



Hardware (Implant) Removal rate in Surgical Treatment of a Consecutive Series of 230 Clavicle Fractures

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Abstract

Background: Surgical treatment in clavicle fractures is becoming increasingly common. However, it is associated with complications and a significant number of reoperations, being implant removal the most frequent procedure. Our objective is to determine the implant removal rate, clinical outcomes and associated complications to surgical management in a hospital with a population subject to workers compensation.

Methods: Retrospective study of clinical and radiologic outcomes in a consecutive series of 230 clavicle fractures surgically treated with an anatomical plate between January 2013 and February 2019 at a Level V trauma center. Patients with previous ipsilateral shoulder fractures, follow-up of less than 6 months, use of complementary osteosynthesis and a history of glenohumeral infection were excluded. We studied the implant removal rate, functional outcomes, time to bone union, return to work and complications.

Results: 230 patients were analyzed with a mean age of 38.3 years (18-69 years). 91.7% of male gender and 90% located in middle third. Implant removal rate of 5.7% (13), due to symptomatic hardware (7), non-union (4), implant fracture (1) and refracture (1). Complication rate of 28.7% (78 in 66 patients), secondary to range of motion deficit (18.7%), perilesional hypoesthesia (3.9%) and chronic pain (3.5%), among others. An average time to bone union of 21 weeks and return to work of 27 weeks. Average range of motion at final follow up was 173° of anterior elevation, 169° of abduction and 81° of external rotation.

Conclusions: The implant removal rate in our series was lower than that reported in the literature, while the clinical results and complications were similar to those described in other series.

Keywords: Clavicular Fracture; Symptomatic Osteosynthesis; Plate; Non Union; Removal Rate

Abbreviation

AP: Anteroposterior

Introduction

Clavicle fractures correspond to 2-5% [1,2] of the total number of fractures in adults, with a reported incidence of 29-64 x 100.000 habitants [2]. It has a bimodal epidemiologic distribution, being

most frequent in men younger than 30 years old and in the population older than 70 years old [2]. Of the total of clavicle fractures, up to 80% [3] correspond to middle third fractures. Of these, the vast majority could be managed with a conservative treatment, with good clinical and functional outcomes. While it is true that historically these results have been based on the studies of Neer [4] and Rowe [5], where the non union rate reported is less than 1%, updated reviews of existing literature have reported a much

higher rate, reaching even 20% [2]. Therefore, a series of different criteria has been established in order to determine which patients would benefit more with surgical treatment, reducing the non-union rates.

Surgical treatment of clavicle fractures, is a procedure which is becoming more frequent nowadays, however, it has a reported complication rate of 43% [6], being implant failure, prominent osteosynthesis, non-union, infection (both superficial and deep), neurovascular injuries and rigidity, the most frequent complications. Some of these complications required reintervention, with a described rate up to 53%. The main causes were symptomatic osteosynthesis, non-union and infection. The surgical procedures associated were implant removal, re osteosynthesis or cleaning surgery and eventual change of osteosynthesis method. Accordingly, the objective of our study is to determine the hardware removal rate, complications and clinical outcomes, related to surgical treat-

ment of clavicle fractures.

Materials and Methods

Retrospective descriptive study of a series of 230 clavicle fractures, surgically treated between January of 2013 and February of 2019, in a Level V Trauma Center, by the same surgical team. This center counts with a captive population, subject to workers compensation. Data recollection was done with medical records and imagenological data, available in digital media.

Patients with a diagnosis of clavicle fracture, were treated with surgical approach if has one of this conditions in radiological study (clavicular shortening more than 1.5 cm, significant displacement more than 100% and fracture comminution) had been operated with anatomical plate (Acumed LLC, Hillsboro, OR, USA) were included in this series (Figure 1).

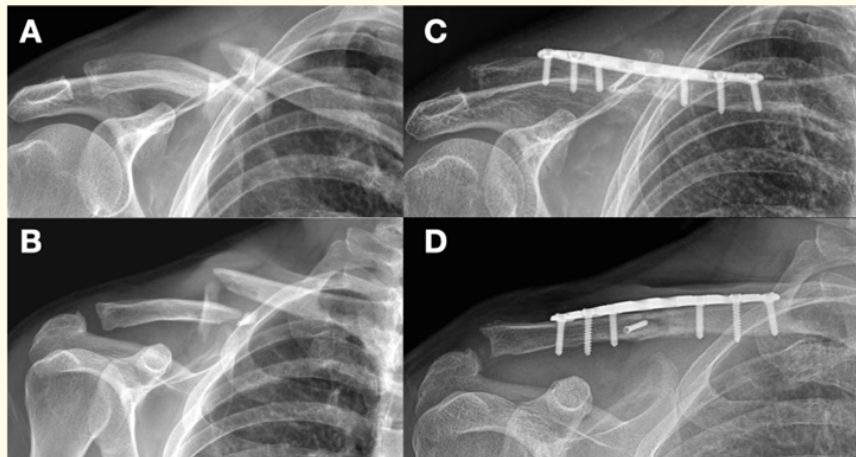


Figure 1: Shows preoperative and post-operative x rays of a shortened displaced comminuted clavicle fracture. Figure A corresponds to an AP clavicle view. Figure B corresponds to a 30-degree cephalic tilt AP clavicle view. Figures C and D show advanced signs of consolidation at four months of follow up

Patients with loss to follow up less than 6 months, previous ipsilateral shoulder fractures, history of glenohumeral infection, use of complementary osteosynthesis methods (like acromioclavicular or coracoclavicular cerclage) and patients not covered by the law of work, were excluded from this study.

The primary outcome analyzed corresponds to hardware removal rate, secondary outcomes evaluated were epidemiological

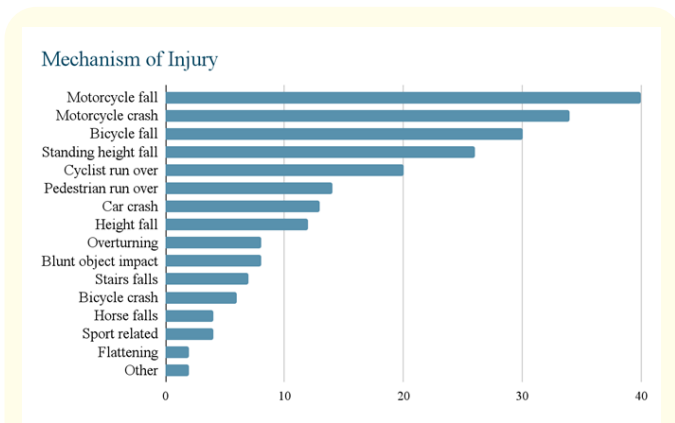
data (age, gender, laterality, fracture location, injury mechanism), functional outcomes (range of motion), time to bone union, return to work and complications.

Radiologic evaluation of fracture healing was evaluated with a series of AP clavicle radiographs, reviewed by two senior surgeons of this study. The absence of radiolucent images in the previous side of the fracture, was the main criteria used to consider a fracture has healed.

Results and Discussion

A total of 230 operated clavicle fractures were analyzed. The mean age of patients was 38.3 years (18-69 years). Minimum follow up time was 6 months, with an average time of 32 months. An estimated 91.7% were male (211) and 53% were left sided (122). In terms of localization, 90% were located in the middle third (207), 8.7% in the lateral third (20) and 1.3% in the medial third (3).

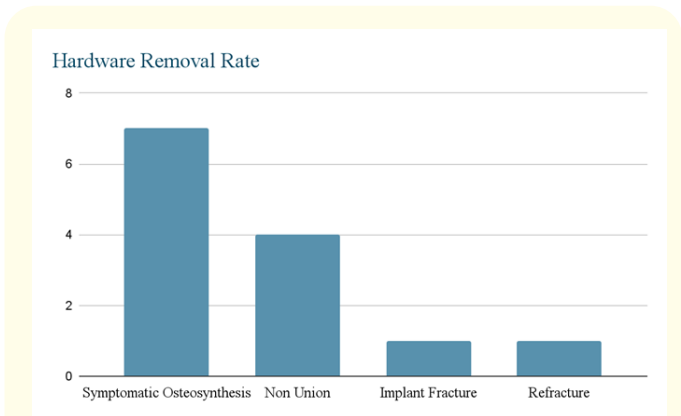
In terms of injury mechanism, the most frequent cause was motorcycle falls (17%), followed by motorcycle crashes (15%), bike falls (13%) and ground level falls (11%) (Graph 1).



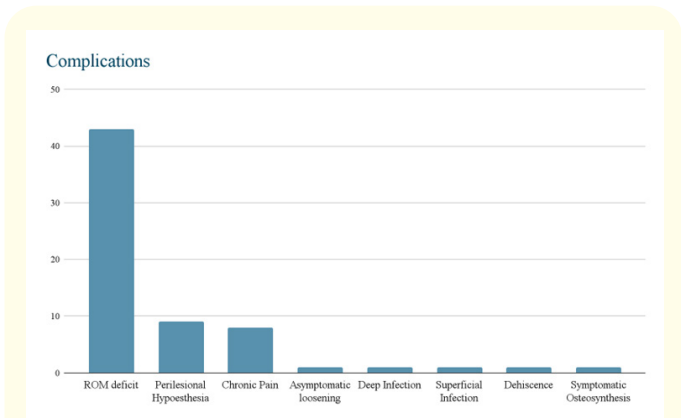
Graph 1: A total number of 230 fracture mechanisms were recorded. Motorcycle falls made up for the vast majority of accidents 17.4% (40), follow by Motorcycle crashes 14.8% (34), Bicycle fall 13% (30), Standing height fall 11.4% (26), Cyclist run over 8.8% (20), Pedestrian run over 6.1% (14), Car crash 5.6% (13), Height fall 5.3% (12), Overturning 3.5% (8), Blunt object impact 3.5% (8), Stairs fall 3% (7), Bicycle crash 2.6% (6), Horse falls 1.7% (4), Sport related 1.7% (4), Flattening 0.8% (2) and other causes 0.8% (2).

The hardware removal rate was 5.7% (13), being symptomatic osteosynthesis (7), non union (4), refracture (1) and implant breakage (1) (Graph 2).

The complications rate was 28.7% (78 complications observed in 66 patients). The most frequent causes were reduced range of motion (18.7%), perilesional hypoesthesia (3.9%) and chronic pain (3.5%) (Graph 3).



Graph 2: A total number of 13 removals were recorded. The main cause of implant removal was Symptomatic Osteosynthesis 53.8% (7), followed by Non Union 30.8% (4), Implant Fracture 7.7% (1) and Refracture 7.7% (1).

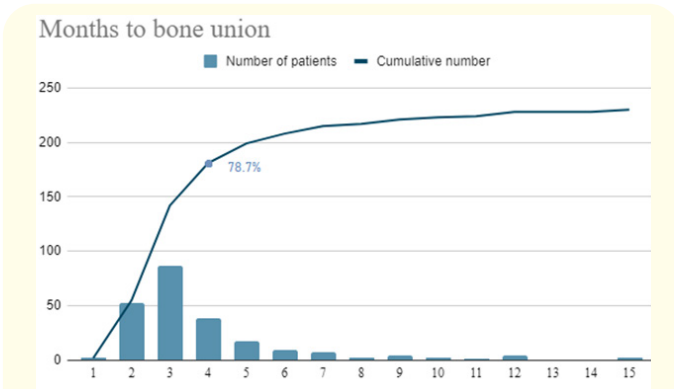


Graph 3: The total number of complications presented were 78 in 66 patients. The most common complication observed was ROM deficit 55.1% (43), followed by Perilesional hypoesthesia 11.5% (9), Chronic pain 10.3% (8), Asymptomatic loosening 1.3% (1), Deep infection 1.3% (1), Superficial infection 1.3% (1), Dehiscence 1.3% (1) and Symptomatic osteosynthesis 1.3% (1).

The union rate was 78.7% at 4 months and was determined, according to clinical and imagenological criteria (Graph 4). The mean time of return to work was 4 months (1-45 months). The mean range of motion at discharge was 173° of anterior elevation (120-180°), 169° of abduction (80-180°) and 81° of external rotation (50-87°) (Figure 2).



Figure 2: Shows a patient’s range of motion results, 4 months after surgery. Figure A shows surgical incision, following tension lines in the skin of approximately 5 cms long. Figure B shows the patient's shoulder forward active elevation; Figure C Active External Rotation in position 1; Figure E Active Internal Rotation in position 1. Figure D shows a Asymptomatic cross body test.



Graph 4: Months to bone union were calculated according to the total number of days it took for the bone to heal, rounded to the closest number of complete months (example 3.3 → 3). Data recorded shows that 78.7% (181) of patients reached bone union in 4 months or less time. 0.9% (2) reached bone union in 1 month; 23% (53) in 2 months, 37.8% (87) in 3 months, 16.9% (39) in 4 months, 7.8% (18) in 5 months, 3.9% (9) in 6 months, 3% (7) in 7 months, 0.9% (2) in 8 months, 1.8% (4) in 9 months, 0.9% (2) in 10 months, 0.4% (1) in 11 months, 1.8% (4) in 12 months, and 0.9% (2) in 15 months.

In our series, we obtained a hardware removal rate of 5.7%, with a minimum follow up of 6 months. A lesser time when compared to other series reported in the literature like Guerra., *et al.* [9] and Leroux., *et al.* [10]. The main cause of implant removal was the same as reported in most of the other studies, symptomatic osteosynthesis (7 of 13 cases). In a recent meta-analysis which reviewed 14 clinical randomized essays, Guerra., *et al.* [9] reported a removal rate of 17.16% for a total of 705 patients with middle third clavicle fractures, 616 were treated with plates and 89 were treated with intramedullary nails. The main cause reported of hardware removal was local plate irritation (76%). Leroux., *et al.* [10], reported a reoperation rate of 24.6% for a total of 1350 patients, where 76.5% were implant removals due to plate related symptoms. Last but nonetheless, Melean., *et al.* [11], in a study with a population subject to labor compensation, reports a hardware removal rate of 11.7%.

In recent times so as to reduce plate related symptoms, new lower profile implants have been chosen along with different surgical methods like the use of two smaller anatomical plates. Allis, *et al.* [12], compares in a retrospective study, 21 patients operated with a superior clavicle plate of 3.5mm versus 23 patients operated with double plates of 2.7 mm and 2.4 mm. In a 2 years follow up period, both groups obtained a bone to union rate of 100%. The double plate group showed a significant decrease in hardware removal rate (29%), while the superior clavicle plate group did not (0%).

The registered rate of non union was 1.7%, similar to what is recorded in other series. Guerra [9], shows a non union rate of 1.1% in a group of 616 patients operated with plate. Axelrod, *et al.* [13] reports similar results in a systematic revision of 17 randomized clinical essays, showing a 2.2% non union rate in a group of 1002 patients operated with plate.

Last but nonetheless, Vautrin, *et al.* [14] reported in a systematic review which includes both randomized and nonrandomized clinical essays, a non union rate of 1.1% in a group of 659 patients.

In terms of other potentially dangerous complications, we obtained a deep infection rate of 0.4%. Even though interventions were required (surgical cleaning/drainage), hardware removal was not needed. Guerra [9] reports a similar infection rate (0.8%).

Bone union was mainly accomplished in the first 2 to 4 months after surgery, achieving a bone to union rate of 78.7% at 12 weeks time. The mean return to work time was 4 months (1-45 months). In terms of clavicle fractures in people subject to labor compensation, there is little to none evidence recorded in the literature. Shields, *et al.* [15], reports a mean return to work time of 196 days, in a group of 36 patients. There were no meaningful differences between non operated and operated patients, although both groups showed an increased variability. In a prospective randomized essay, Melean, *et al.* [11] reports a mean return to work time of 2.9 months and a bone to union rate of 81% at 12 weeks time in the operated patients group.

Being part of this center, a hospital which receives multiple traumatic pathologies in a captive population subject to labor compensation, we were able to compound a series with a relevant number of patients. When compared to the available literature, according to our knowledge there is not a series with a bigger number of patients and the end of follow up than ours.

One of the limitations present in our study, is that being a retrospective analysis, it is subject to biases deep rooted in this type of study.

Of a total of 332 analyzed patients, 102 could not finish follow up due to several reasons, either due to early discharge or due to the lack of the necessary imagenological data, therefore our results may be underrated. Even so, on account of our center's characteristics, every patient who presented a surgically related complication, should re enter our center, even after being discharged and having returned to work. Hence, saying that most patients that did not finish follow up, did not have any sort of major complications, is suggestive.

On the other hand, in terms of defined secondary outcomes, we do not count with an extensive global and specific functional evaluation (only range of motion).

Conclusion

Clavicle fracture is a frequent pathology, mainly associated with high energy mechanisms. The hardware removal rate in our center is less than what is reported in the literature and the main cause of removal is due to plate related symptoms. Complications rates like non union and infection, were similar than other series. We can conclude that no surgical treatment is exempt from complications and reinterventions.

Conflict of Interest

We hereby declare that we do not have any financial interest or any conflict of interest whatsoever.

Bibliography

1. Paladini, P., *et al.* "Treatment of clavicle fractures". *Translational Medicine @ UniSa* 2 (2012): 47-58.
2. van der Meijden Olivier A., *et al.* "Treatment of clavicle fractures: current concepts review". *Journal of Shoulder and Elbow Surgery* 21.3 (2012): 423-429.
3. Wijdicks Frans-Jasper G., *et al.* "Systematic review of the complications of plate fixation of clavicle fractures". *Archives of Orthopaedic and Trauma Surgery* 132.5 (2012): 617-625.

4. NEER C S. "Nonunion of the clavicle". *Journal of the American Medical Association* 172 (1960): 1006-1011.
5. Rowe C R. "An atlas of anatomy and treatment of midclavicular fractures". *Clinical Orthopaedics and Related Research* 58 (1968): 29-42.
6. Böstman O., et al. "Complications of plate fixation in fresh displaced midclavicular fractures". *The Journal of Trauma* 43.5 (1997): 778-783.
7. Ferran Nicholas A., et al. "Locked intramedullary fixation vs plating for displaced and shortened mid-shaft clavicle fractures: a randomized clinical trial". *Journal of Shoulder and Elbow Surgery* 19.6 (2010): 783-789.
8. Canadian Orthopaedic Trauma Society. "Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial". *The Journal of Bone and Joint Surgery. American volume* 89. (2007): 1-10.
9. Guerra Enrico., et al. "Midshaft Clavicle Fractures: Surgery Provides Better Results as Compared With Nonoperative Treatment: A Meta-analysis". *The American Journal of Sports Medicine* 47.14 (2019): 3541-3551.
10. Leroux Timothy., et al. "Rate of and Risk Factors for Reoperations After Open Reduction and Internal Fixation of Midshaft Clavicle Fractures: A Population-Based Study in Ontario, Canada". *The Journal of bone and joint surgery. American volume* 96,13 (2014): 1119-1125.
11. Melean Patricio A., et al. "Surgical treatment of displaced middle-third clavicular fractures: a prospective, randomized trial in a working compensation population". *Journal of Shoulder and Elbow Surgery* 24.4 (2015): 587-592.
12. Allis J Benjamin., et al. "Dual Versus Single-Plate Fixation of Midshaft Clavicular Fractures: A Retrospective Comparative Study". *JB and JS Open Access* 5.2 (2020): e0043.
13. Axelrod Daniel E., et al. "What Is the Best Evidence for Management of Displaced Midshaft Clavicle Fractures? A Systematic Review and Network Meta-analysis of 22 Randomized Controlled Trials". *Clinical Orthopaedics and Related Research* 478.2 (2020): 392-402.
14. Vautrin M., et al. "Does candidate for plate fixation selection improve the functional outcome after midshaft clavicle fracture? A systematic review of 1348 patients". *Shoulder and Elbow* 11.1 (2019): 9-16.
15. Shields Edward., et al. "Patient factors influencing return to work and cumulative financial claims after clavicle fractures in workers' compensation cases". *Journal of Shoulder and Elbow Surgery* 25.7 (2016): 1115-1121.