

A Randomized Controlled Trial Comparing Operative and Nonoperative Treatment of Humeral Diaphyseal Fractures

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Purpose: Fractures of the humeral diaphysis occur in a bimodal distribution and represent 3% to 5% of all fractures. Presently, the standard treatment of isolated humeral diaphyseal fractures is nonoperative care using splints, braces, and slings. Recent data have questioned the effectiveness of this strategy in ensuring fracture healing and optimal patient function. The primary objective of this randomized controlled trial (RCT) was to assess whether operative treatment of humeral shaft fractures with a plate and screw construct provides a better functional outcome than nonoperative treatment. Secondary objectives compared union rates and both clinical and patient-reported outcomes.

Methods: Eligible patients with an isolated, closed humeral diaphyseal fracture were randomized to either nonoperative care (initial sugartong splint followed by functional coaptation brace) or open reduction and internal fixation (ORIF; plate and screw construct). The primary outcome measure was the Disabilities of the Arm, Shoulder and Hand (DASH) score assessed at 2, 6, 16, 24, and 52 weeks. Secondary outcomes included the Short Musculoskeletal Functional Assessment (SMFA), the Constant Shoulder Score, and radiographic parameters. Data accrual was completed a week prior to abstract submission. Preliminary results are reported and complete results will be available for presentation at the OTA Annual Meeting. Independent samples t tests and χ^2 analyses were used to compare treatment groups.

Results: A total of 173 patients were included, with 86 treated nonoperatively and 87 treated with ORIF. There was no significant difference between the two treatment groups for age (mean = 45.7 years, standard deviation [SD] 16.6 for nonoperative group and 41.8, SD 17.1 years for ORIF group; $P = 0.13$), sex (59.3% female in nonoperative group and 62% female in ORIF group; $P = 0.78$), body mass index (mean = 28.7, SD 7.4 for nonoperative group and 27.6, SD 6.2 for ORIF group; $P = 0.30$), or smoking status ($P = 0.78$). There was a significant improvement in the DASH scores at 6 weeks in the ORIF group compared to the nonoperative group (mean = 33.8, SD 21.2 in the ORIF group vs mean = 56.5, SD = 21.1 in the nonoperative group; $P < 0.0001$). At 4-month follow-up, the DASH scores were also significantly better in the ORIF group (mean = 21.6, SD = 19.7 in the ORIF group vs mean = 31.6, SD = 24.6 in the nonoperative group; $P = 0.009$). However, there was no difference in DASH scores at 12-month follow-up between the groups (mean = 8.8, SD = 10.9 vs mean = 11.0, SD = 16.9 in the nonoperative group; $P = 0.39$).

Conclusion: This RCT comparing operative and nonoperative treatment of humeral diaphyseal fractures found significantly improved functional outcome scores in patients treated surgically at 6 weeks and 4 months. However, the early functional improvement did not persist at 1-year follow-up. Further analysis and cost-effectiveness assessment could determine whether early functional improvements outweigh the costs associated with surgical treatment of humeral shaft fractures.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.