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Dual Versus Single-Plate Fixation of Midshaft Clavicular Fractures

A Retrospective Comparative Study

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Background: Implant-related symptoms are the most common reason for reoperation after open reduction and internal fixation (ORIF) of midshaft clavicular fractures. Dual mini-fragment plate fixation is a relatively new solution that may decrease implant prominence while maintaining fixation strength and function. There are minimal published data comparing reoperation rates and clinical outcomes between single, superior-plate constructs and dual mini-fragment plate constructs in the fixation of midshaft clavicular fractures. We hypothesized that reducing plate size with the use of dual mini-fragment plating compared with standard, 3.5-mm, superior plating would minimize implant symptoms and the corresponding need for reoperation while still providing sufficient fixation to allow fracture-healing and return to function.

Methods: We retrospectively reviewed the cases of 44 consecutive patients who underwent ORIF of displaced midshaft clavicular fractures utilizing either a single, 3.5-mm, superior plate construct (21 patients) or a dual, 2.7-mm and 2.4-mm, plate construct (23 patients). Outcomes at a minimum of 2 years were assessed. Primary outcome measures included reoperation for any reason and the American Shoulder and Elbow Surgeons (ASES) Standardized Shoulder Assessment Form, patient self-report section.

Results: There was a 100% union rate in both groups. None (0%) of the 23 patients who received the dual (2.7-mm and 2.4-mm) plate construct and 6 (29%) of the 21 patients who received the single (3.5-mm) plate construct underwent reoperation for implant-related symptoms. Using a Fisher exact test, the rate of reoperation was compared between the groups, and the difference was found to be significant (p = 0.008). Using an unpaired t test, the difference in mean ASES scores was not significant (p = 0.138) between the dual-plate group (98 of 100) and the single superior plate group (96 of 100) with retained implants.

Conclusions: In our comparative retrospective series, dual fixation utilizing a 2.7-mm superior plate and a 2.4-mm anterior plate for the treatment of displaced midshaft clavicular fractures was associated with a significantly lower rate of reoperation when compared with single, 3.5-mm, superior plate fixation.

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

pen reduction and internal fixation (ORIF) of completely displaced midshaft clavicular fractures has been shown to reduce the rates of nonunion and symptomatic malunion and provide an earlier improvement in patient-reported outcomes for shoulder function^{1,2}. The traditional technique for ORIF of these fractures is a single, superiorly or anteriorly placed, 3.5-mm compression plate³. These plates are often very prominent under the skin, and their use has an associated rate of reoperation of 8.1% to 53%,

primarily for implant-related symptoms^{1,4-8}. In the literature, solutions for reducing plate prominence have included superior plating with use of a precontoured, 3.5-mm implant^{9,10} and anteroinferior plating with use of a 2.7-mm implant¹¹⁻¹³. In 2015, Prasarn et al. reported on a dual, mini-fragment plating solution that may further minimize implant prominence¹⁴; however, there are limited data comparing traditional single, 3.5-mm, superior plating and dual mini-fragment plating.

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The purpose of the current study was to retrospectively compare the patient-reported outcomes and rate of implant removal between patients undergoing fixation with a single, superior plate and dual plating for completely displaced clavicular fractures. We hypothesized that reducing plate size with dual mini-fragment plating would minimize implant-related symptoms and the corresponding need for reoperation while still providing excellent fixation to allow fracture-healing and return to function.

Materials and Methods

 \mathbf{I} nstitutional review board approval was obtained before the commencement of this study. This study was designed as a retrospective comparative clinical review and outcome analysis. We identified all consecutive patients with displaced midshaft clavicular fractures (OTA/AO fracture classification, type 15.215) who presented to 1 of 3 fellowship-trained orthopaedic trauma surgeons in a university hospital setting and elected to undergo operative treatment during the period of January 1, 2010, to June 30, 2013. We then excluded from the study patients with the following: pathologic fracture, a duration of >12 weeks from initial injury to presentation, and concurrent ipsilateral distal or proximal clavicular fracture. Forty-four consecutive patients met the inclusion criteria. Twenty-one patients underwent ORIF utilizing a single, 3.5-mm stainless steel plate construct placed superiorly. Among this group, a precontoured clavicular locking compression plate (LCP Superior or Superior Anterior Clavicle Plate; Synthes), in sizes from 6 to 8 holes (85 to 120 mm in length), were used for 20 of the 21 patients. One patient required a 10-hole, 140-mm LCP Reconstruction Plate (Synthes) because of the length of the fracture. Twenty-three patients underwent ORIF utilizing a dual-plate construct consisting of a 12-hole (97 mm in length), 2.7-mm LCP Reconstruction Plate (Synthes) superiorly and an 8-hole (68 mm in length) or 10-hole (84 mm in length), 2.4-mm LCP Plate (Synthes) anteriorly.

The average age in the single-plate cohort was 36 years (range, 16 to 72 years). The average age in the dual-plate cohort was also 36 years (range, 21 to 69 years). Demographics, comorbidities, and mechanism of injury were equivalent between the 2 groups, with the dual-plate group having slightly more fractures with a higher-energy mechanism of injury. Nineteen (90%) of the 21 patients who underwent single-plate fixation either were available for follow up at a minimum of 24 months postoperatively or had undergone implant removal at the time of this study. Twenty-three (100%) of the 23 patients who underwent dual-plate fixation were available for follow-up at a minimum of 2 years postoperatively. Two patients in the single-plate group were ultimately lost to extended follow-up, although they were seen in the immediate postoperative period. The average follow-up for those in the single-plate group who did not undergo implant removal and were not lost to follow-up was 55 months (range, 36 to 75 months). The average follow-up in the dual-plate group was 35 months (range, 26 to 56 months).

The primary end point of the study was reoperation for any reason, including, but not limited to, implant-related symptoms, nonunion, wound problems, and infection. Clinical outcomes

were measured using the American Shoulder and Elbow Surgeons (ASES) Standardized Shoulder Assessment Form, patient self-report section, which has been independently validated as a reliable measure of postoperative functional outcomes¹⁶. This survey was administered to the cohorts at a minimum of 24 months postoperatively. A clinical chart and radiographic review was conducted for all patients.

Statistical Analysis

A Fisher exact test was used to compare the rate of reoperation between the 2 cohorts. An unpaired t test was used to compare the ASES survey results between the 2 groups. Multivariate logistic regression was used to evaluate the data for possible confounding factors, including operative side, plate length, patient age, sex, body mass index (BMI), occupation (active laborer versus sedentary job), and tobacco-use status. Post-hoc power analysis was then used to confirm that the study was adequately powered.

Plating Procedures

The fixation construct was determined by the operating surgeon. Single superior-plate fixation was used by all 3 fellowship-trained trauma surgeons. One surgeon performed all of the dual-plate fixation cases. A longitudinal incision over the anterosuperior border of the clavicle with the creation of a superior full-thickness flap (superior plating) or anterior and superior full-thickness flaps (dual plating) was utilized for exposure. After all excess hematoma and debris were removed, pointed reduction clamps and 1.6-mm Kirschner wires were used to hold the reductions. For the dual-plate cohort, a 2.7-mm reconstruction plate was contoured to the superior border of the clavicle and applied in compression mode when possible. A 2.4-mm LCP was then contoured to the anterior surface of the clavicle and secured with multiple cortical screws over the lateral aspect, followed by medial screws in compression mode when possible (Fig. 1). For the single-plate cohort, following fracture reduction, a 3.5-mm precontoured clavicular LCP was typically applied in compression mode with 3.5-mm cortical screws. For both fixation constructs, butterfly fragments were lagged utilizing 2.7-mm or 2.4-mm cortical screws. The wounds were then irrigated and closed in layers using interrupted absorbable sutures followed by a subcutaneous running absorbable suture.



Fig. 1

Anteroposterior radiograph of a right clavicle demonstrating dual-plate fixation of the clavicular fracture.

For both fixation techniques, early shoulder range of motion postoperatively was encouraged. Weight-bearing was advanced according to patient symptomatology and radiographic findings. Typically, patients were released to weight-bear as tolerated in the affected limb at 6 weeks postoperatively.

Results

Porty-four patients were included in this study. Twenty-one patients underwent ORIF utilizing a single, 3.5-mm, superior plate construct (Table I). Twenty-three patients underwent ORIF utilizing a dual, 2.7-mm superior and 2.4-mm anterior, plate construct (Table II). In the single-plate cohort, there were 7 reoperations in 6 (29%) of the patients as assessed at a minimum of 24 months of clinical follow-up. Among those who underwent implant removal in the single-plate group, the average time to removal was 19 months. Five patients underwent reoperation for removal due to implant-related symptoms. One patient underwent reoperation for wound infection, followed by removal of the implant after fracture union. In the dual-plate cohort, there were no reoperations for any reason, as assessed at a minimum of 24 months of clinical follow-up.

Using a Fisher exact test, the rate of reoperation was compared between the plating groups, and the difference was found to be significant (p = 0.008). ASES surveys were completed by 96% (22 of 23) of the patients in the dual-plate group and 87% (13 of 15) of the patients in the single-plate arm who did not undergo implant removal. The average ASES score in the dual-plate cohort was 98 of 100. The average ASES score in the single-plate cohort was 96 of 100. ASES scores were compared between the 2 groups using an unpaired t test, and the difference in means was not significant (p = 0.1376). Post-hoc power analysis with an alpha of 0.05 demonstrated a power of 80% for this study. Multivariate logistic regression analysis was conducted to evaluate for possible confounding factors influencing plate removal utilizing the R programming language and RStudio Cloud (R Core Team [2019]; R Foundation for Statistical Computing). Both the single-plate group and the full study population were separately analyzed, and no confounding factors were identified either in the single-plate group alone or in the study population as a whole. Specific possible confounders analyzed in the single-plate group alone included age (p = 0.385), sex (p = 0.273), BMI (p = 0.381), plate length (p = 0.385)0.161), side (right versus left) (p = 0.603), tobacco-use status (p = 0.941), and occupation (p = 0.996). Specific possible confounders analyzed for the study population as a whole also included age (p = 0.366), sex (p = 0.611), BMI (p = 0.492), plate length (p = 0.223), side (right versus left) (p = 0.714), tobacco-use status (p = 0.804), and occupation (p = 0.994).

Complications in the 3.5-mm, single-plate cohort were limited to 1 wound infection requiring reoperation (complication rate of 4.8%). Complications in the dual-plate cohort were limited to 1 intraoperative subclavian vein laceration (complication rate of 4.3%). The laceration was sustained during the approach to the superior surface of the clavicle. Rapid hemostasis was obtained by the attending orthopaedic trauma surgeon, and the laceration was repaired intraoperatively with a

single stitch by a vascular surgeon. The ORIF was then completed. The patient required no further treatment and had no reoperations or clinically notable sequelae at 35 months of follow-up.

Discussion

RIF of completely displaced midshaft clavicular fractures has been shown to reduce the rate of nonunion and symptomatic malunion and provide earlier improvement in patient-reported outcomes for shoulder function^{1,2}. Despite these benefits, operative treatment of clavicular fractures with single-plating techniques has a reported reoperation rate of 8.1% to 53%^{1,4-8}. Dual-plate fixation is a novel solution that may reduce implant prominence while maintaining fixation strength and function¹⁴.

The literature demonstrates variable rates of reoperation with single-plating techniques. In the landmark study by the Canadian Orthopaedic Trauma Society, 14.5% of patients required reoperation within 1 year of surgery1. Other studies have demonstrated significantly higher rates of reoperation for superior plates: Singh et al. reported an implant removal rate of 42.9%17, while Ferran et al. reported an implant removal rate of 53% at a minimum of 1 year of follow-up¹⁸. Ashman et al. looked specifically at reoperation rates for superiorly placed precontoured and limited-contact dynamic compression plates (DCPs). They reported a 17% reoperation rate for implant-related symptoms and a 20% reoperation rate for all causes at a minimum of 1 year of follow-up⁹. In a large database study of 1,350 patients undergoing operative treatment of midshaft clavicular fractures in the Ontario Health Insurance Plan, Leroux et al. found a total reoperation rate of 24.6% for all causes and 18.8% for removal due to implant-related symptoms within 2 years of the index surgery¹⁹. Solutions for reducing single-plate prominence have included precontoured, 3.5-mm superior plating and anteroinferior plating using a 2.7-mm DCP. VanBeek et al. retrospectively compared precontoured with standard 3.5-mm plating and found that precontoured plating was associated with a reduction in the rate of reoperation for implant-related symptoms from >20% to 10% at 1 year of follow-up²⁰. Naimark et al. reported similar results with the initiation of precontoured plating¹⁰.

Anteroinferior plating has been shown in studies to provide minimal implant irritation while still providing fracture fixation. Most studies of anteroinferior plating thus far have used 2.7-mm reconstruction plates or DCPs anteriorly. Gilde et al. compared the use of 2.7-mm anteroinferior DCPs with use of 2.7-mm reconstruction plates and found no significant difference in the rate of implant removal; however, the authors noted an increased risk of implant failure for 2.7-mm reconstruction plating. Their published removal rate was 8.9% at a minimum follow-up of 3 months and average follow-up of 9 months¹². Galdi et al. compared 2.7-mm anteroinferior plating and 3.5mm superior plating and found no significant difference in the rate of reoperation for implant-related symptoms, although anteroinferior plating trended toward a lower rate of reoperation, with an unspecified time of follow-up¹¹. Jones et al. reported a 2.3% rate of reoperation for implant-related

Preop. Fracture Displacement	Fracture Classification (OTA/AO)	Implant	Postop. Follow-up <i>(mo)</i>	Reoperation	Complication	ASES Score (of 100)
300%	15.2A	6-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	23	Removal for implant-related symptoms	None	Implant remove
150%	15.2A	6-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	Lost to follow-up	No	None	Lost to follow-u
100%	15.2A	6-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	72	No	None	100
Preop. images not available	Preop. images not available	6-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	23	Removal for implant-related symptoms	None	Implant remove
150%	15.2B	6-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	57	No	None	84
110%	15.2B	6-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	37	Removal for implant-related symptoms	None	Implant remove
200%	15.2C	6 hole, 3.5-mm precontoured LCP Superior Clavicle Plate	62	No	None	100
Preop. images not available	Preop. images not available	6-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	55	No	None	80
250%	15.2B	6-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	72	No	None	90
260%	15.2B	10-hole, 3.5-mm LCP Reconstruction Plate	36	No	None	98
160%	15.2B	7-hole, 3.5-mm precontoured LCP Superior Clavicle Plate with lateral extension	Lost to follow-up	No	None	Lost to follow-u
100%	15.2C	7-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	71	No	None	100
100%	15.2A	7-hole, 3.5-mm precontoured LCP Superior Anterior Clavicle Plate	16	Removal for implant-related symptoms	None	Implant remove
200%	15.2A	7-hole, 3.5-mm precontoured LCP Superior Anterior Clavicle Plate	75	No	None	100
300%	15.2A	7-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	6	Removal for implant-related symptoms	None	Implant remove
140%	15.2C	7-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	48	No	None	100
Preop. images not available	Preop. images not available	7-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	12	Irrigation and debridement, and implant removal	Wound infection	Implant remove
100%	15.2A	8-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	57	No	None	96
100%	15.2B	8-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	36	No	None	98
90%	15.2B	8-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	39	No	None	100
180%	15.2C	8-hole, 3.5-mm precontoured LCP Superior Clavicle Plate	38	No	None	100

Preop. Radiographic racture Displacement	Fracture Classification (OTA/AO)	Implants/Fixation Construct	Postop. Follow-up (mo)	Reoperation	Complication	ASES Score (of 10
298%	15.2B	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	43	No	None	100
285%	15.2A	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	35	No	None	87
280%	15.2A	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	29	No	None	100
250%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	32	No	None	100
200%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	47	No	None	100
200%	15.2A	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	41	No	None	100
200%	15.2A	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	39	No	None	97
200%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	33	No	None	100
200%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	32	No	None	98
200%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	26	No	None	99
188%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	46	No	None	100
164%	15.2A	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	26	No	None	100
158%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	55	No	None	100
158%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	35	No	Subclavian vein laceration	93
150%	15.2A	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	34	No	None	98
145%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	40	No	None	98
123%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	28	No	None	100
107%	15.2B	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	31	No	None	95
100%	15.2A	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	34	No	None	Declined
100%	15.2C	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	26	No	None	100
100%	15.2A	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	26	No	None	100
Preop. images not available	Preop. images not available	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	56	No	None	100
Preop. images not available	Preop. images not available	2.7-mm superior LCP Reconstruction Plate, 2.4-mm anterior LCP Plate	27	No	None	100

symptoms for anteroinferior plating with 2.7-mm DCPs; however, they had further issues, including a relatively high rate of nonunion despite surgical fixation and an overall reoperation rate of 8.5% at a minimum of 1 year of follow-up¹³.

Prasarn et al. presented a biomechanical study and retrospective clinical review of 17 patients with 1 year of follow-up treated with use of a novel 2.7-mm and 2.4-mm dual-plate technique. Biomechanically, they found improved multiplanar bending stiffness and equivalence in axial load and torsion when compared with a single 3.5-mm superior plate and a single 3.5-mm

anteroinferior plate. Clinically, they reported 0 implant removals at 1 year of follow-up¹⁴. Another dual mini-fragment plating series, by Czajka et al., published in 2017, showed an all-cause reoperation rate of 7.4%²¹, which was slightly higher than that of Prasarn et al.¹⁴, although still lower than published single-plate data.

In the present study, the complication rates and clinical outcomes were similar between the 2 groups. A subclavian vein laceration in the dual-plate group was sustained during the approach to the posterior aspect of the superior surface of the clavicle, and as such, was not deemed to be a complication

inherent to the dual-plating technique. Subclavian vessel injury is a recognized complication of operative treatment of clavicular fractures¹⁹. A single wound infection was found in the single-plate group, but wound infection is not thought to be inherently more prevalent with single-plating techniques. Notably, there was no case of fracture nonunion in either group in this study. Prasarn et al. similarly had 0 cases of fracture nonunion utilizing a dual-plating technique¹⁴. The use of a different dual-plate technique, as described by Shannon et al. and Chen et al., similarly had 0 cases of nonunion in their dual-plating cohorts^{22,23}. Jones et al. evaluated single anteroinferior plates, and Ashman et al. evaluated single superior plates, and both reported higher rates of nonunion utilizing both superior and anteroinferior single-plate techniques^{9,13}.

Our study had a number of limitations. As a retrospective study, it was vulnerable to the inherent biases of such a study. Two of the 21 patients in the single-plate group were lost to longer-term follow-up. Neither patient was included in our analysis of patients who underwent reoperation or had a complication. As a result, the reoperation and/or complication rate in the single-plate group may be understated. We also recognize that a risk of both performance and treatment biases is inherent to any retrospective comparative study. The study was conceived well after the treatment period, lessening the risk of intra-study performance bias from group competition. Additionally, it is important to note that the primary impetus for using the dual-plating technique is not specifically to lessen implant removal. As noted by previous studies using dual plating, dual plating of the clavicle is advantageous for the reduction, maintenance of reduction, and fixation of complex fracture patterns^{14,21-23}. Because of the retrospective nature of the study, the ASES Standardized Shoulder Assessment Form was unable to be administered to patients who required implant removal before their implants were removed. The decision to undergo reoperation for implant-related symptoms is a subjective decision ultimately made by the patient but recommended by the surgeon. Quantifying implant-derived symptoms to allow comparison among postoperative patients is difficult, and a precise comparison of symptoms leading to the surgical removal of an implant requires prospective documentation of those symptoms. Inherent in a decision to undergo a second operation

is the decision to accept the risk of surgery in order to obtain the benefit of the surgery. Furthermore, all attending surgeons whose patients were included in this study expressed a strong preference against implant removal throughout the study and only recommend implant removal in cases of notable patient symptoms.

Conclusions

In conclusion, dual-plate fixation utilizing a 2.7-mm superior reconstruction plate and a 2.4-mm anterior LCP for the treatment of displaced midshaft clavicular fractures was associated with a significantly lower rate of reoperation for any reason when compared with single, 3.5-mm, superior plate fixation in our comparative retrospective series. Clinical outcome scores for patients not electing to undergo removal of implants were excellent in both the dual and single-plate fixation groups. Dual mini-fragment plate fixation of displaced midshaft clavicular fractures is a viable treatment option that may reduce the rate of reoperation while providing equivalent clinical outcomes when compared with single, 3.5-mm, superior plate fixation.

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