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Prospective randomized multicentric trial comparing a static implant and a dynamic implant in the surgical treatment of ankle syndesmosis rupture

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INTRODUCTION: Syndesmotic rupture is involved in 13% of ankle fractures and require surgical stabilization. The recent trend towards dynamic fixation with endobuttons is not yet supported by clinical randomized trials.

OBJECTIVES: The purpose of this study is to compare the functional results of two methods used in syndesmosis fixation: 1) Dynamic fixation with endobutton (Tightrope®, Arthrex®) 2) Static fixation with one 3.5mm quadricortical screw.

METHODS: We conducted a randomized double-blind controlled trial involving 70 patients (in five centers) with an acute syndesmotic rupture, stabilized either with Tightrope® (n=34) or 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 one-year follow-up included (at 3, 6 and 12 months) functional status (Olerud-Molander, AOFAS ankle-hindfoot score, time to activities, ankle range of motion) and radiological evaluation (loss of reduction, implant failure). Reinterventions and complications were recorded.

RESULTS: Dynamic fixation was significantly superior with better Olerud-Molander scores at three (68.8 vs 60.2, p<0,05), six (84.2 vs 76.8, p<0,05), and twelve months (93.3 vs 87.6, p<0,05), as well as with better AOFAS scores at three (78.6 vs 70.6, p<0,05), six (87.1 vs 83.8, p=0,13) and twelve 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). Reintervention for any cause was more frequent in the screw group (33.3% vs 5.9%, p<0,05). We couldn't demonstrate major differences in the activity level between the two groups, except that patient with dynamic fixation returned earlier to their previous sporting activity.

CONCLUSION: Dynamic fixation of acute syndesmotic rupture with Tightrope® gives better functional outcome at short and intermediate terms. The implant offers adequate syndesmosis stabilization without breakage or loss of reduction and reintervention rate is significantly lower than with the conventional screw fixation.

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