



# Clavicle nonunion: plate and graft type do not affect healing rates—a single surgeon experience with 71 cases

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**Background:** Clavicle nonunions often result after nonoperative treatment for the acute fracture. Those that require >1 surgical procedure in order for a nonunion to heal are termed recalcitrant. The aims of the present study were to (1) determine healing rates of clavicle nonunions after plate osteosynthesis using either a conventional or locked plate, (2) compare iliac crest bone graft vs. bone morphogenetic protein on nonunion healing, and (3) identify risk factors for the development of a recalcitrant nonunion.

**Methods:** We performed a retrospective analysis of a prospectively collected database of 78 clavicle nonunions treated with open reduction and plate fixation with or without graft augmentation by a single surgeon over 25 years. Seventy-one patients over the age of 18 with at least 12 months of follow-up comprised the study group. We analyzed healing rates after the index clavicle nonunion surgery comparing plate type and graft technique as well as identifying risk factors for developing a recalcitrant nonunion.

**Results:** A total of 62 patients (87.3%) healed after their index nonunion surgery at our institution. Three patients (4.2%) required additional surgery but healed, and 6 patients (8.5%) remain un-united; these 9 patients (12.7%) were defined as recalcitrant. There was no statistically significant difference in healing rates between plate type ( $P = .633$ ) or type of bone graft ( $P = .157$ ). There were no identifiable risk factors for the development of a recalcitrant nonunion.

**Conclusions:** Plate fixation of clavicle nonunions remains a successful method of treatment. The type of plate or the method of bone graft did not produce different results. There were no demographic, patient, or injury characteristics associated with the development of a recalcitrant nonunion.

**Level of evidence:** Level IV; Case Series; Treatment Study

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Although clavicle fractures are a common orthopedic injury, failure to heal is relatively infrequent.<sup>2,8,29</sup> Nonoperative treatment of widely displaced fractures may lead to residual deformity, pain, shoulder asymmetry, or nonunion. Recent randomized clinical trials of displaced clavicle fractures comparing nonoperative with surgical treatment have shown nonunion rates in up to 15% in the

nonoperatively treated patients.<sup>1,2,7,31–34,37,40</sup> These studies have been used to support the use of early internal fixation of displaced clavicle fractures in some adults to reduce the risk of nonunion.

A clavicle nonunion can lead to shoulder fatigue, weakness, and pain. In patients with significant fracture displacement or exuberant callus, compression of the

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subclavian vessels or brachial plexus may lead to a thoracic outlet syndrome or brachial plexopathy.<sup>10,21,28</sup> By far, the most common complaint in patients with an un-united clavicle fracture is pain, which often interferes with their ability to work or participate in recreational activities.<sup>21</sup>

When symptomatic, fracture stabilization with or without biologic augmentation may be indicated to promote union, alleviate pain, and restore function. With atrophic nonunions, iliac crest bone graft (ICBG) is the most common source of autogenous bone due to its high concentration of growth factors, osteoprogenitor cells, and relative accessibility. Using this method of treatment, union rates between 80% and 100% have been reported in numerous clinical trials.<sup>5,9,10,13,14,20-23,26</sup> Nevertheless, there are several potential disadvantages with ICBG and include residual donor site pain, sensory loss, hematoma formation, and iliac fracture.<sup>24</sup> Consequently, there has been considerable interest in less invasive means for biologically stimulating nonunions, such as bone graft substitutes, autologous bone marrow aspirates, platelet-rich plasma, bone morphogenetic proteins (BMP), and other growth factors.<sup>15,16,18,19</sup> Contrariwise, several studies have found that autologous bone graft is not a necessary augment to achieve union.<sup>3,13,20</sup>

The aims of this study were to (1) determine the healing rates of clavicle nonunions after plate osteosynthesis using either a conventional or locking plate, (2) compare the type of graft augmentation (ICBG vs. BMP) on nonunion healing, and (3) identify risk factors associated with the development of a recalcitrant nonunion based on demographics, patient, or injury characteristics.

## Materials and methods

In an institutional review board approved retrospective analysis from a prospectively collected database, 78 patients with a clavicle nonunion were treated with plate fixation by a single surgeon (DAW) between 1992 and 2017. Seven patients were lost to follow-up leaving 71 patients aged 18 years and older with an aseptic clavicle nonunion who had at least 12 months of follow-up after the nonunion repair. Sixty patients (84.5%) were referred from an outside institution, whereas the senior author initially treated 11 patients (15.5%).

A clavicle nonunion was diagnosed when there was pain or motion at the fracture site without signs of progressive healing on radiographs taken between 3 and 5 months after injury, or there was a failure of fixation without signs of healing.<sup>4,12</sup> Nonunion consolidation was defined as the obliteration of the fracture line(s), and cortical continuity on antero-posterior (AP) and 25° cephalad radiographs together with minimal or no pain at the fracture site. No attempt was made to determine the exact time of consolidation of the nonunion. Patients were followed clinically with radiographs obtained at 6 weeks, 3, 6, 9, and 12 months postoperatively.

We defined healed as intended as bony union after our index nonunion surgery with no further surgical interventions required. Healed with a secondary intervention was defined as any additional unplanned surgery directly related to the index procedure

but with the ultimate healing of the nonunion. A nonunion that failed to consolidate was defined as a persistent nonunion. Finally, the term recalcitrant nonunion encompassed those patients who required a secondary nonunion surgery or did not heal.

## Surgical repair for nonunion

Surgery was performed under general or regional anesthesia using a Mayfield headrest. A sterile mobile C-Arm (OEC Elite CFD, General Electric Healthcare, Chicago, IL, USA) image intensifier was positioned on the contralateral side of the table. The nonunion site was exposed through a long incision along the inferior aspect of the clavicle. In patients with a stable nonunion and minimal malalignment, the nonunion was fixed in situ. In these cases, some callous was removed to facilitate plate placement and to decrease hardware prominence. Because most of the nonunions in this series were oligotrophic or atrophic and were displaced and shortened, the nonunion was “taken down.” The fibrous tissue in the nonunion site was removed, the medullary canal opened, and the ends of the nonunion were “fashioned” to enhance bony contact and stability. The goal of surgery was the restoration of anatomic alignment with stable plate osteosynthesis to allow early functional rehabilitation. We used long plate constructs with spaced screws to improve biomechanics, stability, and avoid prior screw holes. Whenever possible an interfragmentary lag screw was used independently or through the plate to improve fixation stability of the nonunion. In patients who had undergone previous surgery, multiple deep tissue cultures were obtained.

All patients were treated with Synthes 3.5 mm or 2.7 mm plates. Conventional nonlocking plates were used during the first 10 years of the study (1992-2002) but were replaced in 2003 with “hybrid” locking plates that allowed both conventional and locking screws. Plates were most often placed superiorly on the clavicle, but in the later portion of the study, a second anterior-inferior 3.5 mm or 2.7 mm plate was added to enhance fixation stability. This included patients with poor bone stock, prior superior screw holes limiting fixation options, and distal third fractures. Graft augmentation was used in all patients with an oligotrophic or atrophic nonunion. Autogenous ICBG was used exclusively during the first 12 years of the study. With the introduction of orthobiologics at our institution in 2004, we frequently used BMP 2 or 7 to eliminate the morbidity of an ICBG. No other bone graft substitutes were used.

Postoperatively, a sling or shoulder immobilizer was used for comfort during the first 2 weeks. Thereafter, patients were encouraged to remove their sling for activities of daily living. Referral to physical was reserved for patients who had not regained at least a 100° of forward shoulder elevation or abduction 6 weeks after surgery. Patients were precluded from heavy lifting or carrying with the affected arm for 8-10 weeks after surgery. Return to sports was allowed when there was radiographic healing but rarely before 4 months.

## Statistical analysis

For bivariate analysis, we divided the patients into 2 cohorts, healed as intended vs. recalcitrant nonunion. Demographic, injury, and index nonunion surgical characteristics were compared between the 2 groups. Continuous data are reported as mean and standard deviation or median and interquartile range, and categorical data as

the number and percentage of patients. Continuous data were compared between healed and recalcitrant nonunion groups with the use of the Student *t*-test or the Wilcoxon rank-sum test when the data were non-normally distributed. Categorical data were compared with the use of the  $\chi^2$  or Fisher exact test as appropriate. All analysis was performed using SAS 9.4 (Cary, NC, USA), and a *P* value of .05 was used to mark statistical significance.

## Results

Of the 71 patients, 62 (87.3%) had healing as intended and 3 (4.2%) required 1 or more secondary interventions to achieve union. Six fractures (8.5%) remained un-united despite secondary interventions. The 9 (12.7%) fractures that required a secondary intervention or that failed to unite were defined as recalcitrant nonunions.

The mean age for all nonunions treated was  $43.8 \pm 11.5$  years, and 64.8% of the patients were male. Nine patients (12.7%) were current smokers, and 3 (4.2%) were diabetic. Fifty-five fractures were midshaft diaphyseal (77.5%), with 53 patients (74.6%) having been treated nonoperatively. Sixty-nine of the 71 fractures (97%) were closed injuries. In patients who had internal fixation of their initial fracture, 14 (77.8%) were treated with a plate. Fifty-seven of the nonunions were atrophic or oligotrophic (80.3%). The median time from injury to nonunion surgery was 7.0 (5.00-12.0) months. Further details are included in Table I.

All nonunions in this series were treated by the senior author using plate osteosynthesis with either a conventional plate (26.8%) or locking small- or mini-fragment plates (73.2%). A total of 19 patients (26.8%) were treated with a conventional 3.5 mm nonlocking plate placed on the superior aspect of the clavicle. In the remaining 52 patients (73.2%), a hybrid locking plate construct was used. In 38 of these patients, a single locked 3.5 mm plate was employed and placed superiorly on the clavicle. In the remaining 14 patients (20%), both a superior and anterior-inferior plate 3.5 mm and/or 2.7 mm were used.

Fourteen hypertrophic nonunions (19.7%) had fixation alone. BMP augmentation was used in 31 patients (43.7%), which included BMP-7 in 25 patients and BMP-2 in the remaining 6 cases. Autogenous iliac crest graft was used in 24 cases (33.8%) that included 3 patients with tricortical intercalary grafts. Two patients (2.8%) had both ICBG and BMP-7 graft augmentation.

When comparing demographic factors between patients who healed as intended (*n* = 62) with those that developed a recalcitrant nonunion (*n* = 9), there was no difference in age ( $43.9 \pm 11.7$  vs.  $42.9 \pm 10.7$ , *P* = .806), male sex (37.1% vs. 22.2%, *P* = .382), smoking history (16.1% vs. 22%, *P* = .474), or diabetes (4.2% vs. 11.1%, *P* = .271). Further details on the initial injury and its treatment are provided in Table II.

Data on the index treatment of the nonunion are provided in Table III. Neither the plate type (*P* = .633) nor the

**Table I** Demographic and injury characteristics of all clavicle nonunions

Injury characteristics	All clavicle nonunions (N = 71)
Age, mean $\pm$ SD	43.8 $\pm$ 11.5
Male sex (%)	64.8
Left clavicle fracture	38 (53.5)
Smoking history	
No	59 (83.1)
Former	3 (4.2)
Current	9 (12.7)
Diabetic	3 (4.2)
Location	
Proximal third	2 (2.8)
Middle third	55 (77.5)
Distal third	14 (19.7)
Open fracture	2 (2.8)
Mechanism of injury	
Low energy	7 (9.9)
High energy	63 (88.7)
Unknown	1 (1.4)
Initial treatment	
Nonoperative	53 (74.6)
Operative	18 (25.4)
Time from injury to nonunion (mo), median (IQR)	7.0 (5.0, 12.0)
Nonunion	
Hypertrophic	14 (19.7)
Atrophic/oligotrophic	57 (80.3)

SD, standard deviation; IQR, interquartile range.

Data are presented as n (%) unless otherwise specified.

type of biological augmentation (*P* = .157) was associated with the development of a recalcitrant nonunion.

Complications were few. There were no postoperative infections after nonunion surgery. However, 2 patients with prior fixation had positive intraoperative cultures that were treated with antibiotics that led to uneventful healing. A total of 9 patients (12.7%) had elective removal of prominent or symptomatic hardware after nonunion consolidation.

## Discussion

We present a large series of clavicular nonunions treated by a single experienced fracture surgeon over two and a half decades. Our results demonstrate that index surgical treatment consisting of deformity correction, stable internal fixation with a plate, and biologic augmentation, when indicated, led to the bony union after the index nonunion surgery in 87.3% of cases with a recalcitrant rate of 12.7%. We found no difference in the recalcitrant rates when comparing plate type or method of biological augmentation. Furthermore, there were no demographic, injury, or treatment variables associated with the development of a recalcitrant nonunion.

**Table II** Injury characteristics

Injury characteristics	Healed as intended (N = 62)	Recalcitrant nonunion (N = 9)	P value
Fracture location			
P3	2 (3.2)	0 (0.0)	.127
M3	50 (80.6)	5 (55.6)	
D3	10 (16.1)	4 (44.4)	
Injury to nonunion surgery (mo), median (IQR)	7.0 (5.0, 11.0)	9.0 (5.0, 29.0)	.417
Open vs. closed			
Closed	60 (96.8)	9 (100.0)	.584
Open	2 (3.2)	0 (0.0)	
Initial treatment			
Nonoperative	46 (74.2)	7 (77.8)	.590
Operative	16 (25.8)	2 (22.2)	
Mechanism of injury			
Low	6 (9.8)	1 (11.1)	1.0
High	55 (90.2)	8 (88.9)	
Excluded unknown	1	0	
Number of prior surgeries, median (IQR)	0.0 (0.0-1.0)	0.0 (0.0-1.0)	.48
History of infection			
No	60 (96.8)	9 (100.0)	.584
Yes	2 (3.2)	0 (0.0)	
Nonunion			
Hypertrophic	14 (24.6)	0 (0.0)	.111
Atrophic/oligotrophic	48 (75.4)	9 (100.0)	

IQR, interquartile range.

Data are presented as n (%) unless otherwise specified.

**Table III** Treatment characteristics

Index nonunion procedure	Healed as intended (N = 62)	Recalcitrant nonunion (N = 9)	P value
Implant			
Conventional plate	16 (25.8)	3 (33.3)	.633
Locked plate	46 (74.2)	6 (66.7)	
Augment			
BMP	28 (45.9)	3 (33.3)	.157
ICBG	18 (29.5)	6 (66.7)	
Excluded BMP and ICBG	1	1	
Excluded no graft	14	0	

BMP, bone morphogenetic protein; ICBG, iliac crest bone graft.

Data are presented as n (%).

Plate osteosynthesis is the most common method of treatment for clavicular nonunions because it provides stable fixation, allows for simultaneous bone grafting, and permits early mobilization of the shoulder. Numerous studies have reported excellent outcomes with union rates of 80%-100% after conventional or locked plating.<sup>10,21,23,36</sup> However, much of the evidence supporting plate fixation of clavicle nonunions was extrapolated from relatively small series.<sup>13,21,22</sup> This large single-surgeon study spanning 25 years encompassed 2 distinct eras in plate design and confirmed high healing rates after plate osteosynthesis independent of plate design.

Surprisingly, few controlled studies compare the type of bone graft used in conjunction with internal fixation of a clavicular nonunion. Paradoxically, a few authors have found that autologous bone graft is not necessary to augment internal fixation. Baker and Mullett<sup>3</sup> treated 15 clavicle nonunions with a precontoured locking plate alone, and all of the nonunions healed. However, the gold standard of treatment for atrophic and oligotrophic nonunions remains autogenous ICBG. We used ICBG in 24 patients (33.8%). This technique led to healing as intended in 18 patients, whereas 6 patients developed a recalcitrant nonunion. BMP was used in 31 patients (43.7%), which led

to healing as intended in 28 patients, whereas 3 of the patients developed a recalcitrant nonunion. We found no statistically significant differences in healing between the 2 grafts.

The rationale for the use of BMP is the large body of published animal and clinical studies showing that BMPs possess potent osteoinductive properties and are equivalent in efficacy to ICBG.<sup>6,11,17,25,28,30,35,38,39</sup> In addition, it eliminated the morbidity of harvesting ICBG. However, brachial plexopathy has been reported with the use of BMP in the treatment of clavicle nonunions.<sup>27</sup> Our data support the concept that BMPs, although not superior to autogenous bone graft, avoid the morbidity of a bone graft harvest and remain a useful alternative to ICBG in atrophic and oligotrophic clavicular nonunions. We report no complications from the use of BMP.

We attempted to identify potential risk factors for the development of a recalcitrant clavicular nonunion but found no significant risk factors. Most studies report their overall union rate of clavicular nonunions despite the number of nonunion surgeries. These reported union rates are derived from small sample sizes and do not compare union rates between patients who heal after the index nonunion surgery and those who require a secondary intervention to unite.<sup>13,21,22</sup> Schnetzke et al<sup>34</sup> stratified the union rates of clavicle nonunions by the number of surgical procedures required to heal. They compared union rates of clavicle fractures with and without ICBG and reported an overall union rate of 93.1% (54 of 68). However, 15.5% (9 of 58) required additional surgery, leading to healing in 5 patients, whereas 4 remained un-united. They reported that patients treated without a bone graft at the time of their nonunion surgery had a 4.7-fold higher risk of developing a recalcitrant nonunion. In our study, we did not find any factors associated with the development of a recalcitrant nonunion.

The strengths of this study include a relatively large sample size, done by a single experienced fracture surgeon with excellent follow-up. However, there were several limitations of this study, which included nonrandomization, selection and reviewer bias, variations in surgical technique given the use of 2 different plating techniques, no cost-analysis, and lack of functional outcome studies. In addition, because the majority of patients were referred for nonunion treatment >6 months from their injury, many did not have original injury radiographs and no analysis on fracture morphology or initial displacement was used to predict recalcitrance.

## Conclusions

There were no statistically significant differences in the healing rates between patients managed with conventional plates and those managed with locking plates. The type of graft augmentation did not influence the rate of

bony union. There were no demographic, patient, or injury characteristics associated with the development of a recalcitrant nonunion.

## Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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