Objective: To compare the rate of malreduction after high fibular fractures associated with syndesmosis injury treated with open reduction and internal fixation, with either 2 screws or 1 knotless TightRope device.

Design: Prospective randomized controlled multicenter trial.

Setting: Eleven academic and community hospitals including Level 1 and Level 2 trauma centers across Canada.

Patients/Participants: One hundred three patients with OTA/AO 44-C injuries with demonstrated radiographic syndesmosis diastasis or instability after malleolar bony fixation were followed for 12 months after treatment.

Methods: Open reduction of the syndesmosis was performed in all cases. Fixation was randomized to either TightRope (1 knotless TightRope, group T) or screw fixation (two 3.5-mm cortical positional screws placed across 3 cortices, group S). Surgical techniques and rehabilitation were standardized. All surgeons were trained or experienced in the use of the TightRope device. Follow-up was performed at 2 and 6 weeks, 3, 6, and 12 months.

Main Outcome Measure: Rate of malreduction based on bilateral ankle computed tomography scan results at 3 months after fixation. Secondary outcome measures included adverse events, reoperation, and validated functional outcomes including the EQ-5D, the Olerud–Molander Ankle Score, the Foot and Ankle Disability Index, and the Work Productivity Activity Impairment Questionnaire. The estimated sample size required to detect a difference in reduction rate was 72 patients, but the estimated sample size required to detect a difference in functional outcome scores was 240 patients, suggesting the study was adequately powered for radiographic results only.

Results: Overall, the rate of malreduction using screw fixation was 39% compared with 15% using TightRope fixation \((P = 0.028, \chi^2)\). Analysis of computed tomography results was performed using a 2-mm translation or 10-degree rotation threshold for malreduction and included fibular translation (anterior, posterior); syndesmosis distance (anterior, posterior, and mid); medial compression; and rotation (fibular and articular). Patients in group T had greater anterior translation \((5.4 \pm 1.8 \text{ mm})\) compared with the contralateral limb \((4.3 \pm 1.3 \text{ mm}, P < 0.01)\) or group S \((4.6 \pm 1.5 \text{ mm}, P = 0.05)\). Group T syndesmoses also had greater diastasis compared with control limb \((4.1 \pm 1.3 \text{ vs. } 3.3 \pm 1.4 \text{ mm}, P < 0.01)\) and less fibular medialization compared with group S \((1.04 \pm 1.8 \text{ vs. } 0.3 \pm 1.8 \text{ mm}, P = 0.05)\). Functional outcome measures demonstrated significant improvements over time, but no differences between fixation groups. Foot and Ankle Disability Index scores at each time interval were 44 \pm 22 (T) versus 45 \pm 24 (S) (6 weeks), 76 \pm 14 versus 73 \pm 17 (3 months), 89 \pm 10 versus 86 \pm 13 (6 months), and 93 \pm 9 versus 90 \pm 14 (12 months) \((all P > 0.2)\). The reoperation rate was higher in the screw group compared with TightRope \((30\% \text{ vs. } 4\%, P = 0.02)\) with the difference driven by the rate of implant removal.

Conclusions: Based on our results, the TightRope device seems to compare favorably with two, 3.5-mm, 3-cortex screw fixation for syndesmosis injuries.

Key Words: Tibiofibular syndesmosis, TightRope, reduction, functional outcomes, CT scan

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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INTRODUCTION

Surgical techniques for reduction and fixation of the tibiofibular syndesmosis continue to improve. Improvements in imaging, surgical techniques, and fixation have improved the
diagnosis and management of these injuries. Historically, syndesmosis fixation has been associated with a significant rate of malreduction.\textsuperscript{1,2} The adverse effects of syndesmosis malreduction of as little as 2 mm on clinical outcomes is becoming increasingly recognized.\textsuperscript{3} Newer surgical techniques and implants have shown promise with respect to improved rates of malreduction.\textsuperscript{4,5}

Previous studies of syndesmosis fixation have shown promise for flexible fixation techniques compared with conventional screw fixation.\textsuperscript{6–17} Drawing a definitive conclusion, however, has been difficult due to variations in diagnostic criteria, imaging techniques, patient selection, or operative techniques. In particular, accurate diagnostic techniques for syndesmosis instability and malreduction are well established in the literature,\textsuperscript{18–20} but variable techniques are described with previous implant studies. In addition, previous studies comparing screw fixation with flexible fixation have used a variety of screw fixation techniques and have failed to show a conclusive advantage.

The purpose of this study was to compare the functional and radiographic outcome of open reduction and internal fixation of syndesmosis injuries using either the TightRope device or screw fixation.

**PATIENTS AND METHODS**

This prospective randomized multicenter clinical trial was funded through a competitive grant process, administered through the Orthopaedic Trauma Association and sponsored by Arthrex. The study was registered with Clinicaltrials.gov (NCT02199249). Sample size analysis determined that 56 patients were required to achieve a power of 0.80 to detect a difference in reduction between the techniques. To account for loss to follow-up, we planned to enroll 72 patients over the 12-month period between July 1, 2015, and June 30, 2016. As of February 2016, we had achieved the enrollment goal. After discussions with the sponsor and the granting agency, additional patients were randomized with the goal of improving the power of the study. Randomization, with stratification by site, was performed through a commercially available, internet-based system (Randomization.net, Interaand Inc). To ensure availability of the correct implants, randomization was performed before surgery; however, if a patient was found to have a negative stress test intraoperatively, they were excluded. In total, 108 patients were randomized at 11 participating sites. Four patients were excluded due to negative intraoperative stress examination, and 1 patient was excluded because the surgeon was not participating leaving 103 patients in the analysis (53 screw fixation, group S; 50 TightRope, group T). Three patients randomized to group T received screw fixation: 2 patients because the TightRope device was unavailable, and 1 patient treated with both devices (Fig. 1). All patients were analyzed according to randomization (intention to treat).

All patients older than 18 years with isolated ankle injuries treated within 14 days of injury. All patients had fibular fractures proximal to the syndesmosis with an associated syndesmosis injury (OTA/AO 44-C injuries).\textsuperscript{21} Exclusion criteria included previous ankle injury, retained implants, pathologic fracture, metabolic bone disease, ligamentous laxity, neurologic disorder, pregnancy, and inability to provide informed consent or maintain follow-up for at least 12 months. There were no differences in demographics between the 2 groups (Table 1).

Key components of surgical technique were standardized for the study. Fixation of malleolar fractures was performed before syndesmosis assessment, including

**FIGURE 1.** Syndesmosis randomized clinical trial consort diagram.
After surgery, posterior malleolar fractures at the surgeon’s discretion. Restoration of fibular length was ensured before syndesmosis fixation. Length-unstable injuries without fibular plate fixation were considered ineligible for TightRope. Patients were treated either with a TightRope (Arthrex, Naples, FL) or screws received from the surgeons’ manufacturer of choice (locking or nonlocking).

Stability testing was performed under fluoroscopy and included an external rotation stress examination. Lateral translation of the talus of 2 mm or greater, as measured by an increase in medial clear space, was used to define syndesmotic instability.22,23 The syndesmosis was then directly visualized using an open technique and reduced anatomically as judged by the surgeon. The reduction was examined at the interface between the anterior fibular border and the anterolateral tibial plafond with direct visualization of the syndesmosis.

The reduction was maintained using either a pointed reduction clamp or with direct manual pressure applied to the fibula, at the surgeon’s discretion. Fixation of the syndesmosis followed; when screw fixation was used (group S), 2 screws were inserted ensuring that the most distal screw was inserted parallel to the ankle mortise 1.5–2 cm proximal to the ankle joint. Three cortices of fixation were achieved for each screw. Patients randomized to group T (TightRope) had surgery performed by surgeons with previous experience or training in the use of the TightRope device. Previous experience was defined as a minimum of 3 surgical cases. Otherwise, surgeons attended a cadaveric training session. Use of the knotless TightRope device followed the manufacturer’s instructions. Arthrex plates were used for malleolar fixation in group T to allow for insertion of the TightRope through the plate when necessary. TightRope tensioning was performed using an anterior cruciate ligament graft tensioner at 20 lb-force.24 After surgery, patients in both groups were immobilized in a reinforced splint.

Standardized postoperative rehabilitation included nonweight-bearing for 6 weeks after surgery, with active range of motion encouraged at the 2-week follow-up. Patients were instructed to begin weight-bearing in an external brace at the 6-week follow-up. At 3 months, patients were mobilized without aids. A custom physiotherapy instruction pamphlet was provided to patients to standardize postoperative rehabilitation.

Patients were reviewed after surgery at 2 and 6 weeks, 3, 6, and 12 months. Follow-up rates were 95% at 2 weeks, 95% at 6 weeks, 96% at 3 months, 88% at 6 months, and 85% at 12 months.

At each follow-up, patients underwent physical examination and review of adverse events. Plain radiographs were analyzed. Patients completed validated functional outcome measures including the EQ-5D; the Foot and Ankle Disability Index (FADI); the Olerud–Molander Ankle Score (OM); the Work Productivity and Impairment Questionnaire (WPAI); and a visual analog score for pain and functional recovery. The EQ-5D measures general health status in many disease states.25–30 The FADI is a region-specific, self-reported outcome measure designed to evaluate function after ankle injury, which includes general and sports subscales.31–34 The OM is a disease-specific tool for evaluation after ankle fracture which combines pain, stiffness, and arthritis.35 The WPAI questionnaire measures impairments related to activity and has been validated and correlated to general outcome measures in a variety of musculoskeletal conditions.36,37

Radiographs were reviewed at each follow-up and analyzed for reduction, including measurement of the medial and tibiobimal clear space. The status of union was assessed and defined as nonunion, delayed union, partial union, and complete union. Syndesmosis implants were assessed and described as intact, loose or broken, or removed.

Computed tomography (CT) scans were performed 3 months after surgery and included both the injured and the contralateral limb. Multiple measurements were made on CT analysis, including anterior, middle, and posterior syndesmosis distance; anterior and posterior translation (to measure fibular subluxation); medial malleolus to medial talus distance (to measure overcompression); and fibular rotation and articular surface angle. A 2-mm or 10-degree threshold defined malreduction. CT images were analyzed by a fellowship-trained orthopaedic surgeon not involved with patient care.

Fifty-six patients (28 per group) were required to achieve 80% power to detect a difference in reduction rate between the 2 techniques. However, depending on the outcome measure selected, between 250 and 5000 patients per group were required to detect a difference in functional outcomes. Although the study was adequately powered to detect a difference in postoperative function. Statistical analysis included t test comparison of outcomes between the 2 treatment groups (for functional outcomes) and chi-square testing (for malreduction).

### RESULTS

Between June 2015 and June 2016, 103 patients at 11 clinical sites were randomized (53 screw fixation, group S; 50 TightRope fixation, group T; Table 1). Two patients in group T were treated with screws only, and 1 patient was treated with a TightRope plus a single screw. All other patients were treated according to protocol.

Reduction was measured on an axial CT scan performed 3 months after surgery. Only 1 patient was noted to have a malreduction on plain radiographs (group S). CT scans were available on 92/103 patients. There was an increased rate of malreduction in group S compared with group T (39%...

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**TABLE 1. Patient Demographics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group T (Mean ± SD)</th>
<th>Group S (Mean ± SD)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>50</td>
<td>53</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>41 ± 12</td>
<td>38 ± 14</td>
<td>0.24</td>
</tr>
<tr>
<td>Sex</td>
<td>77% male</td>
<td>71% male</td>
<td>0.71</td>
</tr>
<tr>
<td>BMI</td>
<td>29 ± 5</td>
<td>32 ± 9</td>
<td>0.06</td>
</tr>
<tr>
<td>% Employed</td>
<td>89%</td>
<td>78%</td>
<td>0.11</td>
</tr>
<tr>
<td>% Work-related injury</td>
<td>4%</td>
<td>9%</td>
<td>0.5</td>
</tr>
<tr>
<td>% MVC</td>
<td>0%</td>
<td>4%</td>
<td>0.4</td>
</tr>
<tr>
<td>% Dislocated</td>
<td>32%</td>
<td>26%</td>
<td>0.65</td>
</tr>
</tbody>
</table>

MVC, Motor Vehicle Collision.
vs. 15%, \( P = 0.03 \)). Malreductions in group S included 5 rotational misalignments, 8 anterior and 2 posterior fibular subluxations, 2 overcompression, and 1 distraction. Malreductions in group T included 2 rotational misalignment, 2 anterior and 2 posterior fibular subluxations, and 1 distraction. Patients in group T had an increase in anterior fibular translation (1.0 ± 1.3 mm), while those in group S had no change (0.0 ± 1.4 mm, \( P = 0.03 \)). Patients in group T had an increase in medial compression while those in group S had a decrease (0.6 ± 1.8 mm wider, group T; vs. 0.3 ± 1.8 mm narrower, group S (Table 2).

Twenty-four adverse events in 21 patients were documented. Of these, 10 required surgery for various reasons including screw irritation (\( n = 7 \), group S), loss of reduction (\( n = 2 \), 1 group T and 1 group S), and deep infection (\( n = 1 \), group T). In addition, there were 2 superficial wound infections; 1 case of wound necrosis requiring dressing changes; 1 embolism, 1 staple irritation, 1 cast problem, 7 screw looseningings, and 6 breakages; and 4 nerve deficits (1 deep peroneal, 2 superficial peroneal, and 1 sural). The rate of unplanned reoperation was 15% in group S and 4% in group T (\( P = 0.02 \)). Eight patients in group S had planned screw removal, resulting in an overall reoperation rate of 30% in group S.

The EQ-5D assesses mobility, activity, pain, and anxiety/depression with a score of 1 representing perfect health. Patients in group T and group S reported similar preinjury values of 0.97 ± 0.09 and 0.96 ± 0.09, respectively (\( P = 0.59 \)). There were no differences in EQ-5D scores between the 2 groups at 6 weeks (0.63 ± 0.19 vs. 0.64 ± 0.22, \( P = 0.85 \)), 3 months (0.79 ± 0.12 vs. 0.78 ± 0.13, \( P = 0.74 \)), 6 months (0.87 ± 0.1 vs. 0.84 ± 0.14, \( P = 0.30 \)), or 12 months (0.88 ± 0.12 vs. 0.91 ± 0.22, \( P = 0.45 \)) (Table 3).

The FADI score assesses the ability to participate in typical activity; sport related activity, and ankle pain. With respect to FADI total score, there were no differences between group T and group S at any time point. Similarly, the FADI sport score showed no significant differences between the groups. However, 10-point higher scores were noted in group T at 12 months which met the threshold of clinical significance (80.5 ± 18.2 vs. 70.8 ± 29.1, \( P = 0.07 \), Table 3).

The OM is commonly used in ankle fracture studies and includes subsections for pain and stiffness, and the ability to perform activity. There were no differences between groups T and S with respect to OMs (\( P > 0.05 \)) (Table 3).

The WPAI assesses function for work and daily activities. There were no differences in total scores; however, patients in group T had a higher rating of daily activity at 6 weeks compared with group S and missed fewer hours of work at 3 months (0.3 ± 1.4 vs. 1.4 ± 2.7, \( P = 0.03 \)). Total work hours were not significantly different between the groups at each interval.

**DISCUSSION**

The management of distal tibiofibular syndesmosis injuries continues to evolve as our techniques, rehabilitation protocols, and implant selection continue to improve. Difficulties with syndesmosis fixation can be broadly divided into 2 groups: inadequate fixation leading to syndesmotic instability, or excessively rigid fixation which potentially contributes to stiffness. Syndesmosis malreduction is an important factor leading to a poor outcome after ankle and syndesmosis fixation.

**TABLE 2.** CT Scan Comparison Between Group T and S (BG) and Within Groups (WG) of Study Limb (SL) and Contralateral Limb (CL)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group T (Mean ± SD) SL</th>
<th>Group T (Mean ± SD) CL</th>
<th>Group S (Mean ± SD) SL</th>
<th>Group S (Mean ± SD) CL</th>
<th>( P ) BG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syndesmosis distance (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior</td>
<td>5.4 ± 1.8</td>
<td>4.3 ± 1.3</td>
<td>4.6 ± 1.5</td>
<td>4.6 ± 1.4</td>
<td>0.05</td>
</tr>
<tr>
<td>( P ) value (WG)</td>
<td>0.004</td>
<td>0.88</td>
<td>0.66</td>
<td>0.19</td>
<td></td>
</tr>
<tr>
<td>Posterior</td>
<td>9.8 ± 2.3</td>
<td>9.8 ± 1.9</td>
<td>10.0 ± 2.1</td>
<td>10.6 ± 2.3</td>
<td>0.93</td>
</tr>
<tr>
<td>( P ) value (WG)</td>
<td>0.61</td>
<td>0.26</td>
<td>0.19</td>
<td>0.93</td>
<td></td>
</tr>
<tr>
<td>Mid</td>
<td>4.1 ± 1.2</td>
<td>3.3 ± 1.0</td>
<td>3.8 ± 1.4</td>
<td>3.7 ± 1.6</td>
<td></td>
</tr>
<tr>
<td>( P ) value (WG)</td>
<td>0.003</td>
<td>0.93</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibular translation (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior</td>
<td>10.2 ± 1.6</td>
<td>10.6 ± 1.53</td>
<td>10.6 ± 2.3</td>
<td>10.8 ± 1.6</td>
<td>0.42</td>
</tr>
<tr>
<td>( P ) value (WG)</td>
<td>0.07</td>
<td>0.44</td>
<td>0.89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior</td>
<td>7.3 ± 1.9</td>
<td>7.5 ± 1.9</td>
<td>7.2 ± 2.0</td>
<td>6.9 ± 1.6</td>
<td>0.56</td>
</tr>
<tr>
<td>( P ) value (WG)</td>
<td>0.65</td>
<td>0.56</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medial compression (mm)</td>
<td>1.0 ± 1.8</td>
<td>0.4 ± 1.3</td>
<td>0.3 ± 1.8</td>
<td>0.6 ± 1.4</td>
<td>0.05</td>
</tr>
<tr>
<td>( P ) value (WG)</td>
<td>0.11</td>
<td>0.08</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibular rotation angle (deg)</td>
<td>12.1 ± 6.4</td>
<td>13.0 ± 7.2</td>
<td>13.0 ± 7.2</td>
<td>15.2 ± 5.6</td>
<td>0.54</td>
</tr>
<tr>
<td>( P ) value (WG)</td>
<td>0.12</td>
<td>0.06</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Articular rotation angle (deg)</td>
<td>11.4 ± 4.9</td>
<td>9.8 ± 4.2</td>
<td>10.2 ± 5.9</td>
<td>9.32 ± 5.8</td>
<td>0.28</td>
</tr>
<tr>
<td>( P ) value (WG)</td>
<td>0.11</td>
<td>0.81</td>
<td></td>
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</tbody>
</table>
The syndesmosis is exposed to approximately 500 N during walking, as well as approximately 7.5 Nm of torque resistance. The syndesmosis must accommodate 1–2 mm of mortise widening, 3–5 degrees of external rotation, and 2–3 mm of proximal and distal migration during gait. In mechanical studies, failure torque and pullout strength were higher with screw fixation compared with TightRope; however, failure in both modes occurs at loads exceeding those experienced clinically. Less data are currently available to guide implant selection strategies restore syndesmosis stability. Cottom et al performed a randomized controlled trial comparing percutaneous screw and TightRope fixation on CT. The clinical importance of syndesmosis diastasis using suture button and malrotation using screw fixation on CT. The clinical importance of slight radiographic malreduction 3 months after surgery is unknown, but malreduction has been associated with adverse outcome.

In this study, the use of either 2 tetricly syndesmosis positional screws or a single flexible TightRope achieved equivalent functional outcomes. However, the rate of malreduction at 3 months and the rate of reoperation were higher using screw fixation. Clinical studies suggest both implant strategies restore syndesmosis stability. Cottom et al found no difference between screw and TightRope fixation at 6 months. Laflamme et al performed a randomized controlled trial comparing percutaneous screw and TightRope fixation and found no difference in postoperative American Orthopaedic Foot and Ankle Scores between the 2 groups. The OM was slightly improved in the TightRope group at 3, 6, and 12 months, but this difference averaged only 6 points (on a 100-point scale). The overall clinical outcome was found to be excellent in both groups. Seven other authors using the American Orthopaedic Foot and Ankle Score Ankle Hindfoot Score found no differences in functional outcome. We used the FADI as a joint specific outcome measure. This measure has a sport-based domain with potential improved sensitivity to detect clinical improvement. We detected larger between-group differences using FADI compared with the OM, but would still require a minimum of 250 patients to detect a difference in functional outcome between the techniques. Andersen et al performed a randomized trial comparing the suture button with a single syndesmotic screw, finding better functional and radiographic results with the suture-button group. Malreduction approached 58% in the screw group at 1 year, compared with 28% in the suture-button group. Andersen et al noted a higher rate of radiographic post-traumatic arthritis in the screw group after 2 years.

One of the primary purposes of this study was to compare the reduction between the 2 fixation techniques at 3 months. Previous trials have assessed syndesmosis reduction using plain radiographs, but this can underestimate the rate of malreduction compared with CT imaging. Similarly, syndesmoses may reduce with weight-bearing. We used CT scans with multiple measurements to assess reduction accuracy. Although only 1 case was malreduced based on plain x-rays, 39% of patients treated with screw fixation, and 15% of patients treated with the TightRope were found to be malreduced based on CT. The degree of malreduction was slight; no patient had greater than 3 mm of translation or diastasis or greater than 20 degrees of fibular rotation with the exception of the malreduction visible on plain radiographs. By comparison, Naqvi et al reported a malreduction rate of 21% using screws considering diastasis alone using a single axial image. Kocadal et al noted an increase in syndesmosis diastasis using suture button and malrotation using screw fixation on CT. The clinical importance of slight radiographic malreduction 3 months after surgery is unknown, but malreduction has been associated with adverse outcome.

Our reoperation rates are higher with screw fixation compared with suture-button constructs. This increased reoperation rate is largely driven by implant removal procedures. Implant removal costs are estimated at USD $2953–$3579 per case. Based on these rates, Neary et al calculated that the suture-button construct was more cost-effective unless the removal rate was less than 10%. Our rate of unplanned reoperation was 15% with screw fixation compared with 4% with the TightRope device.

Limitations regarding our conclusions should be noted. Although we exceeded the predicted enrollment, the study remains underpowered to make conclusions on function. Our radiographic results are based on imaging at 3 months; repeat imaging at 12 months may demonstrate different results. Physical parameters, such as gait analysis, were not included. Regardless, this study is among the largest and most rigorous in the literature to date. The involvement and participation of 11 clinical centers promotes the external validity, plausibility, and generalizability of the results. Further research should focus on longer radiographic and clinical follow-up. Based on our results, the TightRope device seems to compare favorably to screw fixation for syndesmosis injuries.
REFERENCES


APPENDIX 1. Canadian Orthopaedic Trauma Society

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