Surgery versus cast immobilisation for adults with a bicortical fracture of the scaphoid waist (SWIFFT): a pragmatic, multicentre, open-label, randomised superiority trial

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Lancet 2020; 396: 390–401

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Summary

Background Scaphoid fractures account for 90% of carpal fractures and occur predominantly in young men. The use of immediate surgical fixation to manage this type of fracture has increased, despite insufficient evidence of improved outcomes over non-surgical management. The SWIFFT trial compared the clinical effectiveness of surgical fixation with cast immobilisation and early fixation of fractures that fail to unite in adults with scaphoid waist fractures displaced by 2 mm or less.

Methods This pragmatic, parallel-group, multicentre, open-label, two-arm, randomised superiority trial included adults (aged 16 years or older) who presented to orthopaedic departments of 31 hospitals in England and Wales with a clear bicortical fracture of the scaphoid waist on radiographs. An independent remote randomisation service used a computer-generated allocation sequence with randomly varying block sizes to randomly assign participants (1:1) to receive either early surgical fixation (surgery group) or below-elbow cast immobilisation followed by immediate fixation if non-union of the fracture was confirmed (cast immobilisation group). Randomisation was stratified by whether or not there was displacement of either a step or a gap of 1–2 mm inclusive on any radiographic view. The primary outcome was the total patient-rated wrist evaluation (PRWE) score at 52 weeks after randomisation, and it was analysed on an available case intention-to-treat basis. This trial is registered with the ISRCTN registry, ISRCTN67901257, and is no longer recruiting, but long-term follow-up is ongoing.

Findings Between July 23, 2013, and July 26, 2016, 439 (42%) of 1047 assessed patients (mean age 33 years; 363 [83%] men) were randomly assigned to the surgery group (n=219) or to the cast immobilisation group (n=220). Of these, 408 (93%) participants were included in the primary analysis (203 participants in the surgery group and 205 participants in the cast immobilisation group). 16 participants in the surgery group and 15 participants in the cast immobilisation group were excluded because of either withdrawal, no response, or no follow-up data at 6, 12, 26, or 52 weeks. There was no significant difference in mean PRWE scores at 52 weeks between the surgery group (adjusted mean 11·9 [95% CI 9·2–14·5]) and the cast immobilisation group (14·0 [11·3 to 16·6]; adjusted mean difference –2·1 [95% CI –5·8 to 1·6], p=0·27). More participants in the surgery group (31 [14%] of 219 participants) had a potentially serious complication from surgery than in the cast immobilisation group (three [1%] of 220 participants), but fewer participants in the surgery group (five [2%]) had cast-related complications than in the cast immobilisation group (40 [18%]). The number of participants who had a medical complication was similar between the two groups (four [2%] in the surgery group and five [2%] in the cast immobilisation group).

Interpretation Adult patients with scaphoid waist fractures displaced by 2 mm or less should have initial cast immobilisation, and any suspected non-unions should be confirmed and immediately fixed with surgery. This treatment strategy will help to avoid the risks of surgery and mostly limit the use of surgery to fixing fractures that fail to unite.

Funding National Institute for Health Research Health Technology Assessment Programme.

Introduction

Scaphoid fractures account for 90% of all carpal fractures and 2–7% of all fractures.[1] This type of fracture is an important public health problem, as they predominantly affect young (mean age 29 years) active individuals[2] in their most productive working years. Scaphoid fractures are typically caused when the wrist is suddenly extended, either when putting the hand out to break a fall or when

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 is 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 6–10 weeks to allow the broken bone to heal. The 10% of cases that do not heal are then operated on and the fracture is held in place with a screw. In recent years, another method of holding these fractures still as they heal has been to operate on the wrist early after injury and to fix the broken bone with a specialised screw. Even though there is an increasing trend to perform more invasive and costly surgery, which has a bigger effect on service delivery and use of theatre time compared with the minimal intervention of cast immobilisation, there is inconclusive evidence that it produces better patient outcomes. In November, 2018, a systematic review and meta-analysis of surgical versus non-surgical treatment for scaphoid waist fractures with slight or no displacement was published. The authors of this previous report searched PubMed, Embase, and the Cochrane Database of Systematic Reviews for relevant reviews and systematic reviews published between 1946 and February, 2018, and references to other relevant articles were manually retrieved. The authors used the following search terms: "scaphoid bone", "fractures, bone", "surgical procedures, operative", and synonyms of these terms. 14 eligible studies were identified, including ten randomised controlled trials and four cohort studies, involving 765 patients. The data were of variable quality but they 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 bone non-union and shorten the time to bone union. The need for high-quality studies was recommended. We did a rigorously designed, and sufficiently powered, pragmatic, parallel-group, multicentre, open-label, two-arm, randomised superiority trial (SWIFFT) in adults with scaphoid waist fractures displaced by 2 mm or less to find out whether surgical fixation is superior to cast immobilisation and early fixation of fractures that fail to unite, in terms of improved patient outcomes.

Added value of this study

To our knowledge, SWIFFT is the largest randomised trial (involving 439 participants) to compare surgery with cast immobilisation for the treatment of adults with slight or no displacement of scaphoid waist fractures. The trial has doubled the evidence from previous small trials of variable quality. We found no difference in overall patient-reported outcomes at 52 weeks' follow-up between the two groups, and no difference in wrist pain or function subscales, grip strength, or range of movement. In addition, the number of days absent from work due to the wrist injury was similar between the two groups. Although fewer participants in the surgery group had non-union or slight union of the bone at 52 weeks than in the cast immobilisation group, surgery was more likely to lead to potentially serious complications than cast immobilisation.

Implications of all the available evidence

This large and rigorous trial found little difference between the two management pathways for scaphoid waist fractures displaced by 2 mm or less, across a range of outcomes. These findings are timely, as surgical fixation is increasingly being used as the primary treatment for this type of fracture, which is not clearly supported by the evidence from our trial. Cast immobilisation treatment is as effective, provided that any suspected non-unions are confirmed early and fixed surgically. We estimated that 73 scaphoid fractures would need to be treated with early surgical fixation, rather than cast immobilisation and immediate fixation of non-unions, to prevent one additional non-union at 12 months post-injury. Therefore, early fixation could be restricted to fractures that are displaced by more than 2 mm to limit exposure to surgical risks and make better use of theatre time. The results of our trial should be shared with patients when discussing treatment options.

the palm is struck forcibly by an object. Most (64%) scaphoid fractures involve the waist (defined as the middle 60%) of the scaphoid.[3] A scaphoid fracture is considered to be 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 by 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 for treatment of displaced fractures is weak and recommendations are based on case series. When fractures are displaced by more than 2 mm, most clinicians would prefer to reduce the degree of displacement. Non-union of the fracture, if left untreated, almost inevitably leads to arthritis, usually within 5 years.[6] Either non-union or arthritis can cause 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 thought to avoid the need for a cast and to accelerate the return to normal function, work, and sport,[7] but this strategy exposes patients to surgical risks.[8] Eight small randomised clinical trials[9] of variable quality done in the UK, USA, and Sweden, reporting on undisplaced or minimally displaced fractures of the scaphoid waist, provide unclear data on whether surgical fixation provides better outcomes than cast immobilisation. Despite insufficient evidence, there is an increasing trend[10] among clinicians to immediately fix scaphoid fractures for perceived short-term benefits.

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However, concerns remain about the absence of evidence for the long-term benefits and additional risks from surgery, such as malunion, infection, and implant-related problems.

We designed the Scaphoid Waist Internal Fixation for Fractures Trial (SWIFFT) to compare the clinical effectiveness of early fixation with initial cast immobilisation.[11]

Methods

Study design and participants

The SWIFFT trial was a pragmatic, parallel-group, multicentre, open-label, two-arm, randomised superiority trial done at 31 National Health Service (NHS) hospitals in England and Wales. Patients were recruited from orthopaedic departments at these hospitals between July 23, 2013, and July 26, 2016, and they were followed up for 52 weeks after randomisation.

Patients were eligible if they were skeletally mature, aged 16 years or older, and presented to the NHS hospital within 2 weeks of injury, with a clear bicortical scaphoid waist fracture on plain radiographs and could have surgery within 2 weeks of presentation. A bicortical fracture was defined as a break in the continuity of both cortices on any radiographic view. Displaced fractures with a step or gap of 2 mm or less on any of five radiographic views (posterior–anterior, lateral, semi-supine, semi-prone, and elongated scaphoid) were included. The same clinician who established eligibility of participants at each recruiting site also assessed whether the fracture was bicortical or displaced. A research CT scan done at baseline, including the radiographs, were reviewed independently by two senior consultant radiologists (KJ and SC) and a senior orthopaedic surgeon (JJD), who used agreed criteria to help confirm that the fracture conformed to the study eligibility criteria.

Patients were excluded if they had fractures that were displaced by more than 2 mm or involved the proximal or distal pole, had a trans-scaphoid-perilunate dislocation, had multiple injuries in the same limb, had a concurrent wrist fracture in the opposite limb, had insufficient mental capacity to comply with treatment or data collection, were pregnant, or did not reside in the catchment area of a participating hospital to allow follow-up.

The study and all amendments were approved by the East Midlands Research Ethics Committee (13/EM/0154). The published trial protocol[11] and the statistical analysis plan are provided in the appendix (pp 2–18). Participants provided written informed consent. The trial was overseen by an independent steering and data monitoring committee and independent ethics committees.

See Online for appendix

Randomisation and masking

Surgeons first confirmed the eligibility of participants. After participants provided their consent and baseline information, hospital staff used an independent remote randomisation service (York Trials Unit, University of York, York, UK) to randomly assign patients (1:1) to receive either early surgical fixation (surgery group) or below-elbow cast immobilisation followed by immediate fixation if non-union of the fracture was confirmed (cast immobilisation group). Randomisation was stratified, with random block sizes of six and 12, by whether or not there was displacement of either a step or a 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.

Masking of trial participants or clinicians for outcome assessments was not possible. To minimise bias in bone union assessments, all radiographs and CT scans were reviewed independently by two consultant musculoskeletal radiologists (KJ and SC) and a consultant orthopaedic surgeon (JJD), and any disagreements were resolved through discussion. The trial statistician was masked to group allocation until after data collection was complete.

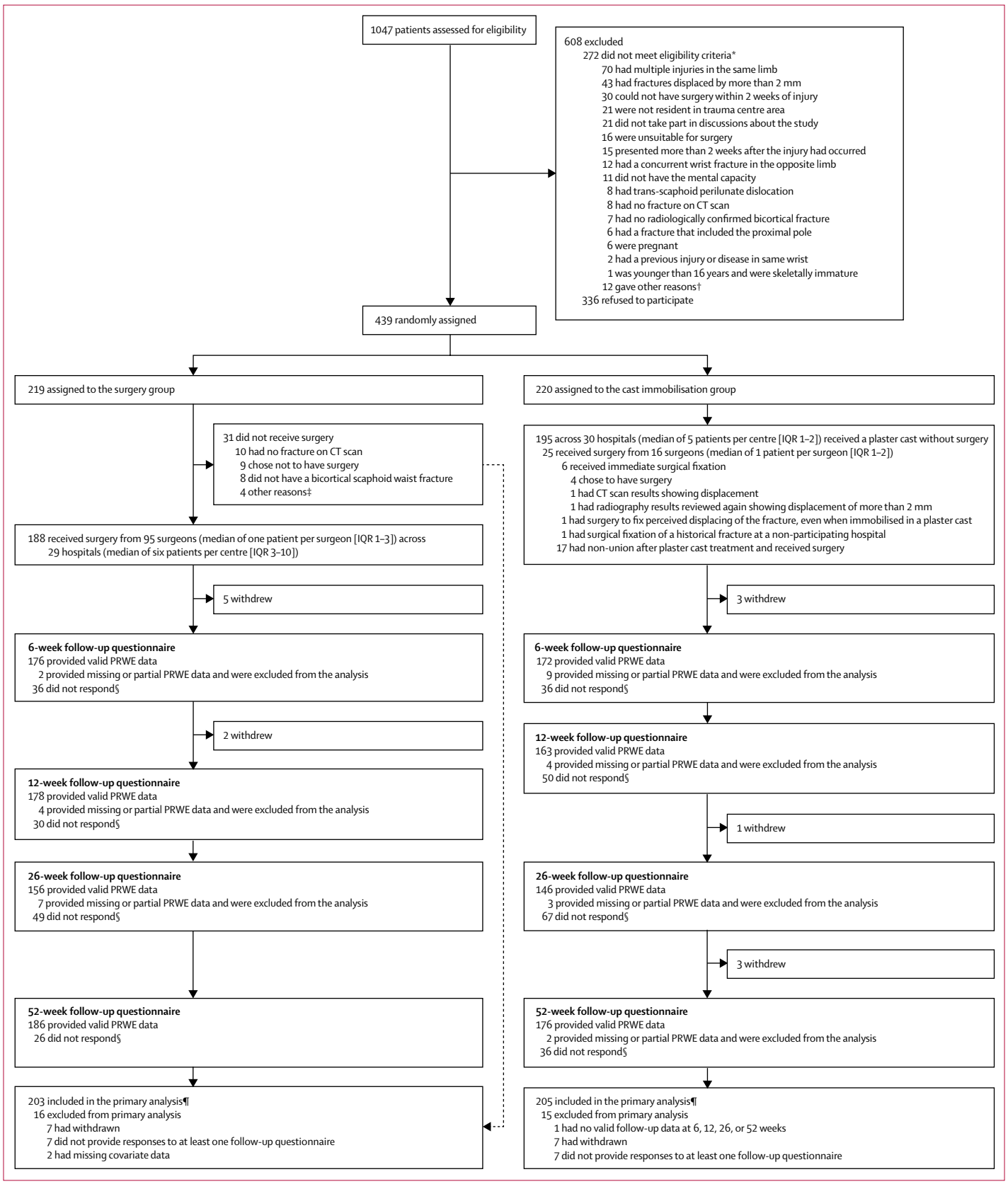
Procedures

In the surgery group, surgical treatment of fractures 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, the surgical approach, and the type of postoperative care were not restricted.

The cast immobilisation comparator group involved below-elbow cast immobilisation for 6–10 weeks, with or without inclusion of the thumb.[5] Rather than using defined criteria, suspected non-union of fractures on radiographs taken at 6–12 weeks was judged by an experienced surgeon at the recruiting site, and they were investigated by CT scan. If non-union was confirmed, immediate surgical fixation was offered. The same surgical procedure used to treat participants in the surgery group was used to treat participants with non-union of fractures after cast immobilisation.[2] This treatment pathway was referred to as the cast immobilisation pathway.

Figure 1: **Trial profile**

PRWE=patient-rated wrist evaluation. *Patient could be ineligible for more than one reason. †Other reasons included missing eligibility data (n=7), being in prison or a young adult defence unit (n=2), having a probable scapholunate disruption (n=1), the treating clinician deemed had 30% fracture in a smoker that the clinician would fix irrespective of study (n=1), and being considered as unreliable because of history of not attending hospital appointments (n=1). ‡Other reasons included that surgery was deemed innapropriate or unnecessary by the surgeon after review of the CT scan (n=2), the surgeon or patient could not find an appropriate time for the surgical procedure to be done (n=1), and admission to hospital with pericarditis (n=1). §Applies to individual timepoints only, as participants responded to questionnaires intermittently. ¶Participants included in primary analysis if they provided valid PRWE data for at least one post-randomisation timepoint, if they had complete covariate data, and if they had not withdrawn from the study.


1047 patients assessed for eligibility
608 excluded
272 did not meet eligibility criteria*
70 had multiple injuries in the same limb
43 had fractures displaced by more than 2 mm
30 could not have surgery within 2 weeks of injury
21 were not resident in trauma centre area
21 did not take part in discussions about the study
16 were unsuitable for surgery
15 presented more than 2 weeks after the injury had occurred
12 had a concurrent wrist fracture in the opposite limb
11 did not have the mental capacity
8 had trans-scaphoid perilunate dislocation
8 had no fracture on CT scan
7 had no radiologically confirmed bicortical fracture
6 had a fracture that included the proximal pole
6 were pregnant
2 had a previous injury or disease in same wrist
1 was younger than 16 years and were skeletally immature
12 gave other reasons†
336 refused to participate
439 randomly assigned
219 assigned to the surgery group
220 assigned to the cast immobilisation group
31 did not receive surgery
10 had no fracture on CT scan
9 chose not to have surgery
8 did not have a bicortical scaphoid waist fracture
4 other reasons‡
195 across 30 hospitals (median of 5 patients per centre [IQR 1–2]) received a plaster cast without surgery
25 received surgery from 16 surgeons (median of 1 patient per surgeon [IQR 1–2])
6 received immediate surgical fixation
4 chose to have surgery
1 had CT scan results showing displacement
1 had radiography results reviewed again showing displacement of more than 2 mm
1 had surgery to fix perceived displacing of the fracture, even when immobilised in a plaster cast
1 had surgical fixation of a historical fracture at a non-participating hospital
17 had non-union after plaster cast treatment and received surgery
188 received surgery from 95 surgeons (median of one patient per surgeon [IQR 1–3]) across 29 hospitals (median of six patients per centre [IQR 3–10])
5 withdrew
3 withdrew
6-week follow-up questionnaire
176 provided valid PRWE data
2 provided missing or partial PRWE data and were excluded from the analysis
36 did not respond§
6-week follow-up questionnaire
172 provided valid PRWE data
9 provided missing or partial PRWE data and were excluded from the analysis
36 did not respond§
2 withdrew
12-week follow-up questionnaire
163 provided valid PRWE data
4 provided missing or partial PRWE data and were excluded from the analysis
50 did not respond§
12-week follow-up questionnaire
178 provided valid PRWE data
4 provided missing or partial PRWE data and were excluded from the analysis
30 did not respond§
1 withdrew
26-week follow-up questionnaire
156 provided valid PRWE data
7 provided missing or partial PRWE data and were excluded from the analysis
49 did not respond§
26-week follow-up questionnaire
146 provided valid PRWE data
3 provided missing or partial PRWE data and were excluded from the analysis
67 did not respond§
3 withdrew
52-week follow-up questionnaire
186 provided valid PRWE data
26 did not respond§
52-week follow-up questionnaire
176 provided valid PRWE data
2 provided missing or partial PRWE data and were excluded from the analysis
36 did not respond§
203 included in the primary analysis¶
16 excluded from primary analysis
7 had withdrawn
7 did not provide responses to at least one follow-up questionnaire
2 had missing covariate data
205 included in the primary analysis¶
15 excluded from primary analysis
1 had no valid follow-up data at 6, 12, 26, or 52 weeks
7 had withdrawn
7 did not provide responses to at least one follow-up questionnaire

All participants received standard written physiotherapy advice detailing rehabilitation exercises. Additional rehabilitation was given at the discretion of the treating clinician.

At baseline, patients completed the patient-rated wrist evaluation (PRWE) questionnaire twice; first to recall the week immediately before their injury to identify if they had any pre-existing wrist problems before the injury had occurred, and second to reflect their post-injury condition. Participants then completed the PRWE questionnaire to document pain and disability after the injury (at 6, 12, 26, and 52 weeks after randomisation), and responses were collected by post, in the hospital clinic, or by telephone.

For research purposes, bone union was assessed by use of plain radiographs and a CT scan at baseline and at 52 weeks. Routine radiographs taken at hospital clinic visits at 6 weeks and 12 weeks after randomisation were also collected. Bone union was defined as complete disappearance of the fracture line[5] on radiographs and complete bridging on CT scans.[12] Partial union was defined as the proportion of the fracture plane traversed by bridging trabeculae on sagittal and coronal multiplanar scaphoid CT reconstructions. The degree of bone union was classified as non-union (0%), slight union (from >0% to 20%), partial union (from >20 to 70%), almost full union (from >70 to <100%), or full union (100%). Malunion, defined as a scaphoid height-to-length ratio of 0·6 or more or 0·7 or more in the scaphoid sagittal plane, was assessed by CT scan at 52 weeks.[13]

The range of movement of both wrists was measured by use of a goniometer, and grip strength in both hands was measured by use of a calibrated Jamar dynamometer, at baseline and at subsequent hospital visits at 6, 12, and 52 weeks after randomisation.

Outcomes

The primary outcome was the total PRWE score at 52 weeks after randomisation. The PRWE measures wrist pain and disability[14] and contains 15 items, each with an 11-point ordered scale. The total PRWE score ranges from 0 (no disability) to 100 (maximum loss of function and marked pain).

Secondary outcomes included the PRWE pain and function subscale scores, 12-item Short Form Health Survey (SF-12) physical and mental component scores,[15] the degree of bone union, range of movement, grip strength, and complications (defined as medical, surgical, or cast-related).

Complications were recorded during hospital visits at 6, 12, and 52 weeks. Participants also reported the number of days absent from work due to the injury when completeing questionnaires at 6, 12, 26 and 52 weeks. The hospital staff completed a form to provide details about the surgical procedure (ie, what was done, by whom, and when) from their accounts of the procedure and also from hospital records.

Statistical analysis

A six-point improvement in PRWE score was deemed to be a conservative[16] minimum clinically important difference. We used a SD of 20,[14] which provided an effect size of 0·3. To observe this effect size with 80% power using a two-sided significance level of 5% required 350 participants. Allowing for 20% attrition, the recruitment target was 438 participants.

Analyses strictly followed a prespecified analysis plan, which was endorsed by the independent oversight committees. Each analysis (apart from the multiple imputation analysis) was done on an available case, intention-to-treat basis, and included every participant for whom relevant outcome and covariate data were obtained. Participants were analysed according to the groups to which they were randomised. We used Stata (StataCorp, Stata Statistical Software: Release 15; College Station, TX, USA) to do the statistical analyses, using two-sided statistical tests at the 5% significance level. Baseline and outcome data were summarised descriptively by treatment group. In the primary analysis we compared total PRWE scores between the two groups using a covariance pattern mixed-effect linear regression model, incorporating all post-randomisation timepoints (at 6, 12, 26, and 52 weeks). Treatment group, timepoint, treatment-by-time interaction, age, baseline fracture displacement (<1 mm or 1–2 mm), and dominance of the 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 (on the basis of minimising the Akaike's information criterion).[17] Diagnostics of model fit revealed that the standardised residuals showed sufficient normality and were uniform against fitted values. Estimates of the difference in total PRWE score were extracted for each timepoint and overall with 95% CIs and p values.

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

Adding smoking status (yes or no) to the primary model (post-hoc analysis reflecting a chance imbalance at baseline), and adding hospital as a random effect (preplanned analysis) to account for potential clustering, were done as sensitivity analyses. To account for non-compliance (surgery to cast immobilisation) and contamination (cast immobilisation to surgery) we did a complier average causal effect (CACE) analysis using two-stage least squares, with randomised treatment as the instrumental variable.[19] Details of further sensitivity analyses are included in the appendix (pp 23–24).

Three pre-planned subgroup analyses were done: one exploring patient treatment preferences at baseline and two exploring fracture displacement, as recorded at randomisation or corrected after review of the study

eligibility forms. Greater benefit of surgery was expected in (1) participants with a baseline preference for surgery, and (2) participants with a displaced fracture.

Analyses of the secondary outcomes were done as described for the primary outcome. Bone union at 52 weeks was dichotomised as "possibly needing surgery" (0–20% union) or "not requiring surgery" (>20–100% union), and was compared between groups by use of logistic regression, adjusting for age, fracture displacement, and dominant hand. Malunion was presented overall and for each treatment group at 6, 12, and 52 weeks (appendix pp 26–27). 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.

This trial is registered with the ISRCTN registry, number ISRCTN67901257.

	All patients randomly assigned			Patients included in the primary analysis*		
	Surgery group (n=219)	Cast immobilisation group† (n=220)	Total (n=439)	Surgery group (n=203)	Cast immobilisation group† (n=205)	Total (n=408)
Sex						
Male	180 (82%)	183 (83%)	363 (83%)	168 (83%)	169 (82%)	337 (83%)
Female	39 (18%)	37 (17%)	76 (17%)	35 (17%)	36 (18%)	71 (17%)
Age, years						
Mean	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	28 (22–39)	29 (23–41)	29 (23–40)	29 (23–39)	29 (23–41)	29 (23–40)
Ethnicity						
White	205 (94%)	195 (89%)	400 (91%)	191 (94%)	180 (88%)	371 (91%)
Other	12 (6%)	25 (11%)	37 (8%)	12 (6%)	25 (12%)	37 (9%)
Unknown	2 (1%)	0	2 (1%)	0	0	0
Highest qualification						
No formal qualifications	24 (11%)	27 (12%)	51 (12%)	22 (11%)	25 (12%)	47 (12%)
Some qualifications or no degree	151 (69%)	129 (59%)	280 (64%)	139 (69%)	120 (59%)	259 (64%)
Degree or higher	41 (19%)	64 (29%)	105 (24%)	41 (20%)	60 (29%)	101 (25%)
Unknown	3 (1%)	0	3 (1%)	1 (1%)	0	1 (0·2%)
Employment status						
Part-time employment	20 (9%)	18 (8%)	38 (9%)	20 (10%)	18 (9%)	38 (9%)
Full-time employment	127 (58%)	120 (55%)	247 (56%)	119 (59%)	111 (54%)	230 (56%)
Self-employed	21 (10%)	36 (16%)	57 (13%)	19 (9%)	31 (15%)	50 (12%)
Student	20 (9%)	21 (10%)	41 (9%)	19 (9%)	21 (10%)	40 (10%)
Retired	7 (3%)	5 (2%)	12 (3%)	7 (3%)	5 (2%)	12 (3%)
Looking after family or home	1 (1%)	6 (3%)	7 (2%)	0	5 (2%)	5 (1%)
Seeking work	9 (4%)	5 (2%)	14 (3%)	8 (4%)	5 (2%)	13 (3%)
Other	11 (5%)	9 (4%)	20 (5%)	10 (5%)	9 (4%)	19 (5%)
Unknown	3 (1%)	0	3 (1%)	1 (1%)	0	1 (0·2%)
Current smoker						
Yes	73 (33%)	56 (26%)	129 (29%)	64 (32%)	50 (24%)	114 (28%)
No	143 (65%)	163 (74%)	306 (70%)	138 (68%)	154 (75%)	292 (72%)
Unknown	3 (1%)	1 (1%)	4 (1%)	1 (1%)	1 (1%)	2 (1%)
Diabetes						
Yes	7 (3%)	4 (2%)	11 (3%)	6 (3%)	4 (2%)	10 (3%)
No	209 (95%)	216 (98%)	425 (97%)	196 (97%)	201 (98%)	397 (97%)
Unknown	3 (1%)	0	3 (1%)	1 (1%)	0	1 (0·2%)
Steroid use						
Yes	6 (3%)	4 (2%)	10 (2%)	6 (3%)	4 (2%)	10 (3%)
No	210 (96%)	216 (98%)	426 (97%)	196 (97%)	201 (98%)	397 (97%)
Unknown	3 (1%)	0	3 (1%)	1 (1%)	0	1 (0·2%)

Data are n (%), mean (SD), or median (IQR). *Participants were included in the primary analysis if they provided valid patient-rated wrist evaluation data at at least one post-randomisation follow-up timepoint and if they had complete covariate data. †Cast immobilisation involved the standard clinical pathway of initial cast immobilisation, with suspected non-unions expected to be confirmed by imaging and immediately fixed with surgery.

Table 1: **Baseline characteristics at randomisation and at the primary analysis by study group**

Role of the funding source

The funders monitored the progress of the trial, but they had no role in study design, data collection, data analysis, data interpretation, writing or approval of the report, nor the decision to submit for 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

Between July 23, 2013, and July 26, 2016 we assessed 1047 patients for eligibility and identified 775 eligible patients. Of these, 439 (57%) patients were recruited from 31 hospitals (median of ten patients recruited per hospital [range 1–61]). Of 336 (43%) eligible patients who did not provide their consent, most (325 [97%] patients) provided a reason for refusing to participate in the study, including a preference for non-operative treatment (n=206), a preference for surgery (n=40), or being unable to commit to follow-up appointments (n=24). 439 (57%) of 775 eligible patients gave consent and were randomly allocated to the surgery group (n=219) or the cast immobilisation group (n=220; figure 1).

	Adjusted mean (95% CI)*		Mean difference (95% CI)	p value
	Surgery group	Cast immobilisation group†		
Primary outcome				
Total PRWE score‡				
Number of patients analysed	203	205	..	..
6 weeks	35·6 (32·6 to 38·6)	39·8 (36·8 to 42·8)	−4·2 (−8·5 to 0·1)	0·06
12 weeks	21·0 (18·1 to 24·0)	26·6 (23·6 to 29·6)	−5·6 (−9·8 to −1·4)	0·01
26 weeks	16·2 (13·5 to 18·9)	16·5 (13·8 to 19·2)	−0·3 (−4·1 to 3·6)	0·89
52 weeks	11·9 (9·2 to 14·5)	14·0 (11·3 to 16·6)	−2·1 (−5·8 to 1·6)	0·27
Averaged over 52 weeks	21·3 (18·9 to 23·6)	24·4 (22·0 to 26·7)	−3·0 (−6·3 to 0·3)	0·07
Secondary outcomes				
PRWE pain subscale score§				
Number of patients analysed	203	206	..	..
6 weeks	18·8 (17·3 to 20·4)	19·0 (17·5 to 20·5)	−0·1 (−2·3 to 2·0)	0·89
12 weeks	13·1 (11·5 to 14·6)	15·0 (13·4 to 16·6)	−2·0 (−4·2 to 0·3)	0·09
26 weeks	11·0 (9·4 to 12·5)	10·6 (9·0 to 12·2)	0·4 (−1·8 to 2·6)	0·75
52 weeks	7·9 (6·4 to 9·5)	9·1 (7·5 to 10·6)	−1·1 (−3·3 to 1·0)	0·31
Averaged over 52 weeks	12·7 (11·5 to 14·0)	13·5 (12·2 to 14·8)	−0·7 (−2·5 to 1·1)	0·44
PRWE function subscale score§				
Number of patients analysed	203	205	..	..
6 weeks	16·7 (14·9 to 18·5)	20·5 (18·7 to 22·3)	−3·8 (−6·3 to −1·3)	0·003
12 weeks	8·1 (6·6 to 9·5)	11·5 (10·0 to 13·0)	−3·4 (−5·6 to −1·3)	0·001
26 weeks	5·4 (4·1 to 6·6)	6·0 (4·7 to 7·3)	−0·6 (−2·4 to 1·2)	0·52
52 weeks	3·9 (2·7 to 5·1)	4·9 (3·7 to 6·1)	−1·0 (−2·6 to 0·7)	0·25
Averaged over 52 weeks	8·6 (7·5 to 9·7)	10·8 (9·7 to 12·0)	−2·2 (−3·8 to −0·6)	0·01
SF-12 mental component score¶				
Number of patients analysed	202	206	..	..
6 weeks	49·7 (48·1 to 51·3)	49·1 (47·5 to 50·7)	0·5 (−1·7 to 2·8)	0·63
12 weeks	50·6 (49·0 to 52·1)	50·7 (49·1 to 52·3)	−0·2 (−2·4 to 2·1)	0·88
26 weeks	51·0 (49·4 to 52·6)	51·6 (49·9 to 53·3)	−0·6 (−3·0 to 1·7)	0·60
52 weeks	51·0 (49·6 to 52·5)	52·3 (50·8 to 53·7)	−1·2 (−3·3 to 0·8)	0·24
Averaged over 52 weeks	50·6 (49·3 to 51·8)	50·9 (49·7 to 52·2)	−0·4 (−2·2 to 1·4)	0·69
SF-12 physical component score¶				
Number of patients analysed	202	206	..	..
6 weeks	43·9 (42·7 to 45·1)	43·4 (42·2 to 44·6)	0·5 (−1·2 to 2·2)	0·59
12 weeks	49·8 (48·7 to 50·9)	47·6 (46·5 to 48·8)	2·2 (0·6 to 3·8)	0·01
26 weeks	51·6 (50·5 to 52·7)	51·6 (50·5 to 52·8)	−0·0 (−1·6 to 1·5)	0·95
52 weeks	53·1 (52·1 to 54·2)	51·5 (50·5 to 52·6)	1·6 (0·2 to 3·1)	0·03
Averaged over 52 weeks	49·6 (48·8 to 50·4)	48·5 (47·7 to 49·3)	1·1 (−0·1 to 2·2)	0·08

(Table 2 continues on next page)

The mean age of participants was 32·9 years (range 16–80) 363 (83%) of all 439 participants were male (table 1), and 269 (61%) participants had fracture displacement of less than 1 mm (appendix p 19). These characteristics were similar to the 336 patients who refused to provide consent, in terms of age (mean age 32 years) and the proportion of patients who were male (268 [80%]). By contrast, ineligible patients were older (mean age 36 years) and the proportion of male patients was lower (203 [75%] of 272 patients) when compared with eligible patients (appendix p 21). Of the 439 patients who were randomly assigned, the left wrist was injured in 233 (53%) patients and the non-dominant limb was injured in 242 (55%) patients (appendix p 19).

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

Of the 219 patients allocated to the surgery group, 188 (86%) patients received surgery an average of 10·2 days (range 3–20) after the injury, and surgery was done by 95 surgeons across 29 hospitals. Data on the operating surgeon were available for 187 of the 188 operations: 120 (64%) operations were done by consultants, 40 (21%) operations were assisted by consultants, three (2%) operations were supervised by consultants, 13 (7%) operations were done by a specialist trainee, and 11 (6%) operations were done by a staff grade or associate specialist. Of the 220 patients allocated to the cast immobilisation group, 214 (97%) patients initially received a plaster cast, but six (3%) patients received surgery shortly after randomisation (mean of 13·5 days [range 5–32] after the injury), which was considered as treatment contamination. One (<1%) of the 214 patients had surgery 29 days after they were randomly assigned because of perceived displacing of the fracture and one (<1%) patient had surgical fixation at a non-participating hospital. Following confirmation of non-union of the fracture, 17 (8%) of 214 patients received surgery an average of 159 days (range 68–358) after the injury. 14 (82%) of these patients had surgery within 26 weeks of randomisation (five of whom had surgery within 12 weeks, as per protocol), whereas three (18%) patients had delayed surgery (appendix p 22).

214 participants in the cast immobilisation group wore a cast for an average of 44·8 days (SD 15·2), and 91 (43%) participants were then given a splint for an average of a further

26·4 days (15·1). Of the 188 participants allocated to the surgery group who underwent surgery, 161 (86%) had minimal or no immobilisation, 26 (14%) had a bandage applied (mean duration not known), 62 (33%) had a splint only (mean duration 28·4 days [SD 19·6]), and 73 (39%) had a cast on for a short period immediately after surgery (mean duration 15·6 days [9·8]) followed by a splint (mean duration 24·7 days [13·9]). The remaining 27 (14%) patients had cast immobilisation: 24 (13%) had a cast only (mean duration 30·9 days [16·7]), and three (2%) had a splint for a mean of 12·7 days (2·5) and then a cast for a mean of 27·7 days (0·6).

Valid PRWE data were provided by 348 (79%) of 439 participants at 6 weeks' follow-up, 341 (78%) at 12 weeks' follow-up, 302 (69%) at 26 weeks' follow-up, and 362 (82%) at 52 weeks' follow-up. The primary analysis included 408 (93%) participants (203 participants in the surgery group and 205 participants in the cast immobilisation group) with a valid PRWE score for at least one follow-up timepoint and with complete covariate data. At 52 weeks, the unadjusted mean PRWE score was 11·4 (SD 16·6) in the surgery group and 14·2 (19·8) in the cast immobilisation group. There was no significant or clinically important difference in PRWE scores between the two groups at 52 weeks, but PRWE scores were lower in the surgery group than in the cast immobilisation group (adjusted mean difference –2·1 [95% CI –5·8 to 1·6], p=0·27; table 2). No significant difference in PRWE scores between the two groups was observed at 26 weeks, or on average over the 52 weeks (table 2 and figure 2). A significant difference in PRWE scores between the two groups was observed at week 12 (p=0·01), and PRWE scores were lower in the surgery group than in the cast immobilisation group at 6 weeks, but this difference was not significant (p=0·06). Even though the point estimates of this difference at 6 weeks did not exceed six points (ie, the threshold of clinical importance used in this study), the CI did include this difference.

Although 362 (82%) of 439 participants had provided valid PRWE data at 52 weeks, these data were missing for at least one follow-up timepoint in 190 (43%) participants. Analysis of complete, multiply imputed datasets for the primary outcome produced similar results to that of the primary analysis population (adjusted mean difference in PRWE scores at 52 weeks –2·1 [95% CI –5·9 to 1·6], p=0·26; appendix p 23).

No significant difference in total PRWE scores between the treatment groups at 52 weeks was observed after additionally adjusting for smoking status as a fixed effect (p=0·14) or for centre as a random effect (p=0·31). The other sensitivity analyses also did not alter our primary findings (appendix pp 23–24).

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

	Adjusted mean (95% CI)*		Mean difference (95% CI)	p value
	Surgery group	Cast immobilisation group†		
(Continued from previous page)				
Grip strength in the affected wrist, kg				
Number of patients analysed	201	206	..	..
6 weeks	23·8 (22·0 to 25·6)	19·4 (17·6 to 21·2)	4·4 (1·8 to 6·9)	0·001
12 weeks	30·9 (29·0 to 32·8)	28·3 (26·4 to 30·2)	2·6 (–0·1 to 5·3)	0·06
26 weeks	37·0 (35·1 to 39·0)	38·0 (36·1 to 40·0)	–1·0 (–3·7 to 1·7)	0·48
52 weeks	30·1 (28·5 to 31·7)	27·9 (26·3 to 29·5)	2·0 (–0·3 to 4·2)	0·08

Data are n (%) or mean (95% CI). PRWE=patient-rated wrist evaluation. SF-12=12-item Short Form Health Survey. *All models specified for relevant outcomes as follows: adjusted mixed-effect linear regression model, as fixed effects, for group (surgery, cast immobilisation), time (6, 12, 26, or 52 weeks), treatment-by-time interaction, age, baseline fracture displacement (<1 mm or 1–2 mm) and dominance of the injured limb (yes or no) with participant as a random effect. †Cast immobilisation involved the standard clinical pathway of initial cast immobilisation, with suspected non-unions expected to be confirmed by imaging and immediately fixed with surgery. ‡Scores ranged from 0 to 100, with lower scores indicating a better outcome. §Scores ranged from 0 to 50, with lower scores indicating a better outcome. ¶Scores ranged from 0 to 100, with 0 indicating the lowest level of health and 100 indicating the highest level of health.

Table 2: **Primary and secondary outcomes**

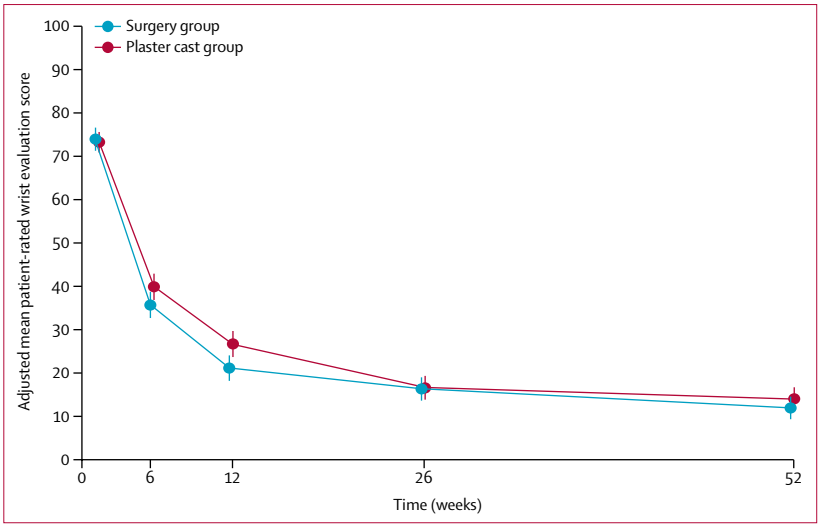


Figure 2: **Adjusted mean patient-reported wrist evaluation scores**
Mean scores and 95% CIs of the primary analysis population in the surgery group and plaster cast group are shown.

We found no significant interaction between randomised group and treatment preference, or fracture displacement assessed at either study enrolment or randomisation (appendix p 29).

No significant difference in the PRWE subscales for pain or function, the SF-12 mental component scores, range of wrist movement, or grip strength were observed between the two groups at 52 weeks (table 2). A significantly higher SF-12 physical component score was observed in the surgery group compared with the cast immobilisation group at 52 weeks (1·6 points [95% CI 0·2–3·1], p=0·03). The results for range of movement and grip strength are summarised in the appendix (pp 25–26).

	Surgery group (n=219)	Cast immobilisation group* (n=220)	Total (n=439)
6 weeks' follow-up			
Full union	47 (22%)	26 (12%)	73 (17%)
Almost full union	81 (37%)	73 (33%)	154 (35%)
Partial union	47 (22%)	70 (32%)	117 (27%)
Slight union	11 (5%)	23 (11%)	34 (8%)
Non-union	2 (1%)	9 (4%)	11 (3%)
Unknown	31 (14%)	19 (9%)	50 (11%)
12 weeks' follow-up			
Full union	102 (47%)	63 (29%)	165 (38%)
Almost full union	45 (21%)	44 (20%)	89 (20%)
Partial union	15 (7%)	33 (15%)	48 (11%)
Slight union	7 (3%)	13 (6%)	20 (5%)
Non-union	0	10 (5%)	10 (2%)
Unknown	50 (23%)	57 (26%)	107 (24%)
52 weeks' follow-up			
Full union	93 (43%)	72 (33%)	165 (38%)
Almost full union	64 (29%)	59 (27%)	123 (28%)
Partial union	3 (1%)	10 (5%)	13 (3%)
Slight union	3 (1%)	5 (2%)	8 (2%)
Non-union	1 (1%)	4 (2%)	5 (1%)
Unknown	55 (25%)	70 (32%)	125 (29%)

Data are n (%). At 6 weeks and 12 weeks' follow-up, bone union was assessed by radiographic imaging. At 52 weeks' follow-up, bone union was assessed on CT imaging. In 22 (7%) of 314 participants, only radiographs were available to assess bone union. The degree of bone union measured by CT imaging was classified as a percentage, with 0% indicating non-union; >0% to 20% as slight union; >20% to 70% as partial union; >70% to <100% as almost full union; and 100% as full union. The degree of bone union measured by radiographic imaging was classified as full, partial, probable, or non-union for each available view, and then summarised for all images together as united, probably united, partially united, probably not united, or not united. *Cast immobilisation involved the standard clinical pathway of initial cast immobilisation, with suspected non-unions expected to be confirmed by imaging and immediately fixed with surgery.

***Table 3*: Bone-union assessment results by follow-up timepoint and study group**

Participants in the surgery group were less likely to have non-union or slight union of the fracture at 52 weeks compared with the cast immobilisation group (four participants *vs* nine participants; table 3), but this difference was not significant (adjusted odds ratio 0·40 [95% CI 0·12–1·33], p=0·13). Malunion assessed at different scaphoid height-to-length ratio thresholds (0·6 and 0·7) are described in the appendix (pp 26–27). For both thresholds, there were no marked differences in the number of participants with malunion between the two groups at all timepoints on the radiographic and CT images.

More participants in the surgery group (31 [14%] of 220 participants) had a potentially serious complication associated with surgery than in the cast immobilisation group (three [1%] of 219 participants), but fewer participants in the surgery group (five [2%]) had cast-related complications than in the cast immobilisation group (40 [18%]). In the surgery group, four (2%) participants had nerve problems (three participants had numbness in the region of the scar and one participant had decreased sensation over and distal to the scar, with tenderness), two (1%) had an infection, and three (1%) developed complex regional pain syndrome (CRPS). In the cast immobilisation group, one (<1%) participant developed transient nerve problems, two (1%) had an infection, and none had CRPS (appendix p 27). The number of patients who had a medical complication was similar in the two groups (four [2%] of participants in the surgery group and five (2%) of participants in the cast immobilisation group). CT images at 52 weeks were assessed for screw penetration from the surface of the bones (in mm) in 142 of the 188 participants who received surgery in the surgery group. Screw penetration was identified in 93 (65%) of these 142 participants (25 [27%] with <1 mm penetration; 44 [47%] with 1–2 mm penetration; and 24 [26%] with >2 mm penetration). Among these 142 participants, the unadjusted mean PRWE score at 52 weeks in those who had screw penetration of less than 1 mm was 8·9 (SD 15·0) compared with 10·8 (13·9) in those who had screw penetration of 1 mm or more.

Eight (4%) of 219 participants in the surgery group underwent reoperation to remove prominent screws (n=6), to fix non-union of the fracture (n=2), and to do a scaphoid excision with four-corner fusion (n=1). One (0·5%) of 220 participants in the cast immobilisation group developed non-union of the fracture that was fixed with surgery, but the participant required reoperation for persistent non-union.

Three participants in the surgery group each reported a serious adverse event, all of which were related to anaesthesia or surgery, and two were unexpected (appendix p 28). The two unexpected events were hospitalisations relating to anaesthesia. One event was an overnight stay for observation following surgery due to raised blood pressure and sinus tachycardia, both of which resolved while in hospital. The other event was a patient who was admitted after a planned surgery, as they were unable to use crutches because of the block used to numb the arm for scaphoid fixation surgery. The expected event was a collapse of the scaphoid fracture resulting in penetration of the screw into the scapho-trapezium joint. The screw was removed, and the bone grafted and stabilised with two Kirschner-wires. The bone still failed to unite, and then the participant had salvage surgery with excision of the scaphoid and a four-corner fusion.

Over the 52-week follow-up period, participants in the surgery group reported an average of 15·6 days (SD 26·7) of lost employment due to the injury compared with 18·2 days (29·1) in the cast immobilisation group (table 4), but this difference was not significant.

Discussion

Adults who have a bicortical scaphoid waist fracture displaced by 2 mm or less that has been immobilised in a below-elbow cast have little difference in pain and function outcomes to those who have the fracture surgically

	Surgery group				Cast immobilisation group*				Total			
	Number of patients	Mean number of days absent from work (SD)	Median number of days absent from work (IQR)	Number of patients reporting no days absent from work	Number of patients	Mean number of days absent from work (SD)	Median number of days absent from work (IQR)	Number of patients reporting no days absent from work	Number of patients	Mean number of days absent from work (SD)	Median number of days absent from work (IQR)	Number of patients reporting no days absent from work
Baseline to 6 weeks	156	13·6 (14·4)	7 (1–26)	32 (21%)	158	13·4 (15·6)	5 (0–30)	47 (30%)	314	13·5 (15·0)	6 (0–30)	79 (25%)
6–12 weeks	161	2·6 (7·5)	0 (0–0)	122 (76%)	149	4·9 (10·9)	0 (0–2)	100 (67%)	310	3·7 (9·4)	0 (0–1)	222 (72%)
12–26 weeks	142	2·0 (10·2)	0 (0–0)	128 (90%)	135	3·7 (14·9)	0 (0–0)	120 (89%)	277	2·8 (12·7)	0 (0–0)	248 (90%)
26–52 weeks	164	1·5 (10·7)	0 (0–0)	150 (91%)	160	1·9 (14·7)	0 (0–0)	146 (91%)	324	1·7 (12·8)	0 (0–0)	296 (91%)
Total	197	15·6 (26·7)	5 (0–21)	60 (30%)	201	18·2 (29·1)	4 (0–30)	72 (36%)	398	..	..	132 (33%)

Data are mean (SD), median (IQR), or n (%). *Cast immobilisation involved the standard clinical pathway of initial cast immobilisation, with suspected non-unions expected to be confirmed by imaging and immediately fixed with surgery.

Table 4: **Participant-reported absence from work due to the injury**

fixed with a screw. We found that cast immobilisation, with suspected non-unions identified and fixed early, was successful in achieving fracture union and substantially reduced the need for surgery. The differences between the surgery and cast immobilisation groups were lower than the prespecified and conservative six points on the PRWE, and were therefore unlikely to be important to patients. Our findings in the intention-to-treat analysis were confirmed by the sensitivity analyses, accounting for crossover and adjusting for fracture displacement, smoking status, and clustering at site. Secondary outcomes of bone union, grip strength, range of movement, and SF-12, support the results of the primary analysis.

At 6 and 12 weeks, when participants in the cast immobilisation group tended to still be wearing a cast, there was some evidence of a difference between the two groups, in terms of pain and function, favouring surgery, but this difference did not exceed six points on the PRWE and its clinical relevance is therefore uncertain. Beyond 12 weeks, there was no difference between the two groups in terms of pain and function, nor did we identify evidence that the the proportion of patients who had non-union and slight union of the fracture differed significantly between the two groups. We observed non-union or slight union of the fracture in four participants in the surgery group and in nine participants in the cast immobilisation group. Complications of infection, nerve problems, and CRPS were ten-times more likely to occur after early surgical fixation (31 [14%] of 219 participants) than after cast immobilisation (three [1%] of 220 participants). The screw penetrated joints in far more participants in the surgery group than anticipated. Among participants in the surgery group in whom screw penetration was identified on their 52 week CT scans, nearly half (44 [47%] of 93 participants) displayed screw penetration of 1–2 mm inclusive, and a quarter (24 [26%] of 93 participants) displayed screw penetration of more than 2 mm, risking irreversible damage. Only six (3%) of the 188 participants who had surgery had the penetrating screw removed. In most participants, screw penetration was identified because we did CT scans at 1 year after randomisation. These findings emphasise the need for careful imaging during surgery. Cast complications, such as the cast being too soft, too tight, or broken, or causing skin soreness, were minor, resolved early, and had no lasting consequences. Reoperations were more frequent after early screw fixation in the surgery group (eight [4%] of 219 participants) than in the cast immobilisation group (one [<1%] of 220 participants). The longer-term consequences of arthritis, malunion, injury, and screw penetration will be investigated in a 5-year review of these participants.

Over the past few decades, the use of surgery has increased, as clinicians and patients anticipated that this treatment strategy would lead to more successful fracture union and quicker return to work than if cast immobilisation was used. We reviewed hospital episode statistics for NHS hospitals in England. The reports indicated that the number of acute scaphoid fracture fixations increased in the years before our study was commissioned (2007–08 [n=1534], 2008–09 [n=1720], and 2009–10 [n=2582]). The proportion of acute fracture fixations[20] rose slightly from 37% in 2007–2008 to 41% in 2008–2009, but then increased sharply to 62% in 2009–2010. The frequency of surgical treatment of acute scaphoid fractures has also increased significantly in the USA from 22·1% in 2006 to 34·1% in 2012.[21] The incidence of primary surgical treatment has increased more than three-fold in Finland between 1997 and 2014.[22] Achieving fracture union is particularly important, as untreated non-union causes wrist arthritis. In our study, we found that the difference in the proportion of patients who had fracture union between those initially treated with cast immobilisation and those fixed with a screw was, however, insignificant. These results are consistent with previous observations.[9] The proportion of patients who had non-union was lower in both groups than we had anticipated, possibly because of the rigour with which the fracture was diagnosed at baseline, and the assessment and treatment of non-union when compared

with previous studies.[9] The number of scaphoid fractures that need to be fixed to avoid one non-union is 73 (95% CI 24–100).[23] We found no difference between the two groups in terms of range of wrist movement or grip strength at 52 weeks, consistent with previous smaller reports.

By contrast with most previous trials,[24] we found little difference in the number of days of lost employment due to injury. This could reflect that 177 (80%) of 220 participants in the cast immobilisation group were initially fitted with a cast that did not include the thumb, thereby permitting early use of the hand. Patients might have felt more secure working in a cast or responded to reassurance they were given on returning to work while still in a cast (or both).

As this was a pragmatic trial, surgeons were allowed to follow their usual practice for cast immobilisation and use of physiotherapy. Most operations were done or supervised by senior surgeons. The number of large and small hospitals and surgeons involved in our study improves the generalisability of our findings to a range of clinical settings. The results are applicable both to participants with undisplaced fractures and to those with fractures displaced by up to 2 mm. Bias was minimised with the high proportion of participants who provided patient-reported outcome measure data at 52 weeks, and our analysis model permitted inclusion of all available data. The large number of participants has doubled the evidence from previous small trials.[25–32]

Limitations of our study included non-compliance (ie, when treatment was not delivered as allocated), which can underestimate the treatment effect. 31 (14%) of 219 patients in the surgery group did not have surgery, compared with six (3%) of 220 patients in the cast group who immediately switched to have surgery. However, analysis accounting for non-compliance supported the results of the primary analyses. Further non-compliance in the cast immobilisation group also occurred, with 17 (8%) participants who had surgery for early identified non-union, five (2%) of whom had surgery within 12 weeks of randomisation (as anticipated in our protocol) and 12 (5%) of whom had surgery after 12 weeks. Of the four (2%) of participants in the cast immobilisation group who had a non-union at 52 weeks, three (1%) were not offered surgery. Even though not all participants in the cast immobilisation group who had non-union underwent immediate fixation, 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 the outcomes.

Any response bias from imbalances in the number of questionnaires returned, which was lower in the cast immobilisation group than in the surgery group, and characteristics of a responder, were minimised by use of a mixed-effect, repeated measures model that included intermittent responders. This model allowed data from 97% of the participants, and almost identical numbers of participants for each treatment group, to be used. Using this model increased the statistical power of the analyses, compared with the use of a two-sample *t* test at a single timepoint 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. Additionally, there were no stringent criteria for surgery that surgeons were required to follow. Those surgeons who did operate, or who were present during the operations, were mostly consultants. The follow-up clinic appointments that were organised at 6 weeks and 12 weeks were consistent with routine clinical practice. The follow-up clinic appointment at 52 weeks, which was the primary endpoint, was to ensure, as much as was feasible, that participants in both treatment groups had the time to complete the treatment pathway being delivered.

These findings are timely, as we see an increasing trend towards primary surgical fixation, which is not clearly supported by our results. Cast immobilisation treatment is as effective as surgical fixation, provided that suspected non-unions are identified early and fixed.

Contributors

JJD was the chief Investigator and lead applicant. SDB, LC, LJ, MN, and GT contributed to the conduct of the trial. CF, AK, CH, NT, and JT provided statistical expertise. SHi and GR provided health economics expertise. PL led the qualitative aspects of the study. JJD, SC, and KJ led the assessment of imaging, and JP assisted in imaging data management. MC and AR provided expertise as orthopaedic surgeons. DT provided expert methodological input. JJD, SDB and CF led the writing of the manuscript and contributed to various aspects of study design. RA, BB, NB, MB, DB, CC, TD, LDM, GG, HH, JH, SHo, PJ, JJ, AL, WM, AM, IM, LM, JN, RP, ZR, SR, PS, AT, and DW recruited participants into the study, followed participants up and collected data, and helped interpret study findings. All authors read and approved the final manuscript.

Declaration of interests

MC is a member of the General Board for the Health Technology Assessment programme; does consultancy work for Heraeus Medical and X-Bolt outside of the submitted work; and reports grants from the National Institute for Health Research (NIHR), Heraeus Medical, and X-Bolt; and reports receiving charitable grants for other research into musculoskeletal trauma outside of the submitted work. CH is a member of the NIHR Health Technology Assessment commissioning board. AR reports receiving educational and research funds from DePuy outside the scope of the submitted work and reports grants from the NIHR during the conduct of the study. All other authors declare no competing interests.

Data sharing

All requests for data should be submitted to JJD (jd96@le.ac.uk) for consideration, as agreed in our publication plan. Access to anonymised data may be granted following review by the Trial Management Group and agreement of JJD. Related documents, including the statistical analyses plan (appendix pp 2–19), will be available on request.

Acknowledgments

The SWIFFT trial was funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (project number 11/36/37). We are indebted to the patients who participated in this trial, without whom the trial would not have been possible. We also thank our Patient Public Involvement group, which provided valuable input throughout the study. We are grateful to

the teams in York and Leicester who contributed to the design of data collection forms and information systems, and who contributed to the management of data. We specifically thank the following individuals who made a valuable contribution to the study: Christopher Bunce, who was responsible for managing imaging procedures during the first 3 years of the trial; Elaine James, who provided comprehensive administrative support to JJD and the trial team. Sarwat Shah, who was the trial coordinator and who contributed to the conduct of the trial, particularly data collection and data management; and Ashley Langton, who was our patient representative in the Trial Management Group, and who contributed to many of the discussions around optimising participant retention and commented on various trial-related materials throughout the study. We also thank the principal investigators, Sue Fullilove, Roland Pratt, Daniel Redfern, Bijayendra Singh, and Lisa Tourret, who recruited participants to the study, followed participants up, and helped to interpret study findings. The views expressed in this article are those of the authors and do not necessarily reflect those of the Health Technology Assessment programme, the National Institute for Health Research, the National Health Service or the Department of Health and Social Care.

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