Femoral Cortical Suspension Devices for Soft Tissue Anterior Cruciate Ligament Reconstruction

A Comparative Biomechanical Study

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Background: Optimization of anterior cruciate ligament (ACL) fixation is desired to improve graft healing. New soft tissue cortical suspension devices for femoral tunnel fixation should be biomechanically evaluated.

Hypothesis: All femoral fixation devices would prevent a clinically significant amount of displacement and support loads significantly larger than in situ forces experienced by the ACL during early rehabilitation.

Study Design: Controlled laboratory study.

Methods: Four cortical soft tissue ACL graft suspension devices were tested under cyclic and pull-to-failure loading conditions in both an isolated device-only setup and as a complete bone-device-tendon construct in porcine femurs using a tensile testing machine.

Results: There were significant differences in the ultimate failure loads among the devices. The highest ultimate failure loads when tested as a construct were observed for the XO Button (1748 N), followed by the Endobutton CL (1456 N), ToggleLoc with ZipLoop (1334 N), and TightRope RT (859 N). Cyclic displacement after 1000 cycles during isolated device testing was less than 1 mm for all devices. Cyclic displacements after 1000 cycles in the porcine construct were 1.88 mm, 2.74 mm, 3.34 mm, and 1.82 mm for the Endobutton, TightRope, ToggleLoc, and XO Button, respectively; all were significantly different from each other except when the Endobutton was compared with the XO Button. The ToggleLoc exceeded the 3.0-mm displacement threshold defined as a clinical failure. The most displacement occurred during the first cycle, especially for the adjustable-length loop devices. Stiffness reapproximated the native ACL stiffness for all constructs.

Conclusion: The Endobutton, TightRope, and XO Button have the necessary biomechanical properties with regard to ultimate failure strength, displacement, and stiffness for initial fixation of soft tissue grafts in the femoral tunnel for ACL reconstruction. The ToggleLoc had sufficient ultimate failure strength but crossed our 3.0-mm clinical failure threshold for cyclic displacement. Although this study was not designed to compare fixed and adjustable-length loop devices, it was noted that both fixed-loop devices allowed less cyclic displacement and initial displacement.

Clinical Relevance: Adjustable-length loop devices may need to be retensioned after cycling the knee and fixing the tibial side to account for the increased initial displacement seen with these devices.

Keywords: ACL reconstruction; femoral fixation; cortical buttons; biomechanics; hamstring graft; soft tissue graft; cortical suspension; adjustable-length loop cortical button; fixed-loop cortical button

Anterior cruciate ligament (ACL) grafts require rigid fixation without slippage in the face of early rehabilitation to achieve biological incorporation. Loss of fixation and graft loosening are reported to be some of the common reasons for failure and revision ACL surgery in the early postoperative period. It has been reported that soft tissue ACL grafts fixed with interference screws have suboptimal biomechanical properties, including decreased ultimate failure loads. Interference screw fixation has also been reported to allow graft slipping, thus lessening graft tension. Because of the reported suboptimal fixation of these devices, newer devices have been developed for femoral fixation of soft tissue grafts, including cortical suspension devices, suture suspension techniques, transfixation devices, and cross screw devices.
There is no agreement on the optimal fixation techniques; therefore, some recent studies have aimed to characterize the biomechanical properties of interference screw fixation, cortical suspension, and transfixation techniques. These studies reported that the cortical suspension devices tested exhibited satisfactory results in terms of slippage and ultimate failure; however, only 1 fixed-loop device was tested in each study. The recent introduction of newer ACL femoral cortical suspension graft fixation devices, including the release of adjustable-length loop technology, for cruciate reconstruction warrants an examination of their biomechanical properties.

The purpose of this study was to compare the fixation strength of 4 ACL graft femoral soft tissue cortical suspension fixation devices in response to cyclic and pull-to-failure loading. We hypothesized that all devices would prevent a clinically significant amount of displacement and support loads significantly larger than in situ forces experienced by the ACL during early rehabilitation.

MATERIALS AND METHODS

Four cortical suspension devices were biomechanically tested using cyclic and pull-to-failure loading. The devices tested in this study were the Endobutton CL (Smith & Nephew Inc, Andover, Massachusetts), the TightRope RT (Arthrex Inc, Naples, Florida), the ToggleLoc with ZipLoop (Biomet Inc, Warsaw, Indiana), and the XO Button (ConMed Linvatec Inc, Largo, Florida) (Figure 1). The Endobutton CL and XO Button are fixed-length loop devices, whereas the TightRope and ToggleLoc have adjustable-length loops that are tightened intraoperatively. Each device was tested in 2 separate states. First, the devices themselves were isolated and tested for their biomechanical properties without being inserted into the ACL porcine model. Additionally, each device was tested in an in vitro setting where they were inserted into an ACL tunnel in a porcine femur and attached to a graft.

Isolated Device Testing

The biomechanical properties of the devices found during construct testing are influenced by the properties of the bone and tendon. To isolate the properties of the fixation devices, absent the bone and tendon, the devices were first tested using a custom apparatus with a steel plate serving as the cortex and force applied to the loop with a steel rod. The cortical buttons were inserted through a tunnel in the steel plate, with the diameter of the tunnel corresponding to the manufacturer's recommendation for the femoral cortical diameter. Devices were isolated to determine whether differences noted in construct testing were attributable to variability of the construct or the devices themselves. Tunnel diameters were 4.0 mm for the TightRope RT and Endobutton CL, 4.5 mm for the ToggleLoc with ZipLoop, and 5.0 mm for the XO Button. The adjustable-length device loops were tightened around a 10.7-mm diameter steel rod (the inner diameter of the Endobutton loop) to ensure consistent loop diameters for each device. The loops were then placed around a 4.5-mm diameter steel rod, corresponding to half the diameter of the 9-mm diameter devices.

Figure 1. The 4 cortical suspension devices tested. From left to right: Endobutton CL, TightRope RT, ToggleLoc with ZipLoop, and XO Button. The figure demonstrates the adjustable-length loops with tightening sutures of the ToggleLoc and the TightRope. The XO Button and Endobutton have fixed-length loops.
doubled-over tendon graft (Figure 2A). The rod was then fixed to the dynamic tensile testing machine actuator, and the steel plate was fixed to the base plate, with the force vector perpendicular to the button. Five devices from each group were tested in this fashion.

**Specimen Testing**

Testing was performed in 40 fresh-frozen porcine cadaver femora (Innovative Medical Device Solutions, Logan, Utah) with 10 devices tested per group. Porcine femora were used because they have been reported to have bone mineral density and morphological and biomechanical characteristics similar to those of the young adult human knee. Soft tissues were removed and the femurs were cut 10 cm proximal to the joint line. Screws were drilled into the femur circumferentially before potting to ensure rigid fixation. The femurs were then potted in line with the femoral axis in a custom-made cylindrical fitting with polymethylmethacrylate (PMMA, Fricke International Inc, Streamwood, Illinois), 2 cm proximal to the predetermined exit of the femoral tunnel.

Bovine flexor tendons (Innovative Medical Device Solutions, Logan, Utah) were used as the grafts, similar to previous reports of their use for similar testing. The grafts were sized to 9 mm in diameter with a graft sizing block. If diameters exceeded 9 mm, the graft was sharply trimmed to 9 mm to ensure consistency between specimens. Tendons were cut to be 180 mm in length and doubled over. Thirty millimeters of each of the free ends were then whipstitched together using polyester/polyethylene suture (FiberWire, Arthrex Inc, Naples, Florida) after looping the graft around the cortical suspension device to be tested. All specimens were kept moist with physiological saline solution during specimen preparation, fixation procedures, and biomechanical testing.

**Device Insertion Techniques**

Devices were inserted according to the manufacturers’ specifications. An industry representative for each device was present during pilot testing to validate the manufacturer’s recommended installation technique for the individual fixation devices. Representatives were not allowed to physically interact with the testing, nor were they allowed to view the data.

Femoral tunnels were placed in the center of the porcine ACL footprint. The exit point was standardized 6 cm proximal to the distal condyles on the anterolateral femoral cortex. Manufacturer-specific guide pins and drills for each individual fixation system were then drilled antegrade with an ACL guide system to ensure uniformity of the exit point on the femur. The tunnel was placed in the porcine ACL footprint on the femur. A caliper measured the resulting total tunnel length. A 9-mm diameter reamer was then drilled to a depth that was 8 mm less than the total length to ensure an 8-mm bone bridge at the lateral femoral cortex. A depth gauge was used to confirm bone bridge depth. Because the shape of the condyles prevented the mechanical grips from securing the graft at 60 mm away from the devices, the distal aspects of the condyles were removed with a saw, distal to the 9-mm tunnel and exiting at the footprint of the original ACL. This technique

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**Figure 2.** (A) Device-only testing setup. The device was passed through a 5-mm-thick steel plate, and the loop was secured around a 4.5-mm diameter steel rod. The rod was secured to the actuator. (B) Construct testing setup. A custom adjustable jig was created to adjust the femoral shaft position to ensure worst-case scenario testing. The graft was clamped 30 mm from the exit of the tunnel, and the condyles were removed to facilitate testing.
had no effect on the structural integrity of the femurs because this portion of the femur was not under load during the testing and it allowed the grips to be placed consistently to secure the tendons at 60 mm of length away from the devices (Figure 2B). The testing order was randomized using a random numbers table. All device passing sutures were removed before testing.

Endobutton CL

The 4-mm cortex drill was reamed over the drill pin, and a depth gauge was used to measure the tunnel distance. A 15-mm loop implant was used to ensure that the button could be flipped properly. The graft was inserted into the femoral tunnel using an eyelet pin loaded with the lead suture. The Endobutton CL device was pulled through the femoral tunnel by applying tension to the lead suture and then flipped after being pulled through the cortex at the proximal end of the tunnel by applying tension to the trailing suture. The device was fixed with the button perpendicular to the outer femoral cortex while distal traction was applied to the graft.

TightRope RT

A 4-mm spade tip guide pin (Arthrex) was drilled through the cortex and the tunnel reamed over it. The passing suture and tensioning sutures were passed through the femoral tunnel using the guide pin. The TightRope RT was passed through the femoral tunnel using the passing suture and flipped on the lateral cortex. The graft was pulled into and seated fully in the tunnel by slowly pulling the tensioning sutures proximally, one at a time, in 2-cm increments.

ToggleLoc With ZipLoop

The femoral 4.5-mm diameter drill was reamed over the guide pin through the lateral cortex. The implant was positioned just beyond the lateral cortex of the femur by pulling the passing suture proximally through the femoral tunnel. The implant was fixed to the cortex by applying distal traction to the graft. The graft was then pulled into the femoral tunnel and seated by pulling the tensioning sutures distally in line with the tunnel.

XO Button

The guide pin was placed and the tunnel reamed to 9 mm. A 5-mm cannulated drill was then used to ream the outer cortex over the guide pin. An additional No. 5 nonabsorbable suture was added to the 15-mm fixed-loop XO Button. Positioning knots were tied into the trailing suture approximately 10 cm away from the device. Tension was applied to the passing sutures while countertension was applied to the trailing suture to pass the device through the tunnel. The knotted suture was then pulled to flip the button on the outer cortex, and traction was placed on the tendons to ensure that the button was seated properly.

Biomechanical Testing

Performance of the fixation devices was tested in response to cyclic and pull-to-failure loading on the Instron ElectroPuls E10000 mechanical test system (Instron Systems, Norwood, Massachusetts). A custom clamp was fabricated to secure the femur to the base plate of the Instron and a custom mechanical grip to fix the graft to the Instron actuator. The construct was positioned so that the application of force on the graft was in line with the long axis of the tunnel to simulate worst-case testing for the device. For device-only testing, the steel plate was fixed to the Instron base plate, and force was applied in line with the long axis of the tunnel. Data were recorded by the Instron WaveMatrix software (Instron Systems) at the rate of 500 Hz. The devices and constructs were preloaded from 10 to 50 N at 0.1 Hz for 10 cycles, followed by 1000 cycles of sinusoidal loading between 50 and 250 N at a frequency of 0.5 Hz. After cyclic loading, the devices and construct grafts were further displaced at 50 mm/min until failure. The mechanism of failure was recorded (pullout, suture breakage, or intrasubstance tendon elongation). Cyclic displacement at 250 N (mm), initial displacement (mm), total displacement (mm), ultimate failure load (N), and pullout stiffness (N/mm) were determined. Initial displacement was defined as the amount of displacement that occurs from the end of the preload cycle (50 N) to the first 50-N point in the cyclic loading profile after the first 250-N load. Total displacement was found by adding the initial displacement to the cyclic displacement after 1000 cycles. The same loading protocol was followed for both the construct and device-only testing.

Statistical Analysis

Statistical analysis was performed with the use of Predictive Analytics Software (PASW) Statistics version 18 (IBM Corporation, Armonk, New York). The study compared data for each group using a 1-way analysis of variance (ANOVA). For ANOVA values that demonstrated a statistically significant difference, a post hoc Tukey HSD (honestly significant difference) test was conducted to assess the location of the means that were statistically significant between the groups. Significant difference was determined to be present for $P < .05$. The observed effect sizes ($f$) for overall comparison of the 4 devices with respect to construct measurements for ultimate failure load and cyclic displacement after 1000 cycles were 11.95 and 3.35, respectively. Both values are drastically larger than the threshold for a “large” effect size defined by Cohen in 1988, leading us to conclude that our sample size was sufficient to provide very high statistical power for the overall comparison tests we performed.3

RESULTS

The highest ultimate failure strength (mean ± SD) when tested as a construct was observed for the XO Button (1748 ± 140 N), followed by the Endobutton (1456 ± 101 N), ToggleLoc (1334 ± 81 N), and TightRope...
(859 ± 43 N). All differences in ultimate failure strength between devices were significant (P < 0.05). The least amount of cyclic displacement (mean ± SD) when tested as a construct after 1000 cycles was observed for the XO Button (1.82 ± 0.23 mm), followed by the Endobutton (1.88 ± 0.25 mm), TightRope (2.74 ± 0.39 mm), and ToggleLoc (3.34 ± 1.28 mm). The ToggleLoc had the most displacement and exceeded the 3.0-mm threshold for clinical failure after 1000 cycles. The Endobutton and XO Button displaced significantly less than the other devices and were not significantly different from each other. Similar trends were observed for the device-only testing. These results, as well as the stiffness, initial displacement, total displacement, and failure type, are reported in Table 1. Statistical significance for ultimate failure, stiffness, cyclic displacement after 1000 cycles, and initial displacement is reported in Table 2.

**DISCUSSION**

Fixation of ACL soft tissue grafts has been reported to have suboptimal biomechanical properties for early graft fixation including ultimate failure, graft displacement, and stiffness. Our study demonstrated that all 4 cortical suspension devices tested had stronger ultimate failure loads (859-1748 N) than the 303 to 590 N reported to be needed in the early rehabilitation and ambulation phases after ACL reconstruction. The cortical suspension devices, when considered as a construct, reapproximated the native ACL stiffness previously reported to be 242 ± 28 N/mm. The differences in cyclic displacement (1.82-3.34 mm), especially when the initial displacement was considered in combination with the cyclic displacement (3.37-6.02 mm), were the most significant clinical factor in using these devices.

Cyclic displacement has an effect on a graft’s ability to heal and the long-term outcome for graft function. If the graft displaces but still heals, patients may experience instability when they return to sport without a rerupture. It has been reported that 3.0 mm or more of side-to-side difference in anterior tibial translation, as measured by KT-1000 arthrometer testing, signifies an ACL failure in nearly all instances. It is unclear exactly how much graft slippage will result in a functional failure. The most displacement seen in any single cycle was the initial displacement observed during the ramp-up of force on the first cycle from preload to cyclic testing. This initial displacement is analogous to the displacement of the graft when tensioned and cycled in surgery. The larger displacements associated with the adjustable-length loop devices should be considered and accounted for by clinicians to avoid instability after reconstruction.

Significant differences in stiffness were observed between the devices during device-only testing. However, when devices were tested in the bone-device-tendon construct, stiffness did not significantly change between devices. Stiffness values within the construct were similar to the native ACL for all devices, which indicates that the devices were the most rigid component of the construct. The stiffness was high enough for all devices to not have clinical significance.

We recognize that this study has some limitations. The study was performed in a porcine model as an analog to young human bone; however, this model has been previously reported to reapproximate the biomechanical properties in a young adult ACL reconstruction. Additionally, the constructs were tested with the force

**TABLE 1**

Biomechanical Properties Reporting Both Device-Only and Construct Testing

<table>
<thead>
<tr>
<th></th>
<th>Ultimate Failure, N</th>
<th>Stiffness, N/mm</th>
<th>Initial Displacement, mm</th>
<th>Cyclic Displacement After 1000 Cycles, mm</th>
<th>Total Displacement, Initial + Cyclic, mm</th>
<th>Failure Type</th>
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<tbody>
<tr>
<td><strong>Device-only testing</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Endobutton</td>
<td>1456 (130)</td>
<td>591 (46)</td>
<td>0.23 (0.04)</td>
<td>0.11 (0.03)</td>
<td>0.42 (0.08)</td>
<td>Suture at button (100%)</td>
</tr>
<tr>
<td>TightRope</td>
<td>841 (55)</td>
<td>413 (63)</td>
<td>0.75 (0.16)</td>
<td>0.30 (0.04)</td>
<td>1.10 (0.20)</td>
<td>Suture at rod (100%)</td>
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<tr>
<td>ToggleLoc</td>
<td>1561 (112)</td>
<td>702 (82)</td>
<td>1.30 (0.19)</td>
<td>0.82 (0.18)</td>
<td>2.18 (0.31)</td>
<td>Suture at button (100%)</td>
</tr>
<tr>
<td>XO Button</td>
<td>2230 (252)</td>
<td>964 (112)</td>
<td>0.81 (0.14)</td>
<td>0.35 (0.06)</td>
<td>1.20 (0.17)</td>
<td>Suture at button (100%)</td>
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<td><strong>Construct testing</strong></td>
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<tr>
<td>Endobutton</td>
<td>1456 (101)</td>
<td>201 (25)</td>
<td>1.20 (0.20)</td>
<td>1.88 (0.25)</td>
<td>3.37 (0.27)</td>
<td>Suture at button (80%); cortex (10%); suture at tendon (10%)</td>
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<tr>
<td>TightRope</td>
<td>859 (43)</td>
<td>208 (20)</td>
<td>1.47 (0.31)</td>
<td>2.74 (0.39)</td>
<td>4.47 (0.65)</td>
<td>Suture at tendon (70%); suture at button (30%); suture at tendon (10%); cortex (10%)</td>
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<tr>
<td>ToggleLoc</td>
<td>1334 (81)</td>
<td>198 (31)</td>
<td>2.45 (1.02)</td>
<td>3.34 (1.28)</td>
<td>6.02 (1.90)</td>
<td>Suture at button (90%); cortex (10%) Button (30%), tendon (20%); suture at tendon (20%); suture at button (20%); cortex (10%)</td>
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<tr>
<td>XO Button</td>
<td>1748 (140)</td>
<td>200 (23)</td>
<td>1.45 (0.29)</td>
<td>1.82 (0.23)</td>
<td>3.50 (0.50)</td>
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*All values shown with standard deviations in parentheses.*
Comparison of Femoral Cortical Suspension Devices

Values When Each Device Was Compared With All Other Devices for Each Tested Biomechanical Property

<table>
<thead>
<tr>
<th></th>
<th>Device-Only Testing</th>
<th>Construct Testing</th>
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<td>Ultimate failure</td>
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<td>Cyclic displacement after 1000 cycles</td>
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<td>TightRope</td>
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<tr>
<td>Initial displacement</td>
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<tr>
<td>TightRope</td>
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</tr>
<tr>
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<td>&lt;.001</td>
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<tr>
<td>XO Button</td>
<td>&lt;.001</td>
<td>.926</td>
</tr>
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</table>

*P values > .05 were considered not statistically significant and are denoted by italics.

To learn more about this study, please click here: http://drlaprade.com

CONCLUSION

The Endobutton, TightRope, and XO Button have the necessary biomechanical properties with regard to ultimate failure strength, displacement, and stiffness for initial fixation of soft tissue grafts in the femoral tunnel for ACL reconstruction. The ToggleLoc had sufficient ultimate failure strength but crossed our 3-mm clinical failure threshold for cyclic displacement. Ultimate failure strength for all devices was greater than the previously reported strength needed for activities of daily living and rehabilitation exercises for all devices. Additionally, all devices reapproximated the native stiffness of the ACL when in a construct. With all devices providing the necessary strength and stiffness for reconstruction, the variability of displacement proved to be the parameter with the most clinically significant implications. Although this study was not designed to compare fixed and adjustable-length loop devices, it was noted that both fixed-loop devices allowed less cyclic displacement and initial displacement. Adjustable-length loop devices may need to be retensioned after cycling the knee and fixing the tibial side to account for the increased initial displacement seen with these devices.

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