Syndesmosis TightRope® XP Implant Scientific Updates

Positive scientific support for the Syndesmosis TightRope implant continues to grow with more than 28 published articles. The TightRope implant for syndesmosis repair has been implanted for over 15 years and there are numerous reports of early return to activity and less morbidity. The technique also eliminates the need for second surgery screw removal.^{1,2}

Street SB, Rawlins M, Miller J

New scientific articles highlighting the benefits of the TightRope implant:

Effectiveness of the TightRope® fixation in treating ankle syndesmosis injuries: a critically appraised topic. *J Sport Rehabil.* 2021;30(4):676-679. doi:10.1123/jsr.2020-0265

- Grade A evidence exists to support the use of TightRope fixation in place of a metallic screw following ankle syndesmosis injury.
- TightRope implant allows normal motion of the fibula in relation to the talus and tibia, leading to reduced complications due to late diastasis.
- Potential for decreased complications and an expedited timeframe for return to normal activities when compared to syndesmotic screw fixation.

Grassi A, Samuelsson K, D'Hooghe P, et al Dynamic stabilization of syndesmosis injuries reduces complications and reoperations as compared with screw fixation: a meta-analysis of randomized controlled trials.

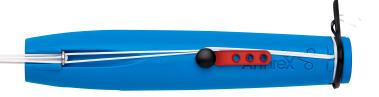
Am J Sports Med. 2020;48(4):1000-1013. doi:10.1177/0363546519849909

- Reduced number of complications and improved clinical outcomes compared to static screw fixation, especially malreduction and clinical instability or diastasis, at a follow-up of 2 years.
- Lower risk of reoperation was found with dynamic fixation as compared to static fixation with permanent screws

Ræder BW, Figved W, Madsen JE, Frihagen F, Jacobsen SB, Andersen MR

Better outcome for suture button compared with single syndesmotic screw for syndesmosis injury: five-year results of a randomized controlled trial. *Bone Joint J.* 2020;102-B(2):212-219. doi:10.1302/0301-620X.102B2.BJJ-2019-0692.R2

- Five years after syndesmotic injury treated with either suture button or syndesmotic screw, better AOFAS and OMA scores, and a lower incidence of ankle osteoarthritis were found in the suture button group
- Significantly smaller difference in anterior tibiofibular distance between the injured and non-injured ankles for the suture button fixation group.





Sanders D,
Schneider P,
Taylor M,
Tieszer C,
Lawendy A-R,
Canadian
Orthopaedic Trauma
Society

Improved reduction of the tibiofibular syndesmosis with TightRope compared to screw fixation: results of a randomized controlled study. *J Orthop Trauma*. 2019;33(11):531-537. doi:10.1097/BOT.0000000000001559.

- The Syndesmosis TightRope implant for syndesmosis injuries is validated for traumatologists in one of the largest and most comprehensive randomized clinical trials to date.
- The surgeons involved were all trained traumatologists at 11 different trauma centers with 103 patients followed for 1 year.
- The superiority of the Syndesmosis TightRope implant over syndesmosis screws was proven, with results showing better reduction, improved daily activities, and quicker return to work with no surgery needed for routine hardware removal.

Shimozono Y, Hurley ET, Myerson CL, Murawski CD, Kennedy JG Suture button versus syndesmotic screw for syndesmosis injuries: a metaanalysis of randomized controlled trials. *Am J Sports Med.* 2019;47(11):2764–2771. doi:10.1177/0363546518804804

- The Syndesmosis TightRope implant technique results in improved functional outcomes and lower rates of broken implant and joint malreduction as compared with the syndesmotic screw technique.
- The primary advantage is that the Syndesmosis TightRope implant allows for anatomic healing of the syndesmosis and avoids implant removal.
- The Syndesmosis TightRope implant technique warrants a grade A recommendation in the treatment of syndesmosis injuries.

Anderson MR, Frihagen F, Hellund JC, Madsen JE, Figyed W Randomized trial comparing suture button with single syndesmotic screw for syndesmosis injury. *J Bone Joint Surg Am.* 2018;100(1):2-12. doi:10.2106/JBJS.16.01011

- Therapeutic level 1 evidence demonstrates that the Syndesmosis TightRope implant is superior to 1 quadricortical syndesmotic screw over a 2-year follow-up of 97 patients.
- Patients treated with a Syndesmosis TightRope implant had higher AOFAS scores, OMA scores, and EQ-5D Index scores as well as lower (better) VAS scores for pain during walking and pain during rest.
- The TightRope implant is a better alternative than 1 quadricortical screw in the treatment of syndesmotic injuries because it provides better anatomical restoration and superior clinical results.

Colcuc C,
Blank M,
Stein T,
Raimann F,
Weber-Spickschen S,
Hoffman R

Lower complication rate and faster return to sports in patients with acute syndesmotic rupture treated with a new knotless suture button device. *Knee Surg Sports Traumatol Arthrosc.* 2018;26(10):3156-3164. doi:10.1007/s00167-017-4820-3

- The Syndesmosis TightRope implant had a 5-week faster return to sport and a 2-week faster return to work compared to syndesmosis screws.
- The Syndesmosis TightRope implant also had a lower complication rate and a lower second surgery rate.
- Both the faster return to sport and the lower complication rate were statistically significant in the knotless suture button vs screw fixation group.

Kortekangas T, Savola O, Flinkkilä T, et al A prospective randomized study comparing TightRope and syndesmotic screw fixation for accuracy and maintenance of syndesmotic reduction assessed with bilateral computed tomography. *Injury*. 2015;46(6):1119-1126. doi:10.1016/j.injury.2015.02.004

- 43 "PER Weber C" fractures were randomized to 1 TightRope implant vs 1 syndesmotic screw.
- The Syndesmosis TightRope implant had lower malreduction and reoperation rates compared to syndesmotic screws.



Latham AJ, Goodwin PC, Stirling B, Budgen A Ankle syndesmosis repair and rehabilitation in professional rugby league players: a case series report. *BMJ Open Sport Exerc Med.* 2017;3(1):e000175. doi:10.1136bmjsem-2016-000175

- Ankle syndesmosis surgery via a double TightRope implant repair followed by the accelerated rehabilitation protocol is as safe as the traditional procedures.
- Accelerated rehabilitation protocol promotes early weightbearing resulting in an
 effective and quick route to return to sport for professional rugby league players.
- A period of 2 months from surgery to return to sport is possible compared to 3 to 6 months postscrew fixation, which is very encouraging for the professional athlete population.

Neary KC, Mormino MA, Wang H Suture button fixation versus syndesmotic screws in supination-external rotation type 4 injuries: a cost-effectiveness analysis. *Am J Sports Med.* 2017;45(1):210-217. doi:10.1177/0363546516664713

- The Syndesmosis TightRope implant was a dominant treatment strategy, because patients spent on average \$1482 less compared to syndesmotic screws.
- The Syndesmosis TightRope implant patients had a higher quality of life by 0.058 QALYs over an 8-year time period.
- Second surgery cost for screw removal was \$14,768 per case.
- Syndesmotic screw fixation required 2 extra clinic visits and \$389 in ankle X-rays.
- Syndesmotic screw fixation had lower quality-of-life measurements.

Laflamme M,
Belzile EL,
Bédard L,
van den Bekerom
MPJ,
Glazebrook M,
Pelet S

A prospective randomized multicenter trial comparing clinical outcomes of patients treated surgically with a static or dynamic implant for acute ankle syndesmosis rupture.

J Orthop Trauma. 2015;29(5):216-223. doi:10.1097/BOT.000000000000245

- The TightRope implant gives better clinical and radiographic outcomes without breakage, loss of reduction, or reoperation.
- The TightRope implant outperformed screws clinically with 0% failure, 0% loss of reduction, and higher AOFAS scores.

Westermann RW, Rungprai C, Goetz JE, Femino J, Amendola A, Phisitkul P The effect of suture-button fixation on simulated syndesmotic malreduction: a cadaveric study. *J Bone Joint Surg Am.* 2014;96(20):1732-1738. doi:10.2106/JBJS.N.00198

- With deliberate malreduction, the TightRope implant fixation results in less post-fixation displacement compared with screw fixation.
- The TightRope implant appears to take advantage of distal tibiofibular anatomy in achieving improved reduction.
- The TightRope implant's ability to allow for natural correction of deliberate malreduction was greatest with posterior off-axis clamping.

Van Heest TJ, Lafferty PM Injuries to the ankle syndesmosis. *J Bone Joint Surg Am.* 2014;96(7):603-613. doi:10.2106/JBJS.M.00094

- The so-called gold-standard syndesmotic screw fixation is being brought increasingly into question as new fixation techniques emerge.
- Suture-button fixation represents a promising alternative.



Nagvi GA, Cunningham P, Lynch B, Galvin R, Awan N Fixation of ankle syndesmotic injuries: comparison of TightRope fixation and syndesmotic screw fixation for accuracy of syndesmotic reduction. *Am J Sports Med.* 2012;40(12):2828-2835. doi:10.1177/0363546512461480

- The TightRope implant had 0% syndesmosis malreduction compared to 22% malreduction with screws.
- The TightRope implant was significantly better at maintaining the reduction, even after a mean duration of 30 months after surgery.
- The TightRope implant provides a more accurate method of syndesmotic stabilization and obviates the need for a second procedure for routine removal.

Rigby RB, Cottom JM Does the Arthrex TightRope® provide maintenance of the distal tibiofibular syndesmosis? A 2-year follow-up of 64 TightRopes in 37 patients. *J Foot Ankle Surg.* 2013;52(5):563-567. doi:10.1053/j.jfas.2013.04.013

- The TightRope implant was advantageous because it rarely required removal, allowed for physiologic motion of the syndesmosis, and resulted in early return to weightbearing.
- The TightRope implant provides long-term stability (24 months), confirmed by radiographic criteria and excellent AOFAS scores.

Qamar F, Kadakia A, Venkateswaran B An anatomical way of treating ankle syndesmotic injuries. *J Foot Ankle Surg.* 2011;50(6):762-765. doi:10.1053/j.jfas.2011.07.001

- The TightRope implant allows for accelerated rehabilitation and improved outcome.
- No failures of fixation despite the early postoperative weightbearing.
- Advantageous in older, obese patients, or patients who cannot comply with a non-weightbearing regimen that is required with screw fixation.
- Cost-effective because it does not require retrieval with a second surgery.

DeGroot H, Al-Omari AA, El Ghazaly SA Outcomes of suture button repair of the distal tibiofibular syndesmosis. *Foot Ankle Int.* 2011;32(3):250-256. doi:10.3113/FAI.2011.0250

- The suture button device represents a viable alternative to screw fixation for syndesmosis injuries.
- Because of the ease-of-use of the device and the ability to allow full weightbearing without concerns about implant breakage, we feel that suture button fixation is superior to conventional metallic screws.

Osbahr, DC, Drakos MC, O'Loughlin PF, et al Syndesmosis and lateral ankle sprains in the National Football League. *Orthopedics*. 2013;36(11):e1378-1384. doi:10.3928/01477447-20131021-18

- 70% of team physicians recommend hardware removal before return to sport.
- No need for removal and second surgery with the TightRope implant.
- No need for removal in cases with obvious diastasis; return to play was 9-16 weeks.

Sagi HC, Shah AR, Sanders RW The functional consequence of syndesmotic joint malreduction at a minimum 2-year follow-up. *J Orthop Trauma*. 2012;26(7):439-443. doi:10.1097/BOT.0b013e31822a526a

- Studies have shown that between 24%-39% of syndesmoses are malreduced.
- 1 mm loss of syndesmotic reduction results in 42% increase in joint contact pressure.



Schepers T

Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. *Int Orthop.* 2012;36(6):1199-1206. doi:10.1007/s00264-012-1500-2

- Rate of implant removal is lower than in the syndesmotic screw group.
- The TightRope implant system has a similar outcome compared with syndesmotic screw or bolt fixation, but might lead to a quicker return to work.

Klitzman R, Zhao H, Zhang LQ, Strohmeyer G, Vora A

Soin SP, Knight TA, Dinah AF, et al

Cottom JM, Hyer CF, Philbin TM, Berlet GC

McMurray D,
Hornung B,
Venkateswanen B,
Ali Z

Coetzee JC, Ebeling PB

Cottom J, Hyer CF, Philbin TM, Berlet GC Suture-button versus screw fixation of the syndesmosis: a biomechanical analysis.

Foot Ankle Int. 2010;31(1):69-75. doi:10.3113/FAI.2010.0069

 Rigid fixation of the syndesmosis with screw fixation may be problematic in allowing physiologic motion of the syndesmosis.

Suture-button versus screw fixation in a syndesmosis rupture model: a biomechanical comparison. *Foot Ankle Int.* 2009;30(4):346-352. doi:10.3113/FAI.2009.0346.

- No difference vs syndesmotic screw in terms of overall fibular motion.
- Provides similar fixation to that of a 4-cortices 3.5 mm screw.

Transosseous fixation of the distal tibiofibular syndesmosis: comparison of an interosseous suture and endobutton to traditional screw fixation in 50 cases. *J Foot Ankle Surg*. 2009;48(6):620-630. doi:10.1053/j.jfas.2009.07.013

- · Late diastasis is avoided since the device remains in place while ligaments continue to heal.
- Advantageous in older, obese, or polytrauma patients that may have difficulty remaining non-weightbearing postoperatively.

Walking on a tightrope: our experience in the treatment of traumatic ankle syndesmosis rupture. *Injury Extra*. 2008;39(5):182. doi:10.1016/j.injury.2007.11.354

- TightRope implant shows favorable results when used to repair syndesmosis.
- Patients are able to be full weightbearing sooner.

Treatment of syndesmoses disruptions: a prospective, randomized study comparing conventional screw fixation vs TightRope® fiber wire fixation - medium term results.

SA Orthop J. 2009;8(1):32-37

- TightRope fixation gives a significantly better overall range of motion than conventional screw fixation.
- Better AOFAS scores at 6, 12, and 27 months.

Treatment of syndesmotic disruptions with the Arthrex Tightrope: a report of 25 cases.

Foot Ankle Int. 2008;29(8):773-780. doi:10.3113/FAI.2008.0773

- · Radiographic reduction maintained.
- Faster time to full weightbearing; no second surgery.



Thornes B,

Ankle syndesmosis injuries treated with the TightRope suture-button kit. *Tech Foot Ankle Surg.* 2006;5(1):45-53.

- Rehabilitation is faster and allows the athlete or patient to return to sport or work sooner.
- TightRope allows physiological micromotion, while resisting diastasis and may be more preferable than a rigid screw.

Pelc HJS, Carmont MR, Sutton PM, Blundell CM TightRope stabilisation of proximal and distal tibiofibular syndesmosis rupture: the floating fibula—a case report. *Injury Extra*. 2009;40(1):16-18. doi:10.1016/j.injury.2008.09.016

Thrones B, Shannon F, Guiney AM, Hession P, Materson E Suture-button syndesmosis fixation: accelerated rehabilitation and improved outcomes. *Clin Orthop Relat Res.* 2005;(431):207-212.

- Better AOFAS scores at 3 and 12 months.
- · Return to work faster; no second surgery.

Thornes B, Walsh A, Hislop M, Murray P, O'Brien M Suture-endobutton fixation of ankle tibio-fibular diastasis: a cadaver study. Foot Ankle Int. 2003;24(2):142-146.doi:10.1177/107110070302400208

- TightRope implant gave a significantly more consistent performance than screw fixation.
- TightRope implant would provide obvious cost savings to both the patient and health service, free up OR time, and eliminate the need for the patient to go through a second procedure.

Seitz WH Jr, Bachner EJ, Abram LJ, et al Repair of the tibiofibular syndesmosis with a flexible implant. *J Orthop Trauma*. 1991;5(1):78-82.

- Provides a more physiologic solution than rigid fixation.
- Allows weightbearing without damage to surrounding bone, while providing reliable fixation of the healing syndesmotic ligaments.

References

- Colcuc C, Blank M, Stein T, Raimann F, Weber-Spickschen S, Hoffman R. Lower complication rate and faster return to sports in patients with acute syndesmotic rupture treated with a new knotless suture button device. Knee Surg Sports Traumatol Arthrosc. 2018;26(10):3156-3164. doi:10.1007/s00167-017-4820-3.
- Laflamme M, Belzile EL, Bédard L, van den Bekerom MP, Glazebrook M, Pelet S. A prospective randomized multicenter trial comparing clinical outcomes of patients treated surgically with a static or dynamic implant for acute ankle syndesmosis rupture. J Orthop Trauma. 2015;29(5):216-223. doi:10.1097/B0T.0000000000000245.

