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ORIGINAL ARTICLE

The use of TightRope fixation for ankle syndesmosis injuries: our experience

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Abstract
Purpose Ten percentage of all ankle fractures sustain an associated syndesmotic injury. TightRope is a relatively new technique for syndesmosis fixation, characterized by a non-absorbable FibreWire held tight between two cortical metal buttons. The purpose of this study was to evaluate the results obtained with the use of this device.
Methods From January 2011 to December 2015, 54 patients with ankle diastases were treated. Eighteen patients were excluded from the study. Fractures of the fibula or tibia requiring fixation were internally fixed using standard AO techniques. Preoperative and the most recent postoperative ankle radiographs were reassessed for measurements of the tibiofibular clear space (TFCS), medial clear space (MCS) and tibiofibular overlap (TFO). Clinical outcomes were assessed at the time of follow-up using the American Orthopaedic Foot and Ankle Society (AOFAS) score, a self-administered Foot and Ankle Disability Index (FADI) score and patients satisfaction.
Results The mean follow-up was 28, 64 months. Mean values for MCS, TFCS and TFO were 1.51–1.53 and 0.25 cm, respectively. The mean AOFAS score was 93.11, and the mean FADI score was 130.11. Twenty-nine (80.6 %) patients reported their outcome as excellent or very good.
Conclusions TightRope technique can achieve flexible fixation of the syndesmosis and permit full range of motion of the tibiofibular joint. Patients can start rehabilitation exercise at an early stage after operation. The results of this study indicate that TightRope fixation is a valid option for syndesmotic injuries.

Keywords Syndesmosis · TightRope · Ankle injury · Ankle fracture · Sports injury

Introduction

Ankle sprain is the most common trauma in sports. Every day 1 out of 10,000 people undergoes to an ankle injury, and in sports practice incidence becomes 5.23 out of 10,000 [1–3].

In 1–18 % of all ankle sprains occur an injury to the syndesmosis between the distal tibia and fibula, particularly after external rotation or dorsiflexion [4]. Symptoms are pain just above the ankle joint and difficulty at toe-off when running.

Approximately 10 % of all ankle fractures and up to 11 % of ankle soft tissue injuries sustain an associated syndesmotic injury [5, 6].

These injuries require stress radiographs with the foot in external rotation [7, 8]. Magnetic resonance imaging, which has been reported to have a sensitivity of 90 %, specificity of 95 % and accuracy of 93 %, is often used [9, 10]. Arthroscopy confirms the diagnosis [6]. Furthermore CT scan may be useful in preoperative planning [11]. Sometimes these injuries may remain undiagnosed, causing long-term disability, longer recovery periods, chronic instability, chronic pain, osteochondral lesions (also of the talus) or arthritic changes may develop [12].

Repair the syndesmotic complex is necessary to avoid further degeneration of the ankle articulation [13].

Several fixation implants have been reported: metal cortical screws, bioabsorbable screws, syndesmotic bolts and TightRope [14–19].

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The most common treatment, recommended by the AO organization, is the metal cortical screw fixation. However, complications are not rare, such as screw loosening, screw breakage, stiffness, prolonged period of protected weight bearing, need for second operation and the risk of late diastasis after early removal or breakage of the screw [20–23].

Surgeons face multiple issues when choosing to repair the syndesmosis with screw fixation [5, 24–32]. Debates are: It would be better to place 3 cortices to allow micromotion or 4 cortices for near absolute rigidity; the length of time needed when the syndesmotic screw should be removed; level of screw placement above the tibial plafond; the weightbearing restrictions to avoid syndesmotic screw breakage; and, if breakage does occur, which has been reported to be as high as 10–29 %, should additional surgery and removal be performed [21, 22].

Another surgical method is the syndesmotic bolt that is more flexible than metal cortical screw fixation, permitting some degree of micromovement [33]. However, it cannot permit the normal range of motion of distal tibiofibular joint, especially the rotation of the fibula [33].

Syndesmotic TightRope and even more flexible fixator have been recently introduced [18, 19, 34–37].

Few studies have reported on the clinical outcomes of TightRope, and the major complication reported is soft tissue irritation over the prominent lateral knot [36–39].

The theoretical advantages of a suture-button device over a metallic syndesmotic screw are that it allows physiologic motion at the syndesmosis while maintaining the reduction, less risk of hardware pain and subsequent implant removal, and it permits earlier return to motion as there is no risk of screw breakage and subsequent recurrent syndesmotic diastasis.

The purpose of this study was to evaluate the results obtained with the use of TightRope in syndesmotic injury.

Materials and methods

From January 2011 to December 2015, 54 patients with ankle diastases were treated with Arthrex TightRope.

The inclusion criterion was that patients sustained distal tibiofibular syndesmotic diastasis with or without ankle fractures, follow-up more than 6 months. Syndesmotic diastasis was defined as tibiofibular clear space (TFCS) more than 6.0 mm on the anteroposterior or mortise radiographs, tibiofibular overlap (TFO) less than 6.0 mm on the anteroposterior radiograph or less than 1.0 mm on the mortise radiographs [40] or medial clear space (MCS) more than superior clear space or 5.0 mm on the anteroposterior radiographs [41]. The exclusion criteria included open ankle fractures or multiple traumas in the ipsilateral lower extremities, the associated pilon fracture, diabetes, neuropathic arthropathy, systemic diseases, dementia, pathological fractures and other problems which made patients unable to comply with instructions.

Table 1 Patients demographics

	Data
Age (yr)	34.28 ± 13.43
Weight (kg)	74.83 ± 9.93
Gender (M/F)	28/8
Side (R/L)	12/24
AO classification	14 Type 44B2
	22 Type 44C2
Weber classification	8 Type B
	28 Type C
Mechanism of injury	12 sport
	24 vehicle accident

Eighteen patients were excluded from the study for insufficient follow-up.

The age ranged between 16 and 66 years (average age 34.28 ± 13.43) at the time of surgery.

Twenty-eight patients were male, and eight patients were female. Twenty-four of the ankles were the left and twelve the right.

The mean patient's weight was 74.83 ± 9.93 kg (range 56–90 kg), and the mean BMI was 24.92.

All the 36 fractures were classified according to the AO classification and the Weber classification (Table 1).

The different traumas were surgical treated by three surgeons (the authors). Fractures of the fibula or tibia requiring fixation were internally fixed using standard AO techniques, and syndesmosis integrity was evaluated using the hook test under fluoroscopy after fixation of the fractures (Fig. 1a–c).

All four cortices were drilled from the open lateral side, 30° anterior to the coronal plane under image guidance, using a 3.5-mm drill bit provided in the prepacked set [42]. The drill hole was performed through one of the empty plate holes, if available. The leading needle was passed through the holes and out from the intact medial skin along with the pull-through sutures, keeping only the white suture under tension and leaving the other slack to keep the oblong button aligned with the holes. Once the leading button passed through the medial tibial cortex, confirmed by imaging, the green and white pull-through sutures were used to toggle the oblong button while giving tension on the FiberWire from the lateral side. Once both the buttons were seated flush with the bone, the free ends of FiberWire on the lateral side were hand tied and cut 0.5 cm long.

All patients were immobilized in a below-knee non-weightbearing cast for 4 weeks followed by physiotherapy and allowed full weight bearing as tolerated. Patients were

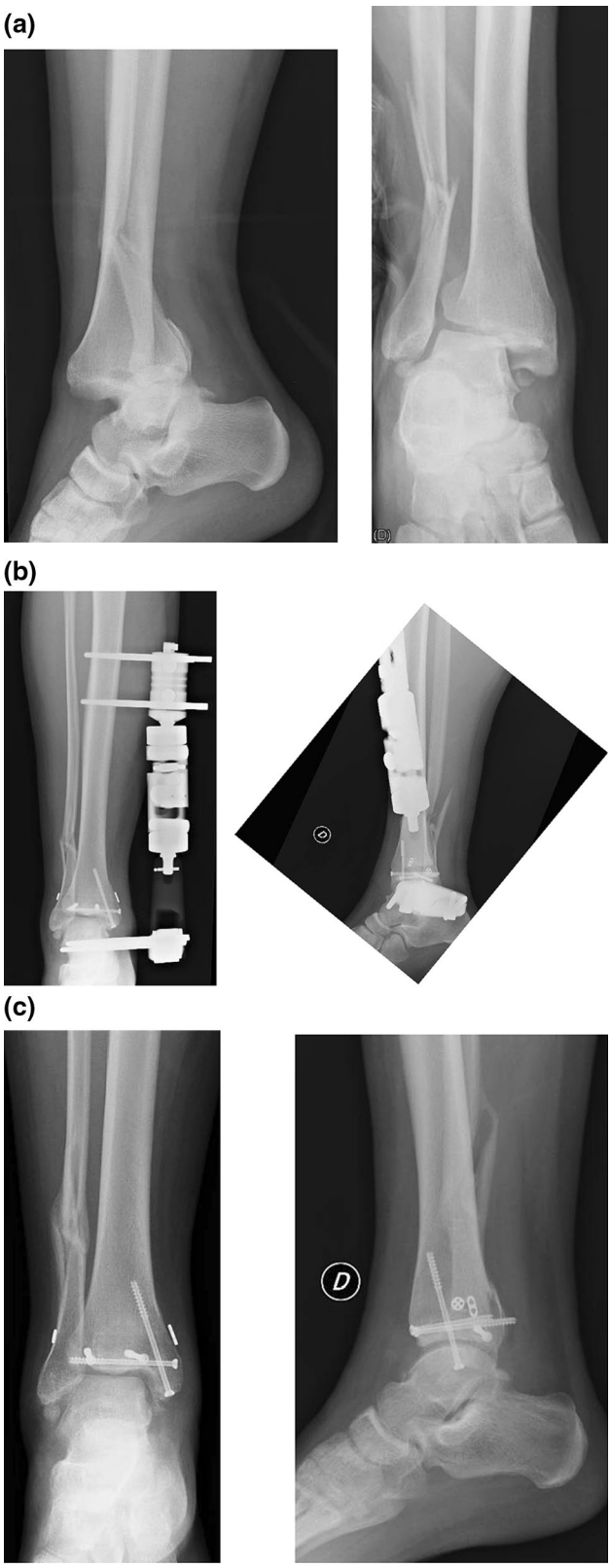

Fig. 1 **a** Boy of sixteen years old with right ankle trauma (Weber C fracture). **b** Reduction in syndesmosis with TightRope, screws for the malleolus fracture and external fixation (FEA) for ankle stability. **c** FEA removal at 3 months after first surgery

clinically and radiologically evaluated at 1, 3, 6 and 12 months after surgery.

Clinical outcomes were assessed at the time of follow-up using the American Orthopaedic Foot and Ankle Society (AOFAS) score.

Preoperative and the most recent postoperative ankle radiographs were reassessed by the authors for measurements of MCS, TFCS and TFO. Furthermore, all patients were contacted at the time of this study to collect latest data using a confidential questionnaire and a self-administered Foot and Ankle Disability Index (FADI) score [43, 44] at the time of follow-up.

Measurements were obtained with digital radiographic software (PACS, Syngo Imaging, Siemens Healthcare, Italy).

All measurements were made on an anteroposterior radiograph, 1 cm proximal to the ankle joint [32]. The tibiofibular clear space (TFCS), medial clear space (MCS) and tibiofibular overlap (TFO) measurements were recorded [40]. Non-weightbearing radiographs were excluded.

Patients were asked to indicate the degree of overall satisfaction with postoperative pain management according to the method proposed by Coughlin (0 = unsatisfied/poor, 1 = somewhat satisfactory/adequate, 2 = satisfactory/adequate, 3 = very good, 4 = excellent) [45].

The preoperative data were correlated with the results of the final follow-up using the Student's t test. A p value <0.05 was considered significant. Statistical analysis was performed using Microsoft Office Excel (2007 version).

Results

The mean follow-up for the 36 patients was 28.64 months (range 6–60 months) after TightRope implantation.

Radiographic measurements were taken on the preoperative, on the postoperative and at follow-up in anteroposterior ankle radiographs 1 cm proximal to the tibial plafond.

Mean values for MCS, TFCS and TFO were 1.51 ± 1.32–1.53 ± 1.34 and 0.25 ± 0.24 cm, respectively, preoperatively, 0.42 ± 0.07–0.46 ± 0.13 and 0.70 ± 0.08 while the follow-up mean MCS was 0.40 ± 0.08 cm, TFCS was 0.46 ± 0.11 cm and TFO was measured as 0.71 ± 0.08 cm (Table 2).

The mean AOFAS score was 93.11 ± 4.38 (range, 86–98) and the mean FADI score was 130.11 ± 2.52 (range, 126–134). Twenty-nine (80.6 %) patients reported their outcome as excellent or very good, while six (16.6 %) reported outcome as good and 1 fair (2.8 %) (Fig. 2).

Only 1 patients required removal of TightRope because of complications related to the lateral knot. It was removed

Table 2 Clinical and radiological data of 36 patients, presented as mean value and standard deviation (SD)

	Data
Distance from tibial plafond	1.73 ± 0.39
Medial clear space	Preop 1.51 ± 1.32
	Postop 0.42 ± 0.07
	FU 0.40 ± 0.08
Tib–Fib clear space	Preop 1.53 ± 1.34
	Postop 0.46 ± 0.13
	FU 0.46 ± 0.11
Tib–Fib overlap	Preop 0.25 ± 0.24
	Postop 0.70 ± 0.08
	FU 0.71 ± 0.08
AOFAS score	93.11 ± 4.38
FADI score	130.11 ± 2.52
TightRope removal	1

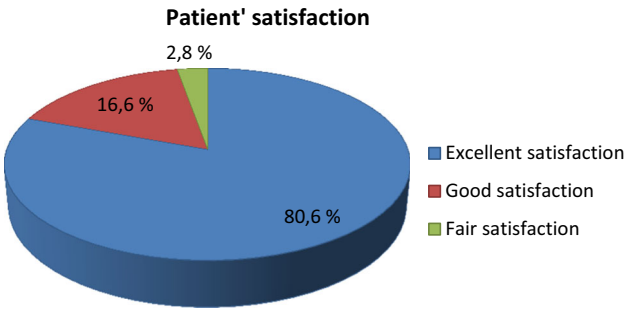

Fig. 2 Patient satisfaction at final follow-up

after 6 months because of a prominent knot causing skin irritation. At the removal of TightRope, there was no sign of diastasis on the radiographs.

Discussion

TightRope is a relatively new technique for syndesmosis fixation. It comprises of a non-absorbable FibreWire held tight between two cortical metal buttons. As the TightRope provides semirigid fixation of syndesmosis, it obviates the need for routine removal of the implant, allows early weight bearing and patients can start physical exercises earlier.

Wiker_y et al. [46], in 2010, performed a long-term review of 48 patients who had been followed up for 8.4 years after syndesmotic rupture. They compared the operative and non-operative limb and found those patients who demonstrated more than 1.5 mm widening of the syndesmosis compared with the contralateral limb had inferior clinical results.

In 2005, Thornes et al. [36] performed a clinical and radiological comparison of 16 patients. In the suture-button group demonstrated significantly better AOFAS score and returned to work earlier than the screw group.

Nonetheless, the obvious benefit of leaving the implant intact indefinitely while resuming full activity avoids, not only a second operation, but also resolves the debatable issue of appropriate timing for syndesmotic screw removal [27].

Longer immobilization and protected weight bearing can lead to joint stiffness and decrease in functional capacity [26].

The physiologic motion of the fibula with normal migrational changes throughout the gait cycle and weight bearing has been described [21, 28, 47–49].

TightRope technique can achieve flexible fixation of the syndesmosis and permit full range of motion of the tibiofibular joint. Patients can start rehabilitation exercise at an early stage after operation. In addition, the TightRope does not require removal and there is no concern about hardware breakage [37].

Teramoto et al. [50] showed a significant increase in diastasis during external rotation force acting on the injured syndesmosis of cadaveric specimens fixed with TightRope, when compared with those fixed with a 4.5-mm cortical screw inserting across 4 cortices. Another potential concern is that the medial button might be pulled into the metaphyseal cortex, leading to reduction failure [51].

The device should be placed at the proper level and orientation. Miller et al. [52] reported that the implant inserted 5 cm proximal to the tibiotalar joint could provide improved pull-out strength.

We insert the TightRope at a mean of 1.73 cm (range 1.24–2.52) from the tibiotalar plateau.

Schepers et al. [23] reported a 22.4 % complication rate from routine syndesmotic screw removal. They also reported recurrent diastasis after removal in 5 (6.6 %).

The rate of implant removal might be as high as 10 % [53].

In the literature on syndesmotic screw fixation, this percentage is dependent on hospital protocol and is slightly over 50 % on average. In a recent review, the functional outcome did not differ in cases with retained or removed syndesmotic screws [27].

The routine removal of syndesmotic screws has been associated with a high complication rate of over 20 %, with both recurrent diastasis and wound infection following elective screw removal occurring in up to 10 % [23, 54].

Some cases of TightRope removal are reported in the literature because of soft tissue inflammation and tibialis anterior tendon entrapment from the medial button [34, 36–39, 55].

We report one case of soft tissue irritation on the lateral side requiring removal of implant at 6 months. We identified that the lateral knot remains prominent especially in

thin individuals and may lead to soft tissue irritation, inflammation or sinus formation.

New discussions have risen whether one or two suture buttons should be used and in which configuration. Naqvi et al. placed a second TightRope in 26 % and DeGroot et al. [34, 35] used more than one in 75 % of their patients.

A final point of consideration is the additional costs and subsequent cost-effectiveness of the TightRope system versus a syndesmotic screw. The additional costs of a syndesmotic screw removed in daycare surgery in Italy are around 700 Euro, which is approximately the cost of two TightRope systems. There is currently no prospective research on the hospital and socioeconomic cost-effectiveness of the TightRope system versus a syndesmotic screw, which takes the following items into consideration: additional surgery for implant removal, complications, number of follow-up clinic appointments, return to work and additional absence from work.

Conclusions

The results of this study, according to the literature [36, 50, 51], indicate that TightRope fixation is a valid option for syndesmotic injuries. As with any technique, there is a learning curve. The insertion technique is simple and provides syndesmosis stabilization without eliminating normal tibiofibular motion and also obviates the need for a routine second operation for hardware removal, making it potentially cost-effective.

The combination of excellent AOFAS and FADI scores suggesting high patient satisfaction and the objective clinical correlation of radiographic maintenance of the ankle mortise strongly suggest that the TightRope® is a valid option. Not only has the TightRope® addressed several key issues related to fixation, but it has also demonstrated 2-year follow-up data with reliable results for patients who had sustained syndesmotic compromise.

Compliance with ethical standards

Conflict of interest The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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