

## A Randomized Controlled Trial Comparing Operative and Nonoperative Treatment of Ulnar Diaphyseal Fractures

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**Purpose:** Complications following ulnar diaphyseal fractures (“nightstick fractures”) are frequent, including high rates of nonunion, malunion, decreased elbow and forearm range of motion, 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 large randomized controlled trial (RCT) aimed to compare clinical, radiographic, and functional outcomes between open reduction and internal fixation (ORIF) and nonoperative treatment for isolated ulnar diaphyseal fractures.

**Methods:** This is a multicenter, open-label, parallel RCT of patients with isolated, closed AO/OTA type 22A and 22B injuries, without extension into the proximal or distal radioulnar joints. Patients were excluded if the fracture was displaced <50%, or there was >30° of angulation. Eligible patients were randomized electronically with a 1:1 ratio using variable block sizes and stratification by recruiting site to one of 2 treatment arms: nonoperative treatment with closed reduction and below-elbow casting, or ORIF with a plate and screw construct. The primary outcome measure is the DASH (Disabilities of the Arm, Shoulder and Hand) score at 12 weeks post-injury. The Short Form 36 (SF-36) and pain visual analog scale (VAS) will be compared between groups. The secondary outcome measures include clinical (range of motion, grip strength), radiologic (time to union), and economic outcomes, assessed throughout patient follow-up until 12 months post-injury. Intention-to-treat analysis will be performed with independent samples t-tests to compare the mean DASH, SF-36, and VAS at 12 months. For secondary analyses, ANOVA (analysis of variance) and pairwise comparisons will be completed between each follow-up time interval. Independent samples t-test will be used for time to union and survival analysis will be used to determine difference in treatment for time to union and return to work.

**Results:** A total of 100 participants were enrolled and randomized (49 ORIF and 51 nonoperative) across 11 participating sites (Table 1). The mean age of the overall cohort is 40.9 ± 14.8 years, with 72% being male. The final follow-up will be completed in March 2023; therefore, the final study results will be available for the 2023 meeting.

**Conclusion:** This will be the largest RCT of operative compared with nonoperative management of isolated ulnar diaphyseal fractures. This is a multicenter study across 11 sites with a large loss to follow-up rate included in the sample size calculation, in order to ensure appropriate statistical power.

Table 1: Demographic comparison of the open reduction and internal fixation (ORIF) treatment arm and the non-operative treatment arm.

	Surgical Fixation (ORIF) N = 49 <sup>1</sup>	Non-operative treatment (Cast) N = 51 <sup>1</sup>	p-value <sup>2</sup>
<b>Age (Calculated)</b>	41 (14)	40 (16)	0.7
Missing	0	2	
<b>Sex</b>			0.042
Female	18 / 49 (37%)	9 / 49 (18%)	
Male	31 / 49 (63%)	40 / 49 (82%)	
Missing	0	2	
<b>AO</b>			0.6
A	41 / 49 (84%)	39 / 49 (80%)	
B	8 / 49 (16%)	10 / 49 (20%)	
Missing	0	2	
<b>Mechanism of Injury</b>			0.6
Direct trauma (blunt)	9 / 47 (19%)	14 / 46 (30%)	
Fall	19 / 47 (40%)	15 / 46 (33%)	
Motor vehicle accident	3 / 47 (6.4%)	5 / 46 (11%)	
Autopedestrian	1 / 47 (2.1%)	0 / 46 (0%)	
Motorcycle accident	1 / 47 (2.1%)	0 / 46 (0%)	
Other	7 / 47 (15%)	4 / 46 (8.7%)	
Sport	7 / 47 (15%)	8 / 46 (17%)	
Missing	2	5	

<sup>1</sup> Mean (SD); n / N (%)

<sup>2</sup> Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test

See the meeting website for complete listing of authors' disclosure information. Schedule and presenters subject to change.