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Biomechanical analysis of an interference screw and a novel twist lock screw design for bone graft fixation

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ABSTRACT

Background: Malpositioning of an anterior cruciate ligament graft during reconstruction can occur during screw fixation. The purpose of this study is to compare the fixation biomechanics of a conventional interference screw with a novel Twist Lock Screw, a rectangular shaped locking screw that is designed to address limitations of graft positioning and tensioning.

Methods: Synthetic bone (10, 15, 20 lb per cubic foot) were used simulating soft, moderate, and dense cancellous bone. Screw push-out and graft push-out tests were performed using conventional and twist lock screws. Maximum load and torque of insertion were measured.

Findings: Max load measured in screw push out with twist lock screw was 64%, 60%, 57% of that measured with conventional screw in soft, moderate and dense material, respectively. Twist lock max load was 78% and 82% of that with conventional screw in soft and moderate densities. In the highest bone density, max loads were comparable in the two systems. Torque of insertion with twist lock was significantly lower than with conventional interference screw.

Interpretation: Based on geometric consideration, the twist lock screw is expected to have 35% the holding power of a cylindrical screw. Yet, results indicate that holding power was greater than theoretical consideration, possibly due to lower friction and lower preloaded force. During graft push out in the densest material, comparable max loads were achieved with both systems, suggesting that fixation of higher density bone, which is observed in young athletes that require reconstruction, can be achieved with the twist lock screw.

1. Introduction

Anterior crucial ligament (ACL) reconstruction is one of the most commonly performed procedures in orthopaedic surgery, with well documented outcomes in a variety of studies. There are good-to-excellent results in approximately 85–95% of patients (Emond et al., 2011). In spite of these results, questions still remain regarding optimal graft-fixation techniques (Emond et al., 2011). Interference screws, widely used since the 1980s, have good fixation strength with the patella tendon graft (bone-tendon-bone) ACL reconstruction (Emond et al., 2011). There have been numerous studies evaluating different fixation methods; the interference screw technique has become a popular choice and a reliable and frequently used method for fixation in ACL repairs (Micucci et al., 2010). The interference screw has dimensions similar to the cancellous screw. Screw designs are constructed with consideration of diameter, length, thread, and pitch to attempt to optimize ACL graft fixation. In the ACL reconstruction the ultimate goals are to fix the graft at the ideal tension and hold it in-place until the bone healing or incorporation is completed.

Loss of fixation of reconstructed graft is uncommon in ACL reconstruction. When failure does occur however, most commonly it occurs by rupture at the tendon–screw interface or possibly due to graft slippage. Some of these failures may in part be due to direct trauma to the tendon during fixation or from abrasion/laceration of the tendon by the edges of the screw implant or bone tunnel. Failure may also occur if and when the screw insertion causes rotation of the graft resulting in an eccentric position relative to the screw. Failure to adequately restore the physiologic length–tension relationship of the tendon graft can be

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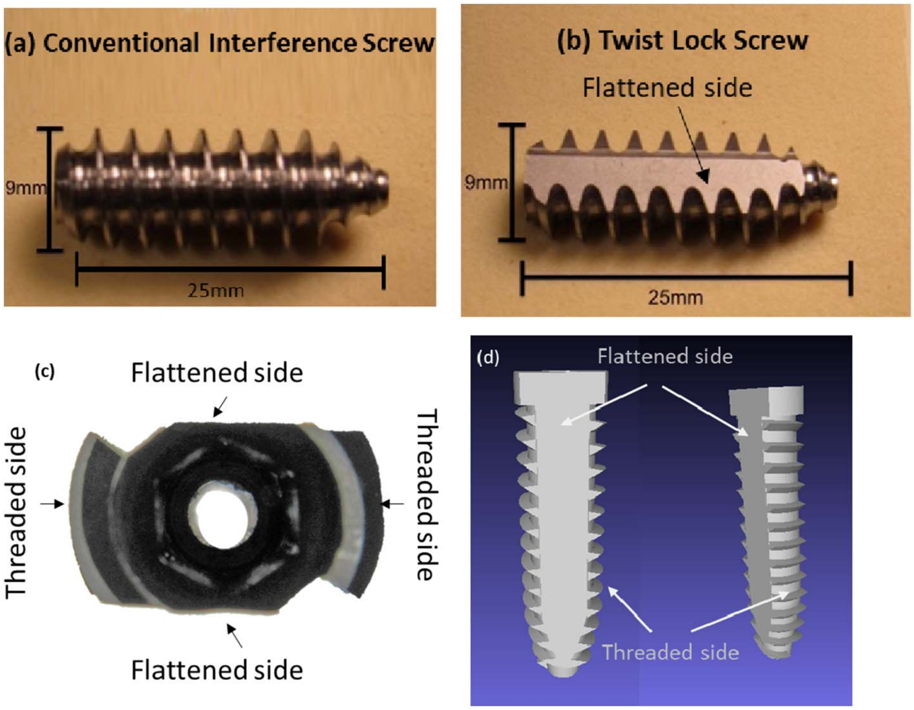

Fig. 1. Profiles of a (a) conventional interference screw (CIS) and (b) the twist lock screw (TLS). The TLS has identical thread outer diameter, root diameter, length of threads and thread shape as CIS, but is flattened on each side. (c) Cross sectional and (d) longitudinal view of the TLS. A rectangular screw was created by flattening parallel sides of a CIS screw, leaving 2 flattened sides and 2 round threaded sides. The leading edge of each thread has a positive rake to facilitate cutting into the bone.

an important contributing factor for reconstruction success. A malpositioned graft may gradually fail through cyclic loading. Additionally, the biological weakening of the graft during the rehabilitation period may be far more significant in a malpositioned circumstance.

During graft fixation, firm tension is applied to the proximal bone plug sutures. The position and pre-tension of the graft are then controlled with insertion of the screw to reach a desired holding power. When isolating the contributions of varying parameters for their effect on holding power of a cancellous screw, the following were found to be key variables in order of importance: (1) host material properties, (2) screw outer thread diameter, and to a much lesser extent (3) screw pitch and (4) screw thread depth (Asnis et al., 1996; Asnis et al., 1997). In this case, host material properties (specifically ultimate shear strength) is dictated by each patient's bone density and quality, which varies and is uncontrollable. Therefore, the design of the screw becomes the next most important set of factors for optimizing screw fixation. Naturally, these may vary according to the intended use of the screw.

The holding power of the screw thread is the amount of force or tension that can be held by the screw thread-bone interface prior to failure and stripping (Asnis et al., 1997). The dimensions of a conventional interference screw (CIS) are important for function and holding power (Asnis et al., 1997; Chapman et al., 1996; Ramaswamy et al., 2010; Uhthoff, 1973). The holding power of a screw is directly influenced by six variables: (1) the major thread or outer diameter (D) which is the distance between the tips of the thread crests; and (2) the engaged thread length (L). The (3) root diameter, which represents the minor or inner thread diameter measured as the distance between the root of the threads, and (4) thread shape have smaller contributions to the holding power (Asnis et al., 1997; Chapman et al., 1996; Ramaswamy et al., 2010; Uhthoff, 1973). Additionally, the (5) thread depth (d), the perpendicular distance between the root of the thread and its crest, and the (6) pitch (p), the distance between the threads, also contribute to holding power. The holding power of a classic helical shaped screw thread can be expressed as $Fs = (S) \times (L\pi D) \times (\text{Thread Shape Factor})$ (1989), where the 'Thread Shape Factor' equals $(0.5 + 2d/3p)$, Fs = shear failure force and S = material ultimate shear strength.

Fixation failure of a screw in a host material most often occurs at the host material interface (e.g. fails on the bone side of the bone-screw interface). The holding power of a screw is frequently tested by its push-out strength, yielding the load needed to push the screw to failure in the host (Asnis et al., 1997; Collinge et al., 2000; Kleeman et al., 1992; Ramaswamy et al., 2010). The force required for push-out failure is related mostly to the 'Material Ultimate Shear Strength'. The second most important factor is the surface area of the cylinder of bone that must be sheared for failure, which is given by $L\pi D$ for spherical screw (1989; Asnis et al., 1997; Koranyi et al., 1970).

The primary purpose of this study is to compare the fixation biomechanics of a conventional interference screw (CIS) to a novel screw design, the Twist Lock Screw (TLS). The Twist Lock Screw is a unique screw designed to address a specific concern associated with interference screw fixation such as controlled positioning and tensioning of graft during fixation. Unlike CIS, where advancement of the screw into position can result in graft plug movement and changes in pre-tension, the TLS screw is designed to be turned 90° to lock the graft into position at the desired position and pre-tension. The locking mechanism design of TLS has less screw thread surface area compared to CIS. Therefore, we hypothesize that the TLS will have lower but sufficient biomechanical fixation properties (max load before failure) compared to CIS, while also reducing the torque required for achieving fixation. In this study, we evaluated the biomechanical fixation properties of CIS and TLS screws in synthetic bone of varying densities using screw and graft push out tests, and have identified conditions under which TLS achieves comparable failure properties to CIS while optimizing positioning and pre-tensioning capability.

2. Methods

The objective of this study was to test interference fixation of CIS and TLS screws. Push-out testing was used to compare the push-out strength of CIS [Biomet® 9 mm × 25 mm] with the TLS [9 mm (cross section for the thread circumference) and 5 mm (cross diameter of the flattened surface) × 25 mm] (Fig. 1). Push out tests were performed in synthetic bone material with the density of 10, 15, and 20 lb per cubic foot (pcf) obtained from Sawbones®. The 10, 15, and 20 pcf synthetic bone material was cut into uniform blocks, with uniform thickness of 2.0 cm. Half of the blocks were then modified for screw push-out testing

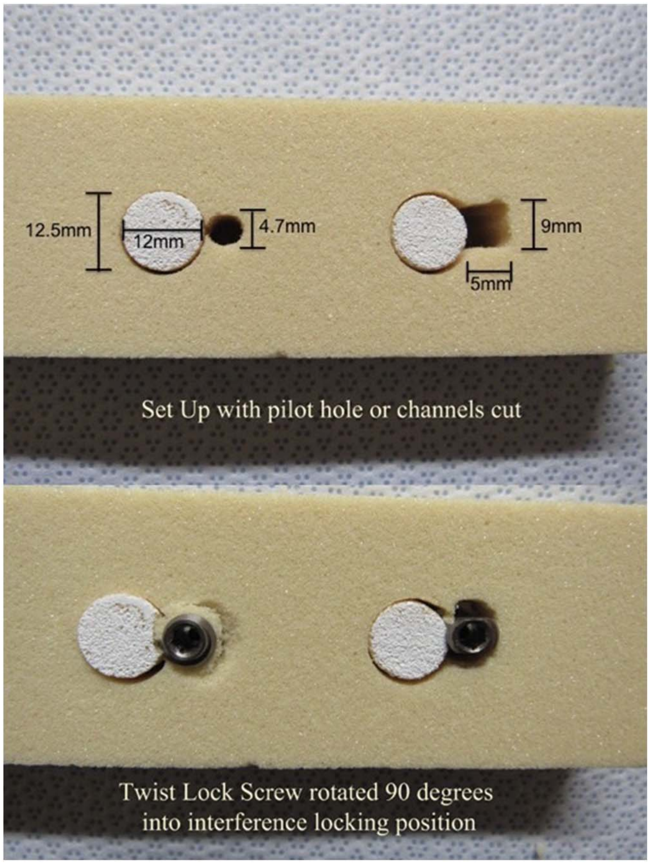

Fig. 2. Top: Graft push out test setup-homogeneous synthetic bone grafts (12 mm diameter) were generated and press fit into a 12.5 mm diameter bone tunnel. To secure the graft into place, a pilot hole or rectangular channel was created to allow for placement of CIS or TLS screw, respectively. Bottom: CIS and TLS screws were positioned prior to testing of graft push out. CIS was rotated into position and TLS was rotated 90° to lock screw into place.

and the other half for graft push-out testing.

2.1. Screw push out tests

The 2.0 cm thick blocks were modified for screw push-out testing by creating a 4 mm circular pilot hole for the CIS and a rectangular channel was made with a chisel 5 × 9 mm for the TLS (Fig. 2). The CIS was placed in the 4 mm pilot hole and manually screwed to a depth that seated the top of the screw flush with the material. A 'rectangular' cross sectional TLS screw was created by modifying a CIS screw. Two opposing sides of a cylindrical screw were flattened, resulting in two 'flat' parallel sides and two rounded sides with the natural curve of the screw threads. The receiving 'rectangular' channel was made using a chisel. The TLS was slid into a rectangular channel, 9 mm × 5 mm, until the head was flush with the 2 cm block, then twisted 90 degrees to lock. The block containing the screw to be tested was then secured to the base of the mechanical testing frame using a vice. This gave support to the entire block during testing. An Instron testing frame (Model 5566, Instron, Norwood, MA, USA) was used for all the mechanical testing. A metal indenter (5 mm in diameter) was aligned with the center of each screw for push out tests until failure. Indenter tip was brought into contact with the screw, and cyclic loading between 10 and 50 N at 0.1 Hz was applied for 10 cycles. A displacement ramp to failure was then applied at a rate of 0.5 mm/s. The resulting max load prior to failure was recorded using a 10 kN load cell. Push out tests were performed on $n = 10$ samples where a new pilot hole was used for each test. Testing between TLS and CIS groups was performed in alternating fashion to avoid any potential drift or bias in the testing setup. The same screw was used from each group for all of the tests.

2.2. Graft push out test

The other half of the blocks were used for test graft push-out. Synthetic bone blocks 20 mm in thickness were drilled to make 12.5 mm holes (simulating the host bone of the tibia). Cylindrical pegs 12 mm in diameter and 2 cm in length were made of the same density sawbone (simulating the bone in the bone-tendon-bone graft construct) and placed in the 12.5 mm holes. The graft slid easily into the hole without significant stability from the press fit of the graft. To lock the graft plug in place with CIS, samples were given a 4 mm pilot hole at the interface of the plug and host, and the CIS (9 mm × 25 mm) was used to lock the graft. To lock the graft plug in place with TLS, a rectangular slot (5 × 9 mm wide) was made in the host and TLS was pushed into the channel. The TLS was then turned 90° with the torque driver to lock the graft (Fig. 2). Torque measurements (Neiko Pro, ¼" Long Shank Toque Driver, 10–50 in-lbs., model 10573B) were taken with torque driver to determine the maximum torque needed to achieve proper screw positioning with both screw types. In all testing scenarios, the maximum torque (inch-pounds or in-lbs) required for screw insertion was measured.

In order to prevent potential damage by the indenter to the graft plug during graft push-out testing, a flat wooden disc was positioned on top of the graft itself, without contacting the threads of the screws. The plug push-out test was performed on $n = 10$ samples per group, again alternating between CIS and TLS groups during testing. Each test was performed with a new graft and tunnel set up held in place with a vice at the base of the testing frame.

2.3. Statistical analysis

In screw push out tests, the max load within each bone density was compared in CIS vs. TLS. In graft push out tests, the max load and max torque were compared in CIS vs. TLS groups. Mean and standard deviation are reported, and statistical comparisons were performed using *t*-test, and significance was set for $p \leq 0.05$.

3. Results

In the 10 pcf (simulating soft cancellous bone), the screw push-out tests resulted in an average max load of 381.5 N (SD: 39.0 N) for CIS before failure, while the TLS had an average of 244.9 N (SD: 11.4 N, $p = 0.000001$, Fig. 3). Similarly, the torque required for insertion was 9.3 in-lb. (SD: 0.7 in-lb) for CIS and 5.0 in-lb. (SD: 0.7 in-lb) for TLS ($p < 0.000001$). The TLS had 65% of the holding power of the CIS, while requiring only 54% of the torque needed for insertion. In terms of graft push-out (Fig. 4), the CIS had a max load of 179.4 N (SD: 28.1 N) before graft advancement, while the TLS had a mean of 139.7 N (SD: 16.0 N, $p = 0.00111$, Fig. 4) in 10 pcf synthetic bone. The torque required for insertion of CIS was 9.8 in-lb. (SD: 0.6 in-lb) and for TLS was 5.5 in-lb. (SD: 0.7 in-lb., $p < 0.000001$, Fig. 5). The TLS had 80% of the holding power of the CIS before graft-plug failure, while requiring only 56% of the torque needed for insertion.

In the 15 pcf (simulating moderate cancellous bone density), the screw push-out test showed the CIS had an average max load of 641.1 N (SD: 44.4 N) before failure, while the TLS had an average max load of 391.0 N (SD: 40.7 N, $p = 0.000001$, Fig. 3). Similarly, the torque required for insertion was 15.5 in-lb. (SD: 0.5 in-lb) for CIS and 7.8 in-lb. (SD: 2.1 in-lb) for TLS ($p < 0.000001$). The TLS had 60% of the holding power of the CIS screw, while requiring only 50% of the torque needed for insertion. In terms of graft push-out testing, the CIS had a mean holding power of 372.2 N (SD: 55.9 N) before graft advancement, while the TLS had a mean of 267.6 N (SD: 21.3 N, $p = 0.005$, Fig. 4). The torque required for insertion was 14.2 in-lb. (SD: 1.0 in-lb) for CIS and 12.6 in-lb. (SD: 1.2 in-lb) for TLS ($p < 0.005$, Fig. 5). The TLS had

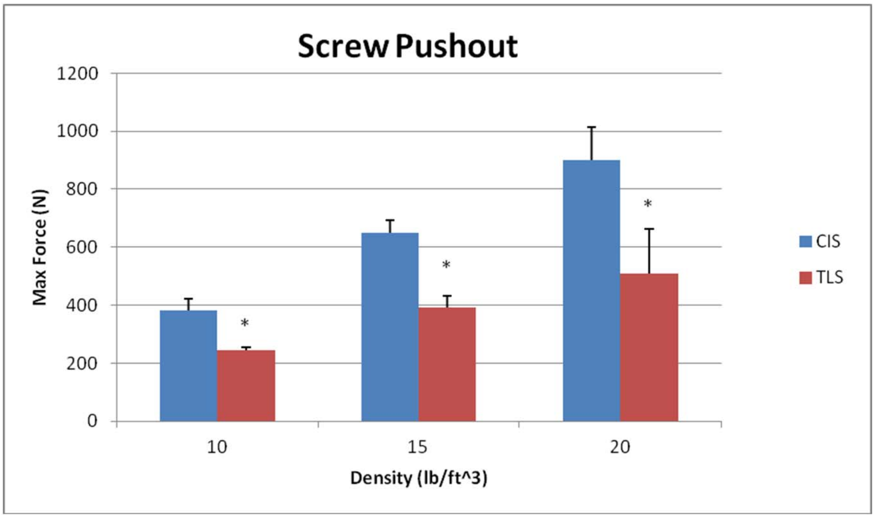

Fig. 3. Max failure load (N) measured during screw push out test using CIS and TLS screw in 10, 15, and 20 pcf density bone material. Failure load significantly increased with bone density for both screw designs. Failure load in TLS screw was significantly lower than CIS screw in all densities evaluated. * $p < 0.001$.

82% of the holding power of the CIS before graft-plug advancement, while requiring 89% of the torque needed for insertion.

In the 20 pcf (simulating denser cancellous bone), the screw push-out test showed the CIS had a mean holding power of 900.4 N (SD: 114.6 N) before failure, while the TLS had a mean of 509.4 N (SD: 154.6 N, $p = 0.000005$, Fig. 3). Similarly, the torque required for insertion was 24.6 in-lb. (SD: 3.0 in-lb) for CIS and 10.8 in-lb. (SD: 4.0 in-lb) for TLS ($p < 0.000001$). The TLS had 57% of the holding power of the CIS, while requiring only 44% of the torque needed for insertion. In terms of graft push-out, the CIS had a max load of 444.2 N (SD: 71.2 N) before graft advancement, while the TLS had a mean of 467.1 N (SD: 74.2 N, $p = 0.489$, Fig. 4). The torque required for insertion was 23.3 in-lb. (SD: 2.1 in-lb) and 15.7 in-lb. (SD: 3.2 in-lb. respectively ($p < 0.000007$, Fig. 5). The TLS had 105% of the holding power of the CIS before graft-plug advancement, while requiring only 67% of the torque needed for insertion.

In all cases of the graft push out tests using both CIS and TLS, failure occurred in the plug at the plug-screw interface. The screw-host interface remained intact and the screw stayed in place relative to the host block. Additional observations were made regarding the use of the CIS during insertion, where some stripping of the bone threads were observed as the screw advanced. Loading of the screw to drive it forward against the resistance of the synthetic bone system caused partial failure of the host threads under load (Fig. 6). Interestingly, such failure of the host threads was not observed in any of the TLS samples.

4. Discussion/conclusion

The goal of this study is to evaluate the fixation biomechanics of a novel twist lock screw (TLS) compared to a conventional interference screw (CIS). The TLS was designed to address a specific concern associated with interference screw fixation such as controlled positioning and tensioning of graft during fixation. Unlike CIS, where advancement of the screw into position can result in graft plug movement and changes in pre-tension, the TLS screw is designed to be turned 90° to lock the graft into position at the desired position and pre-tension. The locking mechanism design of TLS has less screw thread surface area compared to CIS. Our results indicate that max load prior to failure of both screws increases with increasing synthetic bone densities. Our results confirm that the geometric consideration of the TLS constitute lower failure loads compared to CIS in head to head comparison using screw push out. However, certain material property conditions, such as higher synthetic bone density (20 pcf), yield graft fixation in TLS that is comparable to that of CIS. The strong fixation of 20 pcf graft with TLS was achieved using only 67% of applied torque compared to CIS screw.

The CIS is similar to a cancellous screw, specifically as it pertains to the fixation features and properties. The CIS designs are constructed with consideration of diameter, length, thread, and pitch in order to optimize ACL graft fixation. The TLS has the same thread shape and dimensions as a CIS; however, it is flattened on opposite sides producing more of a rectangular shape in cross section (Figs. 1). Each thread

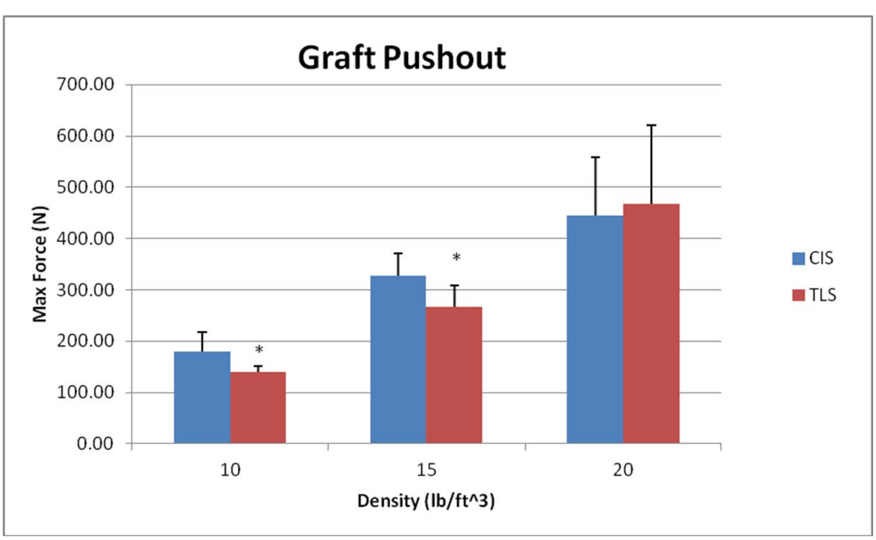

Fig. 4. Max failure load (N) measured during graft push out test using CIS and TLS screw in 10, 15, and 20 pcf density bone material. Failure load significantly increased with bone density for both screw designs. Failure load in TLS screw was significantly lower than CIS screw in 10 and 15 pcf bone densities. In 20 pcf, similar failure loads were observed in CIS and TLS. * $p < 0.005$.

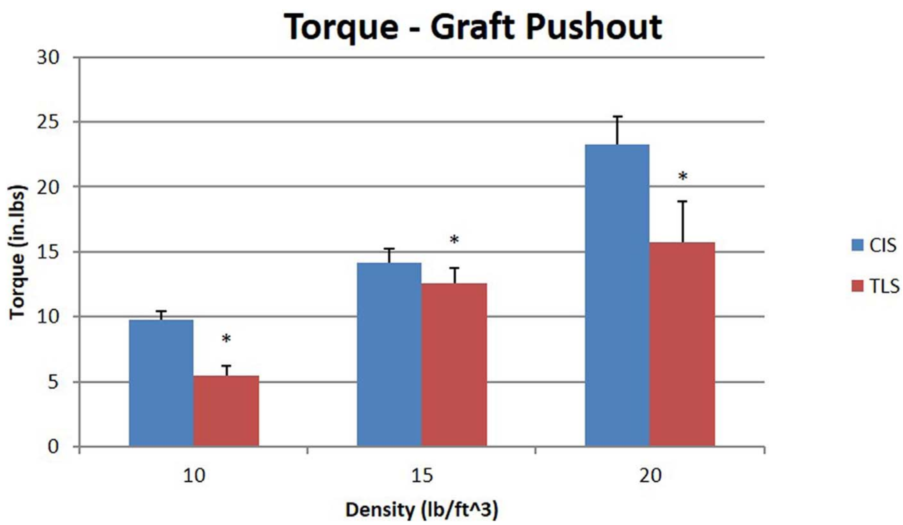

Fig. 5. Max torque (N) measured during graft push out test using CIS and TLS screw in 15 and 20 pcf density bone material. Torque required to secure TLS screw was significantly lower than CIS fixation in both bone densities. *p < 0.001.

Fig. 6. Fixation with CIS screw causes some damage in the bone synthetic material. For the screw to drive forward a significant magnitude of torque is required resulting in high loads which strips some of the initial host threads.

then has a positive rake on the leading side as the screw is turned clockwise (Fig. 1). This makes it cut into the bone more easily and with less resistance. Beyond the construct differences that these implants have, the TLS design has advantages compared to the CIS including; 1) only a quarter of a turn (90°) screw advancement is needed to lock graft, 2) significantly less friction is generated at the bone screw interface, 3) an efficient locking mechanism with minimal bone damage, 4) no preloaded force placed on the bone (screw does not need to push itself forward during advancement), and 5) less mechanical damage at the screw graft bone plug interface. It should also be noted that the efficiency is better and associated torque is lower in locking the TLS, because locking is achieved with a one quarter of a turn, compared to 10 complete turns with CIS.

Often in the bone-tendon-bone ACL procedures the most difficult process is getting and maintaining the proper tension in the new ACL tendon. The TLS screw design allows a tension device (which can accurately set the desired tension) to be placed on the threads holding the bone graft in the tibial canal, sliding the screw in its precut channel, while retaining the proper tension, then turning the screw 90° to lock the graft. This approach has the potential to address typical problems caused by CIS, namely 1) graft movement or damage during insertion, 2) high friction and resistance at the screw thread-bone interface, and 3) significant force required to advance the screw. Control of screw force and friction are important factors because they can lead to stress concentrations that damage the host bone, and may well contribute to fracture and/or deformation of the substrate threads (Emond et al., 2011; Halewood et al., 2011; Micucci et al., 2010). Since this was not the mode of failure of the CIS and TLS groups tested in the current study, additional studies are needed to assess the potential for TLS to minimize such damage.

Our finding indicates that while the CIS had greater holding power in the 10 pcf and 15 pcf synthetic bone, the TLS actually exceeded the holding power of the CIS for graft push-out in the 20 pcf material. Theoretically it was expected that the CIS would have stronger holding power over the TLS simply on the basis of the dimensionality of the two designs. The holding power of the CIS should be in direct proportion to the outer circumference of the cylinder (D) and length of engagement (L) or $L\pi D$. Although both screws had the same thread outer and inner diameters (9.0 mm) and identical thread shape, the CIS has a full circumference 28.26 mm whereas the TLS is more rectangular (9 mm × 5 mm in cross section) and has threads on only two sides of the periphery that measure 10.0 mm combined. The gripping circumference of the TLS is therefore 35% of that for CIS. Following this reasoning the holding power for the TLS may be projected to be only 35% of the CIS. Our results however indicate the TLS in the screw push-out tests demonstrated 64% (10 pfc), 60% (15 pfc), and 57% (20 pfc) of the CIS. The greater holding power is likely due to surface interaction between the TLS cross section with the synthetic boney material. It is also plausible that greater compression of bone plug with CIS screw would decrease the effective gripping circumference, whereas TLS holding power benefits from the fuller engagement of the available gripping circumference in the design.

When evaluating graft/tunnel construct fixation using graft push-out tests, both screws had lower failure load than that measured in screw push out test. The TLS had graft push-out strength that was lower than in CIS in certain bone densities: 78% in 10 pfc, and 82% in 15 pfc. Interestingly, in the highest synthetic bone density (20 pcf), the failure load of CIS and TLS were comparable (TLS failure load was 105% of that of the CIS). This is particularly important given that the 20 pcf material density was considered to be closest to the density of bone found in patients requiring ACL reconstruction, who are frequently young athletes. When the screws were used in the interference mode holding the graft in place, both systems created a contact gap in a portion of the tunnel. This was because of the compression of the graft. In the TLS screw, the graft compression occurred in the flat notched part of the screw, thus is did not compromise holding power. It was also found that the TLS required a significantly lower torque for insertion (56%, 89%, and 67% respectively) over a much shorter period of time compared to CIS fixation. In cases where bone is very osteoporotic, adaptations to the TLS may be performed to enhance fixation. For example, a 2 mm × 2 cm long pin may theoretically be tapped into one of the small spaces left on the flat side of the screw to enhance fixation, while maintaining the features of the controlled position and pre-tensioning afforded by TLS design.

The torque of insertion itself may be a very important factor even in the operating room. "Turning" the screw in bone creates friction, which also generates heat. The resulting heat has the potential to cause thermal necrosis of bone with subsequent loosening of the screw and must be avoided (Ruedi et al., 2007). In the synthetic bone and real bone, the force used in generating high torque may well cause deformation and mechanical damage to the host threads. We observed damage to the synthetic bone plug when advancing the CIS into position, resulting in stripping of the first few threads as the CIS advanced (Fig. 6). A plausible reason would be damage and stripping of the host synthetic bone threads by the increased compression and torque necessary for the CIS to drive itself forward. Such damage was not observed in TLS screw, and such high torque and friction was not required for the TLS screw. Nevertheless, comparable failure loads were achieved by TLS compared to CIS in the highest synthetic bone density. These findings beg the question of whether the holding power of CIS may be in excess of that needed to maintain fixation until early healing of a bone graft. Accordingly, a lower holding power achieved by TLS design or other modification to CIS may not necessarily be detrimental to the success of the fixation.

Strengths of this study include the repeatability associated with a single screw from each group for all tests performed, using a testing material with uniform densities, and a single investigator constructing all of the blocks, holes, and graft plugs with the same set of tools. The CIS procedure does not deviate from the standard way a bone-tendon-bone interference screw fixation of ACL is done, including the use of slightly over sized drill hole. One limitation however is that CIS screws are typically cannulated so that it may be inserted over a guide wire after the creation of bone tunnel and the passing of a graft into the bone socket, yet guide wires were not used in this study for either group. Additionally, in the standard ACL technique, the bone tunnel is often "notched" after the graft is passed to allow room for the interference screw. A similar rectangular notch is made in the TLS technique to aid in the insertion of TLS. The limitation of this study is the assumption that the sawbones synthetic material represents similar mechanical properties to bone. The difficulty in using natural bone is the great variance in densities especially in human cadaveric bone. Differences between cadaveric and fresh human bone observed in operating room must also be considered. Future studies will evaluate the TLS design in absorbable interference screws, which has clinical advantages to metallic interference screws. Further testing is also planned in a human bone model system.

5. Significance

Our study examines the biomechanics of interference screws and evaluates a novel TLS design intended to improve control over placement and pre-tension of graft fixation. The TLS design offers several advantages to the CIS, and achieves comparable graft holding power to CIS in certain synthetic bone material densities. Although this design can be used for both interference fixations in the femur and tibia, focus in this study was in the tibia where the proper tension and minimal bone damage is most important. The femoral fixation can be performed either with the CIS or TLS design. The biomechanics of the interference screw fixation may differ from the surgeon's intuitive impressions, especially in how friction generated during screw advancement may adversely affect fixation integrity.

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