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Ackland David (Orcid ID: 0000-0002-0559-7569)

UNI-CORTICAL AND BI-CORTICAL PLATING IN THE FIXATION OF COMMINUTED FRACTURES OF THE CLAVICLE:

A BIOMECHANICAL STUDY

John M Looft[1], PhD; Lincoln Corrêa[2], MBBS, PhD; Minoo Patel[2,3,4], MBBS, PhD; Mathew Rawlings[1], BSc(hons); David Ackland[1], PhD.

[1]Department of Mechanical Engineering, University of Melbourne, Parkville, Victoria, 3010, AUSTRALIA;

[2]Department of Orthopaedic Surgery, Epworth Healthcare, Richmond, Victoria, 3121, AUSTRALIA;

[3]Centre for Limb Reconstruction, The Epworth Centre, Richmond, Victoria, 3121, AUSTRALIA;

[4]Department of Surgery, Southern Clinical School, Monash University, Clayton, Victoria, 3168, AUSTRALIA

Running head: plate fixation of comminuted clavicle fractures

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Address for correspondence:

David C. Ackland

Department of Mechanical Engineering

University of Melbourne

Parkville, Victoria 3010, AUSTRALIA

Phone: +613 8344 8646

Email: dackland@unimelb.edu.au

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ABSTRACT

Background: Intra-operative neurovascular complications with clavicle fracture fixation are often due to far cortex penetration by drills and screws, but could be avoided using a uni-cortical construct. The objective of this study was to compare the bending and torsional strength of a uni-cortical locking screw plate construct and a hybrid (with central locked and outer non-locked long oblique screws) uni-cortical plate construct for clavicle fracture fixation with that of a conventional bi-cortical locking screw construct of plate fixation.

Methods: Twenty-four human clavicle specimens were harvested and fractured in a comminuted mid-shaft butterfly configuration. Clavicles were randomly allocated to three surgical fixation groups: uni-cortical locking screw, bi-cortical locking screw, and hybrid uni-cortical screw fixation. Clavicles were tested in torsion and cantilever bending. Construct bending and torsional stiffness were measured, as well as ultimate strength in bending.

Results: There were no significant differences in bending stiffness or ultimate bending moment between all three plating techniques. The uni-cortical locked construct had similar torsional stiffness compared to the bi-cortical locked construct; however, the hybrid technique was found to have significantly lower torsional stiffness to that of the bi-cortical locking screw construct (mean difference: 87.5 N.mm/deg, $p=0.028$).

Conclusions: Uni-cortical locked screw plate fixation and hybrid uni-cortical plating fixation with centrally locked screws and outer long, oblique screws may alleviate far cortex penetration, protecting nearby anatomical structures, and may ease implant removal and

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conversion to bi-cortical fixation for revision surgery; however, use of long oblique screws may increase the risk of early loosening under excessive torsion.

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INTRODUCTION

Clavicle fractures account for up to 12% of all bone fractures and 35-45% of fractures around the shoulder girdle.[21, 23, 27] Mid-shaft clavicle fractures are more frequently observed in young males under the age of thirty, typically due to excessive torsional or bending forces during impact.[21, 27] Mid-shaft clavicle fractures represent approximately 69-82% of all clavicle fractures,[11, 20, 21, 23, 27, 31] with 48% of these fractures being displaced and 19% comminuted.[23] They may vary in severity and may occur as a vertical or oblique two-segment break,[11, 20, 30] with 35% of mid-shaft clavicle fractures involving an additional butterfly fragment.[16]

Plate fixation of displaced clavicle fractures has gained popularity with high rates of union, reduced complications and improved patient satisfaction compared to non-operative management.[12, 14] In a systematic review, non-operative treatment of mid-shaft clavicle fractures resulted in a 5.9% non-union rate, more than double that associated with surgical plating.[32] While plate osteosynthesis of mid-shaft clavicle fractures is regarded as a safe and effective procedure, superior and anterior clavicle plating techniques have both been associated with intraoperative neuro-vascular injury.[13, 17, 22, 29] Previous studies have reported brachial plexus compression,[29] subclavian arteriovenous fistula,[6] and subclavian vein air embolus as series complications associated with plating (see [4] for a review). Whilst most of the catastrophic vascular injuries are acute emergencies, reports suggest that iatrogenic neurovascular injury can manifest many years after surgery.[8, 13, 29] Iatrogenic vascular and neurologic injury during bi-cortical clavicle fixation occurs most commonly due to drill or

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screw penetration of the far cortex (posterior and inferior cortices) resulting in catastrophic consequences including death.[1, 3, 4, 6, 28]

The most reliable way to prevent neurovascular injury due to far cortex screw penetration would be to use uni-cortical fixation. A review of the literature shows conflicting results of plate fixation with different fracture models. For example, in a biomechanical study conducted by Little et al (2012), clavicles fixed with locked standard uni-cortical screw fixation failed at significantly lower bending loads compared with those fixed with bi-cortical screws.[18] In contrast, a study using a clavicle saw-bone model reported no significant difference in ultimate load to failure between uni-cortical and bi-cortical fixation techniques.[15] The fracture model employed for biomechanical testing may be an important determinate of the outcome measures. In particular, the vast majority of previously reported biomechanical studies of clavicle fracture fixation employ a simple mid-shaft transverse-cut clavicle model,[5, 18] which may overestimate the construct bending stiffness in the clinical environment.

Comminuted fractures with butterfly fragments are usually high energy fractures. These fractures are inherently less stable than two-segment fractures and present higher risk of symptomatic non-union due to the presence of soft tissue injury, greater displacement between the main fracture segments, and less inherent overall bone rigidity when fixed.[16, 19] While it has been shown that an inferior cortical defect can reduce the strength of a repair construct,[7, 10] little is known about the influence of plate and screw configurations on construct integrity in cases of comminuted fractures.

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Clavicle fracture fixation aims to prevent displacement and shortening of the clavicle, whilst allowing early shoulder mobilisation and use of the arm. Three-point cantilevered bending and rotational testing represent the major forces experienced across the clavicle in abduction and forward elevation of the shoulder. The objective of this study was to develop a standardised comminuted (butterfly) fracture model for evaluation of the bending and rotational strength of plate clavicle fixation constructs for mid-shaft clavicle fracture. The specific aims were firstly, to use this model to test the biomechanical effectiveness of uni-cortical and bi-cortical locked screw superior plate fixation techniques for repairing a comminuted fracture and secondly to compare these results to those of a hybrid uni-cortical plate fixation technique incorporating centrally locked screws and long, obliquely directed non-locked screws at the most distal medial and lateral screw holes. We hypothesised that the hybrid repair construct, with long angulated screws to provide greater purchase, would exhibit similar bending resistance to that of the bi-cortical repair construct.

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METHODS

Specimen preparation

Twenty-four formalin-fixed clavicles were harvested from human cadavers (12 left, 12 right; mean age 77 yrs, range 62 to 94 yrs). This sample size was based on previous biomechanical clavicle fixation studies that employed a group size of 8 specimens yielding a study power of 0.8 in detecting significant differences in in bending and torsion.[5, 18, 24] All soft tissues were removed by sharp dissection. Clavicles were screened for macroscopic abnormalities and degenerative changes prior to testing.

Creation of a standardised fracture and repair construct

Clavicle specimens were assigned to three plate fixation groups: uni-cortical locking screw fixation, bi-cortical locking screw fixation, and a hybrid plating technique which included uni-cortical locking screws placed in the central holes and two uni-cortical non-locking screws orientated obliquely at the most medial and lateral screw holes (Supplementary Material).

A six-hole, decreased curvature clavicle plate (VariAx, Stryker, USA) was placed superiorly on each clavicle, and the most medial and lateral screws secured. A template was then used to outline a standardised 3 mm deep, 20 mm long diamond shaped osteotomy on the inferior surface of the clavicle directly in line with the centre of the fixation plate. Using an oscillating bone saw, a transverse mid-length osteotomy was first performed followed by two triangle-shaped osteotomies on the inferior clavicle surface. The inferior butterfly

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segment was removed and not reattached for testing, since pilot tests indicated that re-fixing of this segment did not contribute substantially to the overall stiffness of the repair construct. The remainder of the fixation screws were then secured. Screws were 3.5 mm diameter between 10 mm and 24 mm in length. Fracture gap reduction was evaluated using digital calipers from pre- and post- operative measurements of the distance between two pins placed on the anterior clavicle surface medial and lateral to the fracture site. All surgeries were performed by a qualified orthopaedic surgeon experienced in trauma surgery of the clavicle.

Biomechanical Testing

Biomechanical testing of repaired clavicle specimens was undertaken using an Instron testing system (Instron, Parker Hydraulics, USA) according to a previously reported experimental protocol.[24] Specimens were attached to custom-designed fixtures by potting the sternal and acromial ends of each clavicle to a depth of 2 centimetres in dental cement. Specimens were first tested non-destructively in torsion with the sternal end rigidly fixed to the lower crosshead and the acromial end fixed to the upper crosshead end-effector (Supplementary Material). The mechanical axis of the clavicle was aligned with the twist-axis of Instron upper crosshead. The acromial end of the clavicle was rotated by applying angular motion at a rate of 0.5 degrees/second[26] until a non-destructive torque limit of of 9 Nm was reached.[24]

Specimens were then oriented horizontally and tested to failure in bending with the sternal end rigidly fixed and the acromial end free. A support was placed just medial to the butterfly osteotomy to shift the peak bending moments from the sternal support to the clavicle

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fracture site. This was required to avoid excessive bending and loosening of the clavicle at the sternal fixture during testing. Bending of the construct was achieved with downward displacement the Instron upper crosshead at a rate of 0.5 mm/second until the ultimate bending strength was achieved, defined at the point of maximum bending load prior to complete repair disruption. During testing, torque, force, and displacement were sampled at 25 Hz.

Angular bending of the construct (degrees) was calculated trigonometrically from the vertical displacement of the crosshead and the moment arm of the applied load about the construct bending fulcrum. Applied bending moment (N.m) was calculated from the product of the applied force and the force moment arm. Bending stiffness (N.m/degrees) was then calculated from the gradient of a linear regression model applied to each specimen's bending moment vs angular displacement relation. Torsional stiffness (N.mm/degree) was similarly calculated from the gradient of a linear regression model applied to each specimen's torque vs angular displacement curve.

Statistical Analysis

Mean torsional stiffness, bending stiffness, ultimate bending moment, and fracture reduction were assessed for the three repair groups using a repeated-measures analysis of variance (ANOVA). Bonferroni post hoc tests for groups of equal variance were used to evaluate between-group differences. Outliers were identified and subsequently adjusted by Winsorizing the data. This was achieved by assigning outliers to the next lowest score to

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preserve statistical power. Standard deviation and data range were used as a measure of the dispersion of results. Level significance was set at ±=0.05.

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RESULTS

Construct stiffness

There was no significant difference in torsional stiffness between the uni-cortical locking screw construct compared and that of the bi-cortical locking screw construct (mean difference: 59.8 N.mm/deg, 95% CI: [-19.6, 139.1], p=0.190). Similarly there was no significant difference between the uni-cortical locking screw construct and the hybrid construct (mean difference: 27.7 N.mm/deg, 95% CI: [-44.6, 100.0], p=0.250) (Table 1). The hybrid construct, however, had a significantly lower torsional stiffness compared to that of the bi-cortical locking screw construct (mean difference: 87.5 N.mm/deg, 95% CI: [28.4, 146.6], p=0.028).

There were no significant differences between any of the constructs' bending stiffness (p>0.05). The hybrid construct did show a trend toward a lower bending stiffness (2.84 ± 1.04 N.m/deg) compared to that of the bi-cortical locking screw construct (3.82 ± 1.45 N.m/deg) and uni-cortical locking screw construct (3.12 ± 1.66 N.m/deg) (Table 1).

Construct ultimate bending moment

There were no statistically significant differences in ultimate bending moment between the three repair constructs (p>0.05). The hybrid construct showed a lower ultimate bending moment (16.7 ± 6.0 Nm) compared to that of the uni-cortical locking screw technique (19.6 ± 6.2 Nm) and bi-cortical locking screw technique (17.3 ± 5.4 N.m) (Table 1).

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Fracture Analysis

A fracture gap reduction of 0.02 ±0.47 mm was observed during clavicle fracture fixation using the hybrid technique, whereas there was little discernible change in fracture gap reduction using the bi-cortical locking screw technique (0.0 ±0.93 mm), and a net increase in fracture gap using the uni-cortical locking screw technique (0.05 ±1.10 mm) (Table 1).

Construct mode of failure

The most common mode of plate fixation failure was bone fracture perpendicular to the bone screws at the medial end of the clavicle plate, which occurred in 9 specimens. Clavicular fracture occurred at the clavicle support in 5 specimens, while screw pull-out at the medial end of the clavicle plate and bone fracture at the medial fixation occurred in 4 specimens, respectively.

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DISCUSSION

There is an increasing trend toward internal fixation for mid-shaft clavicle fractures, with studies showing better functional outcomes and higher union rates. While intramedullary devices are available, plate fixation remains the most commonly used mode of internal fixation of clavicle fractures. This has also resulted in the rise of reported iatrogenic complications, most of which result from far cortex penetration of bi-cortical drills and screws used with plate fixation. Since 2002, there have been 12 reports documenting 2 fatalities and 15 neurovascular injuries. A way of avoiding these complications would be to use plate fixation with uni-cortical screws. It is important, however to demonstrate the biomechanical strength of uni-cortical screw and plate constructs which help to facilitate early mobilisation and avoid non-union or mechanical failure. Whilst bi-cortical locked (or non-locked) plating may be considered the current standard, our study demonstrates equivalent strength with a uni-cortical locked or hybrid construct, affirming our study hypothesis. This is also our early clinical experience. This study provides strong evidence that uni-cortical locked or hybrid constructs may safely replace bi-cortical constructs without compromising fracture fixation stability.

The addition of non-locking oblique screws was found to compress the medial and lateral bone fragments together intraoperatively, which was not observed with the uni-cortical locking and bi-cortical locking technique. This study also demonstrates that screw orientation in clavicle plate fixation may be an important determinate of torsional stiffness. The hybrid technique displayed a trend in lower torsional stiffness than that of the uni-cortical locking screw technique, and a significantly lower torsional stiffness than the bi-cortical technique.

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This finding indicates that obliquely oriented plate screws support less torsional loading of the clavicle than straight uni-cortical screws. This may be due to oblique screws being oriented more closely toward the clavicle axis of twist, thus producing less overall resistance to torsion against the plate. The lower mechanical strength of the hybrid construct associated with screw obliquity was found to offset any potential benefit of increased screw length, which we hypothesised would increase bone purchase and provide greater resistance to loading. The ultimate bending moment in the hybrid construct was lower than that in the uni-cortical construct, which provides further evidence that the long-oblique screws in the hybrid technique had a negligible effect on construct strength in the presence of a butterfly fracture, and perhaps may have negatively influenced construct integrity.

In general, the bending performance of the uni-cortical and bi-cortical screw constructs in this study was not significantly different. This finding is in agreement with a saw-bone biomechanical mode,[25] but contrasts the results of Little et al (2012), who demonstrated significantly lower bending stress and failure load in uni-cortical fixation relative to bi-cortical fixation of embalmed cadaveric specimens (Table 2).[18] This finding is also supported by that of Hamman et al (2011), who showed significantly increased torsional stiffness in bi-cortical constructs relative to those in uni-cortical constructs.[9] These previous studies are based on transverse fracture models that maximise the contact area at the fracture surfaces and therefore reduces the contact force per unit area at these surfaces during bending. This may maximise construct rigidity by transmitting more bending load across the bi-cortical screws. In contrast, the butterfly fracture model employed in the present study created a less stable fracture with a lower fracture surface contact area, resulting in more

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bending transmitted to the plate at the fulcrum and less load absorbed by the screws. This may explain, to an extent, why there was less difference in bending strength between the uni-cortical and bi-cortical screw constructs in the present study compared to previous reports in transverse-fracture models. Agreement of our ultimate bending moment for the bi-cortical locked screw construct (17.3 Nm) with that of other studies that employ transverse fracture models[7, 24] (Table 2) suggests a greater dependence of fracture type on bending resistance for non-destructive loads than destructive load limits.

This study reports the biomechanical performance of three contrasting clavicle plating techniques for butterfly fracture repair. A study exploring superior bi-cortical plating techniques in the presence of an inferior cortical defect[7] reported a bending failure load of 197.9 ± 64.9 N, which is similar to that reported in this study (212.2 ± 55.2 N); however, most previous studies that employ a transverse fracture model tend to demonstrate higher torsional and bending stiffness values than those reported in the present study. For example, our torsional stiffness of the bi-cortical locking screw repair (253.3 N.mm/degrees) was substantially lower than that of a number of studies exploring bi-cortical locked screw[2, 5, 26] and bi-cortical non-locked screw constructs in transverse fracture models (Table 2).[2] Our lower construct torsional stiffness may be due to the reduced fracture surface contact area and resistance to torsional shear stress in the butterfly fracture model.

The present study reports the biomechanical performance of bi-cortical fixation constructs using locked screws in our butterfly fracture model; however, it is likely that similar construct performance may result using non-locked fixation screws. A number of previous studies have reported non-significant torque and bending response between locked

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and non-locked bi-cortical screw constructs,[18, 24, 26] and typically highlight only a trend in higher construct stiffness with the use of locked screws (Table 2). Plate offset from the surface of the bone in locking screw fixation may increase the moment acting on the plate and screws and ultimately weaken the construct, yet the increased rigidity of a locked-screw construct in some cases may also present risk of stress shielding.[2] The role of construct stiffness as well as plate location, bone quality, level of comminution and patient activity, are likely to interact and influence the rate and quality of bone union and ought to be considered in optimizing callus formation and fracture healing.

Our study has a number of limitations. First, the clavicle specimens were inherently variable in their geometry. The s-shape of the clavicle displayed a wide range of observable differences in both medial and lateral bow geometry, which may have introduced a degree of out-of-plane bending moment variability, including twisting during applied bending, and bending during applied torsion. Despite this, our current testing protocol reported data normalised to clavicle length, which is the major bone geometry variable likely to have a substantial influence on bending strength. Secondly, our clavicle specimens were from elderly formalin-fixed cadavers, which may result in lower bone structural integrity than fresh-frozen specimens from younger cadavers. There may also have been between-subject variations in bone mineral density that may have increased the dispersion of the measured data. However, since our specimens were all obtained from a similar age group, we anticipate these effects would not significantly influence between-group differences in construct functional performance. Ultimately, the anatomical variability observed across the specimens may also provide a more realistic distribution of performance outcomes relative to those

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obtained from one given saw-bone model. Finally, our non-destructive torsional testing may have weakened the fixation construct prior to the destructive bending test; however, since each specimen was tested in the same manner, this is not likely to have significantly affected relative differences in bending strength between the three construct groups.

The use of bi-cortical locking screws in plate fixation of comminuted clavicle fractures does not increase construct strength relative to the use of uni-cortical locking screws. The use of long oblique screws at the medial and lateral plate screw holes in the hybrid uni-cortical approach may increase screw purchase, decrease the intraoperative fracture gap, and ease conversion to bi-cortical fixation in cases of revision surgery; however, this fixation approach does not increase bending strength, and may reduce overall construct torsional stiffness.

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TABLE LEGENDS

Table 1: Torsional stiffness, bending stiffness, ultimate bending moment and fracture gap reduction data for uni-cortical locking screw, bi-cortical locking screw, and hybrid fixation techniques. Mean, range, and standard deviation (SD) data are provided.

Table 2: Bending stiffness, torsional stiffness and ultimate bending moment data previously reported for mid-shaft clavicle fixation constructs that employ bi-cortical non-locked screws, bi-cortical locked screws, and uni-cortical locked screws. Data values are reported, with standard deviation immediately below in parentheses.

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	Mean	Minimum	Maximum	SD
Torsional stiffness (N.mm/degrees)				
Bi-cortical locking screw	253.3	173.5	306.4	45.6
Uni-cortical locking screws	193.5	114.1	320.0	71.4
Hybrid	165.8	66.1	221.3	63.2
Bending stiffness (N.m/degrees)				
Bi-cortical locking screw	3.82	1.69	6.32	1.45
Uni-cortical locking screws	3.12	1.14	5.64	1.66
Hybrid	2.84	1.54	4.14	1.04
Ultimate bending moment (N.m)				
Bi-cortical locking screw	17.3	10.0	27.2	5.4
Uni-cortical locking screws	19.6	8.7	27.9	6.2
Hybrid	16.7	11.0	27.7	6.0
Fracture gap reduction (mm)				
Bi-cortical locking screw	0.00	-1.01	1.58	0.93
Uni-cortical locking screws	0.05	-1.23	2.30	1.10
Hybrid	-0.02	-0.67	0.51	0.47

Table 1: Torsional stiffness, bending stiffness, ultimate bending moment and fracture gap reduction data for uni-cortical locking screw, bi-cortical locking screw, and hybrid fixation techniques. Mean, range, and standard deviation (SD) data are provided.

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Bi-cortical non-locked screws

Previous study	Rawlings et al 2016[24]	Celestre et al 20082	Little et al 2012[18]	Robertson et al 2009[26]	Hamman et al 2011[9]	Renfree et al 2010[25]
Bone model	Cadaveric, fresh-frozen	Synthetic	Cadaveric, embalmed	Synthetic	Cadaveric, fresh-frozen	Synthetic
Bending stiffness	1.3 Nm/deg (0.17 Nm/deg)		2.4 Nm^2 (0.2 Nm^2)			8.6 N/mm (3.3 N/mm)
Torsional stiffness	250.6 Nmm/deg (32.6 Nmm/deg)	392 Nmm/deg (107 Nmm/deg)		283 Nmm/deg (58 Nmm/deg)	2.49 Nm/mm (0.78 Nm/mm)	
Ultimate load (bending)	13.1 Nm (1.8 Nm)	345.0 N (70.0 N)	241.5 N (40.8 N)	43.0 Nm (4.0 Nm)		53.0 N (37.0 N)

Bi-cortical locked screws

Previous study	Rawlings et al 2016[24]	Celestre et al 20082	Little et al 2012[18]	Robertson et al 2009[26]	Demirhan et al 2011[5]	Drosdowech et al 2011[6]	Present study
Bone model	Cadaveric, fresh-frozen	Synthetic	Cadaveric, embalmed	Synthetic	Cadaveric, embalmed	Cadaveric, fresh-frozen	Cadaveric, embalmed
Bending stiffness	1.6 Nm/deg (0.2 Nm/deg)		3.2 Nm^2 (0.4 Nm^2)				3.8 Nm/deg (1.5 Nm/deg)
Torsional stiffness	293.1 Nmm/deg (26.6 Nmm/deg)	470.0 Nmm/deg (77.0 Nmm/deg)		307.0 Nmm/deg (34.0 Nmm/deg)	703.2 Nmm/deg (101.0 Nmm/deg)		253.3 Nmm/deg (45.6 Nmm/deg)
Ultimate load (bending)	15.4 Nm (5.3 Nm)	300.0 N (59.0 N)	340.0 N (49.5 N)	30.0 Nm (4.0 Nm)		21.5 Nm (4.0 Nm)	17.3 Nm (5.4 Nm)

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	Uni-cortical locked screws			
Previous study	Little et al 2012[18]	Hamman et al 2011[9]	Renfree et al 2010[25]	Present study
Bone model	Cadaveric, embalmed	Cadaveric, fresh-frozen	Synthetic	Cadaveric, embalmed
Bending stiffness	3.3 Nm² (0.5 Nm²)		7.4 N/mm (2.7 N/mm)	3.1 Nm/deg (1.7 Nm/deg)
Torsional stiffness		1.7 Nm/mm (0.9 Nm/mm)		193.5 Nmm/deg (71.4 Nmm/deg)
Ultimate load (bending)	187.8 N (23.4 N)		56.0 N (23.0 N)	19.6 Nm (6.2 Nm)

Table 2: Bending stiffness, torsional stiffness and ultimate bending moment data previously reported for mid-shaft clavicle fixation constructs that employ bi-cortical non-locked screws, bi-cortical locked screws, and uni-cortical locked screws. Data values are reported, with standard deviation immediately below in parentheses.

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