

Medial Malleolus: Operative or Non-operative (MOON) Trial - A Prospective Randomized Controlled Trial of Operative Versus Non-operative Management of Associated Medial Malleolar Fractures in Unstable Ankle Fractures

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Purpose: Nonoperative management of isolated medial malleolar fractures without significant displacement is supported by positive clinical and patient reported outcomes. There are limited data on the equivalent management of such fractures that are part of a more unstable bi- or trimalleolar injury pattern, following fibular fracture stabilization. The aim of this single-center, prospective randomized controlled trial was to compare the outcome between operative and nonoperative management of well-reduced medial malleolar fractures following fibular stabilization in unstable ankle fractures. The null hypothesis was that there is no difference between groups in the patient-reported outcome at 1 year post-randomization.

Methods: Between October 2017 and July 2020, 154 patients were randomized intraoperatively to either fixation (n = 78) or non-fixation (n = 76) of a well-reduced (fluoroscopic displacement ≤ 2 mm) medial malleolar fracture after fibular stabilization. The primary outcome measure was the Olerud Molander Ankle Score (OMAS) at 1 year post-randomization. Secondary outcome measures included the Manchester-Oxford Foot Questionnaire (MOXFQ) and EuroQol-5 Dimensions-3 Levels (EQ-5D-3L). Accounting for 20% loss to follow-up, a power analysis determined a sample size of 154 patients (77 per group) was required, assuming a standard deviation of 20 points, 80% power, and 5% level of significance to detect a significant difference (10 points) in the OMAS at 1 year. Intention-to-treat analyses were performed.

Results: The mean age of patients included in the trial was 56.1 years (range, 17-92). The 1-year follow-up was 94% (n = 144). Over the course of the study, there was a significant improvement in ankle function reported in both groups ($P < 0.001$). At 1 year following surgery the mean OMAS score for the fixation group was not statistically or clinically significantly different from the non-fixation group (74.3 vs 69.9; mean difference -4.4, 95% confidence interval [CI] -12.3 to 3.5; $P = 0.270$). There was also no significant difference between groups in terms of the MOXFQ (mean difference 3.6, 95% CI -4.3 to 11.3; $P = 0.366$) or the EQ-5D-3L (mean difference -0.06, 95% CI -0.14 to 0.02; $P = 0.176$).

Conclusion: In patients undergoing internal fixation of an unstable ankle fracture, there was no difference in patient-reported outcomes between operatively or nonoperatively managed medial malleolar fractures. These data suggest that well-reduced medial malleolar fractures can be treated nonoperatively following satisfactory fibular stabilization in unstable ankle fractures.