Unicortical Versus Bicortical Locked Plate Fixation in Midshaft Clavicle Fractures

JONATHAN T. BRAVMAN, MD; MICHAL L. TAYLOR, MD; TODD BALDINI, MSC; ARMANDO F. VIDAL, MD

Abstract

Higher rates of poor outcomes in displaced midshaft clavicle fractures treated nonoperatively have recently been reported. Along with expanding indications for operative fixation and increasing application of locked plate constructs, it is unknown whether complications related to bicortical penetration of the clavicle can be avoided using unicortical fixation. The purpose of this study is to compare the biomechanical properties of unicortical and bicortical fixation in precontoured vs manually contoured locking clavicle plates. Forty-eight Sawbone composite human clavicle specimens (item #3408; Pacific Research Laboratories, Vashon, Washington) with a midshaft clavicle osteotomy were reduced and plated in 8 specimens each using a bicortical and unicortical fixation for each of 3 locked plate constructs (3.5-mm LCP Reconstruction Plate; 3.5-mm LCP Superior Clavicle Plate; 3.5-mm LCP Superior Anterior Clavicle Plate; Synthes, Inc, West Chester, Pennsylvania). Specimens were tested for stiffness in axial torsion and cantilever bending and then loaded to failure in 3-point bending. Data were analyzed using 2-way analysis of variance and Tukey's test (P<.05). No significant differences were found between unicortical and bicortical fixation in failure load, cantilever bending, and cross body stiffness. Bicortical fixation was significantly stiffer than unicortical fixation in torsion only for the same plates. Significant differences also existed between plates in torsion. Unicortical locked plate fixation may be a reasonable option in the treatment of displaced midshaft clavicle fracture fixation to avoid complications associated with postero-inferior hardware penetration following clavicle fracture fixation based on the biomechanical performance of these constructs. However, it remains unclear whether these differences will be clinically significant. [Orthopedics. 2015; 38(5):e411-e416.]

The authors are from CU Sports Medicine, Division of Sports Medicine and Shoulder Surgery, Department of Orthopaedics, University of Colorado, Aurora, Colorado.

Drs Taylor and Vidal have no relevant financial relationships to disclose. Dr Bravman is a paid consultant for DJO and Smith & Nephew, has received fellowship support from Smith & Nephew, has received fellowship and research support from Stryker, and has received grants from Synthes, Inc. Mr Baldini’s institution has received a grant from Synthes, Inc and has grants pending with Stryker and Biomet.

Correspondence should be addressed to: Jonathan T. Bravman, MD, CU Sports Medicine, Division of Sports Medicine and Shoulder Surgery, Department of Orthopaedics, University of Colorado, 12631 E 17th Ave, Rm 4501, Mailstop B202, Aurora, CO 80045-2527 (jonathan.bravman@ucdenver.edu).

Received: December 11, 2013; Accepted: July 18, 2014.

doi: 10.3928/01477447-20150504-59
Fractures of the clavicle are common injuries, representing approximately 2.6% of all fractures. Of these fractures, approximately 80% are located in the middle third, or midshaft, of the clavicle. Historically, these injuries have been treated nonoperatively, even when significantly displaced. However, recent renewed interest has been shown in the surgical treatment of displaced and shortened midshaft clavicle fractures because symptomatic nonunion and malunion have been increasingly recognized as a source of persistent shoulder symptoms.

Internal fixation of clavicle fractures has traditionally been performed with either a 3.5-mm limited contact dynamic compression plate (LC-DCP) (Synthes, Inc, West Chester, Pennsylvania) or a 3.5-mm Reconstruction Plate using 3 bicortical screws on either side of the fracture. Although several reports have demonstrated excellent safety and efficacy of primary open reduction and internal fixation, concerns remain about the risk of injury to the neighboring neurovascular structures. A recent cadaveric study analyzing the proximity of the subclavian vessels and brachial plexus to the screw exit point of both anterior and superior plating constructs demonstrated that these important neurovascular structures are as close as 5 mm to these bicortical screws.

Locking plates have become increasingly used throughout the orthopedic community. This trend relates to the increasing older active population with increasing rates of fragility fractures, increased survival of patients with high-energy injuries, and industry push toward new technology and new markets, with general interest in minimally invasive surgery. The clavicle has not been spared from these trends, and several commercially available precontoured locking plate constructs exist for use in this application. The use of unicortical locking constructs in clavicle fracture fixation is appealing because of the potential avoidance or minimization of neurovascular risk. However, despite the increasing popularity and widespread use of locking plate constructs in clavicle fixation, no direct biomechanical comparison exists regarding the strength of these fixation devices when applied to clavicle fractures with unicortical vs bicortical fixation.

Given the recent expanded indications and understanding of the sequelae of clavicle nonunion in displaced midshaft clavicle fractures, the current authors anticipate that the use of locking plates for clavicle fracture fixation will continue to increase. The authors strived to determine whether equivalent biomechanical properties exist in a unicortical locking plate construct compared with a bicortical locking plate construct for fixation of the clavicle. The authors hypothesized that unicortical plating will have equivalent biomechanical properties regarding load to failure and stiffness when subjected to axial compression, axial torsion, cantilever bending, and cross body bending when compared with traditional bicortical plating. In addition, the authors hypothesized that the mode of failure and the type of fracture created at failure would differ between plating techniques. They used composite Sawbone clavicle specimens (item #3408; Pacific Research Laboratories, Vashon, Washington), which has been validated for this type of biomechanical testing, and studied both unicortical and bicortical constructs in superiorly and anteriorly plated positions using a standardized osteotomy (fracture) model. In addition, the authors strived to compare these properties in 2 commercially available precontoured locking plates vs a manually contoured locking reconstruction plate as an aid to guide operative decision regarding optimal implant choice in this setting.

**Materials and Methods**

Forty-eight composite Sawbone clavicle specimens with a precut transverse midshaft osteotomy (OTA classification 15-B1) were obtained. This model was chosen to standardize fracture characteristics and eliminate interspecimen variability regarding osteotomy orientation, bone density, and contour.

To determine the number of samples needed for this study, a power analysis was performed. The mean failure load of a bicortical, superior locking plate of 251 N and SD of 34 N was used for the calculation. An estimate that a 50 N difference in failure load would be clinically significant was also used. The desired power was set at 0.80 and alpha was set at 0.05. The calculation was done on the University of British Columbia Department of Statistics website, resulting in a required sample size of 8.

Eight specimens each were assigned to unicortical or bicortical fixation (Groups I and II, respectively) in 3 different locking plate constructs (subgroups a, b, and c): Groups Ia, Ib, and Ic used fixation with a superiorly placed locking plate with bicortical fixation (Group Ia, small fragment 3.5-mm LCP Reconstruction Plate [manually contoured]; Group Ib, precontoured 3.5-mm LCP Superior Clavicle Plate; Group Ic, precontoured 3.5-mm LCP Superior Anterior Clavicle Plate; Synthes, Inc), whereas Groups IIa, IIb, and IIc used the same plate fixation technique but with different unicortical drilling and fixation (Group IIa, small fragment 3.5-mm LCP Reconstruction Plate; Group IIb, 3.5-mm LCP Superior Clavicle Plate; Group IIc, 3.5-mm LCP Superior Anterior Clavicle Plate; Synthes, Inc). LCP Reconstruction Plates were manually contoured with standard plate bending devices to fit a custom-built jig to ensure reproducible contour/plate characteristics. The precontoured plates (3.5-mm LCP Superior Clavicle Plate and 3.5-mm LCP Superior Anterior Clavicle Plate) were used in a “best fit” manner as applied to the standardized, osteotomized clavicle specimens. All fractures were reduced and plated according to standard orthopedic AO technique, including compressive bone fixation with clamps and proper drilling with all screws placed using a torque-limiting screw-
Specimens were potted in custom fixtures using Dyna-Cast (The Kindt-Collins Company, Cleveland, Ohio) urethane material and were mounted in a custom apparatus to the Instron servohydraulic testing machine (Instron Corp, Norwood, Massachusetts). Similar to a recently published biomechanical study of clavicle fracture fixation, each sample was tested in axial compression, axial torsion, cross body bending (testing anterior stiffness in the transverse plane), and cantilever bending. This method and sequence of testing were chosen in response to critique of previous biomechanical studies of clavicle fracture fixation that imparted 3-point bending loads to failure, which are believed to not resemble the clinically expected loads on the clavicle. Axial torsion and compression testing were conducted in a gimbal fixture to eliminate off axis torques and moments. Axial torsion tests were conducted at 0.25 Hz between ±5° while continuously sampling actuator rotation (degrees) and torque (Nmm) at 50 Hz for the duration of 10 cycles. These rotational boundaries represent approximations of the maximum rotation experienced by clavicle fracture repairs in a previously published study.

After torsional testing, each construct was loaded in axial compression at 0.25 Hz for 10 cycles between 10 and 500 N while continuously sampling actuator displacement (mm) and force (N) at 50 Hz for the duration of the test. (This represents an approximate arm carriage load of 50 kg and is below the maximum compressive failure force reported from previous biomechanical work.) For each test, construct stiffness (Nmm/degrees or N/mm) was calculated for the last 3 cycles and averaged to determine mechanical differences between the types of constructs.

After cyclical loading, specimens were placed in a custom fixation jig to apply cantilever bending forces to the lateral tip of the construct. Specimens were loaded in cantilever bending at 0.25 Hz to 40 N for 10 cycles. Bending stiffness was calculated. Cantilever bending most closely simulates loading of the lateral clavicle by the weight of the limb being suspended from the lateral clavicle. Each specimen was then positioned with a support under the screw in the proximal fragment closest to the fracture. The use of a support has been demonstrated to be necessary to ensure that failure occurs in the plated part of the construct instead of at the medial clamp and mirrors methods used in previous work (Figure 1). Loads were applied to the distal clavicle at a rate of 0.5 mm/s until structural failure, defined as plate or clavicle breakage or bending to 30 mm of actuator displacement. Data for displacement (mm) and force (N) were sampled at 10 Hz for the duration of the test. Bending failure stiffness (N/mm) (defined as the ratio of load and deformation between 10 and 150 N) and bending failure load (N) (defined as the peak load resisted by the construct) were calculated from the load-deformation curves produced.

For descriptive statistics, data were grouped by fixation type and plate type. These data were analyzed using a 2-way analysis of variance (P<.05) to test the dependent variable of fixation type (unicortical vs bicortical). After confirmation of equal variances between groups, a Tukey post hoc correction test (P<.05) for multiple comparisons was used to further evaluate individual statistical comparisons.

**RESULTS**

No significant differences were observed between unicortical and bicortical fixation in cross body stiffness, cantilever bending, or failure load. Bicortical fixation was significantly stiffer than unicortical fixation in torsion for the same plates. Independent of the type of screw fixation, significant differences in torsion stiffness also existed among the plates themselves. The precontoured Superior Plates and Superior Anterior Clavicle Plates were both significantly stiffer than the Reconstruction Plate, but no significant difference was found between the Superior Plates and the Superior Anterior Clavicle Plates. Once again, in compression stiffness no significant difference was found between the unicortical and bicortical constructs for the same plates. However, significant differences existed among the plates in compression stiffness. For bicortical fixation, Superior Plates were stiffer than Superior Anterior Clavicle Plates. For unicortical fixation, Superior Plates were significantly stiffer than both the Reconstruction Plates and the Superior Anterior Clavicle Plates. Numerical data and significant differences are shown in Figure 2.

All specimens failed by the clavicle fracturing adjacent to the plated construct without gross deformation or failure of the plates themselves in any construct. This may be the result of using Sawbones rather than cadaveric bone. During failure testing, the type of fracture (oblique or transverse) and the location of the fracture (at the most medial screw or at the most lateral screw) was noted. These results are shown in the Table. An example of an oblique medial fracture at the screw adjacent to plated construct is shown in Figure 3.

**DISCUSSION**

In contrast to traditional thinking and treatment models regarding nonoperative treatment of displaced midshaft clavicle fractures, recent literature has begun...
to expand the indications and support more global operative fixation in these patients.\textsuperscript{5,11,12,24-27} Fixation, when appropriate, has most often used conventional plating techniques with interfragmentary compression using screws placed in a bicortical fashion.\textsuperscript{10} In the setting of our aging population with increasing rates of osteoporosis, attention has been given to applying locking plate constructs to such fractures to increase the biomechanical properties of fracture fixation. These plates are being increasingly used within the orthopedic community and their indications continue to be expanded.

Complications related to plate fixation in clavicle fractures are rare, although they may be potentially limb threatening. It is clear that the intimate anatomy of the underlying neurovascular structures places them at risk intraoperatively, and technical caution is essential during placement of bicortical screws in this location.\textsuperscript{10} A recent cadaveric study demonstrated that with superior clavicle plating, the distance of screw tips to the subclavian nerve, artery, and brachial plexus was as close as less than 5 mm, with an average of 9.2, 12.2, and 9.8 mm, respectively.\textsuperscript{16} In addition, review of the current literature demonstrates an increased incidence of delayed rather than immediate hardware-related problems regarding screw penetration of the inferior surface of the clavicle.\textsuperscript{13,28-30} Given the idea that surgical indications for clavicle fracture fixation are changing and expanding, taken together with the hypothesis that this will lead to an increased number of these procedures being performed annually, a subsequent increase in hardware-related problems is anticipated. Knowledge that unicortical fixation is equivalent to bicortical fixation would essentially eliminate the theoretic risk of both immediate (intraoperative) and delayed neurovascular complications related to bicortical violation during and following fracture fixation.

Previous biomechanical studies have examined various methods of clavicle fracture fixation,\textsuperscript{19,21-23,31-36} which have demonstrated equivalent biomechanical properties between reconstruction plates and Herbert cannulated screws (Zimmer, Warsaw, Indiana),\textsuperscript{31} increased strength of fixation with plates placed in an anterosuperior position, and superiority of 3.5-mm LC-DCP vs 3.5-mm Reconstruction Plates and 2.7-mm dynamic compression plates in terms of torsional and axial fracture rigidity after fixation.\textsuperscript{22} However, until recently, no data were available concerning the biomechanics of locking plate technology as applied to clavicle fractures, with 5 of the 7 available articles examining this issue published within the past 3 years alone.\textsuperscript{19,21,32-36} In addition, the specific issue of bicortical vs unicortical

<table>
<thead>
<tr>
<th>Plate Type</th>
<th>Medial Fractures</th>
<th>Lateral Fractures</th>
<th>Oblique Fractures</th>
<th>Transverse Fractures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reconstruction Bicortical</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Reconstruction Unicortical</td>
<td>2</td>
<td>6</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Superior Bicortical</td>
<td>2</td>
<td>6</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Superior Unicortical</td>
<td>1</td>
<td>7</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Superior/Anterior Bicortical</td>
<td>6</td>
<td>2</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Superior/Anterior Unicortical</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>19</strong></td>
<td><strong>29</strong></td>
<td><strong>30</strong></td>
<td><strong>18</strong></td>
</tr>
</tbody>
</table>
fixation with locking plate technology has only been addressed by 2 of these studies,\textsuperscript{19,21} where in similar design unicortical locking constructs were compared with bicortical nonlocking constructs. Still, no prior study has compared bicortical and unicortical fixation for the same implants, which the authors believe matches their clinical experience regarding a lack of evidence available to guide this specific aspect of operative decision making.

Similar to the 2 previously published reports examining the issue of unicortical locked fixation,\textsuperscript{21,35} the current data demonstrated no difference between or among plates when using unicortical vs bicortical fixation regarding cross body stiffness, cantilever bending, or ultimate failure load. Consistent with the findings of Hamman et al,\textsuperscript{35} differences existed within and between the various constructs in torsion. Bicortical fixation was stiffer than unicortical fixation in the same plates. Differences also existed between the Superior Plates and the Superior Anterior Clavicle Plates, with both significantly stiffer than the Reconstruction Plates. No difference was found between the Superior Plates and the Superior Anterior Clavicle Plates. In compression stiffness, no significant difference was found between bicortical and unicortical stiffness for the same plates. However, with bicortical fixation, Superior Plates were stiffer than Superior Anterior Clavicle Plates, whereas with unicortical fixation the Superior Plates were significantly stronger than both the Reconstruction Plates and Superior Anterior Clavicle Plates. In addition, based on the prior reports of Partal et al\textsuperscript{33} and Robertson et al,\textsuperscript{19} the results of the current torsional testing were somewhat unexpected. The current authors had hypothesized that the unique gross properties of the Superior Anterior Clavicle Plate would confer a similar benefit of improved strength of bending rigidity demonstrated with the locking Reconstruction Plate in the anteriorinferior position, although this was not observed.

Figure 3: Oblique medial fracture at screw adjacent to plated construct.

Figure 4: Incomplete seating of locking head (on right) compared with proper full seating (on left) due to deformation of the locking hole on manual contouring.

The current study showed that all Sawbone clavicles ultimately failed at or adjacent to either the medial- or lateral-most screw holes outside of the plated construct, with no failure by hardware breakage, plate bending, or screw pullout. This is similar to results demonstrated by Drosdowech et al\textsuperscript{34} for the LCP, although in their study, the Reconstruction Plate failed by bending, which was not observed in the current study. The current authors believe that their observed mode of failure is likely the result of not having a displaced or gapped osteotomy tested, inferring inherent stability in bending to these constructs and thus concentrating the bending loads outside of the plated construct, as was observed.

An additional observation was made qualitatively during plate preparation of the manually contoured Reconstruction Plates. It was noted that if the bending irons were not threaded into the locking holes adjacent to the segment that was being contoured, significant deformation of the holes and threads in these adjacent holes was observed. This resulted in incomplete seating of the locking screw head into the plate, which may have significant biomechanical implications regarding locking effectiveness (Figure 4). This detail is noted in the product literature,\textsuperscript{37} although this was not completely clear to the authors at the outset of this project, as may be the case with the general orthopedic community using this technique.

Several limitations are present in this study. The study was a laboratory evaluation with an osteotomy simulating a midshaft clavicle fracture. Although this may standardize the testing protocol, this method of fracture may not accurately represent the in vivo behavior of such a fracture. The Sawbones model chosen is also not a perfect surrogate for human bone, although the current generation of Sawbones models replicate human bone closely, with both a cortical surface and cancellous intramedullary canal, making this a reasonable and standardized model for testing. In addition, although the mechanical testing protocol attempts to simulate in vivo clavicle motion, it cannot accurately represent the complex cyclical rotation and the axial loading that the clavicle is subject to in patients during daily activities following fixation. Lastly, the simulated 3-point cantilever bending to failure is likely not the manner in which fixation fails in the clinical setting, although it has been standardized as a surrogate measure of overall construct strength for biomechanical testing.

The current data demonstrated biomechanical equivalence of unicortical locked plate fixation when compared with bicortical locked plate fixation in failure load, cantilever bending, cross body stiffness, and compression stiffness in the same plates. However, differences were observed favoring bicortical fixation and Superior Plates in torsion and compression. Thus, unicortical locked plate fixation may be a reasonable option in displaced midshaft clavicle fracture fixation to theo-
theretically avoid complications associated with posteroanterior hardware penetration following clavicle fracture fixation based on the biomechanical performance of these constructs. However, it remains unclear whether these differences will be clinically significant.

**References**