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A prospective randomised study comparing TightRope and syndesmotic screw fixation for accuracy and maintenance of syndesmotic reduction assessed with bilateral computed tomography

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ABSTRACT

Background: The accuracy and maintenance of syndesmosis reduction are essential when treating ankle fractures with accompanying syndesmosis injuries. The primary aim of this study was to compare syndesmosis screw and TightRope fixation in terms of accuracy and maintenance of syndesmosis reduction using bilateral computed tomography (CT).
Study design: Single centre, prospective randomised controlled clinical trial; Level of evidence 1.
Methods: This study (ClinicalTrials.gov, NCT01742650) compared fixation with TightRope® (Arthrex, Naples, FL, USA) or with one 3.5-mm tricortical trans-syndesmotic screw in terms of accuracy and maintenance of syndesmosis reduction in Lauge-Hansen pronation external rotation, Weber C-type ankle fractures with associated syndesmosis injury. Twenty-one patients were randomised to TightRope fixation and 22 to syndesmotic screw fixation. Syndesmosis reduction was assessed using bilateral CT intraoperatively or postoperatively, and also at least 2 years after surgery. Functional outcomes and quality of life were assessed using the Olerud–Molander score, a 100-mm Visual Analogue Scale, the Foot and Ankle Outcome Score, and the RAND 36-Item Health Survey. Grade of osteoarthritis was qualified with follow-up cone-beam CT.
Results: According to surgeons' assessment from intraoperative CT, screw fixation resulted in syndesmosis malreduction in one case whereas seven syndesmosis were considered malreduced when TightRope was used. However, open exploration and postoperative CT of these seven cases revealed that syndesmosis was well reduced if the ankle was supported at 90̊. Retrospective analysis of the intra- and post-operative CT by a radiologist showed that one patient in each group had incongruent syndesmosis. Follow-up CT identified three patients with malreduced syndesmosis in the syndesmotic screw fixation group, whereas malreduction was seen in one patient in the TightRope group ($P = 0.33$). Functional scores and the incidence of osteoarthritis showed no significant difference between groups.
Conclusion: Syndesmotic screw and TightRope had similar postoperative malreduction rates. However, intraoperative CT scanning of ankles with TightRope fixation was misleading due to dynamic nature of the fixation. After at least 2 years of follow-up, malreduction rates may slightly increase when using trans-syndesmotic screw fixation, but reduction was well maintained when fixed with TightRope. Neither the incidence of ankle joint osteoarthritis nor functional outcome significantly differed between the fixation methods.

Introduction

The classic presentation of syndesmotic disruption occurs in addition to Lauge-Hansen pronation-external rotation (PER) Danis-Weber type C ankle fracture [1,2]. Malreduction of the

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syndesmosis that alters tibiofibular joint kinematics is reported to impair ankle function and lead to early osteoarthritis [3–5]. Therefore, accuracy and maintenance of reduction of the syndesmosis are considered essential when treating ankle fractures with concomitant syndesmosis injury [4,6–9].

Metallic trans-syndesmotic screw has been the most popular fixation method to stabilise unstable syndesmosis [10–12]. However, syndesmosis malreduction is reported to occur up to more than 50% in syndesmotic screw fixation [13–18]. A further problem with syndesmosis screws is the potential late diastasis due to screw breakage or screw removal [13,17,19,20].

Flexible TightRope® (Arthrex, Naples, FL, USA) suture-button device was developed for physiologic stabilisation of the ankle mortise; its use has increased rapidly over the last years [21]. Theoretically, this suture-button device allows physiologic motion of the syndesmosis without need for implant removal, which may lower the risk of recurrent syndesmotic diastasis as described after syndesmosis screw removal [11]. Biomechanical investigations have demonstrated that the strength of TightRope device is comparable to a tricortical 3.5 mm syndesmotic screw [22–24]. Several recent studies assessed syndesmosis stabilisation with suture-button device [25–29] and comparative studies reported at least as good functional results with this device in comparison to syndesmotic screw [18,30–33]. Previously the rate of syndesmosis malreduction associated with suture-button device ranged from 0% to 11% [18,25,29,30,33,34].

The majority of earlier studies of syndesmosis fixation used only plain radiographs to assess syndesmosis reduction [8,13,25,26,29,30,35–38]. Intra-operative fluoroscopy and post-operative conventional radiography are currently considered inaccurate to assess syndesmosis reduction; [14,17,18,39] computer tomography (CT) of both ankles is recommended [17,18,40–45].

Only a few published clinical studies with functional results have assessed syndesmotic reduction with bilateral CT, [16–18] and none of them has used both intra-operative and follow-up CT for assessing syndesmosis reduction. Furthermore, only two prospective randomised controlled trial has compared screw and TightRope for syndesmosis fixation [32,33].

The primary purpose of this prospective randomised trial comparing fixation via syndesmosis screw or TightRope was to assess the accuracy and the maintenance of syndesmosis reduction using bilateral CT. The secondary purpose was to compare functional outcome and the rate of OA after at least 2 years of follow-up. Based on previous literature, we hypothesised that the malreduction rate of screw fixation would be 50%, and the malreduction rate of TightRope fixation would be 5%.

Material and methods

Study design

We conducted a prospective randomised trial (ClinicalTrials.gov, NCT01742650) comparing fixation via TightRope® or via one 3.5-mm tricortical trans-syndesmotic screw for the treatment of syndesmosis injury in Lauge-Hansen pronation-external rotation-type ankle fractures. CONSORT-guidelines were followed (http://www.consort-statement.org). The ethical committee of our hospital approved the study protocol.

Study population

All skeletally mature patients (16 years or older) who visited emergency department of an University teaching hospital between January 2010 and December 2011 due to Lauge-Hansen pronation-external rotation (PER) [1], AO/OTA Weber C, [2,46] -type ankle fracture were assessed for study eligibility. Patients with associated pre- or intra-operative evidence of syndesmotic disruption based on plain radiographs or on the manual external rotation test under fluoroscopy, as suggested by Boytim et al. [47] and Pakarinen et al. [48] were considered eligible for enrolment. The senior orthopaedic trauma surgeon responsible for patient care examined the patients and confirmed the diagnosis. Exclusion criteria were previous ankle fracture, concomitant tibia fracture, diabetic or other neuropathy, a delay from trauma to surgery of more than 7 days, pathological fracture, or inadequate co-operation.

Sixty patients with PER IV, Weber C-type ankle fracture were identified. Seventeen patients were excluded due to exclusion criteria (Fig Consort Diagram). 43 (72%) patients were enrolled into the study and 22 of them were randomised to syndesmotic screw group and 21 to TightRope fixation group. Informed consent was obtained from each patient for study participation.

Sample size

Based on previous studies, we hypothesised that 50% of screw-fixed [14,15] and no more than 5% of suture-button fixed [25,30] syndesmosis would be in malposition. Thus, the required sample size was determined to be 19 patients per group ($\alpha = 0.05$, $\beta = 0.1$, dropout rate = 20%).

Randomisation

A computer-generated randomisation list was created by a biostatistician. Randomisation was performed in randomly varying blocks, with the block size varying among 4, 6 and 8. A research assistant who was not involved in patient care sealed the randomisation lists into numbered, opaque envelopes to, ensuring concealment. After repair of the bony injuries, in the operating room an assistant nurse opened a numbered envelope containing the information of the method of syndesmosis fixation.

Interventions

The fractures were fixed in both groups using standard AO (Arbeitsgemeinschaft für Osteosynthesefragen) principles [49]. Fibula fractures were treated either with open direct reduction and rigid fixation with a 1/3 tubular plate with or without lag screw/s, or in high fibula fractures with only syndesmosis fixation. Medial malleolar fractures were reduced and fixed with two 3.5-mm, partially threaded, cancellous screws. Displaced posterior >25% articular fragments were fixed with two 3.5-mm, partially threaded, cancellous screws. After malleolar fixation, syndesmosis was fixed accordance with the outcome of the randomisation (with one 3.5-mm cortical screw purchasing three cortices or with one TightRope® device). The distal tibiofibular joint was reduced without direct visualisation of the syndesmosis and held at its anatomical position by hand or with a reduction clamp without extra compression. The ankle joint was positioned at an angle of 90° between the tibial shaft and the foot during syndesmosis fixation. TightRope device was installed as described by Cottom et al. [25]. A 3.5-mm hole was drilled from lateral to medial through the fibula and tibia at the level of the lower syndesmosis. When plating of the fibular fracture was indicated, the hole was drilled through an empty screw hole. The needle attached to the leading oblong button was passed through the hole. Once the medial button was passed through the medial tibial cortex, confirmed via fluoroscopy and in some cases via a small stab wound, the assembly was tensioned by pulling the free ends of the FiberWire on the