Functional results of dynamic fixation for ankle syndesmotic injuries

Mohamed M.F. Sharaby

Orthopaedic Department, Mansoura University Hospital, Mansoura, Egypt

Correspondence to Mohamed M.F. Sharaby, MD, Lecturer of Orthopedic Surgery, Orthop Consultant in Mansoura University Hospital, Orthopaedic Department, Mansoura University Hospital, Mansoura, Egypt. e-mails: sharaby_mmf@yahoo.com, sharaby_mmf@hotmail.com

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Background
Syndesmotic injuries associated with ankle fractures don't render uniform results despite good reduction and stable internal fixation. An optimal method of fixation needs to be standardized for this type of injuries, resulting in improved ankle function. The aim of this study is to compare the functional and radiological results of TightRope syndesmotic fixation with the traditional screw fixation following syndesmotic ankle injuries.

Patients and methods
Eighty-four patients were included in this prospective study; they were divided into two groups: in the first group, one TightRope was used for syndesmotic fixation, whereas one screw was used in the second group. Clinical evaluation included the American Orthopedic Foot and Ankle Score (AOFAS) score, return to work, and pain and patient satisfaction. Radiological evaluation included both anteroposterior (AP) and lateral views with evaluation of the fixation device, alignment of the ankle, and reduction of syndesmosis.

Results
Of the 42 patients in each group, seven patients from group 1 and one from group 2 were absent at the completion follow up of the rest of the cases. The mean AOFAS hindfoot–ankle score at the final follow-up was 91.7±8.7 (range: 72–100) in group 1 and 89.5±7.1 (range: 66–100) in group 2. The mean initial weight-bearing radiographic measurements for the tibiofibular clear space, tibiofibular overlap, and medial clear space (6 weeks postoperatively) were 3.7±0.5, 6.7±1.5, and 3 ±0.34, respectively, in group 1 and 3.7±0.5, 6.8±0.8, and 3.1±0.6 in group 2. The final weight-bearing radiographic measurements for the tibiofibular clear space, tibiofibular overlap, and medial clear space were 3.8±0.5, 6.3±1.3, and 3.1±0.3, respectively, in group 1 and 3.9±0.5, 6.2±0.8, and 3.3±0.5 in group 2.

Conclusion
TightRope is a reliable option for stabilization of ankle syndesmotic injuries and it may offer a method that is as effective as traditional Arbeitsgemeinschaft Osteosynthesefragen (AO) screw fixation, with the avoidance of the need for another surgery for implant removal.

Keywords:
ankle fracture, comparative study, screw fixation, syndesmotic injury, TightRope fixation

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Introduction

Open reduction and screw fixation is the current standard treatment for displaced injuries of ankle syndesmosis. Despite good decline and stable internal fixation, these injuries do not uniformly have excellent outcomes [1,2].

Even when the syndesmotic reduction is anatomic, screw fixation has potential complications that may adversely affect outcomes. Rigid screw fixation eliminates most if not all of the normal tibiofibular motion, potentially resulting in pain or decreased motion. Pereira *et al.* [3] showed that screw fixation limits the tibiotalar contact area throughout the range of motion of the ankle by locking the fibula and preventing normal fibular motion. In addition, symptomatic hardware failure, or routine screw removal to avoid it, necessitates exposing the patient to a second operation.

The optimum method of stabilization of the disrupted syndesmosis remains controversial. The fiberwire TightRope technique has emerged as an alternative to screw stabilization with an attempt to maintain syndesomtic motion and normal mechanics [4].

The aim of this study is to compare the functional and radiological results of the nonrigid TightRope syndesmotic fixation with the traditional screw fixation following syndesmotic ankle injuries, the success in maintaining good reduction of the inferior tibiofibular joint, and the complications of both techniques.

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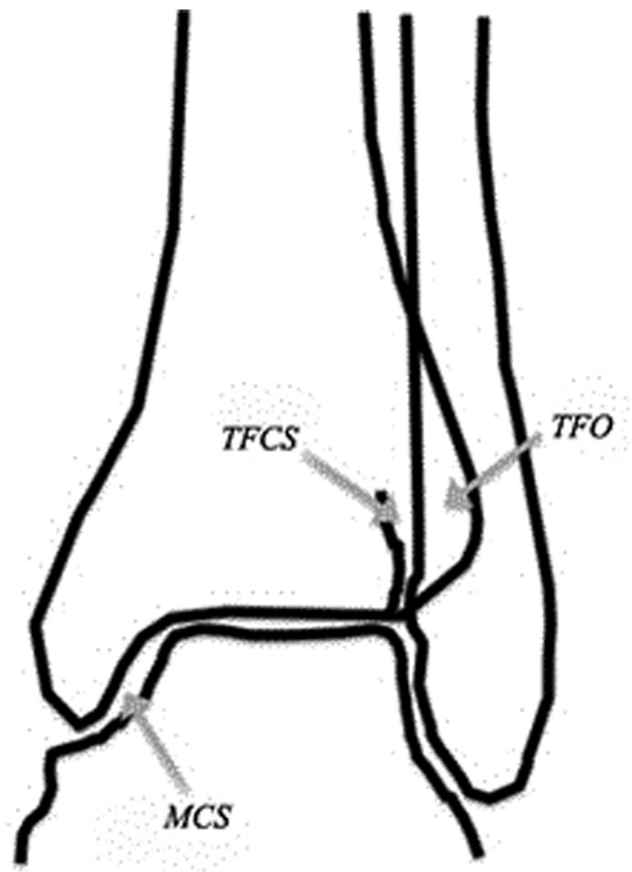
Materials and methods

A prospective randomized clinical trial was conducted during the period June 2013 to March 2015 on skeletally mature (>18 years) patients with ankle fractures associated with syndesmotic injury. Cases were randomly selected and distributed between both according to the inclusion criteria (patients with preoperative evidence of syndesmotic disruption on the basis of plain radiographs or intraoperative by the hook test under fluoroscopy, as suggested by Boytim *et al*. [5] and Pakarinen *et al*. [6]). The study included 84 patients with acute ankle fracture with syndesmotic injury (<2 weeks from trauma). Diabetic patients were excluded from the study as well as cases with connective tissue disorders or neuropathic disorders. Table 1 presents the parameters collected from the corresponding patients including age, sex, side affected, fracture pattern, duration between trauma and surgery as well as duration of follow-up.

Preoperative radiological evaluation included anteroposterior and lateral views, and fractures were classified accordingly by the Lauge–Hansen classification [7]. Postoperative syndesmotic evaluation included both early and final ankle anteroposterior (AP) and lateral views, with measurement of the tibiofibular clear space (TFCS) as the horizontal distance from the lateral border of the posterior tibial malleolus to the medial border of the fibula at the point where the posterior malleolus is the widest on the AP view, tibiofibular overlap (TFO), which is the horizontal distance between the medial border of the fibula and the lateral border of the anterior tibial prominence 1 cm above the plafond on the mortise view, and the medial clear space (MCS) also measured on the mortise view as the horizontal distance between the lateral aspect of the medial malleolus and the medial border of the talus at its widest portion (Fig. 1) [8].

The fractures were fixed using standard Arbeitsgemeinschaft Osteosynthesefragen (AO) principles [9]. Fibula fractures were treated with a one-third tubular plate or reconstruction plate with or without lag screws, or in high fibula fractures with only syndesmosis fixation. Medial malleolar fractures were fixed with two 3.5-mm cancellous screws. All patients were assessed for ankle syndesmotic injuries during the operation by the hook test (pulling the fibula away from the tibia) and stress dorsiflexion and external rotation manipulation under image intensification with

Figure 1



AP view ankle view. MCS, medial clear space; TFCS, tibiofibular clear space; TFO, tibiofibular overlap [8].

Table 1 Demographic data

	Group 1			Group 2			Significant (*P*)
	Minimum	Maximum	Mean±SD	Minimum	Maximum	Mean±SD	
Age	19	61	33.8±10.4	18	65	35.1±12.7	0.6
Duration between trauma and surgery	0	11	1.5±2.4	0	13	2.1±2.9	0.4
Follow-up duration	17	28	22±3.2	16	35	23.3±5	0.1
Sex [*n* (%)]							
Male	20 (57.1)			24 (58.5)			0.5
Female	15 (42.9)			17 (41.5)			
Side [*n* (%)]							
Right	22 (62.9)			25 (61)			0.5
Left	13 (37.1)			16 (39)			

evaluation of the TFO and MCS widening. A measurement of the MCS more than 6 mm or MCS more than 2 mm larger than that of the vertical tibial–talar interval, or TFO less than 1 mm in mortise view were considered indicative of syndesmotic injury [8,10].

After malleolar fixation, the distal tibiofibular joint was reduced without direct visualization of the syndesmosis and held at its anatomical position with a reduction clamp with the ankle joint positioned at 90°. Syndesmosis was fixed with one TightRope in the first group; a 3.5 mm hole was drilled from lateral to medial through the fibula and the tibia at a level more than 1.5 cm proximal to the tibial plafond. When the fibular fracture was plated, a hole was drilled through an empty screw hole. The TightRope was then passed to exit the medial opening with flipping of the TightRope button and the lateral end was hand-tied on the fibula. This was followed by passing of the suture around the fibula under the periosteum to hide the knot. For the second group, a single screw was used for fixation, holding three or four cortices at a level more than 1.5 cm from the tibial plafond as in the first group, and the screw was removed routinely during the third postoperative month.

The same postoperative protocol was adopted for patients in both groups, with plaster-splints applied for all patients following surgery. Mobilization with a walker or double crutches without weight bearing on the operated side was continued for 6 weeks. Splints were removed after 2 weeks and pressure-socks were applied with the foot in a neutral position. After the sixth week, partial weight bearing was initiated on the operated side using double crutches. At the end of the third month, the screws in the second group were removed and complete weight bearing was permitted on the operated side.

Patients were assessed at follow-up using the American Orthopedic Foot and Ankle Score (AOFAS) hindfoot–ankle scoring system [11], at 2, 6, and 12 weeks, and then at 1 and 2 years postoperatively. Moreover, the ability of the patient to ambulate and return to work, including strenuous activities, was also assessed subjectively in the postoperative period. Both pain and patient satisfaction were also evaluated using a 10-point visual analogue scale.

The status of TightRopes was evaluated with respect to any change in the position of the endobuttons in the postoperative radiographs. Alignment of the ankle mortise was also assessed with measurement of the TFCS, TFO, and MCS and radiographic loss of reduction was considered to be present if the TFCS was more than 6 mm, TFO less than 1 mm, or MCS more than 6 mm [8,10].

Statistical analysis

Statistical analysis was carried out using SPSS version 20 (IBM's Chief Privacy Office, 1 New Orchard Road Armonk, NY, USA). Quantitative data were described by means and SD, whereas qualitative data were described using percents. Matching of similar variables between groups as well as test of significance were performed using the independent *t*-test for means and the Pearson χ^2-test for frequency-distributed variables. For nonparametric data, the Mann–Whitney test was used to compare the means. *P* value up to 0.05 was considered significant.

Results

This study included a total of 84 cases of closed ankle fractures with syndesmotic injuries, 42 patients in each group, with eight cases lost during the follow-up period: seven from group 1 and one case from group 2. Preoperative radiological evaluation indicated decreased TFO with an increase in the MCS and TFCS. The fracture patterns identified in this study included Weber type B and C fractures [12] and high fibular fractures (Maisonneuve). No cases were identified as pure syndesmotic injuries (Table 2). The mean age of the patients was 33.8±10.4 years (range: 19–61) years in group 1 and 35.1±12.7 years (range: 18–65) in group 2. The male to female ratio was 20 : 15 in group 1 and 24 : 17 in group 2. The right side was affected in 22 patients in group 1 and 25 patients in group 2. The mean follow-up period was 22±3.2 months in group 1 and 23.3±5 in group 2. The mean AOFAS hindfoot–ankle score at the final follow-up was 91.7±8.7 (range: 72–100) in group 1 and 89.5±7.1 (range: 66–100) in group 2.

The mean initial weight-bearing radiographic measurements for the TFCS, TFO, and MCS (6 weeks postoperatively) were 3.7±0.5, 6.7±1.5, and 3 ±0.34, respectively, in group 1 and 3.7±0.5, 6.8±0.8, and

Table 2 Injury pattern

	Group 1 [*N* (%)]	Group 2 [*N* (%)]
Weber 2	15 (42.9)	15 (36.6)
Weber 3	18 (51.4)	25 (61.0)
Maisonneuve	2 (5.7)	1 (2.4)
Total	35 (100)	41 (100)
Bimalleolar	24 (68.6)	28 (68.3)
Trimalleolar	11 (31.4)	13 (31.7)
Total	35 (100)	41 (100)

3.1±0.6 in group 2. The final weight-bearing radiographic measurements for the TFCS, TFO, and MCS were 3.8±0.5, 6.3±1.3, and 3.1±0.3, respectively in group 1 and 3.9±0.5, 6.2±0.8, and 3.3±0.5 in group 2. The mean difference from the initial to the final radiographic measurements was 0.11, 0.4, and 0.13 mm for the TFCS, TFO, and MCS, respectively, in group 1 and 0.13, 0.58, and 0.29 mm in group 2 (Table 3).

With respect to complications, superficial infection was reported in one case in the TightRope group and in two cases in the screw group with spontaneous improvement. No superficial irritation by the suture of TightRope was detected in any of our cases. Loosening of fixation was detected in two cases in the screw fixation group and one case showed breakage of the screw 5 months after surgery. In the TightRope group, none of the cases showed loss of fixation or subsidence of the button (Figs 2 and 3).

Discussion

Ankle syndesmotic injuries may occur when the distal fibula and tibia are forced apart as a result of external rotation of the talus inside ankle mortise. In addition, the tibia often rotates internally at the same time, resulting in a Lauge–Hansen SER/Danis–Weber type B or PER/Danis–Weber type C ankle fracture or less commonly a Maisonneuve fracture. Purely ligamentous injuries of the syndesmosis are rare and occur when the external rotation force is not sufficient to create a fracture and are termed high ankle sprains [13–15]. Management of this fracture includes proper reduction and stable fixation to maintain the reduction until the ligaments heal. This is necessary to ensure a favorable outcome and to avoid long-term arthrosis within the ankle joint as a result of decreased tibiotalar contact area and the subsequent increase in the contact pressure of that joint [16–18].

Syndesmotic stabilization is essential during ankle fracture management. However, this joint is a dynamic articulation that moves during ankle dorsiflexion with widening of the distal tibiofibular joint space to accommodate the wider portion of the trapezoidal talus. This relative motion is vital for the physiologic function of ankle mortise during weight-bearing and ankle range of motion. Screw fixation of the distal tibiofibular syndesmosis provides a static articulation, which, on the one hand, aids in healing of the injured tibiofibular ligaments, but on the other, changes the dynamic nature of the syndesomsis to a static joint with subsequently possible functional incapacity [19–21]. It was proposed that syndesmotic TightRope fixation creates compression stabilization of the joint without interfering with its normal function, hence allowing the possibility of accelerated rehabilitation and expected improved outcome [22].

According to the clinical results of this study, no statistically significant difference was detected between both groups with respect to the AOFAS score, pain, and patient satisfaction. Patients in the TightRope fixation group could get back to work earlier than those in screw fixation group, but with

Table 3 Postoperative results

	Group 1			Group 2			Significant (*P*)
	Minimum	Maximum	Mean±SD	Minimum	Maximum	Mean±SD	
AOFAS score	72	100	91.7±8.7	66	100	89.5±7.1	0.2
Return to work (weeks)	6	10	7.8±2.1	7	11	8.6±2.7	0.5
Pain visual analogue scale score	7	10	9.2±0.89	7	10	9±0.79	0.7
Patient satisfaction	7	10	8.9±0.99	6	10	8.5±1.1	0.08
Immediate postoperative							
TFCS	3	5	3.7±0.5	3	5	3.7±0.5	0.6
TFO	4	11	6.7±1.5	5	9	6.8±0.8	0.5
MCS	2	4	3±0.34	2	4	3.1±0.6	0.5
Final postoperative							
TFCS	3	5	3.8±0.5	3	5	3.9±0.5	0.8
TFO	4	9	6.3±1.3	5	8	6.2±0.8	0.6
MCS	2	4	3.1±0.3	2	4	3.3±0.5	0.06
Difference							
TFCS	0	0.50	0.11±0.21	0	0.50	0.13±0.22	0.7
TFO	0	1.00	0.4±0.48	0	2.00	0.58±0.59	0.18
MCS	0	1.00	0.13±0.25	0	1.00	0.29±0.4	0.07
Distance of fixation device to plafond (mm)	16	34	25±5.65	15	36	23.9±6.6	0.45

AOFAS, American Orthopedic Foot and Ankle Score; MCS, medial clear space; TFCS, tibiofibular clear space; TFO, tibiofibular overlap.

Figure 2

A 35-year-old male patient with Weber type C fracture with syndesmotic injury, a–c: AP, mortise and lateral preoperative views, d–f: early (4 weeks) weight-bearing AP, mortise and lateral postoperative views, g–i: final postoperative (25 months) weight-bearing AP, mortise and lateral views.

no statistically significant difference. A randomized-controlled trial by Coetzee and Ebeling [23], which included 12 patients in each group, also reported no significant difference in the ankle functional outcome between syndesmotic screw and TightRope fixation. Naqvi *et al*. [24], in their cohort study (which included 23 patients in each group), reported trends toward better clinical outcome in patients treated with TightRope fixation, with more accurate reduction provided with TightRope rather than syndesmotic screws, but with no significant difference between groups.

Figure 3

A 34-year-old male patient with Weber type C ankle fracture with syndesmotic injury, a–c: AP, mortise and lateral preoperative views, d–f: early (4 weeks) weight-bearing AP, mortise and lateral postoperative views, g–i: final postoperative (25 months) weight-bearing AP, mortise and lateral views.

The results of this study indicated no statistically significant difference between the radiological results of both groups with respect to maintenance of reduction during the follow-up period even after screw removal. Manjoo *et al*. [25] reported a review of 106 patients with syndesmotic screw fixation with better functional results in patients in whom syndesmotic screws were removed, fractured, or loosened compared with cases with intact screws, but with an average widening of the TFCS from 3.1 ±0.2 to 4.1±0.2 mm and with no change in the TFO and MCS. On the basis of these findings, they opted for a protocol to leave syndesmotic screws intact for a minimum of 6 months to avoid late diastasis. In their comparative study, Beumer *et al*. [19] detected a significant difference in the TFCS between the

TightRope and syndesmotic screw groups. Despite the routine early removal of screws during the third month, late diastasis was not detected in the screw fixation group of this study as being compared from early postoperative to final follow-up radiographs. In addition, we did not find statistical differences between our groups with respect to TFCS, TFO, or MCS.

Schepers [26] performed a systematic review in 2012 on suture button versus syndesmotic screw repair of acute distal tibiofibular injuries and reported the various complications associated with the use of the TightRope. The most commonly reported complication was prominence of suture on the lateral aspect of the fibula necessitating removal of the TightRope device in some cases. This was reported in 10 of 11 studies reviewed by Schepers including 220 patients, 22 (10%) of whom required removal of the implant. Despite several studies reporting this soft tissue complication because of a prominent knot [27–30], removal of the TightRope makes this procedure lose one of its important advantages, namely, the unnecessary for another surgery with possible complications and increased cost. Hodgson and Thomas [30] used 10 half-hitches when securing the lateral knot to leave a longer length of knotted suture, which was then buried under the fibula. This study has shown that soft tissue irritation following the use of TightRope stabilization of the distal tibiofibular joint does not seem to be a major problem as the sutures were buried routinely under soft tissues, resulting in avoidance of this problem with no need for another surgery for removal of the irritating sutures.

The second complication was wound infection; only superficial infection was reported in both groups, with no statistically significant difference. All cases responded well to antibiotics, with no further need for operative debridement or removal of hardware. Naqvi *et al*. [4] reported infection in three of their 49 patients; in all of these patients, implant removal was required.

Loosening of the fixation device is another complication that was encountered in some studies, especially in the screw fixation groups. No loosening of screws was encountered in most of the cases in this study, which can be attributed to the routine early removal of screws in all cases, except for three cases, where removal was delayed. One disadvantage of the TightRope is the possible pull-through of its medial button through the medial cortex, with subsequent loss of fixation. DeGroot *et al*. [31] have documented osteolysis and subsidence of the suture button through the cortex of the fibula or tibia. 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. To avoid this complication, it was planned in this study to insert the TightRope device into the strong cortical bone of the tibia more than 1.5 cm proximal to the plafond. One TightRope was used in all cases in group 1, with no subsidence in the implant or loss of fixation noted during the period of follow-up. Naqvi *et al.* [4] placed a second TightRope in 26% and DeGroot *et al.* [31] used more than one in 75% of their patients. Considering the long-term effects, the longest follow-up currently is ~2 years. In some studies, osteolysis, subsidence of the implant, and enlargement of the tibial drill-hole at longer follow-up have been noted. Several authors therefore advise continued follow-up to monitor these effects and their possible influence on outcomes [31,32].

Several advantages were described for the TightRope over syndesmotic screw fixation; easy insertion is seemingly a character of both techniques. TightRope is considered a dynamic fixation, allowing for syndesmotic motion during talar movement, with no need for removal compared with the rigid screw fixation. In addition, because of the flexibility of the device, the fibula is pulled into the tibial incisura as it is tightened, potentially leading to an improved reduction of the syndesmosis [22]. Biomechanical studies have shown that TightRope fixation of the syndesmosis has slightly inferior stability compared with screw fixation and allows increased anatomical micromotion [32]. However, this in itself was considered an advantage of maintaining normal mobility of the inferior tibiofibular joint. As a result of this flexibility, physical therapy can be started earlier with a more mobile ankle and with no fear of screw breakage during early loading, with ultimate earlier return to work and sport activities than with the rigid screw fixation. Regarding the cost benefit; the TightRope device – in spite of being apparently more expensive than the screw fixation- however the single procedure with no need for hospital readmission and resurgery seemed to be less costly for this method of fixation [33].

To our knowledge, this study is considered one of the largest prospective cohort series evaluating this technique in terms of patient number. Cases were randomized properly and evaluation was blinded for all cases in both groups. Longer follow-up duration is required to evaluate the development of ankle arthrosis.

Conclusion

The results of this study indicate that the TightRope (Arthrex Inc., Medical Equipment manufacturer in Industry, California, 166 S Brea Canyon Rd, City of Industry, CA, United States) is a valid option for stabilization of syndesmotic injuries and, as the data show, may offer a method that is as effective as traditional AO screw fixation with the avoidance of the need for another surgery for implant removal. It is recommended that in further studies, earlier rehabilitation be taken into consideration with the TightRope fixation because of the advantage of improved mobility at the distal tibiofibular joint with avoidance of external rotation at the ankle joint.

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Conflicts of interest

There are no conflicts of interest.

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