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Effect of Screw Insertion Torque on Push–Out and Cantilever Bending Properties of Five Different Angle– Stable Systems

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Objective: To compare the screw push-out strength and resistance to cantilever bending of 5 different angle-stable systems using 4 different insertion torque values to tighten locking screws.

Study Design: In vitro mechanical testing of 5 screw-plate constructs.

Sample Population: Screw plate constructs (n 1/4 60) were tested; 12 of each design, 3 for each torque value.

Methods: To compare push-out strength, screws were loaded in axial direction on the screw tip until loosening of the locking mechanism was recorded. For cantilever bending test, screws were loaded perpendicularly to their longitudinal axis at 2 mm of distance from the under surface of the plate. Load was applied in displacement control at 1 mm/min.

Results: There was a significant difference between the 5 different angle–stable systems regarding both push–out and cantilever bending strength. There was an influence of insertion torque value on push–out strength for 2 systems and insertion torque value influenced cantilever bending behavior only in 1 locking system.

Conclusions: Locking mechanisms using "thread in thread" principle provided a stronger screw push–out behavior. Screws materials and core diameter of the different screws were directly related to cantilever bending strength.

The application of the locking screw concept to orthopedic surgery was developed in 1931 by Paul Reinhold, who suggested a threaded locking-screw-plate connection.¹ In the past 2 decades, locking plate systems have become increasingly popular for internal fixation in people and their recent use in veterinary surgery has inspired the development of several angle-stable systems used exclusively in animals. Most of the published mechanical studies compare standard locking plates;²⁻⁹ however, few studies compare and validate the mechanical properties of angle-stable systems.^{10–12}

With standard bone plates, screws tightening produces frictional forces between the plate and the bone and, during weight bearing, load is transferred directly from the bone to the plate. For this purpose, screw design is optimized to mainly resist axial tensile forces.¹³ With angle–stable plates, when only locking screws are used, a rigid connection between the plate hole and the screw is achieved and no frictional forces are produced between the plate and the bone. The locking mechanism between the plate and the screw has to maintain a stable environment. Therefore the screw becomes an active load transferring link between the bone and the plate. For this purpose screw design should be optimized to withstand bending moments.¹⁴

The stability of the construct depends not only on the design and size of the implants and if the plate system has been applied in an appropriate fashion, but also on the strength of the locking mechanism. There are 2 main factors that provide correct locking of the screw with the plate, and both are influenced by the surgeon. First, the bone hole for the screw has to be drilled at an appropriate angle. A dedicated drill-guide is used to maintain the desired angle of the drill bit during bone drilling. Erroneous drill-guide insertion can result in incorrect screw insertion angle leading to decreased push-out strength and decreased resistance to cantilever bending.¹⁵ This is particularly true for 90° fixed angle locking systems. But also for multidirectional locking systems the drilling angle has to stay within the range provided by the manufacturer. The 2nd factor that influences screw locking is the insertion torque value applied to the screw during final tightening. Low insertion torque value may lead to screw loosening and high insertion torque value may lead to jamming of the screw.¹⁶ To avoid these problems Synthes (Synthes, Solothurn, Switzerland) recommends the use of a torque limiting screwdriver for screw insertion.¹⁶

At present there are no studies evaluating insertion torque values and the mechanical properties of the locking mechanism in different veterinary systems.

Thus our purpose was to compare the screw push-out strength and resistance to cantilever bending of a single screw plate construct of 5 different locking plates. Our first hypo- thesis was that because of a particular design and different materials, there is a significant difference between the systems regarding push-out strength and cantilever bending strength.

Our second hypothesis was that screw insertion torque value is directly related to push-out strength and cantilever bending behavior of the locking mechanism.

MATERIALS AND METHODS

Locking Systems (Table 1)

3.5 mm String Of Pearls (SOP) Interlocking Plate System (Orthomed Ltd.,

Huddersfield, UK). The SOP consists of a series of cylindrical sections ("internodes") and spherical components ("pearls"). The spherical component of the SOP accepts a standard cortical bone screw. Within the screw hole there is a threaded section in the lower part, and a section into which the screw head recedes. As the screw head is lowered into the spherical component, it comes into contact with a ridge causing the screw head to press fit into the pearl (Fig 1).

3.5 mm Poly Axial (PAX) Advanced Locking System (Securos, Neuhausen, DE). The PAX locking system offers poly-axial screw insertion at an angle of `10°. While the conical screw head is inserted into the plate hole the threads of the screw head induce a plastic deformation of the ridges present in the plate hole. According to the manufacturer, the design of the system allows repetitive screw insertion when correction of the insertion angle is necessary (Fig 1).

3.5 mm Locking Compression Plate (LCP; Synthes, Solothurn, CH). The locking mechanism of the LCP consists of the combi-hole TM, that combines a dynamic compression unit with a locking plate hole. The combi-hole allows placement of standard cortical bone screws (CS) on one side and threaded conical locking head screws (LHS) on the opposite side. The conical screw head has a double helical thread that engages the threaded part of the combi-hole (Fig 1).

3.5 mm Fixin Internal Fixator (Traumavet, Rivoli, IT). The locking mechanism of the Fixin internal fixator consists of a conical shaped screw hole formed by a titanium bushing inserted into a threaded hole in a stainless steel support. Angular stability is ensured by a conical coupling between the surface of the screw head and the surface of the conical hole of the bushing (Fig 1).

3.5 mm Stacked Locking Hole Plates (Veterinary Instrumentation, Sheffield, UK). Veterinary Instrumentation locking plates have round stacked locking holes that allow placement of a standard screw at an angle of `7° in the upper part and placement of a locking screw in the lower part. The conical screw head has a double helical thread which engages into the threaded part of the stacked hole (Fig 1).

Specimen Preparation

To standardize screws insertion, all plates were placed on a specially designed jig which contained a synthetic bone model (Hgw 2372, Amsler & Frey, Schinznach Dorf, CH). The jig secured the bone plate at a constant distance of 2 mm from the synthetic bone, preventing movement between the plate and the synthetic bone during screw insertion (Fig 2). All the holes were prepared using the dedicated drill-guide and appropriate size drill bit supplied by the companies. All screws were inserted using a torque limiting screwdriver (model 584F6, Beta Utensili, Sovico, IT). Screws were inserted into the plate under constant axial force. It was the movement created by the thread engaging the synthetic bone that lowered the screw head into the plate hole. For each locking system, the screw was inserted into the plate at a constant angle of 90°. Once the torque limiting screwdriver reached the proper value, the specimen was gently removed from the jig without touching the plate. Then the screwdriver was reinserted into the screw head, holding the screw-plate construct fixed, while the synthetic bone was removed. Therefore, no force was applied to the screwplate interface and no movement at the level of the screw plate interface has been noticed. For each plate system the insertion torque value was set respectively to 0.8 N m,1.5 N m,2.5 N m, and 3.5 N m and 3 specimens were tested for each value. All tests were performed by means of a universal mechanical testing machine with a 10 kN load cells (model Q/Test 10, MTS Systems Corporation, Eden Prairie, MN).

Screw Push-Out

To evaluate the push-out strength of the locked screws, the

plate was firmly secured to the base of the testing machine. The plate-screw construct was inserted into a special designed jig, leaving accessible only the hole with the screw inserted. The tip of the screw pointing towards the actuator was engaged by a concave surface. Pushout force was applied in the axial direction of the screw at a constant displacement rate of 1 mm/min (Fig 3). At a total displacement of 2 mm the test was stopped. The axial load required to unlock the mechanism was recorded.

Cantilever Bending

To evaluate the cantilever bending strength, the plate was locked in a specially designed jig and the screws to be tested were inserted in the hole close to the plate end. Load was applied by means of a 6 mm wide stainless steel bolt at a constant displacement rate of 1 mm/min (Fig 4). Load was oriented perpendicular to the longitudinal axis of the screw and applied at a 2 mm distance from the under surface of the plate. The load versus displacement curve was recorded. Bending stiffness was defined as the slope of the linear part of the curve and was determined as defined in ASTM-F38217.

The bending load at a displacement of 1.5 mm was measured as described by Kaab et al.¹⁵ The loading of the sample was stopped after a screw displacement of 2 mm. The mechanism of implant failure and screw–implant interface was examined macroscopically for deformation and surface changes.

Statistical Analysis

A Friedman test was used to assess the difference between the 5 systems within the same torque value range and the effect of the insertion torque value on push-out and cantilever bending strength of the locking mechanism for the different plate systems. Statistical significance was set to P < .05.

RESULTS

Screw Push-Out

Load to Failure (Table 2). The highest push-out strength value was for Veterinary Instrumentation (5389 N) using 0.8 N m insertion torque, followed by Synthes (4801 N) at 3.5 N m and Orthomed (3983 N) at 3.5 N m while Securos and Traumavet had the weakest push-out strength at 0.8 N m (551 N and 339 N, respectively). Within the same torque values, there is a significant difference between the 5 angle- stable systems regarding pushout strength (Table 2).

Insertion Torque. There was no significant influence of insertion torque value on push-out strength in Orthomed (P = .09). A significant influence of insertion torque value on push-out strength was found in Securos (P = .03), Synthes (P = .03), Traumavet (P = .03). A significant difference of the insertion torque value was found in Veterinary Instrumentation (P = .04) but it was not related to the increasing of the torque applied (Fig 5).

Failure Mode. The Orthomed SOP failed by breakage of the standard cortical screw thread engaged in the locking hole and plastic deformation of the threaded hole. The Securos Pax Locking failed by plastic deformation of the screw head and the ridges present in the plate hole. The Synthes Locking Compression Plate and the Veterinary Instrumentation Locking Plate failed by plastic deformation of the threads present on the screw head and in the plate hole. The Traumavet Fixin failed by loosening of the conical coupling between the bushing and the screw head. In this system no macroscopically visible plastic deformation was noted (Fig 6).

Cantilever Bending

Stiffness. The highest stiffness was recorded for Synthes (2790 N/mm) at 3.5 N m of insertion torque, Veterinary Instrumentation (2740 N/mm) at 3.5 N m, Traumavet (2442 N/mm) at 1.5 N m, followed by Orthomed (2283 N/mm) at 3.5 N m and Securos (1804 N/mm) at 3.5 N m.

Load at 1.5 mm Displacement (Table 3). The highest load was recorded for Synthes (2182 N) at 3.5 N m of insertion torque and Veterinary Instrumentation (1909 N) at 3.5 N m, followed by Orthomed (1797 N) at 2.5 N m and Traumavet (1672 N) at 1.5 N m, while Securos demonstrated the lowest load within the study (1244 N) at 2.5 N m.

Within the same torque values, there is not a significant difference between the 5 anglestable systems regarding load recorded at 1.5 mm of displacement (Table 2).

Insertion Torque. There was no significant influence of insertion torque value on cantilever bending stiffness for Synthes (P = .12), Veterinary Instrumentation (P = .28), Traumavet (P = .07), and Orthomed (P = .53), whereas a significant influence of insertion torque value on cantilever bending stiffness was found for Securos (P = .03).

There was no significant influence of insertion torque value on the load recorded at 1.5 mm of displacement for Orthomed (P = .09), Synthes (P = .09), Traumavet (P = .08), and Veterinary Instrumentation (P=.14). For Securos however, a significant influence was found (P = .03).

Failure Mode. The Veterinary Instrumentation Locking Plate and the Traumavet Fixin Internal Fixator failed by screw neck bending, while the screw head was still firmly engaged in the plate hole. The Synthes Locking Compression Plate and the Securos Pax Locking failed by plastic deformation of the screw–plate thread interface and no screw bending was seen (Fig 7). The Orthomed SOP failed by deformation of screw threads locked in the plate and at the same time bending of the screw under the plate surface.

DISCUSSION

Five different systems were evaluated, each with a different locking mechanism. Not all screws had the same core diameter or same material composition. The insertion torque value influenced the push–out strength and cantilever bending stiffness in some systems. Overall, all systems failed at very high values that normally would not be reached clinically. The highest push–out strength was found in Veterinary Instrumentation, Synthes and Orthomed. This was statistically significant in comparison with the other systems (P 1/4 . 01). This is mainly because of the "thread in thread" design of the locking mechanism.¹⁷ In particular there is a correlation between the number of threads engaged and the push–out strength recorded. Veterinary Instrumentation has 7 threads present in the screw head and we recorded the strongest push– out values for this system. Synthes and Orthomed have 5 and 2 threads respectively interfaced with the plate hole. A significant difference of the push–out strength, increasing the insertion torque values, was found in Synthes (P =.03). When the insertion torque value was increased from 0.8 N m to

3.5 N m, the push-out strength showed an increase of 12%. We believe that exceeding the 1.5 N m torque limit recommended by the manufacturer will cause an elastic deformation of both sides of the combi-hole and increase the amount of force required to unlock the screw. On the other hand, increasing insertion torque value can result in cold-welding of the screw to the plate and implant removal could be difficult or impossible. Furthermore, at high torque values the screwdriver will damage the hexagonal recess within the screw head.¹⁶ The Orthomed SOP system also relies on a thread in thread locking mechanism and the screw head comes into contact with a ridge causing the screw head to press fit into the pearl. The large contact surface area between the screw thread and the threaded plate hole explain the high push-out strength recorded for this system. Furthermore in this system, increasing the insertion torque values, no significant difference of push-out strength was found (P 1/4 . 09). The lowest push-out strength was found for Securos and Traumavet.

The design of the Securos locking plate relies on plastic deformation of the ridges present in the plate hole. A significant influence of the insertion torque value and the push–out strength was found (P = .03). High torque values are necessary to induce plastic deformation of the vertical ridges present in the plate hole to create a seat for the screw head (Fig 1). During plastic deformation the contact area and frictional forces increase. When the insertion torque value was increased from 0.8 N m to 3.5 N m, the push–out strength showed an increase of 276%. At insertion torques value below 2.5 N m we also noted that the screw head was not completely inserted in the plate hole.

The conical coupling of the Traumavet system had the weakest push-out strength of the systems studied. The conical coupling relies on an axial force created during screw insertion to produce frictional forces between the conical head and the conical hole in the bushing. With this system drill guide insertion is easily executed and the drill guide is automatically inserted with the correct angle. When the insertion torque value was increased from 0.8 N m to 3.5 N m, the push-out strength showed an increase of 416%. At insertion torque values below 2.5 N m we also noted that the screw head was not completely inserted in the bushing. A 2.5 N m insertion torque value is rather low and would be easily reached by a typical veterinary orthopedic surgeon.

Regarding the method of failure for push-out tests, the "thread in thread" systems failed by plastic deformation of threads. Veterinary Instrumentation failed by complete circular thread deformation.

The closed stacked hole completely encircles the screw head evenly distributing the forces across the locking mechanism. In contrast, the Synthes screw head showed a focal deformation of the threads in 2 locations on opposite sides. We believe that the specific method of failure with the 2 limited areas of deformation is because of the design of the combi-hole. During cantilever bending tilting of the screw head towards the open side of the combi-hole was documented. This increases the pressure on the lateral sides of the head resulting in focal deformation of the threads. The standard cortical screw used by the Orthomed system failed by shearing off the outer part of the threads engaged in the pearl while the head remained intact. Unlike all other systems studied, the Orthomed system is the only one not directly using the screw head to lock the screw to the plate. Securos failed by uncoupling of the conical screw head and the bushing without macroscopic deformation of the cone.

Regarding the push-out test set up, it must be pointed out that the space between the 2 flat plates that support the screw plate construct (Fig 3) have a gap greater than the plate hole; in this way the push-out test is a modified 3 point bending which would result in a bending moment that could affect the plate hole and the push-out force recorded, but at the end of our tests we did not appreciate a bending deformation of the plate.

Regarding cantilever bending, the highest bending stiffness was noted for Synthes, Veterinary Instrumentation, and Traumavet constructs. We suspect that the higher bending stiffness was because of the larger core diameter of the screws (Table 3). All these screws have a core diameter >2.5 mm. The core diameter of the screw is directly related to the bending behavior of the screw¹⁸ and a small increase in core diameter of the screw results in a large increase in bending stiffness. For Traumavet and Veterinary Instrumentation no deformation of the screw head and the plate hole occurred. In these systems, the screw head is completely surrounded by the plate hole whereby no distortion of the locking mechanism is allowed. Bending of the screw occurred immediately under the plate surface, at the level of the screw neck. Because of the large core diameter and the open design of the combi-hole, no bending of the Synthes screw was observed. During cantilever bending, the screw was pushed along the long axis of the plate and the head disengaged from the longitudinal part of the plate hole while the sides were still compressing the screw head. This may explain tilting of the head and the 2 local area of deformation on each side. An additional factor occurring during failure was the screw deformation, resulting in an oval shaped screw head. Another important factor to consider is the material and manufacturing process used to produce the implants. Surgical stainless steel has a higher modulus of elasticity than titanium.¹⁹ This could explain the high stiffness values reached by Orthomed even if Traumavet titanium screws have a larger core diameter. The Orthomed system failed by deformation of the screw threads locked in the plate and at the same time bending of the screw under the plate surface. The threaded part of the plate hole is larger than the screw threads and therefore the width of the threads are not fully engaged in the plate. This allows an easy insertion of the screw to better achieve the coupling with the plate. When bending moments were applied to the screw, translation of the screw within the plate hole occurred. For Securos, the plastic deformation of the screw threads occurred mostly in the distal part of the plate hole. This is the point with the highest area of contact between the screw and the plate hole. This suggests the locking mechanism is weaker than the bending force required to bend the core of the titanium screw. This is the only system where a significant correlation between insertion torque value and bending stiffness could be demonstrated (P 1/4 .03). An increase of the insertion torque value resulted in higher deformation of the ridges present in the hole resulting in a better grip of the screw. Therefore for Securos it is recommended to tighten the locking screw with an insertion torque value between 2.5 N m and 3.5 N m.

A major limitation of our study is the fact that it is investigating the mechanical properties of a single screw-plate interface. In a real clinical situation the systems are applied in an appropriate fashion, with 3 screws inserted each bone segment. Furthermore, in a clinical setting implants are subjected to repetitive forces leading to cyclic fatigue failure. Rarely a single load is the reason for failure. Further investigation of fatigue failure of the locking mechanism could provide more in- formation regarding the clinical performance of these systems.

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Company	Composition	Size
Orthorned	316 LVM stainless steel	Thread: 3.5 mm Core: 2.4 mm
Securos	Ti-6A1-4V titanium alloy	Thread: 3.5 mm Core: 2.4 mm
Synthes	316 LVM stainless steel	Thread: 3.5 mm Core: 2.9 mm
Traumavet	Ti-6A1-4V titanium alloy	Thread: 3.6 mm Core: 2.8 mm
Veterinary Instrumentation	316 LVM stainless steel	Thread: 3.5 mm Core: 2.7 mm

Table 1 Summary of Screws Tested



Figure 1 Locking systems used in the study. From left to right: screw head, plate hole, locking mechanism. Orthomed SOP (A); Securos PAX (B), Synthes LCP (C), Traumavet Fixin (D), Veterinary Instrumentation stacked locking hole plate (E).



Figure 2 Jig used for specimen preparation. The custom made jig (A) secures the plate (in this case Fixin) at a 2 mm distance from the bone model (B). The screw is inserted using a torque limiting device (C).



Figure 3 Push-out test set-up. The plate is secured to the base of the testing machine (A). Push-out force is applied in the axial direction on the screw tip by a cylindrical steel actuator (B).



Figure 4 Cantilever bending test set-up. The plate is locked in a specially designed jig (A) and the screw to be tested is inserted in a hole close to the plate end. The force is oriented perpendicular to the long axis of the screw at a 2 mm distance from the back surface of the plate and applied through a 6 mm wide stainless steel bolt (B).

Table 2 Median (Min-Max) Screw Push-Out Strength

b

Insertion torque	Veterinary Instrumentation (N)	Synthes (N)	Orthorned (N)	Securos (N)	Traumavet (N)	P-value ^a
0.8	5389 (5156-5425) 4681 (4612-4690)	4156 (4038–4481) 4289 (4067–4711)	3711 (3597–3745) 3670 (3557–3702)	551 (446–596) 822 (859–715)	339 (249–352) 571 (522–647)	.02
2.5	5133 (5220-5097)	4645 (4575-4768)	3756 (3647–3768)	1428 (1345–1729)	868 (778–1076	.02
P-value ^b	.04	4801 (4580–4835) .03	.09 .09	.03	1285 (1269–1493) .03	.02

^aDifference between the systems within the same torque value.

^bInfluence of the insertion torque on push-out strength.



Figure 5 Push-out strength in relation to implant type and insertion torque. Statistical significance of insertion torque was found in Securos and Traumavet locking plates. The influence was found to be proportional and linear, with an increase of 276% for Securos and 416% for Traumavet, increasing insertion torque from 0.8 N m to 3.5 N m. The other 3 systems reached higher values, but no influence of insertion torque was noted.



Table 3 Median (Min-Max) Bending Load After 1.5 mm Deformation

Insertion Torque (N m)	Synthes (N)	Veterinary Instrumentation (N)	Traumavet (N)	Orthomed (N)	Securos (N)	P-value ^a
0.8	1544 (1522-1689)	1611 (1287-1685)	1425 (1333-1720)	1368 (1401-1179)	257 (200-361)	.10
1.5	2181 (1995-2377)	1605 (1264-1676)	1672 (1460-1695)	1485 (1268-1560)	865 (602-949)	.04
2.5	1838 (1785-2329)	1619 (1469-1897)	1599 (1522-1660)	1798 (1475-1829)	1245 (1158-1263)	.10
3.5	2182 (1911-2338)	1909 (1897-2199)	1632 (1481-1753)	1546 (1495-1847)	1045 (903-1721)	.05
P-value ^b	.09	.14	.08	.09	.03	

^aDifference between the systems within the same torque value.

^bInfluence of the insertion torque on bending load.



Figure 7 Damaged screws after cantilever bending test. Screw neck bending was documented for Veterinary Instrumentation, Traumavet, and Orthomed. Deformation of the screw head inside the plate hole without plastic deformation of the screw neck was documented for Securos and Synthes locking plates.