

Midshaft clavicle fractures treatment: proposal of informed consent for a shared-treatment decision

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Received: April 17, 2022
Accepted: August 3, 2023

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How to cite this article: Goderecci R, Di Filippantonio S, Ciprietti N, et al. Midshaft clavicle fractures treatment: proposal of informed consent for a shared-treatment decision. Lo Scalpello Journal 2023;37:55-57. <https://doi.org/10.36149/0390-5276-250>

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SUMMARY

Fractures of clavicle frequently occur in young active patients and the middle-third of the shaft is the most involved segment. Traditionally mid-shaft clavicle fractures have been treated mainly non-operatively. The literature of the first decade of the 2000s strongly supported a routine indication of surgical treatment for the fracture of this segment, resulting in a clear change of attitude compared to previous years. However, most recent systematic reviews demonstrated an uncertain superiority of surgery over conservative treatment in the acute management of these fractures. In fact, both types of treatment can result in complications that need to be balanced for the individual patient in order to determine the best indication; in addition, increasing attention is being given to the patient's involvement in the decision-making process for the therapeutic choice, which also influences final treatment satisfaction. Herein, we propose an informed consent that is clearly understandable to the patient in which all the points relating to the two types of treatment (conservative vs surgical) are discussed: from a review of the literature, we report the factors and relative percentages that can influence the final result. We believe that this document can be a useful tool in the clinic for an informed and shared choice of treatment with the patient suffering from a fracture of the middle third of the clavicle, potentially influencing surgical practice from a legal point of view.

Key words: clavicle fractures, treatment, informed consent, patient, evidence-based medicine

Fractures of the clavicle constitutes 2.6-4% of all fractures with a higher prevalence in young males ^{1,2}. The most involved segment is the middle-third of the shaft (69-82%); based on reported good results of literature dating to the 1960s, traditionally these fractures have been treated mainly non-operatively ¹⁻⁴; however, these results were influenced by several biases (clavicular site, severity and grade of displacement, inclusion of a variable proportions of children with greater potential for healing and remodeling) ⁵.

In the last 20 years this trend has changed since many studies have shown that in displaced clavicle fractures conservative treatment was followed by higher risks of non-union (15%), malunion (18%), and unsatisfactory clinical results (31%) ^{6,7}. Risk factors for these complications have been identified predominantly in a fracture with shortening greater than 2 cm, when displacement is greater than 100%, when a Z-type fracture (which is a comminuted fracture with a displaced and rotated butterfly fragment between major fragments) is seen, and when notable com-

minution is observed in case of initial severe soft tissue trauma and smoking habitude⁸⁻¹².

The association between both delayed functional recovery after 6 weeks from trauma and smoking have also been suggested to be a significant predictor of symptomatic non-healing in patients managed conservatively: in these cases a second-step surgery should be considered in order to avoid the morbidity of a nonunion¹³.

Delayed operative treatment for clavicular nonunion, following a first non-operative choice, seems to be a reliable and effective procedure with an overall union rates ranging from 90 to 100%: however, the complications following delayed surgery (neurologic symptoms, frozen shoulder or postoperative pain, infection, refracture etc.), even if reported in rare cases, have been reported to occur with a higher incidence than those following acute surgery^{11,14}.

More recent literature has supported a significant increase in the surgical indication such as to determine, in the first decade of the 2000s, a rise of 705% in the surgical treatment of clavicle fractures, with additional implications in terms of cost-benefit ratio for national health systems^{15,16}.

The 2019 Cochrane systematic review by Lenza et al.¹⁷, “Surgical *versus* conservative interventions for treating fractures of the middle third of the clavicle”, on a total of 1469 adult patients, have shown that there is not yet a high level of evidence showing clear superiority of surgical treatment, (considering both studies on ten nailing and plate fixation) over conservative therapy in the acute management of these fractures. The authors concluded that surgery compared with conservative treatment does not improve upper arm function, pain, or quality of life after one year; however, they seem to support that surgery can reduce the risk of treatment failure where secondary surgery is required for nonunion or malunion; they did not definitely provide answers on cosmetic results, considering that even if surgery reduces shoulder deformity it can result in unsightly scars and prominent metalworks. It should also be considered that both types of treatment can result in complications that need to be balanced for the individual patient in order to determine the best indication¹⁷.

We consider that these conclusions mirror what we daily discuss with patients in our trauma clinics, and we are convinced that our task is to make patients aware of the risks and benefits of both types of treatment: the indication should be individualized, with consideration of the patient's age, activity level, job, sport-related implications, comorbidities, and expectations of treatment and we believe that his/her preferences must always be respected; since it has been demonstrated that patient satisfaction with overall treatment is affected by both subjective health outcomes and patient involvement during initial presentation, we propose the following informed consent referring to the most recent scientific literature on the topic (using values and considerations obtained from the references reported herein) in order

to facilitate shared decision-making and ensure correct information about the treatment that may also have enhanced medical-legal value¹⁸⁻²⁰.

“I have been informed that I have a displaced fracture of the middle third of the right/left clavicle.

I have been informed that this fracture can be treated both conservatively and surgically, aware that in both cases there is a risk of non-healing (nonunion) of the fracture: I have also been informed that symptomatic nonunion and malunion are more common in conservatively treated patients (11.5-17.0% and 11.3-18% of cases, respectively) than in operated patients (1.0-2.2% and 1.2-2.2% of cases, respectively); if these complications occur, they can lead to a delayed and more demanding surgery with a higher risk of complications and need for further surgery that, although reported in rare cases, cannot be ignored.

I have been informed that in the case of severe displacement, severe soft tissue compromise, severe comminution, and smoking habit, the risk of nonunion is significantly increased.

In this sense, cessation of smoking becomes an integral part of the treatment.

Age (over 50 years) and female sex seem to have only limited evidence for a higher risk of nonunion.

I have been informed that there is no corroborated scientific evidence demonstrating superiority in terms of shoulder function, quality of life, or pain after one year between surgical and conservative options.

The best functional results in operated patients are mostly evident in the first months after treatment; this may lead to an earlier resumption of work or sport although there are no high-level evidence that demonstrates this possibility definitively. The surgical option appears to reduce the risk of reoperation for the treatment of nonunion or malunion.

In terms of cosmetic results, even if surgery reduces shoulder deformity, it can result in unsightly scars and prominent metalworks.

To date there are no definitive answers in the literature about the risk of an adverse outcome that includes local infection, dehiscence, symptomatic malunion, discomfort leading to implant removal, and skin and nerve problems with surgical treatment; it has been reported that one in four patients (24.6%) require a reoperation within two years after a clavicle ORIF to manage a closed midshaft clavicle fracture: hardware removal for discomfort is a common adverse outcome, with a percentage that ranges from 10.2-18% between operated patients (in particular in women), followed by early mechanical failure (3.4%), and treatment for local infection (2.6-3.2%). Neurovascular injuries and pneumothoraxes are infrequent and should be considered rare complications. Cleared of any reasonable doubt about the specific case of my pathology, I refuse conservative/surgical treatment and agree to undergo conservative/surgical treatment”.

Acknowledgements

We would like to thank the team of the Orthopedics and Traumatology Units of the Hospitals of Teramo and Giulianova for the critical evaluation of the proposed informed consent.

Conflict of interest statement

The authors declare no conflict of interest.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Author contributions

RG: was responsible for the concept of the editorial and the drafting of the article; AC, SDF, NC: were responsible for the concept of the editorial. All authors critically revised the article for important intellectual content and gave final approval of the article.

Ethical consideration

Not applicable.

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