Δ Improved Reduction of the Tibiofibular Syndesmosis with Tightrope Compared to Screw Fixation: Results of a Randomized Controlled Study

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Purpose: Flexible fixation of the tibiofibular syndesmosis is designed to allow increased ankle motion and better outcomes compared to screw fixation, and may improve the rate of anatomic reduction. This randomized, multicenter study compared the rate of malreduction following treatment of high fibular fractures associated with syndesmosis injury treated with open reduction and internal fixation with either screw or Tightrope fixation.

Methods: 103 patients from 11 sites were randomized and received fixation of their AO 44-C injury between June 2015 and June 2016. All patients demonstrated syndesmosis instability following malleolar fixation. Open reduction of the syndesmosis was performed in all cases. Fixation was randomized to either Tightrope (1 knotless Tightrope, Group T) or screw (two 3.5-mm cortical screws, 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 6 weeks, 3, 6 and 12 months. The primary outcome was the rate of malreduction based upon analysis of bilateral CT scans performed 3 months post injury. Secondary outcomes included adverse events and validated functional outcomes including the EQ-5D, Olerud-Molander Ankle Score (OM) and the Foot and Ankle Disability Index (FADI). Based on radiographic analysis, the study was powered for radiographic results only.

Results: The rate of malreduction using screw fixation was 39% compared with 15% using Tightrope (P=0.028). Analysis of CT results was performed using a 2-mm translation or 10°rotation threshold for malreduction and included fibular translation, syndesmosis distance, medial compression and rotation. Group T had greater syndesmosis diastasis compared to control limb (4.1 ± 1.3 vs 3.3 ± 1.4 mm, P=0.005) and less fibular medialization compared to Group S (1.04 ± 1.8 vs 0.3± 1.8 mm, P=0.05). Functional outcome measures demonstrated significant improvements over time, but no differences between the groups (p>0.3). FADI scores at each time interval were: 42 (T) vs 46 (S) (6 weeks), 75 vs 74 (3 months), 88 vs 86 (6 months) and 92 vs 89 (12 months). Unplanned reoperations were higher in the screw group compared to Tightrope (19% vs 2%, P=0.009) largely due to the rate of hardware removal.

Conclusion: Treatment of tibiofibular syndesmosis injury with the Tightrope device achieves lower rates of malreduction and hardware removal compared to screw fixation.

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