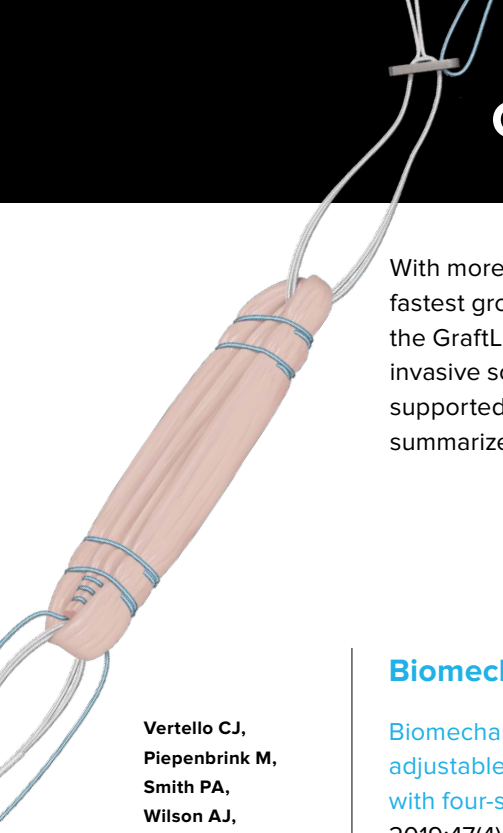
GraftLink® Technique Scientific Update



With more than 7 years of clinical history, the GraftLink technique continues to be one of the fastest growing ACL reconstruction techniques performed worldwide. The clinical benefits of the GraftLink technique — including single-hamstring harvest, larger graft diameter, minimally invasive sockets, and strong, adjustable cortical fixation on the femur and tibia — are now supported in a number of biomechanical and clinical studies. The following document summarizes articles supporting successful outcomes with the GraftLink technique.

Biomechanical Strength

Vertello CJ, Piepenbrink M, Smith PA, Wilson AJ, Wijdicks CA

Biomechanical testing of three alternative quadrupled tendon graft constructs with adjustable loop suspensory fixation for anterior cruciate ligament reconstruction compared with four-strand grafts fixed with screws and femoral fixed loop devices. *Am J Sports Med.* 2019;47(4):828-836. doi.org/10.1177/0363546518825256

- A biomechanical study comparing 3 all-inside GraftLink technique configurations with a technique using a femoral fixed-loop suspensory device and tibial screw ("button and screw technique").
- The 3 GraftLink constructs exhibited small yet statistically significant biomechanical differences among each other. "Constructs that used tibial screw fixation had lower ultimate failure load and higher total elongation compared with the quadrupled tendon constructs."
- Using adjustable, retensionable suspensory fixation devices on both the femur and tibia offers improved biomechanical performance compared to a femoral fixed-loop device and tibial screw.

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 – adjustable-loop device (ALD) without intraoperative preconditioning (group 1), ALD with intraoperative preconditioning (group 2), and continuous-loop device (group 3) – using suspensory femoral fixation and interference screw tibial fixation.
- 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."

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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 TR, 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.
- GraftMax™† button (ConMed) exceeded maximum elongation limits for ACL reconstruction.
- Ultrabutton‡ (S&N) adjustable fixation device lost the greatest amount of force during cycling.

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 fixation provided adequate strength for tibial fixation in ACL reconstruction. The GraftLink construct had a significantly higher load to failure compared to interference screws with comparable cyclic loading.

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

- A 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.

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Clinical Results

Putnis S, Neri T, Grasso S, Linklater J, Fritsch B, Parker D

ACL hamstring grafts fixed using adjustable cortical suspension in both the femur and tibia demonstrate healing and integration on MRI at one year. *Knee Surg Sports Traumatol Arthrosc.* 2020;28(3):906-914. doi:10.1007/s00167-019-05556-6

- Clinical study that evaluated healing and integration of hamstring grafts with TightRope® implant in ACL reconstructions.
- Two hundred thirty-three patients were analyzed for graft failure rate and subjective IKDC, Tegner and Lysholm scores, and MRI imaging.
- "Significant improvements were seen in all clinical scores ($p < 0.001$). MRI analysis showed 71% with fully integrated grafts in the tibia and 24% in the femur, with the remainder all showing greater than 50% integration."

Kouloumentas P, Kavroudakis E, Charalampidis E, Kavroudakis D, Triantafyllopoulos GK

Superior knee flexor strength at 2 years with all-inside short-graft anterior cruciate ligament reconstruction vs a conventional hamstring technique. *Knee Surg Sports Traumatol Arthrosc.* 2019;27(11):3592-3598. doi:10.1007/s00167/019/05456-9

- Prospective clinical study of 90 patients comparing all-inside ACL reconstruction with a semitendinosus tendon autograft and TightRope implant on both the femur and tibia (GraftLink technique) (45) to the "conventional technique" of semitendinosus/gracilis autograft with a TightRope implant on the femur and an interference screw on the tibia (45). Two-year outcomes were compared using knee scores, knee stability testing, and isokinetic testing.
- Results showed similar knee scores and stability but a significant difference in flexor muscle strength with the all-inside (GraftLink technique) group at 2 years post-op.
- All-inside ACL reconstruction is a viable technique that also "provides an advantage over ACL reconstruction with an ST/G graft in terms of improved knee flexion strength at higher angular velocities."

Monaco E, Fabbri M, Redler A, et al

Anterior cruciate ligament reconstruction is associated with greater tibial tunnel widening when using a bioabsorbable screw compared to an all-inside technique with suspensory fixation [published online November 7, 2018]. *Knee Surg Sports Traumatol Arthrosc.* 2019;27(8):2577-2584. doi:10.1007/s00167-018-5275-x

- This comparative study evaluated clinical outcomes and tunnel widening for 44 patients following anterior cruciate ligament reconstruction (ACLR) performed with an all-inside technique (Group A) or a bioabsorbable tibial screw and suspensory femoral fixation (Group B).
- There were no significant differences in clinical outcome measures or femoral tunnel widening between the 'all-inside' (Group A) or 'button and screw' constructs (Group B). However, there was a significantly larger increase in tibial tunnel widening, at both the middle and articular portions, in Group B.
- These findings suggest that 'button and screw' constructs (Group B) result in significantly greater tibial tunnel widening when compared to 'all-inside' constructs (Group A). This is clinically relevant to rebut concerns arising from biomechanical studies regarding the possibility of increased tunnel widening with an 'all-inside' technique.

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Benea H, d'Astorg H, Klouche S, Bauer T, Tomoaia 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, range of motion, and transplant positioning were slightly better using the all-inside technique.
- The all-inside technique, which is a promising option for minimally invasive ACLR, can be considered a "reliable procedure with very good results for pain, stability, and knee function."

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."
- "Current 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 contralateral normal knee at 2 years.

Lubowitz JH, Schwartzberg R, Smith P

Cortical suspensory button versus aperture interference screw fixation for knee anterior cruciate ligament soft-tissue allograft: a prospective, randomized controlled trial. *Arthroscopy.* 2015;31(9):1733-1739. doi:10.1016/j.arthro.2015.03.006

- Radiographs did not show significant tunnel widening of suspensory fixation versus interference screw fixation.
- "Our results show no significant differences in knee AP stability or other outcomes comparing all-inside ACL allograft reconstruction using aperture fixation and all-inside ACL allograft reconstruction using suspensory fixation."

Lopes R, Klouche S, Odri G, Grimaud O, Lanternier H, Hardy P

Does retrograde tibial tunnel drilling decrease subchondral bone lesions during ACL reconstruction? A prospective trial comparing retrograde to antegrade technique. *Knee.* 2016;23(1):111-115. doi:10.1016/j.knee.2015.09.010

- Retrograde drilling (FlipCutter® reamer) of the tibia resulted in less bone edema, and subsequent pain, than the antegrade drilling with standard cannulated reamers.

Lubowitz JH, Schwartzberg R, Smith P, et al

Randomized controlled trial comparing all-inside anterior cruciate ligament reconstruction technique with anterior cruciate ligament reconstruction with a full tibial tunnel. *Arthroscopy.* 2013;29(7):1195-1200. doi:10.1016/j.arthro.2013.04.009

- All-inside ACL reconstruction resulted in less postoperative pain and similar clinical outcomes compared with a full-tunnel technique.

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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).
- The GraftLink technique demonstrated good medium-term subjective and objective outcomes with a low complication and failure rate.

Graft Incorporation and Histology

Smith PA, Stannard JP, Pfeiffer FM, Kuroki K, Bozynski CC, Cook JL

Suspensory versus interference screw fixation for arthroscopic anterior cruciate ligament reconstruction in a translational large-animal model. *Arthroscopy.* 2016;32(6):1086-1097. doi:10.1016/j.arthro.2015.11.026

- Histologic assessments showed significantly better graft incorporation with the GraftLink ACL technique compared with grafts using interference screw fixation in tunnels.
- All GraftLink constructs were intact at 12 weeks; one interference screw construct failed and led to knee laxity.
- The GraftLink technique "was associated with superior tendon-to-bone healing compared with interference screw fixation in tunnels."

Benefits of Single-Hamstring Harvest

Tashiro T, Kurosawa H, Kawakami A, Hikita A, Fukui N

Influence of medial hamstring tendon harvest on knee flexor strength after anterior cruciate ligament reconstruction. A detailed evaluation with comparison of single- and double-tendon harvest. *Am J Sports Med.* 2003;31(4):522-529. doi:10.1177/03635465030310040801

- "Tendon harvest causes significant weakness of hamstring muscle strength at high knee flexion angles, but such weakness can be minimized if the gracilis tendon is preserved."

Gobbi A, Domzalski M, Pascual J, Zanazzo M

Hamstring anterior cruciate ligament reconstruction: is it necessary to sacrifice the gracilis? *Arthroscopy.* 2005;21(3):275-280. doi:10.1016/j.arthro.2004.10.016

- Harvest of a single-hamstring graft led to improved internal and external rotational torque postoperatively compared to harvest of 2 hamstring tendons.

Nuelle CW, Cook JL, Gallizzi MA, Smith PA

Posterior single-incision semitendinosus harvest for a quadrupled anterior cruciate ligament graft construct: determination of graft length and diameter based on patient sex, height, weight, and body mass index. *Arthroscopy.* 2015;31(4):684-690. doi:10.1016/j.arthro.2014.10.013

- Harvesting the semitendinosus from a single posterior incision allowed for a quadrupled graft of desired length and diameter (8 mm or greater) in 95% of cases.

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Systematic Reviews and Meta-analysis

Kamitani A,
Hara K,
Arai Y,
et al

Adjustable-loop devices promote graft revascularization in the femoral tunnel after ACL reconstruction: comparison with fixed-loop devices using magnetic resonance angiography [published online February 26, 2021]. *Orthop J Sports Med.* 2021. doi:10.1177/2325967121992134

- Level 3 cohort study: 42 patients underwent ACLR using quadrupled semitendinosus autograft and inside-out tunnel preparation.
- This is the first study to compare graft revascularization between FLD (S&N Endobutton CL) and ALD (Arthrex TightRope® implant) in vivo, focusing on the contact area between the graft and femoral tunnel wall.
- MRA imaging at 3-months post-ACLR revealed that blood flow reached the superior end of the tendon graft in the femoral tunnel in more patients who underwent ACLR with an ALD than an FLD.
- Findings suggest early (0 to 3 month) revascularization occurs in the superior end of the socket more readily due to the increased graft-to-bone contact area associated with ALD than FLD, which leaves a gap between the graft tip and the superior end of the socket.
- This is a landmark study as the conclusion confirms the long-discussed value of the TightRope implant's ability to retension and fully seat grafts to achieve the "potted-plant" effect.

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†GraftMax is a registered trademark of ConMed.

‡Ultrabutton is a registered trademark of Smith & Nephew.

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