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Does plate type influence the clinical outcomes and implant removal in midclavicular fractures fixed with 2.7-mm anteroinferior plates? A retrospective cohort study

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Abstract

Background: The purpose of this study was to evaluate surgical healing rates, implant failure, implant removal, and the need for surgical revision with regards to plate type in midshaft clavicle fractures fixed with 2.7-mm anteroinferior plates utilizing modern plating techniques.

Methods: This retrospective exploratory cohort review took place at a level I teaching trauma center and a single large private practice office. A total of 155 skeletally mature individuals with 156 midshaft clavicle fractures between March 2002 and March 2012 were included in the final results. Fractures were identified by mechanism of injury and classified based on OTA/AO criteria. All fractures were fixed with 2.7-mm anteroinferior plates. Primary outcome measurements included implant failure, malunion, nonunion, and implant removal. Secondary outcome measurements included pain with the visual analog scale and range of motion. Statistically significant testing was set at 0.05, and testing was performed using chi-square, Fisher's exact, Mann–Whitney *U*, and Kruskall-Wallis.

Results: Implant failure occurred more often in reconstruction plates as compared to dynamic compression plates ($p = 0.029$). Malunions and nonunions occurred more often in fractures fixed with reconstruction plates as compared to dynamic compression plates, but it was not statistically significant. Implant removal attributed to irritation or implant prominence was observed in 14 patients. Statistically significant levels of pain were seen in patients requiring implant removal ($p = 0.001$) but were not associated with the plate type.

Conclusions: Anteroinferior clavicular fracture fixation with 2.7-mm dynamic compression plates results in excellent healing rates with low removal rates in accordance with the published literature. Given higher rates of failure, 2.7-mm reconstruction plates should be discouraged in comparison to stiffer and more reliable 2.7-mm dynamic compression plates.

Keywords: Clavicle fracture, Open reduction, Internal fixation, Reconstruction, Dynamic compression, 2.7 mm

Introduction

For displaced clavicular fractures, plate fixation improves clinical outcomes and patient satisfaction as compared to nonoperative treatment [1-4]. However, plate fixation is related to implant prominence and skin irritation and has previously resulted in implant removal rates of 9% to 64% [3-6]. A recent systematic review of eleven studies showed that nonunion rates after plate fixation were less than 10% in all except one study [6]. Although clavicle fixation has been controversial regarding its use and plate location, recent studies have shown efficient healing, few complications, and excellent return to function for anteroinferior plating [7-9]. Advantages of this technique are avoidance of potentially dangerous infraclavicular structures and reduction of patient complaints due to implant prominence [7].

Regarding stability, a recent biomechanical study showed inferior nonlocking plates to be stiffer than superior locking

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plates [10]. In addition, a finite element study showed that anteroinferior plating best resists the effect of most daily living forces acting on the clavicle and can be considered more mechanically physiological [11]. The anteroinferior plate is perpendicular to the primary force vector and has greater resistance to axial compression of the clavicle during motions of abduction and flexion [10]. Taking these mechanical findings into consideration and following the effort to reduce implant prominence, anteroinferior plating has been performed using 2.7-mm plates [7,12].

Two biomechanical studies have found greater stability with compression plates as compared to reconstruction plates [13,14]. Thus, the primary purpose of this study was to evaluate the rates of fracture union, nonunion, malunion, implant failure, and implant removal with regards to plate type (compression plates vs. reconstruction plates) in midshaft clavicle fractures fixed with 2.7-mm anteroinferior plates utilizing modern plating techniques.

Patients and methods

This study was an Institutional Review Board (IRB)-approved retrospective exploratory cohort review of operatively treated midshaft clavicle fractures at a single large private practice associated with a level I teaching trauma center. Consecutive patients were identified by Current Procedural Terminology (CPT) coding for operative (23515) and nonoperative (23500 and 23505) treatment of diaphyseal clavicle fracture that had initial treatment from 1 March 2002 through 31 March 2012. A total of 718 clavicle fractures were diagnosed and treated during this time period. Operative criteria included significant clavicular shortening (greater than 20 mm on either AP, cephalad, or caudal radiographs), associated neurological injury, associated unstable scapular injury (glenoid neck, acromion, coracoid, or intra-articular glenoid fractures), double suspensory shoulder instability, open clavicular fractures, published criteria for displacement, skin compromise, or polytrauma [1,2,15-17]. Inclusion criteria were skeletally mature (age equal to or greater than 18 years), diaphyseal clavicle fracture that met operative indications, open reduction internal fixation (ORIF) via an anterior-inferior approach, internal fixation with 2.7-mm plate and screws, and a minimum 3 months follow-up confirming radiographic union and return to previous activities and/or employment was established. A minimum follow-up was chosen based on a previous study which showed patients with early fracture healing returned to previous activities at the 3-month interval and skin or soft tissue irritation, fixation failure, or nonunion were also commonly noted by 3 months [12]. A total of 249 midshaft diaphyseal clavicular fractures fulfilled the inclusion criteria. Ninety-three fractures were excluded due to pathological fracture (1), death due to other injuries (1), initial nonoperative treatment with subsequent nonunion (3), lost to follow-up (6), insufficient records/radiographs (17), and follow-up less than 3 months (65). One hundred fifty-six fractures (156) in 155 patients formed the basis of the study.

Patient demographics for all fractures and primary outcomes are displayed in Table 1. Fractures occurred in 41% on the right and in 59% on the left hand side. The

Table 1 Patient demographics by plate type and primary outcomes

	Recon	DCP	*p* value
All fractures	*n* = 71	*n* = 85	
Age	39 ± 15	41 ± 15	0.431
Sex			0.071
Male	43, 60.6%	63, 74.1%	
Female	28, 39.4%	22, 25.9%	
BMI (kg/m^2)	25.5 ± 4.9	25.9 ± 5.1	0.730
Current smoker	19, 26.8%	19, 22.4%	0.523
United fractures	*n* = 65	*n* = 84	
Age	39 ± 15	41 ± 15	0.380
Sex			0.160
Male	41, 63.1%	62, 73.8%	
Female	24, 36.9%	22, 26.2%	
BMI (kg/m^2)	25.6 ± 4.9	25.8 ± 5.1	0.829
Current smoker	16, 24.6%	18, 21.4%	0.646
Nonunion	*n* = 5	*n* = 1	
Age	42 ± 15	32	0.566
Sex			0.121
Male	1, 20%	1, 100%	
Female	4, 80%	0	
BMI (kg/m^2)	25.2 ± 4.3	32.1	
Current smoker	3, 60 %	1, 100%	0.667
Malunion	*n* = 2	*n* = 0	
Age	32 ± 4		UA
Sex			UA
Male	2, 100%		
Female	0		
BMI (kg/m^2)	41.3		UA
Current smoker	0		UA
Implant failure	*n* = 6	*n* = 1	
Age	38 ± 15	19	0.316
Sex			0.571
Male	3, 50%	1, 100%	
Female	3, 50%	0	
BMI (kg/m^2)	28.7 ± 8.1	19.2	0.348
Current smoker	3, 50%	0	0.571

UA, unable to assess; none in comparator group. Continuous variables reported as mean ± standard deviation. Dichotomous variables reported as number, percentage.

mean follow-up was 8.9 months (3 to 54). Fractures were caused by a high-energy mechanism in 92.3% of patients (Table 2). Three fractures were classified as open (one type I and two type II according to Gustilo/Anderson). Associated injuries were found in 82 of the 156 patients (52.6%). Musculoskeletal injuries included 35 ipsilateral shoulder girdle extremity fractures (22.4%), 25 scapula fractures (16.0%), 17 rib fractures (10.9%), and 3 proximal humeral fractures (1.9%).

All patients were treated by four fellowship trained orthopedic trauma surgeons utilizing similar philosophies and modern techniques of plate fixation [12]. Patients were evaluated at regular intervals of 2, 6, 12 weeks, and ongoing according to clinical necessity including, but not limited to, pain, plate irritation, plate prominence, or not achieving complete clinical healing. The attending surgeon was responsible for clinically assessing the patient, interpreting radiographs, and determining primary healing outcomes. Pain was recorded utilizing the visual analog scale from a standardized questionnaire that the patient filled out at scheduled office visits [18]. Range of motion (ROM) using basic clinical measurements was recorded. Radiographs consisted of cephalad and caudal views obtained at each interval [19]. Clavicular displacement was measured using digital software with picture archiving and communication system (PACS) or manually using protractors. Injury patterns were classified according to OTA/AO (Orthopaedic Trauma Association/Arbeitsgemeinschaft fur Osteosynthesefragen) classification [20]. Based on reported clavicle union rates at 10 to 16 weeks following operative fixation [3,7,12,21], a nonunion was defined as a painful, persistent fracture line with no radiographic progression of healing over three consecutive months with or without fixation failure which required surgical revision. A malunion was defined as a fracture that achieved a malpositioned bony union stable from the initial reduction and fixation or a reduction that changed with time. Any change in implant position or alignment regardless of union seen on serial radiographs was deemed an implant failure.

Table 2 Mechanism of injury

Mechanism	Number	Percentage
High energy		
Motor cycle accident (MCA)	45	28.9
Motor vehicle accident (MVA)	37	23.7
Fall	21	13.5
All-terrain vehicle, snowmobile, or watercraft	20	12.8
Bicycling	13	8.3
Sports	6	3.8
Pedestrian versus car	2	1.3
Low-energy fall	9	5.8
Others	3	1.9

Statistical analysis was completed using PASW® version 18 (IBM, Armonk, NY, USA). Descriptive statistics provided percent, range, mean, and median. Chi-square test was used to determine associations based on plate type; Fisher's exact test, to determine comparisons when small ordinal groups existed such as with tobacco use and malunion; Mann–Whitney *U* test, to calculate the comparisons for plate length, working length, lag screws, and cortical screws; and Kruskall-Wallis, to calculate comparisons for OTA/AO classification. Spearman's rho determined correlation between pain and complications. Significance was set at less than 0.05.

Results

Fracture classification for all fractures and primary outcomes is shown in Table 3 and Figure 1. The plate utilization and technical characteristics of fracture fixation based on primary outcome are described in Table 4 and Figure 2. One hundred fifty fractures (96.2%) healed radiographically within 3 months of follow-up. Six of 156 (3.8%) fractures resulted in a nonunion (Figure 3). None of those fractures were open. Four of 39 (10.3%) tobacco users had nonunions as compared to 2 of 116 (1.7%) nontobacco users ($p = 0.035$). Two (one angulation and one translation) of 156 (1.3%) fractures, both treated with recon plates, were

Table 3 Comparison of OTA/AO classification for all fractures and primary outcomes

OTA/AO classification	Recon 71, 45.5%	DCP85, 54.5%	*p* value
All fractures[a]			
B1	35, 49.3%	34, 40.0%	
B2	27, 38.0%	36, 42.4%	0.371
B3	8, 11.3%	15, 17.6%	
United fractures[a]			
B1	31, 49.2%	33, 39.3%	
B2	24, 38.1%	36, 42.9%	0.446
B3	8, 12.7%	15, 17.9%	
Nonunion			
B1	3, 60.0%	1, 100%	
B2	2, 40.0%	0	0.480
B3	0	0	
Malunion			
B1	1, 50%	0	
B2	1, 50%	0	UA
B3	0	0	
Implant failure[a]			
B1	4, 66.7%	1, 100%	
B2	2, 33.3%	0	0.714
B3	0	0	

[a]One fracture was unclassifiable secondary to transfer and lack of preoperative radiographs. UA, unable to assess; none in comparator group.

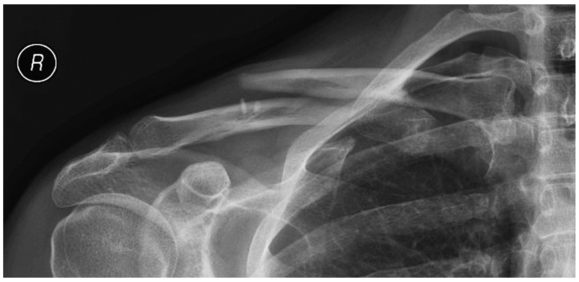

Figure 1 A 15 type B1 fracture. This 15 type B1 fracture occurred in a 55-year-old nonsmoking male with no comorbidities after falling from his bicycle. He underwent ORIF due to concerns of impending skin compromise.

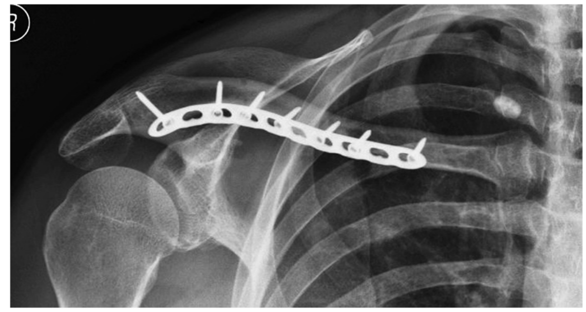

Figure 2 The patient from Figure 1 status post ORIF. Fixation was performed with a ten-hole locked DCP, seven cortical screws, and a working length of one hole adjacent to the fracture site. No surgical complications and good clinical outcomes were observed.

classified as a malunion (Figure 4). None of those fractures were open, and no malunions were associated with pain or necessitated implant removal. Details of nonunion and malunion cases are displayed in Table 5. Implant failure occurred in 7 of 156 fractures (4.5%; 4 in nonunions, 2 in malunions, and 1 in a union). The implant failure observed in the dynamic compression plate (DCP) was the united fracture. The patient sustained a large axial load which resulted in a new clavicular fracture adjacent to the healed fracture with subsequent plate deformation.

Table 4 Technical characteristics of all fractures and primary outcomes

	Recon	DCP	*p* value
All fractures	71, 45.5%	85, 54.5%	
Displacement (mm)[a]	14.4 ± 7.4 (0 to 39)	16.7 ± 8.4 (0 to 36)	0.106
Plate length[b] (holes)	12 (8 to 16)	12 (6 to 12)	<0.001
Working length[b] (holes)	1 (0 to 5)	1 (0 to 4)	0.184
Cortical screws used[b]	8 (6 to 12)	8 (5 to 10)	0.001
Lag screws used[b]	1 (0 to 3)	1 (0 to 4)	0.298
United fractures	64, 90.1%	84, 98.8%	0.014
Plate length (holes)	12 (8 to 16)	12 (6 to 12)	<0.001
Working length (holes)	2 (0 to 5)	1 (0 to 4)	0.123
Lag screws used	1 (0 to 3)	1 (0 to 4)	0.501
Nonunion	5, 7.0%	1, 1.2%	0.058
Plate length (holes)	14 (10 to 16)	10	0.228
Working length (holes)	1 (0 to 3)	3	0.206
Lags screws used	0 (0 to 2)	1	0.299
Malunion	2, 2.8%	0, 0%	0.119
Plate length (holes)	14 (12 to 16)		UA
Working length (holes)	2.5 (1.4)		UA
Lags screws used	0.5 (0 to 1)		UA
Implant failure	6, 8.5%	1, 1.2%	0.029
Plate length (holes)	14 (10 to 16)	10	0.190
Working length (holes)	1 (0 to 4)	0	0.190
Lags screws used	0.5 (0 to 2)	1	0.589

[a]Statistics are reported as the mean ± standard deviation (range); [b]statistics are reported as the median (range). UA, unable to assess; none in comparator group.

Postoperative ROM averaged 170.9° of forward flexion (range, 70° to 180°) and 168.4° of abduction (range, 70° to 180°). Eight of the 14 patients (57.1%) had associated injuries. At the last follow-up visit, 107 (68.6%) patients did not report any pain and pain was not associated with associated injuries ($p = 0.186$) (Table 6). Pain did occur more often in those that had implant removal ($p < 0.001$). Fourteen of 156 fractures (9.0%) had implant removal for skin irritation (7.7%) or prominence (1.3%) (Table 7), but removal was not due to plate type (9/71, 12.7% recon vs. 11/85, 12.9% DCP, $p = 0.961$). Twelve of the 14 (85.7%) patients stated pain improvement with implant removal, but 2 of 14 (14.3%) patients claimed continued pain despite removal. There were no infections or re-fractures associated with implant removal.

Discussion

In many prior studies, clavicular shaft fractures were mainly treated nonoperatively [22-24]. A growing body of evidence

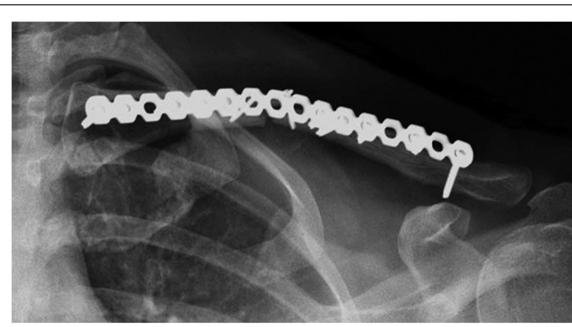

Figure 3 This 49-year-old nonsmoking female sustained a 15 type B2 fracture in a MVA. A nonunion occurred after ORIF with a recon plate. The nonunion and pain improved after surgical revision.

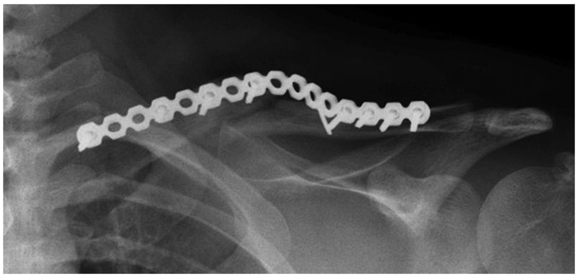

Figure 4 Development of a malunion. This patient was a 29-year-old male who sustained a 15 type B2 fracture after falling 10 ft from a ladder. An angulation malunion occurred after ORIF with a recon plate. He declined revision surgery, callus formation developed, and bony healing eventually occurred.

supports earlier and more predictable results with operative reduction and stabilization of unstable diaphyseal clavicular fractures [2,3]. Modern plate fixation techniques provide reliable healing rates. However, optimal plate position, size, and type remain controversial.

The clavicle contour and anatomy is curved in multiple planes. The recon plate is easier to contour in all planes than the stiffer DCP, which allows bending only along the length of the plate. For superior plating, a recon plate or precontoured plate can fit the 'S'-shaped anatomy more precisely. For anteroinferior plating, the DCP or the recon can be bent to conform to the anatomy very well. Previous biomechanical studies have shown that the DCP demonstrated greater resistance to bending and torque stressors as compared to recon plates [13,14]. This study demonstrated that standard 2.7-mm DCP provides adequate fracture site stability when applied appropriately. Appropriate modern plating techniques entail longer plates (≥10 holes) balanced over the fracture and comminution zone with adequate cortical screw fixation (≥6 cortices) and liberal interfragmentary screw fixation for larger fragments. Dynamic compression plating performs well with extremely low rates of nonunion and implant failure. Despite utilizing modern plating techniques, reconstruction plating does not perform as well as DCPs and are not recommended. In comparison to the 1.69% nonunion rate reported after plate fixation in a recent meta-analysis [25], the 2.7-mm DCP healing rates employing modern techniques should produce similar healing and low nonunion rates as exhibited by 1.2% in this study.

Table 6 Reported pain at final follow-up

Pain	Number ($n = 156$)	Percentage of total	Number with associated injuries ($n = 82$)	Percentage with associated injuries
None (VAS 0)	107	68.6	52	63.4
Mild (VAS 1 to 3)	37	23.7	25	30.5
Moderate (VAS 4 to 6)	1	0.6	0	0
Severe (VAS 7 to 10)	11	7.1	5	6.1

VAS, visual analog scale.

The two malunions occurred with recon plates in this study. Even though the recon plate allows for easier plate bending and accommodation, the plate is too pliable for clavicular stabilization and the complex shoulder girdle movements. The increasing stiffness with modern techniques of longer plates and interfragmentary fixation still leaves the recon plate too flexible for predictable stability and healing. Since the outlet view of the clavicle demands the reduction to be straight with apex cephalad angulation, the straight DCP facilitates initial reduction and final healing in this plane. The recon plate does not resist plastic apex angular deformation with time. Obese patients had a higher rate of clavicular malunions than smaller patients. We cannot fully explain this result except that obese patients may require the use of the upper extremities for mobility [26].

Robinson reported an incidence of 15/100,000 displaced or comminuted midshaft clavicle fractures per year [27]. Studies have reported implant removal rates of 9% to 64% [4-6], and our study resulted in a similar low removal rate of 9.0%. Based on Robinson's rate, this would result in an additional 1.5/100,000 surgical procedures per year

Table 5 Characteristics of malunion and nonunions

	Gender	Age	Tobacco use	Mechanism of injury	OTA classification	Plate type	Number of holes/working length/cortical screws/lag screws
Malunion	Male	29	Past	High-energy fall	15 Type B2	Recon	16/4/8/1
	Male	34	No	MCA	15 Type B1	Recon	12/1/7/0
Nonunion	Male	39	Current	ATV	15 Type B2	Recon	12/1/8/0
	Female	59	Current	MCA	15 Type B1	Recon	14/1/9/0
	Female	47	No	MVA	15 Type B2	Recon	16/3/10/2
	Female	47	Current	MVA	15 Type B1	Recon	10/0/6/0
	Female	19	Past	Low-energy fall	15 Type B1	Recon	14/1/9/0
	Male	32	Current	MVA	15 Type B1	DCP	10/3/6/1

MCA, motorcycle accident; ATV, all-terrain vehicle; MVA, motor vehicle accident.

Table 7 Reasons for implant removal

Reason for implant removal	Number	Percentage	Recon	DCP
Skin/soft tissue irritation	12	7.7	5	7
Prominence	2	1.3	0	2
Other[a]	1	0.6	0	1

[a]Implant failure after union that resulted in a new fracture.

as compared to a maximum of 10/100,000 at 64% removal. Only one patient had a prominent implant and a lateral plate end that could have potentially been avoided with improved plate alignment or centrally applying the plate to the bone over the fracture and at either end. Preliminary fixation at both ends of the plate and outlet imaging optimize plate positioning and lessen prominence.

The major limitation of this study is its retrospective design. With a high number of patients excluded secondary to less than 3 months follow-up, there is a potential for selection bias. Varying associated shoulder girdle injuries could influence clavicular fixation stability, therapy intervention, and persistent pain. The strengths of this study are related to a large consecutive series of acute clavicular midshaft fractures operated with similar plating techniques and philosophies. Nevertheless, despite being a relatively large series, there were insufficient numbers to statistically confirm inferior results of nonunion and malunion in recon plates compared to DCP. Even though larger series would potentially confirm this, we would not recommend utilizing anteroinferior recon plates. Modern fracture fixation techniques were utilized. Despite not having greater than 1 year follow-up in all patients, they were followed until fracture healing was complete, return to function was demonstrated, and plate irritation was stabilized. Unnecessary office visits and radiographic imaging are costly and not warranted.

Conclusions

Anteroinferior clavicular fracture fixation with 2.7-mm dynamic compression plates results in excellent healing rates with removal rates consistent with the lower end of the range in published literature. Given higher rates of failure, 2.7-mm reconstruction plates should be discouraged in comparison to stiffer and more reliable 2.7-mm dynamic compression plates.

Competing interests

The authors do not have any interest that might be interpreted as influencing the research, and ethical standards were followed in the conduct and dissemination of the study. The authors did not receive grants or outside funding in support of their research or preparation of the manuscript.

Authors' contributions

AKG participated in the conception and design of the study, performed the data acquisition, and drafted the manuscript. DLS participated in the conception of the study and performed the statistical analysis. CBJ and MFH participated in the conception and design of the study, provided administrative support, and supervision of the study. All authors carried out the critical revision of the manuscript, read and approved the final manuscript.

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