Biomechanical Comparison of TightRope® SB Implant vs TightRope I and TightRope II Implants for Anterior Cruciate Ligament Reconstruction

Arthrex Research

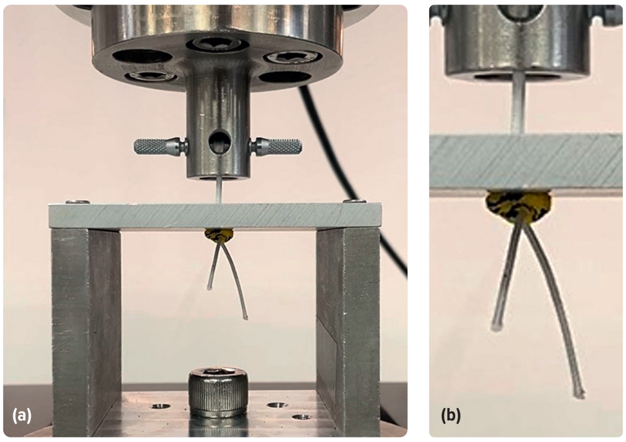
OBJECTIVE

The purpose of this study was to compare the biomechanical performance of the TightRope SB implant to the TightRope I and TightRope II implants for device-only testing following a model of simulated cyclic loading and load to failure for anterior cruciate ligament (ACL) reconstruction.[1] The study also compared specific outcomes to clinically relevant performance thresholds for successful ACL reconstruction, including less than 3 mm of cyclic displacement, greater than 454 N for ultimate load, and greater than 242 N/mm for stiffness.[2-4]

METHODS AND MATERIALS

Three adjustable loop devices (ALDs) were used for this experiment (n = 6, each): TightRope SB (TRSB) implant, TightRope I (TR I) implant, and TightRope II (TR II) implant. The test setup consisted of a box plate with a 6 mm-thick stainless steel plate and a 4 mm hole, replicating the cortex (Figure 1). A clevis and steel dowel pin (6 mm in diameter) were used to simulate the ACL graft. The box plate fixture was mounted to the base of an electromechanical materials testing system (Instron ElectroPuls E3000), and the clevis was mounted to a 5 kN load cell at the machine's actuator. After shuttling ALDs through the top plate and securing the principal loop through the dowel pin, the length was set to 25 mm to replicate a common bony tunnel length for ACL reconstruction.

Figure 1. Box fixture setup

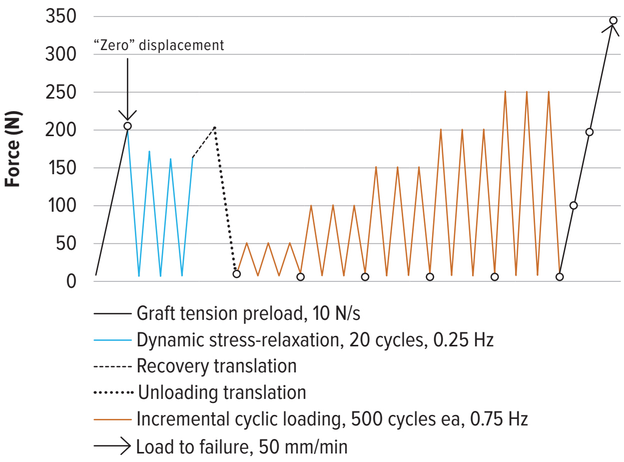


(a) TightRope SB implant shuttled through the top plate and into the clevis and pin.
(b) Close-up of the soft button bunched against the bottom of the top plate.

Biomechanical Testing

Devices were preconditioned at 80 N for 5 minutes to simulate graft pretensioning on a graft preparation board. After preconditioning, the actuator was returned to the initial gauge length, and a preload of approximately 10 N was applied. Constructs were then ramped to 200 N at 10 N/s to simulate a fully tightened ALD, and actuator displacement was zeroed (Figure 2).[5] Devices were subsequently precycled for 20 cycles, and the load was restored to 200 N to simulate passive intraoperative knee cycling followed by ALD retensioning. Cyclic loading was performed at 0.75 Hz for 500 cycles within each load range: 10-50 N, 10-100 N, 10-150 N, 10-200 N, and 10-250 N. The devices were then loaded to failure at 50 mm/min.

Figure 2. Biomechanical test methods



Analysis markers for data analysis are denoted as "o."

Data Analysis

Biomechanical outcomes included total cyclic displacement (mm), ultimate load (N), ultimate load energy (N*mm), linear stiffness (N/mm), and mode of failure. Total cyclic displacement was defined as the cumulative displacement at 10 N in the final cycle (cycle 2500). The ultimate load was defined as the highest recorded load prior to failure. The ultimate load energy was calculated as the integral work of the load-displacement curve from the initial 10 N load through the ultimate load in the load-to-failure step. Linear stiffness was defined as the slope of the best-fit line within the linear elastic region during load to failure, between 100 N and 200 N. Failure was defined as the moment when the load dropped to below 5 N.

Statistical Analysis

All analyses were performed in SigmaPlot (Version 14.0; Systat Software Inc). Based on an a priori power analysis, a sample size of 6 was deemed sufficient to achieve a power of 0.80 at $\alpha = .05$. A one-way analysis of variance (ANOVA) with a post-hoc Tukey test was applied to data that met normality (Shapiro-Wilk) and equal-variance (Brown-Forsythe) assumptions, whereas a Kruskal-Wallis ANOVA on ranks with a post-hoc Tukey test was used for data that did not meet normality assumptions. Additionally, one-sample, one-tailed t tests were performed to test each device's total cyclic displacement, ultimate load, and stiffness to the respective clinically relevant acceptance criteria of 3 mm, 454 N, and 242 N/mm, with one-sample signed-ranked tests applied when normality assumptions were violated.

RESULTS

Cyclic Elongation

The final cyclic displacement values (mean ± SD) for the TRSB, TR I, and TR II were 0.92 ± 0.13 mm, 0.70 ± 0.67 mm, and 0.40 ± 0.08 mm, respectively (Figure 3). All devices were significantly below the 3 mm threshold ($P = .031$ for the TR I and $P < .001$ for the TRSB and TR II). The TR II had less total cyclic elongation than the TRSB ($P = .034$).

Load to Failure

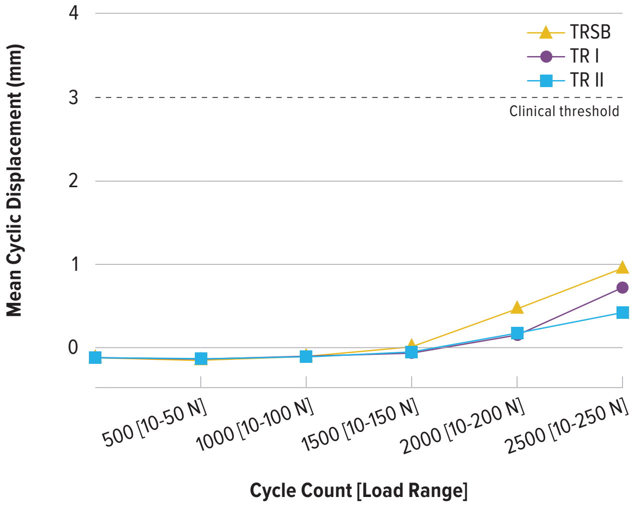
The mean ultimate load, ultimate load energy, and linear stiffness are presented in Figures 4-6 and Table 1. All devices were significantly stronger than the 454 N acceptance criteria ($P < .001$). The TRSB was stronger than the TR II ($P = .041$) and the TR I ($P < .001$), and the TR II was significantly stronger than the TR I ($P < .001$). The TRSB had significantly higher ultimate load energy than the TR II ($P = .012$) and the TR I ($P = .001$).

Regarding linear stiffness, all devices were significantly stiffer than the 242 N/mm acceptance criterion ($P < .001$). The TR II was stiffer than the TRSB ($P < .001$) and TR I ($P = .022$), and the TR I was stiffer than the TRSB ($P < .001$).

Mode of Failure

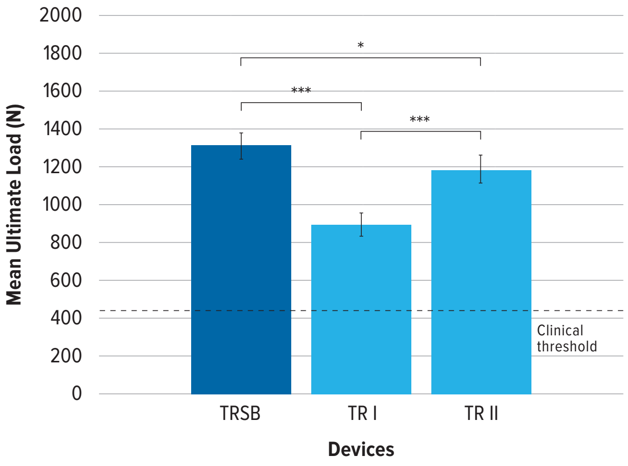
The primary failure modes were loop failure and splice failure at the button interface; Figure 7 details their occurrence per device, along with a visual representation of each. No devices failed due to the button pulling back through the drill hole.

Figure 3. Mean cyclic displacement plot



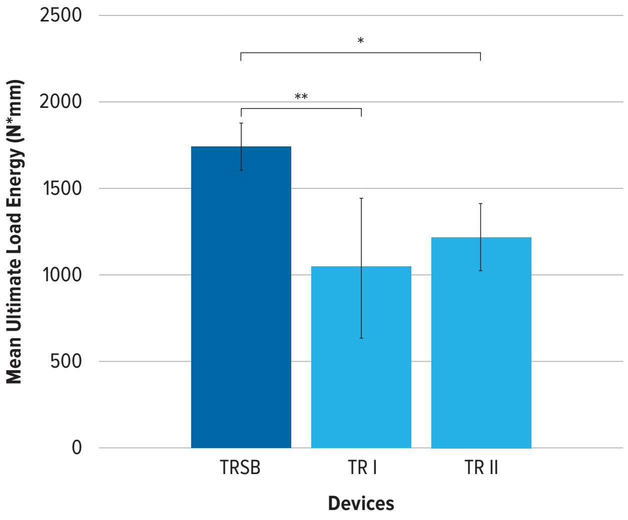
Specific cycle and load range intervals, along with the 3 mm clinical threshold, are shown, with all devices significantly below this threshold.[2]

Figure 4. Mean ultimate load bar graph



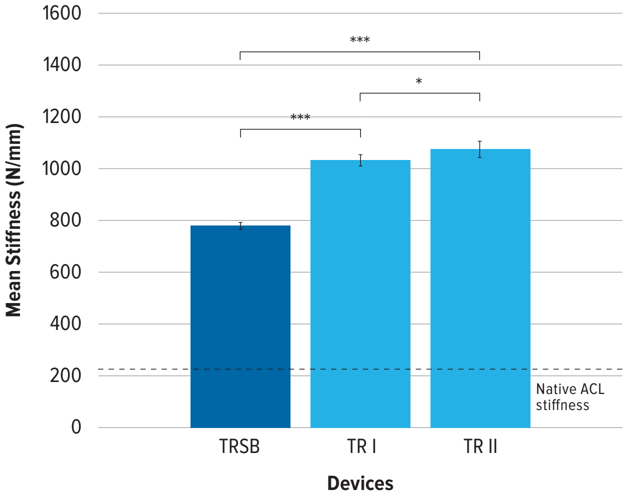
The clinical threshold of 454 N for ACL ultimate load during normal activity is shown, with all devices significantly above the threshold.[3] All values are shown as mean ± SD (*$P < .05$, ***$P < .001$).

Figure 5: Mean ultimate load energy bar graph



Values are shown as mean ± SD (*$P < .05$, **$P < .01$).

Figure 6. Mean linear stiffness bar graph

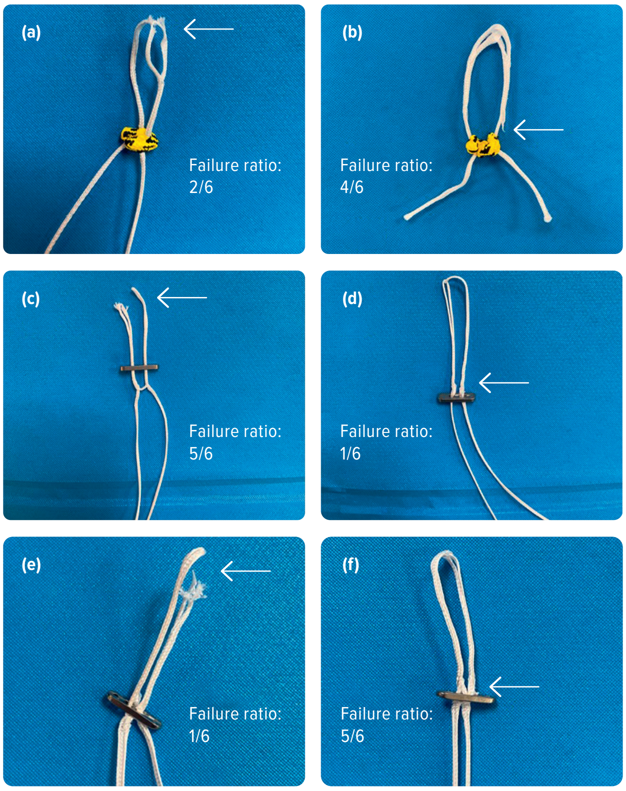


The clinical threshold of 242 N/mm for ACL stiffness is shown, with all devices significantly above this threshold.[4] All values are shown as mean ± SD ($^*P < .05$, $^{***}P < .001$).

Table 1: Load-to-failure outcome data (mean ± SD)

Device	Ultimate Load (N)	Ultimate Load Energy (N*mm)	Stiffness (N/mm)
TightRope® SB implant	1312 ± 80	1718 ± 145	771 ± 11
TightRope I implant	896 ± 71	1023 ± 386	1029 ± 23
TightRope II implant	1193 ± 79	1206 ± 199	1068 ± 29

Figure 7: Failure modes for adjustable loop devices with failure mode occurrence



Loop (left column) and splice (right column) failure modes are shown for the **(a/b)** TightRope SB implant, **(c/d)** TightRope I implant, and **(e/f)** TightRope II implant, with failure ratios indicating the occurrence of each failure mode per device and arrows indicating the failure location.

DISCUSSION

All ALDs remained significantly below the clinical threshold for cyclic displacement and significantly above the previously published native ACL complex's ultimate load and stiffness. Additionally, none of the soft or metal implants failed due to the button breaking or pulling back through the drill hole.

Anterior knee laxity exceeding 3 mm is commonly indicative of an ACL deficiency.[6] Therefore, ALDs were required to remain below this threshold during stepwise cyclic loading, which was performed to simulate repetitive loading during postoperative rehabilitation.[2] Additionally, prior studies have reported ACL ultimate load and stiffness under normal activities to be approximately 454 N and 242 N/mm, respectively.[3-4] Therefore, these values were used as minimum thresholds for ALD ultimate strength and stiffness, as devices must meet or exceed native ACL demands in the reconstructed state.

The findings demonstrate the TightRope SB implant's stability during simulated postoperative rehabilitation, evidenced by a cyclic elongation factor of safety (FoS) of 3.26, and its adequate strength to withstand physiological ACL forces during normal activity, evidenced by a FoS of 2.89 for ultimate load and 3.19 for stiffness. The greater ultimate load energy of the TightRope SB signifies its greater durability and resistance to catastrophic failure.

Overall, the results suggest that the TightRope SB implant provides ample graft fixation and protection, which may be particularly beneficial for tendon-to-bone healing and graft maturation. Additionally, the TightRope SB implant may be a desirable option from a clinical standpoint, as it may mitigate potential issues experienced with traditional metal button devices, such as soft-tissue irritation, hardware prominence, malpositioning, and metal sensitivity.[7-10]

CONCLUSION

All TightRope devices met and substantially exceeded the acceptance criteria for total cyclic displacement (less than 3 mm), ultimate load (greater than 454 N), and stiffness (greater than 242 N/mm), with the TightRope SB implant demonstrating superior ultimate load and ultimate load energy compared to the metal button implants. Although testing was device-only, the results suggest that the TightRope SB implant is a biomechanically viable alternative to preexisting generations of adjustable-loop cortical suspension devices for ACL reconstruction.

References

1. Arthrex, Inc. Data on file (APT-07399). Naples, FL; 2025.
2. Barrow AE, Pilia M, Guda T, Kadrmas WR, Burns TC. Femoral suspension devices for anterior cruciate ligament reconstruction: do adjustable loops lengthen? *Am J Sports Med.* 2014;42(2):343-349. doi:10.1177/0363546513507769
3. Noyes FR, Butler DL, Grood ES, Zernicke RF, Hefzy MS. Biomechanical analysis of human ligament grafts used in knee-ligament repairs and reconstructions. *J Bone Joint Surg Am.* 1984;66(3):344-352.
4. 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(3):217-225. doi:10.1177/036354659101900303
5. Smith PA, Piepenbrink M, Smith SK, Bachmaier S, Bedi A, Wijdicks CA. Adjustable- versus fixed-loop devices for femoral fixation in ACL reconstruction: an in vitro full-construct biomechanical study of surgical technique-based tibial fixation and graft preparation. *Orthop J Sports Med.* 2018;6(4):2325967118768743. doi:10.1177/2325967118768743
6. 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. doi:10.1177/036354658501300607
7. Richman EH, Hop JC, McGinley BM, et al. All-suture cortical button fixation in all-inside anterior cruciate ligament reconstruction with quadriceps tendon autograft. *Arthrosc Tech.* 2025;14(12):103956. doi:10.1016/j.eats.2025.103956
8. Taketomi S, Inui H, Hirota J, et al. Iliotibial band irritation caused by the EndoButton after anatomic double-bundle anterior cruciate ligament reconstruction: report of two cases. *Knee.* 2013;20(4):291-294. doi:10.1016/j.knee.2013.03.013
9. Tajima T, Hosoki M, Miyagi M, et al. Correlation between pierced earrings and the prevalence of metal allergies at Tokushima university hospital: a 15-year retrospective analysis. *Sci Rep.* 2025;15(1):10939. doi:10.1038/s41598-025-86868-1
10. Arthur J, Zale C, Zhou L, Bottoni CR, Gee SM. Anterior cruciate ligament reconstruction using femoral cortical button fixation: a case series of intraoperative malpositioning. *Orthop J Sports Med.* 2023;11(10):23259671231205926. doi:10.1177/23259671231205926