The ACL TightRope family of implants has a long clinical history of over 9 years and 1.5 Million implantations. This update summarizes the published biomechanical and clinical ACL studies for ACL TightRope.
In Vivo Citations – Clinical Outcomes


- Adjustable-loop suspension does not clinically loosen after ACL reconstruction.
- There was no significant difference in postoperative knee stability or graft failure rate between adjustable-loop and fixed-loop femoral cortical suspension in patients undergoing primary ACL reconstruction.


- An all-inside, physeal-sparing ACL reconstruction technique using hamstring autograft demonstrates excellent subjective and objective clinical outcomes in skeletally immature athletes without growth disturbance.


- The results show that postoperative pain, knee stability, ranges of motion, and transplant positioning were slightly better with the all-inside technique.
- The all-inside technique can be considered a valid, reliable procedure with very good results for pain, stability, and knee function. It is a promising option for minimally invasive ACL reconstruction.


- Reports suggest similar results in the early postoperative period when compared with traditional techniques.
- All-inside techniques offer the advantages of improved cosmesis, less postoperative pain, decreased bone removal, and gracilis preservation.


- All-inside ACL reconstruction using the GraftLink® technique leads to improved functional outcomes in active patients at a minimum follow-up of 2 years.
- No difference was noted in stability between the ACL-reconstructed and the contralateral normal knee at 2 years.


- Two-year outcomes of 108 patients treated with ACL reconstruction using the GraftLink technique (FlipCutter® reamer, ACL TightRope® implant, and quadrupled semitendinosus autograft) are reported.
- The GraftLink technique demonstrates good short- to medium-term subjective and objective outcomes with low complication and failure rate.
In Vitro Citations – Biomechanical Validation


- Biomechanical evaluation of 3 ACLR techniques using suspensory femoral fixation and interference screw tibial fixation. The groups were: group 1: adjustable loop (ALD) and screw; group 2: preconditioned adjustable loop (ALD) and screw; and group 3: closed loop (CLD) and screw.
- Surgical placement of an interference screw imparted a time-zero laxity of 0.53 mm and loss of tension (62%).
- The operating characteristics of the TightRope® implant allow for restoration of screw-induced graft slackening and optimizing tension. This was not possible with a fixed-loop device (Endobutton™). Total elongation varied across groups, with group 2 (preconditioned ALD) showing the least elongation (group 1: 2.22 ± 0.52; group 2: 0.65 ± 0.29; and group 3: 1.79 ± 0.28).
- ACLR with femoral TightRope fixation and intraoperative preconditioning allows for the restoration of time-zero screw-imparted slack and leads to significantly reduced cyclic elongation in accordance with native ACL function.


- This was the first study to test biomechanical strength of the entire graft construct with an expanded cycling protocol.
- The largest pull-to-failure force was observed for the TightRope implant/GraftLink® technique construct, which was statistically significantly different than all other devices.
- The ACL TightRope implant was the only device that was effectively retensioned.
- Elongation with the ACL TightRope implant construct was comparable to fixed-loop devices.
- The GraftMax™ button exceeded maximum elongation limits for ACL reconstruction.
- The Ultrabutton™ adjustable fixation device lost the greatest amount of force during cycling.


- Fixed- and adjustable-loop buttons were tested on metaphyseal bone. This type of testing is much more relevant than pure mechanical testing which doesn’t take in vivo conditions (bone, tissue, button position, etc) into consideration.
- The ACL TightRope implant was biomechanically equivalent to fixed-loop button fixation, whereas the Ziploop™ showed statistically significantly lower stiffness and more displacement during cycling.


- An ACL TightRope implant was tested against Endobutton (fixed loop) in a device-only model as well as in biomechanical model.
- There were no significant differences in terms of total displacement, temporal pattern of displacement, or ultimate failure load between the devices.

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**In Vitro Citations – Biomechanical Validation cont’d**


- The TightRope® implant with retensioning increases the ultimate strength (1020 N), reduces the cyclic displacement to 1.81 ± 0.51 mm, and is placed in the sub-2 mm category with fixed-loop devices.


- All-inside GraftLink® continuous-loop soft-tissue graft with TightRope suspensory fixation provided adequate strength for tibial fixation in ACL reconstruction and is superior to interference screw fixation.


- The TightRope implant has 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.
- Ultimate failure strength was greater than the previously reported strength needed for activities of daily living and rehabilitation exercises.
- The TightRope construct reapproximated the native stiffness of the ACL.


- ACL TightRope implants without retensioning were within 0.4 mm of Endobutton devices. This difference was deemed not clinically significant by the authors ($P = .101$).
- Retensioned and knotted ACL TightRope implants displaced less than all other groups, including Endobutton devices. Ultimate loads were similar.
- Retensioned and knotted ACL TightRope implants showed the lowest cyclic displacement. However, all displacements were within a fraction of a millimeter, so there is likely no clinical importance.
In Vitro Citations – Biomechanical Validation


- While the cause of the error is unknown, possible hypotheses are improper loading of the device, improper manipulation of the device, and/or poor calibration of their testing machine.


- Grafts only pretensioned to 11 lb (50 N) for 5 minutes. Arthrex GraftLink® technique pretensions grafts to 20 lb (80 N) on the GraftPro® board. Once implanted, grafts can be tensioned and retensioned after cycling, which would eliminate the first 2 stages of displacement, and bring the total GraftLink technique displacement to 3 mm.
- Graft was prepared insufficiently. Only 3 passes of FiberLoop® suture were used and they were not retained for backup.

*Endobutton is a registered trademark of Smith & Nephew.
†GraftMax is a registered trademark of ConMed.
‡Ultrabutton is a registered trademark of Smith & Nephew.
§Ziploop is a registered trademark of Zimmer Biomet.

Reference