

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

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INTRODUCTION: Conservative treatment 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 tri-malleolar 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 one-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 $\leq 2\text{mm}$) medial malleolar fracture after fibular stabilization. The primary outcome measure was the Olerud Molander Ankle Score (OMAS) at one-year post randomization. Secondary outcome measures included the Manchester-Oxford Foot Questionnaire (MOXFQ) and EuroQol-5D-3L (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 one 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 one-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 one year following surgery the mean OMAS score for the fixation group was not statistically or clinically significantly different to the non-fixation group (74.3 vs. 69.9; mean difference -4.4, 95%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; $p = 0.176$).

DISCUSSION AND 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. This data suggests that well-reduced medial malleolar fractures can be treated nonoperatively following satisfactory fibular stabilization in unstable ankle fractures.