A prospective randomised study comparing TightRope and syndesmotic screw fixation for accuracy and maintenance of syndesmosis 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 syndesmoses 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 90. 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.

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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
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 syndesmotic 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 screws-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 (α = 0.05, β = 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 ensure 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
lateral side. Free ends of the FiberWire were hand-tied on the lateral side of the fibula once both buttons were seated strictly to the bone.

After syndesmosis fixation, intraoperative CT (O-arm, Medtronic Inc., Louisville, CO, USA) of both ankles together was performed. The patient was in the supine position, with lower limbs in the neutral position without external support. The operating surgeon evaluated syndesmosis reduction from axial sections at the level of the epiphyseal scar, approximately 1 cm proximal from tibial plafond; the uninjured ankle was used as reference. If intraoperative CT suggested malreduction, the syndesmosis was exposed, evaluated via direct vision and, when necessary, re-fixed in the anatomical position and re-scanned. In all cases, surgeons left the operating theatre confident that the criteria for the acceptable limits of syndesmosis reduction were achieved. All operations were performed during office hours by a consultant orthopaedic trauma surgeon.

The post-operative treatment protocol was similar in both groups. The ankle was immobilised in a below-the-knee cast with the ankle joint at a 90° for 6 weeks with partial weight bearing. At 6 weeks, the cast was removed, the ankle was examined, and a research physiotherapist instructed the patient in rehabilitation exercises. No additional bracing was used and weight bearing was allowed as tolerated. Patients visited the outpatient clinic at 2, 6 and 12 weeks. Joint congruity and fracture healing were assessed at each time via plain radiographs. Additional visits were scheduled if necessary. Syndesmotic screw was removed only if local irritation occurred [50–52].

Outcome measures

CT of both ankles were performed intraoperatively using O-arm, postoperative CT (Siemens Somatom Sensation 64, Germany) scans were obtained if needed and standing cone-beam CT (CBCT) (Planmed Verity Extremity, Planmed Oy, Helsinki, Finland) with bone algorithm was performed at the final follow-up (minimum of 2 years, mean 36 months in TightRope group vs. 37 months in the syndesmotic screw group). Functional outcomes were assessed at 1 year and at final follow-up, when clinical examination was additionally performed. Two patients from syndesmotic screw fixation group were lost to follow-up (Fig. 1).

Radiological measurements

The operating surgeon assessed the reduction of syndesmosis in the operating room with fluoroscopy and CT by comparing the position the fibula at the tibial incisura and the width of the syndesmosis to those of the uninjured ankle. An experienced musculoskeletal radiologist (S.L.) re-assessed the intra-operative and postoperative CT scans retrospectively. Measurements were made in 1-mm-thick slices using a bone window. CT data were evaluated on a clinical workstation, and a wide window and level settings (1400 window, 300 level) were used for measurements. Axial scans were reformatted parallel to tibial plafond in the coronal and sagittal planes, and the measurements were made 1 cm above the joint space [38,45,48,53] (Fig. 2).

The reduction of the distal tibiofibular joint was assessed by measuring the width of the syndesmosis from both ankles in the anterior (AW) and posterior (PW) borders in axial CT scans.

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**Fig. 1.** CONSORT flow chart.
approximately 1 cm proximal from the tibial plafond. The mean width of the syndesmosis was calculated as described by Mukhopadhyay et al. [40]: \( \frac{\text{AW} \text{injured ankle} - \text{AW} \text{normal side}}{2} \). Malreduction was defined as >2 mm side-to-side difference, in accordance with the literature [14,18,40,53]. One patient had poor-quality intra-operative CT and therefore was excluded from the analysis (Fig. 1).

The same musculoskeletal radiologist assessed syndesmosis reduction with follow-up CBCT performed with the same parameters as intra-operative CT. OA of both ankle joints was assessed via CBCT in accordance with the classification of Morrey and Wiedeman [54,55] (grade 0 = no signs of OA, grade 1 = minimal narrowing of joint space and the formation of osteophytes, grade 2 = marked narrowing of joint space and the formation of osteophytes, and grade 3 = total degeneration of the joint and gross deformity or ankylosis). Side-to-side comparison of ankle joint OA was conducted first and between groups analysis was performed thereafter. The radiologist assessing intraoperative and follow-up CT was blinded to functional results.

Functional measurements

Questionnaires to assess ankle function Olerud–Molander score [56,57], a 100 mm Visual Analogue Scale for function and pain (VAS) [58] and for health-related quality-of-life, the RAND 36-Item Health Survey [59] were sent to patients by postal mail at 1 year and just before the final follow-up visit. Additionally, the Foot and Ankle Outcome Score (FAOS) [60] was used to assess ankle functional outcome at the final follow-up.

At the final follow-up visit, patients were interviewed, possible additional operations for the injured ankle were recorded, and medical files were reviewed. Range of motion of the injured ankle was measured using a goniometer. Maximum dorsiflexion was measured when the patient stood with his/her injured ankle on a 30-cm-high investigation table and patient leaned forward as far as possible with his/her heel remaining on the table. Plantar flexion was measured when the patient sat on an examination table and plantar flexed his/her injured ankle. The angles were then measured between the fifth metatarsal and fibula. The orthopaedic surgeon (S.N) who carried out the latest follow-up visit was blinded to the interventions and to earlier functional and radiological results.

Statistical methods

Data were analysed using an intention-to-treat principle. Summary statistics are presented as mean and standard deviation unless otherwise stated. Simple between-group comparisons were performed using Student’s t-test (continuous variables) and Fisher’s exact test (categorical variables). Within-group comparisons between two time points were analysed using paired-sample t-test. When comparing repeatedly measured data between study groups, Linear Mixed Model (LMM) was utilised. The P-values reported as a result of LMM are: \( P_{\text{time}} \), for the change over time; \( P_{\text{group}} \), for the average between group difference; and \( P_{\text{time} \times \text{group}} \) for the interaction between time and group. Two-tailed P-values are reported. Statistical programmes SPSS (IBM Corp. released 2010. IBM SPSS Statistics for Windows, version 22.0. Armonk, NY: IBM Corp.) and SAS (version 9.3, SAS Institute Inc., Cary, NC, USA) were used for analysis.

Results

Baseline characteristics of the patients are shown in Table 1.

Numbers analysed

One patient from the syndesmosis screw group had poor-quality intraoperative CT and therefore was excluded from the analysis. In addition, two patients from the same group were lost to

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient characteristics at baseline.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years, mean (standard deviation) [range]</td>
<td>46.0 (14.8)</td>
</tr>
<tr>
<td>Sex, male/female</td>
<td>13/8</td>
</tr>
<tr>
<td>Lauge-Hansen PER IV, n/N</td>
<td>21/21</td>
</tr>
<tr>
<td>Anatomy of fibula fracture</td>
<td>9</td>
</tr>
<tr>
<td>Maisonneuve fracture</td>
<td>12</td>
</tr>
<tr>
<td>Weber type C</td>
<td>13</td>
</tr>
<tr>
<td>Fracture anatomy</td>
<td>1</td>
</tr>
<tr>
<td>Fibula</td>
<td>5</td>
</tr>
<tr>
<td>Fibula and medial malleolus</td>
<td>2</td>
</tr>
<tr>
<td>Fibula and posterior malleolus&lt;sup&gt;e&lt;/sup&gt;</td>
<td>5</td>
</tr>
<tr>
<td>Trimalleolar fracture</td>
<td>0</td>
</tr>
<tr>
<td>Open fracture</td>
<td>0</td>
</tr>
<tr>
<td>Co-morbidity, n&lt;sup&gt;f&lt;/sup&gt;</td>
<td>3</td>
</tr>
</tbody>
</table>

<sup>a</sup> Student’s t-test.  
<sup>b</sup> Fisher’s exact test.  
<sup>c</sup> Avulsion fracture of posterior malleolus (<1/3 of distal tibia joint surface), not fixed.  
<sup>d</sup> Arteriosclerosis obliteratoris (ASO), diabetes mellitus, alcoholism, or mental illness.
follow-up. Overall 19 patients in the syndesmosis screw group and 21 in the TightRope group were analysed (Fig. 1).

Radiological results

According to the surgeons’ evaluation from intraoperative CT, one patient had incongruent syndesmosis after screw fixation and open exploration with re-fixation was needed. Seven syndesmosis were considered malreduced after TightRope fixation (Fig. 3A). Open exploration was carried out, but in all cases the syndesmoses were found to be well reduced if the ankle was at 90° of dorsiflexion, and no re-fixation was needed. On postoperative CT of the ankle at 90° of dorsiflexion in a below-knee cast, these patients showed no malreduction of the distal tibio-fibula joint (Fig. 3B). After retrospective re-evaluation of the intraoperative and postoperative CT scans by the musculoskeletal radiologist, one case of malreduction was found to gone unnoticed in each group (Table 2). All syndesmotic screws with malreduced syndesmosis showed signs of loosening. Follow-up standing CBCT showed that syndesmosis was malreduced in three patients in the screw fixation group and in one patient in the TightRope group ($P = 0.33$) (Table 2).

OA was more common in the injured ankle than in the uninjured ankle in both groups, but no significant difference between the screw and the TightRope fixation group existed (Table 3).

Functional results

According to LMM, Olerud–Molander score and VAS scale (function) significantly improved from 1 year to the latest follow-up, but no significant between-group differences at the last follow-up were detected (Table 4). All functional scores improved from one year to the last follow-up within the TightRope group (Olerud–Molander score changed from 75 to 82, $P = 0.008$; VAS pain changed from 15 to 11, $P = 0.02$; VAS function changed from 22 to 16, $P = 0.02$; paired-sample t-tests), whereas in the syndesmotic screw group, only VAS function significantly improved (from 19 to 11 $P = 0.002$; paired-sample t-test). At the final follow-up, FAOS subscales and the range of motion of the injured ankle showed only minor, statistically insignificant, differences between the groups (Table 5). Only one of the eight sections (mental health) of the 36-RAND Health Item Survey significantly differed between groups (Table 4). All functional scores were lower in patients who had malreduced syndesmosis on final follow-up CBCT than in patients with anatomically reduced syndesmosis (Table 6).

Complications and reoperations

One diabetic patient with Maisonneuve fracture and TightRope fixation had post-operative infection in the medial side stab wound; at 6 weeks post-operatively, the infection was diagnosed as caused by Staphylococcus Aureus. It was treated with revision surgery. TightRope fixation was replaced with a syndesmotic screw; screw was applied before the TightRope fixation was removed from the infected medial side. Syndesmotic screw was removed from three patients over 3 months postoperatively due to local irritation. Syndesmotic screw was broken in three patients and intact but loosened in 13 patients at the final follow-up. One patient from the TightRope group had a new accident and a pilon fracture to the same ankle.

Table 2

<table>
<thead>
<tr>
<th>Malreduction of syndesmosis in the syndesmotic screw and TightRope groups$^*$</th>
<th>Screw</th>
<th>TightRope</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malreduction on intra-operative CT$^*$</td>
<td>1/21 (5%)</td>
<td>1/21 (5%)</td>
<td>&gt;0.9$^b$</td>
</tr>
<tr>
<td>Malreduction after 2 years on CBCT$^*$</td>
<td>3/19 (16%)</td>
<td>1/21 (5%)</td>
<td>0.33$^b$</td>
</tr>
</tbody>
</table>

$^*\text{Malreduction was defined as } > 2 \text{ mm side-to-side difference in the mean width of the syndesmosis.}$

$^b\text{Fisher’s exact test.}$

$^c\text{Bilateral intraoperative CT O-arm, patient in supine position.}$

$^d\text{Bilateral CBCT, patient in standing position.}$
Table 4
Function parameters after 1 year and at least 2 years of follow-up. P-values reported with LMM are: $P_{\text{time}}$ for change between measurement points, $P_{\text{group}}$ for average between-group difference, and $P_{\text{time} \times \text{group}}$ for the interaction between time and group.

<table>
<thead>
<tr>
<th></th>
<th>1 year</th>
<th>2 years</th>
<th>$P_{\text{time}}$</th>
<th>$P_{\text{group}}$</th>
<th>$P_{\text{time} \times \text{group}}$</th>
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</thead>
<tbody>
<tr>
<td>Olerud–Molander score</td>
<td>TightRope</td>
<td>75</td>
<td>82</td>
<td>0.002</td>
<td>0.56</td>
</tr>
<tr>
<td>Screw</td>
<td>80</td>
<td>84</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS function</td>
<td>TightRope</td>
<td>22</td>
<td>15</td>
<td>&lt;0.001</td>
<td>0.50</td>
</tr>
<tr>
<td>Screw</td>
<td>19</td>
<td>11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS pain</td>
<td>TightRope</td>
<td>16</td>
<td>12</td>
<td>0.21</td>
<td>0.80</td>
</tr>
<tr>
<td>Screw</td>
<td>13</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>RAN3-36 bodily pain</td>
<td>TightRope</td>
<td>75</td>
<td>78</td>
<td>0.33</td>
<td>0.78</td>
</tr>
<tr>
<td>Screw</td>
<td>72</td>
<td>76</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>RAN3-36 physical function</td>
<td>TightRope</td>
<td>78</td>
<td>87</td>
<td>0.02</td>
<td>0.83</td>
</tr>
<tr>
<td>Screw</td>
<td>76</td>
<td>84</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>RAN3-36 general health</td>
<td>TightRope</td>
<td>70</td>
<td>72</td>
<td>0.17</td>
<td>0.36</td>
</tr>
<tr>
<td>Screw</td>
<td>63</td>
<td>69</td>
<td></td>
<td></td>
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<tr>
<td>RAN3-36 mental health</td>
<td>TightRope</td>
<td>82</td>
<td>87</td>
<td>0.08</td>
<td>0.02</td>
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<tr>
<td>Screw</td>
<td>69</td>
<td>77</td>
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<tr>
<td>RAN3-36 role function (physical)</td>
<td>TightRope</td>
<td>77</td>
<td>85</td>
<td>0.17</td>
<td>0.47</td>
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<tr>
<td>Screw</td>
<td>68</td>
<td>80</td>
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<tr>
<td>RAN3-36 vitality</td>
<td>TightRope</td>
<td>70</td>
<td>73</td>
<td>0.23</td>
<td>0.31</td>
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<tr>
<td>Screw</td>
<td>62</td>
<td>69</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>RAN3-36 social function</td>
<td>TightRope</td>
<td>88</td>
<td>89</td>
<td>0.25</td>
<td>0.27</td>
</tr>
<tr>
<td>Screw</td>
<td>76</td>
<td>86</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RAN3-36 role function (emotional)</td>
<td>TightRope</td>
<td>93</td>
<td>89</td>
<td>0.52</td>
<td>0.09</td>
</tr>
<tr>
<td>Screw</td>
<td>70</td>
<td>83</td>
<td></td>
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</table>

* ROM: range of motion of the injured ankle.

Discussion

The present prospective randomised trial showed that syndesmotic screw and TightRope fixation resulted in a low malreduction rate (5%) and both methods maintained reduction well (syndesmotic screw 84% and TightRope 95%). However, intraoperative CT scanning was unreliable when assessing TightRope fixation, and false positive findings were common. Therefore, the value of intraoperative CT scanning may be questioned and open exploration may be a better technique than CT to confirm syndesmosis reduction especially when using TightRope fixation. Both syndesmotic screw and TightRope yielded similar functional outcomes, and the OA grade did not significantly differ between groups.

Previous studies using intraoperative CT or 3D fluoroscopy reported malreduction rates ranging from 6% to 38% with syndesmotic screw fixation [43,44]. However, only injured side was scanned intraoperatively in these studies, and evaluation of syndesmosis reduction was not based on side-to-side comparison [43,44]. Bilateral imaging is recommended due to remarkable individual variation in measurements of syndesmosis width [17,18,40–42,45]. The fibula is situated centrally only in 30% of uninjured ankles [45]. Therefore, we think that bilateral imaging is essential for assessing syndesmosis reduction; comparing our results to previous reports is difficult.

Less rigid fixation of the suture button device may explain the high rate of false positive findings in the intraoperative CT. Due to flexible feature of the suture button device, fibula can rotate and slide posteriorly slightly when the lower limb is in a free position, i.e., somewhat externally rotated in plantar flexion, because the weight of the foot induces a slight gravity stress to the ankle (Fig. 3A). When the ankle is set at 90°, the fibula rotates internally and syndesmosis reduces, which was verified by open exploration and postoperative CT (Fig. 3B).

Bilateral CBCT suggested that the rate of syndesmosis malreduction in 2 years of follow-up may slightly increase when syndesmotic screw fixation is used, but reduction was well maintained following TightRope fixation. Previous studies of syndesmotic screw fixation using bilateral CT to assess syndesmosis reduction reported malreduction rates of 15–44% over 1.5–8.4 years of follow-up [16–18]. However, none of these studies used both intra- and post-operative CT, and they could not assess whether malreduction rate increased during follow-up. Additionally, they used techniques that were slightly different from ours for measuring syndesmosis reduction, which may have affected the results [16–18]. Furthermore, syndesmotic screws were routinely removed in all of those studies, [16–18] which may have resulted in late diastasis in some cases, as described by Schepers et al. [61] and Hsu et al. [20]. As we did not routinely remove the syndesmosis screws, the different rate of late syndesmosis diastasis may be attributed to different biomechanics of the fixation devices.

Most of previous investigations evaluating TightRope fixation for unstable syndesmosis have reported 0% malreduction rates, but they employed only plain radiography to assess malreduction [25,26,28,29,31,33,34]. Only the study by Treon et al. [34] reported 11% syndesmosis malreduction rate when TightRope was used. Naqvi et al. [18] compared syndesmotic screw and TightRope fixation using CT of both ankles to assess syndesmosis reduction and found no malreduction with TightRope fixation in 23 patients after a minimum of 18 months’ follow-up. Our 5% syndesmosis malreduction rate for TightRope fixation is comparable to the published rates.

The present study showed that mild osteoarthritis was more common in the injured ankle compared with the uninjured ankle after both fixation methods, but no significant differences were detected between techniques. To our knowledge, only Wikeryo
et al. [16] previously assessed the incidence of ankle joint OA in this fracture type, from CT after syndesmosis screw fixation, with episodes of OA reported by 67% of patients. Our study side-to-side comparison determined that OA was one or more grades more serious in the injured ankle than in the uninjured ankle in 58% of patients in the syndesmotic screw fixation group (Table 3). To our knowledge, there are no published studies reporting the incidence of OA assessed via CT for TightRope-fixed ankles. The present study suggests that the method of syndesmosis fixation has no influence on the incidence of OA.

Ankle functional outcomes in our study identified insignificant differences between the syndesmotic screw and the TightRope fixation groups. Only mental health section in RAND 36-Health Item Survey differed significantly (Table 4), but a small sample size may explain this finding. Laflamme et al. [33] in their RCT study reported statistically but not clinically better ankle functional scores when using TightRope fixation compared to syndesmotic screw fixation. A randomised controlled trial by Coetzee and Ebeling [32], which included preliminary results and, a small number of patients, also reported no significant difference in the ankle functional outcome between syndesmotic screw and TightRope fixation. In contrast, Naqui et al. [18] in their cohort study reported trends towards better clinical outcome in patients treated with TightRope fixation, but when they adjusted groups for potential confounders, they find no significant difference between the syndesmotic screw and TightRope fixation cohorts. In our study, all functional scores were lower in patients who had malreduced syndesmosis at the final follow-up CBCT than in those with anatomically reduced syndesmosis (Table 6). Although the difference in Olerud–Molander score between groups was not significant, it exceeded the minimal important clinical difference of the Olerud–Molander scoring system [57]. A larger patient population with syndesmosis malreduction is needed to confirm our finding. Sagi et al. [17] and Naqui et al. [18] also reported inferior functional results with malreduced syndesmosis compared to reduced syndesmosis when assessed via bilateral CT.

The present study is the first published randomised controlled trial, comparing syndesmotic screw and TightRope fixations, to use bilateral CT for syndesmosis reduction assessment. Our 93% follow-up rate was good. Ankle functional outcome measures (Olerud–Molander score [57], VAS [58] and FAOS [60]) used in this study are validated and widely used. Having experienced orthopaedic trauma surgeons operate on ankle fractures during office hours probably improved the quality of surgery. This study has also some limitations to be considered. The musculoskeletal radiologist (S.L) who assessed the CT and CBCT scans was not blinded to the method of syndesmosis fixation. The final follow-up was not carried out exactly 2 years postoperative and there was some variability in the follow-up time (ranging from 27 to 47 months). Although the study was powerful enough to show difference in syndesmosis malreduction rates, it was probably underpowered to demonstrate clinically important differences in functional outcome and in OA grade. To show proposed benefits to ankle joint kinematics and function with TightRope fixation, a larger prospective controlled study would be needed.

Conclusion

Syndesmotic screw and TightRope fixation had similar postoperative malreduction rates in patients with pronation-external rotation, Weber C-type ankle fracture and associated syndesmosis injury. Intraoperative CT scanning of the ankles with TightRope fixation can be misleading due to dynamic nature of the fixation, unless scanning technique is meticulous with the ankle supported in 90 degrees’ angle. After at least 2 years of follow-up, analysis of bilateral CBCT data suggested that the rate of syndesmosis malreduction may have slightly increased when syndesmotic screw fixation was used, but reduction was well maintained after fixation with TightRope. Comparison of the incidence of ankle joint OA and functional outcome revealed insignificant differences following fixation via syndesmotic screw versus fixation via TightRope.

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Conflict of interest

Medical Physicist, PhD Jani Katisko has a consultant service agreement with Medtronic Finland Oy. All other authors declare that they have no financial or personal relationships that could influence this study.

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