Clinical Article

Treatment of syndesmoses disruptions:

A prospective, randomized study comparing conventional screw fixation vs TightRope® fiber wire fixation – medium term results

J Chris Coetzee, MD, MMed Ortho
Minnesota Sports Medicine & Twin Cities Orthopedics
Adjunct Associate Professor, University of Minnesota, Minneapolis

Patrick B Ebeling, MD
Minnesota Sports Medicine & Twin Cities Orthopedics
Adjunct Associate Professor, University of Minnesota, Minneapolis

Reprint requests:
Dr J Chris Coetzee
Minnesota Sports Medicine & Twin Cities Orthopedics
775 Prairie Center Drive #250
Eden Prairie, MN 55344
Tel: 952 944 2519
Fax: 952 944 0460
Email: jcc@ocpamn.com

Abstract

Background:

Open reduction and screw fixation is the current standard treatment for displaced injuries of the ankle syndesmosis. Despite reduction and stable internal fixation, however, these injuries do not uniformly have excellent outcomes. In addition, screw fixation has potential disadvantages.

Materials and methods:

An ongoing prospective, randomized clinical trial comparing conventional screw fixation with TightRope® fiber wire fixation for syndesmosis injuries. The objective of this paper is also to provide an overview of the important anatomical and biomechanical issues relating to syndesmosis injuries.

Results:

At medium term follow-up the TightRope® fiber wire fixation group had a statistically significant better range of motion compared to conventional screw fixation. The AOFAS ankle and hindfoot score did not show a significant difference between the two groups.

Introduction

Open reduction and screw fixation is the current standard treatment for displaced injuries of the ankle syndesmosis.[1-4] Despite reduction and stable internal fixation, however, these injuries do not uniformly have excellent outcomes. There might be several reasons for that, including the mechanism of injury, method of fixation and quality of the reduction.

The syndesmosis is disrupted when an external rotation torque is applied to the ankle. In most cases, a pronation/external rotation injury occurs when an external rotation force is applied to the leg with the foot firmly planted. The injury force starts through either the medial malleolus or Deltoid ligament, travels laterally through the joint, tears the syndesmosis structures, and exits through the fibula. With a complete syndesmosis disruption the ankle joint is left unstable with significant negative consequence if not repaired. A proximal fibular fracture with an intraosseus ligament tear (Maisonneuve injury) may be missed if the proximal fibula is not examined.

The anatomy and biomechanics of the distal tibiofibular syndesmosis is important in the understanding of the function and integrity of the ankle joint. Three main structures provide stability at the syndesmosis: the interosseous tibiofibular ligament, the anterior inferior tibiofibular ligament and the posterior inferior tibiofibular ligament.

With ankle dorsiflexion, the distal fibula will move proximally, posteriorly and externally rotate.[5] Beumer *et al*[6] demonstrated by radiostereometry that an external rotation force externally rotates the fibula and translates it postero-medially.

In a cadaver study, Ogilvie-Harris *et al*[7] showed anterior inferior tibia fibular ligament contributed 35% of the strength of the syndesmosis, the posterior inferior tibia fibular ligament 40% and the interosseous ligament 21%.

Any disruption of the ankle mortise can lead to significant dysfunction of the mechanics of the joint and a missed, unstable injury to the ankle syndesmosis can result in rapid joint degeneration. In November 2006, Lloyd *et al* confirmed the results of Ramsey and Hamilton's earlier study by demonstrating that as little as 1 mm of lateral shift of the talus in the ankle mortise resulted in a 40% loss of tibiotalar contact surface area.[8] Taser *et al*[9] showed with CT scans that a 1 mm separation of the syndesmosis can lead to a 43% increase in ankle volume.

One possible source of poorer results is non-anatomic reduction. Gardner, Helfet *et al* reported that, even in a level 1 trauma center, there was a 52% incidence of malreduction of the tibiofibular syndesmosis in Weber C ankle fractures treated with screw fixation[10] and malreduction has been demonstrated to be an independent predictor of poorer outcome measures.[11]

Even when the reduction is anatomic, however, screw fixation has potential complications which may adversely affect outcomes. Rigid screw fixation eliminates most if not all of the normal tibiofibular motion described above, potentially resulting in pain or decreased motion. Pereira also showed that screw fixation limits the tibiotalar contact area throughout the range of motion of the ankle by locking the fibula and preventing the normal fibular motion.[12] In addition, symptomatic hardware failure, or routine screw removal to avoid it, necessitates exposing the patient to a second operation.

For this study conventional non-cannulated screw fixation was compared to a fiber wire construct. The TightRope® implant (Arthrex Inc, Naples, FL, USA) consists of a preassembled fiber wire and two-button construct *(Figure 1)*. A #5 fiberwire suture is woven between an endobutton and a round button resulting in four bridging strands of suture. Stainless steel and titanium versions are available.

The hypothesis of the study was that the TightRope® system will maintain reduction of the syndesmosis while allowing some rotational, proximal-distal and anterior-posterior motion of the fibula with respect to the tibia.

Screw fixation has potential complications which may adversely affect outcomes

Materials and methods

Included in the study were all syndesmoses injuries that are less than one month old, with or without ankle fractures, in patients younger than 60 years old and a BMI less than 35. Exclusion criteria include: 1) age older than 60 (to avoid the potential, but unconfirmed problem of button pull-out in osteoporotic bone), 2) diabetes needing medication, 3) open fractures, 4) multi-trauma, and 5) open growth plates.

These patients were enrolled in a prospective, randomized clinical trial comparing traditional screw fixation to Tightrope® fiber wire (Arthrex Inc, Naples, FL, USA). Any associated ankle fractures were treated the same in both groups with conventional open reduction and internal fixation.

Evaluation was performed with clinical examination, radiography, AOFAS ankle and hindfoot scale, visual analog scale and a functional questionnaire. The data was collected pre-op, at 6 and 12 weeks, 6 months, 1 year and then annually.

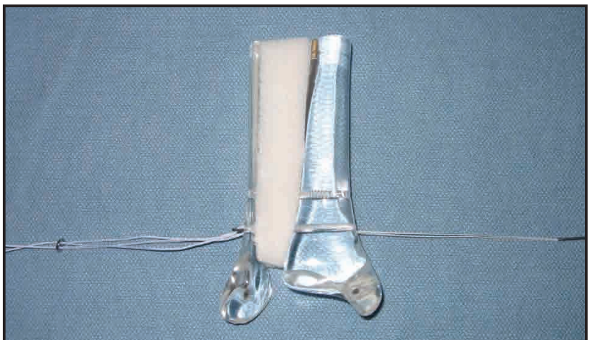

Figure 1:
The TightRope® system

Figure 2:
It is important have an anatomical reduction of the syndesmosis prior to applying fixation. The reduction is held with a large reduction clamp

The GraphPad InStat software was used to do the statistical analysis for the study. The Mann Whitney test was used to get an unpaired two-tailed P value. A p-value smaller than 0.05 was indicative of statistical significance.

Surgical technique

The surgical technique for TightRope® fixation of a syndesmosis injury was similar to that for screw fixation. If there was an associated fibula fracture, it was reduced and fixation placed as indicated by the fracture pattern.

For the purpose of the study we tried to limit the potential variables. In the screw fixation group all had two screws and all included four cortices. In the TightRope® group all but one had two TightRopes®. All fibula fractures were treated with an ORIF. The reasoning behind that was to ensure adequate rotational correction of the fibula, but also to prevent the potential but unconfirmed problem of superior migration/telescoping of the fibula in the TightRope® group. This meant that some of the midshaft fibula fractures that one will usually leave untreated required a plate fixation. The fibula fixation followed the standard AO principles in all cases. In a further attempt to limit variables it was decided not to remove any screws unless a specific reason arose.

In view of the reported difficulty in achieving an accurate reduction of the syndesmosis, it was decided to do an open reduction of the syndesmosis even though it is potentially possible to do it percutaneously in certain cases. The syndesmosis was exposed by dissection anterior over the fibula at the time of the open reduction and care was taken to accurately reduce the fibula into the incisura, achieving both adequate apposition and correct rotation. A large bone clamp was then placed across the ankle to compress the syndesmosis and maintain the reduction *(Figure 2)*.

For the screw fixation group the screw diameter was dependent upon the size of the fibula and ankle, and varied from 4.0 mm, 4.5 mm and 6.5 mm screws. The screws were inserted in the standard compression mode overdrilling the fibula and underdrilling the tibia. The distal screw was placed 1–1.5 cm above the joint line, and the second 2–3 cm proximal. This was the same for the TightRope® placements. For the TightRopes® the 3.5 mm drill included in the TightRope® system was used to drill a hole across the syndesmosis from lateral to medial. When a plate fixation was employed on the distal fibula, one or more of the screw holes could be used for the TightRope®.

The TightRope® needle is advanced from lateral medially through the skin and the endobutton is followed with fluoroscopy as it passes medially. Once the endobutton passes through the medial cortex of the tibia, it is flipped by releasing pressure on the needle medially and pulling on the fiberwire suture laterally. This places the endobutton flat against the medial cortex. The button must lie flat against the bone without any soft tissue interposition to prevent later loosening of the construct. With the reduction clamp left in place, the two ends of the fiber wire are now tensioned on the lateral side to load and compress the medial and lateral buttons and maintain reduction of the syndesmosis. Tension is maintained by tightly knotting the fiber wire over the lateral button.

Postoperative management

The post-op protocol was the same for both groups. The patients were placed in a short leg cast splint and were non-weightbearing for two weeks. After two weeks the splint was removed, and a pneumatic Cam boot was applied. The boot was worn for activities of daily living, but some low impact activities, including biking (with minimal resistance), pool walking and swimming, without kicking, were allowed without the boot if the wounds were fine. It was emphasized that there should be no external rotation force during the first six weeks, and weight was limited to 50 pounds. At six weeks, weightbearing AP, lateral and oblique X-rays of the ankle were obtained. If the syndesmosis appears stable and any associated fractures were healed, patients weaned out of the CAM boot and advance their activities to include straight line walking, jogging and running. Cutting activities were delayed for 3 months, with some adjustment where recovery was quicker or slower than expected. All patients were advised to use a lace-up ankle brace when playing sports for the first 6 months after surgery.

Results

At this point there are 12 patients in each group with at least one 18 months follow-up *(Table I)*. No patients were lost to follow-up.

The complication rate in both groups was low. In the TightRope® group one wire had to be removed at 6 months for ongoing irritation and superficial infection where the large suture knot rubbed on a tight fitting hockey skate. Similarly one large fragment screw was removed due to the prominence of the screw head.

In the screw fixation group one was a pure soft tissue disruption that was treated with two screws and a deltoid repair. Six required only a standard distal fibula plate and screw fixation and deltoid repair, while five required a medial malleolar fixation including one that required a mid-third fibula plate for a Maisonneuve variant.

Two patients required a more proximal fibula fixation, one in the mid-third, and the second in the proximal third. There was also one patient that only required TightRopes®, without any fractures. Seven of the 12 TightRope® patients required medial malleolar screws as well as a fibula plate.

Table I: Demographics

	Screw group	TightRope® group
Male	8	9
Female	4	3
Age	38 (18-55)	35 (18-53
Weight (lbs)	185 (110-250)	179 (114 -239)

One of them was a revision of a failed poorly done fibula fixation that required a longer plate and three TightRopes®.

The follow-up is still fairly short, but at a median 2.3 year follow-up there is no statistical difference in the AOFAS Ankle and Hindfoot score, even though there is a trend for the TightRope® group to do better (p= 0.149). The AOFAS ankle and hindfoot score for the tight rope group was 94 (82–100) and the Screw fixation group was 88 (80–100) *(Table II A and B).*

At this point in the study, the patients in the tightrope group have also demonstrated better objective range of motion measurements and subjectively reported less stiffness and discomfort. Range of motion (ROM) was statistically significantly better in the TightRope® group (p= 0.054) *(Figure 3 and Table III).*

At this early stage, patients receiving TightRope® fixation appear to have results at least equal to those with conventional screw fixation. There is increased ankle motion in the TightRope® group, suggesting that a potential advantage of that device is that it allows for more normal motion in the syndesmoses complex. The patients in the tightrope group had better range of motion than the screw fixation, and also subjectively less stiffness and discomfort *(Figure 4a, b).*

Complications to this point in the screw fixation group include one broken screw and one screw removal for prominent instrumentation. There was one infection in the TightRope® group which required removal of the implant after six months.

Table II A: AOFAS Ankle and Hindfoot Score in the screw fixation group

AOFAS Ankle + Hindfoot Scale Screw fixation	Pre-op (n=12)	6 m (n=12)	12 m (n=12)	27 m (n=9)
Pain	5 (0–20)	24 (20–30)	27.5 (20–40)	33 (30–40)
Function	9 (7–12)	34 (28–50)	38 (31–50)	44 (37–50)
Alignment	1 (0–5)	10 (10)	10 (10)	10 (10)
Total	15 (7–37)	68 (58–90)	75.5 (61–100)	87 (80–100)

Table II B: AOFAS Ankle and Hindfoot Score in the TightRope® Group

AOFAS Ankle + Hindfoot scale TightRope® fixation	Pre-op (n=12)	6 m (n=12)	12 m (n=12)	27 m (n=8)
Pain	5 (0–20)	27.5 (20–40)	32.5 (20–40)	36 (30–40)
Function	9 (7–12)	38.5 (33–50)	42.7 (37–50)	48 (43–50)
Alignment	1 (0–5)	10 (10)	10 (10)	10 (10)
Total 15	(7–37)	76 (63–100)	85.2 (65–100)	94 (82–100)

Table III: ROM comparison

ROM with TightRope®	Normal	Syndesmosis
6 months n=12	DF 12 (6–25) PF 57 (43–85)	DF 7 (0–20) PF 44 (29–80)
18 months n=12	DF 12 (6–226) PF 58 (44–84)	DF 11 (4–20) PF 53 (37–80)
ROM with Screws	**Normal**	**Syndesmosis**
6 months n=12	DF 12 (2–25) PF 55 (40–82)	DF 5 (0–12) PF 39 (23–76)
18 months n=12	DF 10 (2–25) PF 55 (42–80)	DF 8 (2–20) PF 43 (28–70)

Discussion

The potential advantage of the fiber wire fixation is that it allows some of the normal rotation and proximal distal motion of the fibula during the normal gait cycle. The literature about fiber wire fixation for syndesmosis injuries though is sparse.

Several potential concerns have been expressed regarding TightRope® fixation of syndesmosis injuries. There is a concern that TightRope® fixation might be inferior to screw fixation in maintaining reduction of the mortise. Miller *et al*[13] demonstrated that, in a cadaver model, a construct with only two strands of #5, non-fiber wire suture placed through bony tunnels was equivalent to a single 3.5 mm tricortical screw in resisting a distraction force at the mortise. A recent study, though, which also used a cadaver model of syndesmosis injury, demonstrated a significant increase in diastasis during external rotation stress in specimens stabilized with TightRope® fixation compared to those stabilized with a 4.5 mm cortical screw across four cortices.[14]

Figure 3:
Fifteen months after an open reduction and fixation of the fracture. TightRope® fixations were used through the bottom holes of the plate. Excellent restoration of the ankle mortise

Figure 4a:
A typical Weber C fracture pattern as well as a medial joint space widening

Figure 4b:
Conventional fibula fixation with the use of two screws for syndesmosis fixation

Although this is a legitimate concern, there are important differences between the study conditions and the clinical situation. First of all, in the clinical situation external rotation force is avoided in the first 6 weeks to allow initial healing of the syndesmosis (see post-op protocol above). In addition, use of two or more TightRopes® may increase the rigidity of the construct while still maintaining tibio-fibular motion. Further study will be needed in this area.

There is also concern that, over time, the buttons might pull through the cortex rendering the fixation useless. This is especially concerning when the medial button is placed against the metaphyseal cortex. Therefore, it is important to have at least one of the TightRopes® through the thicker, more proximal cortical bone.

In 2005, Thornes *et al* published a consecutive series of patients treated with an early version of a suture-button implant and compared them to an earlier cohort treated with traditional screw fixation. The patients in the suture implant group all maintained their reduction and demonstrated significantly better AOFAS scores at 3 and 12 months and an earlier return to work than the screw fixation group. In addition, 12 of the 16 patients in the screw fixation group underwent implant removal, compared with none in the suture fixation group.[15] This is a level 4 study with limited power.

In the clinical situation external rotation force is avoided in the first 6 weeks to allow initial healing of the syndesmosis

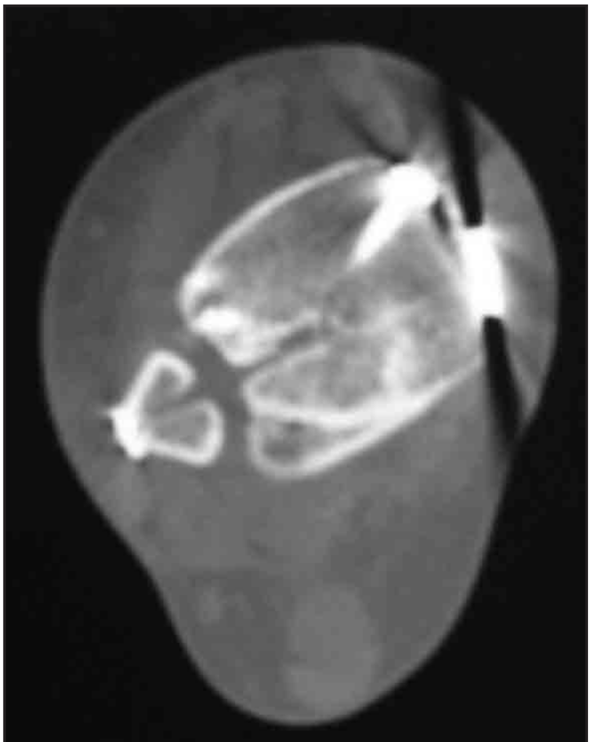

Figure 5:
A CT scan showing perfect reduction of the fibula in the tibial incisura with a TightRope® fixation

Finally, as discussed above, in the treatment of Weber C fractures, TightRope® fixation must be accompanied by plate and screw fixation of the fibula to avoid proximal migration of the distal fibula.

Despite the concerns, TightRope® fixation offers significant potential advantages over conventional screw fixation. Insertion of the device is simple, both in isolation and in combination with fixation of fibula fractures. Also, because the risk of screw failure is eliminated, the potential for a second operation for implant removal, including scheduled removal, is significantly reduced. In addition, due to the flexibility of the device the fibula is pulled into the incisura of the tibia as it is tightened, potentially leading to an improved reduction of the syndesmosis *(Figure 5)*.

Finally, TightRope® fixation offers the potential of syndesmosis stabilization without eliminating normal tibiofibular motion. This may, in turn, lead to better objective ankle motion as well as a decreased subjective stiffness and discomfort.

This article was submitted to an ethical committee for approval. The content of this article is the sole work of the authors. No benefits of any form have been derived from any commercial party related directly or indirectly to the subject of this article.

References

1. Tornetta P, Spoo JE, Reynolds FA, Lee C. Overtightening of the ankle syndesmosis: Is it really possible? *J Bone Joint Surg (Am)* 2001;**83-A**:489-92.
2. McBryde A, Chiasson B, Wilhelm A, Donovan F, Ray T, Bacilla P. Syndesmotic screw placement: A biomechanical analysis. *Foot Ankle Int* 1997;**18**:262-6.
3. Hoiness P, Stromsoe K. Tricortical versus quadricortical syndesmosis fixation in ankle fractures. A prospective, randomized study comparing two methods of syndesmosis fixation. *J Orthop Trauma* 2004;**18**:331-7.
4. Beumer A, Campo MM, Niesing R, Day J, Kleinrensink G-J, Swierstra BA. Screw fixation of the syndesmosis: a cadaver model comparing stainless steel and titanium screws and three and four cortical fixation. *Injury Int J Care Injured* 2005;**36**:60-4.
5. Lundberg A. Kinematics of the ankle and foot - *in vivo* roentgen stereophotogrammetry. *Acta Orthop Scand Suppl* 1989;**223**:1–24.
6. Beumer A, Valstar ER, Garling EH, Niesling R, Ranstam J, Lofvenberg R, Swierstra BA. Kinematics of the distal tibiofibular syndesmosis. Radiostereometry in 11 normal ankles. *Acta Orthop Scand* 2003;**74**:337-43.
7. Ogilvie-Harris DJ, Reed SC, Hedman TP. Disruption of the ankle syndesmosis: Biomechanical study of the ligamentous restraints. *Arthroscopy* 1994;**10**:558-60.
8. Lloyd J, Elsayed S, Hariharan K, Tanaka H. Revisiting the concept of talar shift in ankle fractures. *Foot Ankle Int* 2006 Oct; **27(10)**:793-6.
9. Taser F, Shafiq Q, Ebraheim NA. Three-dimensional volume rendering of tibiofibular joint space and quantitative analysis of change in volume due to tibiofibular syndesmosis diastases. *Skeletal Radiol* 2006 Dec;**35(12)**:935-41. Epub 2006 Mar 15.
10. Gardner MJ, Demetrakopoulos D, Briggs SM, Helfet DL, Lorich DG. Malreduction of the tibiofibular syndesmosis in ankle fractures. *Foot Ankle Int* 2006 Oct;**27(10)**:788-92.
11. Weening B, Bhandari M. Predictors of functional outcome following transsyndesmotic screw fixation of ankle fractures. *J Ortho Trauma* 2005;**19**:102-8.
12. Pereira DS, Koval KJ, Resnick RB, Sheskier SC, Kummer F, Zuckerman JD. Tibiotalar contact area and pressure distribution: The effect of mortise widening and syndesmosis fixation. *Foot Ankle Int* 1996;**17**:269-74.
13. Miller R, Weinhold P, Dahners L. Comparison of tricortical screw fixation versus a modified suture construct for fixation of ankle syndesmosis injury: A biomechanical study. *J Orthro Trauma* 1999;**13**:39-42.
14. Forsythe K, Freedman K, Stover M, Patwardhan A. Comparison of a novel fiberwire-button construct versus metallic screw fixation in a syndesmotic injury model. *Foot Ankle Int* 2008;**29**:49-54.
15. Thornes B, Shannon F, Guiney A, Hession P, Masterson E. Suture-button syndesmosis fixation: accelerated rehabilitation and improved outcomes. *Clin Orthop* 2005;**431**:207-12.