

Δ Tightrope versus Screw Fixation of the Tibiofibular Syndesmosis:

A Long-Term CT Evaluation of Maintenance of Reduction

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Purpose: Flexible fixation techniques combined with anatomic (open) syndesmosis reduction have demonstrated improved functional outcomes and rates of malreduction. Suture-button devices allow physiologic motion of the syndesmosis without need for implant removal, which may lower the risk of recurrent syndesmotic diastasis. There is limited longer-term assessment of the maintenance of reduction between static and flexible syndesmotic fixation using bilateral ankle CT evaluation.

Methods: This is an a priori planned subgroup analysis of a multicenter, randomized clinical trial comparing static syndesmosis fixation (two 3.5-mm screws, Group S) with flexible fixation (single knotless Tightrope, Group T) for patients with AO-OTA 44-C injuries. Patients who completed bilateral ankle CT scans at 3 and 12-month follow-up were included. The primary outcome measure was syndesmotic malreduction based on bilateral ankle CT scans, using the uninjured, contralateral ankle as a control. Anterior (ASD), middle (MSD), and posterior (PSD) syndesmosis distance were calculated to measure syndesmosis reduction. Secondary outcomes included reoperation, adverse events, and functional outcomes including the EuroQol 5 Dimensions (EQ-5D), Olerud-Molander Ankle Score (OM), Foot and Ankle Disability Index (FADI), and Work Productivity Activity Impairment Questionnaire (WPAI). Paired samples t-tests were used to compare injured to control ankles ($R, v 3.5.1$).

Results: 42 patients (24 Group S, 18 Group T) were included. ASD for Group T was 5.22 mm (95% confidence interval [CI] 4.69-5.77) at 3 months compared to 4.26 mm (95% CI 3.82-4.71; $P = 0.007$) in controls and 5.38 mm (95% CI 4.72-6.04) at 12 months compared to 4.44 mm (95% CI 3.73-5.16; $P = 0.048$) in controls. ASD for Group S was 4.63 mm (95% CI 4.17-5.10) at 3 months compared to 4.67 mm (95% CI 4.24-5.10; $P = 0.61$) in controls, but significantly increased to 5.73 mm (95% CI 4.81-6.66) at 12 months compared to 4.65 mm (95% CI 4.15-5.15; $P = 0.04$) in controls. MSD results were similar; Group T had a larger MSD than control ankles at 3 months ($P = 0.03$) and 12 months ($P = 0.01$), while the MSD in Group S was not different at 3 months ($P = 0.80$) but increased at 12 months ($P < 0.01$). 88% (21/24) of Group S had broken or removed screws by 12 months. Unplanned reoperation was 15% in Group S and 4% in Group T ($P = 0.02$), with an overall reoperation rate of 30% in Group S. There was no significant difference between treatment groups for EQ-5D, OM, FADI, or WPAI at 3 or 12-month follow-up.

Conclusion: Tightrope fixation resulted in greater diastasis of the ASD and MSD compared to contralateral, uninjured ankles at 3 and 12 months post-fixation. Group S initially had syndesmotic reduction similar to control ankles, but between 3 and 12 months post-fixation, there was significantly increased syndesmosis diastasis compared to controls. The majority of Group S (88%) had either broken screws or scheduled screw removal, which may explain the increased tibiofibular diastasis seen at 12 months.

Δ OTA Grant

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.