

Δ Operative Versus Nonoperative Treatment of Acute Displaced Distal Clavicle Fractures: A Multicenter Randomized Controlled Trial

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Purpose: While numerous randomized studies have demonstrated the benefits of surgical fixation in midshaft clavicle fractures, the treatment of distal clavicle fractures remain controversial. To date, there have been no RCTs comparing operative and nonoperative treatment of displaced, distal clavicle fractures.

Methods: This is a multicenter RCT, and patients were randomized to (1) open reduction internal fixation (ORIF) with a plate or (2) nonoperative treatment with a sling. Inclusion criteria were: age 16-60 years, with a completely displaced, closed, fracture of the distal third of the clavicle.

Results: In total 57 patients were randomized: 27 to the operative group and 30 to the non-operative group. Mean age was 42 years, and 86% were male. There were no differences between the 2 groups regarding baseline characteristics. Overall, patients demonstrated improvement of DASH and Constant scores at 1 year post injury (mean DASH = 11, mean Constant = 87), but there were no differences between the 2 groups at any time point. There were no differences between the 2 groups with regard to rate of return to work, or return to activity at any time point. Patients in the nonoperative group had a higher rate of nonunion (37% vs 4%, $P = 0.002$), and malunion (40% vs 4%, $P = 0.001$), and a longer time to union (42% at 6 months, vs 95% in the operative group, $P = 0.0001$). The rate of secondary surgical procedures were similar between the 2 groups: 7 patients in the nonoperative group required 10 operations (33%, for surgical fixation of a nonunion and subsequent hardware removal) compared to 13 patients in the surgical group (48%, all for hardware removal, $P = 0.26$).

Conclusion: This is the first randomized controlled trial of distal clavicle fractures. This study reveals that nonoperative treatment of distal clavicle fractures results in high rates of nonunion (37%) and malunion (40%). Plate fixation is safe and effective in significantly lowering the rate of nonunion and malunion; however, patient-related outcomes (DASH and Constant scores) show similar outcome irrespective of treatment. It is possible that the presence of distal clavicle nonunion or malunion causes minimal functional deficits in most individuals. It is also possible that the current outcome measures available are not sensitive enough to capture functional deficits in patients with these injuries, and more investigation is required in this area.

Δ OTA Grant

See pages 401 - 442 for financial disclosure information.