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### Levels of Evidence for Primary Research Question<sup>a</sup>

(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 <sup>d</sup> (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 <sup>b</sup> of Level RCTs (and study results were homogenous <sup>c</sup> )	Systematic review <sup>b</sup> of Level I studies	Systematic review <sup>b</sup> of Level I studies	Systematic review <sup>b</sup> of Level I studies
	Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization)	Retrospective <sup>r</sup> 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 <sup>d</sup> comparative study <sup>e</sup>	Untreated controls from an RCT	Systematic review <sup>b</sup> of Level II studies	Systematic review <sup>b</sup> of Level II studies
I	Systematic review <sup>b</sup> 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 <sup>b</sup> of Level II studies		
	Case control study <sup>a</sup>	Case control study <sup>g</sup>	Study of non consecutive patients; without consistently applied reference "gold" standard	Analyses based on limited alternatives and costs; and poor estimates
ш	Retrospective <sup>f</sup> comparative study <sup>e</sup>		Systematic review <sup>b</sup> of Level III studies	Systematic review <sup>b</sup> of Level III studies
	Systematic review <sup>b</sup> of Level III studies		Case-control study	
			Poor reference standard	
IV	Case series <sup>h</sup>	Case series		Analyses with no sensitivity analyses
v	Expert opinion	Expert opinion	Expert opinion	Expert opinion

<sup>a</sup> A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

<sup>b</sup> A combination of results from two or more prior studies

° Studies provided consistent results.

<sup>d</sup> Study was started before the first patient enrolled.

<sup>e</sup> 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.

<sup>f</sup> The study was started after the first patient enrolled.

<sup>9</sup> 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.

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## CORRELATION BETWEEN QUALITY OF LIFE AND THE CLINICAL RESULTS OF PATIENTS WITH LEPROSY WITH DROP FOOT AFTER TENDON TRANSFER

AVALIAÇÃO DE PACIENTES COM HANSENÍASE PÓS TRANSPOSIÇÃO TENDÍNEA PARA PÉ CAÍDO E SUA CORRELAÇÃO COM A QUALIDADE DE VIDA

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### ABSTRACT

Objective: To evaluate the functional results of surgically correcting drop foot in patients with leprosy and compare their SALSA, Social Participation, and AOFAS score. Methods: Overall, 22 patients were subjected to posterior tibial tendon transfer via the subcutaneous route to the foot dorsum with an average follow-up of 56 months (min 12, max 70). In our sample, 15 of the enrolled patients were men and seven, women, aged between 20 and 73 years old who were operated on from January 2014 to December 2017. The Pearson's correlation test (r) was used to measure the correlation among those scales. A p < 0.05was considered significant between the pre- and pos-operative AOFAS scale scores. Results: Pre-operative average AOFAS score was 59.6 (min 35, max 74) and 77.2 postoperative (min 36, max 97) (p < 0.0001), postoperative Salsa and Social Participation scale, 30.6 and 22.5, respectively. Statistical analysis suggests a strong positive correlation between AOFAS and Salsa scales (r = -0.83) and AOFAS and social participation (r = -0.78). Average dorsiflexion was 5.4 degrees. Conclusion: The surgical correction of drop foot positively affects the quality of life and social participation of patients with leprosy. Level of Evidence III, Retrospective Study.

**Keywords:** Peroneal Neuropathies. Leprosy. Tendon Transfer. Drop foot.

### RESUMO

Objetivo: Avaliar o resultado funcional da cirurgia de correção de pé caído em pacientes hansênicos e comparar as escalas Screening of Activity Limitation and Safety Awareness (SALSA) e de Participação social pós-operatórias com o escore da American Orthopaedic Foot and Ankle Society (AOFAS). Métodos: Avaliamos 22 pacientes submetidos à transposição do tibial posterior para o dorso do pé com mínimo de seguimento de 12 e máximo de 131 meses operados entre janeiro de 2013 e dezembro de 2017. Utilizamos o coeficiente de Pearson (r) para medir o grau de correlação entre as escalas funcionais e consideramos o valor de p < 0,05 na análise dos valores pré e pós-operatórios da AOFAS. Resultados: A média da AOFAS foi de 59,6 no pré-op (mín 35, máx 74) e 77,2 no pós-op (mín 36, máx 97) (p < 0,0001) e das escalas SALSA e participação social de 30,6 e 22,5 no pós-operatório. A análise estatística demonstrou correlação positiva forte (r = -0.83) com as escalas SALSA e de participação social (r = -0,78) quando comparadas ao AOFAS. O grau de dorsiflexão atingido foi de 5,4 graus em média. Linha de pesquisa: Evidência clínica e organizacional, modelos assistenciais, educacionais e avaliação de gualidade em APS – Pós-graduação em Clínica Médica da Faculdade de Medicina da UFRJ. Conclusão: A melhora da função através da correção cirúrgica do pé caído possui correlação direta na melhora da qualidade de vida dos pacientes portadores de hanseníase. Nível de Evidência III, Estudo Retrospectivo.

**Descritores:** Neuropatias Fibulares. Hanseníase. Transferência Tendinosa. Pé caído.

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### INTRODUCTION

Leprosy remains an important public health problem in many countries in the world. Currently, Brazil continues to show a high incidence rate of the disease, behind only India in number of new cases. According to a WHO annual report, in 2018, 208,641 new cases were diagnosed in the world, of which 30,957 were in the

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Americas.<sup>1</sup> Also according to the report, the overall prevalence of the disease was 184,238 cases at the end of 2018, a reduction of 8,474 cases in relation to 2017. Brazil had 28,660 new cases, an increase over the previous year, which had 26,875 cases, totaling 13.7% of cases worldwide. Of these new cases in Brazil, 2,109 already showed a disability grade 2 at the time of diagnosis, showing the great importance of reconstructive procedures to improve these patients' quality of life and function.<sup>2</sup>

The Brazilian Ministry of Health uses tests based on physical examinations and questionnaire responses, including the SALSA/risk awareness and social participation scale — a functional evaluation protocol aiming to know how individuals perform daily activities and interact/participate in their daily lives with their family members and community<sup>3</sup> before, during, and after clinical/surgical treatment.

The results of these patterns have been questioned, since such questionnaires fail to include specific tests to assess the function of affected limbs after surgical intervention since some cases may show a lack of correlation between the actual functional result observed with the SALSA and social participation scale scores.

To better understand function after the surgical treatment of foot drop in patients with leprosy, and aiming to recognize social and labor market reintegration, we used the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot scale,<sup>4</sup> which specifically evaluates lower limb function and symptoms, comparing it with the already established Salsa and Social Participation scales.

### MATERIALS AND METHODS

### **Ethical aspects**

This study complied with the ethical recommendations of the Research Ethics Committee of HUCFF/FM-UFRJ and CNS/MS 196/96. Research was initiated after its approval and registration under no. 96/13. All patients included in this study were duly informed of it and those who agreed to participate gave us their consent by signing informed consent forms, a copy of which was given to them.

### Study design

This is a retrospective and cross-sectional study with functional evaluation, as well as measurement of activity levels and social participation of patients with leprosy subjected to the surgical correction of foot drop via transfer of the posterior tibial tendon to the foot dorsum. The following questionnaires were used and validated in Brazil: SALSA, social participation, and the AOFAS ankle-hindfoot scales.

### **Study population**

Between January 2014 and December 2017, 29 patients with leprosy underwent surgery to correct foot drop. Of these, one died, another suffered amputation below the knee due to complications unrelated to tendon transfer or leprosy, three were lost in follow-up, and two refused to participate in this study. Thus, our sample totaled 22 patients. Among these, 15 individuals were men and seven, women aged from 20 to 83 years old with a minimum of one-year follow-up (mean of 39.1 months, minimum of 12 and maximum of 70 months). Inclusion criteria were patients aged 18 years or older with foot drop caused by leprosy who were submitted to surgical correction via subcutaneous posterior tibial tendon transfer (Table 1). Exclusion criteria were the presence of ulcers or other deformities in the lower limbs in addition to concomitant surgeries on the affected foot and ankle.

### **Data collection**

Functional evaluation was based on 1) measurement of the active range of motion of the tibiotarsal joint via a goniometer parallel to the sole of the foot and the longitudinal axis of the leg, in which positive values correspond to dorsiflexion and negative values to plantar

Table 1. Patients with leprosy subjected to posterior tibial tendon transfer
to treat foot drop. Clinical form of the disease, postoperative time, gender,
operated side, and age at the time of surgery.

Patient	Gender	Side	Age	Postoperative time (months)	Clinical manifestation
1	F	L	73	52	PN, PB
2	М	R	61	17	RT, MB
3	М	R	64	14	PN, MB
4	М	L	35	46	RT, MB
5	М	R	58	28	RV, MB
6	М	R	65	28	RT, MB
7	М	R	50	17	RV, MB
8	М	R	34	51	RV, MB
9	F	L	53	66	RT, MB
10	F	R	59	64	PN, PB
11	F	R	65	38	RV, MB
12	M	R	20	29	PN, MB
13	М	R	57	60	RT, MB
14	М	L	68	37	RT, MB
15	М	R	40	59	RT, PB
16	F	R	50	28	RV, MB
17	М	L	39	69	RV, MB
18	М	R	54	28	RV, MB
19	F	L	46	70	RV, MB
20	M	R	71	12	RV, MB
21	F	R	68	35	RV, MB
22	М	L	62	13	RV, MB

M: male; F: female; R: right; L: left; PN: pure neural; DT: dimorphic tuberculoid; DV: dimorphic virchowian; PB: paucibacillary; MB: Multibacillary.

flexion and 2) muscle strength graduation, according to the criteria established by the modified Medical Research Council (MRC), on a scale ranging from 0 (muscle paralysis) to 5 (normal muscle strength). Patients were asked to answer social participation questionnaires before and after surgical intervention, as well as the SALSA scale, already validated for Brazilian Portuguese, which assesses how individuals perform daily activities and self-care, with their respective scores. The AOFAS scale, which Rodrigues et al.<sup>5</sup> also validated for Brazilian Portuguese, was used on a point scale which considered pain, function, ability to walk, and alignment as parameters. Data were collected by physical examinations and interviews in which the selected questionnaires were applied. After data collection, the information was quantified, digitized, and stored in a spreadsheet on the responsible researcher' computer via the EPI INFO application version 3.4.3. SPSS V.13 for WINDOWS and EPI INFO VERSION 3.4.3 were used for data analysis. Descriptive analysis was shown in illustrative tables, graphs, and observed data.

The AOFAS scores are: 0-20, very severe limitation; 21-40, severe limitation; 41-60, moderate limitation; 61-80, mild limitation; and 81-100, no limitation.

The SALSA scale scores are: 10-24, without limitation; 25-39, mild limitation; 40-49, moderate limitation; 50-59, severe limitation; and 60-80, very severe restriction.

Social Participation Scale scores are: 0-12, no significant restriction; 13-22, slight restriction; 23-32, moderate restriction; 33-52, severe restriction; and 53-90, extreme restriction.

#### Statistical analysis

AOFAS scores were separately compared with SALSA and SOCIAL PARTICIPATION scores by the Pearson's statistical correlation test. A p < 0.05 was considered statistically significant when comparing pre- and postoperative AOFAS.



### Surgical technique

Transfer of the posterior tibial tendon (TTP) to the foot dorsum was performed as described by Srinivasan, Mukherjee, and Subramaniam.<sup>6</sup> The TTP is sectioned next to its insertion in the navicular bone and a second posteromedial incision is performed eight to 12 cm above the medial malleolus to identify the tibialis posterior muscle belly. Next, the TTP is proximally stretched and longitudinally divided (Figure 1). An incision is made in the dorsal region of the foot to individualize the hallucis longus and extensor digitorum longus tendons. Then, two tunnels are constructed in the subcutaneous tissue, superficial to the retinaculum of the extensors and the TTP is then transferred to the foot dorsum (Figure 2). The medial tape is sutured to the extensor hallucis longus (Figure 3) and the lateral tape to the extensor digitorum longus tendon with the foot in dorsiflexion between 20 and 30 degrees (Achilles lengthening is performed if necessary ) (Figure 4), maintaining traction in the distal direction of the TTP tapes and in the proximal direction of the extensor hallucis longus and extensor digitorum longus tendons for good transfer tension (Figures 5 and 6). Postoperative treatment is performed via a cast immobilization boot set in a 20degree dorsiflexion during the first two weeks, followed by another four weeks with an unsupported cast boot in a neutral position. After this period, rehabilitation begins with a removable boot used for an additional six weeks for protection.



Figure 1. Division of the posterior tibial tendon into medial and lateral tapes.



Figure 2. Use of tunneling clamps to subcutaneously transfer the posterior tibial tendon.



Figure 3. Suture of the medial tape to the extensor hallucis longus tendon.



Figure 4. Suture of the lateral tape to the extensor digitorum longus.



Figure 5. Final aspect.



Figure 6. Foot position at the end of the surgery.

#### RESULTS

Table 2 shows the respective pre- and postoperative AOFAS, SALSA, and postoperative social participation scale scores. According to the SALSA scale results, 14 patients showed no limitations, three, mild ones, one, moderate ones, two, severe ones, and two, very severe ones. Social participation was very active, considering that patients' average score was only 22.5 points, with the lowest value of 0 and a maximum of 80 (higher scores indicate greater difficulty in daily activities, working, and social isolation). We found 12 patients with no restrictions, four, with mild ones, no patients with moderate ones, one, with severe ones, and five, with extreme ones.

Average active dorsiflexion was 5.4 degrees (maximum of 20, minimum of -10 degrees) and plantar flexion, -27.9 degrees (maximum of -35, minimum of -12 degrees), with a mean ROM of 28.3 degrees (dorsiflexion + plantar flexion) (Figures 7 and 8). Only two patients failed to reach a neutral dorsiflexion position (0 degree), reflecting a low AOFAS scale score (36 and 52). Mean AOFAS scores were 59.6 in the pre- and 77.2 in the postoperative period with a p < 0.0001. In total, two patients showed inversion deformities due to loss of lateral tape tension, one evolving hindfoot stiffness with varus and forefoot adduction, whereas the other showed a mild deformity which failed to affect the final transfer result, with an 83 AOFAS score. Muscle strength after the minimum six-month follow-up was at least grade three in all patients, and 15 patients reached grade four. Clinically, no patient showed plantar arch fall.

Figures 9 and 10 show the relation between AOFAS and the SALSA and Social Participation scale scores, respectively. We observed an inversely linear relation between AOFAS and other scale scores. The higher the AOFAS, the lower the other scores. The Pearson's correlation coefficient showed a strong correlation for AOFAS with SALSA (r = -0.83447) and for AOFAS with the social participation scale (r = -0.78638), showing that foot drop correction positively affects the daily lives and social reintegration of patients with leprosy.

Societ	y ankie-minulu	or scale scores.		
Patient	SALSA score	Social Participation Scale	AOFAS	Pre-op AOFAS
1	24	5	88	64
2	60	72	52	42
3	31	9	86	74
4	23	5	90	62
5	27	20	83	54
6	21	8	85	68
7	17	22	87	70
8	22	0	72	55
9	76	69	36	35
10	22	5	75	53
11	39	60	66	47
12	19	4	90	72
13	45	80	60	58
14	21	0	78	52
15	12	9	97	67
16	22	1	85	65
17	23	21	66	44
18	24	1	78	62
19	15	13	90	74
20	59	55	67	58
21	23	2	88	64
22	50	36	80	72
	30.68181818	22.59090909	77.22727	59.63636364

**Table 2.** Sample patients' Activity Limitation and Safety Awareness, social participation, and the American Orthopaedic Foot and Ankle Society ankle-hindfoot scale scores.



Figure 7. Case 15 performing active plantar flexion.



Figure 8. Case 15 performing active dorsiflexion.







Figure 10. American Orthopaedic Foot and Ankle Society scores by the Screening of Activity Limitation and Safety Awareness scores.

#### DISCUSSION

The stigma caused by the disease still represents an important factor of social isolation, negatively affecting the relationship of leprosy patients with their families and peers in their community. Most patients show self-stigmatization and self-deprecation, evidenced from three most common aspects: those linked to individuals' representations about leprosy, those related to impairments in physical appearance, and those resulting from disabling and deforming injuries whose effects go beyond aesthetic issues. In this context, the reparative surgery of lower limbs to correct foot drop in patients with leprosy is of fundamental importance to improve foot function and quality of life and promote their subsequent social reintegration.

Correcting foot drop due to leprosy by transfering TTP is well established in the literature,<sup>7,8</sup> but there is controversy between the interosseous or subcutaneous routes. Some authors9-11 recommend the subcutaneous pathway since it is easier to perform, shows no risk of neurovascular injury, provides a larger lever arm, and allows the tendon to slide smoothly, decreasing the possibility of adhesions or invagination of the muscle in the interosseous membrane. Other authors defend the interosseous<sup>12-15</sup> pathway since, in it, the tensile force is more direct, thus producing less inversion and longer insertion and avoiding the effects of tenodesis related to excessive tension at the suture site. In our sample, we observed two cases which showed inversion deformities after subcutaneous TTP transfer. Ishida, Lwin, and Myint<sup>16</sup> reported similar results in 33 patients subjected to TTP transfer. They found four poor results due to loss of lateral tape tension causing inversion deformity. It is interesting to note that of these four cases, three were subjected to interosseous transfer and only one to the subcutaneous one, showing that the interosseous pathway is also liable to this complication.

Soares<sup>17</sup> compared subcutaneous and interosseous pathways in TTP transfers to treat foot drop in patients with leprosy, reporting a high rate of inversion in the group subjected to the subcutaneous pathway, which led to ulceration of the lateral edge of the foot. This author recommends that the subcutaneous pathway should be reserved for patients with calcified and inflexible interosseous membranes. Aiming to standardize the choice of the best route for each patient, Das et al.<sup>18</sup> recommend subcutaneous posterior tibial tendon transfers for patients with leprosy who show selective deep fibular nerve paralysis with fibular strength of grade 4 or higher, reserving the interosseous pathway for patients with a lower degree of fibular strength (3 or less).

We used insertion in the extensor hallucis longus (medial tape) and extensor digitorum longus/third fibular (lateral tape) as recommended by Srinivasian.<sup>6</sup> The advantage of this technique is that, since they are more distal, their insertion sites allow a better lever arm, reactivating the extension of the paralyzed hallux and toes, even if only partially. Moreover, the TTP is sutured to the receptor site with the maximum degree of tension, allowing it to naturally stretch by finding its equilibrium point, thus maximizing its functional response. Other authors recommend insertion in more proximal sites,<sup>19</sup> with the medial tape inserted in the anterior tibial tendon and the lateral tape in the short or long fibular tendon. The advantage of this method is a greater tendon excursion, though with a smaller lever arm, reducing dorsiflexion force.

Our statistical analysis showed a strong positive correlation (via Pearson's test) between AOFAS and SALSA and social participation scales (r = -0.83447, and r = -0.78638, respectively). We observed that each analyzed patient obtained compatible scores in the Salsa, social participation, and AOFAS scales since they follow the same linear regression curve, i.e., they are numerically proportional since the higher the score, the better the function.

Much is known about the disabilities related to leprosy, but very little about how they affect the daily lives of affected people.<sup>20</sup> The SALSA and social participation scales aim to evaluate the extent of the limitation to patients' activities, considering several social, psychological, and physical aspects, and their disability. We observed four patients with severe or very severe limitations on the SALSA scale and five, with extreme restrictions in the social participation scale. We believe that these patients show these limitations due to their relation to other psychosocial aspects of living with leprosy rather than disabilities caused by the condition of their feet, evidenced by the significant improvement to AOFAS scores (p < 0.0001). The limitations of our study are its retrospective nature, the absence of a more objective method to evaluate muscle strength after tendon transfer, and the lack of pre-operative data on the social participation and SALSA scales.

#### CONCLUSION

Improving function via the surgical correction of foot drop has a direct correlation to improving the quality of life of patients with leprosy, as shown by the strong correlation between both SALSA and social participation scales with the AOFAS scale after the subcutaneous transfer of the posterior tibial tendon to the foot dorsum.

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### INFLUENCE OF FEMORAL OFFSET ON FUNCTIONAL CAPACITY OF PATIENTS WITH TOTAL HIP ARTHROPLASTY

## INFLUÊNCIA DO OFFSET FEMORAL NA CAPACIDADE FUNCIONAL DE PACIENTES COM ARTROPLASTIA TOTAL DE QUADRIL

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### ABSTRACT

Objective: To correlate vertical (VFO) and horizontal (HFO) femoral offset with hip range of motion (ROM), peak muscle torque (PT), functional, capacity, and lower limb length in patients with total hip arthroplasty (THA). Methods: A cross-sectional case control study, in which 22 individuals (10 men and 12 women) - aged 61 (41-72), and within 23 (10-40) postoperative days - were evaluated for active hip ROM (fleximetry); Isometric PT (portable dynamometer); functional capacity (Timed up and Go test (TUG) and Harris Hip Score questionnaire); lower limb length (measuring tape); and VFO and HFO (radiographs). Results: The operated limb showed a reduction in length (p = 0.006), ROM for abduction (p = 0.001), flexion (p = 0.003), and external rotation (p = 0.003), as well as in all PT (p < 0.05) when compared with the contralateral limb. Moderate correlations were observed between VFO and external rotators (r = 0.487; p = 0.021); HFO and external rotators PT (r = -0.508; p = 0.016); and the difference between the VFO (operated and non-operated limb) and the TUG (r = -0.570; p = 0.006). Conclusion: Changes to the femoral offset seem to influence functional capacity, as well as the movement and external rotators PT of the hips in patients with THA, considering the postoperative period evaluated. Level of Evidence III, Case Control Study.

**Keywords:** Arthroplasty, Replacement, Hip. Muscle Strength. Hip Injuries.

#### RESUMO

Objetivo: Correlacionar achados do offset femoral vertical (OFV) e horizontal (OFH) aos da amplitude de movimento do quadril (ADM), pico de torque muscular (PT), capacidade funcional (CF) e comprimento dos membros inferiores (CM) em pacientes com artroplastia total de quadril (ATQ). Métodos: Estudo transversal, caso controle (nível de evidência III), foram avaliados 22 indivíduos (10 homens e 12 mulheres) com idade de 61 (41-72) anos e 23 (10-40) dias de pós-operatório, quanto à: ADM ativa do quadril (fleximetria); PT isométrico (dinamômetro portátil); CF - teste Timed up and Go (TUG) e questionário Harris Hip Score (HHS); CM (fita métrica); e OFV e OFH a partir de radiografias. Resultados: O membro operado apresentou redução no CM (p = 0,006), ADM de abdução (p = 0,001), flexão (p = 0,003) e RE (p = 0,003), e em todos os PT (p < 0,05) em comparação ao membro contralateral. Correlações moderadas encontradas entre: OFV e RE  $(r = 0.487; p = 0.021); OFH \in PT \text{ dos } RE (r = -0.508; p = 0.016);$ e a diferença do OFV (membro operado e não operado) e o TUG (r = -0,570; p = 0,006). Conclusão: Alterações no OF parecem influenciar a CF, bem como o movimento e o PT dos RE do guadril em pacientes com ATQ para o período pós-operatório avaliado. Nível de Evidência III, Estudo de Caso-Controle.

**Descritores:** Artroplastia de Quadril. Força Muscular. Lesões do Quadril.

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### INTRODUCTION

Total hip arthroplasty (THA) consists in the surgical replacement of the femur (femoral head) and pelvic (acetabulum) components of the hip joint.<sup>1</sup> The number of THA performed in the world has been growing annually. It is estimated that, by the year 2046, the number of THA performed worldwide will have increased 219%, representing a higher cost to the health system.<sup>2</sup> Preoperative planning is essential for the proper choice of prosthetic components to restore the biomechanics of the hip to normal conditions.<sup>3</sup> The measurements of the vertical (VFO) and horizontal (HFO) femoral offset can be considered both in surgical planning and in the verification of postoperative results. Previous studies have shown

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positive associations between femoral offset (FO) and hip abductors muscle strength.<sup>4-10</sup> A more lateral position of the femur followed by a greater offset could provide a biomechanical advantage, associated with greater stability of prosthetic components. It is believed that this positioning would allow a better range of motion (ROM) and strength production by the hip abductors, as well as an improvement in the tension of soft tissues.<sup>11</sup> However, more studies are needed to verify the possible relationships between the radiographic variables and the clinical outcomes.

Thus, this study aims to correlate the findings of FO with those of hip ROM, hip muscle peak torque, lower limb length, and functional capacity in patients subjected to primary THA surgery.

### MATERIALS AND METHODS

A cross-sectional study was conducted with patients subjected to primary THA surgery in hospitals in Porto Alegre, south of Brazil. Prior to data collection, a written informed consent was obtained from all participants. This study was approved by the Federal University of Health Science Research Ethics Committee (protocol 3.049.371) and a registered in Clinical Trials (NCT3208829) as part of a larger study. Individuals with postoperative complications (infections, deep vein thrombosis, prosthesis dislocation, periprosthetic fractures, and neural injuries), THA surgery on the contralateral limb less than a year prior to this study, and other orthopedic surgeries on the lower limbs were excluded from the study. All surgeries were performed using the posterior hip approach.

Participants attended a single evaluation session with the same experienced and trained assessor, between 10 to 40 days after surgery. In this evaluation, data regarding age, body mass index (BMI), lower limb length (LLL), hip ROM, hip muscle peak torque (PT), and functional capacity were obtained. The LLL was measured using a tape measure, considering the anterior superior iliac spine and the medial malleolus as anatomical points, with the patients in the supine position with the lower limbs extended.

Active ROM was assessed bilaterally using a fleximeter (model FL6010, Sanny, Brazil). Participants were instructed to perform each movement twice and were interrupted if compensatory movements (pelvis or trunk) were observed. Figure 1 shows the positions used.<sup>12</sup>



Figure 1. Range of motion assessment positions.

A: assessment of left hip extension; B: assessment of left hip abduction; C: assessment of left hip internal rotation; D: assessment of left hip external rotation; E: assessment of left hip flexion.

Hip muscle PT was measured bilaterally, using a portable dynamometer (Micro-Fet II model, Hoggan Health Industries). Three measurements of maximum voluntary isometric contraction were performed for each movement and the average of the values was used for analysis. Each measurement lasted 5 seconds with an interval of 30 seconds for resting. Figure 2 shows the positioning protocol of the evaluation, and the placing of the dynamometer according to the evaluated muscle group: abductors, dynamometer positioned approximately 10 cm above the knee joint; extensors, approximately 10 cm above the popliteal foramen; flexors, 10 cm above the patella; internal and external rotators, 5 cm above the lateral and medial malleolus (Figure 2).<sup>13</sup> All PT measurements were normalized by body mass according to the equation PT = peak of torque (Nm)/body mass (Kg)  $\times$  100.

Functional capacity was assessed using Timed Up and Go Test (TUG) and Harris Hip Score (HHS) questionnaire, both of which have excellent validity and reliability.<sup>14,15</sup> To perform the TUG test, participants had to rise from a chair, without the support of their arms, walk 3 meters at their usual speed, using their auxiliary devices if necessary, until they reach a mark on the floor; then they had to turn around, walk back to the chair, and sit down.<sup>16,17</sup> The HHS has a score ranging from 0 to 100, distributed across the domains: pain, function-gait, function-activity, deformity, and ROM. According to the obtained scores, the results were classified: poor, below 70 points; normal, 70-79 points; good, 80-89 points; and excellent, 90-100 points.<sup>9</sup>



Figure 2. Muscle torque assessment positions.

A: hip internal rotator isometric muscle torque assessment; B: hip external rotator isometric muscle torque assessment; C: hip flexors isometric muscle torque assessment; D: hip abductor isometric muscle torque assessment; E: hip extensors isometric muscle torque assessment.



VFO and HFO measurements were performed from radiographs of the pelvis (anteroposterior view), with the patient in the supine position and lower limbs neutrally positioned, obtained in the hospitals computerized systems. The VFO was determined by the distante from the center of the femoral head to the starting point for lesser trochanter (Figure 3). HFO was defined as the distance comprised by a line passing perpendicularly from the center of rotation of the femoral head to the meeting point with another line that passes through the long axis of the femur (Figure 3). According to the literature, from the difference between the HFO of the operated limb and the non-operated limb, the HFO can be classified as: increased, difference of 5 mm or more with the operated limb being bigger; reconstructed, difference of up to 5 mm between the limbs; and reduced, difference of less than 5 mm, with the operated limb being smaller.9,18,19



The Shapiro-Wilk test was used to verify data distribution. In the descriptive analysis, measures of central tendency (median, minimum, and maximum) were applied. In order to analyze the reliability of the ROM and PT measurements, the Intraclass Correlation Coefficient (ICC) was used, which can be classified as excellent (ICC > 0.75), satisfactory (ICC = 0.40-0.75), and weak (ICC < 0.40), of which only those classified as at least satisfactory ( $\alpha$  < 0.05) are considered relevant.<sup>20</sup> For the intra-group comparative analysis (operated lower limb and non-operated lower limb) the Wilcoxon test was applied for nonparametric data. For correlational analyses, Spearman's Linear Correlation was used. A significance level ( $\alpha$ ) of 5% and a confidence interval of 95% were adopted. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) for Windows (version 22.0).

### RESULTS

The data found in this study had a non-normal distribution. In total, 22 individuals (10 men and 12 women) were included; they had a median age of 61 (41-72) years, a BMI of 29.48 (21.59-37.01) kg/m<sup>2</sup>, and were evaluated 23 (10-40) days after surgery. Table 1 has further information on the characterization of the sample.

All participants received routine care during the hospitalization period, with daily physiotherapy sessions and guidelines related to postoperative care. Regarding functional capacity, the individuals presented a time of 26.41 (12.30-60.38) seconds in performing the TUG test and a score of 57.45 (37.20-73.50) on the HHS (Table 1). The internal reliability of the measurements obtained in this study was considered excellent for both hip PT (ICC = 0.95-0.98; p > 0.05) and ROM (ICC = 0.93-0.99; p < 0.05).

Table 2 shows the data regarding FO, LLL, ROM, and PT. No statistically significant differences were found between the lower limbs (operated and non-operated) according to the VFO (p = 0.152) and HFO (p = 0.162). However, from the values of the difference between members for the HFO, 2 individuals were classified as increased HFO, 2 as reduced, and 8 as reconstructed. Statistically significant differences, with lower values in the operated limb, were found in the comparisons between the lower limbs, in relation to the LLL (p = 0.006); hip abduction (p = 0.001), flexion (p = 0.003) and external rotation (p = 0.003) ROM and peak torque for hip flexion (p = 0.002), abduction (p = 0.001), extension (p = 0.001), external values (p = 0.002).

rotation (p = 0.002) and internal rotation (p = 0.001)(Table 2). Regarding the correlation between the FO (VFO and HFO) and other variables, some relationships were found, but only the following were statistically significant: VFO and external rotation ROM (r = 0.487; p = 0.021); HFO and external rotators PT (r = -0.508; p = 0.016); and moderate correlations with the TUG test (r = -0.570; p = 0.006) was found when using the difference between the operated and non-operated VFO.

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Table 1. Total hip arthropiasty patients characterization.			
	THA patients (n = 22)		
Age (years)	61.00 (41.00 - 72.00)		
Sex (M/F)	10/12		
Height (m)	1.67 (1.39 - 1.78)		
Weight (kg)	77.00 (57.00 - 100.50)		
BMI (kg/m2)	29.58 (21.59 - 37.010)		
P.O. Period (days)	23.00 (10.00 - 40.00)		
Fixation Type (H/C)	14/8		
Contralateral hip prosthesis (Y/N)	5/17		
Auxiliary Device (1C/2C/W)	2/8/12		
TUG(s)	26.41 (12.30 - 60.38)		
HHS	57.45 (37.20 - 73.50)		

1C: one crutch; 2C: two crutches; BMI: body mass index; C: cemented; F: female; H: hybrid; M: male; N: no; P.O.: postoperative; THA: total hip arthroplasty; TUG: Timed Up and Go Test; Y: yes; W: walker. Values expressed as median (minimum-maximum).

**Table 2.** Comparison between operated and non-operated lower limbsfor joint range of motion (degrees), normalized muscle torque peaks(Nm/kg), femoral offset (mm), and lower limb length (cm).

(,		(),		
		OLL	NOLL	
L	LL	86.25 (72.00 - 99.00)*	87.00 (73.00 - 97.00)	
VOF		30.00 (21.00 - 44.00)	28.00 (20.00 - 45.00)	
Unset	HOF	17.50 (10.00 - 22.00)	17.50 (13.00 - 33.00)	
	Flexion	41.50 (11.00 - 56.00)*	60.00 (15.00 - 90.00)	
	Extension	19.50 (10.00 - 26.00)	19.00 (7.00 - 40.00)	
ROM	Abduction	15.00 (8.00 - 32.00)*	21.50 (14.00 - 40.00)	
	IR	15.00 (6.00 - 30.00)	17.50 (4.00 - 35.00)	
	ER	10.00 (3.00 - 26.00)*	18.00 (1.00 - 37.00)	
	Flexion	114.00 (54.00 - 247.00)*	186.00 (52.00 - 257.00)	
	Extension	67.00 (30.00 - 173.00)*	117.00 (37.00 - 323.00)	
PT	Abduction	68.00 (36.00 - 184.00)*	114.00 (16.00 - 314.00)	
	IR	43.00 (29.00 - 137.00)*	92.00 (36.00 - 202.00)	
	ER	73.00 (30.00 - 137.00)*	109.00 (38.00 - 167.00)	

HFO: horizontal femoral offset; IR: internal rotation; ER: external rotation; LLL: lower limb length; OLL: operated lower limb; NOLL: non-operated lower limb; PT: peak muscle torque; ROM: range of motion; VFO: vertical femoral offset. Values expressed as median (minimum-maximum). \*p > 0.05.



### DISCUSSION

Our study correlated the findings of FO with those of hip ROM, hip PT, LLL, and functional capacity, as well as compared the operated and non-operated lower limbs in patients undergoing primary THA surgery. The main findings of this study refer to the scores of functional capacity, the differences between the operated and non-operated limbs, and the correlations between the measurements of the FO and the individuals' ROM, PT, and functional capacity.

Based on the score of the HHS questionnaire, classified as bad, and the time of 26.41 (12.30-60.38) seconds taken to perform the TUG test, we observed that the individuals in this study showed a reduction in their functional capacity considering the post-operative period evaluated. According to Bohannon,<sup>21</sup> the time taken to perform the TUG test increases with age. In a population aged 60-69 years an 8.1 (7.1-9.0) seconds time should be considered a reference value, and in a population aged 70-79 year, a 9.2 (8.2-10.2) seconds time should be considered normal. Values higher than those of reference suggest disturbances.<sup>21</sup> These alterations may be related to balance, muscle strength,

and/or mobility disorders, and are frequently found in individuals in the post-operative period of THA, as is the case of the patients in this study (about 23 days post-operatively).<sup>22-25</sup>

Our findings are in line with those of other studies, which also found positive correlations between the FO and THA patients' functional capacity.<sup>26,27</sup> In this study, statistically significant correlations were found between FO and the TUG test, but not with HHS questionnaire. These findings suggest that the greater the difference between the operated and the non-operated lower limb, that is, when there is an increase in VFO in the operated in relation to the non-operated limb, there is a decrease in the time to perform the TUG test and an increase in the score obtained. The association found with the TUG test, but not with HHS, may be related to the fact that the TUG is a dynamic test that comprises movements used in daily life, being more directly involved and dependent on biomechanical issues, since it allows assessing sitting balance, transferring from sitting to standing position, stability in ambulation, and change of direction.<sup>26</sup>

Contrary to our findings, Buecking et al.<sup>27</sup> found correlations between the FO and the HHS questionnaire, but not with the TUG test; whereas Hartel et al.<sup>28</sup> found no correlations between FO and functional capacity. It is worth mentioning, however, that those studies differ from ours regarding patients profile; their patients had a higher age average,<sup>27,28</sup> underwent THA due to femoral neck fracture,<sup>27,28</sup> and, in some cases, had associated pathologies (dementia, sarcopenia and/or neurological disorders),<sup>28</sup> which makes comparing studies difficult.

The reductions found in the operated limb, compared to the nonoperated limb, in relation to hip ROM and PT, can be expected due to the trauma of the surgical procedure, especially in the postoperative period, such as that of our study. According to our knowledge, this study was one of the few to search for correlations between FO and hip ROM in patients with THA. Positive correlations were found, suggesting that an increased VFO could be related to the greater hip external rotation range of motion. In a study by McGrory et al.,<sup>7</sup> positive correlations between FO and ROM were also found, but in relation to hip abduction.

Several studies point to a positive correlation between the FO and the muscular strength of the hip abductors, suggesting that a restored or slightly increased FO would bring mechanical advantage to the hip abductor muscles, greater stability and functionality, and smaller reaction force in the hip joint.<sup>5,8,9,23</sup> Our study did not find such correlations, but it was the first to find a correlation between FO and hip external rotators PT. The results suggest that the higher the HFO, the lower the external rotators PT, that is, an increased HFO in the operated limb would result in a lower muscle force generation of external rotors, represented by a lower PT.

It is difficult to compare the results from our study with those found in other studies, as they differ methodologically from ours in some points: exclusively assessing hip abductors muscle strength;<sup>5,8,9,19</sup> longer postoperative period (6 months to 29 years);<sup>5,9,19</sup> measuring muscle strength in an isokinetic dynamometer;<sup>5,9,19</sup> measuring FO through computed tomography; and using either HFO alone or global FO (sum of HFO and VFO).<sup>5,8,9,19</sup>

The main limitations of this study refer to the impossibility of grouping individuals for comparison according to the increase and decrease in FO, due to the sample size; and the use of simple radiographs instead of computed tomography to measure the FO, which may have underestimated the real differences. According to Sariali et al.,<sup>29</sup> measurement on radiographs leads to an underestimation of the FO between 3.5-13 mm. We believe, however, that this underestimation does not seem to be relevant in this case, as we used the comparison between the operated and non-operated sides. Furthermore, simple radiography is a low-cost and accessible test that does not expose the patient to greater risks, being widely used to measure FO in the clinical setting.

### CONCLUSIONS

Our findings allow us to conclude that changes in the femoral offset measurements (horizontal and vertical), resulting from the surgical procedure of total hip arthroplasty, can influence the patient's functional capacity, as well as their range of motion and muscle strength of the external rotators of the hip. These results reinforce that biomechanical factors resulting from surgery must be considered in future works.

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## CLINICAL AND FUNCTIONAL ANALYSIS AFTER TOTAL KNEE ARTHROPLASTY

## ANÁLISE CLÍNICA E FUNCIONAL APÓS ARTROPLASTIA TOTAL DE JOELHO

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### ABSTRACT

Osteoarthritis is a major cause of disability worldwide. Objective: To evaluate the effects of Total Knee Arthroplasty of subjects with knee osteoarthritis by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Methods: Prospective, non-randomized study with convenience sampling. We included subjects with knee osteoarthritis with indication for surgical treatment. We used WOMAC to evaluate the level of pain, joint stiffness, physical activity, and quality of life in the preoperative and postoperative phase six months after unilateral surgery. We compared WOMAC to the factors age, gender, Body Mass Index and the type of angular deformity of the knee. Results: In total, we analyzed 58 patients with significant improvements in pain relief, joint stiffness, level of physical activity, and quality of life six months after total knee arthroplasty according to WOMAC. Conclusion: Total knee arthroplasty showed positive effects on the quality of life of patients with knee osteoarthritis. Level of Evidence II, Cohort Study.

**Keywords:** Osteoarthritis. Arthroplasty, Replacement, Knee. Quality of Life.

#### RESUMO

A Osteoartrite é uma das principais causas de incapacidade mundial. Objetivo: Avaliar os efeitos da Artroplastia Total de Joelho (ATJ) de sujeitos com osteoartrite de joelho com o Índice de Osteoartrite WOMAC (Western Ontario and McMaster Universities). Métodos: Estudo prospectivo não randomizado, com amostragem de conveniência. Foram incluídos sujeitos com diagnóstico de osteoartrite de joelho com indicação de tratamento cirúrgico. Foi utilizado o WOMAC para avaliar o nível de dor, rigidez articular, atividade física e qualidade de vida na fase pré-operatória e no pós-operatório com seis meses após a realização da cirurgia (unilateral). O WOMAC foi comparado aos fatores idade, sexo, Índice de Massa Corpórea (IMC) e o tipo de deformidade angular do joelho. Resultados: Foram analisados 58 pacientes, observou-se melhoras significantes na dor, rigidez articular, nível de atividade física e qualidade de vida, seis meses após a artroplastia total de joelho de acordo com o WOMAC. Conclusão: A ATJ apresentou efeitos positivos na qualidade de vida dos pacientes com osteoartrite de joelho. Nível de Evidência II, Estudo de Coorte.

**Descritores:** Osteoartrite. Artroplastia do Joelho. Qualidade de Vida.

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### INTRODUCTION

The focus of osteoarthritis (OA) treatment should involve aspects such as pain, joint stiffness, and quality of life.<sup>1-3</sup> Among the treatment modalities, different studies present the benefits of clinical and surgical treatment.<sup>4-7</sup> Regarding surgical treatment, scientific evidence shows the efficacy of total knee arthroplasty (TKA) in the aforementioned aspects. Regardless of the technique, the current literature indicates positive effects in short-, medium-, and long-term.<sup>4,6,7</sup>

Different factors are related to the positive effects produced by total arthroplasty. Aspects such as gender, age, body mass index (BMI), socioeconomic status, comorbidities, anxiety, depression, and pain catastrophizing can influence pain after surgery.<sup>8</sup>

The literature shows several studies on survival time and implants alignment, which does not necessarily correlate with absence of pain and improvement of function, therefore, it is important to use instruments that measure the clinical effectiveness of TKA in individuals with OA, the impact of surgery on function and on quality of life (QOL). Among the different instruments that assess quality of life are the Medical Outcomes Study Short Form 36 (SF-36), and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).<sup>9</sup> WOMAC is a specific questionnaire for individuals with osteoarthritis and can be used to assess pain, joint stiffness, level of physical activity, and quality of life before and after surgery. Thus, our study aimed to evaluate the effects of TKA in individuals with OA, using the WOMAC.

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

The study was conducted at Centro Estadual de Reabilitação e Readaptação Dr. Henrique Santillo. Correspondence: Helder Rocha da Silva Araujo. Av. Ver. José Monteiro, 1655, Goiânia, GO, Brazil, 74653230. drhelderrocha@hotmail.com

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#### MATERIAL AND METHODS

This prospective non-randomized study with convenience sampling, conducted from April 2017 to December 2017, was approved by the Research Ethics Committee of the Institution (CEP 2.854.059). All selected individuals agreed to participate in the study. Individuals with gonarthritis referred to surgical treatment were included, as illustrated in Figure 1. The individuals were evaluated in the pre- and postoperative phase (six months) after TKA procedure with Rotaflex® prosthesis (Víncula, Brazil). Clinical evaluation was performed using the WOMAC Osteoarthritis Index. WOMAC Osteoarthritis Index was compared with age, gender, BMI, and type of knee deformity. Individuals of all genders, aged between 55 and 80 years, were included in the study. Individuals with secondary gonarthritis to rheumatoid arthritis, fracture sequelae, or infection were excluded.

### Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS) software, version 23.0. The Shapiro-Wilk test was used to verify data normality. In the inferential analysis, paired Student's t-test (parametric data) or Wilcoxon (nonparametric data) were performed to compare pain, joint stiffness, level of physical activity, and QOL before and after TKA. Student t-tests for independent samples (parametric data) or Mann-Whitney U (nonparametric data) were used to compare pain, joint stiffness, level of physical activity, and general QOL before and after TKA in the subgroups gender (women × men), age (< 65 years ×  $\geq$  65 years), BMI and kind of deformity (valgus × varus). A 95% confidence interval and a P < 0.05 significance level were established.

### RESULTS

In total, 58 individuals participated in the study, 42 (72.4%) women and 16 (27.6%) men. Out of the total, 43 (74.1%) had varus deformity and 15 (25.9%) valgus deformity. Table 1 shows the general



Figure 1. Total knee arthroplasty.

characteristics of the sample. Regarding age, the sample was composed of older adults (66.89 years  $\pm$  6.34), presenting:

Table 2 shows the comparison of QOL before and after TKA. Note that, all domains showed improvements (P < 0.05).

Table 3 shows the comparison of QOL—before and after TKA in the gender subgroup (women  $\times$  men). Notably, all gender showed improvement in all evaluated domains (P < 0.05). No differences were found between genders.

Table 4 shows the comparison of QOL before and after TKA in the age subgroup (older than 65 years × younger than 65 years). Both subgroups presented positive outcomes regarding pain relief, joint stiffness, physical activity, and QOL (P < 0.05) after surgical treatment. The results showed differences between participants younger or older than 65 years in the domain of physical activity and QOL before TKA, with those older than 65 years showing better results (P < 0.05). We found no differences in pain intensity, joint stiffness, physical activity, and QOL after surgery. Table 5 shows the comparison of QOL before and after TKA, in the BMI subgroup (< 30 kg/m<sup>2</sup> ×  $\ge$  30 kg/m<sup>2</sup>). Both subgroups presented improvements in all WOMAC domains (P < 0.05).

We found differences between participants with BMI < or > 30 kg/ m<sup>2</sup> in the domains pain intensity, joint stiffness, physical activity,

Table 1. General characteristics ( $N = 58$ )	).
Characteristic	Mean (SD)
Age (years)	66.89 (6.34)
Weight (kg)	80.79 (16.52)
Height (m)	1.63 (0.09)
BMI (kg/m )	30.02 (5.14)

SD: standard deviation.

Table 2. Quality of life before and after total knee arthroplasty evaluated
by WOMAC (N = 58).

	Arthro	plasty	Difference		
WOMAC	Before Mean (SD)	After Mean (SD)	(95% CI)	P*	
Pain	12.72 (4.25)	4.93 (3.51)	- 7.78 (6.07 - 9.48)	< 0.001	
Joint stiffness	4.78 (2.1)	1.76 (1.93)	- 3.02 (2.23 - 3.8)	< 0.001	
Physical activity	45.02 (12.16)	17.54 (10.95)	- 27.47 (23.03 - 32.92)	< 0.001	
Overall score	62.52 (17.02)	24.24 (14.66)	- 38.28 (32.06 - 44.50)	< 0.001	

WOMAC: Western Ontario and McMaster Universities.

\*Student's t-test

Table 3. Quality of life before and after total knee arthroplasty evaluated
by WOMAC regarding gender (N = 58).

	Ger	nder	Difference	
WOMAC	Women Mean (SD)	Men Mean (SD)	(95% CI)	Р
Pain (0-2)				
Before	12.74 (4.64) <sup>a</sup>	11.81 (4.67)°	0.93 (- 1.81 - 3.66)	0.501
After	5.23 (3.4) <sup>a</sup>	4.33 (3.79)°	0.89 (- 1.34 - 3.13)	0.426
Joint stiffness (0-8)				
Before	4.95 (2.26) <sup>b</sup>	4.19 (2.1) <sup>d</sup>	0.76 (- 0.54 - 2.07)	0.181
After	1.97 (2.07) <sup>b</sup>	1.33 (1.58) <sup>d</sup>	0.63 (- 0.59 - 1.85)	0.321
Physical activity (0-68)				
Before	43.14 (14.66) <sup>a</sup>	43.75 (12.62)°	-0.61 (-8.93 - 7.71)	0.884
After	18.81 (9.73) <sup>a</sup>	14.93 (13.1)°	3.87 (- 3.04 - 10.79)	0.103
Overall score (0-96)				
Before	60.83 (20.27) <sup>a</sup>	59.75 (17.99)°	1.08 (- 10.5 - 12.67)	0.852
After	26 (13) <sup>a</sup>	20.6 (17.54)°	5.4 (- 5.17 - 15.97)	0.096

a: paired Student's t-test (P < 0.05); b: Wilcoxon test (P < 0.05); c: paired Student's t-test (P < 0.05); d: Wilcoxon test (P < 0.05).



and general QOL before TKA, and subjects with BMI < 30 kg/m<sup>2</sup> showed the best results (P < 0.05). The results showed no differences in these parameters after TKA. Table 6 shows the comparison of QOL before and after surgery regarding deformity. Both groups improved their overall WOMAC score(P < 0.05). We found no differences between the subjects with varus and valgus in the domains pain intensity, joint stiffness, physical activity, and QOL before and after TKA.

### DISCUSSION

We observed positive effects of TKA on pain relief, joint stiffness, physical activity level, and QOL of individuals with gonarthritis after six months. Regarding the positive effects, our results corroborate three systematic meta-analysis reviews aimed to show the best scientific evidence related to the effects of this surgery.<sup>4,6,7</sup>

Shan et al.<sup>6</sup> and Zhou et al.<sup>7</sup> found a significant clinical effect of TKA at medium- and long-term on pain relief, joint stiffness, level of physical activity, and QOL. Also, regarding positive effects, the results of this study corroborate several randomized controlled<sup>10-12</sup> and uncontrolled trials<sup>13,14</sup> that evaluated these outcomes at different moments.

Gooch et al.<sup>10</sup> and Tasker et al.<sup>12</sup> showed the medium-term effects of TKA on different aspects. The former compared the effects

**Table 4.** Quality of life before and after total knee arthroplasty evaluated by WOMAC regarding age (N = 58).

	Age (	years)	Difference	
WOMAC	≤ 65 Mean (SD)	> 65 Mean (SD)	(95% CI)	Р
Pain (0-2)				
Before	13.76 (3.3) <sup>a</sup>	12.1 (4.66)°	1.66 (- 0.93 - 4.25)	0.204
After	5 (3.14) <sup>a</sup>	4.9 (3.77) <sup>c</sup>	0.1 (- 2.08 - 2.29)	0.921
Joint stiffness (0-8)				
Before	5.29 (1.4) <sup>b</sup>	4.48 (2.4) <sup>d</sup>	0.81 (- 0.47 - 2.1)	0.155
After	1.41 (1.41) <sup>b</sup>	1.97 (2.17) <sup>d</sup>	- 0.55 (- 1.74 - 0.63)	0.354
Physical activity (0-68)				
Before	50.59 (9.79) <sup>a</sup>	41.76 (12.38)°	8.83 (1.74 - 15.91)	0.016 <sup>e</sup>
After	19.35 (8.37) <sup>a</sup>	16.48 (12.22)°	2.87 (- 3.89 - 9.63)	0.397
Overall score				
Before	69.65 (13.41) <sup>a</sup>	58.34 (17.72)°	11.30 (1.27 - 21.33)	0.028°
After	25.76 (11.37) <sup>a</sup>	23.34 (16.41) <sup>c</sup>	2.42 (- 6.68 - 11.52)	0.595

a: paired Student's t-test (P < 0.05); b: Wilcoxon test (P < 0.05); c: paired Student's t-test (P < 0.05); d: Wilcoxon test (P < 0.05); e: Student's t test (P < 0.05).

<b>Table 5.</b> Quality of life before and after total knee arthroplasty evaluated
by WOMAC regarding body mass index ( $N = 58$ ).

	B	MI	Difference	
WOMAC	< 30 Mean (SD)	≥ 30 Mean (SD)	(95% CI)	Р
Pain (0-2)				
Before	11.17 (4.92) <sup>a</sup>	14.25 (3.32)°	- 3.08 (- 5.52 0.64)	0.014
After	4.35 (3.24) <sup>a</sup>	5.52 (3.75)°	– 1.17 (– 3.25 - 0.91)	0.262
Joint stiffness (0-8)				
Before	4.17 (2.2) <sup>b</sup>	5.42 (1.95) <sup>d</sup>	- 1.25 (- 2.45 0.41)	0.043
After	1.3 (1.39) <sup>b</sup>	2.22 (2.29) <sup>d</sup>	– 0.92 (– 2.04 - 0.21)	0.2
Physical activity (0-68)				
Before	38.04 (12.01) <sup>a</sup>	51.71 (10.26)°	- 13.67 (-20.16 7.17)	0.001
After	14.78 (9.41) <sup>a</sup>	20.3 (11.86)°	- 5.52 (- 11.88 - 0.84)	0.087
Overall score (0-96)				
Before	53.38 (17.2) <sup>a</sup>	71.38 (14.69)°	- 18 (- 27.29 8.7)	0.001
After	20.43 (12.43) <sup>a</sup>	28.04 (15.97)°	- 7.6 (- 16.11 - 0.89)	0.078

a: paired Student's t-test (P < 0.05); b: Wilcoxon test (P < 0.05); c: paired Student's t-test (P < 0.05); d: Wilcoxon test (P < 0.05); e: Student's t-test, Mann-Whitney U test (P < 0.05).

**Table 6.** Quality of life before and after total knee arthroplasty evaluated by WOMAC regarding deformity (N = 58).

	Defo	rmity	Difference	
WOMAC	Varus Mean (SD)	Valgus Mean (SD)	(95% CI)	Р
Pain (0-2)				
Before	12.28 (4.46) <sup>a</sup>	13.64 (4.87)°	- 1.36 (- 4.18 - 1.45)	0.336
After	4.89 (3.24) <sup>a</sup>	5.1 (4.55)°	– 0.21 (– 2.77 - 2.35)	0.869
Joint stiffness (0-8)				
Before	4.81 (2.2) <sup>b</sup>	4.71 (2.33) <sup>d</sup>	0.1 (- 1.28 - 1.47)	0.91
After	1.67 (1.78) <sup>b</sup>	2.1 (2.47) <sup>d</sup>	- 0.43 (- 1.83 - 0.97)	0.826
Physical activity (0-68)				
Before	44.56 (13.61) <sup>a</sup>	41.43 (14.02)°	3.13 (- 5.32 - 11.58)	0.473
After	18.47 (10.84) <sup>a</sup>	14.2 (11.24)°	4.27 (- 3.59 - 12.14)	0.28
Overall score (0-96)				
Before	61.65 (18.94) <sup>a</sup>	59.79 (19.96)°	1.86 (- 9.96 - 13.69)	0.761
After	25.03 (14.09) <sup>a</sup>	21.4 (17.06)°	3.63 (- 7 - 14.25)	0.495

a: paired Student's t-test (P < 0.05); b: Wilcoxon test (P < 0.05); c: paired Student's t-test (P < 0.05); d: Wilcoxon test (P < 0.05).

of surgery performed with standard care versus specific care, whereas the latter study compared the effects of conventional versus minimally invasive arthroplasty, both found positive effects of TKA regardless of the method.

Regarding the correlations in the different subgroups of the study, the results showed that TKA benefited subjects regardless of gender, age, BMI, or deformity. No differences were found among subgroups. Different studies reviewed if aspects such as gender,<sup>8,15</sup> age,<sup>8</sup> BMI,<sup>16,17</sup> and type of deformity are related to better functioning after the surgery.

O'Connor's study<sup>18</sup> shows the absence of gender differences regarding surgery satisfaction, corroborating the results of our study.<sup>8</sup> Regarding functioning, the systematic review with meta-analysis by Kuperman et al.<sup>19</sup> indicated no differences in pain and functioning after TKA between young and older individuals, corroborating our results. Among the different characteristics of the individuals, BMI is the most studied factor in the literature. Our results showed that non-obese and obese people benefit from TKA and we found no functional differences after surgery. Different studies show that non-obese subjects have better functioning after TKA, however this difference is small and no differences occur in most studies regarding gains after surgery between these populations.<sup>16,17</sup>

We suggest that future studies evaluate the effect of TKA on other variables such as patient satisfaction and central sensitization, employing a larger sample size. The studies by Kuperman et al.,<sup>19</sup> Boyce et al.,<sup>16</sup> and Kerkhoffs et al.<sup>17</sup> indicate that postoperative pain is one of the main factors for patient dissatisfaction and that central sensitization is a risk factor for dissatisfaction and persistent pain. Thus, we also suggest future studies with longer follow-up time to verify whether such similarities in functioning will be maintained over time. Future studies should also compare other treatment modalities, and even non-surgical approaches to analyze if TKA is the best intervention.

### CONCLUSION

TKA shows positive effects on pain relief, joint stiffness, level of physical activity, and general QOL in individuals with gonarthritis. Individuals' quality of life improved regardless of gender, age, obesity, or knee deformity.

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### CLINICAL RESULTS OF MEDIAL PATELLOFEMORAL LIGAMENT RECONSTRUCTION

## RESULTADOS CLÍNICOS DA RECONSTRUÇÃO DO LIGAMENTO PATELOFEMORAL MEDIAL

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### ABSTRACT

Objective: To assess clinical results of patients who underwent medial patellofemoral ligament (MPFL) reconstruction after a minimum of two years of follow-up. Methods: Patients' medical records were assessed for residual instability, patient satisfaction, and post-operative functional outcomes. Results: Fifty-one patients were analyzed, out of which 56.87% were women. Patients' mean age was 30.8 years (16 to 57 years). The mean follow-up time was 68.7 months (37 to 120 months). Length between first dislocation and surgery was less than 1 year for 58.82% of patients, between 1 and 5 years for 37.25%, and over 5 years for 3.93%. Patients showed a high degree of satisfaction (96.08% would undergo surgery again), with recurrence rate of 11.76%. Twenty-two patients reported knee symptoms, including pain from movements (72.72%), weakness (18.18%), constant pain (13.63%), and crepitus (4.54%). Considering dissatisfied patients, patients with dislocation recurrence, and patients with symptoms, five cannot practice physical activity, out of which only three blame their knee. Conclusion: MPFL reconstruction showed a recurrence rate of 11.7%, with high patient satisfaction, good functional results, and high rate of return to sports, after a minimum of two years of follow-up. Level of Evidence IV, Case Series.

**Keywords:** Patellofemoral Joint. Patellar Dislocation. Patella. Reconstructive Surgical Procedures.

### RESUMO

Objetivo: Avaliar o resultado clínico de pacientes submetidos à reconstrução do ligamento patelofemoral medial (LPFM), acompanhados por mínimo de dois anos. Métodos: Avaliação de prontuários para informações sobre instabilidade residual, satisfação do paciente e resultado funcional pós-operatório. Resultados: Foram analisados 51 pacientes. 56,87% do sexo feminino e média etária 30,8 anos (16 a 57). Tempo médio de acompanhamento de 68,7 meses (37 a 120). Intervalo entre primeira luxação e cirurgia foi menos de 1 ano em 58,82%, entre 1 e 5 anos em 37,25% e mais de 5 anos para 3,93%. Os pacientes apresentaram alto grau de satisfação (96,08% fariam a cirurgia novamente), com 11,76% de recidiva. Houve persistência de sintomas em 22 pacientes, sendo dor ao movimento o principal (72,72%), seguido de fragueza (18,18%), dor constante (13,63%) e crepitações (4,54%). Somando os pacientes insatisfeitos aos que tiveram recidiva da instabilidade e os sintomáticos, 5 não conseguem praticar atividade física, mas apenas 3 por causa do joelho. Conclusão: A reconstrução isolada do LPFM demonstrou índice de recidiva de 11,7%, com alto nível de satisfação dos pacientes, ótimos resultados funcionais e alta taxa de retorno ao esporte, em acompanhamento mínimo de 2 anos. Nível de Evidência IV, Série de Casos.

**Descritores:** Articulação Patelofemoral. Luxação Patelar. Patela. Procedimentos Cirúrgicos Reconstrutivos.

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### INTRODUCTION

The medial patellofemoral ligament (MPFL) is the main primary medial restrictor of the patella in the first  $30^{\circ}$  of flexion, restricting its lateral dislocation in 60% to 80%.<sup>1,2</sup> After the first dislocation episode, the chance of recurrence is about 50%, even with adequate conservative treatment.<sup>2</sup>

Surgical procedures for the treatment of this pathology have recently become more known, with increased knowledge of the biomechanics of the patellofemoral joint and the pathophysiology of patellar instability and advanced surgical techniques.<sup>3,4</sup> Professionals discuss which of the techniques would be more

effective, which would have fewer post-operative complications, and what types of graft and fixation material to use.<sup>2,3</sup> Preferences vary from one country to another, but the current trend would be a specific indication for each patient depending on their joint changes.<sup>3,5</sup>

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

The study was conducted at the Uniort.E Hospital de Ortopedia and the Hospital Evangélico de Londrina. Correspondence: Roque Gondolfo Junior. Rua General Estilac Leal, 129, apt. 104, Block B, Florianópolis, SC, Brazil, 88080760. roquegjr@yahoo.com.br

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Isolated medial patellofemoral ligament (MPFL) reconstruction is the most used treatment for recurrent patellar instability. It is also associated with other stabilization methods, including tibial tubercle osteotomy and trochleoplasty.<sup>3,6</sup>

MPFL reconstruction has complications like all surgical treatment, despite its high success rates. Most common complications include the recurrence of patellar instability, recurrent seizure, joint stiffness, and patellar fracture.<sup>1,2,7,8</sup> A careful surgical technique can prevent these by reconstructing ligament anatomy and isometry, followed by adequate rehabilitation.<sup>9</sup> Gravesen et al.<sup>10</sup> report that the risk of persistent patellar morbidity after eight years of MPFL reconstruction surgery can reach 21%.

Surgeons should therefore wisely choose between isolated MPFL reconstruction or reconstruction associated with other procedures to increase final stability and improve functional results.<sup>1,11-13</sup>

This study aimed to assess patients who underwent isolated MPFL reconstruction on their degree of satisfaction, incidence of recurrent instability, time between the first dislocation and surgery, most common symptoms, and how many of them returned to physical activities without knee-related limitations.

### MATERIALS AND METHODS

The study was approved by the Research Ethics Committee of the Associação Evangélica Beneficiente de Londrina — AEBEL under CAAE no. 28015219.0.0000.5696.

Patients subjected to reconstruction of the medial patellofemoral ligament with flexor tendon graft by the same medical team were selected. Three experienced surgeons performed the surgeries (MVD, AOQ, and JPFG). Patients should have a minimum follow-up of two years, with complete medical records and possibility of contact to complement data when needed. Surgery was indicated in the case of a second episode of instability after attempting an unsuccessful conservative treatment for at least three months.

Exclusion criteria were patients with less than 24 months of surgery and patients who had undergone any other patellofemoral stabilization procedure, including tibial tubercle osteotomy, lateral retinacular release, or trochleoplasty.

Surgery technique: the patients were operated on under spinal anesthesia, with tourniquet. Longitudinal access was performed on the goose foot to remove one of the flexor tendons (semitendinosus tendon in 40 patients and the gracilis in 11 patients). Grafting was prepared with two free grafts. Standard portal arthroscopy was then performed for joint evaluation. Double medial longitudinal access (one incision in the medial region of the patella and another in the medial femoral condyle) was performed in 16 patients whereas single longitudinal access (between the patella and the medial femoral condyle) was performed in 35 patients. Two anchors were placed in the medial region of the patella (one in the superomedial and the other in the middle). In four patients, two confluent tunnels were used instead of anchors, in the same anatomical points of the patella. The graft was then fixed to the anchors or passed through the patellar tunnels. Next, a guide wire was placed between the adductor tubercle and the medial epicondyle of the femur to assess graft isometry. If isometry is correct, a tunnel as thick as the graft was performed. The free graft was transposed into this tunnel and fixed with an interference screw with the knee at 30° of flexion, without excessive tension. Patients used no type of orthosis post-operatively. Crutches were recommended for partial load until the patient felt safe walking at full load. Range of motion was allowed according to what the patient could endure, gradually increasing with physiotherapy. Stationary biking was allowed two weeks after surgery, going for a walk after six weeks, running and going to the gym after three months, and returning to contact sports after six months.

Initially, 87 patients were selected, out of which 28 had incomplete medical records, one died, and seven were lost to follow-up, thus being excluded from the final analysis (Figure 1).

In total, 51 patients were analyzed. Medical records were consulted for the following information: name; date of birth; date of surgery; operated side (right or left lower limb); degree of satisfaction with the surgery (dissatisfied, partially satisfied, satisfied, or extremely satisfied); if the patient would do the surgery again (yes or no); had a new episode of patellar dislocation after surgery (yes or no); length between the first episode of dislocation and surgery (1 year, between 1 and 5 years, over 5 years); currently has symptoms in the knee (yes or no), if yes, which symptoms: weakness; "feeling that the knee will bend on its own and the risk of falling," crepitus, joint swelling/effusion, pain on stairs or slopes/when squatting or getting up from chairs, constant pain; practices physical activities (yes or no), if yes, does the knee interfere with the activity? (yes or no), if not, is the knee the reason for not practicing? (yes or no).

Data obtained were analyzed by descriptive statistics.



### RESULTS

Out of the 51 patients analyzed, 22 (43.13%) were men and 29 (56.87%) were women. The mean age was 30.8 years, ranging from 16 to 57 years. The right side was the most affected, corresponding to 50.98% of the cases. The mean follow-up time was 68.7 months, ranging from 37 to 120 months. Regarding the degree of satisfaction, one patient was dissatisfied, five were partially satisfied, 21 were satisfied, and 24 were extremely satisfied. Out of the six dissatisfied or partially satisfied patients, five would undergo surgery again and three could practice physical activity. The three who could not practice physical activity blamed their knee for it. The time between the first dislocation and surgery was less than 1 year for 58.82% of patients, between 1 and 5 years for 37.25%, and over 5 years for only 3.93%. Out of the 51 assessed patients, 49 (96.08%) would do the surgery again.

Six patients reported instability recurrence (11.76% index), out of which four were satisfied with the surgery, one was extremely satisfied, and only one was partially satisfied. All would undergo surgery again and only one of the two who did not practice physical activity blamed the knee symptoms.

Among the 22 patients who still complained of symptoms in the knee, 16 reported pain from movements (going up and down stairs, slopes, getting up from the chair, squatting), four reported weakness, three had constant pain, and only one had crepitus (Tables 1 and 2).

Among the 51 patients, 32 practiced physical activity, out of which 30 felt that their knee did not interfere with exercising. Of the 19 patients who did not practice physical activity, only four blamed the knee for their limitation (Table 2).

No cases of patellar fracture or joint stiffness were observed.



		No.	%
Conder	Male	22	43.13
Gender	Female	29	56.87
	Mean	30.8	
Age (years)	Maximum	57	
	Minimum	16	
	Right	26	50.98
Side	Left	22	43.13
	Bilateral	3	5.89
	Unsatisfied	1	1.96
Degree of estisfaction	Partially satisfied	5	9.8
Degree of Sausiaction	Satisfied	21	41.17
	Extremely satisfied	24	47.07
Would undergo	Yes	49	96.08
surgery again	No	2	3.92
I am with the dama on the state	< 1 year	30	58.82
Length Detween first dislocation and surgery	1-5 years	19	37.25
dislocation and surgery	> 5 years	2	3.93
De et en en time time	Mean	68.7	
Post-operative time	Maximum	120	
(monuis)	Minimum	37	

**Table 1.** Data from the medial patellofemoral ligament reconstruction questionnaire.

 Table 2. Data from the medial patellofemoral ligament reconstruction questionnaire.

	Yes	22	Weakness	4	
		43.13%	Crepitus	1	
Sumptomo			Pain from movements	16	
Symptoms			Constant pain	3	
	No	29			
		56.87%			
	Yes	32	Does your knee	Yes	2
Do you practice		62.74%	get in the way?	No	30
physical activities?	No	19	Is it because of	Yes	4
		37.26%	your knee?	No	15

### DISCUSSION

This study's main outcome was that most patients who underwent isolated reconstruction of MPFL with a minimum follow-up of two years had a high degree of satisfaction, returned to sports, and had few symptoms. This indicates that the surgery could sufficiently restore patellar stability and knee function in these patients, with low morbidity.

The mean age of the patients (30.8 years) corroborated with that of patients from other studies, always ranging between 20 and 30 years old.<sup>7,8,12,14-17</sup> Our patients' mean follow-up time of 68.7 months was longer than that in most studies.<sup>5-8,12,15-18</sup>

Length between first dislocation and surgery was less than 1 year for 58.82% of patients, between 1 and 5 years for 37.25%, and over 5 years for 3.93%. This shows that patients sought treatment early, probably due to several symptoms and limitations and the low success rate of the conservative treatment, which causes instability recurrence in about 50% of patients.<sup>2</sup> The literature on this procedure reports several complications, the most common being joint stiffness, anterior knee pain, patellar fracture, and instability recurrence.<sup>1,2,7,8</sup> This study had no cases of patellar fracture or stiffness.

The 11.76% incidence of instability recurrence was slightly higher than described in the literature, usually ranging from 0 to 10%.<sup>2,5-9,11,13-15,18-22</sup> However, several studies divide the recurrence rates of dislocation, subluxation, and apprehension, which, if counted together, can increase the overall rate, thus being comparable to our results. The study's data was obtained using a questionnaire completed by the patient, who might have considered other symptoms as instability. The "black out" symptom of the quadriceps, for example, is very often confused with instability.

Out of the 51 patients, 22 still had knee-related complaints after surgery. The study by Zhang and Li<sup>16</sup> assessed 68 patients, out of which eight presented symptoms during daily activities, 46 during sports practice, and none felt pain while resting. In our study, 16 patients still had movement-related pain and three had constant pain. In Feller, Richmond and Wasiak's<sup>19</sup> study, 40% of patients complained of anterior knee pain. The study by Von Engelhardt et al.<sup>18</sup> assessed 23 patients, out of which four had knee-related complaints.

Among our patients, only four did not return to physical activities because of their knee. In their study, Von Engelhardt et al.<sup>18</sup> reported that of 23 patients evaluated, only one did not return to sports practice. The study by Feller, Richmond and Wasiak<sup>19</sup> found that 81% of assessed patients undergoing isolated reconstruction of the patellofemoral ligament returned to sports.

About 96.08% of our patients would undergo surgery again, whereas all of Von Engelhardt et al.'s<sup>18</sup> patients would do the surgery again.

This study has limitations. This is only an assessment of the results of a surgical technique, not to be compared with other techniques or the conservative treatment. A final physical examination and imaging of these patients could have eliminated bias, showing a more comprehensive analysis of the results. Similarly to Feller. Richmond and Wasiak.<sup>19</sup> we used a simple and non-validated questionnaire, focusing on the key points of our objectives, including satisfaction, symptoms, and knee function. No questionnaire, such as the Tegner Activity Scale, for example, assessed the level of physical activity. However, none of our patients were professional athletes, practicing only recreational activities. No questionnaire was applied before surgery, limiting our statistical result assessment and comparison with the literature. The variation of the type of graft used (semitendinosus or gracilis tendon) and of the patellar fixation (tunnel confluences or anchors) could have also biased the study. Matzkin<sup>9</sup> states that choosing graft and fixation methods is less important to the final success than reconstructing the original anatomy of the ligament; however, literature shows that the gracilis tendon graft can cause a higher rate of dislocation recurrence.23

### CONCLUSION

Isolated reconstruction of the medial patellofemoral ligament showed a recurrence rate of 11.7% with high patient satisfaction, excellent functional results, and a high rate of return to sports, all after at least two years of follow-up.

AUTHORS' CONTRIBUTIONS: Each author contributed individually and significantly to the development of this article. RGJ: literature review, data collection and analysis, writing of the article; HSE: literature review, data collection and analysis; JPFG: data analysis, final review of the article; AOQ: final review of the article; MVD: data analysis, final review of the article.



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ORTHOPEDICS AND TRAUMATOLOGY

### FRAGILITY FRACTURES IN BRAZIL: CROSS-SECTION STUDY

### FRATURAS POR FRAGILIDADE NO BRASIL: ESTUDO TRANSVERSAL

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### ABSTRACT

Objective: To evaluate the involvement of orthopedists and orthopedic residents with fragility fractures, in its clinical, therapeutic, and social aspects. Methods: Cross-sectional observational and prospective study that took place in the period from June to August 2020. Results: 540 participants were analyzed. The population consisted of orthopedists (85.56%; N = 462) and residents (14.44%; N = 78), with a greater proportion of individuals from 41 to 50 years of age (36.67%; N = 198) and from the Southeast region (57.22%; N = 309). For 47.04% (N = 254) of the participants, the profile of the patient at risk for fragility fracture corresponds to: woman, sedentary, smoker and over 60 years of age. The consensus among the participants (97.96%; N = 529) is that fragility fractures occur in or near home environments. Moreover, 47.59% (N = 257) believe that the first fragility fracture is the most important predictive risk factor for subsequent occurrences and 63.89% (N = 345) of the participants claim to attend more than 15 cases per vear. Regarding treatment. 74.44% (N = 402) are dedicated exclusively to orthopedic aspects (68.33%; N = 369). However, 62.41% (N = 337) of the participants believe that patients with fragility fractures should receive medication and supplements. Likewise, 70.74% (N = 382) of the participants consider that home security measures and training of family members are important, and they attribute the role to the multidisciplinary team. Conclusions: Fragility fractures are frequent in the routine of Brazilian orthopedists. However, they are not familiar with adjuvant treatments for fragility fractures, acting almost exclusively in the orthopedics aspects of these injuries. Level of Evidence II, Prospective Study.

Keywords: Femoral Fractures. Osteoporosis. Osteoporotic Fractures.

RESUMO

Objetivo: Avaliar o entendimento entre ortopedistas e residentes em ortopedia sobre as fraturas por fragilidade, em seus aspectos clínicos, terapêuticos e sociais. Métodos: Estudo transversal, observacional e prospectivo que ocorreu no período de junho de agosto de 2020. Resultados: Foram analisados 540 participantes. A população foi composta por ortopedistas (85,56%; N = 462) e residentes (14,44%; N = 78), com prevalência de idade entre 41 e 50 anos (36,67%; N=198) e oriundos da região Sudeste (57,22%; N = 309). Para 47.04% (N = 254) dos participantes o perfil do paciente em risco para fratura por fragilidade corresponde a: mulher, sedentária. tabagista e acima dos 60 anos de idade. Sendo consenso entre os participantes (97,96%; N = 529) que as fraturas por fragilidade ocorrem em ambientes domiciliares ou próximo a eles. Além disso, 47,59% (N = 257) dos participantes acreditam que a primeira fratura por fragilidade seja o fator de risco preditivo mais importante para novo episódio de fratura e 63,89% (N = 345) dos avaliadores atendem mais de 15 casos por ano. Em relação ao tratamento. 74.44% (N = 402) dedicam-se exclusivamente aos aspectos ortopédicos (68,33%; N = 369). No entanto, 62,41% (N = 337) dos participantes acreditam que paciente devam receber medicamentos e suplementos. Da mesma forma, 70,74% (N = 382) dos avaliadores consideram que medidas de segurança domiciliar e treinamento de familiares sejam importantes e atribuídas a equipe multiprofissional. Conclusão: As fraturas por fragilidade são freguentes na rotina dos ortopedistas brasileiros. No entanto, estes não estão familiarizados com tratamentos adjuvantes nas fraturas consideradas por fragilidade, atuando quase que exclusivamente nos aspectos ortopédicos envolvidos nestas lesões. Nível de Evidência II, Estudo Prospectivo.

Descritores: Fraturas do Fêmur. Osteoporose. Fraturas Osteoporóticas.

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### INTRODUCTION

Osteoporosis is a disease characterized by decreased density and deterioration of the bone microarchitecture, predisposing the appearance of fractures due to the mechanical fragility established.<sup>1</sup> The diagnosis of this disease can be made by identifying fractures in the spine, proximal regions of the humerus and femur, or even in the distal region of the radius, without the presence of major trauma. Injuries that occur without high-energy trauma are called "fragility fractures" and the main clinical manifestations of osteoporosis are then considered.

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

The study was conducted at Department of Orthopedics and Traumatology, Paulista School of Medicine, Universidade Federal de São Paulo. Correspondence: Luiz Fernando Cocco. Rua Napoleão de Barros, 715, São Paulo, SP, Brazil, 04024002. Icocco@unifesp.br

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The introduction of effective strategies that prevent fragility fractures is extremely important, especially for older adults,<sup>2</sup> since the presence of previous fracture increases the risk of a second fracture. To avoid future sequelae, this pattern of fractures must be recognized, instead of only treating the fractures without relating them to osteoporosis. An easy and low-cost prevention method is the early diagnosis of osteoporosis using tests capable of evaluating bone mineral density, which could help the adoption of treatment.<sup>3,4</sup>

If, on the one hand, prevention does not require many expenses, the treatment, however, is costly. One study by Mayo Clinic, with data from 2000 to 2011, reveals that osteoporotic fractures accounted for 4.9 million hospitalizations with an expenditure of US\$ 5.1 billion, higher than that caused by acute myocardial infarction (2.9 million and US\$ 4.3 billion), stroke (3.3 million and US\$ 3 billion) and breast cancer (700,000 and US\$ 0.5 billion).<sup>5</sup>

In Brazil, there are still few data and information on the occurrence of osteoporotic fractures, despite the large number of affected patients, high morbidity and mortality rates due to chronic-degenerative diseases, and the increased life expectancy, which contributes to the increase in numbers related to this public health problem; therefore, more studies on the subject are needed. Thus, this study aims to evaluate the involvement of orthopedists and residents in Orthopedics with fragility fractures, in its clinical, therapeutic, and social aspects.

### MATERIALS AND METHODS

### Study

Cross-sectional observational and prospective study that occurred in the period of June 2020, in the department of Orthopedics and Traumatology of the Hospital São Paulo of the Federal University of São Paulo – UNIFESP (EPM), São Paulo. The study follows the ethical and legal precepts, it was submitted and approved by the Research Ethics Committee of UNIFESP/EPM, opinion no. 31720320.5,000,5505

### Inclusion criteria

The research is intended exclusively for resident physicians of Orthopedics and Traumatology enrolled in services accredited by SBOT (Brazilian Society of Orthopedics and Traumatology) and orthopedists in activity in Brazil, of both sexes, who voluntarily filled out and sent the questionnaire correctly and completely, and who are in accordance with the informed consent form.

### **Questionnaire application**

The questionnaire on the particularities of fragility fractures was sent to the regional Orthopedics and Traumatology societies linked to SBOT, as well as to the reference medical residency services of each region of the country.

The questionnaires were developed and applied online on the Google Forms platform, being forwarded to orthopedists and to residents in Orthopedics and Traumatology, exclusively in digital form, via email; not being made available in person. The answers were presented in multiple choice format; however; with the possibility of selecting only one option per question.

The questions addressed epidemiological, diagnostic, therapeutic, and preventive conditions involving the population considered at risk for this type of disease. The waiting time for return of responses was 30 days from the email date.

### **Statistical analysis**

The descriptive analysis of the answers was expressed as frequency and proportion. The results were tabulated and organized in spreadsheets in Excel (Chicago, USA).

### RESULTS

The study population consisted of 540 participants, with no exclusions. We had a significantly higher participation of orthopedists (85.56%; N = 462) compared to residents (14.44%; N = 78), which justifies the prevalence of age between 41 and 50 years (36.67%; N = 198). Most participants (57.22%; N = 309) came from the Southeast region (Table 1).

Regarding epidemiological aspects, we observed that most participants (47.04%; N = 254) believe that the patient profile that present risk of fragility fracture include: woman, sedentary, smoker, and over 60 years of age. Participants considered fragility fractures as those that affects the hip, wrist, shoulder, or spine (53.52%; N = 289) (Table 2).

A consensus among participants (97.96%; N = 529) is that fragility fractures occur in or near home environments, revealing an important information for the implementation of public policies aimed at prevention. Additionally, 47.59% (N = 257) believe that the first fragility fracture is the most important predictive risk factor for a subsequent occurrence. Among the participants, 67.78% (N = 366) considered that the fragility fracture should be notified to the health regulatory agencies in municipal, state, or federal level, and 63.89% (N = 345) attend more than 15 cases per year.

Regarding treatment, 74.44% (N = 402) of the participants dedicate themselves exclusively to the orthopedic aspects of the case, considering only the patient and the fracture characteristics (68.33%; N = 369). For 62.41% (N = 337) of the participants, patients undergoing follow-up after fragility fractures should receive some adjuvant drug treatment (alendronates, hormones, vitamin D, calcium, among others), as a preventive measure for a next fracture. However, they refer their patients to other specialists to conduct this therapy. Similarly, 70.74% (N = 382)

Table 1 Description of the study participants

Variable	N	%
Specialization		
Orthopedist	462	85.56
Resident in Orthopedics	78	14.44
Age		
from 20 to 30 years	88	16.30
from 31 to 40 years	159	29.44
from 41 to 50 years	198	36.67
over 51 years	95	17.59
Region		
North	42	7.78
Midwest	57	10.56
Northeast	61	11.30
South	71	13.15
Southeast	309	57.22
Specialty		
Spine	10	1.85
Pediatric Orthopedics	10	1.85
External Fixator	12	2.22
Tumor	13	2.41
Foot/ankle	27	5.00
Hand	34	6.30
Hip	52	9.63
Knee	63	11.67
Shoulder and Elbow	76	14.07
Orthopedic trauma	104	19.26
No subspecialty	139	25.74
Total	540	100.00



**Table 2.** Epidemiological and clinical aspects of fragility fractures in theview of Brazilian orthopedists.

Survey	N	%
You consider that the patient at risk of		
presenting Fragility Fracture is:	4.0	
I don't believe there's a characteristic profile of a patient at risk	13	2.41
woman, obese, sedentary, after menopause	118	21.85
men or women over 60 years of age have similar risks of having fragility fractures	155	28.70
woman, smoker, over 60 years, and sedentary	254	47.04
You consider Fragility Fractures as those that:		
affect patients over 60 years of age	13	2.41
affect patients over 60 years of age with diagnosis of osteoporosis	104	19.26
result exclusively from low-energy traumas	134	24.81
affect hip, wrist, shoulder, or spine in patients over 60 years of age	289	53.52
You consider Fragility Fractures to occur:		
in car accident		
in sports environment	1	0.19
resulting from metastatic fractures	10	1.85
usually in a home environment or near patients' homes	529	97,96
You consider that the main risk for Fragility Fracture is:		
consolidation difficulties due to compromised bone quality	17	3.15
the high costs and prolonged time of hospital admissions	21	3.89
general clinical complications and risk of death	245	45.37
New fractures due to fragility	257	47.59
Do you consider that Fragility Fractures		
should be of mandatory notification?*		
No	174	32.22
Yes	366	67.78
Total	540	100.00

\*For municipal, state, or federal public health control agencies

of the participants consider that home security measures and family training are important, but attributed it to the multidisciplinary team of physiotherapists, nurses, and social workers (Table 3).

### DISCUSSION

Despite the epidemiological and economic relevance of fragility fractures, there is still no standardized clinical approach to the treatment of this disease.<sup>1,6</sup> Thus, our study evaluated the involvement of orthopedists and of residents in Orthopedics with fragility fractures in its clinical, therapeutic, and social aspects. This information, besides being relevant to the care of the population, serves as a basis for public health policies involving this disease.

More than half of the answers came from professionals of the Southeast region (57.22%; N = 309), something expected if we consider that most of the country's medical education and training services are concentrated in this region. Moreover, Southeast region is responsible for the largest investments (53.4% in 2008, 52.4% in 2009, and 48.5% in 2010)<sup>5</sup> and number of procedures (43.2% in 2008, 44.3% in 2009, and 48.3% in 2010) when compared with the other regions of the country.<sup>2</sup>

According to the orthopedists interviewed, the profile of the patient at risk for a fragility fracture corresponds to: woman, sedentary, smoker, and over 60 years of age. The results corroborate Brazilian publications that reported a higher prevalence of frailty in sedentary women over 60 years of age.<sup>7</sup>

Table 3. Treatment of fragility fractures in the view of Brazilian of	orthop	oedists.
Survey	N	%
How many Fragility Fractures do you treat each year?		
Less than 5	47	8.70
between 5 and 10	71	13.15
between 10 and 15	77	14.26
More than 15	345	63.89
You treat Fragility Fractures:	1	
by being responsible for clinical/geriatric	44	7.50
and orthopedic aspects by choice	41	7.59
by being responsible for clinical/geriatric and orthopedic	01	16 0E
aspects due to lack of multidisciplinary team	91	10.00
in a multidisciplinary manner, dedicating myself	402	74 44
exclusively to orthopedic aspects	402	/
Your orthopedic conducts in the treatment		
of Fragility Fractures are usually:		
preferably non-surgical due to the multiple	64	11.85
clinical comorbidities generally present		
preterably surgical, with bone tragility	107	19.81
being one of the main reasons		
similar to other tractures, considering only the	369	68.33
Do you believe that complementary treatments		
should be instituted in Fragility Fractures?*		
No. since I'm not familiar with these medications	10	1.85
No, since there is no evidence in the literature to justify its inclusions	15	2 78
Yes, and I do the prescriptions of these medications for my patients	178	32.96
Yes, but I refer my patients to other doctors for these treatments	337	62.41
Do you consider that the recommendations for natients		02.11
who are victims of Fragility Fractures are:#		
inefficient in preventing new fractures	2	0.37
important, they are carried out by me due to	1	
lack of a multidisciplinary team involved	156	28.89
important, they are performed by a multidisciplinary	000	70.74
team (physiotherapists, nurses, social workers)	382	/0./4
Total	540	100.00

\*Treatments with alendronates, bisphosphonates, hormones, vitamin D, calcium, among other therapies; #related to home safety, prevention of new falls, and training of close family members.

Among the interviewees, 63.89% (N = 345) of the participants treated more than 15 patients with a diagnosis of fragility fracture per year. These numbers are relevant and in agreement with estimates that indicate a national projection of 10 million individuals affected by osteoporosis, with a prevalence of 11 to 23.8% for all types of bone fragility fracture.<sup>8</sup>

Nevertheless, fragility fractures are not officially considered for notification to public health agencies. However, 67.78% (N = 366) of the participants agree that this increase in the list of diseases of compulsory notification would help public policies become more efficient in the prevention and treatment of fragility fractures. Similarly, 47.59% (N = 257) of the interviewees considered that the first fragility fracture is the most important predictive factor for a new fracture. This response corroborates the literature data that shows that the existence of a previous history of fragility fracture is an indicator for the occurrence of future fractures.<sup>3,4,9</sup> Another relevant result was that 74.44% (N = 402) of the participants dedicate themselves exclusively to orthopedic aspects (basically surgical procedures) in cases of osteoporotic fractures - 62.41% (N = 337) refer patients to other specialists to treat osteoporosis and secondary prophylaxis (use of medications, hormones, and vitamins). Evidence shows that the administration of drugs, such as alendronate and etidronate, can prevent fragility fractures.<sup>10,11</sup>



Moreover, 70.74% (N = 382) of the interviewees transfer to the multidisciplinary team (physiotherapists, nurses, and social workers) the role of guiding patients, victims of fragility fractures, on home safety, prevention of new falls, and training of family members. Since most osteoporotic fractures occur by fall, the reduction of this event is extremely important to prevent a secondary fracture. Thus, the rehabilitation of patients with fragility fractures should be performed by a multidisciplinary team.<sup>12</sup>

The costs of treating fragility fractures are high; higher than other diseases, such as acute myocardial infarction.<sup>5</sup> In cases in which the fragility fracture has already been diagnosed and treated, establishing secondary prophylaxis could decrease 30 to 60% of the recurrence of this type of lesion.<sup>4</sup>

The multidisciplinary management of patients with osteoporosis is a reality in large centers, with increasingly better preventive and therapeutic results. The increase in life expectancy will make this condition increasingly present in clinical practice and in the training of orthopedists, making evident the need of public health policies aimed at the patients at risk.

### CONCLUSION

Patients with fragility fractures are frequent in the daily practice of most Brazilian orthopedists. Orthopedists and residents in Orthopedics and Traumatology are not familiar with adjuvant treatments for fragility fractures, acting almost exclusively on the orthopedic aspects of these lesions.

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SHOULDER AND ELBOW

### EVALUATION OF SCAPULAR DYSKINESIA IN PATIENTS THAT UNDERWENT A LATARJET PROCEDURE

### AVALIAÇÃO DA DISCINESIA ESCAPULAR EM PACIENTES SUBMETIDOS À CIRURGIA DE LATARJET

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### ABSTRACT

Objective: To quantitatively assess the scapular movement of patients who underwent Latarjet surgery and to identify if they present scapular dyskinesia (SD), as well as correlate with the clinic state and the elevation degree of the shoulder. Methods: A cross-sectional study was carried out at the Movement Analysis Laboratory (LAM), at the Institute of Physical Activity and Sport Sciences, that quantitatively evaluated, using spherical retroreflective markers, the scapular movements of the control group (10 volunteers) and 22 patients (23 operated shoulders) that had been submitted to Latarjet surgery, between 2011 and 2016, with at least one year postoperative. The results of the control group were used as a parameter of normality and compared to those of the operated group. Posterior inclination, superior rotation, and medial rotation of the scapula were evaluated at angles of 60°, 90°, and 120° of elevation, both in ascending and descending phases. The statistical analysis used was the multivariate variance (MANO-VA), comparing the right and left sides of the control group and, subsequently, the control group with the postoperative group (p = 0.05in all tests). Results: When comparing the mean of the results of the quantitative evaluation of the control group with the operated group, no statistically significant differences were found between the two groups and between the dominant and non-dominant sides of the control group. Conclusion: Latarjet surgery does not cause SD, although there are alterations in some plane of the scapular movements in the ascending and/or descending phase. Level of Evidence III, Retrospective Comparative Study.

### RESUMO

Objetivo: Avaliar, de forma quantitativa, o movimento escapular dos pacientes submetidos à cirurgia de Latarjet e identificar se apresentam discinesia escapular (DE). Além disso, correlacionar com a clínica e com o grau de elevação do ombro. Método: Estudo transversal realizado no Laboratório de Análise do Movimento (LAM), no Instituto de Ciências da Atividade Física e Esporte que avaliou de forma quantitativa, utilizando marcadores retro-refletivos esféricos, os movimentos escapulares do grupo controle (10 voluntários) e 22 pacientes (23 ombros operados), submetidos à cirurgia de Latarjet, entre os anos de 2011 e 2016, com pelo menos um ano de pós-operatório. Foram utilizados os resultados do grupo controle como parâmetro de normalidade e posteriormente comparados aos do grupo de pacientes operados. Avaliadas a inclinação posterior, rotação superior e rotação medial das escápulas nos ângulos de 60°, 90° e 120° de elevação, tanto na fase ascendente quanto na descendente. A análise estatística utilizada foi a multivariada da variância (MANOVA) comparando os lados direito e esquerdo do grupo controle e posteriormente o grupo controle com o grupo pós-operatório (p = 0.05 em todos os testes). Resultados: Ao compararmos a média dos resultados da avaliação quantitativa do grupo controle com o grupo dos operados, não foram evidenciadas diferenças estatisticamente significativas entre os dois grupos, assim como os lados dominante e o não dominante do grupo controle. Conclusão: A cirurgia de Latarjet não causa DE, apesar de haver alterações em algum plano dos movimentos escapulares na fase ascendente e/ou descendente. Nível de Evidência III, Estudo Retrospectivo Comparativo.

Keywords: Dyskinesias. Joint Instability. Scapula.

Descritores: Discinesias. Instabilidade Articular. Escápula.

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### **INTRODUCTION**

The scapula is essential for the proper functioning of the upper limb.<sup>1</sup> Its posterior position to the costal arches forms a pseudoarticulation

controlled by muscles that either originate or insert themselves in this bone<sup>2</sup> and performs as a stable platform for the functioning

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

The study was conducted at Grupo de Cirurgia de Ombro e Cotovelo, Departamento de Ortopedia e Traumatologia, Faculdade de Ciências Médicas da Santa Casa de São Paulo and Laboratório de Análise do Movimento, Instituto de Ciências da Atividade Física e Esporte, Universidade Cruzeiro do Sul. Correspondence: Guilherme do Val Sella. Rua Rio de Janeiro, 224, apt. 72, São Paulo, SP, Brazil, 01240010. gvsella@gmail.com

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of the muscles of the scapular waist, promoting a kinematic balance in three planes, allowing the humerus to move efficiently.<sup>3</sup> The three planes of movements of the scapula are: coronal, in which the upper and lower rotation of the scapula occurs; axial, in which lateral and medial rotations occur; and sagittal, in which anterior and posterior inclinations occur.<sup>4</sup>

Kibler and Sciascia<sup>5</sup> determines as scapular dyskinesia (SD) any change in scapula movement, regardless of the cause. The dynamic alteration of scapular control is present in 67-100% of athletes with shoulder alterations, but are often asymptomatic.<sup>6</sup> The term SD is very generic and any change in the proper functioning of the shoulder girdle may be the cause of the alteration, such as muscle fatigue, neurological dysfunction, postural changes, diseases of the glenohumeral joint (instability, labial lesions, impact syndrome, rotator cuff tendinitis, and adhesive capsulitis), or as a response to muscle inhibition due to a painful stimulus.<sup>7,8</sup> The association between SD and shoulder pathology is uncertain, since the relationship between cause and effect is still unclear.<sup>9</sup>

The Latarjet surgery consists in performing permanent disinsertion of the pectoralis minor muscle tendon, of the medial part of the coracoid process, as well as the coracoacromial and coracohumeral ligaments, followed by an osteotomy and transfer of part of the coracoid process, together with the short head of the biceps brachial muscle and the coracobrachialis muscle, to the anteroinferior edge of the glenoid cavity, securing it with two screws parallel to the articular surface.<sup>10</sup> This is one of the most popular techniques for the treatment of shoulder instability, with good and excellent results in 82.7% of cases.<sup>11</sup> It is considered a non-anatomical technique and is possibly associated with the alteration of the position and motricity of the scapula, evolving to an SD.<sup>12</sup>

Cerciello et al.<sup>13</sup> were the first to investigate the effects of the Latarjet surgery in the scapula positioning, using computed tomography images. Currently, several methods are used for scapular evaluation, including gualitative and guantitative methods. Qualitative scans are simpler to perform, they are based on an inspection from the patient's back while they make repeated movements of elevation of the upper limbs as the examiner observes for any indications of SD.<sup>14</sup> Quantitative methods are more reliable than qualitative ones.<sup>15</sup> Although complex and costly, they offer a more objective and accurate way to evaluate the movements of the scapula in the three planes.<sup>16</sup> The insertion of intracortical pins associated with an electromagnetic device is evidently the most accurate; however, it is an invasive and painful method.<sup>16</sup> Other noninvasive methods, based on optical or electromagnetic tracking devices, have been developed to analyze scapula movement and have been used for diagnostic and evaluation purposes.<sup>17,18</sup> In this study, we used the method developed by Salvia et al.<sup>19</sup> which consists of capturing, with special cameras, spherical retroreflective markers fixed on the skin in specific anatomical references in the trunk and upper limbs. We believe that patients in the postoperative period of Latarjet surgery may develop SD. Our study aims to quantitatively evaluate the scapular movement of these patients, identify patients with SD. and correlate with the clinical status and the elevation degree of the shoulder.

### MATERIAL AND METHODS

A cross-sectional study was conducted, in which the participants were divided into a control group and a group of operated patients. The control group had, as inclusion criteria, adults without any alteration, symptoms, or previous surgical procedures to the shoulders. The participants were subjected to qualitative evaluation by the method described by Roche et al.<sup>14</sup> Patients who did not have SD according to this method were included in the control group, totaling 10 participants (20 shoulders). The quantitative evaluation

of these were then performed by the method developed by Salvia et al.,<sup>19</sup> with the standard deviation of these results as parameters of normality. In this group, six men and four women were evaluated, with a mean age of 28.5 years, ranging from 21 to 54 years. All 10 patients were right-handed and showed no statistically significant difference between the dominant and non-dominant sides.

In the operated group, 23 shoulders of 22 patients were included, all with more than one year of Latariet surgery, performed between 2011 and 2016. These patients were referred to the Movement Analysis Laboratory (LAM), at the Institute of Physical Activity and Sport Sciences, Universidade Cruzeiro do Sul, for evaluation. Initially, 51 patients had undergone Latarjet surgery with the Shoulder and Elbow Group of Santa Casa de São Paulo. Of these, 26 patients attended LAM and underwent clinical and guantitative evaluation. Four patients were excluded: three of which had associated diseases that prevented the elevation of the upper limbs of at least 120° and one had sequela from head trauma and was not able to remain in an orthostatic position without assistance. One patient had both shoulders operated, totaling the 23 shoulders that entered the study. In the group of operated patients, 20 men and 2 women were evaluated, with a mean age of 35.7 years, ranging from 18 to 68 years. The mean postoperative time was three years and five months, ranging from six years and eight months to one year and three months. Only two patients presented postoperative pain and six remained with 90° abduction apprehension. Surgery was performed on the dominant side in 69.5% of the cases with a 156° postoperative mean movement arch, 57° lateral rotation, and medial rotation at the height of the tenth thoracic vertebra.

The quantitative evaluation was performed by means of spherical retroreflective markers fixed with appropriate adhesive tape in specific anatomical references in the trunk and upper limbs. following the recommendations of the International Society of Biomechanics.<sup>20</sup> To define the trunk segment, markers were fixed in the spinous process of the seventh cervical vertebra (C7), in the spinous process of the eighth thoracic vertebra (T8), in the jugular notch, and in the xiphoid process. The scapula was defined using markers at the lower and upper angles of the scapulae, at the posterior angle of the acromions, and in the coracoid processes. The lateral and medial epicondyle of the humerus and the more distal and lateral portion of the styloid processes of the radiuses and ulnas were used to define the segments of the arms and forearms. In addition to these markers, rigid sets with spherical retroreflective markers (clusters) were fixed with appropriate adhesive tape in the flattest region of the acromions and between the markers of C7 and T8, and with elastic band on the side of the arms (Figure 1).



Figure 1. Arrangement of spherical retroreflective markers (dark base) and clusters (light base).

A: posterior view; B: anterior view; C: side view.

The three-dimensional recording of all markers was performed by eight special cameras (Vicon, Inc.), controlled by a specific unit (Giganet Lab Unit, Vicon, Inc.) that allows the synchronization of these cameras and sends the acquired signals to a computer via a specific computer program (Nexus, Vicon, Inc.). Initially, data were collected from the participants in orthostatic, neutral, and static position to record the reference position. The participants were then subjected to the dynamic part of the evaluation, performing unilateral circumduction movements to estimate the articulation center of the shoulders. Subsequently, with the upper limbs close to the body, following verbal command, they performed six repetitions of maximum elevation and return to the initial position in a comfortable time interval, ranging between three and five seconds. The first elevation for each patient was discarded and the last five were considered. The posterior inclination, upper rotation, and medial rotation of the scapulae (Figure 2) were evaluated at the angles of 60°, 90°, and 120° elevation, both in the ascending and descending phase.



A: coronal plane; B: axial plane; C: sagittal plane.

The data acquired during the evaluations were reconstructed in the Nexus program (Vicon, Inc.), and the trajectories of each spherical retro-reflective marker were stored for further analysis in the MotionMonitor (Innovative Sports Training, Inc.) and Matlab (Math Works, Inc.) programs.<sup>21</sup>

The rotations in the three planes of movement of the right and left scapular thoracic joint were calculated by Euler angles representations and following the convection recommended by Van Der Helm<sup>22</sup> and Wu et al.<sup>20</sup>

The statistical treatment of the data was performed using multivariate analysis of variance (MANOVA) to verify possible differences between the right and left sides of the control group and later to compare the control group with the postoperative group. The significance level was maintained at p = 0.05 and all tests were conducted in the *Statistical Package for the Social Sciences* program (SPSS Inc, IBM Company, Chicago, IL, USA).

The study was approved by the Research Ethics Committee (CAEE: 73695317.4.0000.5479) and does not present a conflict of interest.

### RESULTS

Figure 3 shows the results used as parameters of normality, which were defined by the mean of the five attempts considered for the 10 patients (20 shoulders) of the control group, after comparing the values of the dominant side with the non-dominant side (no statistically significant differences were found). It is important to highlight that

the values shown in Figure 3 refer to the degrees of inclination of the scapula in its three movement planes. Zero angulation represents the neutral position of the scapula; the positive values represent the anterior slope, lateral rotation, and superior rotation; and the negative values represent the posterior slope, medial rotation, and lower rotation, as shown in Figure 2.

When comparing the mean of the results of the quantitative evaluation of the control group with the postoperative group, for the elevations angles of 60°, 90°, and 120°, both in the ascending and descending phase, it was found that there was no statistically significant difference between the two groups; therefore, patients who underwent the surgical procedure were within the normality interval determined by the control group, as shown in Figure 4.

During the qualitative evaluation, SD was observed in 52.1%, totaling 16 patients in the operated group. The quantitative results of



**Figure 3.** Mean ( $\pm$  standard error) of the inclination, upper rotation, and medial rotation of the scapula relative to the trunk during the ascending (left) and descending (right) phases of the shoulder elevation movement to the right (white squares) and left (black squares) sides of the control group participants.

these patients were compared with the those of the control group, no statistically significant differences were seen between both groups. In the individual quantitative evaluation of these 16 patients, we observed that seven (43.75%) presented values outside the standard deviation of normality (showing acceptable variance for more and for less, from the mean of the results), as determined by the control group, at some point in the ascending and/or descending phase. However, only one patient presented results outside the standard deviation in the three measurement angles, in both the ascending and descending phase, and another patient in the three angles of the descending phase.





### DISCUSSION

One of the greatest difficulties in evaluating SD is the subjectivity of the tests. Studies evaluating the intra- and inter-observer results of static, radiographic, and recorded clinical examination tests, i.e., in qualitative ways, concluded that the reproducibility of the results is poor or unsatisfactory.<sup>15,16</sup>

The difficulty of performing a precise and reproducible measurement by qualitative methods can be due to the lack of standardization on scapular positioning in healthy individuals during rest; of a method that has clinical application, capable of providing measures related to the actual scapular kinematics; and lack of standardization in the nomenclature used to describe movements, plans, and axes.<sup>23</sup> When we survey the literature for the existence of SD after the Latarjet surgery, we found divergences in the results. Burkhart et al.<sup>24</sup> concluded that Latarjet surgery does not alter the movement of the scapula; Cerciello et al.<sup>13</sup> concluded that SD occurs in the first weeks, but the patients no longer present changes in scapular movements after six months postoperatively; and Carbone et al.<sup>12</sup> concluded that 25% of the patients had SD, with clinical repercussions.

The mean results of our study showed no statistically significant difference in scapular movements between the control group and the operated group. However, when we made an individual evaluation of each operated patient, separating the results of each plane from the scapular movements, in both the ascending and descending phase, we observed that all presented values outside the standard deviation in at least one plane of the scapular movements at some point in the ascending and/or descending phase. These results, however, were not sufficient to significantly alter the balance of forces during the movement of the scapula.

Only two patients in the operated group had divergent results from the others. One patient (4.3%) presented results outside the normality pattern determined by the control group in two planes of scapula movement, both in the ascending and descending phase, in the three measurement angles. Another patient obtained similar results, but only in the descending phase. When the means of the results were made, it was observed that these alterations were not sufficient to lead to an imbalance of the scapular movement and consequently to a SD. Both patients returned to their previous activities without limitations, pain complaints, or recurrences of glenohumeral dislocation.

As a limiting factor of the method, we highlight the difficulty, during clinical evaluation, to evaluate SD in overweight patients, since the adipose layer made it difficult to adequately visualize scapular movements. Patients who practiced sports and had a more developed muscle mass were also more difficult to evaluate SD.

We highlight the importance of this study as the pioneer in quantitatively evaluating scapular movements after Latarjet surgery. Another limitation is that we did not evaluate the movement and the shoulder position prior to the operation. Since SD could be present in some patients before surgery, a pre-surgery evaluation could have avoided this limitation.

### CONCLUSION

The Latarjet surgery does not cause SD, although there are changes in some plane of the scapular movements in the ascending and/ or descending phase. In this case, a compensation mechanism occurs by rebalancing the forces that act during the movements of the scapula, preventing the patient from presenting SD.

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### INCREASED RISK OF SPORTS INJURIES AMONG MEDICAL STUDENTS: CROSS-SECTIONAL STUDY

## ELEVADO RISCO DE LESÕES ESPORTIVAS EM ALUNOS DE MEDICINA: ESTUDO TRANSVERSAL

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### ABSTRACT

Objective: To evaluate the nature and rate of sports injuries in medical students, as well as the risk factors at these events. Methods: All student-athletes (218) from a Medical School, integrated in at least one of the six team sport modalities (soccer, rugby, indoor soccer, handball, basketball, and volleyball) in 2017, were included. Injuries affecting their performance, regardless of time loss, were included. Athlete-exposure (A-E) was defined as one student-athlete participating in one practice or game. Results: Injury rates were significantly higher in junior medical students (1<sup>st</sup> - 3<sup>rd</sup> year) (7.58 per 1000 A-E, 95%CI = 6.11-9.06) than in senior medical students  $(4^{th} - 6^{th} \text{ year})$  (4.49 per 1000 A-E, 95%CI = 3.26-5.73) (p < 0.001). Multi-sports athletes had higher injury rates (10.69 per 1000 A-E, 95%CI = 8.22-13.17) than single-sport athletes (4.49 per 1000 A-E, 95%CI = 3.51-5.47) (p = 0.002). More than 60% of reported injuries occurred in the lower limbs and the mechanism that accounted for most injuries in games was player contact (51%); whereas in practice, it was non-contact (53%). Conclusion: Junior medical students present a higher injury rate than seniors. Medical students practicing more than one modality had a higher injury rate than those involved in just one sport modality. Level of Evidence IV, Cross-Sectional Study.

### RESUMO

Objetivo: Avaliar a incidência e as características das lesões esportivas em alunos de medicina, assim como os fatores de risco envolvidos. Métodos: Todos os alunos (218) da Faculdade de Medicina da Universidade de São Paulo que integravam seis modalidades esportivas (futebol, rugby, futsal, handebol, basquete e vôlei) em 2017 foram incluídos. Foram incluídas as lesões que afetaram a performance, independente do tempo de afastamento. Uma exposição-atleta (E-A) foi definida como a participação de um aluno em um jogo ou treino. Resultados: A taxa de lesão foi maior em alunos do 1º ao 3º ano (7,58 por 1000 E-As 95% IC = 6,11-9,06) do que em alunos do  $4^{\circ}$ ao  $6^{\circ}$  ano (4,49 por 1000 E-As 95% IC = 3,26-5,73) (p < 0.001). Alunos praticantes de mais de uma modalidade apresentaram maior taxa de lesão (10,69 por 1000 E-As, 95% IC 8,22-13,17) do que alunos praticantes de apenas uma modalidade (4.49 por 1000 E-As, 95% IC 3,51-5,47) (p = 0.002). Mais de 60% das lesões ocorreram nos membros inferiores e o principal mecanismo em jogos foi contato com outro jogador (51%), e em treinos foi lesão sem contato (53%). Conclusão: Alunos do 1 ° ao 3 ° ano apresentaram maior taxa de lesão do que alunos do 4º ao 6º ano. Alunos praticantes de mais de uma modalidade apresentaram maior taxa de lesão do que alunos praticantes de apenas uma modalidade. Nível de Evidência IV, Estudo Transversal.

Keywords: Athletic Injuries. Students, Medical. Epidemiology.

Descritores: Traumatismos em Atletas. Estudantes de Medicina. Epidemiologia.

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#### INTRODUCTION

Medical School is a highly demanding course with potential drawbacks for students. Rates of depression and anxiety disorders are higher amongst medical students than among their nonmedical counterparts, and problems such as burnout and substance abuse are more frequent.<sup>1</sup> Growing evidence that physical exercise could be an option in facing these problems exist.<sup>2</sup> Participating regularly in a group fitness classes, in opposition to exercising alone or not at all, can lead medical students to decrease their perceived stress and increase their the physical, mental, and emotional quality of life.<sup>3</sup> In Brazil, medical schools have a strong tradition in competitive sports tournaments. In addition to full-term classes and academic activities, medical students also participate in weekly practices and games in several sports modalities. Despite bringing several benefits to their quality of life, physical activity is a risk factor for musculoskeletal injuries.<sup>4</sup>

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

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The knowledge and surveillance of sports injuries are key components for preventing these events. According to van Mechelen, Hlobil, and Kemper,<sup>5</sup> to prevent sports injuries, a four-step procedure should be followed: 1) identify the problem; 2) establish cause and mechanism; 3) develop, evaluate, and implement interventions; and 4) reevaluate these strategies through continuous surveillance. The purpose of this study was to evaluate the injury rate and the nature of sports injuries in medical students, as well as the risk factors involved.

### **METHODS**

All student-athletes from the University of São Paulo Medical School (a 6-year course), Brazil, integrated in at least one of the six team sport modalities (soccer, rugby, indoor soccer, handball, basketball, and volleyball) in 2017 were included, totalizing 218 participants. An appropriate institutional review board approved the project (CAPPesq 3.044.669 – 28/11/2018) and each participant provided written informed consent before participation. The study is in accordance with the Helsinki Declaration of 1975, which was revised in 1983.

Data from exposures and injuries for the 2017 season were collected separately. Regarding exposures, a form summarizing the number of practices and games and the average number of participants for each activity were submitted weekly by each team through Google forms based on the National Collegiate Athletic Association (NCAA) exposure report (Appendix 1).<sup>6</sup> The authors collected data regarding injuries retrospectively, after the last practice or game of the 2017 season, based on the NCAA questionnaire (Appendix 2).<sup>6</sup> Demographic data on age, gender distribution, year of Medical School, and number of sports practiced were also collected at the end of the season.

A reportable injury had to meet the following criteria: 1) injury occurred as a result of participation in a university practice or game, and 2) injury resulted in restriction of the student-athletes participation or performance, regardless of time loss. Exposure was defined as one athlete participating in one practice or one game (athlete-exposure, A-E).<sup>6</sup>

Data on injury mechanisms (non-contact, other contact, player contact, and unknown), site of injury by body part (head and neck, upper limbs, torso and back, lower limbs, and other system), and severity of injury were analyzed as percentages. Injuries that resulted in at least 21 days away from sports activities were classified as severe.

A cross-sectional analysis was performed after injury and exposure data compilation. The analysis includes a comparison of injury rates in three categories: sports event (game vs. practice), year of medical school (junior athletes  $1^{st}$ -  $3^{rd}$  year vs. senior  $4^{th}$ - $6^{th}$  year) and the number of sports practiced (single-sport athletes vs. multi-sports athletes). Multi-sports athletes were those integrated in at least two sports modalities. Injury rates were expressed as the number of injuries per 1000 A-E,<sup>6</sup> with a confidence interval of 95%. For comparison between injury rates, the chi-squared test was used, with p-value < 0.05

### RESULTS

#### Sample characteristics

In total, 218 student-athletes, from the six-year medical course, were included. 57.3% were men and 53% were enrolled from 1<sup>st</sup> to 3<sup>rd</sup> year, with a mean age of 22.51 (± 2.6) years. 159 (73%) integrated a single sport modality, whereas 59 (27%) were multisport athletes.

#### Number of injuries

Among the 218 student-athletes, 118 (54%) suffered at least one injury during the season. Among those, 72% (85) suffered just one injury, 23% (27) suffered two injuries, 3.2% (5) suffered three injuries and 0.6% (1) suffered four injuries. Altogether, in 2017, 25.622 exposures and 158 injuries were totaled.

Game and practice injury rates

The game injury rate (15.18 per 1000 A-E, 95%Cl = 10.96-19.40) was 3.21 times higher than the practice injury rate (4.72 per 1000 A-E, 95%Cl = 3.8-5.6) (Table 1). These rates equal one injury every 3.3 games and 1 injury every 10.6 practices for a team of 20 participants, across all sports.

Table 1. Comparison of injury rates in three categories: Sports event,
Year of Medical School, and Number of Sports Practiced.

	Injury rate per 1000 A-E, (95%IC)	р
Sports event		
Game	15.18 (10.96-19.40)	< 0.001
Practice	4.72 (3.8-5.6)	
Year of medical school		
Juniors (1 <sup>st</sup> -3 <sup>rd</sup> year)	7.58 (6.11-9.06)	< 0.001
Seniors (4 <sup>th</sup> -6 <sup>th</sup> year)	4.49 (3.26-5.73)	
No. of sports practiced		
Single-sport athlete	4.49 (3.51-5.47)	0.002
Multi-sports athlete	10.69 (8.22-13.17)	

### Distribution of injuries by body part

Figure 1 shows the distribution of injuries by body part. In both practices and games, more than 60% of the reported injuries were located in the lower limbs. Ankle (24.7%) and knee (14.6%) accounted for the most injuries. The incidence of ankle sprain was 1.40 per 1000 A-E (95%CI = 0.93-1.87) and incidence of anterior cruciate ligament (ACL) tear was 0.39 per 1000 A-E (95%CI = 0.14-0.63).



**Figure 1.** Distribution (percentages) of injuries by body part for games and practices for 6 sports in 2017.

### Injury mechanism

Figure 2 shows the injury mechanisms in relation to practice and game. The mechanism involved in most injuries in games was player contact (51%) and in practice was non-contact (53%).



**Figure 2.** Distribution (percentages) of injuries by injury mechanism for practice and games for 6 sports in 2017. Player contact: contact with another competitor; Other contact: contact with the playing surface, apparatus, ball or with other in the environment (e. g., wall, fence, spectators); Non-contact: no apparent contact (rotation on a planted foot) or other.

### Juniors x seniors injury rates

Junior student-athletes ( $1^{st} - 3^{rd}$  year) injury rate (7.58 per 1000 A-E 95%IC = 6.11-9.06) was 1.68 times higher than senior student-athletes ( $4^{th} - 6^{th}$  year) injury rates (4.49 per 1000 A-E 95%IC = 3.26-5.73), across all sports (Table 1).

### Single-sports x multi-sports athletes injury rate

Multi-sports athletes' injury rate (10.69 per 1000 A-E, 95%IC 8.22-13.17) was 2.40 times higher than single sports injury rate (4.49 per 1000 A-E, 95%IC 3.51-5.47), across all sports (Table 1).

### **Time loss**

The mean time loss was 40.1 days (95%Cl = 30.62-49.59). There was a high incidence of severe injuries (48%). The knee accounted for most of the severe injuries (25.9%) followed by leg and ankle (20.7%), and shoulder (14.2%).

### Injury rates by sport

As shown in Figure 3, the highest injury rates were: men's indoor soccer (8.75 per 1000 A-E), men's basketball (8.72 per 1000 A-E), and rugby (8.45 per 1000 A-E).



DISCUSSION

This study analyzes the injury rate and nature of sports injuries in medical students. Although enrolled in a high demanding course with 6 years of duration and full-term classes, medical students engage in weekly practices and competitive sports tournaments in Brazil. We found high rates of game and practice injuries (15.18 per 1000 A-E, 95%Cl = 10.96-19.40 or one injury every 3.3 games and 4.72 per 1000 A-E, 95%Cl = 3.8-5.6 or 1 injury every 10.6 practices for a team of 20 participants). A retrospective analysis of 396 student-athletes – including medical students – conducted by our group for the 2013 season, found similar rates.<sup>7</sup>

The sudden increase in physical demand, considering that most students lead a sedentary lifestyle prior to entering Medical School, may explain the higher incidence of injuries in junior students ( $1^{st} - 3^{rd}$  years) compared with seniors ( $4^{th} - 6^{th}$  years), 7.58 per 1000 A-E 95%CI = 6.11-9.06 and 4.49 per 1000 A-E 95%CI = 3.26-5.73, respectively. A Chinese study with university athletes identified freshman students as a risk group for sports injuries.<sup>8</sup> These findings reinforce the importance of an adequate pre-participation assessment as well as a pre-season plan.

Another possible risk factor of injuries in this population is the considerable number of students practicing more than 1 sport modality (27%). These multi-sports athletes presented a higher injury rate (10.69 per 1000 A-E, 95%CI = 8.22-13.17) than students practicing a single modality (4.49 per 1000 A-E, 95%CI = 3.51-5.47). The frequency of practices and games was strongly associated with physical activity-related injuries in a study with more than four thousand university students.<sup>8</sup> Moreover, it is well known that insufficient sleep time, less than six hours per day, is associated with fatigue injuries,<sup>9</sup> a very common concern among medical students.

In contrast with NCAA, a high prevalence of non-contact injuries was found. This was the main mechanism of practice injuries (53%) and the second most common of game injuries (36%). Non-contact injuries represented just 36% and 17% of practices and game injuries in the NCAA, respectively (10). Medical students also had a high incidence of ACL tear (0.39 per 1000 A-E, 95%CI = 0.14-0.63) compared with NCAA (0.15 per 1000 A-E, 95%CI = 0.14-0.15).<sup>10</sup> The high incidence of non-contact injuries may reflect poor physical conditioning of medical students, reinforced by the fact that neuromuscular training programs decrease non-contact injuries such as ACL tear.<sup>11</sup>

Regarding body part injuries, lower limbs represented most of practice and games injuries. Following previous literature,<sup>12</sup> the ankle was the most common location of injury (26%), followed by the knee (15%). However, considering severe injuries, the knee was the most affected (26%), followed by the leg and the ankle (21%). The well-established preventive programs to reduce lower limbs injuries are a potential alternative to improve sports safety among medical students.<sup>13</sup>

### CONCLUSION

Junior medical students presented a higher injury rate than seniors. Medical students practicing more than one modality had a higher injury rate than those involved in just one sport modality.

Future preventive programs should focus on lower limb injuries, especially in junior medical students and in those practicing more than one sport modality.

### **Study limitations**

This study may be susceptible to memory bias, meaning that a subject may have reported only the injuries that he was able to remember at the end of the season. Another important limitation

is that participating in a match accounted for 1 A-E regardless of time played, due to the technical limitation on accurately assessing time on court or field. Therefore, the expected injury rate may vary significantly among participants with drastically different amounts of minutes played per match.

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### APPENDIX I 2017 EXPOSURE REPORT

**EXPOSURE DEFINITION:** One athlete participating in one practice or competition where he or she is exposed to the possibility of an athlete injury (athlete-exposure, A-E). Game participants must have actual playing time.

1. Sport:

(1) men's soccer (2) rugby (3) men's volleyball (4) women's volleyball (5) men's handball (6) women's handball (7) men's indoor soccer (8) women's indoor soccer (9) men's basketball (10) women's basketball

2. Week: .....

3a. Number of practices this week: .....

3b. Average number of participants per practice: .....

4a. Number of games this week: .....

4b. Number of participants with actual playing time:

Game 1: ..... Game 2: ..... Game 3: ..... Game 4: ..... Game 5: ....

Additional comments (optional):

This questionnaire is a version of Injury Surveillance System from NCAA (Dick, R., Agel, J., and Marshall, S.W. (2007). National collegiate athletic association injury surveillance system commentaries: Introduction and methods. Journal of Athletic Training 42, 173-182.)

With permission of Brian Hainline, MD NCAA Chief Medical Officer

### APPENDIX II 2017 INJURY QUESTIONNAIRE

<b>INJURY DEFINITION: A rep</b> 1. Occurs as a result of par student-athlete's participation	ortable injury is defined as one t ticipation in an organized univers n or performance regardless of tin	hat: ity practice or contest; and 2. In ne loss.	njury resulted in restriction of the	
<ol> <li>Name:</li> <li>Phone number:</li> <li>Medical School Year (1<sup>st</sup> – 6 4. Gender: (1) male (2) fema 5. Height:</li> </ol>	 t <sup>h</sup> ): le			
<ol> <li>Weight:</li> <li>Sports practiced: (1) soccer</li> <li>Playing position:</li> <li>Dominant body side: (1) rigit</li> </ol>	(2) rugby (3) volleyball (4) har  nt (2) left	ndball (5) indoor soccer (6) ba	asketball	
INJURY No.1				
1. Sport of injury no.1:				
<b>2. Month of injury no.1:</b> (1) jan (2) feb (3) mar (4)	apr (5) may (6) jun (7) jul (8)	aug (9) sep (10) oct (11) no	ov (12) dec	
3. Injury no.1 occurred durin	g:			
(1) Preseason (before first reg (2) Regular season	gular-season match)	(3) Postseason (after final regu (99) other:	ular-season match)	
4. Injury no.1 occurred in:				
(1) Practice		(2) Game		
5. Injury no.1 occurred durin	g:			
(1) game or practice first half		(2) game or practice second h	alf	
6. This injury no.1 is a:				
<ol> <li>New injury</li> <li>Recurrence of injury from</li> <li>Recurrence of injury from</li> <li>Complication of previous</li> </ol>	this season previous season (this sport) injury (this sport)	<ul><li>(5) Recurrence of other-sport injury</li><li>(6) Recurrence of non-sport injury</li><li>(7) Complication of other-sport injury</li></ul>		
7. Main body part injured in	injury no.1:			
<ol> <li>(1) head</li> <li>(2) face</li> <li>(3) teeth</li> <li>(4) neck</li> <li>(5) upper back</li> <li>(6) ribs</li> <li>(7) sternum</li> <li>(8) lower back</li> <li>(9) abdomen</li> </ol>	<ul> <li>(10) shoulder</li> <li>(11) clavicle</li> <li>(12) scapula</li> <li>(13) upper arm</li> <li>(14) forearm</li> <li>(15) elbow</li> <li>(16) wrist</li> <li>(17) hand</li> <li>(18) finger(s)</li> </ul>	<ul> <li>(20) pelvis or hips</li> <li>(21) groin</li> <li>(22) buttocks</li> <li>(23) upper leg</li> <li>(24) knee</li> <li>(25) lower leg</li> <li>(26) ankle</li> <li>(27) foot</li> <li>(28) toe (s)</li> </ul>	<ul> <li>(29) stomach</li> <li>(30) spleen</li> <li>(31) kidney</li> <li>(32) external genitalia</li> <li>(33) coccyx</li> <li>(34) breast</li> <li>(99) other:</li> </ul>	



8. Body side injured:				
(1) right		(2) left		
9. Knee injury:				
<ol> <li>(1) collateral ligament</li> <li>(2) anterior cruciate ligament</li> <li>(3) posterior cruciate ligament</li> <li>(4) torn cartilage (meniscus)</li> </ol>		<ul><li>(5) patella and or patella tendon</li><li>(6) other tendon</li><li>(99) other:</li></ul>		
10. This injury involved:				
<ol> <li>(1) contact with another competitor</li> <li>(2) no apparent contact (other)</li> <li>(3) contact with apparatus/ball</li> <li>(4) contact with other in environment (e.g.,wal</li> </ol>	l, fence, spectators)	(5) no apparent conta (6) contact with playir (99) other:	act (rotation on planted foot) ng surface 	
11. Primary type of injury no.1:				
<ol> <li>(1) contusion</li> <li>(2) laceration</li> <li>(3) bursitis</li> <li>(4) tendinitis</li> <li>(5) ligament sprain (incomplete tear)</li> <li>(6) ligament sprain (complete tear)</li> <li>(7) muscle-tendon strain (incomplete tear)</li> <li>(8) muscle-tendon strain (complete tear)</li> <li>(9) osseous edema</li> <li>(10) torn cartilage</li> </ol>	<ul> <li>(11) AC separation</li> <li>(12) dislocation (parti</li> <li>(13) dislocation (com</li> <li>(14) fracture</li> <li>(15) stress fracture</li> <li>(16) concussion</li> <li>(17) heatstroke</li> <li>(18) hemorrhage</li> <li>(19) infection</li> <li>(20) avulsion (tooth)</li> </ul>	al) plete)	<ul> <li>(21) nerve injury</li> <li>(22) blisters</li> <li>(23) hernia</li> <li>(24) foreign object in body orifice</li> <li>(25) internal injury (non-hemorrhage)</li> <li>(26) infection</li> <li>(27) periostitis</li> <li>(28) inguinal hernia</li> <li>(99) other:</li> </ul>	
12. Did this injury require surgery?				
(1) Yes, in-season	(2) Yes, postseason		(3) No	
13. Describe the joint surgery?				
<ul><li>(1) Arthrotomy</li><li>(2) Diagnostic arthroscopy</li><li>(3) Operative arthroscopy</li></ul>		(4) no joint surgery: (99) other:		
14. Injury assessment (best assessment p	procedure):			
<ul><li>(1) clinical exam by athletic trainer</li><li>(2) clinical exam by physician</li><li>(3) X-ray</li><li>(4) MRI</li></ul>		<ul><li>(5) other image techr</li><li>(6) surgery</li><li>(7) blood work lab tes</li><li>(99) other:</li></ul>	iique st 	
15. Days lost from sport activity:				

This questionnaire is a version of Injury Surveillance System from NCAA (Dick, R., Agel, J., and Marshall, S.W. (2007). National collegiate athletic association injury surveillance system commentaries: Introduction and methods. Journal of Athletic Training 42, 173-182.)

With permission of Brian Hainline, MD NCAA Chief Medical Officer

Additional comments (optional):



### EPIDEMIOLOGY, CLASSIFICATION, AND TREATMENT OF BILATERAL FRACTURES OF THE DISTAL RADIUS

## EPIDEMIOLOGIA, CLASSIFICAÇÃO E TRATAMENTO DE FRATURAS BILATERAIS DO RAIO DISTAL

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### ABSTRACT

Objective: To study epidemiology, fracture pattern, associated injuries, and treatment of individuals with bilateral distal radius fracture, in a tertiary hospital. Methods: Retrospective cross-sectional study developed based on patients with bilateral distal radius fracture from January 2012 to November 2017. Demographic data, trauma mechanism, radiological patterns, degree of deviation, associated injuries, classification of fractures according to the Association of Osteosynthesis (AO), the Salter-Harris (SH) and Frykman scales, and type of treatment used in each case. Results: 13 cases were included in the trial, 10 adults and three children. In infants, the mean age was 9.6 years (7-11 years), and low-energy trauma was described in all these cases. In total, 66.6% of the children presented the SHII classification . In adult patients, the mean age observed was 43.5 years (27-56 years), with high-energy trauma reported in four (40%) cases. The AO 23C.3 and 23B.2 classifications were the most prevalent in adults. Conclusion: In adult individuals, there was a higher incidence of open fractures, wrist joint involvement, ulna fracture, and concomitant injuries, with high-energy trauma observed only in this group, corresponding to half of the cases. Level of Evidence IV, Case Series.

**Keywords:** Radius Fractures. Epidemiology. Wrist Injuries. Clinical Study.

### RESUMO

Objetivo: Estudar epidemiologia, padrão de fraturas, lesões associadas, e tratamento dos indivíduos com fratura de rádio distal bilateral, em um hospital terciário. Métodos: Estudo transversal retrospectivo desenvolvido a partir de pacientes com fratura de rádio distal bilateral no período entre janeiro de 2012 e novembro de 2017. Foram analisados dados demográficos, mecanismo de trauma, padrões radiológicos, grau de desvio, lesões associadas, classificação das fraturas de acordo com AO, Salter Harris (SH) e Frykman, e tipo de tratamento empregado em cada caso. Resultados: 13 casos foram incluídos no ensaio, sendo 10 adultos e três crianças. Nos infantes, a média de idade foi de 9,6 anos (7-11 anos), e o trauma de baixa energia esteve descrito na totalidade destes casos. A classificação SHII esteve presente em 66,6% das crianças. Nos pacientes adultos, a média de idade observada foi de 43,5 anos (27-56 anos), com o mecanismo de trauma de alta energia relatado em quatro (40%) casos. A classificação AO 23C.3 e 23B.2 foram as mais prevalentes nos adultos. Conclusão: Em indivíduos esqueleticamente maduros, observou-se maior incidência de fraturas expostas, acometimento articular do punho, fratura de ulna e lesões concomitantes, sendo o trauma de alta energia observado apenas neste grupo, correspondendo a metade dos casos. Nível de Evidência IV, Série de Casos.

**Descritores**: Fraturas do Rádio. Epidemiologia. Traumatismos do Punho. Estudo Clínico.

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### INTRODUCTION

Distal radius fractures, which occur up to 3 cm from the articular surface between the radius and the proximal row of the carpal bones, correspond to the most common injuries of the upper limbs, representing approximately 17.5% of all fractures of the human skeleton and up to a sixth of all fractures treated in emergencies.<sup>1-3</sup> The distal radius fracture presents a well-established distribution pattern among children/adolescents, with a higher prevalence

in individuals aged 5–14 years, and among adults, especially among men aged over 40 years and women aged over 60 years. In this group, the literature describes a two to three times higher incidence of injury in females, with osteoporotic disease being considered a significant risk factor, usually involving low-energy trauma with hyperextended and flat hand.<sup>2</sup> In the younger population, high-energy trauma, such as in automobile accidents, has greater impact as an injury mechanism.<sup>4</sup> In these circumstances,

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The study was conducted at Instituto Doutor José Frota.

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other associated injuries can be observed since these are polytrauma patients, implying greater morbidity.<sup>5</sup> However, although common in one limb, bilateral distal radius fracture is rare, with few case series in the literature, even in large trauma care centers.<sup>6</sup> Fracture patterns and demography seem to vary when comparing unilateral and bilateral radius fractures, with the higher prevalence of bilateral fractures in men, for example, who usually experience high-energy trauma.<sup>5,6</sup> Furthermore, compared to unilateral fractures, bilateral fractures are associated with worse functional prognosis, especially in patients with residual deformities, and the morbidity involved in this type of injury is still unknown.<sup>5,7</sup>

Thus, this study aims to describe demographic variables, trauma mechanism, radiographic patterns, and injuries associated with bilateral distal radius fractures, in addition to the type of therapy provided for each individual in our series.

### MATERIALS AND METHODS

In a retrospective analysis of medical records from visits conducted from January 2012 to November 2017, 18 patients were diagnosed with bilateral distal radius fracture. The survey was implemented via an active search in the database of a tertiary hospital, using the International Disease Code (ICD-10) S52.5, which corresponds to fractures of the lower extremity of the radius. The medical records and image files of the respective patients were examined. Inclusion criteria were patients of both sexes and all ages with a record of bilateral distal radius fracture, regardless of having associated injuries or not. Patients whose medical records and/or radiographs contained deficiencies or did not meet the parameters evaluated in this study were excluded.

All radiographs in anteroposterior (AP) and lateral views were evaluated by a physician, member of the Brazilian Society of Orthopedic Trauma and the Association of Osteosynthesis (AO)/Trauma.

Among the 18 patients, five were excluded from the analysis, two for lack of medical records of the initial emergency care and three for lack of radiographs before specific treatment. The final amount of the study sample was 13 patients.

The descriptive analysis presented, in tables, the observed data, expressed as mean  $\pm$  standard deviation (SD) for numerical data, and frequency (n) and percentage (%) for categorical data. The graphs were constructed to illustrate the relative distribution of the gravity scales. The statistical analysis was processed using the SAS® System version 6.11 statistical software (SAS Institute, Inc., Cary, North Carolina).

### RESULTS

The results are outlined in the tables below (Table 1, Table 2, and Table 3).

Tab	Table 1. Case series, energy of trauma, degree of deviation, associated injuries, and exposure. Instituto Doutor Jose Frota.									
<u> </u>			Deviation	Deviation of degree		racture	Accepted injuries	Exposed fracture		
#	Age	Sex	Energy of trauma	R	L	R	L	Associated injuries	R	L
1	35	М	Low	38°	34°	No	Yes	-	No	No
2	52	М	High	5°	11°	No	Yes	-	No	Yes
3	52	F	Low	21°	20°	No	No	Traumatic brain injury	No	No
4	11	М	Low	23°	16°	Yes	Yes	-	No	No
5	7	М	Low	0°	36°	Yes	Yes	-	No	No
6	30	M	High	19°	9°	No	No	Tibial fracture	No	No
7	11	М	Low	29°	34°	No	Yes	-	No	No
8	56	М	High	39°	3°	Yes	No	Pubic symphysis diastasis	Yes	No
9	56	F	High	0°	21°	No	Yes	-	Yes	Yes
10	41	М	High	18°	30°	No	No	-	No	No
11	55	F	Low	11°	9°	Yes	Yes	-	No	No
12	27	М	Low	21°	23°	No	No	Scaphoid fracture	No	No
13	31	М	Low	10°	5°	No	Yes	traumatic brain injury + mandible fracture	No	No

F: female; M: male, R: right; L: left.

Table 2	Fable 2. Fracture classification and patterns. Instituto Doutor José Frota.										
щ.	Articular involvement		Posterior comminution		AO/Salter-Harri	AO/Salter-Harris Classification			Frykman Classification		
#	R	L	R	L	R	L	R	L	R	L	
1	Yes	Yes	Yes	Yes	23C3.2	23C3.1	IV-C	IV-B	VII	VIII	
2	Yes	Yes	No	No	23B3.1	23C3.1	IV-B	IV-B		VIII	
3	No	No	Yes	No	23A2.1	23A2.1		II		1	
4	No	No	No	No	SH-II	SH-II	-	-	-	-	
5	No	No	No	Yes	Metaphyseal	Metaphyseal	-	-	-	-	
6	Yes	Yes	Yes	Yes	23B2.1	23B2.1	IV-B	IV-B			
7	No	No	Yes	Yes	SH-II	SH-II	-	-	-	-	
8	Yes	Yes	No	No	23C1.3	23C1.2	IV-B	IV-C	VIII		
9	Yes	No	No	No	23B1.1	23A2.1		II			
10	Yes	Yes	Yes	Yes	23C3.2	23B3.1	IV-C	IV-B		IV	
11	No	No	Yes	Yes	23A1.2	23A1.2		II			
12	Yes	No	Yes	No	23B2.1	23B2.1	IV-B	IV-A			
13	Yes	Yes	No	Yes	23C1.2	23C3.1	IV-A	IV-B		IV	



Table 3	able 3. Fracture classification, exposure, and treatment. Instituto Doutor José Frota.									
щ	AO/Salter Harris	Exposed	fracture	Fracture treatment						
#	R L	R	L	R	L					
1	23C3.2 23C3.1	No	No	Elective surgery	Elective surgery					
2	23B3.1 23C3.1	No	Yes	Elective surgery	External fixation + Elective surgery					
3	23A2.1 23A2.1	No	No	Closed reduction + cast	Closed reduction + cast					
4	SH-II SH-II	No	No	Elective surgery	Elective surgery					
5	Metaphyseal bilateral	No	No	Closed reduction + cast	Closed reduction + cast					
6	23B2.1 23b2.1	No	No	Closed reduction + cast	Elective surgery					
7	SH-II SH-II	No	No	Elective surgery	Elective surgery					
8	23C1.3 23C1.2	Yes	No	External fixation + Elective surgery	Elective surgery					
9	23B1.1 23A2.1	Yes	Yes	External fixation + Elective surgery	External fixation + Elective surgery					
10	23C3.2 23B3.1	No	No	Elective surgery	Elective surgery					
11	23A1.2 23A1.2	No	No	Closed reduction + cast	Closed reduction + cast					
12	23B2.1 23B2.1	No	No	Elective surgery	Closed reduction + cast					
13	23C1.2 23C3.1	No	No	Elective surgery	Elective surgery					

### DISCUSSION

Distal radius fractures are among the most prevalent fractures of the upper limbs, representing approximately one sixth of all fractures treated in emergency departments.<sup>8</sup> This type of injury is commonly found in older adults, which is related to the progression of osteopenia in the aging process, corroborating the occurrence of osteoporotic fractures due to fragility in places such as distal radius, proximal humerus, lumbar spine, and hips.<sup>8</sup> In younger individuals, car accidents, falls from height (greater than 2 meters), and sports activities are more prevalent as a trauma mechanism, although, in this group, the occurrence of bilateral distal radius fracture is still poorly described.<sup>6</sup> Stone et al.,<sup>9</sup> also described electric shock from domestic sources (110-220 v, 50-60 Hertz) as a trauma mechanism associated with bilateral distal radius fracture, in addition to other injuries, such as fracture of the humerus and scapula, and the bilaterality of lesions should always be considered in these patients. Currently, there are no epidemiological studies of bilateral distal radius fractures in the Brazilian literature. Thus, our study becomes relevant, considering the distribution pattern of uni or bilateral fractures of the distal radius, due to the greater degree of complexity of such cases and the presence of associated injuries. Moreover, our study allowed for a comparative assessment of injuries in both adult and child. From our sample, high-energy trauma often described as a trauma mechanism in the adult population can be associated as a determining factor for the risk of exposed fracture, joint wrist involvement, associated ulna fracture, or the occurrence of concomitant injury elsewhere, a fact that can lead to greater morbidity and potential complications.

Van der Vliet et al.,<sup>10</sup> published a study comparing, by applying questionnaires, the functional evolution of patients with polytraumatized distal radius fractures and victims of high-energy trauma with victims of low-energy trauma. The final sample of the study was 345 patients, who were grouped into three groups, multiple trauma patients with an Injury Severity Score (ISS)  $\geq$  16, victims of non-multiple high-energy trauma with an ISS < 16, and victims of low-energy trauma. For functional assessment of patients, the following questionnaires were applied by the researchers: assessment of quality of life, health-related quality of life (HRQoL), and Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) for functional assessment of the affected wrist. At the end of the study, a mean HRQoL of 0.84, 0.85, and 1.0 was observed for polytrauma patients, high-energy traumas, and low-energy traumas, respectively, while the mean QuickDASH was 7, 11, and 5 for these respective groups; effectively associating high-energy trauma with a worse prognosis in cases of distal radius fracture. Notably, this study evaluated patients with unilateral fractures; thus, the morbidity and mortality involved in bilateral fractures, which can be potentially greater, are still poorly described in the literature.<sup>6</sup> In a recent observational study with a sample of 22,962 patients with unilateral distal radius fracture, there was a mortality of 93 (0.4%) cases in 30 days and 679 (2.9%) cases in one year of fracture.11

Another retrospective cross-sectional study, with a sample of 93 patients diagnosed with bilateral distal radius fracture found a total of 51 (55%) children and 42 (45%) adults, similar to our results. In children, 44 (86%) cases suffered low-energy trauma, with concomitant injuries recorded in only two (4%) cases, with SHII and Torus fractures being the most prevalent, corresponding to 30 (29%) and 32 (31%) cases, respectively. However, in the adult population, 37 (88%) patients suffered high-energy trauma, with associated injuries recorded in 16 (38%) cases, with joint fractures being the most prevalent, corresponding to 44 (52%) cases.<sup>5</sup> In that study, a variety of eight types of associated injuries were observed, among which Cranioencephalic Trauma (TBI), long bone fractures, acute carpal tunnel syndrome, and pelvic ring fractures were the most prevalent.<sup>5</sup> However, the aforementioned study, like ours, does not include the follow-up of patients, preventing an assessment of functional evolution or radiographic parameters after treatment.

Graham et al.,<sup>7</sup> when assessing radiological parameters, range of motion of the wrist and data obtained by a functional assessment questionnaire of the upper limb, QuickDASH, in 10 patients with bilateral distal radius fracture who underwent surgical treatment with open reduction and internal fixation, showed no statistically significant difference in functional results in the recovery of the range of motion (ROM) of the wrist, and in the restoration of radiological parameters when compared with studies involving patients with unilateral fractures.

Khonglan, Ahmed, and Borgohaim,12 in the case report of a pianist patient, victim of an automobile accident, with bilateral distal radius fracture and associated metacarpal-phalangeal dislocation reinforced the importance of early functional rehabilitation of these injuries after adequate reduction and fixation, ensuring adequate fracture consolidation and satisfactory functional gain in three months of evolution. Such an emphasis on early rehabilitation in the postoperative period of distal radius fractures was also given in a prospective and randomized study, in which 30 patients with distal radius fracture undergoing open reduction and internal fixation were followed in series.<sup>6</sup> The patients were divided into two groups of 15 individuals, one group was subjected to early physical therapy mobilization, and another group maintained with immobilization for



five weeks. Those in the first group showed a better range of motion and grip strength, at the end of the six-month follow-up.<sup>6</sup> Raudasoja et al.<sup>13</sup> described the importance of maintaining the radial height and the congruence of the articular surface of the wrist, in addition to early joint mobilization, as fundamental radiological restoration parameters for satisfactory functional recovery. According to their study, priority should be given to open reduction and internal fixation surgery in order to obtain anatomical reduction.

Good results were also described by Ravikumar et al.,<sup>14</sup> in a case report of a pregnant woman, 28 years old, 34 weeks of gestational age with bilateral distal radius fracture due to a fall, with satisfactory consolidation of the fractures in four weeks. In this case, hyperestrogenism and increased cardiac output, attributed to the third trimester of pregnancy, were considered essential for the satisfactory early consolidation of fractures.

One of our biggest limitation is the lack of randomized clinical studies with serial functional assessment of patients with treated bilateral distal radius fracture, making the clinical evolution and morbidity of this condition uncertain. Despite the numerical limitation of our sample, statistical significance can be attributed to our study given the overall low prevalence of the studied condition. Another limitation was the lack of access to the specific surgical treatment involved in each injury and what motivated the types of fixations, such as radiological findings, the extent of the soft tissue injury or skin coverage, the patient's clinical conditions and other associated injuries, and the time of fracture. Since this is a study developed at a major traumatology reference center with numerous orthopedists – specialized in orthopedic trauma and who were active in the emergency where there is no protocol for conducting each type of injury – the inter-observer bias regarding the initial care for each case interferes with its evolution and outcome, resulting in a confounding bias for our study.

Thus, it is extremely important for future perspectives on the subject, the development of randomized controlled clinical studies, with a larger number of patients diagnosed with bilateral distal radius fracture, thus enabling a statistically significant "follow-up." Since this is a new topic, with scarce scientific studies – most of which are case reports – the evolutionary functional evaluation and the radiological restoration of fractures, considering the different treatments, are rarely described in the literature, even when comparing with patients with unilateral fractures of the distal radius, in such a way that the functional impact and morbidity of this condition is still uncertain.

### CONCLUSION

In adults, there was a greater incidence of open fractures, wrist joint involvement, ulna fracture, and concomitant injuries, with high-energy trauma exclusively observed in this group, corresponding to half of the cases.

New randomized clinical studies should be elaborated, with statistically significant samples, enabling a follow-up of patients with bilateral distal radius fracture and, consequently, estimating the functional impact and morbidity of this condition.

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### INTRAVERTEBRAL EXPANDABLE IMPLANTS IN THORACOLUMBAR VERTEBRAL COMPRESSION FRACTURES

## IMPLANTES INTRAVERTEBRAIS EXPANSÍVEIS NAS FRATURAS VERTEBRAIS DORSOLOMBARES EM COMPRESSÃO

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### ABSTRACT

Current scientific evidence enhances the importance of the anatomic restauration of vertebral bodies with compression fractures aiming, as with other human body joints, to obtain a biomechanic and functional spine as close as the one prior to the fracture as possible. We consider that anatomic reduction of these fractures is only completely possible using intravertebral expandable implants, restoring vertebral endplate morphology, and enabling a more adequate intervertebral disc healing. This enables avoiding disc and osteodegenerative changes to that vertebral segment and its adjacent levels, as well as the anterior overload of adjacent vertebral bodies in older adults a consequence of post-traumatic vertebral flattening - thus minimizing the risk of adjacent vertebral fractures. The ability of vertebral body fracture reduction and height maintenance over time and its percutaneous transpedicular application make the intravertebral expandable implants a very attractive option for treating these fractures. The authors show the direct and indirect reduction concepts of vertebral fractures, review the biomechanics, characteristics and indications of intravertebral expandable implants and present a suggestion for updating the algorithm for the surgical treatment of vertebral compression fractures which includes the use of intravertebral expandable implants. Level of Evidence V, Expert Opinion.

**Keywords:** Prostheses and Implants. Spinal Fractures. Spine. Fractures, Compression. Fracture Fixation.

### RESUMO

A evidência científica atual aponta para a importância de obter restauração anatómica dos corpos vertebrais com fraturas em compressão, tal como acontece em outras articulações do corpo humano, de modo a garantir uma coluna biomecânica e funcionalmente mais próxima da prévia à fratura. Consideramos que a redução anatómica destas fraturas apenas se consegue na totalidade com a aplicação de implantes intravertebrais expansíveis, restaurando a morfologia das plataformas vertebrais e assim proporcionando uma cicatrização do disco intervertebral mais adequada. Isto permite minimizar a progressão para alterações disco e osteodegenerativas desse segmento vertebral e dos níveis adjacentes, bem como em idosos evitar a sobrecarga anterior dos corpos adjacentes consequente ao achatamento pós--traumático e assim minimizar o risco de fraturas vertebrais adjacentes. A capacidade de redução da fratura e de manutenção da altura do corpo vertebral ao longo do tempo, bem com a sua aplicação percutânea transpedicular, torna os implantes intravertebrais expansíveis uma opção muito atrativa no tratamento destas fraturas. Os autores apresentam os conceitos de redução direta e indireta de fraturas vertebrais, revêm a biomecânica, características e indicações dos implantes intravertebrais expansíveis, finalizando com uma proposta de atualização do algoritmo de tratamento cirúrgico das fraturas vertebrais em compressão que inclui a aplicação de implantes intravertebrais expansivos. Nível de Evidência V, Opinião do Especialista.

**Descritores:** Próteses e Implantes. Fraturas da Coluna Vertebral. Coluna Vertebral. Fraturas por Compressão. Fixação de Fratura.

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### INTRODUCTION

The treatment of fractures of the thoracolumbar spine, in particular the compression fractures, has evolved rapidly over the past 30 years, having considerably changed the indications, techniques and surgical implants. The morbidity of anterior approaches to anterior spine reconstruction has caused an exaggerated tendency to treat vertebral compression fractures by pedicular fixation, often increasing the number of fixed levels. However, loss of support in the anterior spine, a region that receives 80% of all axial loads, will inevitably overload the posterior instrumentation, sometimes

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resulting in instrumentation failure, loss of vertebral body height, and local and post-traumatic segmental kyphosis, with clinical and functional repercussions.<sup>1-6</sup> In view of this, the minimally invasive techniques of augmenting the fractured vertebral body have gained increasing popularity due to their ability to stabilize the anterior spine through the percutaneous posterior pathway, enabling good results in symptomatic relief, convalescence speed, functional and guality of life indices, and spine anatomy and biomechanics restoration.7-9 Expanding intravertebral implants are devices capable of controlled self-expansion applied percutaneously via posterior access transpedicular. They are introduced inside the fractured vertebral body, which usually shows a compression fracture. Their expansion can reduce the fracture of the vertebral body, restoring its height, integrity, and stability. The application of expansive intravertebral implants, also known as armed kyphoplasty, in addition to allowing the immediate analgesia and stabilization benefits of vertebroplasty and kyphoplasty, also allow the maintenance of the restored vertebral height, which is demonstrated in several studies with medium and long-term follow-up.7-23 This is because, after vertebral platforms height is restored, they are mechanically supported by the expanded device (functioning as a interior support or sustentaculum), decreasing or preventing vertebral flattening, minimizing the risk of local and post-traumatic segmental kyphosis, and ensuring the stable anterior support of vertebral body height.7,8,24-27 In this way, expansive intravertebral implants have gained popularity in the treatment of vertebral body compression fractures due to its guarantee of stable anterior support at the level of the vertebral body performed percutaneously, transpedicularly, reserving the high invasibility of corpectomy and reconstruction with spacers or massive allograft for cases requiring anterior neurological decompression of the vertebral canal.24,25,28

Importance of anatomical reduction in vertebral compression fractures

The authors of this article defend the importance of obtaining, as indicated for the other joints of the human body, an anatomical restoration (or the closest to it) of vertebral bodies which suffered compression fractures (by correcting the vertebral kyphosis angle, vertebral height, and the morphology of vertebral platforms) in order to ensure a biomechanically and functionally spine closer to the one prior to the fracture. Thus, it is sought in young individuals to avoid progression to disc alterations and osteodegenerative disorders of this vertebral segment and adjacent levels and in older adults to avoid the anterior overload of adjacent bodies and thus minimize the risk of adjacent vertebrae fractures.<sup>8,11,16,24,28</sup> Restoring the original anatomy of vertebral platforms enables the recreation of the original position of the often injured intervertebral disc, promoting its proper healing and pressurization and minimizing the invagination of the nucleus pulposus to the interior of the vertebral body, possibly compromising bone healing. This allows a better physiological load damping, potentially minimizing accelerated degeneration and reducing the overload of the suprajacent vertebral body and, thus, the risk of adjacent fractures.<sup>2,6,29-33</sup> A study showed, by functional magnetic resonance, that the apparent diffusion coefficient of the intervertebral disc suprajacent to vertebral compression fractures, after a mean 2.67 years, was significantly higher in fractures treated with expandable intravertebral implants, in which the anatomy of the vertebral platform is restored (thus showing coefficients similar to normal control discs), than fractures subjected to conservative treatment, which maintains the central flattening of the vertebral platform.<sup>34</sup> The diffusion coefficient of suprajacent discs decreased as the post-fracture degree of vertebral kyphosis increased. This coefficient represents the water and nutrient diffusion levels to the nucleus pulposus, thus suggesting the importance of anatomically reducing the vertebral platform supporting the disc to ensure its adequate water and nutritional intake. This study also demonstrates that the application of intravertebral cement has minimal influence on the diffusion of nutrients and water through the vertebral platforms for discs. Thus, the traumatic deformation of the vertebral platform compromises its diffusion circuits to the nucleus pulposus, promoting its dehydration, malnutrition, and the accelerated progression to post-traumatic disc degeneration. Moreover, supraiacent discs, after a mean 2.67 years, were in a significantly more advanced state of degeneration after conservative treatment (83.33% of which with Pfirrmann grades II and III) than those which had undergone intravertebral implant treatment (78.57% showed a Pfirrmann grade I, and the others, a grade II).7,10,28,34 In particular case of osteoporotic fractures, it is currently recognized that it is essential to restore vertebral body height at the time of the first fracture to prevent the domino effect of the disease, i.e., the consecutive occurrence of osteoporotic fractures in adjacent vertebrae due to anterior spine overload after the first uncorrected vertebral flattening. Vertebral flattening progressively diverts the load axis to a more anterior position, exposing the osteoporotic vertebral bodies to excessive anterior loads and favoring spine kyphotization and a cascade of consecutive pathological fractures.9,35

## Concepts of anatomical reduction of vertebral compression fractures

Expandable intravertebral implants introduce the concept of direct fracture reduction (Figure 1), that is, performed by an expanded implant at the exact fracture location within the vertebral body. If the fracture occurs by mechanism in compression, these implants will do the opposite, they expand the vertebral body, the reverse mechanism to the one that caused the fracture, being therefore a very effective method of fracture reduction. The classic indirect reduction by distraction and lordosis maneuvers through pedicle instrumentation of adjacent vertebrae reduces the cortical ring of the vertebral body due to the effects of containment of the anterior and posterior longitudinal ligaments and the peripheral portions of the vertebral platforms because of containment of the fibrous ring of the intervertebral disc. In turn, only direct reduction by expandable intrasomatic implants enables the restoration of the central part of the vertebral platforms, showing their importance in post-traumatic anatomical reduction and the promotion of adequate disc healing (Figure 1).<sup>2,6,36-37</sup> Moreover, these implants, in view of the integrity of common longitudinal anterior and posterior ligaments and the insertion of the fibrous ring in vertebral platforms, also enable anterior and posterior bone fragments to effectively return to their original positions, respectively, by ligamentotaxis and anulotaxis. Thus, they also reduce the peripheral parts of vertebral platforms and cortical rings.<sup>1,7-22,27,28,30,34,36,38-41</sup> Therefore, we consider that, to obtain the complete desired anatomical reduction of a vertebral compression fracture, direct reduction with expandable intravertebral implants is always necessary to correct the central depression of vertebral platforms. Moreover, in some fractures, this maneuver is sufficient for total fracture reduction and stabilization. Thus, when an initial indirect reduction by adjacent pedicular instrumentation is required, in order to also anatomically restore the central part of vertebral platforms it is necessary to associate it with a direct reduction by expandable intravertebral implants. Several studies have shown that, if expandable intravertebral implants are correctly positioned, the fear that they increase posterior wall retropulsion in burst compression fractures is unverified. On the contrary, by performing ligamentotaxis and anulotaxis at the time of implant expansion, the increased vertebral body height causes the posterior wall to move anteriorly, moving away from the vertebral canal and approaching its original position, restoring the posterior vertebral body height and making an indirect decompression of the vertebral canal.<sup>1,7,11,12,18,36,38,40,41</sup>





Figure 1. A: Indirect fracture reduction by distraction and lordosis maneuvers performed through instrumentation in the pedicles of adjacent vertebrae. Note the reduction of posterior wall retropulsion and restoration of anterior and posterior sagittal heights of the vertebral body. However, central flattening of the upper vertebral platform persists with no complete restoration of the middle sagittal height of the vertebral body (red arrowhead); B: Direct reduction of the fracture via expandable intravertebral implants. Note the elevation of the entire upper vertebral platform (arrowhead); C: Indirect reduction and direct reduction combined. Notice how direct reducion complements the indirect reduction manouvers, allowing the total anatomical restoration of the vertebral body, that is, the reduction of the cortical ring and also of the central portion of the vertebral platforms.

### Biomechanics of expandable intravertebral implants

Table 1 shows the features of the two main expandable intravertebral devices currently available, the VBS<sup>®</sup> (Vertebral Body Stenting) and the SpineJack<sup>®</sup> systems, the most commonly used worldwide.<sup>42-44</sup> Technological evolution will certainly bring expandable intravertebral implants with different mechanisms and morphology which will effectively ensure the anatomical restoration of vertebral platforms. In short, according to the authors' opinion and according to Table 1, the VBS<sup>®</sup> implant reduces and replaces the flattened and destroyed vertebral body, does not intending to wait for bone healing, while the SpineJack<sup>®</sup> implant reduces and preserves the flattened vertebral body, intending to bone healing.

Implant name	VBS® (Vertebral Body Stenting)	SpineJack®
Illustration		€
Morphology	Cylindrical shape network (stent). Two implants by bipedicular access	Similar to a carjack with upp and lower lamellae. Two implants by bipedicular acces
Material	Chromium-cobalt	Titanium
Expansion direction	Circumferential and centrifugal in the coronal plane (craniocaudal + lateral)	Bidirectional in craniocauda or vertical direction
Expansion mechanism	Hydraulic, by a kyphoplasty ballon (pressure and volume controlled)	Mechanic
Expansion force	Maximum pressure of 30 Atm; Maximum expansion volumes: #Small stent = 4 ml; #Medium stent = 4.5 ml; #Large stent = 5 ml	Expansion force of 500 Newtons; Maximum expansion heights: #Small implant, 4.2 size = 12.5 mm; #Medium implant, 5.0 size = 17 mm; #Large implant, 5.8 size = 20 mm
Goal	Fracture reduction and space filling – Indicated for osteopenia, lithic injuries, and A4 burst traumatic fractures	Fracture reduction, preservation of non-fracture trabeculae – Indicated for A1, A2, and A3 fractures with healthy bones
Rationale	VBS® is a reduction and space-filling implant system since it can multidirectionally expand (vertically and laterally). It is indicated for reconstructing or replacing the vertebral body without waiting for vertebral fracture healing. Stents are implants that form two cavities, coated by a casing of impacted trabeculae, within the vertebral body by expanding and impacting surrounding bony trabeculae. These implants form cavities that, after being filled with cement or bone graft, replace much of the vertebral body, filling and stabilizing it. Moreover, they minimize cement extravasation by recreating the walls of the vertebral body via impaction of bony trabeculae containing the cement.	SpineJack <sup>®</sup> is a more power reduction implant and preserver of non-fractured native bone trabeculae, rather than a filler, as it has only vertical expansion and not lateral. In these cases, fracture reduction and healir is intended, rather than replacing the vertebral body This implant only reduces ar sustains the vertebral body since it shows neither cavita shape nor lateral expansior It is incapable of destroying intact lateral trabeculae and does not create significant empty space inside the vertebral body. Thus, it is useful when it is intended to reduce the fracture and obta bone healing, preserving as much of healthy bone as possible. Therefore, we consider this implant not ideal for replacing the comminuted vertebral body lytic or porotic, a vertebra th does not have content and needs intrasomatic fillino it

 Table 1. Features of the two main expandable intravertebral implants



#### Indications of expandable intravertebral implants

The problem of vertebral compression fractures is located at the vertebral body, it is the one that is fractured, so it makes sense that some direct reduction and stabilization action on this same vertebral body is necessary. Indirect reduction by adjacent pedicular instrumentation, in addition to failing to correct vertebral platform depression, is incapable of providing vertebral bodies with sufficient integrity to receive loads. Indirect reduction maneuvers increase cortical ring height. However the interior of the vertebral body, previously filled with a resistant bony trabecular meshwork is now weak, showing only crushed bony trabeculae, which often results in progressive vertebral flattening and can lead to non-union situations. As such, we consider that the application of expansive intravertebral implants is indicated when an anatomical and sustained reduction of the fracture is intended, as such in most vertebral compression fractures. The purpose of anatomical reduction is in traumatic compression fractures to avoid an early development of degenerative discoarthropathies caused by the persistence of vertebral flattening, and in osteoporotic compression fractures to avoid domino effect of anterior overload caused by vertebral flattening, decreasing thus the risk of adjacent vertebral fractures and the progression of pathological kyphotization of the spine. The literature lacks well-defined flattening and kyphotic values for vertebral bodies which would justify their reduction. Yet, some authors point to the flattening of about one third of the vertebral body height, vertebral kyphoses equal to or greater than 15° and/or Beck sagittal indices equal to or lower than 0.7.9,11,24,28,35 It is increasingly considered that the reconstruction of the anterior column, particularly the vertebral body, an important support for axial loads predominant in bipedal gait, is essential to rebuilding a spine both biomechanically and physiologically more similar to the one prior to the fracture.<sup>1,8,16</sup> Therefore, it is currently considered that reducing and stabilizing vertebral bodies with expandable intravertebral implants is indicated in compression fractures of the vertebral body, i.e., in type-A fractures in the AO Spine classification, whether traumatic, osteoporotic or tumoral.<sup>3,5,24,38,44,45</sup> Attention is drawn that there may be room for conservative treatment, especially in A1-, A2-, and A3-type fractures, particularly in cases with flattening of less than one third of the vertebral body height and vertebral kyphoses below 15° whose patients can verticalize their trunk without relevant pain.<sup>28,44</sup> However, treatment should always be analyzed on a case-by-case basis, considering that more pronounced deformities may be acceptable in cases in which life-expectancy is short and patients' reduced functionality fail to justify surgical reduction and stabilization. Despite this, it is important to verify that pain relief, standing up, gait, and remaining recovery are usually faster in patients who undergo augmentation of the vertebral body with cement ("up and go" in a few hours and unrestricted activity in 24 hours, often without any pain).44,46 Kyphoplasty and expandable intravertebral implants have also shown promising results in face of fractures subjected to conservative treatment which had symptomatically and chronically evolved to post-traumatic necrosis, often with associated flattening and kyphosis.47 Initially, expandable intravertebral implants were considered a reduction and stabilization method complementary to pedicular instrumentation. Nevertheless, several recent studies have shown that most vertebral compression fractures (type-A fractures in the AOSpine classification), i.e., those with intact posterior ligament complexes, can be effectively treated only with these intravertebral implants, which work, at the same time, as a reduction and stabilization device of the vertebral body, with no need for pedicular instrumentation if anterior stabilization is effective.8,24,25,38,40,44 This is very relevant insofar as most dorsolumbar fractures are compression ones. Thus, they are included in the indication for expandable intravertebral implants, many of which dispense pedicular screws.<sup>10</sup> We highlight below the two special situations in which compression fractures require pedicular screw instrumentation. In complete A4 burst fractures, we recommend, in addition to intravertebral implants, the application of pedicular screws above and below the fracture due to the complete separation of the vertebral body from posterior elements. The fractured vertebra can also be instrumented with short intermediate pedicular screws, as shown by Cianfoni A et al. who published a circumferential vertebral fixation technique without arthrodesis in which fenestrated intermediate screws are inserted inside the stents, working, after cement filling, as anchorage of the posterior elements to the vertebral body, stabilizing all Denis columns.<sup>48</sup> Regardless of the comminution degree of the A4 fracture, if expandable intravertebral implants support the vertebral body, pedicular instrumentation of only one level above and below the fracture is sufficient for a safe construction, consisting in a circumferential stabilization (posterior + anterior), dispensing fixation of further levels due to stable anterior support.<sup>49</sup> We also highlight the cases in which the fracture caused important segmental kyphosis. In these cases, segment reduction is impossible with only intravertebral implants in the fractured body. Thus, we initially recommend reducing segmental kyphosis by distraction and lordosis maneuvers via the pedicular instrumentation of adjacent levels, followed by applying intravertebral implants in the fractured body aiming to complement the reduction of its platforms and maintain this reduction over time. In summary, most compression vertebral fractures may dispense stabilization with pedicle screws since the immediate stabilization of the vertebral body by expansive intravertebral implants enables avoiding the need for discharge that segment with pedicle screws at adjacent levels until there is vertebra healing. The advantage of being able to dispense pedicle fixation is the maintenance of mobility of the segments adjacent to the fractured vertebra, allowing a more physiological biomechanics of the discs and the spine in general, which in theory accelerates patient rehabilitation and minimizes progression of discoarthropathies degenerative changes by compensatory hypermobility of the following unfixed levels. Moreover, it enables avoiding the risk of screw pull-out in the porotic bone and the eventual need to cement them or use expandable screws, as well as eliminating the need for a second surgery to extract the instrumentation. Intravertebral expansive implants also have place in those type B and C fractures of the AOSpine classification associated with a compression component at the vertebral body, however, in these cases it is mandatory to be associated with pedicular screws instrumentation because the posterior elements are compromised and need stabilization.7,44

Authors' algorithm for treating vertebral compression fractures

In this section, we present the algorithm followed by the authors for treatment of vertebral compression fractures, applying the referred principles of importance of anatomical reduction and the use of expansive intravertebral implants (Figures 2 and 3).

In healthy bones and AOSpine A1-type traumatic fractures with values equal to or higher than 15° kyphosis and flattening of one third of the height, or A2- and A3-type fractures, we prefer reduction and stabilization with SpineJack<sup>®</sup> implants. In these fractures, typically in younger patients, in which most of the intrasomatic bony trabeculae are still preserved, the goal is to maintain them, restore vertebral body height and the



healthy bone	A1, A2, and A3 AOSpine traumatic	Need to restore the vertebral body height — = Fracture reduction ↓ Aim to wait for fracture healing	Implant to reduce the fracture by vertical expansion, without filling spaces or creating cavities (SpineJack)
healthy bone	A4 AOSpine traumetic compression fractures (healthy but comminuted bone)	Need for connection of the fractured vertebral body to the pedicles and adjacent levels Need to reconstruct the vertebral body = Fracture reduction + Vertebral body filling Aim to wait for fracture healing (incorporation or integration of bone graft)	Pedicular instrumentation of the adjacent levels with our without intermediate instrumentation of the fracture level Implant to fill space by multidirectional expansion and creator of intrasomatic cavities to be filled with bone graft (VBS)
Fragile bone (porotic or lithic)	Osteoporotic or neoplastic pathologic compression fractures	Need to reconstruct or replace the → vertebral body = Fracture reduction + Vertebral body filling ↓ Aiming to replace the fragile vertebral body rather than waiting for fracture healing	Implant to fill space by multidirectional expansion and creator of intrasomatic cavities to be filled with bone cement (VBS)

**Figure 2.** Schematic representation of the objectives for each type of vertebral compression fracture, according to bone quality and the AOSpine classification, as well as the justification for choosing the expandable intravertebral implant to be applied and the need or not for pedicular instrumentation.

morphology of the vertebral platforms, and wait for fracture healing, thus obtaining an anatomical and biomechanical vertebra similar to the one prior to the fracture. The implants used for this purpose are SpineJack®, which by its exclusively vertical expansion, elevate the vertebral platforms without destroying many surrounding bone trabeculae (it does not occupy relevant space), then requiring only a minimal amount of bone cement to stabilize the implants. In these fractures, the objective is to wait for their bone healing in an anatomic position. The minimum amount of injected cement does not affect the bone healing process. In A1-, A2-, and A3-type fractures, we consider that direct reduction by expandable implants is sufficient to achieve anatomical restoration and fracture stabilization, except in cases of segmental kyphosis greater than 15°, which require indirect reduction by pedicular instrumentation. Due to the frequent body-pedicle dissociation of type A4 fractures, we initially perform percutaneous pedicle instrumentation at the adjacent levels above and below, then indirect reduction by distraction and lordosis maneuvers through this instrumentation, followed by further direct reduction of the vertebral body and stabilization of the restored height with VBS® implants. Thus,



**Figure 3.** Graphic algorithm of the surgical options for reducing and stabilizing each type of vertebral compression fracture according to the AOSpine classification. A1, A2, and A3 fractures according to AOSpine<sup>44</sup> — reduction and stabilization with SpineJack<sup>®</sup> expandable intravertebral implants; A4 AOSpine fractures — initial reduction with maneuvers by pedicular instrumentation, additional reduction and replacement of the vertebral body with expansive intravertebral VBS<sup>®</sup>-type implants filled with bone graft (final image in yellow/brown represents the bone graft inside the stents); Osteoporotic compression fractures – reduction and stabilization with expansive intravertebral VBS<sup>®</sup>-type implants filled with bone graft (final image in yellow/brown represents the bone graft inside the stents); Osteoporotic compression fractures – reduction and stabilization with expansive intravertebral VBS<sup>®</sup>-type implants filled with bone cement. Note the reduced depressions of the upper and lower platforms after expansion of the implants. Final image in gray represents the cement inside the stents.

in these fractures with severe destruction of the vertebral body, we subjected the fracture to both types of reduction, initially indirect (pedicular instrumentation) and then direct (expandable implant), seeking to obtain the best possible anatomical restoration. We believe intraosseous vascularization of the vertebral body to be compromised in A4-type fractures. Thus, in these fractures, bone healing is not expected, as such we immediately



move toward reconstructing/replacing the vertebral body with cylindrical implants, the stents. These make further reduction of the vertebral body through multidirectional impaction of the surrounding bone trabeculae, in particular by elevation of the central portion of the vertebral platforms, and guarantee the maintenance of this reduction as interior supports (interior sustentaculum). As we recommend for fractures with porotic bone, some authors indicate the intrasomatic application of polymethylmethacrylate cement for A4 burst fractures with healthy bone (even for young patients), arguing that fracture healing takes place even in the presence of cement, as fracture gaps between bone trabeculae and cement are filled by bone callus.<sup>2,6,24,25,35,50-52</sup> However, in view of this type of fractures in healthy bone and young ages, we prefer to fill the stents with bone graft, usually cancellous allograft granules from bone bank. We apply the graft with minimal impaction so as to not compromise bone matrix structure or nutritional diffusion until its revascularization, aiming at its colonization by osteoprogenitor cells, vascular invasion, and bone incorporation. With this filling, we intend to obtain a vertebra biomechanically similar to unfractured ones, i.e., more physiological in the distribution of loads than those filled with polymethylmethacrylate, a biologically inert cement, which makes difficult the future pedicular instrumentation of the vertebra, as well as somehow influencing its biological activity, healing, and remodeling. We consider this option important especially for active young and middle-aged individuals who would request their spine in long term, in which a more rigid vertebra, caused by intrasomatic filling with polymethylmethacrylate cement, can alter the normal balance of the rachis in terms of elasticity and segmental stiffness, which can lead to discovertebral degeneration and adjacent body fractures. Another option could be the intra-stent application of the biologically active and osteoconductive calcium phosphate cement, which is slowly reabsorbed and replaced by bone, unlike the inert polymethylmethacrylate. This biological version of a cement shows its progressive osteointegration while the structure, consistency, and height of the vertebral body, as well as the calcium phosphate cement itself, are mechanically protected by expandable intravertebral impl ants.<sup>2,3,6,24,25,35,39,45,53-56</sup> Still, we prefer for an intrasomatic filling with bone graft, aiming to provide a bone matrix capable of osteoconduction and osteoinduction, thus favoring consolidation to obtain a vertebral body whose morphology and biomechanics are similar to those pre-fracture with a metallic interior endoskeleton filled with the incorporated graft. Several studies have assessed the isolated intrasomatic application of bone graft (without intravertebral expandable implants) in fractures. However, they found a progressive flattening of these vertebrae and graft resorption, probably due to the insufficient mechanical support capacity of the isolated bone graft which suffered excessive loads compromising its integrity and incorporation.<sup>4,31,57-60</sup> Thus, we consider the application of bone graft inside the stents to be fundamental, ensuring not only the maintenance of vertebral height but also protecting the bone graft and minimizing its resorption until its incorporation, obtaining a vertebra with a metallic endoskeleton which is fully filled by bone. The limited histological evidence of cases of isolated intrasomatic application of bone graft (without intravertebral expandable implants) showed, in some patients, the absence of intrasomatic graft incorporation and microscopic findings of partial graft necrosis are frequent

even in the presence of clinical evidence and bone healing imaging. This suggests a probable excessive load on the graft to be incorporated (not protected by intravertebral implants) and a weak relation between histology and clinic. However, long-term prospective studies are needed to show the advantages of intrasomatic bone graft application, or its substitute, associated with intravertebral implants in these fractures.4,31,57-60 In our opinion, the comminution of both vertebral platforms of A4-type fractures makes in these cases the SpineJack<sup>®</sup> reduction mechanism less effective since it is based on metal lamelae applied against vertebral upper and lower platforms. If these platforms show comminuted fractures, there is an increased risk of the metallic lamelae either crossing fracture lines and entering the disc space or of them raising only one platform fragment, resulting in an incomplete reduction. In turn, an implant with greater trabecular impaction surface, such as VBS®, enables a more effective direct reduction of A4 fractures, as it impacts the bone trabeculae around them, reinforcing the bone casing of the vertebral body. On the other hand, in fractures with adjacent segmental kyphosis greater than 15°, we prefer to start by indirect reduction maneuvers via pedicular instrumentation, followed by direct reduction by intravertebral implants. If neurological deficits are present, nervous decompression, most often laminectomy, is associated with the aforementioned steps. Corpectomy and filling with massive spacers or allografts is reserved for situations requiring anterior decompression of the vertebral canal.

In turn, in fragile bone fractures, i.e., osteoporotic or neoplastic pathological fractures and traumatic fractures in porotic bone, we usually prefer VBS reduction and stabilization filled with polymethylmethacrylate cement. The rarefaction and marked destruction of intrasomatic bony trabeculae in this type of fracture entails the replacement of most of the inner empty vertebral body with another material. In these fractures, typical of an older population, immediate stabilization is sought for rapid symptomatic relief and functional recovery, rather than waiting for fracture healing or a vertebra biomechanically similar to the others. Thus, the marked bone rarefaction of the vertebral body is compensated by applying two VBS<sup>®</sup> cement-filled cylindrical implants that occupy a considerable space, to obtain a rigid and stable vertebral body. SpineJack<sup>®</sup> is mainly a reduction implant and not a space-filler. Thus, we usually do not use it in osteoporotic fractures, in which we intend to occupy and immediatly stabilize the intrasomatic space.

### CONCLUSION

Current scientific evidence points to the need for the anatomical reduction of compression vertebral body fractures, what can only be achieved in totality with the application of expansive intravertebral implants, restoring the morphology of the vertebral platforms. Percutaneous transpedicular posterior access, the ability to fracture reduction and maintenance of vertebral body height, makes these implants a very attractive option in the treatment of compression fractures of the vertebral bodies, whether of a traumatic, osteoporotic or tumoral nature. Currently, there is no scientific evidence regarding comparative studies on the preferential use of an expandable implant over another. So, for now, the decision is made based on surgeons' opinion. Large prospective studies are needed to consolidate treatment efficacy and elucidate how each expandable intravertebral implant is to be indicated.



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# HOW TO PERFORM A META-ANALYSIS: A PRACTICAL STEP-BY-STEP GUIDE USING R SOFTWARE AND RSTUDIO

## COMO REALIZAR UMA METANÁLISE: UM GUIA PRÁTICO PASSO A PASSO UTILIZANDO O SOFTWARE R E O RSTUDIO

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#### ABSTRACT

Meta-analysis is an adequate statistical technique to combine results from different studies, and its use has been growing in the medical field. Thus, not only knowing how to interpret metaanalysis, but also knowing how to perform one, is fundamental today. Therefore, the objective of this article is to present the basic concepts and serve as a guide for conducting a meta-analysis using R and RStudio software. For this, the reader has access to the basic commands in the R and RStudio software, necessary for conducting a meta-analysis. The advantage of R is that it is a free software. For a better understanding of the commands, two examples were presented in a practical way, in addition to revising some basic concepts of this statistical technique. It is assumed that the data necessary for the meta-analysis has already been collected, that is, the description of methodologies for systematic review is not a discussed subject. Finally, it is worth remembering that there are many other techniques used in meta-analyses that were not addressed in this work. However, with the two examples used, the article already enables the reader to proceed with good and robust meta-analyses. Level of Evidence V, Expert Opinion.

### Keywords: Meta-Analysis. Guideline. Software.

RESUMO

Metanálise é uma técnica estatística adequada para combinar resultados provenientes de diferentes estudos, seu uso vem crescendo e ganhando cada vez mais importância no meio médico. Assim, não apenas saber interpretar metanálise, como também saber realizar uma, mesmo que simples, é fundamental na atualidade. Portanto, o objetivo principal deste artigo é apresentar os conceitos básicos que a norteiam e servir de quia para a condução de uma metanálise utilizando os softwares R e RStudio. Para isso, através do presente artigo o leitor tem acesso aos comandos básicos existentes nos softwares R e RStudio, necessários para a condução de uma metanálise. A grande vantagem do R é o fato de ser um software livre. Para um melhor entendimento dos comandos, dois exemplos foram apresentados de forma prática, além de revisados alguns conceitos básicos dessa técnica estatística. É suposto que os dados necessários para a metanálise já foram coletados, ou seja, descrição de metodologias para revisão sistemática não é assunto discutido. Por fim, vale relembrar que existem muitas outras técnicas utilizadas em metanálises que não foram abordadas neste trabalho. Todavia, com os dois exemplos utilizados, o artigo já habilita o leitor a proceder boas e robustas metanálises. Nível de Evidência V, Opinião do Especialista.

Descritores: Metanálise. Guia. Software.

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### **INTRODUCTION**

Scientific research has been growing in all areas of knowledge, and in medicine it is no different. The same theme may be researched in several medical centers around the world. With the expansion of evidence-based medicine, the more studies on the same topic, the better the medical practices related to it.<sup>1</sup>

However, the existence of many studies on the same subject may limit the access of medical professionals to all of them, either due

to the time or fees. Studies that aggregate the results of two or more studies on the same issue, in addition to facilitating and gathering evidence, would reduce the individual errors (biases) of each study, producing a powerful synthesis on a specific topic. The tool to achieve this is meta-analysis.<sup>2</sup>

Meta-analysis uses statistical methods to summarize the results of independent studies. By combining information from all relevant studies on the same topic, a meta-analysis can estimate

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the effects of a given intervention more accurately than each study individually.  $^{\rm 3}$ 

In 1904, by arguing that studies on the preventive effect of inoculations against enteric fever were too small to allow a reliable conclusion (making the error size too great and the power of the studies too low), Karl Pearson, through correlations, combined the data from five studies, thus creating the first known meta-analysis.<sup>4</sup> But it was only in the 1970s that the term meta-analysis was first used, becoming increasingly popular since then.<sup>5</sup>

Therefore, the main objective of this article is to present the basic concepts that guide a meta-analysis and to serve as a guide for conducting a meta-analysis using the R and RStudio software.

### The data of a meta-analysis

For studies to be combined through a meta-analysis, it is necessary to define which results will be combined. We shall work with 2 examples:

As example 1, two surgical techniques seek to improve knee stability, technique A (experimental) and technique B (control). Let us say that there is a test to ascertain the stability of the knee (X test) and that if the test is positive, it means that the knee is unstable, similar to the pivot-shift test.<sup>6</sup> Assuming that three authors decided to compare the two techniques (A and B), using the stability test X before and after surgery in both techniques (Table 1).

 Table 1. Number of patients with positive X test before and after surgery of techniques A and B.

Author	PREOP – Number of patients subjected to technique A with positive X test	POSTOP – Number of patients subjected to technique A with positive X test	PREOP – Number of patients subjected to technique B with positive X test	POSTOP – Number of patients subjected to technique B with positive X test
1	18	8	21	18
2	30	10	60	31

In this example 1, we will work with discrete quantitative variables, which assume only values belonging to an enumerable set, which can assume only a countable finite or infinite number of values. Discrete variables are usually the result of counts. Examples: number of children, number of bacteria per milliliter of urine and number of cigarettes smoked per day.<sup>7</sup>

As example 2, we will work with continuous quantitative variables, which assume any value in a certain range of variation, for which fractional values make sense. They should usually be measured by means of some instrument. Examples: weight (scale), height (ruler), time (clock), blood pressure and age. Continuous variables are usually expressed in the form of an average of values followed by a measure of dispersion, typically the standard deviation.<sup>7</sup>

In example 2, we consider that there is a functional score w, such as the IKDC<sup>8</sup> in which the higher the score, the better the result and which would serve to evaluate the post-operative clinical outcome of a given surgical technique. Assuming that three authors decided to compare two techniques, A (experimental) and B (control), using the functional score W in the postoperative period of the two techniques (Table 2).

### The basics of a meta-analysis

In a meta-analysis, the results of two or more independent studies are combined. The results of medical studies can be demonstrated in numerous ways. The two most common are the results expressed by measure of association and the results expressed by mean difference.

### **Table 2.** Result of the postoperative w score of techniques A and B.

Author	Technique A – number of participants	Technique A – post op w score (Mean)	Technique A – w score (Standard deviation)	Technique B – number of participants	Technique B – post op w score (Mean)	Technique B – w score (Standard deviation)
1	18	96.30	1.80	30	90.30	3.73
2	30	86.90	9.30	60	84.30	9.80
3	42	79.20	18.80	45	76.70	17.20

Measures of association were developed with the objective of evaluating the relationship between a risk factor and its outcome. Among these measures we highlight the Relative Risk (RR) and the odds ratio (OR).<sup>7</sup> RR and OR estimate the magnitude of the association between exposure to the risk factor and the outcome, indicating how many times the occurrence of the outcome in the exposed is greater than that among the unexposed.

For example, the result of a hypothetical study showed that smokers (exposed to the risk factor: cigarette) have a 5 times greater chance (RR), that is, 400% more, of progressing to lung cancer than non-smokers (unexposed).

When there is no difference between the exposed and unexposed, we say that the RR is equal to 1. When exposure to a factor increases the chances of an event occurring, as in the example above of smokers, the RR is greater than 1. When exposure to a factor decreases the chances of an event occurring, the RR is less than 1 (however, it is not negative, that is, it varies from 0 to < 1).<sup>9</sup>

Simply put, if we have a RR > 1, the RR expresses how many times the exposure can lead to the outcome. In the smokers' example above, the RR is equal to 5. When the RR is less than 1, the relative risk reduction (RRR), also known as efficacy, can also be calculated using the following formula: RRR or Efficacy =  $(1 - RR) \times 100$ . If in a study the RR of 0.27 is found as a result, we can say that in this study the exposure to a factor decreased 73% the risk of an event occurring  $(1 - 0.27) \times 100 = 73\%^9$ 

Another way to express the results of a survey is through the mean difference (MD). In some studies, the outcome is measured through score scales such as IKDC.<sup>8</sup> These scales produce numerical scores for each patient, rather than dichotomous "yes/no" results. As we have seen above, this type of variable is called continuous, and it is common to calculate its mean in the two groups to be compared. In our example 2, to evaluate the best result technique (highest w score), A or B, it is necessary to compare the means of the w scores of the two groups throughout the study. One of the problems of this type of outcome measured by continuous variable is that, although it is possible to affirm that patients who used the A technique had a higher score in the w score, it is difficult to extract a clinical meaning from this difference. It is easier to understand a 25% increase in the return to sport using technique A than a difference of 6 points on a functional scale/score. When there is no difference between the averages of the groups, we say that the MD is equal to 0.

After obtaining the results of the studies chosen to compose the meta-analysis, the measures are aggregated based on the weighting of the results of all individual studies. This weighting is given by the sample size (number of patients) of each study, culminating in the measure of general association: the result of our meta-analysis.<sup>7,10</sup> It is worth remembering that in a meta-analysis, only equal association measures should be compared: RR with RR or OR with OR. It is not possible to compare RR of one study with MD of another study.<sup>7,10</sup>

### Confidence interval and p-value

When performing a clinical study, it is unlikely that the actual magnitude is exactly that found in the study. This happens due



to the natural occurrence of random variations inherent to the researcher and/or the research situation. That is, the relative risk value found may be, and typically is, greater or lesser than the true value. For this reason, it is essential to measure the statistical accuracy of the data, which will allow the reader to perceive the confidence of the data presented.<sup>7</sup>

The confidence interval is a range of possible values for the actual magnitude of the effect. In clinical biomedical studies, the minimum accepted confidence interval is 95%, typically expressed as 95% Cl. That is, a study with 95% Cl means that if we take a random sample and build 100 confidence intervals, 95 would contain the real parameter.<sup>11</sup> In terms of accuracy, the narrower the confidence interval, the greater the accuracy of the results. Among the factors that can increase the accuracy of the confidence interval, the sample size is inserted, that is, the larger the sample, the greater the accuracy.<sup>12</sup>

The confidence intervals present information similar to those derived from the p-value (statistical significance). If the relative risk value 1 (equal effects of the intervention and control group) is present between the lower and upper limit of the confidence interval, then the p-value will be greater than or equal to 0.05 (statistically non-significant difference). However, if the relative risk value 1 is not within the confidence interval interpolated by the lower and upper limits, then the p-value will be less than 0.05 (statistically significant difference).

### Fixed-effects models and random-effects models

In meta-analysis there are basically two types of models that can be adopted: the fixed effects model and the random effects model.<sup>2</sup> The fixed-effect model assumes that the effect of interest is the same in all studies and that the differences observed between them are due only to sampling errors, the so-called variability within the studies. In a simplified way, it is as if the methods with fixed effects considered that the variability between the studies occur only by chance and ignored the heterogeneity between them.<sup>3</sup>

Random effect models assume that the effect of interest is not the same in all studies. In this sense, they consider that the studies that are part of the meta-analysis form a random sample of a hypothetical population of studies. However, although the effects of the studies are not considered equal, they are connected through a probability distribution, usually supposed to be normal. For this reason, they create combined results with a greater confidence interval (but less precision), and thus are the most recommended models. Despite having this advantage, methods with random effects are criticized for attributing greater weight to smaller studies.<sup>3</sup>

There is no formal rule for choosing the model. Generally, when there is no important diversity or heterogeneity, studies with greater statistical power (greater population and greater intervention effect) have more "weight." In this case, the fixed-effects model is used, which assumes that all studies showed the same effect: for example, when the objective is to estimate a treatment effect for a specific population, not extrapolating this effect to other populations.<sup>13</sup> When there is diversity and heterogeneity among the studies, it is more recommended to use the random effects model, which distributes weight in a more uniform way, valuing the contribution of small studies. For example, when the researcher combines several studies that have the same objective, but that were not conducted in the same way. In this case, it is possible to extrapolate the effects to other populations, which makes for a more comprehensive analysis.<sup>13</sup>

### Heterogeneity

In a meta-analysis, usually preceded by a systematic review, however similar the selected studies may seem, they are not considered identical as to the effect of interest. For example, in a meta-analysis of studies in which the efficacy of a new surgical procedure is being tested, there may be a difference in the selected groups: one group may be healthier in one study than in another, the age group of patients may vary from study to study, among other factors that may influence the effect of treatment.

When this difference between groups happens, that is, when the variability between the studies is not just random, we say that the studies are heterogeneous. In the presence of heterogeneity, other meta-analysis techniques (such as subgroups and meta-regression) can be considered to explain the variability between groups. However, these types of analysis require a large number of studies. When it is not possible to count on so many studies, the random effects model is recommended, as seen in the topics above.<sup>14</sup>

Thus, it is clear that in choosing between the fixed effects model and the random effects model, the evaluation of heterogeneity plays an important role in this choice. The most used ways to verify the existence of heterogeneity in meta-analyses are by Cochran's Q test and Higgins and Thompson's l<sup>2</sup> statistic.<sup>3</sup>

### Cochran's Q test

Cochran's Q test presents as null hypothesis the assertion that the studies that make up the meta-analysis are homogeneous, that is, the higher the Q value, the more heterogeneity. Thus, a problem is that the value of Q varies between 0 and infinity. A deficiency of this test is having a low power when the number of studies that make up the meta-analysis is small. On the other hand, when the number of studies is very large, it leads to false heterogeneities. In this test, a p-value is also calculated, which indicates whether or not heterogeneity is significantly different from zero.<sup>10</sup>

### The I<sup>2</sup> Statistic

The  $I^2$  statistic, proposed by Higgins and Thompson, is obtained from the Q statistic of the Cochran test and the number of studies. The  $I^2$  statistic can vary from negative values to 100%. When the value is negative it is equal to 0. The p-value of  $I^2$  is equivalent to the p-value of  $Q^2$ .

Higgins et al. suggest a scale in which an l<sup>2</sup> value closer to 0% indicates non-heterogeneity among studies, while those closer to 25% indicates low heterogeneity, those closer to 50% indicates moderate heterogeneity and those closer to 75% indicates high heterogeneity among studies.<sup>2</sup>

### **Forest plot**

The forest plot is a graphical and friendly way to demonstrate the results of a meta-analysis. It has two axes: the X and the Y (Figure 1). The Y-axis (vertical line), or central trend axis, is a line that indicates that at that point there is no difference between the interventions under study, that is, Relative Risk equal to 1 or Mean Difference equal to 0.



Figure 1. Axes of the forest plot.

The X-axis (horizontal line) is where the numerical dispersion of the meta-analysis results occurs. The X axis is cut in half by the Y axis and, as stated above, at this point (RR = 1 or MD = 0) there is no difference between interventions. What is to the right of this point favors an intervention and what is to the left favors another intervention. The further away from the Y-axis, the greater the effect/ strength of this intervention (Figure 2).

Each individual study that makes up the meta-analysis is represented by three structures: a solid geometric shape (typically a square), a horizontal line, and a small vertical line in the center of the square (Figure 3).

The vertical line corresponds to the individual result of each study. If it is to the left of the Y axis, the result indicates a tendency of an intervention; if it is to the right of Y, it indicates a tendency for the other intervention; if it is in the center of Y, it indicates no difference between the two interventions under study (Figure 3).

The geometric shape (square) has its area as an estimate of the size of the individual effect of the study. That is, the larger the square, the greater the relative weight of the study in the meta-analysis (Figure 3).

The horizontal line corresponds to the individual confidence interval of each study. If the entire line is to the left of the Y-axis, the result indicates that there is a statistically significant trend of an intervention (p < 0.05); if the entire line is to the right of Y, it indicates that there is a statistically significant trend for the other intervention (p < 0.05); if the line crosses or even "touches" the Y axis, it indicates that there is no statistically significant difference between the two interventions under study (p > 0.05) (Figure 3).

The diamond (rhombus), which appears below the studies, synthesizes the combined effect of all the studies that make up the meta-analysis. That is, the Diamond is the meta-analysis "in itself." The center of the Diamond corresponds to the result of the meta-analysis, and its location (to the left or right of the Y-axis) defines which intervention has the most "advantage." The Diamond width corresponds to the confidence interval of the meta-analysis. If any part of the Diamond of the meta-analysis crosses or even "touches" the Y-axis, it indicates that there is no statistically significant difference between the two interventions under study (p > 0.05) (Figure 3).



Figure 2. Forest plot intervention trends.





### Meta-analysis in R

R is a free programmable statistical software, with a focus on data analysis. It consists of a platform on which the so-called "packages" (similar to applications) can be installed to perform certain functions. There are thousands of packages with different functions implemented, not to mention the user collaborations that the software receives. This guide will use the *metapackage* ("application"), which is sufficient for a good and simple meta-analysis.

#### Installing the R

The first step is to access the page www.r-project.org and in the left menu, under download, choose the alternative "CRAN." Now choose any of the CRAN *mirrors*, preferably one from Brazil (ex: http://cran.fiocruz.br/). This will redirect to one of the software's download pages. In "Download and Install R," choose the desired platform (Linux, Mac, Windows), download the installer (Latest release) and run it.

R is not software with a user-friendly interface. Some basic operations can be laborious. Thus, our second step is to install another software: RStudio. RStudio provides a good interface for importing and viewing files, installing packages, and exporting charts. In a simplistic analogous way, it is as if the R software is a kind of "Command Prompt" and RStudio is a kind of "Windows system." To download R Studio, go to the following page: http://www.rstudio. com/products/rstudio/download/ and under "Installers for ALL Platforms" choose the most appropriate platform (Windows, Mac or Linux) and run the installation. RStudio is not required to be installed, but as stated above it greatly optimizes time during a meta-analysis. There are *free* and paid versions, and the *free* version is enough for the basics we are proposing.

As stated above, the package we will use in our meta-analysis is the "meta." To install meta (Figure 4), open RStudio (remember to install R before), (A) click Packages; (B) click Install; (C) The box for installation will open and then type the name meta. Click install and after installing, make sure that the meta package is enabled, that is, with the "check" in the box next to its name. Installing the package is only necessary once, but whenever you restart RStudio, you must enable the package by checking this option in the box (Figure 5).





File	s Plots Packages	Help Viewer		-
0	nstall 🜘 Update		C,	
	Name	Description	Version	
	datasets	The R Datasets Package	4.0.3	
	foreign	Read Data Stored by 'Minitab', 'S', 'SAS', 'SPSS', 'Stata', 'Systat', 'Weka', 'dBase',	0.8-80	۲
✓	graphics	The R Graphics Package	4.0.3	
1	grDevices	The R Graphics Devices and Support for Colours and Fonts	4.0.3	
	grid	The Grid Graphics Package	4.0.3	
	KernSmooth	Functions for Kernel Smoothing Supporting Wand & Jones (1995)	2.23-17	۲
	lattice	Trellis Graphics for R	0.20-41	
	lme4	Linear Mixed-Effects Models using 'Eigen' and S4	1.1-26	
	MASS	Support Functions and Datasets for Venables and Ripley's MASS	7.3-53	۲
6	Matrix	Sparse and Dense Matrix Classes and Methods	1.2-18	•
	meta	General Package for Meta-Analysis	4.16-2	•
	metafor	Meta-Analysis Package for R	2.4-0	
	memods	Formal Methods and Classes	4.0.3	
	mgcv	Mixed GAM Computation Vehicle with Automatic Smoothness Estimation	1.8-33	۲
	minqa	Derivative-free optimization algorithms by quadratic approximation	1.2.4	٠
	nime	Linear and Nonlinear Mixed Effects Models	3.1-149	•
	nloptr	R Interface to NLopt	1.2.2.2	•
	nnet	Feed–Forward Neural Networks and Multinomial Log– Linear Models	7.3-14	۲
	parallel	Support for Parallel computation in R	4.0.3	

Figure 5. Enabling meta.

Building a database of example 1

The simplest way to create a database for analysis in R is to create a table in Microsoft Excel, Numbers (macOS), or another spreadsheet editor.

In example 1, knee stability is assessed with the Pre- and Postoperative X-test of 2 surgical techniques, A and B.

Thus, the database of example 1 will consist of a table with five columns, necessarily in this sequence (Figure 4):

Column 1: name of the studies: in this case, 3 studies;

Column 2: number of events in the experimental/treatment group (evtto – Number of patients subjected to technique A with a

positive X test POSTOP): in this case, 8, 10 and 12 patients, respectively in the 3 studies;

Column 3: total sample of the experimental/treatment group (ntto – Number of patients subjected to technique A with a positive X test PREOP): in this case, 18, 30 and 42 patients, respectively in the 3 studies;

Column 4: number of events in the control group (evcont – Number of patients subjected to technique B with a positive X test POSTOP): in this case, 18, 31 and 20 patients, respectively in the 3 studies;

Column 5: total sample of the control group (ncont – Number of patients subjected to technique B with a positive X test PREOP): in this case, 21, 60 and 45 patients, respectively in the 3 studies.

The first line defines the name of the five variables (study, evtto, ntto, evcont and ncont). The name is indifferent; however, special characters (such as diacritics or cedillas) should not be used and, if possible, everything should be lowercase (Figure 6).

When saving the database, it must be saved in the format "CSV" (variables separated by a comma). For example 1 we will name the file "testex.csv" (Figure 7).

We then have the database of example 1 ready to be imported by RStudio. Now we will open RStudio and in the menu we will go to File, Import dataset, From Text (base)... Select the testex.csv file. Make sure the parameters are the same as in Figure 8 and click the import button. The *Name* field is equivalent to the name of the variable that will be assigned within the R with the database data, in this case, "testex." Leave the Heading option checked as Yes so that the first row of the worksheet matches the name of the database columns.

Now the R imported the database within the variable "testex." Type testex in the RStudio console and hit "enter/return" to see the assigned value inside this variable (Figure 9). Now we have our example 1 database imported into RStudio, ready for analysis.



	А	В	С	D	E
1	estudo	evtto	ntto	evcont	ncont
2	autor 1	8	18	18	21
3	autor 2	10	30	31	60
4	autor 3	12	42	20	45

**Figure 6.** Example 1 database worksheet (x-test). Note that in relation to Table 1, columns B and C are inverted, as well as D and E. This is due to the meta package requiring the study event to come first (in this case the number of patients with a positive x test POSTOP) and then the total sample (number of patients subjected to the surgical technique – positive PREOP).



Figure 7. Exporting spreadsheet to CSV. A: Excel; B:Numbers.



<pre>&gt; View(testex)</pre>										
> test	ex									
est	Jdo	evtto	ntto	evcont	ncont					
1 auto	r 1	8	18	18	21					
2 auto	r 2	10	30	31	60					
3 auto	r 3	12	42	20	45					
>										
Figure 9. Data	base (	of example	1 (testex) i	in RStudio.						

Meta-analyzing Example 1 – Test X

Once the database is imported, we will proceed with the metaanalysis itself. We will use the *meta* package to run these analyses (remember to enable it, with the "check" in the box next to the name).

To perform the meta-analysis of example 1, which uses discrete quantitative variables and categorical outcome (instability improves or not with the procedure) we will use the "*metabin*" command.

We will create a variable for the metabin command of our example 1 meta-analysis, the testex. We will call it "metanalisetestex." Thus, the command line will be:

metanalisetestex = metabin (evtto, ntto, evcont, ncont, study, data = testex)

Type the line above and hit "enter/return." Remember that the names testex (database created from example 1) and metanalisetestex (variable created for the metabin command) are chosen by the author of the review, and can be any name; however, they are easy to remember and do not contain special characters.

Apparently, nothing happened, but RStudio saved the meta-analysis result within the metanalisetestex variable. By typing metanalisetestex into the console and enter/return, the software will show us the results (Figure 10).

As such, we have the results of the meta-analysis. Didactically, we can divide the results into four parts (Figure 11).

In the first part (Figure 11), we have each of the individual studies, with their relative risk (RR), confidence interval (95%CI) and weight

Console ~/ 🖈	
<pre>&gt; metanalisetestex = metabin (evtto, ntto, evcont, ncont, estudo, data=testex) &gt; metanalisetestex</pre>	
RR 95%-CI %W(fixed) %W(random)	
autor 1 0.5185 [0.3006: 0.8944] 29.4 35.4	
autor 2 0.6452 [0.3677; 1.1319] 36.5 33.3	
autor 3 0.6429 [0.3603; 1.1471] 34.1 31.4	
Number of studies combined: k = 3	
RR 95%-CI z p-value	
Fixed effect model 0.6072 [0.4371; 0.8434] -2.98 0.0029 Random effects model 0.5965 [0.4313; 0.8250] -3.12 0.0018	
Quantifying heterogeneity: tau^2 = 0; tau = 0; I^2 = 0.0% [0.0%; 48.5%]; H = 1.00 [1.00; 1.39]	
Test of heterogeneity: Q d.f. p-value	
0.40 2 0.8170	
Details on meta-analytical method: - Mantel-Haenszel method	
- DerSimonian-Laird estimator for tau^Z	
- Mantel-Haenszel estimator used in calculation of Q and tau^2 (like RevMan 5) >	

**Figure 10.** Results of the example 1 meta-analysis (x-test for stability of 2 surgical techniques).



**Figure 11.** Four parts of the result of the example 1 meta-analysis (test x). 1: studies that make up the meta-analysis; 2: summary measure (the "result" itself) of the meta-analysis; 3: measures of heterogeneity of the meta-analysis; 4: tests used in the meta-analysis.

(%W) in the analyses by both the fixed effects model and the random effects model. In our example, three studies were combined (k = 3). In the second part (Figure 11), we have the summary measure of the meta-analysis, that is, the "result itself." This part shows the relative risk (RR), the confidence interval (95% -CI) and the z-value (statistical test of the significance of the global effect, that is, a mathematical measure equivalent to the location and width of the diamond in the forest plot) for the fixed and random effects model, with their respective p-values (remembering that this p-value is what describes whether or not the study was statistically significant, with p < 0.05).

In the third part (Figure 11), we have measures of heterogeneity of the meta-analysis. The tau-squared (tau<sup>2</sup>) and tau reflect the variability between studies in the meta-analysis of random effects, that is, the closer to zero the lower the variability between studies (this estimate is always calculated when the random effects model is used and its value does not have much interpretation applied). The  $I^2$  statistic ( $I^2$ ), followed by its standard deviation, as already mentioned, is an excellent indicator of heterogeneity. Similar to the I<sup>2</sup> statistic, the h (H) statistic and its standard deviation measure the heterogeneity of the studies, and when H is close to 1 we have evidence of homogeneity between the studies. Finally, in the third part, the value of the Q test (already mentioned above) is presented with its p-value (not to be confused with the p-value of the second part) and the degrees of freedom (d.f.), which is the number of studies minus 1 (k-1), which helps in the calculation of the I<sup>2</sup> statistic. Finally, in the fourth part (Figure 11), it is detailed which tests were used in the meta-analysis in question.

To create the forest plot of the meta-analysis, the forest command is used. By typing forest (meta-analysis name), RStudio will create a forest plot of the meta-analysis. In this case type in the console: forest (metanalisetestex)

If you want to omit the result/diamond of the fixed model from the forest plot (Figure 12), set the comb.fixed argument to false by typing the following command line in the console:

forest (metanalisetestex, comb.fixed = FALSE)

metanalisetestex in example 1. RStudio provides numerous ways to edit the forest plot. It is only necessary that, inside the parentheses, after the name of the variable that we attribute to our meta-analysis. a "comma" (,) is placed and the argument corresponding to what we want to edit in the forest plot. We emphasize that numerous edits can be made to the same forest plot, just follow the sequence "comma" (,) and the argument. For example, if we want the forest plot of example 1 (testex) to omit the diamond of the fixed-effect model result and the diamond of the random-effect model to be blue in color, my command will be:

forest(metanalisetestex, comb.fixed = FALSE, col.diamond = "blue") In Table 3, there are some useful commands to edit the forest plot (commands are in English):

Table 3. Commands for editing the forest plot in RStudio. Follow the sequence: forest (meta-analysis name, command 1, command 2, command 3. .... command n).

Command	Function
test.overall = TRUE	Displays the p-value (which determines the statistical significance of the study) and the Z-value ("diamond width calculation") in the fixed and random models
comb.fixed = FALSE	Omit in the chart the result/diamond of the fixed model
comb.random = FALSE	Omit the result/diamond from the random model in the graph
col.diamond = "blue"	Changes the color of the diamond (defaults to gray). Place the desired color in English between the "quotation marks." In the example it is blue.
lab.e = "Medication A"	Rename the experimental groups of the studies (the default is Experimental). Place the desired name in quotation marks. In the example it is Medication A.
lab.c = "Medication B"	Change the name given to the control groups of the studies (the default is Control). Place the desired name in quotation marks. In the example it is Medication B.
xlab = "Favors A – Favors B"	Places a text below the X-axis (horizontal). Place the desired name in quotation marks. In the example it is Favors A – Favors B

Study	Experin Events	nental Total	Co Events	ontrol Total	Risk Ratio	RR	95%-CI We	ight
autor 1	8	18	18	21		0.52	[0.30; 0.89] 35	.4%
autor 2	10	30	31	60		0.65	[0.37; 1.13] 33	.3%
autor 3	12	42	20	45		0.64	[0.36; 1.15] 31	.4%
Random effects model	- 0 0	90		126		0.60	[0.43; 0.82] 100	.0%
Heterogeneity: $I^{-} = 0\%$ , $\tau^{-}$	= 0, <i>p</i> = 0	.82			0.5 1 2			

Figure 12. Forest plot of the meta-analysis of example 1 in the random effect model (x-test for stability of 2 surgical techniques, A and B).

The conclusion of the meta-analysis data from example 1 is that the risk is lower than the occurrence of persistence of instability (positive x test) in the Experimental group (technique A), RR = 0.5965 ("rounded" to 0.60 in the forest plot) (Figure 13). We can say that the use of technique A reduced the incidence of instability measured by the x test in the postoperative period by close to 40% (1-RR), compared to technique B [Relative Risk (RR) of 0.5965; confidence interval at the 95% level (95% Cl) between 0.4313 and 0.8250; and p-value of 0.0018 (in the random effect model). The I<sup>2</sup> statistic indicates non-heterogeneity between studies ( $l^2 = 0.0\%$ , with a heterogeneity test p-value of 0.8170).

### Basic forest plot editing

As we have seen, to create a forest plot in RStudio just type in the forest command line and between the parentheses put the name of the variable that we assign to our meta-analysis, in the case



Figure 13. Forest plot of the meta-analysis of example 1 in the random effect model demonstrating advantage for technique A, with RR of 0.6 (x-test for stability of 2 surgical techniques, A and B).

Building a database of example 1

In example 2, three authors compared two surgical techniques, A (experimental) and B (control), using the functional w score in the postoperative period in both techniques, in which the higher the score, the better the result.

Thus, the database of example 1 will consist of a table with five columns, necessarily in this sequence (Figure 4):

Column 1: name of the studies: in this case, 3 studies;

Column 2: total sample of the experimental/treatment group (ne – Number of patients subjected to technique A): in this case, 18, 30 and 42 patients, respectively in the 3 studies;

Column 3: continuous quantitative variable of the event in the experimental/treatment group (me – Mean of the w score in the POSTOP period of patients subjected to technique A): in this case, 96.30; 86.90 and 79.20, respectively in the 3 studies;

Column 4: standard deviation of the continuous quantitative variable of the event in the experimental/treatment group (SDE – Standard deviation of the w score in the POSTOP period of patients subjected to technique A): in this case,  $\pm$  1.80;  $\pm$  9.30 and  $\pm$  18.80, respectively in the 3 studies;

Column 5: total sample of the control group (nc – Number of patients subjected to technique B): in this case, 30, 60 and 45 patients, respectively in the 3 studies;

Column 6: continuous quantitative variable of the event in the control group (mc – Mean w score in the POSTOP of patients subjected to technique B): in this case, 90.30; 84.30 and 76.70, respectively in the 3 studies;

Column 7: standard deviation of the continuous quantitative variable of the event in the control group (sdc – Standard deviation of the w score in the POSTOP of patients subjected to technique B): in this case,  $\pm$  3.73;  $\pm$  9.80 and  $\pm$  17.20, respectively in the 3 studies;

The first line defines the name of the seven variables (study, ne, me, sde, nc, mc and sdc). The name is indifferent; however, special characters (such as diacritics or cedillas) should not be used and, if possible, everything should be lowercase (Figure 14).

When saving the database, it must be saved in the "CSV" format (as seen above). For example 2 we will name the file "scorew. csv." Now we will open RStudio and in the menu we will go to File, Import dataset, From Text (base)... Select the scorew.csv file. Make sure the parameters are the same as in Figure 8 and click the import button. The *Name* field is equivalent to the name of the variable that will be assigned within the R with the database data, in this case, "scorew." Leave the Heading option checked as Yes so that the first row of the worksheet matches the name of the database columns.

Type scorew in the RStudio console and hit "enter/return" to see the assigned value inside this variable (Figure 16). Now we have our example 2 database imported into RStudio, ready for analysis.

	А	В	С	D	E	F	G
1	estudo	ne	me	sde	nc	mc	sdc
2	autor 1	18	96,3	1,8	30	90,3	3,73
3	autor 2	30	86,9	9,3	60	84,3	9,8
4	autor 3	42	79,2	18,8	45	76,7	17,2

**Figure 14.** Example 2 database worksheet (w score). The first line presents the names of the seven variables. study: names of the studies involved; ne: number of patients subjected to technique A; me: mean score W in the POST-OP of patients subjected to technique A; sde: standard deviation of score W in the POST-OP of patients subjected to technique B; mc: mean score W in the POST-OP of patients subjected to technique B; mc: mean score W in the POST-OP of patients subjected to technique B; sdc: standard deviation of score W in the POST-OP of patients subjected to technique B; sdc: standard deviation of score W in the POST-OP of patients subjected to technique B. Remember to remove the  $\pm$  sign of standard deviations.



Figure 15. Importing the CSV scorew file into RStudio.

>	View(scorew)												
>	score	V											
	estud	do	ne	me	sde	nc	mc	sdc					
1	autor	1	18	96.3	1.8	30	90.3	3.73					
2	autor	2	30	86.9	9.3	60	84.3	9.80					
3	autor	3	42	79.2	18.8	45	76.7	17.20					
>													

Figure 16. Database of example 2 (scorew) in RStudio.

Meta-analyzing Example 2 – w score

To perform the meta-analysis of example 2, we will use the "*metacont*" command of the *meta* package (remember to enable it, with the "check" in the box next to the name).

We will create a variable for the metacont command of our meta-analysis of example 2, the scorew. We will call it "metanalisescorew." Thus, the command line will be:

metanalisescorew = metacont (ne, me, sde, nc, mc, sdc, study, data = scorew)

Type the line above and hit enter/return and RStudio will save the result of the meta-analysis inside the metanalisescorew variable. By typing metanalisescorew into the console and enter/return, the software will show us the results (Figure 17).

Thus we have the results of the meta-analysis of example 2, the w score. As we saw with example 1, we can divide the results of example 2 into four parts: 1. Studies that make up the meta-analysis; 2. Summary measure (the "result" itself) of the meta-analysis; 3. Measures of heterogeneity of the meta-analysis; and 4. Tests used in the meta-analysis. However, in example 2, because continuous quantitative variables are used, the result is not expressed as relative risk (as in example 1) but as mean difference (MD). That is, author 1 demonstrated a mean of 6 more "points" in the w score when using the A technique in relation to B; author 2 demonstrated a mean of 2.6 more "points" in the w score when using the A technique in relation to B; and author 3 demonstrated a mean of 2.5 more "points" in the w score when using the A technique in relation to B. By typing forest (meta-analysis name), RStudio will create a forest plot of the meta-analysis. In this case type in the console: forest (metanalisescorew)



<pre>&gt; metanalisescorew = metacont (ne, me, sde, nc, mc, sdc, estudo, data=scorew) &gt; metanalisescorew</pre>
MD 95%-CI %W(fixed) %W(random)
autor 1 6.0000 [4.4274; 7.5726] 84.3 65.8
autor 2 2.6000 [-1.5502; 6.7502] 12.1 25.0
autor 3 2.5000 [-5.0882; 10.0882] 3.6 9.3
Number of studies combined: $k = 3$
MD 95%-CI z p-value
Eixed effect model $5,4619$ [4,0182: 6,9056] 7,42 < 0,0001
Random effects model 4 8266 [2 3891: 7 2640] 3 88 0 0001
Quantifying heterogeneity: tau^2 = 1.7081 [0.0000; >100.0000]; tau = 1.3069 [0.0000; >10.0000] I^2 = 30.1% [0.0%; 92.7%]; H = 1.20 [1.00; 3.71]
Test of beteresensity,
lest of heterogeneity:
2.86 2 0.2391
Details on meta-analytical method: - Inverse variance method - DerSimonian-Laird estimator for tau^2 - Jackson method for confidence interval of tau^2 and tau
>
Figure 17. Results of the meta-analysis of example 2 (functionality w

Figure 17. Results of the meta-analysis of example 2 (functionality w score of two surgical techniques).

If you want to omit the fixed model result from the graph, set the *comb.fixed* argument to false by typing the following command line in the console:

forest (metanalisescorew, comb.fixed = FALSE)

The conclusion of the meta-analysis data from example 2 is that the experimental group (subjected to technique A) presented on average 4.8266 more "points" in the w score (MD, random effect model) in relation to the control group (subjected to technique B), MD = 4.8266 ("rounded" to 4.83 in the forest plot) (Figure 18). It is worth highlighting that in this example, what is to the right of the Y-axis is advantageous for technique A. We can say that the use of technique A has a better clinical result, measured by the w score in the postoperative period, compared to technique B [Mean Difference (MD) of 4.8266; confidence interval at the 95% level (95% CI) between 2.3891 and 7.2640; and p-value of 0.0001 (in the random effect model)]. The I<sup>2</sup> statistic indicates non-heterogeneity between studies (I<sup>2</sup> = 0.0%, with a heterogeneity test p-value of 0.8170).

### CONCLUSIONS

Through this article, the reader has access to the basic commands existing in the R and RStudio software, necessary for conducting a meta-analysis. The great advantage of R is the fact that it is a free software. For a better understanding of the commands, two examples were presented in a practical way, in addition to reviewing some basic concepts of this statistical technique. It is assumed that the data necessary for meta-analysis have already been collected, that is, description of methodologies for systematic review is not the discussed subject. Finally, it is worth remembering that there are many other techniques used in meta-analysis that were not addressed in this work. However, with the two examples used, the article already enables the reader to perform good and robust meta-analyses.

Study	Total	Expe Mean	rimental SD	Total	Mean	Control SD		Mea	n Diffe	rence	MD	95%-CI	Weight
autor 1 autor 2 autor 3	18 30 42	96.30 86.90 79.20	1.8000 9.3000 18.8000	30 60 45	90.30 84.30 76.70	3.7300 9.8000 17.2000			+		6.00 2.60 2.50	[ 4.43; 7.57] [-1.55; 6.75] [-5.09; 10.09]	65.8% 25.0% 9.3%
<b>Random effects model</b> Heterogeneity: $I^2 = 30\%$ , $\tau^2$	<b>90</b> <sup>2</sup> = 1.70	81, p =	0.24	135		-1	10	-5	0	5	<b>4.83</b>	[ 2.39; 7.26]	100.0%

Figure 18. Forest plot of the meta-analysis of example 2 in the random effect model (functionality w score of two surgical techniques).

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