Original Article

Redesigning Metal Interference Screws Can Improve Ease of Insertion While Maintaining Fixation of Soft-Tissue Anterior Cruciate Ligament Reconstruction Grafts

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Purpose: To compare the fixation strength and loads on insertion of a titanium alloy interference screw with a modified tip against a conventional titanium interference screw. **Methods:** Slippage of bovine digital extensor tendons (as substitutes for human tendon grafts) under cyclic loading and interference fixation strength under a pullout test were recorded in 10 cadaveric knees, with 2 tunnels drilled in each femur and tibia to provide pair-wise comparisons between the modified-tip screw (MS) and conventional screw (CS). To analyze screw insertion, 10 surgeons blindly inserted pairs of the MS and CS into bone-substitute blocks (with polyester shoelaces as graft substitutes), with insertion loads measured using a force/torque sensor. **Results:** No differences were found between the MS and CS either in graft slippage from the femur ($P = .661$) or tibia ($P = .950$) or in ultimate load to failure from the femur ($P = .952$) or tibia ($P = .126$). On insertion, the MS required less axial force application (78 ± 38 N, $P = .001$) and fewer attempted turns (2 ± 1, $P < .001$) to engage with the bone tunnel than the CS (99 ± 43 N and 4 ± 4, respectively). In 90% of the paired insertion tests, the screw identified by the surgeon as being easier to initially insert was the MS. **Conclusions:** The MS was found to be easier to engage with the bone tunnel and initially insert than the CS while still achieving similar immediate postsurgical fixation strength. **Clinical Relevance:** The study shows that screw designs can be improved to ease insertion into a bone tunnel, which should reduce any likelihood of ligament reconstruction graft damage.

Intra-articular reconstruction of the anterior cruciate ligament (ACL) is a commonly performed surgical procedure to restore function of the knee to the pre−ACL-ruptured state. When biological tissue autograft such as bone−patellar tendon−bone or hamstring tendon graft is used, an interference screw is often used to directly fix the graft by compressing it against the walls of the bone tunnels.[1]

Once started, as a screw advances through the bone, the surgeon assesses the strength of fixation through the resistance to advancing the screw or even a squeaking noise when fixation is especially firm; these

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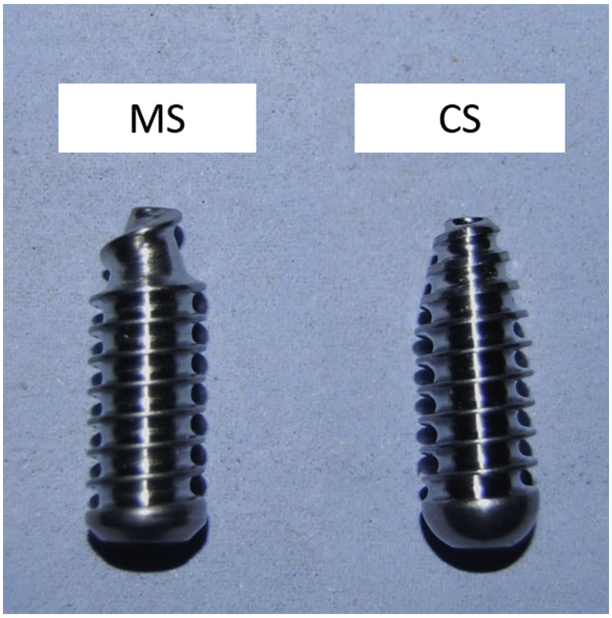

Fig 1. The interference screw with a modified tip (MS, left) has been designed to engage with the bone tunnel more easily than the conventional interference screw (CS, right).

are subjective measures of the insertion torque being applied.[2,3] A critical period is initial screw insertion: If the screw is difficult to start into the bone tunnel and requires many revolutions and manual force to "bite," there is a risk of lacerating or damaging the tendinous fibers of the graft.[4-6]

To maximize fixation strength, the surgeon selects the screw of the largest diameter that can be inserted without excessively damaging the graft. This is a subjective decision based on the surgeon's judgment, which is in turn based on his or her experience, as well as the resistance of the bone to drilling and insertion of the femoral screw. When using interference screws that do not "start easily," a surgeon may choose to allay fears of graft damage by inserting a smaller-diameter screw, which could compromise graft fixation security. To overcome this compromise, a metal screw with a modified tip has been designed to engage with a bone tunnel more easily and quickly than conventional designs (Fig 1).

The aim of this study was to compare the fixation strength and loads on insertion of a titanium alloy interference screw with a modified tip against a conventional titanium interference screw. The hypotheses were that there would be no difference between the screws in terms of graft slippage and ultimate strength of fixation but that the modified-tip screw (MS) would require less axial force and fewer turns to engage with the graft tunnel.

Methods

Fixation Strength Test

After ethics approval was obtained, 10 fresh-frozen human cadaveric knees (8 female and 2 male knees) with a median age of 43 years (range, 29-65 years) were obtained from a tissue bank (5 left and 5 right knees). All soft tissues and the fibula were removed from each specimen. The femur and tibia were then potted in separate 60-mm-diameter cylindrical steels pots using polymethyl methacrylate bone cement.

Fresh-frozen pre-prepared bovine digital extensor tendons (Innovative Medical Device Solutions, Logan, UT), which have properties similar to human hamstrings,[7] were used for the ACL grafts. The tendons were folded in half, forming 8-mm-diameter grafts.

In each bone, two 8-mm bone tunnels were prepared for testing the fixation of the MS (Quick-Start; Innovate Orthopaedics, Huddersfield, England) and a conventional screw (CS) (RCI; Smith & Nephew, London, England). All screws were titanium alloy and measured 9 mm diameter by 25 mm long. The MS had a decreasing thread pitch from the tip to the main parallel body of the screw, whereas the CS had an even thread pitch throughout (Fig 1). In the tibia, 1 tunnel was drilled in a conventional ACL reconstruction position from anteromedial on the tibial metaphysis up to the ACL attachment area in the tibial plateau, and a second tunnel was drilled as a mirror image from the anterolateral aspect up anteriorly to the conventional tunnel aperture (Fig 2). In the femur, 1 tunnel was drilled from the femoral ACL attachment in a proximal-lateral-anterior direction, and one mirror-image tunnel was drilled through the medial condyle from an aperture on the medial side of the intercondylar notch. All bone tunnels were 40 mm long.

A pre-prepared allocation scheme for screw type between the conventional and mirror-image tunnel placements, as well as order of testing, was used to ensure equal numbers of the CS or MS in each tunnel position (e.g., the MS was used in 5 specimens in conventional tibial tunnel positions and in another 5 specimens in mirror-image tibial positions). This was used to control for bone quality variations and eliminate testing bias. The tendon graft was threaded through the bone tunnel and tensed to 20 N, then the chosen screw was inserted into the distal aperture (outside in for the tibia and inside out for the femur).

A servohydraulic materials testing machine (model 8874; Instron, High Wycombe, England) was used for testing the specimens. A purpose-built bone mounting with several degrees of freedom allowed the bone tunnel to be positioned coaxial with the test machine axis to represent the worst-case loading scenario. For

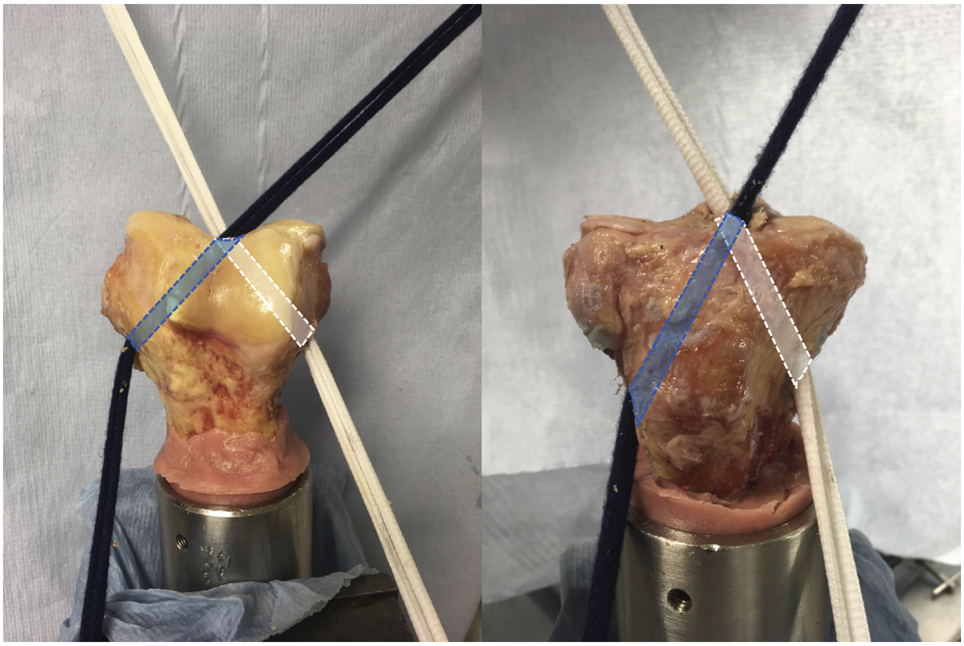

Fig 2. Forty-millimeter conventional (white) and mirror-image (blue) tunnel placements in right-sided femur (left) and right-sided tibia (right).

both tibial and femoral tests, the free loop end of the graft was secured over a shackle bolt clamped in an Instron crosshead fixture (Fig 3). After the application of 20 preconditioning cycles between 0 and 50 N, 1,000 cycles between 70 and 220 N of tension were applied at 1 Hz. This number has been used previously to represent the loads experienced by the ACL during normal walking.[8] The minimum displacement at each load cycle was recorded; previous work has shown that creep elongation of bovine digital extensor tendons alone was negligible compared with slippage from the graft-bone fixation point[5]; therefore, any change in this value was equated to the amount of graft slippage from the bone. After this cyclic loading, a pullout test was applied to the graft at 1,000 mm/min. The test ended when the graft pulled out of the bone, and the maximum force was recorded as the ultimate load to failure.

Insertion Test

A purpose-built rig (Fig 4) was designed to hold a block of polyurethane foam (Sawbones Europe, Malmö, Sweden) with a density of 0.48 g/cm^3 as representative of good-quality, high-density cancellous bone.[9,10] Each block was predrilled with 2 pairs of 8-mm holes as substitute bone tunnels, through which polyester shoelaces were inserted and tensed with 20 N from hanging weights (this substituted as a tensioned soft-tissue graft in the tunnel). The polyurethane block was mounted on a force/torque sensor (Omega 85; ATI Industrial Automation, Apex, NC) to record loading data during the experiment.

Ten consultant surgeons (none of whom were authors of the study) were each asked to insert 1 MS and 1 CS into a pair of tunnels. The order of insertion of the MS and CS for the pair of tunnels was randomized, and the screw design was blinded from the surgeon by holding a graft sizing tube over the screw, guidewire, and screwdriver head. During screw insertion, the axial force and torque were recorded, and from analysis of

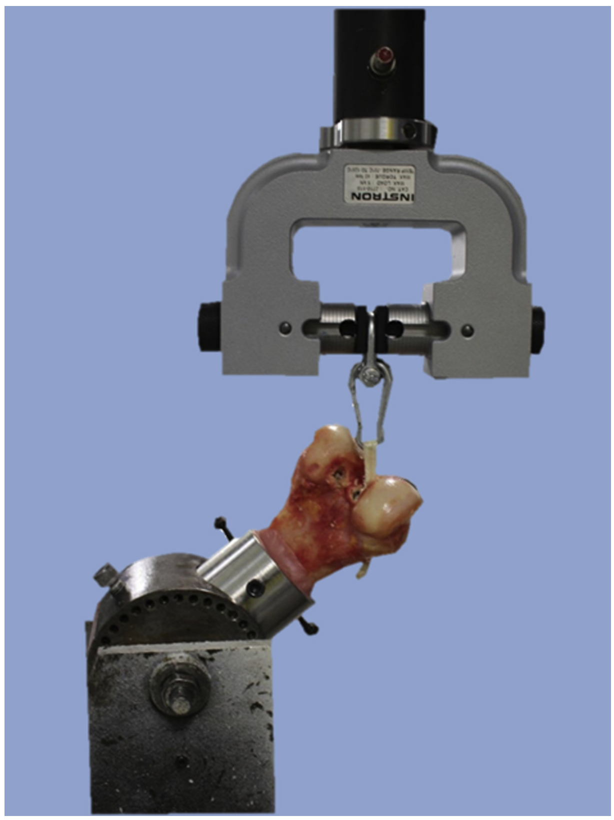

Fig 3. Fixation strength test setup with femur.

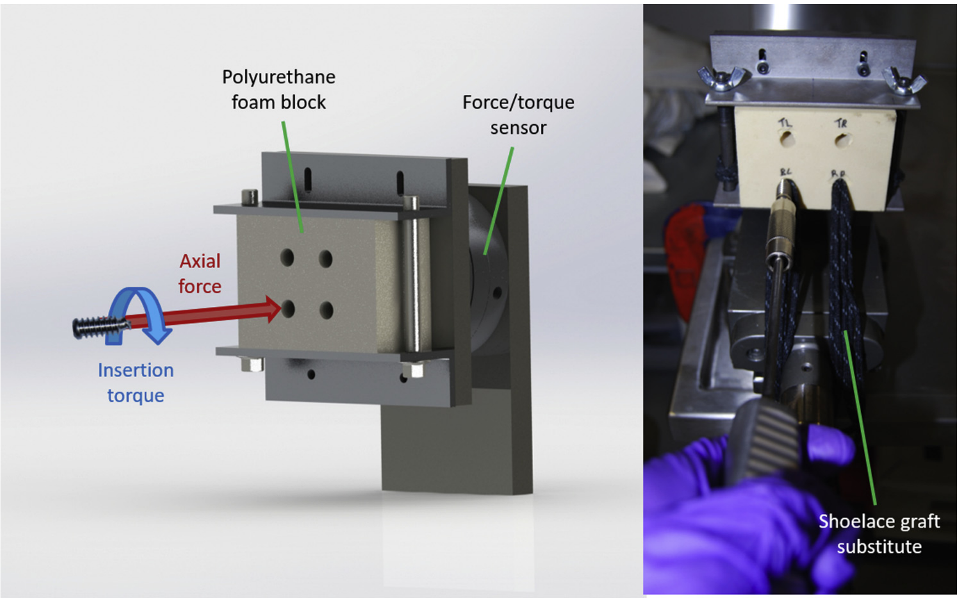

Fig 4. The insertion test rig included a polyurethane foam block mounted in front of a force/torque sensor (left), and a graft sizing tube was held by the tester over the screw (right) so that the surgeon was blinded to the screw design.

pilot data, the screw was deemed to have first engaged with the tunnel when it exceeded a threshold torque of 0.2 Nm. The following data were analyzed: the number of attempted turns until the screw engaged (denoted by the number of force peaks prior to engaging); the initial torque when the screw engaged; the axial force when the screw engaged; the maximum axial force experienced during the insertion; and the average torque during the first 5 turns of the screw after engaging (the term "turn" was defined as an attempted rotation of the screw made by the surgeon, as denoted by a peak in the torque/axial force data, and did not refer to a full revolution of the screw or screwdriver). Each surgeon inserted 4 pairs of MS and CS and was asked after insertion of each pair of MS and CS (while still blinded) which screw felt the easiest to initially insert.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics software (version 23; IBM, Armonk, NY). Sets of data were tested for normality using the Shapiro-Wilk test. For the fixation test, paired-samples *t* tests were performed to compare graft slippage and ultimate load to failure between the MS and CS. On the basis of standard deviations found from a previous study, a power analysis was performed: To achieve a power of 0.80 with an α of .05, 10 specimens were required for paired analysis.[11] Outliers in the data (Appendix Table 1) were accepted because they did not influence the mean difference; moreover, although they elicited an increase in variability, they did not change the conclusion of the paired-samples *t* test. For the insertion test, the peak axial force was assessed using a paired-samples *t* test; the data for insertion axial force, initial insertion torque, and average torque from 5 turns were found not to be distributed normally and thus were assessed using the nonparametric Wilcoxon signed rank test, as was the number of attempted turns before engaging.

Results

Fixation Strength Test

Table 1 shows the graft slippage results for the femur and tibia. No significant difference was found between the CS and MS in graft slippage from the femur ($P = .661$) or tibia ($P = .950$). Table 2 shows the ultimate load to failure for the femur and tibia. No significant difference was found between the CS and MS in ultimate load to failure for the femur ($P = .952$) or tibia ($P = .126$).

Table 1. Mean Femoral and Tibial Graft Slippage After Cyclic Loading for Both Devices

	CS	MS
Femur (n = 10)		
Mean graft slippage, mm	3.1	3.7
Range, mm	1.4-5.7	1.1-14.4
Standard deviation, mm	1.4	4.1
Upper 95% limit, mm	4.1	6.6
P value	.661	
Tibia (n = 10)		
Mean graft slippage, mm	3.4	3.4
Range, mm	1.4-9.2	1.7-7.0
Standard deviation, mm	2.3	1.6
Upper 95% limit, mm	5.0	4.6
P value	.950	

CS, conventional screw; MS, modified-tip screw.

Table 2. Mean Femoral and Tibial Ultimate Strength for Both Devices

	CS	MS
Femur (n = 10)		
Mean pullout load, N	641	644
Range, N	455-904	498-707
Standard deviation, N	133	75
Lower 95% limit, N	546	590
P value	.952	
Tibia (n = 10)		
Mean pullout load, N	569	634
Range, N	433-691	459-862
Standard deviation, N	87	126
Lower 95% limit, N	507	544
P value	.126	

CS, conventional screw; MS, modified-tip screw.

Insertion Test

Table 3 shows the data from the insertion test. One pair of data was not recorded fully during the test and was thus excluded from the analysis, leaving 39 pairs of data from the 10 consultant surgeons.

The CS screw took an average of 4 turns before engaging with the tunnel, whereas the MS engaged on average after 2 turns ($P < .001$, Wilcoxon signed rank test). In terms of axial force applied by the surgeon, the initial force required to engage the screw in the tunnel was larger for the CS than the MS ($P = .001$, Wilcoxon signed rank test). This was also found to be the case for the peak axial force required for the CS versus the MS ($P < .001$, paired-samples *t* test).

The initial insertion torque when the screw engaged was larger for the MS than the CS ($P < .001$, Wilcoxon signed rank test). This was also the case when averaging the first 5 turns after the screw had engaged for the MS versus the CS ($P < .001$, Wilcoxon signed rank test). When the surgeons were asked to provide subjective feedback about which screw felt easiest to initially insert into the tunnel (while blinded to the choice of screw), the MS was chosen in 35 of 39 pairs (90%).

Discussion

The most important finding of this study was that the MS engaged with the bone tunnel more easily than the CS without compromising the fixation strength of soft-tissue grafts to the bone tunnels. This has practical implications for achieving good results in soft-tissue reconstruction because being able to quickly engage and confidently insert a larger-diameter screw can enhance graft fixation.

Graft slippage under cyclic loading and ultimate failure loads have historically been used as biomechanical measures of the performance of graft fixation.[1] Previous studies with similar loading protocols have found comparable failure loads to this study.[8,11,12] Järvinen et al.[12] applied 1,500 cycles between 50 and 200 N at a lower frequency (0.5 Hz) followed by the same pullout rate as this study but using a bioabsorbable screw and found slippage of 3.0 ± 1.5 mm and a failure load of 498 ± 104 N. When applying a significantly lower pullout speed (50 mm/min) to the same design of screw as the CS in this study, Aga et al.[13] found a higher failure load (818 ± 114 N) than our tibial finding (569 ± 87 N). The choice of elongation rate likely explains the difference in failure loads: In this study, a high rate leading to a lower bound of failure load was chosen to better reflect traumatic incidents.[14]

The fixation strength test determined no difference between the MS and CS in terms of graft slippage in the tibia or femur under cyclic loading and ultimate strength of fixation. The design of the MS was intended to only improve the initial engagement with the graft and tunnel opening, but further down the screw, the MS had a similar thread profile to the CS. No difference in fixation between the MS and CS was therefore found because the same-diameter screws provided the same amount of compression of the graft between the screw bodies and the bone tunnel walls. However, in clinical practice, easier screw insertion will lead to the surgeon choosing a larger screw diameter, which has the advantage of strong graft fixation. The length of screw (25 mm) was constant for both screws to eliminate any

Table 3. Data From Insertion Test (n = 39)

	CS	MS
No. of attempted turns before engaging	4 ± 4**	2 ± 1
Initial axial force applied when engaged, N	99 ± 43*	78 ± 38
Peak axial force applied, N	126 ± 47**	96 ± 34
Initial insertion torque when engaged, Nm	0.2 ± 0.1**	0.3 ± 0.1
Average torque from first 5 turns when engaged, Nm	0.3 ± 0.1**	0.8 ± 0.2
Which screw felt easiest to initially insert (blinded feedback by surgeon)?	4	35

NOTE. Data are presented as mean ± standard deviation or number.
CS, conventional screw; MS, modified-tip screw.
*Significant difference between CS and MS ($P = .001$).
**Significance at $P < .001$.

potential effect; a previous study found a longer screw tended to provide more consistent fixation but was not statistically significantly stronger than a shorter screw.[15]

Many studies have used a torque-meter attached to the screwdriver to find the insertion torque of screws in either polyurethane bone substitutes[16–19] or animal or human cadaveric bones.[12,20–23] The testing rig used in this study had a force/torque sensor mounted behind the polyurethane block that measured not only the insertion torque but also the axial force applied by the surgeon. This important factor, which was not investigated in the torque-meter studies, is an objective measure of how much work is required by the surgeon to ensure the screw engages with the tunnel and graft.

The insertion test supported the hypothesis that the MS would require fewer turns to initially engage the screw into the graft tunnel and less axial force applied by the surgeon through the screwdriver than the CS. The data reflect the design of the modified tip, which was intended to give greater purchase and grip the tunnel easily. This finding was further supported by the subjective feedback from the surgeons that in 90% of the cases, the MS felt as if it engaged more easily than the CS even though the choice of screw was blinded to them. Other designs of fixation implants not limited to soft-tissue reconstruction are actively attempting to reduce the amount of insertion force, or “push in,” to lower the fracture risk and soft-tissue graft disruption.[24]

Once the screw engaged with the tunnel, the MS showed a higher insertion torque than the CS for both initial torque and the average of the first 5 turns. This finding implies that the MS grips more quickly with the bone tunnel than the CS. Studies have suggested that the peak insertion torque of an interference screw could be an indicator of the strength of fixation.[20,21,25] For example, Brand et al.[21] found a positive correlation between the maximum insertion torque and fixation failure load. However, from the fixation strength test, it was shown that there was no effect on graft fixation performance between the MS and CS. Future studies should be conducted to conclude whether the MS provides any advantages regarding long-term outcomes, reduction in bone tunnel divergence, or fixation of bone−patellar tendon−bone grafts, wherein positioning of the screw with the bone block is critical.[26]

Limitations

This study showed limitations regarding its application to clinical practice. For the fixation strength test, pre-prepared bovine tendons were used instead of human hamstrings to ensure adequate graft length for the paired tests and to control the diameter and quality of the grafts throughout. However, bovine tendons have similar properties to human hamstring tendons and therefore were considered a good substitute.[7] The pullout and cyclic data collected from the cadaveric specimens only related to the immediate postsurgical state, and important longer-term effects such as graft-tunnel healing and integration could not be investigated.[22] The hypothesis would be that no difference between the screw designs of the same diameter would be found longer term because the graft compression against the tunnel walls should be similar. The tunnels were not made in normal ACL reconstruction positions to ensure that the paired tunnels were controlled at 40 mm in length and avoided tunnel convergence. Because the loads were all applied coaxial to the tunnel longitudinal axis and were randomly allocated, this should not have biased the conclusions of the study.

Although the rigid polyurethane foam blocks used in the insertion test have been used in many previous studies as a bone substitute,[17,18,27] they do not accurately model the structure or transition from cortical to cancellous bone. The hard-density blocks were considered by the 10 consultant surgeons as an accurate representation of the feeling of screw−cortical bone interaction and, per the ASTM International standard for testing orthopaedic devices and instruments, a consistent and uniform medium with which to test the comparative properties of the 2 screws.[28] Polyester shoelaces with hanging weights were used as a reproducible and controllable surrogate because the surgeons believed it provided an appropriate tactile feel of a tendon graft providing resistance to inserting the screws in terms of filled space within the bone tunnel, as well as the opposing force associated with tensioning a graft by hand. However, although clear statistically significant differences were found between the screws, care must be taken when extrapolating the values of axial load and insertion torque to a clinical setting.

Conclusions

The MS was found to be easier to engage with the bone tunnel and initially insert than the CS while still achieving similar immediate postsurgical fixation strength.

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Appendix Table 1. Graft Slippage and Pullout Load

	Conventional Interference Screw		Modified-Tip Screw	
No.	Graft Slippage, mm	Pullout Load, N	Graft Slippage, mm	Pullout Load, N
FEM1	2.5	490	2.1	651
FEM2	4.2	455	6.2	661
FEM3	2.1	583	4.0	515
FEM4	4.4	670	1.1	707
FEM5	5.7	559	1.4	692
FEM6	1.4	749	1.8	707
FEM7	2.0	727	2.1	687
FEM8	1.5	663	1.4	663
FEM9	3.1	904	14.4*	498
FEM10	4.1	608	2.7	661
TIB1	5.0	536	4.9	519
TIB2	3.1	571	3.0	657
TIB3	2.2	680	4.3	602
TIB4	2.1	555	2.2	459
TIB5	9.2*	441	2.6	762
TIB6	3.1	691	3.7	862
TIB7	2.2	620	1.9	691
TIB8	1.5	609	1.7	707
TIB9	3.8	433	7.0	510
TIB10	1.3	552	2.9	569

FEM, femur; TIB, tibia.

*In both cases, it was visually observed that the screw had not engaged fully with the graft in the tunnel and a large amount of slippage occurred under the cyclic loads. However, these outliers were still accepted in the analysis because they did not influence the conclusion of the paired-samples *t* test.