



# Do postoperative outcomes vary between midshaft clavicle fractures of 2, 3, or more than 3 fragments?

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## Abstract

**Objective** This study aims to assess differences in clinical and surgical outcomes associated with the surgical treatment of midshaft clavicle fractures of different complexities based on fragment number. Additionally, the investigation seeks to present the outcomes of a series of patients who underwent surgery at our institution.

**Materials and methods** A retrospective analysis was conducted on the medical records of patients aged over 18 who underwent midshaft clavicle fracture surgery at our center from November 2009 to May 2021. Patients were categorized based on the number of fracture fragments into groups of two, three, or more than three fragments. Consolidation, implant removal, complications, surgical duration, and functional outcomes (assessed through VAS, ASES, and Constant–Murley scale) were evaluated for each specific group and for the overall cohort.

**Results** In total, 260 patients were analyzed. There were no significant differences in any of the parameters between the three groups except for surgical time, which was shorter in simple fractures than in those with more than three fragments (68.2 min vs. 75.3 min;  $p = 0.01$ ). Pseudoarthrosis rate was 2.69%, implant removal rate was 9.61%, and 4.23% of patients presented with complications other than the previous ones. Functional results were excellent, with averages of 97.3 (72.7–100) for the ASES score, 97.5 (75–100) for the Constant score, and 0.6 (0–8) on the VAS.

**Conclusion** According to our results, there were no differences in postoperative results between simple and multifragmentary midshaft clavicle fractures. Patients across all groups reported satisfactory results.

**Keywords** Clavicle fracture · Clavicle osteosynthesis · Internal fixation · Multifragmentary fracture

## Introduction

Clavicle fractures comprise 2.6–4% of all fractures in adult patients [1, 2]. They are usually caused by direct trauma and are very common in contact sports, horse riding, cycling, or motocross [2, 3]. Therefore, they usually occur in young patients, although there is a bimodal distribution justified by falls from their own height in elderly patients [2, 4].

According to Allman, clavicle fractures can be classified as mid-diaphyseal, lateral, and medial [5], the first being the most frequent, accounting for 80% of all fractures of the bone [1, 2].

Traditionally, midshaft fractures were treated conservatively, mainly because of the publication of two large case series by Neer and Rowe, who reported a low incidence of pseudoarthrosis for these injuries [1, 2]. However, more recent studies have reported pseudoarthrosis rates close to 15% for conservative treatment of displaced midshaft fractures or fractures generating clavicle shortening greater than two centimeters [6, 7]. Furthermore, clavicle shortening nonunion has proved to affect scapular kinematics [8]. Given that scapular dyskinesia is associated with more pain and worst shoulder function, surgical treatment may reduce the risk of these complications [9].

Although there is abundant literature comparing the results of surgical treatment versus conservative treatment

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as well as between different types of surgical treatment, we have found little evidence linking the nature of the fracture to the expected results in the postoperative period [6, 7, 10, 11].

The objectives of this study were to evaluate the multifragmentary nature of midshaft clavicular fractures as a risk factor for poor functional results, pseudoarthrosis, and complications and to report the results and complications for a series of cases surgically treated in our center. The final purpose of this study was to test the hypothesis that an increase in the complexity of the fracture is not directly associated with worse clinical radiological results and can't thus predict postoperative results. This study was approved by the institutional ethics committee (protocol N° 6525 PRIISA 8065).

## Materials and method

### Patients

We retrospectively analyzed the medical records of a consecutive series of patients who underwent reduction and osteosynthesis of clavicle midshaft fractures between November 2009 and May 2021 at our institution (Case Series according to Oxford Center for Evidence-Based Medicine).

Surgery was indicated for patients with midshaft clavicle fractures (Allman type 1 and 15.B according to AO

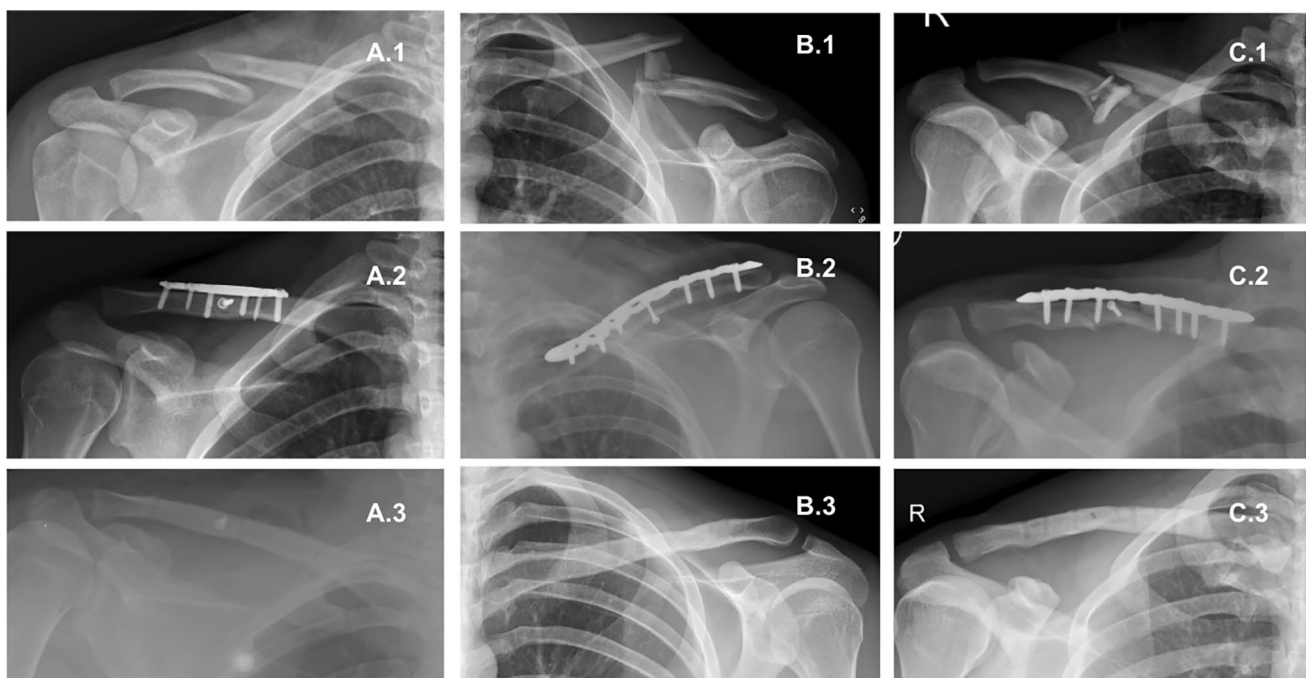
classification) with shortening greater than 20 mm, displacement greater than 100% of clavicular height, comminution or skin tenting.

Patients under 18 years of age, with fractures of the lateral or medial 1/3 of the clavicle, with other associated fractures of the shoulder girdle, associated neurovascular injuries, or clinical follow-up of less than one year were excluded from this analysis. Similarly, patients who were cognitively unable to answer questionnaires on clinical function were excluded.

Preoperative radiographs of eligible patients were analyzed and grouped according to the number of fracture fragments into two-fragment fractures, three-fragment fractures, and more than three-fragment fractures. The purpose of this study was to compare the clinical and surgical results between the three groups (Fig. 1).

### Surgical and postoperative technique

All patients received intravenous cefazolin as antibiotic prophylaxis during induction of anesthesia. Surgery was performed with the patient in a beach chair position. A longitudinal incision, along the length (long axis) of the clavicle, was made from medial to lateral and centered on the fracture site. We aimed for anatomical reduction in fragments when feasible. Interfragmentary screws (2.8 mm) were utilized to achieve compression where possible. For



**Fig. 1** Anteroposterior radiographs of the clavicle showing patient evolution since the midshaft clavicle fracture: **A** 2 fragments; **B** 3 fragments; **C** more than 3 fragments. Midshaft clavicle fracture (.1),

after osteosynthesis using an anatomic locking plate and compression screws (.2) and after hardware removal (.3):

fractures with intermediate fragments amenable to repair, the fracture was simplified by fixing the intermediate fragment with an interfragmentary compression screw alongside one of the main fragments. In cases of comminuted fractures, the fracture site was bridged. Fixation was achieved using a single superior precontoured clavicle locking plate of 3.5 mm in all instances (South American Implants or DePuy Synthes), securing it with at least three bicortical screws on each side of the fracture. When necessary, the plate was contoured using bending pliers in order to best fit the patient's anatomy. Intraoperatively, fluoroscopy was performed to confirm that the screws did not protrude from the underside of the clavicle.

In the immediate postoperative period, the patients were immobilized with a conventional sling for four weeks. During this period, they followed a self-rehabilitation protocol, during which they were encouraged to move their elbow, wrist, and hand. Subsequently, they continued with mobility exercises for the shoulder and a gradual return to normal life until three months postoperatively.

## Outcomes

Follow-up clinical imaging was performed at regular intervals for all patients. The outcomes were divided into clinical and surgical.

Regarding the clinical results, pain was evaluated using the Visual Analogue Scale (VAS), asking the patient to mark their perception of pain on the operated shoulder on a scale from 1 to 10 [12]. The ASES (American Shoulder and Elbow Surgeons) and Constant–Murley scores were used to assess functional results [12]. The ASES score combines patient-reported outcomes and physician-assessed measures to determine the overall function and pain level of the shoulder [6]. The Constant–Murley evaluates shoulder pain, activities of daily living, range of motion, and strength [7]. Both scores range from 0 to 100, with higher scores indicating better shoulder function.

Within the surgical objectives, the incidence of pseudoarthrosis, removal of the implant due to irritation or discomfort

associated with it, other complications, and surgical time were evaluated. Pseudoarthrosis was interpreted as a lack of callus between the ends of the visible fracture in at least two radiographic views and at least six months after surgery (Fig. 2). “Other complications” included all those other than pseudoarthrosis or symptoms associated with irritation or discomfort from material.

## Statistical analysis

Quantitative variables are presented as means with standard deviations, and t-tests were used to compare between the groups. Categorical variables were analyzed using the Chi-square test. Statistical significance was set at  $P < 0.05$ . STATA software was used to perform statistical analyses. Our sample size was predetermined, as it encompassed all eligible patients meeting the inclusion criteria; therefore, a power calculation was performed to ensure the robustness of the study's statistical findings. (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: Stata-Corp LLC).

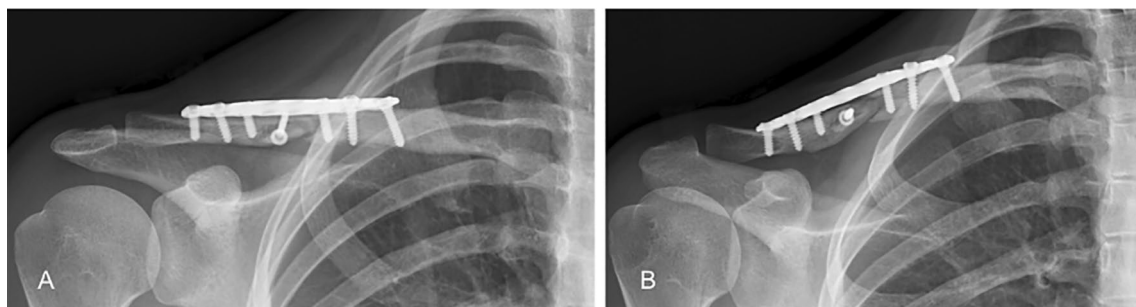
## Results

### Patient demography

During the evaluation period, 307 clavicular fractures were operated on at our center. After establishing the inclusion and exclusion criteria, 260 patients were analyzed (Fig. 3). The follow-up period was a minimum of one year. The average age was 36.3 years (18–80), and 82.6% of the patients were men. The incidence of fractures with two fragments was 33.1%, 35% with three fragments and 31.9% with more than three fragments (Table 1).

### Clinical outcomes

At the final follow-up, functional scores results were excellent for the series with an average of 97.3 (72.7–100)



**Fig. 2** Pseudoarthrosis of right clavicle fracture seven months postoperatively: **A** Anteroposterior X-ray of clavicle, **B** Zanca X-ray of clavicle

for the ASES score, 97.5 (75–100) for the Constant score, and 0.6 (0–8) for the pain VAS. Moreover, these were very similar among the three evaluated groups, showing no significant differences in terms of ASES, Constant, and pain VAS scores (Table 2).

Given the fixed sample size, encompassing all patients surgically intervened for midshaft clavicular fractures, a power calculation was performed to ascertain the study's statistical robustness. This calculation revealed a 99% power to detect an 8-point difference in the Constant Score, which is recognized as the minimum clinically important difference for midshaft fractures, between the two smaller groups (3 fragments vs. more than 3 fragments) [10]. The analysis considered the observed standard deviation (see Table 2) and employed a 5% significance level with a two-sided test.

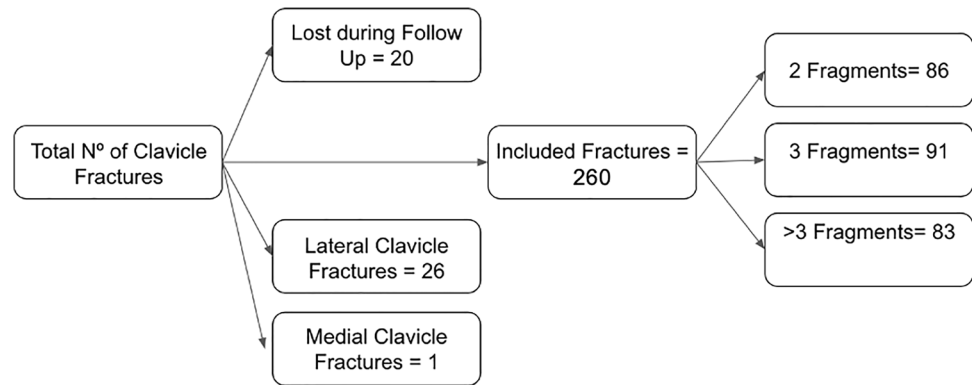
### Surgical outcomes

The absolute incidence of pseudoarthrosis at one year in our series was 2.69% (95% CI 1–5.5%;  $n = 7$ ). Three two-fragment fractures did not heal, two from the three-fragment group, and two from the more than three-fragment group (3.49%, 2.20%, and 2.41%, respectively). There was no significant difference in pseudoarthrosis between groups (Table 2).

At the end of the follow-up period, 9.61% of implants were removed. The incidence of implant removal was not significantly different between the three fracture types. The implant was removed in twenty-five patients due to discomfort or irritation, in two cases due to refractures, and in one case due to acromioclavicular dislocation (Table 2).

Eleven patients (4.23%) presented with complications other than irritation, discomfort associated with the implant, or pseudoarthrosis. Two patients presented postoperative

**Fig. 3** Flow chart: patient selection and grouping according to number of fractures



**Table 1** Demographic distribution

	2 Fragments	3 Fragments	> 3 Fragments	p
Male: female	68:20	81:10	76:7	<b>&lt; 0.001</b>
Age—mean (range)	34 (18–68)	37.4 (18–80)	37.3 (18–79)	0.16
Right: left	44:42	33:58	40:43	0.14
Dominant: non-dominant side	48:38	41:50	41:42	0.356

< 0.001 is in bold given that it is the only statistically significant result ( $p < 0.05$ )

**Table 2** Surgical and Functional Results

	All patients (N=260)	2 Fragments (N=86)	3 Fragments (N=91)	> 3 Fragments (N=83)	p Value
Pseudoarthrosis—% (n)	2.69% (7)	3.49% (3)	2.20% (2)	2.41% (2)	0.564
Implant removal—% (n)	9.61% (25)	9.30% (8)	7.59% (7)	12.04% (10)	0.8
Complications—% (n)	4.23% (11)	3.48% (3)	4.39% (4)	4.81% (4)	0.527
Surgical time in minutes mean (SD)	72.6 (21.5)	68.27 (20.7)	74.05 (22.3)	75.31 (20.6)	<b>0.012</b>
ASES—mean (SD)	96.9 (6.25)	96.76 (7.94)	97.23 (4.86)	97.79 (5.18)	0.28
Constant—mean (SD)	97.16 (5.82)	97.24 (6.73)	97.05 (5.71)	98.15 (4.61)	0.29
Pain VAS—mean (SD)	0.73 (1.03)	0.73 (1.18)	0.69 (1.01)	0.76 (0.84)	0.06

stiffness that was resolved with kinesic therapy, four patients presented hardware loosening, one patient suffered a thrombosis of the subclavian vein ipsilateral to the fracture, one presented with wound dehiscence, and other three post-surgical infections that required surgical debridement were reported. There was no statistically significant difference in the rate of complications among the three groups of patients (Table 2).

The mean surgery time was 73.1 min (30–180). Although there were no significant differences in surgical time between fractures with 2 and 3 fragments, nor between those with 3 and more than 3 fragments, surgical time was significantly shorter for 2-fragment fractures than for more complex fractures with more than 3 fragments (average 67.7 min vs. 76.1 min;  $p=0.012$ ) (Table 2).

## Discussion

The main objective of this study was to evaluate differences in the incidence of consolidation, complications, and functional results between midshaft clavicular fractures of different complexities. We did not find any significant differences in these parameters between fractures of two, three, or more than three fragments.

In line with other similar studies that cover this topic, although there were no significant differences between the groups, the results reported by the patients in both the pain VAS and ASES or the Constant–Murley scale were excellent. We report an average value of less than one for the pain VAS and greater than 97 points for the last two [2, 13–17, 21].

After the publication by COTS, reporting better functional results and a lower incidence of nonunion for midshaft clavicle fractures treated with reduction and osteosynthesis than those treated conservatively, surgery was validated as better than the alternative in displaced and shortened fractures [13]. This group reported nonunion rates of 3.22% for surgical treatment. In 2019, Woltz et. al reported a 2.4% nonunion rate after ORIF [18]. These results are similar to those obtained in our study, with a 2.69% incidence of pseudarthrosis.

Hardware removal rate after clavicle fracture plating is very variable and has been reported to be of up to 60% in some series [11–13]. However, in many cases these is due to implant withdrawal in asymptomatic patients either because of cultural reasons or patient's preferences. At the end of the follow-up period, in our population, the implant was removed due to irritation or discomfort associated with the material in 9.61% of the patients. This rate is similar to that of other publications, like the systematic review by Wijdicks et al. which reports 9% of removal [18–20]. We believe our low removal rate is related to the fact that we do

not routinely advise patients to have plate removal and that even though some patients experience hardware irritation, they choose not to undergo a second surgery to have the implants extracted.

A systematic review conducted by Amer et al. in 2020 reported an average postoperative infection rate of 5.02%, which ranged from 0 to 20.6% in different studies. COTS showed postoperative infections in 4.83% of the patients surgically treated with plates [13]. In our series, the postoperative infection rate was 1.15%, which was slightly lower than the average reported in the literature.

Regarding surgical time, a significant difference was found between fractures with two fragments (67.7 min) and those with more than three fragments (76.1 min) ( $p=0.012$ ). Although the statistical result was significant, favoring less complex fractures, it is our perception that a difference of eight minutes does not appear to be clinically important.

To the best of our knowledge, this is the only series of cases comparing functional and surgical results for fractures of different complexities in terms of the number of fragments. The results obtained were similar for all the parameters in the three groups. Although there was a difference in surgical time between simple and multifragmentary fractures, it does not seem to be clinically important. However, the general results obtained in this study were comparable to those reported in the literature, and we believe that for this reason, the confirmation of our hypothesis could be extrapolated to other populations outside our center.

Our study had multiple limitations that are inherent to its design. As this was a retrospective study, there was a selection bias in terms of the patients who underwent surgery because we do not know the reason for the surgical indication in each patient. Perhaps due to this same bias, we obtained a young (36.3 years) and predominantly male (83%) population for our study. Due to the retrospective design, certain patients could not be included due to missing postoperative data. Furthermore, having many patients providing x-rays from other institutions posed a challenge in retrospectively evaluating healing time. Our center is educational, and because of its role in training residents, many of these fractures may have been operated on by experienced or trainee surgeons interchangeably. We do not know the number of surgeries performed by either staff surgeons or residents in each group, and this may lead to overestimation of surgical time in some cases.

## Conclusion

Our single-center retrospective case study revealed that there are no differences in the incidence of pseudarthrosis, implant removal, associated complications, or functional results after reduction and osteosynthesis with anatomic locking plates

in the treatment of simple and multifragmentary clavicle midshaft fractures. Therefore, assuming the application of a correct surgical technique, number of fragments does not seem to have an impact on clinical and functional outcomes. Likewise, we observed that although the material removal rate remains high (9%), the results reported by the patients are very satisfactory.

## Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

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