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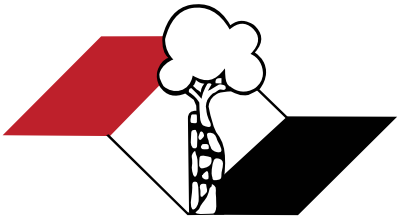

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ACKNOWLEDGEMENTS

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

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Levels of Evidence for Primary Research Question[a]

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

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

[a] A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
[b] A combination of results from two or more prior studies.
[c] Studies provided consistent results.
[d] Study was started before the first patient enrolled.
[e] Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.
[f] The study was started after the first patient enrolled.
[g] Patients identified for the study based on their outcome, called "cases" eg, failed total arthroplasty, are compared with patients who did not have outcome, called ''controls'' eg, successful total hip arthroplasty.
[h] Patients treated one way with no comparison group of patients treated in another way.

SUMMARY

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Original Article

DOI: http://dx.doi.org/10.1590/1413-785220233102e264305
FOOT AND ANKLE

ANKLE ARTHRODESIS WITH INTRAMEDULLARY RETROGRADE NAIL FOR BONE TUMORS. PRELIMINARY RESULTS AND SURGICAL TECHNIQUE

ARTRODESE DO TORNOZELO COM CAVILHA INTRAMEDULAR RETRÓGRADA PARA TUMORES ÓSSEOS. RESULTADOS PRELIMINARES E TÉCNICA CIRÚRGICA

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ABSTRACT

Objective: Present the preliminary results of a case series using the surgical ankle arthrodesis technique with an intramedullary retrograde nail for bone tumors. Methods: We present the preliminary data of 4 patients, 3 males and 1 female, with a mean age of 46,2 (range 32 to 58) years, with histology proven Giant Cell Tumour of bone in 3 and osteosarcoma in 1. The mean resection length of distal tibia was 11,75 (range 9 to 16) cm, and all the patients underwent reconstruction with a tibiotalocalcaneal arthrodesis with an intercalary allograft fixed by a retrograde intramedullary nail. Results: Oncological follow-up evolved without evidence of local recurrence or disease progression in all patients. After a mean time of 69.5 (range 32 to 98 months), patients had a mean MSTS12 functional score of 82.5% (range 75 to 90). All tibial arthrodesis and diaphyseal osteotomy sites were fused within 6 months with a return to activities without complications related to coverage skin or infection. Conclusion: No complications were recorded; all arthrodesis and diaphysial tibial osteotomy sites fused by 6 months, and the mean follow-up of those patients was 69,5 (range 32 to 988) months, with a mean functional MSTS score of 82,5% (range 75-90). ***Level of Evidence: IV; Retrospective Case Series.***

Keywords: Tumors. Ankle. Intramedullary nailing. Neoplasms, bone tissue. Giant cell tumors. Osteosarcoma.

RESUMO

Objetivo: Apresentar os resultados preliminares de uma série de casos utilizando a técnica cirúrgica de artrodese do tornozelo com haste intramedular retrógada para tumores ósseos. Métodos: Apresentamos os dados preliminares de quatro pacientes, três homens e uma mulher, com idade média de 46,2 (variação de 32 a 58) anos, com histologia comprovada de tumor de células gigantes em três e osteossarcoma em um. O comprimento médio de ressecção da tíbia distal foi de 11,75 (variação de 9 a 16) cm, e todos os pacientes foram submetidos à reconstrução com uma artrodese tibiotalocalcaneana com um aloenxerto intercalar fixado por uma haste intramedular retrógrada. Resultados: O acompanhamento oncológico evoluiu sem evidências de recidiva local ou progressão da doença, em todos os pacientes. Após um tempo médio de 69,5 (variação de 32 a 98 meses), os pacientes tiveram uma pontuação média funcional MSTS12 de 82,5% (variação de 75 a 90). Todos os locais de artrodese e osteotomia diafisária tibiais foram fundidos em 6 meses com retorno às atividades de vida diária sem complicações relacionadas à cobertura ou infecção.Conclusão: Não foram registradas complicações; todos os locais de artrodese e osteotomia diafisária da tíbia fundiram-se em 6 meses, e o acompanhamento médio desses pacientes foi de 69,5 (variação de 32 a 988) meses, com uma pontuação média funcional MSTS de 82,5% (variação de 75-90). ***Nível de Evidência IV; Série de Casos Retrospectivos.***

Descritores: *Neoplasias. Tornozelo. Fixação intramedular de fraturas. Neoplasias de tecido ósseo. Tumores de células gigantes. Osteossarcoma.*

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INTRODUCTION

For a long period of time, those rare tumours located at the distal tibia, were candidates for amputation, mostly due to the poor soft tissue coverage. With the development of more effective arthrodesis surgical techniques, the use of chemotherapy in malignant tumours, and the need to save the limb in tumours of a benign nature, and also in patients that refused amputation, limb salvage surgery has become a demand for the majority of situations. Reconstructive options in distal tibia tumours include the use of a custom made prosthesis, a modular prosthesis, osteoarticular allografts and ankle arthrodesis by the use of free or vascularized bone grafts. The fixation for the arthrodesis is variable, from antegrade nailing, plates and more recently with retrograde intramedullary nails.
A few small series have been reported in the literature dealing with this tumour location and the particular needs for reconstruction.[1-9]

PATIENTS AND METHODS

Medical records, operative reports, radiographs and histologic records of all patients included in the study were reviewed.
From 2007 to 2013, four patients with distal tibia bone tumours, were submitted to tumor resection and reconstruction by ankle arthrodesis with intercalary allograft and fixation with a retrograde transtalar intramedullary nail.
There were 3 males and 1 female, with a mean age at diagnosis of 46,2 (range 32 to 58) years. 3 patients had a benign bone tumour (giant cell tumour), all of which were Stage 3 (according with the Enneking Staging System)[10] and one patient had a malignant bone tumour (osteosarcoma) Stage IIB, using the same Staging System.
This patient with high grade malignant osteosarcoma, was treated with neoadjuvant and adjuvant chemotherapy, with a four drug regimen composed by Methotrexate; Adriamycin, Ifosfamide and Cisplatin, and obtained a Huvos Grade IV response[11] after neoadjuvant chemotherapy.
All patients underwent surgical treatment, with a tumour resection with wide margins in the case of the sarcoma, and marginal in the benign aggressive GCT. A sample from the bone marrow of the proximal side of the tibia osteotomy stump, was obtained, and evaluated by frozen section, to access margins adequacy, and to avoid spread of the disease during nail insertion. In the 4 patients an ankle arthrodesis was obtained using an intercalary allograft, fixed with a retrograde intramedullary tibiotalocalcaneal nail and an additional proximal osteotomy site fixation with an anti-rotation plate, and surround filling of the osteotomy with autologous bone chips from the iliac crest.
After suture removal, the patients were immobilized with a cast for 4 weeks without weight bearing. After four weeks the plaster was changed to a delta cast with the application of a walking shoe sole, and progressive weight bearing was allowed, until full weight bearing is reached around ten weeks post-operatively. The patients remain in the cast for 6 months and walk with full weight bearing with the support of a cane.
Clinical and radiograph follow-up was obtained every month. (Table 1)

Surgical technique

At the start of the surgical procedure autologous bone chips are harvested from the iliac crest.
One of the major difficulties after distal tibia resection is to obtain correct alignment for the ankle and foot while doing the arthrodesis. This difficulty is potentiated by the gap space at the distal tibia in the resection location, which favours additional movement, sometimes without proper control during the process of nailing.
To avoid malalignment of the ankle and foot during the arthrodesis process and also to eliminate difficulties at the selection of the nail entry point in the calcaneus avoiding a fracture, the next surgical step is to mount an external tubular fixator, putting a Chance pin at the foremost desirable position at the proximal tibia, another pin at the posterior tip of the calcaneus, and a third pin at the third metatarsal bone to position the foot. (Figure 1)
That way the foot and ankle can be maintained in a proper position for the arthrodesis – with ankle neutral dorsiflexion, 5 degrees heel valgus and external rotation of the foot in relation to the tibia comparable to that of the normal contralateral side, of approximately 5 to 10 degrees. Also under fluoroscopy the relation between the calcaneus and the tibia, can be confirmed, allowing the proper valgus inclination that will permit the correct nailing positioning because by this method the normal lateral offset of the calcaneus in relation with the tibia is corrected.[13]
The positioning of the external fixator is applied in a way that does not make the surgical resection any more difficult.
In all patients surgery was performed using an anterior approach to the ankle and in osteosarcoma case a lateral approach was

Figure 1. External fixator in place, keeping the length and position of the foot during surgery.

Table 1. Patients data.

Patient	Age (years) Gender	Diagnosis, stage, margins	Length of tibial resection (cm)	Bone grafts	Fixation technique	Complications	Follow-up (m)	Functional scores -MSTS/ISOLS
1	58 Male	GCT 3 Marginal	9	Allograft + Autologous bone chips from iliac crest	Retrograde intramedullary nail + antirotational plate and screws	No	98	80
2	40 Male	GCT 3 Marginal	12	Allograft + Autologous bone chips from iliac crest	Retrograde intramedullary nail + antirotational plate and screws	No	86	85
3	32 Male	Osteosarcoma IIB Wide	16 (fibula 12)	Allograft + Autologous bone chips from iliac crest	Retrograde intramedullary nail + antirotational plate and screws	No	62	90
4	55 Female	GCT 3 Marginal	10	Allograft + Autologous bone chips from iliac crest	Retrograde intramedullary nail + antirotational plate and screws	No	32	75

added to facilitate the distal fibula resection together in the same surgical specimen with the distal tibia where the tumour had origin. The average resection length of distal tibia was 11,75 (range 9 to 16) cm, and the tibial osteotomy was performed at least 3 cm proximal to the tumour extension as determined by preoperative MRI.

Following tumour resection the defects were reconstructed with a tibia allograft selected previously from our Bone Bank, matching the dimensions of the resected bone based on the preoperative planning scans. An allograft that is slightly undersized than the host bone is preferred but the most important match is at the proximal osteotomy site.

The articular cartilage of the dome of the talus is removed with a high speed burr, after which an elliptical tip burr is used to carefully we carefully design around the talus dome a groove where the distal part of the allograft is to be seated. (Figure 2) If needed additional autologous bone chips, previously harvested from the iliac crest can be used.

This way an ankle arthrodesis is obtained using an allograft in an intercalary position.

After all these steps are achieved, a retrograde intramedullary nail is inserted from bellow checking the calcaneotalotibial progression under fluoroscopy control, in a way that when the tip of the nail abuts the talus dome, there is visual control of the position.

In the next surgical step, and now that the correct arthrodesis position of the foot and ankle is assured, distraction of the surgical gap is done, using the external fixator to obtain it, and the allograft, is carefully positioned in place, modifying its size if necessary. With the alignment been maintained by the external fixator, the graft is now compressed again using the external fixator[14], and then the nail is progressed proximally through the interior of the allograft and after inside the host proximal tibial bone. With this surgical technique, the correct position for the arthrodesis is assured as well as the correct placement of the allograft in the most anatomic position, and avoiding possible allograft fracture during the progression of the nail.

Because of the length of resections, straight nails, between 200 and 300 mm, are used depending on the resection length.

As a final step at the proximal host-allograft bone osteotomy site, an antirotational plate, is placed laterally, also compressing the osteotomy site, supported by cortical screws, and the cancellous autografts harvested from the iliac crest are then placed around the osteotomy site. (Figure 3)

Surgery is finalized with a careful suturing and soft tissue coverage under a suction drainage system. Good soft tissue coverage is pivotal, and if primary wound closure could not be achieved then flaps coverage may be required, although it was not needed in this group of patients. An antalgic posterior cast is than applied.

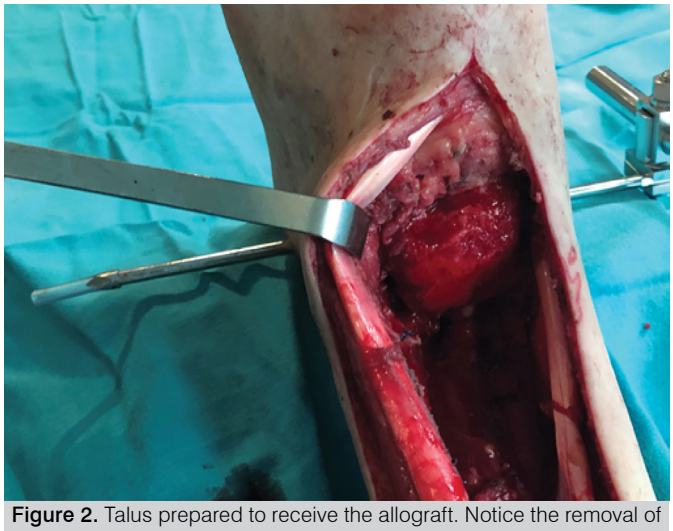

Figure 2. Talus prepared to receive the allograft. Notice the removal of cartilage, the adaptation of the dome to the allograft size, and the design of a groove to receive the allograft extremity.

Figure 3. Image after the procedure final, before closing. (Transtalar nail insertion, external fixator removal, foot positioning correction, passage of the proper screws through the nail, autologous grafting and antirotation plating).

RESULTS

Oncological follow-up progressed with no evidence of local recurrence or disease progression, for all patients. At last follow-up after a mean time of 69,5 (range 32 to 98) months, the patients had a mean functional MSTS[12] score of 82,5% (range 75-90) at last follow-up. All arthrodesis and diaphysial tibial osteotomy sites fused by 6 months. All patients have returned to their previous professions, all of them walk without canes and one of them swims regularly. There were no complications related with skin coverage, wound breakdown or infection.

DISCUSSION

After distal tibia resections for bone tumours different reconstructive options have been reported.

The use of a large prosthesis in the ankle joint has a high risk for septic and mechanical complications, mostly late, like prosthetic loosening or talar collapse, that contribute to increasing functional disability over time. These complications are also known from the literature, related with the use of prosthetic replacements even in degenerative pathologies. This evidence can be based on Abudu et al,[2] Lee et al[15] and Shekkeris et al[8] series where an early functional recovery was reported, but significant midterm complications including deep infections and aseptic loosening arose. With time the function continues to deteriorate with growing disability, discomfort and pain.

Massive osteoarticular allografts are not commonly used at this location, mainly because of joint instability and allograft fracture often associated with implant failure.[1]

Because of the previous reasons the most used reconstructive technique for limb salvage surgery of the distal tibia is ankle arthrodesis, because it provides a stable joint and residual satisfactory function. Reconstruction techniques to achieve ankle arthrodesis described after distal tibia tumour resection include different and variable types of grafts and fixation materials.

Vascularized autogenous fibula or iliac crest grafts, autogenous and/or allograft cortical structural grafts, were used by different

authors, who also using different types of fixation, varying from Illizarov external fixators to plates or antegrade nails.[1,3,4,6,7]
Moore et al[5] reported on 9 patients with resections followed by reconstruction with ankle arthrodesis using a massive allograft and retrograde nail fixation, with a major complication rate of 44,4% and an MSTS mean score of 73.
Recently Xu et al[9] reported on a series of 5 patients with a high grade malignant osteosarcoma of the distal tibia, in whose reconstruction an allograft and a retrograde intramedullary nail was used, with good functional results and few complications.
Dieckmann[16] et all, firstly described a tibiotalocalcaneal arthrodesis with a retrograde nail, for the surgical treatment of malignant tumours with resection of the entire fibula.
Table 2 summarizes the available literature reports.
What can be pulled out of that table, is the following: 1) The published series report on a few number of cases 2) Even the series that present a larger number of cases, the surgical reconstruction methods were different in the same series, which can bias the results. 3) Although arthrodesis is a function-limiting procedure, a MSTS score greater than 70 was reported in the majority of the series. 4) For the same series good results, in terms of pain, support-free walking and emotional acceptance, were achieved.[17]
One of the issues when using a retrograde nail is that it's use results in the sacrifice of the subtalar joints, when its involvement in the tumour is not present, and a need to extend the arthrodesis to that joint is oncologically unjustified. We strongly think, that although not necessary in relation to an oncology point of view, the possibility of secondary arthritic changes in adjacent foot joints that occur, with time, due to the loss of tibiotalar motion is quite significant, and more frequently found in the subtalar joints.[18] The sacrifice of the subtalar joints supressing the motion also in this joint, decreases significantly the pain and increases the mechanical support of the arthrodesis, contributing also for the short period that the distal calcaneotalofibular fusion demands to occur (4 to 6 months), and with the achievement of that distal fusion, allowing stability for a quicker proximal osteotomy fusion. (Figure 4)

Figure 4. Post operative XR at 10 months post-operative, with allograft incorporation on both osteotomies sites.

Table 2. Summary of the literature based on published series.

Author Publication year	Number of cases	Reconstruction	Complications	ISOLS/MSTS score	Follow-up Years
Abudu [1] 1999	5	Custom-made semiconstrained rotating hinge prosthesis	Deep infection (1) Early aseptic loosening of talar component (1) Local recurrence (1)	Initial 1 y – 81 Decreased in time for 50	5,5
Lee [14] 1999	6	Custom-made hinged prosthesis	Infection (1) Talar collapse (1)	80,5	5,3
Shekkeris 2009[8]	6	Endoprosthetic replacement	Infection 2 (lead to amputation)	70%	9.6
Engelhardt and Morant [15] 1993 Taylor[7] 2003	1 1	Illizarov bone transportation	-	-	6
Bishop [3] 1995	4 tumor cases 7 trauma/osteomyelitis	<4 cm defect – iliac crest vascularized graft >4 cm defect vascularized fibula	Deep infection (1) Non Union (1) (amputations)	-	-
Shalaby [6] 2006	6	Autogenous fibular strut graft (vascularized in 3) + cancelous autogenous graft Illizarov fixation	New grafting (2) Local recurrence (1)	70	-
Moore [5] 2005	9	Massive allograft and retrograde nail fixation	Fractures (3) Non union (1) Mechanical complications (3) 65,4% rate new surgery	73	-
Xu [9] 2017	5	Allograft and retrograde nail fixation	Subcutaneous fluid in 4	74,3%	3,6
Casadei [4] 1994	12	Different reconstructions: Autografts Autografts + cortical allografts Vascularized fibula Fixation with Kuntcher or Grosse-Kempf nail/or plates	Deep infection (2) Graft Fractures (4)	-	5,6
Campanacci [1] 2008	8	Cortical structural allografts and/or autogenous grafts. <8 cm defect – autografts >8 cm defect auto + allografts Fixation: Antegrade nail 6 Plate 2	Donor site (tibia): Infection (1) Fracture (1) Deep infection (1) – amputation Local recurrence (1)	80,4	4,5

CONCLUSION

In our experience, even in this small series, in cases of distal tibia tumours, ankle arthrodesis using an intercalary allograft, fixed by a retrograde intramedullary nail is an efficient method of limb reconstruction after tumor resection. The surgical technique described, led to an absence of complications and successful fusion in every case with good functional and oncological outcomes.

AUTHORS' CONTRIBUTION: The authors declare that they contributed individually and significantly in equal measure to developing this article, with substantial contributions in work conception and design, acquisition, analysis, data interpretation; writing or critical review of its intellectual content; approving the final version of the manuscript to be published; and agreeing to be held responsible for all aspects of the work to ensure that any issues related to the completeness or accuracy of its parts are properly investigated and resolved.

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FOOT AND ANKLE

CAN THE PERCUTANEOUS CHEVRON AND AKIN (PECA) TECHNIQUE CORRECT THE PRONATION OF THE FIRST METATARSAL IN HALLUX VALGUS?

A TÉCNICA PERCUTÂNEA DE CHEVRON E AKIN (PECA) PODE CORRIGIR A PRONAÇÃO DO PRIMEIRO METATARSO EM HALUX VALGO?

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ABSTRACT

Objective: Pronation of the first metatarsal in hallux valgus has recently been discussed among foot and ankle surgeons. This study aimed to evaluate the potential radiographic correction of moderate and severe hallux valgus using the percutaneous Chevron and Akin (PECA) technique. Methods: We evaluated 45 feet in 38 patients (mean age 65.3 years old [36 - 83]; 4 men; 34 women; 7 bilateral) who underwent surgical correction using the PECA technique. The radiographic images evaluated were anteroposterior radiographs obtained pre- and postoperatively at least 6 months after surgery, including the metatarsophalangeal angle, the intermetatarsal angle, pronation of the first metatarsal, displacement of the distal fragment, medial sesamoid position and bone union. Results: All parameters evaluated showed significant postoperative improvement, including correction of pronation of the first metatarsal ($p < .05$) and position of the sesamoid ($p < .05$). There was a union of osteotomies in all feet. No complications were observed, such as screw loosening or necrosis of the first metatarsal head. Conclusion: The PECA technique can correct pronation of the first metatarsal in moderate and severe hallux valgus, and other deformity-associated parameters. ***Level of Evidence IV; Case Series.***

Keywords: Hallux valgus. Minimally invasive surgical procedures. Pronation.

RESUMO

Objetivo: *A pronação do primeiro metatarso no hálux valgo tem sido um tema de discussão recente entre os cirurgiões de pé e tornozelo. O objetivo deste estudo foi avaliar o potencial de correção radiográfica do hálux valgo moderado e grave utilizando a técnica percutânea de Chevron e Akin (PECA).* ***Métodos:*** *Avaliamos 45 pés em 38 pacientes (média de idade 65,3 anos [36 - 83]; 4 homens; 34 mulheres; 7 bilaterais) submetidos à correção cirúrgica pela técnica PECA. As imagens radiográficas avaliadas foram radiografias anteroposteriores obtidas no pré e pós-operatório com no mínimo 6 meses após a cirurgia, incluindo ângulo metatarsofalângico, ângulo intermetatarsal, pronação do primeiro metatarso, deslocamento do fragmento distal, posição do sesamoide medial e união óssea.* ***Resultados:*** *Todos os parâmetros avaliados apresentaram melhora significativa no pós-operatório, incluindo correção da pronação do primeiro metatarso ($p < 0,05$) e posição do sesamoide ($p < 0,05$). Houve união de osteotomias em todos os pés. Não foram observadas complicações, como soltura do parafuso ou necrose da cabeça do primeiro metatarso.* ***Conclusão:*** *A técnica PECA pode corrigir a pronação do primeiro metatarso no hálux valgo moderado e grave, bem como outros parâmetros associados à deformidade.* ***Nível de Evidência IV; Série De Casos.***

Descritores: *Hallux valgus. Procedimentos cirúrgicos minimamente invasivos. Pronação.*

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INTRODUCTION

Hallux valgus is a complex disorder of the foot and can be considered a deformity in three planes: frontal, transverse and sagittal.[1] Coronal deformity, which is characterized by pronation of the first metatarsal, is present in up to 87% of individuals with hallux valgus.[2]

If not corrected in surgical treatment of hallux valgus, pronation of the first metatarsal is associated with an increased chance of

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recurrence.[3] Correction of rotational deformity through the open technique using distal and proximal osteotomies and cuneometatarsal arthrodesis has been described.[4-8]
The percutaneous chevron and Akin (PECA) technique, which was developed by Vernois and Redfern, is among the third generation of percutaneous surgeries for hallux valgus correction and uses stable internal fixation with screws.[9]
Studies comparing PECA with open techniques have consistently demonstrated that the percutaneous technique obtains clinical and radiographic results similar to those of open techniques[10,11] but with reduced scar and pain in the postoperative period.[12-14] However, whether the PECA technique acts in the coronal plane and promotes correction of the pronation of the first metatarsal has not been evaluated.
The objective of this study was to evaluate the correction of hallux valgus associated deformities in both the transverse and coronal planes in a series of patients who underwent hallux valgus correction using the PECA technique.

METHODS

Radiographic analysis was performed of a series of consecutive cases of patients diagnosed with hallux valgus undergoing surgical treatment using the PECA technique between August 2018 and December 2019. The surgeries were performed by the same team, in a single center, supervised by the senior author (MVPF), experienced in minimally invasive surgery. The study was approved by the local ethics committee (Plataforma Brasil Protocol CAAE: 32878720.0.0000.5474) and followed the Declaration of Helsinki and the Guidelines for Good Clinical Practice.
The total number of patients undergoing surgical treatment was 38, of whom 7 were bilateral, totaling 45 feet. The mean age was 65.3 years with a standard deviation of 10.7, and the age range was 36 to 83 years. The left foot was the most operated (53.3%), and most patients were female (90.5%).
The inclusion criteria were as follows: (1) patients with clinical and radiographic diagnosis of moderate and severe hallux valgus[15] (metatarsophalangeal angle greater than 20 degrees and intermetatarsal angle greater than 11 degrees) and (2) symptomatic patients without improvement with at least 6 months of conservative treatment. Patients with sequelae or previous surgeries of the foot and ankle, incomplete data or inadequate radiographic images, Charcot arthropathies, active infection or decompensated diabetes mellitus were excluded from the present study.
The distal metatarsal metaphyseal osteotomy (DMMO) procedure for the percutaneous treatment of metatarsalgia, the method for which has been described in several published studies,[16-20] was performed in combination with hallux valgus correction using the PECA technique in 19 feet (43%).
All patients were operated on by the same team and supervised by a surgeon experienced in minimally invasive foot and ankle procedures.

Surgical technique and postoperative care

The surgical technique used in this study was a modification of the technique originally described by Vernois and Redfern.[9] We did not fix any Akin osteotomy, which was maintained only with bandage.
The patients underwent the procedure in the supine position on the operating table, and no tourniquet was used on the limb. We identified the site for osteotomy according to clinical and fluoroscopic markings.
An approximately three-millimeter incision was made using a specific scalpel blade in the region of the proximal curve of the medial eminence of the first metatarsal. A space was created by placing a periosteal elevator for percutaneous surgery to facilitate the introduction of the burr in the region proximal to the joint capsule. Chevron osteotomy was then performed with a 2 x 20 mm *Shannon*-type burr positioned in the neck of the first metatarsal. The dorsal portion of the osteotomy was straight and perpendicular to the dorsal cortex. The plantar portion was performed at an angle to prevent dorsal displacement of the head.
Next, a periosteal elevator was inserted into the intramedullary canal through the same incision as described by Lai et al.[12] by moving the distal fragment as far as possible to the lateral region. The control of the position of the distal fragment was determined by the image intensifier. At no time was there an attempt to supine the distal fragment; only the distal fragment was transferred, and the alignment was maintained in the sagittal plane. To facilitate displacement, the surgeon pulled and performed slight varization of the hallux.
Next, a 2.0-mm Kirchner wire was used to create the screw path approximately four to 5 centimeters proximal to the first incision, from the base of the first metatarsal to the central region of the head, always passing through the two proximal cortical sites. Then, the wire was percutaneously removed, the guidewire of the screws was inserted, and the osteotomy was fixed with two cannulated screws.
Lateral release of the soft tissues was performed percutaneously and only in cases where the surgeon judged that there was a contracture of the lateral structures perpetuating the valgus deformity. Lateral release was always performed after fixation of the head with a specific scalpel blade lateral to the extensor hallucis longus tendon. After release, in cases where some degree of valgus persisted, Akin osteotomy was performed. The Akin procedure required a new incision, always distal to the chevron osteotomy incision, performed with the same burr and guided by the image intensifier. No osteotomy was fixed.
Finally, the surgical area was cleaned with saline solution, and the incisions were sutured with 4-0 nylon. The postoperative dressing included dry gauze, gauze strips to stabilize and position the toes and finally a crepe and elastic bandage. The patients were encouraged to perform immediate weight bearing using specific sandals with rigid soles. The dressing was changed weekly by the medical team for 3 weeks, and then the patient was instructed to change it at home for up to 4 weeks, depending on other procedures performed in combination with hallux valgus correction.
No antithrombotic drug prophylaxis was prescribed. All patients were discharged on the same day and returned to the outpatient clinic within one week.

Radiographic evaluation

Radiographic images were taken by the same group of technicians with patients standing with full body weight and feet in the plantigrade position. The anteroposterior (AP) view was obtained, and radiographs considered inadequate were excluded from this study.
The angles considered in our evaluation were the metatarsophalangeal angle, better known as the hallux valgus angle (HVA), and the intermetatarsal angle (IMA). These angles were measured in the preoperative radiograph and in the last evaluation performed. We also evaluated the position of the sesamoid as described by Hardy and Clapham[21] on a scale ranging from one to seven. The displacement of the distal fragment after osteotomy was divided into three different groups: less than or equal to 50% displacement (group I), greater than 50% and less than 100% (group II) and greater than or equal to 100% (group III), as shown in the examples in Figure 1. To better determine the degree of displacement, the first radiographic image following the surgical procedure was used to avoid images with calluses that could influence the result.

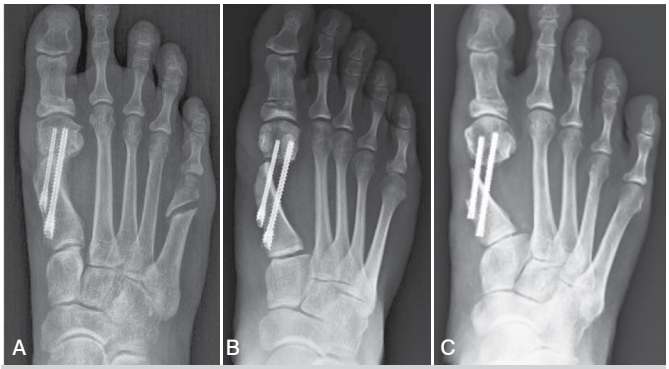

Figure 1. A) Displacement of the distal fragment less than or equal to 50%. B) Displacement of the distal fragment between and 50% and 100%. C) Displacement of the distal fragment greater than or equal to 100%.

The stages of pronation were measured using AP radiographs with weight bearing considering the lateral shape of the first metatarsal head. (Figure 2)

We chose to use the classification of the first metatarsal pronation in the hallux valgus described by Okuda et al.,[3] which was divided into type A (angular), type R (round) and type I (intermediate). As demonstrated by Yamagushi,[22] the presence of a rounded contour in the lateral region of the head of the first metatarsal in the AP view is evidence of pronation because this contour is the silhouette of the lateral condyle.

The greater the pronation is, the more visible the contour of the condyle, resulting in a more rounded appearance of the lateral aspect of the head. Type A corresponds to the absence of pronation or mild pronation up to 20 degrees. Type I corresponds to moderate pronation between 20 and 30 degrees, and type R corresponds to pronation of 30 degrees or more.[23]

Three authors (P.M., T.F.S. and M.C.D.) performed the pre and postoperative classification independently. The result was recorded in a form that only the author (G.F.F.) had access to. In cases where there was no consensus, the senior author (M.V.P.F.) decided the classification.

Image analysis was performed digitally using Centricity® Universal Viewer Zero Footprint software (GE Healthcare, Barrington, IL, USA).

Statistical data analysis

Continuous variables were tested for a normal distribution using the Shapiro-Wilk test.[24] The Wilcoxon signed rank test[25] and paired Student's t test[26] were used for comparisons of nonnormally and normally distributed data, respectively.

Comparisons between unpaired continuous variables were performed using Student's t-test[26] for parametric variables and the Mann-Whitney U test for nonparametric variables.

Categorical variables were measured using their proportion, and the chi-square test was performed.[27] The Pearson correlation test was used to measure the degree of correlation between two numerical and parametric variables.

All statistical evaluations were performed using the software R,[28] specifically using the *Stats* package, both open source. A value of $p \leq .05$ was adopted as the statistical level of evidence.

RESULTS

The mean postoperative follow-up time was 13.1 months with a standard deviation of 4.9 months; the postoperative follow-up time ranged from 6 to 22 months. There was no loss of follow-up of any patient. Most of the deformities were considered moderate and represented 51.1% of the sample; severe cases represented the remainder. Lateral soft tissue release was required in only 33.3% of cases.

Moderate or severe pronation of the first metatarsal was found in the preoperative radiographic images in 32 feet (71.1%), of which 20 were type I and 12 were type R. After the surgical procedure, the pronation was corrected (type A) in 14 feet (43.7%) feet, partially corrected (from type R to type I) in eight feet (25.0%) and unchanged in 10 feet (31.3%). Type A pronation was evidenced in the preoperative radiographs in 13 feet, which represented 28.9% of the total sample. Of these, 11 maintained the same pronation, and two increased the pronation for type I after surgical correction.

The radiographic evaluation showed a statistically significant improvement in HVA ($p < .001$), IMA ($p < .001$) and pronation of the first metatarsal ($p < .05$), as shown in Table 1.

The final pronation of the first metatarsal had a mean HVA of 6.84 degrees in type A and 11.25 degrees in type I, with no significant difference ($p = .057$). Similarly, there was no significant difference in IMA ($p = .89$), with a mean IMA of 5.72 degrees for type A and 5.45 degrees for type I.

The displacement distribution of the distal fragment of the first metatarsal in the osteotomy was 35.5% group I, 37.8% group II and 26.7% group III.

No relationship was found between the postoperative stages of pronation and the displacement groups obtained during the surgical procedure ($p = .34$), and the frequency of each group is shown in Figure 3.

A statistically significant variation in the sesamoid position was observed after surgical correction ($p < .05$). The distribution of classifications between the groups is shown in Table 2.

The correlation between HVA before and after surgery showed a Pearson correlation coefficient of -0.01, without statistical significance ($p = .94$).

Complications

All osteotomies resulted in a bone union. We did not observe any loosening or breakage of the screw. No patient with necrosis of the first metatarsal head was identified. No patient underwent any additional surgical procedure.

Figure 2. A) Preoperative image classified as pronation type R (round). B) Postoperative image classified as pronation type A (angular).

Table 1. Pre and postoperative radiographic results of hallux valgus measurements.

Outcome	Preoperative	Postoperative	Statistical analysis
HVA, mean and SD	40.1 ± 6.5	8.8 ± 7.6	p < .001
IMA, mean and SD	16.1 ± 3.2	5.6 ± 4.0	p < .001
Pronation of the first metatarsal	Type A = 13 (28.9%)	Type A = 25 (55.6%)	p < .05
	Type I = 20 (44.4%)	Type I = 20 (44.4%)	
	Type R = 12 (26.7%)	Type R = 0 (0%)	

Abbreviations: HVA: hallux valgus angle; IMA: intermetatarsal angle; SD: standard deviation;

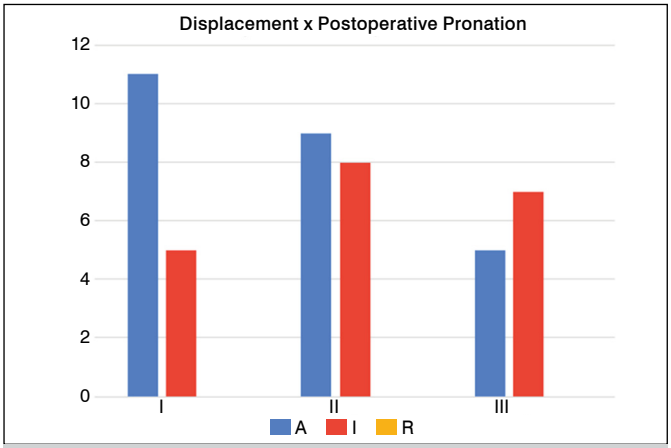

Figure 3. Relationship between displacement and postoperative pronation of the first metatarsal.

Table 2. Position of the sesamoid on AP radiography before and after surgery.

Grade	Preoperative	Postoperative
I	0	4 (8.9%)
II	0	12 (26.7%)
III	0	15 (33.4%)
IV	0	7 (15.5%)
V	3 (6.7%)	6 (13.3%)
VI	14 (31.1%)	1 (2.2%)
VII	28 (62.2%)	0
Normal position (Grade I to IV)	0	38 (84.4%)
Incongruent Position (Grade V to VII)	45 (100%)	7 (15.6%)

Statistical analysis with the chi-square test ($p < .05$)

DISCUSSION

The patients included in this study had mean preoperative HVA and IMA of 40.1 and 16.1 degrees, respectively. Thus, the cases in this series are, on average, more severe cases than those previously described in reports using the same technique. In the other series in which the PECA technique was used, the preoperative HVA ranged between 25 and 31.4 degrees, and the IMA ranged between 11.7 and 15.6 degrees.[10-14,29]

Despite having patients with more pronounced deformities, the radiographic results at the end of the follow-up were similar to those of the other series. Our patients had mean final HVA and IMA of 8.8 degrees and 5.6 degrees, respectively, while in previous studies, mean final HVA and IMA varied between 8.5 and 10.9 degrees and between 5 and 10.2 degrees, respectively.

In our series, 24 feet had preoperative HVA between 40 and 50 degrees, and three feet had HVA above 50 degrees. There was no correlation between the preoperative HVA values and the values achieved after the surgical procedure, which indicates that the PECA technique can potentially be used in both severe and moderate cases.

Okuda et al.[3] demonstrated that the presence of pronation of the first ray and incomplete reduction of the sesamoid in the postoperative period are risk factors for hallux valgus recurrence. Pronation is characterized by a positive round sign, where the lateral cortical of the first metatarsal head has a rounded shape and causes dorsolateral deviation of the sesamoid. In the PECA technique, osteotomy is performed on the metatarsal neck, and the head is pushed to the side, while the hallux is pulled and subjected to slight varization.

We believe that this maneuver naturally corrects the pronation of the toe and by ligamentotaxis corrects the position of the head. All patients who had a round sign in the preoperative period did not present this sign in the postoperative period. In addition, the percentage of patients who were classified as type A in the preoperative period, indicating mild or absent pronation, increased from 29 to 55% after surgery ($p < .05$).

We did not identify any other study in which the PECA technique was used and which postoperative rotation was evaluated. There are few described techniques that can correct pronation of the first metatarsal. Most procedures were developed for lateral displacement and varus correction, such as the open chevron and Scarf procedures, and are unable to perform rotation correction.[23]

Procedures that allow correction of head rotation include rotational biplanar chevron osteotomy,[4] proximal oblique sliding closing wedge osteotomy,[6] proximal supination osteotomy,[7] proximal rotational metatarsal osteotomy[8] and arthrodeses, such as the Lapidus procedure[30] and metatarsophalangeal arthrodesis.

Yasuda and colleagues obtained a significant decrease in pronation by using a crescentic osteotomy at the base of the first metatarsal.[7] In the preoperative period, 83% of patients had a positive round sign, compared to 20% in the postoperative period.

There was no difference between the correction of pronation and the degree of displacement of the head, which indicates that in this sample, it was not necessary to translate more than 100% of the head in relation to the metatarsal for the correction of rotation. The burr, with a thickness of 2 mm, makes a cut that allows some degree of rotation, even when there is contact between the head and the diaphysis.

In addition, we performed an oblique plantar portion of the osteotomy to avoid dorsal displacement of the distal fragment. However, this type of osteotomy could limit the rotation of the head to some degree in cases where the displacement is less than 100%. In theory, straight osteotomies would facilitate rotation.

Shibuya et al. conducted a retrospective cohort study to identify the predictive factors of hallux valgus recurrence.[31] The only associated factor was the position of the medial sesamoid in the postoperative period, with rates of 50 and 60% relapse when the position was greater than four or five, respectively.

The evaluation of the sesamoid position in our series showed that there was a significant correction. The percentage of feet with the sesamoid in the normal position (less than or equal to four) ranged from 0 in the preoperative period to 84% in the postoperative period ($p < .05$). As there is a relationship between pronation and sesamoid position,[32] these numbers reinforce the hypothesis that there was indeed pronation correction in most patients.

As we only analyzed radiographic results, the evaluation of complications was limited. In 26% of patients, head displacement was performed above 100% of the diaphysis width, resulting in absence or minimal contact between the fragments and raising concerns about non union. However, union occurred in all patients. The fact that the osteotomy was percutaneous, with minimal aggression to the soft tissue envelope, most likely contributed to these results.

The study has some limitations. The first is the evaluation of rotation by means of AP radiography of the foot. Studies are still needed to demonstrate whether this method has intra and interobserver reliability and is comparable to computed tomography, which probably the most accurate method for performing this evaluation. Another important limitation is the relatively short follow-up, which was as little as 6 months in some cases and may have overestimated the potential for correction using this technique if there is recurrence of rotation over time. Finally, the mean age of the sample was above that of the general population, which limits the analysis for other age groups.

CONCLUSION

The percutaneous chevron and Akin technique can correct pronation of the first metatarsal in moderate and severe hallux valgus, as well as other parameters associated with this deformity.

<< SUMÁRIO

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. GFF, MCMD, and MVPF: writing the manuscript. MVPF, GFF, PM, TFS, and MCMD: surgery, patient follow-up, and clinical data compilation. GFF and MVPF data evaluation of the statistical analysis. All authors performed the literature search and manuscript review and contributed to the intellectual concept of the study.

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FOOT AND ANKLE

EXERCISES AND NEUROMUSCULAR ELECTRIC STIMULATION FOR MEDIAL LONGITUDINAL ARCH: CLINICAL TRIAL

EXERCÍCIOS E ESTIMULAÇÃO ELÉTRICA NEUROMUSCULAR PARA ARCO LONGITUDINAL MEDIAL: ENSAIO CLÍNICO

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ABSTRACT

Objective: The extrinsic muscles, such as the posterior tibialis and long flexor of the hallux and the intrinsic of the foot, are part of the active subsystem of the central system of the foot and play an essential role in the control of the medial longitudinal arch resulting from difficulty in contracting the muscle, neuromuscular electrostimulation (NMES) becomes a resource combined with strengthening and recommended for rehabilitation. T this work aims to evaluate the effectiveness of NMES associated with exercise in deforming the medial longitudinal arch. Methods: This is a randomized blind clinical trial. 60 asymptomatic participants were divided into three groups: NMES, exercise and control. The NMES and exercise group performed seven exercises for the intrinsic and extrinsic muscles twice a week for 6 weeks, and the NMES group used an NMES associated with five exercises. Navicular height and medial longitudinal arch angle were taken before and after the intervention period. Results: No statistically significant differences existed between groups for navicular height and medial longitudinal arch angle. Conclusion: NMES associated with exercise does not change the characteristics of the medial longitudinal arch in association with asymptomatic. ***Level of Evidence I; Randomized clinical trial.***

Keywords: Electrical stimulation therapy. Foot. Foot deformities. Talipes Valgus. Talipes Cavus.

RESUMO

Objetivo: Os músculos extrínsecos, como o tibial posterior e flexor longo do hálux e os intrínsecos do pé fazem parte do subsistema ativo do foot core system e exercem papel essencial no controle do arco longitudinal medial. Devido à dificuldade na contração desses músculos, a eletroestimulação neuromuscular (EENM) torna-se um recurso aliado ao fortalecimento e é recomendada para reabilitação. O objetivo desse trabalho é avaliar a eficácia da EENM associada ao exercício na deformação do arco longitudinal medial. Métodos: Este é um ensaio clínico randomizado cego. 60 participantes assintomáticos foram divididos em três grupos: EENM, exercício e controle. O grupo EENM e exercício realizaram sete exercícios para os músculos intrínsecos e extrínsecos duas vezes por semana por seis semanas, sendo o grupo EENM utilizou a EENM associada a cinco exercícios. A altura do navicular e o ângulo do arco longitudinal medial foram medidos antes e após o período de intervenção. Resultados: Não houve diferenças estatisticamente significativas entre os grupos para a altura do navicular e ângulo do arco longitudinal medial. Conclusão: A EENM associada ao exercício não altera as características do arco longitudinal medial em indivíduos assintomáticos. ***Nível de Evidência I; Estudo Clínico Randomizado.***

Descritores: *Terapia por Estimulação Elétrica. Pé. Deformidades do Pé. Pé Chato. Pé Cavo.*

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INTRODUCTION

The main structure of load bearing and shock absorption of the foot is the medial longitudinal arch. Changes in medial longitudinal arch can affect the foot biomechanics, change the distribution of plantar loads in individuals with injuries in their feet or in any other joints, and cause pain.[1-3]

The foot core system is a paradigm for understanding the medial longitudinal arch functionality that compares it to the spine stability. There are three subsystems in this theory: the passive, including the foot bones, plantar fascia and ligaments; the neural, with muscle and tendinous receptors, local and global, in ligaments and on the plantar skin; and the active, with intrinsic

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The study was conducted at the Irmandade da Santa Casa de Misericórdia de São Paulo.
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muscles, local and extrinsic stabilizers, that are essential for the foot global movements.[4]
Several types of exercise have been proposed to increase the muscle activation with a focus on the active contribution of medial longitudinal arch. However, these are muscles difficult to feel and contract.[5,6] If muscles regulate the deformity and stiffness of the medial longitudinal arch, there would be a possibility that the electric stimulation applied to intrinsic muscles could affect the natural contraction ability, resulting in increasing of the height and decreasing of the medial longitudinal arch length.[7]
The idea of stimulating the medial longitudinal arch with neuromuscular electric stimulation (NMES) as a way to activate these muscles seems reasonable and logical. Our objective was thus to evaluate the effect of NMES and of NMES plus exercising on anatomical changes of the medial longitudinal arch.

METHODS

Trial design

This parallel randomized controlled trial involved sedentary adults (not practicing any physical activity) without foot pain who were evaluated in a physiotherapy service of a university hospital between January 2017 and March 2018. The protocol was approved by the institutional review board (62766716.4.0000.5479) and registered at clinicaltrials.gov (NCT03117244). All participants signed informed consent forms. We report this trial according to the CONSORT Statement of Randomized Trials, especially the extension for Non-pharmacologic treatments[8] and TIDieR reporting guideline.[9]

Participants

We recruited participants for this trial through the institutional and the researchers' personal social medial channels. We invited them to come to our physiotherapy clinic for the initial screening, which included personal health history and demographics and basic anthropometry and physical examination, as well as exercising habits. We excluded individuals reporting neurological diseases, and any foot or leg fracture, muscular or joint injury or surgery in the previous 12 months. We also excluded participants with previous or current rigid flat foot or valgus calcaneus higher than 10 degrees.
Interventions and groups
We allocated participants into three comparison groups: the Exercise, the NMES and the Control groups. In the Exercise group, participants received individual training twice a week for six weeks, at each participant's most convenient time (morning or afternoon). In the NMES, they received the same exercises plus electric stimulation as described below, twice a week for six weeks, also at the most convenient time for the individual. Participants randomized to the control group were examined and then told to keep their routines and activities of daily life. We just asked them to come back to the service in six weeks for a new evaluation.
The participants in the Exercise group performed a total of seven movements as described in Figure 1 and Table 1.
Figure 1 shows the stance for each exercise and the muscles activated in the movements. The same exercises (intensity and duration) were proposed for all participants in this group, with no modifications according to anthropometry.
In the NMES group, during the exercises numbered 1 to 5 (as shown in Figure 1), participants also received electrical stimulation to the foot. We applied the depolarized, biphasic, symmetrical current with rectangular pulses of medium frequency modulated in low using a pulse generator (Sonophasys, EUS.0503, KLD Biosistemas, São Paulo, Brasil), and two self-adhesive silicone electrodes (Self-Adhesive Electrode Valutrode 5x5cm, Arktus, Santa Tereza do Oeste, Paraná, Brazil) placed in the region of the muscular belly of the flexor halluci, posterior tibialis and muscles intrinsic of the foot. The carrier frequency was 2500Hz, the modulation frequency was 50Hz, with an output duty cycle of 20%, one second up and down ramp and an on-and-off time with a 1:1 ratio, with the on proportional to the expenditure to perform the series of exercises. The same physiotherapist administered the interventions (the exercises and neuromuscular electric stimulation) for all participants in both groups.

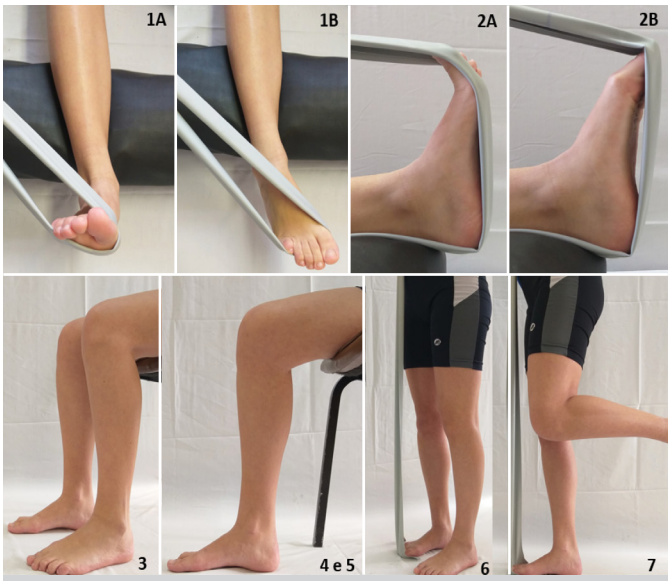

Figure 1. Stances for the proposed exercises for intrinsic and extrinsic muscles of the foot. 1: initial (A) and final (B) stances for posterior tibialis muscle exercise; 2: initial (A) and final (B) stances for the long flexor of the hallux exercise; 3: stance for the short-foot exercise with bipedal support while sitting; 4 and 5: stance for the short-foot exercise with unipedal support while sitting (picture showing the support on the right foot); 6: stance for exercise for intrinsic and extrinsic muscle while standing and using a rubber band; 7: stance for the single-leg exercise for intrinsic and extrinsic muscle with unipedal support.

Table 1. Intrinsic and extrinsic foot muscles exercise protocol for the intervention groups.

Muscle	Position	Frequency per week					
		1st	2nd	3rd	4th	5th	6th
Tibial posterior	Lying	3x15 r	3x15 r	3x15 r	3x15 r	3x30 r	3x30 r
Long flexor of the hallux	Lying	3x15 r	3x15 r	3x15 r	3x15 r	3x30 r	3x30 r
Intrinsic	Sitting-bipedal	3x15 r	3x15 r	3x15 r	3x15 r	3x30 r	3x30 r
Intrinsic	Sitting-unipedal	3x15 r	3x15 r	3x15 r	3x15 r	3x30 r	3x30 r
Intrinsic	Sitting-unipedal	3x30 s	3x30 s	3x30 s	3x30 s	3x60 s	3x60 s
Intrinsic and extrinsic	Standing-bipedal	3x30 s	3x30 s	3x30 s	3x30 s	3x60 s	3x60 s
Intrinsic and extrinsic	Standing-unipedal	3x30 s	3x30 s	3x30 s	3x30 s	3x60 s	3x60 s

r=repetitions; s=seconds; #=Stance shown in the Figure 1 panel.

Evaluations and outcomes

For two weeks, we trained an independent physical therapist (author RDPA), with five years of experience, to perform the evaluations for this study. In the training we focused on anatomical structures palpation, identification of reference points and the measurements to be taken.
After training, the physical therapist evaluated 10 healthy volunteers as a pilot study, in two occasions with a one-week interval, and we registered these measurements. We calculated the intraclass

correlation coefficient between the two measurements of the same individual, presetting the rule that a coefficient lower than 0.4 would not be acceptable.[10]

The evaluator took the basic demographic and clinical history of the included participants. Then, he measured the angle of the calcaneus, with the patient lying in prone position, with feet off the gurney. He palpated the calcaneus medially and laterally and bisected it, marking its lower and middle points, to form a line between the points. This way, he identified the subtalar neutral. With palpation of the talus, he measured the varus or valgus of the calcaneus using a plastic goniometer with protractor and two 20cm rulers (SH5205, Carci, São Paulo, Brasil).[11]

The therapist then asked the participant to sit, with hips, knees and ankles flexed at 90 degrees, and identified other anatomical points with a marker: the center of the medial malleolus, the tuberosity of the navicular and the head of the first metatarsus. Next, he palpated the lateral and medial aspects of the talus, with the subtalar joint in neutral position and measured the medial longitudinal arch angle and the navicular height. The therapist repeated these measurements with the participant standing with bipedal support, with the subtalar in a relaxed position.[11]

To measure the medial longitudinal arch angle, the evaluator placed the center of the goniometer in the tuberosity of the navicular, with its ends facing the center of the medial malleolus and the head of the first metatarsus.[12] For the navicular height, he measured the distance (in centimeters) between the ground and the tuberosity of the navicular.[12] All measurements were made in both feet of each participant by same evaluator.

Randomization and blinding

The author DMGN performed the randomization for this study using a list from the randomization.com (website). We generated a randomization sequence for 60 participants initially using the first and original generator that uses the method of randomly permuted blocks. When the participant arrived for the preliminary evaluation for inclusion, if the individual was considered eligible and consented to participate, DMGN consulted the list and warned the physiotherapist about the allocation.

In this trial, due to the nature of the interventions used, it was not possible to blind participants: they all knew what intervention they were receiving or not. The physical therapist who administered the interventions, guiding the exercises and applying the electric stimulation. We asked participants to hide the allocation from this evaluator (i.e., not telling him if they performed exercises or not, for example).

Sample size and statistical analysis

We calculated sample size (ANOVA) and data from the pilot study (during the evaluator training). We adopted a significance level of 5%, power of 80% and the navicular height as the primary outcome, considering as significant a minimum of 20% of difference between means, with a standard deviation of 0.75. According to these assumptions, the sample size should be of 16 participants per group. Assuming some loss, we worked with a sample size of 20 participants per group.

For the intraclass correlation coefficient (ICC) calculation, for the pilot study, we determined the standard error measurement with standard deviation between the first and the second measurements, with the standard deviation multiplied by the square root (1 – ICC).[13]

We compared the study evaluations between groups and between moments (before and after the intervention). For this, we used the Shapiro-Wilk normality test to verify distribution. We described the measurements using medians, minimum and maximum values and used the Kruskal Wallis test for the non-parametric observations.

For the parametric observations, we used means, standard deviations and the ANOVA test. The level of significance adopted for all tests in this study was 5% and the software was SPSS version 13.1.

RESULTS

In the study period, we recruited 60 participants, and 50 of these completed the follow-up, as shown in Figure 2. The reason for dropouts in the intervention groups was schedule conflicts with work or personal appointments.

Table 2 shows anthropometric evaluations and the similarity between groups at baseline.

For the pilot evaluation, the ICC and the SEM between measurements were 0.98 cm and 0.15 degrees for navicular height and medial longitudinal arch angle respectively in the neutral position of the subtalar, and 0.98 cm and 0.11 degrees for the relaxed position, as well as 0.97 and 0.02 cm for neutral position of the navicular height, 0.92 and 0.06 cm for the navicular height for the relaxed position. This means the variation was acceptable.

The medial longitudinal arch angle and navicular height measurements (respectively on Tables 3 and 4) show that neither exercise nor electric stimulation resulted in significant outcome changes.

DISCUSSION

In this randomized controlled trial, exercising only or with electric stimulation did not result in any difference in the medial longitudinal arch measurements. To our knowledge, this is the first randomized trial using NMES and exercises assessing the changes in the medial longitudinal arch.

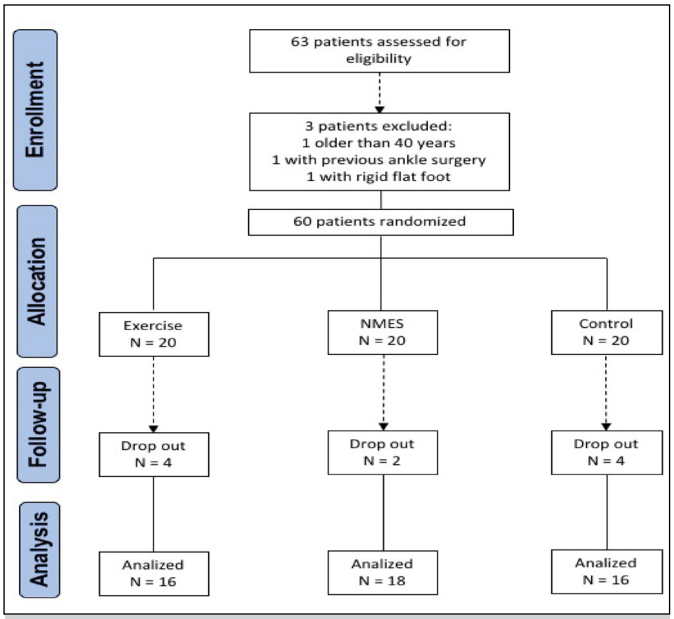

Figure 2. Flowchart of patients' inclusion and exclusion in the study.

Table 2. Baseline demographic and anthropometric data per group (n=48).

Variable	Groups			p
	Exercise(n=16) Mean(SD)	NMES(n=18) Mean(SD)	Control(n=16) Mean(SD)	
Age (years)	26(5)	27(5)	26(5)	0.519
Sex (Female/Male)	11/5	14/4	12/4	-----
Height (m)	1.65(0.1)	1.65(0.1)	1.65(0.1)	0.930
Weight (kg)	60.8(9.9)	69.3(18.8)	65.2(13.4)	0.367
BMI (kg/m)	22.1(2.2)	25.1(5.2)	23.7(3.7)	0.171

NMES=neuromuscular electric stimulation; SD=standard deviation; BMI=body mass index.

Table 3. Mean, minimum and maximum medial longitudinal arch angle measurements per groups.

Variable	Exercise(n=16)	NMES(n=18)	Control(n=16)	p
SIT pre right	150 (144-155)	146 (142-150)	146 (140-151)	0.439
BIP pre right	149 (144-153)	144 (140-148)	146 (141-150)	0.318
SIT pos right	151 (147-155)	148 (146-151)	149 (146-153)	0.555
BIP pos right*	148 (138-159)	146 (138-158)	150 (136-155)	0.344
SIT pre left	151 (143-158)	148 (145-151)	150 (145-155)	0.730
BIP pre left	149 (142-155)	144 (141-147)	147 (142-152)	0.336
SIT pos left	150 (146-154)	148 (147-150)	151 (145-156)	0.626
BIP pos left	149 (145-153)	144 (141-147)	147 (143-151)	0.186

*Median value. NMES=neuromuscular electric stimulation; SIT=sitting stance; BIP=bipedal support.

Table 4. Mean and minimum and maximum navicular height measurements per group (cm).

Variable	Exercise(n=16)	NMES(n=18)	Control(n=16)	p
SIT pre right	5.0 (4.6-5.3)	5.0 (4.7-5.3)	5.2 (4.8-5.6)	0.520
BIP pre right	4.3 (4.0-4.7)	4.1 (3.8-4.4)	4.5 (4.0-5.0)	0.295
SIT pos right	5.3 (3.8-6.0)	5.0 (4.3-6.2)	5.5 (4.3-6.4)	0.595
BIP pos right*	4.4 (4.1-4.8)	4.3 (4.0-4.6)	4.7 (4.3-5.1)	0.236
SIT pre left	5.0 (4.6-5.5)	4.8 (4.5-5.1)	5.2 (4.8-5.6)	0.285
BIP pre left	4.3 (4.1-4.7)	4.0 (3.8-4.3)	4.5 (4.0-5.1)	0.146
SIT pos left	5.1 (4.8-5.5)	4.9 (4.6-5.3)	5.3 (4.8-5.7)	0.408
BIP pos left	4.5 (4.2-4.8)	4.3 (3.9-4.6)	4.7 (4.2-5.1)	0.260

*Median value. NMES=neuromuscular electric stimulation; SIT=sitting stance; BIP=bipedal support.

Typical values for navicular height were between 3.6 and 5.5 cm and 130 and 152 degrees for medial longitudinal arch angle in a study in Denmark.[12] Our participants had values within these ranges both before and after exercising and electric stimulation, indicating that, if any, the effects of the intervention were not evidenced by anatomical changes.

Short-foot exercises can reactivate muscular components of the core system that may be inactive, allowing these muscles to contribute to the absorption and propulsion during activities involving the foot,[6] such as walking and standing. Mulligan et al observed improvements of the medial longitudinal arch and the dynamic balance of the foot after four weeks of intrinsic muscle at-home training.[14] Hashimoto et al also evaluated the effects of strength training for the intrinsic flexor muscles. The authors measured the medial longitudinal arch length and transverse arch of the foot, after an eight-week program with 200 repetitions a day, three times a week, with a load of three kilos. They observed increased strength and decreased length of the arches.[15] However, both were before-and-after studies, with no control group.[14,15]

The motivation for this study was the lack of properly conducted randomized clinical trials evaluating the value of adding electrical stimulation to exercise in the rehabilitation or freeing of the core foot.[4,6] Kelly et al thought about the possibility of using a direct current to stimulate the hallux abductor, short finger flexor and plantar square. The authors observed transient changes in navicular height and medial longitudinal arch angle through 3D kinematics, which probably fired the intrinsic muscles to control stiffness and deformation of the medial longitudinal arch. The experiment, however, was small, with nine healthy males, and with no control group.[7]

Recently, Ebrecht et al[16] conducted a randomized trial on the effect of an NMES intervention on intrinsic foot muscles cross-sectional area as a proxy for muscle strength. The authors aimed to verify if NMES would change the cross-sectional area as measured by ultrasound, improve arch stability and reduce muscle fatigue. The measurements were made after 20 minutes of running in a treadmill, barefoot, for all participants (except the passive control group), with subgroup analysis for experienced or beginner runners. Arch stability and fatigue were evaluated through the static navicular drop. No strengthening effect was verified of the intrinsic foot muscles using NMES. However, there was little information on the NMES parameters of application and the authors themselves questioned if the intervention had been too short or the cross-sectional area and the navicular drop would be suitable to display muscle strength. The small sample size, especially for subgroup analyses, is a concern too. The authors suggested that a study with people who do not exercise was needed.

Using NMES in healthy muscles is a controversial issue in the literature, but studies have investigated adding NMES with exercise for muscles of the leg, some with positive results,[17] others without.[18] One explanation for the failure of NMES in these studies would be that in general they used participants with no neural or mechanical impairments whereas in a physical rehabilitation context of injured muscles or wasting or denervation following periods or immobilization maybe it could have detectable effects.[19] We opted, thus, to choose a simple and basic measurement, possible to be performed without special equipment, and an area of the body not explored by well-conducted and reported RCTs, the medial longitudinal arch of the foot.

A limitation of our study would be that we did not classify the different types of feet (normal, pronated and supine) at baseline. However, we do not have data on the prevalence of foot pronation in our population, and the only reference data for "normality" available are based on populations that differ substantially in ethnicity and anthropometry[12] from ours.

The participants in our study intervention groups trained twice a week, but the literature is controversial as to the ideal frequency of exercises to gain muscle strength. A recent systematic review with meta-analysis with subgroup analysis found that the training frequency produced better results for multiarticular exercises, training of upper limbs, for young adults and for the female sex. No significant association was found between the frequency and the strength gain for uniarticular exercises and training of the lower limbs for a male, middle-aged and elderly population.[20] Again, this shows that the disparity of training protocols, and not the NMES per se, could be responsible for the lack of effects we found. We studied young adults, with 74% of females, twice a week, but there is no evidence that an increase in exercise frequency would help.

Future studies should focus on the motor control of the muscles involved, that is, they must be active at the moment of the support and impulse phase of walking and running and interventions must be focused on this. The medial longitudinal arch should be the focus of investigations, including static and dynamic deformation. The strengthening of medial longitudinal arch muscles should be studied in symptomatic patients for foot and ankle disorders. However, the outcomes of the work must be better designed, analyzed and reported by researchers, allowing the comparison between protocols.

CONCLUSION

NMES associated with exercise does not change the characteristics of the medial longitudinal arch in association with asymptomatic.

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AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. PAS: Study design, experimental study planning, data analysis and interpretation, manuscript writing and final reviewing; NDMG: randomization, interpreted data and final reviewing; ARDP: evaluations, collected data and final reviewing; JCC: Study design and reviewed the manuscript critically; designed the study interpreted; DFDG: Study design and reviewed the manuscript critically; designed the study interpreted, data and wrote the manuscript; AVLS: Study design, experimental study planning and reviewed the manuscript critically.

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METAL ION RELEASE ACCORDING TO LEG LENGTH DISCREPANCY IN CERAMIC-ON-METAL HIP ARTHROPLASTY

LIBERAÇÃO DE ÍONS METÁLICOS SEGUNDO DISCREPÂNCIA NO COMPRIMENTO DA PERNA APÓS ARTROPLASTIA METAL-CERÂMICA TOTAL DE QUADRIL

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ABSTRACT

Objective: The ceramic-on-metal (CoM) bearing has the theoretical advantages over ceramic-on-ceramic (CoC) and metal-on-metal bearings. This study aimed to analyze factors affecting the metal ion release of CoM bearings and compare clinical performance with CoC bearings. Methods: The 147 patients were divided into 96 patients in group 1 (CoM group) and 51 patients in group 2 (CoC group). Additionally, within group1, 48 patients and 30 patients were sub-categorized into group 1-A with leg length discrepancy (LLD) less than 1cm and group 1-B greater than 1 cm. The level of serum metal ions, functional scores and plain radiographs were obtained for the analysis. Results: The level of cobalt (Co) 2-years after surgery and chromium (Cr) 1-year after surgery showed significantly higher in the group1 than the group2. LLD indicated statistically significant positive correlation between serum metal ion levels among CoM bearing THAs. In comparison of the average metal ions level changes, group 1-B showed higher level of metal ion than group 1-A.Conclusion: In patients underwent THA with CoM bearings, large LLD have a higher risk of complications associated to metal ions. Therefore, it is critical to reduce the LLD to 1 cm or less in using CoM bearing. ***Level of Evidence III; Case Control Study.***

Keywords: Leg length inequality. Ions. Surgical procedures, operative. Follow-Up Studies. Arthroplasty, replacement, hip.

RESUMO

Objetivo: Uma superfície metalocerâmica (CoM) apresenta vantagens teóricas sobre as superfícies cerâmica-cerâmica (CoC) e metal-metal. Este estudo teve como objetivo analisar os fatores que afetam a liberação de íons metálicos das superfícies CoM e comparar o desempenho clínico com as superfícies CoC. Métodos: Os 147 pacientes foram divididos em 96 pacientes no grupo 1 (grupo CoM) e 51 pacientes no grupo 2 (grupo CoC). No grupo 1, 48 pacientes foram subcategorizados em grupo 1-A, com discrepância de comprimento das pernas (LLD) menor que 1 cm; e 30 pacientes no grupo1-B maior que 1 cm. O nível de íons metálicos séricos, escores funcionais e radiografias foram obtidas para a análise. Resultados: Os níveis de cobalto (Co) 2 anos após a cirurgia e de cromo (Cr), após o primeiro ano da cirurgia mostraram-se significativamente mais altos no grupo 1 do que no grupo 2. A LLD indicou correlação positiva estatisticamente significativa entre os níveis de íons do soro metálico entre os portadores de THA de CoM. Em comparação com as alterações médias dos níveis de íons metálicos, o grupo 1-B revelou um nível de íons metálicos mais alto do que o grupo 1-A. Conclusão: Em pacientes submetidos a THA com superfícies CoM e elevada LLD têm um maior risco de complicações associadas a íons metálicos. Sendo fundamental reduzir LLD para 1 cm ou menos no uso de superfícies CoM. ***Nível de Evidência III; Estudo de Controle de Caso.***

Descritores: *Desigualdade de membros inferiores. Íons. Procedimentos cirúrgicos operatórios. Seguimentos. Artroplastia de quadril.*

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INTRODUCTION

Over the last decade, the increasing demand for total hip arthroplasty (THA) in younger, healthier, and high activity patients has led to the use of hard-on-hard bearing surface. In order to improve a long-term survival of THA, hard-on-hard bearings, such as ceramic-on-ceramic (CoC) and metal-on-metal (MoM), are often used. Despite its lower rate of wear and osteolysis, ceramic breakage due to brittleness of CoC bearing has been often reported.[1] Several studies have reported that CoC bearing produce 0.004% head fracture and 0.22% liner fracture.[2] On the other hand, main concerns for MoM bearings are metal ion release such, as cobalt (Co) and chromium (Cr), and their potential interactions with immune system leading to local reactions, such as pseudotumor and aseptic lymphocyte dominated vasculitis

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

The study was conducted at the Jeju National University Hospital in Jeju-do, South Korea.
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as well as systemic adverse effects on cardiovascular, nervous, and endocrine systems due to massive wear.[3]

To minimize complications associated with CoC and MoM bearings, a mixture of different hard bearing surfaces has created a novel option, such as the ceramic-on-metal (CoM) bearing, where a ceramic femoral head articulates with a metal alloy liner. The theoretical advantage of such combination is that it can be considered in patients with high physical activity needs due to a lower risk of component breakage compared to CoC bearings and reduced acetabular wear and metal debris production compared with MoM bearings.

Several in vitro hip simulator analyses have been conducted to investigate the wear rate of CoM bearings. Affatato et al.[4] and Reinders et al.[5] reported significantly greater wear in CoM bearings compared with CoC bearings. Despite benefits of in vitro study in understanding wear behaviors of each THA design, only few studies investigated the in vivo performance of CoM bearings by comparing serum metal ion levels and quantitative clinical scores between CoM and MoM bearings.

Hence, the objective of this study was to analyze factors that affect the metal ion release of the CoM bearing and to compare clinical performance with CoC bearings using validated functional outcome scores and complications.

MATERIALS AND METHODS

Patients

This study was a retrospective, case-control study, in which a total of 173 primary THAs and 147 patients were enrolled into the study. THA was performed using 114 CoM bearings in 96 patients and 59 CoC bearings in 51 patients. All these surgeries were performed by 1 skilled orthopedic surgeon in a single institution in the same manner. In the group 1 (CoM group), 18 patients underwent bilateral THAs, while the remaining 78 patients underwent unilateral THAs. In the group 2 (CoC group), 8 patients and 43 patients underwent bilateral and unilateral THAs, respectively. Vincent et al.[6] reported that less than 1cm of postoperative leg length discrepancy is acceptable in THA. Among the unilateral CoM THA group, the 2 groups were divided based on leg length discrepancy (LLD) before and after surgery. 48 patients with LLD increased by less than 1cm were classified into group 1-A, and 30 patients with LLD increased by more than 1cm were classified into group 1-B. All patients undergoing THA between March 2010 and December 2015.

The inclusion criteria were as follows: (1) patients aged over 20 years; (2) patients with primary and secondary osteoarthritis, hip degeneration after previous septic arthritis, femoral neck fracture and osteonecrosis of femoral head; (3) Follow-up for at least 3 years after surgery.

The exclusion criteria were as follows: (1) women of child bearing chance; (2) history of prior THA or hip fusion (3) inflammatory joint disease; (4) renal function impairment (glomerular filtration rate <30 ml/min); (5) metabolic bone diseases except osteoporosis; (6) patients with an incomplete past medical history and physical examinations. Serum metal ion levels, clinical functional outcomes, and surgical parameters were evaluated in all patients. The patient sex, age, body mass index (BMI), follow-up periods and preoperative diagnoses were investigated as demographic factors. A flow diagram for excluded cases is shown in Figure 1.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Jeju National University Hospital (IRB No. 2015-06-010 and date of approval Aug 03, 2015).

Informed Consent Statement: Patient consent was waived because this was a retrospective and observational study with routine treatment.

Surgical Technique and implant

All patients received identical devices in each group except only for acetabular liner (metal or ceramic). Pinnacle acetabular shell consist of Titanium-6Aluminium-4Vanadium alloy (Pinnacle; DePuy®, Warsaw, IN, USA), Biolox delta femoral head consist of Zirconia toughened Alumina composite and cementless collarless femoral stem consist of Titanium-6Aluminium-4Vanadium alloy (Summit; DePuy®, Warsaw, IN, USA) were used in all of the patients. The

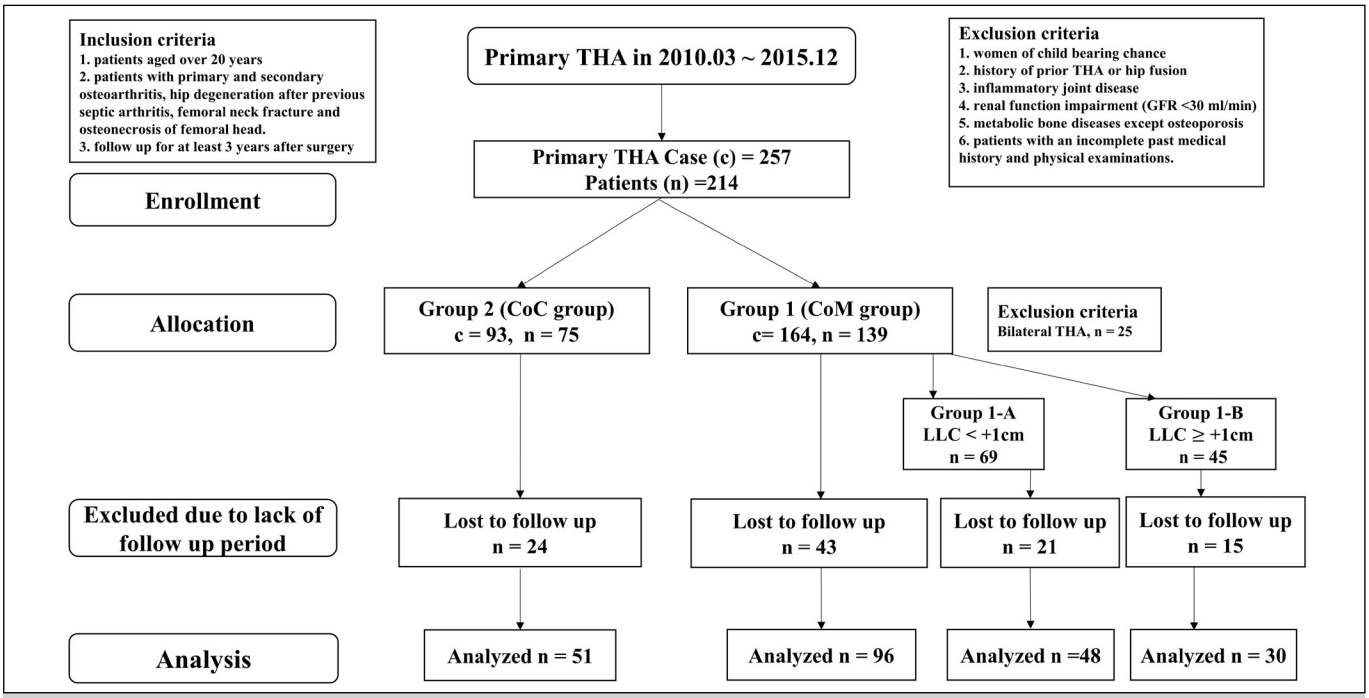

Figure 1. Patient enrollment flow diagram. This study involved 147 THA patients.

<< SUMÁRIO

group 1 used the Cobalt-Chromium-Molybdenum alloy (Ultamet; DePuy®, Warsaw, IN, USA) as the acetabular metal liner and group 2 used Biolox delta liners consisting of Zirconia-Alumina as a ceramic liner.

All operations were carried out by a single orthopedic surgeon (NGW), and the surgical techniques used for the procedure were identical for all patients via posterior approach. Standard postoperative care and rehabilitation was carried out for all THA patients in the same manner. The patients were followed up in outpatient clinics at 1 month, 3 months, 6 months, 1 year and annually after the operation.

Metal ion level measurements

Blood sampling for the metal ion analysis was obtained from all patients at 3 months, 6 months, 1 year and annually after the operation. The sample was obtained using a stainless-steel hypodermic needle attached to a plastic collecting tube, needles and collecting tubes were from the same batches. The serum Co and Cr levels were measured using a plasma mass absorption spectrometry (Spectr AA-800H, Varian Inc., Palo Alto, California, USA). The limits of detection Co and Cr were 0.05μg/L and 0.1μg/L, respectively. The toxic cut-off levels for Co and Cr were 7.00 μg/L and 7.00 μg/L or above, respectively.[7] In CoC bearings, Co and Cr ion measurement was measured for a quality control. The Co and Cr change (ΔCo and ΔCr) was the calculation of the difference between levels of serum Co and Cr just before and 3 years after surgery. Any changes in serum ion levels were marked + for an increase and – for a decrease. All laboratory analyses were performed by personnel who were blinded to the protocol.

Clinical outcome measurements

All patients were evaluated for clinical outcomes using the Harris Hip Score (HHS)[8] and Western Ontario McMaster Universities Osteoarthritis Index (WOMAC)[9] preoperatively and at 3 months, 6 months, 1 year and annually after the operation. To identify the squeaking, we performed physical examination and history taking about friction sound during the outpatient clinic visit. The research nurse completed the questionnaire directly to the patients who visited outpatient clinic by a blind protocol.

Radiologic outcome measurements

Radiological assessment was undertaken on preoperatively, immediately postoperatively, at 6 weeks, 3 months, 6 months, 1 year, 2 years postoperatively and annually follow-up. Acetabular component inclination was recorded by measuring the angle between a horizontal inter-ischial line and a line drawn across the mouth of the component at the widest projection of the ellipse on a long-standing radiograph of the entire lower extremity. Acetabular component anteversion was measured as the angle formed by the long axis of the ellipsoid projection of the cup base and a vertical line on translateral radiographs.[10] Assessment on postoperative radiographic measurements of leg length as defined by Paley et al.[11] used long-standing radiographs of the entire lower extremity. The images were taken at the point when patients were stand on full weight bearing after the operation. Any LLDs were marked + for an increase and – for a decrease. For interobserver agreement of the LLD was assessed by two independent orthopedic surgeons (RYH and CML). The kappa value was 0.78, indicating substantial agreement according to the Landis and Koch criteria.[12]

Statistics

The Clinical characteristics and surgical factors for continuous variables between the group 1 and 2 were analyzed using the Student t-test and Mann-Whitney test. In contrast, the Chi-square test and Fisher's exact test were used for categorical variable analysis. Pearson's correlation analysis method was used to determine the relationship between blood metal ion level and patient-related factors, surgical factors, clinical scores and location of acetabular component positions. A linear mixing model was used because there was an omission value of the measured serum metal ion level as a method to identify the change in blood metal ion levels repeated after surgery. Statistical analysis was performed using the SPSS Statistics version20.0 (IBM Corp., Armonk, NY). Statistical significance was defined as a p value < 0.05.

RESULTS

A total of 173 cases and 147 patients were analyzed. There were 59 male and 88 female patients with the mean age of 61.4±14.6 years. The mean of the follow-up period was 6.99 ±1.36 years. The preoperative diagnosis was avascular necrosis of the femoral head in 88 cases (49.1%), proximal femoral fractures in 49 cases (29.3%), primary osteoarthritis in 24 cases (14.4%), secondary osteoarthritis in 9 cases (5.4%) and previous septic arthritis in 3 cases (1.8%). Group 1 had 114 cases, including 96 patients, and group 2 had 59 cases, including 51 patients. No differences were observed with gender (p= 0.243), age (p = 0.756), BMI (p = 0.588) and follow-up periods (p = 0.142) between the group 1 and 2. (Table 1)

Table 1. Demographic and surgical characteristics of the patients for each group.

Characteristic	Group 1 (CoM[a]; N=96)	Group 2 (CoC[b]; N=51)	p value
Gender {Patients (hips)}			**0.243**
Male	41 (50)	18 (22)	
Female	55 (64)	33 (37)	
Age			
Mean (range)	61.0 (25-90)	61.8 (35-85)	0.756
BMI[c]			
Mean (range)	24.3 (15.8-39.1)	24.7 (17.7-49.0)	0.588
Diagnosis {Patients (hips)}			
AVN[d]	44 (57)	24 (31)	
Primary OA[e]	13 (16)	8 (8)	
Secondary OA[e]	5 (5)	3 (4)	
Trauma	33 (35)	14 (14)	
Previous septic arthritis	1 (1)	2 (2)	
Follow-up (years)			
Mean (range)	5.1 (3.7-7.0)	4.7 (3.4-7.1)	0.142
LLD[f] (mm)			
Mean (range)	6.1 (-1.1-23.3)	5.3 (-1.3-17.1)	0.348
Acetabular cup inclination			
Mean (range)	41.0 (25.9-55.0)	42.3 (25.7-.54.4)	0.101
Acetabular cup anteversion			
Mean (range)	23.3 (8.2-38.7)	23.6 (6.2-35.2)	0.755
Cup size			
Mean (range)	50.5 (44-60)	49.3 (44-56)	0.270
Head size			
Mean (range)	34.5 (28-36)	33.5 (28-36)	0.113
Operation time (minute)			
Mean (range)	91.0(61-229)	105.6 (74-259)	0.047*
IntraOP[g] Bleeding (ml)			
Mean (range)	864.7 (150-4500)	836.6 (150-2500)	0.760

a: ceramic-on-metal, b: ceramic-on-ceramic, c: body mass index, d: avascular necrosis, e: osteoarthritis, f: leg length discrepancy, g: intraoperative. * Statistically significant.

Although the surgical characteristics of each group were similar, the mean operation time was longer ($p = 0.047$) in the group 2. No differences were observed with LLD ($p = 0.348$), acetabular cup inclination ($p = 0.101$), acetabular cup anteversion ($p = 0.755$), cup size ($p = 0.270$), head size ($p = 0.113$) and intra-operative bleeding ($p = 0.760$) between group 1 and 2. (Table 1)

When Co and Cr serum ion levels were continually examined over time, there was no significant difference between the 2 subgroups until postoperative 1 year for Co and postoperative 6 months for Cr. However, since then, there have been statistically significant changes in serum Co and Cr levels between the 2 groups. In the group 1, serum cobalt ion level measured at 2 years ($p = 0.041$) and 3 years ($p = 0.026$) after surgery were higher than in the group 2. In the group 1, serum Cr ion levels measured at 1 year after surgery ($p < 0.001$), 2 years ($p < 0.001$), and 3 years ($p = 0.001$) were higher than in the group 2. It is shown in Figure 2A, B and Table 2 that the serum metal ion level is plotted according to the time of examination. The linear mixed model was used to analyze the interaction between time and the serum metal ion level repeatedly measured in the group 1 and 2. The results were statistically significant at both the Co ($p = 0.017$) and Cr ($p < 0.001$) serum ion levels.

Clinical outcomes of group 1 and 2 were analyzed based on the results of the most recent examination. No statistical differences in pain ($p = 0.131$), stiffness ($p = 0.065$), function ($p = 0.054$) and total WOMAC scores ($p = 0.083$). Similarly, no significant differences were seen between the 2 groups in HHS ($p = 0.159$) (Table 2). The squeaking incidence were observed in 15 cases in the group 1 (15.6%) and in 6 cases in the group 2 (11.1%). There was no statistically significant difference in friction incidence between group 1 and 2. ($p = 0.358$).

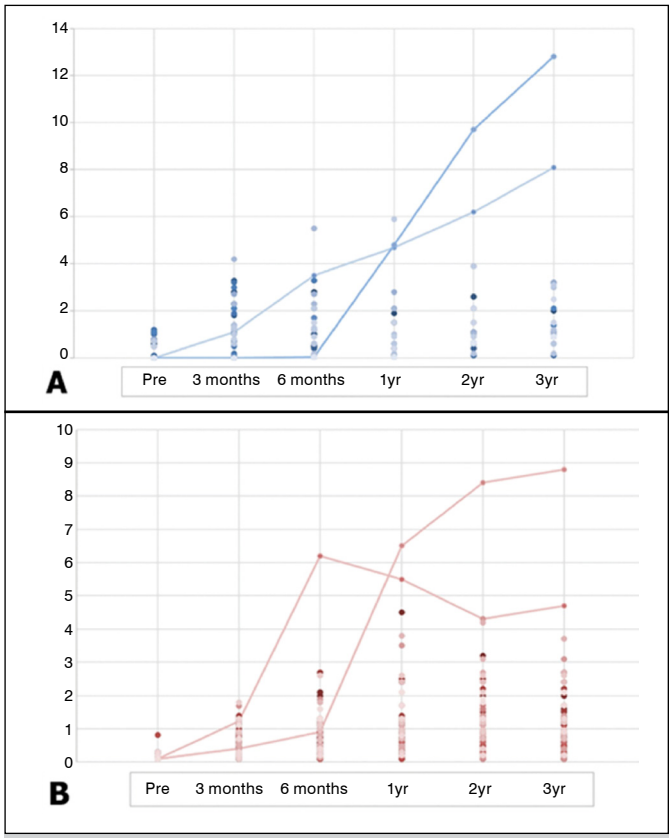

Figure 2. (A) Serum cobalt ion levels of each patient (μg/L; blue line: revisional arthroplasty patients) (B) Serum chromium ion levels of each patients (μg/L; red line: revisional arthroplasty patients).

Table 2. Comparison of Serum ion levels at each time point and functional scores between the 2 subgroups.

Group		Group 1 (CoM[a]; N=96)	Group 2 (CoC[b]; N=51)	p value
Metal ion (μg /L) Cobalt (range)	**Time point**			
	pre	0.22±0.32 (0.00-1.20)	0.14±0.45 (0.00-1.60)	0.874
	3 months	0.56±0.97 (0.00-4.20)	0.32±0.78 (0.00-2.10)	0.230
	6 months	0.47±1.05 (0.05-5.50)	0.50±1.19 (0.00-3.60)	0.920
	1 year	0.59±1.43 (0.05-6.90)	0.30±0.50 (0.05-2.10)	0.213
	2 years	1.38±2.56 (0.65-9.70)	0.24±0.70 (0.05-2.90)	0.041*
	3 years	1.49±1.59 (0.90-12.80)	0.29±0.81 (0.00-2.10)	0.026*
Chromium (range)	pre	0.27±0.13 (0.00-0.82)	0.25±0.19 (0.00-0.63)	0.792
	3 months	0.43±0.40 (0.00-1.80)	0.31±0.38 (0.00-1.81)	0.352
	6 months	0.67±0.90 (0.10-6.20)	0.37±0.53 (0.10-2.70)	0.096
	1 year	1.47±1.47 (0.10-6.50)	0.41±0.30 (0.10-1.98)	< 0.001*
	2 years	2.02±2.09 (0.10-8.40)	0.28±0.22 (0.10-1.90)	< 0.001*
	3 years	1.76±1.92 (0.10-8.80)	0.26±0.21 (0.10-1.45)	0.001*
WOMAC[c]				
Pain (0-20)		2.63±3.43 (0.10-8.80)	1.13±2.72 (0.10-8.80)	0.131
Stiffness (0-8)		0.82±1.37 (0.10-8.80)	0.74±0.74 (0.10-8.80)	0.065
Function (0-68)		12.89±13.70 (0.10-8.80)	11.85±9.53 (0.10-8.80)	0.054
Total (0-96)		12.34±17.49 (0.10-8.80)	10.45±11.35 (0.10-8.80)	0.083
HHS[d] (0-100)		83.80 9.85 (61-96)	87.76 7.06 (72-96)	0.159

a: ceramic-on-metal, b: ceramic-on-ceramic, c: Western Ontario and McMaster Universities Osteoarthritis Index, d: arris Hip Score. Values are expressed as mean ± standard deviation (range, μg/L in metal ion). * Statistically significant.

Correlations among last follow-up serum metal ion level, patient related factors, surgical characteristics, acetabular component positions and clinical outcomes were assessed in CoM THA patients. There were statistically significant positive correlations between serum Co levels and LLD ($r = 0.211$, $p = 0.046$) as well as between the serum Cr levels and LLD ($r = 0.281$, $p = 0.007$). In addition, surgical characteristics, acetabular cup position, head and cup size did not show any correlations with the metal ion level (Table 3). In comparison of average changes in metal ion levels, group 1-B (0.25 ± 0.77 μg/L) showed more increases than group 1-A (0.13 ± 0.31 μg/L) in Co ion, but it did not have statistical significance ($p = 0.055$). Also, group 1-B (0.68 ± 0.77 μg/L) showed higher increases in Cr ion level changes than group 1-A (0.34 ± 0.34 μg/L) with statistical significance ($p = 0.025$). (Table 3)

There were 2 patients in the group 1 with adverse local reactions to metal debris (ARMD) with metal liner wear. Revision arthroplasty was performed with CoC bearing to improve painful symptoms and prevent systemic adverse reactions induced by metal ions debris. Furthermore, other complications include periprosthetic fracture in greater trochanter, which was treated with internal fixation, and postoperative wound infections, which was controlled after simple wound irrigation and debridement.

DISCUSSION

MoM bearing is relatively vulnerable to wear, and CoC bearing has risks of breakage that would require revision operation even though its occurrence is relatively lower. Consequently, CoM bearings has been proposed as a durable alternative treatment option for patients with high physical activity needs.

The use of CoM bearing is advantageous in expansion in the selection of various sizes of ceramic heads even in a small acetabular cup. In our study, most pateints were performed with THAs using head sizes less than diameters of 36mm, and there is report on

Table 3. Correlation between each variable and serum metal ion levels in the patients with CoM group. Comparison of serum metal ion levels change in unilateral CoM group, according to the difference of leg length after surgery.

CoM[a] group Factor	Cobalt	P value	Chromium	p value
Age	r = -0.056	0.602	r = 0.034	0.753
BMI[b]	r = 0.075	0.481	r = 0.079	0.458
Op.[c] time	r = -0.002	0.984	r = 0.047	0.659
Op.[c] Bleeding	r = -0.021	0.843	r = -0.025	0.816
AI[d]	r = 0.189	0.074	r = 0.126	0.236
AA[e]	r = 0.172	0.070	r = 0.182	0.074
LLD[f]	r = 0.211	0.046*	r = 0.281	0.007*
Head size	r = 0.107	0.316	r = 0.096	0.367
Cup size	r = -0.030	0.777	r = 0.041	0.698
HHS[g]	r = 0.135	0.405	r = 0.117	0.471
Pain	r = 0.019	0.868	r = 0.110	0.342
Stiffness	r = 0.004	0.971	r = 0.104	0.370
Function	r = -0.009	0.937	r = 0.028	0.811
Total WOMAC[h]	r = -0.003	0.979	r = 0.052	0.657
CoM[a] group (N = 78)			**p value**	
Metal ion (g /L)	**Group 1-A[i] (N = 48)**	**Group 1-B[j] (N = 30)**		
ΔCo[k]	0.13±0.31	0.25±0.77	0.055	
ΔCr[l]	0.34±0.34	0.68±0.76	0.025*	

a: ceramic-on-metal, b: body mass index, c: operation, d: acetabular cup inclination, e: acetabular cup anteversion, f: leg length discrepancy, g: Harris Hip Score, h: Western Ontario and McMaster Universities Osteoarthritis Index, i: LLD < +1cm, j: LLD ≥ +1 cm, k: serum cobalt ion level change, l: serum chromium ion level change. r, Pearson's coefficient of correlation. * Statistically significant.

statistically lower rates of dislocation on head diameters of 36mm than 28mm. It can theoretically reduce dislocation and increase ROM compared to other bearings.[13] However, Han et al.[14] ironically concluded that the large ROM is the factor that increases the metal ion levels. In addition, there were studies that differential hardness bearing improves fluid film lubrication and reduces adhesive wear and that in vitro studies have proven that differential hardness through a CoM bearing avoids stripe wear.[15]

In several previous biomechanical and clinical studies, CoM bearing is reported to reduce the metal wear and metal ion release compared to the MoM bearing.[16] However, the CoM bearings showed the results over a wide range of performance in vivo studies. Affatato et al.[4] reported more wears occurred in the CoM bearing than in the CoC bearing, and Reinders et al.[5] no differences in mean wear rates between CoM and CoC bearings.

In this study, the serum ion levels of Co ($p = 0.026$) and Cr ($p = 0.001$) at 3 years postoperatively were significantly higher in the group 1 than in the group 2. Han et al.[14] demonstrated that serum metal ion levels in the CoM bearings were a 6.5-fold and 9-fold higher in the Co and Cr, respectively, in comparison to non-CoM bearings. In this study, the metal ion levels in the group 1 showed a 5.1-fold higher level of Co and a 6.8-fold higher level of Cr than those in the group 2.

The patterns of metal ion changes in the 2 subgroups were noted in relation to time with statistical significances (Co: $p = 0.017$; Cr: $p < 0.001$) and showed gradual increases with the number of cycles similar to previous studies.[4,5] It has increased to a similar level to other studies[14] only to the extent without the toxic effect.[7] Even though the serum metal ion level did not show any correlations with other variables like age, BMI, surgical factor, acetabular cup position and clinical outcomes, LLD showed positive correlations with both Co (r = 0.211, $p = 0.046$) and Cr (r = 0.281, $p = 0.007$) serum ion levels. In addition, group 1-B indicated larger serum ion level changes in Co and Cr than group 1-A, and the increase of Cr level in group 1-B showed statistical significance ($p = 0.025$). These results suggest that LLD may affect the functional position of the cup and the edge load. A recent study by Renkawitz et al.[17] reported the occurrence of unphysiological gait on patient with more than 5mm leg length difference after THAs. Other studies of risk factors for metal ion releases in THA with CoM bearing suggested BMI and amount of anteversion,[18] but no association was found in our study.

There have been few direct comparisons of clinical results with the CoM and CoC bearing. As the squeaking incidence of about 10% reported in the previous study,[19] the squeaking incidence of CoC and CoM bearing in our study was 11.1% and 15.6%, respectively. In addition, the difference in the squeaking rate between group 1 and 2 was not statistically significant ($p = 0.358$). In this study, there were 2 patients in group 1 who suffered from metal liner wear along with outlier serum metal levels, and both patients received revision arthroplasty with CoC bearings. This result shows that revision rate occurred in only 2 out of 114 (1.8%) cases, which is a good result compared to other studies.[20] Their surgical findings revealed massive metal debris with ARMD (Figure 3A, B) as well as metal staining in the ceramic head and severe wear at the inferior edge. The LLD were 18.7mm and 14.3mm in first and second patients with revision arthroplasty, respectively. According to the surgical findings, the ceramic head was metal stained, and the taper was relatively clean (Figure 3C, D). Therefore, the metal liner wear on the CoM bearing is considered to be the cause, and the possibility of edge loading due to the difference in leg length after surgery is suspected.

There are several limitations to this study. Our study was not conducted with randomization and blinding protocol in all the procedures for surgery and data collection. Therefore, explanations of all the variables utilized in our study are vulnerable to possible inherent biases. There is a problem with the mismatch that the number of patients and the gender ratio between the 2 subgroups. And although the number of patients sampled is not small, not all patients were followed-up. In addition, the study has a limitation that the confirmation of squeaking depended entirely on the patient's

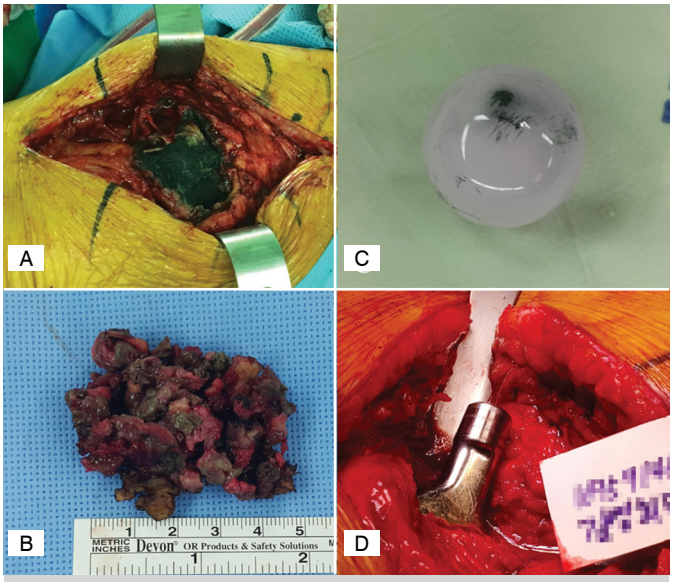

Figure 3. (A) Massive metal debri and adverse local reactions to metal debris were observed around the hip joint (B) Massive metal debri and metal staining of soft tissue were observed (C) Metal debri staining was observed on the ceramic head by metal liner wear (D) Taper of the stem was relatively clean and had few scratches.

answer. On the other hand, the strength of the study is that 1 skilled orthopedic surgeon operated all patients in the same manner at the 1 institution

CONCLUSION

Our results suggest that CoM bearing THAs show effective hip function in both short-term and mid-term similar to CoC bearing THAs even though serum ion levels of Co and Cr were relatively higher in CoM group and especially higher in patients with LLD more than 1 cm. Therefore, it is critical to minimize LLD less than 1cm during CoM bearing THA operation, and in cases with postoperative LLD more than 1 cm, periodic changes of serum metal ion levels as well as possible clinical symptoms of metal ion toxicity should be carefully examined.

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INFECTION

MEDICAL RESIDENCE IN ORTHOPEDICS AND TRAUMATOLOGY – NATIONAL OVERVIEW AND ANALYSIS OF EVALUATION CONCORDANCE BETWEEN CNRM/SBOT DURING THE COVID-19 PANDEMIC

RESIDÊNCIA MÉDICA EM ORTOPEDIA E TRAUMATOLOGIA – PANORAMA NACIONAL E ANALISE DE CONCORDÂNCIA DE AVALIAÇÃO CNRM/SBOT DURANTE A PANDEMIA DE COVID-19

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ABSTRACT

Objective: Describe the national scenario of the orthopedics and traumatology Medical Residency Program (MRP) in 2020/2021, showing the distribution of vacancies by states and regions of Brazil, the number of residents and the percentage of agreement between the accredited services that offer the program by the Brazilian Society of Orthopedics and Traumatology (SBOT) and by the National Commission for Medical Residency linked to the Ministry of Education (CNRM/MEC). Methods: This is a descriptive, cross-sectional study. Data from the CNRM and SBOT system referring to residents attending orthopedics and traumatology Programs in 2020/2021 were analyzed. Results: In the analyzed period, there were 2.325 medical residents in orthopedics and traumatology in vacancies authorized by the CNRM/MEC in Brazil. The southeast region was predominant, with 57.2% of vacancies, totaling 1.331 residents. The discrepancy was notable compared to other regions, the south region with 16.9% (392), the northeast with 15.1% (351), the midwest with 7.7% (180), and the north with 3.1% (71). In addition, there was an accreditation agreement of 53.8% in evaluating services between the SBOT and CNRM, with distinctions among the states. Conclusion: The analysis showed differences between regions and states, considering the vacancies of PRM in orthopedics and traumatology and the concordance of evaluations by institutions accredited by MEC and SBOT. It is aim to work together with a view to qualifying and expanding residency

RESUMO

Objetivo: Descrever o cenário nacional do Programa de Residência Médica (PRM) em Ortopedia e Traumatologia em 2020/2021, período da maior incidência da covid-19, apontando a distribuição de vagas pelos Estados e Regiões do Brasil, o quantitativo de residentes em curso e a porcentagem de concordância entre os serviços credenciados pela Sociedade Brasileira de Ortopedia e Traumatologia (SBOT) e pela Comissão Nacional de Residência Médica vinculada ao Ministério da Educação (CNRM/MEC). Métodos: Estudo descritivo, transversal. Foram analisados dados do Sistema da CNRM e da SBOT referentes aos residentes cursando Ortopedia e Traumatologia durante o período declarado de pandemia no Brasil. Resultado: No período analisado haviam 2.325 médicos residentes cursando os PRM de Ortopedia e Traumatologia no Brasil em vagas autorizadas pela CNRM/MEC. Predomínio na região Sudeste, com 57,2% do total de vagas no Brasil, totalizando 1.331 residentes com discrepância em comparação às outras regiões, com 16,9% (392) residentes na região Sul, 15,1% (351) no Nordeste, 7,7% (180) no Centro-Oeste e 3,1% (71) no Norte, cursando o PRM em Ortopedia. Em relação à avaliação dos serviços realizada pela SBOT e pela CNRM, há uma concordância média de 53,8% entre o credenciamento por ambas, com também distinções entre as Unidades da Federação. Conclusão: A análise demonstrou diferenças entre regiões e estados em relação à oferta de vagas nos Programas de Residência em Ortopedia e Traumatologia, bem como quanto à concordância entre as avaliações das instituições credenciadas pela CNRM e/ou SBOT. Há necessidade de

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programs for the training of specialist physicians, in accordance with the needs of the public health system and adequate medical practice, is necessary. The analysis during the pandemic period, associated with the restructuring of several health services, demonstrates the stability of the specialty in adverse scenarios. ***Level of evidence II; Economic And Decision Analyzes – Developing an Economic or Decision Model.***

Keywords: Medical Residency. Orthopedics. Medical Education. Health Systems.

um trabalho conjunto entre ambas visando para ampliação e qualificação dos cenários de prática e preceptoria na formação do novo especialista, considerando as necessidades do SUS e o exercício da boa prática médica. A análise no período da pandemia, associado a reestruturação de muitos serviços de saúde, demostra a estabilidade da especialidade em cenários adversos. ***Nível de evidência II; Análises econômicas e de decisão – Desenvolvimento de modelo econômico ou de decisão.***

Descritores: *Residência Médica. Ortopedia. Educação Médica. Sistemas de Saúde.*

INTRODUCTION

Medical residency is a postgraduate education performed under in-service training, with a deepening in some medical areas. The National Medical Residency Commission (CNRM), linked to the Ministry of Education (MEC), is responsible for the organization, accreditation, and monitoring of the Medical Residency Programs (MRP) distributed throughout Brazil.[1]

Currently, these programs are developed in 55 medical specialties and 61 areas recognized by the Mixed Specialties Commission (CME), composed of the CNRM, Federal Council of Medicine (CFM), and the Brazilian Medical Association (AMB). orthopedics and traumatology MRP has three years duration and is a requirement to continue in Hand Surgery specialty.[2-4]

In the United States, the orthopedics residency is among the most competitive, without a simultaneous increase in vacancies.[5] In Brazil, until 2018, also seemed to have an increased interest in the specialty, as shown in a nationwide study, recent graduates who intend to attend medical residency were asked their first option. Six specialties accounted for 53.3% of preferences, one of them being orthopedics and traumatology (5.2%).[6] In parallel, another study showed data from 2010 to 2019 and a 96.9% increase in orthopedics vacancies in the country, from 487 to 959.[7]

However, there is still a need for studies that address the particularities of orthopedics and traumatology MRPs, such as the relationship between candidate and vacancy in the selection processes, weaknesses and qualities of the program, compliance with the competency matrices, among others.

The services offering the MRP are constantly evaluated following CNRM regulations.[8] In 2018, the CNRM/MEC made resolutions that enable and encourage joint assessment between educational evaluators and specialty societies to increase qualification between the training services processes.

This measure eases the tension between the best possible understanding expected by specialty societies and CNRM/MEC regarding the importance and necessity of the evolution of the evaluation of Medical Residency Programs that unite several components, both of health services that are training scenarios for the specialist, and of the quality of care that impact good medical practice.

Therefore, the aim of this study is to describe the national scenario of orthopedics and traumatology MRPs in 2020/2021, showing the distribution of vacancies by states and regions of Brazil, the number of residents in total and per year, and the percentage of agreement between accredited services that offer the program by the Brazilian Society of Orthopedics and Traumatology (SBOT) and by the CNRM/MEC in 2020/2021. Also included in the data analysis was the MRP of hand surgery, a specialty that has the MRP of orthopedics and traumatology as a prerequisite.

METHOD

This is a descriptive, cross-sectional study, conducted from a collection of pre-existing data, in electronic[9], based on the National Commission on Medical Residency System (SisCNRM) data through the MEC electronic portal (http://siscnrm.mec.gov.br/login/login), extracted between August 2020 and on April 2021. The database is generated by information provided by the Medical Residency Committees (COREME) in each institution responsible for the resident registration. Variables with the number of residents attending orthopedics and traumatology specialty and hand surgery sub-specialty in 2020/2021 were selected to analyze the total, by state, of residents first-year (R1), residents second-year (R2), and residents third-year (R3) for the specialty and R1 and R2, for the sub-specialty. Institutions that listed the MRP status as "approved," "overdue," "diligence," and "requirement" in SisCNRM were included.

As for the process of authorization with the Research Ethics Committee, the study is part of the research exempted from registration because it is a research that aims to deepen theoretical situations that emerge spontaneously in professional practice, which does not reveal data that can identify the individual.

The evaluation system of Medical Residency Programs for accreditation follows the regulations of the National Residency Commission regarding authorizing acts and is based on the pillar: structure-process-result, determined by on-site visit, document verification, interviews and analysis of the execution of the pedagogical project. For comparison purposes, the services accredited by SBOT in 2020 were analyzed (https://sbot.org.br/wp-content/uploads/2020/08/Servicos_credenciados_2020.xls). The established criteria are determined by the Specialty Society and are based on their own criteria with main emphasis on the qualification of the teaching staff and scenarios for the implementation of the competence matrix.

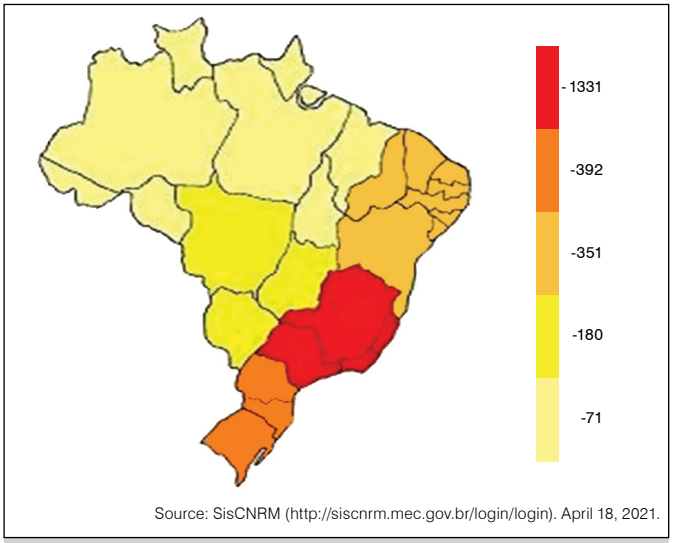
In addition, a literature review was performed based on bibliographic research in the PUBMED database using the keywords "[MEDICAL RESIDENCY]," "[ORTHOPEDICS]," "[MEDICAL EDUCATION]" and their correspondents in Portuguese, and articles from the past five years were searched. A manual search was also performed on the SBOT website for discussions.

RESULTS

In Brazil, there were 2.325 medical residents registered in the orthopedics and traumatology MRP in vacancies authorized by the CNRM/MEC in the analyzed period. The southeast region was predominant, totaling 1.331 residents, which represents 57.2% of the total number of residents in orthopedics and traumatology MRP in the country.

The discrepancy was notable compared to other regions, the south region with 16.9% (392), the northeast with 15.1% (351), the midwest with 7.7% (180), and the north with 3.1% (71). (Figure 1)

Of the total, 812 (34.9%) are enrolled in R1, 753 (32.4%) in R2, and 750 (32.3%) in R3, showing little waiver during the 3 years of the MRP. SisCNRM data also show 10 (0.4%) residents attending an additional fourth-year (R4) in various services in Brazil. (Table 1), a low number given the possibility of extending training considering several specialized services in Brazil.



Source: SisCNRM (http://siscnrm.mec.gov.br/login/login). April 18, 2021.

Figure 1. Number of resident physicians enrolled in Orthopedic and Traumatology Medical Residency Programs by region of Brazil in 2021.

As for the distribution by state, São Paulo (SP) had the higher number of residents, with 830, corresponding to 35.7% of the total number of residents in the country, distributed between R1 280 (33.7%), R2 273 (32.9%) and R3 277 (33.4%). These data showed the residents concentration in this state, followed by the states of Minas Gerais (MG), with 262 (11.3%), and Rio de Janeiro (RJ), with 211 (9.1%). Along with SP, they justify the southeast region with the highest number of ongoing residents.

As for the states with the lowest numbers of residents, Tocantins (TO), Amapá (AP), and Acre (AC) accounted for 5, 5, and 4, respectively, followed by the Rio Grande do Norte (RN), as the only state that did not have residents attending the orthopedics MRP in the period.

Considering the distribution by Brazilian state between R1, R2, and R3, there was homogeneity between vacancies offered per year, without considerable discrepancies, following the verification of little dropout during the course regardless of the location.

Regarding the hand surgery MRP, 124 residents were registered. The highest number of vacancies remained in the southeast, with 75% (93), followed by the south 11.3% (14), northeast 9.7% (12), north 2.4% (3), and midwest 1.6% (2). (Table 2)

SP state accounted for 65 (52%) residents in this sub-specialty, 33 R1, and 32 R2, followed by RJ, Pernambuco (PI), and Minas Gerais (MG) with 15, 12, and 12, respectively. Espírito Santo (ES), Goiás (GO), Pará (PB), Paraná (PR), Santa Catarina (SC) and Rio Grande do Sul (RS) had lower numbers, ranging from 1 to 8. The remaining states did not have residents attending hand surgery MRP. (Table 1)

As for the orthopedics and traumatology MRPs accredited by the CNRM/MEC in 2020, according to SisCNRM (Table 3), Brazil had a total of 274 services, considering those in "approved," "overdue," "diligence," and "exigency."

SP was the state with the highest number MRPs, with 64 (23.35%), followed by MG 36 (13.1%), RJ 32 (11.7%), PR 26 (9.5%), and RS 17 (6.2%), with the same sequence when analyzing the accredited vacancies by state, which reinforces the tendency and concentration in the southeast region, followed by the south, to the detriment of the others regions.

In the analyzed period, the North region presents the lowest concentration, totaling 11 accredited programs, with PA being the state with the highest number (3), followed by AM and TO (2) and AC, AP, Rondônia (RO), and Roraima (RR) (1). The number of programs in the other states varied between 4 and 13.

Regarding the different status of the MRPs within the CNRM, there were 230 accredited services as "approved", 5 as "overdue," 36 as "exigency," and 3 as "diligence". (Table 3)

Table 4 shows the number of services by states that offer training in orthopedics and traumatology accredited by the SBOT in 2020 and the quantity of MRP accredited by the CNRM/MEC, considering those in the abovementioned status.

Table 1. Number of medical residents enrolled in each year of training in orthopedic and traumatology and hand surgery by state in 2021.

	Orthopedic and Traumatology					Hand Surgery		
State	R1	R2	R3	R4	Total	R1	R2	Total
AC	3	0	1	0	4	0	0	0
AL	10	5	7	0	22	0	0	0
AP	2	1	2	0	5	0	0	0
AM	8	6	7	0	21	0	0	0
BA	44	35	43	0	122	0	0	0
CE	15	15	14	0	44	0	0	0
DF	35	33	30	0	98	0	0	0
ES	9	9	10	0	28	1	0	1
GO	20	17	22	0	59	1	1	2
MA	7	6	6	0	19	0	0	0
MT	6	3	3	0	12	0	0	0
MS	4	3	4	0	11	0	0	0
MG	90	86	83	3	262	6	6	12
PA	8	8	8	0	24	1	2	3
PB	9	8	7	0	24	0	0	0
PR	70	62	56	0	188	3	3	6
PE	29	31	32	0	92	6	6	12
PI	6	5	4	0	15	0	0	0
RJ	71	71	68	1	211	7	8	15
RN	0	0	0	0	0	0	0	0
RS	46	42	38	0	126	3	3	6
RO	2	2	2	0	6	0	0	0
RR	1	3	2	0	6	0	0	0
SC	29	24	19	6	78	1	1	2
SE	6	4	3	0	13	0	0	0
SP	280	273	277	0	830	33	32	65
TO	2	1	2	0	6	0	0	0
Total	812	753	750	10	2325	62	62	124

AC: Acre; AL: Alagoas; AP: Amapá; AM: Amazonas; BA: Bahia; CE: Ceará; DF: Distrito Federal; ES: Espírito Santo; GO: Goiás; MA: Maranhão; MT: Mato Grosso; MS: Mato Grosso do Sul; MG: Minas Gerais; PA: Pará; PB: Paraíba; PR: Paraná; PE: Pernambuco; PI: Piauí; RJ: Rio de Janeiro; RN: Rio Grande do Norte; RS: Rio Grande do Sul; RO: Rondônia; RR: Roraima; SC: Santa Catarina; SP: São Paulo; SE: Sergipe; TO: Tocantins. **Source**: SisCNRM (http://siscnrm.mec.gov.br/login/login). April 18, 2021.

Table 2. Number of medical residents enrolled in orthopedic and traumatology and hand surgery in 2021.

	Orthopedic and Traumatology	Hand Surgery
Region	Number of residents (%)	Number of residents (%)
North	71 (3.1%)	3 (2.4%)
Northeast	351 (15.1%)	12 (9.7%)
Southeast	1.331 (57.2%)	93 (75%)
Midwest	180 (7.7%)	2 (1.6%)
South	392 (16.9%)	14 (11.3%)
Total	2,325	124

Source: SisCNRM (http://siscnrm.mec.gov.br/login/login). April 18, 2021.

Table 3. Number of orthopedic and traumatology Medical Residency Programs (CNRM/MEC) by state in 2020.

	Approved	Overdue	Deligence	Requirement	Total
aC	1	-	-	-	1
AL	3	-	1	1	5
AP	1	-	-	-	1
AP	1	-	-	1	2
BA	11	-	-	2	13
CE	5	-	-	2	7
DF	7	-	-	1	8
ES	2	-	-	2	4
GO	6	-	-	1	7
MA	4	-	-	-	4
MT	3	-	-	1	4
MS	1	-	-	-	1
MG	33	1	-	2	36
PA	3	-	-	-	3
PB	3	-	-	-	3
PR	22	-	-	4	26
PE	11	-	-	2	13
PI	1	-	-	1	2
RJ	27	-	1	4	32
RN	-	1	-	-	1
RS	14	1	1	1	17
RO	-	-	-	1	1
RR	-	-	-	1	1
SC	8	2	-	3	13
SE	3	-	-	-	3
SP	58	-	-	6	64
TO	2	-	-	-	2
TOTAL	230	5	3	36	274

AC: Acre; AL: Alagoas; AP: Amapá; AM: Amazonas; BA: Bahia; CE: Ceará; DF: Distrito Federal; ES: Espírito Santo; GO: Goiás; MA: Maranhão; MT: Mato Grosso; MS: Mato Grosso do Sul; MG: Minas Gerais; PA: Pará; PB: Paraíba; PR: Paraná; PE: Pernambuco; PI: Piauí; RJ: Rio de Janeiro; RN: Rio Grande do Norte; RS: Rio Grande do Sul; RO: Rondônia; RR: Roraima; SC: Santa Catarina; SP: São Paulo; SE: Sergipe; TO: Tocantins. **Source**: SisCNRM (http://siscnrm.mec.gov.br/login/login). October 31, 2020.

Table 4. Number of accredited services by the National Commission on Medical Residency System (SisCNRM) compared to the Brazilian Society of Orthopedics and Traumatology (SBOT) offering orthopedics and traumatology Medical Residency Programs by state in 2020.

	Accredited services			
	SBOT	SISCNRM	BOTH	Total
AC	-	-	1	1
AL	-	4	1	5
AP	-	-	1	1
AM	-	-	2	2
BA	3	8	5	16
CE	1	2	4	7
DF	-	1	7	8
ES	-	-	4	4
GO	1	3	5	9
MA	1	2	2	5
MT	-	3	1	4
MS	-	-	1	1
MG	4	14	20	38
PA	2	3	-	5
PB	-	2	1	3
PR	3	12	14	29
PE	2	4	8	14
PI	1	1	1	3
RJ	1	15	17	33
RN	-	1	-	1
RS	2	7	9	18
RO	-	-	1	1
RR	-	1	-	1
SC	4	5	5	14
SE	-	2	1	3
SP	8	13	50	71
TO	-	2	-	2
TOTAL	34	104	161	299

AC: Acre; AL: Alagoas; AP: Amapá; AM: Amazonas; BA: Bahia; CE: Ceará; DF: Distrito Federal; ES: Espírito Santo; GO: Goiás; MA: Maranhão; MT: Mato Grosso; MS: Mato Grosso do Sul; MG: Minas Gerais; PA: Pará; PB: Paraíba; PR: Paraná; PE: Pernambuco; PI: Piauí; RJ: Rio de Janeiro; RN: Rio Grande do Norte; RS: Rio Grande do Sul; RO: Rondônia; RR: Roraima; SC: Santa Catarina; SP: São Paulo; SE: Sergipe; TO: Tocantins. **Source**: SisCNRM (http://siscnrm.mec.gov.br/login/login). October 31, 2020; Brazilian Society of Orthopedics and Traumatology (SBOT). October 31, 2020. (https://sbot.org.br/wp-content/uploads/2020/08/Servicos_credenciados_2020.xls)

There are 299 accredited services for training in orthopedics in Brazil, with 161 institutions with assessments in common, representing on average 53.8% of agreement between the SBOT and MEC assessments for accreditation of services. However, it was also found that 34 (11.37%) institutions are accredited only by SBOT and 104 (34.78%) only by CNRM/ MEC.

Thirteen of the states (48.14%) had more than 50% agreement between both evaluations. 4 states in the North Region: AC, AP, AM, RO, in addition to the states of ES and MS, had 100% agreement. However, they also had a smaller number of institutions that offer residency programs.

Among the states with the highest number of institutions was the Distrito Federal (DF), which had the highest percentage of agreement (87.5%) among both accredited services by SBOT and CNRM/MEC. Then comes SP with 71 training services in total, with an agreement of 70.42%, with eight (11.3%) exclusively accredited by the SBOT, 13 (18.3%) by the CNRM/MEC, and 50 in both. Followed by Ceará (CE) and PE with 57.1%, GO with 55.5%, MG with 52.6%, and RJ with 51.5%.

Alagoas (AL) was in evidence among the states with less than 50% agreement, with five institutions offering training services, four exclusively by the CNRM and one by both, with 20% agreement. In addition, Mato Grosso (MT) (25%), Bahia (BA) (31.25%), PB, Piauí (PI) and Sergipe (SE) (33.33%), SC (35.7%), Maranhão (MA) (40%), PR (48.27 %) and RS (50%). Also noteworthy were the states that did not have joint accredited services, with a 0% agreement rate, such as PA, RN, RO, and TO.

The only states that had service accredited only by the CNRM/ MEC were RN and RO with 1 and 2, respectively. The status of RO was "exigency." The one in RN was "overdue," which justifies the absence of residents in orthopedics. PA, in turn, had two institutions that were exclusive to the SBOT and three to the CNRM/MEC, not having a common record.

DISCUSSION

The number of medical schools has been increasing in recent years in Brazil, but specialized, suitable, and structured a health

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service has not accompanied this number, making it impossible to increase the vacancies for residency programs.[10]

Although expanding these vacancies is necessary, it is essential to give attention to their distribution throughout the country. However, the expansion must be based on the conditionalities for its opening and accreditation, such as those required through MRPs periodic evaluations, to maintain the quality of training.[8]

The Medical Demography study[7] showed in 2020 that the country counted a total of 17,906 physicians specializing in orthopedics and traumatology, with a ratio of 8.52 per 100,000 inhabitants. As for the distribution by region, there was a southeast predominance (52.9%), followed by the south (17%), northeast (16%), midwest (10%), and north (4.1%).

In addition to numbers, the hypotheses for the data presented must be discussed. Since only the orthopedics specialist can train the residents in this area, there is a clear relation between the concentration of specialists and the number of medical residency vacancies in the southeast region of Brazil. This can indicate quality in orthopedic physicians' training, considering that preceptorship is essential for adequate training.

The southeast discrepant prevalence of 57.2% is too related to the concentration of more developed and traditional training centers in educational services – the first medical residency program registed in Brazil was in 1945 at the University of São Paulo – conditioned to suitable practice services for teaching, qualified training, technological resources for care and teaching, and budget for residency scholarship.[11]

In addition, it is questioned whether the socio-economic analysis influences the distribution of orthopedics and traumatology MRPs, considering that a large portion of residents leave their home state to specialize and do not return, when cursed in major urban centers.[12]

Only 38% of medical students and 23.7% of residents return home after completing their studies and/or specialization.[10,14] The possible causes for this migration are the search for better working conditions and career opportunities.[10,12] Thus, the concentration of MRPs also promotes the concentration of specialists in these regions.

Regarding the criteria for accreditation of medical residency programs, Decree No. 7,562 of 2011[8] determines that the vacancies distribution, ideally following the epidemiological profile of the Unified Health System (SUS). As for this data, for example, data rates of hip fractures due to frailty in the elderly, Peterle et al[14] found in their study that 28% of the records of femoral fractures in Brazil are the SP state. Therefore, there is compatibility between the health needs and training centers for orthopedics specialists in these regions.

However, what about other pathologies, such as orthopedic trauma, which is one of the main causes of care in emergency rooms. Or would it be the fact that patients also migrate to states and regions with greater structures for the treatment of their health problems? Should this epidemiological data be considered in the evaluation system of both institutions: CNRM and SBOT? How many specialists does Brazil need?

The CFM can only register as specialists (granting the Specialist Qualification Registration Certificate) physicians who present at least one of these two documents: Certificate of Completion of Medical Residency accredited by the National Commission for Medical Residency (CNRM) or Specialist Title granted by Brazilian Association or Society of the respective specialty.[15]

In orthopedics and traumatology, the resident must pass a demanding exam to receive the Specialist Title in Orthopedics and Traumatology (TEOT).[16,17]

CNRM/MEC Resolution No. 25[18] from 2019 provides for cooperation between CNRM and medical specialty societies in the MRPs' on-site evaluation visits, aiming to bring them closer together. However, as presented in this study, a greater relationship between the CNRM and SBOT is still necessary for better integration, since there is only 53.8% agreement in the accreditation between both assessments.

The study did not aim to evaluate the quality of MRP, interest of graduates of medical courses in the specialty, pedagogical project of MRP, idleness of vacancies or system of evaluation of the graduate is in MRP or training centers SBOT, but to signal, through quantitative data, assumptions that can unite and qualify the evaluation criteria between SBOT and CNRM, with a critical analysis, in addition to numerical discrepancy of data distribution of MRP and residents medical in the country.

CONCLUSION

The analysis performed in this study showed significant differences between regions and states of Brazil considering the offer of vacancies in the orthopedics and traumatology MRPs and the distribution of institutions accredited by the MEC and/or SBOT, which follows the sociodemographic and the country's health services. The services are concentrated in the southeast, followed by the south, compared to of the north region.

This may explain why the specialists stay in those regions where there is a greater concentration of orthopedics and traumatology services, both for the possibility of training in the specialty, and the chance to join the labor market in the area after finishing training. This also COULD explains why they do not return to their home state?

In turn, fulfilling the criteria which define medical residency under the responsibility of health institutions, university or not, and under the guidance of highly qualified ethical and professional physicians, the CNRM has been meeting its regulatory role based on pedagogical criteria regarding the accreditation of the most suitable services for the specialist training.

Thus, it is essential to identify the demographic arrangement of orthopedic training in the country, comparing it with the necessity of investment in specialized supplies and equipment and qualified professionals for the training of residents, as well as the epidemiological scenario of the incidence of pathologies to be treated by this specialty in the states and regions of Brazil.

In order to broaden the discussion, the debate on the training of orthopedic and traumatology specialists aims to contribute to the health systems management regarding more equitable investment planning in new services for the practice of the specialists, which will generate new job opportunities to encourage these specialists to establish their professional career in regions far from the larger centers.

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DOES PARTIAL MEDIAL KNEE ARTHROPLATIES HAVE BETTER RESULTS THAN TOTAL ONES?

ARTROPLASTIAS PARCIAIS MEDIAIS DO JOELHO TÊM RESULTADOS MELHORES DO QUE AS TOTAIS?

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ABSTRACT

Objective: Compare the results of medial unicompartmental knee arthroplasty (UKA) using a mobile platform and total knee arthroplasty (TKA) in patients with isolated medial osteoarthritis. Methods: Retrospectivecross-sectional study. Preoperative radiographs of 602 patientswho underwent knee arthroplastybetween February 2017 and February 2020 were evaluated. Isolated medial osteoarthritis was found in 125 patients. Of these, 57 underwent UKA and 68 TKA. With chart analysis and telephone interviews, we compared patients' clinical outcomes and degree of satisfaction. The statistical analysis used a confidence level of 5%. Results: The group of UKA patients obtained 65.8% of favorable results against 79.1% of those undergoing TKA in the function questionnaire ($p<0.0001$). The complication rate was statistically similar between the groups($p>0.5$). Most patients were satisfied or very satisfied in both groups (88.6% of UKA and 91.2% of TKA) ($p>0.999$). Conclusion: Patients submitted to UKA or TKA have presented the same degree of satisfaction and rate of postoperative complications when comparing patients with isolated medial osteoarthritis. UKA patients had less favorable results onthe clinical functional questionnaire than patients undergoing total arthroplasty. ***Level Of Evidence III;Retrospective Study.***

Keywords: Knee. Arthroplasty. Osteoarthritis.Arthroplasty, replacement, knee.

RESUMO

Objetivo: Comparar os resultados da artroplastia unicompartimental do joelho (UKA) medial com plataforma móvel e artroplastia total do joelho (TKA) em pacientes com osteoartrose medial isolada. Métodos: Estudo transversal retrospectivo. Foram avaliadas radiografias pré-operatórias de 602 pacientes submetidos à artroplastia de joelho entre fevereiro de 2017 e fevereiro de 2020. A osteoartrose medial isolada foi encontrada em 125 pacientes, destes em 57 haviam sido submetidos a UKA e 68 TKA. Com análise de prontuários e entrevistas telefônicas comparamos os resultados clínicos e o grau de satisfação dos pacientes. A análise estatística utilizou nível de confiança de 5%. Resultados: O grupo de pacientes com UKA obteve 65,8% de resultados favoráveis contra 79,1% daqueles submetidos à TKA no questionário de função ($p<0,0001$). A taxa de complicações foi estatisticamente semelhante entre os grupos ($p>0,5$). A maioria dos pacientes estava satisfeita ou muito satisfeita em ambos os grupos (88,6% de UKA e 91,2% de TKA) ($p>0,999$). Conclusão: Pacientes submetidos a UKA ou TKA apresentaram o mesmo grau de satisfação e taxa de complicações pós-operatórias quando comparados pacientes com osteoartrite medial isolada. Os pacientes da UKA apresentaram resultados menos favoráveis ao questionário clínico funcional do que os pacientes submetidos à artroplastia total. ***Nível de Evidência III; Estudo Retrospectivo.***

Descritores*: Joelho. Artroplastia. Osteoartrite.Artroplastia do Joelho.*

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INTRODUCTION

Unicompartmental Knee Arthroplasty (UKA) is an alternative to total knee arthroplasty (TKA).[1] Studies demonstrated that medial UKA is associated with a shorter hospital stay, lower infection rate and better range of motion, compared to TKA.[2-4]

However, some studies have shown that UKA has a higher rate of revisions in up to 10 years compared to TKA.[4-6] This higher rate of reoperations relates directly to the surgeon's experience with UKA through the number of surgeries performed annually, as 80% of knee surgeons perform less than 10 UKAs per year.[7] The TOPKAT

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

The study was conducted at the Hospital de OrtopediaUniort.e Londrina and School of Medicine at PUCPR- Londrina Campus.
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randomized clinical trial found similar rates of surgical revisions in patients undergoing UKA and TKA.[8] A systematic review of over 8000 patients who underwent Oxford® unicompartmental medial arthroplasty demonstrated that the rate of revisions alone was higher in UKA. However, if considered all surgical reapproaches, this number was higher in TKA.[6]

Some individuals with an indication for unicompartmental medial prosthesis often still undergo total prosthesis in our country because they are still not available in some centers, and some surgeons are still unaware of the indications and techniques.[9]

In this study, we compared the clinical outcomes and degree of satisfaction of patients with isolated medial compartment osteoarthritis of the knee who underwent medial knee replacement with the Oxford Mobile Platform or TKA in the same period with at least six months of postoperative follow-up.We hypothesized that there were better clinical outcomes and a higher degree of satisfaction in patients undergoing UKA.

METHODS

The study was approved by the Ethics and Research Committee of the Institution (CAAE: 31747020.8.0000.0020).

A retrospective cross-sectional study with chart analysis and telephone interviews was conductedto compare the clinical outcomes and degree of satisfaction. Patients who underwent Oxford® mobile bearing medial unicompartmental arthroplasty or total knee arthroplasty by our knee surgery group between February 2017 and February 2020 were selected.

Inclusion criteria were patients with preoperative radiographs that fit the radiographic criteriafor medial unicompartmentalarthroplasty,[10-11] undergoing total or medial unicompartmental arthroplasty with a follow-up of at least six months, with complete medical records and the possibility of phone contact. The analysis of all preoperative radiographs and medical records excluded patients with less than 6 months of follow-up, patients older than 75, and younger than 50 years of age, to form two homogeneous groups concerning age and follow-up time.

The following information was searched in the medical records: name, birth date, date of surgery, side (left or right knee), kind ofsurgery (UKA or TKA), and complications. After telephone contact, reading and approval of the consent form, the patient answered a questionnaire that consisted of the following questions: degree of satisfaction with the surgery (very dissatisfied, somewhat dissatisfied, somewhat satisfied, satisfied or very satisfied), whether he/she would do the surgery again (yes or no), whether he/she would recommend the same surgery to an another patient (yes or no), the length of hospitalization (number of days), if there was a readmission in the first 30 days after surgery, if there was deep vein thrombosis in the first 30 days after surgery, if there was an acute myocardial infarction in the first 30 days after surgery, if there was a stroke in the first 30 days after surgery, if died in the first 30 days after surgery, if had wound problems, if have undergone new surgery (debridement, surgery for arthrofibrosis, peri-prosthetic fracture, or revision surgery), if have had revision surgery, what was the cause (stiffness, infection, aseptic loosening, peri-prosthetic fracture or persistent pain after surgery), and if have any symptoms in the knee (yes or no), if yes what symptoms are present: any walking difficulty (yes or no), can support body weight on the operated leg (yes or no), any difficulty using stairs (yes or no), any difficulty squatting (yes or no), usually have swelling in the knee (yes or no), can bend the knee to 90 degrees of flexion (yes or no), does it bother with any crepitus or “noise” when you move the knee (yes or no).

The Chi-square (x2) or Fisher’s Exact test were used in statistical analysis to evaluate the qualitative variables. For quantitative variables, Shapiro-Wilk test was firstly applied to analyze normality. Subsequently, the Mann-Whitney test for non-normal data and the t test for variables with Gaussian distribution. The results were analyzed using GraphPad Prism8 software (GraphPad Software Inc., La Jolla, CA, USA), with a 5% confidence level established for all tests applied.

RESULTS

A total of 602 radiographs of patients undergoing TKA (545) and UKA (57) between February 2017 and February 2020 were evaluated. After applying the radiographic criteria,[10-11] 477 patients were excluded. Of the 125 included, 57 had been submitted to UKA and 68 to TKA.There were13 patients of the UKA group that lost follow-up and 14 patients of the TKA group. There were 9 patients in the UKA group and 20 in the TKA outside the limits of maximum and minimum age and follow-up time. (Figure 1)

The two groups were homogeneous in terms of age, sex, and follow-up time. (Table 1)

Regarding the results of the clinical functional questionnaire, 65.8% of the answers from the patients submitted to UKA were favorable, against 79.1% of those submitted to TKA.Such data was statistically significant (p< 0.0001).(Table 2)

There was no difference between groups regarding the satisfaction rate (P>0.999) (88.6% in the UKA and 91.2% in the TKA). (Table 3)

Regarding the complications rate there was no statistical difference between groups(p>0.5). (Table 4)

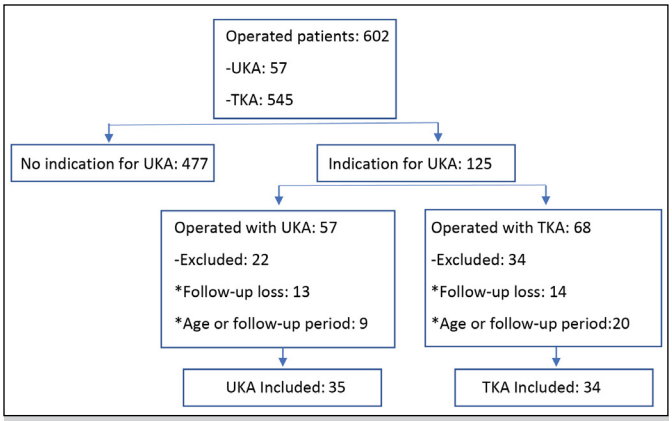

Figure 1. Study flowchart.

Table 1. Demographic data.

	UKA	TKA	P Value
Age (years)	64,1 ± 9,6	64,1 ± 6,9	0,998
Male n (%)	9 (25,7)	9 (26,5)	>0.999
Follow-up time (years)	25.8 ± 10,7	30,2 ± 9,7	0,072

Table 2. Clinical functional questionnaire.

	UKA	TKA	OR (CI 95%)	P Value
Favorable results	65.8%	79,1%	0,51 (0,36 - 0,72)*	<0,0001

* As a reference to the UKA; If the reference is the TKA, the OR is = 1.97 (1.39 - 2.78).

Table 3. Satisfaction rate.

	UKA (n=35)	TKA (n=34)	OR (CI 95%)	P Value
Satisfied or very satisfied	31 (88,6%)	31 (91,2%)	0,75 (0,18 - 3,00)*	>0.999

* Fischer’s exact test. OR concerning UKA; if reference is to TKA, it gets OR=1.33 (0.33 - 5.61).

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Table 4. Complications.

	UKA	TKA	OR (CI 95%)	P Value
Incidence of complications, n(%)	9 (25,7)	12 (35,3)	0,63 (0,22 - 1,70)	0.440
Superficial and deep infections, n(%)	3 (8,6)	5 (14,7)	0,54 (0,14 - 2,38)*	0.477
Readmission within 30 days, n(%)	1 (2,9)	3 (8,8)	0,30 (0,02 - 2,16)*	0.356
Revision surgery (aseptic loosening), n(%)	3 (8,6)	1 (2,9%)	3,09 (0,43 - 41,23)*	0,613

* Fischer's exact test.

DISCUSSION

This study showed that there was no significant difference between TKA and UKA concerning satisfaction, in patients with medial osteoarthritis.

The "TOPKAT" randomized clinical trial[8]showed a trend toward patients being more satisfied with the unicompartmentalarthroplasty, but no statistical difference between the groups. We found a trend in favor of the total knee arthroplasty but no statistical difference between groups. There was also no statistical difference regarding complications. Literature presents extensive retrospective studies demonstrating fewer complications in medial UKA and a higher number of revisions when compared to the TKA.[4,5,7] However, these studies compare groups of patients undergoing total and unicompartmentalarthroplasty without considering the degree of preoperative impairment. Therefore, in our study, we compared two homogeneous groups (medial focal osteoarthritis).This was possible because the unicompartmental medial prosthesis was not yet routinely performed by all surgeons in the group. Many patients were still unaware of this option, while some health insurances did not authorize this type of implant when the surgeries were performed. Therefore, many patients that would have a precise indication for medial UKA underwent total knee arthroplasty. The "TOPKAT" randomized clinical trial[8] also compared the results of unicompartmental and total knee arthroplasty in patients who had similar preoperative impairment degrees. It showed similar number of complications.In the same study,[8] the authors discuss that the higher numbers of complications shown in previous large retrospective studies[3-5]could be a consequence of the lack of experience of the surgeon where the unicompartmental surgery was performed. The results of our study did not confirm this thesis completely, although there was a higher number, but no statistical difference, of aseptic loosening in the unicompartmental prosthesis group.The follow-up of a higher number of patients may show a statistically significant difference.

The rate of favorable responses found about function and symptoms in the knee was higher in patients submitted to UKA compared to those submitted to TKA. This data differs from that found in the literature[8] and we believe that it may have been influenced by our team's less experience in performing unicompartmental arthroplasty compared to total arthroplasties at the time of the surgeries. Another fact that may have influenced the answers to the clinical and functional questionnaire is the tendency to create higher patient expectations of clinical and functional results with UKA because it is a less invasive and more preservative surgery when compared to TKA.

We found several limitations in our study. First, the average follow-up time was approximately two years, whereas we predicted durability of more than ten years in most arthroplasty cases.Second, the number of patients is limited for a retrospective cohort on this topic. Third, our patients are from a single center which limits the representativeness of the population. Fourth, we have no preoperative clinical or functional evaluation. Fifth, we did not do any objective functional tests on the patients, just a simplified, non-standardized questionnaire about clinical symptoms and signs. This may make it difficult to compare our results with other studies.

CONCLUSION

Patients with isolated medial osteoarthritis who underwent unicompartmentalmedial mobile bearing arthroplasty had the same degree of satisfaction and postoperative complication rate as patients who underwent total knee arthroplasty. These patients had less favorable clinical functional questionnaire answers than patients who had undergone TKA.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. JPFG: drafted and reviewed the article, performed statistical analysis and contributed to the intellectual concept of the study and the entire research project; VKJS: drafted the article, sought volunteers and analyzed the data; LBM drafted the article, sought volunteers and analyzed the data; LDP: drafted the article, sought volunteers and analyzed the data, VHJS: drafted the article, sought volunteers and analyzed the data, AOQ: reviewed the article and contributed to the intellectual concept of the study; PRB: performed statistical analysis and reviewed the article; MVD: reviewed the article and contributed to the intellectual concept of the study. All authors read and approved the final manuscript.

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PEDIATRICS ORTHOPEDIC

FLEXIBLE INTRAMEDULLARY NAILS IN PEDIATRIC SUBTROCHANTERIC FEMUR FRACTURE: BIOMECHANICAL STUDY

HASTES FLEXÍVEIS NA FIXAÇÃO DE FRATURA SUBTROCANTÉRICA DE FÊMUR PEDIÁTRICO: ANÁLISE BIOMECÂNICA

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ABSTRACT

Objective: Evaluate the stability provided by two flexible intramedullary nails (FINs) in a simulation of fractures at the proximal levels in pediatric femur models. Methods: Two FINs were inserted in 18 synthetic models of pediatric femurs. Fractures were simulated at one of three levels, and the models were divided into the following groups (n=6): diaphysis (control), subtrochanteric and trochanteric. Flex-compression tests were performed with force up to 85 N. Relative stiffness and the average deformation was obtained. Torsion tests were performed by rotating the proximal fragment until 20°, to obtain the average torque. Results: At flex-compression, the set's average relative stiffness and average deformations were: 54.360x10³ N/m and 1.645 mm in the control group, respectively. In the subtrochanteric group, the relative stiffness was 31.415x10³ N/m (-42.2%) and the deformation was 2.424 mm (+47.3%) ($p<0.05$). For the trochanteric group, the relative stiffness was 30.912x10³ N/m (+43.1%) and the deformation was 2.508 mm (+52.4%) ($p<0.05$). In torsion, the average torque was 1.410 Nm in the control group; 1.116 Nm in the subtrochanteric group (-20.8%), and 2.194 Nm in the trochanteric group (+55.6%) ($p<0.05$). Conclusion: FINs do not seem to be biomechanically competent for the treatment of proximal femoral fractures. ***Level of Evidence I; Therapeutic Studies - Investigating the results of treatment.***

Keywords: Femoral fractures. Fracture fixation, intramedullary. Hip fractures.

RESUMO

Objetivo: avaliar a estabilidade proporcionada por duas hastes intramedulares flexíveis na simulação de fraturas nos níveis proximais em modelos pediátricos de fêmur. Métodos: Duas hastes foram inseridas em 18 modelos sintéticos de fêmures pediátricos. As fraturas foram simuladas em um dos três níveis, e os modelos foram divididos nos seguintes grupos (n=6): diáfise(controle), subtrocantérico e trocantérico. Testes de flexão-compressão foram realizados com força de até 85N. A rigidez relativa e a deformação média foram obtidas. Os testes de torção foram realizados girando o fragmento proximal até 20°, para obter o torque médio. Resultados: Na flexo-compressão, a rigidez relativa média e as deformações médias do conjunto foram: 54,360x10³ N/m e 1,645 mm no grupo controle, respectivamente. No grupo subtrocantérico a rigidez relativa foi de 31,415x10³ N/m (-42,2%) e a deformação foi de 2,424 mm (+47,3%) ($p<0,05$). Para o grupo trocantérico a rigidez relativa foi de 30,912x10³ N/m (+43,1%) e a deformação foi de 2,508 mm (+52,4%) ($p<0,05$). Na torção, o torque médio foi de 1.410 Nm no grupo controle; 1,116 Nm no grupo subtrocantérico (-20,8%) e 2,194 Nm no grupo trocantérico (+55,6%) ($p<0,05$). Conclusão: As hastes intramedulares flexíveis não parecem ser biomecanicamente competentes para o tratamento das fraturas proximais do fêmur. ***Nível de Evidência I; Estudos terapêuticos - Investigação dos resultados do tratamento.***

Descritores*: Fraturas do fêmur. Fixação intramedular de fraturas. Fraturas do quadril.*

Citation: Cruz MAF, Battaglion LR, Volpon JB. Biomechanical analysis of flexible intramedullary nails in a simulated pediatric subtrochanteric femur fracture. Acta Ortop Bras. [online]. 2023;31(2)Esp.: Page 1 of 4. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Femur fractures represent approximately 1.6% of all bony lesions in children, with a 2.6 to 3.0 times higher incidence in boys than in girls.[1,2] In the last few decades, treatment strategies for these fractures have moved from a conservative management to a more rational approach that favours surgical treatment as a result of the development of implants specially designed for children. Therefore, conservative treatment is now reserved for infants, and surgical fixation is predominantly used for older children and adolescents.[3] The stabilization of diaphyseal fractures of the femur with a flexible intramedullary nail (FIN) inserted percutaneously decreases morbidity, provides stability, and does not disrupt callus formation.[3]

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

The study was conducted at the Bioengineering Laboratory, Ribeirão Preto School of Medicine, Universidade de São Paulo.
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The method is effective, quick, and easyly performed, with minimal complications to treat diaphyseal fractures of the immature femur.[4] Therefore, currently, FIN is used for treating patients older than 4 years of age or, even younger, when comorbidities are present such as obesity, spasticity, or poor bone quality.[5]

However, the utility of FINs is restricted when the fracture is excessively comminuted or when it is not located in the diaphysis of the bone.[6,7] Some studies tried to establish the limits for using FINs when the fracture is located in the distal metaphysis or in the subtrochanteric region. Volpon et al. created a bone defect at the transition site between the diaphysis and distal metaphysis in models of pediatric femur and found that the stability provided by FINs was not significantly compromised.[8] However, when the fracture is situated at proximal metaphysis the use of FINs is controversial.[9,10,11]

Based on this premise, the objective of the present investigation was to evaluate the mechanical stability provided by two FINs in simulated fractures (osteotomies) at the subtrochanteric and trochanteric regions in pediatric femur models.

METHODS

Eighteen femur models of synthetic bone corresponding to the femur of a nine-year-old child (Sawbone Inc., Pacific Research Laboratories Inc., WA, United States) were used. This synthetic bone has been validated for its mechanical properties being similar to those of human bones.[12,13]

Flexible titanium nails (Titanium Elastic Nail - TEN®, TiGa 114v, DePuy Synthes®, Switzerland) were used to fix osteotomies created at three levels in the femur models. The nails had a diameter of 3.5 mm, corresponding to approximately 74% of the diameter of the medullary canal. The implants were inserted in a retrograde manner and each model was then radiographed to ensure the correct positioning of the nails.

After nail insertion, the models randomly received a cut (osteotomy) at one of three levels to simulate the location of the fractures. Three groups were created (n=6 each): trochanteric (osteotomy at the level of the lesser trochanter); subtrochanteric (osteotomy 3.5 cm distal to the lesser trochanter); and the control (osteotomy at the mid-diaphysis).[14] Each osteotomy was complete and had an oblique inclination of 20° in the craniocaudal direction in the sagittal plane.

The groups were subjected to flex-compression in a universal testing machine (DL 10000; load cell 50 kgf, EMIC, PR, Brazil). The bone models were placed in an upright position but with a slight inclination of 7º in the varus position to simulate the *in vivo* load.[15] An axial compression force of up to 85.0 N was applied to the femoral head at a speed of 0.1 mm/s (Figure 1 A). The relative stiffness and deformation were obtained.

The same sets were placed into a torsion machine (55 MT; Instron®, MA, USA), so that the distal end was fixed and the proximal end rotated externally at a rate of 0.5°/s until 20º of rotation was attained (Figure 1 B) with determination of the torque.

Statistical analysis

Measurements of the central tendency of the mechanical tests, variability, and position were estimated. A normality test was performed by the Shapiro-Wilk method. The deformation (mm) and torque (Nm) variables were approached using analysis of variance and Tukey's test. The relative stiffness variable (N/m) was analysed by a Kruskal-Wallis test for multiple comparisons and by a Dunn test to determine the groups with significant differences. A significance level of 5% ($p<0.05$) was established. The software used was R, version 3.6.3 (The CORE TEAM, 2020, Vienna, Austria).

RESULTS

In flex-compression, the relative stiffness and deformation are shown in Table 1. At 85N, the relative stiffness values in trochanteric and subtrochanteric groups showed no difference between them ($p>0.05$), but their values were different from that of the control group ($p<0.05$) (Figure 2). The deformation in trochanteric and subtrochanteric groups was not different ($p>0.05$), but they were different from the control group ($p<0.05$) (Figure 3).

The mean torque values at 20° of rotation are shown in table 1. The control and subtrochanteric group values were significantly different from that of the trochanteric group ($p<0.05$), but there was no difference between the former two ($p>0.05$) (Figure 4).

DISCUSSION

Clinically, the fixation of fractures at the diaphysis of the femur with flexible intramedulary nails give good and uneventful outcomes, but the complications increase as the fracture is located more proximally.[10,11] Therefore, we simulated fractures at that level fixed with two flexible nail implants.

In fractures at the subtrochanteric region the proximal fragment tends to flex, abduct, and externally rotate due to the muscular action. There is also a strong mechanical lever caused by the angle between the diaphysis and femoral neck, which causes a substantial tendency to produce a varus deformity.[16] Such specific conditions lead to extraordinary mechanical demand on the implant. Clinical

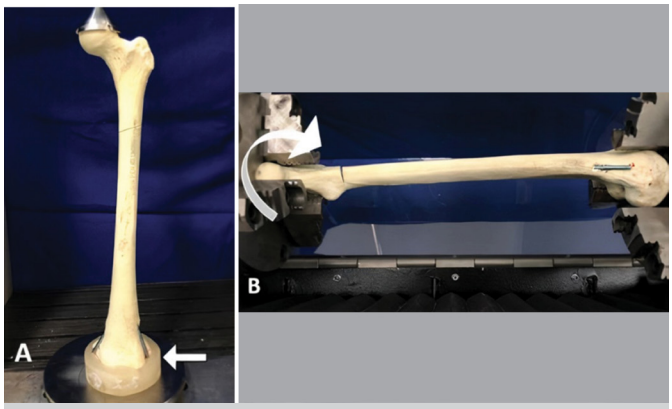

Figure 1. Mechanical tests. A - For flex-compression, the distal end of the femur was fitted into an acrylic model (white arrow), and a metal cup to simulate the acetabulum was fitted on the femoral head to receive the progressive vertical force. B - Torsion set up. The distal femur was held fixed and the proximal third was rotated externally until 20°.

Table 1. Overall results of the mechanical tests.

Groups	Mean	Median	SD	Minimum	Maximum	IQR
	Relative stiffness (x 10 N/m)					
Diaphysis	54.360	46.335	20.569	36.610	86.230	24.005
Subtrochanteric	31.415 (-42.2%)	31.510	6.416	24.590	39.590	10.198
Trochanteric	30.912 (-43.1%)	31.505	4.076	25.090	35.350	5.938
	Deformation (mm)					
Diaphysis	1.645	1.743	0.540	0.923	2.364	0.676
Subtrochanteric	2.424 (+47.3%)	2.358	0.492	1.805	3.016	0.750
Trochanteric	2.508 (+52.4%)	2.447	0.277	2.198	2.956	0.310
	Torque (Nm) - 20º angulation					
Diaphysis	1.410	1.478	0.322	0.906	1.749	0.410
Subtrochanteric	1.116 (-20.8%)	1.037	0.281	0.825	1.601	0.279
Trochanteric	2.194 (+55.6%)	2.178	0.123	2.030	2.390	0.104

SD indicates standard deviation IQR, interquartile range.

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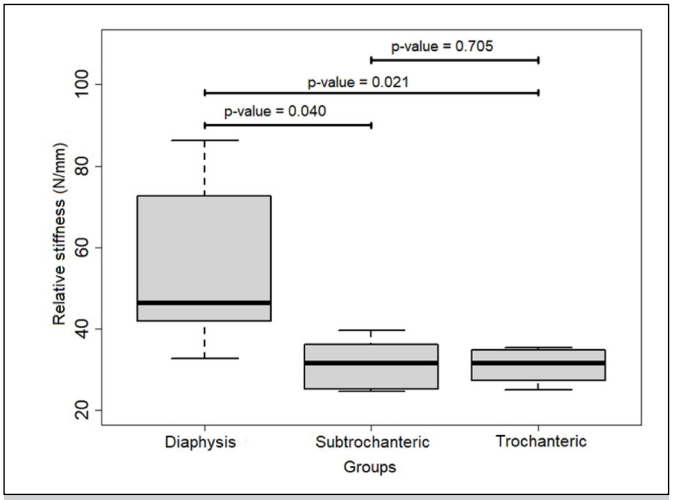

Figure 2. Box plot of relative stiffness in flexo-compression test. p-value<0.05 indicates statistical significance. Figure is presented as median and interquartile range.

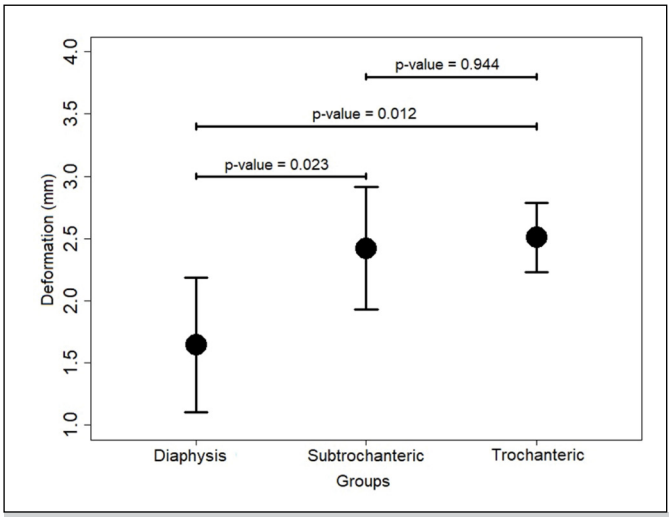

Figure 3. Error plot of deformation in flexo-compression test; p-value<0.05 indicates statistical significance. Figure is presented as mean and standard deviation.

data reported by Li et al. on the effect of major complications of elastic nails on the stabilization of the subtrochanteric fractures[9] support our results of flex-compression tests, which showed that a deformation in that region was around +149.8% of the value obtained in the mid-diaphyseal region. But we could not ascertain the ultimate limit of the deformation and the failure point of the systems because we worked in the mechanical elastic phase only. Other authors confirmed these findings and concluded that plates are better implants for proximal femoral fractures than flexible nails.[10,11] However, Xu et al. compared the fixation of subtrochanteric fractures in children with FIN and locking plates and found that two methods can result in good functional outcomes.[11] Some auhors presented a series of cases treated with FINs and showed that fracture located in the proximal region of the femur presented good outcome in children and adolescents and recommended using this

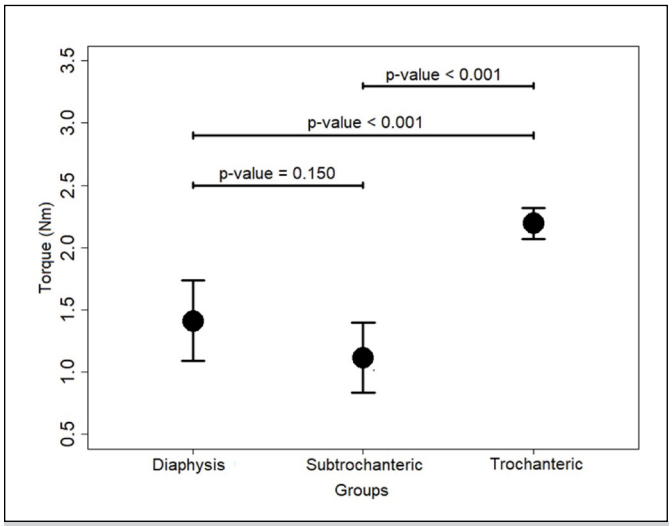

Figure 4. Error plot of torque in torsion test; p-value<0.05 indicates statistical significance. Figure is presented as mean and standard deviation.

technique.[17,18] Nevertheless, the number of patients were relatively limited in both reports, and the authors used spica casting or knee bracing to provide an extra stabilization.[17,18] More recently, Basa *et al.* evaluated 20 patients with subtrochanteric fracture treated with FIN and showed that all fractures obtained excellent or satisfactory results.[19] Furthermore, reduction loss was a less common complication than originally thought in paediatric patients.[19]

In the flexion-compression test a load of 85.0 N was applied to the systems. This value was selected after taking into account the mass of the non-weight bearing lower limb (approx. 8.5 kg). It was previously used by Volpon et al.;[8] additionally, this load allowed the deformation to be restricted to the elastic phase of the nails, thus fulfilling the objective of the study.

In torsion we found that the group of femurs with osteotomy in the most proximal region presented greater stiffness at 20° of rotation (+ 155% of the value in the control group). This may be explained by the greater contact area between the proximal and distal fragments in the area of cancellous bone. Neverheless, this parameter should be evaluated together with the other findings and not in isolation.

Our study has some limitations. First, both FINs were inserted retrograde. Maybe an anterograde insertion of one nail or penetrating the apophysis of the greater trocanter could increase the stability.[6,20] Second, we tested the implant behavior based on the forces applied without accounting for partial weight-bearing, and, third, mechanical tests do not mimic real fractures because the soft tissue influence are not considered. However, when mechanical tests are used, it has been found that they provide a good correlation with clinical results. In addition, they provide information that spare time and contribute to patient's safety.

CONCLUSION

Our results suggest that the stability provided by FINs in groups of proximal osteotomies may not be adequate for the use of these implants. Therefore, recommendation of using two FINs for treating children's proximal femur fractures is not supported by our results, and when using 3.5 mm flexible nails to stabilize subtrochanteric fractures, the addition of a brace or cast for 4 weeks is prudent.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. CMAF: acquisition, analysis, and interpretation of data and drafting of the manuscript. BLR: assisted in the mechanical tests and analysis of data; VJB: Initial study design, acquisition, analysis, and interpretation of data, drafting of the manuscript and final approval of the version to be published.

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PEDIATRICS ORTHOPEDIC

PREVALENCE OF POSTURAL CHANGES IN SCHOOL CHILDREN AND ADOLESCENTS

PREVALÊNCIA DE ALTERAÇÕES POSTURAIS EM CRIANÇAS E ADOLESCENTES ESCOLARES

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ABSTRACT

Objective: Investigate the prevalence of postural changes and correlate them with body weight and the weight of schoolchildren's backpacks in a school in the city of São João del-Rei-MG. Material and Methods: The study is an original type, with a cross-sectional design, where 109 schoolchildren of both sexes and mean age of 13 years were evaluated. The New York scale was used for posture analysis, measuring body weight, height, backpack weight, and Body Mass Index (BMI). The ANOVA statistical test and Pearson's correlation test were used, considering a significance level of 0.05. Results: According to the results, the general average of the scores of postural problems was 68.7 points, with a predominance in the head, spine, hips, trunk, and abdomen. The regions of shoulder, feet, and neck presented mean scores below seven. The mean height was 1.61 m, body weight 56.03 kg, backpack weight 4.49 kg and BMI was 21.51 kg/m. Conclusion: Postural alterations are highly prevalent among the evaluated students. The most affected body segments are the head, spine, hips, trunk, and abdomen. However, this finding was not related to the weight of the backpacks or the students' body weight. However, different parameters must be used to analyze the factors that may be related to such findings, such as ergonomic changes, inadequate habits, growth spurt, among others. ***Evidence Level III, Cross-sectional Observational Study.***

Keywords: Posture. Body weight. Students. Body mass index. Adolescent. Scoliosis.

RESUMO

Objetivo: Investigar a prevalência de alterações posturais e correlacionar com o peso corporal e o peso das mochilas dos escolares em uma escola no município de São João del-Rei-MG. Métodos: O estudo é do tipo original, com delineamento transversal onde foram avaliados 109 escolares, com média de idade de 13 anos, de ambos os sexos. A escala de Nova Iorque foi utilizada para análise de postura, medição do peso corporal, altura, peso da mochila e Índice de Massa Corporal (IMC). Foi utilizado o teste estatístico ANOVA e o teste de correlação de Pearson, considerando o nível de significância de 0,05. Resultados: De acordo com os resultados, a média geral dos escores dos problemas posturais foi de 68,7 pontos, com predomínio na região da cabeça, coluna, nos quadris, no tronco, e no abdômen. As regiões dos ombros, pés e pescoço apresentaram médias de escores menores que 7. A média da altura foi de 1,61m, do peso corporal de 56,03kg, do peso das mochilas de 4,49 kg e 21,51 kg/m do IMC. Conclusão: Conclui-se que existe uma alta prevalência de alterações posturais entre os escolares avaliados. Sendo que, os segmentos corporais mais comprometidos são, a cabeça, a coluna vertebral, os quadris, o tronco e o abdômen. No entanto, esse achado não foi relacionado ao peso das mochilas ou ao peso corporal dos escolares. Assim, diferentes parâmetros devem ser utilizados para analisar os fatores que podem estar relacionados a tais achados, como alterações ergonômicas, hábitos inadequados, estirão de crescimento, entre outros. ***Nível de Evidência III, Estudo Transversal Observacional.***

Descritores: *Postura. Peso corporal. Estudantes. Índice de Massa Corporal. Adolescente. Escoliose.*

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INTODUCTION

Postural deviations are prevalent problems in the adult population but are also identified in children and adolescents. The most common postural alterations in the population are anteroposterior changes (scoliotic manifestations), dorsal hyperkyphosis, and lumbar hyperlordosis.[1]

These postural deviations may be related to muscle imbalances that cause diversions at the positional or structural levels, *e.g.*, if

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The study was conducted at the Schools at the Municipality of São João Del-Rei, Minas Gerais, Brazil.
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the individual remains for a long time in a specific position, such as sitting, lying down, or standing.[2] Among other factors, the ones that stand out most when associated with postural changes and lower back pain in schoolchildren are sex,[1,3,4] body composition, excessive loads imposed on the individual daily, and the time spent in a specific position.[2]

Recent studies have found associations between the way students carry school bags and their total weight - below or above 10% of their total body weight[4,5] and lower back pain.[3] In the study by Barbosa et al.[6] associations were identified between backpack weight and postural changes among 5th and 9th grade students. However, the influence on postural changes in children and adolescents has not yet been elucidated.

The present study is extremely important because it investigated the prevalence of postural changes among schoolchildren and adolescents in São João del-Rei-MG, Brazil, seeing that such alterations develop in this age group, causing significant musculoskeletal limitations in the adult phase of these individuals. The identification and prevention of these disorders can benefit these children and adolescents regarding the awareness of how backpacks should be transported and how important an adequate body composition is for the quality of life of students.

Based on this knowledge, it will be possible to guide public health programs that can intervene early to improve the quality of life of these children and adolescents.

Thus, the present study aimed to investigate the prevalence of postural changes and analyze whether such changes correlate with the body weight or backpack weight of schoolchildren and adolescents aged between 11 and 15 years old in a school in the city of São João del-Rei-MG, Brazil.

METHODS

This descriptive, cross-sectional study was carried out in August 2019 in a public school in the city of São João del-Rei, Minas Gerais, Brazil.

Sample

The evaluated school has 150 students, and 109 students were evaluated in August 2019 (punctual prevalence), aged between 11 and 15 years (average age 13 years) and of both sexes, who agreed to participate in the present study. Their guardians signed the Free and Informed Consent Term at the time of registration, according to Resolution No. 466/2012 of the National Health Council. The anonymity and confidentiality of the research subjects' data were guaranteed.

Instruments and Procedures

The New York scale was used for the postural assessment of the students, where 10 different body segments were analyzed, adopting the following scores: 10 for normal posture; 5 for moderate postural alterations, and 0 for severe postural alterations. The scale is visual where the observer identifies the body alignment of the individual who is positioned in the anterior, profile and posterior view. It is a scale widely used among researchers in the area. The postural classification was obtained by adding the scores of each item. Scores between 56-65 were considered normal posture; between 40-55 moderate postural change, and between 01-39 points severe postural change. Each individual's posture was evaluated in the dorsal and anterior view (frontal plane), including the head, shoulders, spine, hips, feet, and plantar arch regions, and in the lateral view (sagittal plane), including the neck, chest, shoulders, thoracic spine, torso and pelvis, lumbosacral spine, and abdomen. The postural assessment lasted an average of 2 minutes. First, a screen was placed, and a 4-meter fixed support plumb was hung in front of the screen. A line of adhesive tape was placed on the floor directly below the plumb line, perpendicular to the screen. A distance of three meters from the examiner was considered. Each examined individual was positioned between the screen and the plumb line, facing the screen for the first part of the evaluation and then in profile position for the second part of the evaluation. The plumb line passed directly through the midline of the students' chest.[7]

Another trained evaluator measured their height and body weight. In order to assess height, a portable stadiometer for adults was used, with a retractable tape measure with an extension of up to 210 cm. A portable electronic scale was used to determine the students' body weight, with a capacity of 150 kilograms (kg) and a graduation of 100 grams (g). At the same time, another evaluator weighed the students' backpacks containing school supplies using a portable electronic scale, with a capacity of 150 kg and a graduation of 100 g.

Statistical analysis

The data were assessed by analysis of variance (ANOVA) and Pearson's correlation test, considering a significance level of 5%. The analysis was performed using the GraphPad Prism 5.0 statistical program.

RESULTS

The data of the present study identified that all the children evaluated presented some alteration or postural deviation in some region of the body. The overall mean score of postural changes found was 68.7 points. Significant changes were observed in the head region, with a score of 7.5; in the spine, with a score of 7.45; in the hips, with 7.36; in the torso, with 7.77; and in the abdomen, with 7.86. The shoulders, feet, and neck regions had mean scores lower than 7, as shown in Table 1.

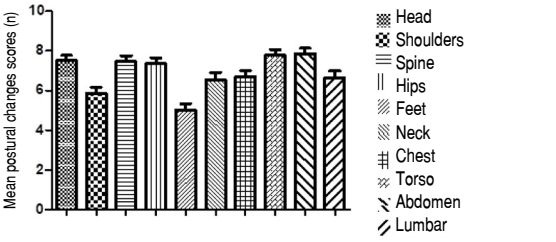
The data presented in Figure 1 demonstrate a significant difference between the mean scores of the postural changes of the analyzed body segments ($p=0.00018$; $F=8.7431$).

General data related to height, body weight, and the weight of students' backpacks were analyzed, as shown in Table 2, where the following values were observed: mean height of 1.61 m; mean body weight of 56.03 kg; mean backpack weight of 4.49 kg. The mean BMI was 21.51 kg/m.

There was no correlation between the postural changes x backpack weight ($p=0.2765$; $r=0.10516$); body weight x backpack weight ($p=0.8690$; $r=-0.015976$); body weight x postural changes ($p=0.7902$; $r=0.025651$). There was, however, a correlation between body weight x height ($p=0.00013$; $r=0.47214$). A difference was observed among the means of the postural changes analyzed ($p=0.0028$; $F=8.7431$).

Table 1. Mean scores of the postural evaluation scale per body segment.

Analyzed Body Regions	Mean Scores of the Scale
Head	7.5
Shoulders	5.86
Spine	7.45
Hips	7.36
Feet	5
Neck	6.54
Chest	6.68
Torso	7.77
Abdomen	7.86
Lumbar	6.64



	Head	Shoulders	Spine	Hips	Feet	Neck	Chest	Torso	Abdomen	Lumbar
Mean	7,5	5,86	7,45	7,36	5,00	6,54	6,68	7,77	7,86	6,63
Standard	2,77	3,17	3,16	2,92	3,65	3,76	3,41	2,99	2,75	3,59
Deviation	0,26	0,30	0,30	0,28	0,35	0,32	0,32	0,29	0,26	0,34

Figure 1. Mean postural changes of the body segments.

Table 2. Means of the general parameters analyzed among the students.

Height (m)	1.61
Body Weight (kg)	56.03
Weight of the Backpacks (kg)	4.49
Total Score on the Postural Changes Scale (No.)	68.67
BMI (kg/m)	21.51

DISCUSSION

The data obtained in the present study showed that the overall mean of the postural changes scale did not present high means among the children, in which the final score was 68.67 points. However, significant changes were observed in regions such as the head, spine, hips, torso, and abdomen. This corroborates the study by Ugras *et al.* (2010),[3] where postural changes were also evidenced among children between 10 and 14 years old. In that study, 72.2% of the children had scoliosis (Cobb) angles between 10 and 20°, while 27.3% had Cobb angles greater than 20°. The study by Chaves *et al.* (2017)[2] also revealed a high incidence of postural changes in the cervical region, the head, shoulders, thoracic spine, the lumbar area, and the lower limbs among students between 10 and 18 years old.

According to Reis-Diniz *et al.* (2012),[8] during adolescence, the growth spurt occurs, and ergonomic, genetic, and lifestyle-related factors can favor the appearance of postural changes at this stage of life. Another event that favors the occurrence of postural changes is obesity. According to Brandalize and Leite (2010),[9] obesity worsened the posture of adolescents, contributing to the appearance of postural changes. In the study by Barbosa et al. (2019)[6] higher weights were found in the backpacks of overweight and obese students.

In the present study, obesity was not evidenced among the children analyzed, where the mean body weight was 56 kg and the BMI was 21.51 kg/m for children with a mean age of 13 years. No correlation regarding postural changes, body weight, and the BMI of the children evaluated was found since the correlation index was 0.0089 ($p>0.05$).

According to the Brazilian Society of Pediatrics (2017), children with BMIs of more than 21.5 and a mean age of 13 years are considered overweight (Ministry of Health, 2017).[10] Bravin (2016)[11] stated in her study that the prevention of childhood obesity with physical activity is essential to reduce diseases in this population. The author mentioned that the appearance of diseases such as metabolic disorders, diabetes, and postural changes is common in this population.

In the present study, no correlation was found between backpack weight and the children's postural assessment scores. In the studies by Mattioli et al. (2017)[12] and Batista et al. (2016),[4] the authors stated that the ideal weight for backpacks should be 10% of the student's body weight. In the two studies, it was observed that most of the evaluated students carried backpacks weighing more than 10% of their body weight.

The mean weight of the student's backpacks herein was 4.5 kg, which corresponds to 8% of the students' body weight. Thus, such percentage does not significantly impact their posture, indicating that the postural changes evidenced in this study were not related to the mean weight carried in the students' backpacks. In the study by Alami et al (2020),[13] weights were found in students' backpacks that were greater than 10% of their body weight. In the study by Kafle (2020),[14] weight overload in students' backpacks was also evidenced, correlated with the presence of musculoskeletal pain. The author concluded that there a correlation between excessive weight carried in the backpack with the appearance of postural changes and pain among students.

In the study by Lekpa et al. (2021)[15] who evaluated 1070 schoolchildren in Douala, Cameroon, no correlations were observed between the weight of backpacks and the presence of low back pain. In study, the mean weight of backpacks below 10% of the students' body weight was also found, and the factors associated with low back pain were female sex, practice of competitive sports, sitting position and low back pain in the evaluated family members. In the work by Alfageme-García et al. (2020)[16] carried out among students who had a neutral foot and carried high weights in their backpacks, it was evidenced the development of pronated foot among students after 3 years.

Postural changes in students may have different triggering factors, and body weight and backpack weight are not parameters directly related to the appearance of these changes.[17-20]

Study limitations

One limitation in the present study was that it was carried out at only one school in the interior of Minas Gerais, Brazil. Further studies are needed in other elementary and secondary education institutions, as well as in private institutions, for comparisons with the data obtained at this public institution.

CONCLUSION

It is concluded that there is a high prevalence of postural alterations among the evaluated students. The most affected body segments are the head, spine, hips, trunk and abdomen. However, this finding was not related to the weight of the backpacks or the body weight of the students. Thus, different parameters must be used to analyze the factors that may be related to such findings, such as ergonomic changes, inappropriate habits, growth spurt, among others.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. BBR; PSA; MAS; PSS; MVA; ACG; LCMD; PCS: Substantial contribution to the conception or design, or acquisition and data analysis.

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PEDIATRICS ORTHOPEDIC

PROXIMAL HUMERAL LOCKING PLATE: A VIABLE ALTERNATIVE FOR FIXATION OF DISTAL FEMORAL FRACTURES IN CHILDREN

PLACA DE FIXAÇÃO DE ÚMERO PROXIMAL: UMA ALTERNATIVA PARA FIXAÇÃO DE FRATURAS DO FÊMUR DISTAL EM CRIANÇA

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ABSTRACT

Distal femoral metaphyseal fractures are rare in children, and the proximity of the fracture to the growth plate makes their approach challenging. Objective: Evaluate outcomes and complications of treatment of distal femoral metaphyseal fractures in children with proximal humeral locking plates. Method: Retrospective study between 2018 and 2021, including seven patients. The analysis included general characteristics, trauma mechanism, classification, clinical and radiographic outcomes, and complications. Results: The mean follow-up was 20 months, the average age was nine years, five patients were boys, and six fractured on the right side. Five fractures were caused by car accidents, one by falling from their own height and one by playing soccer. Five fractures were classified as 33-M/3.2 and two as 33-M/3.1. Three fractures were open, Gustilo IIIA. All seven patients recovered mobility and resumed their pre-trauma activities. All seven healed, and one fracture was reduced to 5 degrees valgus, without any other complications. Six patients had the implant removed and did not present refracture. Conclusion: Treatment of distal femoral metaphyseal fractures with proximal humeral locking plates is a viable option that offers good results and fewer complications, saving the epiphyseal cartilage. ***Level of Evidence II; Controlled study without randomization.***

Keywords: Surgical Procedures, Operative. Femoral Fractures. Children.

RESUMO

As fraturas metafisárias distais do fêmur são raras em crianças, a proximidade da fratura com a placa de crescimento torna a sua abordagem desafiadora. Objetivo: Avaliar resultados e complicações do tratamento das fraturas da metáfise distal do fêmur em crianças com placas de úmero proximal. Método: Estudo retrospectivo entre 2018 e 2021 incluindo sete pacientes. A análise incluiu características gerais, mecanismo do trauma, classificação, resultados clínicos, radiográficos e complicações. Resultados: A média do acompanhamento foi de 20 meses, a idade média foi de nove anos, cinco pacientes eram meninos e seis fraturas do lado direito. Cinco fraturas por acidentes automobilísticos, uma por queda da própria altura e uma jogando futebol. Cinco fraturas classificadas como 33-M/3,2 e duas como 33-M/3,1. Três fraturas foram expostas, Gustilo IIIA. Todos os sete pacientes recuperaram a mobilidade e retomaram às atividades anteriores ao trauma. Todas as sete fraturas consolidaram, uma fratura foi reduzida com valgo de 5 graus, e não houveram outras complicações. Seis pacientes tiveram o implante removido e não apresentaram refratura. Conclusão: O tratamento das fraturas da metáfise distal do fêmur com placas de úmero proximal é uma opção viável que oferece bons resultados com poucas complicações, poupando a cartilagem epifisária. ***Nível de Evidência II; Estudo controlado sem randomização.***

Descritores: *Procedimentos cirúrgicos operatórios. Fraturas do fêmur Crianças.*

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INTRODUCTION

Fractures of the distal metaphysis of the femur are relatively uncommon in pediatric patients and correspond to 12% of all femoral fractures in this population.[1] The treatment choice for these pediatric fractures generally depends on several factors, including age, body weight, trauma energy, and occurrence of associated injuries and open fracture.[2] Most children younger than 6 years who present with closed fractures and without other injuries should receive conservative treatment with closed reduction and cast immobilization. However, treating these fractures can be challenging in pediatric patients older than 6 years, particularly when surgical fixation is required, since no consensus exists regarding the optimal implantation technique in this setting. The most critical challenges in selecting the implants are to ensure that they offer stability until the fracture

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consolidates and to prevent physeal injury during insertion of the implant. Often, the area between the fracture line and the distal femoral physis is very narrow, and it becomes difficult to insert the implant without damaging this critical growth region. (Figure 1)[3]
The literature describes several techniques for surgical fixation of distal femoral fractures in children. These include percutaneous fixation with Kirschner wires, monolateral and circular external fixation, elastic intramedullary nailing, submuscular bridge plating, and open reduction and internal fixation with plates.[4]
Stabilization of distal femoral fractures using proximal humeral locking plates has been described by Abdelgawad et al.[5] and is also used by Bor et al.[6] The shape of the plate adapts well to the lateral cortex of the distal femur, and the design of the plate allows screws to be inserted in multiple planes in this small distal fragment without violating the distal physeal plate.
Based on these considerations, the aim of this study was to evaluate the results and complications of treating distal metaphyseal fractures of the femur using open reduction and fixation with proximal humeral locking plates in children and adolescents.

MATERIALS AND METHODS

Retrospective study conducted between 2018 and 2021 at a tertiary trauma hospital. We reviewed the medical records of skeletally immature patients with fractures of the distal end of the femur stabilized with proximal humeral locking plates. (Figures 2)
The data analyzed included the patients' sex and age at the moment of the trauma, the side of the fracture (right or left), the mechanism of the injury, the classification of the fracture according to the AO Pediatric Comprehensive Classification of Long Bone Fractures,[7] the associated injuries (if present), and the occurrence of open fracture according to Gustilo & Anderson.[8]
We also evaluated whether the patient received any treatment before the definitive fixation, the duration of hospital stay, the occurrence of events during follow-up, and information about removal of the plate.
Outcomes and complications were assessed by the degree of knee joint mobility after surgery, fracture consolidation, return to previous activities, and occurrence of angular deviation, leg length discrepancy, growth disorder, and infection.
We excluded patients with incomplete medical record data, skeletal immaturity, and follow-up shorter than 1 year.

Figure 1. Heim's square.

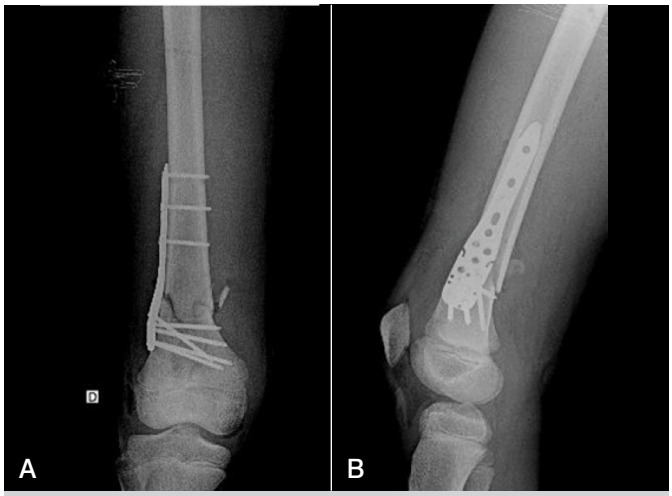

Figure 2. (A and B) Immediate postoperative images of one of the patients with fracture of the distal femoral metaphysis that received fixation with a proximal humeral locking plate. Left: anteroposterior view; right: lateral view.

The study's protocol was approved by the institution's research ethics committee (CAAE: 41066020.2.0000.5225) according to the Brazilian National Health Council Resolutions 196/96 and 251/97.

RESULTS

Eight pediatric patients with fractures of the distal end of the femur were treated with open reduction followed by fixation with proximal humeral locking plates between 2018 and 2021 at our institution. After excluding one patient with a follow-up shorter than 1 year, the final analysis included eight patients.
Five of the patients were boys, and six fractures affected the right side. The median age of the patients at the moment of the trauma was 9 years (range 8–13 years). Five patients had fractures due to high-energy trauma from motor vehicle accidents: one was hit by a truck, and three were involved in motorcycle-car, bicycle-car, and car-car collisions. One patient had a spastic cerebral palsy with bone fragility and presented the fracture after falling on the same level, and the another one broke his femur playing soccer, he had a non-ossifying fibroma (NOF).
Three patients had associated injuries - one had an associated ipsilateral leg fracture (floating knee), one presented with associated pulmonary contusion, grade IV liver injury, and iliac wing fracture, and the other had a NOF.
Based on the AO classification, five fractures were classified as 33-M/3.2 and two as 33-M/3.1. Three fractures were open and classified as type IIIA according to Gustilo & Anderson. (Table 1)
Five patients had received provisional treatment before the definitive fixation. All three patients with open fractures had undergone cleaning, debridement, and external fixation, while the two other patient - who had a closed femoral fracture due to a car accident - had received external fixation.
The median duration of hospital stay was 9 days (range 2–31 days), and the median duration of follow-up was 20 months (range 12–41 months).
All patients present complete recovery of mobility (Table 2), and all fractures consolidated. One patient had a 5-degree valgus deviation that was maintained during fixation and remained until final consolidation, with no deviation in antecurvatum or recurvatum.
All seven patients were able to resume the same activity level they had before the fractures. (Figures 3)

Table 1. General characteristics of the patients included in the study.

Patient	Age (years)	Sex	Mechanism of trauma	AO classification	Type of fracture
1	8	Female	Car-car collision	33-M/3.1	Closed
2	8	Male	Hit by a truck	33-M/3.2	Open GA IIIA
3	9	Female	Fall on the same level	33-M/3.2	Closed
4	12	Male	Bicycle-car collision	33-M/3.2	Open GA IIIA
5	13	Male	Motorcycle-car collision	33-M/3.2	Open GA IIIA
6	10	Male	Playing soccer	33-M/3.1	Closed
7	12	Male	Car-car collision	33-M/3.2	Closed

Source: Authors (2021). Abbreviations: AO classification, AO Pediatric Comprehensive Classification of Long Bone Fractures; GA IIIA, Gustilo & Anderson classification type IIIA.

Table 2. Surgical results and complications among the patients included in the study.

Patient	Postoperative mobility	X-ray	Physeal injury	Leg length discrepancy
1	0 – 135°	No deviation	No	No
2	0 – 140°	No deviation	No	No
3	0 – 130°	5-degree valgus	No	No
4	0 – 140°	No deviation	No	No
5	0 – 135°	No deviation	No	No
6	0 – 140°	No deviation	No	No
7	0 – 140°	No deviation	No	No

Source: Authors (2021).

Figure 3. (A, B and C) Preoperative, immediate postoperative, and 1 year after surgical fixation of fracture of the distal end of the femur with posterior humeral locking plating.

There were no cases of infection, physeal injury, or leg length discrepancy.

Six patients had the locking plates removed and presented no refracture. In the remaining two patients, the fractures have consolidated and the removal of the implant has been planned.

DISCUSSION

Fractures of the distal end of the femur are the most uncommon types of fractures affecting this bone. These fractures usually result from high-energy trauma and develop intrinsic instability when presenting with deviations.[3] This poses a problem for the surgeon, who must reduce the fracture and offer optimal stabilization until consolidation. In younger children, fixation of these fractures with crossed Kirschner wires is sufficient. However, older children require a more stable fixation. The narrow fragment between the fracture and the growth plate makes it extremely difficult to obtain stability of the fracture without damaging this critical structure.

Butcher & Hoffman[9] described 10 fractures of the distal femur treated with reduction and percutaneous fixation with crossed Kirschner wires. Six patients presented good results, two progressed with a flexion deformity of 10 degrees, one progressed with a valgus deformity of 6 degrees, and one patient had a transient common peroneal nerve palsy. Although crossed-wire fixation is an excellent method to treat younger children with distal femoral fractures, this therapeutic strategy is not sufficient to stabilize the fixation in adolescents.

Canavese et al.[3] treated 24 patients with fractures of the distal femoral metaphysis using elastic stable intramedullary nailing and observed two pseudoarthrosis and three fracture deviations. Long leg casting was used for 3 to 4 weeks to reduce pain and prevent further deviations.

Li et al.[10] compared the treatment of distal femoral fractures using external fixation versus elastic stable intramedullary nailing and observed similar clinical and radiographic results with both techniques. Compared with elastic intramedullary nailing, external fixation had the advantage of a shorter operative time and obviated the need for another surgical procedure for hardware removal, but had the disadvantages of more frequent pin tract infection, soft tissue irritation, and pain site scarring. External fixation was also associated with two refractures within 1 month from the hardware removal.

Sabharwal[11] reported optimal results after treating five fractures of the distal femoral metaphysis using circular external fixation. The author reported no need for pin repositioning due to infection, and all patients recovered knee and hip mobility 3 months after the fixator was removed, while one patient developed transient foot drop.

Kanlic et al.[12] used submuscular bridge plating to treat 51 femoral fractures, of which only 6% affected the distal metaphysis. The authors reported good results with the method. However, they described one patient in whom only one plate screw (PCL) would be available for fixation of the distal fragment and proceeded with fixation of the epiphysis using two screws to ensure more stability but increased the risk of physeal injury. In most distal metaphyseal fractures of the femur in children, fixation of the distal fragment using three screws is not feasible, which is the major problem with conventional compression plates (DCP and LCP).

To increase the stability of the fixation in distal femoral fractures, Lin et al.[4] described good results and no implant fractures with an interchangeable titanium plate with three screw holes in the distal femoral epiphysis and another plate that adapts to the first one, thus allowing the fixation of both to the proximal fragment of the femur. However, this adaptation of one plate over the other weakens the fixation. Additionally, the fixation of the epiphysis increases the chance of physeal injury.

In an attempt to provide more stability to the fixation of the distal metaphysis fragment without violating the physeal plate, Abdelgawad et al.[5] described two distal femoral fractures treated with proximal humeral locking plates, reporting good results and no physeal injury.

Proximal humeral locking plates have the advantage of adapting well to the contour of the distal femur, allowing the fixation of the distal fragment with up to six screws, depending on the fracture line. The screws can be placed in multiple planes — divergent, convergent, and straight — providing greater stability. A disadvantage is the width of 3.5 mm of the humeral plate, which may not offer sufficient stability in larger patients.

In our series, five fractures were comminuted and two was transverse. Five patients had suffered high-energy trauma. After the initial stabilization, all fractures consolidated without further deviation. Fixation of a fracture in a patient with cerebral palsy and bone fragility was performed with a residual valgus deformity of 5 degrees, which was maintained until final consolidation. We observed no physeal injuries, angular deviations, or leg length discrepancies.

Three fractures were open, and none of the patients presented postoperative infection or vascular or nerve damage. All patients returned to the activity levels that they had before the trauma.

A 13-year-old patient with floating knee had an open comminuted grade IIIA fracture. Even though the proximal humeral plate was only 3.5 mm wide, it provided sufficient stability for consolidation of the fracture without further deviation in this patient. (Figures 4)

We removed the plates from six patients, while the remaining one patient is waiting to schedule the procedure to avoid valgus deviation due to plate retention, as described by Kelly et al.[13]

The present study is limited by the retrospective design and the small number of cases, explained by the rarity of these fractures. Compared with other studies in the literature evaluating proximal humeral locking plates to treat distal femoral fractures in children, ours is the one with the largest number of patients.

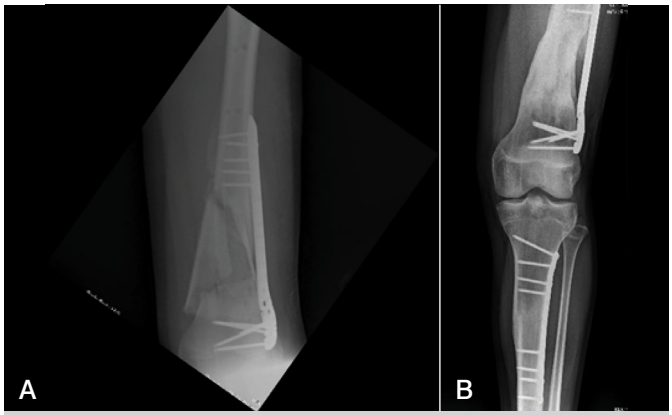

Figure 4. (A and B) A 13-year-old patient with floating knee and an open comminuted femoral fracture (grade IIIA). Left, immediate postoperative period; right, 13 months after surgery.

CONCLUSION

In conclusion, proximal humeral locking plating is a viable fixation option to treat distal femoral metaphyseal fractures in children and adolescents without violating the physis and yielding good results with few complications.

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FIXATION METHODS IN LATARJET: BIOMECHANICAL COMPARISON OF SCREW TYPES AND PLATE FIXATION

MÉTODOS DE FIXAÇÃO EM LATARJET: COMPARAÇÃO DE TIPOS DE PARAFUSOS E FIXAÇÃO DE PLACAS

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ABSTRACT

Objective: Latarjet procedure is often preferred in recurrent shoulder dislocations accompanied by glenoid bone loss. It is observed that the superiority of bone graft fixation methods is still controversial. The aim of this study is to biomechanically compare the bone graft fixation methods in the Latarjet procedure. Methods: 15 third-generation scapula bone models were divided into 3 groups. Graft was fixated in the first group with fully-threaded cortical screws of 3.5mm diameter, in the second group two 16 mm partially-threaded cannulated screws of 4.5mm diameter, and in the third group via a mini plate and screw. The hemispherical humeral head was placed on the tip of the cyclic charge device, and thus, the charge applied to the coracoid graft was homogeneous. Results: No statistically significant difference was found between paired comparisons ($p>0.05$). The forces in 5 mm displacement in total vary between 502-857N. Total stiffness measurements ranged between 105 and 625; the mean value was 258.13±53.54 with no statistically significant difference by groups ($p = 0.958$). Conclusion: This biomechanical study showed that there is no difference between three coracoid fixation options in terms of fixation strength. Unlike previous assumptions, plate fixation is not biomechanically superior to screw fixation. Surgeons should consider their personal preferences and experience in choosing fixation methods.

Keywords: Shoulder joint. Surgical procedures, operative. Biomechanical phenomena.

RESUMO

Objetivo: O procedimento Latarjet é normalmente preferencial em deslocamentos recorrentes do ombro acompanhados por perda óssea da glenóide. Observa-se que a superioridade dos métodos de fixação dos enxertos ósseos ainda é controversa. O objetivo deste estudo é comparar biomecanicamente os métodos de fixação de enxerto ósseo no procedimento Latarjet. Métodos: 15 modelos de escápulas de terceira geração foram divididos em 3 grupos. O enxerto foi fixado no primeiro grupo com parafusos corticais totalmente rosqueados com 3,5 mm de diâmetro, no segundo grupo com dois parafusos canulados parcialmente rosqueados de 16 mm de diâmetro de 4,5 mm e no terceiro grupo através de miniplaca e parafuso. A cabeça hemisférica umeral foi colocada na ponta do dispositivo de carga cíclica e, desta forma, a carga aplicada ao enxerto coracoide foi homogênea. Resultados: Nenhuma diferença estatisticamente significativa foi encontrada entre as comparações pareadas ($p>0,05$). As forças em 5 mm de deslocamento no total variam entre 502-857N. As medidas de rigidez total variaram entre 105 e 625 e o valor médio foi 258,13±53,54, sem diferença estatisticamente significativa por grupos ($p = 0,958$). Conclusão: Este estudo biomecânico mostrou que não há diferença entre três opções de fixação de coracoides em termos de resistência à fixação. Ao contrário de suposições anteriores, a fixação de placas não é biomecanicamente superior à fixação de parafusos. Os cirurgiões devem considerar suas preferências pessoais e sua experiência na escolha de métodos de fixação.

Descritores: *Articulação glenoumeral. Procedimentos cirúrgicos operatórios. Fenômenos biomecânicos.*

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<< SUMÁRIO

INTRODUCTION

Capsulolabral repair procedures, so called Bankart repair, and coracoid bone block transfer procedures are two options for surgical management of anterior shoulder instability that are currently used in clinical practice.[1] However; in the setting of recurrent anterior shoulder instability, caution should be paid to osseous structure of the glenoid as it is an important factor for clinical outcomes.[2,3] Isolated capsulolabral repair in management of recurrent shoulder instability with significant glenoid bone loss is associated with high recurrence rates.[4,5] Presence of bony defects on glenoid and humeral head or insufficiency of soft tissue which is required to perform a capsulolabral repair are main indications for coracoid bone block transfer procedures which have become the gold standard for treatment of recurrent anterior shoulder instability with various techniques described.[6]

Latarjet procedure has been used with an increasing frequency and has become the gold standard treatment for treatment of recurrent shoulder instability with glenoid bone defect since its first description in 1954.[7] This procedure consists of transfer of coracoid process, like Bristow procedure, along with conjoined tendon through a split of subscapularis muscle to anteroinferior portion of the glenoid[8,9] and has been demonstrated to be very successful in treatment of shoulder instability in young athletes with bony defects or in patients with hyperlaxity.[10,11]

Stable and strong initial fixation of transferred bone block is a prerequisite for success of this procedure in order to minimize the risk of non-union and to initiate a reliable rehabilitation with early mobilization. Non-union was reported to be one of the most common causes of recurrence and it has been shown that failure mechanism was triggered by non-union in 42.3% and by graft resorption in 23.1% of the cases.[12,13] Despite multiple modifications; rationale of this procedure mostly remains the same. Fixation of the coracoid process most commonly performed using two parallel screws with good long-term outcomes and high fusion rates.[14,15] Different implants for fixation have also been proposed such as interference screws[15] or plates.[16] Many previous studies comparing different fixation methods have been conducted as the importance of the initial stability and strength of coracoid fixation was understood.[15,17-19]

Fixation of coracoid graft using mini-plate has been favored by some authors with consideration of stronger initial fixation, better stability, uniform load distribution between graft and glenoid and therefore faster union.[20] However; to our knowledge, there are no biomechanical study comparing fixation strength of mini-plate to other fixation implants in current literature.

The purpose of this biomechanical study was to compare strength of initial fixation, load-to-failure and mode of failure of Latarjet procedure performed by two cortical screws, two partially-threaded cannulated screws and mini-plate. We hypothesized that there would be no significant biomechanical difference among three fixation methods.

METHODS

This study was approved by the institutional review board and was performed in accordance with the principles of the Declaration of Helsinki. The ethics committee protocol approval number is 2017-475636. Fifteen third-generation scapula bone models (Selbone®) were obtained. A bony defect which covers 25% of the articular surface of glenoid on anteroinferior portion was created by cutting saws using a template adapted to glenoid surface of each bone model similarly as described by Itoi et al.[21] Afterwards, each bone model underwent coracoid transfer procedure according to the technique described by Latarjet.[7] Coracoid osteotomy was performed using a 10x0.5 mm cutting saw at coracoid base with graft length 20-25 mm. The concave inferior surface of the coracoid process was rasped and flattened in order to obtain a better fixation into the defective region of glenoid.

Fifteen samples were allocated into 3 groups. Group 1 consisted of fixation using two 3.5mm fully threaded cortical screws (Response Ortho NJ, USA). In second group, fixations were performed using two 16 mm partially threaded cannulated screws with 4.5mm diameter (Response Ortho NJ, USA) and in third group, mini plate and screws (Arthrex®, USA) were used for fixation.

In group 1, following the creation of glenoid defect and coracoid osteotomy, two holes were drilled through coracoid graft using a 3.5mm cannulated drill bit over two parallel Kirschner wires. Then, the coracoid graft was positioned onto defective glenoid area flush with or slightly embedded (<1mm) to articular surface and two glenoid holes were drilled through two holes which were drilled on coracoid graft using a 2.5mm drill bit while holding the graft in correct position. Fixation was then performed using two 3.5 mm fully threaded cortical screws at appropriate length following length measurements and specimens were prepared for tests. (Figure 1)

In group 2, coracoid graft was positioned in a similar way to group 1 and temporarily fixed to glenoid using two parallel Kirschner wires. Then both coracoid graft and glenoid holes were drilled using a 3.2mm cannulated drill bit over these K-wires. Following length measurements, fixation was performed using two 16 mm partially threaded cannulated screws of 4.5mm diameter. After ensuring that the threads of cannulated screws are attached to the glenoid neck, which is the most distal cortex, in order to avoid rotational displacement, K-wires were removed and specimens were prepared for tests. (Figure 1)

In group 3, osteotomized coracoid graft was positioned to the defective area similarly to group 1 and group 2 and temporarily fixed using two parallel K-wires paying attention to plate hole positions. Then, both graft and glenoid holes were drilled using a 3.2mm cannulated drill bit. Following length measurements, plate was inserted over K-wires and fixation was performed using two 4.5 mm partially-threaded cannulated screws. Attention was paid that notches of the plate were in contact with graft cortex and compressed the coracoid. (Figure 1)

Each specimen was inserted into a round-shaped, polyvinyl chloride container filled with polyester paste and benzoyl peroxide, which is a hardener and accelerator, and held in adequate position until the specimen is solidified. (Figure 1)

Biomechanical Test

All samples were subject to testing with an electrodynamics test device (MTS Acumen ™ Electrodynamic Test Systems, Eden Prairie, MN, USA). The test protocol has been prepared according to previous biomechanical studies.[17,18] The hemispherical stainless-steel part that would simulate the humeral head was placed on the tip of cyclic charge device thus, homogeneous load distribution to graft was aimed. The prepared samples were inserted to test device so that a vertical load to coracoid graft would be applied in order to simulate the worst-case scenario. (Figure 2)

Figure 1. Sample of 2 cortical screw fixation and mini-plate fixation.

Figure 2. Simulate the worst-case scenario.

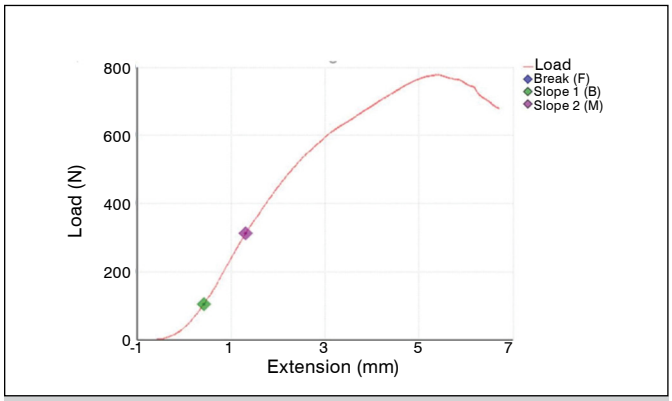

Figure 3. Sample of load-displacement graph.

In order to precondition the construct, 100 cycles of load were performed between 0 and 20N and a break of 30 minutes was carried out following preconditioning. Then the constructs were tested to failure with static load applied to all specimens with loading speed set to 1 mm/minute until macroscopic failure occurs. A load-displacement graph (Figure 3) was obtained for each tested specimen and data obtained from the test device. On the basis of previous data by Giles et al.[22] failure was determined as 5mm displacement of the graft relative to its initial position. The primary outcome was determined as load required in Newton (N) for 5mm of graft displacement (load-to-failure). Load-to-failure results and mode of failure were documented for data analysis.

Statistical Analysis

All analyses were performed using GraphPad Prism Software for Windows (Version 8.0.1, San Diego, California, USA). Mean, standard deviation, median, range, minimum and maximum were used as descriptive statistical methods in order to analyse the data. Distribution of variables was tested using Shapiro-Wilk test and Kolmogorov-Smirnov test. Comparisons between three study groups were performed using analysis of variance (ANOVA). Post-hoc pairwise comparisons between groups were performed using Tukey's. The significance level was at $p=0.05$ for all analyses. A post-hoc power analysis was performed on to primary outcome (load-to-failure) using (G*Power software version 3.1.9.6; Germany).

RESULTS

The mode of failure in group 1 was complete screw pull-out without screw deformation in four cases (80%) and glenoid fracture in one case (20%). In group 2, mode of failure was screw pull-out in three cases (60%) and glenoid fracture in two cases (40%). The mode of failure with plate fixation was screw pull-out in two cases (40%) and glenoid fracture in three cases (60%) (Figure 4). None of the samples failed between container-bone model interface.

Overall load-to-failure ranged between 502-857 N with a mean of 700±109N. Mean load-to-failure was 707.8±116.9 N (range: 545-800N), 687.8±99.3N (range: 587-810N) and 705.2±132.1N (range: 502-857N) respectively in three study groups. No statistically significant difference was observed between three groups ($p=0.958$). (Figure 5), (Table 1)

Two-tailed post-hoc power analysis revealed that the power of the study was 81.9% for load-to-failure with 15 samples and $\alpha=0.05$.

DISCUSSION

The main finding of the present study was that accordingly to our hypothesis, initial strength and stability of the coracoid fixation did not differ biomechanically between cortical screws, cannulated

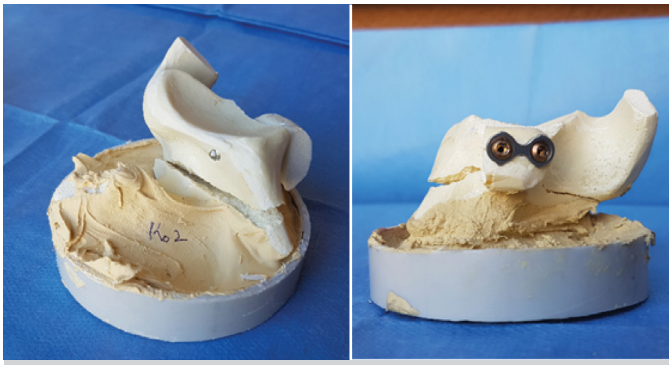

Figure 4. Glenoid neck fracture during the test.

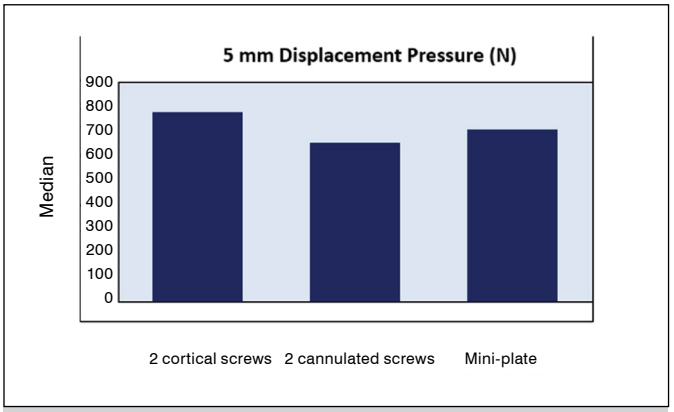

Figure 5. Difference between three groups.

Table 1. Load-to-failure values of three study groups.

	Load-to-failure (N)		
	n	Min-Max (Median)	Mean SD
Group 1 (cortical screw)	5	545-800 (779)	707.8 ± 116.9
Group 2 (cannulated screw)	5	587-810 (654)	687.8 ± 99.3
Group 3 (plate)	5	502-857 (706)	705.2 ± 132.1
[b]p(Group 1 vs Group 2)		0.961	
[b]p(Group 1 vs Group 3)		0.999	
[b]p(Group 2 vs Group 3)		0.970	
Total [a]p=0.958	15	502-857 (638)	700.26 ± 248.75

(Min: minimum, Max: maximum, SD: standard deviation, [a]: one-way ANOVA test, [b]: Tukey's test).

screws and mini-plate. These findings implicate that surgeons may choose the fixation methods based on their experience and preference without significantly altering the construct biomechanically.

The Latarjet procedure is being more frequently used in recent years and successful results have been reported in management of recurrent shoulder instability.[23-25] However; complication rate following bone block transfer procedures has been reported to be between 15 and 30%.[6,26] Reported complications include infection, nerve injuries, glenoid fracture, graft non-union or osteolysis and recurrent instability.[6,27-31] Accurate positioning and proper fixation of the coracoid graft have been reported to be essential for clinical success of this procedure in order to withstand the axial and shear forces of the glenoid joint and to avoid fixation failure which can lead to graft non-union and recurrent instability.[5,26] Therefore, choosing the optimal fixation method plays an important role for success of this procedure.

Screw fixation is the most commonly used technique for fixation of coracoid graft and studied by many previous biomechanical or clinical studies. In their cadaveric study, Shin et al. did not find significant biomechanical difference between different screw types (cancellous, cortical and cannulated screws) and fixation methods (unicortical and bicortical).[18] Another cadaveric study by Weppe et al. compared the initial fixation strength of two metal bicortical screws and a bioabsorbable interference screw and showed that metal screws provided stronger fixation.[15] A recent biomechanical study by Alvi et al. biomechanically compared solid and cannulated screws and consistently found no significant difference in terms of load or cycles to failure.[19]

Anatomical proximity of the suprascapular nerve to exit sites of the screws in bicortical fixation method poses the possibility of an iatrogenic injury of the suprascapular nerve due to drilling or to the prominence of the screws.[32,33] Therefore, fixation with two unicortical screws has been proposed in order to avoid possible nerve injury. However; in contrast to previous study by Shin et al.[18] Schmiddem et al. recently showed that monocortical fixation was significantly weaker compared to bicortical fixation.[17] In our study, we performed bicortical fixation, which is a prerequisite in order to obtain sufficient initial fixation strength to our opinion and consistently to previous data, we found no biomechanical difference between cortical and cannulated screws.

The Latarjet mini-plate has been developed in order to obtain better biomechanical properties and is thought to enhance compression of the graft to glenoid bone surface. The plate has a wedge profile and allows medial rotation of the coracoid graft with applied compression and therefore improves the contact between coracoid graft and glenoid bone surface. The figure of eight[8] configuration of the plate provides a better torsional orientation and four spikes of the plate improves the stability in plate-graft interface. Consequently, these properties are believed to allow even distribution of the load to the bone compared to conventional screw fixation methods. A retrospective case series by Chaudhary et al. reported outcomes of 24 patients with failed arthroscopic Bankart repair and who were treated with Latarjet procedure using mini-plate fixation. Authors reported good clinical outcomes and no recurrence of instability.[20] Another study by Di Giacomo et al. clinically and radiologically compared their results with mini-plate fixation to the results of their previous study without using mini-plate. They divided the coracoid bone graft into eight parts and evaluated for osteolysis using post-operative computed tomography scans. Their results showed that only deep part of the distal coracoid was significantly less involved in osteolysis with mini-plate fixation without any clinical difference. Authors concluded that mini-plate fixation did not provide reduced risk for graft osteolysis but they recommended its use to improve graft stability.[16] However; there is a paucity of data concerning biomechanical properties of mini-plate fixation in Latarjet procedure and to our knowledge, our study is the first biomechanical study comparing mini-plate fixation to different screw fixation methods. The findings of our study revealed that mini-plate fixation was biomechanically comparable to fixation with two cortical or cannulated screws.

There are several limitations to the present study which are inherent to a biomechanical bone model study. Inability of the biomechnical test setup to reflect in vivo mechanics may be listed as a limitation of our study. Eventhough our test setup aimed to assess strength of graft fixation rather than glenohumeral joint stability, effects of soft tissue structures such as sling effect of conjoined tendon, capsular repair and subscapularis muscle could not be represented in a biomechanical test setup with bone models. Another limitation is that all native forces effecting coracoid graft, such as counter pull force produced by biceps muscle which is a contributing factor for fixation failure especially in early post-operative period, could not be reproduced in our test model. The load was applied in a single direction, perpendicular to coracoid graft which may not accurately represent in vivo graft loading after Latarjet procedure. Also due to our test mechanism we have been tested only load-to-failure loading. Absence of cyclical loading, which is known as another failure mechanism of Latarjet procedure, is another limitation of our study. However, we simulated the worst-case scenario which allowed better standardization of the load magnitude acting on the graft. Finally, the study was conducted as time-zero analysis therefore post-union biomechanics could not be evaluated.

There are also some strengths of the study. Due to homogeneity of the used bone models, possible standardization problems related to cadavers (age, gender, bone quality) have been avoided. A uniform surgical technique was performed and biomechanical testing was designed and standardized to simulate the worst-case scenario.

CONCLUSION

Strength of initial fixation is essential for the success of Latarjet procedure and the findings of this biomechanical study showed that no difference exists between three coracoid fixation options (cortical screws, cannulated screws and mini plate) in terms of fixation strength. Unlike previous assumptions, plate fixation is not biomechanically superior to screw fixation. Surgeons should consider their personal preference and experience choosing fixation methods but further research with high evidence are needed.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. AU and EM: Designing the trial, acquiring, analyzing, and interpreting the data, writing and editing the manuscript. CM: Acquiring, analyzing, and interpreting the data, editing the manuscript. SK: Designing the trial, acquiring, analyzing, and interpreting the data. KO: Conception of the study, designing the trial EA: Conception of the study, designing the trial, acquiring, analyzing, and interpreting the data, writing and editing the manuscript.

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TRAUMA

COMPARING GAIT AND HIP SCORES IN FEMORAL NECK AND INTERTROCHANTERIC FRACTURES

COMPARAÇÃO DE ESCORES DE MARCHA E QUADRIL EM FRATURAS DO COLO FEMORAL E INTERTROCANTÉRICAS

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ABSTRACT

Objective: Treatment modality is controversial in the unstable IT fractures. Ideal hemiarthroplasty treatment for unstable IT fractures should be comparable to that for FN fractures. Therefore, the aim of this study was to compare patients who underwent cementless hemiarthroplasty for a diagnosis of FN and unstable IT in terms of clinical outcomes, functional scores, and smartphone-based gait analysis data. Methods: Case matching was applied to 50 patients with FN fracture and 133 patients with IT fracture who underwent hemiarthroplasty treatment, they were compared in terms of, preoperative and postoperative walking status, and Harris hip scores. Smartphone-based gait analysis was applied to 12 patients in the IT group and 14 patients in the FN group who could walk without support. Results: There was no significant difference between patients with IT and FN fractures regarding Harris hip scores, preoperative, and postoperative walking status. In the gait analysis, gait velocity, cadence, step time, step length, and step time symmetry values were observed to be significantly better in patients in the FN group. Conclusion: Cementless hemiarthroplasty operations for unstable IT fractures have similar hip scores to FN fractures. However, the walking speed and walking symmetry data were seen to be worse. This result should be considered in the selection of appropriate treatment. ***Level of evidence III; Retrospective study.***

Keywords: Smartphone. Gait analysis. Hip fractures. Hemiarthroplasty.

RESUMO

Objetivo: O tratamento das fraturas instáveis da IT possui modalidades de tratamento com diferentes teorias. Hemiartroplastia é o tratamento ideal para fraturas instáveis (IT), devendo ser comparável à hemiartroplastia para fraturas do colo femoral (FN). Portanto, o objetivo deste estudo foi comparar pacientes que foram submetidos a hemiartroplastia não cimentada para diagnóstico do FN e IT instável em seus resultados clínicos, considerando a escala de estado funcional e a análise dos dados de habilidade de marcha coletadas por um smartphone. Métodos: A combinação de casos foi aplicada a 50 pacientes com fratura FN e 133 pacientes com fratura IT submetidos ao tratamento de hemiartroplastia, a habilidade de marcha pré e pós-operatório, incluindo suas pontuações Harris Hip, foram comparadas. A análise de marcha foi executada com smartphone em 12 pacientes do grupo IT e 14 pacientes do grupo CF, que conseguiam andar sem apoio. Resultados: Não foram encontradas diferenças significativas entre os pacientes com fraturas IT e FN em relação às pontuações Harris Hip nem quanto ao estado de marcha pré e pós-operatório. Na análise da marcha, os valores de velocidade, cadência, tempo de passo, comprimento do passo e simetria do tempo de passo foram significativamente melhores nos pacientes do grupo FN. Conclusão: As operações de hemiartroplastia não cimentada para fraturas instáveis de IT, têm pontuação de quadril semelhantes às fraturas FN. Entretanto, os dados de velocidade de caminhada e simetria de caminhada mostraram-se inferiores. Esses resultados devem ser considerados na escolha do tratamento adequado. ***Nível de evidência III; Estudo retrospectivo.***

Descritores: *Smartphone. Análise da marcha. Fraturas do quadril. Hemiartroplastia.*

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INTRODUCTION

The incidence of proximal femur fractures in the elderly population is increasing around the world.[1,2] As these fractures constitute a global health problem with high morbidity and mortality rates, appropriate treatment has become more important.[3] In the treatment of displaced femoral neck (FN) fractures in elderly patients, hemiarthroplasty is a globally accepted and widely used method.[4]

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

The study was conducted at the Aksaray Education and Research Hospital, Turkey.
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However, the optimal treatment for intertrochanteric femur (IT) fractures is controversial. Intramedullary nailing is a frequently preferred method because of the high potential for union due to the rich vascular network of the intertrochanteric region, the biomechanical advantages, and that it can be performed with a minimally invasive surgical technique.[5-7] Despite the advantages of intramedullary nailing, it is one of the most preferred methods in the treatment of hemiarthroplasty, sometimes due to physician and sometimes patient-related factors.

Therefore, various hemiarthroplasty methods have been reported in the treatment of unstable IT fractures, aiming to prevent complications mentioned above and allow full weight-bearing immediately after surgery.[8,9] Unlike FN fractures, the common purpose of these methods is to maintain the stability of the prosthesis despite the impaired abductor mechanism that occurs in IT fractures. (Figure 1) Therefore, ideal hemiarthroplasty treatment for unstable IT fractures should be comparable to hemiarthroplasty treatment for FN fractures. However, there are few studies that have compared the results of hemiarthroplasty for FN fractures with hemiarthroplasty for unstable IT fractures.[10,11] The hypothesis of this study was that hemiarthroplasty operations performed for IT region fractures would yield clinical and functional results similar to those of hemiarthroplasty operations performed for FN fractures, with an average follow-up of more than 1 year. Therefore, the aim of the study was to compare the clinical results, functional scores and smartphone-based gait analysis data of patients who underwent hemiarthroplasty for FN and IT fractures.

MATERIAL AND METHODS

Approval for the study was granted by the Local Ethics Committee (Ethical approval: File Number: 2100005070). All involved subjects gave informed consent to the work. The hospital archives were screened to identify patients aged ≥70 years who underwent cementless hemiarthroplasty with proximal femur fracture between 2014 and 2020. A total of 211 patients were identified, of which 28 were excluded for various reasons; 10 could not be contacted, perioperative information was not available for 6, and 12 patients had another lower extremity operation. Thus, a total of 183 patients were evaluated, comprising 50 patients with displaced FN fracture and 133 patients with unstable IT fracture. Case matching was applied to 50 FN patients and 133 IT fracture patients using the factors of age, gender, body mass index (BMI), bone mineral density (BMD), American Society of Anesthesiologists (ASA) score, and pre-injury walking status. As a result of the matching process, 40 patients were in the IT group and 40 patients were in the FN group as the control group. (Figure 2) The demographic data of the patients before and after matching are presented in Table 1.

All operations were performed using a standard posterolateral approach. For patients with FN fracture, a cementless Biomet® Bi-Metric Plasma Spray porous coating tapered femoral stem was used with the standard surgical technique. In patients with IT fracture, a TipMed® S-2 anatomical modular hip prosthesis-uncemented, distal handle femoral stem and perforated stem combination were used. Major and minor trochanter fractures and short external rotator muscle groups were fixed with cerclage wire passed through the perforations. The short external rotator muscle groups and capsule were sutured to the posterior border of the gluteus medius in all patients. In all patients, length was obtained by measuring the contralateral leg. A bipolar head was used in all patients.

Antibiotic prophylaxis with cefazolin was administered to the patients 30-60 minutes before the operation and was continued for up to 48 hours postoperatively. Low molecular weight heparin was administered daily subcutaneously and continued for three weeks. Weight-bearing was permitted on the operated extremity on the first postoperative day and patients were advised to use a walker until they had regained sufficient muscle strength and balance. Excessive flexion and adduction were not permitted for six weeks postoperatively. The patients were followed up with clinical and radiological examinations at 6 weeks, 6 months, 1 year and annually thereafter. The Harris hip score (HHS)[12] was recorded. The pre-injury walking ability of the patients was evaluated in three categories as without support, with support, and unable to walk. These 3 categories were also used for the postoperative evaluations of walking ability. At the final follow-up examination, smartphone-based gait analysis was applied to patients from both groups who could walk without support. These patients, who could walk continuously without the assistance of another person or a walking aid, walked barefoot

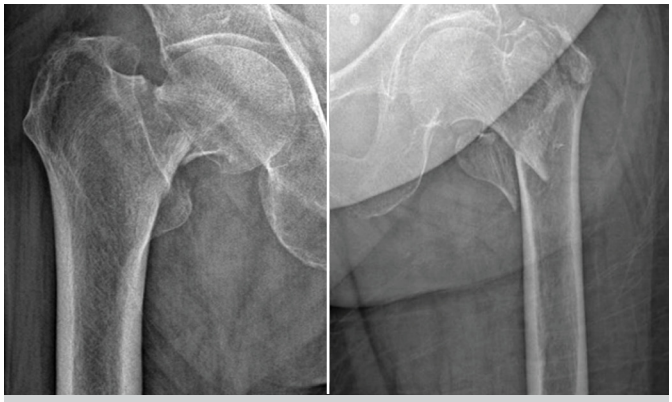


Figure 1. Radiographs of a 78-year-old male patient with a displaced femoral neck fracture and an 83-year-old female patient with an unstable intertrochanteric fracture.

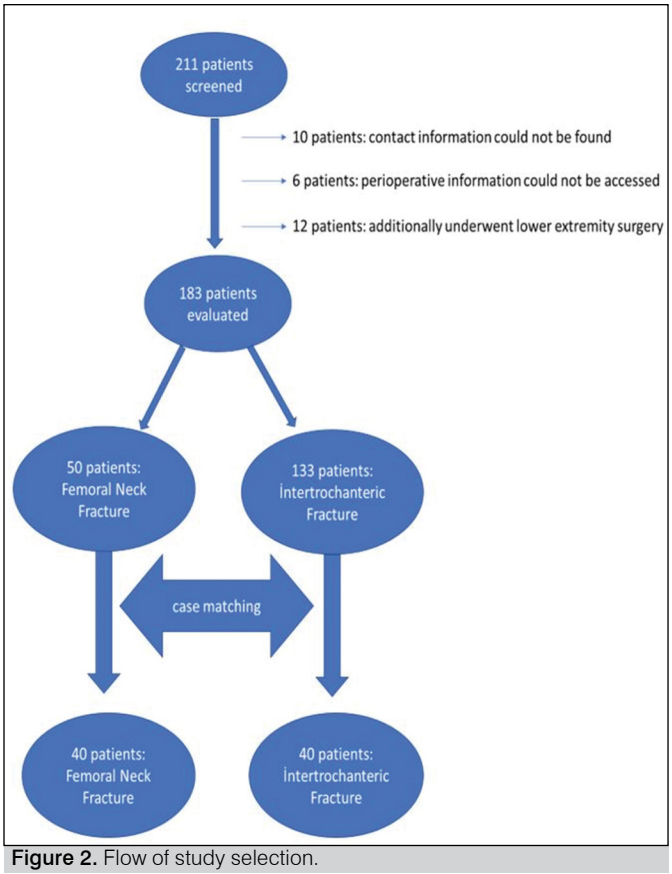


Figure 2. Flow of study selection.

<< SUMÁRIO

Table 1. Patients included in the study and statistical matching between the two groups.

Case variables	Patients included in the study			After matching two groups.		
	Intertrochanteric group (n=133)	Femoral neck group (n= 50)	P value	Intertrochanteric group (n=40)	Femoral neck group (n=40)	P value
Age (years)	83.11±6,32	82.72 ±7,62	0,724	82.48± 6.714 (71-95)	82.53± 7.383 (71-98)	0.975
Gender			0.414			1.000
Male	54	17		14	14	
Female	79	33		26	26	
Affected side			0.160			0.502
Right	59	28		19	22	
Left	74	22		21	18	
Bone mineral density (T-score)	3.759±0.52	3.808±0.46	0.569	3.785±0.49	3.81±0.48	0.786
Body mass index(kg/m^2)	26.58±3.48	26.40±2.62	0.742	26.33±3.02	26.58±2.64	0.695
ASA score	2.53±0.646	2.42±0.642	0.322	2.40±0.632	2.33±0.572	0.580
Pre-injury walking ability			0.970			0.695
Without support	75	28		25	23	
With support	50	19		13	16	
Unable to walk	8	3		2	1	
Anesthesia			0.607			0.556
General:regional	11:122	3:47		2:38	1:39	
Follow-up period(months)	17.80±12.68 (6-72)	15.26±11.48 (6-75)	0.218	18.58±12.03 (6-66)	15.03±12.45 (6-75)	0.198

ASA: American Society of Anesthesiologists. Values presented: mean±standard deviation.

along a 10-m walkway at a self-selected walking speed with a smartphone attached by a belt to the body above the third lumbar vertebrae in a horizontal orientation. (Figure 3)[13-15]
The gait analysis was applied using the Gait Analyzer version 1.0.1 (Control One LLC, NM, USA) smartphone application running on Samsung Galaxy Note 10 Plus smartphone (143.3×71.1×6.3 mm; 141 g), as described in a previous study.[15] Calibration was performed by walking 5 meters before testing each new patient. The gait data during calibration were not included in the assessment. The data collected by the Acceleration Sensor LSM6DSO (STMicroelectronics, Geneva, Switzerland) were low-pass filtered before further analysis (fourth-order zero-lag Butterworth filter at 20 Hz). In the new graphic, the heel strike time points were determined using the relevant mathematical formulas. The gait velocity, step time (ST), step length (SL), cadence, step length symmetry, step time symmetry, and vertical COM (vert-COM) parameters were measured in all patients. (Figure 4)

Statistical analysis

Statistical analysis of the data obtained in the study was performed using SPSS version 22 software (SPSS Inc., Chicago, IL, USA). The characteristics of the patient populations were analyzed using the Chi-square test for categorical variables and the student's t-test for continuous variables. The Mann-Whitney U test was applied to data that did not show normal distribution. A value of $p<0.05$ was accepted as statistically significant in all the analyses.

RESULTS

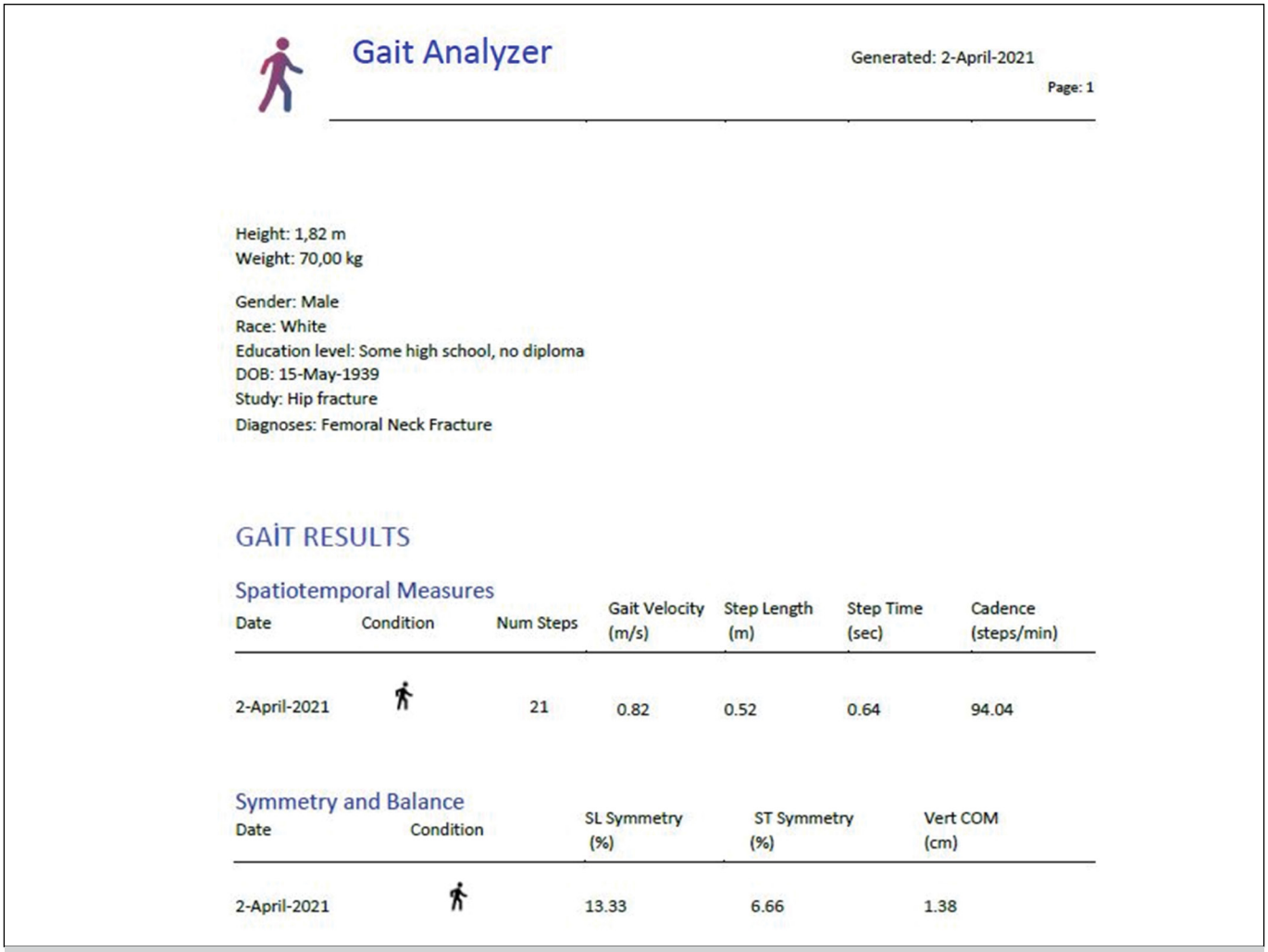
No significant difference was observed between the assisted walking times of the patients. No significant difference was observed between the post-operative walking ability and final Harris Hip scores of the 33 IT patients and 36 FN patients without mortality ($p>0.05$). (Table 2) Smartphone-based gait analysis was applied to 14 patients in the FN group and 12 patients in the IT group who were able to walk without support. The gait velocity, cadence, step time, step length and step time symmetry values were observed to be

Figure 3. Back and side view of smartphone placed on the body.

Table 2. Postoperative ambulatory capability and Harris Hip scores of the two groups.

Variables	Intertrochanteric group (n = 33)	Femoral neck group (n = 36)	P-value
Starting day of ambulation with support	4.83±3.1	4.65±2.42	0.779
Final Walking Ability			0.894
Without support	12	14	
With support	19	19	
Unable to walk	2	3	
Total number of patients	33	36	
Harris Hip score	65.58±9.04	64.33±10.34	0.598
Number of patients	33	36	

Values presented: mean±standard deviation.



Gait Analyzer

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Height: 1,82 m
Weight: 70,00 kg

Gender: Male
Race: White
Education level: Some high school, no diploma
DOB: 15-May-1939
Study: Hip fracture
Diagnoses: Femoral Neck Fracture

GAİT RESULTS

Spatiotemporal Measures

Date	Condition	Num Steps	Gait Velocity (m/s)	Step Length (m)	Step Time (sec)	Cadence (steps/min)
2-April-2021		21	0.82	0.52	0.64	94.04

Symmetry and Balance

Date	Condition	SL Symmetry (%)	ST Symmetry (%)	Vert COM (cm)
2-April-2021		13.33	6.66	1.38

Figure 4. Output from the application for a femoral neck fracture patient at 18 months after surgery.

significantly better in the FN group patients ($p<0.05$). No significant difference was determined between the groups of patients applied with gait analysis in respect of age, gender, BMI, side, leg length, step length symmetry, and vertical COM values ($p>0.05$). (Table 3)

DISCUSSION

The most important finding of this study was that the gait velocity value of the patients who underwent arthroplasty due to FN was significantly better than that of the patients who underwent arthroplasty due to IT. There are many studies showings that life expectancy increases with increasing gait velocity in elderly patients.[16] However, in the current study, no significant difference was observed between the FN and IT patients in respect of mortality rates, which was consistent with the findings of the few similar studies in literature.[10]

The selection of the femoral stem can be difficult for the most appropriate treatment of IT fractures. Many of the studies on this subject have made comparisons between patients with different bone strength, muscle strength and, more importantly, fracture morphology. Taking the treatment results of FN fractures, in which the intertrochanteric region muscle and bone structures remain intact, as a reference, can bring another perspective to measuring the effectiveness of the treatment of IT fractures and reaching the ideal treatment option. In a study by Chang et al., patients

Table 3. Gait analyses of the patients able to walk without support.

Case variables	Intertrochanteric group (n=12)	Femoral neck group (n=14)	P value
Age (years)	77.33±3.47	76±03	0.307
Gender			0.356
Male	1	3	
Female	11	11	
BMI	26.5±3.06	27.0±2.14	0.630
Affected side Right:left	7:5	5:9	0.249
Right leg length	87.42±8.68	89.36±8.96	0.582
Left leg length	87.58±8.55	89.14±8.5	0.647
Gait velocity	0.59±0.12	0.74±0.07	0.001
Cadence	75.45±14.13	86.72±8.48	0.019
Step time	0.82±0.19	0.69±0.08	0.031
Step length	0.46±0.058	0.50±0.05	0.044
Step time symmetry	30.05±31.04	11.90±17.40	0.002
Step length symmetry	26.68±13.71	20.16±8.69	0.154
Vertical COM	1.43±0.34	1.52±0.31	0.485

Values presented: mean±standard deviation.

applied with cementless prosthesis for FN and IT fractures were compared.[10] No significant difference was determined in respect of the amount of bleeding, blood transfusion and HHS. Similar results were observed in the current study. However, the functional status of patients with PROMs may not always be parallel.[17] It has been shown that while postoperative HHS values improved in patients with unstable IT fractures, the gait parameters seen in gait analysis did not improve at the same rate.[17]

Various applications were developed and installed on smartphones, and with these applications, gait analysis became possible without the need for an additional program, computer or engineering knowledge. Several recent articles have been published showing that smartphone-based gait analysis is reliable and valid and therefore smartphone-based gait analysis was used in this study.[13,14,18]

The normal function of the muscles attached to the proximal femur is very important for both prosthesis stability and walking functions.[19] Dysfunction in these muscles in IT fractures is expected to impair the gait parameters measured in patients. In a study of unilateral partial hip arthroplasty patients, the average walking speed was found to be 0.5 m/s.[11] In another gait analysis study of patients with FN and IT hip fractures, it was stated that walking speed and gait symmetry parameters observed in IT region fractures were worse.[20] These findings seem to be compatible with those of the current study. In addition, the mean walking speed in patients with hip fracture has been reported to be 0.6 m/s (SD=0.2). In the current study, the mean walking speed was found to be 0.67 m/s (SD=0.12) in all patients with FN and IT fractures. Although gait symmetry parameters are the main parameters of gait analysis, it has been shown that improving these parameters reduces energy consumption in patients.[21] The main symmetry parameters in spatiotemporal gait analysis are step time symmetry and step length symmetry parameters. However, the relationship between these two parameters and their contribution to energy consumption is a matter of debate.[22,23] In a study in which healthy individuals walked on a treadmill at increasing speeds, it was shown that step time symmetry values deteriorated while step length symmetry values remained constant at varying speeds. The authors stated that the step time symmetry value was broken first so that the body can aim to keep the step length symmetry value constant to ensure optimal energy consumption.[24] These findings are consistent with those of the current study. While no significant difference was observed in the step length symmetry value between the current study groups, a significant difference was determined in the step time symmetry value.

The strength of this study was that it was a case-control study conducted in a single centre. However, the study had some limitations such as being retrospective, having a relatively small sample size, the lack of HHS values during follow-up, the evaluation of only final values, and that gait parameters could not be evaluated in assisted walking patients.

CONCLUSION

Hemiarthroplasty operations in hip region fractures should not be considered as a single type of an operation due to their results. The same choice produces different results depending on the region of fracture. The orthopaedic surgeon should consider that the hemiarthroplasty treatment for IT fractures will have worse gait results compared to the hemiarthroplasty treatment for FN fractures. Hemiarthroplasty treatment should not be preferred as much as possible in IT fractures.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. SA: Conceptualization, Writing – original draft, Data curation. Formal Analysis. HZ: Formal Analysis, Writing– review & editing.

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TRAUMA

INVERSE RELATIONSHIP BETWEEN PLASMA PROTEINS AND SATISFACTORY SURGICAL WOUNDS OUTCOME

RELAÇÃO INVERSA ENTRE PROTEÍNAS PLASMÁTICAS E DESFECHO SATISFATÓRIO DE FERIDAS CIRÚRGICAS

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ABSTRACT

Objective: This study investigated the factors associated with satisfactory early postoperative wound conditions. Method: A prospective study was conducted with patients (n=179) submitted to osteosynthesis in general, in a hospital orthopedics service. In the preoperative period, patients underwent laboratory exams and the surgical indications were based on the type of fracture and the patient's clinical conditions. In the postoperative period, patients were evaluated based on the presence of complications and considering their surgical wounds. Chi-square, Fisher, Mann-Whitney, and Kruskal-Wallis tests were used in the analysis. To identify the factors associated with wound condition, univariate and multiple logistic regression analysis was used. Results: In the univariate analysis, each transferring unit reduction increased the chance of satisfactory outcome by 1.1% (p=0.0306; OR= 0.989 (1.011); 95%CI= 0.978;0.999; 1.001;1.023). The presence of SAH increased 2.7 fold the chance of satisfactory outcome (p=0.0424; OR= 2,667; 95%CI= 1,034;6,877). Hip fracture increased 2.6 fold the chance of satisfactory outcome (p=0.0272; OR=2.593; IC95%=1.113; 6.039). And the absence of a compound fracture increased 5.5 fold the chance of satisfactory wound outcome (p=0.0004; OR=5,493; 95%CI=2,132;14,149). In the multiple analysis, patients with non compound fractures were 9.7 times more likely to experience a satisfactory outcome when compared to patients with compound fractures (p=0.0014; OR=9,687; 95%CI= 2,399; 39,125). Conclusion: There was an inverse relationship between plasma proteins levels and satisfactory surgical wounds outcome. Only exposure remained associated with wound conditions. ***Level Of Evidence: II, Prospective Study.***

Keywords: Osteosynthesis, Fracture. Postoperative Complications. Surgical Wound. Albumin. Transferrin.

RESUMO

Objetivo: Este estudo investigou os fatores associados à condição satisfatória de ferida pós-operatória precoce. Método: Foi desenvolvido um estudo prospectivo com pacientes (n=179) submetidos a osteossínteses em geral, em um serviço de ortopedia hospitalar. No período pré-operatório os pacientes foram submetidos a exames laboratoriais e as indicações cirúrgicas foram baseadas no tipo de fratura e condições clínicas. No período pós-operatório, os pacientes foram avaliados conforme a presença de complicações e feridas operatórias. Foram utilizados na análise os testes Qui-quadrado, Fisher, Mann-Whitney, Kruskal-Wallis. Para identificar os fatores associados à condição da ferida, foi utilizada a análise de regressão logística univariada e múltipla. Resultados: Na análise univariada, cada unidade a menos de transferrina, aumentou a chance de condição satisfatória em 1.1% (p= 0.0306; OR= 0.989 (1.011); IC95%= 0.978;0.999; 1.001;1.023). A presença de HAS aumentou a chance de condição satisfatória em 2.7 vezes (p=0.0424; OR= 2.667; IC95%= 1.034;6.877). Fratura de quadril aumentou a chance de condição satisfatória em 2.6 vezes (p=0.0272; OR=2.593; IC95%=1.113;6.039). E não apresentar fratura exposta, aumentou a chance de condição satisfatória da ferida em 5.5 vezes (p=0.0004; OR=5.493; IC95%=2.132;14.149). Na análise múltipla, fraturas sem exposição, apresentaram chance 9.7 vezes maior de apresentar condição satisfatória do que insatisfatória; quando comparadas às que apresentaram exposição (p=0.0014; OR=9.687; IC95%= 2,399; 39.125). Conclusão: Houve uma relação inversa entre proteínas plasmáticas e presença de feridas operatórias satisfatórias. Apenas a exposição se manteve associada à condição da ferida. ***Nível de Evidência: II; Estudo Prospectivo.***

Descritores: *Osteossíntese. Complicações Pós-Operatórias. Ferida Cirúrgica. Albumina. Transferrina.*

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INTRODUCTION

Surgical site complications are the most feared complications after those of osteosynthesis, as observed in a systematic review and meta-analysis performed by Shao *et al*, 2017.[1] As reported in a study by Renz *et al*, 2017[2] infection rates of 1 to 5% occur in the case of closed fractures osteosynthesis and up to 30% in compound fractures, making the diagnosis of infections associated with osteosynthesis challenging.[2]

The incidence of peri-implant infections may vary according to the wound site, patient's age, gender, race and existing comorbidities, such as diabetes, obesity or rheumatoid arthritis[3,4] and a large increase in demand for hip and knee arthroplasties is estimated by the year 2030.[3] In a hospital-based case-control study[4] that evaluated the risk factors for infections in hip and knee arthroplasties, logistic regression analysis indicated that patients with diabetes, advanced age, body mass index (BMI) $\geq$28 kg/m^2 and alcohol abuse or living in rural areas were at increased risk of periprosthetic joint infection.[4]

In a study that evaluated the relative risk of postoperative mortality and periprosthetic joint infection associated with comorbidities in patients undergoing total knee arthroplasty (TKA),[5] the authors showed that the independent risk factors for postoperative mortality at 90 days were congestive heart failure, metastatic cancer, kidney disease, peripheral vascular disease, cerebrovascular disease, lymphoma, cardiac arrhythmia, dementia, pulmonary circulation disorders, and chronic liver disease. In the same study[5] it was found that independent risk factors for periprosthetic joint infections were congestive heart failure, chronic pulmonary disease, preoperative anemia, diabetes, depression, renal disease, pulmonary circulation disorders, obesity, among others.[5]

Blood glucose control is an important factor in preventing surgical site infection and some studies indicate a correlation between obesity, hyperglycemia, diabetes and increased risk of osteosynthesis and arthroplasties infections.[6,7]

Other investigations point to an important association of serological malnutrition with postoperative wound complications.[8] Both malnutrition and obesity could favor postoperative complications;[9] malnutrition additionally could favor late infections.[10]

Other findings in the literature indicate that malnutrition diagnosed by albumin, transferring levels and total lymphocyte count could be associated with postoperative complications, thus suggesting the need for further investigations into the predictive value of these indices in the evaluation of postoperative complications.[11]-

In view of the above, the present study investigated factors associated with early satisfactory postoperative wound condition in patients in the process of fracture osteosynthesis in general.

METHOD

Study Design, Participants, ethical approval and inclusion and exclusion criteria

The study was prospective, performed with patients undergoing osteosynthesis procedures in general, in a hospital orthopedics service of a Public Health Service-SUS. The study started after approval by the Institution's Ethics and Research Committee and the signing of the Free and Informed Consent Form (FICF).

All patients in the process of osteosynthesis in general, in elective or urgent surgeries, in a period of 6 months during the year 2021 were included. Patients requiring intensive pre-surgical support and compensation of the clinical condition for elective surgery were excluded. After reviewing the inclusion and exclusion criteria, one hundred and seventy-nine (n=179) patients were considered for this study.

Methodological procedures

Patients were admitted to the Hospital Emergency Care Service and came on their own or were brought in by rescue teams. They were screened and attended by the orthopedic team, who identified the fractures and the need for emergency surgery or elective surgery. In the preoperative period, all patients underwent laboratory tests and surgical indications were based on the type of fracture and the patients' clinical conditions. In the postoperative period, patients were evaluated according to the presence of wound complications. After the surgery and hospital discharge, patients returned to the outpatient clinic for post-surgical evaluation and for evaluation of the operative wounds conditions (satisfactory and unsatisfactory). The same preoperative, intraoperative and postoperative procedures were used, with patients who were discharged between 24 and 48 hours from admission. The variables assessed were:

a. Demographic and clinical data:- data such as gender, age, presence of comorbidities, even if mild or controlled, such as diabetes mellitus, Systemic Arterial Hypertension (SAH), alcohol abuse and smoking were collected.

b. Patient-reported body weight and height upon admission and BMI was calculated.[12,13]

c. Laboratory tests: complete blood count, coagulogram, electrolytes and plasma proteins. Nutritional status was assessed based on plasma proteins levels such as albumin's and transferrin's. Plasma albumin levels <3.5 g/dl and transferrin <200 mg/dl were considered to reflect a malnourishment condition.[14]

d. Osteosynthesis surgeries were performed according to the fracture that occurred and according to the techniques described in the AO.[15]

e. Surgical and other variables:- the occurrence of intraoperative complications, amputations, neurological and vascular injuries were assessed intraoperatively. The occurrence of postoperative cardiovascular reactions was also assessed.

This project was approved by the Pontifical Catholic University of Campinas-SP-Brazil's Ethics Committee (reference number:- 5.182.817).

Statistical Analysis

A descriptive analysis of the variables was performed to characterize the population, with frequency data for the categorical variables and position and dispersion measure for the continuous variables. To compare proportions, the chi-square or Fisher's exact test was used, when necessary. To compare continuous or sortable measures between two groups, the Mann-Whitney test was applied and the Kruskal-Wallis test was applied among three groups, followed by Dunn's test, when necessary. To identify the factors associated with wound condition, univariate and multiple logistic regression analysis were used. The variable selection process used was stepwise. The significance level adopted for the tests was 5%.[16,17,18]

RESULTS

The mean age of the population (n=179) was 47.87±24.41 years (median=48); 36.3% (n=65) were female and 63.7% (n=114) were male. The age groups were 10.1% (n=18) between 0 and 18 years of age; 62.6% (n=112) between 19 and 65 years old and 27.4% (n=49) were aged over 65 years. In this series, 67.3% (n=115) had no comorbidities, 18.7% (n=32) had only one comorbidity and 14% (n=24) had two to four comorbidities. The most frequent comorbidities were diabetes mellitus (10.5%, n=18); SAH (25.7%, n=44); smoking (8.2%, n=14) and alcohol abuse (5.8%, n=10). The wound condition 7 days postoperatively was considered satisfactory in 70.8% (n=121) and unsatisfactory in 29.2% (n=50). By BMI, 59.7% (n=86) were overweight, 31.9% (n=46)

had adequate body weight and 8.3% (n=12) were underweight. As for the fractures site, 72.6% (n=130) had fractures of the lower limbs and 27.4% (n=49) of the upper limbs. A total of 30.2% (n=54) patients had hip fractures, involving acetabulum=3.7% (n=2), femoral neck=13.0%(n=7), femoral diaphyseal=1.9% (n=1), periprosthetic hip fracture=1.9% (n=1) and transtrochanteric femoral fracture = 79.6% (n=43). Compound fractures were observed in 12.3% (n=22) patients while 87.7% (n=157) did not present with open fractures.

Women were older (p<0.0001), and a higher percentage had diabetes mellitus (p=0.0030), cardiovascular diseases (p=0.0010), SAH (p=0.0229), comorbidities in general (p=0.0001) and a higher percentage of hip fracture (p=0.0004). Men had a higher percentage of preoperative complications (p=0.0277).

The age group between 0-18 years had lower BMI (p=0.0026), higher percentage of BMI adequacy (p<0.0001), lower blood glucose (p=0.0256), higher albumin (p=0.0004) (higher percentage within the normal values), without comorbidities (p<0.0001), higher percentage of International Normalized Ratio (INR) above normal (p=0.0347) and higher percentage of transferrin within normality (p=0.0004).

The age group between 19-65 years had higher BMI (p=0.0313) (higher percentage of overweight and obesity), low frequency of comorbidities (p<0.0001), higher percentage of lower limb fractures (p=0.0435) and with open fracture (p=0.0292), higher percentage of preoperative complications (p=0.0074), higher percentages of hemoglobin (p=0.0056) and hematocrit within the normal range (p=0.0060).

The age group above 65 years exhibited low weight by BMI classified by age (p<0.0001), lower values of hemoglobin (p<0.0001), hematocrit (p=0.0002), platelets (p=0.0197), International Normalized Ratio (INR) (p=0.0347), albumin (p=0.0004) and transferrin (p=0.0111). There were even higher values of blood glucose (p=0.0256), hemoglobin (p=0.0056), hematocrit (p=0.0060), International Normalized Ratio (INR) below normal values (p=0.0347), higher percentage of protein depletion by albumin (p=0.0154) and transferrin (p=0.0004). Higher percentages of diabetes mellitus (p<0.0001), cardiovascular diseases (p<0.0001), comorbidities in general (p<0.0001), lower limb fractures (p=0.0435) and hip (p<0.0001), also were more observed in this age group.

Wounds with satisfactory conditions at 7 days were characterized by lower transferring values (p=0.0440), albumin below the reference (p=0.0463), without preoperative complications (p=0.0001), without open fracture (p=0.0001), hip fractures (p=0.0239) and patients with SAH (p=0.0372). (Table 1)

In the univariate analysis, each unit less in the transferrin level increased the chance of satisfactory condition by 1.1%. *(p=0.0306;*

Table 1. Descriptive analysis and comparisons of the variables studied with the wound condition 7 days postoperatively (N=179).

Variables	Category	Unsatisfactory Wound Condition N= 50	Satisfactory Wound Condition N= 121	P-value
Age (years)	X±DP	42.58 ± 21.55	48.37 ± 24.49	0.2070
Body mass index	X±DP	26.30 ± 2.96	26.22 ± 3.32	0.7365
Number of comorbidities	X±DP	0.27 ± 0.57	0.54 ± 0.89	0.0768
Hemoglobin	X±DP	13.25 ± 2.02	12.80 ± 2.02	0.2787
Hematocrit	X±DP	38.63 ± 6.13	38.07 ± 5.77	0.7808
Leukocytes	X±DP	11854.22 ± 5475.24	11959.37 ± 12349.28	0.5162
APTT	X±DP	28.39 ± 4.18	28.33 ± 5.06	0.9654
INR	X±DP	1.01 ± 0.10	1.04 ± 0.14	0.2709
Platelets	X±DP	214973.64 ± 90480.86	232412.27 ± 77547.05	0.6980
Blood glucose	X±DP	124.09 ± 32.85	118.65 ± 30.73	0.4462
Albumin	X±DP	4.07 ± 0.51	3.85 ± 0.63	0.3284
Transferrin	X±DP	251.19 ± 37.93	222.60 ± 58.08	0.0440
Gender				
female	N (%)	13 (26.0%)	48 (39.7%)	0.0896
male	N (%)	37 (74.0%)	73 (60.3%)	
Age Group (years)				
up to 18 years	N (%)	5 (10.0%)	13 (10.7%)	0.1830
19-65 years	N (%)	37 (74.0%)	73 (60.3%)	
> 65 years	N (%)	8 (16.0%)	35 (28.9%)	
Classified body mass index				
overweight	N (%)	25 (65.8%)	59 (59.6%)	0.6494
adequate	N (%)	10 (26.3%)	34 (34.3%)	
underweight	N (%)	3 (7.9%)	6 (6.1%)	
Diabetes				
no	N (%)	45 (93.8%)	103 (88.8%)	0.4004
yes	N (%)	3 (6.3%)	13 (11.2%)	
Smoking				
no	N (%)	47 (97.9%)	106 (91.4%)	0.1780
yes	N (%)	1 (2.1%)	10 (8.6%)	

Alcoholism				
no	N (%)	46 (95.8%)	110 (94.8%)	1.0000
yes	N (%)	2 (4.2%)	6 (5.2%)	
Hypertension				
no	N (%)	42 (87.5%)	84 (72.4%)	0.0372
yes	N (%)	6 (12.5%)	32 (27.6%)	
Presence of comorbidities				
no	N (%)	38 (79.2%)	77 (66.4%)	0.1036
yes	N (%)	10 (20.8%)	39 (33.6%)	
Number of comorbidities				
0	N (%)	38 (79.2%)	77 (66.4%)	0.1906
1	N (%)	7 (14.6%)	21 (18.1%)	
2-4	N (%)	3 (6.3%)	18 (15.5%)	
Limb				
lower	N (%)	33 (66.0%)	89 (73.6%)	0.3204
upper	N (%)	17 (34.0%)	32 (26.4%)	
Hip				
no	N (%)	42 (84.0%)	81 (66.9%)	0.0239
yes	N (%)	8 (16.0%)	40 (33.1%)	
Compound fracture				
no	N (%)	36 (72.0%)	113 (93.4%)	0.0001
yes	N (%)	14 (28.0%)	8 (6.6%)	
Osteosynthesis				
no	N (%)	21 (42.0%)	46 (38.0%)	0.6274
yes	N (%)	29 (58.0%)	75 (62.0%)	
Preoperative complications				
soft parts	N (%)	3 (6.0%)	6 (5.0%)	0.0001
exposed soft parts	N (%)	17 (34.0%)	10 (8.3%)	
no complications	N (%)	30 (60.0%)	105 (86.8%)	
Hemoglobin				
low	N (%)	17 (37.0%)	43 (36.1%)	0.9216
normal	N (%)	29 (63.0%)	76 (63.9%)	
Hematocrit				
low	N (%)	21 (45.7%)	50 (42.4%)	0.7034
normal	N (%)	25 (54.3%)	68 (57.6%)	
Leucocytes				
low	N (%)	23 (51.1%)	57 (50.4%)	0.9395
normal	N (%)	22 (48.9%)	56 (49.6%)	
APTT				
low	N (%)	6 (13.3%)	19 (16.4%)	0.6320
normal	N (%)	39 (86.7%)	97 (83.6%)	
INR				
low	N (%)	5 (10.9%)	9 (7.6%)	0.7992
above	N (%)	7 (15.2%)	19 (16.1%)	
normal	N (%)	34 (73.9%)	90 (76.3%)	
Platelets				
low	N (%)	7 (15.9%)	16 (14.5%)	0.8302
normal	N (%)	37 (84.1%)	94 (85.5%)	
Blood glucose				
<100	N (%)	4 (17.4%)	19 (34.5%)	0.2932
100-125	N (%)	10 (43.5%)	17 (30.9%)	
>125	N (%)	9 (39.1%)	19 (34.5%)	
Albumin				
low	N (%)	3 (10.7%)	17 (30.4%)	0.0463
normal	N (%)	25 (89.3%)	39 (69.6%)	
Transferrin				
low	N (%)	4 (15.4%)	17 (32.1%)	0.1146
normal	N (%)	22 (84.6%)	36 (67.9%)	

INR:- International Normalized Ratio. APTT:- Activated Partial Thromboplastin Time. [1] Mann-Whitney test; [2] Chi-square test; [3] Fisher's exact test.

OR=0.989 (1.011); 95%CI= 0.978;0.999; 1.001; 1.023). The presence of SAH increased the chance of satisfactory outcome by 2.7 times *(p=0.0424; OR= 2,667; 95%CI= 1,034;6,877)*. Hip fracture increased the chance of satisfactory outcome by 2.6 times *(p=0.0272; OR=2,593; 95%CI=1,113; 6,039*). And absence of open fracture, increased the chance of satisfactory wound outcome by 5.5 times *(p=0.0004; OR=5.493; 95%CI=2.132; 14.149)*. In our series, only compound fractures remained associated with wound condition. Closed fractures patients were 9.7 times more likely to present a satisfactory outcome when compared to those with compound fractures *(p=0.0014; OR=9.687; 95%CI= 2.399; 39.125*). (Table 2)
There was a statistical difference for the number of comorbidities (p=0.0066), presence of SAH (p=0.0473), presence of comorbidities (p=0.0015) and number of grouped comorbidities (p=0.0046), compared with serum albumin levels. (Table 3)
There was also a statistical difference for the number of comorbidities (p=0.0161), presence of SAH (p=0.0090), presence of comorbidities (p=0.0081) and number of grouped comorbidities (p=0.0310), compared with serum transferrin levels. (Table 4)
The odds ratios and relevant 95% confidence intervals for the main factors associated with satisfactory wound condition after 7 days are reported in Figure 1.

DISCUSSION

The purpose of this investigation was to assess the risk factors associated with postoperative complications in patients undergoing fracture osteosynthesis process in general. The findings in this investigation pointed to several controversies, observed in previous studies.[9,10] In our series, contradictory outcomes were found in

Table 2. Univariate and multiple logistic regression analysis for the study of factors associated with wound condition at 7 days.

Variables	Category	p-value	OR	95% CI
Univariate analysis [1]				
Age		0.1478	1.011	0.996;1.025
BMI	adequate vs overweight	0.3978	1.441	0.618;3.357
	underweight vs overweight	0.8244	0.847	0.196;3.659
Albumin		0.1271	0.539	0.243;1.192
Transferrin		0.0306	0.989 (1.011)	0.978;0.999 (1.001;1.023)
Diabetes	no vs yes	0.3371	0.528	0.143;1.945
Smoking	no vs yes	0.1613	0.226	0.028;1.813
Alcoholism	no vs yes	0.7860	0.797	0.155;4.096
Arterial hypertension	yes x no	0.0424	2.667	1.034;6.877
Number of comorbidities	0 vs 2-4	0.0971	0.338	0.094;1.218
	1 vs 2-4	0.3625	0.500	0.112;2.223
Limb	LL vs UL	0.3215	1.433	0.704;2.917
Hip	yes vs no	0.0272	2.593	1.113;6.039
Compound fracture	no vs yes	0.0004	5.493	2.132;14.149
Osteosynthesis	yes vs no	0.6276	1.181	0.604;2.309
Blood glucose	normal vs above	0.1375	2.507	0.745;8.432
Albumin	below vs normal	0.0566	3.632	0.964;13.680
Transferrin	below vs normal	0.1226	2.597	0.773;8.722
Multiple analysis [2]				
Compound fracture	no vs yes	0.0014	9.687	2.399; 39.125

BMI: body mass index. LL: lower limb. UL:-upper limb. [1] Univariate analysis: modeling the probability of satisfactory condition. Univariate logistic regression; OR=odds ratio, 95% CI (95% confidence interval for OR). [2] Multiple Analysis:- stepwise variable selection process.

Table 3. Descriptive analysis and comparison of comorbidities with serum albumin.

Variables/ Comorbidities	Category	Albumin * Low (n=20)	Albumin * Normal (n=68)	p-value
Number of comorbidities	X DP	1.11 ± 0.81	0.63 ± 1.08	0.0066
Diabetes				
No	N (%)	13 (68.4%)	56 (87.5%)	0.0778
Yes	N (%)	6 (31.6%)	8 (12.5%)	
Smoking				
No	N (%)	17 (89.5%)	56 (87.5%)	1.0000
Yes	N (%)	2 (10.5%)	8 (12.5%)	
Alcoholism				
No	N (%)	16 (84.2%)	60 (93.8%)	0.1933
Yes	N (%)	3 (15.8%)	4 (6.3%)	
Arterial hypertension				
No	N (%)	9 (47.4%)	46 (71.9%)	0.0473
Yes	N (%)	10 (52.6%)	18 (28.1%)	
Comorbidities				
No	N (%)	5 (26.3%)	43 (67.2%)	0.0015
Yes	N (%)	14 (73.7%)	21 (32.8%)	
Number of comorbidities grouped				
0	N (%)	5 (26.3%)	43 (67.2%)	0.0046
1	N (%)	7 (36.8%)	10 (15.6%)	
2-4	N (%)	7 (36.8%)	11 (17.2%)	

**Albumin.* [1] Mann-Whitney test; [2] Chi-square test; [3] Fisher›s exact test.

Table 4. Descriptive analysis and comparison of comorbidities with serum transferrin.

Variables/ Comorbidities	Category	Transferrin* Below (n=21)	Transferrin* Normal (n=61)	p-value
Number of comorbidities	X DP	1.16 ± 1.07	0.61 ± 1.00	0.0161
Diabetes				
No	N (%)	13 (68.4%)	51 (86.4%)	0.0924
Yes	N (%)	6 (31.6%)	8 (13.6%)	
Smoking				
No	N (%)	17 (89.5%)	52 (88.1%)	1.0000
Yes	N (%)	2 (10.5%)	7 (11.9%)	
Alcoholism				
No	N (%)	17 (89.5%)	54 (91.5%)	1.0000
Yes	N (%)	2 (10.5%)	5 (8.5%)	
Arterial hypertension				
No	N (%)	8 (42.1%)	44 (74.6%)	0.0090
Yes	N (%)	11 (57.9%)	15 (25.4%)	
Comorbidities				
No	N (%)	6 (31.6%)	39 (66.1%)	0.0081
Yes	N (%)	13 (68.4%)	20 (33.9%)	
Number of comorbidities grouped				
0	N (%)	6 (31.6%)	39 (66.1%)	0.0310
1	N (%)	6 (31.6%)	9 (15.3%)	
2-4	N (%)	7 (36.8%)	11 (18.6%)	

**Transferrin.* [1] Mann-Whitney test; [2] Chi-square test; [3] Fisher›s exact *test.*

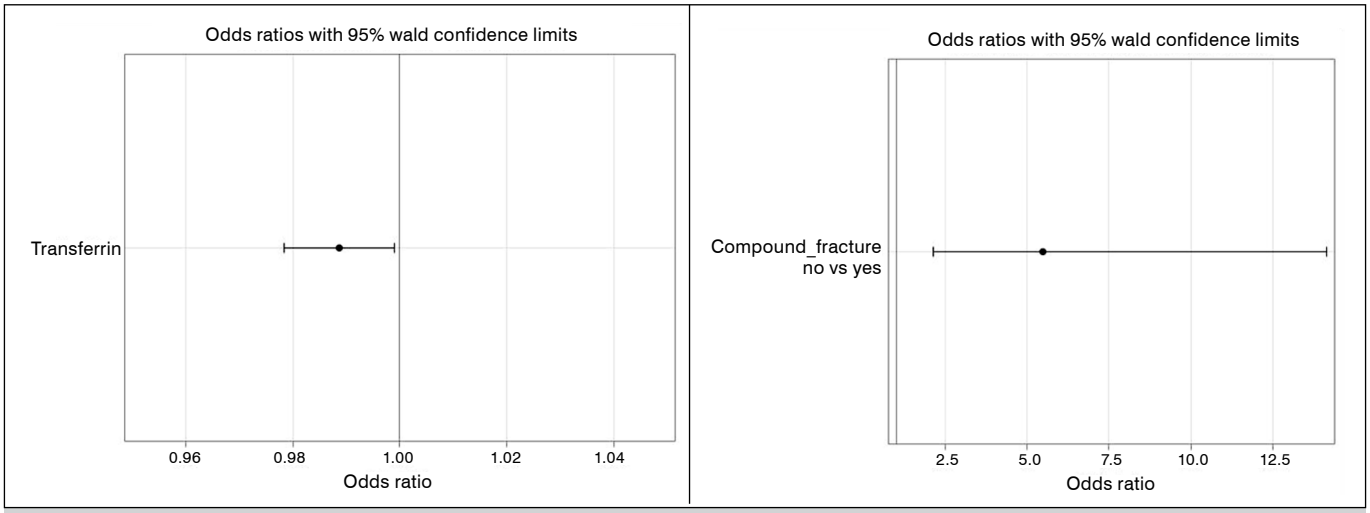

Figure 1. Odds ratios and relevant 95% confidence intervals for the main factors associated with satisfactory wound condition after 7 days.

connection to plasma proteins and their association with postoperative wounds, showing that reduced transferrin plasma levels increased the chances of patients presenting satisfactory wound outcome; these findings are opposed to those found in other investigations reported in the literature.[8,9,10,11] These findings suggest the need for further investigations, probably with a larger sample size, multicenter studies and in normal times in emergency room and hospital emergency room visits, considering that our study was conducted in a period of full blown Covid 19 pandemic. Another factor that deserves to be highlighted in the present investigation refers to the fact that the presence of SAH was associated with a satisfactory wound outcome, a factor that could suggest or raise a hypothesis that these patients were undergoing treatment for the disease (SAH). However, as this issue was not the object of this study, these considerations cannot be confirmed in the present investigation. Another finding observed in our study was the fact that patients with hip fractures and without open fractures presented satisfactory wound outcomes, as well as patients with lower levels of albumin and transferrin and without preoperative complications. Another relevant finding is that there was a significant association between a greater number of comorbidities and lower than normal levels of albumin and transferrin. Our data also showed an association between the presence of hypertension and lower than normal levels of albumin and transferrin. Finally, in our sample, in our orthopedic hospital service, which serves a representative population of a large metropolitan region, only compound fractures were associated with the wound outcome.

Unlike the findings in this investigation, in a study[14] that evaluated the relationship between some nutritional parameters and the development of periprosthetic joint infection in patients undergoing total joint arthroplasty, the authors showed through multivariate analysis that lower levels of albumin and hemoglobin, were significantly associated with periprosthetic joint infection.[14] In this same study, the authors observed that albumin had the highest specificity and positive predictive value compared to all the other markers investigated.[14] Other relevant findings, different from the results observed in the present study, show interesting data; pointing out that hypoalbuminemia could be used as a preoperative predictor of outcomes and the understanding of the effects of malnutrition on perioperative complications could guide surgical interventions.[10]

Another study suggested that the investigation of nutritional status should not be neglected when considering total joint arthroplasty in patients with low body weight,[9] and that even severe obesity may not be associated with a higher risk of death after arthroplasty.[9]

There are also investigations showing the incidence of surgical site infection in a retrospective study with patients undergoing primary joint arthroplasty, pointing out that plasma serum albumin levels below 36.7g/L, BMI≥28 and ASA ≥3 were considered risk factors of postoperative wound infection.[19] Deep wound infections in patients undergoing knee replacements were also observed in those with reduced albumin and transferring levels and lymphocyte counts.[20] The findings of our work suggest that it may not be relevant to require plasma protein tests in patients with this type of trauma in emergency care and hospital emergency services. Perhaps in other clinical and surgical situations, this requirement would be relevant. But it is important to highlight the fundamental role of the nutritional status in optimizing clinical and surgical outcomes, and in preventing postoperative infections and wound complications, as observed in another investigation that showed that albumin, prealbumin and transferring levels may be predictive of wound complications after total knee arthroplasty.[21] In the present study, we used linear regression analysis to assess changes over time and highlighted the fundamental role of nutritional investigation.[21] It is also important to note that the present study was conducted at a referral service for traffic accidents and we believe that most men suffered fractures of the lower limbs not related to the hip, as they were victims of traffic accidents, and most women had hip fractures, probably related to osteoporosis. It is necessary that these findings be further investigated in future research, perhaps with a larger sample and reproduced in other research centers.

Study limitations

The small sample size can be considered the main limiting factor of this investigation. Another limiting factor can be attributed to the issue of data collection in a hospital emergency service and emergency room, which may have influenced the findings of albumin and transferrin. Another limiting factor refers to the fact that this work was conducted during the full blown period of Covid-19 pandemic.

CONCLUSION

In this series, the findings allowed us to conclude that there was an inverse relationship between plasma proteins and surgical wounds outcome considered satisfactory. Only compound fractures were associated with wound outcome.

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