## The HUmeral Shaft Fracture FIXation (HU-FIX) Study: A Prospective Randomised Trial of Operative *Versus* Non-Operative Management of Fractures of the Humeral Diaphysis

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INTRODUCTION: This single-centre prospective randomised trial aimed to assess whether there was any difference in outcome between surgery and bracing for adults with an isolated, closed humeral shaft fracture.

METHODS: Seventy patients (mean age 49 years, 54% female) were randomised to either open reduction and plate fixation (n=36/70) or functional bracing (n=34/70). Seven patients did not receive their assigned treatment (operative n=5/32, non-operative n=2/32); intention-to-treat analyses were employed. The primary outcome measure was the DASH score at 3 months. Secondary outcomes in the year following intervention included health-related quality of life (HRQoL), pain scores (using a visual analogue scale), shoulder/elbow range of motion, complications and return to activity. RESULTS:

At 3 months, 66 patients (94%) had complete follow-up. The mean DASH favoured surgery (operative 24.5 *vs* non-operative 39.4), and the mean difference (MD 15.0, 95% CI 4.4 to 25.6, p=0.006) exceeded the minimum clinically-important difference. Surgery was also associated with a superior DASH at 6 weeks (MD 14.7, p=0.005), but not at 6 months or one year. Surgery was associated with superior HRQoL over the first 6 months according to EuroQol scores (EQ-5D 6wks: MD 0.126, p=0.03; EQ-VAS 6mths: MD 7, p=0.039) and the SF-12 Mental Component Summary score (6wks: MD 9.3, p=0.001; 3mths: MD 6.9, p=0.008; 6mths: MD 7.1, p=0.007). Pain scores were also superior over the first 6 months in the surgery group (body pain 6wks: MD 12/100, p=0.02; body pain 6mths: MD 10/100, p=0.023; limb pain 6mths: MD 1.2/10, p=0.027). Surgery conferred superior shoulder elevation, abduction and external rotation at 6 weeks and 3 months, along with elbow flexion at 3 months and one year (all p<0.05). Brace-related dermatitis was more common in the non-operative group (18% *vs* 3%; OR 7.8, p=0.049). There were eight nonunions (non-operative 18% *vs* operative 6%; OR 3.8, p=0.14). There was no difference in return to work, but surgery conferred a higher rate of return to sport (94% *vs* 57%; p=0.027). There were no other differences in outcomes between groups.

DISCUSSION AND CONCLUSION: Surgery confers early functional advantages over bracing, along with a lower nonunion rate. However, these benefits should be considered in the context of potential operative risks and the absence of any difference in outcomes at one year.