

Single Screw Fixation Compared with Double Screw Fixation for Treatment of Medial Malleolar Fractures: A Prospective Randomized Trial

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Purpose: With medial malleolar fractures, surgeons typically utilize 2 screws to ensure rotational control of the bone fragment. A prospective randomized trial was performed to determine whether single or double screw fixation of the medial malleolus resulted in better long-term health outcomes. The primary outcome was a comparison of physical functioning summary score on Short Form-36 (SF-36) questionnaires between patients in the 2 groups.

Methods: Giving each group 80% power to detect a difference of 5%, a sample size of 63 patients per group was utilized. Any patients who crossed over from the single screw (SS) to the double screw (DS) group, or vice versa, were analyzed according to the “intention to treat” principle. 140 patients were randomized to receive either 1 or 2 screws to repair their medial malleolar fracture followed by equivalent rehabilitation. 13 patients were excluded due to early loss to follow-up or withdrawal (n = 127; initial SS n = 61, initial DS n = 66). Clinical assessment occurred at the time of surgical consultation and 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 24 months postoperatively. Functional outcome results were also measured at the same time points using functional outcome questionnaire SF-36 and AHS.

Results: There were no differences between the groups as far as demographic data or complications. 14 patients crossed over from the DS group to the SS group based on intraoperative decisions by the surgeon (fragment too small for 2 screws [“intention to treat” still followed]) leaving SS (n = 75) and DS (n = 52). Between groups there was no significant difference in operating room (OR) time (SS mean OR time = 44.5 (± 21.9) minutes; DS mean OR time = 47.0 (± 18.3) minutes; P = 0.5). There were no significant differences between SS and DS groups on all 8 categories of SF-36 scores at the baseline, 3-month, or 24-month follow-up time points. Despite this number of patients, there was no indication of a difference when it came to hardware pain or need for removal.

Conclusion: The 2-year functional outcome scores prove that single screw medial malleolar fixation provides an equally safe and effective method of fracture care as compared to double screw fixation. Approximately 21% of patients (14 of 66) receiving DS fixation can be expected to crossover to receive SS fixation as a safer alternative (avoid fracturing small malleolus). A single screw used by surgeons in this study provided no failures in fixation, malunion, or rotation.