

The HUmeral Shaft Fracture FIXation (HU-FIX) Study: A Prospective Randomized Trial of Operative Versus Nonoperative Management of Fractures of the Humeral Diaphysis

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Purpose: This single-center prospective randomized trial aimed to assess the superiority of operative fixation compared with nonoperative management for adults with an isolated, closed humeral shaft fracture.

Methods: 70 patients (mean age 49 years, 54% female) were randomized to either open reduction and plate fixation (n = 36) or functional bracing (n = 34). Seven patients did not receive their assigned treatment (operative n = 5/32, nonoperative n = 2/32). The primary outcome measure was the Disabilities of the Arm, Shoulder and Hand (DASH) score at 3 months. Secondary outcomes in the year following intervention included health-related quality of life (HRQoL), shoulder/elbow range of motion (ROM), complications, and return to activity. Results were analyzed based upon intention-to-treat.

Results: At 3 months, 66 patients (94%) had complete follow-up. The mean DASH favored surgery (operative 24.5 vs nonoperative 39.4; mean difference [MD] 14.9; P = 0.006). Surgery was also associated with a superior DASH at 6 weeks (operative 38.4 vs nonoperative 53.1; MD 14.7, P = 0.005). No difference was seen at 6 months or 1 year. Surgery was associated with superior EuroQol scores at 6 weeks (median EQ-5D [EuroQol 5 Dimensions] 0.760 vs 0.585; P = 0.030) and 6 months (median EQ-VAS [EuroQol Visual Analog Scale] 90 vs 80; P = 0.039), with superior median SF-12 MCSs [Short Form-12 Mental Component Summary scores] at 6 weeks (54.7 vs 42.5; P = 0.001), 3 months (57.8 vs 48.0; P = 0.008), and 6 months (57.9 vs 53.2; P = 0.007). Surgery conferred superior recovery of shoulder elevation, abduction, and external rotation at 6 weeks and 3 months, and elbow flexion at 3 months and 1 year (all P<0.05). Brace-related dermatitis affected 7 patients (operative 3% vs nonoperative 18%; odds ratio [OR] 7.8, P = 0.049). No differences in other complications were found. Eight patients (11%) developed a nonunion (operative 6% vs nonoperative 18%; OR 3.8, P = 0.140). There was no difference in return to work, but surgery conferred a higher rate of return to sport (94% vs 57%; P = 0.027).

Conclusion: Surgery confers early advantages over bracing, in terms of patient-reported upper limb function, HRQoL, and shoulder/elbow ROM. However, these benefits should be considered in the context of potential operative risks and the absence of any difference in patient-reported outcomes at 1 year.