

Improved outcomes with surgical management of clavicular fractures? A retrospective study of matched pairs comparing conservative and surgical approach

O. CORNU^{1,3}, M. DRISSI KAITOUNI¹, O. MIRI¹, S. MORAD², J. MANON^{1,3}, G. LAMBEAU², M. BONNELANCE¹, C. DETREMBLEUR³, D. PUTINEANU^{1,3}, K. TRIBAK¹

¹Orthopaedic and Trauma Department, Cliniques universitaires Saint-Luc, UCL, UCLouvain, Brussels, Belgium; ²Orthopaedic and Trauma Department, Centre Hospitalier Chrétien du Mont Legia, Liège, Belgium; ³NMSK Research laboratory, IREC, UCLouvain, Brussels, Belgium.

Correspondence at: Olivier Cornu, Orthopaedic and Trauma Department, level -2/pathway 650, Cliniques universitaires Saint-Luc UCL, Avenue Hippocrate 10, 1200 Brussels, Belgium, Phone +32 2 764 2560, Fax: +32 2 764 8904, Email: olivier.cornu@uclouvain.be

Clavicle fractures represent one of the most frequent type of fractures. However, there is no consensus on the treatment of these fractures and their relative indications for surgery. The purpose of this study is to determine whether surgical treatment of mid-diaphyseal clavicular fractures indeed results in fewer complications and better radiological outcomes, as current trends suggest, in comparison to conservative treatment. A retrospective multicenter study was conducted between January 2005 and April 2017, involving adult patients aged 16 to 75 years with mid-diaphyseal clavicular fractures. Out of a total of 715 clavicle fractures assessed, 220 met the inclusion criteria for this study. The research encompassed a matched-pair cohort, comparing clavicle fractures treated surgically and those managed conservatively. The consolidation rate was respectively 94.5% in the operative group, and 89.1% in the conservative group. There was no statistically significant difference in terms of consolidation (p-value: 0.219). The surgical group had an infection rate of 1.8%. Additionally, 31.8% of patients experienced hardware-related discomfort, and 43.6% required a secondary surgery to remove the plate. The results of this study reveal a similar rate of consolidation between the two treatment approaches. However, there is a noticeable but not significant difference in pseudarthrosis incidence in the conservative group, which is typically asymptomatic and does not usually require surgical intervention. On the other hand, patients who have undergone osteosynthesis often experience hardware-related discomfort and may require a subsequent procedure for hardware removal. Low profile dual plating might reduce this inconvenient.

Keywords: Clavicle fracture, conservative treatment, plate fixation, complications.

INTRODUCTION

Clavicular fractures are highly common, especially among young athletes, particularly cyclists. They represent 10% of all traumatic fractures, with an incidence rate of 29-64 per 100,000 individuals^{1,2}.

Various classification systems, such as Robinson's, Allman's, Neer, and AO trauma classification³ are used to categorize clavicular fractures. However, these classifications often lack a comprehensive description of factors such as fracture location (diaphyseal or lateral), comminution, displacement, and instability. It is important to note that mid-diaphyseal fractures make up approximately 80% of all clavicular fractures¹.

Traditionally, mid-diaphyseal clavicular fractures have been perceived as having good healing potential, which has led to their primary treatment through conservative methods. This typically involves immobi-

lization with a sling, and some practitioners may also utilize a collar and cuff, along with the use of analgesics. However, there are conditions that always require surgical intervention, including situation with a risk to the skin, a floating shoulder, vascular or nerve damage, or an open fracture.

However, in recent times, surgical approaches have become more prominent in treatment strategies. Depending on the medical centers and the surgeon's assessment, conditions that were previously considered as relative indications for surgery, such as a shortening of ≥ 2 cm, activity level, age, and dominant side, are now more frequently managed surgically⁴. Surgical intervention typically involves open reduction and internal fixation (ORIF), which can be achieved through plate and screw fixation or by using titanium elastic nails (TEN)⁵.

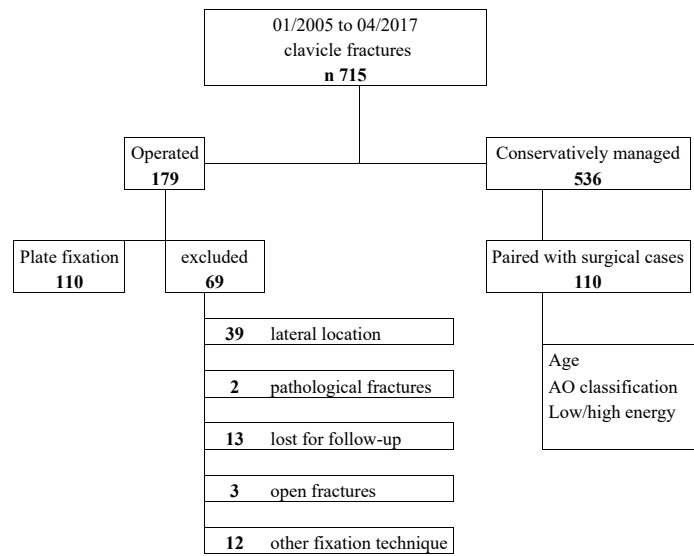


Figure 1. — Flowchart of the patients' recruitment in both hospitals and their distribution.

Despite the numerous recent studies⁵⁻⁹ on the subject, a consensus regarding the treatment of fractures and their relative indications for surgery has not been reached.

This study aims to determine whether surgical treatment of mid-diaphyseal clavicular fractures results in fewer complications and a better radiological outcome, as suggested by current trends, compared to conservative treatment.

MATERIALS AND METHODS

A retrospective, multicenter study was carried out in the Departments of Orthopedics and Traumatology at Saint-Luc University Clinics (CUSL) and the Centre Hospitalier Chrétien Liège (CHC). The study protocol received approval from the university's ethics committee (reference N° B403201523492). Medical records of adults aged 16 to 75 years, who were hospitalized between January 2005 and April 2017 with mid-diaphyseal clavicular fractures, were subject to review. A total of 715 clavicles fractures were admitted to both hospitals. Out of these, 179 underwent surgical treatment, while 536 were managed conservatively. Within the surgical group, 69 cases were excluded, primarily due to lateral fracture location (rather than mid-shaft), open fractures, or the use of an alternative fixation method other than a plate. This left 110 cases available for analysis. In the conservative group, 110 patients were selected to match the surgical group based on age, fracture classification and trauma type (Figure 1)

Initially, surgical patients were selected based on specific inclusion criteria. These criteria encompassed

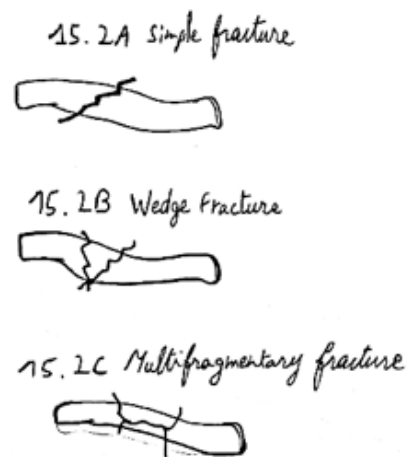


Figure 2. — AO Classification of midshaft clavicle fractures.

mid-diaphyseal non-pathological clavicle fractures with adequate follow-up, extending until complete consolidation and/or subsequent surgery related to the fracture or complications. Cases involving medial or lateral clavicular fractures, open fractures, pathological fractures, insufficient follow-up, that could have influenced the treatment of the clavicular fracture were excluded from this study. The patient were also classified in high and low energy trauma, low-energy mechanisms were defined by a fall, while high-energy mechanisms are defined by high-speed trauma or a fall from a height.

Afterward, patients treated conservatively, with matching characteristics such as age, gender, trauma mechanism, AO fracture classification¹⁰ (Figure 2), were selected to correspond to those in the surgical group.

Table I. — Baseline Characteristics of Included Patients

	Surgical group (n=110)	Conservative group (n=110)	Chi square	P-value
Sex			0.687	0.407
Men (n (%))	90 (81.8%)	84 (76.4%)		
Women (n (%))	20 (18.2%)	26 (23.6%)		
Age (years)	37.1 (14.3)	37.1 (14.4)		
Follow-up (months)	12 (8.8)	60.4 (5.5)		

Table II. — Ao classification

	Surgical group (n=110)	Conservative group (n=110)
A	46 (41.8%)	47 (42.7%)
B	52 (47.3%)	52 (47.3%)
C	12 (10.9%)	11 (10%)

Conservative treatment consisted of wearing a sling for 6 weeks, followed by gentle physiotherapy and no-weight-bearing during this period. More active physiotherapy was permitted starting from the 6th week onward. Scheduled follow-up appointments included a systematic check-up at 4 weeks, with involved X-ray assessment, followed by subsequent appointments every 2 months until consolidation. The follow-up was extended to union, or in the case of non-union, until a decision was made not to operate, considering the complication as well tolerated.

Surgical treatment involved osteosynthesis using plates and screws by an anterior approach with open reduction and plate fixation, followed by one week using an elbow sling for pain relief purposes. Follow-up appointments were initially scheduled at 3 weeks with routine X-ray monitoring. Subsequent visits occurred at 6 weeks, 3 months, 6 months or until bone consolidation was observed. During the initial 3 weeks, patients were advised to engage in gentle physiotherapy and avoid load-bearing activities.

Fracture classification involved reviewing the initial post-trauma radiograph using the AO trauma classification for clavicular fractures. Non-union was defined as the absence of radiological consolidation at six months without any progress in bone consolidation on X-rays within the prior three-month period. Patient monitoring continued until complete recovery without ongoing complications.

Fracture related infection was defined according to the definition and major criteria established by an international expert group¹¹.

Discomfort was defined as any complaint from the patient about its fracture/fracture related treatment, such as worsening of pain complaints with weather condition

Table III. — Associated trauma

Associated Trauma	Surgical group (110)	Conservative group (110)
No associated fracture	88 (80%)	86 (80%)
Rib fractures	6 (5.5%)	4 (3.6%)
Poly trauma	5 (4.5%)	4 (3.6%)
Pneumothorax	4 (3.6%)	3 (2.7%)
Coracoïde fractures	1 (0.9%)	1 (0.9%)
Humeral fractures	3 (2.7%)	0
Other fractures	3 (2.7%)	11 (10%)

changes or complaints related to implant prominence and irritation.

Data were collected from electronic medical records by two doctors (Tables I to III) which included patient age, co-morbidities, fracture details, follow-up duration, treatment, AO classification, consolidation duration, range of motion, surgical and post-treatment complications, and the need for secondary surgery.

Data analysis was conducted without considering the hospital (CHC or UCL). The outcomes were assessed using Chi-square test, and a multivariate analysis was performed using a logistic regression with Sigma plot 13.0 software. Any outcomes with p-values less than 0.05 were considered statistically significant. We used Chi-square test to compare the most common complications between the surgical group and the conservative group, which included pain, non-union, radiological complications, and functional limitations. Logistic regression method used to analyze the relationship between a binary outcome variable (Y variable=RX consolidation) and more predictor variables (X variables: age, gender, etiology factor, associated trauma, OA classification) in both groups.

RESULTS

The male-to-female ratio was respectively 76.3 % in the surgical group and 81.8 % in the conservative group (Table I). Both cohorts exhibited similar distributions

Table IV. — Consolidation and complication: results of chi-square test

	Surgical group (110)	Conservative group (110)	OR/RR	P-value
Consolidation	104 (94.5%)	98 (89.1 %)	0.97	0.219
Non –union	6 (5,5%)	12 (10.9%)	0.56	<0.2
Pain	7 (6.4%)	3 (4.8%)	0	1
Discomfort	35 (31.8%)	0	2.47	<0.001
Infection	2 (1.8%)	0	0	0.477
Full mobility	77 (70%)	93 (84.5%)	1.135	0.287

Table V. — result of logistic regression for conservative group (Y Variable: radiological consolidation)

Predictor variables	Coefficient	Standard Error	P-value
Age	0.0246	0.0250	0.324
Low/High energy trauma	0.219	0.214	0.307
Associated Trauma	0.103	0.113	0.363
Gender	-0.803	0.757	0.289
OA Classification	-0.573	0.555	0.301

Table VI. — Result of logistic regression for surgical group: (Y Variable: radiological consolidation)

Predictor variables	Coefficient	Standard Error	P-value
Age	-0.00543	0.0313	0.862
Low/High energy trauma	0.000000896	0.000000563	0.111
Associated Trauma	-0.0306	0.253	0.904
Gender	-1.213	1.046	0.246
OA Classification	1.830	0.797	0.02

across AO classification categories A, B1 and B2 (Table II)

In the conservative group, the majority (92.1%) patients were immobilized with an 8-bandage, while only a few (2.6%) used an elbow sling, and a very small number (1.8%) opted for a shoulder and arm sling immobilizer.

Fracture mechanisms are similar in both groups, resulting in isolated clavicular fractures in 80% of cases without any other associated injuries (Table III).

In the surgical group, 104 patients (94.5%) achieved radiological consolidation compared to 98 (89.1%) in the conservative group (Table IV). Pain and discomfort were more prevalent in the surgical group. However, there was no significative difference in the mobility (P value 0.287).

Only 2 patients from surgical group (1.8%) experienced infections requiring removal hardware

Table VII. — Indication for hardware removal

	Surgical group (110)
No hardware removal	62 (56.4%)
Discomfort	35 (31.8%)
Pain	2 (1.8%)
Non union	1 (0.9%)
Patient’s request	8 (7.3%)
Infection	2 (1.8%)

before fracture consolidation. In one case, the infection resulted from the use of cortisone cream on the healing wound, leading to wound dehiscence. However, both patients eventually achieved consolidation.

In the conservative group, there were 12 cases of non-union. Among them, 3 patients had symptomatic

pseudarthrosis requiring treatment, 4 experienced painful pseudarthrosis but did not opt for surgery, and 5 had asymptomatic pseudarthrosis that was well managed. Logistic regression analysis did not reveal any significant predictor variables influencing the development of pseudarthrosis (as shown in Table V).

In the surgical group, there were 6 cases of non-unions. Among these, 2 cases underwent surgical revision with grafting and new osteosynthesis, 3 patients had their plates removed and received non-operative treatment for non-union, and 1 case did not undergo surgical revision. Logistic regression analysis did identify AO classification as predictor of non-union ($p < 0.02$) (Table VI) with an increased risk for the AO grade C (Table VI).

In the surgical group, 48 patients (43.6%) required secondary surgeries, with 35 of them (31.8%) undergoing a second procedure primarily due to hardware-related discomfort (Table VII). Secondary plate fixation for non-union was performed in 4.5% of the surgical group and 2.7% in the conservative group. No cases of refracture were reported following hardware removal.

DISCUSSION

This retrospective matched-pair cohort study, comparing surgically and conservatively treated clavicle fractures, found no significant difference in terms of consolidation (p -value: 0.219). However, we did observe a noticeable but not significant difference in pseudarthrosis incidence in the conservative group (p -value = 0.013). Most fractures in the conservative group healed successfully, and there is no supporting evidence for superior functional outcomes associated with surgical treatment⁵.

Interestingly, we found that patients in the surgical group reported better pain control after osteosynthesis compared to conservative treatment. However, the presence of hardware could lead to discomfort and may require additional procedures to remove the plate. It is widely recognized that the subcutaneous placement of the clavicle plate can result in significant hardware discomfort, as documented by Hulsmans et al.¹². Our study confirms this observation, as the discomfort associated with the plate was indeed substantial, but there is probably some discomfort in conservative treatment but that it is rarely noted in the patients files. Discomfort rate was similar to those reported by Kamachi et al but hardware removal was nearly twice higher¹³. A recent metanalysis demonstrated that low profile dual plating has a lower incidence of implant related complaints and re-intervention rate than single

plating group¹⁴ and could be a positive option to avoid re-operation.

Full mobility is achieved in both groups, with no significant difference noted. Robinson et al.⁹ similarly found no distinction in terms of return to work, even for manual labor.

The nonunion incidence was higher (however not significantly in our study) in the conservative group, leading to instances where patients required surgery after initial conservative treatment. In the literature, the incidence of nonunion varies greatly, but remains higher for conservative treatment varies between 3 to 29%¹⁵⁻¹⁸ compared with 1% and 6%^{19,20} for the surgical group.

Numerous techniques are available for clavicle osteosynthesis, including the uses of nails, Knowles pins, pins, external fixators, and plates²¹⁻²⁵. However, plates and nails remain the most utilized methods. Recent studies have demonstrated that there is no clear superiority between plates and nails^{6,12,23}. Minimally invasive surgery is now becoming increasingly popular to preserve the perifracture hematoma and promote healing²⁶⁻²⁹. However, up to this point, no comprehensive cohort study comparing the two surgical techniques has been carried out. In our series, all surgeries were performed as open procedures, and there was no significant occurrence of pseudarthrosis. The only predictive factor was AO classification Grade C comminutive fractures.

As in most relatively recent studies, we found a low infection rate^{7,30}. In the literature, The primary operative complication reported is pneumothorax during drilling or injury to the subclavian artery when manipulating the bone^{27,31}. However, in our study, we did not observe these complications. Risks factors for non-union typically include shortening of the clavicle by more than 2 cm, high velocity trauma, and recurrent fractures at the same anatomic site^{32,33}.

In the study by Postacchini et al.³⁴, they suggest that non-union in the conservative group can be attributed to factors such as the patient's sex, age, or a too short period of immobilization of the fracture. In our series, the only patient who was immobilized for only three weeks developed non-union. It is important to note that patients in the conservative treatment may choose operative treatment after the appearance of complications or non-union. Hillen et al.³², explain that clavicle malunion is a distinct clinical condition that can be treated successfully. Union is generally obtained with new stable fixation and, when appropriate, with bone grafting augmentation⁴². As surgical management of clavicular non-union might be related to com-

complications, non-operative treatment might be considered and resulted in a favorable outcome⁴³.

Rare complications with significant clinical repercussions, such as osteomyelitis or injury to the brachial plexus, even in patients undergoing conservative treatment were also reported^{35,36}. These complications were not observed in this study.

The conservative treatment appears to be associated with a (non-significant) increase in non-union and functional complications. However, it is important to note that these complications rarely lead to surgical treatment and do not result in poor clinical outcomes. Additionally, it's worth mentioning that primary osteosynthesis can also lead to 10% of non-union, possibly due to the surgical intervention devitalizing the fracture site³⁷.

The observation of a patient developing pseudarthrosis after only three weeks of immobilization is noteworthy. The conservative treatment approach, using a figure-of-eight bandage for 4 weeks with gentle physiotherapy and no-load bearing during this period, is currently being reconsidered as the gold standard in the conservative management of clavicle fractures. A prospective randomised study compared conservative treatment with a sling and figure-of-eight bandage, revealing similar outcomes for both techniques but noting that patients in the latter group experienced more pressure sores in the axillae³⁸.

The literature suggests that conservative treatment for midshaft clavicle fractures is associated with a higher rate of nonunion and functional deficits compared to surgical treatment⁷.

Comorbidities such as obesity, tobacco use, diabetes, and alcohol consumption are important factors to consider, as they can influence the healing of fractures in both the surgical and conservative treatment groups. Liu et al., have shown that smoking and fracture displacement are risk factors for pseudarthrosis³³. However, smoking did not appear to have an influence in our series.

Our observations are limited to medio clavicular fractures and cannot be extended to lateral or acromioclavicular fractures. This choice reduce bias since the fracture mechanisms and rate of pseudarthrosis can vary depending on the location of the clavicle fracture^{39,42}.

Using the AO classification to categorize the fractures in your study is a sound choice, as anatomically based classifications tend to exhibit high inter- and intra-observer reliability, as explained by Van Tongel et al.⁴³,

CONCLUSION

Finally, even though there was a noticeable but not significant difference in pseudarthrosis incidence in the conservative group, the chances to have pseudarthrosis are twice higher in this group. However, it's worth noting that secondary surgeries were more frequent in the surgical group, often due to discomfort related to the hardware. Both treatment approaches result in similar functional outcomes. Therefore, surgery may be considered for younger patients who want a faster return to activity and are willing to accept the potential need for a subsequent procedure to remove the hardware.

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