

Earlier Functional Recovery with Operative Treatment of Isolated Ulnar Diaphyseal Fractures: A Multi-centre Randomized Controlled Trial

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INTRODUCTION: Complications following ulnar diaphyseal (“nightstick”) fractures are frequent, including non-union, malunion, decreased elbow and forearm range of motion (ROM), and prolonged pain. There is no consensus on optimal treatment, as prospective research is scarce and follow-up can be challenging in this population. This randomized controlled trial (RCT) aimed to compare clinical, radiographic, and functional outcomes between open reduction and internal fixation (ORIF) and non-operative treatment. We hypothesized that ORIF would result in earlier functional recovery with minimal complications.

METHODS: This is a multi-centre, open-label, parallel RCT of consecutive adult patients with isolated, closed AO/OTA type 22-A and B injuries, without extension into the proximal or distal radio-ulnar joints. Patients were excluded if the fracture was displaced <50%, or there was >30-degrees of angulation. Following institutional research ethics board approvals at each participating site, eligible patients were randomized electronically with a 1:1 ratio using variable block sizes, and stratification by recruiting site, to one of two treatment arms: non-operative treatment with below-elbow casting, or ORIF with a plate and screw construct. A 50% loss-to-follow-up rate was accounted for in order to ensure appropriate statistical power. The primary outcome measure was the Disabilities of Arm, Shoulder, and Hand (DASH) score. Secondary outcomes included the pain Visual Analogue Scale (VAS), ROM, grip strength, adverse events, and time-to-union (modified RUST score) until 12 months post-injury. Intention-to-treat analysis was performed with independent samples t-tests, Fisher’s Exact, ANOVA, and pairwise comparisons between each follow-up time interval.

RESULTS: A total of 101 participants were randomized across 11 participating sites, with 99 included in the analysis (50 ORIF and 49 non-operative). There were no differences between groups in age (41.0 years for ORIF vs. 40.0 years for non-operative), sex (32 male for ORIF vs. 40 for non-operative), smoking status, body mass index, or OTA/AO classification (all $p < 0.05$). There were significantly improved DASH scores at 6-weeks (Figure 1), grip strength at 6- and 12-weeks, ROM at 6-weeks, and earlier fracture healing in the ORIF group (all $p < 0.05$). There was no significant difference in pain VAS between groups at any timepoint. The adverse event rate was 7.1% (ORIF group) and 28.0% (non-operative group), with a significantly higher non-union rate in the non-operative group ($p = 0.02$).

DISCUSSION: This is the largest multi-centre RCT comparing ORIF and non-operative treatment for isolated ulnar diaphyseal fractures to date and the multi-centre design enhances generalizability. There was a large, but expected, loss-to-follow-up rate that was accounted for in the sample size calculation. Earlier, but limited duration improvement in clinical and functional outcomes was found in those treated with ORIF, with a low adverse event rate.

SIGNIFICANCE/CLINICAL RELEVANCE: This multi-centre RCT comparing ORIF and non-operative treatment for isolated ulnar diaphyseal fractures found earlier functional recovery and radiographic fracture healing for those treated with ORIF with a lower complication rate compared to non-operative treatment. This novel data can be used to inform shared decision-making with patients based on their functional demands.

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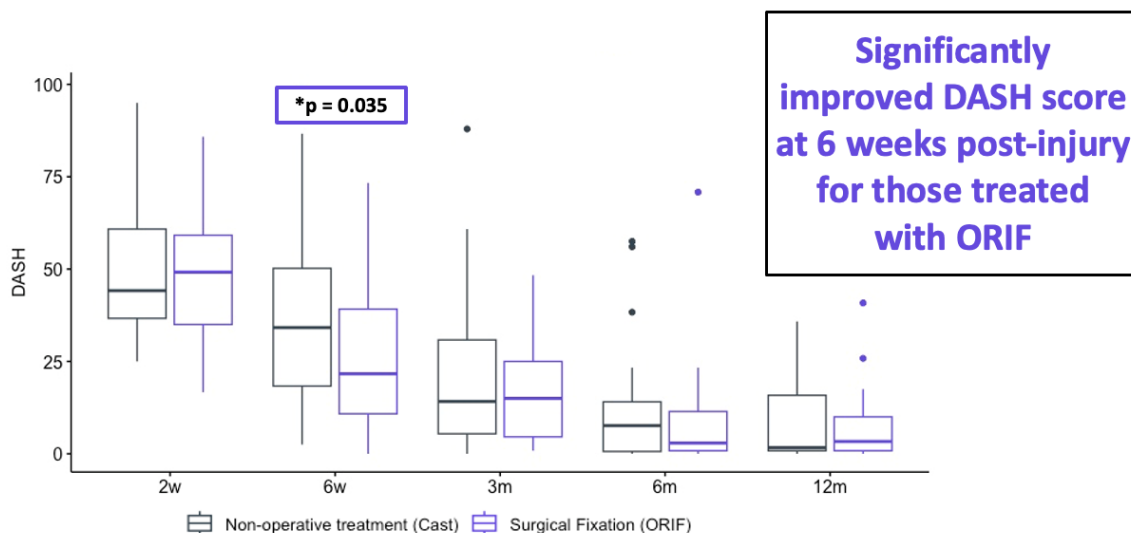


Figure 1: Comparison of the Disabilities of Arm, Shoulder, and Hand (DASH) score between the open reduction and internal fixation (ORIF) treatment arm and the non-operative treatment arm over 12-month follow-up demonstrates earlier patient-reported functional recovery in the ORIF group at 6-weeks post-injury.