Δ Multicenter, Prospective, Observational Trial of Non-Operative Versus Operative Treatment for High-Energy Midshaft Clavicle Fractures

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Purpose: We sought to determine if nonoperative or operative treatment of displaced clavicle fractures delivers better clinical and patient-based outcomes, which will help the surgeon better determine the optimal treatment for a given patient with a clavicle fracture.

Methods: A multicenter, observational study was performed from 2003-2018 of displaced midshaft clavicle fractures (OTA 15.2). Adults with closed clavicle fractures displaced over 100% or shortened by more than 1.5 cm were eligible for enrollment. Seven Level I trauma centers participated throughout the United States. Patients were followed for 2 years following enrollment. Allowable fixation methods at the discretion of the surgeon consisted of anterior-inferior or superior plating, or intramedullary fixation. Patients were analyzed based on treatment type, DASH (Disabilities of the Arm, Shoulder and Hand) scores (3, 6, 12, and 24 months), and reoperation.

Results: A total of 412 patients were enrolled. Of these, 203 were treated with internal fixation by plate and screws, 26 were treated by intramedullary fixation, and 183 were treated nonoperatively. Average age of all patients treated by plate or intramedullary fixation was 35 years and the average age in the nonoperative group was 40 years. Fixation, whether pins or plates, versus nonoperative treatment showed similar DASH scores at 12 and 24 months. The pin group had poorer DASH scores at 3 and 6 months ($P<0.05$). At 3 and 6 months the plating group was not significantly better than the nonoperative group. The risk of surgery after initial treatment, whether operative or not, was not different (hazard ratio 1.20, 95% confidence interval 0.54, 2.66, $P = 0.65$). However, when surgery for hardware removal is excluded there is a significantly higher risk for surgery in the nonoperatively treated group (hazard ratio 0.32, 95% confidence interval 0.11, 0.96, $P = 0.04$).

Conclusion: At every time point studied up to 2 years, the DASH scores for operative fixation with plates and nonoperative treatment were no different. Hardware removal remains the most likely reason for repeat operative intervention in the plate and pin groups, while surgery for nonunion was the most likely reason for late surgery in the nonoperative group.

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