocilizumab, interleukin 6 inhibitors, umifenovir, and favipiravir.³⁵

Regarding remdesivir, it seems to be safe for use in human pregnancies, as shown in trials conducted in Ebola.³⁷

A large retrospective cohort study with UK data showed that prescribing macrolide antibiotics, erythromycin, clarithromycin and azithromycin, during the first trimester of pregnancy was associated with an increased risk of severe malformations. The authors recommended that other antibiotics be prescribed until further research is available.³⁸

The study by Huybrechts et al. suggested a small increase in the risk of malformations associated with the use of hydroxychloroquine in the first trimester of pregnancy. The authors indicated that if hydroxychloroquine is useful for COVID-19 in ongoing studies, there is a need to assess potential risks and benefits due to the possibility of malformations.³⁹

Vaccines

Some vaccines serve primarily to protect pregnant women from severe morbidity or mortality. Vaccines against COVID-19 are categorized as molecular and cellular, stimulating the proliferation of immune system memory cells against SARS-CoV-2. The risks associated with the vaccine have led to the exclusion of pregnant women from clinical trials, currently preventing high-quality evidence. However, due to the mass vaccination campaigns, the chances of immunization of women increases. Because of this, pregnant women need to be under improved and adequate safety monitoring conditions.⁴⁰ One of the common concerns is the fear of side effects from vaccines. Recently, rare blood clots have emerged after the administration of two vaccines in some patients. The data available shows the available vaccines are better at preventing hospitalization, severe disease and death than they are at preventing symptomatic COVID-19.41

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SURGICAL TREATMENT FOR RHIZARTHROSIS: A SYSTEMATIC REVIEW OF THE LAST 10 YEARS

TRATAMENTO CIRÚRGICO DE RIZARTROSE: UMA REVISÃO SISTEMÁTICA DOS ÚLTIMOS DEZ ANOS

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ABSTRACT

Introduction: Comparison of different surgical techniques to treat patients with rhizarthrosis or carpometacarpal osteoarthritis of the thumb. Materials and Methods: A systematic review was conducted using three electronic databases. Randomized, controlled trials in patients who underwent surgery for the treatment of rhizarthrosis were included. The literature review followed the PRISMA protocol. Results: A total of 15 articles involving a total population of 958 patients were selected. Seven different surgical techniques were compared. Conclusions: We conclude that no procedure is superior to another in terms of pain, physical function, overall patient assessment, range of motion, or strength. Outcome measurements should be standardized to enable better comparison between surgical techniques. *Level of evidence II, Systematic Review.*

Keywords: Rhizarthrosis. Thumb osteoarthritis. Trapeziometa-carpal joint.

RESUMO

Introdução: Comparação de diferentes técnicas cirúrgicas em pacientes com rizartrose ou osteoartrite carpometacárpica do polegar. Materiais e Métodos: A revisão sistemática foi conduzida em três bancos de dados eletrônicos. Foram incluídos estudos clínicos randomizados e controlados com pacientes submetidos ao tratamento cirúrgico para tratamento de rizartrose. A revisão da literatura seguiu o protocolo PRISMA. Resultados: Foram selecionados 15 artigos, envolvendo uma população total de 958 pacientes. Foram comparadas sete técnicas cirúrgicas distintas. Conclusões: Concluímos que nenhum procedimento é superior a outro em termos de dor, função física, avaliação geral do paciente, amplitude de movimento ou força. A mensuração dos desfechos obtidos devem ser padronizadas a fim de possibilitar melhor comparação entre as técnicas cirúrgicas assim como, permitir uma análise estatística fidedigna. **Nível de Evidência II; Revisão Sistemática**.

Descritores: Rizartrose. Osteoartrite do polegar. Articulação trapeziometacárpica.

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INTRODUCTION

Rhizarthrosis or thumb carpometacarpal osteoarthritis (CMC OA) is a common condition of pain and functional limitation in the hand. CMC OA affects 66% of women older than 55 years¹ and an estimated 22% of the general population aged 50 years and over are symptomatic² Typically, patients have pain in the base of the thumb and with the progression of the disease: atrophy of thenar muscles, subluxation of the first carpometacarpal joint, loss of pinch and grip strength. Eaton et al.³ describes 4 stages of thumb joint OA, based on radiological criteria with the end stage involving CMC and scaphotrapeziotrapezoid (STT) joints. In the early stages, patients can be treated with splinting of the thumb, along with anti-inflammatory drugs, steroid injections, and thumb-strengthening exercise⁴. Orthosis may reduce pain, however it does not improve function, dexterity and strength⁵.

For those who fail nonsurgical treatment, surgery must be considered. Several surgical techniques have been performed, and include: trapezial excision with or without ligament reconstruction and tendon interposition (LRTI), arthroscopy and debridement, arthroplasty, trapeziometacarpal arthrodesis (TMA)⁶.

In 2010, Vermeulen et al⁷ published a systematic review including 35 articles, 9 of which not included in previous reviews.

This study aimed to conduct a systematic review of randomized controlled studies on different kinds of surgical treatment in rhizarthrosis from the last 10 years.

MATERIALS AND METHODS

This review followed the PRISMA protocol⁸. The search was carried out in the PUBMED, EMBASE, and Cochrane databases using the following terms (PICOS method): Patient: rhizarthrosis (Eaton

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

The study was conducted at the Hospital das Clínicas de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, SP, Brazil. Correspondence: Ricardo Lucca Cabarite Saheb. Av. dos Bandeirantes 3900, 11º andar, Ribeirão Preto, SP, Brazil. 14048-900. rsaheb@usp.br

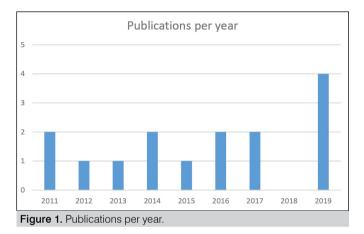
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stages II-IV) ; Intervention: Surgery; Comparison: Different kinds of surgical treatment; Outcomes: Pain, function, grip and pinch strength; Study design: randomised controlled trials.

The review was conducted in October 2019 and repeated in April 2020, and included studies from the last ten years (between 2011 to 2019) (Figure 1). Search terms included "rhizarthrosis", "thumb carpometacarpal joint" and " thumb osteoarthritis". There was no restriction on publication language. First of all, a list was created with the titles and abstracts of studies potentially relevant and two independent reviewers (R.L.C.S and B.A.S.V.) applied the search. If the abstract suggested inclusion in our study, the full manuscript was retrieved and reviewed. Conflicts could be solved by a third researcher, however it was not necessary.

The same two reviewers, in an independent manner, extracted the data, which included: participants, intervention, comparison between techniques, scores, results and conclusion.



RESULTS

A total of 29 articles contained titles and abstracts relevant to the study and were selected for a complete reading of the text. After this stage, 15 articles were included, of which 958 patients were selected. Five studies compared different techniques of trapezial excision with ligament reconstruction and tendon interposition (LRTI). Esenwein et al. (2011)⁹, compared T + LRTI using abductor pollicis longus (APL) or flexor carpi radialis (FCR). Similar results can be obtained using the technically less demanding APL-procedure when compared with the FCR-technique 8 months postoperatively. Vermeulen et al. $(2014)^{10}$, compared T + LRTI (FCR) with or without bone tunnel, and obtained faster recovery in tunnel group, however, 12 months after surgery, the functional outcome was similar. Spekreijse et al.¹¹ (2015), comparing T + LRTI(FCR) with or without bone tunnel, showed that improved function, strength, and satisfaction obtained at 1 year after, was maintained after 5 years. Zajonc et al.¹² (2016), in 38 patients, compared T +LRTI (APL) from Lundborg and Sirotakova techniques. Both resection-suspension arthroplasty procedures led to a statistically significant postoperative reduction of pain, a significant improvement in radial and palmar abduction, a significant gain in guality of life and significant asymptomatic proximalization of the first metacarpal bone. Nanno et al.13 (2019), compared T +LRTI (APL) original and modified. There were no statistically significant differences in the thumb palmar abduction angle, pinch power, grip strength, Quick DASH score, or VAS score between groups. Patients in group 2 had a significantly better range of motion of radial abduction.

Three studies compared trapeziectomy versus trapeziectomy with or without LRTI. Salem et al.¹⁴ (2011) and Gangopadhyay et al.¹⁵ (2012), studying 114 and 153 patients, respectively showed similar objective

and subjective outcomes between groups, so there appears to be no benefit to tendon interposition or ligament reconstruction in the longer term, furthermore Corain et al.¹⁶ (2016), demonstrated that the trapezium excision and bone space distraction technique requires a smaller incision, a shorter surgical time, an easier surgical technique, and a less painful recovery, maintaining overlapping levels of functional restore.

Other three studies compared trapezial excision with or without LRTI versus trapeziometacarpal arthrodesis (TMA). The first study by Vermeulen et al.¹⁷ was published in 2014. This study in 38 patients showed similar results in DASH and PRWHE scores twelve months after surgery, however fewer moderate and severe complications were related after trapeziectomy with ligament reconstruction and tendon interposition. A second study was published by Hippensteel et al.¹⁸ in 2017, comparing 52 patients. There were no significant differences in the amount of change in grip or pinch strength, patientreported outcomes, or functional hand testing between groups. The incidence of complications was similar between operative groups, but revision surgery was more common after TMA. The third study from Li et al.¹⁹ published in 2019, in 39 patients, showed that arthrodesis displayed better pinch strength, while arthroplasty displayed better motor function. Patients were satisfied with the effects of both techniques.

One study compared arthroplasty versus trapeziectomy and LRTI (Thorkildsen et al. 2019)²⁰, in 40 patients. The results in the early rehabilitation were significantly better in the joint replacement group, as well as the range of motion in abduction and extension was better at the final follow-up. Patient satisfaction was high in both groups despite more complications after joint replacement. Trapeziectomy with ligament reconstruction and tendon interposition proved to be a safe and effective treatment with few complications in this trial. Another study compared arthroplasty cemented and uncemented (Hansen et al. 2013)²¹, with 16 patients in each group, showing aimilar good require between et al.

similar good results between groups at all measurement points in grip strength, pain and DASH score. Another one study compared trapezial excision versus trapezial denervation. Salibi et al.²² (2019), in 45 patients, associated trapezial

denervation. Salibi et al.²² (2019), in 45 patients, associated trapezial denervation with fast recovery, by the other hand 30% of these patients needed a reoperation.

The last study compared trapezial excision with LRTI versus trapezial excision and allograft. This study from Marks et al.²³, published in 2017, comparing 60 patients, showed similar outcomes, with more complications in the second group. Allograft was used only in cases of severe instability.

The DASH (The Disabilities of the Arm, Shoulder and Hand) score was the most frequently used (9 articles), followed by VAS (Visual Analogue Scale) (8 articles). (Figure 2).

The rhizarthrosis stage was classified according to Eaton in 12 articles. Three studies did not define the classification.

DISCUSSION

The aim of the study was to provide an updated review of the current literature (last 10 years), according to most used surgical procedures. We did not perform a statistical analysis because of the great heterogeneity between the included articles. Our search strategy identified 15 articles, none of them includes in previous systematic reviews.

First, we reviewed five studies comparing different techniques of trapeziectomy with ligament reconstruction and tendon interposition. No evidence of superiority between techniques was demonstrated. The second group of studies, compared trapeziectomy alone and trapeziectomy with or without LRTI. Similar objective and subjective outcomes were obtained between groups, moreover trapezium



excision isolated requires a smaller incision, a shorter surgical time, an easier and a less painful recovery.

The third group, including three studies, compared trapezial excision with or without LRTI versus trapeziometacarpal arthrodesis (TMA). Complications and repeat surgeries are more frequent following TMA compared to trapeziectomy with or without LRTI. One author suggested that arthrodesis displayed better pinch strength, while arthroplasty displayed better motor function.

When evaluating the study on arthroplasty versus trapezial excision with LRTI, we conclude that the results in the early rehabilitation were significantly better in the joint replacement group, as well as the range of motion in the final follow-up, by the other hand more complications were associated to the joint replacement group.

The study comparing cemented and uncemented arthroplasty, showed similar good results with both techniques.

Another study compared trapezial excision versus trapezial denervation and concluded that 30% of patients undergone trapezial denervation, needed a second surgical procedure.

Finally, an article comparing trapezial excision with LRTI versus trapezial excision and allograft, conclude that allograft should be used only in cases of severe instability, due to associated complications with the technique (Tables 1 and 2).

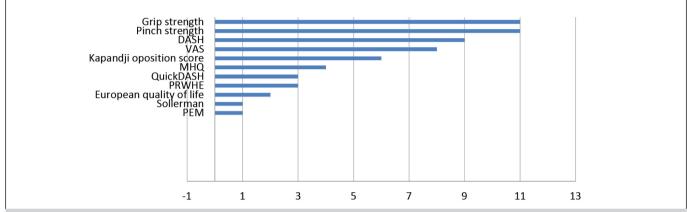


Figure 2. The Disabilities of the Arm, Shoulder and Hand; VAS = Visual Analogue Scale; MHQ = Michigan Hand Outcome Questionnaire; PRWHE = Patient rate wrist/hand.

Authors	Study	Nº of patients per group	Procedure	Author's conclusion
Hippensteel et al. ⁶ (2017)	RCT	27	CMC arthrodesis	There were no significant differences in the amount of change in grip or pinch strength,
		25	LRTI	patient-reported outcomes, or functional hand testing between TMA and LRTI. The TMA group had significantly increased thumb tip opposition distance. The TMA group was complicated by a 26% overall nonunion rate of which 8% were symptomatic. The LRTI group (Wagner incision) had a significantly increased incidence of superficial branch of the radial nerve paresthesia. The incidence of complications was similar between operative groups, but revision surgery was more common after TMA.
Esenwein et al. ⁹ (2011)	RCT	30	T + LRTI(APL)	Similar results can be obtained using the technically less demanding APL-procedu
		25	T+LRTI (FCR)	when compared with the FCR-technique 8 months postoperatively.
Vermeulen et al. ¹⁰ (2014)	RCT	36	T+ LRTI(FCR) with tunnel	After the bone tunnel technique, patients have better function and less pain 3 months
		36	T +LRTI (FCR) without tunnel	after surgery than do those in the nonebone tunnel group, which indicates faster recovery. However, 12 months after surgery, the functional outcome was similar.
Spekreijse et al. ¹¹ (2015)	RCT	36	T+ LRTI(FCR) with tunnel	This study showed that improved function, strength, and satisfaction obtained
		36	T +LRTI (FCR) without tunnel	at 1 year after trapeziectomy with LRTI with or without the use of a bone tunnel for stage IV TMC thumb osteoarthritis was maintained after 5 years.
	RCT	19	T + LRTI(APL) Lundborg	Both resection-suspension arthroplasty procedures led to a statiscally signifcant
Zajonc et al. ¹² (2016)		19	T + LRTI(APL) Sirotakova	postoperative reducion of pain, a significant improvement in radial and palmar abduction, a significant gain in quality of life and significant assymptomatic proximalisation of the first metacarpal bone. There was no significant difference in postoperative strength.
Nanno et	RCT	10	T +LRTI (APL original)	There were no statiscally significant differences in the thumb palmar abduction
al. ¹³ (2019)		20	T+LRTI(APL modif)	angle, pinch power, grip strength, Quick DASH score, or VAS score between groups. Patients in group 2 had a significantly better range of motion of radial abduction.
	RCT	59	Т	There were no significant differences between the two treatments in any
Salem et al. ¹⁴ (2011)		55	T+LRTI (FCR)	subjective or objective outcome measure at 6-year follow-up Eighty-two percent of the thumbs were painless or only ached after use. The DASH and Patient Evaluation Measure scores were significantly better than preoperatively.
Gangopadhyay et al. ¹⁵ (2012)		53	Т	The outcomes of these 3 variations of trapeziectomy were similar after a
	RCT	46	T + TI (PL)	minimum follow-up of 5 years. There appears to be no benefit to tendon
		54	T +LRTI (FCR)	interposition or ligament reconstruction in the longer term

Corain et	RCT	64	T + TI (APL)	We demonstrate that the trapezium excision and bone space distraction technique
al. ¹⁶ (2016)		56	T + hematoma and distraction	require a smaller incision, a shorter surgical time, an easier surgical technique, and a less painful recovery, maintaining overlapping levels of functional restore.
Vermeulen et al. ¹⁷ (2014)		21	T + LRTI (FCR)	Women who are forty years or older with trapeziometacarpal osteoarthritis have fewer moderate
	RCT	17	Arthrodesis	and severe complications after trapeziectomy with ligament reconstruction and tendon interposition and are more likely to consider the surgery again under the same circumstances than are those who undergo arthrodesis. Twelve months after surgery, the PRWHE and DASH scores were similar in both groups. We do not recommend routine use of arthrodesis with plate and screws in the treatment of women who are forty years or older with stage-II or III trapeziometacarpal osteoarthritis.
Li et al. ¹⁸ (2019)	RCT	22	Arthrodesis	In Chinese patients, both techniques relieved pain and improve grip strength.
		17	T + LRTI (FCR)	Arthrodesis displayed better pinch strength, while arthroplasty displayed better motor function. Patients were satisfied with the effects of both techniques.
Thorkildsen et al. ¹⁹ (2019)	RCT	20	T + LRTI	Significantly better function in the joint replacement group in the early rehabilitation period as shown
		20	uncemented prostheses	by the secondary outcome measures, Kapandji score and strength of key and tip pinch. In addition, the range of motion in abduction and extension was better at the final follow-up. Patient satisfaction was high in both groups despite more complications after joint replacement. Trapeziectomy with LRTI proved to be a safe and effective treatment with few complications in this trial.
Hansen et	RCT	16	cemented prostheses	Grip strength, pain, and DASH scores were similar between groups at all measurement points.
al. ²⁰ (2013)		16	uncemented prostheses	Early implant fixation and clinical outcome were equally good with both cup designs.
Salibi et al. ²¹	RCT	19	Trapeziectomy	There was no difference between the two treatments. First CMCJ denervation does not
(2019)		26	Trapezial denervation	appear to be superior to trapeziectomy. However, the advantage of rapid rehabilitation makes it more favored by patients but at the expense of 30% reoperation rate.
Marks et al. ²² (2017)	RCT	29	T +LRTI (FCR)	The use of the FCR tendon or allograft for trapeziectomy with suspension interposition
		31	T+ allograft	arthroplasty in patients with CMC I OA leads to similar outcomes with more complications, mainly tendon irritations, associated with the latter. Allograft was used only in cases of severe instability requiring a larger amount of suspension-interposition material or for revision procedures after failed suspension-interposition with the FCR tendon.

RCT = Randomized controlled trials; T = Trapezectomy; LRTI = Ligament reconstruction and tendon interposition; APL = Abductor Pollicis Longus; FCR = Flexor Carpi Radialis; CMC = Carpometacarpal.

Table 2. Most reported complications.

Authors	Eaton stage	Most reported complications
Hippensteel et al. ⁶ (2017)	II/III/IV	Sensory disturbances in the radial nerve territory
Esenwein et al. 9 (2011)	III/IV	wound infection
Vermeulen et al. ¹⁰ (2014)	11/111	Sensory disturbances in the radial nerve territory/ scar tenderness/ FCR tendinitis
Spekreijse et al.11 (2015)	IV	FCR tendinitis
Zajonc et al.12 (2016)	II/III/IV	
Nanno et al.13 (2019)	III/IV	
Salem et al.14 (2011)	-	Numbness in the radial nerve territory
Gangopadhyay et al. ¹⁵ (2012)	II/III/IV	Superficial radial nerve dysfunction
Corain et al. ¹⁶ (2016)	III/IV	FCR tendinitis
Vermeulen et al. ¹⁷ (2014)	IV	FCR tendinitis
Li et al. ¹⁸ (2019)	11/111	Numbness in the radial nerve territory
Thorkildsen et al.19 (2019)	-	cup loosening/ dislocation/ infection
Hansen et al. ²⁰ (2013)	11/111	cup loosening
Salibi et al. ²¹ (2019)	-	
Marks et al.22 (2017)	II/III/IV	FCR tendinitis

CONCLUSION

We conclude that no procedure is superior to another in terms of pain, physical function, patient global assessment, range of motion, or strength. Furthermore, because differences between the various techniques are small, researchers should focus on developing more sensitive outcome measures that are indicative of the specific changes in hand function after CMC OA. We suggest that outcomes measures be standardized. The Disabilities of the Arm, Shoulder and Hand (DASH) perhaps the most indicated like a Patient Report Outcomes (PRO), in association with Visual Analogue Scale (VAS), grip and pinch strengths.

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