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BIOMECHANICAL PERFORMANCE OF AN INTRAMEDULLARY ECHIDNA PIN FOR FIXATION OF COMMINUTED MID-SHAFT CLAVICLE FRACTURES

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ABSTRACT

Background: Surgical fixation of comminuted mid-shaft clavicle fractures commonly employs intramedullary devices; however, pins with smooth surfaces are prone to migration, whilst threaded pins can be challenging to remove postoperatively. The aim of this study was to evaluate the biomechanical performance of clavicles repaired using a novel Echidna pin intramedullary device, and a non-threaded Knowles pin. The Echidna pin features retractable spines that engage with the bone to minimise migration and facilitate ease of device removal.

Methods: Twenty-eight cadaveric clavicle specimens were harvested, and a mid-shaft wedge-shaped osteotomy performed to simulate a comminuted butterfly fragment. Specimens were allocated randomly to either the Echidna pin or Knowles pin fracture repair groups. Following surgery, eight specimens in each group underwent 200 cycles of four-point bending, whilst six specimens in each group underwent torsional testing and pull-out. Cyclic construct bending stiffness, torsional stiffness and ultimate strength were recorded.

Results: Echidna pin intramedullary repair constructs showed significantly greater bending stiffness (mean difference: 0.55 $Nm.degree^{-1}$, 95% CI [-0.96, -0.14], p = 0.01) and pull-out strength (mean difference, 146.03 N, 95% CI: [29.14, 262.92], p=0.019) in comparison to Knowles pin constructs. There was no significant difference in torsional stiffness between Echidna pin and Knowles pin repair constructs (p>0.05).

Conclusion: The Echidna pin intramedullary device, which exhibits greater bending strength and pull-out strength than that of the Knowles pin, may produce a more stable clavicle fracture reduction compared to that of commercially available threadless intramedullary pins.

INTRODUCTION

Fractures of the clavicle represent approximately 44% of all shoulder girdle fractures[1]. Mid-shaft fractures represent 81% of clavicle fractures due to the increased traumatic bending moments incurred in this region, as well as absence of major muscular stabilizers such as pectoralis major and trapezius[1-4]. Surgical treatment of displaced clavicle fractures is indicated in cases of non-union with concomitant pain, severe malpositioning, skin tenting and a fracture gap greater than half of one clavicle diameter, as well as open fractures[5], and has been associated with reduced rates of non-union post-operatively[3,6-11]. Plate fixation is the gold standard of surgical clavicle fracture repair [4], but is known to result in greater wound size and associated skin numbness, increased risk of infection, reduced muscular stability, prolonged healing, and neurovascular complications resulting from screw penetration through the far cortex of the clavicle[3,5,10,12-17].

Intramedullary clavicle fracture fixation bridges clavicle fragments via small incisions on the lateral aspect of the shoulder and over the fracture site[5], which can decrease wound infection risk, reduce pain, improve healing times compared with plated fixation[4,5,18,19]. This has been shown to reduce operating times[5,10,12,18], and has reduced the refracture rate compared to plated fixation due to the absence of fixation screw holes[15,16,20]. Titanium Elastic Nails, Rockwood pins, and non-threaded Knowles pins[5,11,18,21,22] can be easily placed intraoperatively, safely removed after healing, and have been employed with good clinical, functional and cosmetic outcomes[5,23-25]; however, smooth intramedullary devices are prone to migration, which can ultimately risk injury of adjacent neurovascular structures and viscera[18,21,26]. The Herbert cannulated bone screw is reverse threaded, and locks cortical bone

fragments during fracture reduction; however, its removal is challenging and may result in bone damage, and thus this implant is typically considered permanent[27,28]. Biomechanical studies have demonstrated that clavicles repaired with Rockwood pins perform similarly in bending to those fixed with plates[29]. Torsional testing of repair constructs, which simulates the loads incurred by the clavicle during mid-late flexion, has shown that locking-intramedullary devices are more resistant to torsional loads than their non-locking equivalents, but are outperformed by traditional plated repair[20].

The Echidna pin, which was designed as an alternative to currently commercially available intramedullary devices (Fig. 1), features retractable spines that anchor the implant within the bone of the intramedullary canal, reducing risk of migration, increasing construct stability and facilitating ease in device removal[27]. It lacks a lateral head, and therefore resides entirely beneath the surface of the bone. Preliminary research has demonstrated improved bending stiffness compared with that of the Herbert Screw[27]; however, the functional performance of the Echidna pin under cyclic bending-fatigue conditions, as well as axial loading, has not been evaluated, and its fixation strength has not been compared to that of conventional removable intramedullary pins. The aim of the present study was to evaluate the bending fatigue strength, torsional strength and ultimate tensile capacity of the Echidna Pin intramedullary fixation device in a human cadaveric model of a comminuted mid-shaft clavicle fracture, and to compare the results with those of the Knowles pin. The comparisons may be generalisable to those of other minimal-feature pins, e.g. Steinmann pins and K-wires.

METHODS

Specimen preparation

Twenty-eight embalmed clavicles (fourteen matched pairs) were harvested from human cadavers (mean age 82.5 years, range [55- 91] years, 14 left, 14 right). A sample size of 28, with 14 specimens per group, was chosen as this has been shown to yield a study power of 0.8 for detecting differences in stiffness during bending [27,30]. Soft tissue was removed by sharp dissection and all specimens were radiographically screened for macroscopic osseous degeneration or fracture (Hologic Fluoroscan Insight 2, Marlborough, USA). A wedge-shaped osteotomy was performed on each specimen to represent a Group C (AO classification) mid-shaft comminuted fracture. The clavicular half-length was determined using digital callipers, and a standardised diamond-shaped template, 20 mm long and 8 mm wide, was used to define the outline of the osteotomy on the inferior surface of the clavicle. An oscillating bone saw was then used to create the wedge-osteotomy, removing the portion of outlined bone to a depth of 3mm, before a transverse mid-shaft cut through the entire mid-shaft of the clavicle was performed. Ethical approval was obtained through the University of Melbourne Department of Anatomy and Neuroscience Human Ethics Advisory Group (1851556.2).

Surgical Repair

Clavicle pairs were randomly allocated to Knowles pin (Syntec Scientific Corporation, Taichung, Taiwan) and Echidna pin fixation groups (Echidna Surgical Solutions Pty Ltd, Ringwood, Australia). The Echidna pin was deployed into the intramedullary canal using a previously described methodology, without the application of torsion[27]. The intramedullary

canal of each specimen was identified and predrilled to allow placement of each intramedullary device from the posterolateral aspect. The fixation spines were deployed into the cortical bone using a digitally calibrated torque wrench, resulting in a mean torque of 1.20 ± 0.03 Nm. Compression of the fracture site was simultaneously performed by manual reduction of both fracture fragments. The Echidna pin intramedullary devices were chosen from three lengths (80 mm, 90 mm or 100 mm) using radiographic bone-size measurement, and were all 5 mm in diameter. Knowles pins were inserted from the posterolateral aspect using a previously described method, utilising predrilling of the intramedullary canal and prefixation with Steinmann pins before replacement with the Knowles pin and manual fracture reduction[26]. Knowles pins were chosen from three lengths (76.2 mm, 88.9 mm and 101.6 mm) and were a standard diameter of 4.8 mm. Both Echidna pin and Knowles pin devices were manufactured from 316LVM implant grade surgical steel. Post-operative radiographs of all specimens were taken to ensure correct and consistent placement of each device (Fig. 1).

Cyclic bending testing

Eight matched pairs of repair constructs underwent cyclic four-point bending testing on an Instron Materials Testing Machine (Instron, Model 3521, Parker Hydraulics). Two inferior load supports with rounded-tip end-effectors were separated by a fixed 70 mm to ensure coverage of the shortest intramedullary device, while two superior fixtures were separated by 23mm and attached to a uniaxial load cell (Supplementary Material, Fig. S1). Each clavicle was positioned such that the fracture was aligned at the mid-point between the upper and

lower supports. Clavicles underwent cyclic loading of 150 N at a rate of 1 Hz to a maximum of 500 cycles, and the load then increased by 150N and the cyclic loading repeated, until a maximum 600N was reached or until failure of the bone-implant construct. Displacement and force data from the Instron cross-head were digitally recorded using the Instron computer Wave-Matrix system (Instron, Massachusetts, USA). Angular displacement of the repair construct (degrees) was calculated trigonometrically from the tangent of the vertical displacement of the Instron cross head (mm) and the horizontal moment arm of the applied force (23.5mm). The applied bending moment (N.m) was calculated as half of the measured compressive load multiplied by the moment arm of 23 mm. Repair construct bending stiffness for each load application was then computed using a line of best fit from the resultant bending moment vs angular displacement curve. The mean bending stiffness for each load was taken as the average bending stiffness for each cycle within the load.

Torsion and tension testing

Six pairs of clavicles underwent non-destructive torsional testing followed by a pull-out tension test to failure using the Instron Materials Testing Machine. The acromial and sternal ends of the clavicle were embedded in custom holding fixtures using dental plaster and were rigidly attached the Instron Materials Testing Machine (Supplementary Material). Torsional loading was then performed with the sternal end of the clavicle fixed by rotating the acromial end of the repair construct by 3° clockwise at a rate of 0.5°/s, before returning to neutral, then rotating the construct 3° in the anticlockwise direction at the same rate[27]. Following torsional testing, clavicle pull-out testing was conducted by displacing the acromial aspect upwards at a rate of 0.5 mm/s to a maximum 40 mm of displacement. Torsional stiffness

(N.mm/deg) was calculated as the gradient of the torque vs. angular rotation curve[27]. The ultimate tensile strength of the repair construct was defined as the maximum applied force during the pull-out test (N).

Data analysis

A univariate analysis was used to compare mean bending stiffness, total cycles to failure, torsional stiffness and pull-out force between Knowles pin and Echidna pin fixation groups. Data normality and equality of variance was assessed using Levene's test for equality of variances. A Bonferroni post hoc test was used to determine the statistical significance of testing parameters. Mean data and 95% confidence intervals were reported, and standard error of the mean (SEM) used as a measure of the dispersion of results. Significance was set at $p<0.05$. Data analyses were performed using the Statistical Package for Social Sciences (PASW Statistics 22, SPSS Inc., Chicago, IL).

RESULTS

Construct bending

The Echidna pin construct had a significantly larger mean bending stiffness at the 600 N load cycle, compared with that of the 150 N load cycle (mean increase: 1.44 Nm/degree, 95% CI [0.4, 2.5], $p= 0.016$), whereas, the Knowles pin did not observe a significant difference in stiffness with change in load cycle ($p>0.05$) (Table 1). The overall mean bending stiffness across all loads was found to be significantly greater for the Echidna pin repair construct

compared to that of the Knowles pin construct (mean difference: 0.55 Nm/degree, 95% CI [-1.0, -0.1], p = 0.01) (Table 1). There was no significant difference in the mean number of bending cycles endured by the Knowles pin (1135 ± 192 cycles) and Echidna pin repair constructs (859 ± 208) (p>0.05). There was no significant difference in mean bending stiffness of the Knowles and Echidna pin repair constructs at the 150N, 300N, 450N and 600N load cycles (p>0.05) (Table 1).

Construct torsion

The mean torsional stiffness of the Echidna pin repair construct was 38.0 ± 20.5 N.mm/degree and 56.4 ± 31.8 N.mm/degree in the clockwise and anticlockwise directions, respectively. The Knowles pin constructs showed a non-significant trend towards lower torsional stiffness compared with that of the Echidna pin in the clockwise direction (mean difference: 21.1 N.mm/degree, 95% CI [-30.6,72.6], p =0.30) and anticlockwise direction (mean difference: 16.5 N.mm/degree, 95% CI [-17.3,50.2], p=0.39) (Supplementary Material, Fig. S2). The mean pull-out strength of the Echidna pin repair construct was significantly larger than that of the Knowles pin repair construct group (mean difference, 146.0 N, 95% CI: [29.1, 262.9], p=0.019).

DISCUSSION

Intramedullary fixation of mid-shaft clavicular fractures has been shown to reduce refracture rate and improved cosmetic outcomes compared to plate fixation[15,16,20]; however, smooth-profile pins such as the Steinmann and Knowles pin risk migration, while post-operative

removal of threaded devices such as the Herbert screw present technical challenges and risk of bone fracture[28]. The Echidna pin was designed to anchor into bone surrounding the intramedullary canal using retractable spines, reducing the risk of migration and increasing construct stability, whilst allowing for ease of device removal[27]. The findings of the present study showed that the change in cyclic stiffness of Echidna pin repair construct was significantly greater than that of the Knowles pin repair construct. There was no significant difference between the Echidna and Knowles pin in torsional stiffness, while the Echidna pin repair construct demonstrated significantly greater maximal pull-out strength in comparison to that of the Knowles pin repair construct.

The Echidna pin repair construct was significantly more resistant to bending than that of the Knowles pin construct, as demonstrated by a 18% larger overall bending stiffness in the Echidna pin. This finding suggests that the Echidna pin is likely to provide more effective immediate resistance to postoperative bending loads such as those occurring during upper limb pushing and lifting[31]. These findings corroborate those of Ackland et al[27], where the Echidna pin repair constructs showed significantly greater cantilever bending stiffness in comparison to that of the Herbert cannulated bone screw. Clinically, implants that display high resistance to bending at the fracture site may reduce malunion, improve stabilisation of fracture fragments and contribute to improved healing[8,20].

The bending stiffness of the Echidna pin was found to increase significantly by 77% between the 150N and 600N cycles, compared with the non-significant increase of 25% for the

Knowles pin repair. This suggests that the Echidna pin capacity to resist repetitive bending loads increases with the number of cycles, which may be attributed to the locking spines further engaging with bone across increasing load cycles. Repair constructs with increased strength and rigid fixation may allow for earlier return to active movement after mid-shaft clavicular repair[4,32]. The Echidna pin survived a mean 859 ± 207.7 cycles before failure, compared with 1134.8 ± 192.0 for the Knowles pin. This finding, although non-significant, suggests the absence of intramedullary anchoring in the Knowles pin results in higher cycles to failure, but with the potential of increased risk of tissue damage due to pin migration.

During upper limb flexion, clavicular torsion forces and moments are concentrated on the clavicular mid-shaft. We showed no significant difference in clockwise or anticlockwise torsional stiffness between the Echidna pin repair construct and the Knowles pin construct. A similar pattern was observed by Ackland et al (2017), who reported no significant difference in mean torsional stiffness between the Echidna pin and Herbert bone screw[27]. This finding suggests that torsional load on the repair construct appears to be insensitive to intramedullary pin type. This may be due to the low resistance of pins to torsion in comminuted fracture models that do not have a substantial bone fragment contact surface, in contrast to transverse fracture models where fracture surfaces have maximal contact area. This outcome suggests that high shoulder elevation, which is associated with greater clavicle torsion, should be avoided in the early-postoperative period prior to callus formation to facilitate healing of comminuted fractures repaired with intramedullary pins.

A complication associated with use of smooth surface profile intramedullary devices such as the Knowles pin is increased likelihood of implant migration [8,14,18]. Lateral deviation of the prosthesis can cause irritation to skin and subcutaneous tissue, whilst medial migration may contact and damage the brachial plexus and surrounding viscera [14,18,22,26]. Whilst the locking spines of the Echidna pin appear not to influence torsional outcomes compared with the Knowles pin in this cadaveric model, the Echidna pin did display a significantly greater axial pull-out strength compared with the Knowles pin. This suggests the Echidna pin repair construct demonstrates greater resistance to axial loading and is likely to maintain a more stable reduction of the fracture components. The deployment and retraction of the Echidna pin spines required a mean 1.2 Nm of torque, which is substantially less than the maximal flexion torque capacity of the human wrist (8.0-11.9 Nm)[33], suggesting ease of intraoperative pin placement and post-operative removal.

There are a number of study limitations. Firstly, the clavicles used in this study were from elderly cadaveric specimens and may not be representative of young adults; however, the cadaveric specimens provide native homogeneous isostropic bone material behaviour, with the dispersion of results representative of implant behaviour across a population – a finding that cannot be readily deduced using standardised saw-bone models. Secondly, the small sample size of the present study may have resulted in some underpowering; however, the sample size of 16 was sufficient to detect significant between group differences in bending stiffness[30]. Third, there may have been some mismatch between the length of the clavicle and the finite number of pin sizes available, together with the spacing of the end-effectors during

bending testing, which may have had some interaction with the pins; however, spacing of the fixtures during bending was standardised and matched pairs employed for the two study groups. Fourth, the biomechanical model employed did not consider fracture healing or bone remodelling on the functional performance of the pin *in vivo*. Finally, the position of the spines at the lateral and central thirds of the Echidna pin were intended to provide optimal construct stability in cases of mid-third clavicle fractures; however, further testing is required to evaluate construct strength in cases of off-centre fracture.

In conclusion, a novel Echidna pin clavicle repair construct demonstrated greater stability and resistance to load during bending and pull-out testing compared to that of a threadless Knowles pin in a cadaver model. This finding may suggest greater fracture stability, and ultimately reduced likelihood of pin migration with the use of the Echidna pin. Future studies ought to evaluate clinical performance and longevity of the Echidna pin against other commercially available intramedullary devices.

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SUPPORTING INFORMATION

- Instron load testing apparatus details and supporting diagrams (Fig. S1)
- Differences in bending stiffness, torsional stiffness and pull-out strength between groups (Fig. S2)

FIGURE CAPTIONS

Fig. 1: The Echidna pin intramedullary fixation device which features retractable spines within the pin body, an actuator assembly interface, and a tapered pin head (A), radiographic image of the comminuted midshaft clavicular fracture surgically repaired with a Knowles pin intramedullary device (B) and Echidna pin intramedullary device (C).

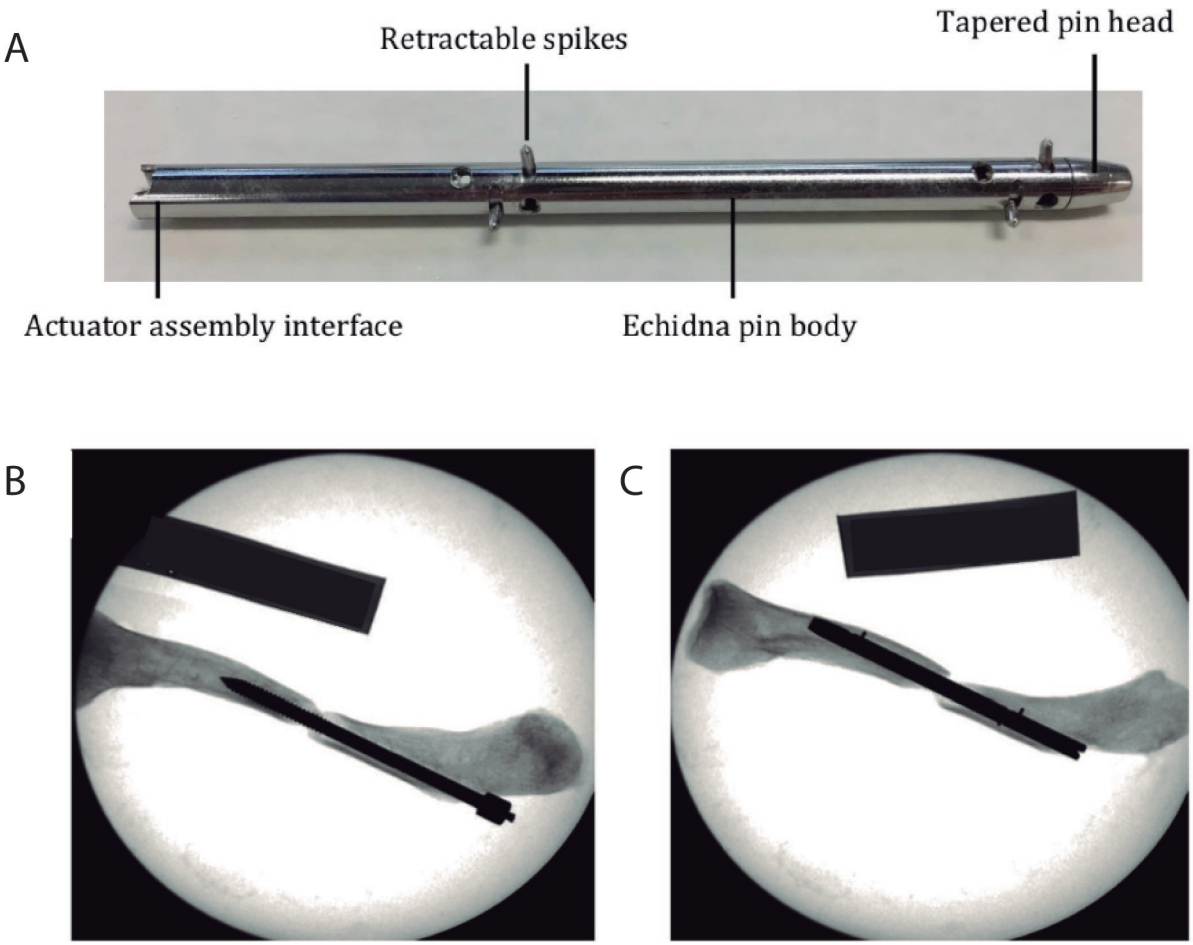

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Table 1: Bending stiffness (N.m/degree) of clavicle repair constructs at 150, 300, 450, 600 N and overall stiffness for the Knowles pin and Echidna pin repair constructs. Mean and standard error of the mean (SEM) are provided. Symbol definitions are as follows: ϕ indicates a significant difference in mean stiffness at a given load relative that at 150 N, while γ denotes significant difference in overall mean construct stiffness between groups across all cycles ($p<0.05$).

	Load Increment									
	150 N		300 N		450 N		600 N		Overall mean	
	Mean	SEM	Mean	SEM	Mean	SEM	Mean	SEM	Mean	SEM
Knowles Pin	1.92	0.27	1.97	0.49	2.33	0.23	2.40	0.53	2.07	0.45
Echidna Pin	1.88	0.60	2.62	0.70	3.07	0.77	3.33^{ϕ}	0.09	2.45^{γ}	0.85