Biomechanical Comparison of Fixation Techniques in Midshaft Clavicular Fractures

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Objectives: The purpose of this study is to evaluate the biomechanical properties and the stability among a locking clavicle plate (LCP), a dynamic compression plate (DCP) and an external fixator (Ex-fix) in an unstable displaced clavicle fracture model under torsional and three-point bending loading.

Materials and Methods: Forty-eight human adult formalin-fixed clavicles were paired according to their bone mineral density homogeneously into three groups: LCP, DCP, and Ex-fix. Each specimen was osteotomized at the midshaft. Torsional and three-point bending forces were performed for 1000 cycles with stiffness recorded at 10 cycles (initial) and then at 100-cycle intervals thereafter. Initial stiffness, failure loads, and the percentage of initial stiffness at the various intervals were compared using analysis of variance.

Results: The mean initial stiffness values (Nmm/deg) for torsion were 703.2 (LCP), 448.1 (DCP), and 365.2 (Ex-fix). The mean failure moments (Nmm) for torsion were 7671.7 (LCP), 4370.3 (DCP), and 2999.7 (Ex-fix). The mean initial stiffness (Nmm) for bending were 32.6 (LCP), 23.4 (DCP), and 20.6 (Ex-fix). The mean failure loads (N) for bending were 213.2 (LCP), 131.1 (DCP), and 102.7 (Ex-fix). For both torsion and bending, an overall significant difference among the three constructs in terms of failure loads and also a significant difference between the locking plate and the other two models only in terms of initial stiffness was seen. For torsion and bending, at all cyclic intervals, there was a significant difference between the locking plate and the other two models. After 700 cycles, a significant difference was also detected between the DCP and Ex-fix in torsion, but no difference was found between these groups at any cyclic interval in bending.

Conclusions: The locking plate is significantly more stable than DCP and Ex-fix under torsional and bending cyclic loading in a displaced fracture clavicle model.

Key Words: clavicular fracture, biomechanical testing, osteosynthesis implants, torsion, bending, cyclic loading

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INTRODUCTION

Operative treatment may be a preferable alternative to conservative treatment with high rates of union and patient satisfaction when treating midshaft clavicular fractures with substantial displacement and shortening.[1–4] Important advantages of surgery include anatomic restoration and early mobilization and rehabilitation as a result of the stability of the osteosynthesis.[1,5]

Various operative solutions have been proposed ranging from interfragmentary screws, wire sutures,[6] intramedullary pinning with Kirschner wires,[7] Knowles pins,[8] modified Hagie pins,[9] titanium elastic nails,[10] cannulated screws,[11] external fixation,[12] compression plates and precontoured clavicle locking plate fixations.

The purpose of this study is to evaluate the biomechanical properties and stabilities of three different implant systems on a displaced midshaft clavicle fracture model under torsion and bending loads and to compare their initial stiffness, failure loads, and changes in stiffness under cyclic loading for each implant system.

MATERIALS AND METHODS

Pilot Study

Twelve cadaveric clavicles and 48 sawbones (Sawbones Europe AB, Malmo, Sweden) were tested for cyclic loading and then failure to construct the main scenario of the experimental study. Two cadaveric bones and eight sawbones were used for each group on bending and torsion tests. The mean torsional failure peak moment (± standard deviation) was 4966.3 (± 2371.7) N.mm and the mean bending failure peak load was 143.3 (± 51.3) N. The rate of cyclic loading amplitude has been chosen to be 75% of the load to failure value of pilot studies to achieve a high-level stress condition overall the clavicle system.[13]

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Implants that were used for experimental setup were assured complimentary by representative companies (Ilerimed, Acumed locking clavicle plate; OrtoPro, DCP; Tasarımmed, external fixator).

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Power Analysis

Estimating the number of specimens for each group by using our pilot study, we performed the power analysis using the mean values with maximum standard deviations obtained from pilot testing. Eight bones were used in every group for torsional tests for α: 0.05 β: 0.16, the power (1-β): 0.84 (84%); and in three-point bending tests for α: 0.05 β: 0.19, the power (1-β): 0.81 (81%). Powers for two testing setups were higher than 80%, and we thus decided to use groups of eight ($n = 8$).

Forty-eight human cadaveric formalin-fixed clavicles were obtained from donors aged 42 to 68 years with no history of malignancy, metabolic disease, or autoimmune disease. After harvest, all attached muscle and soft tissue was removed. Radiographs of each bone were taken to rule out major structural anatomic abnormalities. To standardize clavicles, dual-energy x-ray absorptiometry in the forearm setup was performed for each specimen. To simulate soft tissue during the scanning procedure, every bone was surrounded by a 1-cm thick envelope of semolina in a rectangular plastic box.[13] The mean bone mineral density of the clavicles was 0.531 g/cm^2 with a range of 0.441 to 0.704 ± standard deviation ± 0.133. Specimens were allocated homogeneously into three groups according to their bone mineral density (BMD). The mean BMD was kept constant among groups: Group 1, locking compression plate (LCP; Locking clavicle plate system; Acumed, Hillsboro, OR) group; Group 2, dynamic compression plate (DCP; OrtoPro-Covision Medical, Carlton Ind, Park Carlton Nottinghamshire, UK) group; Group 3, External fixator (Ex-fix; Tasarımmed Ltd Sti–Mini LRS, Eyup, Istanbul, Turkey) group (Fig. 1). Three groups of 16 were further separated into six subgroups of eight with eight specimens being tested in torsion and eight in bending for each implant.

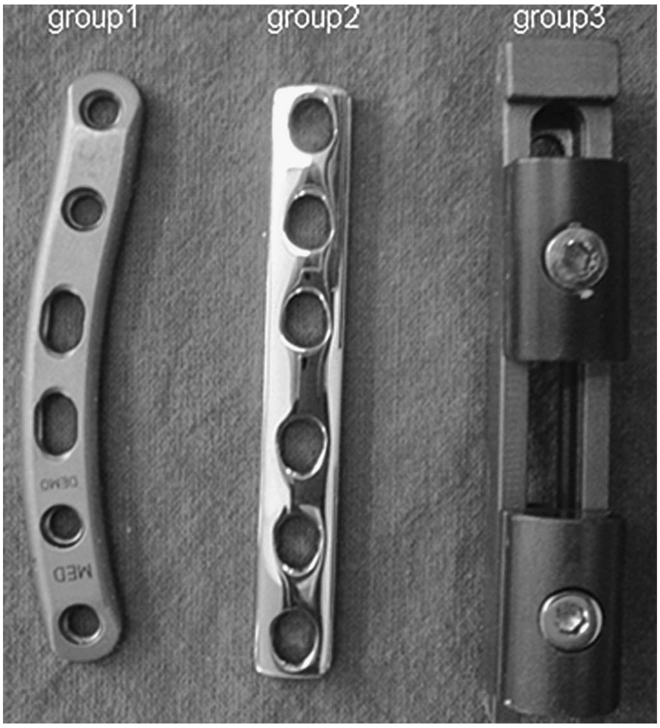

FIGURE 1. Group 1: Locking clavicle plate. Group 2: Dynamic compression plate. Group 3: External fixator.

Surgical Technique

Before performing the osteotomy, plates and fixators were implanted on the superior part of the clavicle. Clavicles were then osteotomized in the midshaft and a 5-mm cylindrical bone segment was removed with an oscillating saw to simulate a displaced fracture or a nonunion model.

In Group 1, a 3.5-mm six-hole LCP was applied to the superior surface of the midshaft. The plate location was measured beforehand in every specimen to place plate holes exactly equidistant to the osteotomy site. Four of the six holes were of the locking type, and the other two holes were of the compressive type. Compressive holes were placed symmetrically on each side of the osteotomy gap. After drilling by guide and tapping, the locking holes were fixed by 3.5-mm fully threaded locking bicortical screws. The other two 3.5-mm standard bicortical screws were inserted in the center of the adjacent compressive holes. Screws were tightened to 1.5 N-m using a torque wrench.

In Group 2, a 3.5-mm six-hole DCP was applied in the same configuration as Group 1. Standard 3.5-mm bicortical screws were inserted in the center of the holes symmetric to the osteotomy site after drilling and tapping and tightened to 1.5 N-m.

In Group 3, an Ex-fix was fixed with four 3-mm Schanz screws. Two of them were placed on the acromial side and the other two on the sternal side symmetric and equidistant to the osteotomy. After placing one Schanz screw perpendicular to the superior surface of the clavicle using a drill guide, we applied the fixator to this Schanz screw and implanted the others screws bicortically using the drill guide over the Ex-fix holes. There was a fixed 4-cm distance between the fixator and the bone.

After implant fixation, we performed the osteotomy with an oscillating saw. A 5-mm cylindrical bone segment was removed, taking care to avoid contact between the saw blade and the implant through the use of a small rongeur.

Preparation for Biomechanical Study

Each end of the clavicle for torsional tests and only the sternal end for bending tests were encrusted into plastic molds filled with polyester cement (DYO Chemical Inc, Izmir, Turkey). Two perpendicularly crossed Kirschner wires were inserted into the ends of bones, which were buried into the cement, to provide stability between the cement and bone units.

Biomechanical Test

The clavicle moves in both the anteroposterior and superoinferior directions as well as rotating about its long axis both anteriorly and posteriorly during normal motion of the arm. Greater motion occurs at the sternoclavicular joint than at the acroclavicular joint. The clavicle has been shown to rotate 40° to 50° during active forward elevation of the arm and is exposed to torsional and bending forces.[14] We constructed our experimental setup on these biomechanical properties.

Specimens were positioned in the testing machine by putting the acromial end into the fixed support of the stable base cylindrical metal plate for torsion tests. Forces were applied on the sternal end for the torsion group (Fig. 2A).

Other specimens were positioned by fixing the sternal end for bending tests in an application support that permitted rotations as a pin joint to eliminate the occurrence of reaction torques around the fixed sternal end so as to obtain a modified three-point bending apparatus. Forces were applied on the acromial end for bending group (Fig. 2B).

Cyclic torsional and three-point bending tests were performed using a servohydraulic universal testing machine (MTS 858 Mini Bionix II Axial/Torsional universal testing machine, Eden Prairie, MN). Load and torque values were recorded by MTS axial/torsional Load Cell (2500 N/ 25 N-m) located on a fixed support for torsional tests and on an application support for bending tests at 0.5 Hz. Linear and angular displacement values were collected using standard transducers of the MTS 858. Torsional and three-point bending forces were applied to each specimen for 1000 cycles in all subgroups. Load-displacement data were collected and recorded initially (after 10 cycles) and at 100 cycle increments up to a total of 1000 cycles. Failure load values were obtained after 1000 cycles with a loading velocity of 15°/min for torsion and 15 mm/min for bending tests. The bending and torsional stiffness values were calculated using the linear portions of the load-displacement and torque-angular rotation curves obtained at 100 cycle intervals with the units of N/mm and Nmm/deg, respectively.

Statistical Analysis

Initial stiffness, failure loads, and the percentage change from initial stiffness at 100 cyclic intervals for each test were compared between groups. One-way analysis of variance and Bonferroni post hoc statistical tests were used to determine which results were significantly different from each other with the level of significance set at $P < 0.05$ for a 95% confidence interval.

RESULTS

Initial Stiffness and Failure Loads

Torsion Test

The mean initial stiffness ± standard deviation were 703.23 ±101.11 Nmm/deg for the LCP group, 448.12 ±88.91 Nmm/deg for the DCP group, and 365.19 ± 50.11 for the Ex-fix group (Table 1). There were significant differences between the LCP group and the others ($P < 0.05$). There was no significant difference between DCP and Ex-fix group ($P = 0.176$).

The mean failure moments were 7671.77 ± 678.28 Nmm for the LCP group, 4370.31 ± 626.48 Nmm for the DCP group, and 2999.72 ± 473.74 Nmm for the Ex-fix group. There were significant differences between the LCP group and the other groups ($P < 0.05$). There was a significant difference between the DCP and Ex-fix groups ($P < 0.05$).

Bending Test

The mean initial stiffness was 32.61 ± 2.19 N/mm for the LCP group, 23.43 ± 3.27 N/mm for the DCP group, and 20.56 ± 1.92 N/mm for the Ex-fix group. There were significant differences between the LCP and other groups ($P < 0.05$). There was no significant difference between the DCP and Ex-fix groups in initial stiffness ($P = 0.103$).

The mean failure loads were 213.19 ± 11.86 N for the LCP group, 131.06 ± 11.47 N for the DCP group, and 102.71 ± 17.19 N for the Ex-fix group. There were significant differences between the LCP group and the other groups ($P <$

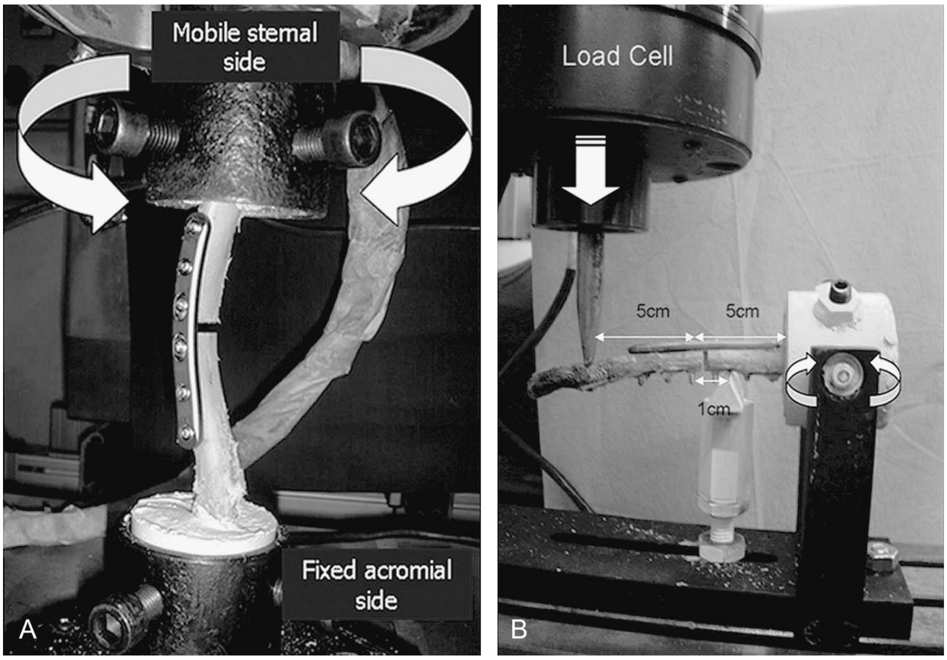

FIGURE 2. Torsion (A) and three-point bending (B) test setup.

TABLE 1. Mean Initial Stiffness and Failure Loads

	Initial Stiffness		Failure Load/Moment	
Test modes	Torsion Nmm/deg (± SD)	Bending N/mm (± SD)	Torsion N.mm (± SD)	Bending N (± SD)
Group 1 Anatomic LCP	703.23 (±101.11)	32.61 (±2.19)	7671.77 (±678.28)	213.19 (±11.86)
Group 2 DCP	448.12 (±88.91)	23.43 (±3.27)	4370.31 (±626.48)	131.06 (±11.47)
Group 3 Ex-fix	365.19 (±50.11)	20.56 (±1.92)	2999.72 (±473.74)	102.71 (±17.19)

SD, standard deviation.

0.05). There was a significant difference between the DCP and Ex-fix group ($P < 0.05$).

Mode of Failure

Torsion Test

LCP (torsion)

During cyclic loading, there was no sign of major instability (Fig. 3). Loosening was seen only at the compressive screws closest to the osteotomy site. After failure loads were applied, six specimens failed at the acromial side and two specimens failed at the sternal side. There was no observed loosening of the locking screws and the superior cortex of the bone remained flush with the plate surface.

DCP (torsion)

We observed instability and toggling on the bone–implant unit during cyclic loading after a mean of 700 cycles. Failures were observed in five specimens on the acromial side and on three specimens at the sternal side around screw insertions.

Ex-fix (torsion)

Instability was seen at the Ex-fix system in particular after a mean of 300 cycles. Two specimens failed at the acromial side, one at the sternal side, and the other five failed through fatigue of the Ex-fix system itself.

Bending Test

LCP (bending)

There was no instability seen during cyclic loading (Fig. 4). The bone–implant unit was stable. After failure loads were applied, seven specimens failed at the sternal part across from the last screw's insertion; one specimen failed by pullout of screws closest to the osteotomy site.

DCP (bending)

During cyclic loading after a mean of 500 cycles, we detected instability of the bone–implant unit. There were screws loosening at the sternal side. We noted sternal side failures in all eight specimens after failure loads were applied.

Ex-fix (bending)

After 400 cycles, the Ex-fix system began to move without stability. Bone failures were observed around the Schanz screws on the acromial side in three specimens, at the sternal side in one specimen, and Ex-fix implant failures were seen in four other specimens.

Percentage of Initial Stiffness and Statistical Analysis

Torsion Test

Percentage values recorded were as follows: at 100 cycles, LCP group: 99.06%, DCP group: 94.52%, and Ex-fix

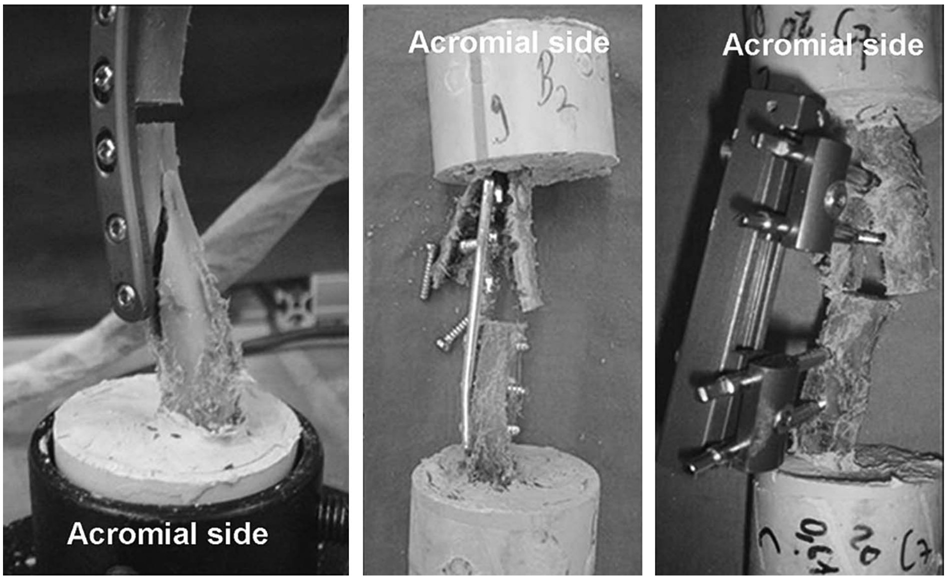

FIGURE 3. Failure modes (torsion tests).

FIGURE 4. Failure modes (bending tests).

group: 93.3%; at 700 cycles, LCP group: 97.11%, DCP group: 87.66%, and Ex-fix group: 80.1%; and at 1000 cycles before failure loading, LCP group: 96.5%, DCP group: 81.92%, and Ex-fix group: 68.85% (Fig. 5).

Bending Test

Percentage values recorded were as follows: at 100 cycles, LCP group: 99.5%, DCP group: 97.35, and Ex-fix group: 96.51%; and at 1000 cycles, LCP group: 96%, DCP group: 80.03%, and Ex-fix group: 69.27% (Fig. 6).

After the statistical analysis, it was discovered that at all cyclic intervals after 100 cycles there was a significant percentage difference in the initial stiffness between the locking plate and the other systems in both the bending and torsion tests ($P < 0.05$). There was a significant difference between the compression plate and Ex-fix after 700 cycles in the torsion test ($P < 0.05$), and no difference was found between these two groups in the bending test at any cyclic interval.

The locked group was significantly stiffer initially when compared with the DCP and Ex-fix groups and retained significantly more stiffness when compared with the other two groups at each cyclic interval (Figs. 5 and 6).

DISCUSSION

Clavicular fractures are relatively common injuries, accounting for 2.6% of all fractures and most commonly occurring in young active persons.[1] Fractures of the midshaft account for approximately 80% of all clavicular fractures and traditionally have been treated nonoperatively.[1] The relative risk reduction for the nonunion of displaced fractures when comparing plating versus nonoperative treatment was 86%.[2–4,15] McKee et al reported a significant decrease in strength parameters in the fractured versus uninjured side after conservative treatment of displaced clavicular fractures.[16] However, long-term recent studies have shown that fractures resulting from high-energy trauma, those with shortening more than 20 mm or substantial

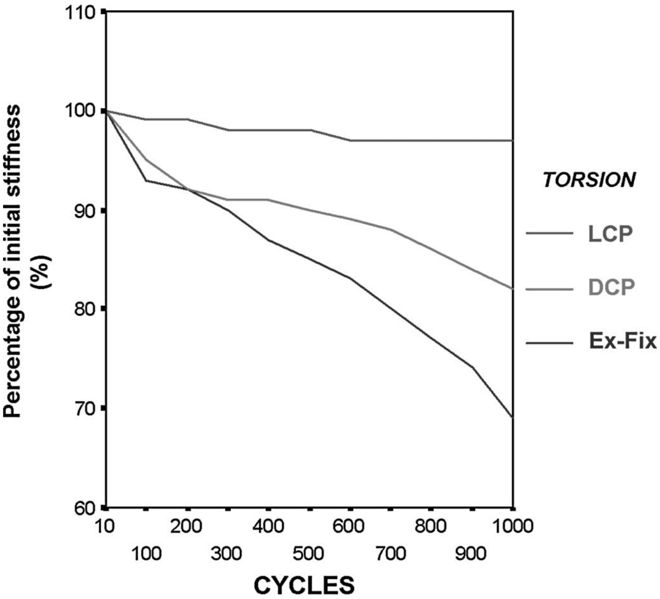

FIGURE 5. Graphs illustrating the percentage change in stiffness relative to the initial stiffness during cyclic torsion in three groups.

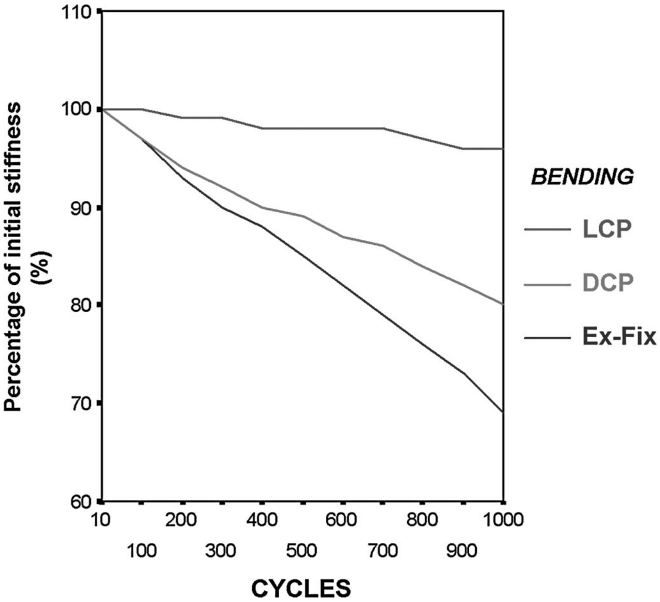

FIGURE 6. Graphs illustrating the percentage change in stiffness relative to the initial stiffness during cyclic bending in three groups.

displacement, an angular deformity of more than 30°, and comminuted fractures are prone to either nonunion or symptomatic malunion.[2,17] A multicenter, randomized clinical study of 111 patients with completely displaced midshaft clavicular fractures showed that early primary plate fixation results in improved patient-oriented outcomes, improved surgeon-oriented outcomes, earlier return of function, and decreased rates of nonunion.[1] The use of open reduction and plate fixation has gained popularity in the treatment of displaced midshaft clavicular fractures. The proponents of early plate fixation argue that it affords rapid pain relief and promotes functional recovery.[18]

Recent studies report low operative complication rates along with successful union ranging from 94% up to 100% as a result of primary plate fixation in acute midshaft clavicle fractures.[19] With the development of locked, anatomic plates, biomechanical comparisons were performed between locked and conventional unlocked plates in various recent experimental studies.[13,20–24]

Several biomechanical studies have compared different methods of fixation of the midshaft clavicular fracture.[7,19–22,25–27] Superior plating had a significantly higher bending failure load and stiffness in cantilever bending load. [20–22,26] LC-DCP,[20] locked contourable compression plates,[21] and a locking clavicle reconstruction plate[22] provided the best stiffness against axial, bending, and torsional loading. Although plate constructs were superior to intramedullary fixation with cyclic four-point bending,[25] no significant difference was seen between them with three-point bending.[27]

There are also several biomechanical studies comparing stabilities of these three implant systems for other types of fracture. Locked plates were significantly more stable than unlocked plates under torsional and bending cyclic loading on humerus and radius fracture models.[13,23,24] Plate fixation was superior to external fixation in maintaining stability in experimental studies comparing internal and external fixation on the proximal tibia.[28,29]

In our study design, we preferred the superior placement of plates, because this has been shown to be biomechanically superior in certain studies. Reconstruction plates, LC- DCP (low-contact DCP; Synthes, Solothurn, Switzerland), and DCP (Synthes) were compared in compression and torsion tests on osteotomized clavicles.[20] The authors concluded that superior plating with LC-DCP provided the best stiffness, rigidity, and strength. In another study, axial torsion and axial compression cyclic loading stiffness as well as bending failure stiffness of contoured locked and unlocked constructs were tested.[21] These authors reported that repairing a midshaft fracture with a superior locked plate was more advantageous than anterior–inferior plating in terms of both load to failure and bending failure stiffness. Robertson et al using a similar methodology compared the biomechanical stability of locking and nonlocking clavicle reconstruction plates for midshaft transverse fractures.[22] They concluded that locked plates were stiffer than nonlocked plates in compression but that no significant difference existed between them either in torsion or cantilever bending.[22] Mean torsional stiffness and bending failure load results of these two correlative studies were lower than our values, especially for locked plates. Because our study investigated compression and torsion forces using an increasing cyclic load to failure, application of torsional and bending forces was established separately by loading through 1000 cycles and then applying a load to failure for each specimen. This disparity might have occurred as a result of the use of titanium alloy plates in our study.

External fixator applications are only occasionally used in clavicle fractures. For temporary stabilization of open fractures or fractures with neurovascular injury, the external fixator can be considered an operative solution.[12,30–33] Our study indicated that although appropriate for temporary fixation, external fixation probably is not a reasonable treatment option long term.

Our study did have certain limitations. First, we did not use fresh-frozen cadaver clavicles as an experimental model. There is only one study using cadaveric formalin-fixed clavicles.[20] Three other studies used fresh-frozen clavicles,[25–27] whereas two other studies[21,22] used synthetic constructs.[21,22,25–27] Recent studies report that fixed or frozen bones can safely be used for mechanical testing, at least for storage periods of up to 1 year.[34,35] Another study found that long-term preservation did significantly affect ultimate strain in compression.[36] In an actual biomechanical study,[37] the mean and standard deviations calculated for the BMD of fresh-frozen clavicles scanned by the same dual-energy x-ray absorptiometry method were very similar to our mean BMD of formalin-fixed clavicles. The BMD of the embalmed specimens were probably different from the average patient with a clavicle fracture; however, to build a standard model, we used cadaveric bones stratified into groups according to their bone densitometry values. Second, a diaphyseal transverse fracture was the only fracture pattern examined in the study. We chose this fracture to have a standard displaced fracture model.

CONCLUSION

Superiorly placed, locked plating of the clavicle appears to be significantly more stable than unlocked dynamic compression plates or external fixators under torsional and bending cyclic loading in an unstable displaced clavicle fracture model.

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