Scaphoid Waist Internal Fixation for Fractures Trial (SWIFFT): A Randomized Controlled Trial, Economic Evaluation, and Nested Qualitative Study of Cast Immobilization versus Surgical Fixation for the Treatment of Adult Patients with a Bicortical Fracture of the Scaphoid Waist

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**Purpose:** Scaphoid fractures account for 90% of carpal fractures, and despite insufficient evidence of its effectiveness, immediate surgical fixation of this fracture has been increasing. We set out to establish whether there was a clinically meaningful difference between early surgical fixation using standard CE marked headless compression screws compared with below-elbow cast treatment for 6 to 10 weeks (with early fixation of CT- confirmed nonunion) of these fractures in adults.

**Methods:** We compared clinical and cost-effectiveness of these 2vtreatment pathways in a multicenter, pragmatic, randomized controlled trial using remote randomization with an economic evaluation and nested qualitative study. Adults ( $\geq$ 16 years), presenting within 2 weeks of injury with a clear, bicortical fracture of the scaphoid waist seen on scaphoid series radiographs were recruited in 31 UK hospitals from July 2013 with final follow-up in September 2017. The primary outcome and end point was the Patient-Rated Wrist Evaluation (PRWE) total score at 52 weeks, with a clinically relevant difference of 6 points. Secondary outcomes included PRWE total scores at other time points (6, 12, and 26 weeks), PRWE pain and function subscales, Short Form (SF)-12 questionnaire, bone union, range of movement and grip strength, complications, and return to work.

**Results:** The mean age of the 439 participants was 32 years, 363 were men (83%), and 269 had an undisplaced fracture (61%). The primary analysis was on 408 participants (surgery n = 203 of 219, 93%; cast n = 205 of 220, 93%) using intention to treat. There was no clinically relevant difference in the total PRWE at 52 weeks: cast group mean 14.0 [95% confidence interval [CI] 11.3 to 16.6] and surgery group mean 11.9 (95% CI 9.2 to 14.5); adjusted mean difference of -2.1 in favor of surgery (95% CI -5.8 to 1.6, P = 0.27). Nonunion rate was very low in both groups. Eight participants in the surgery group had 11 reoperations, and 1 participant in the cast group required a reoperation for nonunion. The base-case economic analysis of a lifetime extrapolated model confirmed that the initial use of cast with immediate fixation of nonunions was the most cost-effective option. The nested qualitative study identified patients' desire to have a "sense of recovering," which surgeons should address at the outset.

**Conclusion:** Adult patients with an undisplaced or minimally displaced scaphoid waist fracture should have the wrist immobilized in cast and all suspected nonunions immediately investigated and those confirmed urgently fixed.

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.