Performance of mixed screw-plate interfaces from four manufacturers

by

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Abstract

Objective: To analyze the mechanical strength and stability of constructs created by intermixing locking compression plates (LCP) and screws (LS) from four manufacturers (A-D).

Design: In-vitro study

Methods: Each construct consisted of one LCP ("A-D") and six LS ("a-d"). All LS within a construct were from the same manufacturer, while the LCP was either from the same or a different manufacturer. Constructs in which both LCP and LS originated from the same manufacturer served as controls. Two copies of each were assembled (#1 and #2). Compressive cyclic axial loading was applied to all #1 constructs. Subsequently, all constructs (#1 and #2) underwent micro computed tomography (micro-CT) to evaluate average thread engagement (ATE), thread engagement height (TEH), angle of insertion, and distance from screw head to plate. Following micro-CT imaging, the #2 constructs were subjected to cyclic loading. Three screws from each #1 and #2 construct were then tested for peak reverse torque (PRT) (n=6) and the three remaining screws were tested for push-out strength (n=6).

Results: ATE and TEH were strongly correlated with each other. "A.a" had the highest mean ATE, TEH and PRT within the "A" plate cohort (A.a-A.d); "B.b" had the highest TEH and PRT, while "B.d" had the highest ATE within the "B" plate cohort (B.a-B.d); "C.b" had the highest TEH and ATE while "C.d" had the highest PRT within the "C" plate cohort (C.a-C.d); and "D.b" had the highest ATE and TEH while "D.d" had the highest PRT within the "D" plate cohort (D.a-D.d). Data analysis for screw push-out was limited due to small sample size. All plates with "a" screws (A.a, B.a, C.a, and D.a) had significantly different distance from all plates with screws "b-d" ($p<0.05$), while the distance of screws "b-d" in all plates did not differ from each other ($p>0.05$). The screws in the "A" plates showed a significantly lower angle (further from 90°) than "C" plates ($p = 0.012$) and "D" plates ($p = 0.029$).

Conclusion: Under the conditions of these mechanical tests, the "B" system consistently showed the most secure fixation in the parameters measured, and was more accommodating of mixing B-system screws or plates with plates or screws from other manufacturers, with the exception of those from manufacturer A. The A system proved to be the least adaptable to mixing with screws or plates from other manufacturers. Further studies are warranted to determine the clinical relevance of intermixing orthopedic implant components, particularly with respect to fracture healing and patient outcomes.

Table of Contents

List of Figures vi

List of Tables vii

Acknowledgements viii

Chapter 1 - Literature Review 1

Chapter 2 - Introduction 11

Chapter 3 - Materials and Methods 13

Chapter 4 - Results 20

Chapter 5 - Discussion 31

References 38

List of Figures

Figure 3--1. Plates and Screws from the Four Manufacturers. 13
Figure 3--2. Order of Testing. 15
Figure 3--3. Cyclic Loading 16
Figure 3--4. Screw Push-Out 18
Figure 4--1. Correlation between Average Thread Engagement (ATE) and Thread Engagement Height (TEH) 20
Figure 4-2. Average Thread Engagement (ATE) and Thread Engagement Height (TEH) between #1 and #2 Constructs 21
Figure 4--3. Average Thread Engagement (ATE) and Thread Engagement Height (TEH) for Plates "A-D." 22
Figure 4--4. Average Thread Engagement (ATE) and Thread Engagement Height (TEH) for Screws "a-d." 23
Figure 4--5 Average Thread Engagement (ATE) and Thread Engagement Height (TEH) for all Constructs. 24
Figure 4--6. Distance for all Constructs. 27
Figure 4--7. Screw Push-Out (N) for all Constructs. 29

List of Tables

Table 3-1. The Constructs.. 15

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Chapter 1 - Literature Review

Early surgical repair of fractures prioritized direct fracture exposure, precise anatomic reconstruction, and rigid fixation. Despite their reliability, conventional plates, such as the dynamic compression plate (DCP), used in this regard often require extensive soft tissue disruption and compromise of the biological environment. This can potentially lead to complications such as delayed union, non-union, implant failure, and/or infection. Newer fracture repair methods follow the principle of Biologic Osteosynthesis which is a term given to the prioritization of functional alignment, relative fracture stability, and promotion of an optimal biological environment.[43] The limited-contact dynamic compression plate (LC-DCP), a modification of the DCP, was created to decrease periosteal compromise and more evenly distribute stiffness.[52,63] Locking plates were then developed to address problems with the dynamic compression plate (DCP) including loss of fixation in osteoporotic bone, loss of fracture reduction with imperfectly contoured plates, and compression-induced resorption of bone.[26,52,75]

Locking implants promote the biological osteosynthesis principles and minimize soft tissue damage through indirect reduction, minimally invasive surgeries, and minimal disturbance of the fracture hematoma.[74] Locking implants have threads in the screw heads and plate holes that anchor into each other, thus creating a stable, fixed-angle, construct. The stability of locking plates depends on this interlock between the screw head and plate hole.[6] Thus, locking plates and screws have biomechanics more similar to external skeletal fixators than plates, and are therefore sometimes referred to as internal fixators.[43,58,78] In contrast, conventional plates and screws are stabilized by the friction created at the plate-bone contact zone.[42,43]

Locking implants include systems such as polyaxial locking plates (PLPs) and locking compression plates (LCPs). The LCP can be used as a compression plate, locked internal fixator, or a combination depending on the surgeon's goals and the properties of the fracture.[30,52,78] The PLP allows locking screws to be angled while still maintaining the integrity of the interface at the screw head and plate. The PLP may be useful in osteoporotic bones, periarticular and periprosthetic fractures, polytraumatized patients, and high-grade comminuted fractures of long bone diaphyses.[52,57,74] There are also polyaxial advanced locking plates (PAX) that allow more angular freedom than the standard PLP. Standard locking systems have greater resistance to rotational failure at the screw/plate interface than polyaxial angle locking systems.[76]

When comparing locking implants to conventional plates and screws, several advantages are noted. Since locking plates do not require the plate-bone friction to be stable, the plates do not need to be perfectly contoured, thus decreasing operative time and minimizing any structural strain placed on the plates during contouring.[78] Because these plates do not need to be contoured the bone, it is easier to place them in a minimally invasive manner and thus preserve the periosteal blood supply.[12,73] However, one paper found no difference in healing when using locking compression plates (LCP) versus limited contact-dynamic compression plate (LC-DCP) when placed in a minimally invasive plate osteosynthesis (MIPO) manner.[82] Another advantage of locking implants is the strong screw-plate interface. A standard rule-of-thumb is that there should be three screws (engaging six bone cortices) on either side of a fracture to create a strong construct. Due to the strong screw-plate interface, mono-cortical locking screws have stability similar to that of a conventional screw engaging two bone cortices, thus increasing their versatility and usefulness in areas with minimal bone stock or weak bone such as pelvic/spinal/scapula stabilization; juxta-articular or highly comminuted fractures.[42,52] However, bi-cortical screws are stiffer as compared to mono-cortical screws,[19] and three-screw constructs are stronger than two screw constructs in cyclic torsion,[8] four-point bending[62] and loadcontrolled compression testing[61] when evaluating LCPs. Finally, the locking constructs are more resistant to screw pull-out than conventional plates. This is because the locking construct ensures applied loads are distributed more evenly across all supporting screws, thus avoiding the stress at one screw-bone interface.[17,20,43] Instead, failure of locking implants requires concurrent axial pull-out of all implants or compressive failure of the bone surrounding the screws.[43]

As there are many different implants available to the surgeon, it is important to understand their mechanical behavior to select the most appropriate implant for the patient. Most often, implants are mechanically tested for strength and stability. Strength refers to an implant's ability to withstand mechanical load and resist micromotion, while stability refers to an implant's ability to maintain its position and resist displacement. Stability is further divided into primary and secondary stability. Primary stability is the initial mechanical engagement of the implant with surrounding bone at the time of placement and the resistance of the implant to acute failure, whereas secondary stability is the stability that develops over time as bone remodeling occurs around the implant and the resistance of the implant to cyclic/fatigue failure. Primary stability and secondary stability have been associated with bone quality, bone volume, bone density, implant location, surgical technique insertion torque, and implant size and shape.[37,40,49,60,64,66,72] Good primary stability is essential to prevent micromotion and ensure appropriate osseointegration,[69] as micromotion may interfere with the formation of a fibrin clot on the implant surface during the early healing process.[18]

Though the gold standard of assessing osteointegration is histopathology, there are multiple studies showing that a less invasive option such as micro-computed tomography (microCT) is equivalent.[9,16,54] In addition to assessing osseointegration, microCT has been used to evaluate implant microarchitecture.[53,71] Many papers describe how to optimize microCT techniques to ensure the highest quality images.[5,15,38] In addition to evaluating the microarchitecture of implants, microCT has been used to confirm screw angulation[47] and calculate average thread engagement,[6,31] and its findings have been correlated with mechanical testing. It has been shown that as the insertion angle increases (0-15 degrees), the average thread engagement and bending strength of the constructs decreases.[31] Two papers used microCT to assess average thread engagement between two locking systems before and after mechanical testing and showed that only partial thread engagement is needed to retain the locking mechanism.[46,48] Another paper evaluated average thread engagement and screw push-out strength of off-axis insertions in polyaxial locking system plates inserted at 1.5 or 2.5Nm.[6] The study reported that average thread engagement decreases with off-axis insertion angles and increases with applied torque, and that pushout strength strongly correlates with ATE. [6] Therefore, microCT is a promising avenue for further exploring the screw-plate interface.

Many studies have examined how insertion angles affect implant strength and stability. Dynamic compression plates (DCP) and polyaxial locking plates (PLP) allow screws to be inserted off-angle, but locking compression plates (LCP) require an exact insertion angle to ensure appropriate thread engagement. Locking screws placed at over five degrees of angulation have been shown to decrease the strength of the construct by 30%, and ten degrees of angulation can decrease the strength of the construct by 50%.[45] Another paper analyzed screw insertion angle on 3.5 LCP and 3.5 PLP, and found that the 3.5 LCP had higher push-out strength than the 3.5 PLP when screws were placed at zero degrees, and both plates had decreased push-out force when screws were placed abaxially at zero, five, and ten degrees for LCP and zero, five, ten, fifteen, and twenty degrees for PLP.[47] One paper assessed screw strength by applying a transverse force parallel to the plate in the same or opposite direction of the initial screw angulation at insertion angles of zero, five, and ten degrees off-axis in a 4.5mm LCP and found that any off-axis insertion significantly weakened constructs.[27] In one paper, authors assessed zero, five, and ten degree insertion angles in a PAX system using screw push-out; they found that the zero and five degree insertion angles had significantly higher push-out forces than ten degree insertion angles.[13] One paper evaluated a polyaxial locking plate at zero degrees and ten degrees off the longitudinal plane and ten degrees off the transverse plane and found that zero degrees had the greatest stiffness under compression and withstood the most load cycles in torsional testing.[57] Another paper found that for each one degree increase in screw-plate angle, there was an average decrease of approximately 0.4 Nm screw-plate interface strength.[76] Therefore, based on these studies, abaxial screw placement can weaken constructs, and screws should be placed at zero degrees where possible, regardless of the type of plate.

Insertion torque is the rotational force required to screw an implant into a bone, which reflects the bone's resistance and thus the implant's primary stability. It has been found that higher bone density is associated with higher insertion torque, and lower bone density requires lower insertion torque.[55] Most manufacturers recommend a 1.5Nm torque when inserting screws into locking plates (primary author's personal communication with multiple company representatives) and torque limiter attachments have been created to prevent overtightening screws. The optimum screw tightness is approximately 70-80% of the maximum torque.[25] However, excessive torque can cause the screw to seize in the plate hole and/or cold welding.[7,21,29,59] Additionally, too high of an insertion torque can decrease osseointegration, increase marginal bone loss, and contribute to implant failure.[51,56,65] Surgical removal of failed implants can be very difficult, but studies that have evaluated ways to effectively remove them.[33,41,50,59] Interestingly, it has been shown that orthopedic surgeons are more likely than researchers to strip screws by over-tightening them in artificial bone.[24] Thus, most manufacturers recommend using a torque-limiting screwdriver. However, one paper showed that the use of a torque-limiting screw does not guarantee an equal connection between all screws in the same plate.[46] Additionally, other papers have shown that the torque required to remove a screw is often less than the torque used to insert the screw due to a settling effect, so screws should be retightened about 10 minutes after the initial tightening.[70,81] However, the screws should not be unnecessarily loosened and tightened again. One paper showed that loosening and tightening locking screws in the same plate hole can maintain sufficient strength up to four times, but significant damage to the screw head threads occurred starting from the fifth tightening-untightening cycle.[3] Therefore, an appropriate insertion torque is important to ensure adequate implant stability.

Multiple papers have evaluated how insertion torque affects mechanical testing. One paper analyzed the push-out strength of screws at five different insertion torques in the atraumatic rigid fixation (ARIX) system and found that low insertion torques can cause screw loosening whereas higher insertion torques result in screw head stripping and plate hole deformation.[44] One paper looked at the effects of 1.5Nm and 2.5Nm insertion torque on screw push-out strength in LCP and PLPs, and found that LCPs had higher screw push-out force with a higher insertion torque, but there was no difference in screw push-out strength in PLPs at either insertion torque.[47] Another paper analyzed whether increasing insertion torque in a 4.5mm LCP at 50%, 150%, or 200% of the manufacturer's guidelines would overcome the weakened strength when screws were inserted at five or ten degrees off axis.[27] They found that increasing torque did increase strength, but the zero-degree angulation at 100% insertion torque was still stronger.[27] Analysis of five angle-stable systems at four insertion torque values for screw push-out and resistance to cantilever bending showed there was only an influence on insertion torque value for two systems on push-out strength and one system for cantilever bending, but there were significant differences between companies within insertion torques of 0.8, 1.5, 2.5, and 3.5Nm.[11] In a paper assessing 2.5Nm and 3.5Nm insertion torques in a PAX system using screw push-out, the 3.5Nm insertion torque had significantly higher push-out forces than 2.5Nm.[13] Based on these papers, it may be ideal to insert the screws at a higher torque than the manufacturer's recommendations, but care must be taken as there is risk associated with overtightening.

In contrast to insertional torque, peak reverse torque is the force required to remove an implant and is associated with secondary stability, or osseointegration. Several studies have used peak reverse torque testing as a surrogate to evaluate osseointegration by measuring the friction between the screw and plate.[14,79] One paper evaluated peak reverse torque in a 4.5mm DCP plate with non-self-tapping and self-tapping cortical screws used to stabilize a 2.5cm mid-tibia defect in goats.[36] Radiographs were taken at days 7, 15, 30, and 60, and the goats were sacrificed at day 60. All screws were then removed, and the peak reverse torque was measured. They found that the self-tapping screws were more likely to have higher peak reverse torque than the non-self-tapping screws, and the screws in the proximal tibia segment had significantly lower peak reverse torque than the screws in the distal tibia segment, possibly due to greater load-bearing in the proximal segment and greater bone density in the distal segment.[36] Another paper also evaluated peak reverse torque in a 2.5cm mid-tibia defect in goats, but used 4.5mm thick locking plates.[35] They used 4 screws per segment, and measured peak reverse torque in goats at three, six, nine, and twelve months post-operatively. They found that locking screw #4 (the most distal screw in the proximal segment) had significantly lower peak reverse torque than screw #5 (the most proximal screw in the distal segment), and that the peak reverse torque was higher than in the previous study using DCP and cortical screws.[35] Another paper analyzed removal torque in intramedullary nails with four interlocking screws used to stabilize a one cm segmental femoral defect in a canine for sixteen weeks.[80] Mechanical testing was performed to failure in six animals, and four animals did not undergo additional mechanical testing. Broken screws required less torque to remove, and screws closer to the fracture required more torque to remove than screws further from the fracture.[80] Thus, peak reverse torque tends to increase with screws closer to the fracture line and appears greater in areas of higher bone density.

Most mechanical testing involves loading implants to failure, with one event of progressively increasing loading until there is catastrophic failure of the implants. Examples of mechanical testing to failure include four-point bending,[11,13] cyclic torsion,[8] and screw push-out.[11,13] These loads are often supraphysiologic, and thus their direct clinical relevance is questionable. Most patients never sustain similar conditions during fracture healing, as this would require a single event with progressively increasing loads, which is extremely unlikely. A more clinically relevant testing method is cyclic loading which tests for fatigue failure, and this has been used in many studies.[34,39, 77] Cyclic loading should be limited to the expected physiologic loading for the implants being used. Four-point bending and cyclic torsion could also be used to test for fatigue failure, if the set parameters mimic clinical loading. For example, when testing implants commonly used for 30kg patients, loading should be limited to 355N as this is the approximate thoracic limb force for a 30kg dog.[67] However, repetitive cyclic loading can be time-consuming and costly, which may explain the prevalence of failure testing.

There are many papers that have compared the strength between LCP and LC-DCP implants. In non-destructive four-point bending and torsion, cyclical testing in torsion, and loading to failure in torsion, the LC-DCP failed earlier than the LCP and the LCP was stiffer than the LC-DCP in lateral-medial bending.[1] Similarly, the LCP had subtle mechanical superiority compared with the LC-DCP when tested under anteroposterior bending, mediolateral bending, and torsion.[28] However, other papers showed that the LC-DCP was superior to the LCP in mechanical testing. When comparing 2.4 LCP with 2.4 LC-DCP during eccentric cyclic loading, it was found that two of the LCP constructs had gross failure while none of the LC-DCP did, and that stiffness was lower in the LCP constructs.[39] This was thought to be because LCP constructs were not compressed to the bone and thus had a longer working length across a fracture, making them less stiff.[39] Another paper evaluated 3.5 LCP against 3.5 LC-DCP under static compression, cyclic compression, and cyclic torsion.[23] The LCP were stiffer in monotonic loading but had less stiffness in dynamic testing. This was also thought to be due to the LCP constructs not being contoured to the bone.[23] However, the contouring does not always seem to affect mechanical testing. One paper found no difference between a semi-contoured locking compression plate-rod construct (LCP-rod) and an anatomically contoured limited-contacted dynamic compression plate-rod construct (LC-DCP-rod) under cyclic axial loading and loading to failure.[32] Similarly, another paper found no difference between DCP, LCP applied flush to the bone, and LCP at 2mm from the bone in performance during static and dynamic loading tests, but an LCP 5mm from the bone was significantly weaker.[2] As it is difficult to draw conclusions about which implant is better given the controversy in the literature, the surgeon must carefully select the type of implant in the clinical setting to best support their patient's healing.

In addition to analyzing LCP versus LC-DCP, many papers have compared other implant characteristics. One study evaluated the biomechanical properties of DCP, stainless steel LC-DCP, titanium LC-DCP (Ti LC-DCP), LCP, 10mm and 11mm advanced locking plate systems (ALPS 10, ALPS 11), string of pearls (SOP), and Fixin system under a single cycle to failure in bending.[10] They found the SOP constructs had the highest bending stiffness and strength, while the ALPS, Fixin, and Ti LC-DCP had the lowest.[10] Another paper evaluated five different angle-stable systems, including the Orthomed SOP, Securos polyaxial system, Synthes LCP, Traumvet Fixin, and Veterinary instrumentation stacked locking hole plate using four insertion torques in push-out strength and cantilever bending test.[11] They found that locking mechanisms with “thread in thread” had stronger screw push-out, but cantilever bending seemed more related to screw material and core diameter.[11] To the best of the authors’ knowledge, no previous studies have evaluated how intermixing company materials could influence strength and stability.

Anecdotally, some veterinary surgeons are already mixing implants from different companies despite most companies advising against this practice. Our profession has no published guidance on whether this practice is appropriate in clinical situations. Knowing the impact of intermixing implants is important in cases of ordering errors, shipment delays, or other factors that negatively affect supply. Intermixing company materials could also decrease costs, which is often a limiting factor in veterinary medicine. If intermixing locking implants is inappropriate, fracture healing complications (implant failure, delayed union, malunion, etc.) could result. If intermixing materials is acceptable, surgeons could choose the most cost-effective implants regardless of whether matching components are available. This could be extrapolated to have financial effects on human orthopedics. These results could therefore have significant impacts on cost and time savings in veterinary and human orthopedics

Therefore, this study explored how intermixing manufacturers’ materials influenced construct strength and stability by analyzing microCT measurements and mechanical testing.

Chapter 2 - Introduction

Locking compression plates (LCP) and locking screws (LS) are widely used in orthopedic surgery, especially in osteoporotic bone, periarticular and periprosthetic fractures, polytraumatized patients, and high-grade comminuted fractures of long bone diaphyses.[4,52,57,74] Locking implants can be placed using biological osteosynthesis principles to minimize soft tissue damage through indirect reduction, minimally invasive surgeries, and minimal disturbance of the fracture hematoma.[74] Locking implants have threads in the screw heads and plate that engage each other, thus creating a stable fixed-angle construct. The stability of LCP depends on the strength of the interlock between the screw head and plate.[6] Thus, LCP and LS have biomechanics more similar to external skeletal fixators than conventional plates and are sometimes referred to as internal fixators.[43,58,78]

Previous studies have analyzed implant strength and stability using peak reverse torque (PRT),[35,36,80] screw push-out strength,[11,13,47] and average thread engagement (ATE) via micro-computed tomography (micro-CT).[6,31,46,48] PRT measures the torque required to remove a screw from a plate and is therefore associated with the implant's likelihood of loosening during loading. The push-out strength of a screw assesses how much force a screw withstands before being displaced from the plate. ATE describes how well threads of a screw head engage with threads of a plate hole and has been correlated with screw push-out strength,[6] angle of insertion,[6] and bending strength of constructs.[31]

Currently, manufacturers advise against intermixing implants due to design discrepancies; however, no studies have evaluated this to our knowledge. Anecdotally, some veterinary surgeons already mix implants from different manufacturers. The ability to safely intermix implants could reduce veterinary orthopedic costs, a driving force in pet owners' decisions regarding the care of their pet. Additionally, it could allow surgeons to bypass inventory or shipping delays and therefore expedite fracture repair for their patients.

The first objective of our study was to determine if LCP and LS constructs from different manufacturers (“Mixed") could be as strong as LCP and LS constructs from the same manufacturer (“Control”). A second objective was to determine if one manufacturer’s system performed better during testing. We introduce two novel micro-CT analyses to measure the interlock of plate hole and screw head by calculating the thread engagement height (TEH), and by measuring distance from the top of the screw head to the top of the plate (Distance) as a value for how well the screw was seated in the plate. We hypothesize that the Control group will perform better on mechanical testing (peak reverse torque, screw push-out) and micro-CT analysis (ATE, THE, distance) than the Mixed group.

Chapter 3 - Materials and Methods

Locking plate systems

Systems were based on availability and popularity in veterinary surgery. They were assigned as manufacturers of A-D (A: Arthrex, B: Synthes, C: Movora VOI, D: Movora Everost) (see Figure 3-1).

Figure 3--1. Plates and Screws from the Four Manufacturers.

Plates “A-D” with “A” at the top of the image and “D” at the bottom. Screws “a-d” with “a” at the left of the image and “d” at the right of the image.

Specimen preparation

Two, seven-hole 3.5mm locking plates from companies B-D were prepared with six locking screws from a given manufacturer in holes 1-3 and 5-7 (the plate and six screws constitute one construct). Manufacturer A plates are eight-hole 3.5mm locking plates, as these have six locking holes whereas their seven-hole plate only had five locking holes. Screws were placed in holes 1, 3-6, and 8 in the eight-hole manufacturer A plate. Each plate was secured to two ¾" Delrin rods with a one cm space to simulate a one cm fracture gap. Each screw hole was drilled with a guide locked at 90°, and the Delrin rods were manually held to prevent slippage during drilling and screw insertion. All constructs were made by the same operator (BD). Two copies of each construct were prepared (construct #1 and construct #2), for a total of 32 constructs (see Table 3-1). The screws were initially tightened to manufacturer guidelines (1.5 Nm), but this created subjectively loose constructs, so they were either hand-tightened by a board-certified small animal orthopedic surgeon (WR) (#1 constructs) or tightened with a digital hand-held torque-limiting screwdriver (Proxxon 23347 Micro-Click MC 5 Torque Screwdriver) to 3.5Nm (#2 constructs). The constructs with a plate and screws from the same manufacturer were the control group. On each construct, the screws were then labelled U-Z, with U, V, and W on one side of the simulated fracture gap and X, Y, and Z on the other side of the simulated fracture gap, with W and X closest to the gap. The order of testing is outlined in Figure 3-2.

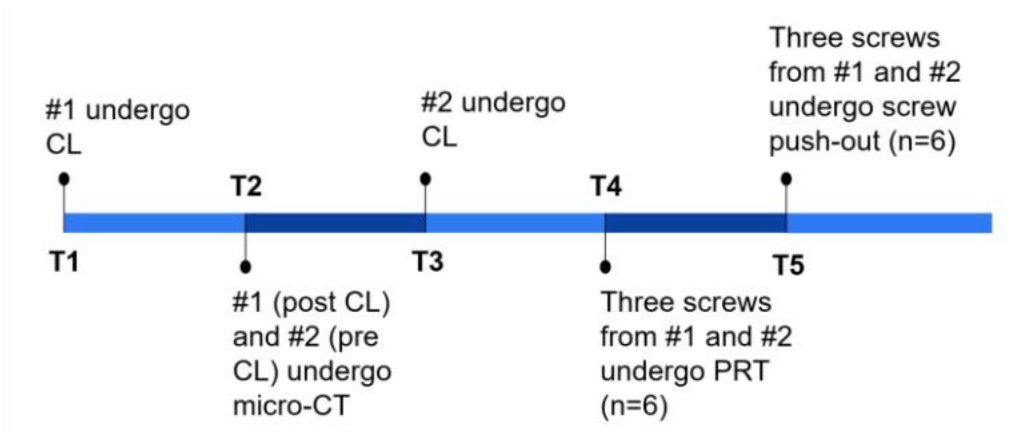
Table 3--1. The Constructs.

The first uppercase letter (A, B, C, D) corresponds to the manufacturer plate, and the second lowercase letter (a, b, c, d) corresponds to the manufacturer screw. Two copies of each construct were assembled for a total of 32 constructs.

A.a1 and A.a2	B.a1 and B.a2	C.a1 and C.a2	D.a1 and D.a2
A.b1 and A.b2	B.b1 and B.b2	C.b1 and C.b2	D.b1 and D.b2
A.c1 and A.c2	B.c1 and B.c2	C.c1 and C.c2	D.c1 and D.c2
A.d1 and A.d2	B.d1 and B.d2	C.d1 and C.d2	D.d1 and D.d2

Figure 3--2. Order of Testing.

Figure legend: #1 = #1 constructs, #2 = #2 constructs, CL = cyclic loading, micro-CT = micro computed tomography, and PRT = peak reverse torque.



Cyclic loading for #1 constructs

Each construct was mounted on a custom frame for the cyclic loading (see Figure 3-3) and subjected to 10,000 cycles of compressive axial loading at a frequency of 1 Hz, as previously described.[34] Compressive axial load was limited to 355N as previously described,[77] as 355N has been shown to be the approximate thoracic limb force for a 30kg dog.[67]

Figure 3--3. Cyclic Loading

Each construct was mounted to a customized frame for cyclic loading and subjected to 10,000 cycles of compressive axial loading, limited to 350N.

Micro-CT Analysis - Average thread engagement (ATE) and Thread Engagement Height (TEH)

After #1 constructs had undergone cyclic loading ("post-samples") and before #2 constructs had undergone cyclic loading ("pre-samples"), all 32 constructs with all six screws were assessed by micro computed tomography (micro-CT) to measure average thread engagement (ATE) and thread engagement height (TEH). These two metrics were calculated using micro-CT as previously described.[6] Based on contact of the screw-plate interface, each cross-section image of the construct was scored between 0%-100%. ATE is the arithmetic mean of all the scores for each construct. TEH is the number of images for which the score was greater than 0% multiplied by slicing offset equal to 50 µm. This was repeated for 196 threaded interfaces (2 pre and post groups × 4 plate types × 4 screw types × 6 screws per each construct).

Micro-CT Analysis - Angle of Insertion

Each screw hole was drilled with a guide locked at 90°. The angle of insertion for each screw was measured as previously described.[47]

Micro-CT Analysis - Distance from the Top of the Plate Hole to the Top of the Screw, "Distance"

The distance from the top of the plate hole to the top of the screw was measured in millimeters for each screw.

Cyclic loading for #2 constructs

After #2 constructs had undergone micro-CT analysis, they were subjected to cyclic loading using the same protocol as #1 constructs.

Peak reverse torque (PRT)

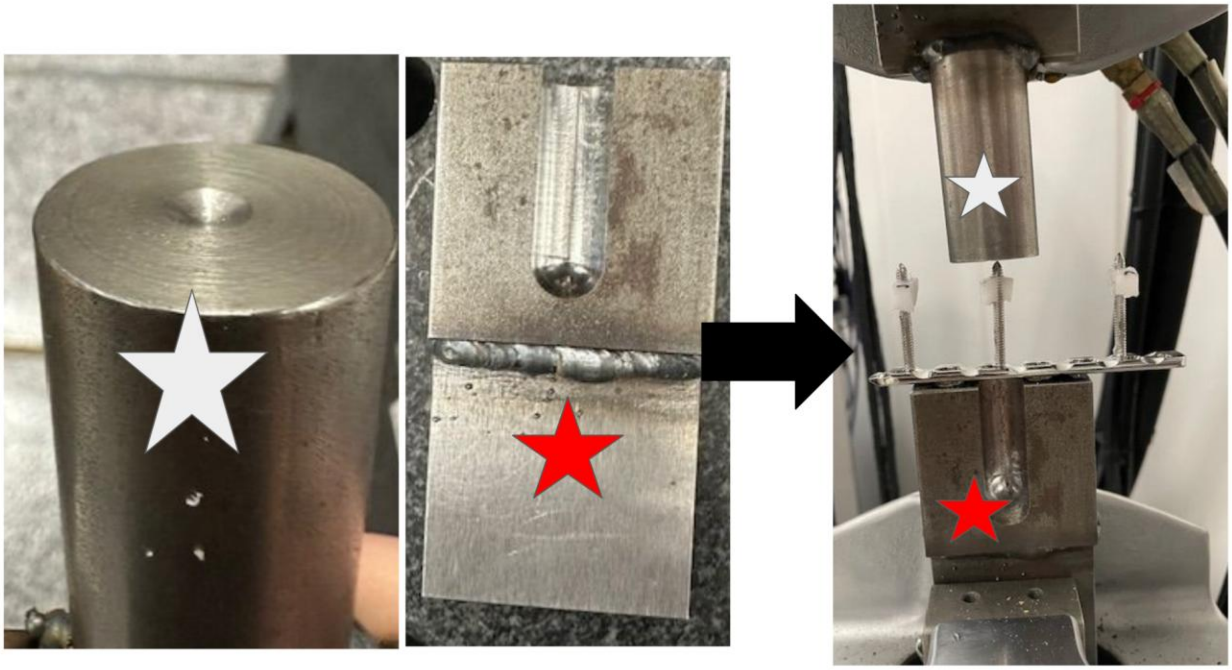
After cyclic loading and micro-CT analysis, PRT was measured with a hand-held torque-measuring screwdriver (Cedar DID-4 Digital Torque Screwdriver), as previously described.[35] As PRT has been shown to be decreased for screws in the proximal segment[36] and screws closest to a fracture gap,[80] PRT was measured on alternating screws to ensure a representative sample for each construct ("U", "W", and "Y" from #1 constructs and screws "V", "X", and "Z" from #2 constructs). The constructs with matching components served as controls.

Screw push-out

After undergoing cyclic loading, micro-CT analysis, and removing screws to measure PRT, screw push-out was assessed on the remaining screws ("V", "X", and "Z" from #1 constructs and screws "U", "W", and "Y" from #2 constructs) (see Figure 3-3). The Delrin rod was removed from the constructs with a scroll saw. Each construct was mounted to a custom-made frame to allow the screw to fall out, and force was applied through a custom-made steel piston (see Figure 3-4). The push-out force was applied in the axial direction on the screw tips using a servo-hydraulic testing machine at a loading speed of 0.1 mm/min and recorded at 10 Hz as previously described.[11,13,44] The axial load required to unlock the screws from the plate was recorded. The constructs with matching companies served as controls.

Figure 3--4. Screw Push-Out

Each construct was mounted on a custom-made frame to allow the screw to fall out (red star), and the axial force was applied through a custom-made steel piston with a divot to fit the screw tip (white star).



Statistical analysis:

ATE, TEH, PRT, distance, angle of insertion, and screw push-out were reported as means. Shapiro-Wilk tests were performed to assess the normality of the residuals. Multi-way ANOVA was used to assess how different construct combinations affect ATE, TEH, angle of insertion, PRT, and distance. The following were considered independent factors:

- plate type (A, B, C and D),
- screw type (a, b, c and d),
- #1 constructs and #2 constructs

Post-hoc Tukey tests were performed to test for any statistically significant differences between groups. If the prerequisite for ANOVA was not met, Kruskal Wallis test was used instead, followed by Dunn's post-hoc test. Statistical significance was set to a p-value of <0.05.

Chapter 4 - Results

Thread engagement height (TEH) and Average Thread Engagement (ATE) – Micro-CT Analysis

TEH and ATE were strongly and nonlinearly correlated with each other (R^2=0.639, $p<0.001$) as depicted in Figure 4-1. Therefore, the results are presented together. Figure 4-2 shows the mean TEH and ATE between #1 and #2 constructs. The #1 constructs had significantly higher TEH and ATE than #2 constructs ($p<0.05$). Figures 4-3, 4-4, and 4-5 show the mean TEH and ATE between plates, screws, and constructs, respectively.

Figure 4--1. Correlation between Average Thread Engagement (ATE) and Thread Engagement Height (TEH)

TEH and ATE were strongly and nonlinearly correlated with each other (R^2=0.639, $p<0.001$).

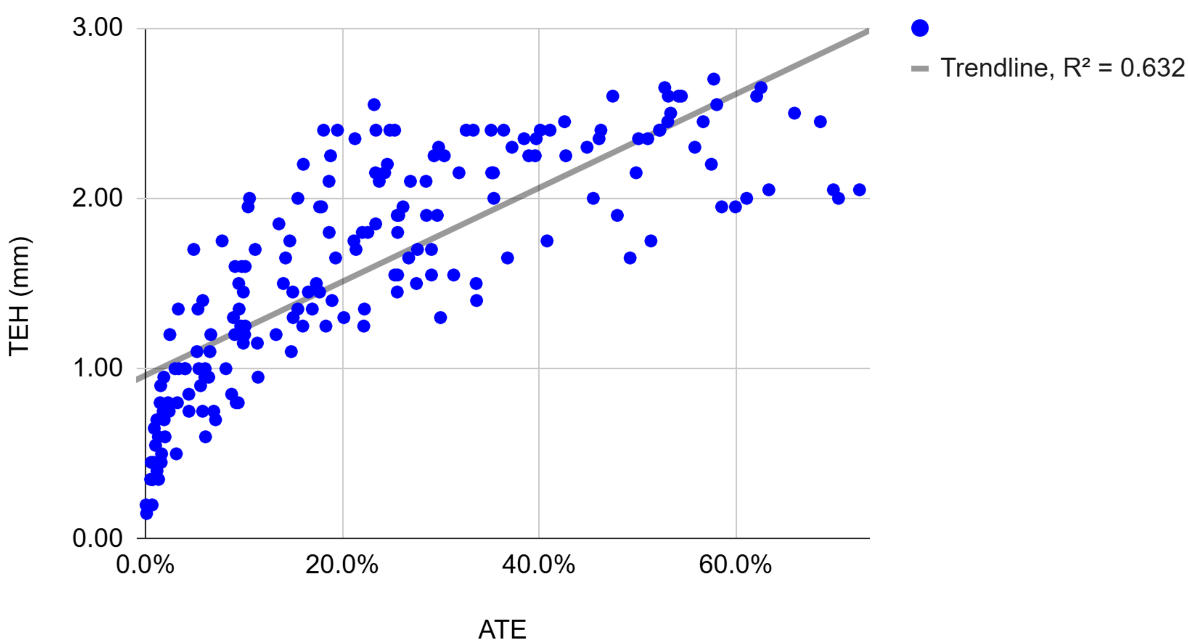
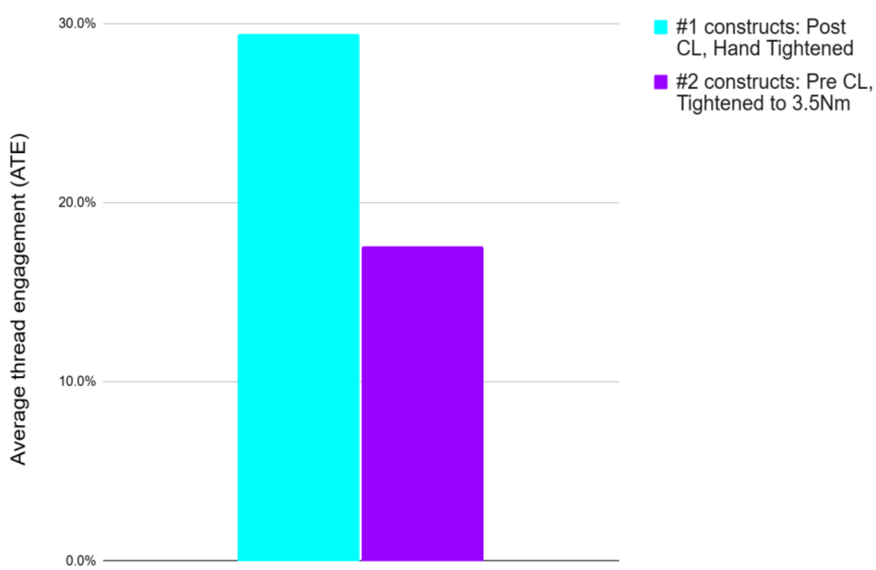


Figure 4-2. Average Thread Engagement (ATE) and Thread Engagement Height (TEH) between #1 and #2 Constructs

The mean average thread engagement (ATE) for #2 constructs (pre-cyclic loading, tightened to 3.5 Nm by a torque limiting screwdriver) and #1 constructs (post-cyclic loading, hand-tightened by a board-certified veterinary orthopedic surgeon) was 17.5% and 29.5%, respectively. The mean thread engagement height (TEH) for #2 constructs (pre-cyclic loading, tightened to 3.5 Nm by a torque limiting screwdriver) and #1 constructs (post-cyclic loading, hand-tightened by a board-certified veterinary orthopedic surgeon) was 1.39 and 1.83, respectively. The #1 constructs had significantly higher TEH and ATE than #2 constructs ($p<0.05$).



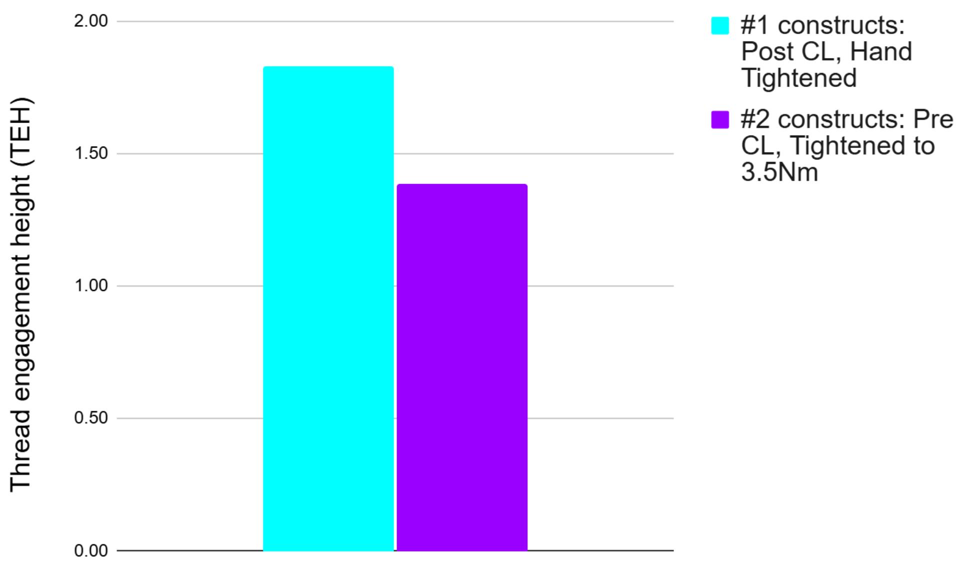


Figure 4--3. Average Thread Engagement (ATE) and Thread Engagement Height (TEH) for Plates "A-D."

The mean ATE for plates "A-D" was 11.9%, 35.5%, 25.5%, and 21.2%, respectively. The mean TEH for plates "A-D" was 1.21, 2.09, 1.29, and 1.84, respectively. Plates "A" and "C" had significantly lower TEH than plates "B" and "D" ($p<0.05$). Plate "B" had significantly higher ATE than all other plates ($p<0.05$), and plate "A" had significantly lower ATE than all other plates ($p<0.05$). There were no other significant differences in plate pairwise comparisons for ATE or TEH ($p>0.05$).

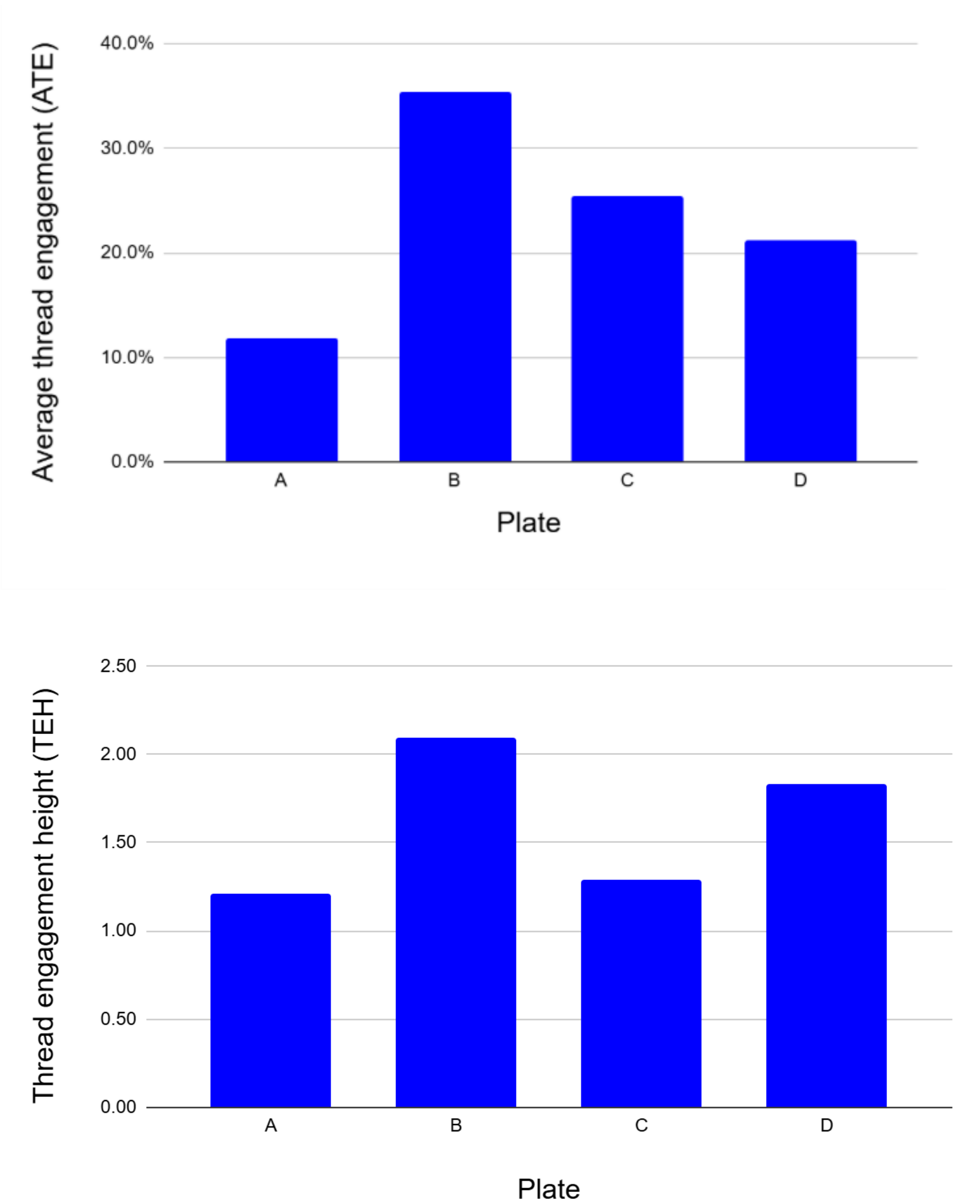


Figure 4--4. Average Thread Engagement (ATE) and Thread Engagement Height (TEH) for Screws "a-d."

The mean TEH for screws "a-d" was 1.11, 1.89, 1.70, and 1.73, respectively. The mean ATE for screws "a-d" was 10.2%, 34%, 25%, and 25.3%, respectively. The "a" screws had significantly lower TEH and ATE than all other screws ($p<0.05$). The "b" screws had significantly higher ATE than “a” and “c” screws ($p<0.05$). There were no other significant differences in screw pairwise comparisons for ATE or TEH ($p>0.05$).

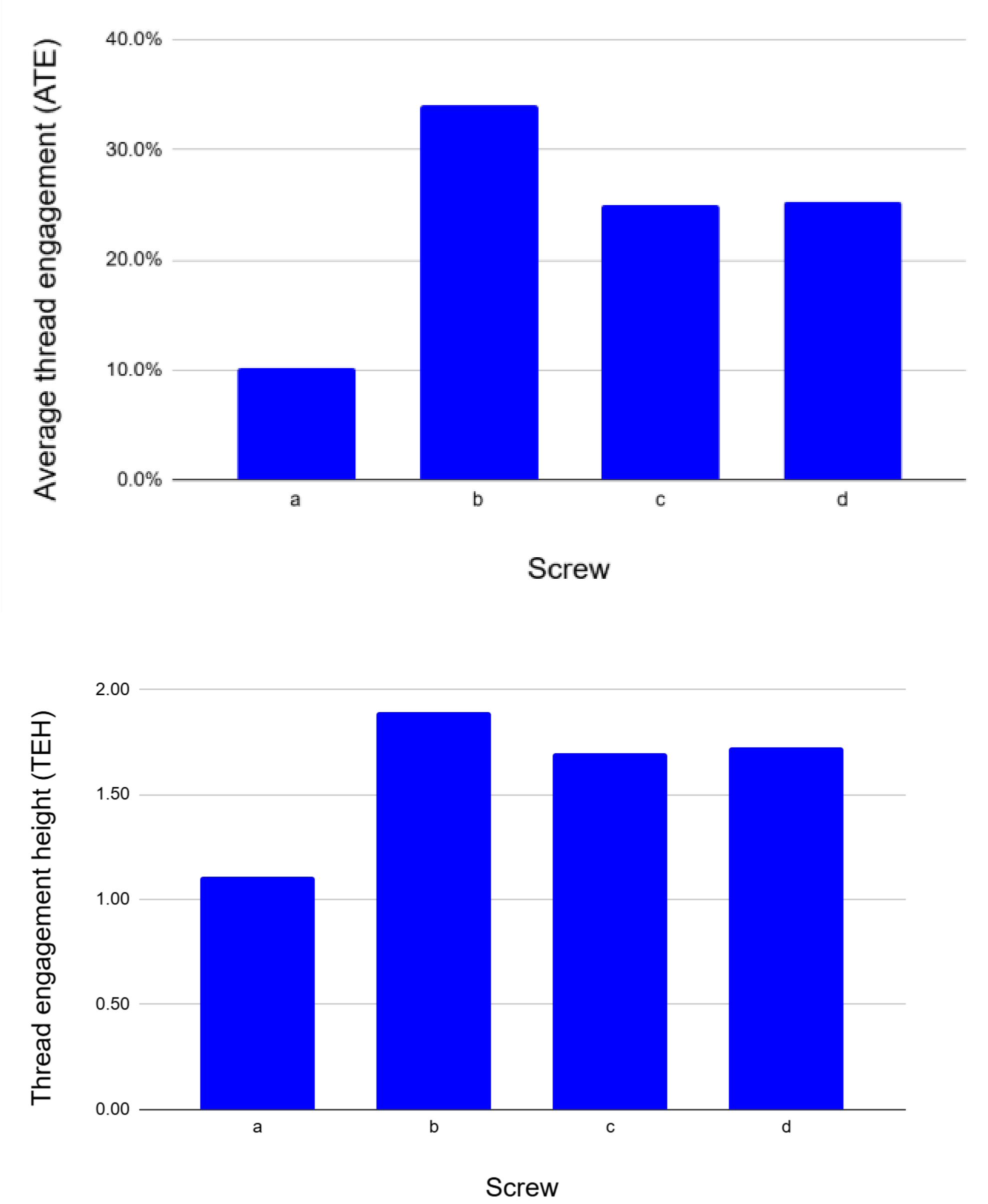
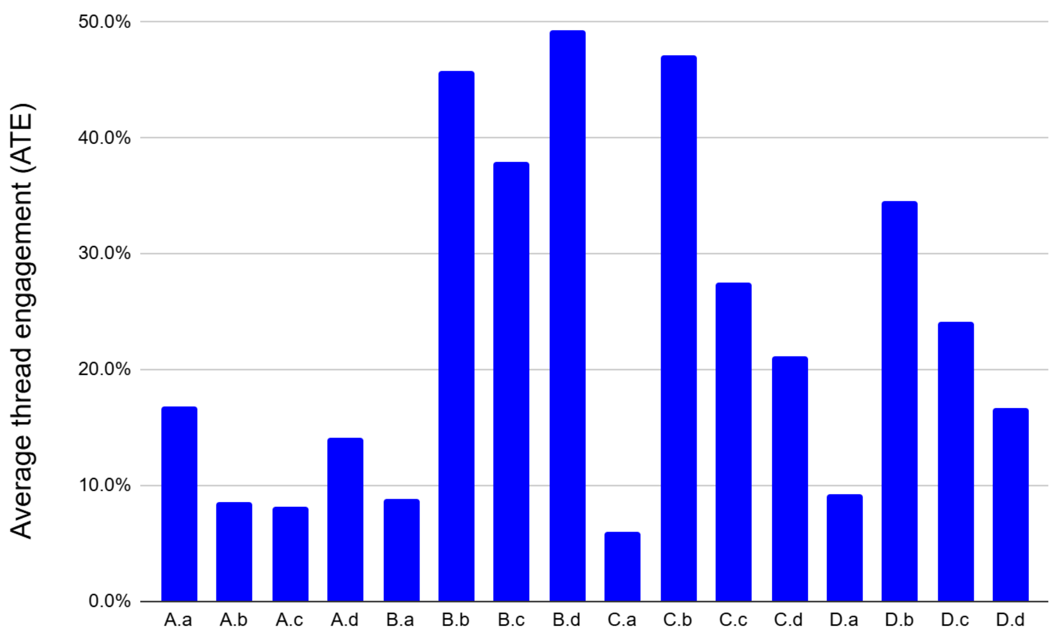
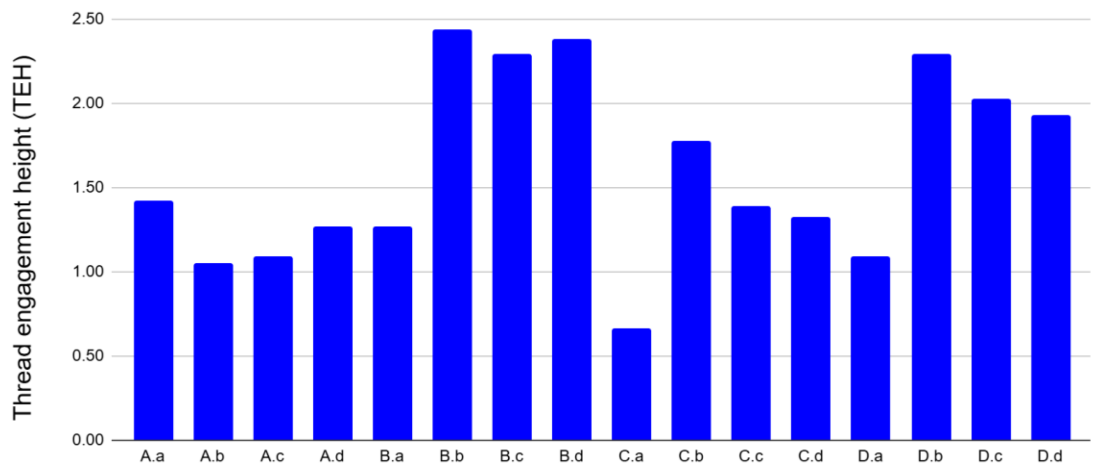


Figure 4--5 Average Thread Engagement (ATE) and Thread Engagement Height (TEH) for all Constructs.

When analyzing the “control” versus “mixed” constructs, “A.a” had the highest mean ATE and TEH for “A” plate cohort (A.a-A.d); “B.d” had the highest mean ATE and “B.b” had the highest mean TEH for the “B” plate cohort (B.a-B.d), and “C.b” and “D.b” had the highest mean ATE and TEH for the “C” plate cohort (C.a-C.d) and “D” plate cohort (D.a-D.d).

For the “A” plate cohort (A.a-A.d), there were no significant differences in TEH or ATE between constructs ($p>0.05$). For the “B” plate cohort (B.a-B.d), “B.a” had significantly lower TEH and ATE than all other B constructs ($p<0.05$). For the “C” plate cohort (C.a-C.d), “C.a” had significantly lower ATE than “C.b” and “C.c” ($p<0.05$), “C.a” had significantly lower TEH than all other C constructs ($p<0.05$), and “C.b” had significantly higher ATE and TEH than all other C constructs ($p<0.05$). For the “D” plate cohort (D.a-D.d), “D.a” had significantly lower ATE than “D.b” and “D.c” ($p<0.05$), “D.a” had significantly lower TEH than all other D constructs ($p<0.05$), and “D.b” had significantly higher ATE than D.a and D.d ($p<0.05$). There were no other significant differences in pairwise comparisons for ATE or TEH ($p>0.05$).





Angle of Insertion – Micro-CT Analysis

There were slight variations in the angles of insertion, varying from 83.5-89.9° with a mean of 87.84°. There was no correlation between angle of insertion and PRT, ATE, or TEH. The mean angle for #2 constructs (pre-cyclic loading, tightened to 3.5 Nm by a torque limiting screwdriver) and #1 constructs (post-cyclic loading, hand-tightened by a board-certified veterinary orthopedic surgeon) was 87.74° and 87.94°, respectively. The mean angles for plates "A-D" were 87.24°, 87.88°, 88.17°, and 88.08°, respectively. The mean angles for screws "a-d" were 87.58°, 88.12°, 87.76°, and 87.90°, respectively. When analyzing the "control" versus "mixed" constructs, "A.b" had the highest angle (closest to 90°) of "A" plate cohort (A.a-A.d), "B.d" had the highest angle of "B" plate cohort (B.a-B.d), "C.d" had the highest angle of "C" plate cohort (C.a-C.d), and "D.b" had the highest angle of "D" plate cohort (D.a-D.d).

The "A" plates showed a significantly lower angle (further from 90°) than "C" plates ($p = 0.012$) and "D" plates ($p = 0.029$). All other pair-wise comparisons were not significant.

Distance – Micro-CT Analysis

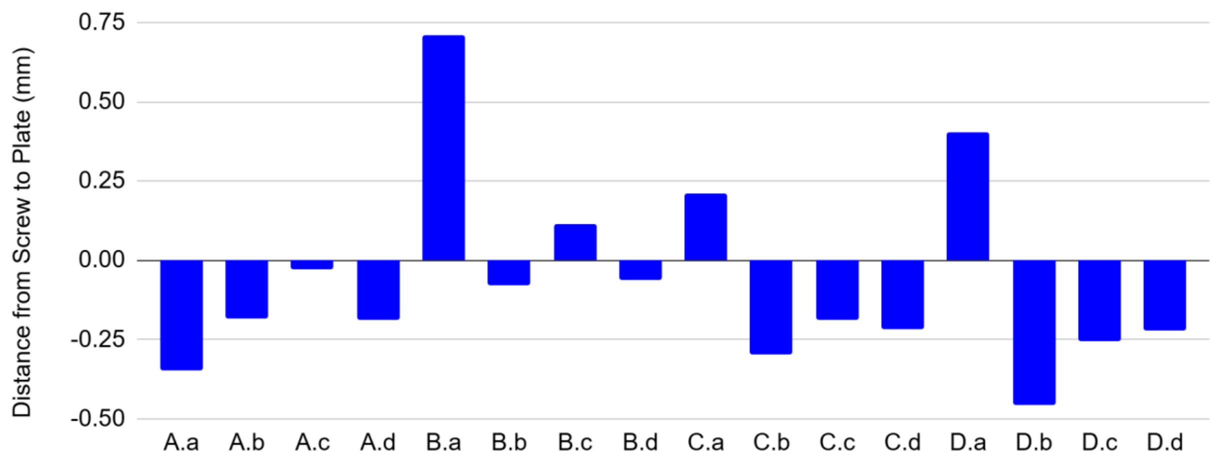
Screws varied as to the depth of seating within the plate. A positive value was assigned when the top of the screw was above the top of the plate, and a negative value was assigned when the top of the screw was below the top of the plate. The distance varied from 1.03mm to –0.85mm, with a mean of –0.07mm. There was no correlation between distance and ATE, TEH, PRT, or angle of insertion.

The mean distance for #2 constructs (pre-cyclic loading, tightened to 3.5 Nm by a torque-limiting screwdriver) and #1 constructs (post-cyclic loading, hand-tightened by a board-certified veterinary orthopedic surgeon) was –0.16mm and 0.03mm, respectively. The mean distance for plates "A-D" was –0.19mm, 0.17mm, -0.12mm, and –0.13mm, respectively. The mean distance for screws "a-d" was 0.25mm, -0.25mm, -0.09mm, and –0.17mm, respectively.

The distance was significantly higher for #1 constructs than #2 constructs ($p<0.001$). The distance for "B" plates was significantly higher than "A" ($p<0.001$), "C" ($p = 0.0003$), and "D" ($p = 0.0002$) plates, while the distance for plates "A", "C", and "D" were not significantly different from each other. The distance for "a" screws was significantly higher than "b" ($p<0.001$), "c" ($p<0.001$), and "d" ($p<0.001$) screws, while screws "b-d" were not significantly different from each other ($p>0.05$). See Figure 4-6 for the distance for all constructs.

Figure 4--6. Distance for all Constructs.

For all plate cohorts (A.a-D.d), all plates with "a" screws (A.a, B.a, C.a, and D.a) had significantly different distances from all plates with screws "b-d" ($p<0.05$), while the distance of screws "b-d" in all plates did not differ from each other ($p>0.05$).



Peak Reverse Torque (PRT)

PRT was assessed on screws “U”, “W”, and “Y” from #1 constructs and “V”, “X”, and “Z” from #2 constructs. PRT was not correlated with ATE, TEH, angle of insertion, or distance. The mean PRT for #2 constructs (tightened to 3.5 Nm by a torque limiting screwdriver) and #1 constructs (hand-tightened by a board -certified veterinary orthopedic surgeon) was 2.3 Nm and 1.1 Nm, respectively. The mean PRT for plates and screws are as follows: A: 1.69 Nm B: 1.98 Nm, C: 1.85 Nm, D: 1.28 Nm, a: 1.72 Nm, b: 1.79 Nm, c: 1.41 Nm, d: 1.89 Nm. When analyzing the “control” versus “mixed” constructs, “A.a,” “B.b,” “C.d,” and “D.d” had the highest mean PRT within the “A-D” plate cohorts, respectively.

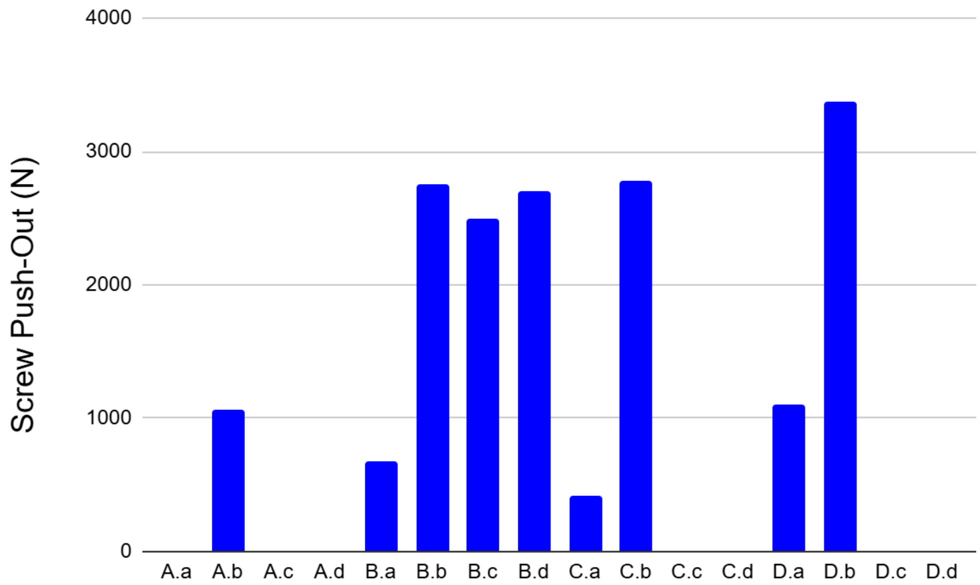
The #2 constructs had significantly higher PRT than #1 constructs ($p<0.05$), and “B” plates had significantly higher PRT than “D” plates ($p<0.05$), but all other pair-wise comparisons showed no statistically significant difference ($p>0.05$).

Screw Push-out

The Delrin rods were removed from each construct with a scroll saw, and screw push-out was assessed on screws “V”, “X”, and “Z” from #1 constructs and screws “U”, “W”, and “Y” from #2 constructs. Due to sample integrity, multiple screws could not be assessed (A.a: U, V, X; A.b: U, A.c: all screws; A.d: U, W, X, Z; B.a: W; B.b: U; B.c: U, V, Z; B.d: U, C.a: V, X, Z; C.b: V, Z; C.c: U, V, X, Z; C.d: U, V, X, Z; D.a: U, V, Z; D.b: U, Z; D.c: U, V, X, Y, Z; D.d: U, V, X, Y, Z). Two screws in construct “A.a” were outliers and thus were excluded from further analysis. Descriptive statistics are only reported on constructs that had 3 or more measurements (A.b, B.a, B.b, B.c, B.d., C.a, C.b, D.a, D.b). The mean screw push-out for plates and screws are as follows: A:1063.05 N, B: 2123.27 N, C: 1770.24 N, D: 2267.18 N, a: 839.70 N, b: 2375.94 N, c: 2501.10 N, and d: 2707.41 N. See Figure 4-7 for screw push-out for all constructs.

Figure 4--7. Screw Push-Out (N) for all Constructs.

The mean screw push-out for all constructs with 3 or more screws available for analysis. Though only descriptive results can be reported due to limited sample size, it is notable that only the “B” plate cohort (B.a-B.d) maintained integrity of all their constructs after the delrin rods were removed, while the A, C, and D plate cohorts only maintained 1 (A.b) or 2 (C.a,C.b; D.a,D.b) constructs.


Screw Push-Out (N)
4000
3000
2000
1000
0
A.a
A.b
A.c
A.d
B.a
B.b
B.c
B.d
C.a
C.b
C.c
C.d
D.a
D.b
D.c
D.d

Chapter 5 - Discussion

To the best of the authors' knowledge, this is the first study to investigate the mechanical strength and stability of constructs created by intermixing orthopedic implant components from different manufacturers. Based on the results of the mechanical testing, the study hypothesis that constructs composed of plates and screws from the same manufacturer ("Control") would demonstrate higher PRT, screw push-out strength, and Micro-CT analysis (ATE, TEH) compared with intermixed constructs ("Mixed") was rejected. Though we cannot comment on the screw push-out values due to a small sample size, it is notable that only the "B" plate cohort (B.a-B.d) maintained all constructs after removing the delrin rods. When evaluating controls versus mixed constructs, "A.a" had the highest mean ATE, TEH and PRT within the "A" plate cohort (A.a-A.d); "B.b" had the highest TEH and PRT, while "B.d" had the highest ATE within the "B" plate cohort (B.a-B.d); "C.b" had the highest TEH and ATE while "C.d" had the highest PRT within the "C" plate cohort (C.a-C.d); and "D.b" had the highest ATE and TEH while "D.d" had the highest PRT within the "D" plate cohort (D.a-D.d). For our secondary objective, under the conditions of these mechanical tests, the "B" system consistently showed the most secure fixation in the parameters measured, and was more accommodating of mixing B-system screws or plates with plates or screws from other manufacturers, with the exception of those from manufacturer A. The A system proved to be the least adaptable to mixing with screws or plates from other manufacturers. Based on this testing, the authors' recommendations for intermixing constructs are that "A" plates be used with "a" screws, and "B-D" plates be used with "b" or "d" screws.

Currently, companies advise against mixing implants from different manufacturers, presumably due to design discrepancies; to the best of the authors' knowledge, no studies have evaluated this. Anecdotally, some veterinary surgeons mix implants from different companies. Knowing the impact of intermixing implants is important in cases of ordering errors, shipment delays, or other factors that negatively affect supply. If mixing locking implants is inappropriate, complications in fracture healing (implant failure, delayed union, malunion, etc.) could result. If acceptable, surgeons could alleviate patients' suffering more quickly, without waiting for specific implants. Additionally, mixing company materials could reduce costs, which are often a limiting factor in veterinary medicine. If intermixing materials is acceptable, surgeons could choose the most cost-effective implants regardless of whether matching components were available. This could potentially have financial implications for human orthopedics as well.

Regarding the novel micro-CT-based assessment of screw-plate interlocking by calculating TEH, we found a very strong correlation with ATE, suggesting that TEH may serve as a reliable metric for evaluating screw–plate interface engagement in future investigations. ATE describes how well threads of a screw head engage with the threads of a plate hole and is the arithmetic mean of all the scores for each construct. The calculation of ATE has been well-described elsewhere.[6] This is the first report describing TEH, which is the number of images for which the score was greater than 0% multiplied by a slicing offset equal to 50 μm. ATE has been correlated with screw push-out strength,[6] angle of insertion,[6] and bending strength of constructs.[31] Our data in this study (PRT, angle of insertion, distance) were not correlated with ATE or TEH. There were too few data points on screw push-out to run statistics. Additional research is needed to better understand the relationship between TEH and mechanical testing.

Interestingly, the #1 constructs had significantly higher TEH and ATE than the #2 constructs, despite the #1 constructs having undergone cyclic loading prior to micro-CT analysis. The compressive cyclic loading may have allowed the threads of the LCP and LS to engage further, thus increasing ATE and TEH. Though the manufacturers recommended tightening the screws to 1.5 Nm, this created subjectively loose constructs, so the screws were subsequently either hand tightened by a board-certified orthopedic surgeon (WR, #1 constructs) or tightened to 3.5 Nm by a torque-limiting screwdriver (#2 constructs). It is possible that the hand-tightened screws on #1 constructs were tightened to a force larger than 3.5 Nm, as higher torque (2.5 Nm compared to 1.5 Nm) is associated with higher ATE.[6] Additionally, it has been shown that orthopedic surgeons are more likely to overtighten and strip screws in artificial bone than are researchers.[24] However, we found no evidence that any of the screws were stripped during PRT testing, based on the experience of the individual performing this test. Additionally, PRT was not associated with ATE and TEH. It seems logical that constructs with higher thread engagement would have higher PRT, but only partial thread engagement is needed to retain the locking mechanism.[46,48] It is possible that the #2 constructs were cross-threaded, thus decreasing ATE and TEH but increasing PRT. However, there was no statistically significant difference in angles of insertion between #1 and #2 constructs, so cross-threading of #2 constructs seems unlikely. Despite the lack of statistically significant correlation with PRT and ATE or TEH, there were similar findings, namely that "A.a" had the highest mean ATE, TEH and PRT within the "A" plate constructs, and "B.b" had the highest TEH and PRT within the "B" constructs. As this is the first study to report TEH and to evaluate the correlation between PRT and ATE, additional testing is needed to better understand the relationship between PRT, ATE, and TEH.

Though a guide was used to drill each screw hole at 90°, we found variability in angle of insertion from 83.5-89.9°, with a mean of 87.84°. Each Delrin rod was manually stabilized in a custom-made holding device, but it is likely that there was some motion during drilling, which resulted in variable angles of insertion. Our study found that the screws in "A" plates had significantly lower angles (further from 90°) than “C” and “D” plates, which may have negatively impacted their performance in our study, but there was no correlation with angle of insertion and ATE, TEH, or PRT. We suspect that the “A” plates had greater micromotion during drilling, as these were the longest plates (see Figure 3-1) and possibly were the hardest to manually stabilize. Micro-CT has been used to confirm the angle of insertion,[47] and the effect of angle of insertion on construct strength has been studied.[13,27,31,45,47] It has been shown that placing locking screws at over five degrees of angulation significantly decreases the strength of the construct by 30%, and ten degrees of angulation can significantly decrease the strength of the construct by 50%.[45] Another paper found that for each one degree increase in screw-plate angle, there was an average decrease of approximately 0.4Nm screw-plate interface strength.[76] Therefore, due to the possibility of micromotion during drilling, the authors recommend that plates be secured to the bone with bone forceps or pins during clinical practice before drilling screw holes to minimize any variation in angle of insertion that could decrease the strength of the screw-plate interface.

The relationship of the plate-bone distance and implant stability has been studied,[22,68] but the distance between the top of the screw head and the top of the plate hole has not been studied, to the best of the authors’ knowledge. We believed that studying this distance could relate to how well the threads from the screw head engage with the plate hole, and suspected that a larger positive or negative difference would correlate with less thread engagement and worse performance in mechanical testing. Interestingly, in all plate cohorts (A.a-D.d), all plates with “a” screws (A.a, B.a, C.a, and D.a) had significantly different distances from all plates with “b-d” screws ($p<0.05$), while the distances of “b-d” screws in all plates did not differ from each other ($p>0.05$). Additionally, the “a” screws had positive values for “B-D” plates while the “b-d” screws had negative values for "B-D" plates. The "a" screw head has a different geometry than the "b-d" screw heads (see Figure 3-1), and this could explain the difference in distance. Despite the large difference in distance, we found no correlation between distance and ATE, TEH, PRT, or angle of insertion. As this is the first study to evaluate distance, additional studies are needed to better understand its relationship to performance in mechanical testing and its potential clinical applications.

Screw push-out strength has been used to evaluate the integrity of locking implants.[11,13,47] However, the clinical applicability of this test is questionable as locking implants are more resistant to screw pull-out than conventional plates because the locking construct ensures that applied loads are distributed more evenly across all supporting screws, thus avoiding stress at a single screw-bone interface.[17,20,43] Instead, failure of locking implants requires concurrent axial pull-out of all implants or compressive failure of the bone surrounding the screws.[43] Unfortunately, our sample size was diminished due to sample integrity. Though it is interesting to note that the "B" plate was the only group that maintained all of their constructs ("a-d"), conclusions and interpretations are unable to be made.

Most mechanical testing in the literature involves loading implants to failure.[8,11,13] However, the clinical relevance of these tests is questionable as they involve a single event with progressively increasing loads until catastrophic failure, often applying supraphysiologic loads to implants. In clinical scenarios, implants fail more frequently due to fatigue failure. Therefore, the authors believe cyclic loading is a more clinically relevant mechanical test to explore implant stability, and it has been used in multiple other studies.[34,39, 77] Our study limited cyclic loading to 355N, as 355N has been shown to be the approximate thoracic limb force for a 30kg dog.[67] Though we had performance differences between our constructs in our other testing (PRT, ATE, TEH), none of our constructs showed failure during our physiologic cyclic loading, and thus it is possible they would be successful in clinical scenarios. However, more research is needed before using these mixed constructs in patients.

There are numerous limitations to this study. One limitation is the sample size. Though using a uniform bone surrogate such as Delrin Rods and having each construct made by the same researcher limits individual variability and created more homogenous samples, larger sample sizes should be used in future studies to strengthen conclusions and interpretations. Another limitation is related to its in-vitro design, as in-vitro designs are not perfect replica of in-vivo scenarios. Despite our goal to replicate repetitive physiologic loading with cyclic loading in this study, cyclic loading was only tested in compression, and there are other forces such as torsion and bending that can act on implants during patient healing. Our other mechanical tests (peak reverse torque, screw push-out) are also not perfect replicas of clinical scenarios, as a single progressively increasing load is rarely the reason for implant failure. An additional limitation is that the majority of the screw push-out samples were lost during sample preparation by removing the Delrin rods with a scroll saw, which limits our interpretation of these results. Ideally, we would've created additional constructs without the Delin rod specifically for screw push-out testing, but we were limited by sample size and cost.

To the best of the authors' knowledge, this is the first study to investigate the mechanical strength and stability of constructs created by intermixing orthopedic implant components from different manufacturers. Based on our mechanical testing (PRT) and micro-CT analysis (ATE, THE), the "B" system consistently showed the most secure fixation in the parameters measured, and was more accommodating of mixing B-system screws or plates with plates or screws from other manufacturers, with the exception of those from manufacturer A. The A system proved to be the least adaptable to mixing with screws or plates from other manufacturers. Based on this testing, the authors' recommendations for intermixing constructs are that "A" plates be used with "a" screws, and "B-D" plates be used with "b" or "d" screws. The novel micro-CT-based assessment of TEH showed a very strong correlation with ATE, suggesting that TEH may serve as a reliable metric for evaluating screw–plate interface engagement in future investigations. However, more research is needed to better understand the novel micro-CT measurements of distance and TEH. Further studies need to be performed to determine if these mechanical testing results can be verified for in vitro and in vivo scenarios.

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