Proximal Fracture of the Humerus: Evaluation by Randomization (ProFHER) Trial

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Background/Purpose: Proximal humeral fractures are common injuries, accounting for 5% to 6% of all adult fractures, with an estimated 706,000 having occurred worldwide in 2000. Around half (51%) of these fractures are displaced, the majority of which involve the surgical neck (40% of all fractures). Cochrane review has found, at each update, insufficient evidence from randomized controlled trials to inform practice, including whether surgical intervention, even for specific fracture types, produces consistently better outcomes, and well-designed trials are needed to answer this question. The ProFHER trial was designed to evaluate the clinical and cost-effectiveness of surgical versus nonsurgical treatment for adults with displaced fractures of the proximal humerus involving the surgical neck.

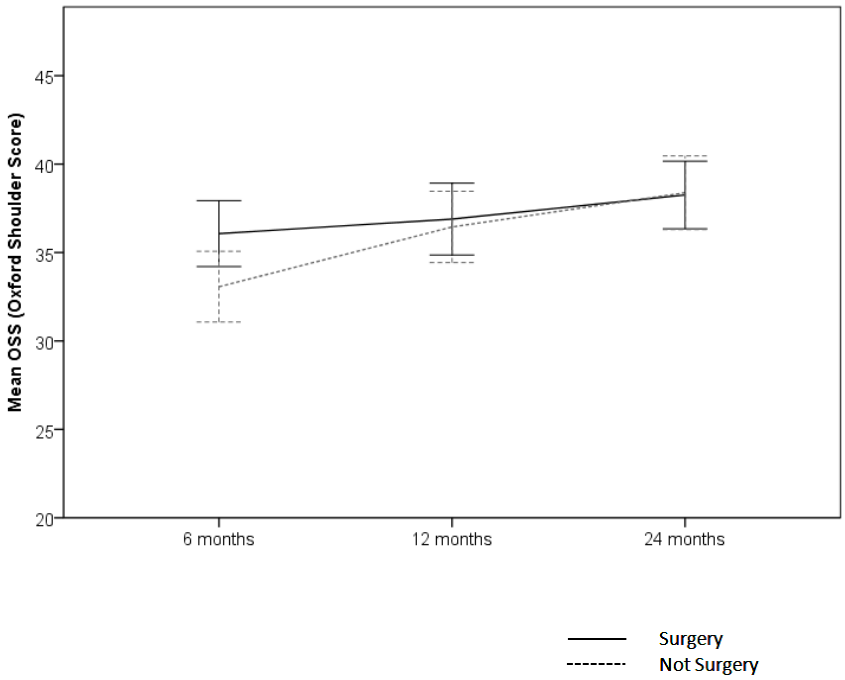
Methods: The ProFHER trial is a pragmatic parallel group multicenter randomized controlled trial, with an economic evaluation. Recruitment was undertaken in the orthopaedic trauma departments of 33 hospitals from September 2008 to April 2011. Surgeons used surgical techniques of fracture fixation or humeral head replacement with which they were experienced. Initial nonsurgical treatment was sling immobilization. Rehabilitation was standardized and included outpatient and community based rehabilitation. The primary outcome was the Oxford Shoulder Score (OSS; scale 0 to 48, higher scores indicating better outcome) assessed over 6, 12, and 24 months. The trial was powered to detect a clinically important difference of 5 OSS points. Secondary outcomes were the Short-Form 12, EuroQol-5D-3L, complications, subsequent therapy, and mortality.

Results: The 250 participants (125 randomized to each group), aged 16 years or older, presented within 3 weeks of sustaining a displaced fracture of the proximal humerus that involved the surgical neck. Of these, 215 participants (106 surgery, 109 not surgery) completed follow-up. There was no significant between-group difference in OSS over the 2-year period (0.75 points in favor of surgery, 95% confidence interval [CI] -1.33 to 2.84; P = 0.48), nor at individual time points. We found no statistically significant between-group differences in secondary outcomes, including surgical or fracture-related complications (30 vs 23 patients) and secondary surgery to shoulder (11 each group). Surgery cost significantly more over 2 years.

Conclusion: Current surgical practice does not result in a better patient-reported outcome for most adults with displaced proximal humeral fractures involving the surgical neck, and is not cost-effective in this setting.

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.

Comparison of OSS by treatment groups:



See pages 47 - 108 for financial disclosure information.

Participant Flow:

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.