

A Biomechanical and Clinical Comparison of Midshaft Clavicle Plate Fixation

Are 2 Screws as Good as 3 on Each Side of the Fracture?

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Background: The standard of care for plating displaced midshaft clavicle fractures has been 6 cortices of purchase on each side of the fracture. The use of locking plates and screws may afford equivalent biomechanical strength with fewer cortices of purchase on each side of the fracture.

Purpose: To compare the biomechanical and clinical performance of 3- versus 2-screw constructs for plating displaced midshaft clavicle fractures.

Study Design: Controlled laboratory study/cohort study; Level of evidence, 3.

Methods: Lateral fragments of simulated midshaft fractures in 10 pairs of cadaveric clavicles were randomly assigned to plate fixation with either 3 nonlocking screws or 2 locking screws. Cyclic tensile loads were applied along the long axis of the clavicle. The constructs were then loaded to failure with pullout forces applied parallel to the long axis of the screws. Additionally, clinical outcomes of patients who had midshaft clavicle fractures that were surgically repaired were retrospectively identified and compared; 21 patients were treated with 3-screw constructs and 20 with 2-screw constructs.

Results: Biomechanically, there were no significant differences for cyclic displacement, stiffness, yield load, or ultimate load between groups. Forces required for screw pullout were considerably higher than physiologic forces experienced by a healing clavicle in vivo. Clinically, there were no significant differences in American Shoulder and Elbow Surgeons, Constant, visual analog scale, and Single Assessment Numeric Evaluation scores; complications; or mean time to union. Additionally, we found that the plates used in the 2-screw group were consistently shorter.

Conclusion: Plate fixation of displaced midshaft clavicle fractures with 4 cortices of purchase with 2 locking screws demonstrated no significant differences biomechanically when compared with fixation with 6 cortices of purchase and 3 nonlocking screws. Clinically, there were no significant differences in outcomes or complications seen in patients receiving 2- or 3-screw constructs.

Clinical Relevance: Clinical benefits of using the 3-screw construct for plate fixation include decreased surgical exposure, morbidity, and cost, and the use of shorter and noncontoured straight plates eliminates the extra time and technical difficulty associated with matching longer contoured plates to the complex morphology of the clavicle.

Keywords: midshaft; clavicle; fractures; fixation; biomechanical; retrospective; clinical outcomes

Clavicle fractures occur relatively frequently, representing approximately 2.6% of all fractures and 44% of those in the shoulder girdle, including the proximal humerus and scapula.²⁵ Of these fractures, those of the middle third of the clavicle are the most common, ranging from 69% to 82%.^{20,25,28} Studies comparing operative with nonoperative treatment have shown that plate fixation of displaced midshaft clavicular fractures results in improved functional outcomes and a lower rate of malunion and nonunion. One

study showed that the risk of nonunion after plating was 2.5%, which was significantly lower than the 5.9% for the nonoperative treatment. For displaced fractures, the risk of nonunion after plating was 2.2%, which was significantly lower than the 15.1% for nonoperative treatment.³³ In a 1-year follow-up study, patients with surgical treatment had a higher level of patient satisfaction, surgeon-oriented outcomes, and earlier functional return to activity.² Therefore, operative repair has been demonstrated to be a safe and reproducible treatment option in clinical studies.^{3,16,33}

Standard surgical technique for plate fixation of midshaft clavicle fractures involves placing at least 3 bicortical

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screws in the medial and lateral clavicle fragments to obtain 6 cortices of purchase on either side of the fracture site; however, with the increasing use of locking plate fixation, the minimum number of cortices required per segment is now a topic of debate.^{1,4,14,27} Clinically, plate breakage, plate bending, and screw pullout have been reported to be the most common types of hardware failure observed in clavicle fixation.^{2,9,15} Biomechanical testing with more physiologic cantilever bending models demonstrated failure of the construct by fracture of the clavicle near the end of the plate, through the lateral screw hole, or by bending of the plate at the fracture site. Since more physiologic cantilever bending models fail by fracture of the clavicle or plate bending, they do not allow us to directly compare differences in screw fixation strength between a 2-locking and a 3-nonlocking screw construct. Therefore, to more directly compare differences in screw fixation strength, we employed a simpler and more appropriate “worst-case scenario” in-line pullout model.

Additionally, a retrospective study was conducted in an attempt to identify differences in outcomes between patients who have undergone clavicle-plating procedures with 3 screws on each side of the fracture and those with 2. The use of shorter plates with fewer screws has the potential to make plating midshaft clavicle fractures less invasive and technically less difficult. Plating over a shorter distance within the straight segment of the midshaft of the clavicle has the potential to eliminate the need to use contoured plates, which have been difficult to match to the natural curved geometry of the clavicle, and many plating systems do not take into account differences in patient body habitus or sex.^{17,23,29}

METHODS

Biomechanical Analysis

Ten matched pairs of embalmed cadaveric clavicles were obtained (Rosalind Franklin University of Medicine and Science), with ages ranging from 53 to 94 years and a mean age of 72 ± 16 years. Only clavicles without signs of damage, fractures, or irregularities were included. A single clavicle from each matched pair was randomly assigned to fixation with either a 2-screw locking construct or a 3-screw nonlocking construct, and the contralateral clavicle was assigned to the opposite fixation method, giving us a sample size of 10 for each group. A power analysis ($\alpha = 0.05$ and $P = .80$), based on significant differences in cycles to failure and torque reported by Grawe et al¹³ for 2-screw locking constructs and 3-screw nonlocking constructs in a normal bone model,

indicated that a sample size of 4 would be adequate to detect significant differences between the groups. Previously reported data regarding ex vivo biomechanical comparisons of fixation constructs have used a sample size of 5.^{10,12,13,24,30} Due to our availability of 10 pairs of clavicles, we chose to proceed with a sample size of 10 for our biomechanical study. Fixation methods utilized either right-sided (AR-2655CR; Arthrex) or left-sided (AR-2655CL; Arthrex) 7-hole midshaft clavicle plates. All holes accept either locking or nonlocking 3.5-mm diameter screws.

Simple transverse fractures were simulated in the midshaft of the clavicle with an oscillating saw. The appropriate sided plate, left or right, was applied to the superior surface of the lateral clavicular fragment with the center hole of the fixation plate situated over the simulated fracture line. Superior plating and anterior-inferior plating are both accepted and proven methods for fixation of clavicle fractures; however, optimal plate position is still a debated topic.^{5-8,19,21,22,27,31,32} The senior author (S.C.C.) has experienced a low incidence of complications with superior plating and believes that the superior surface provides a more straight surface for plate fixation, so we designed our biomechanical study to represent this surgical technique. Preliminary testing demonstrated that the lateral clavicular fragment performed biomechanically inferior to the medial fragment; therefore, only the lateral fragment of the clavicle was used in our study.

For the nonlocking group, the plate was fixed to the superior surface of the lateral clavicle fragment with three 3.5-mm bicortical nonlocking screws. Holding the plate in position on the bone, we drilled 3 parallel bicortical holes through the lateral clavicular fragment with a 2.5-mm-diameter drill. Two nylon straps, with 3 holes corresponding to the location of the 3 screws, were placed between the bone and the plate to allow us to apply pullout forces between the plate and the bone and in line with the long axis of the screws. The screws were inserted through the 3 lateral holes of the plate and the nylon straps and into the bone with bicortical purchase (Figures 1-3).

For the locking group, the same technique and plate type were utilized except that we drilled 2 parallel bicortical holes through the lateral clavicular fragment with the same 2.5-mm-diameter drill and placed 2 bicortical 3.5-mm locking screws in the first and third hole positions on the plate (Figure 1).

For cyclic testing, the medial aspect of the plate was connected to a vise fixture of the testing apparatus (model 8871; Instron Corp), and the lateral aspect of the clavicle was secured in another fixture with 3 degrees of freedom to allow for proper specimen orientation (Figure 2). The samples were cycled between 10 N and 75 N for 250 cycles,

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Ethical approval for this study was obtained from Adventist Midwest Health (institutional review board registration Nos. IRB00003793 and IRB00002450).

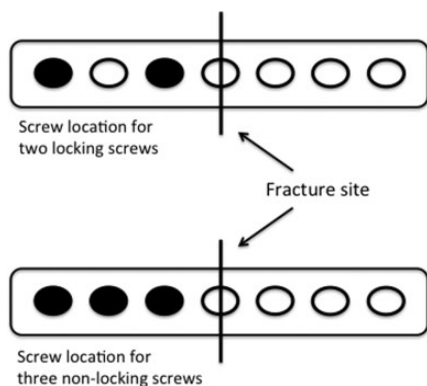


Figure 1. Location for compression plate application using 2 locking screws and 3 nonlocking screws.

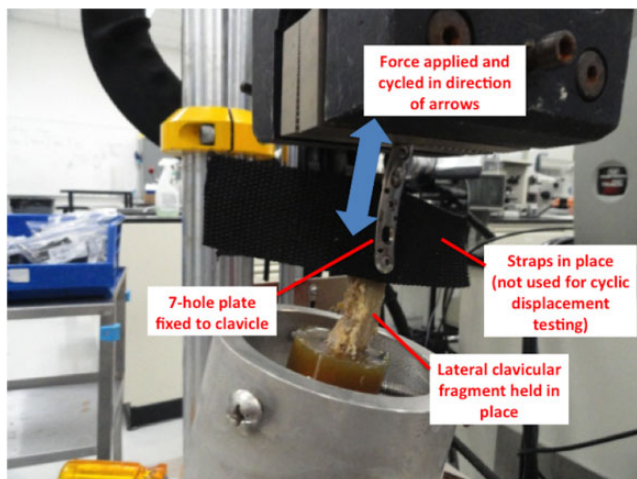


Figure 2. Apparatus setup for cyclic load testing. The force was applied parallel to the long axis of the clavicle in a cyclical manner. The nylon straps are in place between the plate and the bone to keep the constructs consistent among the types of loading; however, they were not utilized for cyclic loading testing.

loading along the long axis of the clavicle, and cyclic displacement was recorded. The tensile load cycled from 10 N to 75 N at a rate of 1 Hz. The maximum load of 75 N represented the force on the clavicle in full external rotation of the shoulder, and 10 N represented the force on the clavicle with the shoulder in the neutral position.²⁶ Displacement was measured from the crosshead position at minimum and maximum loads for each cycle.

The samples were then reoriented in the testing apparatus, and force was applied parallel to the long axis of the screws by pulling the 2 nylon straps between the plate and bone in opposite directions at a rate of 0.5 mm/s until failure (Figure 3). Ultimate load, yield load, and stiffness were measured with the linear approximation tool in OriginPro 8 software (OriginLab Corp). Stiffness was calculated from the linear portion of the load-displacement curve, and all linear approximations were required to have an R^2 value ≥ 0.99 .

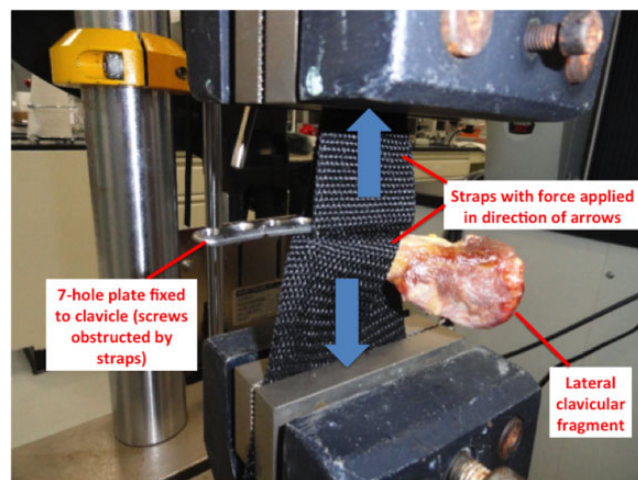


Figure 3. Apparatus for in-line pullout testing. Force was applied parallel to the long axis of the screws so that each strap provided a distraction force between the plate and the bone. Force was applied until failure of the construct occurred.

Statistical analysis of the samples was performed with a paired t test ($\alpha = 0.05$). SigmaPlot 11.0 (Systat Software Inc) was used to perform the calculations. Error is reported as standard deviation.

Retrospective Analysis

We identified a cohort of 41 consecutive patients who underwent plate fixation for a midshaft clavicle fracture and then had at least 12 months of postoperative follow-up. Of these, 21 patients received 3 screws on each side of the fracture site, followed by another 20 patients who received 2 screws. Type of fixation for these patients was confirmed by looking at postoperative radiographs on our picture archiving and communication system (Figure 4).

All fractures were plated superiorly. Initially, the senior author plated all midshaft clavicle fractures with 3 non-locking bicortical screws on each side of the fracture site; then, sometime after the availability of locking screws, the senior author switched to plating all midshaft clavicle fractures with 2 screws (at least 1 locking) on each side of the fracture site. The number of screws selected for each patient was chosen regardless of patient, clavicle size, or fracture pattern. Patients were instructed to wear a sling for 6 weeks after the operation. During those 6 weeks, they were allowed gentle passive supine shoulder flexion and abduction to 90°, as well as active shoulder internal and external rotation with the arm at the side and active range of motion of the elbow, wrist, and hand. After 6 weeks, patients were allowed to discontinue with the sling and progress range of motion and gradual strengthening.

Analysis of medical records allowed us to determine if there were any complications associated with the plating procedures. Radiographs from postoperative follow-up visits were also reviewed. Time to union was determined by radiographic disappearance of the fracture line.

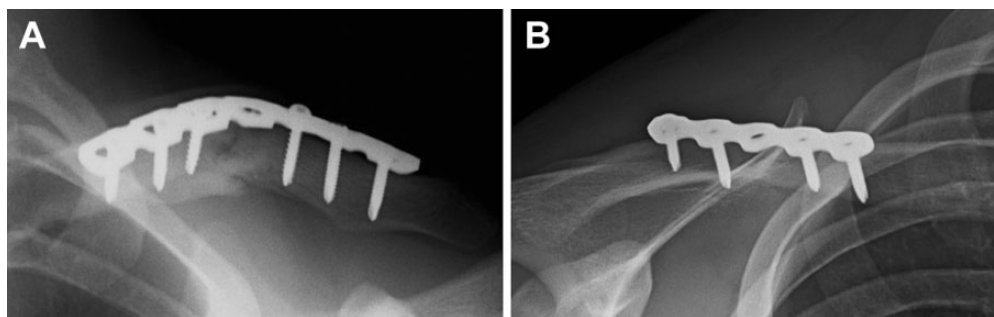


Figure 4. Plain radiographs from patients who received midshaft clavicle open reduction and internal fixation with (A) 3 screws proximal and distal to the fracture site versus (B) 2 screws proximal and distal to the fracture site.

TABLE 1

Results of Biomechanical Analysis Based on Midshaft Clavicle Fixation Constructs With 2 Locking Screws or 3 Nonlocking Screws on Each Side of the Fracture^a

Biomechanical Results	2 Screws	3 Screws	P Value
Cyclic displacement, mm	0.20 ± 0.12	0.12 ± 0.10	.20
Pullout stiffness, N/mm	217 ± 75	214 ± 70	.94
Pullout yield load, N	2465 ± 1092	2670 ± 1165	.65
Pullout ultimate load, N	2496 ± 1102	2715 ± 1150	.62

^aValues are presented as mean ± SD.

Radiographs of the plated clavicles were taken at approximately 2 weeks and 6 weeks postoperatively and were repeated until the radiographic union of the fracture was evident by disappearance of the fracture line.

Under a protocol approved by an institutional review board, patients were contacted and asked to participate in the patient-reported outcomes portion of the study, and those who agreed were sent a questionnaire with an informed consent form (or assent and parental consent for minors) via the Outcomes Based Electronic Research Database (OBERD; www.oberd.com). The questionnaire consisted of the American Shoulder and Elbow Surgeons (ASES) shoulder assessment, Constant score, visual analog scale (VAS) pain score, and the Single Assessment Numeric Evaluation (SANE).

Statistical analysis of the data was performed with a heteroscedastic *t* test ($\alpha = 0.05$). Microsoft Excel was used to perform the calculations and for plotting the data. Error is reported as the standard error of the mean (SEM).

RESULTS

Biomechanical Analysis

There were no statistically significant differences in cyclic displacement between the fixation constructs using 2-locking and 3-nonlocking screws (Table 1). The stress-strain curves exhibited no evidence of failure for all tested constructs during cyclic tensile loading.

During pullout load-to-failure testing, the 2-locking and 3-nonlocking screw fixation methods demonstrated no

TABLE 2

Results of Retrospective Study Analyzing the Procedures and Outcomes of Patients Who Received Midshaft Clavicle Fixation Procedures With 2 or 3 Screws on Each Side of the Fracture^a

Clinical Outcomes	2 Screws	3 Screws	P Value
Time to union, wk	11.9 ± 1.0	11.4 ± 1.1	.74
Plate length, cm			
Overall	7.24 ± 0.30	9.56 ± 0.23	<.001
Comminuted fractures	8.05 ± 0.36	9.86 ± 0.18	<.001
Noncomminuted fractures	6.24 ± 0.20	8.30 ± 0.62	.039
ASES shoulder assessment	94.3 ± 3.6	98.0 ± 0.8	.35
Constant score	33 ± 1.7	30.6 ± 1.7	.34
VAS pain score (100 points)	3.43 ± 2.2	1.0 ± 1.0	.34
SANE	94.7 ± 3.4	94.7 ± 1.8	.99

^aValues are presented as mean ± SEM. ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation; VAS, visual analog scale.

significant differences in stiffness, yield load, or ultimate load (Table 1). For the construct with 2 locking screws, 8 of 10 failed because the screws pulled out from the bone; 1 failed by the nylon strap slipping in the clamp, and 1 failed by the ripping of the nylon strap. For the construct with 3 nonlocking screws, 7 of 10 failed because the screws pulled out from the bone; 2 had the nylon strap slip from the clamp, and 1 ripped the nylon strap.

Retrospective Analysis

No significant differences were noted in radiographic time to union between the 3- and 2-screw groups (Table 2).

Examination of our records revealed a significant difference between the 2 groups in the length of the plates used during the fixation procedures (Figure 5). Overall, we found that the mean length of plate used in the 3-screw group was significantly longer (Table 2) ($P < .001$). Furthermore, when comparing the types of fractures, we found that longer plates were used for comminuted fractures in the 3-screw group versus the 2-screw group ($P < .001$). Similarly, when looking at fractures that were not comminuted, we discovered that shorter plates were used overall and that the

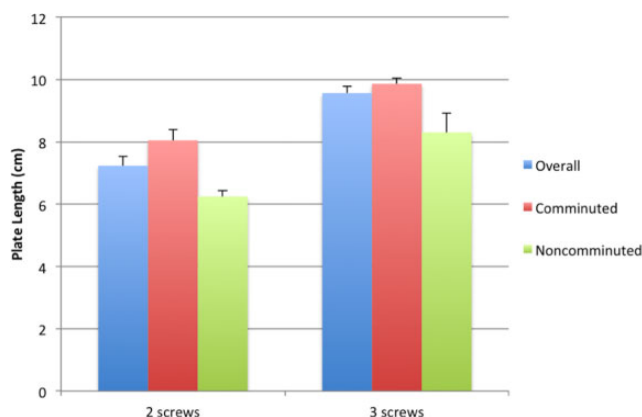


Figure 5. Differences in plate length used for fixation with either 2 or 3 screws on each side of the fracture. Plates were significantly shorter in the 2-screw group regardless of the type of fracture (comminuted vs noncomminuted). Values are presented as mean \pm SEM.

plates used in the 3-screw group were significantly longer than those used in the 2-screw group ($P = .039$) (Table 2).

Overall, complication rates were found to be low, with 3 cases of painful implants requiring removal and 1 case of nonunion and implant failure in the 3-screw group (19%) and 2 cases of painful implant requiring removal in the 2-screw group (10%). There were no cases of infected implants identified. The case of implant failure resulted in 15° bending of the midportion of the plate in a young patient who was noncompliant with his sling and tried to resume activities earlier than recommended. This patient had a highly comminuted 4-part fracture, which, when examined on postoperative radiographs, showed that the 2 comminuted fragments healed on the lateral segment; however, there was nonunion at the medial segment, where plate bending was seen. Revision was recommended, and the patient had the bent plate removed and a new plate inserted.

Patient-reported outcomes were available for only 5 patients with 3 screws on each side of the fracture and 7 with 2 screws. There were no significant differences found between the 2 groups for all questionnaires (ASES, Constant, VAS pain score, and SANE); however, numbers were limited (Table 2).

DISCUSSION

With pullout loading in a midshaft clavicular fracture-plate cadaveric model, there were no significant differences between fixation with 2 locking versus 3 nonlocking screws with regard to stiffness, yield, or ultimate load. Subfailure cyclic tensile loading along the axis of the clavicle and plate also revealed no differences in displacement between groups. In our retrospective clinical comparison, the patients with 2 screws per side of the fracture site and those with 3 screws performed clinically similar with regard to outcome scores (ASES, Constant, SANE, VAS). Fractures in both groups demonstrated

radiographic healing before 12 weeks postoperatively, with low complication rates. Three painful implant cases requiring removal and 1 nonunion and implant failure occurred in the 3-screw group, and 2 cases of painful implant requiring removal occurred in the 2-screw group. Additionally, we found that the mean plate length used in the 3-screw group was significantly longer than that for the 2-screw group for all fractures (9.56 ± 0.23 cm vs 7.24 ± 0.30 cm, $P < .001$), comminuted fractures (9.86 ± 0.18 cm vs 8.05 ± 0.36 cm, $P < .001$), and noncomminuted fractures (8.30 ± 0.62 cm vs 6.24 ± 0.20 cm, $P = .039$).

We chose a simple pullout testing model to allow a direct comparison of plate fixation using 2 locking versus 3 nonlocking screws because most biomechanical studies utilizing more physiologic testing methods, such as cantilever bending of midshaft clavicle fracture-plating constructs, demonstrated modes of failure independent of screw fixation. Most fail by bending of the plate or fracture of the clavicle through an end screw hole, and they fail at loads much lower than the pullout loads demonstrated by this study.^{11,15,22}

Specifically, a 4-point bending model discovered that midshaft fracture-plate constructs failed at forces much lower than our values, ranging from 540 to 1080 N; however, that study did not report the methods of failure, as it focused more on screw displacement distances.¹¹ An axial loading model revealed that 3 nonlocking bicortical screws failed at a mean load of 664.7 ± 167.5 N by the methods of failure of plate bending (6/10), fracture of clavicle at a screw hole (2/10), and failure at their testing apparatus (2/10).¹⁵ In a cantilever bending model, failure of 3-screw locking constructs occurred at an mean of 444.8 ± 102.3 N, mostly by method of fracture at the most medial screw hole.²² With these more physiologic testing models, failure of the fracture-plate constructs occurred with modes of failure independent of screw fixation or purchase strength at loads 3 to 10 times less than that of the mean pullout fixation strength discovered in our study for either the 2 locking or 3 nonlocking screw constructs (2496 ± 1102 N and 2715 ± 1150 N, respectively). Therefore, given the availability of locking screw constructs, screw fixation with either 2 or 3 screws on each side of the fracture does not appear to be the limiting factor in the biomechanical strength of the midshaft clavicle fracture-plate fixation.

Another biomechanical study of 2 locking versus 3 nonlocking screws in normal and osteoporotic bone models demonstrated that both types of constructs perform differently depending on the method of loading and the bone quality.¹³ With torsional loading in normal bone, where screw pullout was sometimes responsible for failure, the authors discovered that the construct with 3 nonlocking screws demonstrated higher stiffness and maximum torque over the locking plate with 2 screws: 461.7 ± 9.0 GPa vs 370.9 ± 55.0 GPa and $10,632 \pm 728$ N mm vs 9044 ± 715 N mm, respectively. However, with eccentric bending in osteoporotic bone, the construct with 2 locking screws performed better than fixation with 3 nonlocking screws, demonstrating significantly less maximal displacement (1.44 ± 0.2 mm vs 1.88 ± 0.4 mm). No significant differences were found between constructs with eccentric bending in

normal and osteoporotic bone with regard to maximal load to failure (641 ± 22 N for locking vs 626 ± 40 N for nonlocking in normal bone and 306 ± 55 N for locking vs 326 ± 10 N for nonlocking in osteoporotic bone). The methods of failure were not reported for this study.¹³

Regardless of the method of testing, the absolute values of force required to disrupt the superior plate-midshaft clavicle fracture constructs in all of the aforementioned studies far exceed the level of force encountered in vivo by the clavicle during normal shoulder motion. A study of physiologic forces on the shoulder determined that during the shoulder motions of abduction, internal rotation, and external rotation, the peak 3-dimensional vector sum forces are 44.4 ± 24.8 N, 6.6 ± 2.6 N, and 21.4 ± 4.7 N, respectively.¹⁸ Therefore, according to the results of in vitro biomechanical studies and consistent with our clinical study, fixation with either 2 locking or 3 nonlocking screws on each side of the midshaft clavicle fracture should provide sufficient mechanical strength to promote fracture healing under normal restricted postoperative conditions.

Plate fixation of clavicle fragments with 2 locking screws rather than 3 nonlocking screws on each side of the fracture allowed for the use of shorter, less-contoured plates during the treatment of displaced comminuted or noncomminuted midshaft clavicle fractures. The results from our study suggest that, owing to the use of newer locking constructs, using fewer screws and shorter plates may not ultimately compromise fixation strength despite establishing fewer cortices of purchase. Potential clinical impacts include decreased number of implanted screws and cost, decreased plate inventory, decreased surgical exposure and morbidity, and decreased surgical time. From the experience of the senior author (S.C.C.), the ability to maintain adequate fixation strength with fewer screws allows the surgeon to plate "short and straight." Specifically, the surgeon can select a short and straight noncontoured plate and attain adequate fixation along the straight segment of midshaft of the clavicle, avoiding the need for a greater inventory of right and left contoured plates and the difficulty and extra time required to fit longer precontoured plates or bend longer, straighter plates to accommodate the variability in clavicular anatomy of each individual.

Limitations of our study include the small numbers tested biomechanically; 10 paired clavicles may not have been able to detect smaller biomechanical differences between the 2 groups. Screw pullout loads to failure for both groups in our study were much greater (2496 ± 1102 N for 2 locking screws and 2715 ± 1150 N for 3 nonlocking screws) than the load to failure with other more physiologic biomechanical testing models, where failure was not related to screw purchase, and with physiologic shoulder loads seen postoperatively in vivo (44.4 ± 24.8 N with shoulder abduction, 6.6 ± 2.6 N with internal rotation, and 21.4 ± 4.7 N with external rotation).¹⁸ These findings all support the biomechanical adequacy of employing the use of 2 locking screws per side of the fracture and that the use of 2 locking versus 3 nonlocking screws is not the limiting factor in midshaft clavicle fixation. The small number of responses to questionnaires and the retrospective nature of the clinical study are also limitations, but this

retrospective series did corroborate the results of biomechanical study that plate fixation with 2 locking screws, just as with 3 nonlocking screws, per side of the fracture is biomechanically adequate and can achieve clinically successful and comparable results with regard to rate of union and complications.

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