

ACL TightRope® Implant Scientific Update

The TightRope® implant, which has been used in 2 million procedures globally,¹ simplifies ACL reconstruction and facilitates advanced techniques such as the GraftLink® technique. This update summarizes the published biomechanical and clinical ACL studies for the ACL TightRope implant.

In Vivo Citations – Clinical Outcomes

Ranjan R,
Gaba S,
Goel L,
et al

[In vivo comparison of a fixed loop \(EndoButton CL\) with an adjustable loop \(TightRope RT\) device for femoral fixation of the graft in ACL reconstruction: a prospective randomized study and a literature review.](#) *J Orthop Surg (Hong Kong)*. 2018;26(3):2309499018799787. doi:10.1177/2309499018799787.

- IKDC and Lysholm scores, knee stability by AP laxity, and SSD using KT-1000 were used to determine functional outcomes between TightRope® (TR) and EndoButton (EB) during ACL reconstruction.
- Knee stability and SSD were statistically insignificant between the two groups at both 6 months and 2 years. At final follow-up (2 years), the IKDC and Lysholm results between TR and EB were similar, however at 6 months the EB appeared to be better.
- ACL reconstruction with either TR or EB for femoral fixation “gives substantially equivalent functional results and knee stability at mid-term follow-up.”

Onggo JR,
Nambiar M,
Pai V

[Fixed- versus adjustable-loop devices for femoral fixation in anterior cruciate ligament reconstruction: a systematic review.](#) *Arthroscopy*. 2019;35(8):2484-2498. doi:10.1016/j.arthro.2019.02.029.

- A multidatabase search was performed in July 2018 according to PRISMA guidelines. Articles directly comparing fixed-loop devices (FLDs) and adjustable-loop devices (ALDs) were included.
- Thirteen biomechanical, 2 prospective, and 6 retrospective studies were included. Clinical studies showed no statistically significant differences in clinical, functional, radiologic, and complication outcomes between the two groups.
- FLDs and ALDs produced similar clinical outcome scores and graft re-rupture rates. “Biomechanical outcomes were improved with retensioning of ALDs after tibial fixation, as per manufacturer recommendations.”

Boyle MJ,
Vovos TJ,
Walker CG,
Stabile KJ,
Roth JM,
Garrett WE, Jr

[Does adjustable-loop femoral cortical suspension loosen after anterior cruciate ligament reconstruction? A retrospective comparative study.](#) *Knee*. 2015;22(4): 304-308. doi:10.1016/j.knee.2015.04.016.

- 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.



Benea H,
d'Astorg H,
Klouche S,
Bauer T,
Tomoia G,
Hardy P

[Pain evaluation after all-inside anterior cruciate ligament reconstruction and short term functional results of a prospective randomized study.](#) *Knee.* 2014;21(1):102-106. doi:10.1016/j.knee.2013.09.006.

- 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.

Blackman AJ,
Stuart MJ

[All-inside anterior cruciate ligament reconstruction.](#) *J Knee Surg.* 2014;27(5):347-352. doi:10.1055/s-0034-1381960.

- 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.

Schurz M,
Tiefenboeck TM,
Winnisch M,
et al

[Clinical and functional outcome of all-inside anterior cruciate ligament reconstruction at a minimum of 2 years' follow-up.](#) *Arthroscopy.* 2016;32(2):332-337. doi:10.1016/j.arthro.2015.08.014.

- 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.

Yasen SK,
Borton ZM,
Eyre-Brook AI,
et al

[Clinical outcomes of anatomic, all-inside, anterior cruciate ligament \(ACL\) reconstruction.](#) *Knee.* 2017;24(1):55-62. doi:10.1016/j.knee.2016.09.007.

- 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 rates.

In Vitro Citations – Biomechanical Validation

Monaco E,
Bachmaier S,
Fabbri M,
Lanzetti RM,
Wijdicks CA,
Ferretti A

[Intraoperative workflow for all-inside anterior cruciate ligament reconstruction: an in vitro biomechanical evaluation of preconditioning and knot tying.](#) *Arthroscopy.* 2018;34(2):538-545. doi:10.1016/j.arthro.2017.08.283.

- Four all-inside ACL reconstruction groups were evaluated. Groups included one or both sides knotted and with and without intraoperative preconditioning.
- Initial graft tension is increased with intraoperative preconditioning in single-side knotted and both-side knotted groups versus without preconditioning. Furthermore, dynamic elongation is reduced for single-side knotted and both-side knotted constructs.
- “All-inside ACL reconstruction with preconditioning according to intraoperative workflow leads to a statistically significant improved mechanical behavior and may allow for optimizing initial graft tension and elongation for all-inside ACL reconstruction to reduce knee laxity.”



Noonan BC,
Bachmaier S,
Wijdicks CA,
Bedi A

[Intraoperative preconditioning of fixed and adjustable loop suspensory anterior cruciate ligament reconstruction with tibial screw fixation – an in vitro biomechanical evaluation using a porcine model.](#) *Arthroscopy.* 2018;34(9):2668-2674. doi:10.1016/j.arthro.2018.04.014.

- 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.

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.

- 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 is 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.

Nye DD,
Mitchell WR,
Liu W,
Ostrand RV

[Biomechanical comparison of fixed-loop and adjustable-loop cortical suspensory devices for metaphyseal femoral-sided soft tissue graft fixation in anatomic anterior cruciate ligament reconstruction using a porcine model.](#) *Arthroscopy.* 2017;33(6):1225-1232.e1. doi:10.1016/j.arthro.2016.12.014.

- 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.



Chang MJ,
Bae TS,
Moon YW,
Ahn JH,
Wang JH

[A comparative biomechanical study of femoral cortical suspension devices for soft-tissue anterior cruciate ligament reconstruction: adjustable-length loop versus fixed-length loop.](#) *Arthroscopy*. 2018;34(2):566-572. doi:10.1016/j.arthro.2017.08.294.

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

Johnson JS,
Smith SD,
LaPrade CM,
Turnbull TL,
LaPrade RF,
Wijdicks CA

[A biomechanical comparison of femoral cortical suspension devices for soft tissue anterior cruciate ligament reconstruction under high loads.](#) *Am J Sports Med*. 2015;43(1):154-160. doi:10.1177/0363546514553779.

- 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.

Smith PA,
DeBerardino TM

[Tibial fixation properties of a continuous-loop ACL hamstring graft construct with suspensory fixation in porcine bone.](#) *J Knee Surg*. 2015;28(6):506-512. doi:10.1055/s-0034-1394167.

- 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.

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. doi:10.1177/0363546512469875.

- 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 implant construct reapproximated the native stiffness of the ACL.

Noonan BC,
Dines JS,
Allen AA,
Altchek DW,
Bedi A

[Biomechanical evaluation of an adjustable loop suspensory anterior cruciate ligament reconstruction fixation device: the value of retensioning and knot tying.](#) *Arthroscopy*. 2016;32(10):2050-2059. doi:10.1016/j.arthro.2016.02.010.

- ACL TightRope® RT implants were tested against the Endobutton device using an expanded cycling protocol similar to previous studies (Barrow et al, *Am J Sports Med*. 2014;42(2):343-349; Johnson et al, *Am J Sports Med*. 2015;43(1):154-160). ACL TightRope implants were tested without retensioning, with retensioning, with knotted shortening strands, and with retensioning plus knotted shortening strands.
- 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.



Kusano M,
Kazui A,
Uchida R,
Mae T,
Tsuda T,
Toritsuka Y

[Loop length change of an adjustable-length femoral cortical suspension device in anatomic rectangular tunnel anterior cruciate ligament reconstruction with a bone-patellar tendon-bone graft and associated clinical outcomes.](#) *Arthroscopy*. 2018;34(11):3063-3070. doi.org/10.1016/j.arthro.2018.06.034.

- This clinical study evaluated ACL reconstruction with a BTB graft fixed using a BTB TightRope implant.
- The loop length of the BTB TightRope implant was measured by CT at 1 and 12 weeks after the surgery. Subjective and objective outcomes scores were also assessed at 2 years postoperatively.
- The loop length change of the BTB TightRope implant was negligible at 12 weeks. At 2 years postoperatively, 98% of patients were graded as normal or nearly normal according to IKDC with side-to-side difference of 0.2 mm.

Uchida R,
Nakamura N,
Suzuki T,
et al

[Excellent bone plug-socket integration at 8 weeks after anterior cruciate ligament reconstruction using an adjustable-length loop cortical fixation device.](#) *J ISAKOS*. 2019;4(1):9-14. doi:10.1136/jisakow-2018-000244.

- This clinical study evaluated bone plug-socket integration in ACL reconstructions using the BTB TightRope implant.
- Twenty patients with BTB TightRope implants underwent CT at 4 and 8 weeks postoperatively for assessment of the union between the graft and socket wall. Patients were also evaluated at 2 years using IKDC and KT-2000 knee stability measurement.
- Excellent bone integration was observed at 8 weeks. All knees were rated normal or nearly normal according to IKDC with a mean side-to-side difference of 0.2 mm. Adjustable-length loop cortical fixation devices could be safely applied for anatomic rectangular tunnel (ART) ACL reconstruction.

Mickelson DT,
Lefebvre T,
Gall K,
Riboh JC

[Adjustable-loop femoral cortical suspensory fixation for patellar tendon anterior cruciate ligament reconstruction: a time zero biomechanical comparison with interference screw fixation.](#) *Am J Sports Med*. 2018;46(8):1857-1862. doi.org/10.1177/0363546518771365.

- This biomechanical study compared BTB TightRope® implants and metallic interference screws in an ACL reconstruction.
- Human BTB grafts were fixated into porcine femurs with a BTB TightRope implant or metallic interference screw and biomechanically tested.
- Authors compared time zero biomechanical properties between metallic interference screws and ALCFD for femoral fixation of bone-tendon-bone grafts in ACL-R.
- The ALCFD and interference screws were divided into two groups (8 samples each) and human bone-tendon-bone allografts were fixated in porcine distal femurs. The constructs were preconditioned and subjected to cyclic loading before being pulled to failure.
- The loads to failure (mean \pm SD, 700 \pm 256 N vs 688 \pm 215 N, $P = .92$) and linear stiffness (219 \pm 48 N/mm vs 218 \pm 49 N/mm, $P = .97$) were not significantly different between the ALCFD and interference screw groups, respectively. The authors concluded that adjustable-loop devices are acceptable alternatives to an interference screw for femoral fixation during ACL-R with BTB grafts.



Barrow AE,
Pilia M,
Guda T,
Kadmas WR,
Burns TC

Mayr R,
Heinrichs CH,
Eichinger M,
Coppola C,
Schmoelz W,
Attal R

(Misleading Literature) In Vitro Citations – Biomechanical Validation

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.

- See DeBerardino TM, Smith PA, Cook JL. Femoral suspension devices for anterior cruciate ligament reconstruction: letter to the editor. *Am J Sports Med.* 2014;42(2):NP15-6.
- 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.

Biomechanical comparison of 2 anterior cruciate ligament graft preparation techniques for tibial fixation: adjustable-length loop cortical button or interference screw. *Am J Sports Med.* 2015;43(6):1380-1385. doi:10.1177/0363546515574062.

- 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

1. Arthrex, Inc. Data on file (as of July 10, 2018). Naples, FL; 2018.