Title:

Surgery compared with cast immobilization for adults with a bi-cortical fracture of the scaphoid waist (SWIFFT): a multicentre, pragmatic, open-label, parallel-group, two-arm randomised clinical trial

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Abstract

Background

Scaphoid fractures account for 90% of carpal fractures and occur predominantly in young men. Immediate surgical fixation of this fracture has increased, in spite of insufficient evidence of improved outcomes over non-surgical management. We compared the clinical effectiveness of surgical fixation with cast immobilization and early fixation of those that fail to unite, for ≤2 mm displaced scaphoid waist fractures in adults.

Methods

This pragmatic, multicentre, open-label, parallel-group, two-arm randomised clinical trial included adults who presented to orthopaedic departments of 31 hospitals in England and Wales with a clear, bicortical fracture of the scaphoid waist on radiographs. Participants were randomly assigned to early surgical fixation or below-elbow cast immobilization followed by immediate fixation of confirmed non-union. The primary outcome was the Patient Rated Wrist Evaluation (PRWE) total score at 52 weeks post-randomisation. Registration ISRCTN67901257.

Findings

Interpretation

Adult patients with ≤2 mm displaced scaphoid waist fracture should have initial cast immobilization and suspected non-unions confirmed and immediately fixed. This will help avoid risks of surgery and mostly limit its use to fixing non-union.

Funding

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Keywords: Scaphoid fracture; screw fixation; plaster cast; union; randomised controlled trial

Research in Context:

Evidence Before this study:

Fracture of the scaphoid bone (one of eight small bones in the wrist) is common in young active people and typically caused by a fall on the hand or the hand being suddenly forced backwards. Traditionally the treatment has been to rest the wrist in a plaster cast for six to ten weeks and allow the broken bone to heal. The one in ten that do not heal are then operated on and held still with a screw. In recent years, another way of holding these fractures still while they heal has been to operate early on the wrist and to fix the broken bone with a special screw. While there has been an increasing trend to perform more costly and invasive surgery, which also has a bigger impact on service delivery and use of theatre time, compared to a minimal intervention of cast immobilisation, there is inconclusive evidence that it produces better patient outcomes.

In February 2018, a systematic review and meta-analyses was conducted of surgery compared with nonsurgical treatment for scaphoid waist fracture with slight or no displacement. PubMed, Embase and Cochrane Library were searched and the references for relevant reviews and systematic reviews were manually retrieved. The keywords used were "scaphoid bone", "fractures, bone" and "surgical procedures, operative" and synonyms for these terms. There were 14 eligible studies, including 10 RCTs and 4 cohort studies, that included 765 patients. The evidence was of variable quality and showed that there was no difference in patient satisfaction, pain, and patient-reported outcomes between surgical treatment and cast immobilisation. Although there was evidence that surgical treatment could reduce the incidence of non-union and shorten the time to union. The need for high-quality studies was recommended.

We undertook a rigorously designed, and sufficiently powered, randomised, pragmatic, parallel group, two-arm, superiority trial called SWIFFT to determine whether surgical fixation compared with cast immobilization and early fixation only of those that fail to unite for ≤2 mm displaced scaphoid waist fractures in adults improved patient outcomes.

Added value of this study:

To our knowledge, SWIFFT is the largest randomised trial (439 participants) to compare surgery with cast immobilisation in the treatment of adults with sight or no displacement of scaphoid waist fractures. It has doubled the evidence from previous small trials of variable quality. There was no evidence of a difference in overall patient-reported outcome at 52 weeks, nor for the pain or function sub-scales of the patient-reported outcome, grip strength, or range of movement. Time off work was similar between the two groups. While fewer participants in the surgery group (n=4, 2%) compared with cast immobilization (n=9, 4%) had non- or slight union at 52 weeks (p=0·13), surgery was more likely to lead to potentially serious complications.

Implications of all the available evidence:

This large and rigorous trial found little difference between the two management pathways for scaphoid waist fractures displaced ≤ 2mm, across a range of outcomes. These findings are timely as we see an increasing trend towards primary surgical fixation, which is not clearly supported by this evidence. Cast immobilization treatment is as effective, provided that suspected non-unions are confirmed early and fixed. The numbers of scaphoid fractures to surgically fix to avoid one non-union was estimated to be 73. Early fixation, therefore, could be restricted for displaced fractures that are >2mm to limit exposure to surgical risks and make better use of theatre time. These results should be shared with patients when discussing treatment options.

Introduction

Scaphoid fractures account for 90% of carpal fractures and 2-7% of all fractures.[1] It is an important public health problem as it predominantly affects young active individuals (mean age 29 years)[2] in their most productive working years. The scaphoid fractures are typically

caused when the wrist is suddenly extended either when putting the hand out to break a fall or when the palm is struck forcibly by an object. Most (64%) involve the waist (middle 60%) of the scaphoid.[3] A scaphoid fracture is considered displaced if there is a step or gap of 1 mm or more.[4] Scaphoid fractures disrupt the proximal carpal row and alter how the wrist is stabilised to permit the hand and digits to function efficiently.

The aim of treatment is to stabilise the fracture to permit healing by either immobilising the wrist in a cast or passing a screw across the fracture. About 10-15% of undisplaced or minimally displaced fractures do not heal in a cast.[5] At present the evidence of treatment of displaced fractures is weak and recommendations are based on case-series. When displacement of the fracture is more than 2 mm most clinicians would prefer to reduce the fracture. Non-union, if untreated, almost inevitably leads to arthritis, usually within five years.[6] This causes symptoms of pain and stiffness at a young age. Therefore, the standard non-operative pathway is to fix a fracture that has not healed after initial cast immobilisation.[2]

Immediate surgical fixation is said to avoid the need for a cast and accelerate return to function, work, and sport[7] but exposes patients to surgical risks. Eight small randomised clinical trials in United Kingdom, United States of America (USA) and Sweden,[8] of variable quality, reporting on undisplaced or minimally displaced fractures of the scaphoid waist, provide unclear evidence on whether surgical fixation gives better outcomes than cast immobilization. Despite insufficient evidence there is an increasing trend[9] to immediately fix this fracture for perceived short-term benefits, but concerns remain about the lack of evidence on long-term benefits and additional risks from surgery, such as malunion, infection, and implant related problems.

The Scaphoid Waist Internal Fixation for Fractures Trial (SWIFFT) was designed to compare the clinical effectiveness of early fixation with initial cast immobilization.[10]

Methods

Study design and participants

This was a pragmatic, open-label, multicentre, stratified, parallel-group, superiority, randomised clinical trial. Patients were recruited between July 2013 and July 2016 from

orthopaedic departments at 31 United Kingdom (UK) National Health Service (NHS) hospitals. Follow-up was to 52 weeks post-randomisation for all patients.

Patients were eligible if they were skeletally mature, aged 16 years or older, and presented to the NHS within two weeks of injury with a clear bicortical scaphoid waist fracture on plain radiographs and could have surgery within two weeks of presentation. A bicortical fracture was defined as when on any radiographic view the continuity of both cortices were broken. Displaced fractures with ≤2 mm step or gap on any of five radiographic views (posterior-anterior, lateral, semi-supine, semi-prone, elongated-scaphoid) were included. Both the assessment of whether the fracture was bicortical or displaced was undertaken by the clinician establishing eligibility at the recruiting site. A research CT scan done at baseline, including the radiographs, were reviewed independently by two senior consultant radiologists and a senior orthopaedic surgeon (Chief Investigator) who used standardised criteria to help confirm fracture eligibility.

Patients were excluded if fractures had displacement >2 mm or involved the proximal or distal pole, they had a trans-scaphoid-perilunate dislocation, multiple injuries in the same limb, concurrent wrist fracture in the opposite limb, or insufficient mental capacity to comply with treatment or data collection, they were pregnant, or not resident in a participating site's catchment area to allow follow-up.

The study and all amendments were approved by the Research Ethics Committee – East Midlands (REC reference 13/EM/0154). The published trial protocol,[10] and the analysis plan are available (Supplement 1). The trial was overseen by independent steering and data monitoring and ethics committees.

Randomisation and blinding

Surgeons confirmed eligibility. After providing consent and baseline information, patients were allocated (1:1) randomly by hospital staff to one of the two treatment groups using an independent remote randomisation service (York Trials Unit, YTU, University of York).

Randomisation was stratified, using random block sizes of six and twelve, by whether or not there was displacement of either a step or gap of 1-2 mm inclusive on any radiographic view.

Registering participants before remote computer-generated randomisation with randomly varying block sizes ensured allocation concealment.

It was not possible to blind trial participants or clinicians for outcome assessments. To minimise bias in bone union assessment, all radiographs and Computed Tomography (CT) scans were reviewed independently by two consultant musculoskeletal radiologists and a consultant orthopaedic surgeon (Chief Investigator) and disagreements resolved through discussion. The statistician was blind to group allocation until after data collection was complete.

Interventions

Surgical treatment was by percutaneous or open surgical fixation depending on the surgeon's preferred technique. Standard CE marked headless compression screws were used.[2] The type of implant used was not restricted nor was the surgical approach or the postoperative care.

The comparator was below elbow cast immobilization for six to ten weeks, with or without inclusion of the thumb.[5] If non-union was suspected based on the clinical judgement of an experienced surgeon at the recruiting site, rather than defined criteria, on six to 12- week radiographs, it was investigated using CT and, if confirmed, immediate surgical fixation offered. The surgical procedure to treat a non-union was as described above.[2] This pathway is referred to as the "cast immobilization" group.

All participants received standardised, written physiotherapy advice detailing rehabilitation exercises. Additional rehabilitation was at the treating clinician's discretion.

Data collection and outcome measures

Participant-completed questionnaires were collected in the hospital at baseline and we asked about their wrist problem for the week before injury; and completed at six, 12, 26, and 52 weeks post-randomisation by post, in hospital clinic or by telephone.

The primary outcome was the Patient Rated Wrist Evaluation (PRWE) total score. The PRWE measures wrist pain and disability.[11] It contains 15 items, each with a ten-point ordered scale, and the total score range is from 0 (no disability) to 100. The primary end-point was 52 weeks.

Secondary outcomes were the PRWE subscale scores of pain and function, the Short Form 12 (SF-12) health survey physical and mental component scores,[12] bone union, range of movement, grip strength, and complications.

Bone union was determined using the plain radiographs and a CT scan performed for research purposes at baseline and 52 weeks. Routine radiographs taken at six and 12-week hospital clinic visits were also collected. Union was defined as complete disappearance of the fracture line[5] on radiographs and complete bridging on CT scans.[13] Partial union was recorded as the proportion of the fracture plane traversed by bridging trabeculae on CT sagittal and coronal multiplanar scaphoid reconstructions and union was categorised as none (0%), slight (>0-20%), partial (>20-70%), almost full (70-<100%) and full (100%). Malunion was assessed on the 52-week CT scan, as the ratio of Scaphoid height to length ≥0·6 or ≥0·7 in the scaphoid sagittal plane.[14]

The range of movement of both wrists was measured using a goniometer and grip strength of both hands using a calibrated Jamar dynamometer at baseline and at six, 12, and 52 weeks post-randomisation, during hospital visits.

Complications, defined as medical, surgical, or cast related, were recorded at six, 12 and 52-week hospital visits. Participants reported the number of injury-related days off work. Data on details of surgery were also collected.

Statistical methods

A six-point improvement in PRWE score was deemed a conservative[15] minimum clinically important difference. Using a SD of 20,[11] this gave an effect size of 0·3. To observe this effect size with 80% power using a two-sided 5% significance level requires 350 participants. Allowing for 20% attrition, the recruitment target was 438 participants.

Analyses strictly followed a prespecified analysis plan, endorsed by the independent oversight committees. Analyses were on an intention-to-treat basis, and were performed in Stata v15[16] using two-sided statistical tests at the 5% significance level. Baseline and outcome data are summarized descriptively by treatment group. The primary analysis compared total PRWE scores between the two groups using a covariance pattern, mixed-effect linear regression model incorporating all post-randomisation time points (six, 12, 26

and 52 weeks). Treatment group, time point, treatment-by-time interaction, age, baseline fracture displacement (< 1mm/1-2mm), and dominance of injured limb were fixed effects. Participant was a random effect accounting for repeated observations per patient. An unstructured covariance pattern for the correlation between the observations for a participant over time was specified (based on minimizing the Akaike's information criterion).[17] Diagnostics of model fit revealed that the standardised residuals demonstrated sufficient normality and were uniform against fitted values. Estimates of the difference in total PRWE score were extracted for each time point and overall, with 95% confidence intervals (CI) and p-values.

Any response bias was minimised by using a repeated-measures model in the primary analysis, which allowed inclusion of intermittent responders. Multiple imputation by chained equations assessed the effect of missing data.[18]

Adding smoking status (yes/no) to the primary model (post-hoc analysis reflecting a chance imbalance at baseline) and adding centre as a random effect to explore for potential clustering were undertaken as sensitivity analyses. To account for non-compliance (surgery to cast immobilization) and contamination (cast immobilization to surgery) a complier average causal effect (CACE) analysis was conducted using two-stage least squares, with randomised treatment as the instrumental variable.[19] Further sensitivity analyses are in supplementary material.

We planned three subgroup analyses: one exploring patient treatment preferences at baseline and two exploring fracture displacement as recorded at randomisation or corrected after Study Eligibility Form review. Greater benefit of surgery was expected in i) participants with a baseline preference for surgery, and ii) in patients with a displaced fracture.

Analyses of the secondary outcomes was as described for the primary outcome. Bone union at 52 weeks was dichotomised as "possibly needing surgery" (0-20% united), and "not requiring surgery" (>20%-100% union) and compared between groups using logistic regression adjusting for age, fracture displacement, and dominant hand. Malunion was presented overall and for each treatment group at six, 12 and 52 weeks (Supplementary Table 5). The presence of medical, surgical, or cast complications was analysed by logistic

regression, adjusting for age, hand dominance, and fracture displacement. All serious and non-serious adverse events were summarised by treatment group.

Role of the funding source

The funders monitored the trial progress but had no role in study design, data collection, data analysis, data interpretation, or writing or approving or the decision to submit the publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

We identified 775 eligible patients and 439 (57%) were recruited (Figure 1) across 31 sites (median 10 patients per site, range 1-61). Most (n=325, 97%) of the 336 patients who did not consent to the study despite being eligible gave a reason, and most were accounted for by: preference for non-operative treatment (n=206); preference for surgery (n=40); or unable to commit to follow-ups (n=24). Participants who gave consent were randomly allocated to surgery (n=219) or cast immobilization (n=220).

The mean age was 33 years (range 16-80), 363 (83%) were male (Table 1) and 269 (61%) had fracture displacement <1 mm (Supplementary Table 1). These characteristics were similar to the 336 patients who refused consent (mean age 32 years, n=268, 80% male), whereas ineligible patients (n=272) were older (mean age 36 years) with a lower proportion of males (n=203, 75%) (Supplementary Table 2). The left wrist was injured in 53·1%, and the non-dominant limb in 55·1% (Supplementary Table 1).

Baseline characteristics were similar between groups, except for ethnicity, education, and smoking status (Table 1).

Of the 219 patients allocated to surgery, 188 (86%) received surgery, on average 10·2 days (range 3-20) after injury, and performed by 95 surgeons across 29 sites. Data on operating surgeon were available for 187 of the 188 operations; 163 were either performed (n=120, 64%) or assisted/supervised (n=43, 23%, assisted 40, supervised 3) by consultants. The remaining 24 were performed by a specialist trainee (n=13) or staff grade/associate specialist (n=11). Of the 220 patients allocated to cast immobilization, 214 (97%) had a cast initially and six (3%) received surgery (mean 13·5 days after injury, range 5-32) shortly after

randomisation (contamination). One of the remaining 214 patients had surgery 29 days after randomisation due to perceived displacing of the fracture and one had fixation at a non-participating hospital. Following confirmation of non-union, 17 (8%) received surgery, on average 159 days (range 68-358) after injury. Fourteen of these had surgery within 26 weeks of randomisation (only five within 12 weeks as per protocol), while three had delayed surgery. (See Supplementary Tables 3 and 4 for further detail.)

Following randomisation, participants in the cast immobilization group wore a cast for an average of 44·8 days (SD 15·2); 91 (41%) then were given a splint for an average of a further 26·4 days (SD 15·1). Of the 188 participants allocated to the surgical fixation arm who underwent surgery 86% had minimal or no immobilisation: 26 (14%) had a bandage applied (duration not available); 62 (33%) had a splint only (mean 28·4 [SD 19·6] days); and 73 (39%) had a cast on for a short period immediately after surgery (mean 15·6 [SD 9·8] days) followed by a splint (24·7 [SD 13·9] days). The remaining (14%) were immobilised in a cast: 24 (13%) had a cast only (mean 30·9 [SD 16·7] days); and three had a splint for a mean of 12·7 days [SD 2·5] then a cast for a mean of 27·7 days [SD 0·6].

Primary outcome and sensitivity analyses

Valid PRWE data were provided by 348 participants (79%) at six weeks, 341 (78%) at 12 weeks, 302 (69%) at 26 weeks, and 362 (82%) at 52 weeks. The primary analysis included 408 (93%) participants (203 surgery; 205 cast immobilization) with a valid PRWE score for at least one follow-up time point and complete covariate data. At 52 weeks, the unadjusted mean PRWE score was 11·4 (SD 16.6) in the surgery group and 14·2 (SD 19·8) in the cast immobilization group for which there was no evidence of a ceiling effect. There was no evidence of a statistically significant or clinically important difference in PRWE score between groups at 52 weeks (adjusted mean difference -2·1 favouring the surgery group, 95% CI -5·8 to 1·6, p=0·27), at 26 weeks nor over the whole 52 weeks (Table 2; Figure 2). There was a statistically significant difference at week 12 (p=0·01) and weak evidence of a difference at six weeks (p=0·06) favouring surgery. While the point estimates of the difference do not exceed 6 points (the threshold of clinical importance we are using in this study), the confidence intervals do include this difference.

Although 83% of participants had provided a PRWE at 52 weeks, PRWE data were missing for at least one follow-up time-point in 190 participants (43%). Analyses on complete,

multiply imputed datasets produced similar results to the primary analysis (adjusted mean difference -2·1, 95% CI -5·9 to 1·6, p=0·26 at 52 weeks) (Supplementary Table 5).

There was no statistically significant difference in total PRWE score between the treatment groups at 52 weeks after adjustment for smoking status (p=0·14) or clustering for site (p=0·31). The other sensitivity analyses did also not alter our primary findings (Supplementary Table 5).

The CACE estimate of the treatment effect at 52 weeks was a difference of -3·1 in favour of the surgery group (95% CI -7·3 to 1·1, p=0·15). Therefore, the non-compliance described did not have an effect on the primary findings.

Subgroup analyses

There was no statistically significant interaction between randomised group and treatment preference, or fracture displacement assessed at either study enrolment or randomisation (Supplementary Figure 1).

Secondary outcomes

We found no statistically significant differences between groups at 52 weeks for the PRWE pain or function subscales, the SF-12 mental component score, range of wrist movement, or grip strength (Table 2). There was a difference in SF-12 physical component score favouring the surgery group of 1·6 points (95% CI 0·2 to 3·1, p=0·03). Range of movement and grip strength are summarised in Supplementary Table 6.

Participants in the surgery group were less likely to have non- or slight union of their fracture at 52 weeks (Table 3) but this difference was not statistically significant (four vs nine participants, adjusted odds ratio 0·40, 95% CI 0·12 to 1·33, p=0·13). Supplementary Table 7 presents the malunion assessed at different thresholds of ratio of scaphoid height to length (0·6 and 0·7). For both thresholds there were no marked differences between groups in malunion at all time-points on the radiographic and CT images.

More participants in the surgery group experienced a surgery-related potentially serious complication than in the cast group (n=31, 14% vs n=3, 1%), but fewer had cast-related complications (n=5, 2% vs n=40, 18%). In the surgery group, four experienced nerve events

(numbness in the region of the scar, n=3 and decreased sensation over the scar and distally with tenderness, n=1), two had infection, and three developed Complex Regional Pain Syndrome (CRPS); while in the cast group, one developed transient nerve problems, two had infection, and none had CRPS (Supplementary Table 8). The number experiencing a medical complication (n=4, 2% vs n=5, 2%) was similar in the two groups. CT images at 52 weeks were assessed for screw penetration from the surface of the bones in mm for 142 of the 188 participants who received surgery; screw penetration was identified in 93 (65%) participants (<1 mm, n=25 [27%]; 1-2 mm inclusive, n=44 [47%]; and >2 mm, n=24 [26%]). For these 142 participants the unadjusted mean PRWE at 52 weeks for those who had screw penetration <1mm was 8·9 (SD 15·0) and for those ≥1mm was 10·8 (SD 13·9).

Eight of 219 (4%) participants in the surgery group had 11 re-operations; the re-operations were to remove prominent screws in six and for non-union in two, with one requiring scaphoid excision and a four-corner fusion. One of 220 allocated to initial cast immobilization developed non-union that was fixed but required re-operation for persistent non-union.

There were three serious adverse events, one for each of three participants in the surgery group; all were related to anaesthesia or surgery, and two were unexpected (Supplementary Table 9).

Over the 52 week period, surgery group participants reported an average of 15·6 days of lost employment compared to 18·2 days in the cast immobilization group (Table 4). This difference is not statistically significant.

Discussion

Adults who have a bicortical scaphoid waist fracture with 2 mm or less displacement immobilised in a below elbow cast have little difference in pain and function to those having the fracture surgically fixed with a screw. Cast immobilisation, with suspected non-unions identified and fixed early, was successful in delivering fracture union and very substantially reduced the need for surgery. The differences between groups were below the pre-specified and conservative six points on the PRWE and therefore unlikely to be important to patients. Our findings on the intention-to-treat analysis were confirmed by sensitivity analyses accounting for crossover, and adjusting for fracture displacement, participants' smoking

status and clustering at site. Secondary outcomes of bone union, grip strength, range of movement, and SF-12 support the primary analysis findings.

Early on, when more participants in the cast group were still in a cast, differences in pain and function were statistically significant, favouring surgery, but below six points on the PRWE and so of uncertain clinical relevance. Beyond 12 weeks there was no difference between groups, nor did this study identify evidence that the rate of non- and slight union was statistically significantly different between surgical fixation and cast immobilisation. We observed this state in four (three slight union and one non-union) participants in the surgery group and nine (five slight union and four non-union) of those who were treated in a plaster cast. Complications of infection, nerve problems and CRPS were ten-times more likely after early fixation (14·2%) than in the cast group (1·4%). The screw penetrated joints in far more participants than anticipated, in half the screw protruded by 1-2 mm and in a quarter by over 2 mms risking irreversible articular cartilage damage and early degenerative arthritis but only six had penetrating screws removed. In most, screw penetration was seen because we did CT scans at one year. This emphasises the need for careful imaging during surgery. Cast complications (soft, tight or broken cast, skin soreness) were minor, resolved early and had no lasting consequence. Reoperations were more frequent after early screw fixation (4% vs <1%) for six of these participants the re-operations were for implant related problems and for two they were for non-union, with one requiring scaphoid excision and a four-corner fusion. The longer-term consequences of arthritis, malunion, injury, and screw penetration will be investigated in a five-year review of these participants.

Over the last few decades the use of surgery has increased as clinicians and patients anticipated better union rate and quicker return to work. We reviewed Hospital Episode Statistics (HES) for National Health Service (NHS) hospitals in England. These recorded a two-thirds increase (1534, 1720 and 2582) of acute scaphoid fracture fixations for the years 2007/8, 2008/9 and 2009/10 before this study was commissioned. The rate of surgical fixation[20] rose very slightly from 37% to 41% from 2007/8 to 2008/9 but then increased sharply to 62% in 2009/10. The rate of surgical treatment of acute scaphoid fractures has also increased significantly in the USA from 22·1% in 2006 to 34·1% in 2012. The incidence of primary surgical treatment has increased more than threefold in Finland between 1997 and 2014. Achieving union is particularly important since untreated non-union causes wrist arthritis. The difference in union rate between those fractures initially treated in a cast and

those fixed with a screw was, however, insignificant. This confirms previous observations.[8] The rate of non-union was lower than we anticipated in both groups, possibly due to the rigour with which the fracture was diagnosed at baseline and the treatment and assessment of non-union compared with previous evidence. The numbers of scaphoid fractures we need to fix to avoid one non-union is 73 (95% CI 24 to 100).[21] There was no difference between groups for range of wrist movement or grip strength at 52 weeks confirming previous smaller reports.

In contrast to most previous trials,[22] we found very little difference in days of lost employment. This may reflect that around 78% were treated initially in a cast which did not include the thumb and therefore permitted early use of the hand. Patients may have felt more secure working in a cast and responded to reassurance regarding return to work in a cast. As this was a pragmatic trial, surgeons were allowed to follow their usual practice for immobilisation and use of physiotherapy. Most operations were performed or supervised by senior surgeons. The number of large and small hospitals and surgeons involved improves generalisability to a range of clinical settings. The findings are applicable to both participants with undisplaced fractures and those displaced up to 2 mm. Bias was minimised with the high rate of questionnaires returned at the primary end point and our analysis model permitted inclusion of all available data. The large number of participants has doubled the evidence from previous small trials.[23-30]

Limitations include non-compliance, when treatment was not delivered as allocated, which can underestimate the treatment effect. In the surgery group, 31 patients (14%) did not have surgery compared with six patients (3%) in the cast group who immediately switched to surgery. However, analysis accounting for non-compliance supported the results of the primary analyses. Further non-compliance in the cast immobilisation pathway, of 17 participants who had surgery for early identified non-union, five had it within 12 weeks from randomisation as anticipated in our protocol and 12 were treated after 12 weeks. Three of the four participants in the cast group who had a non-union at 52 weeks were not offered surgery. Even though not all participants in the cast immobilization group who had non-union had it immediately fixed, participants in the surgery group did not have less pain or better function at 52 weeks. Although clinicians assessing grip and movement range could not be blinded to the treatment, multiple clinicians assessed outcomes.

Any response bias from imbalance in return rates (lower in the plaster cast group) and characteristics of a responder, was minimised by using a mixed-effect, repeated measures model which included intermittent responders which allowed data from 97% of the participants with an almost identical numbers of participants included for each treatment group, to be used. The use of this statistical model increased the statistical power of the analyses, compared with the use of a two sample t-test at a single time point used for the sample size calculation.

The pragmatic design of the SWIFFT trial helps to ensure that results are relevant to most settings. The criteria used to enrol participants in the trial were minimised as much as possible. Nor were there stringent criteria as to which surgeons could operate on participants. Those surgeons who did operate, or were present during the operation, were mostly consultants. The follow-up clinics that were organised at six and 12 weeks were consistent with routine clinical practice. The follow-up clinic at 52 weeks, which was the primary end-point, was to ensure as much as feasible that participants in both treatment groups had the time to complete the treatment pathway being delivered. The findings are also applicable to both participants with undisplaced and ≤2 mm displaced fractures.

Conclusion

This large and rigorous trial found little difference between the two management pathways for scaphoid waist fractures displaced ≤2 mm, across a range of outcomes. These findings are timely as we see an increasing trend towards primary surgical fixation which is not clearly supported by this evidence. Cast immobilization treatment is as effective, provided that suspected non-unions are confirmed early and fixed.

Contributors

JD was the Chief Investigator and lead applicant. SB, LC, LJ, MN and GT contributed to trial conduct. CF, AK, CH, NT and JT provided the statistical expertise. SH and GR provided the health economic expertise. PL led on the qualitative aspects of the study. JD, SC, JK and JP led on the assessment of imaging. MC and AR provided expertise as orthopaedic surgeons. DT provided expert methodological input. JD, SB and CF led on writing the manuscript. All these authors contributed to various aspects of study design. RA, BB, NB, MB, DB, CC, TD, LD, GG, HH, JH, SH, PJ, JJ, AL, WM, AM, IM, LM, JN, RP, ZR, SR, PS, AT, DW

recruited participants into the study, followed up participants and collected data, and helped interpret study findings. All authors read and approved the final manuscript.

Trial Steering Committee

Wendy Baird (independent chair), Joseph Dias (chief investigator), Peter Burge (independent member, orthopaedic surgeon), Jonathan Cook (independent member, statistician), Richard Palmer (independent member, user representative), Nick Welch (independent member, user representative), Carolyn Maloney (observer, sponsor representative), David Hetmanski (observer, sponsor representative).

Data Monitoring Ethics Committee

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Disclaimer

The views expressed are those of the authors and do not necessarily reflect those of the Health Technology Assessment programme, NIHR, the National Health Service or the Department of Health and Social Care.

Data sharing agreement

All data requests should be submitted to the corresponding author for consideration as agreed in our publication plan. Access to anonymised data may be granted following review with the Trial Manager Group and agreement of the Chief Investigator (Prof Joseph Dias and corresponding author). Related documents including the Statistical Analyses Plan will be available on request.

Declaration of interests

MC is a member of the General Board for the HTA programme. MC also does consultancy work for Industry, although not in relation to this study, and his institution has received money from the NIHR, Industry and Charitable grants for other research into musculoskeletal trauma. CH is a member of the NIHR HTA commissioning board. AR's department has received educational and research funds from DePuy Limited outside the scope of this work and has received grants from the NIHR during the conduct of the study.

672 **Table 1. Baseline characteristics for all randomised participants and those included in**

673 **the primary analysis, by treatment group**

	All Randomised Patients			Patients in Primary Analysis[a]		
	Surgery (n=219)	**Cast immobilization[b] (n=220)**	**Total (n=439)**	**Surgery (n=203)**	**Cast immobilization[b] (n=205)**	**Total (n=408)**
Sex, No. (%)						
Male	180 (82·2)	183 (83·2)	363 (82·7)	168 (82·8)	169 (82·4)	337 (82·6)
Female	39 (17·8)	37 (16·8)	76 (17·3)	35 (17·2)	36 (17·6)	71 (17·4)
Age, years						
Mean (SD)	32·9 (13·2)	32·9 (12·2)	32·9 (12·7)	33·2 (13·2)	32·9 (12·4)	33·1 (12·8)
Median (IQR)	28 (22, 39)	29 (23, 41)	29 (23, 40)	29 (23, 39)	29 (23, 41)	29 (23, 40)
Ethnicity, No. (%)						
White	205 (93·6)	195 (88·6)	400 (91·1)	191 (94·1)	180 (87·8)	371 (90·9)
Other	12 (5·5)	25 (11·4)	37 (8·4)	12 (5·9)	25 (12·2)	37 (9·1)
Missing	2 (0·9)	0 (0·0)	2 (0·5)	0 (0·0)	0 (0·0)	0 (0·0)
Education, No. (%)						
No formal qualifications	24 (11·0)	27 (12·3)	51 (11·6)	22 (10·8)	25 (12·2)	47 (11·5)
Some qualifications	151 (68·9)	129 (58·6)	280 (63·8)	139 (68·5)	120 (58·5)	259 (63·5)
Degree or higher	41 (18·7)	64 (29·1)	105 (23·9)	41 (20·2)	60 (29·3)	101 (24·8)
Missing	3 (1·4)	0 (0·0)	3 (0·7)	1 (0·5)	0 (0·0)	1 (0·2)
Employment status, No. (%)						
Part-time	20 (9·1)	18 (8·2)	38 (8·7)	20 (9·9)	18 (8·8)	38 (9·3)
Full-time	127 (58·0)	120 (54·5)	247 (56·3)	119 (58·6)	111 (54·1)	230 (56·4)
Self-employed	21 (9·6)	36 (16·4)	57 (13·0)	19 (9·4)	31 (15·1)	50 (12·3)
Student	20 (9·1)	21 (9·5)	41 (9·3)	19 (9·4)	21 (10·2)	40 (9·8)
Retired	7 (3·2)	5 (2·3)	12 (2·7)	7 (3·4)	5 (2·4)	12 (2·9)
Looking after family/home	1 (0·5)	6 (2·7)	7 (1·6)	0 (0·0)	5 (2·4)	5 (1·2)
Seeking work	9 (4·1)	5 (2·3)	14 (3·2)	8 (3·9)	5 (2·4)	13 (3·2)
Other	11 (5·0)	9 (4·1)	20 (4·6)	10 (4·9)	9 (4·4)	19 (4·7)
Missing	3 (1·4)	0 (0·0)	3 (0·7)	1 (0·5)	0 (0·0)	1 (0·2)

	All Randomised Patients			Patients in Primary Analysis[a]		
	Surgery (n=219)	**Cast immobilization[b] (n=220)**	**Total (n=439)**	**Surgery (n=203)**	**Cast immobilization[b] (n=205)**	**Total (n=408)**
Current smoker, No. (%)						
Yes	73 (33·3)	56 (25·5)	129 (29·4)	64 (31·5)	50 (24·4)	114 (27·9)
No	143 (65·3)	163 (74·1)	306 (69·7)	138 (68·0)	154 (75·1)	292 (71·6)
Missing	3 (1·4)	1 (0·5)	4 (0·9)	1 (0·5)	1 (0·5)	2 (0·5)
Diabetes, No. (%)						
Yes	7 (3·2)	4 (1·8)	11 (2·5)	6 (3·0)	4 (2·0)	10 (2·5)
No	209 (95·4)	216 (98·2)	425 (96·8)	196 (96·6)	201 (98·0)	397 (97·3)
Missing	3 (1·4)	0 (0·0)	3 (0·7)	1 (0·5)	0 (0·0)	1 (0·2)
Steroid use, No. (%)						
Yes	6 (2·7)	4 (1·8)	10 (2·3)	6 (3·0)	4 (2·0)	10 (2·5)
No	210 (95·9)	216 (98·2)	426 (97·0)	196 (96·6)	201 (98·0)	397 (97·3)
Missing	3 (1·4)	0 (0·0)	3 (0·7)	1 (0·5)	0 (0·0)	1 (0·2)

[a] Participants included in primary analysis if they provided valid PRWE data for at least one post-randomisation time point and complete covariate data.

[b] The "Cast immobilization" group was the standard clinical pathway using cast immobilisation initially and expecting suspected non-unions to be confirmed on imaging and immediately fixed.

SD, standard deviation; PRWE, Patient Rated Wrist Evaluation

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676 **Table 2. Primary and secondary outcomes**

	Mean (95% CI)[a]		Mean Difference (95% CI)	p-value
	Surgery	Cast immobilization[b]		
Primary outcome: PRWE total score[c]				
No. of	203	205		
At 6 wk	35·6 (32·6, 38·6)	39·8 (36·8, 42·8)	-4·2 (-8·5, 0·1)	0·06
At 12 wk	21·0 (18·1, 24·0)	26·6 (23·6, 29·6)	-5·6 (-9·8, -1·4)	0·01
At 26 wk	16·2 (13·5, 18·9)	16·5 (13·8, 19·2)	-0·3 (-4·1, 3·6)	0·89
At 52 wk	11·9 (9·2, 14·5)	14·0 (11·3, 16·6)	-2·1 (-5·8, 1·6)	0·27
Over 52	21·3 (18·9, 23·6)	24·4 (22·0, 26·7)	-3·0 (-6·3, 0·3)	0·07
Secondary outcome: PRWE pain subscale score[d]				
No. of	203	206		
At 6 wk	18·8 (17·3, 20·4)	19·0 (17·5, 20·5)	-0·1 (-2·3, 2·0)	0·89
At 12 wk	13·1 (11·5, 14·6)	15·0 (13·4, 16·6)	-2·0 (-4·2, 0·3)	0·09
At 26 wk	11·0 (9·4, 12·5)	10·6 (9·0, 12·2)	0·4 (-1·8, 2·6)	0·75
At 52 wk	7·9 (6·4, 9·5)	9·1 (7·5, 10·6)	-1·1 (-3·3, 1·0)	0·31
Over 52	12·7 (11·5, 14·0)	13·5 (12·2, 14·8)	-0·7 (-2·5, 1·1)	0·44
Secondary outcome: PRWE function subscale score[d]				
No. of	203	205		
At 6 wk	16·7 (14·9, 18·5)	20·5 (18·7, 22·3)	-3·8 (-6·3, -1·3)	0·003
At 12 wk	8·1 (6·6, 9·5)	11·5 (10·0, 13·0)	-3·4 (-5·6, -1·3)	0·001
At 26 wk	5·4 (4·1, 6·6)	6·0 (4·7, 7·3)	-0·6 (-2·4, 1·2)	0·52
At 52 wk	3·9 (2·7, 5·1)	4·9 (3·7, 6·1)	-1·0 (-2·6, 0·7)	0·25
Over 52	8·6 (7·5, 9·7)	10·8 (9·7, 12·0)	-2·2 (-3·8, -0·6)	0·01
Secondary outcome: SF-12 mental component score[e]				
No. of	202	206		
At 6 wk	49·7 (48·1, 51·3)	49·1 (47·5, 50·7)	0·5 (-1·7, 2·8)	0·63
At 12 wk	50·6 (49·0, 52·1)	50·7 (49·1, 52·3)	-0·2 (-2·4, 2·1)	0·88
At 26 wk	51·0 (49·4, 52·6)	51·6 (49·9, 53·3)	-0·6 (-3·0, 1·7)	0·60
At 52 wk	51·0 (49·6, 52·5)	52·3 (50·8, 53·7)	-1·2 (-3·3, 0·8)	0·24
Over 52	50·6 (49·3, 51·8)	50·9 (49·7, 52·2)	-0·4 (-2·2, 1·4)	0·69
Secondary outcome: SF-12 physical component score[e]				
No. of	202	206		
At 6 wk	43·9 (42·7, 45·1)	43·4 (42·2, 44·6)	0·5 (-1·2, 2·2)	0·59
At 12 wk	49·8 (48·7, 50·9)	47·6 (46·5, 48·8)	2·2 (0·6, 3·8)	0·01
At 26 wk	51·6 (50·5, 52·7)	51·6 (50·5, 52·8)	-0·0 (-1·6, 1·5)	0·95
At 52 wk	53·1 (52·1, 54·2)	51·5 (50·5, 52·6)	1·6 (0·2, 3·1)	0·03
Over 52	49·6 (48·8, 50·4)	48·5 (47·7, 49·3)	1·1 (-0·1, 2·2)	0·08
Secondary outcome: grip strength (kg) for affected wrist				

No. of	201	206		
At 6 wk	23·8 (22·0, 25·6)	19·4 (17·6, 21·2)	4·4 (1·8, 6·9)	0·001
At 12 wk	30·9 (29·0, 32·8)	28·3 (26·4, 30·2)	2·6 (-0·1, 5·3)	0·06
At 52 wk	37·0 (35·1, 39·0)	38·0 (36·1, 40·0)	-1·0 (-3·7, 1·7)	0·48
Over 52	30·1 (28·5, 31·7)	27·9 (26·3, 29·5)	2·0 (-0·3, 4·2)	0·08

[a] adjusted mean and 95% confidence interval, unless otherwise stated. All models specified as follows for relevant outcome: mixed-effect linear regression model adjusted, as fixed effects, for group (surgery, cast immobilization), time (6, 12, 26, 52 weeks), group x time interaction, age, baseline fracture displacement (<1 mm, 1-2 mm) and dominance of injured limb (yes, no) with participant as a random effect

[b] The "Cast immobilization" group was the standard clinical pathway using cast immobilisation initially and expecting suspected non-unions to be confirmed on imaging and immediately fixed.

[c] Score range 0-100; lower score indicates better outcome

[d] Score range 0-50; lower score indicates better outcome

[e] 0 (lowest level of health) to 100 (highest level of health)

687 **Table 3. Summary of union assessment by time point and randomised group**

Time point[a]	Union[b]	Surgery (n=219)	Cast immobilization[c] (n=220)	Total (n=439)
At 6 wk, No. (%)	Union	47 (21·5)	26 (11·8)	73 (16·6)
	Almost full union	81 (37·0)	73 (33·2)	154 (35·1)
	Partial union	47 (21·5)	70 (31·8)	117 (26·7)
	Slight union	11 (5·0)	23 (10·5)	34 (7·7)
	Non-union	2 (0·9)	9 (4·1)	11 (2·5)
	Missing	31 (14·2)	19 (8·6)	50 (11·4)
At 12 wk, No. (%)	Union	102 (46·6)	63 (28·6)	165 (37·6)
	Almost full union	45 (20·5)	44 (20·0)	89 (20·3)
	Partial union	15 (6·8)	33 (15·0)	48 (10·9)
	Slight union	7 (3·2)	13 (5·9)	20 (4·6)
	Non-union	0 (0·0)	10 (4·5)	10 (2·3)
	Missing	50 (22·8)	57 (25·9)	107 (24·4)
At 52 wk, No. (%)	Union	93 (42·5)	72 (32·7)	165 (37·6)
	Almost full union	64 (29·2)	59 (26·8)	123 (28)
	Partial union	3 (1·4)	10 (4·5)	13 (3)
	Slight union	3 (1·4)	5 (2·3)	8 (1·8)
	Non-union	1 (0·5)	4 (1·8)	5 (1·1)
	Missing	55 (25·1)	70 (31·8)	125 (28·5)

[a] 6 and 12 weeks from radiographic images, 52 weeks from CT unless missing in which case radiographic imaging was considered; [b] union on CT measured as a percentage (0-100%), and categorised as: 0% = non-union, >0-20% = slight union, >20-70% = partial union, >70-100% (but not including 100) = mostly full union, and 100% = union

[c] The "Cast immobilization" group was the standard clinical pathway using cast immobilisation initially and expecting suspected non-unions to be confirmed on imaging and immediately fixed.

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690 **Table 4. Participant reported time off work (days) due to the injury**

	Surgery			Cast immobilization[a]			Total		
	n	*Mean (SD) Median (IQR)*	*% reporting 0 days*	*n*	*Mean (SD) Median (IQR)*	*% reporting 0 days*	*n*	*Mean (SD) Median (IQR)*	*% reporting 0 days*
Baseline to 6 weeks	156	13·6 (14·4) 7 (1, 25.5)	20·5	158	13·4 (15·6) 5 (0, 30)	29·8	314	13·5 (15·0) 6 (0, 30)	25·2
6-12 weeks	161	2·6 (7·5) 0 (0, 0)	75·8	149	4·9 (10·9) 0 (0, 2)	67·1	310	3·7 (9·4) 0 (0, 1)	71·6
12-26 weeks	142	2·0 (10·2) 0 (0, 0)	90·1	135	3·7 (14·9) 0 (0, 0)	88·9	277	2·8 (12·7) 0 (0, 0)	89·5
26-52 weeks	164	1·5 (10·7) 0 (0, 0)	91·5	160	1·9 (14·7) 0 (0, 0)	91·3	324	1·7 (12·8) 0 (0, 0)	91·4
Total	197	15·6 (26·7) 5 (0, 21)	30·5	201	18·2 (29·1) 4 (0, 30)	35·8	398	16·9 (27·9) 5 (0, 25)	33·2

691 [a]The "Cast immobilization" group was the standard clinical pathway using cast immobilisation initially and
692 expecting suspected non-unions to be confirmed on imaging and immediately fixed.
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Figure 1. SWIFFT trial profile

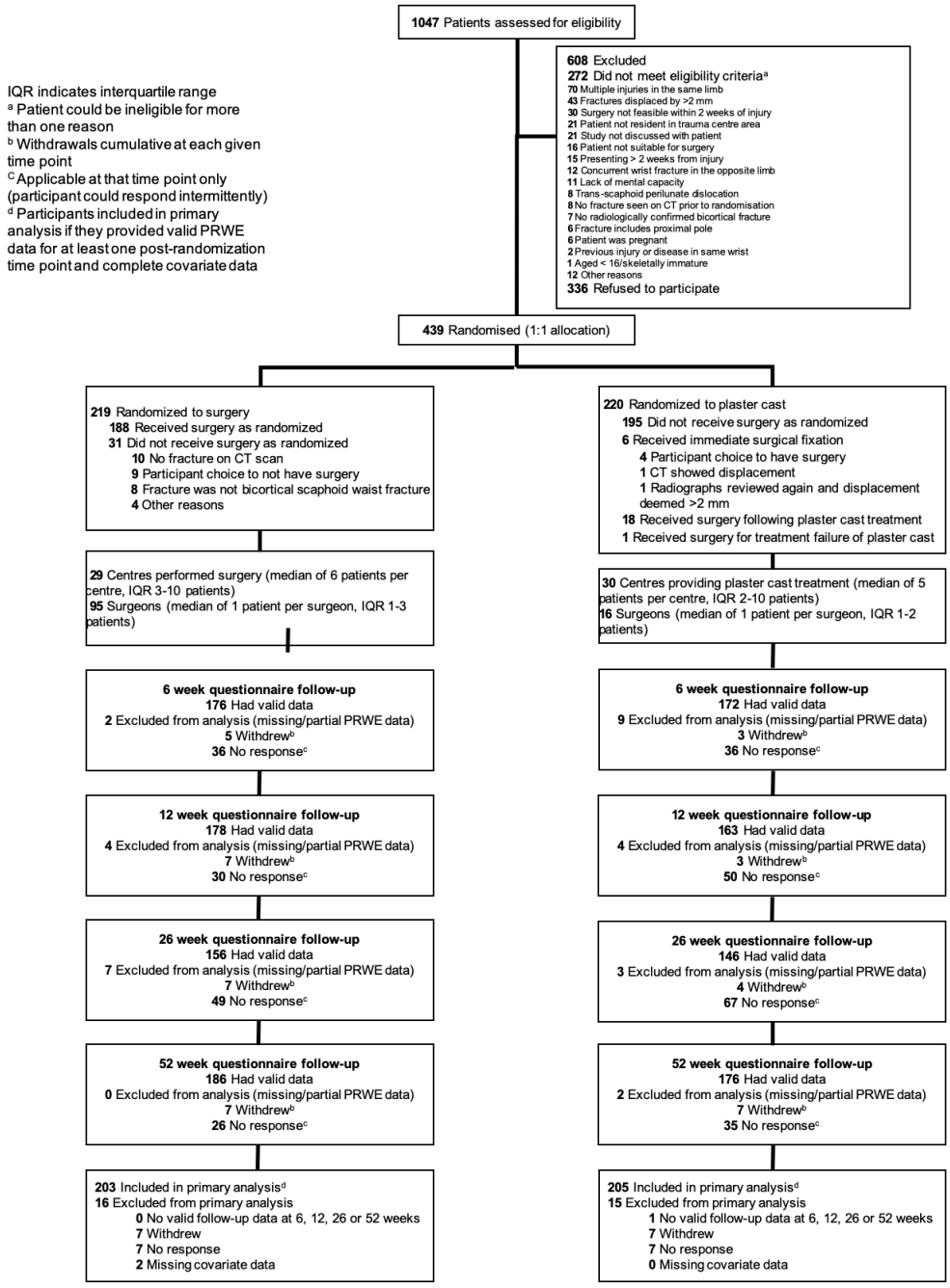
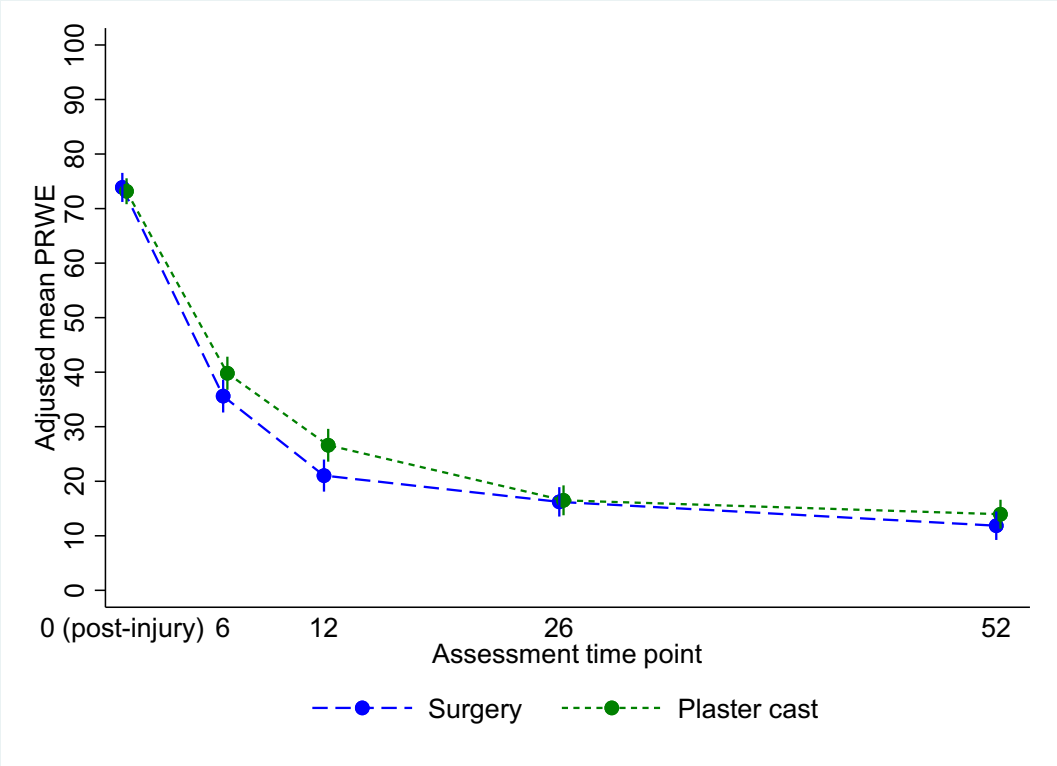


Figure 2: Adjusted mean PRWE scores (with 95% CIs) for primary analysis over time by randomised group



Web extra material

Supplementary Table 1. Baseline fracture details for all randomised patients and those included in the primary analysis, by treatment group

	All Randomised Patients			Patients in Primary Analysis[a]		
	Surgery (n=219)	**Cast immobilization[b] (n=220)**	**Total (n=439)**	**Surgery (n=203)**	**Cast immobilization[b] (n=205)**	**Total (n=408)**
Baseline (pre-injury) PRWE score						
Mean (SD)	3·1 (10·8)	3·6 (11·8)	3·4 (11·3)	3·3 (11·2)	3·8 (12·2)	3·5 (11·7)
Median (IQR)	0 (0, 1)	0 (0, 1)	0 (0, 1)	0 (0, 1)	0 (0, 1)	0 (0, 1)
Baseline (post-injury) PRWE score						
Mean (SD)	73·9 (19·8)	73·2 (17·4)	73·5 (18·6)	73·8 (20·1)	73·4 (17·3)	73·6 (18·8)
Median (IQR)	78·5 (65·5, 87·5)	76 (63·5, 86·5)	77·5 (64·0, 87·0)	78·5 (63·5, 88·0)	76 (64·0, 70·0)	77·5 (64·0, 87·5)
Days since injury[c]						
Mean (SD)	5·1 (3·1)	5·3 (3·3)	5·2 (3·2)	4·9 (3·0)	5·4 (3·3)	5·2 (3·2)
Median (IQR)	5 (3, 7)	5 (3, 8)	5 (3, 7)	4 (2, 7)	5 (3, 8)	5 (3, 7)
Affected wrist, No. (%)						
Left	115 (52·5)	118 (53·6)	233 (53·1)	110 (54·2)	110 (53·7)	220 (53·9)
Right	104 (47·5)	102 (46·4)	206 (46·9)	93 (45·8)	95 (46·3)	188 (46·1)
Missing	0 (0·0)	0 (0·0)	0 (0·0)	0 (0·0)	0 (0·0)	0 (0·0)
Dominant Hand, No. (%)						
Yes	100 (45·7)	95 (43·2)	195 (44·4)	92 (45·3)	89 (43·4)	181 (44·4)
No	117 (53·4)	125 (56·8)	242 (55·1)	111 (54·7)	116 (56·6)	227 (55·6)
Missing	2 (0·9)	0 (0·0)	2 (0·5)	0 (0·0)	0 (0·0)	0 (0·0)
Fracture displacement, No. (%)						
No displacement (<1mm)	135 (61·6)	134 (60·9)	269 (61·3)	123 (60·6)	123 (60·0)	246 (60·3)
Displacement (≥1mm, ≤2mm)	84 (38·4)	86 (39·1)	170 (38·7)	80 (39·4)	82 (40·0)	162 (39·7)
Previous wrist problems on						

	All Randomised Patients			Patients in Primary Analysis[a]		
	Surgery (n=219)	**Cast immobilization[b] (n=220)**	**Total (n=439)**	**Surgery (n=203)**	**Cast immobilization[b] (n=205)**	**Total (n=408)**
same side, No. (%)						
Yes	43 (19·6)	45 (20·5)	88 (20·0)	43 (21·2)	42 (20·5)	85 (20·8)
No	173 (79·0)	173 (78·6)	346 (78·8)	159 (78·3)	161 (78·5)	320 (78·4)
Missing	3 (1·4)	2 (0·9)	5 (1·1)	1 (0·5)	2 (1·0)	3 (0·7)
Injury mechanism, No. (%)						
Fall from standing, walking or running	92 (42·0)	91 (41·4)	183 (41·7)	85 (41·9)	82 (40·0)	167 (40·9)
Fall from height	28 (12·8)	34 (15·5)	62 (14·1)	26 (12·8)	31 (15·1)	57 (14·0)
Fall from moving object	42 (19·2)	31 (14·1)	73 (16·6)	41 (20·2)	31 (15·1)	72 (17·6)
Hit on palm of hand	36 (16·4)	34 (15·5)	70 (15·9)	34 (16·7)	34 (16·6)	68 (16·7)
Punched something	4 (1·8)	12 (5·5)	16 (3·6)	4 (2·0)	10 (4·9)	14 (3·4)
Road traffic accident	9 (4·1)	8 (3·6)	17 (3·9)	9 (4·4)	7 (3·4)	16 (3·9)
Other	6 (2·7)	10 (4·5)	16 (3·6)	4 (2·0)	10 (4·9)	14 (3·4)
Missing	2 (0·9)	0 (0·0)	2 (0·5)	0 (0·0)	0 (0·0)	0 (0·0)
Treatment preference, No. (%)						
Surgery	93 (42·5)	101 (45·9)	194 (44·2)	89 (43·8)	96 (46·8)	185 (45·3)
No surgery	13 (5·9)	19 (8·6)	32 (7·3)	11 (5·4)	16 (7·8)	27 (6·6)
No preference	110 (50·2)	99 (45·0)	209 (47·6)	102 (50·2)	92 (44·9)	194 (47·5)
Missing	3 (1·4)	1 (0·5)	4 (0·9)	1 (0·5)	1 (0·5)	2 (0·5)

[a] Participants included in primary analysis if they provided valid PRWE data for at least one post-randomisation time point and complete covariate data;
[b] The "Cast immobilization" group was the standard clinical pathway using cast immobilisation initially and expecting suspected non-unions to be confirmed on imaging and immediately fixed.
[c] time from injury to screening; [d] response categories not mutually exclusive
SD, standard deviation; PRWE, Patient Rated Wrist Evaluation

Supplementary Table 2. Patient baseline characteristics of different populations

	Screened (n=1047)	Ineligible (n=272)	Eligible (n=775)	
			Non-consenting (n=336)	Consenting (n=439)
Sex, No. (%)				
Male	834 (79·7)	203 (74·6)	268 (79·8)	363 (82·7)
Female	210 (20·1)	66 (24·3)	68 (20·2)	76 (17·3)
Missing	3 (0·3)	3 (1·1)	0 (0·0)	0 (0·0)
Age, y				
N	1040	266	335	439
Mean (SD)	33·7 (14·8)	36·6 (17·5)	32·5 (14·6)	32·9 (12·7)
Median (IQR)	29·2 (22·5, 41·6)	30·0 (23·4, 47·4)	28·2 (21·1, 39·8)	29·3 (23·1, 40·4)
Days since injury[a]				
N	1044	269	336	439
Mean (SD)	1·0 (1·8)	1·2 (2·5)	1·0 (1·5)	0·8 (1·4)
Median (IQR)	0 (0, 1)	0 (0, 1)	1 (0, 1)	1 (0, 1)
Displacement involvement[b], No. (%)				
Displacement	342 (32·7)	61 (22·4)	111 (33·0)	170 (38·7)
No displacement	651 (62·2)	160 (58·8)	222 (66·1)	269 (61·3)
Missing	54 (5·2)	51 (18·8)	3 (0·9)	0 (0·0)

SD, standard deviation

[a] time from injury to first contact with NHS (presentation at A&E or other); this is consistent with the inclusion criterion for patients to present at a participating site within two weeks of injury

[b] as recorded on the Study Eligibility Form

Supplementary Table 3: Treatment received - surgery group (n=219)

Treatment pathway	Definition of pathway	N (%)	Further details
Crossover	Participant immediately switched to plaster cast following consent and randomisation, no surgery	31 (14·2)	• Thirty participants received plaster cast (n=16), splint (n=3), or combination both (n=11), for a median of 52 days (range 9-84) post-randomisation. • One participant did not receive any treatment as no fracture was observed on CT scan.
Routine treatment	Participant had one surgery within the 12 months from randomisation and no subsequent plaster cast and/or splint	24 (11·0)	• Surgery took place a median of 4 days (range 0-9) post-randomisation, no subsequent treatment recorded except bandaging.
Treatment failure	Participant had surgery and subsequent plaster cast and/or splint due to treatment failure e.g. poor stability from surgery	0 (0·0)	-

Further routine treatment	Participant had surgery and subsequent plaster cast and/or splint following routine practice	156 (71·2)	• Surgery took place a median of 4 days (range 0-15) post-randomisation. • All received plaster cast (n=23), splint (n=40) or a combination of both (n=93) for a median of 37 days (range 2-89) following surgery.
	Participant had index surgery but there was subsequent evidence of non-union, so was offered further surgery	2 (0·9)	• One participant received two surgeries within 12 months from randomisation (259 days after initial surgery); plaster cast worn for 17 days after surgery, followed by a splint. • One participant underwent three surgeries within 12 months from randomisation; the second taking place 176 days after the index surgery, and the third 125 days after the second surgery.
	Participant had index surgery and received further surgery (not for non-union)	6 (2·7)	• Revision surgery (n=1), or for removal of screw (n=5) • All received a splint (n=2) or a combination of plaster cast and splint (n=4) for a median of 44 days (range 22-105) following their index surgery. • All underwent only one further surgery within 12 months from randomisation; this took place a median of 235 days (range 97-347) after index surgery.

Supplementary Table 4: Treatment received – plaster cast group (n=220)

Treatment pathway	Definition of pathway	N (%)	Further details
Crossover	Participant immediately switched to surgery following randomisation	6 (2·7)	• Surgery took place a median of 9 days (range 0-24) post-randomisation. • Participants received a plaster cast (n=3), a splint (n=1) or a combination of both (n=2) for a median of 41 days (range 35-74) following surgery.
Routine treatment	Participant treated conservatively – no surgery	193 (87·7)	• 192 participants received a plaster cast (n=109) or a combination of plaster cast and splint (n=83) for a median of 43 days (range 7-101) post-randomisation. • One participant was followed up at a different hospital so

			treatment was unknown, but was immobilised in plaster cast at enrolment to the trial.
Treatment failure	Surgery undertaken to stabilise the fracture (before five weeks from randomisation). This is not a cross-over because the patient did have a plaster cast applied.	1 (0·5)	• Plaster cast worn following randomisation but fracture seen to be displacing so surgical fixation undertaken 29 days post-randomisation and a splint was worn thereafter (unknown length of time). • Surgery was undertaken to remove the screw 96 days after initial fixation.
Further routine treatment – surgery (after five weeks post-randomisation)	Surgery was undertaken after five weeks from randomisation – not owing to a failure to unite	1 (0·5)	• One participant received surgery within 6 months of randomisation at a non-participating hospital to fix a historic fracture.
Further routine treatment – surgery recommended (after five weeks post-randomisation) as per specified treatment pathway because of failure to unite.	Surgery was not received	2 (0·9)	• Operation was scheduled but then delayed, participant self-discharged after wait and declined all further treatment/offers of surgery. • Non-union suspected at 12 weeks but the surgeon decided not to operate.
	One surgery performed within 12 months of randomisation	16 (7·3)	• 13 received urgent fixation of non-union (within 6 months of randomisation). • Three participants received late fixation, between 6 and 12 months after randomisation. The reasons for two of these are unknown; one participant opted to attend a private hospital for their fixation as they were told there would be a 4-5 month wait for surgery at treating centre.
	Two or more surgeries were performed within 12 months of randomisation	1 (0·5)	• Participant received initial surgical fixation within 3 months of randomisation, a further surgery 6 months later for persistent non-union and surgery to remove the wires

			from the second operation a month later.

Sensitivity analyses for the primary outcome

Timing of data collection
The primary analysis model was repeated only including data collected one week either side of the 6-week time point, two weeks either side of the 12-week time point, 6 weeks either side of the 26-week time point, and eight weeks either side of the 52-week time point.

Displacement and absence of fracture assessed by independent review of baseline imaging data
Discrepancies between the displacement of the fracture (<1 mm, or 1-2 mm inclusive) judged by the treating clinician on plain radiographs and stratified on in the randomisation, and the judgement agreed by three independent reviewers of the baseline CT scans and radiographs were observed. Baseline radiographic images were available and reviewed for all but one participant (in the surgery arm). Baseline CT images were available and reviewed for 431 participants (surgery n=214, 97%; cast immobilization n=217, 99%). Both baseline and CT images were reviewed for 431 (98%) participants, radiographs only for 7 (2%) participants, and neither for one participant (<1%). The maximum fracture displacement, in millimetres, observed on either the CT or radiographic images was identified and used to categorise the participant's fracture displacement as: <1 mm; 1-2 mm, inclusive; and >2 mm. Overall, 213 (82%) of the 261 fractures that were deemed not to be displaced by the treating clinician at baseline were classified as not displaced (<1 mm) on review, 39 (15%) as displaced 1-2 mm, 8 (3%) as >2 mm, and 1 (<1%) missing. Of the 178 fractures that were deemed to be displaced (1-2 mm) by the treating clinician at baseline, 112 (63%) were classified as not displaced (<1 mm) on review, 47 (26%) as displaced 1-2 mm, and 19 (11%) as >2 mm.

The primary analysis model was repeated including, as a fixed effect covariate, baseline fracture displacement judged by the three raters instead of that randomised on, producing very similar results to the primary analysis.

Consensus was reached between the three raters that displacement of the fracture was greater than 2 mm for 27 (6%) randomised participants. A fracture could be seen on radiographic imaging for all but one of the 438 participants (n=437, 100%) for whom these data were available, and on CT imaging for 426 (99%) of 431 participants. For four of the five participants for whom a fracture could not be seen on their CT, it could be seen on the radiographic images; thus, consensus was reached between the three raters that only one participant did not actually have a fracture (participant allocated to surgery group). Sensitivity analyses of the primary outcome model were conducted that excluded these participants.

Supplementary Table 5. Sensitivity analyses for the primary outcome

	Mean (95% CI)[a]		Mean Difference (95% CI)	p-value
	Surgery	Cast immobilization		
Data derived by multiple imputation[a]				
No. of patients	219	220		
At 6 wk	35·1 (32·1, 38·1)	39·8 (36·7, 42·9)	-4·7 (-9·0, -0·5)	0·03
At 12 wk	20·7 (17·9, 23·6)	26·6 (23·7, 29·5)	-5·9 (-9·9, -1·9)	0·007
At 26 wk	16·1 (13·4, 18·8)	16·4 (13·7, 19·2)	-0·3 (-4·2, 3·5)	0·87
At 52 wk	12·0 (9·3, 14·6)	14·1 (11·4, 16·8)	-2·1 (-5·9, 1·6)	0·26
Adjusting for clustering by site				
No. of patients	203	205		
At 6 wk	36·2 (32·6, 39·8)	40·2 (36·6, 43·8)	-4·0 (-8·2, 0·3)	0·07

At 12 wk	21·6 (18·1, 25·1)	27·0 (23·4, 30·6)	-5·4 (-9·5, -1·2)	0·01
At 26 wk	16·8 (13·5, 20·1)	16·9 (13·6, 20·3)	-0·1 (-3·9, 3·7)	0·96
At 52 wk	12·5 (9·2, 15·7)	14·4 (11·1, 17·7)	-1·9 (-5·6, 1·8)	0·31
Overall	21·9 (18·8, 24·9)	24·8 (21·7, 27·8)	-2·8 (-6·1, 0·4)	0·09
Adjusted for smoking status (post-hoc)				
No. of patients	202	204		
At 6 wk	35·3 (32·3, 38·3)	40·0 (36·9, 43·0)	-4·7 (-9·0, -0·4)	0·03
At 12 wk	20·7 (17·8, 23·7)	26·8 (23·8, 29·8)	-6·0 (-10·2, -1·8)	0·01
At 26 wk	15·9 (13·2, 18·6)	16·7 (14·0, 19·5)	-0·8 (-4·7, 3·0)	0·67
At 52 wk	11·3 (8·8, 13·9)	14·2 (11·5, 16·8)	-2·8 (-6·5, 0·9)	0·14
Overall	20·9 (18·6, 23·2)	24·6 (22·2, 26·9)	-3·6 (-6·9, -0·3)	0·03
Timing of data collection				
No. of patients	190	190		
At 6 wk	37·3 (33·9, 40·7)	37·7 (34·2, 41·2)	-0·4 (-5·3, 4·4)	0·86
At 12 wk	20·6 (17·5, 23·8)	26·4 (23·1, 29·7)	-5·7 (-10·3, -1·2)	0·01
At 26 wk	15·2 (12·5, 17·9)	15·4 (12·7, 18·1)	-0·2 (-4·0, 3·6)	0·93
At 52 wk	10·8 (8·2, 13·3)	13·8 (11·2, 16·5)	-3·1 (-6·7, 0·6)	0·10
Overall	19·9 (17·6, 22·2)	22·2 (19·9, 24·5)	-2·4 (-5·6, 0·9)	0·16
Including displacement as agreed by three independent raters				
No. of patients	203	205		
At 6 wk	35·5 (32·5, 38·5)	39·8 (36·8, 42·8)	-4·3 (-8·5, -0·0)	0·05
At 12 wk	21·0 (18·0, 23·9)	26·6 (23·6, 29·6)	-5·6 (-9·8, -1·4)	0·01
At 26 wk	16·2 (13·6, 18·9)	16·5 (13·8, 19·2)	-0·3 (-4·1, 3·6)	0·89
At 52 wk	11·9 (9·3, 14·5)	13·9 (11·3, 16·6)	-2·1 (-5·8, 1·6)	0·27
Overall	21·2 (18·9, 23·5)	24·4 (22·0, 26·7)	-3·1 (-6·3, 0·2)	0·07
Excluding those with no fracture				
No. of patients	202	205		
At 6 wk	35·7 (32·6, 38·7)	39·8 (36·8, 42·8)	-4·1 (-8·4, 0·1)	0·06
At 12 wk	21·1 (18·1, 24·0)	26·6 (23·6, 29·6)	-5·5 (-9·7, -1·3)	0·01
At 26 wk	16·3 (13·6, 19·0)	16·5 (13·8, 19·2)	-0·2 (-4·1, 3·6)	0·91
At 52 wk	11·9 (9·3, 14·6)	14·0 (11·3, 16·6)	-2·0 (-5·8, 1·7)	0·29
Overall	21·3 (19·0, 23·6)	24·4 (22·0, 26·7)	-3·0 (-6·3, 0·3)	0·08
Excluding those with displacement >2mm				
No. of patients	191	192		
At 6 wk	35·0 (31·9, 38·0)	39·8 (36·7, 42·9)	-4·8 (-9·2, -0·5)	0·03
At 12 wk	20·7 (17·6, 23·7)	26·2 (23·1, 29·3)	-5·6 (-9·9, -1·3)	0·01
At 26 wk	15·7 (13·0, 18·3)	16·3 (13·6, 19·0)	-0·6 (-4·4, 3·2)	0·76
At 52 wk	11·4 (8·8, 13·9)	13·7 (11·0, 16·3)	-2·3 (-6·0, 1·4)	0·22
Overall	20·7 (18·4, 23·0)	24·1 (21·7, 26·4)	-3·3 (-6·6, 0·0)	0·05

[a] separate linear regression analysis models for each time point run on the multiply imputed dataset

Supplementary Table 6. Wrist range of movement and grip strength of affected wrist

Wrist range of movement and grip strength – affected wrist		**Surgery**	**Cast immobilization**	**Total**
Baseline		**N=216**	**N=218**	**N=434**
Beighton Laxity	Mean (SD)	1·1 (2·0)	0·9 (1·7)	1·0 (1·8)
Score	Median (IQR)	0·0 (0·0, 2·0)	0·0 (0·0, 1·0)	0·0 (0·0, 1·0)
	Min, max	(0·0, 10·0)	(0·0, 8·0)	(0·0, 10·0)
Extension (°)	Mean (SD)	32·0 (18·6)	28·9 (17·2)	30·4 (17·9)
	Median (IQR)	30·0 (20·0, 42·0)	30·0 (18·0, 40·0)	30·0 (20·0, 40·0)
	Min, max	(0·0, 135·0)	(-15·0, 90·0)	(-15·0, 135·0)
Flexion (°)	Mean (SD)	35·0 (25·5)	34·9 (21·7)	35·0 (23·6)
	Median (IQR)	30·0 (20·0, 45·0)	35·0 (22·0, 44·0)	32·0 (20·0, 45·0)
	Min, max	(0·0, 160·0)	(0·0, 162·0)	(0·0, 162·0)
Radial Deviation (°)	Mean (SD)	14·3 (9·5)	14·3 (9·6)	14·3 (9·6)
	Median (IQR)	13·0 (10·0, 20·0)	14·0 (9·0, 20·0)	13·0 (9·0, 20·0)
	Min, max	(0·0, 60·0)	(0·0, 70·0)	(0·0, 70·0)
Ulnar Deviation (°)	Mean (SD)	18·0 (10·9)	18·6 (11·0)	18·3 (10·9)
	Median (IQR)	17·0 (10·0, 22·5)	18·0 (10·0, 25·0)	18·0 (10·0, 25·0)
	Min, max	(0·0, 70·0)	(0·0, 60·0)	(0·0, 70·0)
Forearm Rotation	Mean (SD)	66·9 (26·7)	63·6 (27·8)	65·3 (27·3)
Supination (°)	Median (IQR)	75·0 (56·5, 85·0)	70·0 (50·0, 85·0)	73·0 (50·0, 85·0)
	Min, max	(0·0, 124·0)	(-10·0, 118·0)	(-10·0, 124·0)
Forearm Rotation	Mean (SD)	72·2 (23·1)	71·2 (25·0)	71·7 (24·0)
Pronation (°)	Median (IQR)	80·0 (67·5, 90·0)	80·0 (68·5, 90·0)	80·0 (68·0, 90·0)
	Min, max	(0·0, 100·0)	(0·0, 105·0)	(0·0, 105·0)
Grip Strength (kg)	Mean (SD)	9·6 (10·0)	9·8 (10·6)	9·7 (10·3)
	Median (IQR)	6·0 (2·0, 15·3)	7·0 (2·0, 12·7)	6·7 (2·0, 14·4)
	Min, max	(0·0, 61·7)	(0·0, 58·0)	(0·0, 61·7)
6 weeks		**N=189**	**N=200**	**N=389**
Extension (°)	Mean (SD)	51·0 (20·2)	40·0 (18·3)	45·4 (20·0)
	Median (IQR)	50·0 (38·0, 60·0)	40·0 (28·0, 50·0)	45·0 (30·0, 56·0)
	Min, max	(5·0, 135·0)	(0·0, 90·0)	(0·0, 135·0)
Flexion (°)	Mean (SD)	51·6 (28·3)	40·1 (23·4)	45·7 (26·5)
	Median (IQR)	49·0 (30·0, 65·0)	35·0 (25·0, 50·0)	40·0 (30·0, 60·0)
	Min, max	(5·0, 162·0)	(-5·0, 158·0)	(-5·0, 162·0)
Radial Deviation (°)	Mean (SD)	21·7 (10·7)	21·3 (12·8)	21·5 (11·8)
	Median (IQR)	20·0 (15·0, 28·0)	20·0 (11·0, 28·0)	20·0 (13·0, 28·0)
	Min, max	(0·0, 60·0)	(0·0, 70·0)	(0·0, 70·0)
Ulnar Deviation (°)	Mean (SD)	29·3 (12·1)	23·5 (13·0)	26·3 (12·9)
	Median (IQR)	30·0 (20·0, 38·0)	20·0 (15·0, 30·0)	25·0 (18·0, 35·0)
	Min, max	(1·0, 60·0)	(0·0, 70·0)	(0·0, 70·0)
Forearm Rotation	Mean (SD)	82·4 (15·7)	74·9 (20·3)	78·5 (18·6)
Supination (°)	Median (IQR)	90·0 (80·0, 90·0)	80·0 (65·0, 90·0)	85·0 (72·0, 90·0)
	Min, max	(0·0, 131·0)	(0·0, 108·0)	(0·0, 131·0)
Forearm Rotation	Mean (SD)	82·8 (14·4)	80·1 (15·5)	81·4 (15·0)
Pronation (°)	Median (IQR)	90·0 (80·0, 90·0)	85·0 (75·0, 90·0)	90·0 (80·0, 90·0)
	Min, max	(0·0, 110·0)	(10·0, 104·0)	(0·0, 110·0)
Grip Strength (kg)	Mean (SD)	24·1 (12·7)	20·1 (14·0)	22·0 (13·5)
	Median (IQR)	23·3 (15·3, 32·7)	18·2 (9·3, 28·7)	20·0 (11·3, 30·7)
	Min, max	(0·0, 77·3)	(0·0, 81·7)	(0·0, 81·7)
12 weeks		**N=172**	**N=164**	**N=336**
Extension (°)	Mean (SD)	61·1 (17·7)	56·9 (19·5)	59·1 (18·7)
	Median (IQR)	60·0 (50·0, 70·0)	55·0 (43·5, 70·0)	60·0 (45·0, 70·0)
	Min, max	(13·0, 125·0)	(2·0, 125·0)	(2·0, 125·0)
Flexion (°)	Mean (SD)	62·0 (23·7)	55·3 (22·3)	58·7 (23·2)
	Median (IQR)	60·0 (45·0, 75·0)	55·0 (41·0, 70·0)	58·0 (45·0, 72·0)
	Min, max	(15·0, 144·0)	(5·0, 144·0)	(5·0, 144·0)

Radial Deviation (°)	Mean (SD)	26·1 (12·7)	26·2 (14·5)	26·1 (13·6)
	Median (IQR)	25·0 (18·0, 30·0)	23·0 (15·0, 32·0)	24·0 (18·0, 30·0)
	Min, max	(5·0, 80·0)	(0·0, 80·0)	(0·0, 80·0)
Ulnar Deviation (°)	Mean (SD)	35·4 (12·7)	31·6 (13·7)	33·5 (13·3)
	Median (IQR)	35·0 (28·0, 40·0)	30·0 (22·0, 40·0)	31·0 (25·0, 40·0)
	Min, max	(10·0, 80·0)	(0·0, 80·0)	(0·0, 80·0)
Forearm Rotation	Mean (SD)	87·1 (13·8)	82·3 (18·2)	84·7 (16·3)
Supination (°)	Median (IQR)	90·0 (85·0, 90·0)	90·0 (80·0, 90·0)	90·0 (80·0, 90·0)
	Min, max	(10·0, 140·0)	(0·0, 126·0)	(0·0, 140·0)
Forearm Rotation	Mean (SD)	86·5 (8·5)	83·4 (13·8)	85·0 (11·5)
Pronation (°)	Median (IQR)	90·0 (85·0, 90·0)	90·0 (80·0, 90·0)	90·0 (80·0, 90·0)
	Min, max	(26·0, 104·0)	(0·0, 120·0)	(0·0, 120·0)
Grip Strength (kg)	Mean (SD)	30·8 (12·5)	28·2 (14·4)	29·5 (13·5)
	Median (IQR)	29·3 (22·3, 39·3)	28·5 (18·7, 37·8)	28·7 (20·0, 38·7)
	Min, max	(0·0, 82·0)	(0·0, 89·0)	(0·0, 89·0)
52 weeks		**N=163**	**N=146**	**N=309**
Extension (°)	Mean (SD)	68·4 (21·0)	68·8 (15·5)	68·6 (18·6)
	Median (IQR)	70·0 (56·0, 80·0)	70·0 (56·0, 80·0)	70·0 (56·0, 80·0)
	Min, max	(15·0, 140·0)	(40·0, 115·0)	(15·0, 140·0)
Flexion (°)	Mean (SD)	69·8 (20·3)	68·4 (16·4)	69·1 (18·5)
	Median (IQR)	70·0 (55·0, 85·0)	70·0 (60·0, 80·0)	70·0 (58·0, 80·0)
	Min, max	(20·0, 152·0)	(22·0, 105·0)	(20·0, 152·0)
Radial Deviation (°)	Mean (SD)	32·2 (17·4)	32·5 (14·5)	32·4 (16·1)
	Median (IQR)	28·0 (20·0, 40·0)	30·0 (22·0, 40·0)	30·0 (20·0, 40·0)
	Min, max	(6·0, 90·0)	(8·0, 80·0)	(6·0, 90·0)
Ulnar Deviation (°)	Mean (SD)	40·6 (14·8)	39·9 (13·7)	40·3 (14·3)
	Median (IQR)	40·0 (30·0, 50·0)	40·0 (30·0, 49·0)	40·0 (30·0, 50·0)
	Min, max	(8·0, 90·0)	(12·0, 80·0)	(8·0, 90·0)
Forearm Rotation	Mean (SD)	88·3 (13·3)	85·2 (13·9)	86·8 (13·6)
Supination (°)	Median (IQR)	90·0 (86·0, 90·0)	90·0 (80·0, 90·0)	90·0 (85·0, 90·0)
	Min, max	(30·0, 136·0)	(30·0, 122·0)	(30·0, 136·0)
Forearm Rotation	Mean (SD)	86·8 (10·5)	86·2 (9·5)	86·5 (10·0)
Pronation (°)	Median (IQR)	90·0 (85·0, 90·0)	90·0 (85·0, 90·0)	90·0 (85·0, 90·0)
	Min, max	(5·0, 114·0)	(40·0, 109·0)	(5·0, 114·0)
Grip Strength (kg)	Mean (SD)	36·9 (12·7)	37·4 (14·2)	37·2 (13·4)
	Median (IQR)	36·2 (28·7, 44·8)	38·5 (28·7, 46·2)	37·3 (28·7, 45·2)
	Min, max	(10·3, 109·7)	(4·7, 88·3)	(4·7, 109·7)

Malunion

Scaphoid height and length was measured by the three independent raters of the CT and plain radiographs. Malunion was determined by calculating the ratio of the scaphoid height to length, and determined using thresholds of both 0·6 and 0·7 (Supplementary Table 4). ten Berg et al.[14] noted a ratio of 0·69 as the upper 95% CI of a normal population so we used this (0·7) to define malunion in addition to the 0·6 we proposed in our protocol. By default, more participants are classified as having malunion using the 0·6 threshold than 0·7. Considering those with non-missing data only, at 6 weeks, 175 (94%) participants in the surgery group and 180 (90%) in the cast immobilization group had malunion based on the 0·6 threshold. At 0·7, the figures are 52 (28%) and 51 (26%), respectively. Malunion at both thresholds remained reasonably steady in both groups at 6, 12 and 52 weeks on radiographic images. However, at 52 weeks, on CT, the rate of malunion occurred in 60 (38%) participants in the surgery group and 45 (33%) in the cast immobilization group at the 0·6 threshold, and increased to 7 (5%) and 7 (5%), respectively, at 0·7.

Supplementary Table 7. Malunion assessed at thresholds of scaphoid ratio height to length of 0·6 and 0·7 by randomised group and time point

Time point	Union	Surgery (n=219)	Cast immobilization (n=220)	Total (n=439)
0·6 threshold				
Baseline	No malunion	30 (13·7)	28 (12·7)	58 (13·2)
(Radiographs)	Malunion	182 (83·1)	190 (86·4)	372 (84·7)
	Missing	7 (3·2)	2 (0·9)	9 (2·1)
Baseline	No malunion	154 (70·3)	160 (72·7)	314 (71·5)
(CT)	Malunion	63 (28·8)	54 (24·5)	117 (26·7)
	Missing	2 (0·9)	6 (2·7)	8 (1·8)
6 weeks	No malunion	12 (5·5)	20 (9·1)	32 (7·3)
	Malunion	175 (79·9)	180 (81·8)	355 (80·9)
	Missing	32 (14·6)	20 (9·1)	52 (11·8)
12 weeks	No malunion	10 (4·6)	12 (5·5)	22 (5·0)
	Malunion	159 (72·6)	151 (68·6)	310 (70·6)
	Missing	50 (22·8)	57 (25·9)	107 (24·4)
52 weeks	No malunion	9 (4·1)	13 (5·9)	22 (5·0)
(Radiographs)	Malunion	148 (67·6)	128 (58·2)	276 (62·9)
	Missing	62 (28·3)	79 (35·9)	141 (32·1)
52 weeks	No malunion	97 (44·3)	90 (40·9)	187 (42·6)
(CT)	Malunion	60 (27·4)	45 (20·5)	105 (23·9)
	Missing	62 (28·3)	85 (38·6)	147 (33·5)
0·7 threshold				
Baseline	No malunion	167 (76·3)	173 (78·6)	340 (77·4)
(Radiographs)	Malunion	45 (20·5)	45 (20·5)	90 (20·5)
	Missing	7 (3·2)	2 (0·9)	9 (2·1)
Baseline	No malunion	214 (97·7)	212 (96·4)	426 (97)
(CT)	Malunion	3 (1·4)	2 (0·9)	5 (1·1)
	Missing	2 (0·9)	6 (2·7)	8 (1·8)
6 weeks	No malunion	135 (61·6)	149 (67·7)	284 (64·7)
	Malunion	52 (23·7)	51 (23·2)	103 (23·5)
	Missing	32 (14·6)	20 (9·1)	52 (11·8)
12 weeks	No malunion	117 (53·4)	118 (53·6)	235 (53·5)
	Malunion	52 (23·7)	45 (20·5)	97 (22·1)
	Missing	50 (22·8)	57 (25·9)	107 (24·4)
52 weeks	No malunion	96 (43·8)	101 (45·9)	197 (44·9)
(Radiographs)	Malunion	61 (27·9)	40 (18·2)	101 (23·0)
	Missing	62 (28·3)	79 (35·9)	141 (32·1)
52 weeks	No malunion	150 (68·5)	128 (58·2)	278 (63·3)
(CT)	Malunion	7 (3·2)	7 (3·2)	14 (3·2)
	Missing	62 (28·3)	85 (38·6)	147 (33·5)

Supplementary Table 8. Non-serious adverse events by randomised group

Non-serious adverse events	Surgery (n=219)	Cast immobilization (n=220)	Total (n=439)
No. participants reporting ≥1 adverse events, No. (%)^	24 (11·0)	29 (13·2)	53 (12·1)
Total number of non-serious adverse events	30	36	66
Number of non-serious events per participant, No. (%)^			
0	195 (89·0)	191 (86·8)	386 (87·9)
1	19 (8·7)	23 (10·5)	42 (9·6)
2	4 (1·8)	5 (2·3)	9 (2·1)
3	1 (0·5)	1 (0·5)	2 (0·5)
Adverse events of anaesthesia and/or surgery[a], No. (%)[¥]			
Screw related complication	9 (30·0)	1 (2·8)	10 (15·2)
Nerve or vessel event	4 (13·3)	1 (2·8)	5 (7·6)
Infection	2 (6·7)	2 (5·6)	4 (6·1)
Complex Regional Pain Syndrome	3 (10·0)	0 (0·0)	3 (4·6)
Symptoms consistent with non-union	1 (3·3)	0 (0·0)	1 (1·5)
Other	5 (16·7)	0 (0·0)	5 (7·6)
Any of the above	24 (80·0)	4 (11·1)	28 (42·4)
Adverse events of cast treatment[a], No. (%)[¥]			
Pain related to the cast	2 (6·7)	6 (16·7)	8 (12·1)
Symptoms consistent with non-union	0 (0·0)	8 (22·2)	8 (12·1)
Pressure sores	0 (0·0)	5 (13·9)	5 (7·6)
Pain due to tight cast	1 (3·3)	2 (5·6)	3 (4·6)
Soft cast/broken cast that leads to movement of wrist	0 (0·0)	2 (5·6)	2 (3·0)
Any of the above	3 (3·0)	23 (63·9)	26 (39·4)
Other[a], No. (%)[¥]			
Reinjury	2 (6·7)	7 (19·4)	9 (13·6)
Allergy to dressing	0 (0·0)	2 (5·6)	2 (3·0)
Substance abuse	1 (3·3)	0 (0·0)	3 (1·5)
Any of the above	3 (3·0)	9 (25·0)	12 (18·2)
Grading[b], No. (%)[¥]			
Mild	22 (73·3)	28 (77·8)	50 (75·8)
Moderate	7 (23·3)	7 (19·4)	14 (21·2)
Severe	1 (3·3)	0 (0·0)	1 (1·5)
Missing	0 (0·0)	1 (2·8)	1 (1·5)
Causality[b], No. (%)[¥]			
Not related	2 (6·7)	8 (22·2)	10 (15·2)
Unlikely to be related	2 (6·7)	2 (5·6)	4 (6·1)
Possibly related	10 (33·3)	2 (5·6)	12 (18·2)
Probably related	4 (13·3)	1 (2·8)	5 (7·6)
Definitely related	12 (40·0)	23 (63·9)	35 (53·0)
Expectedness[b], No. (%)[¥]			
Expected	25 (83·3)	25 (69·4)	50 (75·8)
Unexpected	5 (16·7)	11 (30·6)	16 (24·2)

[a] retrospectively and independently classified by two clinicians, disagreements discussed and resolved; [b] classifications as provided on Adverse Event Initial Report Form by reporting clinician

^ percentages out of number of randomised participants' [¥] percentages out of number of events

Supplementary Table 9. Serious adverse events by randomised group

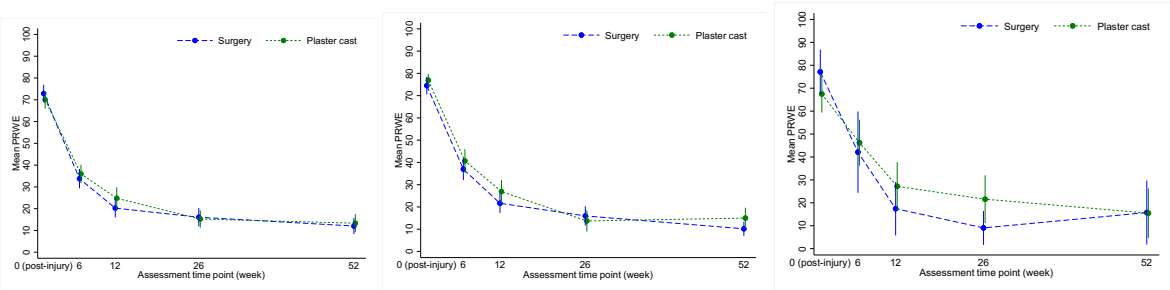
Serious adverse events	Surgery (n=219)	Cast immobilization (n=220)	Total (n=439)
No. participants reporting ≥1 adverse events, No. (%)^	3 (1·4)	0 (0·0)	0 (0·0)
Total number of serious adverse events	3	0	0
Number of serious events per participant, No. (%)^			
0	216 (98·6)	220 (100·0)	436 (99·3)
1	3 (1·4)	0 (0·0)	3 (0·7)
Type of event[b], No. (%)[¥]			
Hospitalisation	2 (66·7)	0 (0·0)	2 (66·7)
Persistent or significant disability/incapacity	1 (33·3)	0 (0·0)	3 (33·3)
Adverse events of anaesthesia and/or surgery[a], No. (%)[¥]			
Anaesthetic complication	2 (66·7)	0 (0·0)	2 (66·7)
Symptoms consistent with non-union	1 (33·3)	0 (0·0)	1 (33·3)
Causality[b], No. (%)[¥]			
Definitely related	3 (100·0)	0 (0·0)	3 (100·0)
Expectedness[b], No. (%)[¥]			
Expected	1 (33·3)	0 (0·0)	1 (33·3)
Unexpected	2 (66·7)	0 (0·0)	2 (66·7)
Duration[b], No. (%)[¥]			
≤24 hours	2 (66·7)	0 (0·0)	2 (66·7)
>24 hours	1 (33·3)	0 (0·0)	1 (33·3)

[a] retrospectively and independently classified by two clinicians, disagreements discussed and resolved; [b] classifications as provided on Adverse Event Initial Report Form by reporting clinician
^ percentages out of number of randomised participants' [¥] percentages out of number of events

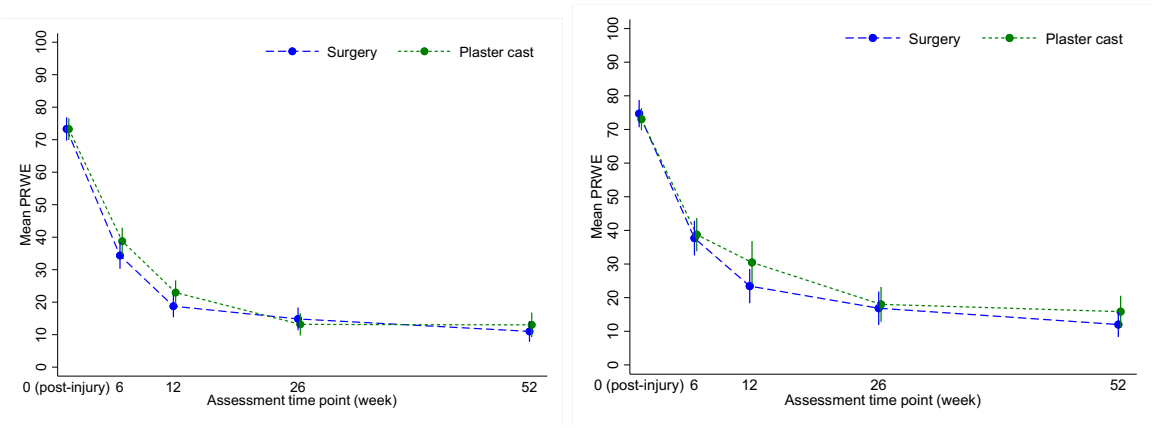
There was no evidence of a difference between the two groups in the overall rate of participants experiencing at least one surgical, medical or cast complication regardless of severity or impact up to 52 weeks (surgery group, n=39, 18%; plaster cast group, n=51, 23%, OR 0·72, 95% CI 0·45 to 1·15; p=0·17).

Supplementary Figure 1. Unadjusted mean PRWE scores (with 95% CIs) over time by patient treatment preference; fracture displacement at randomisation

(a) No preference (b) Preference for surgery and (c) Preference for no surgery



(d) <1 mm and (e) ≥1 mm and ≤ 2 mm



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