

Operative Performance of All-Inside GraftLink® ACL Reconstruction Using TightRope® II Implants

Arthrex Orthopedic Research

Background

Evolving adjustable-loop devices (ALDs) with the latest design innovations have fostered a resurgence of interest in their operational performance for anterior cruciate ligament reconstruction (ACLR). Currently, there is a paucity of data available on the loop shortening and stabilization behavior of all-inside ACLR using TightRope II implants.

Purpose / Hypothesis

This study compares the all-inside ACLR graft tensioning and elongation behavior with femoral knotless TightRope II implant fixation to fully knotted TightRope I constructs. It was hypothesized that TightRope II implant suspension would provide similar graft tensioning behavior to the TightRope implant, and cyclic testing with complete unloading would result in less elongation for the femoral knotless TightRope II construct.

Material and Methods

Test Groups

A femoral knotless all-inside construct with the TightRope II implant (group 1) suspension was tested and compared to a fully knotted TightRope I implant (group 2) configuration (Figure 1). For each test group, 8 samples were tested. Fresh porcine tibias (age 6 months) and a femoral-sided acrylic block were used as human bone substitutes for full-construct testing. All tibias were prepared with a 9 mm-diameter, 25 mm-length graft tunnel using a cannulated drill over a 4 mm spade-tipped guide pin, leaving a 15 mm bone bridge (Figure 1B). Bovine flexor tendon grafts were harvested from adult bovine hind limbs. For all groups, tendons with 9 mm quadrupled graft diameter measured with a graft sizing block and an overall length of 70 mm were prepared according to all-inside reconstruction

surgical technique guidelines [SurgTech]. Tendons and porcine tibias were stored at -20 °C and thawed at room temperature for 2 hours and overnight, respectively, before biomechanical testing. All specimens were kept moist with physiological saline solution during specimen preparation and testing.

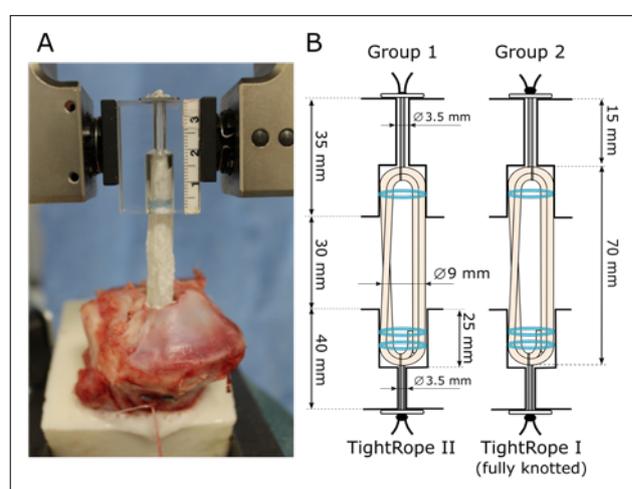


Figure 1. Experimental setup (A) with schematic illustration of bone tunnel and graft-related definitions (B)

Construct Fixation

All grafts from both groups were preloaded at 80 N for 5 minutes before testing to allow stress relaxation. The tibia and the acrylic block were secured to the base plate and actuator of a dynamic testing machine (ElectroPuls E10000, Instron, Norwood, MA) using custom clamps (Figure 1A). Tensile load was applied on the entire ACL graft construct. An ACL length over flexion angle relation was used to transfer the in vivo ACL kinematics during weight-bearing knee flexion in a unidirectional motion to allow for incorporation into the test methodology. It was found that the ACL

experiences consistent length decreases of 1 mm and 3 mm at 30° and 90°, respectively, during flexion activity starting from full extension.¹ In our knee model, a joint space of 30 mm represents a knee in full extension and a 29 mm joint space represents a knee in 30° of flexion. Graft insertion was performed at a position replicating 30° of knee-angle flexion (29 mm joint space) by the ALD passing through the tibia and the (femoral-sided) acrylic block. The button of the femoral ALD was flipped and the ABS button attached to the tibial ALD. All passing sutures were removed. The femoral ALD was manually adjusted by alternating pulling on the shortening strands to allow graft tunnel docking. According to the native ACL behavior, the transition from a strained to an unstrained ACL occurs around 30° of flexion angle during active motion. The simulated 30° knee flexion position served as reference for later elongation analysis between the groups and the native ACL.

Biomechanical Testing

Graft tensiing was performed with the tibial-sided ALD at 30 mm joint space, simulating a fully extended knee. Graft tensiing was performed manually by

alternating pulling on the shortening strands in line with the actuator axis at 6 different load levels (100 N, 150 N, 200 N, 250 N, 300 N, and 350 N) with residual graft tension measured after traction release by the test machine. After final tensiing, all tibial and femoral TRI devices were knotted with 4 half-hitch suture knots. Cyclic peak loading was performed in force-control mode and started at 50 N over 500 cycles with a test frequency of 0.75 Hz. Peak loading was then increased in 50 N increments every 500 cycles up to 300 N for a total of 3000 cycles. The valley elongation of each load cycle was defined in position control mode relative to the peak elongation with an actuator translation of 3 mm. Actuator translation relative to the peak elongation provided for a complete unloading-loading situation at all load levels and represented the most suitable mechanical testing conditions to prove the fixation stability of the friction-based ALD retention mechanism. Metrics for primary outcome comparison of the tensiing and stability testing included residual graft tension (Figure 2, c, e, g, i, k, and m), total elongation (Δa_t), ultimate load, and stiffness. The total elongation quantified the final graft loading situation at 10 N relative to the reference position (simulated 30° flexion angle).

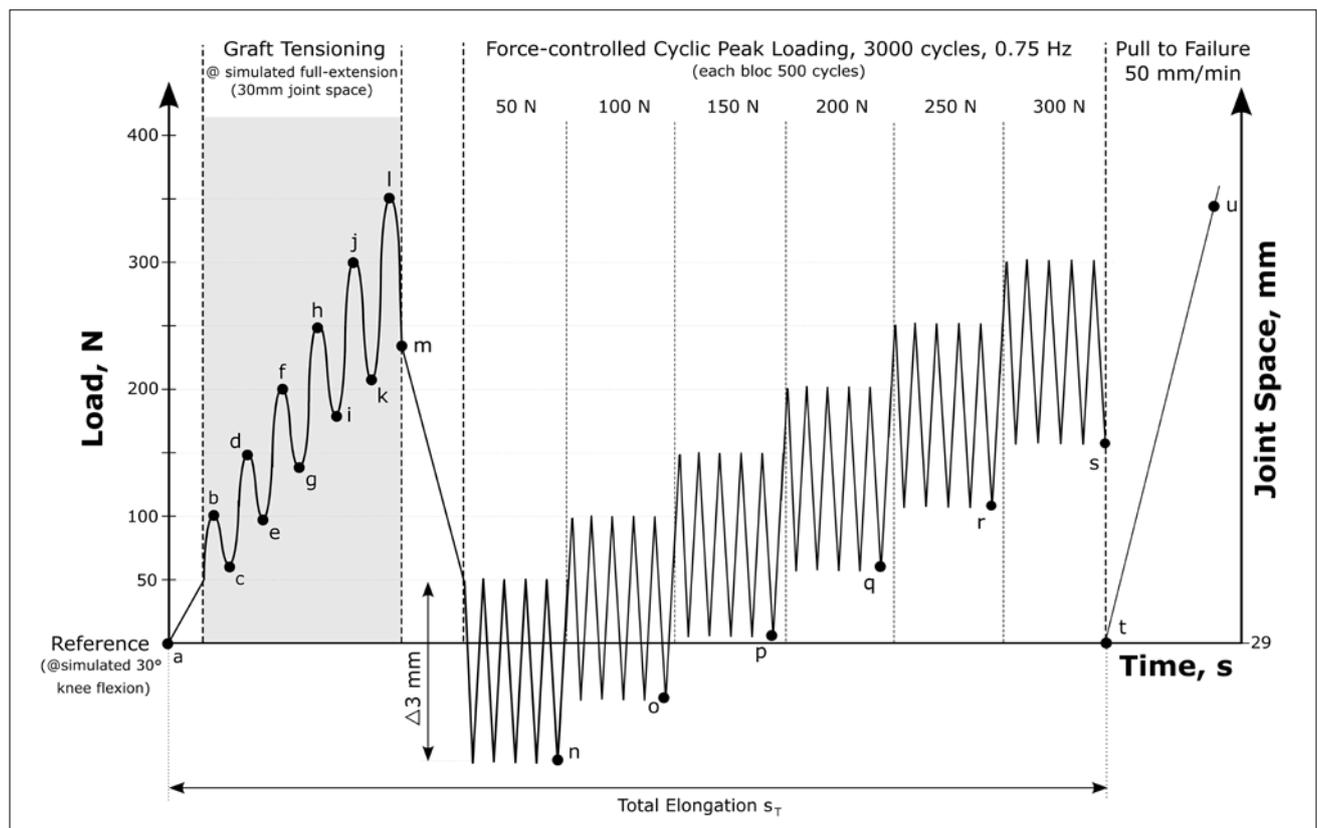


Figure 2. Test methodology with graft tensiing, cyclic and pull-to-failure loading protocol

Ultimate load was determined during pull-to-failure with the mechanism of failure noted. Groupwise statistical analysis was performed using Sigma Plot Statistics for Windows, version 13.0 (Systat Software, San Jose, CA) using a 2-tailed Student t-test. The significance level was set at $P < .05$. Load-displacement data during cycling and pull-to-failure were recorded using WaveMatrix software (Instron, Norwood, MA, USA) with a sampling rate of 750 Hz and a translational accuracy of test machine actuator below 0.01 mm.

Results

Alternating pulling on the shortening strands showed a similar graft tensening behavior between TightRope® II and TightRope I constructs without significance at any applied traction level. Linear regression analysis of combined tensening data provided a linear gradient of 1.47 with an accuracy of $R^2 > 0.98$ (Figure 3).

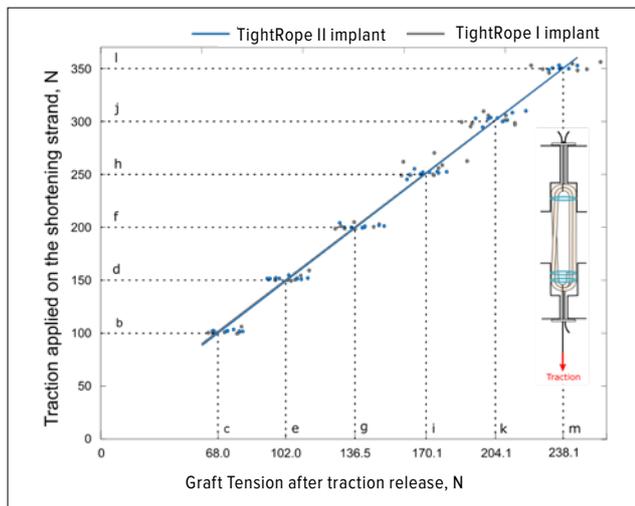


Figure 3. Linear regression analysis of the tensening data over all traction levels

The total elongation at the end of testing showed significantly lower elongation ($p = 0.002$ for the TightRope II implant group (0.36 ± 0.31 mm) compared to the TightRope I implant group (1.02 ± 0.37 mm). The final loading situations of both groups were in line with the functional behavior of the native ACL (Figure 4).

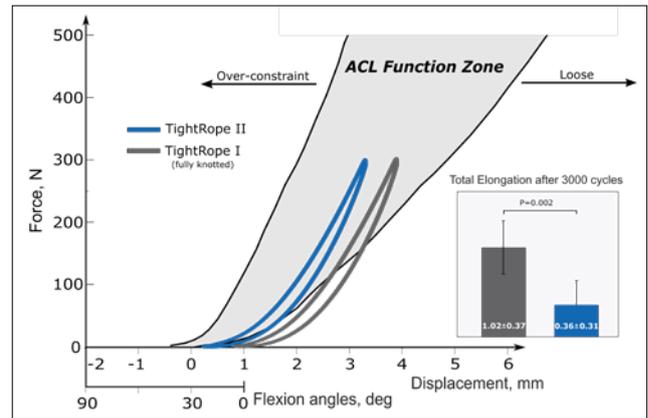


Figure 4. Final loading situation at the end of testing with significantly less elongation for TightRope II constructs in reference to the native ACL behavior¹

None of the specimens failed during cyclic testing. Therefore, all constructs were subjected to a final load-to-failure test. The TightRope II implant group revealed significantly higher ultimate failure load (1024.1 ± 78.6 N versus 892.2 ± 46.6 N) and stiffness (160.5 ± 5.9 N / mm versus 151.1 ± 3.1 N / mm) than the TightRope I implant group (Figure 5). The common mode of failure for both groups was suture tearing of the ALD.

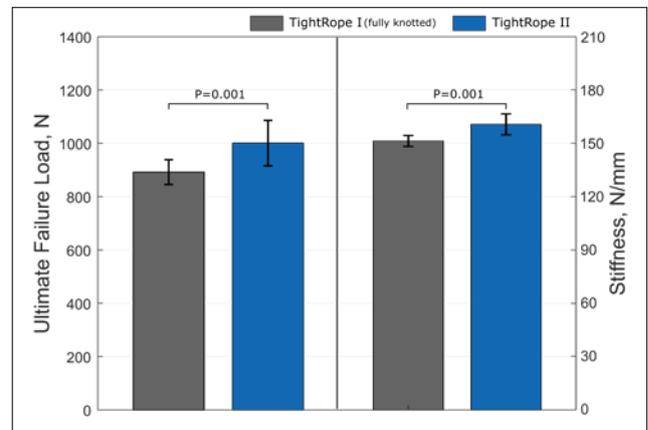


Figure 5. Ultimate failure load and stiffness test results

Conclusion

The overall behavior of all-inside ACLR graft tensioning with TightRope® II fixation was similar to TightRope I constructs. ALD retensioning at the highest applied traction level (350 N) led to a residual graft tension of about 238 N before cyclic loading. Repetitive graft unloading-loading situations at various load levels up to 300 N represented the most suitable testing conditions to prove the fixation stability of the knotless TightRope II implant friction-based dual-locking mechanism. Cyclic loading of the all-inside ACLR construct with the knotless TightRope II implant was able to achieve significantly lower total elongation ($p = 0.001$) compared to a fully knotted TightRope I implant configuration. The relation of flexion angle and ACL length during active knee flexion activity was used to compare the final graft loading situation to the functional behavior of the native ACL. The loading capability of both all-inside ACL constructs complied with the native ACL functional behavior. The clinical relevance of avoiding an additional suture knot stack, especially on the femoral side, may simplify the intraoperative workflow and reduce postoperative knot irritation. Actual test results demonstrated the necessary time-zero biomechanical properties of the TightRope II device with regard to ultimate failure strength, displacement, and stiffness for soft-tissue graft fixation in all-inside ACLR.

Summary

All-inside ACLR using TightRope II implants provides similar graft tensioning behavior compared to TightRope I implants. A knotless TightRope II construct provided higher stabilization compared to a knotted TightRope I construct with significantly increased ultimate failure load and stiffness with reduced total elongation, complying with the native ACL function zone.

Reference

1. Bachmaier S, Smith PA, Bley J, Wijdicks CA. Independent suture tape reinforcement of small and standard diameter grafts for anterior cruciate ligament reconstruction: a biomechanical full construct model. *Arthroscopy*. 2018;34(2):490-499. doi:10.1016/j.arthro.2017.10.037