

Comparison of deltoid ligament repair and syndesmotic fixation in malleolar fractures

Comparaç o do reparo do ligamento deltoide e fixa o da sindesmose em fraturas maleolares

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ABSTRACT

Objective: The aims were to assess residual deltoid ligament instability after lateral malleolus osteosynthesis and to compare the outcomes of deltoid suture and syndesmotic fixation.

Methods: A consecutive series of 65 eligible patients with a displaced or minimally displaced fibula fracture identified on a stress radiograph were prospectively enrolled. The patients were randomized into two groups, namely, group I (deltoid repair) and group II (syndesmotic fixation). We assessed the competence of the deltoid ligament intraoperatively using a manual stress test. Only the patients with residual medial instability (Medial Clear Space greater than 4 mm) were randomly assigned for treatment by deltoid ligament repair with anchor or syndesmotic fixation.

Results: Of all the patients, 60 (92.2%) had positive preoperative manual stress test results. After fracture osteosynthesis, the test results were still positive in 13 (21.6%) patients, 8 (13.3%) patients from group I, both superficial and deep layers sutured with a bone anchor, and 5 patients (8.3%) from group II, stabilized with a syndesmotic 4-cortical screw. At the end of the surgery, a new manual stress test was performed, which proved stability in all the patients. The average follow-up period was 23.5 months. In groups I and II, the AOFAS scores were 95 and 93, the EQ-5D measures were 0.758 and 0.743, the visual analogue scale (VAS) scores were 16.7 and 19.2, and the Medial Clear Space values were 2.7 ± 0.5 mm and 2.6 ± 0.4 mm, respectively, without statistically significant differences.

Conclusion: In 21.6% of cases, residual medial instability persisted after osteosynthesis of the lateral malleolus. The deltoid repair and syndesmotic fixation groups showed similar functional and radiological outcomes.

Level of Evidence II; Therapeutic Studies; Prospective Comparative Study.

Keywords: Ankle fracture; Ankle joint; Joint instability; Radiography; Outcome assessment (health care); Comparative study.

RESUMO

Objetivo: Avaliar a instabilidade residual do ligamento deltoide ap s osteoss ntese do mal olo lateral e comparar os resultados de sutura deltoide e fixa o da sindesmose.

M todos: Foram selecionados prospectivamente uma s rie de 65 pacientes consecutivos eleg veis com fratura minimamente ou n o desviada da f bula identificada atrav s da radiografia sob estresse. Os pacientes foram divididos em dois grupos, grupo I (reparo do deltoide) e grupo II (fixa o da sindesmose). Avaliamos a fun o do ligamento deltoide no intraoperat rio usando o teste de estresse manual. Somente aqueles com instabilidade residual medial (espa o livre medial maior que 4 mm) foram aleatoriamente designados para o tratamento de reparo do ligamento deltoide com fixa o por  ncora ou fixa o da sindesmose.

Resultados: Do total de pacientes, 60 (92,2%) apresentaram um resultado positivo no teste de estresse manual pr -operat rio. Ap s a osteoss ntese da fratura, o teste ainda era positivo em 13 (21,6%) casos, 8 (13,3%) do grupo I, tanto com camadas superficiais e profundas reparadas com  ncora  ssea e 5 (8,3%) do grupo II, estabilizado com parafuso transsindesmal cortical 4 mm. Ao final da cirurgia foi realizado um novo teste de estresse manual, comprovando estabilidade em todos pacientes. O per odo m dio de seguimento foi de 23,5 meses. Nos grupos I e II as pontua es do AOFAS foram 95 e 93, as medidas do EQ-5D foram de 0,758 e 0,743, as pontua es da escala visual anal gica (EVA) foram 16,7 e 19,2, e os valores do espa o livre medial foram de $2,7 \pm 0,5$ mm e $2,6 \pm 0,4$ mm, respectivamente, sem diferen a estatisticamente significante.

Work performed at the Hospital de S o Francisco Xavier, Centro Hospitalar de Lisboa Ocidental (CHLO), Lisboa, Portugal.

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Conclusão: Em 21,6% dos casos, a instabilidade residual medial persistiu após a osteossíntese do maléolo lateral. Os grupos de reparo deltoide e fixação da sindesmose apresentaram resultados funcionais e radiológicos semelhantes.

Nível de Evidência II; Estudos Terapêuticos; Estudo Comparativo Prospectivo.

Descritores: Fratura do tornozelo; Articulação do tornozelo; Instabilidade articular; Radiografia; Avaliação de resultados (cuidados de saúde); Estudo comparativo.

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INTRODUCTION

With an incidence of 168.7 annual cases per 100,000 individuals, malleolar fractures are a common diagnosis in young males as a result of sports accidents and in elderly females following a fall. The most common type of ankle fracture in all age and sex groups is a lateral malleolus fracture, representing 55% of all ankle fractures⁽¹⁾.

The congruence of ankle surfaces during loading, static ligament complexes and dynamic tendon muscle units are the main contributors to the stability of joints. The deltoid ligament (DL) is responsible for medial stabilization, limiting anterior, posterior and lateral translation of the talus. The deep layer assists in stabilizing the talus and resisting posterior translation and valgus angulation, with the prevention of lateral displacement of the talus from the medial malleolus being the most important contributor to stability⁽²⁻⁵⁾.

Identification of a DL injury in an isolated and aligned lateral malleolar fracture remains fundamental to differentiating the degree of stability of these fractures.

Recent reports suggest that DL reconstruction promotes functional recovery, relieves pain and decreases the medial clear space (MCS). Other studies have compared conservative treatment, DL repair, and surgical treatment with or without DL repair⁽⁶⁻¹¹⁾.

Even so, controversy still exists as to whether surgical repair is necessary. Many previous reports have argued that results are independent of the option chosen by the surgeon, noting that deep DL rupture is difficult to repair and that stabilization of the ankle mortise can also be achieved through classic screw fixation of the tibiofibular syndesmosis⁽¹²⁻¹⁴⁾.

In this context, the aims of the present study were to assess residual DL instability after lateral malleolus osteosynthesis with manual stress radiographs and to compare the outcomes from deltoid suture and syndesmotic fixation groups.

METHODS

Study population

This study was approved by the Research Ethics Committee.

Between February 2016 and November 2017, all patients presenting to a level-1 trauma hospital with an isolated lateral malleolar fracture were screened in the emergency room. The inclusion criteria were the presence of skeletally mature and a displaced or minimally displaced fibula fracture; patients were excluded if they had previous ankle trauma, had an isolated medial or posterior malleolar fracture, were operated on by other surgeons, had an injury that occurred more than 15 days prior, or were transferred to another hospital.

A total of 105 patients were admitted, and forty patients were excluded: twenty-six had nondisplaced fibula fracture, two were operated on by colleagues, two had an acute lesion that occurred more than 15 days prior, and ten were transferred due to insurance reasons. In total, 65 eligible patients were included in the present randomized prospective comparative study. All participants signed a written informed consent form, and the law regarding data protection was respected.

Study protocol

In this study, all patients with a nondisplaced or minimally displaced fibula fracture on standard radiographs were submitted to gravity stress radiographs for assessing the integrity of the deltoid ligament. The patient was positioned laterally on the ipsilateral side of the injured ankle. The most distal half of the leg was dependent off the end of the table, allowing the weight of the foot to create a lateral force across the ankle joint. Then, a mortise radiograph was taken based on previously reported studies^(15,16).

A widened medial clear space (MCS) greater than 4 mm was the cut-off point for the decision-making process in treating ankle fractures.

All patients with previous gravity stress radiograph positive or a lateral malleolar fracture with rotational de-

viation greater than 2 mm were indicated for surgery. The patients were randomized into two groups, group I (deltoid repair) and group II (syndesmotic fixation). The randomization was carried out using the Leon Gordis table, considering all odd numbers as belonging to group I and even numbers to group II⁽¹⁷⁾.

All the fractures were operatively treated according to Arbeitsgemeinschaft für Osteosynthesefragen-Association for the Study of Internal Fixation (AO-ASIF) principles.

The manual stress test was performed in the operating room under anesthesia, before and after malleolar osteosynthesis, with the ankle in dorsiflexion and eversion, and with lateral translation and external rotation force applied under fluoroscopy (Philips® number PT600074933). The images were recorded digitally through the IMPAX® system, and the MCS was measured in millimeters by using the same reading criteria: the distance between the medial border of the talus and the lateral border of the medial malleolus on a perpendicular line positioned 5 mm below the talar dome.

After malleolar osteosynthesis, if the manual stress test was positive, in group I, the DL was repaired with one bone anchor, placed on the anterior and distal surfaces of the medial malleolus, with n°. 2 sutures; the advancement of the deep deltoid ligament was then performed. The superficial deltoid could then be reconstructed with either another suture anchor or suture to the periosteum. If continued widening persisted, syndesmotic fixation could be added to offload the deltoid repair. In group II, the syndesmosis was fixed according to the degree of instability, in cases of diastasis associated with a high fibular fracture (Maisonneuve), a plate with two metallic, 3.5-mm, 4-cortical screws, placed parallel to and 2-4 cm proximal to the ankle joint line was used, entering from the posterolateral aspect of the distal fibula and directed 30° anterior into the tibia. When the fibula fracture was lower, trans-syndesmotic fixation with a single 3.5-mm, 4-cortical screw was used. If continued widening persisted, another syndesmotic screw was added. The manual stress test was performed on all patients at the end of surgery.

At follow-up, the pain was graded by visual analogue scale (VAS) score and expressed in numbers (0-100, where zero represented pain-free patients and 100 the highest possible pain level). The EQ-5D questionnaire (EuroQuol group 1990, registration ID L-29195) was used to measure health-related quality of life, and the American Orthopedic Foot and Ankle Society (AOFAS) ankle-hindfoot scale evaluated patient recovery. The MCS was reviewed and recor-

ded using a 15° anteroposterior X-ray image. All complications were recorded during the follow-up.

Data analysis

The Statistical Package for Social Sciences (SPSS) version 23 was used for descriptive statistical analysis. The categorical data are presented as percentages, while the continuous variables are characterized by measures of central tendency and dispersion. The chi-square test (χ^2) was used to evaluate the association between two variables, and Student's t-test or Mann-Whitney test was employed to verify the normality of the study population. To evaluate if there was a linear relationship between the two groups, the Spearman correlation coefficient was used. Statistical significance was defined at the 5% level ($p \leq 0.05$), according to international recommendations.

RESULTS

Of the 65 remaining patients (33 in group I and 32 in group II), 25 (38.5%) were male and 40 (61.5%) female; the mean age was 50.7 ± 17.5 years old (range 14-85). Thirty-one patients (47.7%) had a right-side fracture and 34 (52.3%) had a left side fracture, with 47 fractures (72.3%) due to a simple fall, 15 (23.1%) occurring during sports, and 3 (4.6%) resulting from traffic accidents (Table 1).

In addition to DL injury, syndesmotic disruption was also observed in 31 (51.7%) patients ($\chi^2 p=0.504$), which was classified as 44B in 25 (80.6%) patients and 44C in six (19.4%) patients. Of the type 44B fractures, 10 (3.2%) were Wagstaffe-Le Fort fractures, and the majority were classified as type 44B2.3 fractures ($\chi^2 p=0.149$), without differences with statistical significance between groups.

Table 1. Epidemiological study between two groups

		Group I (N=33)	Group II (N=32)	P-value χ^2
Gender	Male	14 (21.5%)	11 (17.0%)	0,505
	Female	19 (29.2%)	21 (32.3%)	
Age	Mean	51.4 ± 16.1	50 ± 19.1	0,605
Laterality	Right	20 (30.8%)	11 (16.9%)	0,034
	Left	13 (20.0%)	21 (32.3%)	
Accident	Fall	22 (33.8%)	25 (38.5%)	0,574
	Sport	9 (13.8%)	6 (9.2%)	
	Traffic	2 (3.1%)	1 (1.5)	
AO Classification	44A	2 (3.1%)	1 (1.5%)	0,225
	44B	28 (43.1%)	28 (43.1%)	
	44C	3 (4.6%)	3 (4.6%)	

Source: Prepared by the author based on the results of the research.

In the operating room, prior to surgery, the manual stress test confirmed a DL injury in 60 (92.3%) patients. After fracture osteosynthesis, the test was still positive in 13 (21.6%) cases, 8 (13.3%) from group I, with both superficial and deep layers sutured with one bone anchor - three of these patients underwent DL suture and fixation with one syndesmotic screw; and 5 (8.3%) from group II, with four fractures stabilized with one 4-cortical syndesmotic screw and the other with two screws. There were no differences with statistical significance between the groups (χ^2 $p=0.672$).

At the end of the surgery, a new manual stress test was performed, demonstrating stability in all cases (χ^2 $p=0.746$); (Figures 1 and 2). The association between

residual instability and fracture type was evaluated: in group I, three were 44B2.1, four 44B3.1 and one 44C3.1; in group II, three were 44B2.1, one 44B3.1 and one 44C1.1 (χ^2 $p=0.05$).

For groups I and II, the preoperative MCS values were 5.8 ± 2.2 mm (range 4.0-17.0) and 6.1 ± 3.0 mm (range 4.0-17.0); after osteosynthesis, the MCS values were 3.3 ± 0.8 mm (range 2.1-6.1) and 3.4 ± 0.9 mm (range 2.1-6.1), respectively. The MCS values at the final follow-up in groups I and II were 2.7 ± 0.5 mm (range 2.1-4.4; $p=0.851$) and 2.6 ± 0.4 mm (range 2.1-3.7), respectively, without differences with statistical significance, (T Student $p=0.285$); The findings of the comparative MCS analysis groups are presented in table 2.

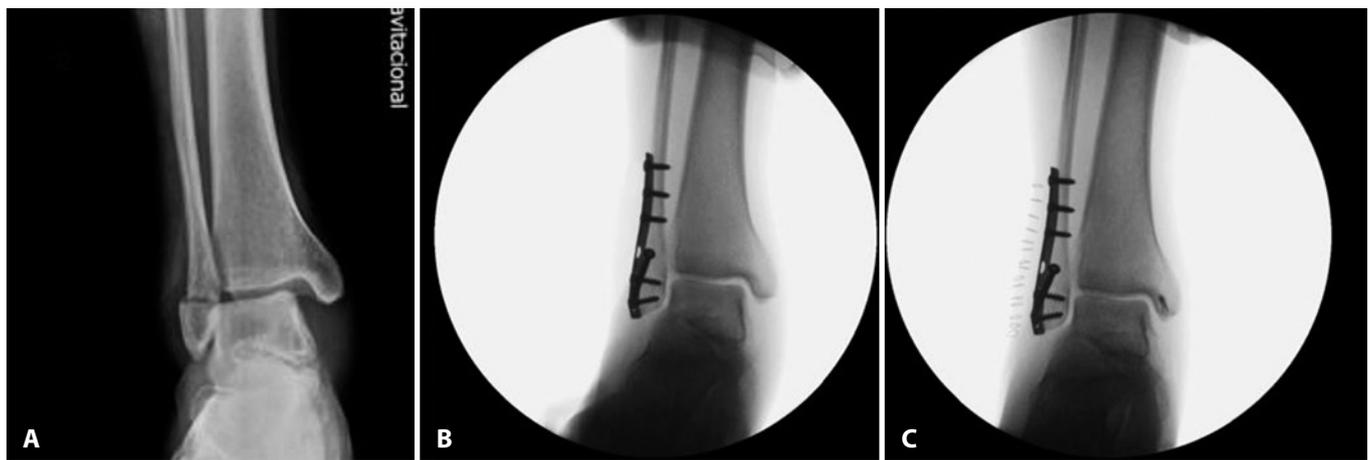


Figure 1. A) Manual stress X-ray, lateral malleolus fracture 44B3.1, medial clear space widening ≥ 5 mm. B) Residual medial instability. C) Repair with an anchor.

Source: Authors' personal archive.



Figure 2. A) Manual stress X-ray, lateral malleolus fracture 44B3.1, medial clear space widening ≥ 4 mm. B) Residual medial instability. C) Weightbearing X-ray: Final follow-up, stability with syndesmotic screw.

Source: Authors' personal archive.

Table 2. Comparison of medial clear space between two groups

Lesion		Group I				Group II			
		Stress	After	End	Follow-up	Stress	After	End	Follow-up
No instability	N (%)	3 (4.6)	25 (38.5)	33 (100)	33 (100)	2 (3.1)	27 (41.5)	32 (100)	32 (100)
	Mean	3.6±0.5	2.8±0.4	2.8±0.4	2.8±0.7	3.8±0.1	2.8±0.2	2.6±0.2	3.0±0.7
	95% CI	2.9-4.2	2.3-3.3	2.3-3.2	1.9-3.7	2.5-5.1	0.8-4.7	0.8-4.7	-3.4-9.4
Instability	N (%)	30 (46.1)	8 (12.3)	0 (0)	0 (0)	30 (46.1)	5 (7.7)	0 (0)	0 (0)
	Mean	5.8±2.2	3.3±0.8	3.1±0.5	2.7±0.5	6.1±3.0	3.4±0.9	3.1±0.6	2.6±0.4
	95% CI	5.1-6.5	3.1-3.6	2.9-3.3	2.6-2.9	4.7-7.4	3.0-3.8	2.9-3.4	2.4-2.7
P-value (T Student or Mann-Whitney)		0.000	0.051	0.114	0.851	0.004	0.198	0.363	0.285

N (%) = Total patients; Mean= Mean medial clear space (mm ± standard deviation); CI = Confidence interval; Stress= Manual stress test; after= after lateral malleolar osteosynthesis; End= Postoperative.

Source: Prepared by the author based on the results of the research.

Table 3. Clinical AOFAS evaluation between two groups

EQ-5D	Group	Mean	95% CI	Range	P-value
					(Mann-Whitney)
6 month	I	0.705±0.248	0.618-0.793	1/0.247	0.341
	II	0.660±0.235	0.566-0.755	1/0.351	
≥1 year	I	0.758±0.239	0.673-0.842	1/0.527	0.503
	II	0.743±0.245	0.644-0.841	1/0.456	

AOFAS= American Orthopaedic Foot and Ankle Society (ankle-hindfoot); CI= Confidence interval; Mean= Mean medial clear space (mm ± standard deviation); Range= maximum-minimum.

Source: Prepared by the author based on the results of the research.

Table 4. Clinical EQ-5D evaluation between two groups

VAS	Group	Mean	95% CI	Range	P-value
					(Mann-Whitney)
6 month	I	18.8±21.3	11.2-26.3	70/0	0.881
	II	18.1±21.2	9.5-26.6	60/0	
≥1 year	I	16.7±22.3	8.8-24.6	70/0	0.686
	II	19.2±22.8	10.0-28.4	70/0	

EQ-5D questionnaire; CI= Confidence interval; Mean= Mean medial clear space (mm ± standard deviation); Range= maximum-minimum.

Source: Prepared by the author based on the results of the research.

Table 5. Clinical VAS evaluation between two groups

VAS	Group	Mean	95% CI	Range	P-value
					(Mann-Whitney)
6 month	I	18.8±21.3	11.2-26.3	70/0	0.881
	II	18.1±21.2	9.5-26.6	60/0	
≥1 year	I	16.7±22.3	8.8-24.6	70/0	0.686
	II	19.2±22.8	10.0-28.4	70/0	

VAS= visual analogue scale; CI= Confidence interval; Mean= Mean medial clear space (mm ± standard deviation); Range= maximum-minimum.

Source: Prepared by the author based on the results of the research.

The average follow-up period was 23.5 months (range, 12-36). The AOFAS scores at greater than 6 and greater than 12 months after surgery were 90.5±10.0 and 95±4.9 for group I and 88.3±10.1 and 93±8.4 for group II (p=0.374 and 0.306), respectively (Table 3). The EQ-5D

scores at ≥6 and ≥12 months after surgery were 0.705±0.2 and 0.758±0.2 for group I and 0.660±0.2 and 0.743±0.2 for group II (p=0.341 and 0.503), respectively (Table 4). The VAS scores at ≥6 and ≥12 months after surgery were 18.8±21.3 and 16.7±22.3 for group I and 18.1±21.2 and 19.2±22.8 for group II (p=0.881 and 0.686), respectively (Table 5).

We recorded complications in both groups I and II: devices were removed one year after surgery due to lateral discomfort in five (7.7%) and seven (10.8%) patients, respectively. Medial calcifications occurred in three (4.6%) and one (1.5%) patients, respectively, though with no significant symptoms. Two syndesmotic screws broke in group I in two patients, one was in a 65-year-old female, classified as 44B3.1, with an MCS of 17.7 mm, occurring 6 months after the fracture, and the other in a 29-year-old male, classified as 44C3.1, with an MCS of 8.5 mm after a reduction maneuver, occurring 10 months after surgery. In group II, 11 months after surgery, an 86-year-old male patient died after suffering a myocardial infarction. The incidence rates of complications between the two groups showed no statistical significance, with Kolmogorov-Smirnov test values of 0.000 for groups I and II, with no normal distribution (p=0.263 and 0.177, respectively); therefore, the Mann-Whitney test was applied (p=0.160 and 0.310, respectively). Spearman's correlation coefficient showed evidence of a direct linear relationship between the two groups, though not a perfect relationship (r=0.323).

DISCUSSION

When a lateral malleolus fracture occurs in association with a deep layer's disruption of the deltoid ligament, it should be considered unstable and should be surgically treated to restore ankle anatomy and stability. After lateral malleolus fixation, persistence of a significantly increased

MCS, with or without syndesmosis diastasis, should raise suspicion that the integrity of the DL has been somehow compromised^(18,19). In 2018, Rigby and Scott⁽¹⁶⁾ warned that stressing the medial ankle after fracture repair was often a neglected technique. They suggested a standard open reduction and fibular internal fixation, followed by debridement and repair of the DL. However, if continued widening of the MCS persisted, the addition of a syndesmotic fixation could be an option to alleviate stress on the DL repair.

In the current study, the manual stress test results in groups I and II were still positive in 13 (21.6%) cases, sutured with bone anchor or stabilized with a syndesmotic 4-cortical screw, respectively; only three patients with severe instability underwent DL suture and fixation with syndesmotic screw, but without differences with statistical significance between groups (χ^2 $p > 0.05$).

In the follow-up, the MCS values decreased in both groups, consistent with Zhao et al.⁽¹⁰⁾, who compared the surgical outcomes of ankle fracture treatment with or without DL repair. They concluded that surgical repair of DL helps decrease the postoperative MCS and malreduction rate, especially for AO type-C ankle fractures. Gu et al.⁽⁶⁾ also evaluated MCS decrease for ankle fractures surgically treated with or without DL repair and concluded that DL reconstruction plays a positive role in the restoration of MCS, healing fractures, improving ankle function and reducing chronic pain. In 2018, Wu et al.⁽²⁰⁾ reported on 59 ankle fractures with suspected DL injury and tested the utility of the intraoperative tap test/technique for distal tibiofibular syndesmosis and DL rupture and compared the outcomes of syndesmotic fixation with DL repair including suture anchor. They concluded that the integrity of the DL has an important role not only for the syndesmotic lesion but also in preventing the widening of the MCS. Consistent with our findings, they had good functional and radiologic outcomes. However, they reported a greater malreduction rate and a greater risk of screw breakage after syndesmotic screw fixation⁽²⁰⁾; in contrast, in our study, two cases had

broken syndesmotic screws, but there were no cases of loss of reduction or poor alignment at the follow-up.

Meanwhile, in our study, the AOFAS scale improvement in the DL suture group was slightly higher, though without statistically significant differences ($p > 0.05$). Additionally, EQ-5D scores improved, though they were slightly better in group I, though again without statistically significant differences ($p > 0.05$). Moreover, the VAS scores after treatment decreased in both groups, at a lower % for group I, though also with no statistical significance differences ($p > 0.05$).

Metitiri et al.⁽²¹⁾ highlighted the high degrees of error and inaccuracy in measurements, which could be a disadvantage and limitation for the manual stress test in detecting instability. Arthroscopy has been reported for assessing DL injury and may be considered a valid alternative^(19,22,23).

The strengths of the present study include the prospective nature of the identification and assessment of our patients. The tests were performed exclusively by the first author to avoid operator bias in the analysis. The weaknesses include the relatively small sample size; additionally, the analysis of radiographs depends on the image quality and technician experience. The inclusion of fractures with different mechanisms of action is also a weakness and can be a confounding factor in the analysis. In addition, the follow-up should also be longer because the consequences of syndesmotic and/or DL instability include arthritic degeneration of the ankle joint.

Further comparative studies using a larger sample size are needed to investigate the advantages of direct repair of the DL.

CONCLUSION

In 21.6% of the cases, residual medial instability persisted after osteosynthesis of the lateral malleolus, as detected by the manual stress test. The deltoid repair and syndesmotic fixation groups showed similar functional and radiological outcomes, with no statistically significant differences.

Authors' contributions: Each author contributed individually and significantly to the development of this article: IR *(<https://orcid.org/0000-0003-2747-6060>) conceived and planned the activities that led to the study, wrote the article, participated in the review process, approved the final version; JR *(<https://orcid.org/0000-0002-0009-6802>) interpreted the results of the study, participated in the review process; PXF *(<https://orcid.org/0000-0002-6685-2367>) interpreted the results of the study, participated in the review process; RT *(<https://orcid.org/0000-0002-5739-7286>) interpreted the results of the study, participated in the review process; HR *(<https://orcid.org/0000-0002-5736-5778>) interpreted the results of the study, participated in the review process; JGC *(<https://orcid.org/0000-0002-7633-0589>) participated in the review process, approved the final version. *ORCID (Open Researcher and Contributor ID).

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