Effectiveness of the TightRope® Fixation in Treating Ankle Syndesmosis Injuries: A Critically Appraised Topic

Scott Benson Street, Matthew Rawlins, and Jason Miller

Clinical Scenario: Ankle fractures are a frequent occurrence, and they carry the potential for syndesmosis injury. The syndesmosis is important to the structural integrity of the ankle joint by maintaining the proximity of the tibia, fibula, and talus. Presently, the gold standard for treating an ankle syndesmosis injury is to insert a metallic screw through the fibula and into the tibia. This technique requires a second intervention to remove the hardware, but also carries an inherent risk of breaking the screw during rehabilitation. Another fixation technique, the Tightrope™, has gained popularity in treating ankle syndesmosis injuries. The TightRope™ involves inserting Fiberwire® through the tibia and fibula, which allows for stabilization of the ankle mortise and normal range of motion. **Clinical Question:** In patients suffering from ankle syndesmosis injuries, is the Tightrope™ ankle syndesmosis fixation system more effective than conventional screw fixation at improving return to work, pain, and patient-reported outcome measures? **Summary of Key Findings:** Five studies were selected to be critically appraised. The PEDro checklist was used to score 2 randomized control trials, and the Downs & Black checklist was used to score the cohort study on methodology and consistency. Two systematic reviews were also appraised. All 5 articles demonstrated support for using the TightRope™ fixation. **Clinical Bottom Line:** There is moderate evidence to support the use of the TightRope™ syndesmosis fixation system, as it provides both clinician- and patient-reported outcomes that are similar to those using the conventional metallic screw, with a shortened time to recover and return to activity. **Strength of Recommendation:** Grade A evidence exists in support of using the TightRope™ fixation system in place of the metallic screw following ankle syndesmosis injury.

Keywords: syndesmotom screw, lower leg, ankle treatment, ankle mortise

Clinical Scenario

In the United States, it is estimated that around 40,000 ankle fractures occur annually.¹ Ankle fractures also carry the potential for disrupting the ankle syndesmosis, occurring in an estimated 10% of all ankle fractures.² The ankle syndesmosis is crucial for maintaining the structural integrity of the joint by maintaining the proximity of the tibia, fibula, and talus bones.³ Syndesmosis injuries can present with various obstacles during the rehabilitation process, including prolonged disability, recovery periods, and uncertainty regarding the ideal treatment approach.⁴⁻⁶

There are several surgical options to consider in maintaining the structural integrity of the ankle joint after a grade II or higher syndesmosis injury has occurred. The current “gold standard” is the metallic syndesmotom screw.⁷ In this procedure, screws are implanted through the fibula into the tibia to stabilize the syndesmosis. Complications arising from this intervention include broken screws and potential infection, as 2 surgeries have to be conducted (one for inserting and a second for removal of the screws). Another option that is garnering more attention due to recent high-profile cases is a preassembled suture-button device, known as the TightRope™ (Arthrex, Inc, Naples, FL).⁷ The Tightrope™ has been in use since the mid-2000s.⁸ This surgical procedure is performed by inserting a No.5 FiberWire® loop (Arthrex) through the tibia and fibula and placing tension on the FiberWire®. This provides

physiologic stabilization of the ankle mortise and reduces the need for a second procedure to remove the hardware.²

Focused Clinical Question

In patients suffering from ankle syndesmosis injuries, is the Tightrope™ ankle syndesmosis fixation system more effective than conventional screw fixation at improving return to work, pain, and patient-reported outcome measures?

Summary of Key Findings

PubMed, SportDiscus, and Google Scholar were searched, as well as reference lists, which resulted in 5 articles relating to the efficacy of utilizing the TightRope™ surgical procedure in the treatment of syndesmosis injuries.^{2-4,7,9} The search was limited to articles published within the last 10 years. Two randomized control trials and one cohort study comparing the TightRope™ procedure with a metallic syndesmotom screw met the inclusion requirements and were utilized. Two systematic reviews were also included, as they compared results for various ankle injuries and outcomes.

Among the randomized control trials and cohort study, 133 patients underwent either the syndesmotom screw or the TightRope™ procedure.^{2,3,7} Patient-reported outcome scores were measured using the American Orthopedic Foot and Ankle Society, Foot and Ankle Disability Index, or the Olerud-Molander Ankle Score.^{2,3,7} All of the included articles demonstrated similar scores between the procedures; however, patients undergoing the TightRope™ experienced a reduction in the need to have a second surgical procedure to remove hardware.^{2-4,7,9} With the reduced

Street is with the West Virginia Wesleyan College, Buckhannon, WV, USA. Rawlins is with the University of Rochester's Medical Center, Rochester, NY, USA. Miller is with the Moravian College/Denver Nuggets, Denver, CO, USA. Rawlins (matt_rawlins@urmc.rochester.edu) is corresponding author.

need for a second surgical procedure, the TightRope™ allowed for a quicker return to normal activity by up to 2 weeks.^{2,3,7,9} Return to sport was up to 5 weeks quicker with the TightRope™ as compared with the traditional metallic syndesmotic screw.^{2,3,7,9}

Normal fibular motion is allowed in relation to the talus and tibia with the TightRope™ procedure.^{2,3} By allowing normal motion during the healing process, complications related to late diastasis are reduced.² It also allows for a faster return to normal gait due to the reduction in the need to regain these accessory movements.

Clinical Bottom Line

The ankle TightRope™ fixation may provide similar outcomes, with the potential for decreased complications and an expedited timeframe for return to normal activities when compared with the syndesmotic screw fixation for those individuals with syndesmotic injuries who require surgical fixation.

Strength of Recommendation

The strength of recommendation is grade A for using the TightRope™ fixation system to stabilize syndesmotic injuries. Two systematic reviews (level 1a evidence), 2 randomized control trials (level 1b), and 1 cohort study (level 2b) demonstrated consistent patient outcomes in favor of the TightRope™ fixation system.

Search Strategy

Terms Used to Guide Search Strategy

- **P**atient/client group: Ankle syndesmotic injury
- **I**ntervention (or assessment): Tightrope™ Fixation
- **C**omparison: Syndesmotic screw fixation
- **O**utcome(s): Return to activity, pain reduction, patient-reported outcome measures

Sources of Evidence Searched (Databases)

- PubMed (November 2019)
- SportDiscus (November 2019)
- Google Scholar (November 2019)
- Additional resources obtained via review of reference lists

Inclusion and Exclusion Criteria

Inclusion Criteria

Studies that compared outcomes for the Tightrope™ ankle syndesmosis fixation with the syndesmotic screw as interventions were included if they met the following:

- Limited to English language
- Limited to the past 10 years (2009–2019)
- Level 2 evidence or higher

Exclusion Criteria

- Studies greater than 10 years old (published before January 1, 2009)
- Non-English articles
- Articles without online full-text availability

Results of Search

A literature search was performed utilizing the databases PubMed, SportDiscus, and Google Scholar. About 330 articles appeared in the initial search of combined databases search prior to screening of inclusion/exclusion criteria. Once the articles were screened for criteria, 5 relevant studies were located and categorized, as shown in Table 1.

Summary of Best Evidence

Four level 1 studies and one level 2 study were selected for inclusion and appraisal in this critically appraised topic (Table 2).

Table 1 Summary of Study Designs of Articles Retrieved

Level of evidence	Study design/ methodology	Number located	Author
1a	Systematic review	2	Vancolen et al ⁴ Schepers ⁵
1b	Randomized control trial	2	Coetzee and Ebeling ⁷ Colcuc et al ³
2b	Cohort	1	Naqvi et al ²

Table 2 Characteristics of Studies Identified as Best Evidence

Author	Vancolen et al ⁴	Schepers ⁵	Coetzee and Ebeling ⁷	Colcuc et al ³	Naqvi et al ²
Study design	Systematic review	Systematic review	RCT	RCT	Cohort
Participants	Initial search generated 1306 studies, but only 10 full-text studies met the inclusion criteria	6 biomechanical studies, 7 clinical full-text studies, 4 abstracts, and 27 studies were identified	24 individuals who sustained syndesmotic injury who needed surgical intervention	110 patients eligible, only 62 met criteria, and 8 were lost to follow-up. Only 54 patients were analyzed	61 patients eligible, but only 55 met the inclusion criteria for ankle fracture with associated syndesmotic injury
Intervention investigated	Operative and Nonop, both with rehabilitation	TightRope™ or Syndesmotic Screw Fixation	TightRope™ or Syndesmotic Screw Fixation	TightRope™ or Syndesmotic Screw Fixation	TightRope™ or Syndesmotic Screw Fixation

(continued)

Table 2 (continued)

Author	Vancolen et al ⁴	Schepers ⁵	Coetsee and Ebeling ⁷	Colcuc et al ³	Naqvi et al ²
Outcome measure(s)	Return to sport, functional outcomes including AOFAS, Olerud–Molander Ankle Score, Edwards and DeLee Ankle Rating	Return to activity, Olerud–Molander Ankle Score, AOFAS score	AOFAS ankle and hindfoot scale, VAS, and a functional questionnaire	Time to return to sport, Olerud–Molander Ankle Score, AOFAS score, FADI with sports module, VAS, and radiographs	Syndes. Reduction via CT scan, FADI, AOFAS, time to weight-bearing and complications
Main findings	Complications were found in operative syndesmotomic screw group. High levels of return to sport were found in operative and nonoperative groups in each study. Mean time to return to sport was 46 d	Biomechanical studies showed larger failure loads in TightRope TM versus screw fixation. Functional outcome studies showed similar scores in AOFAS between screw fixation and TightRope TM . Less complications with TightRope TM	2 Syndesmotomic screws needed to be removed and 1 TightRope TM needed to be removed. At median 2-y follow-up, AOFAS scores were similar, but ROM in the TightRope TM were better compared with syndesmotomic screw	5 individuals in the syndesmotomic screw group had complications, with 1 in the TightRope TM group needing it removed. No significant differences between groups in VAS scores, AOFAS score, Olerud–Molander Ankle Score, and FADI. Time to return to work and sport was less in TightRope TM group	5 malreductions of syndesmosis in syndesmotomic screw group and 0 in TightRope TM . Weight bearing at 8 wks with TightRope TM , and 9 wks with syndesmotomic screw. FADI (82.42, 81.22) and AOFAS (89.56, 86.52) scores were similar between fixation type.
Level of evidence	1a	1a	1b	1b	2b
Validity score	N/A	N/A	PED(ro) 6	PED(ro) 8	Downs & Black 19
Conclusion	High return to sport rate after syndesmotomic injury. Difficulty due to lower sample size and comparative studies to compare nonop to operative treatment	TightRope TM fixation has similar functional outcomes, with less likelihood of complications. May lead to earlier return to activity than syndesmotomic screw	TightRope TM fixation has similar outcomes as screw fixation, with decreased risk of complications, and helps to maintain tibiofibular motion	TightRope TM fixation has lower risk of complications and allows for an earlier return to work and sport. Other outcomes were similar between types and fixation	TightRope TM provides less risk of syndesmotomic malreduction compared with Syndesm. Screw fixation. Overall, other outcomes were similar between types of fixation

Abbreviations: AOFAS, American Orthopedic Foot and Ankle Society; CT, computed tomography; RCT, randomized control trial; VAS, visual analog scale.

Implications for Practice, Education, and Future Research

All 5 studies demonstrated a reduction in the necessity for a second intervention to remove hardware in groups using the TightRopeTM fixation system.^{2–4,7,9} The studies also report better recovery time and a quicker return to work/activity in participants who underwent the TightRopeTM intervention.^{2–4,7,9} Finally, clinician-based and patient-reported outcomes were not significantly different between groups undergoing the traditional metallic screw fixation and the TightRopeTM fixation.^{2–4,7,9} None of the included studies demonstrated an increase in recovery time, return to work, or worsened outcomes due to the TightRopeTM fixation system.^{2–4,7,9}

Based on the included studies, individuals suffering from ankle syndesmosis sprains may benefit from undergoing intervention with the TightRopeTM ankle fixation system. While these findings may be the result of methodological differences across studies, such as the study design, it may be a result of the treatment and rehabilitation performed postsurgically. Although 2 of the studies^{2,3} reported that postsurgical treatment and rehabilitation were the same between the groups, it is unknown how subjects progressed throughout those programs based on the intervention they received. One systematic review⁴ reported that a progressive

protocol was used for both the operative and nonoperative treatment groups included in their review. The subjects' protocols included progressive coordination, muscular endurance, and motor control exercises.⁴

Future research for the TightRopeTM fixation system could determine a phased rehabilitation protocol. Research should also explore other injuries in areas of the body where this type of fixation system could be beneficial, including, but not limited to, acromioclavicular joint sprains, proximal tibiofibular joint dislocations, and radioulnar joint injuries. This critically appraised topic should be reviewed in 2 years, or when additional evidence becomes available that may alter the clinical bottom line for this clinical question.

Acknowledgment

The authors claim no conflicts of interest in the production of this critically appraised topic.

References

- Shibuya N, Davis ML, Jupiter DC. Epidemiology of foot and ankle fractures in the United States: an analysis of the National Trauma Data Bank (2007 to 2011). *J Foot Ankle Surg.* 2014;53(5):606–608. doi:10.1053/j.jfas.2014.03.011

2. Naqvi GA, Cunningham P, Lynch B, Galvin R, Awan N. Comparison of tightrope fixation and syndesmotic screw fixation for accuracy of syndesmotic reduction. *Am J Sports Med.* 2012;40(12):2828–2835. PubMed ID: [23051785](#) doi:[10.1177/0363546512461480](#)
3. Colcuc C, Blank M, Stein T, et al. 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. PubMed ID: [29224059](#) doi:[10.1007/s00167-017-4820-3](#)
4. Vancolen SY, Nadeem I, Horner NS, Johal H, Alolabi B, Khan M. Return to sport after ankle syndesmotic injury: a systematic review. *Sports Health.* 2019;11(2):116–122. PubMed ID: [30550364](#) doi:[10.1177/1941738118816282](#)
5. Schepers T. Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. *Int Orthop.* 2012;36(6):1199–1206. PubMed ID: [22318415](#) doi:[10.1007/s00264-012-1500-2](#)
6. Levy DM, Reid K, Gross CE. Ankle syndesmotic injuries: a systematic review. *Tech Orthop.* 2017;32(2):80–83. doi:[10.1097/BTO.0000000000000226](#)
7. Coetzee JC, Ebeling PB. Treatment of syndesmoses disruptions: a prospective, randomized study comparing conventional screw fixation vs TightRope™ fiberwire fixation—medium term results. *SA Orthop J.* 2009;8(1):32–37.
8. Thornes B, McCartan DMB. Ankle syndesmosis injuries treated with the TightRope™ Suture-Button Kit. *Tech Foot Ankle Surg.* 2006;5(1):45–53. doi:[10.1097/00132587-200603000-00010](#)
9. Osbahr DC, Drakos MC, O’Loughlin PF, et al. Syndesmosis and lateral ankle sprains in the National Football League. *Orthopedics.* 2013;36(11):e1378–e1384. PubMed ID: [24200441](#) doi:[10.3928/01477447-20131021-18](#)