Femoral Suspension Devices for Anterior Cruciate Ligament Reconstruction: Do Adjustable Loops Lengthen?

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Femoral Suspension Devices for Anterior Cruciate Ligament Reconstruction

Do Adjustable Loops Lengthen?

Aaron E. Barrow,[†] MD, Marcello Pilia,[‡§] PhD, Teja Guda,[§] PhD, Warren R. Kadrmas,[†] MD, and Travis C. Burns,[*†] MD
Investigation performed at San Antonio Military Medical Center, Fort Sam Houston, Texas, and University of Texas–San Antonio, San Antonio, Texas

Background: Cortical suspension devices are commonly used for femoral graft fixation during anterior cruciate ligament (ACL) reconstructive surgery. Adjustable-length fixation devices provide technical advantages over fixed-length loops but may be more susceptible to lengthening during cyclic loading.

Hypothesis: Both fixed-length and adjustable-length femoral cortical suspension devices would withstand ultimate loads greater than those normally experienced by the native ACL and would prevent clinically significant lengthening during prolonged cyclic loading.

Study Design: Controlled laboratory study.

Methods: Mechanical testing was performed on 3 ACL graft cortical suspensory devices by use of an extended cyclic loading (4500 cycles at 10-250 N) and pull-to-failure protocol. Two adjustable-length devices were additionally tested with the free suture ends tied.

Results: Total displacement after 4500 cycles of tensioning at variable loads (expressed as mean ± SD) was 42.45 mm (±7.01 mm) for the Arthrex TightRope RT, 5.76 mm (±0.35 mm) for the Biomet ToggleLoc, and 1.34 mm (±0.03 mm) for the Smith & Nephew EndoButton CL Ultra ($P < .001$). The Arthrex TightRope reached clinical failure of 3 mm lengthening after fewer cycles (1349 ± 316) than the Biomet ToggleLoc (2576 ± 73) ($P < .001$). The Smith & Nephew EndoButton did not reach clinical failure during cyclic testing. With the free suture ends tied, after 4500 cycles, the Arthrex TightRope had a significant decrease in lengthening to 13.36 ± 1.86 mm ($P < .037$) There was also a significant difference in ultimate load between the TightRope (809.11 ± 52.94 N) and the other 2 constructs ($P < .001$).

Conclusion: The ultimate load of all graft-fixation devices exceeded the forces likely to be experienced in a patient's knee during the early postoperative rehabilitation period. However, the adjustable-length fixation devices experienced a clinically significant increase in loop lengthening during cyclic testing. This lengthening is partially caused by suture slippage into the adjustable-length loop.

Clinical Relevance: Adjustable-length ACL graft cortical suspension devices lengthen under cyclic loads because free suture ends are pulled into the adjustable loop. This may allow for graft-fixation device lengthening during the acute postoperative period.

Keywords: ACL reconstruction; soft tissue graft; cortical suspension; cortical button; cyclic loading; TightRope; EndoButton; ToggleLoc

The success of anterior cruciate ligament (ACL) reconstruction surgery depends on surgical technique, graft selection, and the mechanical properties of the fixation device used to secure the graft before integration.[8,35] Recent studies have shown that anatomic positioning of femoral and tibial bone tunnels best restores native knee kinematics by allowing for appropriate graft tension throughout range of motion.[29,43,45] Along with maintaining appropriate tunnel positioning, graft-fixation devices must provide sufficient fixation to ensure that graft tension is maintained until incorporation to native bone.[20,35] The rate of graft incorporation evaluated in animal models depends significantly on the type of graft implanted: 6

*Address correspondence to Travis C. Burns, MD, Deparment of Orthopedics and Rehabilitation, San Antonio Military Medical Center, 3551 Roger Brooke Drive, Fort Sam Houston, TX 78234 (e-mail: travis.c.burns.mil@mail.mil).
[†]San Antonio Military Medical Center, Fort Sam Houston, Texas.
[‡]United States Army Institute of Surgical Research, Fort Sam Houston, Texas.
[§]University of Texas–San Antonio, San Antonio, Texas.

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weeks for bone–patellar tendon–bone autograft, 8 to 12 weeks for soft tissue autograft, and up to 6 months for allograft reconstructions.[15,17,30] During the time before incorporation, the graft is dependent on tibial and femoral fixation devices to maintain normal ACL graft tension. An increase in the length of the graft-fixation device construct during the early postoperative period can lead to micromotion at the graft-bone interface, loss of graft tension, and clinical failure.[16,20] Graft micromotion alone has been shown to cause tunnel widening and impaired healing.[31]

The most common ACL graft femoral fixation implants are broadly categorized as interference devices, cortical suspension devices, and cross pins.[1,7,8,20] The literature has shown positive clinical outcomes for all 3 types of devices, and no definitive superiority has been shown for one mode of fixation over another for either bone-tendon-bone or soft tissue grafts.[22,35,38] However, a few biomechanical studies have shown concern that interference devices may allow for relatively increased graft slippage and failure at lower ultimate loads when used to secure hamstring tendon grafts.[33,36] Cross-pin devices, in contrast, have been shown to provide rigid fixation and high failure loads but have been associated with several intra- and postoperative complications.[9-11,19,24,26]

Fixed-length cortical suspension devices such as the EndoButton (Smith & Nephew Inc, Andover, Massachusetts) have been shown in biomechanical studies to be a good option for soft tissue graft fixation in terms of limiting graft slippage and providing sufficient fixation strength.[18,20,28] However, there are technical challenges to inserting fixed-length devices. Because the loop length is predetermined, the surgeon must drill the femoral tunnel to a specific depth while selecting a corresponding device of appropriate length. An error in measurement can lead to an inability to pass the button through the lateral femoral cortex or can result in insufficient graft length in the femoral tunnel for incorporation.[7] Furthermore, recent emphasis on anatomic femoral tunnel placement results in shorter tunnel length and further concern for sufficient graft length in the femoral tunnel.[37]

The Arthrex TightRope RT (Arthrex Inc, Naples, Florida) and ToggleLoc with ZipLoop (Biomet Inc, Warsaw, Indiana) are cortical suspension devices that allow for adjustment of the suspension loop length after insertion. The adjustable loop length provides greater ease of insertion, allows complete graft fill of the femoral tunnel, obviates the need to calculate the loop length, and allows the same implant to be used regardless of tunnel placement or depth.[12,18] The potential disadvantage of the adjustable-length design is loop lengthening after fixation, which can lead to graft loosening and consequently surgical failure.

The purpose of this study was to test the high-cycle mechanical integrity of the TightRope and ToggleLoc under physiologically relevant loads and compare their performance with that of a clinically established fixed-length device, the EndoButton CL Ultra (Smith & Nephew, Memphis, Tennessee). We also evaluated whether tying the loose ends of the adjustable loop affected the lengthening of the TightRope and ToggleLoc fixation devices during cyclic loading.

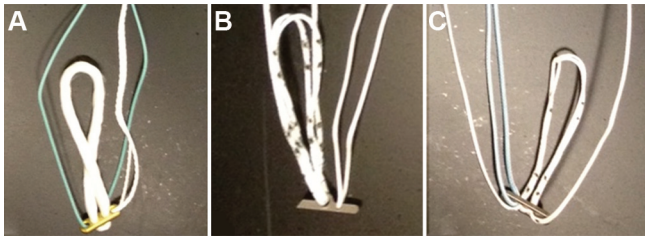

Figure 1. Cortical fixation devices tested: (A) EndoButton CL Ultra, (B) ToggleLoc with ZipLoop, (C) TightRope RT.

MATERIALS AND METHODS

Implant Description

The ToggleLoc with ZipLoop, the TightRope RT, and the 40-mm EndoButton CL Ultra were tested in this study (Figure 1). Each of the buttons were measured with digital calipers: the ToggleLoc with Zip Loop measured 13.26 × 2.03 mm, the TightRope RT measured 13.04 × 3.36 mm, and the EndoButton CL Ultra measured 12.15 × 3.93 mm. The Arthrex TightRope RT has a titanium button with an adjustable length ultrahigh molecular weight polyethylene and polyester suture running through the button. The Biomet ToggleLoc with Zip Loop is a stainless steel and titanium alloy button with an adjustable-length ultrahigh molecular weight polyethylene, polyester, and polypropylene suture running through the button. The Smith & Nephew EndoButton CL Ultra is a titanium button with a fixed length of a continuous-loop polyester suture, available in multiple premeasured sizes.

Experimental Setup

The study was designed to isolate the mechanical properties of the suture-button devices while minimizing potential confounding variables that cannot be controlled by the surgeon, such as bone quality. Each item was tested in an identical manner with a servo-hydraulic MTS Insight 5 (MTS Systems, Eden Prairie, Minnesota) with a 5-kN load cell. To recreate the in vivo surgical setup, a bone tunnel was replicated by drilling a 4.5-mm-diameter hole in a 5-mm-thick stainless steel baseplate. The 4.5-mm tunnel diameter is in accordance with manufacturers' recommendations or published testing protocol for all 3 devices tested.[2,4,32] The button was then fed through the tunnel and secured against the plate surface, acting as the lateral femoral cortex (Figure 2). The free end of the suture loop was placed over a 5-mm-diameter stainless steel rod attached to the MTS crosshead, and the steel plate was attached to the machine base (Figure 2).[28] In this setup, the MTS servo-hydraulic actuator pulls tension in line with the device suture loop and perpendicular to the button.

Each device was secured between the baseplate and steel rod as recommended by the manufacturers in their published technique guides.[2,5,23] Before testing began, the loop length of the EndoButton device (41 mm) was determined while positioned in the apparatus as described above. Each adjustable-length loop device was subsequently

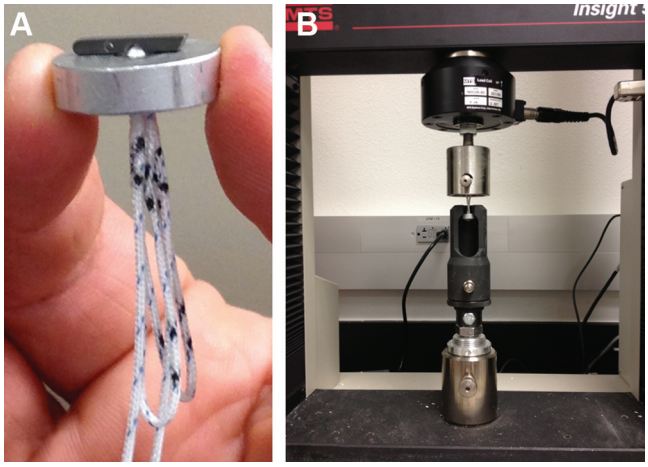

Figure 2. (A) Device mounted onto the stainless steel plate. (B) The test setup showing the mounting of the fixation device and the stainless steel plate and rod used to conduct the test.

set to this same length by securing it to the baseplate and steel rod at the preset distance. Tightening of the adjustable-loop devices was also done according to the manufacturers' published instructions. After the devices were secured in the MTS apparatus, a preload of 20 N at 20 mm/min was applied to simulate intraoperative tensioning. It was predetermined experimentally that 20 N of preload would be the average load applied by the senior author (T.C.B.) during device suture tensioning. All devices were loaded on the MTS testing apparatus with the loop configuration set to the manufacturer's recommendations.

All measurements during cyclic and load-to-failure testing were determined by recording the MTS crosshead displacement by use of the Testworks control package provided by the manufacturer. The MTS was calibrated for accuracy of both load and displacement before testing. Displacement measurement variability was within 0.01 mm and load measurement variability was within 0.05 N.

All devices were tested through the completion of 4500 cycles at variable loads from 10 to 250 N and then to construct failure at ultimate load. The cyclic tests were performed in load control mode; the mean, minimum, and maximum loads as well as load-displacement curves of the median sample are in the Appendix (available online at http://ajsm.sagepub.com/supplemental). Each of the devices was tested with its own suture as specified by the manufacturer's recommendations. Each load test was performed with a new, prepackaged device. Mechanism of failure was recorded for each device. Three millimeters of device lengthening was chosen to indicate "clinical failure" based on KT-1000 arthrometer testing showing that a side-to-side difference in anterior tibial translation is a sensitive determinant of symptomatic ACL failure.[13]

Mechanical Testing: Unknotted

After the samples were secured in the experimental setup, they then underwent cyclic preconditioning between 10 and 50 N at a rate of 1 Hz for 10 cycles. Preconditioning was performed to remove slack from the construct and ensure simultaneous engagement of both the suture and the button. Upon completion, construct displacement was recorded and reset to 0. Cyclic loading was then performed between 10 and 50 N at 1 Hz for 500 cycles. The force was then increased in 25-N increments every 500 cycles up to 250 N, for a total of 4500 cycles. At completion of the cyclic testing protocol, each sample underwent load-to-failure testing at a rate of 20 mm/min. Table 1 summarizes the testing protocol. Load-displacement curves were recorded and data were analyzed to determine loop lengthening (displacement) and the ultimate tensile strength. Six samples of each device were tested. As recommended by the manufacturers, the adjustable suture ends were left unknotted for the adjustable-length devices.[2,5]

TABLE 1
Summary of the Testing of Each Suture[a]

Testing Mode	No. of Cycles	Rate	Load
Preload	—	—	20 N
Cyclic preconditioning	10	1 Hz	10-50 N
Cyclic loading	500	1 Hz	10-50 N
	500	1 Hz	10-75 N
	500	1 Hz	10-100 N
	500	1 Hz	10-125 N
	500	1 Hz	10-150 N
	500	1 Hz	10-175 N
	500	1 Hz	10-200 N
	500	1 Hz	10-225 N
	500	1 Hz	10-250 N
Pull to failure	—	20 mm/min	Failure

[a]Each suture was subjected to 4 types of stretching: preload, cyclic preconditioning, cyclic loading, and pull to failure for a total of 4500 cycles.

Mechanical Testing: Knotted

Six samples of the ToggleLoc and TightRope were then tested after the free suture ends were secured with 6 half-hitch suture knots tied with an arthroscopic knot pusher. These samples were tested under the same experimental setup and cyclic loading protocol as the unknotted devices.

Statistical Analysis

In this study, the independent variables were fixation device and device knotting. The dependent variables were number of cycles at 3 mm of lengthening, total lengthening after 4500 cycles, and load to failure. The study compared data for each group of devices using a 2-factor analysis of variance (ANOVA). For ANOVA values that demonstrated a statistically significant difference, a post hoc Bonferroni 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 $P < .05$. A post hoc power analysis performed on the difference in device extensions at the earliest load cycle (after 500 cycles from 10 N to 50 N) revealed that the power of the test with $\alpha = .05$ was 0.957,

TABLE 2
Average Device Extension After the Initial 20-N Tightening, After 10 Cycles of 10- to 50-N Preconditioning, and After 4500 Cycles of Cyclic Loading, and the Number of Cycles at Clinical Failure (3 mm) for All Devices Tested

Suture	Setup	Preload Elongation, mm	Preconditioning Elongation, mm	Total Elongation at 4500 Cycles, mm	Ultimate Load, N	3-mm Elongation, cycles
TightRope	Unknotted	0.26 ± 0.07	0.15 ± 0.10	42.45 ± 7.01	809.11 ± 52.94	1349 ± 316
	Knotted	0.27 ± 0.04	–0.03 ± 0.00	13.36 ± 1.86	1074.50 ± 50.04	1680 ± 194
ToggleLoc	Unknotted	0.63 ± 0.07	–0.03 ± 0.00	5.76 ± 0.35	1652.13 ± 45.11	2576 ± 73
	Knotted	0.21 ± 0.05	0.43 ± 0.03	5.63 ± 0.86	1419.00 ± 87.31	2076 ± 342
EndoButton	Closed loop	0.31 ± 0.02	–0.04 ± 0.00	1.34 ± 0.03	1529.38 ± 26.07	—

indicating that the study was sufficiently powered. Results are expressed as mean ± standard deviation.

RESULTS

The Arthrex TightRope reached clinical failure of 3 mm of lengthening after fewer cycles (1349 ± 316 cycles) than did the Biomet ToggleLoc (2576 ± 73 cycles) ($P < .001$). The Smith & Nephew EndoButton did not reach clinical failure during cyclic load testing. The TightRope also showed greater lengthening (42.45 ± 7.01 mm) at completion of 4500 cycles compared with both the ToggleLoc (5.76 ± 0.35 mm) and the EndoButton (1.34 ± 0.03 mm). The differences in total lengthening were statistically significant for all devices ($P < .001$). The preload, preconditioning, and cumulative elongation for each cycle group are shown in Table 2. The load displacement curves of the median sample of the devices tested are available in the online Appendix.

There was a statistically significant difference in ultimate load at mechanical failure between the TightRope (809.11 ± 52.94 N) and the other 2 constructs ($P < .001$). Ultimate load at failure for the ToggleLoc was 1652.13 ± 45.11 N and for the EndoButton 1529.38 ± 26.07 N. The difference between the ToggleLoc and EndoButton was not statistically significant ($P > .05$).

During testing of the 2 adjustable-length devices with the free ends knotted, the TightRope and ToggleLoc reached 3 mm of lengthening after 1680 ± 194 and 2076 ± 342 cycles, respectively ($P < .008$). At 4500 cycles, the TightRope's total displacement was reduced to 13.36 ± 1.86 mm ($P = .037$), while the ToggleLoc's displacement (5.63 mm ± 0.86 mm) was not significantly different than during unknotted testing ($P > .05$). The change in ultimate load for both the TightRope (1074.5 ± 50.04 N) and ToggleLoc (1419.0 N ± 87.31 N) was not significant ($P > .05$).

The method of construct failure for all TightRope and ToggleLoc devices during both modes of testing was suture breakage near its contact at the button device. The mode of failure for all EndoButton devices was midsubstance suture loop breakage. The cyclic loading protocol and device failure for each device can be seen in the Video Supplement.

DISCUSSION

Failure of an ACL graft cortical fixation device can occur either if the device breaks under load or if it lengthens to the point that the graft has insufficient tension to provide near-normal ACL laxity.[13] The critical time period for fixation device performance is the early 6- to 12-week postoperative period, before graft incorporation has occurred.[15,17,30] It is estimated that graft-fixation devices experience loads of at least 450 to 500 N during early rehabilitation.[40] Cortical suspension device breakage under in vivo forces has not been reported in the literature, and multiple mechanical studies, including the results of this study, have shown that many cortical fixation devices currently available have sufficient ultimate strength and stiffness to withstand the anticipated in vivo forces.[1,12,18,28]

However, all of the femoral suspensory fixation devices evaluated in these studies were susceptible to varying degrees of lengthening during cyclic loading, with the adjustable-length devices exhibiting increased lengthening compared with fixed-loop constructs.[12,18,28] The primary purpose of this study was to evaluate the potential effect of prolonged cyclic loading on fixation device elongation. The clinical concern is that lengthening of a fixation device during the acute postoperative period leads to decreased graft tension as well as graft slippage within the bone tunnel.[1] Slippage negatively affects both postoperative healing and clinical outcomes because of increased graft laxity.[20,31] The clinically relevant amount of allowable graft-fixation device construct lengthening is not known. However, ACL failure has been described as greater than 3 mm of difference between side-to-side anterior tibial translation; therefore, we used 3 mm of loop lengthening as our benchmark of clinical failure.[13]

The results of our study show that for all devices, elongation began with the initiation of testing and progressed as long as cycling continued from 10 to 4500 cycles (Figure 3). As there was no end point to the elongation, clinically the TightRope and ToggleLoc may continue to lengthen until the graft heals to the surrounding tissue. The 2 adjustable-loop fixation devices underwent elongation at a greater overall magnitude and rate than the fixed-loop EndoButton, with the unknotted TightRope devices showing increased elongation as cyclic load force increased (Figure 4). In a recent biomechanical study, Petre et al[28] found that after only 1000 cycles of sinusoidal loading from 50 to 250 N, the EndoButton (0.42 ± 0.08 mm), the TightRope (1.10 ± 0.20 mm), and the ToggleLoc (2.18 ± 0.31 mm) displaced less than 3 mm. Through the first 1000 cycles in our study, we showed increased lengthening of the TightRope (3.22 ± 1.33 mm) and slightly less

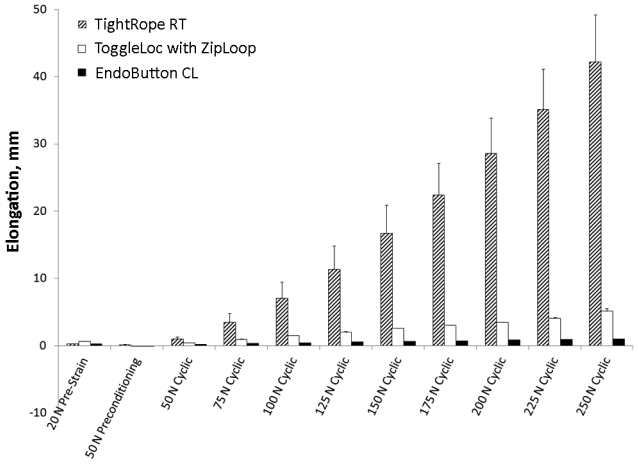

Figure 3. The average loop extension (in millimeters) after 500 cycles at each 25-N load increment for all devices (without suture knotting).

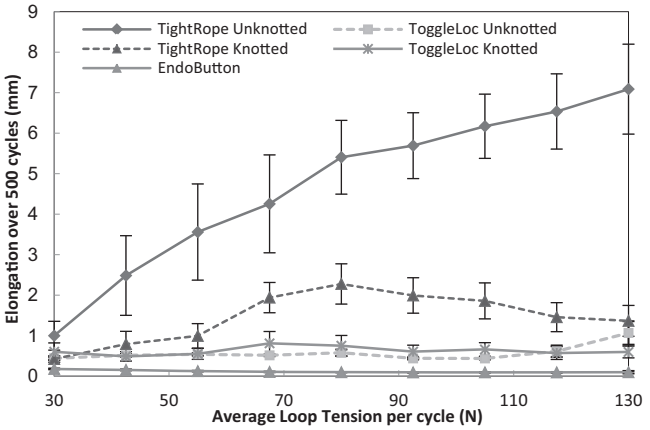

Figure 4. Relative extension over each block of 500 cycles for the 3 grafts (with or without suture knotting). The unknotted TightRope shows a trend of increasing elongation with increasing load, while the EndoButton shows no increase in elongation with load and a decrease in relative extension with an increasing cumulative cycle number. No statistical difference with knotting is observed for the ToggleLoc.

lengthening with the ToggleLoc (0.95 ± 0.06 mm) and EndoButton (0.33 ± 0.02 mm) compared with Petre et al.[28]

The slight difference in our results through the first 1000 cycles with those published by Petre et al[28] is likely explained by the different loading parameters. They loaded the devices from 50 to 250 N for 1 test of 1000 cycles. We increased our load every 500 cycles for a total of 4500 cycles. Through 1000 cycles, our testing loaded the devices between 10 and 75 N. The lower maximum load in our protocol to this point likely accounts for the decreased lengthening of the EndoButton and ToggleLoc. The increased lengthening of the Arthrex TightRope, on the other hand, may be attributed to the friction locking mechanism "unlocking" at very low loads, akin to a Chinese finger trap. Our minimum loads approaching 0 N is lower than prior studies, but seems consistent with forces experienced by the ACL.[3,25,40] The cyclic load minimum approaching 0 N and the increased number of cycles led to important differences in our results with lengthening of the Arthrex TightRope. It is possible that in vivo lengthening also continues for as long as the device is placed under cyclic stress, only stopping when graft-to-bone healing occurs. Therefore, the more important clinical concern regarding the mechanical properties of adjustable-length suspensory fixation devices may not be the intensity of load experienced postoperatively but rather the volume of cycles.

We chose to test the devices through 4500 cycles because that represented more than twice the number of cycles previously reported in the literature. Although the average number of cycles that occur in a postoperative ACL patient's knee is not known, it has been reported that the average ambulatory person has greater than 6000 gait cycles per day.[41] It is reasonable to extrapolate from our data that if we had chosen to continue cyclic testing longer, the devices would have continued to lengthen at the same rate.

The elongation of the devices is particularly concerning given the relatively small loads under which it began to occur. The ToggleLoc's total elongation reached 5 mm while being cycled at 10 to 250 N (4500 total cycles), while the TightRope had already elongated beyond 5 mm while being cycled at only 10 to 100 N (1500 total cycles). At a normal pace, the native ACL is subjected to forces of 303 N during level-ground ambulation and up to 445 N during walking on a downhill slope, significantly higher than our cyclic loading parameters.[14,19] A minimum load of 10 N was selected because of the low load experienced by the ACL in midflexion.[3,25,40] Although there is no gold-standard ACL reconstruction rehabilitation protocol, advancement of weightbearing status and increased range of motion are usually based on quadriceps muscle strength, and most protocols allow weightbearing as tolerated before the expected time of graft incorporation.[34,39,44]

Although some of the elongation for all 3 devices can be attributed to plastic deformation of the loop material, the reason for increased elongation in the adjustable-loop devices may also be related to the product design.[12] We hypothesize that the "one-way" tensioning apparatus on the adjustable-loop fixation devices fails to prevent suture slippage and loop lengthening during cyclic loading. Per manufacturer recommendation, the loose suture ends used to pull the graft into the tunnel during initial placement are not routinely secured.[6,14] With each cycle, the loose suture ends are pulled into the device's "loop," effectively lengthening the graft-fixation construct. To confirm this theory, we drew a stripe with colored marker on the loose suture of one of each of the adjustable-length devices, approximately 3 mm from the button-loop interface. As cyclic loading proceeded, the stripe gradually migrated into the loop, indicating that the loose ends of suture were being pulled into the loop.

To ascertain whether securing the loose sutures would reduce lengthening, we performed additional cyclic testing on the TightRope and ToggleLoc devices with the loose ends secured using standard surgical half-hitch knots. We hypothesized that tying the suture ends would reduce

slippage into the continuous loop. With this modification, both devices lengthened at a slower rate during cyclic loading (Figure 4). Through 4500 cycles, the TightRope device had a statistically significant decrease in lengthening, to 13.10 ± 1.86 mm. The ToggleLoc also had slightly less total cyclic lengthening, although this difference was not statistically significant. Ultimate load did not change significantly for either device.

In contrast to prior studies with fewer cyclic loads and higher minimum loads, our results indicate that adjustable-loop cortical suspension devices may lengthen sufficiently by approximately 2000 to 3000 cycles to cause clinical failure. Furthermore, this failure may occur at loads far lower than are experienced by the early postoperative ACL graft. However, because there are not currently any published clinical outcome studies for either the Arthrex TightRope or the Biomet ToggleLoc with ZipLoop in ACL reconstructions, the potential for in vivo device failure at any specific number of cycles or loads remains theoretical.

The in vitro, mechanical nature of the study causes several limitations. In vivo factors such as intra-articular fluid and tissue healing response within the bone tunnels and soft tissue might potentially affect elongation. These factors cannot be adequately replicated in a laboratory setting. A steel plate, rather than animal or human cadaver bone, was used to represent the lateral femoral cortex.[21,26] This design was primarily selected so that the mechanical properties of the device being tested were the only variable, rather than bone quality or tunnel characteristics. Previous cyclic loading tests have shown that cortical suspension devices usually fail at either the button-suture interface or in midsubstance, not at the button-cortex interface.[1] Furthermore, testing the devices against a metal "cortex" represents the best case performance for the devices, and any lengthening or failure due to bone contact in vivo would be in addition to our reported values.

Another consideration is that an animal or human cadaver model may have provided a more accurate representation of the force vectors experienced by the suspension devices in vivo. However, Petre et al[28] and Kamelger et al[18] reported increased lengthening in both fixed and adjustable-length devices when tested in a porcine biomechanical model compared with mechanical testing in a metal rig alone. This suggests that the devices may potentially show even further lengthening under in vivo stresses compared with the in-line loads applied during mechanical testing.

Finally, our study only subjected the devices to a maximum load of 250 N. As mentioned earlier, this is far lower than what might actually be experienced in the postoperative ACL. A cyclic loading protocol of 50 to 250 N was previously used in several similar peer-reviewed articles comparing fixed-length and adjustable-length cortical suspension devices, as well as in one industry-published study directly comparing the 2 adjustable-loop devices tested in this study.[4,18,28] We chose to use a similar maximum load (250 N) to facilitate data comparison. Only one of these studies (Petre et al[28]) specifically stated that the investigators had also used varied loading magnitudes rather than a linear increase in load during testing. We decided on a varied loading protocol to simulate the approximate ramping up of load experienced as postoperative physiotherapy begins clinically from initial motion-alone exercise and progresses to increasing load bearing. The focus of our study design was to show that under loads similar to what has been previously reported, cortical suspension devices will continue to lengthen as long as they continue to be cycled. As shown in Figure 4, however, it is not unreasonable to hypothesize from our data that further increasing the load applied would lead to even more displacement. Conner et al[12] used a porcine model to compare the EndoButton and ToggleLoc using a cyclic load protocol of 50 to 450 N at 1 Hz for 2000 cycles. Although the focus of the study was comparison of anterior versus lateral femoral cortical position of the suspension device, their results show that at only 2000 cycles the ToggleLoc had lengthened greater than 3 mm in both anatomic positions while the EndoButton did not.[12] Further research is needed to fully elucidate the independent effect of increased loads compared with increased number of cycles on suspension device performance.

CONCLUSION

The effect of cyclic loading on lengthening of the adjustable-length devices is a potential area of clinical concern. The TightRope and ToggleLoc lengthened greater than our 3-mm threshold for failure during cyclic loading. The TightRope RT showed the greatest elongation over the cyclic loading test. The displacement of the adjustable-length devices can be limited with knot tying but not sufficiently to prevent elongation.

A Video Supplement for this article is available in the online version or at http://ajsm.sagepub.com/supplemental.

REFERENCES

1. Ahmad CS, Gardner TR, Groh M, Arnouk J, Levine WN. Mechanical properties of soft tissue femoral fixation devices for anterior cruciate ligament reconstruction. *Am J Sports Med*. 2004;32(3):635-640.
2. Andrews J. *ToggleLoc Fixation Device with ZipLoop Technology: ACL Reconstruction Bone-Tendon-Bone Surgical Protocol*. Warsaw, IN: Biomet Sports Medicine; 2009.
3. Arnold MP, Verdonschot N, van Kampen A. ACL graft can replicate the normal ligament's tension curve. *Knee Surg Sports Traumatol Arthrosc*. 2005;13:625-631.
4. Arthrex. *Arthrex ACL TightRope and Biomet ZipLoop with ToggleLoc: Mechanical Testing*. Vol LA0179A. Naples, FL: Arthrex Inc; 2010.
5. Arthrex. *ACL TightRope RT for Femoral Fixation: Surgical Technique*. Vol LT0159A. Naples, FL: Arthrex Inc; 2011.
6. Arthrex. *ACL Reconstruction With Arthrex Tightrope: Surgical Technique*. Naples, FL: Arthrex, Inc; 2012.
7. Beynnon BD, Johnson RJ, Abate JA, Fleming BC, Nichols CE. Treatment of anterior cruciate ligaments, part 1. *Am J Sports Med*. 2005;33(10):1579-1602.
8. Beynnon BD, Johnson RJ, Abate JA, Fleming BC, Nichols CE. Treatment of anterior cruciate ligament injuries, part 2. *Am J Sports Med*. 2005;33(11):1751-1767.

9. Chen NC, Boykin RE, Millett P.J. Broken femoral cross pin after hamstring anterior cruciate ligament reconstruction: case report. *J Knee Surg*. 2007;20(3):245-248.
10. Choi NH, Lee JH, Victoroff BN. Do broken cross-pins compromise stability after anterior cruciate ligament reconstructions with hamstring tendons? *Arthroscopy*. 2007;23(12):1334-1340.
11. Choi NH, Son KM, Victoroff BN. A pitfall of transfix fixation during anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc*. 2008;16(5):479-481.
12. Conner CS, Perez BA, Morris RP, Buckner JW, Buford WLJ, Ivey FM. Three femoral fixation devices for anterior cruciate ligament reconstruction: comparison of fixation on the lateral cortex versus the anterior cortex. *Arthroscopy*. 2010;26(6):796-807.
13. Daniel DM, Stone ML, Sachs R, Malcom L. Instrumented measurement of anterior knee laxity in patients with acute anterior cruciate ligament disruption. *Am J Sports Med*. 1985;13(6):401-407.
14. Gittins M. *Femoral Fixation for ACL Reconstruction: Surgical Protocol. BioMet Sports Medicine I*. Vol BSM0174.0 ed. Warsaw, IN: Biomet Inc; 2008.
15. Goradia VK, Rochat MC, Grana WA, Rohrer MD, Prasad HS. Tendon to bone healing of a semitendinosus tendon autograft used for ALC reconstruction in a sheep model. *Am J Knee Surg*. 2000;13:143-151.
16. Hiejne A, Fleming BC, Renstrom PA, Peura GD, Beynonn BD, Werner S. Strain on the anterior cruciate ligament during closed chain kinetic exercises. *Med Sci Sports Exerc*. 2004;36:935-941.
17. Jackson DW, Grood ES, Goldstein JD, et al. A comparison of patellar tendon autograft and allograft used for anterior cruciate ligament reconstruction in the goat model. *Am J Sports Med*. 1993;21(2):176-185.
18. Kamelger FS, Onder U, Schmoelz W, Tecklenburg K, Arora R, Fink C. Suspensory fixation of grafts in anterior cruciate ligament reconstruction: a biomechanical comparison of 3 implants. *Arthroscopy*. 2009;25(7):767-776.
19. Kokkinakis M, Ashmore A, El-Guindi M. Intraoperative complications using the Bio-Transfix femoral fixation implant in anterior cruciate ligament reconstruction. *Arch Orthop Trauma Surg*. 2010;130(3):375-379.
20. Kousa P, Jarvinen TLN, Vihavainen M, Kannus P, Jarvinen M. The fixation strength of six hamstring tendon graft fixation devices in anterior cruciate ligament reconstruction, part I: femoral site. *Am J Sports Med*. 2003;31(2):174-181.
21. Krueger CA, Wenke JC, Masini BD, Stinner JD. Characteristics and impact of animal models used for sports medicine research. *Orthopedics*. 2012;35(9):e1410-1415.
22. Matsumoto A, Yoshiya S, Muratsu H, et al. A comparison of bone-patellar tendon-bone and bone-hamstring tendon-bone autografts for anterior cruciate ligament reconstruction. *Am J Sports Med*. 2006;34(2):213-219.
23. McCainn L. ToggleLoc device trans tibial surgical video. 2008. http://www.biomet.com/sportsmedicine/video/transTibialSurgTech.cfm. Accessed March 30, 2013.
24. Misra R, Strover A, El-Shazly M. Intra-articular protrusion of malpositioned transfix implant following anterior cruciate ligament reconstruction. *Arthroscopy*. 2006;22(2):226, e1-e4.
25. More RC, Karras BT, Neiman R, et al. Hamstrings—an anterior cruciate ligament protagonist: an in vitro study. *Am J Sports Med*. 1993;21:231-237.
26. Ozer H, Oznur A. Complications following hamstring anterior cruciate ligament reconstruction with femoral cross-pin fixation. *Arthroscopy*. 2005;21(11):1407-1408.
27. Pearce AI, Richards RG, Milz S, Schneider E, Pearce SG. Animal models for implant biomaterial research in bone: a review. *Eur Cell Mater*. 2007;13:1-10.
28. Petre BM, Smith SD, Jansson KS, et al. Femoral cortical suspension devices for soft tissue anterior cruciate ligament reconstruction: a comparative biomechanical study. *Am J Sports Med*. 2013;41(2):416-422.
29. Petsche TS, Hutchinson MR. Loss of extension after reconstruction of the anterior cruciate ligament. *J Am Acad Orthop Surg*. 1999;7:119-127.
30. Rodeo SA, Arnocky SP, Torzilli PA, Hidaka C, Warren RF. Tendon-healing in a bone tunnel: a biomechanical and histological study in the dog. *J Bone Joint Surg Am*. 1993;75(12):1795-1803.
31. Rodeo SA, Kawamura S, Kim HJ, Dynybil C, Ying L. Tendon healing in a bone tunnel differs at the tunnel entrance versus the tunnel exit: an effect of graft-tunnel motion? *Am J Sports Med*. 2006;34:1790-1800.
32. Rosenberg T. *ACL Reconstruction With the Acufex™ Director Drill Guide and EndoButton™ CL Fixation System*. Vol 10600026 Rev A. Andover, MA: Smith & Nephew, Inc; 2005.
33. Scheffler SU, Sudkamp NP, Gockenjan A, Hoffman RFG, Weiler A. Biomechanical comparison of hamstring and patellar tendon graft anterior cruciate ligament reconstruction techniques: the impact of fixation level and fixation method under cyclic loading. *Arthroscopy*. 2002;18:304-315.
34. Shelburne KB, Pandy MG, Anderson FC, Torry MR. Pattern of anterior cruciate ligament force in normal walking. *J Biomech*. 2004;37(6):797-805.
35. Shelton WR FB. Autografts commonly used in anterior cruciate ligament reconstruction. *J Am Acad Orthop Surg*. 2011;19(5):259-264.
36. Stadelmaier DM, Lowe WR, Ilahi OA, Noble PC, Kohl HW. Cyclic pull-out strength of hamstring tendon graft fixation with soft tissue interference screws: influence of screw length. *Am J Sports Med*. 1999;27(6):778-783.
37. Takeda Y, Iwame T, Takasago T, et al. Comparison of tunnel orientation between transtibial and anteromedial portal techniques for anatomic double-bundle anterior cruciate ligament reconstruction using 3-dimensional computed tomography. *Arthroscopy*. 2013;29(2):195-204.
38. Taylor DC, DeBerardino TM, Nelson BJ, et al. Patellar tendon versus hamstring tendon autografts for anterior cruciate ligament reconstruction: a randomized controlled trial using similar femoral and tibial fixation methods. *Am J Sports Med*. 2009;37(10):1946-1957.
39. van Grinsven S, van Cingel REH, Holla CJM, van Loon CJM. Evidence-based rehabilitation following anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthosc*. 2010;18(8):1128-1144.
40. Wascher DC, Markolf KL, Shapiro MS, et al. Direct in vitro measurement of forces in the cruciate ligaments, part 1: the effect of muliplane loading in the intact knee. *J Bone Joint Surg Am*. 1993;75:377-386.
41. West RV, Harner CD. Graft selection in anterior cruciate ligament reconstruction. *J Am Acad Orthop Surg*. 2005;13(3):197-207.
42. Winter CC, Brandes M, Müller C, et al. Walking ability during daily life in patients with osteoarthritis of the knee or the hip and lumbar spinal stenosis: a cross sectional study. *BMC Musculoskelet Disord*. 2010;11:233.
43. Woo SL, Hollis JM, Adams DJ, Lyon RM, Takai S. Tensile properties of the human femur-anterior cruciate ligament-tibia complex: the effects of specimen age and orientation. *Am J Sports Med* 1991;19:217-225.
44. Wright RW, Preston E, Fleming BC, et al. A systematic review of anterior cruciate ligament reconstruction rehabilitation: part I: continuous passive motion, early weight bearing, postoperative bracing, and home-based rehabilitation. *J Knee Surg*. 2008;21(3):217-224.
45. Zantop T, Diermann N, Schumacher T, Schanz S, Fu FH, Petersen W. Anatomical and nonanatomical double-bundle anterior cruciate ligament reconstruction: importance of femoral tunnel location on knee kinematics. *Am J Sports Med*. 2008;36(4):678-685.