The effect of screw angulation and insertion torque on the push-out strength of polyaxial locking screws and the single cycle to failure in bending of polyaxial locking plates

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Keywords
Polyaxial, push-out strength, bone plate, locking plates, locking screws, insertion torque, screw angulation

Summary
Objective: To evaluate the mechanical properties of the Polyaxial Advanced Locking System (PAX) in screw push-out and four-point bending.

Materials and methods: Screw push-out: PAX locking screws were applied to first generation PAX plates at three different insertion angles with two different insertion torques. A load was applied parallel to the screw axis, and screw push-out force was measured. Four-point bending: PAX plates were applied to a bone model and a fracture gap was simulated. Bending stiffness, bending strength, and bending structural stiffness were evaluated and compared to published data.

Results: Screw push-out forces were significantly higher at 0 and 5 degree insertion angles when compared with an insertion angle of 10 degrees. An insertion torque of 3.5 Nm also produced significantly higher push-out forces compared to 2.5 Nm. Four-point bending: Qualitative comparison of the data gained in this study with previously published data suggests that the PAX system bending stiffness and bending structural stiffness seems to be higher than that of other veterinary orthopaedic implants, but the bending strength was similar.

Clinical relevance: The PAX locking system offers the benefit of polyaxial screw insertion while maintaining comparable biomechanical properties to other currently available orthopaedic implants.

Introduction
A biological approach to fracture management has recently shifted the focus away from the recommendations for absolute fracture stability and anatomic reconstruction that were initially set forth by the AO to techniques that minimize operative injury. The development of locking bone plate systems has been instrumental in this biologically supportive approach. Locking plates function as single-beam constructs and behave more like external fixators than conventional dynamic compression plates (DCP) (1). The overall stability at the fracture site is dictated by the stiffness of the locking construct, by the strength of the locking interface, and less by the interaction between the implants and the bone (2). By contrast, the stability of DCP relies on compression of the plate to the bone using a defined number of screws which create friction at the plate-bone interface (1-3, 8). The benefits of locking plates include maintenance of periosteal vascular integrity, enhanced minimally invasive surgical applications, decreased risk of loss of fracture reduction during screw tightening, and a minimized need for precise anatomic contouring (1, 2, 4, 6-8).

While locking plates have many advantages, they are not without disadvantages. Two described limitations include the difficulty of screw removal and the fixed angle at which locking screws must be inserted. Over-tightening and cross-threading can lead to cold welding between locking screws and plates, which would prevent routine screw removal (5). This is a problem not seen with DCP and is more common among titanium implants as they have a greater capacity to deform when compared to stainless steel (5). Additionally, the requirement of inserting locking screws perpendicular to the plate is a technical limitation of most currently available veterinary locking plate systems including the Dynamic Compression Plate (DCP"): Synthes®, Paoli, PA, USA.
ComPact UniLock, Locking Compression Plate (LCP), String-of-Pearls (SOP), Fixin, and the Advanced Locking Plate System (ALPS). Two of these systems, the LCP and ALPS, were designed to address this problem by allowing the application of both locking and standard screws whereby screw angulation can be performed with standard screws (3, 6). Additionally, the SOP plate addresses the problem by allowing pearls to be angled independently of each other with the screw following the angle of the pearl.

A new veterinary locking plate system, Polyaxial Advanced Locking System (PAX) (Figure 1), was created to capture the advantages offered by locking plate technology while eliminating the aforementioned disadvantages. The PAX system is an angle-stable construct that, according to the manufacturer, allows up to 10 degrees of angulation of screws within the plates without compromising the screw-plate locking mechanism (7). This is possible because the titanium alloy of the screw is twice as hard as the titanium of the plate. As the screw is inserted into the PAX plate, plastic deformation of the plate hole occurs around the screw-head threads (7). Essentially, the harder screws ‘cut’ threads into the softer plates. Moreover, this mechanism of locking should minimize the effect of cold welding between the screw and the plate. Should screw removal be required, the screws have the same ability to cut a path out of the plate.

Recent studies have been performed to evaluate and compare the mechanical properties of commonly used veterinary locking implants including screw push-out strength, single cycle to failure with four-point bending of plates alone, and single cycle to failure with four-point bending of a synthetic bone-plate construct (3, 4, 8).

Figure 1 First (left) and second (right) generation PAX plates.

Figure 2 The picture illustrates screws that are inserted at a five degree angle.

The purpose of this study was to report the PAX locking screw push-out strength at different angles and torques of insertion, and to describe the four-point bending properties of the 3.5 mm PAX plates using the exact testing protocols utilized for testing other locking plate systems in order to make direct comparisons to previously published data. We hypothesized that screw push-out strength would not be affected by the angle of insertion. By contrast, we hypothesized that torque of insertion would affect push-out strength regardless of the angle of screw insertion.

Materials and methods

Experiment 1: Screw push-out

There were two groups within this experiment for evaluation of both insertion angle and insertion torque. Group A: Eighteen, 3.5 mm PAX locking screws were applied to 5-hole 3.5 mm first generation PAX locking plates with two screws per plate (i.e. 3 plates and 6 screws per insertion angle). Screws were inserted at three different angles, zero degrees (perpendicular to the plate), five degrees, and 10 degrees relative to the perpendicular axis to the plate (Figure 2). This allowed six samples to be tested per insertion angle. All screws were inserted using an angled drill guide to ensure consistency of screw placement (Figure 3). Each inserted screw angle was confirmed using a protractor. All screws in group A were inserted with 2.5 Nm of torque, as recommended by the manufacturer, using a torque-limiting screwdriver. All screws were inserted by one author (AJK).

Group B: This group was identical to group A with the exception that all screws were inserted at a torque of 3.5 Nm using a torque-limiting screwdriver. A torque of 3.5 Nm was chosen as it can be achieved in

Figure 3 The picture demonstrates the use of a drill guide which allowed for accurate drilling of pre-determined angles.

Cedar Torque Measurement Digital Torque Tester Wrench Model DI-5N: Sugisaki Meter CO. Ltd., Inashiki-shi, Ibaraki, Japan
a clinical setting. All three angles were tested as they were for group A.

All plates were tested in a custom designed fixture that maintained plate position while being tested. The screw tips were axially loaded in displacement control at a rate of 1 mm/min using a servo-hydraulic testing machine until the locked screw to plate coupling failed and the screw completely pushed out of the plate (Figure 4). A two kilonewton load cell, verified to be within <0.25% accuracy, was used. Data were collected using an IEEE interface with software written for control of displacement and data collection from the mechanical testing frame.

**Experiment 2:**

**Plate-construct four-point bending**

Six, 8-hole second generation 3.5 mm PAX locking plates were applied to short-fibre filled epoxy cylinders as previously described with a final bone model–plate construct consisting of a 25 mm gap (3). Six (3 per bone model segment) bicortical 3.5 mm locking screws were inserted perpendicular to the plate at a torque of 2.5 Nm, as recommended by the manufacturer, using a torque-limiting screwdriver. The dimensions of the plate holes of the first and second generation PAX plates were identical.

All samples were subjected to single cycle four-point bending in accordance to the ASTM Standard Specification and Test Method for Metallic Bone Plates (Figure 5) (9). Each sample was manually centred on the support rollers with the portion of the plate with the minimum section modulus facing the loading direction. Centre span and loading span distances remained constant for all samples in each group with the centre span and loading distances being 140 mm and 50 mm, respectively. Displacement-controlled testing to failure was performed at a rate of 0.1 mm/s until plastic deformation occurred. Load and displacement data were recorded at 10 Hz. Bending stiffness, defined as the maximum slope of the elastic portion of the load versus load-point displacement curve (N/mm), was determined for each bone plate. Bending moment deflection curves were generated using commercially available spreadsheet software. Bending stiffness was calculated by determining the maximum slope of the elastic portion of the load versus load-point displacement curve, which was determined using linear regression analysis for a best fit (minimum $r^2 = 0.99$). Bending strength (yield point) was defined as the bending moment needed to produce a 0.2% offset displacement in the bone plate. A line representing the slope of the bending stiffness was offset by 0.28 mm displacement (ASTM 0.2% offset method, $q = 0.002 X/a$), where $a$ equals the centre span roller distance, which was overlaid on the graphs. The point at which the bending-moment deflection curves intersected the offset bending stiffness slopes was the bending strength reported in Nm as described by the ASTM standard. Bending structural stiffness is defined as the normalised effective bending stiffness of the bone plate that takes into consideration the effects of the test setup configuration. Thus, bending structural stiffness of the bone construct is an indicator of the stiffness of the bone plate that is independent of the test configuration. It is simply related to the geometry of the bone plate and the material used in manufacturing the bone plate.

**Statistical Analysis**

For the screw push-out test, we performed a two-factor ANOVA to determine whether insertion torque and insertion angle had an effect on the push-out force. Tukey multiple comparisons were performed to determine whether there were any differences between the three insertion angles. Statistical analyses were performed using statistical software. A significance level of 0.05 was used for all analyses.

**Results**

Significant differences were noted for both angle and torque when each was evaluated as an individual variable (Table 1). However, the interaction of the two variables was not significant ($p = 0.527$). There was a significantly lower push-out force for an insertion angle of 10 degrees (1080 N) as compared to angles of zero degrees (1530 N; $p < 0.0001$) and five degrees (1440 N; $p < 0.0001$)
The mean push-out force for an insertion torque of 3.5 Nm (1560 N) was significantly greater than that for an insertion torque of 2.5 Nm (1140 N; p < 0.0001). The mean push-out forces for each level of insertion angle and torque are reported in Table 1 and Table 2.

The means for bending stiffness, bending strength, and bending structural stiffness of the PAX plates are reported in Table 3 along with the previously published data (mean ± SD) of eight different bone plates (3). While statistical analysis was not performed, qualitative comparison of the mean values shows that the plates appeared to fall into four groups based on their bending stiffness and bending structural stiffness:

- PAX plate (104 N/mm, 11.3 Nm²)
- SOP (76.0 N/mm, 8.23 Nm²), ALPS-11 (74.9 N/mm, 8.11 Nm²), and DCP (69.9 N/mm, 7.57 Nm²)
- LCP (60.9 N/mm, 6.60 Nm²) and SS LC-DCP (57.4 N/mm, 6.22 Nm²)
- Fixin (46.0 N/mm, 4.98 Nm²), Ti LCP-DCP (43.5 N/m, 4.71 Nm²), and ALPS-10 (39.6 N/mm, 4.29 Nm²)

For bending strength, there was no clear delineation of the plates into distinct groups.

### Discussion

Our results demonstrate that both angle of insertion and insertion torque affect the axial push-out force of the PAX locking screws. The resistance to push-out was not significantly different between zero or five degrees of screw angulation, but it was significantly less when screws were angled at 10 degrees (p < 0.05). These results are probably due to both the length and depth in which the cutting threads in the screws heads engaged within the plate holes. By definition, length of engagement refers to the distance over which the threads of the plate contact the threads of the screw; and depth of engagement refers to the amount of overlap between the threads of the plate and the threads of the screw. In the present study, when screws were applied at zero and five degree angles, the screw heads appeared to be completely seated within the

<table>
<thead>
<tr>
<th>Factor</th>
<th>Level</th>
<th>Push-out force (N) (mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angle</td>
<td>0</td>
<td>1530 ± 299^a</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>1440 ± 242^a</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>1080 ± 217^b</td>
</tr>
<tr>
<td>Torque</td>
<td>2.5</td>
<td>1140 ± 288^a</td>
</tr>
<tr>
<td></td>
<td>3.5</td>
<td>1560 ± 338^b</td>
</tr>
</tbody>
</table>

Table 1 These values represent individual variables. Values shown are mean ± standard deviation (SD). Superscripted upper and lower case letters indicate significant differences among torque and angle, respectively.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Level</th>
<th>Push-out force (N) (mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angle</td>
<td>0</td>
<td>1350 ± 72.4</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>1250 ± 224</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>825 ± 197</td>
</tr>
</tbody>
</table>

Table 2 These values reflect the interaction of both the angle and torque. Values shown are mean ± standard deviation (SD). No significant differences were noted.

<table>
<thead>
<tr>
<th>Implant</th>
<th>Number</th>
<th>Bending stiffness (N/mm)</th>
<th>Bending strength (Nm)</th>
<th>Bending structural stiffness (Nm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>Mean</td>
</tr>
<tr>
<td>Polyaxial Advanced Locking System (PAX)</td>
<td>6</td>
<td>104</td>
<td>6.18</td>
<td>8.25</td>
</tr>
<tr>
<td>Dynamic compression plate (DCP)</td>
<td>4</td>
<td>69.9^a</td>
<td>17.9</td>
<td>9.76^b,c</td>
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<tr>
<td>Stainless steel limited-contact DCP (SS LC-DCP)</td>
<td>4</td>
<td>57.4^b</td>
<td>0.44</td>
<td>9.16^c</td>
</tr>
<tr>
<td>Titanium limited-contact DCP (Ti LC-DCP)</td>
<td>4</td>
<td>43.5^c</td>
<td>3.39</td>
<td>6.32^a</td>
</tr>
<tr>
<td>Locking compression plate (LCP)</td>
<td>4</td>
<td>60.9^b</td>
<td>12.6</td>
<td>10.1^b,c</td>
</tr>
<tr>
<td>Advanced locking plate system (ALPS)-10</td>
<td>4</td>
<td>39.6^c</td>
<td>2.45</td>
<td>5.20^a</td>
</tr>
<tr>
<td>ALPS-11</td>
<td>4</td>
<td>74.9^a</td>
<td>3.32</td>
<td>11.8^b,c</td>
</tr>
<tr>
<td>String-of-Pearls (SOP)</td>
<td>4</td>
<td>76.0^a</td>
<td>6.89</td>
<td>12.7^a</td>
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<tr>
<td>Fixin</td>
<td>4</td>
<td>46.0^c</td>
<td>1.47</td>
<td>6.68^a</td>
</tr>
</tbody>
</table>

Table 3 Values shown are mean ± standard deviation (SD). Superscripted letters indicate significant differences within each respective group. The PAX plate was the only construct tested in this study. The remaining data was published by Blake et al. (3).

Footnote:
P Limited Contact Dynamic Compression Plate (LC-DCP®): Synthes®, Paoli, PA, USA
plate hole suggesting that full length of engagement was achieved at both angles. By comparison, a small portion of the screw heads inserted at a 10 degree angle did not engage the plate holes, suggesting less than a full length of engagement (Figure 6) and therefore less holding power.

In addition to a decrease in length of engagement, increasing the angle of screw insertion would also be expected to lower the depth of engagement. One report evaluating screw push-out force at varying insertion angles for the LCP demonstrated a decreased push-out force at both five and 10 degree angles of insertion due to uneven screw-plate thread engagement, but this decrease was only significant for 10 degrees (12). It was concluded that the decrease in stability up to an angle of five degrees would not be relevant in a clinical application (12). Although the study by Kääb and colleagues did not use the term ‘depth of engagement’, a reduction in the contact area between the screw-plate interface was noted. We suggest that a similar situation exists for the PAX implants. While the insertion angle of 10 degrees had a significant lower push-out force than the zero and five degree angles, it is higher than the pullout strength reported for the 3.5 cortical screws in bone (13, 14).

Screws inserted with an insertion torque of 3.5 Nm had significantly greater resistance to screw push-out than those at inserted with a torque of 2.5 Nm. Given the design of the PAX plate and screws, this finding is not unexpected. The PAX plate holes have a conical shape so that the diameter of the hole becomes smaller from top to bottom and the screw heads have a slightly larger diameter conical head shape. As the screw head is advanced within the plate, the depth of engagement increases as the wider screw thread cuts a deeper thread into the narrower plate hole. This deeper connection of the threads would create more resistance to screw push-out. Increasing the torque of insertion can lead to cold welding between locking titanium screws and plates which is why torque-limiting drivers are generally recommended with these systems. However, because of the difference between the PAX screw and plate titanium alloy hardness, the value of improved depth of engagement through increased torque of insertion is not negated by cold welding complications. Generating 2.5 to 3.5 Nm of torque by hand is feasible as torque outputs as high as 4 to 5 Nm are reported (15). Moreover, the amount of torque generated by hand depends on multiple variables including the shape, size, and material of the screwdriver handle, strength of the person operating the screwdriver, and gloved versus not gloved.

The results demonstrate that the bending stiffness and bending structural stiffness of the second generation PAX plate constructs exceeded that of other commonly used veterinary orthopaedic implants although this comparison was not supported by statistical analyses. The bending strength of the PAX system appeared similar to that of the LCP, DCP, SS LC-DCP, and Fixin, but not the SOP and ALPS-11. A study comparing the exact same experimental condition is necessary to confirm these findings.

For implant bending strength, there was seemingly a large amount of overlap between groups. This is probably attributed to the complex interactions between the implants and bone models which affect the mechanical properties of plate constructs (3). Screw variables that may affect this interaction include screw number, core diameter, monocortical versus bicortical, cortical versus locking, material (titanium versus stainless steel), and locking mechanism. Plate variables include length, modulus of elasticity, and section modulus. With the exception of the Ti ALPS 11, the highest mean values for bending strength appeared to be produced by the stainless steel implants. The Ti ALPS 11 had the largest section modulus and it was the longest titanium plate tested in a previous study (3). Bending strength increases in cantilever and four-point bending fracture gap models when longer plates with less screws are tested compared to shorter plates with more screw holes filled (16). Considering all available screws holes were filled for all implants, the length of the implants tested may account for the observed difference in the bending strengths. Additionally, the Fixin plate appeared weaker than other stainless steel plates, probably due to its smaller section modulus and short plate length.

The PAX compared favourably to the LCP, DCP, and SS LC-DCP with regard to bending strength, despite it being titanium and one of the shortest implants in its group. Its improved bending strength is probably due to a larger section modulus (31.9 mm²) than the compression plates.

There are multiple limitations to the present study. Controlled in vitro mechanical testing is neither a true representation of the precise forces encountered in vivo nor an exact indicator of how implants will respond to the more complex interaction of forces. Information on the evaluation of screw push-out data is limited, and there are no
published recommendations for acceptable or ideal push-out strength values. While our testing method provides relevant mechanical data, it is not likely to be the same manner of loading that would be encountered in vivo. In addition, the strength of a locking plate construct does not rely on a single screw’s resistance to push-out but rather on the sum all screws. It is also likely that the screw would pull-out of the bone before being pushed-out of the plate in vivo. (1). The bending testing in this study evaluated plate-constructs using a bone model substitute. While the bone substitute has been validated, cadaveric bones are considered to be the gold standard for biomechanical testing (3). This study also evaluated the mechanical properties during single cycle failure. Cyclic testing would provide important additional information on how these implants might perform clinically. Another potential limitation of this study is the lack of statistical analysis for the plate-construct group. However, since both the testing protocol and testing machine were identical between studies, we feel the comparisons are of value.

Conclusion

Based on the results of this study, the PAX plating system offers the benefit of polyaxial locking screw placement up to 10 degrees off-axis and it compared favourably to other commonly used veterinary plates in a plate-construct model during four-point bending. While there was a significant loss of push-out strength between zero or five degrees and 10 degrees of screw angulation, it is unlikely to be clinically relevant as the mean push-out strength still remained high. Torque of insertion has a significant effect of screw push-out strength and use of a torque measuring driver would be ideal with this system, as with any locking plate system. However, based on our observations, a screw head that is flush with the plate profile or slightly countersunk within the hole has probably achieved adequate depth of engagement. Further clinical evaluation of the PAX system is warranted.

Acknowledgements

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Conflicts of interest

Author Brian Bufkin has received an honorarium from Securos for course instruction. Author Matthew Barnhart receives royalties from the sales of some Securos products and is a paid lecturer for the company. Author Andrew Kazanovicz is a biomedical engineer employed by Securos.

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