Evaluation of 3 Fixation Devices for Tibial-Sided Anterior Cruciate Ligament Graft Backup Fixation

Christopher A. Verioti, DO, Matthew C. Sardelli, MD, and Tony Nguyen, MD

Abstract

We conducted a study to biomechanically evaluate 3 methods of tibial-sided fixation for anterior cruciate ligament reconstruction: fully threaded interference screw only, interference screw backed with 4.75-mm SwiveLock anchor, and fully threaded bio-interference screw backed with 4.5-mm bicortical screw (all Arthrex).

Thirty skeletally mature porcine tibiae were used. The first group was prepared by graft fixation within the tibial tunnel using only an interference screw. The second and third groups included an interference screw with 2 types of secondary fixation: 4.5-mm bicortical post and SwiveLock anchor. Mechanical testing consisted of 500 cycles between 50 and 250 N at 1 Hz, followed by a pull to failure conducted at 20 mm per minute.

Ultimate load-to-failure testing demonstrated the largest mean (SD) load tolerated in the post/washer group, 1148 (186) N, versus the SwiveLock group, 1007 (176) N, and the screw-only group, 778 (139) N. There was no statistical difference between the 2 backup fixation groups.

Use of a SwiveLock anchor as backup fixation at the tibial side in soft-tissue anterior cruciate ligament reconstruction is a safe, effective alternative to a bicortical post and provides statistically equivalent pullout strength with unlikely requirement for future hardware removal.

Restoration of stability with return to activity is generally expected after anterior cruciate ligament (ACL) reconstruction; long-term success rates range from 75% to 95%.[1] However, graft failure occurs most frequently with soft-tissue grafts fixated only with interference screws.[2,3] Fixation failure also occurs more frequently at the tibial site.[2] This failure has been attributed to extensive graft slippage in cases of soft-tissue fixation with interference screws.[2] Interference screw fixation alone, with a double-looped hamstring tendon graft, fails at 350 N in young human tibiae.[4,5] However, failure is limited with use of a bone–tendon–bone graft or with backup fixation, particularly at the tibial site.[3] The superiority of bicortical fixation has also been proven.[5-7]

In addition, as shown in a goat model, ACL graft fixation is a major cause of failure in the immediate postoperative period, before biological incorporation of the graft.[8] Fixation techniques for soft-tissue grafts must withstand stresses during the healing period (grafts may take up to 12 weeks to incorporate).[9] Failures may result from forces exerted on the graft—forces that may be as high as 450 to 700 N during daily activities.[10,11] Within the tibial tunnel, various fixation devices are used, including interference screws, staples, pins, buttons, and interference screw/sheath constructs.[12,13] Primary fixation is commonly achieved with interference screws because of their ease of insertion and greater stiffness. However, fixation of the soft-tissue graft is influenced by several variables, including bone density, insertion torque, thread geometry, and interference screw material.[14-16] Many of these variables, which are a source of inconsistency and concern during the immediate postoperative period, have led surgeons to seek alternative methods of backup fixation at the tibial site. Nevertheless, good clinical and subjective results have been found after ACL reconstruction with a 4-stranded semitendinosus tendon at 10-year follow-up.[17]

An anchor used in rotator cuff repair is the SwiveLock system (Arthrex). Major advantages of this system include ease and speed of insertion, good strength, and reduced need for later hardware removal.

We conducted a study to biomechanically evaluate 3 methods of tibial-sided fixation for ACL reconstruction: fully threaded interference screw only, interference screw backed with 4.75-mm SwiveLock anchor, and fully threaded bio-interference screw backed with 4.5-mm bicortical screw. We hypothesized that a fully threaded bio-interference screw backed with a 4.75-mm SwiveLock anchor would provide mechanical strength no different from that provided by backup fixation with a bicortical post at the tibial site. We further hypothesized that SwiveLock backup fixation would provide more strength than fixation with bio-interference screw alone.

Authors' Disclosure Statement: The authors report no actual or potential conflict of interest in relation to this article.

Materials and Methods

The design of this study was adapted from one used by Walsh and colleagues,[3] who compared 3 fixation methods: retrograde interference screw, suture button, and combined fixation. Tibiae inspected before selection showed no signs of injury or abnormality. Bovine extensor tendons, which lacked any defects along their entire length, were stored in saline 0.9% solution. Both the tibiae and the extensor tendons were stored at –20°C before completion of the tibial-sided ACL reconstruction. Thirty fresh-frozen, skeletally mature porcine proximal tibiae were selected and thawed at 4°C before preparation. Specimens were prepared by potting the diaphysis in fiberglass resin, and a tunnel 9 mm in diameter was drilled through the anteromedial aspect of the tibia.

For consistency, one author (CAV) prepared all 30 specimens. Both tails of all 30 bovine extensor tendons were whip-stitched with No. 2 FiberLoop (Arthrex) 9 mm in diameter. Grafts and tibiae were randomly divided into 3 sample groups. The first group was prepared by antegrade graft fixation within the tibial tunnel using a fully threaded 9×28-mm BioComposite interference screw (Arthrex). The second and third groups used the same primary fixation within the tibial tunnel along with 2 types of secondary fixation. These backup fixation groups included a 4.5-mm titanium bicortical post (Arthrex) and a 4.75-mm BioComposite SwiveLock C anchor (Arthrex) (**Figure 1**). The FiberLoop at the ends of the distal graft tails for backup groups were fixated 1 cm distal to the tibial tunnel and tapped before insertion of backup devices (**Figures 2A, 2B**). Insertion was completed after 4.5-mm bicortical and 4.75-mm unicortical drilling and tapping of the anteromedial cortices for the titanium posts and SwiveLocks, respectively. The free ends of the whip-stitched No. 2 FiberLoop were tied to the proximal end of the titanium post with a single surgical knot followed by 5 square knots.[3] The free ends of the No. 2 FiberLoop were inserted into the eyelet of the 4.75-mm SwiveLock and 1 cm directly inferior to the tibial tunnel. Interference fit of FiberLoop with SwiveLock was achieved within the corticocancellous bone of the tibiae. All samples retained a 30-mm tendon loop superior to the tibial plateau to simulate intra-articular ACL length. Specimens were then stored at –20°C and thawed at 4°C before biomechanical testing.

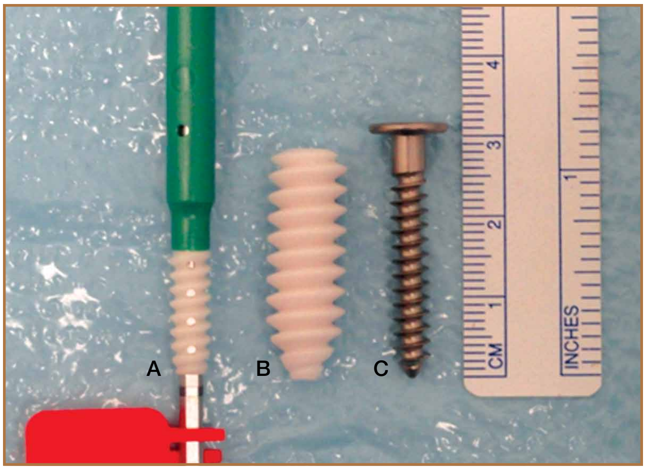

Figure 1. (A) 4.75-mm SwiveLock, (B) 9×28-mm BioComposite interference screw, and (C) 4.5×30-mm titanium bicortical post (all Arthrex).

Each of the 30 tibiae was tested once. Each testing group consisted of 10 porcine tibiae. The tendons were kept moist during the entire testing procedure by spraying them thoroughly with saline 0.9% solution. Mechanical testing was performed with an Instron 8871 system with a 5-kN load cell secured to the crosshead. A fixed-angle aperture, attached to the testing surface, was adjusted so that the tendon would be pulled in line with the tibial tunnel. A hook fixture suspended from clevis and dowel was used to secure the tendon to the crosshead (**Figure 3**). A small preload of 5 N manually applied to each sample was followed by a precycling regimen of 10 cycles between 10 N and 50 N at 1 Hz. Precycling was performed to remove slack from the system. Mechanical testing consisted of 500 cycles between 50 N and 250 N at 1 Hz followed by pull to failure at 20 mm per minute. Load and displacement data were recorded at 500 Hz.

An a priori power analysis was not performed because 6 specimens per group in the study from which the testing protocol was adapted demonstrated sufficient power among 3 testing categories.[3] In addition, other studies have demonstrated similar testing protocols using 10 specimens per testing group.[7,12,13,18] The data for each sample were analyzed with OriginPro 8.0 software (OriginLab). Ultimate load, yield load, stiffness, and cyclic displacement of the 3 sample groups were compared with 1-way analysis of variance ($\alpha = 0.05$). Holm-Sidak tests were used for post hoc analysis.[19] $P < .05$ was statistically significant.

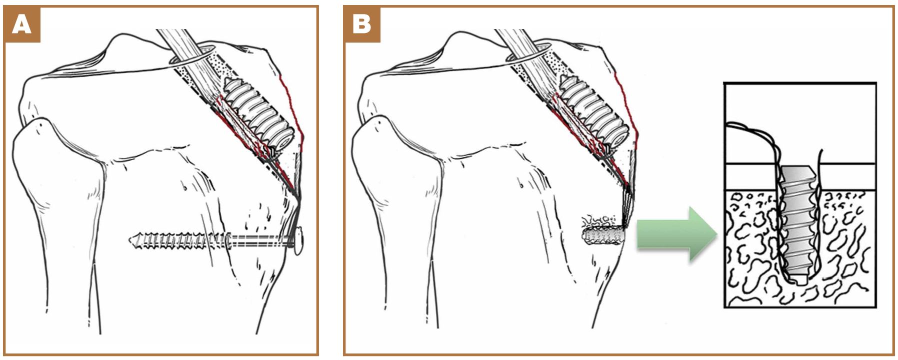

Figure 2. (A) Schematic representation of backup fixation with titanium bicortical post. Free end of whip-stitched No. 2 FiberLoop (Arthrex) is tied to proximal end of post and inserted bicortically. (B) Schematic representation of backup fixation with 4.75-mm SwiveLock. Free end of No. 2 FiberLoop is inserted into eyelet of SwiveLock and 1 cm distal to tibial tunnel. Interference fit of FiberLoop with SwiveLock is achieved within corticocancellous bone.

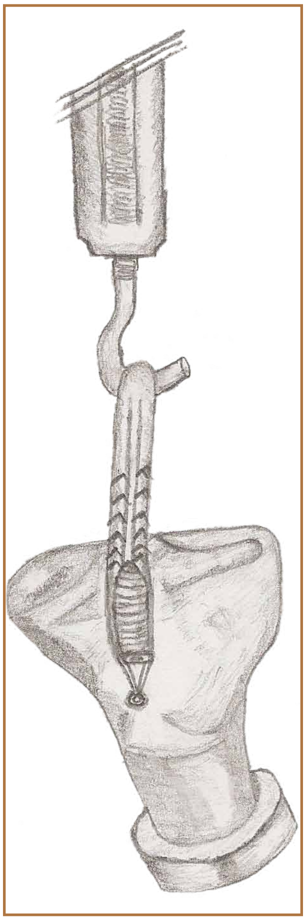

Figure 3. Schematic drawing of porcine tibia with SwivеLock backup fixation shows pullout directly in line with long axis of tibia.

Results

None of the 30 specimens failed during preloading. Modes of failure were consistent among groups. All 10 specimens in the interference-screw-only group failed by graft slippage past the screw in the tibial tunnel. Nineteen of the 20 specimens in the backup-fixation groups failed by graft slippage past the screw and suture cutout through the distal graft tail. In the bicortical-post backup group, 1 failure was attributed to tendon tearing proximal to whip-stitching. There were no instances of hardware breakage or failure of either titanium screw or SwiveLock anchor.

Mean (SD) cyclic displacement was higher in the interference-screw-only group, 3.5 (2.2) mm, than in the SwiveLock backup group, 2.6 (0.5) mm, and the bicortical-post backup group, 2.1 (0.6) mm; no statistical significance was demonstrated between any 2 of these groups alone (P = .12) (**Figure 4**).

Mean (SD) pullout stiffness was higher in the bicortical-post backup group, 192 (48) N/mm, than in the SwiveLock backup group, 164 (53) N/mm, and the screw-only group, 163 (64) N/mm (P = .42) (**Figure 5**). Mean (SD) initial load at 5 mm of displacement was higher in the bicortical-post backup group, 482 (156) N, and the SwiveLock backup group, 423 (94) N, than in the screw-only group, 381 (169) N (P = .30).

Mean (SD) yield load was higher in the bicortical-post backup group, 829 (253) N, than in the SwiveLock backup

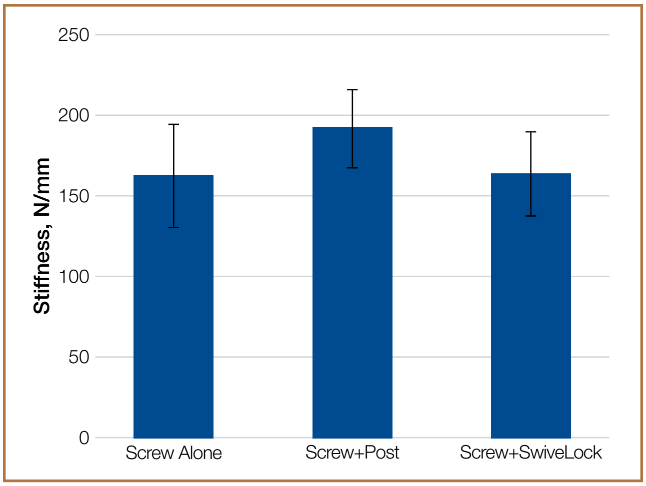

Figure 5. Mean (SD) pullout stiffness was higher in bicortical-post group, 192 (48) N/mm, than in SwiveLock group, 164 (53) N/mm, and interference-screw-only group, 163 (64) N/mm (P = .42). No statistical significance was demonstrated between any 2 groups alone.

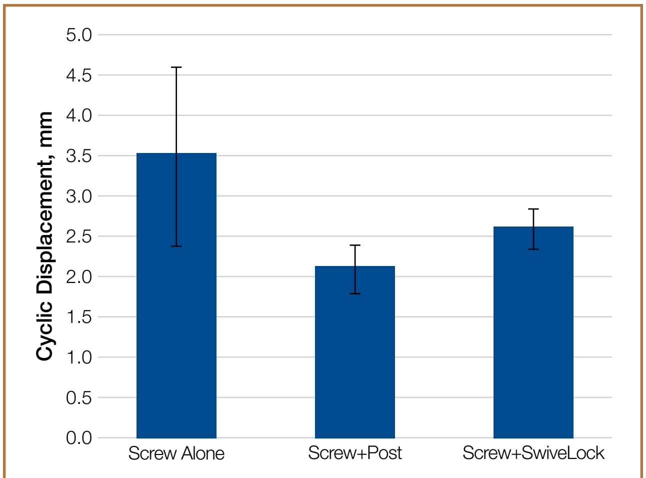

Figure 4. Mean (SD) cyclic displacement was higher in interference-screw-only group, 3.5 (2.2) mm, than in SwiveLock backup group, 2.6 (0.5) mm, and bicortical-post backup group, 2.1 (0.6) mm (P = .12). No statistical significance was demonstrated between any 2 groups alone.

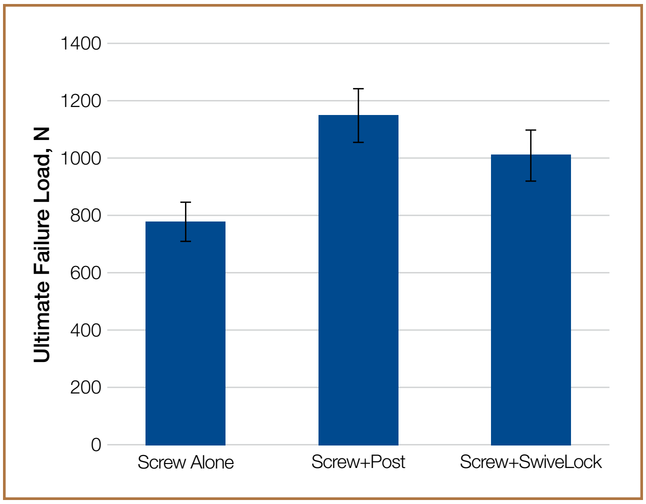

Figure 6. Mean (SD) ultimate failure load was higher in bicortical-post group, 1148 (186) N, than in SwiveLock group, 1007 (176) N, and interference-screw-only group, 778 (139) N. Statistical significance was demonstrated between screw-only and bicortical-post groups (P < .001) and between screw-only and SwiveLock groups (P = .005). However, no statistical difference was demonstrated between bicortical-post and SwiveLock groups (P = .1).

group, 642 (172) N, and the interference-screw-only group, 496 (133) N ($P = .003$). Statistical significance was demonstrated between the screw-only and bicortical-post groups ($P = .002$) and between the screw-only and SwiveLock groups ($P = .048$). There was no statistical difference between the bicortical-post and SwiveLock groups ($P = .07$).

Mean (SD) ultimate load to failure was higher in the bicortical-post backup group, 1148 (186) N, than in the SwiveLock backup group, 1007 (176) N, and the interference-screw-only group, 778 (139) N (**Figure 6**). The difference was statistically significant, whereby the screw-only group failed at a lower load compared with the bicortical-post group ($P < .001$) and the SwiveLock group ($P = .005$). The 2 backup groups were not statistically different ($P = .1$).

Discussion

We investigated whether a fully threaded bio-interference screw backed with a 4.75-mm SwiveLock anchor would provide mechanically equivalent pullout strength within the tibial tunnel during ACL reconstruction with soft-tissue allografts in comparison either with a fully threaded bio-interference screw backed with a bicortical post or with a fully threaded bio-interference screw without backup fixation. The results of the study support this hypothesis. With SwiveLock used for backup fixation, there was no significant difference in stiffness or cyclic load displacement between the screw-only, SwiveLock, and bicortical-post groups. However, adding backup fixation could particularly help improve fixation consistency. Specifically, although after only 500 cycles there was no statistically significant difference in cyclic displacement, continued cycling may be clinically relevant if graft slippage exceeded limits to allow for healing within the tibial tunnel. Conversely, a significantly larger difference was found between the SwiveLock, bicortical-post, and screw-only groups in yield load and ultimate load to failure. However, there was no significant difference between the SwiveLock and bicortical-post groups.

In this study, interference screw with SwiveLock backup demonstrated a mean (SD) ultimate load to failure of 1007 (176) N, comparable to that found by Walsh and colleagues[3] for retrograde bio-interference screw with suture button, 1027 (157.11) N. In a study comparing quadrupled hamstring tibial graft fixation, Intrafix (DePuy Mitek) and an 8×25-mm Bioscrew (Linvatec) demonstrated mean (SD) single-cycle yield loads of 1332 (304) N and 612 (176) N, respectively.[13] These results are similar to the ultimate yield loads in the present study: bicortical-post group, 1148 (186) N; SwiveLock group, 1007 (176) N; screw-only group, 778 (139) N. Differences may be attributed to hamstring tendons used in a quadrupled manner in the aforementioned study.[12,13] Last, mean (SD) ultimate load to failure in a study that used only a retrograde bio-interference screw (9×20 mm) was 679.00 (109.44) N,[3] similar to the 778 (139) N found for interference-screw-only in the present study. The difference is likely attributable to the longer screw (9×28 mm) in our study. Using SwiveLock C in cortical bone, Barber and colleagues[18] found mean (SD) loads to failure up to 711.9 (89.1) N.

Clinically, it has been shown that a statistically significant increase in anterior laxity occurred between 4 months and 2 years in 10.7% of patients who underwent hamstring ACL reconstruction.[20] The knees were clinically categorized as unstable or severely abnormal. The authors concluded that the clinical outcome was more likely influenced by the methods used to fix the free ends of the graft, specifically with 2 staples or a washer. To simulate early postoperative rehabilitation in the present study, cyclic loading of the graft was performed. Ultimate load to failure was then determined in order to evaluate catastrophic failure strength of the backup fixation devices in comparison with the interference-screw-only group without supplementary fixation.

It has been shown in autologous hamstring ACL reconstruction that a centrally placed polyethylene screw with sheath (Intrafix) performed as well as a standard, eccentrically placed metal interference screw with staple.[10] It is therefore logical that backup fixation with use of a similar device (eg, SwiveLock, bicortical post) is necessary to ensure comparable clinical outcomes in relation to a screw/sheath device that has been shown to endure the highest yield loads.[2,9,12,13,21-23] Potential benefits of using SwiveLock anchors for backup fixation include a statistically significant increased mean (SD) ultimate yield load of 229 (176) N over interference screw only. These results are similar to those in comparable studies: 218.3 (59.7) N[24] and 165 (24.15) N[25] in healthy bone with a reported bone mineral density (BMD) of 1.39 g/cm^2, similar to that of skeletally mature porcine tibia (1.220-1.675 g/cm^2).[3] In addition, ease of insertion of this device over a bicortical post was demonstrated. The titanium post required bicortical drilling as well as measurement with a depth gauge to ensure adequate screw length. This process appeared to require more time during specimen preparation and theoretically could prove to be more dangerous clinically.[7] However, caution in using a SwiveLock anchor in osteoporotic bone is advised because of reduced pullout strength.[26] In this case, bicortical-post backup fixation may be more suitable. Moreover, although not demonstrated in this study, hardware prominence and irritation with a post may cause postoperative morbidity necessitating future removal.[20] Hardware removal was the most common reason for additional surgery using hamstring tendons as graft.[20] A second surgery for hardware removal was required in 21% of these patients.[20] This is unlikely to occur with a SwiveLock, as the anchor is buried within cortical bone.

Limitations

Regarding use of nonhuman tissues in a biomechanical model, porcine tibiae and bovine extensor tendons were used because of availability, consistency among specimens, and cost-effectiveness. However, bovine extensor tendons have been shown to exhibit stiffness and viscoelastic properties similar to those of a human hamstring graft.[27] In addition, the BMD of the porcine tibiae used in this study was not tested because of time involved and cost-efficiency. However, it has been shown that average BMD of porcine tibiae, 1.220-1.675 g/cm^2, is similar to that in a young athletic population, 1.24-1.62 g/cm^2.[3,28-31] We therefore assumed similarity to a young athletic population and uniformity of BMD of the porcine tibiae used in this study.

In addition, the biomechanical testing protocol did not simulate physiologic loading within the tibial tunnel. Moreover, the testing protocol used loads of only 250 N during cyclic testing for 500 cycles. This simulates only the early rehabilitation period and not the healing period, which may last up to 12 weeks.[9] In addition, as previously mentioned, forces on the graft may be as high as 450 to 700 N.[11,32] Pullout testing in line with the long axis of the tibia was performed in order to compare mechanical testing results with those of similar studies.[3,12,13] Last, the *P* of .07 for the comparison of ultimate load to failure between the 2 backup fixation groups suggests that this study may have been underpowered.

Conclusion

This study demonstrated an effective, alternative, and equivalent backup fixation device that can help prevent graft slippage within the tibial tunnel during soft-tissue ACL reconstruction. Potential benefits of using SwiveLock anchors for backup fixation include a significantly increased ultimate yield load (229 N) when supplementing an interference screw, ease of insertion compared with a bicortical post, and the improbable need for future hardware removal. We support using SwiveLock for supplementary fixation at the tibial tunnel site when using soft-tissue grafts in ACL reconstruction.

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Acknowledgments: The authors thank Josh Karnes and John Konicek for assistance in use of their laboratory and implants.

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Am J Orthop. 2015;44(7):E225-E230.

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