

A Prospective Randomized Multicentric Trial Comparing a Static Implant to a Dynamic Implant in the Surgical Treatment of Acute Ankle Syndesmosis Rupture

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Purpose: Syndesmosis rupture is involved in 13% of ankle fractures and requires surgical stabilization. The recent trend toward dynamic fixation with an Endobutton is not yet supported by clinical randomized trials. The purpose of this study is to compare the functional outcome after stabilization of an acute syndesmosis rupture with either a static implant (a 3.5-mm metallic screw through four cortices) or a dynamic device (TightRope, Arthrex).

Methods: We conducted a randomized double-blind controlled trial involving 70 subjects (in five centers) with an acute syndesmosis rupture, stabilized either with a TightRope (n = 34) or a quadricortical screw (n = 36). The two groups were similar regarding demographic, social and surgical data. Main outcome was Olerud-Molander score at 6 months. A 1-year follow-up included (at 3, 6, and 12 months) functional status (Olerud-Molander, AOFAS [American Orthopaedic Foot & Ankle Society] ankle-hindfoot score, time to activities, ankle range of motion) and radiological evaluation (loss of reduction, implant failure). Reoperations and complications were recorded.

Results: Subjects with dynamic fixation achieved significantly higher performances as described with the Olerud-Molander scores at 3 (68.8 vs 60.2, $P < 0.05$), 6 (84.2 vs 76.8, $P < 0.05$), and 12 months (93.3 vs 87.6, $P < 0.05$). We also observed better AOFAS scores at 3 (78.6 vs 70.6, $P < 0.05$), 6 (87.1 vs 83.8, $P = 0.13$), and 12 months (93.1 vs 89.9, $P = 0.13$). Plantar flexion was superior with dynamic fixation at all times. Implant failure was higher in the screw group (36.1% vs 0%, $P < 0.05$). Loss of reduction was observed in 4 cases in the static screw group (11.1% vs 0%, $P = 0.06$). Reoperation for any cause was more frequent in the screw group (33.3% vs 5.9%, $P < 0.05$). We could not demonstrate major differences in the activity level between the two groups, except that subjects with dynamic fixation returned earlier to their previous sporting activities.

Conclusion: Dynamic fixation of acute ankle syndesmosis rupture with the TightRope gives better functional outcomes at short and intermediate terms. The implant offers adequate syndesmosis stabilization without breakage or loss of reduction and reoperation rate is significantly lower than with the conventional screw fixation.

- The FDA has not cleared this drug and/or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an "off label" use). For full information, refer to page 496.