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Joseph T. Cox

J Christopher Gayton

Matthew P. Noyes

Gregory C. Gould

Ronald J. Markert
Wright State University, ronald.markert@wright.edu

See next page for additional authors

Authors

Joseph T. Cox, J Christopher Gayton, Matthew P. Noyes, Gregory C. Gould, Ronald J. Markert, and Michael J. Prayson

Biomechanical Comparison of Hybrid versus Non-locking Screw Fixation for Midshaft Clavicle Fractures

Joseph T Cox MD[1], J Christopher Gayton MD[1], Matthew P Noyes MD PT[1], Gregory C Gould BS[1], Ronald J Markert PhD[1], Eric G Verwiebe MD[1], Michael J Prayson MD[1]*

Abstract

Objectives: Recent studies report nonunion rates of up to fifteen percent for nonoperative treatment of displaced, comminuted, or shortened midshaft clavicle fractures. Additionally, authors suggest operative treatment of these comminuted displaced midshaft clavicle fractures leads to a more satisfactory clinical outcome. Biomechanically, clavicle fracture plate fixation has been analyzed for locking versus non-locking screw use, but little evidence on hybrid screw use exists. We hypothesized that fixation of a comminuted midshaft clavicle fracture model with a pre-contoured hybrid screw-plate construct would increase stiffness and load-to-failure compared to a non-locking screw construct.

Methods: Fourteen matched pairs of fresh frozen cadaveric clavicles were randomized into two groups: hybrid screw fixation (n=7 pairs) and non-locking screw fixation (n=7 pairs). One clavicle from each pair was randomly selected to receive a 1cm midshaft gap osteotomy and plate fixation, while the remaining clavicle was tested as the intact control. The clavicles were tested through four-point bending to determine stiffness and load-to-failure.

Results: The hybrid construct was seventeen percent more stiff compared to the non-locked construct, although this did not reach statistical significance (p=0.09). The non-locked construct was significantly less stiff than the intact clavicle, whereas there was no significant difference in stiffness between the hybrid construct and the intact clavicle. Load-to-failure was not significantly different between the hybrid and non-locked constructs.

Conclusion: There was a trend towards higher stiffness of the hybrid construct compared to the non-locked construct. A similar study with more statistical power is needed to fully elicit the true differences in stiffness and load-to-failure between the two constructs.

Level of Evidence: Basic Science Study – Biomechanical Level I

Keywords: Clavicle Fracture; Midshaft; Hybrid; Plate Fixation; Non-locking; Open Reduction Internal Fixation

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*Corresponding e-mail: mjprayson@premierhealth.org
1* Department of Orthopaedic Surgery
    Wright State University Boonshoft School of Medicine, Dayton, OH 45409

1. Introduction

The middle portion of the clavicle is the most common location for fracture, accounting for 69% to 82% of all clavicle fractures (Neer 1960, Eskola et al. 1986, Postachini et al. 2002, Lazarides and Zafiropoulos 2006, Canadian Orthopaedic Trauma Society 2007, Partal et al. 2010). Historically, conservative treatment was reported to achieve union in up to 97% of these fractures, regardless of displacement (Eskola et al. 1986, Nordqvist and Petersson 1994, Robinson et al. 2004). However, recent studies indicate that nonunion occurs in approximately 15% of displaced midshaft clavicle fractures. Additionally, patients who heal radiographically after conservative treatment may have residual sequelae including shortening, weakness, pain, asymmetry and neurologic symptoms (Robinson et al. 2004, Nowak et al. 2005, Collinge et al. 2006, Lazarides and Zafiropoulos 2006, Hill et al. 2007, Jeray 2007, Celestre et al. 2008, Anderson et al. 2011).

Several systematic reviews and a large multicenter randomized controlled trial have all demonstrated improved fracture union and patient satisfaction when treating displaced midshaft clavicle fractures operatively as opposed to nonoperatively (Canadian Orthopaedic Trauma Society 2007, Zlowodzki et al. 2005, Virtanen et al. 2012). Plate fixation is one of the most common methods of internal fixation for clavicle fractures, and optimal plate location and use of locking screws continue to be investigated. While several studies have shown anteroinferior placement of midclavicular plates to be clinically reliable (Kloen et al. 2002, Zlowodzki et al. 2005, Collinge et al. 2006), superior plate placement appears biomechanically superior with regards to cantilever bending (Iannotti et al. 2002, Celestre et al. 2008, Robertson et al. 2009). Additionally, Celestre et al (2008) found that fully locked constructs in the clavicle can withstand greater forces in load-to-failure and bending failure stiffness than non-locked plating. Hence, for comminuted fractures, superiorly placed plates with locking screws should be considered, but little data exists on hybrid plate fixation.

By using both locking and non-locking screws in a hybrid configuration, it may be possible to increase the stiffness of the construct compared to non-locking screws alone. The hypothesis of this investigation was that pre-contoured superior plate fixation of a comminuted midshaft clavicle fracture model using a hybrid screw configuration would have increased load-to-failure and increased stiffness compared to a completely non-locked construct.

2. Materials and Methods

2.1 Specimen Procurement
Fourteen pairs of fresh clavicles were obtained from adult human cadavers (seven male and seven female). The clavicles were stripped of any residual tissue, radiographed, and inspected grossly to confirm there were no inherent defects of the harvested bones. After DEXA scanning, the clavicles were stored in a -20 degree Celsius freezer until thawed for testing. Thawing was done in room temperature saline for 24 hours to prevent exposure to air and dessication (Gardner et al. 2012). The mechanical testing of all specimens was completed within 50 hours of thawing (Cartner et al. 2011).

2.2 Specimen Preparation
The fourteen matched pairs of clavicles were randomly assigned to one of two groups, either the hybrid plating group or the non-locked plating group. In each group, one specimen from each clavicle pair was randomized to an experimental subgroup to receive osteotomy and plating by coin flip, and the remaining clavicle was left intact. Testing of the intact clavicles was performed so that each plated clavicle had an intact contralateral matched clavicle to which mechanical strength could be compared.

For both experimental subgroups, a 1cm gap osteotomy was made at the midpoint of the clavicle and then secured using a clamp in preparation for fixation. The specimens in both groups were fixed using a superiorly placed pre-contoured eight-hole titanium plate (Acumed, Hillsboro, OR, USA) using standard fixation technique. In the hybrid plating group, the two holes closest to the fracture were filled with 3.5mm bicortical locking screws, and the two most medial and two most lateral holes were filled with bicortical 3.5mm non-locking screws. In the standard plating group, bicortical non-locking cortical screws were placed in six holes, filling three holes on either side of the fracture. Proper plate placement and screw length were confirmed by visual inspection. New plates and screws were used for each clavicle.

2.3 Biomechanical Testing
After fracture fixation, clavicles were placed on a four-point bending jig mounted on an EnduraTEC (Minnetonka, MN) servopneumatic biomechanical testing apparatus. Figure 1 demonstrates an intact clavicle placed in the biomechanical 4-point bending apparatus. Due to the constraints of our machine, the plated clavicles were placed with the superior side down, facing the widest two points of the four-point bending apparatus. The narrower, superior two contact points of the bending apparatus were placed at 1.5cm from either side of the gap osteotomy on the anatomical inferior aspect of the clavicle (Figure 2A and 2B). This apparatus was based on the International Organization Standards for testing bone plate strength and stiffness (ISO 9585 1990) and simulates having the weight of the arm act on the lateral side of the clavicle.

Fig. 1. Intact clavicle placed in four point bending apparatus.

Once loaded onto the machine, *in vivo* postoperative stresses were simulated by cyclic testing from 20N to 150N through 5000 cycles at 2Hz. It has been reported in previous literature that the weight of a 250-pound person's arm holding a 5 pound object creates a downward force on the distal clavicle of 75N (Taylor et al. 2011). To achieve this state with our apparatus, a force of 150 Newtons was applied in four-point bending, thus creating 75 Newtons at the proximal and distal contact points of the bending jig (Figure 2A). Stiffness of the construct was considered to be the slope of the load-displacement curve between 20N and 150N, as the load was applied to the clavicle. WinTest software v2.56 was utilized for testing control and data acquisition.
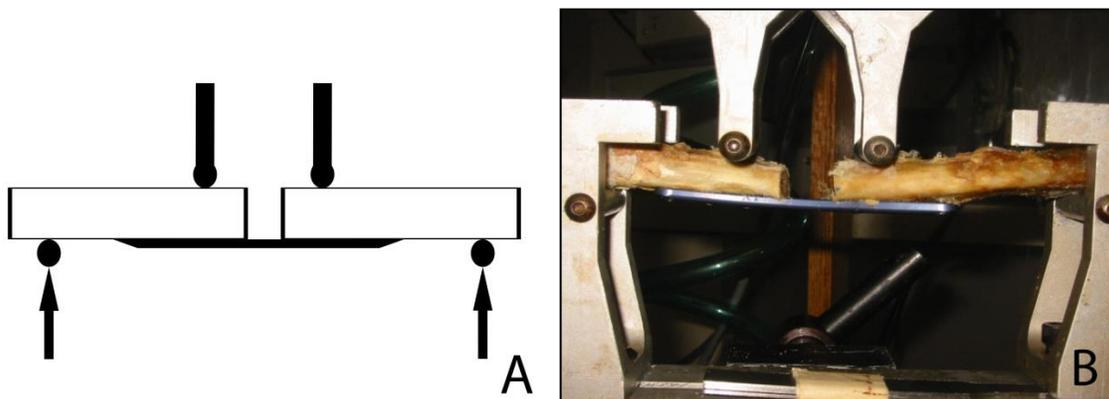

Fig. 2. Schematic of clavicle in 4 point bending apparatus (A) and representative plated clavicle placed into the 4-point bending apparatus (B).

At the completion of the cyclic loading, load-to-failure was performed by using a ramp test conducted in 0.25mm/sec increments until failure occurred in each clavicle. Load-to-failure was defined as the plate bending to irreversible deformation, the bone fracturing, the screws stripping from the bone, or the plate breaking. Additionally, the type of failure was recorded and reported for each group. Types of failure included bending of the plate, fracture of the medial shaft, fracture of the lateral shaft, fracture through the lateral-most screw, and fracture of both the medial and lateral shaft. Figure 2B demonstrates a plated clavicle that fractured through the lateral-most screw.

2.4 Statistical Analysis
Continuous variables were reported as means and standard deviations. Categorical variables were reported as counts and percents. The independent samples t-test was used to compare groups on characteristics measured on a continuous scale (i.e. age, BMD, length of clavicle, load-to-failure, and stiffness). The chi-square test or Fisher's exact test was used to compare groups on characteristics measured on a categorical scale (i.e. sex and laterality). Inferences were made at the 0.05 level of significance.

3. Results

Pre-intervention comparisons of the plated clavicles randomized to hybrid or non-locked fixation constructs showed no significant differences in age, bone mineral density, or length of the clavicles. The mean age of the cadaveric clavicle specimens were 75.6 ± 12.9 years and 75.1 ± 16.4 years in the hybrid and non-locking groups, respectively (p = 0.96). Bone mineral density in the hybrid

group was 0.342 ± 0.140 and in the non-locking group 0.378 ± 0.148 (p = 0.65). The length of the clavicles were 15.1 ± 1.3 cm and 16.0 ± 1.5 cm in the hybrid and non-locking groups, respectively (p = 0.29) (Table 1).

Table 1 shows the load-to-failure and stiffness comparisons between the hybrid and the non-locking test groups. There was no significant difference between the two groups with respect to load-to-failure, but stiffness of the construct in the hybrid group trended towards significance (p = 0.09) when compared to the non-locked group.

Table 1 Comparison of hybrid versus non-locking midshaft clavicle fixation constructs

	Hybrid (n=7)	Non-Locked (n=7)	P-Value
Age (years)	75.6 ± 12.9	75.1 ± 16.4	0.96
Bone Mineral Density	0.342 ± 0.140	0.378 ± 0.148	0.65
Length (cm)	15.1 ± 1.3	16.0 ± 1.5	0.29
Load to Failure (N)	734.6 ± 275.4	654.9 ± 365.6	0.65
Stiffness (N/mm)	249.1 ± 90.8	163.2 ± 81.0	0.09

When comparing the hybrid constructs to the contralateral intact clavicles, there was no significant difference for load-to-failure or stiffness (Table 2). Load-to-failure of the non-locked construct was not significantly different than that of the intact clavicle. However, the non-locked construct showed significantly less stiffness when compared to its contralateral intact clavicle [p=0.017] (Table 3). Representative load-displacement curves for the intact clavicle and hybrid and non-locking constructs can be seen in Figure 3. Also, there were no significant differences when comparing all plated clavicles (n=14) to all intact clavicles (n=14) (data not included).

Table 2 Comparison of the hybrid plate construct versus the contralateral matched intact clavicles

	Hybrid (n=7)	Intact Control (n=7)	P-Value
Load to Failure (N)	734.6 ± 275.4	915.1 ± 343.5	0.30
Stiffness (N/mm)	249.1 ± 90.8	357.3 ± 145.9	0.12

Table 3 Comparison of the non-locked plate construct versus the contralateral matched intact clavicles

	Non-Locked (n=7)	Intact Control (n=7)	P Value
Load to Failure (N)	654.9 ± 365.6	790.8 ± 296.6	0.46
Stiffness (N/mm)	163.2 ± 81.0	301.5 ± 103.7	0.017

During load to failure testing, the intact and plated clavicles failed in different modes. Of the fourteen intact clavicles, failure occurred by fracture through the proximal third (n=2), the middle third (n=6), or the lateral third (n=6).   The seven clavicles plated with the hybrid construct failed by plate bending (n=1), fracture through the lateral-most screw (n=4), and fracture through the medial-most screw (n=3).   The seven clavicles that were fixed with the non-locked superior plate

failed by plate bending (n=3) and fracture through the lateral-most screw (n=4). There were no failures through the medial-most screw in the non-locked plated clavicles.
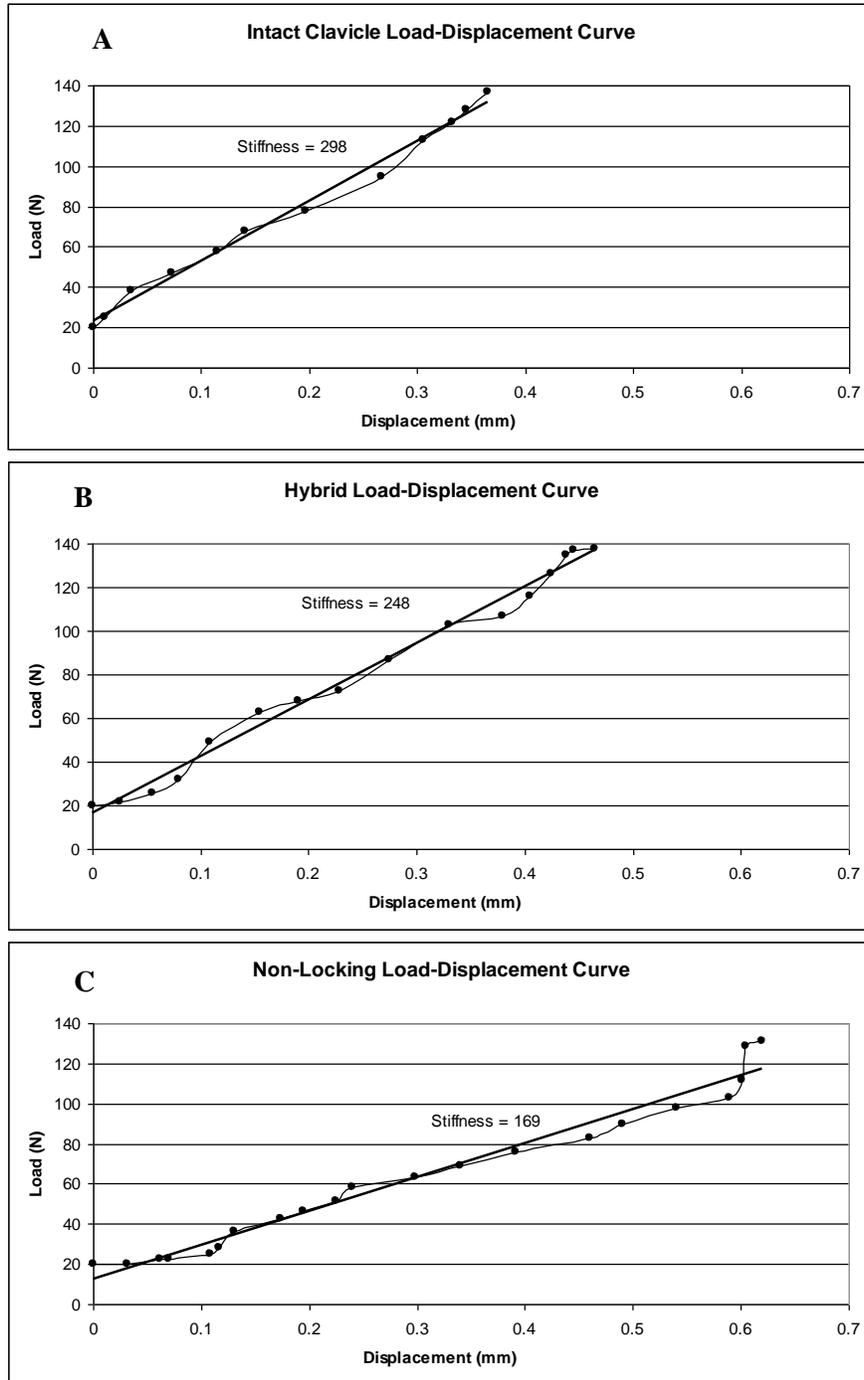

Fig. 3. Representative load-displacement curves for the intact clavicle (A), hybrid construct (B) and non-locking construct (C). The stiffness for each specimen is labeled within the graph.

4. Discussion

Nonunion occurs in approximately 15% of displaced midshaft clavicle fractures (Zlowodzki et al. 2005). Malunion is seen in up to 31% of these fractures treated nonoperatively, resulting in shortening, weakness, pain, asymmetry, and neurologic symptoms (Robinson 2004, Nowak et al. 2005, Collinge et al. 2006, Jeray 2007, Celestre et al. 2008, Hillen et al. 2010). Due to the high rate of negative sequelae, recent studies suggest operative treatment for midshaft clavicle fractures when there is shortening of >2cm, significant displacement, significant comminution, an open fracture, tenting of the skin, vascular compromise, or a high energy mechanism (Neer 1960, Bostman et al. 1997, Nordqvist et al. 1998, Lazarides and Zafiropoulos 2006, Hill et al. 2007).

A systematic review by Zlowodzki et al (2005) of 2144 midshaft clavicle fractures found operative treatment of displaced midshaft clavicle fractures to have a relative risk reduction for nonunion of 86%. Their review indicated that plate fixation of displaced midshaft clavicle fractures resulted in nonunion in only 10 of 460 patients (2.2%), compared to 24 of 159 patients (15.1%) treated nonoperatively. In addition, a review by Taylor et al (2011) found six randomized controlled trials and seven other clinical studies of clavicle fractures since 1966. These authors concluded that there is moderate evidence favoring operative treatment for displaced midshaft clavicle fractures.

The Canadian Orthopaedic Trauma Society (2007) conducted a multicenter, randomized controlled trial where 132 patients with displaced clavicle fractures were randomized to either operative treatment with superior clavicle plating or nonoperative treatment in a sling. They found that the operative group was significantly less likely to have nonunion (3.2% vs 14.3%, p = 0.042). This study also reported a statistically and clinically significant difference in Constant and DASH scores supporting operative treatment over non-operative management of displaced midshaft clavicle fractures.

Finally, a multicenter, randomized controlled study is currently underway comparing operative versus nonoperative treatment for displaced midshaft clavicle fractures that will provide additional evidence as to whether plate fixation of these fractures is superior to nonoperative treatment (Stegeman et al. 2011). However, even with the knowledge gained from the previously mentioned studies, the ideal fixation construct for surgical treatment of displaced, comminuted midshaft clavicle fractures has yet to be determined.

This investigation used a precontoured midshaft clavicle plate (Acumed, Hillsboro, OR, USA) for several reasons. First, this implant is commonly used for the fixation of midshaft clavicle fractures. Second, it is low profile and in our experience is well tolerated *in vivo*. Third, operative time with a pre-contoured plate is generally shorter, a factor that will decrease operative cost and risk to the patient (Goswami et al. 2008). Finally, this implant affords the choice of locking or non-locking screws in each hole. The use of locking technology to create stiffer constructs is often preferred in both osteopenic bone and comminuted fractures (Celestre et al. 2008). By using a hybrid construct that has both locking and non-locking screws, a surgeon should theoretically be able to modulate the rigidity of the fracture fixation by choosing an increasing or decreasing number of locking screws.

The position of the locking screws was also chosen for a specific reason. Prior studies have shown that a locked screw placed between the fracture site and an unlocked screw has a protective effect on the non-locked screw, significantly increasing the amount of torque required to remove the non-locked screw when compared to a similar construct with a non-locked screw placed on either side of the fracture site (Freeman et al. 2010, Dalstrom et al. 2012).

Our results did not demonstrate a significant difference between the hybrid and non-locking groups with regards to stiffness or load-to-failure when comparing non-locking and hybrid fixation of comminuted midshaft clavicle fractures using a superiorly placed pre-contoured plate. Interestingly, however, the hybrid construct's greater stiffness compared to the non-locking construct did trend towards significance, and our data showed that non-locked constructs, but not hybrid constructs, displayed significantly less stiffness than the intact clavicles. By comparing the stiffness and load-to-failure of the constructs as percentages of their intact controls, our data suggest that the hybrid construct was 16% more stiff compared to the non-locking construct but had only a 2.5% difference in load-to-failure.

Celestre et al (2008) created midshaft osteotomies in synthetic clavicles and found that superiorly locked plates had a 57% greater bending failure stiffness compared to superior non-locked plates. Robertson et al (2009) also created transverse midshaft osteotomies in synthetic clavicles and demonstrated that a fully locked construct did not significantly influence the stiffness in torsion or bending compared to a non-locked construct. They did find that the locked plate was significantly stiffer in axial compression than the non-locked plate. In a similar study with synthetic clavicles, Taylor et al (2011) created a one centimeter midshaft clavicle gap osteotomy and found no difference between a superiorly placed locked versus non-locked construct.

The differences in these studies may be due to factors such as fracture type and use of synthetic clavicles. In the studies by Celestre et al (2008) and Robertson et al (2009), only a simple osteotomy was performed. This type of fracture model allows cortical apposition after fracture fixation, which consequently increases the resistive force to bending (Khan et al. 2008). Since many displaced midshaft clavicle fractures are comminuted, the biomechanical testing of plating constructs for the midshaft clavicle is more appropriate with a gap osteotomy rather than a simple osteotomy.

Unlike earlier studies by Celestre et al (2008), Robertson et al (2009), and Taylor et al (2011), we used cadaveric clavicles. While some would consider the use of cadaveric specimens a limitation, we believe that the use of fresh frozen cadaver specimens provides a more realistic scenario for creating a comminuted midshaft clavicle model. Cadaveric specimens have structural, mechanical, and morphologic properties that closely mimic *in vivo* clavicles (Gardner et al. 2012). We acknowledge that there are variations in age, cortical thickness, bone mineral density, and trabecular structure that impact the biomechanical properties being investigated, but we attempted to control for these differences by using matched cadaver pairs. While synthetic clavicles have little variability among specimens, there is scant evidence to support that their mechanical behavior is similar to that of real bone (Gardner et al. 2012).

Our study had several limitations. First, we performed only cantilever bending while the *in vivo* clavicle experiences torsion, axial loading, and cantilever bending (Partal et al. 2010). With that

said, one of the main forces acting on the *in vivo* clavicle and a superiorly-placed plate is cantilever bending (Harrington et al. 1993). Thus, we tested for what we considered to be the most important mode of failure in comparing the hybrid and non-locking constructs.

Second, the type of bending apparatus for producing the downward force on the lateral clavicle raises an issue. To simulate the force of an arm on the lateral clavicle, our apparatus used two medial contact points and two opposing lateral contact points to produce the bending moment about the plate. This biomechanical testing protocol was based on the International Organization for Standardization's recommendation for determination of bending strength and stiffness of bone plates (ISO 9585 1990), but we do recognize that there is no hinge about the clavicle *in vivo* such as that in our bending apparatus (Smith et al. 1996). There have also been multiple studies using similar three- and four-point bending apparatuses (Iannotti et al. 2002, Celestre et al. 2008, Goswami et al. 2008, Robertson et al. 2009, Taylor et al. 2011). Previous studies show a higher incidence of fracture at the middle third of the clavicle compared to the medial or lateral thirds (Rowe 1968, Nordqvist et al. 1994, Robinson 1998, Postacchini et al. 2002, Jeray 2007). In our study, the fact that intact clavicles fractured at a similar rate at the middle third and the lateral third may be indicative of the shortcomings of the biomechanical testing scenario. Also, the small number of medial third fractures (n=1) was not consistent with earlier studies.

Third, our study had low statistical power. Working with restricted resources and knowing that a sample size of approximately 255 cadavers was needed in each group to achieve 80% power, we chose to conduct an exploratory study.

In summary, there is growing literature to support internal fixation of displaced comminuted midshaft clavicle fractures, but controversy still exists over the optimal type of fixation. Our results did not show any significant difference between stiffness or load-to-failure when comparing hybrid and non-locked comminuted midshaft clavicle fractures in a cadaver model. Therefore, we conclude that there is no clear mechanical advantage to using hybrid clavicle fixation in the treatment of comminuted midshaft clavicle fractures. Future biomechanical studies with more power are needed to fully elicit the true differences in strength between the two constructs and improve our understanding of the optimal fixation for these fractures.

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