

# Superior versus anteroinferior plating for mid-shaft clavicle fractures: a randomized clinical trial

## Fracturas diafisarias de clavícula manejadas con placa superior versus anterior: ensayo clínico aleatorizado

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### Abstract

**Background:** Clavicle fractures represent 2.5-4% of all fractures observed in emergency services. 80% occurs in the middle third. Treatment by plating requires a higher level of evidence. **Objective:** To compare the functional outcomes of mid-shaft clavicle fractures managed with superior plating compared to anteroinferior plating. **Trial Design:** A randomized, double-blind, parallel, superiority clinical trial. **Patients and methods:** Patients with fractures of the clavicles AO15B1 and AO15B2 were studied. Patients were randomized to be treated with either 3.5 mm superior or anteroinferior plating. A rehabilitation program was designed for both groups. The primary outcome measure was the Disability of Arm, Shoulder, and Hand (DASH) score; secondary outcomes included pain, union rate, and complication rates. **Results:** Twenty-eight patients were studied and were eligible for analysis. Significant differences were found in the function assessed with the DASH score at 30 days for the superior plating compared with anteroinferior (43.74 vs. 29.26, respectively,  $p = 0.027$ ), 60 days (23.97 vs. 11.18,  $p = 0.021$ ), and 90 days (9.52 vs. 3.5,  $p = 0.016$ ). One loosening with superficial infection was found with superior plating. **Conclusions:** Using an anteroinferior reconstruction plate in diaphyseal fractures offers better functional results than the upper plate in patients with fractures of the middle third of the clavicle.

**Keywords:** Clavicle. Bone fractures. Surgical technique. Bone plates. Treatment outcome.

### Resumen

**Antecedentes:** Las fracturas de clavícula comprenden el 2.5-4% de todas las fracturas observadas en los servicios de emergencia. El 80% se presentan en el tercio medio. La posición de la placa como tratamiento requiere mayor nivel de evidencia. **Objetivo:** Comparar los resultados funcionales de las fracturas diafisarias de clavícula manejadas con placa superior versus placa anteroinferior. **Método:** Ensayo clínico aleatorizado, doble ciego, paralelo, de superioridad. Se estudiaron pacientes con fractura diafisaria de clavícula AO15B1 y AO15B2. Se manejaron con placa de reconstrucción de 3.5 mm colocada en forma superior o anteroinferior. Se diseñó un programa de rehabilitación para ambos grupos. El resultado primario fue medido con el cuestionario DASH y los resultados secundarios incluyeron dolor, presencia de consolidación y complicaciones. **Resultados:** Fueron elegibles para análisis 28 pacientes. Se encontraron diferencias significativas de la escala DASH a los 30 días para la maniobra superior comparada con la inferior (43.74 vs. 29.26, respectivamente;  $p = 0.027$ ), a los 60 días (23.97 vs. 11.18;  $p = 0.021$ ) y a los 90 días (9.52 vs. 3.5;  $p = 0.016$ ). **Conclusiones:** El uso de placa de reconstrucción anteroinferior en las fracturas diafisarias ofrece mejores resultados funcionales en comparación con la placa superior en pacientes con fracturas de tercio medio de clavícula.

**Palabras clave:** Clavícula. Fracturas óseas. Técnica quirúrgica. Placas óseas. Resultados de tratamiento.

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Date of reception: 08-11-2022

Date of acceptance: 13-05-2023

DOI: 10.24875/CIRU.22000562

Cir Cir. 2024;92(2):141-149

Contents available at PubMed

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## Introduction

Clavicle fractures involve approximately 2.4-4% of all body fractures and represent 44% of shoulder fractures. 80% of these fractures occur in the middle third of the clavicle<sup>1</sup>. This condition is more common in men and occurs most often between the ages of 30 and 70<sup>2</sup>. Clavicle fractures have been treated conservatively for decades, but the increase in pseudoarthrosis has forced to review other treatments<sup>3</sup>. In the '60s, percentages of 0.8-0.13% of pseudoarthrosis were described<sup>4,5</sup>. In the '90s, the frequency of pseudoarthrosis was described as around 13-15%<sup>6,7</sup>. Surgical management of displaced fractures with reconstruction plates, which have acceptable biomechanical resistance<sup>8-10</sup>, is currently encouraged. Several publications analyze the advantages of superior and anteroinferior techniques of reconstruction plating for fractures of the mid-shaft of the clavicle, with results based on fracture union and some aspects related to surgical technique<sup>11-13</sup>, without measuring clinical outcomes.

The clinical outcomes with superior and anteroinferior plating are very important for the return to daily living activities and the return to work. In countries with emerging economies, where social security services cover periods of paid incapacity, a rapid return to work without relapses or physical restrictions is a priority in terms of the effectiveness and efficiency of the treatment.

The main objective of the present study is to compare the functional outcomes of patients with mid-shaft clavicle fractures managed with 3.5 mm superior reconstruction plating compared to anteroinferior plating. Our research hypothesis is that the anteroinferior reconstruction plating has at least 10% better outcomes measured with the Disability of Arm, Shoulder, and Hand (DASH) score, pain, and complications associated compared with superior reconstruction plating in AO 15B1 and B2 mid-shaft clavicle fractures.

## Patients and methods

### *Study design and ethical approval*

Ethical approval for the study was granted by the Local Committee for Research and Research Ethics, registered number R-2017-2105-2, and ClinicalTrials.gov: NCT03533634. Ethical approval was granted for two treatment groups: superior reconstruction plating,

considered the "control" or "conventional" surgical management, and anteroinferior reconstruction plating. This is a randomized, parallel, double-blinded clinical trial in patients with AO15B1 and AO15B2 clavicle fractures in a third-level trauma and orthopedics hospital conducted between 2018 and 2020. During the study period, 327 patients were received with clavicle fractures, and 77% had fractures of 15B1 and B2 (Fig. 1). The exclusions were mainly due to the presence of obesity and/or associated comorbidities. When the calculated sample size, the effect size of our research hypothesis, and a statistical power > 0.80 were reached, the Ethics Committee was informed to conclude with recruitment. Patients who met the criteria for inclusion were extensively explained the purpose of the study and its objectives and were invited to participate. Patients had the opportunity to assimilate this information and ask questions before consenting to the trial. Patients who agreed to participate in the study signed informed consent, and their demographic data were collected. A soft sling was placed on the affected side to prevent fracture displacement. The corresponding pre-surgical protocol was carried out (complete blood count, blood chemistry test, prothrombin time, activated partial thromboplastin time test, ABO group, Rh type test, electrocardiogram, and chest X-rays).

Inclusion criteria were patients with isolated mid-shaft clavicle fractures AO15B1 and B2, in the age range of 18-60 years with a closed fracture of traumatic origin with < 7 days of evolution. Patients had to be able to consent to the trial.

Exclusion criteria included poly-trauma, patients with associated systemic diseases, patients with a previously injured shoulder, patients with a body mass index (BMI) > 35, and the inability to give consent.

The primary outcome measure was clinical assessment using the DASH scale, and secondary measures included pain, mobility, loosening of metalwork, and infection.

### *Randomization*

Once the patient met the criteria for inclusion, randomization was performed by using sealed and opaque envelopes containing a sequence of random even and odd numbers in a 1:1 ratio. Even numbers were assigned to anteroinferior management and odd numbers to superior plating. Patients were blinded to their surgical procedure. Randomization was performed

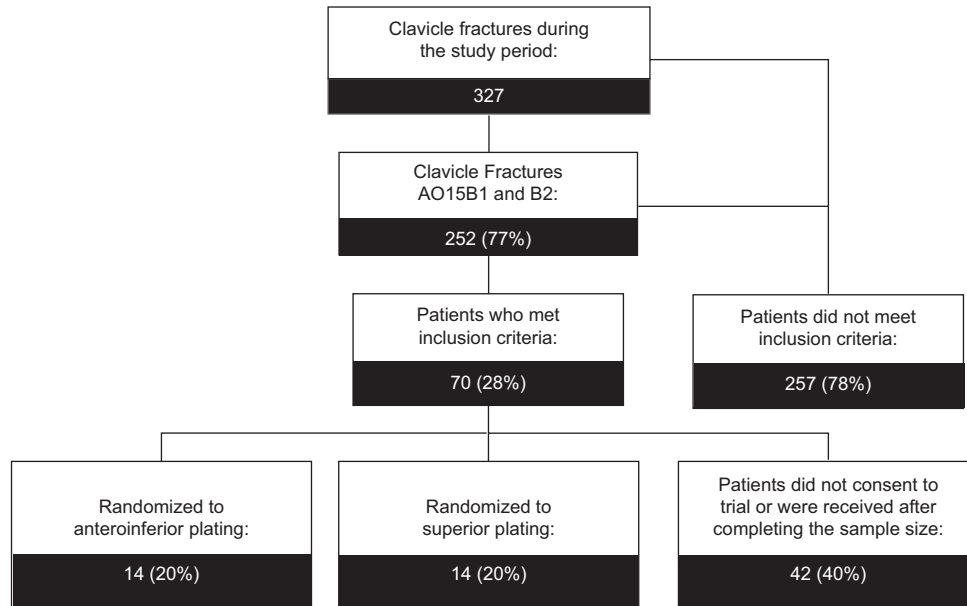


Figure 1. Flow diagram demonstrating distribution of patients in the study.

by traumatology and orthopedics residents blinded to the implementation of the present study.

Physicians who evaluated the clinical data during the follow-up were previously standardized for the application of the DASH scale and blinded to the surgical procedure performed. Statistical analysis was also performed without the information of the treatment applied.

### **Superior reconstruction plating method**

Under general anesthetic and with antibiotic prophylaxis, the patients were placed in a beach chair position. The operating side was prepped and draped, and a longitudinal incision was made on the anterior edge of the clavicle over the area of the fracture site. The morphology of the fracture was corroborated. Open reduction was performed with reduction clamps. A malleable plate was then placed on the superior surface of the clavicle, molded anatomically, and used to measure the length of the implant. Reconstruction plates with seven or more holes were selected. The goal was to achieve three bi-cortical screws in both the proximal and distal fragments as a minimum. The selected implant was molded with the malleable plate as a template, and its correct position was verified. Cortical screws (3.5 mm) were inserted, and implant stability was verified (Fig. 2). Subcutaneous tissue was closed with an absorbable suture of 2-0 and the

skin with a nylon suture of 3-0. The wound was covered with sterile gauze and a transparent adhesive dressing (Tegaderm).

### **Anteroinferior reconstruction plating method**

Under general anesthetic and with antibiotic prophylaxis, the patients were placed in a beach chair position. The operating side was prepped and draped, and a longitudinal incision was made one centimeter below the anterior edge of the clavicle over the area of the fracture site. The morphology of the fracture was corroborated. Open and direct reduction was performed with reduction clamps. A malleable plate was then placed on the anteroinferior surface of the clavicle, molded anatomically, and used to measure the length of the implant. Reconstruction plates with seven or more holes were selected. The goal was to achieve three bi-cortical screws in both the proximal and distal fragments as a minimum. The selected implant was molded with the malleable plate as a template, and its correct position was verified. Cortical screws (3.5 mm) were inserted, and implant stability was verified (Fig. 3). Subcutaneous tissue was closed with an absorbable suture of 2-0 and the skin with a nylon suture 3-0. The wound was covered with sterile gauze and a transparent adhesive dressing (Tegaderm).

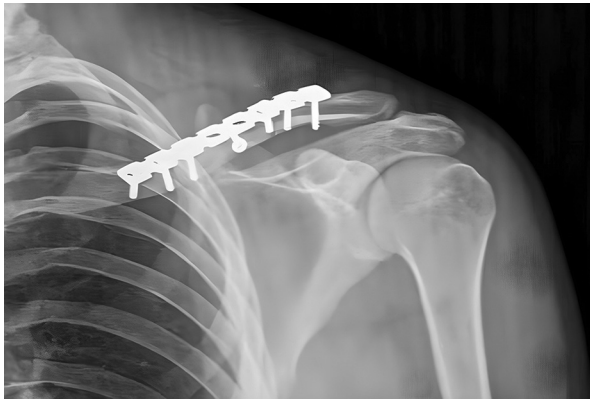


Figure 2. Post-operative X-rays with superior reconstruction plating.



Figure 3. Post-operative X rays with anteroinferior reconstruction plating.

### Post-op management

All patients received prophylactic antibiotics, proper analgesia, and a soft sling placed on the operated side. Patients were clinically reviewed within a post-operative week, surgical wound healing was evaluated, and they were referred to physiotherapy to begin with glenohumeral range of motion exercises. Patients received training to perform Codman's pendulum exercises, abduction, and flexion limited to 90 degrees from the first to the 4<sup>th</sup> week. From the fourth to the 8<sup>th</sup> week, isotonic and isometric strengthening exercises were performed. From the 6<sup>th</sup> week onwards, they were given full ranges of mobility.

### Follow-up

Patients were observed in the consultation by the attending physicians and surgical team. Anteroposterior

X-rays were performed at the second and 6<sup>th</sup> weeks, at 3 months, and at 6 months, 1 year, and 2 years, to assess consolidation. DASH score was conducted at every visit. Throughout the follow-up period, patients were monitored for wound or metalwork complications.

### Outcome scoring

Outcome scoring was performed by a trained orthopedist, unaware of the type of surgery performed. The primary evaluation was the DASH score, which evaluates the abilities to perform activities of daily living, medium- and high-effort activities, the pain, and the social impact related to the injury of the affected extremity. The DASH scale is evaluated with a score from 0 to 100 points, with 0 points being the best possible rating (absence of disability). The secondary outcomes were evaluated with a visual analog scale (VAS) (0-10), a range of active and passive mobility, and metalwork complications (X-ray interfaces, screw loosening).

### Calculation of the sample size

The sample size calculation was based on a prospective study of mid-shaft clavicle fractures. A statistical power of 0.80 and a statistical significance of 0.05 were assumed, with a standard deviation of 7.4<sup>14</sup>, to detect a difference of 10% in the primary measurement (DASH scale; 2-tail test),<sup>15</sup> estimating 14 patients per group. Demographic data, functional outcome data, and complications were analyzed using the statistical program SPSS V21.0 (Demo).

### Results

During the study period, 28 patients with clavicle fractures (AO 15B1 and 15B2) were recruited, randomly assigned to the treatment group, and distributed equally. Fourteen patients for anteroinferior plating and fourteen for superior plating. Superior plating was considered the "control" maneuver. Patient exclusions were mainly due to the presence of obesity and associated comorbidities.

We recruited 24 male and 4 female patients with a median age of 24.5 ± 9.87 years (range, 18-56). We had a male-to-female ratio of 6:1, but the gender distribution for both treatment arms had no statistically significant differences. The demographic data are shown in table 1.

**Table 1. Demographics and results of patients with clavicle fracture AO 15B1 y 15B2 treated with reconstruction plate anteroinferior vs superior (n = 28)**

Variable	Anteroinferior	Superior	p (U Mann-Whitney)
Number of patients	14	14	
Male: Female Ratio	12:2	12:2	
Mean Age (years)	27.71 ± 4.4	31.8 ± 12.1	0.310
Mean Weight (kg)	69.42 ± 11.7	74.28 ± 16.0	0.511
Mean Height (m)	1.55 ± 3.9	1.7 ± 9.4	0.085
Mean BMI	25.21 ± 3.7	25.04 ± 3.25	0.734
Mean time of fixation (days)	1.14 ± 1.35	1.07 ± 0.51	0.482
Mean DASH (90 days)	3.27 ± 5.8	9.7 ± 8.8	0.004
Mean VAS (90 days)	0.06 ± 0.24	0.45 ± 0.7	0.125
Number United	14 (100%)	14 (100%)	

BMI: body mass index kg/m<sup>2</sup>.

Most patients had no pathological personal history, and only one presented metalwork loosening and infection (Table 2). The patient was conventionally managed with reoperation, surgical debridement, and antibiotic management. The patient had radiographic evidence of union and no relapse of infection at 90 days.

The sample was evaluated by the DASH and VAS scales at 30, 60, and 90 days, 6 months, 1 year, and 2 years post-operatively. In both groups, the days of evolution (time from the fracture to surgical management) had a median of 1 day (range 0-4 days).

The homogeneity of the sample is shown in table 3.

The mean DASH score in the anteroinferior plating group was 3.5, and in the superior plating group was 9.52. The mean pain measured 0.06 in the anteroinferior plating group and 0.45 in the superior group, both measured at 90 days. Significant differences were found between groups in the DASH score at 30 days for the superior plating compared to the anteroinferior (43.74 vs. 29.26, respectively, p = 0.027; CI 95% 2.3|26.59) and the visual analog scale at 30 days for the superior plating compared to the anteroinferior (5.11 vs. 3.44, respectively, p = 0.003; CI 95% 0.39|2.94). Significant differences were also found in DASH scores at 60 and 90 days and VAS between groups at 60 days. No differences in VAS were found from day 90 between groups (Table 4).

**Table 2. Distribution of the qualitative characteristics of the sample**

(n = 28)	Frequency	%	Rate	Ratio (R/I)	95% IC
Gender					
Male	24	85.71	0.85	6.0	0.27 1.32
Female	4	14.28	0.14	0.16	
PPH					
Absent	26	92.85	0.928	13	-2.39 0.16
Endometriosis	1	3.57	0.035	0.07	
Asthma	1	3.57	0.035	0.07	
Affected side					
Right	14	50.0	0.5	1.0	0.68 31.4
Left	14	50.0	0.5	1.0	
Lateral dominancy					
Dominant	15	53.57	0.535	1.15	0.64 27.95
Non-dominant	13	46.42	0.464	0.86	
Loosening					
Absent	27	96.42	0.964	27	-3.3 0.1
Present	1	3.57	0.035	0.03	
Infection					
Absent	27	96.42	0.964	27	-3.3 0.1
Present	1	3.57	0.035	0.03	
BMI					
Normal	13	46.42	0.464	0.86	0.72 35.09
Overweight	13	46.42	0.464	0.86	
Obesity	2	7.14	0.071	0.07	

Rate per 1000 inhabitants, PPH: pathological personal history; BMI: body mass index; 95% CI: 95% confidence interval.

One patient underwent metalwork removal of the superior plating group due to soft tissue irritation. The metalwork removal was performed after 2 years of surgical management, and the patient achieved complete fracture union.

DASH scores at 30, 60, and 90 days were categorized at a 50% cut-off point to perform dichotomic adjustment and obtain the risks associated with the interventions performed. VAS was categorized into adverse pain (greater than or equal to 7) and non-adverse pain (< 7) for the creation of associated risks. The “control” was superior plating and was analyzed as the exposure factor (Table 5).

## Discussion

In the present study, mid-third clavicle fractures AO 15B1 and B2, managed with superior and anteroinferior reconstruction plating, achieved a 100% union rate with no major complications and avoidance of persistent pain, weakness, or alterations in shoulder mobility. This patient was treated at a tertiary referral



**Table 3. Homogeneity of the sample obtained from patients with clavicle fracture AO 15B1 and 15B2**

Variable	SUP plate n (%)	AINF plate n (%)	$\chi^2$	p*-value
Gender				
Male	12 (42.9)	12 (42.9)	0.00	1.00
Female	2 (7.1)	2 (7.1)		
PPH				
Absent	13 (46.4)	13 (46.4)	2.0	0.368
Endometriosis	0 (0.0)	1 (3.6)		
Asthma	1 (3.6)	0 (0.0)		
AO				
15B1.2	3 (10.7)	4 (14.3)	1.762	0.890
15B1.3	3 (10.7)	1 (3.6)		
15B2.1	3 (10.7)	4 (14.3)		
15B2.2	3 (10.7)	4 (14.3)		
15B2.3	2 (7.1)	1 (3.6)		
Lateral Dominance				
Right-handed	13 (46.4)	12 (42.9)	0.373	0.500
Left-handed	1 (3.6)	2 (7.1)		
Affected Side				
Right	10 (35.7)	4 (14.3)	5.143	0.023
Left	4 (14.3)	10 (35.7)		
Loosening	13 (46.4)			
Absent	1 (3.6)	14 (50.0)	1.307	1.000
Present		0 (0.0)		
Infection				
Absent	13 (46.4)	14 (50.0)	1.307	1.000
Present	1 (3.6)	0 (0.0)		
BMI				
Normal	7 (25.0)	6 (21.4)	2.769	0.250
Overweight	5 (17.9)	8 (28.6)		
Obesity	2 (7.1)	0 (0.0)		

SUP; Superior, AINF; Anteroinferior. \*  $\chi^2$  de Pearson o Fisher's exact test,  $\alpha = 0.05$ ; PPH: pathological personal history; BMI: body mass index.

center with a mean follow-up of 2 years. All fractures presented union 6 months after the surgical procedure. The last evaluations were performed via telephone secondary to the social distancing due to the SARS-CoV-2 pandemic.

Clavicle fractures represent 2-5% of injuries in adults and 10-15% of injuries in children. They represent 44-66% of shoulder girdle fractures. We found no bimodal distributions in the presentation of our cases and found a mean age of 27.7 years, not different from that found in the literature that marks a mean age of 29.3 years ( $p < 0.05$ ), and the presentation between men and women in our sample was 6-1, contrasting with what was previously reported of a 3:1 ratio<sup>16</sup>. In the sample obtained, weight, height, and BMI showed independence with the results of the

fracture and with the functional results. No reports in the literature make a causal relationship between these variables and the presence of fractures. However, in post-menopausal patients with decreased bone quality in a study conducted by Compston et al., the only factor that was associated with proximal humerus fractures and clavicle fractures was not the weight or BMI but height, where, for every 10 cm of height, the risk of suffering a clavicle fracture increased by 73%<sup>17</sup>. In the Gnudi et al. series, BMI was considered a risk factor for proximal humerus fractures (OR 1.077)<sup>18</sup>. Our patients managed normal or overweight BMIs, and only two were obese. We did not find a relationship between height, weight, BMI, and clavicle fractures or a relationship with the type or fracture complexity in our analysis. Our sample size was not calculated to this objective, and results finding no causality or risk should be interpreted carefully. Clavicle fractures are poorly characterized in terms of their relationship with other comorbidities. In our sample, we had two people with previous diseases that did not modify the result after surgery; one of the patients had endometriosis, and another patient was asthmatic. Our criteria excluded all chronic diseases to accomplish better control; further investigation of patients with associated comorbidities should be done.

Clavicle fractures are usually also associated with head injuries, chest injuries, or vascular injuries<sup>19</sup>. No patient in our study has these associations, so we treated isolated medium-energy mid-shaft clavicle fractures.

The complications associated with clavicular fractures range from damage to the subclavian vasculature to neuropraxia of the posterior branches of the brachial plexus, hemothorax, and pneumothorax. Complications related to the surgical procedure are the non-union, the migration of osteosynthesis material, paresthesia, and vascular or nerve lesions<sup>20</sup>. We had one patient with metalwork loosening and an infection. This patient was re-operated and managed conventionally for the infection, achieving an adequate evolution with consolidation and absence of infection at 3 months. A neat surgical technique and careful control of the post-operative period allow adequate control of complications. Although the follow-up was performed for 2 years, satisfactory results were obtained within 90 days of the post-operative period with complete recovery. Return to activities and reduction of pain were two variables found with no statistical difference after 90 days. Both surgical techniques

**Table 4. Comparative analysis between the two assigned treatment groups (superior reconstruction plate vs. anteroinferior) for patients with clavicle fracture AO 15B1 and 2 (n = 28)**

Variable	Group	Media	SD	p*-value	CI 95% of the difference	Power (1-β)
Days to fixation	Superior	0.5	0.51	0.161	-1.4 0.06	41.65
	AINF	1.21	1.31			
DASH 30	Superior	43.74	20.06	0.027	2.3 26.59	> 80
	AINF	29.26	9.16			
DASH 60	Superior	23.97	13.98	0.021	3.55 22.01	> 80
	AINF	11.18	9.3			
DASH 90	Superior	9.52	9.1	0.016	0.09 11.9	> 80
	AINF	3.5	5.7			
DASH 180	Superior	6.63	6.8	0.009	-0.29 8.72	78.26
	AINF	2.41	4.6			
DASH 360	Superior	5.11	5.58	0.016	-0.47 7.21	> 80
	AINF	1.75	4.2			
DASH 720	Superior	3.44	4.3	0.044	-0.95 5.01	> 80
	AINF	1.4	3.32			
VAS 30	Superior	5.11	1.97	0.003	0.39 2.94	> 80
	AINF	3.44	1.22			
VAS 60	Superior	2.67	1.65	0.006	0.67 2.99	> 80
	AINF	0.8357	1.30			
VAS 90	Superior	0.45	0.70	0.125	-0.02 0.79	> 80
	AINF	0.0643	0.24			
VAS 180	Superior	0.35	0.49	0.114	0.08 0.063	> 80
	AINF	0.0	0.0			
VAS 360	Superior	0.28	0.46	0.210	0.02 0.54	> 80
	AINF	0.0	0.0			
VAS 720	Superior	0.21	0.42	0.325	-0.01 0.44	> 80
	AINF	0.0	0.0			

AINF: anteroinferior; SD: standard deviation; \*U de Mann-Whitney, CI95%: Confidence interval; DASH: The disabilities of the arm, shoulder and hand score; VAS: visual analogue scale.

presented good results after 3 months of follow-up; however, the anteroinferior plating showed better functional results after 6 months of treatment. We found among our colleagues the perception that anteroinferior plating technique is more complex than superior plating. The anteroinferior technique requires adequate molding of the plate and requires a stable instrumented reduction to obtain satisfactory results. Anatomically, the anteroposterior placement of the screws decreases the likelihood of injury to the subclavian vessels below the clavicle. Which are more exposed to injury when the screws are introduced cephalocaudally. By placing the superior reconstruction plate, the plate requires a slight pre-molding, and even in clavicles with a sufficient anteroposterior length

(clavicular width, at least greater than one cm), the plate may not even require pre-molding. This makes the superior plating technique apparently simpler but more likely to cause inadvertent arterial injury, especially among surgeons with poor training placing screws in high-risk sites.

The functional outcomes assessed by the *DASH* scale showed significant differences throughout follow-up in both treatment groups. During the 1<sup>st</sup> year of the post-operative period, the anteroinferior plating technique had better functional outcomes for the performance of activities of daily living and work compared with superior plating. This result remained until the 2<sup>nd</sup> year of the post-operative period. The placement of anteroinferior pre-molded plates does not

**Table 5. Risk measures for patients with clavicle fracture AO 15B1 and 15B2, treated with open reduction and reconstruction anteroinferior plate (factor group) versus superior (control) (n = 28)**

Risk measure	DASH > 50	VAS adverse (> 7)
ER	-0.429	-0.214
CI 95%	2.44 -3.3	1.07 -1.5
ARR	0.429	0.214
CI 95%	4.74 -6.02	1.49 -1.07
NNT	2.333	4.667
CI 95%	3.29 -2.44	-1.67 -7.66
RR	0.17	0.33
CI 95%	1.58 4.77	1.46 3.53

DASH: the disabilities of the arm, shoulder and hand score; VAS: visual analogue scale; ARR: absolute risk reduction; ER: excess risk; NNT: number needed to treat; RR: relative risk; CI95%: confidence interval 95%.

interfere with the mobility of the clavicle; they are not placed subcutaneously, and the integral mobility of the shoulder girdle is not compromised<sup>21</sup>. Pain was controlled with both techniques from the 3<sup>rd</sup> month of treatment, showing no differences until the 2<sup>nd</sup> year of management, which is comparable with the literature previously analyzed. However, no study has performed long-term management up to 2 years post-operatively as the present one<sup>12,21</sup>.

In the present study, we used molded reconstruction plates due to their low cost compared to other types of blocked anatomical plates. In emerging economies, this is a factor of great importance. The use of these reconstruction plates was a feasible option with adequate results in the short, medium, and long term. The use of reconstruction plates reduces costs compared to low-contact anatomical plates.

Due to social distancing related to the SARS-CoV-2 pandemic, follow-up in the 2<sup>nd</sup> year was necessary to be carried out strictly by telephone, which constitutes a source of bias for such evaluations.

## Conclusions

Our results provide evidence that surgically managed AO 15B1 and B2 fractures present adequate clinical and functional outcomes. Anteroinferior reconstruction plating in mid-shaft clavicle fractures offers better outcome scores compared to superior plating. The pain was significantly less in anteroinferior plating in the first 3 months of follow-up. After

this period, the differences were not statistically significant (2 years of follow-up). Functional results obtained by the *DASH* scale showed better results using anteroinferior plating compared to superior plating. Both methods achieved 100% union, and only the superior plating technique presented minor complications that did not affect the functionality after 90 days of the post-operative period. We recommend the use of anteroinferior plating for clavicle mid-shaft fractures as a safer and more stable method compared to superior plating, which maintains its outcomes 2 years after surgery.

## Funding

No author has received any financial payments or other benefits from any commercial entity related to the subject of this article.

## Conflicts of interest

The authors state that there are no conflicts of interest in this manuscript.

## Ethical disclosures

**Protection of human and animal subjects.** The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

**Confidentiality of data.** The authors declare that they have followed the protocols of their work center on the publication of patient data.

**Right to privacy and informed consent.** The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

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