Dual Mini-Fragment Plating Is Comparable With Precontoured Small Fragment Plating for Operative Diaphyseal Clavicle Fractures: A Retrospective Cohort Study

Malcolm R. DeBaun, MD, Michael J. Chen, MD, Sean T. Campbell, L. Henry Goodnough, MD, PhD, Cara Lai, BS, Brett P. Salazar, Julius A. Bishop, MD, and Michael J. Gardner, MD

Objectives: To compare precontoured (Pc) small fragment plating to dual mini-fragment plating (DmF) for open reduction and internal fixation of diaphyseal clavicle fractures.

Design: Retrospective cohort.

Setting: Level 1 trauma center.

Patients/Participants: A total of 133 patients with displaced fractures of the diaphyseal clavicle (OTA/AO 15-B1, -2, and -3) treated with open reduction and internal fixation with a minimum of 1 year follow-up or until radiographic and clinical union.

Intervention: Two patient cohorts were identified: (1) patients treated with orthogonal DmF plate constructs and (2) patients treated with Pc clavicle-specific plates.

Outcome Measurements: Union rate and implant removal were assessed using standard descriptive statistics. Odds ratios, 95% confidence intervals, and *P* values (*P*) were calculated.

Results: There were 60 DmF and 74 Pc patients. There were no significant differences between groups with respect to age, sex, surgeon, body mass index, or mode of fixation. There was no significant difference in union (98.3% DmF; 100% Pc, $P = 0.45$) or maintenance of reduction (98.3% DmF; 100% Pc, $P = 0.45$). A total of 8% of DmF patients had symptomatic implant removal compared with 20% of Pc patients (odds ratio 0.36, confidence interval 0.12–1.05, $P = 0.061$).

Conclusions: This retrospective comparative study found no difference in union or maintenance of reduction for diaphyseal clavicle fractures fixed with DmF compared with Pc plating. Patients treated with DmF plates may have lower rates of symptomatic implant removal.

Key Words: clavicle fracture, mini-fragment, dual plate fixation, precontoured

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

(*J Orthop Trauma* 2020;34:e229–e232)

INTRODUCTION

The ideal construct for fixation of a diaphyseal clavicle fracture is of interest to orthopaedic surgeons.[1] Symptomatic implant removal after fracture healing is common given the subcutaneous location of the clavicle.[2,3] Proposed constructs for mitigating this risk include single precontoured (Pc) clavicle-specific plates or intramedullary devices.[3–8] Although standard plating or intramedullary fixation techniques lead to comparable outcome scores, both techniques continue to be associated with high rates of implant-related irritation.[2,9–13] Dual mini-fragment (DmF) plating has recently been suggested to be biomechanically and clinically favorable, resulting in high union rates and excellent clinical outcomes with low rates of secondary surgery for symptomatic implant removal.[14,15] These assertions, however, are based on case series only. Therefore, the goal of this investigation was to directly compare DmF and Pc plating. We hypothesized that DmF plating techniques offer similar primary union rates with lower rates of symptomatic implant removal compared with Pc clavicle-specific plating for treatment of displaced diaphyseal clavicle fractures.

PATIENTS AND METHODS

After institutional review board approval, our institutional research repository was queried for clavicle fractures treated with open reduction and internal fixation using current procedural terminology code 23,515, between years 2009 and 2019 by one of 2 trauma fellowship-trained orthopaedic surgeons. Two patient cohorts were identified: (1) patients treated with mini-fragment constructs consisting of combinations of dual anterior and superior 2.7-, 2.4-, or 2.0-mm straight plates with combination holes for locking and nonlocking screw fixation contoured manually intraoperatively (Figs. 1A, B) and (2) patients treated with a Pc anterior or superior 3.5-mm clavicle-specific plate (Fig. 2). Surgical decision-making with regards to fixation strategy and implant choice was up to the discretion of the treating surgeon. However, all fractures were treated in accordance with standard mechanical principles with a goal of primary bone healing/absolute stability for simple fractures and secondary

Accepted for publication December 18, 2019.
From the Department of Orthopaedic Surgery, Stanford University, Redwood City, CA.
The authors report no conflict of interest.
Reprints: Michael J. Gardner, MD, Department of Orthopaedic Surgery, Stanford University School of Medicine, 450 Broadway St, MC 6342, Redwood City, CA 94063 (e-mail: michaelgardner@stanford.edu).

DOI: 10.1097/BOT.0000000000001727

bone healing/relative stability for comminuted patterns. Lag screws by technique were used when possible. Despite the fact that plates with locking options were used, conventional screws were favored. As a matter of principle, the surgeons do not believe that locking screws are typically necessary in diaphyseal clavicle fractures. All fractures were treated with at least 2 points of fixation on each side of the fracture. Plates were generally on the long side, without a specific formula, but often 2.4-mm plates were in the range of 14–16 holes long. All DmF constructs were treated with a superior recon-style plate to facilitate ease of manual contouring and an anterior strength plate. Postoperative protocols were the same between surgeons. Immediately after surgery, all patients were made non-weightbearing and out of sling for pendulum exercises, with progressive weight bearing starting at 6 weeks postoperatively if signs of clinical and radiographic healing were confirmed. Patients were informed of the risk of symptomatic implants necessitating removal and instructed to return to clinic as needed once fracture union was achieved.

Inclusion criteria were patients with displaced diaphyseal clavicle fractures (OTA/AO 15-B1, -2, and -3) treated with open reduction and internal fixation with a minimum of 1-year follow-up or until radiographic and clinical union.[16] Patients with nonunion repair were excluded. Standard patient demographics, type of fixation, mode of fixation (lag screw and neutralization or bridge or compression plating), removal for implant-related irritation, and major complications requiring revision surgery were extracted retrospectively. All symptomatic implant removal procedures were performed electively after union and based on the patients' request to have the implants removed secondary to soft tissue irritation from the plates confirmed on physical examination.

Primary outcome was the union rate as defined by bridging bone on radiographs and absence of pain or tenderness at the fracture site on clinical examination. Based on previously published union rates to calculate effect size, a power analysis showed that a total of 60 patients in each group were required to have a power of 80%, when alpha was set at 0.05.[17] Categorical and continuous variables were analyzed using the Fisher exact tests and independent *t*-tests, respectively. A logistic regression analysis was performed to determine the odds ratio and 95% confidence interval of implant removal for symptomatic implants between DmF and Pc plating groups. Significance was set at $P < 0.05$.

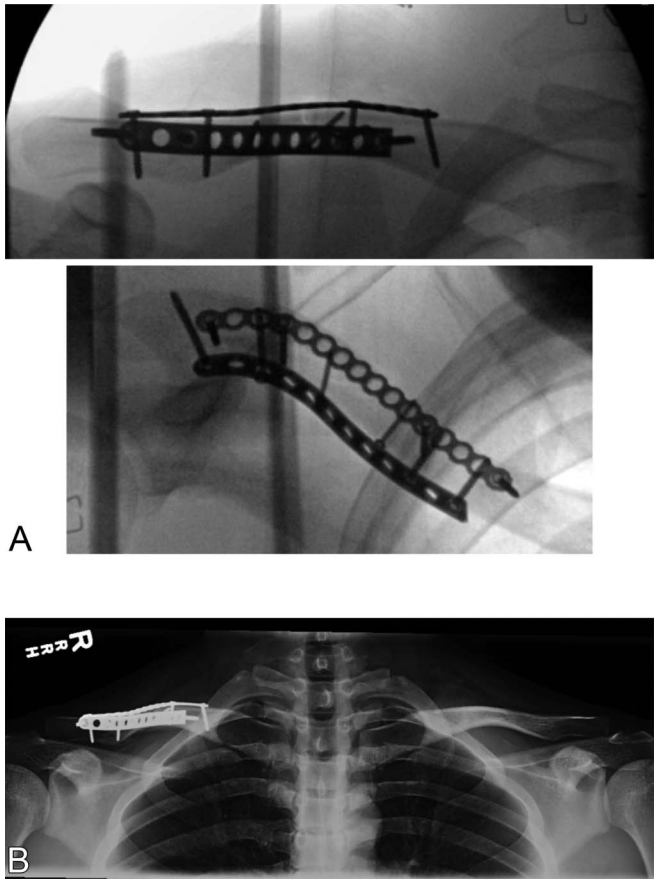

FIGURE 1. A, Orthogonal intraoperative imaging of a patient with a diaphyseal clavicle fracture treated with 2.0-mm lag screws and dual superior 2.4-mm/anterior 2.7-mm mini-fragment plates in neutralization mode. B, Radiograph demonstrating a healed diaphyseal clavicle facture fixed with DmF plating in the same patient.

RESULTS

For our primary outcome, there was no significant difference in the union rate (98.3% DmF vs. 100% Pc plating, $P = 0.45$). No difference was found for maintenance of reduction and fixation (98.3% DmF vs. 100% Pc plating, $P = 0.45$) between groups. Of the 60 patients treated with DmF, 5 patients (8.3%) underwent removal of symptomatic implants compared with 15 patients (20.2%) from the 74 treated with Pc plates ($P = 0.086$ (odds ratio 0.36, confidence interval 0.12–1.05, $P = 0.061$) Table 1).

A total of 133 (78% male) patients with an average age of 44 ± 15 (mean ± SD) years were included in this study. One patient sustained bilateral clavicle fractures at different timepoints, and each fracture was included separately. The average length of follow-up was 36 weeks (range 12–192 weeks). Patients with less than 1-year follow-up (98 patients)

FIGURE 2. Patient with healed diaphyseal fracture treated with a 3.5-mm precontoured small fragment clavicle-specific plate in bridge mode with locking and nonlocking screw fixation.

TABLE 1. Comparison of Dual Mini-Fragment Plating Versus Single Precontoured Small Fragment Plating for Fixation of Diaphyseal Clavicle Fractures

	DmF	Precontoured	*P*
Total	60	74	
Union without loss of reduction	58 (97%)	74 (100%)	0.45
Nonunion	1 (98%)	0	0.45
Loss of reduction/fixation	1 (98%)	0	0.45
Heterotopic ossification	1 (98%)	0	0.45
Removal of symptomatic implants	5 (8%)	15 (20%)	0.08
Precontoured plate location			
Superior		14 (19%)	
Anterior		60 (81%)	
Mini-fragment plate configuration			
S2.0, A2.4	5 (8%)		
S2.4, A2.4	14 (23%)		
S2.4, A2.7	8 (13%)		
S2.7, A2.4	31 (52%)		
S2.7, A2.7	2 (3%)		

had either fully healed fractures or sustained a complication requiring reoperation. There were no significant differences between plating groups with respect to age, sex, surgeon, body mass index, or mode of fixation (Table 2). In the DmF group, there was 1 patient with a nonunion, 1 patient with fixation failure requiring revision surgery, and 1 patient who underwent excision of heterotopic bone. There were no complications in the Pc group.

DISCUSSION

Although nonoperative treatment of displaced diaphyseal clavicle fractures often leads to good outcomes, operative treatment is associated with increased union rates, earlier return to work, better function, and may be more cost-effective.[12,17–25] However, implant-related soft tissue irritation with secondary surgery for removal is common using traditional plating and intramedullary nailing techniques.[2,3,9] DmF plates offer a low-profile alternative for fixation, and this retrospective study found no difference in union or implant failure rates as compared with a Pc small-fragment clavicle plate. There was a trend toward lower rates of implant removal in the DmF group (8% vs. 20% Pc). Surgeons can consider DmF plate fixation as an effective and viable lower profile alternative to Pc small-fragment clavicle plating.

Dual plating is becoming more popular for definitive fixation for various locations such as the humerus, distal femur, and proximal tibia among others.[26–30] Dual plating of the clavicle has also been advocated both for fixation of acute injures as well as management of nonunion.[31–33] In a clinical and biomechanical evaluation, Prasarn et al[14] first introduced the concept of DmF plating of acute midshaft clavicle fractures. In their study, a superior 2.7-mm reconstruction plate paired with an anterior 2.4-mm locking compression plate demonstrated biomechanical comparability to a single anterior or superior 3.5-mm locking reconstruction plate. Seventeen patients with displaced midshaft clavicle fractures were treated with the aforementioned DmF plate construct, and all demonstrated maintained reduction to union without subsequent implant removal over the 1-year follow-up. Another study demonstrated low rates of symptomatic implant removal (4%) in 81 clavicle shaft fractures treated with the same DmF plate construct.[15] Chen et al[34] were the first to demonstrate efficacy with respect to union of dual plating for acute clavicle fractures compared with single plating. However, their study did not provide construct details, although relatively thick 2.7-mm pelvic reconstruction plates placed anteriorly were mentioned.

Multiple combinations of mini-fragment plates were used in our series (Table 2). Although this study was not powered to compare different mini-fragment constructs, the only fixation failure was in a patient treated with a superior 2.7-mm and anterior 2.4-mm plate. There were 19 patients (32%) treated with only 2.4-mm or smaller DmF plates. All of these patients in this subgroup healed uneventfully without fixation failures or loss of reduction. Further study may consider the safety and efficacy of DmF plating for diaphyseal clavicle fractures using only plate sizes smaller than 2.7 mm to further reduce prominence. It has been our observation that dual 2.4-mm plates would provide adequate fixation for diaphyseal clavicle fractures, and these plates are lower profile than 2.7-mm plates, which would likely lead to lower removal plates.

This study was retrospective and therefore vulnerable to inherent bias. Furthermore, patients were operated on by only 2 surgeons, both fellowship trained in orthopaedic trauma with extensive experience with manual plate contouring. As such, our results may not be generalizable. In addition, there were no intraoperative complications related to vascular or pulmonary injury in our cohort. Awareness of implant position in relation to vulnerable anatomy and atraumatic drilling technique, however, should be emphasized when plating clavicles.

Although DmF plating displayed a lower rate of implant removal compared with Pc plating, the difference was not statistically significant. We suspect that low-profile DmF constructs do lead to lower rates of symptomatic implant removal,

TABLE 2. Patient Demographics, Surgeon of Record, and Fixation Strategy

	DmF	Precontoured	*P*
Age (mean ± SD)	44 ± 16	44 ± 14	1
Sex			0.22
Male	43	60	
Female	17	14	
BMI	25 ± 4.3	24 ± 3.3	0.54
Surgeon of record			0.61
Surgeon A	50	65	
Surgeon B	9	9	
Fixation strategy			0.16
Lag/neutralize	27	39	
Bridge	25	32	
Compression	8	3	

BMI, body mass index.

but our study was underpowered to detect this difference (130 patients in each group would be needed). Our aim was to compare removal rates between constructs without significant treatment bias secondary to surgeon preference. We are reassured that there was no significant difference in construct choice between surgeon despite the data suggesting different removal rates depending on plating choice. There was no defined or discernible temporal cutoff between fixation constructs over the study period. Anecdotally, however, DmF plating became the more popular choice as of recent. Also, cost-effectiveness comparatively between treatment groups was outside of the scope of this study but should be considered, especially when taking in to account the differential rate of secondary procedures for implant removal. Finally, our follow-up was not adequate to investigate functional outcome differences between treatment groups, given most patients who healed only followed up as needed. However, we did have sufficient follow-up to confirm uneventful fracture union.

In conclusion, this retrospective study found no difference in rates of union or complications between DmF and Pc plating of diaphyseal clavicle fractures. Patients treated with DmF plates may have lower rates of symptomatic implant removal. Additional prospective research is warranted to better understand the efficacy of DmF as compared with Pc plating of the clavicle.

REFERENCES

1. Wiesel B, Nagda S, Mehta S, et al. Management of midshaft clavicle fractures in adults. *J Am Acad Orthop Surg.* 2018;26:e468–e476.
2. Ashman BD, Slobogean GP, Stone TB, et al. Reoperation following open reduction and plate fixation of displaced mid-shaft clavicle fractures. *Injury.* 2014;45:1549–1553.
3. Schemitsch LA, Schemitsch EH, Kuzyk P, et al. Prognostic factors for reoperation after plate fixation of the midshaft clavicle. *J Orthop Trauma.* 2015;29:533–537.
4. Galdi B, Yoon RS, Choung EW, et al. Anteroinferior 2.7-mm versus 3.5-mm plating for AO/OTA type B clavicle fractures: a comparative cohort clinical outcomes study. *J Orthop Trauma.* 2013;27:121–125.
5. VanBeek C, Boselli KJ, Cadet ER, et al. Precontoured plating of clavicle fractures: decreased hardware-related complications? *Clin Orthop Relat Res.* 2011;469:3337–3343.
6. Fuglesang HFS, Oksum MA, Wikeroy AKB. Mini-Invasive intramedullary fixation of displaced midshaft clavicle fractures with an elastic titanium nail. *JBJS Essent Surg Tech.* 2018;8:e16.
7. Judd DB, Pallis MP, Smith E, et al. Acute operative stabilization versus nonoperative management of clavicle fractures. *Am J Orthop (Belle Mead NJ).* 2009;38:341–345.
8. Mueller M, Rangger C, Striepens N, et al. Minimally invasive intramedullary nailing of midshaft clavicular fractures using titanium elastic nails. *J Trauma.* 2008;64:1528–1534.
9. Hulsmans MH, van Heijl M, Houwert RM, et al. High irritation and removal rates after plate or nail fixation in patients with displaced midshaft clavicle fractures. *Clin Orthop Relat Res.* 2017;475:532–539.
10. Andrade-Silva FB, Kojima KE, Joeris A, et al. Single, superiorly placed reconstruction plate compared with flexible intramedullary nailing for midshaft clavicular fractures: a prospective, randomized controlled trial. *J Bone Joint Surg Am.* 2015;97:620–626.
11. Leroux T, Wasserstein D, Henry P, et al. Rate of and risk factors for reoperations after open reduction and internal fixation of midshaft clavicle fractures: a population-based study in ontario, Canada. *J Bone Joint Surg Am.* 2014;96:1119–1125.
12. Houwert RM, Smeeing DP, Ahmed Ali U, et al. Plate fixation or intramedullary fixation for midshaft clavicle fractures: a systematic review and meta-analysis of randomized controlled trials and observational studies. *J Shoulder Elbow Surg.* 2016;25:1195–1203.
13. Chan G, Korac Z, Miletic M, et al. Plate versus intramedullary fixation of two-part and multifragmentary displaced midshaft clavicle fractures - a long-term analysis. *Injury.* 2017;48(suppl 5):S21–S26.
14. Prasarn ML, Meyers KN, Wilkin G, et al. Dual mini-fragment plating for midshaft clavicle fractures: a clinical and biomechanical investigation. *Arch Orthop Trauma Surg.* 2015;135:1655–1662.
15. Czajka CM, Kay A, Gary JL, et al. Symptomatic implant removal following dual mini-fragment plating for clavicular shaft fractures. *J Orthop Trauma.* 2017;31:236–240.
16. Meinberg EG, Agel J, Roberts CS, et al. Fracture and dislocation classification compendium-2018. *J Orthop Trauma.* 2018;32(suppl 1):S1–S170.
17. Woltz S, Krijnen P, Schipper IB. plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a meta-analysis of randomized controlled trials. *J Bone Joint Surg Am.* 2017;99:1051–1057.
18. Pearson AM, Tosteson AN, Koval KJ, et al. Is surgery for displaced, midshaft clavicle fractures in adults cost-effective? Results based on a multicenter randomized, controlled trial. *J Orthop Trauma.* 2010;24:426–433.
19. Ahrens PM, Garlick NI, Barber J, et al. The clavicle trial: a multicenter randomized controlled trial comparing operative with nonoperative treatment of displaced midshaft clavicle fractures. *J Bone Joint Surg Am.* 2017;99:1345–1354.
20. Woltz S, Stegeman SA, Krijnen P, et al. plate fixation compared with nonoperative treatment for displaced midshaft clavicular fractures: a multicenter randomized controlled trial. *J Bone Joint Surg Am.* 2017;99:106–112.
21. McKee RC, Whelan DB, Schemitsch EH, et al. Operative versus nonoperative care of displaced midshaft clavicular fractures: a meta-analysis of randomized clinical trials. *J Bone Joint Surg Am.* 2012;94:675–684.
22. Canadian Orthopaedic Trauma S. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. *J Bone Joint Surg Am.* 2007;89:1–10.
23. Tamaoki MJS, Matsunaga FT, Costa A, et al. Treatment of displaced midshaft clavicle fractures: figure-of-eight harness versus anterior plate osteosynthesis: a randomized controlled trial. *J Bone Joint Surg Am.* 2017;99:1159–1165.
24. Xu J, Xu L, Xu W, et al. Operative versus nonoperative treatment in the management of midshaft clavicular fractures: a meta-analysis of randomized controlled trials. *J Shoulder Elbow Surg.* 2014;23:173–181.
25. Guerra E, Previtali D, Tamborini S, et al. Midshaft clavicle fractures: surgery provides better results as compared with nonoperative treatment: a meta-analysis. *Am J Sports Med.* 2019:47:3541–3551.
26. Higgins TF, Klatt J, Bachus KN. Biomechanical analysis of bicondylar tibial plateau fixation: how does lateral locking plate fixation compare to dual plate fixation?. *J Orthop Trauma.* 2007;21:301–306.
27. Prasarn ML, Ahn J, Paul O, et al. Dual plating for fractures of the distal third of the humeral shaft. *J Orthop Trauma.* 2011;25:57–63.
28. Steinberg EL, Elis J, Steinberg Y, et al. A double-plating approach to distal femur fracture: a clinical study. *Injury.* 2017;48:2260–2265.
29. Rollick NC, Bear J, Diamond O, et al. Orthogonal plating with a 95-degree blade plate for salvage of unsuccessful cephalomedullary nailing of atypic femur fractures: a technical trick. *J Orthop Trauma.* 2019;33:e246–e250.
30. Vance DD, Vosseller JT. Double plating of distal fibula fractures. *Foot Ankle Spec.* 2017;10:543–546.
31. Suter C, von Rohr M, Majewski M, et al. A biomechanical comparison of two plating techniques in lateral clavicle fractures. *Clin Biomech (Bristol, Avon).* 2019;67:78–84.
32. Shannon SF, Chen X, Torchia M, et al. Extraperiosteal dual plate fixation of acute mid-shaft clavicle fractures: a technical trick. *J Orthop Trauma.* 2016;30:e346–350.
33. Sadiq S, Waseem M, Peravalli B, et al. Single or double plating for nonunion of the clavicle. *Acta Orthop Belg.* 2001;67:354–360.
34. Chen X, Shannon SF, Torchia M, et al. Radiographic outcomes of single versus dual plate fixation of acute mid-shaft clavicle fractures. *Arch Orthop Trauma Surg.* 2017;137:749–754.