

Treatment of a Recalcitrant Non-union of the Clavicle

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ABSTRACT

Background: Plate fixation is the treatment of choice for a midshaft clavicle non-union. Those non-unions that require >1 surgical procedure to heal are termed *recalcitrant non-union*. Regardless of the number of previously failed procedures, our surgical strategy is aimed at achieving an optimal mechanical and biological environment to facilitate healing.

Materials and methods: We performed a retrospective analysis of 14 patients with a recalcitrant clavicle non-union treated with open reduction and plate fixation combined with graft augmentation when indicated. Healing rates after index surgery were analysed. All patients were observed for at least 12 months.

Results: All patients healed at a mean time of 193.2 days (range 90–390). Five of the 14 patients had at least one positive surprise culture, for which they received antibiotic treatment. At the latest follow-up, no patient reported pain or discomfort. Mean disability of the arm, shoulder and hand (DASH) score was 16.3 points (range 0–40), indicating only mild residual impairment. A possible link was found between the time between injury and definitive surgery and the time to healing [Pearson correlation 0.527, sig. (two-tailed) 0.000].

Conclusion: This study shows 100% bone healing and good functional outcomes after surgical revision for a recalcitrant clavicle non-union.

Keywords: Clavicle, Plate fixation, Recalcitrant non-union.

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INTRODUCTION

Midshaft fractures of the clavicle comprise roughly 80% of all clavicle fractures.¹ Standard treatment of these fractures remains controversial, with the pendulum recently having swung towards operative fixation.² A diaphyseal clavicle non-union can occur after operative and non-operative treatment of a clavicle fracture, with a reported incidence of 0.1–15%.³ A non-union often results in inferior outcome with pain, limited motion, deformity and strength deficit.⁴

Surgical treatment of a clavicle non-union—with its easily accessible location—is considered a relatively straightforward procedure. As such, the threshold to operate a clavicle non-union in general orthopaedic practice is low in our country. In our study, we defined a non-union as a fracture that has little or no potential to heal 4 months after non-operative treatment and/or surgery. Using the definition of Wiss and Garlich, we coin a non-union that has failed at least one attempt at non-union repair as a recalcitrant non-union.⁵ This paper reviews the results of 14 adult patients treated for a recalcitrant clavicle non-union.

MATERIALS AND METHODS

This is a retrospective study in a level 1 trauma centre. Approval by the institutional review board was waived due to the retrospective design of this study. A total of 105 midshaft clavicle fractures (AO/OTA Type 15.2A, 15.2B and 15.2C) were treated with open reduction and plate fixation with or without graft augmentation by the senior author (a fellowship-trained orthopaedic trauma surgeon) between February 2003 and October 2019. Indications were acute displaced shaft fractures ($n = 59$, including two patients with bilateral midshaft clavicle fractures), delayed union ($n = 9$), failed fixation ($n = 3$, defined as early pull-out of plate and screws) or non-union ($n = 34$, including 14 recalcitrant non-unions).

Twelve recalcitrant non-unions (86%) were initially treated at outside hospitals and were referred to our institution. The remaining

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93 midshaft clavicle fractures were operated by the senior author, of which two developed a recalcitrant non-union.

Exclusion criteria were age under 18 ($n = 10$) at the time of injury or a pathologic fracture/non-union ($n = 2$). During the same period, four diaphyseal malunions underwent corrective osteotomy and plate fixation and 25 lateral clavicle fractures/non-unions and one medial clavicle non-union underwent plating. These were also excluded.

The surgery that led to final healing is referred to as the index surgery. All records and radiographic images were available for review with at least 12 months of follow-up for all patients.

Patients were followed clinically with radiographs obtained at 6 weeks, 3, 6, 9 and 12 months or until the union was seen.

We defined healed as bony union after our index non-union surgery with no further surgical interventions required. Radiographic evidence of union was assessed by an independent musculoskeletal radiologist. The clavicle was healed when bridging callus and cortical healing of three out of four cortices were noted.

With more than one plate on the clavicle, it becomes more difficult to judge cortical bridging. Hence, we have a lower threshold for obtaining a dual-energy computed tomography (CT) to confirm healing in fractures and non-unions that are treated with dual plating. Clinical data regarding union, including fracture mobility, tenderness and pain, were obtained at the follow-up visit. Absence of pain on palpation and absence of pain during shoulder range of motion testing, in combination with healing seen on the radiologic studies, were used to determine the healing of the non-union.

Patient evaluation included clinical and radiological assessment with laboratory investigations including C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) and leucocytes. Post-operative complications were screened in the medical record.

Pearson correlation coefficients were calculated to investigate the relationship between the time of injury and index surgery and the time to healing. A significance level of $p < 0.05$ (two-tailed) was used. Statistical analysis was performed using the statistical software package SPSS, version 20.0 (SPSS Inc., Illinois, USA).

Surgical Technique

The patient is placed in the beach chair position. If iliac bone graft harvest is anticipated, the ipsi- or contralateral iliac crest is draped free. Ideally, the previous scar is used. After exposure, all failed hardware, intervening non-union tissue and devitalised areas are removed sharply. Five deep tissue cultures at different sites of the wound are obtained prior to administering intravenous antibiotics (2 g of cephazolin). Both ends of the non-union are opened with a 2-mm drill. If there is a sclerotic cap at the end, it is resected with a micro-sagittal saw under continuous cooling. If restoration of length is needed (based on preoperative evaluation comparing the injured with the healthy side), placement of an intercalary tricortical iliac crest graft is done. In cases with large bone defects (>3 cm), a vascularised fibular graft is used. Once alignment and length are restored, plate fixation is done. In this series, plate type was either a single 3.5-mm pelvic reconstruction locking compression plate (LCP, DePuy Synthes, Amersfoort, the Netherlands) that was contoured to fit on the anteroinferior surface or two locking plates in orthogonal (dual plating) fashion.^{6,7} When using two plates, one plate (2.4- or 2.7-mm recon LCP) is placed on the superior surface, and the second one (3.5- or 2.7-mm straight LCP) is placed anteroinferiorly.⁷ If possible, one or two lag screws are placed across the non-union site and through the plate. If no lag screws can be placed due to the geometry of the non-union, plate fixation is done under compression. For the 3.5-mm plate, we used eccentric drilling to compress the non-union. For the smaller 2.4-/2.7-mm plates, we use a pointed reduction clamp placed either in two small drill holes outside of the plate or with one tine of the clamp in a screw head and one tine in a small drill hole across the non-union.

Cortical screws are used preferably, whereas on the lateral end of the clavicle, we use locking screws as in most patients, the distal end of the clavicle has less purchase with standard screws. We err on the long side when choosing the plate length. Decortication of both non-union ends for 1.5 cm is done using a sharp osteotome making small petals (shingling).

In one patient, all four previous attempts to treat the non-union had been with a plate placed on the superior aspect. In this case, we positioned the 3.5-mm plate on the superior surface because de-vascularising the (antero) inferior surface for plate placement would compromise the vascularity unnecessarily.

Either autologous cancellous from the iliac crest and/or demineralised bone matrix putty (DBM, DePuy Synthes, Amersfoort, the Netherlands) is used as bone grafts if required. The arm was placed in a Gilchrist sling for comfort for a few days. Pendulum exercises were started on post-operative day 1. The patients were restrained from active abduction more than 60° for 6 weeks.

Most patients stayed overnight post-operatively [especially if iliac crest bone graft (ICBG) was taken]. In the early period (until 2015), tissue cultures were kept for only 4 days. Cultures are nowadays kept for 14 days. If more than one positive culture was found, the infectious disease specialist was consulted, and an antibiotic regimen was started based on their advice.

RESULTS

Patient characteristics are shown in Table 1. The mean age at the time of index surgery was 50 years (range 36–77). Six (42.9%) of the patients were male. The initial fracture was most often the result of a low-energy trauma.

Average number of operative procedures per patient performed prior to the index surgery was 2.6 (range 1–4). It took place at an average of approximately 7 years (range 0.65–35.2) after the initial injury. All patients experienced disability because of pain, discomfort or stiffness in the adjacent shoulder. In nine of the patients, a single LCP of 3.5 mm was placed, of which seven on the anterior-inferior border of the clavicle and one on the superior clavicle. One patient required a vascularised fibular graft to replace the large missing bone segment. This reconstruction was temporarily protected with a long-spanning 3.5-mm superior plate crossing over the acromioclavicular (AC) joint onto the scapular spine. In four patients, a double-plating technique was performed using a 3.5- and 2.7-mm LCP in one patient, 2.4- and 2.7-mm LCP in two patients and double 2.7-mm plates in one patient. One patient required three plates for the reconstruction (one 2.4 mm with two 2.7-mm plates).

In all except one patient, autogenous (ICBG) was placed on the decorticated areas of the non-union, including three patients with ICBG combined with DBM. All 14 (100%) recalcitrant non-unions healed clinically and radiographically. In six patients, a dual-energy CT was obtained to confirm healing. All these had been treated with dual plating (five patients with two 2.4-/2.7-mm plates, and one with a 3.5-mm anteroinferior plate and a 2.7-mm superior plate). In one patient, a CT was obtained because of a lung nodule. This chest CT confirmed non-union healing.

Mean time to union was 193.2 days (range 90–390). One patient was referred to us with an infected non-union with exposed hardware (Fig. 1). She was a healthy patient who sustained a midshaft clavicle fracture during judo. The fracture was initially treated non-operatively for 16 weeks. She underwent plate fixation at an outside hospital, followed by two more attempts that included revision of plate fixation and addition of cerclage wires. Given the combination of poor soft tissues, infection and instability, we planned a staged procedure. First priority was infection control and optimisation of the soft tissues. Following recovery from infection and healing of the soft tissue, definitive plate fixation combined with bone grafting was performed. Fracture union with full return of function was achieved at 8 months follow-up. The plate has since been removed because of the history of infection. In 13/14 cases, cultures were taken at the time of revision fixation. Five of these 13 patients had at least one “surprise” positive culture. All

Table 1: Patient characteristics

Patient	Age (years)/gender	Mechanism of injury	Comorbidity	Number of previous clavicle surgeries	Time from injury to index surgery (years)	Type of fixation	Bone graft	Complications	Time from index surgery to union (days)	DASH score
1	43/F	Judo	None	3	1.01	3.5 AI	ICBG	None	90	4.2
2	41/F	Fall	None	4	1.93	3.5 S	ICBG	None	240	22.5
3	44/F	Stumbled over a dog	None	4	4.21	2.4/2.7 DP	ICBG	None	120	4.2
4	53/F	Car accident	None	4	35.16	3.5 S	Free fibular graft	None	180	40
5	47/M	Fall	None	2	1.03	2.4/2.7 DP	ICBG + DBM	None	120	0
6	44/F	Motorcycle accident	Asthma	1	2.33	2.4/2.7 DP	ICBG + DBM	None	90	10
7	55/F	Fall during handball match	None	4	33.82	2.7/2.4/2.4	ICBG	None	240	23.3
8	53/M	Fall	None	1	2.27	3.5 AI	ICBG	None	90	0
9	77/M	Fall during a transient ischemic attack	None	2	1.50	3.5 AI	ICBG	None	210	19.2
10	58/F	Fall	Tuberculosis	2	0.65	3.5 AI	ICBG	None	390	6.7
11	48/M	Motocross accident	None	2	3.27	3.5 AI	ICBG + DBM	None	360	35.8
12	48/M	Road bike accident	None	4	4.14	3.5 AI 2.7 S	ICBG	None	270	25
13	36/F	Fall during skiing	None	2	2.01	3.5 AI	ICBG	None	165	26.7
14	54/M	Fall from a slide	None	2	4.49	3.5 AI	ICBG	None	140	10

AI, anteroinferior; S, superior; ICBG, iliac crest bone graft; DBM, demineralised bone matrix

cultures obtained from these five patients were incubated for 14 days. Four of these five patients (80%) had cultures positive for *Propionibacterium acnes* (now known as *Cutibacterium acnes*), and one patient had a dual infection with *Staphylococcus saccharolyticus* and *Propionibacterium acnes*. All five were treated with a 3-month course of clindamycin 600 mg orally three times a day. One of these switched to amoxicillin 500 mg three times a day due to an allergy to clindamycin.

At the final follow-up, all patients had nearly full range of motion of the shoulder and reported no or moderate pain and returned to their daily living activities. DASH scores were obtained in all of the patients, with the mean DASH score of 16.3 points (range 0–40) at a mean of 6.5 years (range 1–15) after the index non-union surgery (Table 1). Three patients had a DASH score above 30 points, due to their inability to “place an object on a shelf above their head”. However, by their own reporting, this does not interfere with their quality of life. All patients were satisfied with the result. At the time of the latest follow-up, hardware was still in place in 13 of the 14 patients.

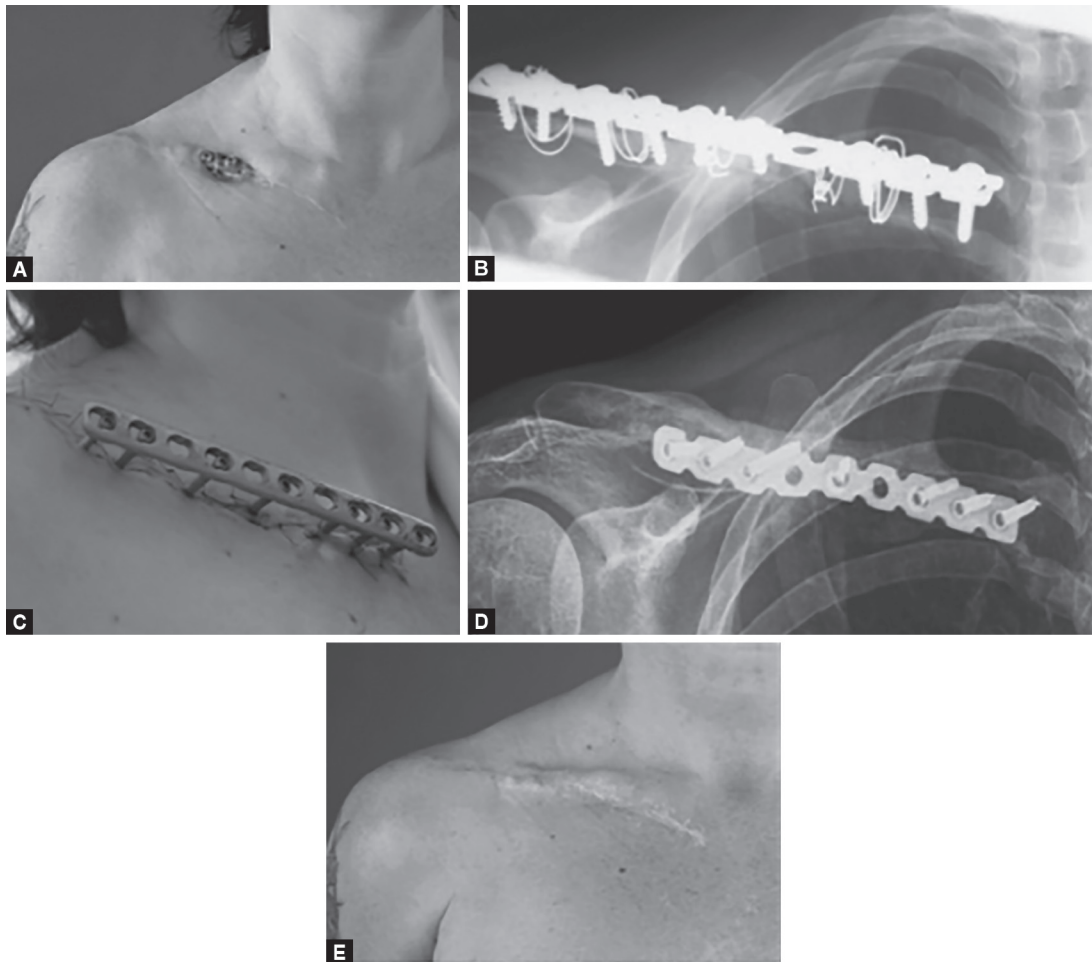
Pearson correlation coefficients were calculated to investigate the relationship between the time of injury and index surgery and the time to healing (time from index surgery to time of healing). The success of the index non-union procedure for the treatment of recalcitrant non-union of the clavicle correlated closely with the time from injury to index surgery [0.527, sig. (two-tailed) 0.000]

(Fig. 2). This finding may be due to an avascular bed formation in time. Though there could be a possible link between the two time periods, a causal relationship cannot be confirmed. Although the range of time from injury to index surgery in the present series might have a beneficial influence on the time to union, no significant difference was observed in terms of complication rates.

DISCUSSION

Our results demonstrate that when adhering to the classic non-union treatment principles of thorough debridement (including removal of failed hardware), alignment, rigid fixation and liberal use bone graft, there is no reason a recalcitrant clavicle non-union cannot heal. There is a possible link between the time of injury and index surgery and the time to healing. This does, however, not appear to correlate with functional outcomes.

Several alternatives for plate fixation have been described for a clavicle non-union repair, such as intramedullary fixation,⁸ external fixation⁹ and total claviclectomy.¹⁰ We prefer plating as described herein, as we think that intramedullary fixation does not provide compression, external fixation is cumbersome with a frame that has to be in place for 3–6 months and unsatisfying results have been published previously by our department regarding patients undergoing total claviclectomy.¹⁰



Figs 1A to E: Staged non-union repair. During the first surgery, a thorough wound debridement (A) and removal of all hardware (B) were performed; Stability was provided with a straight 3.5-mm titanium LCP (DePuy Synthes, Amersfoort, the Netherlands) as an external fixator; (C) The second stage of the reconstruction was performed using a 3.5-mm titanium pelvic reconstruction LCP on the anteroinferior aspect of the clavicle; (D) ICBG was placed around the non-union; (E) The infected recalcitrant non-union healed without complications

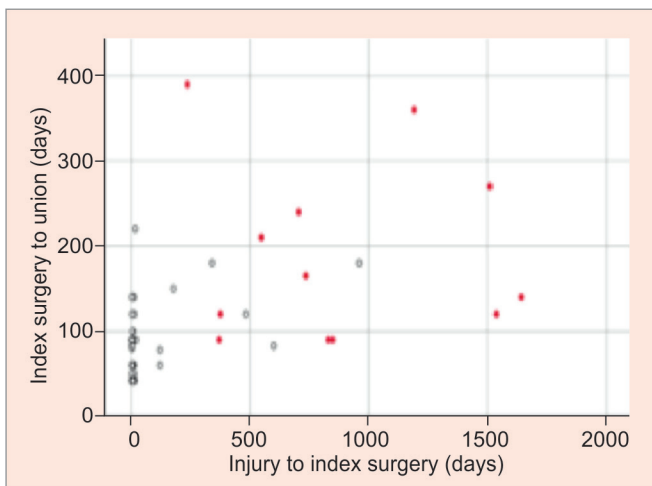


Fig. 2: Relationship between time elapsed between injury and index injury and time to healing. Red: recalcitrant clavicle non-union; White: clavicle fracture. A significant positive correlation is seen between the time of injury to definitive surgery and the time to healing [Pearson correlation 0.527, sig. (two-tailed) 0.000]

Although good results have been reported after plate fixation on the superior aspect of the clavicle, these plates are prominent under the skin and have a very high reoperation rate of 8.1–53% for implant-related symptoms.^{11,12} Using anteroinferior plating reduces plate prominence^{13–15} and has shown a low hardware removal rate (5.6%).¹⁶ Our choice of fixation of a midshaft clavicle fracture or non-union has evolved over time. Initially, we used 3.5-mm LCP anteroinferior plating.¹³ Variations in clavicle anatomy prevent anatomic fitting of pre-contoured clavicle-specific plates.¹⁶ Therefore, more recently we have moved to double (orthogonal plating) with one plate on the superior surface with the second-placed anteroinferior.⁷ Dual plating of the clavicle has been shown to be advantageous for (maintenance of) reduction, minimising implant prominence and offers better multiplanar-bending stiffness compared to single plating.⁷

Autogenous ICBG, with or without the addition of demineralised bone matrix, remains the gold standard for treatment of atrophic/ oligotrophic non-unions. Complications of pain, numbness and donor site morbidity can be reduced with attention to detail. Obtaining optimal bone contact between non-union ends with compression—even if it means shortening the total length—is advisable for small defects (up to 1.5 cm). Larger defects (1.5–3 cm)

should be bridged with a tricortical ICBG, as shortening more than 1.5 cm may lead to altered mobility and/or strength. A vascularised bone transfer, such as a vascularised fibular graft, can be used for larger defects (>3 cm). Advantages of the fibular graft are its diameter and consistency that make it suitable to withstand the forces transmitted through the shoulder girdle. Additionally, it is possible to adapt its shape to the original clavicle.¹⁷

One of the most important factors is to determine whether the non-union is infected. To date, there is no preoperative test that can perfectly detect an infection in a non-union.^{18,19} Infected non-unions are often treated with a two-stage surgical protocol including aggressive surgical debridement with intraoperative cultures,^{20–23} stability and an appropriate course of antibiotics. It is still unknown what implications these “surprise” positive cultures have on the result of the non-union surgery, as most literature is available from patients undergoing arthroplasty surgery, rather than from non-union repair surgery.^{23,24} The significance of a positive *Cutibacterium acnes* culture after clavicle surgery is a matter of controversy.²⁵

The limitations of the present study are its retrospective nature and small sample size. Inherent biases such as selection bias and small variations in surgical technique (one vs two plates and plate size) should be taken into account.

Additionally, there is no consensus as to what defines a “recalcitrant non-union”, ranging from “at least 1 failed surgical treatment”,⁵ to “a non-union that has not healed for 10 years or more”.²⁶ Finally, the operating surgeon has more than average experience in non-union surgery. As these recalcitrant cases can be challenging—often with a frustrated patient—early referral to a colleague interested in non-union surgery may improve success rates.

On the contrary, we see some strengths in the current paper. Although retrospective, the current study includes a clearly defined group of patients treated with a consistent and reproducible technique by a single surgeon (no performance bias) and without any loss to long-term follow-up in combination with an objective outcome score.

CONCLUSION

One or more failed surgical attempts to treat a clavicle non-union do not impair the healing potential. This series provides clinically relevant information on outcomes after applying a consistent approach for recalcitrant non-union repairs. Debridement, alignment, plate fixation with or without graft augmentation lead to fracture healing in patients with recalcitrant non-union of the clavicle.

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