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Title: Scaphoid Waist Internal Fixation for Fractures Trial (SWIFFT): a randomised controlled trial, economic evaluation and nested qualitative study of cast versus surgical fixation for the treatment of adult patients with a bi-cortical fracture of the scaphoid waist

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

Authors: Joseph Dias[1], Stephen Brealey[2], Liz Cook[2], Caroline Fairhurst[2], Sebastian Hinde[3], Paul Leighton[4], Surabhi Choudary[5], Matthew Costa[6], Catherine Hewitt[2], Stephen Hodgson[7], Laura Jefferson[8,2], Kanagaratnam Jeyapalan[1], Ada Keding[2], Matthew Northgraves[2], Jared Palmer[1], Amar Rangan[2,9], Gerry Richardson[3], Nicholas Taub[10], Garry Tew[11,2], John Thompson[10], David Torgerson[2] on behalf of the SWIFFT Collaborators

[1] University Hospitals of Leicester NHS Trust, Gwendolen Road, Leicester, LE5 4PW, UK

[2] ARRC Building, Department of Health Sciences, University of York, York, Y010 5DD, UK

[3] Centre for Health Economics, University of York, York, Y010 5DD, UK

[4] School of Medicine, University of Nottingham, Queen's Medical Centre, Nottingham, NG7 2UH

[5] Queen Elizabeth Hospital Birmingham, University Hospital Birmingham NHS Trust, Mindelsohn Way, Edgbaston Birmingham B15 2WB

[6] NDORMS, University of Oxford, The Kadoorie Centre, John Radcliffe Hospital, Oxford, OX3 9DU, UK

[7] Department of Orthopaedic Surgery, Bolton NHS Foundation Trust, Royal Bolton Hospital, Minerva Road, Bolton, BL4 0JR

[8] Area 4, Seebohm Rowntree Building, Department of Health Sciences, University of York, York, YO10 5DD, UK

[9] NDORMS, University of Oxford, OX3 7LD, UK

[10] Department of Health Sciences, University of Leicester, George Davies Centre, University Road, Leicester LE1 7RH

[11] Department of Sport, Exercise and Rehabilitation, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom.

Corresponding author: Dr Stephen Brealey

Contact details: 01904 321357 stephen.brealey@york.ac.uk

Competing interests: M Costa is a member of the General Board for the HTA programme. M Costa 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. C Hewitt is a member of the NIHR HTA commissioning board. A Rangan'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.

Abstract

Background: Scaphoid fractures account for 90% of all carpal fractures and occur predominantly in young men. Despite insufficient evidence of its effectiveness, there has been an increase in immediate surgical fixation of this fracture.

Objective: To compare clinical and cost-effectiveness of surgical fixation with cast treatment and early fixation of those that fail to unite for scaphoid waist fractures in adults.

Design: Multicentre, pragmatic, open-label, parallel two-arm randomised controlled trial using a remote randomisation service with an economic evaluation and nested qualitative study.

Setting: Orthopaedic departments of 31 hospitals in England and Wales recruited from July 2013 with final follow-up in September 2017.

Participants: Adults (aged ≥ 16 years), presenting within two weeks of injury with a clear, unequivocal bicortical fracture of the scaphoid waist seen on (scaphoid series) plain radiographs.

Interventions: Early surgical fixation using standard CE marked headless compression screws. Below elbow cast immobilisation for six to ten weeks, and urgent fixation of confirmed non-union.

Main outcome measures: The primary outcome and end-point was the Patient Rated Wrist Evaluation (PRWE) total score at 52 weeks, with a clinically relevant difference of six points. Secondary outcomes included PRWE pain and function subscales, Short Form 12-item questionnaire (SF-12), bone union, range of movement and grip strength, complications and return to work and unpaid recreational activities. Resource use and the EuroQol (EQ-5D-3L) were collected for the health economic evaluation.

Results: The mean age of the 439 participants was 33 years, 363 were male (83%) and 269 had an undisplaced fracture (61%). The primary analysis was on the 408 participants providing valid PRWE outcome data for at least one post-randomisation time-point (surgery n=203 of 219, 93%; cast n=205 of 220, 93%) using the principles of intention-to-treat (participants analysed in the group to which they were originally randomised regardless of non-adherence to their allocated treatment). There was no clinically relevant difference in the total PRWE at 52 weeks: cast group mean 14.0 [95% confidence interval (CI) 11.3 to 16.6] and surgery group mean 11.9 (95% CI 9.2 to 14.5); adjusted mean difference of -2.1 in favour of surgery (95% CI -5.8 to 1.6, p=0.27). Non-union rate was low in both groups (surgery group n=1, 0.5%; plaster cast group n=4, 1.8%) and 73 patients need to be offered surgery over cast, to prevent one extra non- union at 52 weeks. Eight participants in the surgery group had 11 re-operations, and one participant in the cast group required a re-operation for non-union. The base-case economic analysis at 52 weeks showed that the cost of surgical intervention was £1,295 more per patient (95% CI £1,084 to £1,504) than that of cast treatment. Quality of life differences were not significant. The base-case analysis of a lifetime extrapolated model confirmed that the initial use of cast with immediate fixation of non-unions was the most cost-effective option. The nested qualitative study identified patients desire to have a "sense of recovering" which surgeons should address at the outset.

Limitation: The control treatment pathway was initial cast treatment with early confirmation of non-union and early fixation of un-united fractures. Of 17 participants who had surgery for confirmed non-union, 14 had it within six months from randomisation and three were treated after six months. Three of four participants in the plaster cast group, who had a non-union at 52 weeks, had not been offered surgery.

Conclusions: Adult patients with an undisplaced or minimally displaced scaphoid waist fracture should have the wrist immobilised in cast and all suspected non-unions immediately investigated and those confirmed urgently fixed.

Future work: Patients will be followed-up at five years to include an investigation of the outcome of the partial union of the fracture and the consequences of degenerative arthritis,

malunion and screw problems on their quality of life. This long-term follow-up will further inform the areas of uncertainty in the extrapolated model.

Trial registration: ISRCTN67901257

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List of abbreviations

A&E	Accident and Emergency
AE	Adverse Event
AIC	Akaike's Information Criterion
AVN	Avascular Necrosis
BSSH	British Society for Surgery of the Hand
CACE	Complier Average Causal Effect
CE	Conformity European
CEAC	Cost-Effectiveness Acceptability Curve
CI	Confidence Interval/ Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRPS	Chronic Regional Pain Syndrome
CT	Computed Tomography
DASH	Disabilities of the Arm, Shoulder and Hand questionnaire
DMC	Data Monitoring Committee
EQ-5D	EuroQol 5 Dimensions
EVPI	Expected Value of Perfect Information
GP	General Practitioner
HES	Hospital Episode Statistics
HRQoL	Health Related Quality of Life
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
IQR	Interquartile Range
ITT	Intention-To-Treat
IV	Instrumental Variable
MAR	Missing At Random
MCS	Mental Component Summary

MI	Multiple Imputation
MPR	Multiplanar Reconstruction
MRI	Magnetic Resonance Imaging
NHB	Net Health Benefit
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NNT	Number Needed to Treat
OA	Osteoarthritis
ONS	Office for National Statistics
OR	Odds Ratio
PACS	Picture Archiving Communication System
PCS	Physical Component Summary
PEM	Patient Evaluation Measure
PI	Principal Investigator
PP	Per Protocol
PRWE	Patient Rated Wrist Evaluation
PSA	Probabilistic Sensitivity Analyses
PSS	Personal Social Services
QALY	Quality Adjusted Life Years
QOL	Quality of Life
QQ	Quantile-Quantile
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RSJ	Radio-Scaphoid joint
SAE	Serious Adverse Event
SD	Standard Deviation
SF-12	Short Form 12-Item Questionnaire
SNAC	Scaphoid Non-union Advanced Collapse

SQL	Structured Query Language
STJ	Scapho-Trapezium Joint
TMG	Trial Management Group
TSC	Trial Steering Committee
UHL	University of Hospital Leicester
UK	United Kingdom
YTU	York Trials Unit

Plain English Summary

Fracture of the scaphoid bone (one of eight small bones in the wrist) is common in young active people, caused by a fall on the hand or the hand being suddenly forced backward. The usual treatment is to rest the wrist in a plaster cast for six to ten weeks and allow the broken bone to heal. In one in ten cases treated in a plaster cast, the bone does not heal and an operation is needed. In the operation, the broken bone is held still with a screw. In the last few years, it has become more common to fix the broken bone with a screw in the first few days after injury, instead of resting the wrist in plaster cast. It is not clear if fixing the bone early with a screw compared with resting the wrist in a cast gives better outcomes for patients and if one treatment gives more value for money to the National Health Service (NHS).

In this study, 439 adult patients agreed to either have surgery to hold the broken scaphoid with a special screw or to have the wrist held still in a plaster cast (with surgery offered after six weeks to those that are still not healed). The decision about which treatment to use was made using randomisation, which is similar to tossing a coin. Patients reported their own wrist pain and function at six, 12, 26 and 52 weeks. Information was also collected on general health, bone healing, grip strength and range of movement, complications from treatment and costs.

No important differences were found in patients' wrist pain and function at 52 weeks. The bone did not heal properly in four patients in the surgery group compared with nine patients in the plaster cast group at 52 weeks. For one of these patients in the surgery group and four in the plaster cast group, the bone did not join at all. There were eight patients in the surgery group who had further surgery following their initial operation to fix their wrist, and one patient in the cast group who required repeated surgery because their bone did not join at all. The overall cost of treating with a plaster cast was cheaper than early surgery. The preferred treatment, therefore, is to use plaster cast initially and immediately fix the bone with a screw if it doesn't heal.

Scientific Summary

Background

Scaphoid fractures account for 90% of all carpal fractures, and occur predominantly in young, active men. Typically, the scaphoid fractures 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 fractures (64%) affect the waist of the scaphoid. Despite insufficient evidence, there is an increasing trend to immediately surgically fix this fracture rather than immobilise the wrist in a cast and then only fix those that fail to unite.

Objectives

The objective was to evaluate the clinical and cost-effectiveness of surgical fixation compared with cast treatment (with early fixation of those that fail to unite) of scaphoid waist fractures in adults. There was also a qualitative study to explore the patient experience of fracture and its treatment, and to investigate attitudes towards, and experiences of, participating in a surgical clinical trial.

Design

The Scaphoid Waist Internal Fixation for Fractures Trial (SWIFFT) was a multicentre, pragmatic, open-label, parallel two-arm randomised controlled trial (RCT) with an economic evaluation (within-trial and extrapolated analysis) and nested qualitative study. Patients were randomised on an equal basis to receive either of the two treatment options via a remote randomisation service. Randomisation was stratified by the presence or lack of displacement of the fracture. This was defined as a step or gap 1 to 2mm inclusive, as seen on any radiographic view. Random block sizes of six and twelve were used. Follow-up was at six, 12, 26 and 52 weeks. Data collection included imaging [radiographs and Computed Tomography (CT) scan] at baseline, six, 12 and 52 weeks. Hospital forms and participant questionnaires were also used to collect data. There was no blinding of outcome assessment.

The economic evaluation assessed the relative cost-effectiveness of surgical fixation compared with cast treatment using costs and outcomes collected over 52 weeks. The costs

and outcomes were extrapolated and modelled over the lifetimes of a patient cohort due to the potential long-term future burden of osteoarthritis and other adverse events. This model permitted the inclusion of additional treatment pathways and analyses of a number of relevant scenarios to explore the key drivers of cost-effectiveness that warrant extra focus and future research.

The nested qualitative study used purposive sampling of those SWIFFT trial participants who indicated a willingness to be interviewed within six weeks of randomisation and at 52 weeks (n=30). Both men and women, experiencing different treatments, of different ages and occupations were purposively selected. Patients who declined to participate in the trial were also purposively selected to be interviewed (n=10). All interviews were semi-structured and where possible undertaken face-to-face at a time and location convenient to the participant.

Setting

Trial recruitment was undertaken from the orthopaedic departments of 30 National Health Service (NHS) hospitals in England and one hospital in Wales. Patients were recruited from fracture clinics from 23rd July 2013 until 26th July 2016.

Participants

Adults (aged ≥ 16 years), presenting at a participating site within two weeks of their injury, for which surgery could be undertaken within two weeks of presentation to the NHS, and with a clear, unequivocal bicortical fracture of the scaphoid waist seen on a scaphoid series of plain radiographs were considered for inclusion. Patients were excluded from the trial if: their fracture had >2mm displacement as these are likely to be unstable and require surgical intervention; they had a concurrent wrist fracture in the opposite limb; they had a trans-scaphoid perilunate dislocation; they had multiple injuries in the same limb; they lacked mental capacity to comply with treatment or data collection; they were pregnant since radiation exposure would be contraindicated; or they were not resident in the trauma catchment area of a participating site to allow follow-up.

Interventions

Early percutaneous or open surgical fixation using standard CE marked headless compression screws. The choice of implant was the surgeon's decision. To avoid learning curve problems, surgeons used techniques with which they were fully familiar. The comparator was below elbow cast immobilisation for six to ten weeks, with or without inclusion of the thumb and urgent fixation performed when non-union was confirmed. All participants randomised into the two groups received standardised written physiotherapy advice, detailing the exercises they needed to perform for rehabilitation following their injury.

Main outcome measures

The primary outcome and end-point was the Patient Rated Wrist Evaluation (PRWE) total score (scale 0-100, with lower scores indicating a better outcome) at 52 weeks. It was also completed at six, 12 and 26 weeks. The trial was powered to detect a clinically relevant difference in the PRWE of six points assuming a standard deviation of 20 (equivalent to an effect size of 0.3) at 52 weeks.

Secondary outcomes were the subscale scores of pain and function of the PRWE; Short Form 12-item questionnaire (SF-12) physical and mental component summary scores (PCS and MCS); bone union; range of movement and grip strength; complications; return to work and unpaid recreational activities; and the resource use and the EuroQol (EQ-5D-3L) were collected, and a literature review performed, to inform the health economic evaluation.

All patient-reported outcomes (i.e. PRWE, SF-12, EQ-5D-3L, return to work and unpaid recreational activities) were collected by post, in hospital clinic, or occasionally over the telephone, at six, 12, 26 and 52 weeks. Bone union was assessed on radiographs at six, 12 and 52 weeks and CT scans at 52 weeks. The other outcomes (i.e. range of movement and grip strength and complications) were collected in routine hospital clinics at six and 12 weeks, and additionally at 52 weeks.

Statistical analysis

Analyses were conducted using the principles of intention-to-treat (ITT), analysing participants in the groups to which they were originally randomised, using two-sided statistical tests assessed at the 5% significance level.

The primary outcome (total PRWE scores) were compared between the two groups using a covariance pattern, mixed-effect linear regression model incorporating all post-randomisation time points. Treatment group, time point, a treatment-by-time interaction, participant age at randomisation, baseline fracture displacement and dominance of injured hand were included as fixed effects, and participant as a random effect (to account for the repeated observations per participant). This analysis included any participant with valid PRWE outcome data for at least one post-randomisation time point. It therefore does not include the small number of participants who provided no post-randomisation PRWE data. An estimate of the difference between treatment groups in total PRWE score was extracted for each time point, and overall, with a 95% confidence interval (CI) and p-value. The treatment effect estimate for the 52 week time point served as the primary outcome. The treatment effects for the six, 12 and 26 week time points, and the overall effect, served as secondary outcomes.

Sensitivity analyses were specified a priori to explore the effect of the following: missing data (using multiple imputation by chained equations); handling multi-site data (including site as a random effect [within which participants were nested] in the model as described for the analyses of the primary outcome); timing of data collection by repeating the analysis of the primary outcome only including data collected within agreed timeframes around each time point; exploring the effect on the primary analysis of separately excluding participants who three raters agreed on the baseline images that (i) there was no fracture or (ii) displacement of the fracture was greater than 2mm; and complier average causal effect (CACE) analysis to explore the effect of non-compliance. Current smoking status (yes/no) was included as a covariate in the primary analysis model in a post-hoc sensitivity check to adjust for a chance imbalance at baseline. In total, three subgroup analyses were undertaken: one exploring patient treatment preferences as expressed at baseline; and two exploring baseline fracture displacement.

The secondary outcomes of pain and function subscales of the PRWE; PCS and MCS of the SF-12; and grip strength were summarised descriptively for each time point by treatment group and overall, and were analysed using the same method as the primary outcome adjusting for the same covariates. Extent of union was presented at six, 12 and 52 weeks by trial arm. Regression methods were used to analyse the union data only at 52 weeks dichotomising participants as 'probably need surgery' and 'probably don't need surgery' and also using the repeated measures of dichotomised union at six, 12 and 52 weeks. Rates of malunion (based on ratio of the scaphoid height to length at thresholds of 0.6 and 0.7) were presented overall and for each treatment group at six, 12 and 52 weeks. Complications that were defined as medical, surgical or plaster cast were presented for each treatment group at six, 12 and 52 weeks using only data collected at the hospital but not the data on complications identified elsewhere. Logistic regression that adjusted for age, hand dominance and fracture displacement was used to analyse the data for participants who had at least one of these complications over 52 weeks. This analysis did not address the severity of the complication nor all the complications identified elsewhere. All serious and non-serious adverse events and complications noted on review of imaging were summarised by treatment group.

Economic analysis

The perspective of the economic analysis was that of the United Kingdom (UK) NHS and Personal Social Services. For the within-trial-analysis, the EQ-5D-3L was collected from patient questionnaires to permit the estimation of quality-adjusted-life-years (QALYs) for each patient for the 52 weeks of the trial. The resource use data, collected from patient questionnaires and hospital forms, were used to estimate costs that were expressed in UK pounds sterling at 2017 prices. Differences in mean costs and QALYs at 52 weeks were used to estimate the incremental cost-effectiveness ratio (ICER) of surgery compared with cast for a "within-trial" analysis. Multiple imputation of missing data was used with an ITT analysis to estimate a base-case ICER, adjusting for the baseline quality of life. The extrapolated analysis used data from a literature review and from the trial to estimate the health and resource use implications beyond the timeframe of the trial for four treatment options: no treatment; cast immobilisation only; cast immobilisation followed by immediate surgery for confirmed non-union; and surgical fixation. This included estimating the ICER and net health benefit (NHB) for the four treatment options, estimating the probability of each strategy as being cost-effective at a given willingness-to-pay threshold using a cost-effectiveness

acceptability curve (CEAC), and a series of scenario analyses to explore the impact of structural uncertainty on the results.

Qualitative analysis

The discursive, exploratory and semi-structured nature of the data led to an inductive, thematic approach to the data analysis. A systematic and structured approach was used, including data familiarisation, theme identification and thematic model generation, to explore the data on its own terms and to prioritise the insight generated therein.

Clinical effectiveness results

Of the 1047 patients who met the inclusion criteria, there were 775 who were eligible, of whom 439 were randomised. The mean age of the trial participants was 33 years, 363 were male (83%) and 269 had an undisplaced fracture (61%). The independent review by three raters of baseline imaging confirmed that only one participant had no fracture.

Of the 219 participants allocated to surgery, 188 (86%) received treatment as allocated. The main operating surgeon was most commonly a consultant (66%), and the consultant was also the most common assisting surgeon when a specialist trainee was the operating surgeon. Of the 220 participants allocated to plaster cast, only six (3%) immediately switched to surgery following randomisation. Of 17 participants in the plaster cast group who had surgery for early identified non-union in the plaster cast group, 14 had it within six months from randomisation and three were treated after six months. Three of the four participants in the plaster cast group who had identified non-union at 52 weeks had not been offered surgery during the 52 week follow-up.

The primary analysis was on the 408 participants providing valid PRWE outcome data for at least one post-randomisation time-point (surgery n=203 of 219, 93%; cast n=205 of 220, 93%) using the principles of intention-to-treat (participants analysed in the group to which they were originally randomised regardless of non-adherence to their allocated treatment). There was no clinically relevant difference in the total PRWE at 52 weeks: cast group mean 14.0 (95% confidence interval [CI] 11.3 to 16.6) and surgery group mean 11.9 (95% CI 9.2 to

14.5); adjusted mean difference of -2.1 in favour of surgery (95% CI -5.8 to 1.6, p=0.27). CACE analysis, to take into account non-compliance, found at 52 weeks an increased difference in favour of surgery in the total PRWE of -3.1 (95% CI -7.3 to 1.1, p=0.15). The adjusted mean difference in total PRWE at 6 weeks in favour of surgery was -4.2 (95% CI -8.5 to 0.1, p=0.06), at 12 weeks was -5.6 (95% CI -9.8 to -1.4, p=0.01), at 26 weeks was -0.3 (95% CI -4.1 to 3.6, p=0.89) and overall was -3.0 (95% CI -6.3 to 0.3, p=0.07). The sensitivity analyses that have been described produced similar results on the total PRWE to the primary analysis. This included the post-hoc sensitivity analysis that adjusted for smoking status. No significant interaction was observed between randomised allocation and treatment preference nor fracture displacement on the total PRWE.

For secondary outcomes, the adjusted mean difference at 52 weeks in favour of surgery in PRWE pain subscale was -1.1 (95% CI -3.3 to 1.0, p=0.31) and for the function subscale was -1.0 (95% CI -2.6 to 0.7, p=0.25). For the SF-12 MCS at 52 weeks, the adjusted mean difference was -1.2 points (95% CI -3.3 to 0.8, p=0.24) favouring the plaster cast group. In PCS was 1.6 (95% CI 0.2 to 3.1, p=0.03) favouring the surgery group, although there was no statistically significant difference at 6 or 26 weeks. There was little difference in range of movement at 52 weeks between the two groups, or in adjusted mean grip strength. The rate of non-union in both groups was low. Participants in the surgery group (4 of 219, 1.8%) compared with plaster cast (9 of 220, 4.1%), were less likely to have non- or only slight union of their fracture at 52 weeks (i.e. probably need surgery vs probably don't need surgery), but this difference was not statistically significant. Based on these figures, 44 patients would need to be offered surgery over cast, to prevent one extra non or slight union at 52 weeks. At 52 weeks, using the 0.7 threshold of the ratio of scaphoid height to length, malunion increased between baseline and 52 weeks on CT scans and was similar (3.2%) in the two groups. The rate of screws penetrating the neighbouring joint of 1 mm or more was unexpectedly high (36.2%, 68/188 who had initial surgery). There were eight participants in the surgery group who had 11 re-operations, and one participant in the cast group required a re-operation for a non-union. There were no intra-operative complications. Surgical complications occurred in 14.2% in the surgery group and 1.4% of the plaster cast group. Cast issues, usually minor, occurred in 2.7% and 20.5% respectively. There were inconsistencies in reporting complications between the complication and adverse event form. Plaster cast softening or breaking and symptoms of non-union were described as "adverse

events". At least one non-serious "adverse event" was reported for 24 (11.0%) participants in the surgery group and 29 (13.2%) in the plaster cast group. All three serious adverse events were in the surgery group. Further complications were also identified on review of the imaging. One patient in the surgery group required partial wrist fusion for surgery related complications.

Cost-effectiveness results

The base-case economic analysis showed that, at 52 weeks, the cost of initial surgical intervention was, on average, £1,295 more per patient (95% CI £1,0084 to £1,504) than the cost of cast immobilisation with surgery for non-union. Surgery was slightly more beneficial in terms of utilities, but this difference was not significant. The cost per QALY for surgery compared to cast immobilisation with early fixation of confirmed non-union was £81,962.

The economic evaluation base-case analysis of the extrapolated long-term model established that the initial use of cast with immediate fixation of confirmed non-union was the most cost-effective option over the discounted lifetime of the patient, with a 61% probability of being cost-effective at the willingness-to-pay threshold of £20,000/QALY. The NHB at this threshold was also the highest at 19.02. This was followed by primary surgical fixation, the use of a cast without a surgical option, and finally no treatment.

Qualitative study findings

The nested qualitative study identified that how a patient understands their scaphoid fracture and perceives their own "sense of recovering" was important in their assessment of treatment success. Notably, the act of plaster cast removal was an important threshold in a patient's sense of returning to normal. A broadly positive attitude towards surgery amongst those interviewed, reflected the finding at baseline that when consenting participants did have a preference for treatment it was predominantly in favour of surgery. This may have been a consequence of participants' concerns about the duration of immobilisation in plaster cast and the uncertainty (however small) of the need for further treatment.

Conclusions

Among adults with a waist scaphoid fracture that is undisplaced or minimally displaced, the clinical and cost-effective strategy is that patients should be immobilised in cast, all suspected non-unions immediately investigated and those confirmed urgently fixed. Surgeons should address, at the outset, patients' desire to have a "sense of recovering".

Recommendation for future research

The planned five-year follow-up of trial participants will help explore the outcomes of participants with a partial union of the scaphoid fracture, and the impact of the progression of degenerative arthritis, malunion and screw problems (mal-position and penetration within joints) on quality of life. This will further inform the areas of uncertainty in the extrapolated model.

Trial registration

ISRCTN67901257

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Chapter 1 Introduction

Scaphoid fracture accounts for 90% of all carpal fractures[1] and 2-7% of all fractures.[2] It is an important public health problem as it predominantly affects young active individuals (mean age 29 years)[3] in their most productive working years.

The scaphoid fractures typically 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 fractures (64%) affect the waist of the scaphoid but 5% affect the proximal pole (proximal 20% of the scaphoid) and around 13.3 % involve the distal part of the scaphoid. The tuberosity fractures in 18.1%. Figure 1 illustrates this.

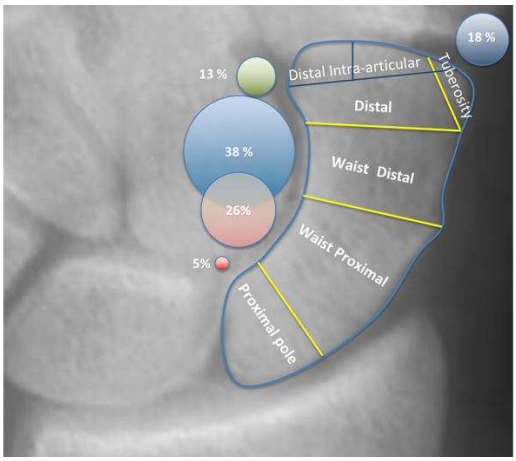


Figure 1: Locations of scaphoid fractures
This shows the location of the scaphoid fracture and the proportions reported.[4] Non-tuberosity fractures account for 81.9% of all scaphoid fractures and 78.2% of these involve the waist.

The scaphoid, lunate and triquetrum form the proximal carpal row attached to each other by ligaments. These bones are subject to loads when the muscles whose tendons cross the wrist bones contract. This row acts together like a helix. When the scaphoid flexes under load, the

triquetrum extends so the middle section, the lunate, remains in a neutral and stable position.[5, 6]

A fracture of the scaphoid breaks this helix so now the two parts rotate; the distal scaphoid fragment flexing under load while the remainder of the proximal carpal helix extends. The proximal carpal row can no longer stabilise the distal carpal row, and hence the wrist. The resulting abnormal loading between the distal part of the broken scaphoid and the distal radius leads to cartilage degeneration and arthritis, while the proximal part extends causing carpal collapse. This pattern after failure of union is called the SNAC (Scaphoid Non-union Advanced Collapse) wrist.[7]

Scaphoid fractures disrupt the proximal carpal row and alter the complex mechanics of this row thereby altering how the wrist is stabilised to permit the hand and digits to function efficiently.

About 88-90% of these fractures unite when treated initially in a plaster cast. However, 10-12% of the scaphoid fractures treated with plaster cast do not unite, with a higher incidence (14-50%) in displaced fractures.[8-10] The retrograde intra-osseous circulation[11] jeopardises the blood circulation, particularly in the proximal scaphoid and may explain the higher failure of union in proximal fractures. Non-union if untreated almost inevitably leads to arthritis, especially in the radio-scaphoid joint, usually within five years.[12, 13] This disables patients at a very young age.

Diagnosis of the fracture is usually confirmed in emergency departments on radiographs of the scaphoid taken in different projections and it is usual to obtain a “scaphoid series of radiographs” which include a posterior-anterior, lateral and 45-degree supination and pronation views, as shown in Figure 2. In addition, an elongated view of the scaphoid is obtained to avoid missing fractures which may be obscured due to the palmar and radial inclination of the scaphoid. It is possible to have an incomplete fracture of the scaphoid and these usually heal un-eventfully[14]. However, clear and bicortical fractures cause clinical concern as these are more likely to be unstable.

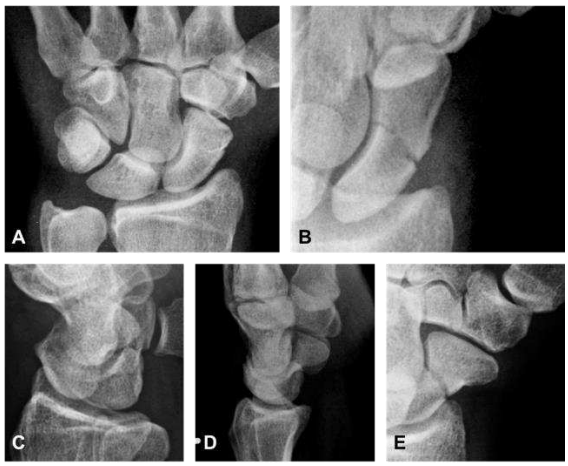


Figure 2: Five radiographic views of the scaphoid

Figure 2 shows the five radiographic views. A. Posterior anterior view – the fracture is just visible. B. Elongated scaphoid view. The fracture is "clear" and "bicortical". Also, the gap could be over 1 mm and the radial margin shows a small step. C is the semi-supine oblique view. D. On the lateral view alignment can be assessed. E. The semi-prone view also shows the fracture and suggests displacement.

Treatments

Getting the fracture to heal restores the integrity of the proximal carpal row and thereby the stability of the wrist. This stability restores hand function, reduces the feeling of weakness and significantly reduces the risk of carpal collapse and the resulting arthritis[15] (Scaphoid Non-union Advanced Collapse SNAC).

The aim of treatment is to immobilise the fracture as the physiological processes of healing occur. The immobilisation of the fracture fragments relative to one another can be done in various ways. Movement between fracture fragments can be constrained by immobilising the injured wrist in a cast or by surgically introducing a screw across the fracture.

Fixation

Immediate surgical fixation may avoid the need to immobilise the wrist in a cast and could accelerate return to function, work and sport[16] but requires the person to have an operation and be exposed to surgical risks. The fracture is fixed with a standard CE marked headless screw generating compression at the fracture site but avoiding the pressure effects of the screw head on articular cartilage. This can be done either percutaneously or open.[17-19] The surgical techniques are well described and are now standard.[20-22] These screws have not changed during the recruitment period for this study. Some surgeons use splintage for the first few weeks after surgery.

Cast treatment

The usual treatment is immobilisation in a below elbow cast for 6-10 weeks, followed by mobilisation. The type of below elbow cast used does not affect union rate.[8] The 10- 12% patients who develop non-union seen on radiographs and/or CT scan, usually have urgent surgical fixation. This is the current standard non-operative pathway.[3]

Current evidence

There are eight randomised controlled trials (RCTs)[3, 18, 23-28] reporting on 463 participants with undisplaced or minimally displaced fractures of the scaphoid waist who had either of these two treatments. These RCTs had small sample sizes (range from 25 to 88) and have been systematically reviewed nine times[29-37] and these reviews all commented on the low quality of evidence.

Some studies reported that fracture fixation facilitated earlier restoration of function and return to previous activity level, especially if a cast or splint was not used after fixation, but patients had a higher rate of complications of between 9 and 22 percent although these were usually minor.[3, 18, 25]

It is unclear whether patients who had surgical fixation of undisplaced or minimally displaced scaphoid fractures had better longer-term benefit than those treated in a cast.
The rate of union was similar between surgical and cast treatment with early fixation of those fractures that failed to unite.[3] Another study,[28] reported similar outcomes at 10 years.

Displaced fractures

A scaphoid fracture is considered displaced if there is a step or gap of 1mm or more.[38] Angulation and rotation between fragments are more difficult to assess. A systematic review reported that non-union occurs in around 18% of displaced fractures[39] and that when treated in a cast the relative risk of non-union between undisplaced and displaced fractures is 4.4 (95% confidence interval 2.3-8.7).[39] At present the evidence of treatment of displaced fractures is weak and recommendations are based on case-series.[40] When the displacement is >2mm clinicians consider the fracture so unstable that they usually recommend early reduction and fixation.

Increase in surgical activity

Despite insufficient evidence there is an increasing trend[41] to immediately fix this fracture rather than immobilise in a cast for 6 weeks and only fix those 10% to 12% that fail to unite.[3] This current trend to fix fractures may be attributed to short-term benefits, but concerns remain about the lack of evidence on long-term benefits and additional risks from surgery, such as malunion, infection, implant related problems and avascular necrosis (AVN). Hospital Episode Statistics (HES) for National Health Service (NHS) hospitals in England 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[42] rose very slightly from 37% to 41% from 2007/8 to 2008/9 but then increased sharply to 62% in 2009/10. This trend of increasing intervention rate emphasized the need for this study.

Economic aspects

There is also poor information on the economic aspects[43] of this injury and its treatment. One study used a decision analytical model[43] and utility scores were obtained from 50 medical students. This study concluded that early fixation provided more quality adjusted life years compared to cast treatment and consumed less economic resources. However a different view, from studies of both non-randomised (95 patients) and randomised evidence (52 patients), is that cast treatment is economically less costly, has also been suggested[44, 45] based on comparison of direct and indirect costs in patients who had their fracture treated in a cast or had it fixed.

What do patients feel and experience?

There is little published on patient experiences and preferences after a scaphoid fracture. Understanding our patient's priorities helps efficient patient-centred clinical decision making. We know little about the patient's experience of their recovery and the impact of the injury and its treatment on them. We also have poor understanding of the issues pertinent to recruiting participants in surgical, clinical trials.[46, 47]

Five-year review

The long-term consequences of cast immobilisation and internal fixation have not been adequately determined in RCTs. The consolidation of partial union of the fracture has not been investigated, nor has progression of carpal mal-alignment or the development of arthritis. Although this report focusses on outcomes at 52 weeks the study will investigate function, impairment and arthritis at five years.[48]

Null hypothesis

There is no difference in the Patient Rated Wrist Evaluation (PRWE)[49] score at 52 weeks follow-up between adults with a scaphoid waist fracture treated with screw fixation versus plaster cast immobilisation and fixation of only those fractures that fail to unite.

Research question

Our aim was to determine the effectiveness and cost-effectiveness of surgical fixation versus plaster cast treatment (with early fixation of 10-12% that fail to unite) of scaphoid waist fractures in adults in an adequately powered multi-centre pragmatic RCT (SWIFFT)[48] and to qualitatively investigate patient experiences of their treatment and participation in the trial.

Research objectives

1	Our primary objective was to determine the effectiveness of surgical fixation versus non-operative plaster cast treatment (with fixation of those that fail to unite, estimated as 10% to 12% of the total) of scaphoid waist fractures in adults. Outcome was assessed using the PRWE[50] (a patient self-reported assessment of wrist pain and function)

at 52 weeks which was the primary end point. The PRWE was also completed at six, 12, 26 weeks and will be completed at five years. The power of the study permitted identification of a clinically meaningful difference of six points in the PRWE.

Our secondary objectives were:

2 To assess radiological union of the fracture at 52 weeks using radiographs and CT scans; recovery of wrist range and strength; return to work and unpaid recreational activities and; complications.

3 To conduct an economic analysis to investigate the cost-effectiveness of surgical fixation versus initial immobilisation in a plaster cast.

4 To qualitatively explore patient experiences of fracture and its treatment; and investigate attitudes towards, and experiences of, participating in a surgical, clinical research trial.

5 To undertake a five-year clinical review of all trial participants to determine the long-term consequences of cast immobilisation and internal fixation.

Chapter 2 Trial design and methods

This chapter describes the trial design and methods to address the objectives about the clinical effectiveness of the healthcare interventions being compared. The methods of the health economic evaluation and the nested qualitative study are described in their respective chapters.

Trial design

This was a multi-centre, stratified (displacement present or not, with equal allocation [1:1]), parallel-group design conducted in England and Wales of patients aged 16 years or over with a clear bi-cortical fracture of the scaphoid waist as seen on plain radiographs. Patients were randomly assigned to either immediate surgical fixation or initial non-operative wrist immobilisation in a below elbow cast with later surgical fixation of only those fractures that failed to unite.

Participants

The diagnosis of fracture was on standard radiographic views available at each hospital i.e. posterior-anterior, lateral, semi 45° prone, semi 45°supine and an elongated scaphoid view e.g. Ziter.[51] If these radiographic views were not taken routinely at a participating site, we sought to obtain them after the patient had consented into the trial to confirm eligibility before randomisation.

A research Computerised Tomogram (CT) scan was also taken at baseline to compare with the CT scan at 52 weeks for the bone union assessment. The baseline CT scan was taken within two weeks of the patient's injury (i.e. before randomisation) or if that was not feasible, before surgery if the patient was allocated to surgery. It was decided that although eligibility assessment should be based on the radiographic views, because a baseline CT scan was available it was necessary for a member of the radiology team to confirm whether a fracture was visible or not. If the baseline CT scan was viewed before randomisation, and a member of the radiology team could not confirm to the participating site staff that there was a clear bicortical fracture of the scaphoid waist, the surgeon would decide whether to continue to recruit the patient. This was to prevent the potential for an immediate crossover to plaster cast if the surgeon thought there was a not a sufficiently visible fracture to operate on. If this happened after randomisation, the patient remained in the trial because there was a fracture

on the series of radiographic views. This could, however, influence the surgeon's decision to continue to operate on the patient when allocated to surgery i.e. could lead to a cross-over.

Inclusion criteria

Patients were eligible for the trial if they:

- were skeletally mature and aged 16 years or older
- presented at a participating site within two weeks of their injury and within which time it was feasible to have surgery
- had a clear, unequivocal bicortical fracture of the scaphoid waist seen on a series of plain radiographs of the scaphoid which:

    a) did not involve the proximal pole (proximal fifth of the scaphoid) and

    b) included minimally displaced fractures with less than or equal to 2mm step or gap on any radiographic view.

Exclusion criteria

Patients were excluded from the trial if:

- their fracture had >2mm displacement as these are likely to be unstable and require surgical intervention
- they had a concurrent wrist fracture in the opposite limb
- they had a trans-scaphoid perilunate dislocation
- they had multiple injuries in the same limb
- they lacked mental capacity to comply with treatment or data collection
- they were pregnant because radiation exposure would be contraindicated
- they were not resident in the trauma catchment area of a participating site to allow follow-up.

Setting

The trial recruited from the orthopaedic departments of 30 National Health Service hospitals in England and one hospital in Wales. There were three additional hospitals in England that screened for patients but did not recruit to the trial. Recruitment started in July 2013 and final follow-up was in September 2017. All 34 participating Trusts have been listed (*see Appendix 1*).

Interventions

Cast treatment followed by surgical fixation if there is confirmed non-union

Control treatment was non-operative with wrist immobilisation in a below elbow cast for six to ten weeks, followed by mobilisation. The below elbow cast could include the thumb or not as this does not affect union rate.[8] Early CT was obtained if plain radiographs at six to twelve weeks raised the suspicion of non-union. If non-union was confirmed on radiographs and/or CT scan, urgent surgical fixation was expected to be performed and was encouraged by the trial team who monitored this with the completion of the Six and Twelve Week Treatment Confirmation Forms (see *Supplementary File 1 and 2*). The surgical procedure to treat a non-union and post-operative care was similar to the surgical arm of this trial. Cast immobilisation, identification and confirmation of non-union at 6 to 12 weeks and immediate surgical fixation of confirmed non-union is the current standard non-operative pathway.[3]

Surgical fixation

Surgical treatment was by percutaneous or open surgical fixation depending on the surgeon's preferred technique. Standard CE marked headless compression screws[18, 52] were used to avoid the pressure effects of the screw head on articular cartilage. These are standard surgical techniques.[20-22] The type of implant used was not restricted but the screw used was recorded (see *Supplementary File 3*). The surgical approach or the postoperative care was not specified but was left to clinical discretion, as it was expected that most surgeons would use some splintage for the first few weeks after surgery. The application of a plaster cast or splint following surgery and its duration was recorded. It was agreed at each recruiting site which surgeons would fix the scaphoid fractures and that surgeons would use techniques with which they were familiar to avoid learning curve problems.

Rehabilitation

All participants randomised into the two groups received standardised, written physiotherapy advice detailing the exercises they needed to perform for rehabilitation following their injury (see *Supplementary File 4*). All participants were advised to move their shoulder, elbow and finger joints fully within the limits of their comfort. Those participants treated in a cast, performed range-of-movement exercises at the wrist as soon as their plaster cast was removed at the six week follow-up appointment when there were no concerns regarding bone union. Those participants who had the fracture fixed began their wrist exercises as soon as

comfort permitted, if they did not have a plaster cast, or as soon as the cast was removed. Any other rehabilitation input beyond the written information sheet (including a formal referral to physiotherapy) was the decision of the treating clinicians. A record of any additional rehabilitation input (reason for referral and number of appointments) was recorded at the 52-week hospital visit.

Outcomes

The outcomes and the time points when various outcomes were assessed are described below.

Primary outcome

The primary outcome and end-point for the trial was the Patient Rated Wrist Evaluation (PRWE) total score at 52 weeks from randomisation. The PRWE was completed at baseline for the time before and after injury, and at six, 12, 26, 52 weeks and will be completed at five years after randomisation. The PRWE is a 15-item questionnaire that is completed by the participant. It is a brief, reliable and valid instrument for assessing wrist pain and disability.[50, 53] Scoring for all the questions is on a ten-point ordered scale, ranging from 'no pain' or 'no difficultly' (0) to 'worst ever pain' or 'unable to do' (10). A total score can be computed on a scale of 0 to 100 (0 = no disability), as well as two non-overlapping subscales (pain and function) which are weighted equally. PRWE was chosen as the primary outcome as patient reported functional outcomes are favoured for decision making and it allows assessment of both wrist pain and function.

Two small RCTs[3, 18] of patients with fractures of the scaphoid have demonstrated that there is little change in objective and subjective outcomes between 26 and 52 weeks. For the 10% to 12% of patients who are treated initially in cast but do not heal, surgery should be performed between six and twelve weeks from randomisation. Therefore, if assessed at 26 weeks this would leave only 14 to 20 weeks for healing and recovery to take place. To allow all patients the time to heal from surgery and to stabilise from any complications, 52 weeks was chosen as the primary end point.

Secondary outcomes

Secondary outcomes were: health-related quality of life; bone union; range of movement and grip strength; return to work and unpaid recreational activities; and complications.

Health related quality of life

PRWE: The total scores at other time points (six, 12, and 26 weeks) as well as the PRWE subscale scores of pain and function were secondary outcomes.

Short Form 12-Item Questionnaire (SF-12): The SF-12 is a 12 item generic patient-reported outcome measure of physical and mental health, the population norms of which have a mean of 50 and standard deviation of 10; higher scores indicate better health.[54] The SF-12 was completed at six, 12, 26 and 52 weeks to measure the potential broader consequences of a scaphoid fracture on both the participants' physical and mental health.

EuroQol (EQ-5D-3L): The EQ-5D is a validated, generic patient-reported outcome measure covering five health domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with three response options to each domain.[55, 56] The use of this non-fracture-specific instrument allows the assessment of health-related quality of life outcomes in the health economic analysis. The EQ-5D has high validity and reliability in proximal humerus fractures[57] and hip fractures.[58] It was completed at baseline, six, 12, 26 and 52 weeks.

Bone Union

The secondary outcome of bone union[59] was determined at 52 weeks (in line with the primary end point). A research CT scan was obtained and a series of plain radiographs undertaken comprising posterior-anterior, lateral, 45° semi-prone, 45° semi-supine views and an elongated scaphoid view e.g. Ziter type view. Routine radiographs were also collected for bone union assessment at six and 12 week hospital clinics.

Union was defined as complete disappearance of the fracture line[8] on radiographs and complete bridging on CT scans[60, 61] from those taken at baseline. Partial union was based on the proportion of the fracture plane traversed by bridging trabeculae on true sagittal and coronal multiplanar reconstructions of the scaphoid on CT. CT was used to determine non-union as there is only poor to moderate inter-observer agreement (range of Kappa from 0.11 to 0.53) when determining the union of a scaphoid fracture on plain radiographs.[62]

Scaphoid fracture displacement was assessed on radiographs and on a CT scan.[63]

Malunion was assessed on the 52 week CT scan,[64] which was defined as the ratio of Scaphoid Height to Length ≥ 0.6 in the true sagittal axis of the scaphoid, to assess any humpback deformity.[65]

A limitation of this assessment of bone union, however, was that the presence of the screw to fix the fracture would unblind the observer as to whether the participant had an operation or not. To minimise the potential for this to introduce bias, two consultant radiologists with a special interest in musculoskeletal radiology and a consultant orthopaedic surgeon (Chief Investigator), interpreted the plain radiographs and CTs independent of each other. All three met to discuss cases where there was discordance in line with rules defined in a Standard Operating Procedure (see *Supplementary File 5*). The two radiologists were both employed at participating hospital sites (Leicester and Birmingham). During the trial they did not report on plain radiographs or CTs of the scaphoid during clinical practice, in an attempt to maintain independence when reporting on imaging of trial participants.

Range of movement and grip strength

The range of movement of both wrists was measured using a goniometer[66] and grip strength of both hands was measured using a calibrated Jamar dynamometer.[67-70] Both were recorded at baseline, six, 12 and 52 weeks (see *Supplementary File 6*). The measurements were performed with the subject seated, arm by the side, elbow bent at 90 degrees and the wrist in neutral position for rotation.[71] Staff were advised to use the second setting on the Jamar dynamometer except for participants with large hands where the third setting was used.[72] The Beighton Joint Laxity Score (excluding the thumb count for the injured wrist) was recorded at baseline to measure hypermobility of joints.[73] These assessments were standardised across participating sites using an instruction sheet (see *Supplementary File 7*).

Return to work and unpaid recreational activities

This was established through participant self-report on the number of days off work and ability to perform usual activities when at work and when performing unpaid recreational activities. This was recorded at six, 12, 26 and 52 week follow-up.

Complications

Expected and unexpected complications were recorded at the six, 12 and 52 week hospital visits (see *Supplementary File 8*). The expected complications included:

- Infection, defined as "Surgical Site Infection".[74]
- Delayed wound healing, defined as any wound that has not healed by two weeks.
- Complex Regional Pain Syndrome (CRPS), defined as puffy painful swelling of the whole hand restricting full tuck of the fingers at two weeks.
- Nerve events (hypoaesthesia or numbness in the territory of the palmar cutaneous branch of the median nerve, superficial division of the radial nerve or the median nerve).
- Vessel events (large (>2 cm) haematoma in the line of the radial artery).
- Screw related complications (protrusion of either end into the adjacent joint, fracture or bending of the screw, a radiolucent halo around any part of the screw >1mm, screw backing out or moving).
- Degenerative change in the adjacent joints.[75]
- Avascular necrosis[76] of the proximal pole of the scaphoid.

In addition, the three raters reviewed the imaging at each time-point for complications. This included assessing the presence or not of osteoarthritis, presence or not of screw penetration, screw lucency (none, <1mm, 1-2mm) and avascular necrosis (no radiodensity, just radio-dense, marked radiodensity on 1 view or one MPR, marked radiodensity on >1 views or MPRs).

Sample size

For surgery to justify its increased costs and the exposure to risk, it must result in greater or quicker improvement in patients' wrist symptoms and function compared with non-operative management. A six point improvement in the PRWE in the surgery group (compared to the controls) was chosen to be a minimally clinical important difference. The standard deviation of PRWE at 52 weeks was taken to be 20 points from the PRWE User manual.[49] This figure was reported for distal radius fracture rather than scaphoid fracture at six months. The only published evidence for scaphoid fracture implies a standard deviation in the range of eight to ten points;[28] however, this estimate was at a median of ten years after

the patient's injury. To be conservative, a standard deviation of 20 was chosen. This gives a standard effect size of 0.3 for the 6 point PRWE difference. A superiority design was used to observe an effect size of 0.3 at 80% power using a two-sided 5% significance level requiring 350 participants in total. After allowing for 20% attrition, the recruitment target was 438 participants (219 surgery and 219 plaster cast). The estimate of attrition was expected to be realistic given that four previous RCTs (three studies were single centre and one study had two centres) of the treatment of scaphoid fractures had reported response rates for completion of patient-reported functional outcomes to be between 77% and 100%.[31]

There were no planned interim analyses for the trial or stopping guidelines. There was, however, an internal pilot study from which the data contributed to the final analyses. The primary reason for the pilot study was to check the assumptions about site set up, patient recruitment and feasibility of the trial. The independent oversight committees reviewed the progress that was made during the internal pilot and recommended that the trial should continue with the planned increase in the number of sites. In the absence of a standard deviation for the primary outcome at 52 weeks, this was estimated from the participants who were recruited into the internal pilot study. This estimate corroborated the standard deviation chosen for the sample size calculation.

Recruitment

A Research Nurse identified potentially eligible patients, referred from Accident and Emergency Departments, or other sources (e.g. walk-in centre, cottage hospital), to fracture clinics. The orthopaedic surgeon confirmed eligibility (see *Supplementary File 9*) and invited the patient to consider joining the study. The Research Nurse or clinician provided the patient with an information sheet (see *Supplementary File 10*) and answered any questions. The patient was asked to consent at that time or was offered up to 48 hours to discuss the study with family or friends before deciding whether to take part or not. When patients gave consent (see *Supplementary File 11*), they were asked to complete a baseline form (see *Supplementary File 12*). The site staff then contacted York Trials Unit (YTU), either by telephone or via the internet, to access the secure randomisation service. For patients who did not consent, a form was completed to record: reasons for non-consent, patient and surgeon treatment preferences, and the agreed treatment plan (see *Supplementary File 13*). Both patients that consented to take part in the trial, using the main trial information sheet (see

Supplementary File 10), and those that did not consent into the trial, using a separate information sheet (see *Supplementary File 14*), were invited to take part in an interview. This is explained further in Chapter 5.

Strategies for achieving adequate participant enrolment to reach the target sample size included seeking advice from a patient focus group, sharing best practice with the Research Nurses at participating sites, and bi-annual discussion with our Principal Investigators (PIs) at the scientific meetings of the British Society for Surgery of the Hand (BSSH). Hospital staff were provided with training about study procedures at the Site Initiation Visits and with a Trial Site Manual. During the trial, training and reminders were implemented using e-mail bulletins, face-to-face meetings with the PI's at BSSH conferences and a training day with Research Nurses. In addition, the Trial Co-ordinators provided support and guidance to staff at participating sites (e.g. when new staff joined or replaced existing site staff) and also sought guidance from the Chief Investigator (CI).

Randomisation

The randomisation sequence was based on a computer-generated randomisation algorithm provided by a remote randomisation service (telephone or online access) at YTU. The unit of randomisation was the individual patient on a 1:1 basis. As the non-union rate for displaced scaphoid fractures is 14% compared with 10% for transverse undisplaced fractures,[8, 10, 39] randomisation was stratified by the presence or not of displacement as assessed by the staff at the recruiting site. Random block sizes of six and twelve were used. Displacement was defined as a step or gap 1mm to 2mm inclusive as seen on any radiographic view. The Research Nurse used the remote randomisation service to register eligible and consenting participants before computer generation of the allocation. The Research Nurse then informed the treating surgeon of the allocation. This ensured treatment concealment and immediate unbiased allocation.

Blinding

As the trial was pragmatic and compared surgery with initial cast treatment, blinding of participants and clinicians to treatment allocation was not possible. When possible, the treating surgeon took no part in the postoperative assessment of participants. The statistician was blind to group allocation until after data were hard locked and no further changes could be made. To minimise bias in the assessment of bone union, all radiographs and CT scans

were assessed independently by two consultant musculoskeletal radiologists and a consultant orthopaedic surgeon (Chief Investigator). Any disagreement was resolved through discussion.

Statistical methods

Analyses were conducted using the principles of intention to treat, including all randomised participants in the groups to which they were allocated, where data were available. Analyses were conducted in Stata v15[77] using two-sided statistical tests assessed at the 5% significance level.

Recruitment

Site and patient recruitment was presented. The characteristics of the population of patients screened, ineligible, and eligible stratified by consent were summarised. The flow of participants through the trial was presented in a Consolidated Standards of Reporting Trials (CONSORT) diagram.

Baseline characteristics of randomised participants

Baseline participant characteristics and fracture details were summarised descriptively overall and by randomised group both as randomised, and 'as analysed' comparing the groups as included in the primary outcome analysis model (i.e., have full data for the baseline covariates and valid PRWE data for at least one post-randomisation time point). No formal statistical comparisons were undertaken on baseline data.

Follow-up

For each time point, the number of participant questionnaires sent and returned, with median (interquartile range [IQR]) days to completion and return was presented by treatment group and overall. The number of questionnaires completed at home, over the telephone or in the hospital was reported. Return rates for hospital forms were tabulated by randomised group and time point.

Hospital visits

Participants were asked to attend for a hospital follow-up visit at six, 12 and 52 weeks post-randomisation. Baseline participant characteristics and fracture details were summarised descriptively overall and by randomised group according to whether participants attended the hospital visit at each time point.

Compliance with random allocation and treatment received

The treatment received by participants in the two groups was summarised, with reasons for treatment crossover.

Primary outcome (Patient Rated Wrist Evaluation) analysis

The PRWE was assessed at baseline (pre and post-injury; prior to randomisation), and at six, 12, 26 and 52 weeks post-randomisation. The PRWE total score is a value between 0 and 100, where a higher score indicates worse pain and functioning. The score is computed by scoring the two subscales out of 50 (Pain: sum of items 1-5; Function: sum of items 6-15 divided by two) and summing them, so that pain and function problems are weighted equally. If there was up to one missing item in each subscale, then the missing item was replaced by the mean of the completed items within that subscale.[78] If two consecutive responses (between 0 and 10) to a particular item were selected then the higher of the two (worse response) was taken for analysis. Other ambiguous responses were treated as missing. If more than one item was missing in either subscale then a score for that subscale, nor for the total, could be calculated.

The number and percentage of participants with valid and partial PRWE data was reported by randomised group and time point. Baseline participant characteristics and fracture details were summarised descriptively overall and by randomised group according to whether participants had valid PRWE outcome data at each post-randomisation time point. Total PRWE scores were summarised by time point according to whether participants had valid data for: i) all post-randomisation time points; ii) at least one, but not all, post-randomisation time points; iii) and no post-randomisation time points. PRWE scores (subscales and total) were summarised descriptively by treatment group and overall.

Total PRWE scores were compared between the two groups using a covariance pattern, mixed-effect linear regression model incorporating all post-randomisation time points. Treatment group, time point, a treatment-by-time interaction, participant age at randomisation, baseline fracture displacement and dominance of injured hand were included as fixed effects, and participant as a random effect (repeated observations per participant). Fracture displacement was used as a stratification factor in the randomisation; however, there were several instances where the wrong displacement category was used in the

randomisation. Such stratification errors were identified when there was a discrepancy between data provided at randomisation and data recorded on the Study Eligibility Form. Where the randomisation data were incorrect a file note was raised and the trial statistician was notified; where the data on the Study Eligibility Form were incorrect this was amended. The displacement used in the randomisation was the variable included in the primary analysis, but the errors were discussed. The primary model was not adjusted for baseline total PRWE as in this young population we expected that the pre-injury PRWE would be low and have little variability, and post-injury PRWE would be confounded as patients would likely be in a plaster cast.

An unstructured covariance pattern for the correlation between the observations for a participant over time was specified in the final model based on Akaike's information criterion (AIC)[79] (smaller value preferred).

An estimate of the difference between treatment groups in total PRWE score was extracted from the repeated measures model for each time point, and overall, with a 95% confidence interval (CI) and p-value. The primary end point is the treatment effect estimate at 52 weeks. Estimates for the treatment effect at other time points (six, 12 and 26 weeks) and overall serve as secondary outcomes. This repeated measures approach is more efficient and parsimonious than conducting separate linear regressions for each time point, and also allows for the 'overall' (across the whole 52 weeks) effect to be investigated using the same model. The analysis takes advantage of the extra information provided at, and the correlation between, all post-randomisation time points. The standard errors for treatment effects at individual time points are calculated using information from all time points and are hence more robust and accurate than standard errors calculated from separate analyses at each time point. An additional advantage of the mixed model approach is that the presence of missing data across time points does not cause a problem under the assumption that they are missing at random. For the estimates at a single time point, say at 52 weeks, it is primarily the observations at that time point that determine the treatment effect and power; however, owing to the covariance between the post-randomisation time points, greater power and precision is obtained than that from a comparison using only the 52 week data[80].

Model assumptions were checked as follows: the normality of the standardised residuals was checked using a QQ (Quantile Quantile) plot, and homoscedasticity was assessed by means of a scatter plot of the standardised residuals against fitted values.

Sensitivity analyses

Missing data

Any response bias was partially minimised by using a mixed-effect, repeated measures model, which allows the inclusion of intermittent responders in the primary analysis. Multiple imputation by chained equations was also used to handle missing PRWE outcome data. Missing outcome and covariate data was predicted by age, fracture displacement, hand dominance, and available PRWE data at other follow-up time points. A 'burn–in' of 10 was used and 20 imputed datasets were created. Separate linear regressions were then run on the multiply imputed dataset to compare the PRWE between the two groups at six, 12, 26 and 52 weeks, adjusting for age, displacement and dominance of injured wrist. Estimates were combined using Rubin's rules via the *mi estimate* command in Stata[81].

Handling multi-site data

Participants were recruited from multiple sites. To investigate whether site affects the outcome, a sensitivity analysis was conducted including site as a random effect (within which participants were nested) in the model as described for the primary analysis.[82]

Timing of data collection

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

Post-hoc sensitivity analysis including smoking status

Current smoking status (yes/no) was included as a covariate in the primary analysis model in a post-hoc sensitivity check since this factor was found to be imbalanced by chance at baseline between the randomised groups and thought to be associated with healing and complications. The decision to conduct this sensitivity analysis was taken after the primary analysis results were known and was not pre-specified in the statistical analysis plan.

Displacement and lack of fracture as 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 reported. The primary analysis model was rerun including a variable indicating the level of displacement judged by the three raters instead of that randomised on.

The number of cases are reported where consensus was reached between the three raters that (i) there was no fracture, or (ii) displacement of the fracture was greater than 2 mm, based on their assessment of the baseline radiographs/CT scans, since these were exclusion criteria. Separate sensitivity analyses of the primary outcome model were conducted excluding these patients.

Complier average causal effect (CACE) analysis

To account for non-compliance (surgery to plaster cast) and contamination (plaster cast to surgery) a complier average causal effect (CACE) analysis was conducted. A two-stage least squares instrumental variable (IV) approach[83, 84] was used with randomised treatment as the IV (implemented using the *ivregress* command in Stata) to compare PRWE scores at 52 weeks, adjusting for age, fracture displacement, and hand dominance. For this analysis, it was assumed that participants allocated to the plaster cast group have the same probability of non-compliance as those allocated to the surgery group *had they been offered the surgery*; that participants allocated to the surgery group have the same probability of contamination as those allocated to the plaster cast group *had they been offered non-surgical management*; and that being simply offered the allocated treatment has no effect on the outcome. These assumptions were plausible under randomisation which should balance covariates across the two groups.

Subgroup analysis

In total, three subgroup analyses were undertaken: one exploring patient treatment preferences as expressed at baseline; and two exploring fracture displacement. Due to the errors in classification of fracture displacement at randomisation, two approaches for the

displacement subgroup analysis were taken: one using displacement as defined at randomisation; and one using the classification given on the Study Eligibility Forms. Total PRWE scores are summarised by randomised group and time point, stratified by the levels of the baseline factor of interest. To investigate whether the treatment effect varied across the levels of these baseline factors the factor was included in the primary analysis model alongside an interaction between randomised treatment allocation and baseline factor, using a two-sided p-value of 0.05. Interpretation of these models was made cautiously, since the trial was not powered for interactions.[85, 86]

Descriptive summaries of baseline participant and fracture data, and PRWE scores are presented for:

- participants in the plaster cast arm stratified by whether or not they needed surgery due to non-union; and
- participants in the surgery arm stratified by whether or not the surgical screw used was too long and caused cartilage damage as determined on the CT scans by the three independent raters.

There were two feasibility requirements for this trial: (i) that a CT scan was performed within two weeks of a patient's injury (or before surgery if this occurred earlier); and (ii) that for patients in the surgery arm, surgery was performed within two weeks from presentation to A&E or other clinic. It was considered a protocol deviation if these tasks were performed outside of these parameters. A linear regression for the surgery arm only investigated whether time from injury to surgery in days is predictive of total PRWE score at 52 weeks, adjusted for age, fracture displacement and hand dominance. Descriptive summaries of baseline participant and fracture data, and PRWE scores are presented for:

- participants stratified by whether or not their CT scan was performed within two weeks of a patient's injury (or before surgery if this occurred earlier); and
- participants in the surgery arm stratified by whether or not their surgery was performed outside the target two-week period from first presenting at A&E or other clinic.

Secondary analysis

Secondary outcomes

The secondary outcomes of pain and function subscales of the PRWE; physical and mental health component summaries of the SF-12; and grip strength were summarised descriptively for each time point by treatment group and overall, and were analysed using the same method as the primary outcome adjusting for the same covariates. The most appropriate choice of covariance structure was identified separately for use with each outcome, which was always an unstructured pattern.

Union

Plain radiographs at six, 12 and 52 weeks and CT images at 52 weeks were reviewed by three independent raters at the end of the trial for union of the fracture. Union, as reviewed on CT images at 52 weeks, was 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 united, and 100% = complete union. The same categories of union were used for radiograph images at six, 12 and 52 weeks. Extent of union was presented for each time point by trial arm. Participants were dichotomised at each time point as 'Probably need surgery' (non- and slight union) and 'Probably don't need surgery' (partial to complete union) and analysed using a logistic regression model (52 week data only). It was originally planned to additionally conduct a mixed-effect logistic regression model to compare the treatment groups at 52 weeks, with participant as a random effect to account for the repeated measures of union at six, 12 and 52 weeks, adjusting for age, displacement and dominance of injured wrist as fixed effects. However, this model did not converge. As an alternative sensitivity check, multiple imputation was used to impute the dichotomised union variables at six, 12 and 52 weeks (imputation included union variables, age, displacement, dominance of injured wrist and allocation). A 'burn–in' of ten was used and 20 imputed datasets were created. A logistic regression was run on the multiply imputed dataset to compare union between the two groups at 52 weeks, adjusting for age, displacement and dominance of injured wrist.

The 52-week PRWE scores for patients overall and who did and did not attend for imaging at 52 weeks was summarised by treatment group.

Malunion

Scaphoid height and length was measured by the three independent raters of the CT and plain radiographs. Malunion was defined using a ratio of scaphoid height to length of greater than 0.6. During the study, literature was published which suggested that a threshold ratio of 0.7 might be more appropriate[87] than 0.6.[64] Rates of malunion at the 0.6 and 0.7 thresholds are presented overall and for each treatment group at six, 12 and 52 weeks.

Complications

Complications were defined as medical, surgical and plaster cast related, and were assessed by clinical examination at six, 12 and 52 weeks. The number of patients who experienced a complication of a certain type was summarised by trial arm. The presence of any medical, surgical or cast complication recorded on the Complication Form up to 52 weeks was analysed by logistic regression, adjusting for age, hand dominance and fracture displacement.

Cases when two out of the three raters agreed on imaging that there was a complication were reported.

Adverse events

All serious and non-serious adverse events were summarised by treatment group.

Agreement analysis

A descriptive analysis of agreement between the three raters was performed. Radiographs provide categorical grades of fracture, displacement and union and these were summarised by cross-tabulating the results from each pair of raters and calculating their percentage agreement. The CTs provide continuous measures of displacement and of the percentage union. Agreement between these continuous measures was summarised in Bland-Altman plots that compare each pair of raters and the limits of agreement were calculated. 95% confidence intervals were provided for all numerical summaries.

Data management

All hospital forms, imaging CDs and participant questionnaires were sent from and returned to YTU. A central database at YTU was used to prompt the sending out and return of participant questionnaires and hospital Case Report Form (CRF). This included automated email reminders to participating sites to help ensure the timely return of hospital CRFs.

Essential trial documentation, which individually and collectively permits evaluation of the conduct of a clinical trial and the quality of the data produced, was kept with the Trial Master File and Investigator Site Files. This documentation will be retained for a minimum of five years after the conclusion of the trial in accordance with Good Clinical Practice. The postal questionnaires and hospital CRFs will be stored for a minimum of five years after the conclusion of the trial as paper records; and a minimum of 20 years in electronic format.[88]

Design of patient questionnaires and hospital CRFs

The patient questionnaires and hospital CRFs were designed using TeleForm software (version 10; Cardiff Software, Cambridge, UK). Specification CRFs were populated with variable names and appropriate scoring. To maximise data quality, when hospital CRFs were returned to YTU, key variables required for the statistical analysis were reviewed for completion and accuracy by a Trial Co-ordinator/Research Data Administrator who resolved any queries with the Research Nurse at the site. The hospital sites were reimbursed according to a payment schedule for the completion of CRFs and provision of research imaging up to a total of £430.30. This was agreed between each trust and trial sponsor using a Clinical Trial Agreement. No checks regarding data quality of the postal questionnaires were made on immediate return to YTU. A Trial Co-ordinator did, however, as a duty of care, check whether a participant responded with the extreme answers to the following: questions 4a, 4b, 6a and 6b of the SF-12; the last EQ-5D question; and checked free text responses for whether the participant could be at harm. When this occurred the PI and RN at the reruiting site were notified by email.

After this initial check, all postal questionnaires and hospital CRFs were prepared for scanning by a Research Data Administrator using the TeleForm software. When a form would not scan, the data were manually entered. When a form was scanned, the data were then verified depending on what TeleForm identifies as requiring correction. The verified data were then temporarily held in the Download Database and available for second

checking. This involved each hard copy of all forms being compared against the entry stored in the Download Database and correcting the electronic data as necessary. All data were scanned, downloaded and second checked in the Validate Database. The automated data validation was undertaken by the Data Manager who applied predetermined rules to check for agreed variables whether the data were recorded correctly. Data that had been validated were then held in the Survey Database and available upon a formal request from the trial statistician and health economist.

Strategies to follow-up patients

Participants at the six, 12, 26 and 52 week follow-ups were notified by post to expect the questionnaire (see *Supplementary File 15*) two weeks before it was due. Reminder letters were sent at two and four weeks after the due letter was sent out. When there was no response to reminder letters, a Trial Co-ordinator at YTU contacted participants by telephone who were invited to answer a minimum of the primary outcome (PRWE) and EQ-5D. At 52 weeks only (the primary time-point for the study), in addition to the six week telephone call, a letter to non-responding participants requested the completion of the PRWE only. At 26 weeks, when participants did not attend a hospital appointment, an unconditional incentive of £5 was included with the postal questionnaire. At 52 weeks, a £40 payment was made to participants who attended the clinic. For the final 11 months of the follow-up period for the study, participants were also offered up to £40 to cover their travel expenses or more if this was agreed with the trial team. The participants could complete the follow-up questionnaires during the clinic visits.

Various techniques were used to minimise loss to follow-up. This included regular participant newsletters which publicised progress about the study at the trial website (http://www.swifft.co.uk/). A trial 'tagline' was placed on postal envelopes to participants to highlight the importance of their involvement in the research i.e. "SWIFFT Study: Patients helping to improve healthcare through research". As the return of postal questionnaires can be improved when participants are included in a prize draw,[89] anyone who returned their questionnaire at 26 weeks could win an iPad worth £500. Participants who attended their hospital clinic appointment at 52 weeks were also entered into a prize draw to win an iPad worth £500. If at 52 weeks it was difficult to arrange the hospital appointment, a letter was sent from the hospital to the participant along with a leaflet to encourage their attendance.

Other strategies to collect follow-up data on participants who did not return their questionnaire or attend clinics included: using a participating hospital's Picture Archiving Communication Systems (PACS) for the local area/region to retrieve imaging of patients; access Summary Care Records to view participants' addresses and/or the General Practitioner they were registered with to help contact them; and ask a participants General Practitioner whether they have had an operation on their scaphoid fracture.

A trial participant could withdraw from the study at any time for any reason but any data collected up to that point was used in the analysis. A participant could withdraw from all data collection, or from postal questionnaire collection or hospital data collection only, which was recorded using a Change in Status Form (see *Supplementary File 16*).

Data management for the review of imaging

The forms used to capture assessments of the scaphoid fracture and conduct measurements on the imaging collected, were created using the 'Design' module in Formic Fusion Software (5.5.1 Build 005, Formic Limited, Middlesex, UK) and include SWIFFT Master Radiograph Form, SWIFFT Baseline CT Form and SWIFFT 52 Week CT Form.

Once completed by reviewers, variables within each form were checked visually for completeness and whether measurements were within an expected range. Completed forms were then scanned using the Formic 'Capture & Process' module and responses were reviewed. The Formic scanning software flagged hand-written text and those checkboxes with no mark or more than one mark; these were manually corrected to reflect the entry on the form. The scanned image of the form was also held within the data to permit independent verification. Once exported to the 'SWIFFT logging database' (Microsoft Access) data then went through a final electronic check to ensure all measurements were within the limits assigned by the Chief Investigator and to check for errors in measurements e.g. cm instead of mm. The data was then checked for these rules in Stata v15[77] and potential problems were flagged and checked by each reviewer.

Data from the three reviewers was assessed and classification conflicts on fracture displacement at baseline and state of union at 52 weeks identified and resolved in "conflict resolution meetings" using specific forms: SWIFFT Conflict CT Form, SWIFFT Conflict

Radiograph Form and SWIFFT 52 Week Inter-Observer Conflict forms which were used when conflicts were resolved. Predefined agreement rules were used to generate the final data based on all three reviewers' assessments.

All conflicts identified were reviewed by all reviewers at face to face/teleconference meetings. All reviewers looked at images together and a collective decision was made and recorded. From the 439 baseline radiographs reviewed, 106 were taken back to a conflict meeting. Of the 431 CT's reviewed at baseline, 155 were taken back to a conflict meeting to agree displacement thresholds. These baseline conflicts were reviewed over 26 meetings between September 2013 and February 2018. At 52 weeks, 297 radiographs were reviewed and 292 CT scans. All radiographs and CT scans at 52 weeks which were classified as a "non-union" by any one reviewer were brought back to the conflict resolution meeting for confirmation. Of both radiographs and CT scans, only 17 were taken back to three conflict meetings to agree the state of union.

Finally, the reviewers also agreed the ones that did not have an identifiable fracture on baseline radiographs (one) and CT scans (five). There were also a total of 52 conflicts identified on the categorical data at baseline. For baseline radiographs, 15 conflicts were identified from the categorical classification of the orientation of the fracture line. These were reviewed by all reviewers and were resolved. For baseline CT's, 37 conflicts were identified involving the fracture line (27) and fracture location (10). All of these were reviewed at a conflict meeting in January 2018 and were all resolved.

Adverse event management

Adverse events (AEs) were defined as any untoward medical occurrence in a trial participant and which did not necessarily have a causal relationship with the treatment. Serious AEs (SAEs) were defined as any untoward medical occurrence that:

- Result in death
- Are Life-threatening
- Require hospitalisation or prolongation of existing inpatient hospitalisation
- Result in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect

- Any other important medical condition which, although not included in the above, may require medical or surgical intervention to prevent one of the outcomes listed.

(S)AEs related to the scaphoid fracture injury and its treatment during the 12 months after randomisation were recorded by site PIs on a CRF (see *Supplementary Files 17 and 18*). SAEs were notified to the trial office within 24 hours of the PI becoming aware of it and AEs within five days. The categorisation of causality and expectedness was confirmed by the CI. AEs that were expected with this injury to the wrist and related to anaesthesia and/or surgery were: infection, CRPS, screw related complications, chondrolysis, delayed wound healing, nerve or vessel events, fracture of scaphoid tuberosity and nausea and/or disorientation. AEs specific to the plaster cast were: soft cast/broken cast that led to movement of the wrist, CRPS, pressure sores, nerve compression or pain due to a tight cast. Movement in a cast was considered untoward as it could mean the fracture was not properly immobilised and could result in failure to unite.

All (S)AEs were routinely reported to the Trial Management Group, Trial Steering Committee, Data Monitoring Committee and Sponsor. SAEs that were related to the research and unexpected were reported to REC. The CI reviewed all (S)AEs that were unresolved at initial reporting a month later. This was to ensure that adequate action had been taken. Additional reviews at one-month intervals were conducted until the CI confirmed that no further monitoring was required.

The CI was also informed, by the reviewers of the radiographs/CT scans collected for the study, of any abnormalities identified. The CI judged whether the abnormality was clinically important and could impact on patient safety (e.g. a protruding screw). The need to notify the PI of the site, and whether to record this as an AE, was also considered. No actions or treatments were discussed with the PI.

Ethical approval and monitoring

Standard NHS cover for negligent harm was available. There was no cover for non-negligent harm.

Ethics committee approval and any changes to the project protocol

The SWIFFT Trial was approved by Derby Research Ethics Committee – East Midlands on 21 May 2013 (REC reference 13/EM/0154). NHS permission was given by the Research and Development department of each participating site. A summary of the changes made to the protocol since the original REC approval have been listed (*see*

Appendix 2). The trial protocol was published in BMC Musculoskeletal Disorders.[48]

Trial management group (TMG)

The day-to-day management of the trial was overseen by the TMG who met on a quarterly basis. A representative of the Sponsor attended when available. These meetings monitored progress with recruitment (e.g. enrolment, consent, eligibility); allocation to study groups; adherence of the trial interventions to the protocol; retention of trial participants; monitoring of (S)AEs and reasons for participant withdrawal. The review of progress was undertaken at a participating site level and, as necessary, feedback was given to the PI and Research Nurses at each site.

Trial steering committee (TSC)

A TSC was appointed by the funding body to provide overall supervision for the trial and to advise on its continuation. Membership is listed in the Acknowledgement section.

Data monitoring committee (DMC)

The DMC was appointed by the funding body with access to the unblinded comparative data as provided by a statistician at YTU who was independent of the trial team. The DMC monitored the data and recommended to the TSC whether there were any ethical or safety reasons why the trial should not continue. Membership is listed in the Acknowledgement section.

Patient and public involvement

A patient who had a fracture of their left wrist and was treated at the Sponsor site commented on study documentation and was invited to TMG meetings. Alternatively, their opinion was sought outside of these meetings. This patient also contributed to a video that was posted on the trial website, which was publicised in a newsletter to participants, to encourage completion of postal questionnaires and attendance at hospital visits. In Leicester, a group of eight individuals (six of whom had experience of a scaphoid fracture and two who hadn't but were typical of the patient

population i.e. male under 30) met to advise the TMG on strategies to maximise the retention of trial participants and who were also contacted by email for advice.[90] This meeting was led by the CI, a senior qualitative researcher and the patient representative on the TMG. This group will also advise on the summary of the findings for trial participants and other dissemination activities. In one of our newsletters to participants, a photograph and positive feedback about their involvement in the trial, was included from the participant who won the prize draw of the iPad at the 26 week follow-up. Two members of the Patient Liaison Group of the British Orthopaedic Association were independent members of the TSC and advised on strategies to maximise recruitment and retention.

Chapter 3 Clinical effectiveness results

Recruitment

Site recruitment

In our original protocol we estimated that we would need 17 sites to recruit patients into SWIFFT. The number of sites was increased to meet the slightly lower than planned recruitment rate. Forty sites were approached to take part in SWIFFT between May 2013 and March 2015 and, in total, 34 sites were set up and opened to recruitment, the last of which commenced screening/recruitment in June 2015. Thirty three sites screened at least one patient, and thirty one recruited at least one participant (median 10, range 1 to 61). Two of the three sites that did not recruit any participants screened one and two patients respectively, one of which was eligible but non-consenting. The lead site, Leicester Royal Infirmary within the University Hospitals of Leicester NHS Trust, recruited the highest number of patients of all sites (n=61). Table 1 presents the number of patients recruited by each site, ordered by when each site was set up to recruit (Leicester first), with sites identified at Trust level. One hospital from each Trust took part in the SWIFFT trial. All sites agreed to recruit an average of one patient per month, but only two sites achieved this.

Table 1: SWIFFT recruitment by hospital site

Site	Date Opened	Months Open	Number recruited	Average recruits per month
University Hospitals of Leicester NHS Trust	01/07/2013	37	61	1.6
South Tees Hospitals NHS Foundation Trust	17/08/2013	36	10	0.3
University Hospitals Coventry & Warwickshire NHS Trust	09/09/2013	35	24	0.7
Nottingham University Hospitals NHS Trust	25/09/2013	35	27	0.8
Chelsea and Westminster Hospital NHS Foundation Trust	19/11/2013	11[a]	0	0.0
Southport and Ormskirk Hospitals NHS Trust	21/11/2013	13[a]	0	0
Bolton NHS Foundation Trust	02/12/2013	32	17	0.5
Northumbria Healthcare NHS Foundation Trust	06/02/2014	30	5	0.2
Oxford University Hospitals NHS Trust	07/02/2014	30	35	1.2
University Hospital Southampton NHS Foundation Trust	10/02/2014	30	17	0.6
Royal Berkshire NHS Foundation Trust	10/02/2014	30	9	0.3
Salford Royal Hospital NHS Foundation Trust	10/02/2014	30	4	0.1
Brighton and Sussex University Hospitals NHS Trust	26/02/2014	30	5	0.2
Worcestershire Acute Hospitals NHS Trust	10/03/2014	8[a]	0	0.0
Hampshire Hospitals NHS Foundation Trust	17/03/2014	29	6	0.2
Royal United Hospital Bath NHS Trust	17/03/2014	29	23	0.8
Poole Hospital NHS Foundation Trust	22/04/2014	28	5	0.2
Royal Cornwall Hospitals NHS Trust	09/05/2014	27	24	0.9
Cardiff and Vale University Health Board	12/05/2014	27	22	0.8

Maidstone and Tunbridge Wells NHS Trust	21/05/2014	27	5	0.2
Taunton and Somerset NHS Foundation Trust	01/06/2014	26	7	0.3
Plymouth Hospitals NHS Trust	09/06/2014	26	20	0.8
Peterborough and Stamford Hospitals NHS Foundation Trust	12/06/2014	26	17	0.7
Cambridge University Hospitals NHS Foundation Trust	16/06/2014	26	5	0.2
The Royal Liverpool and Broadgreen University Hospitals NHS Trust	17/06/2014	26	5	0.2
Barts Health NHS Trust	20/06/2014	26	24	0.9
Gloucestershire Hospitals NHS Foundation Trust	10/07/2014	25	15	0.6
North Bristol NHS Trust	01/09/2014	23	13	0.6
University Hospitals Bristol NHS Foundation Trust	06/10/2014	22	10	0.5
Newcastle upon Tyne Hospitals NHS Foundation Trust	10/11/2014	21	11	0.5
Medway NHS Foundation Trust	12/11/2014	21	2	0.1
Lancashire Teaching Hospitals NHS Foundation Trust	24/11/2014	21	1	0.05
University Hospitals Birmingham NHS Foundation Trust	16/02/2015	18	6	0.3
King's College Hospital NHS Foundation Trust	22/06/2015	14	4	0.3

[a] withdrew interest in recruiting to SWIFFT trial

Patient recruitment

Our required sample size was 438 participants, which we aimed to achieve by the end of March 2016; however, recruitment was slightly slower than anticipated in the final few months and we agreed with the trial Sponsor, Funder and REC (February 2016) to extend recruitment beyond March 2016 until the 438 patients had been recruited.

The first participant was randomised on 23rd July 2013. As of 31st July 2016, 439 patients had been enrolled in the trial and sites were notified that recruitment should cease; thus, patients were recruited over 37 months. Figure 3 and Figure 4 demonstrate our final recruitment figures.

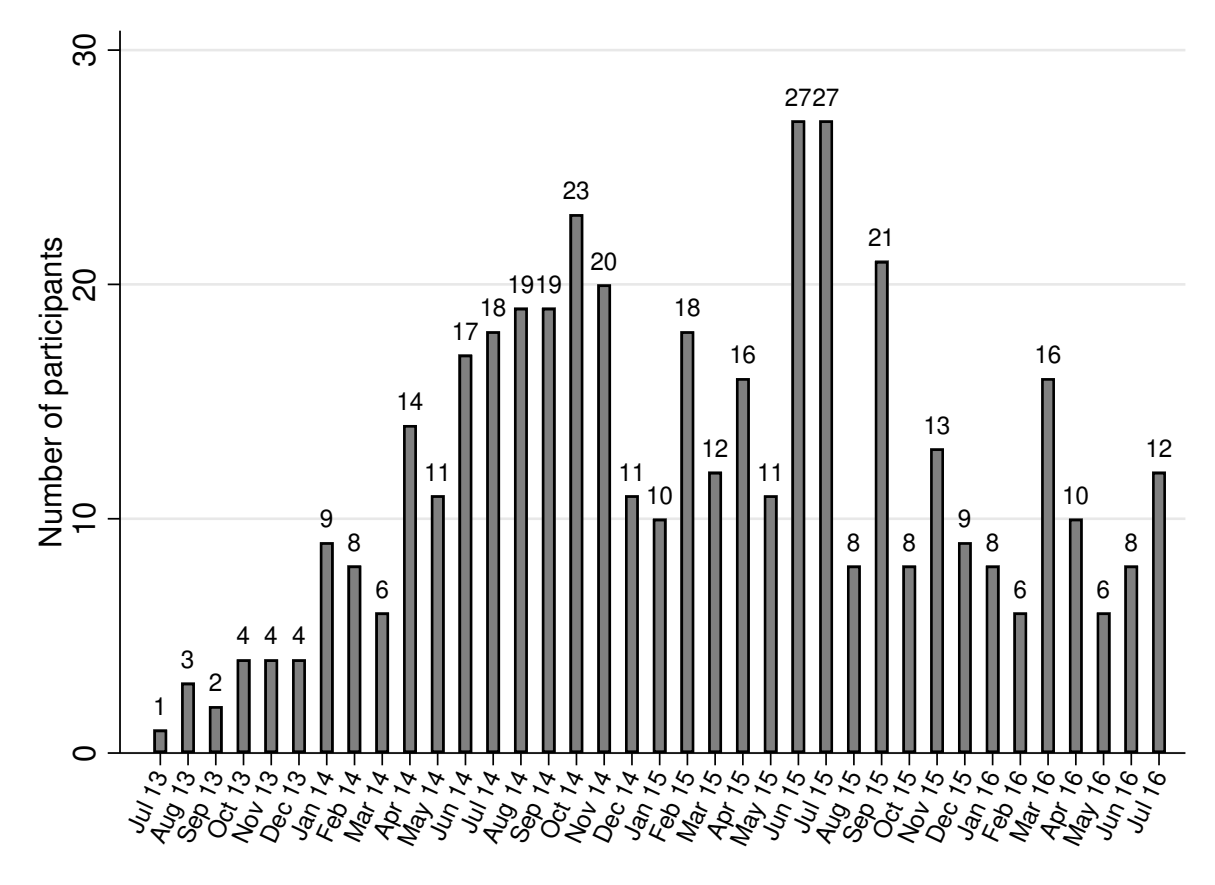


Figure 3: Recruitment into the SWIFFT trial by month

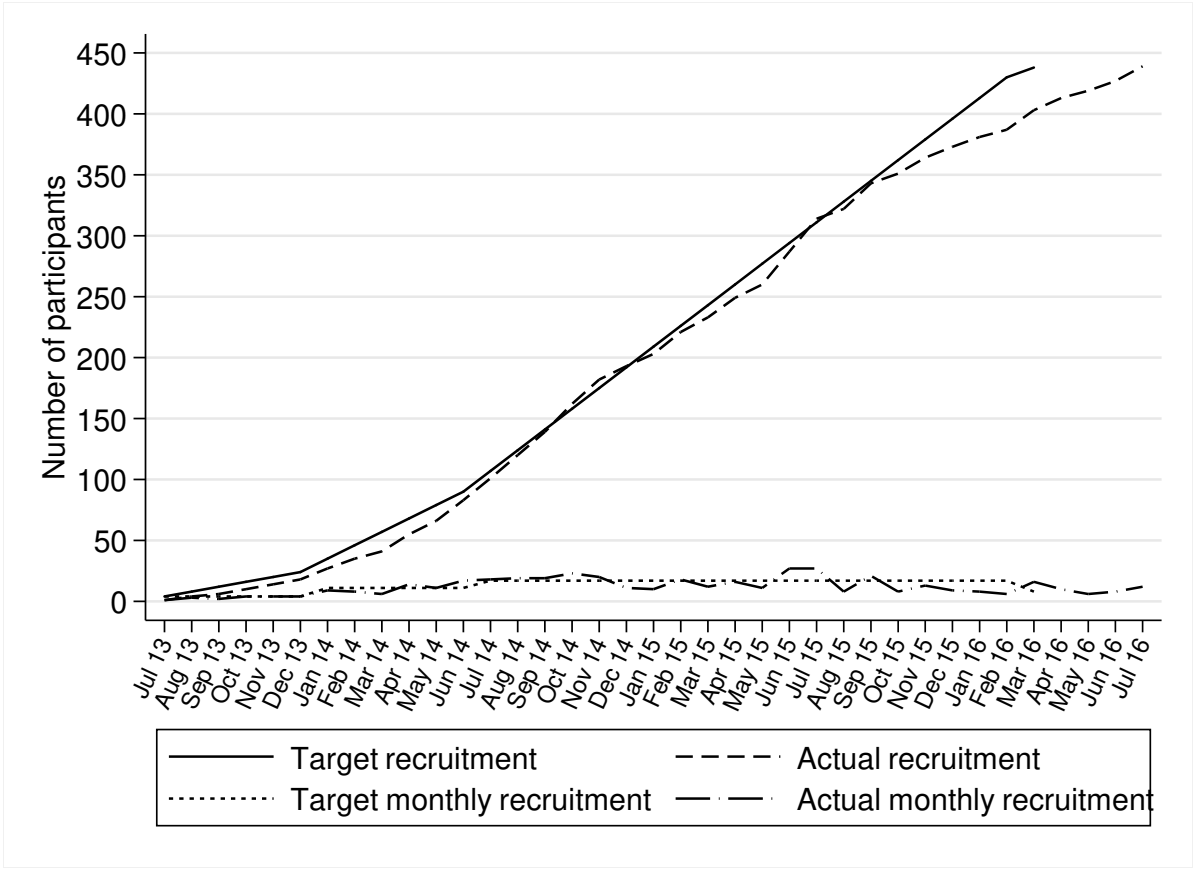


Figure 4: Recruitment targets of participants into the SWIFFT trial

Characteristics of screened patients

A total of 1047 patients who met the inclusion criteria (aged 16 or above and skeletally mature, presenting within two weeks of injury with a radiologically confirmed clear and bicortical fracture of the scaphoid waist that does not include the proximal pole) were assessed for participation in the trial from July 2013 to July 2016, of which 775 (74.0%) were eligible, and 439 (41.9%) were eligible and consenting, and were randomised. The number of participants screened per site ranged from one to 133 (median 23), and the percentage of screened participants who were eligible per site ranged from 0 to 100% (median 83.3%). Table 2 displays the characteristics of the different populations. Eligible patients tended to be younger, and were more likely to be male and have a displaced fracture than ineligible patients. There were no marked differences between consenting and non-consenting patients in gender, age and time since injury, however there is an indication that consenting patients were more likely to have a displaced fracture than non-consenting patients. The number (% screened) of patients for whom each of the following types of radiograph was used to determine eligibility is: elongated scaphoid (n=910, 86.9%); posterior-anterior view (n=1024, 97.8%); 45° semi-supine (n=610, 58.3%); lateral view (n=1017, 97.1%); and 45° semi-prone (n=834, 79.7%). Screened patients had a median of four scaphoid radiographic views taken.

Table 2: Patient baseline characteristics of different populations

Characteristic	Screened (n=1047)	Ineligible (n=272)	Eligible (n=775)	
			Non-consenting (n=336)	Consenting (n=439)
Gender, n (%)				
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 (years)				
n	1040	266	335	439
Mean (SD)	33.7 (14.8)	36.6 (17.5)	32.5 (14.6)	32.9 (12.7)
Median (min, max)	29.2 (16.0, 94.8)	30.0 (16.2, 94.8)	28.2 (16.0, 79.7)	29.3 (16.1, 80.6)

Time since injury (days)[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 (min, max)	0 (0, 14)	0 (0, 14)	1 (0, 9)	1 (0, 10)
Displacement involvement[b], n (%)				
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; min, minimum; max, maximum

[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

Reasons for exclusion

A total of 272 (26.0%) of the 1047 patients screened were ineligible for the trial for one or more reasons (*see Table 3*). Twenty-nine of these should strictly never have been screened for participation in the trial since they did not fulfil the inclusion criteria: injury more than two weeks old (n=15); did not have a radiologically confirmed bicortical fracture (n=7); fracture included the proximal pole (n=6); and skeletally immature (n=1). A further 156 patients failed at least one of the exclusion criteria, most commonly having a concurrent other injury in the same limb (n=70). The remaining 87 were ineligible for another reason: the site did not think it was feasible for the patient's surgery (if allocated) to be scheduled within two weeks from presentation (n=30); patient not approached about study (e.g. they presented at the weekend when there was no clinician available to confirm eligibility) (n=21); patient deemed unsuitable for surgery (n=16); fracture seen on radiography but not on subsequent CT scan (n=8); or other miscellaneous/unknown reason (n=12).

Table 3: Reasons for patient ineligibility for the SWIFFT trial

Reason for ineligibility, n (%)	Number ineligible (n=272)
Exclusion criteria (n=156) – reasons not mutually exclusive	
Fracture displaced by greater than 2 mm	43 (15.8)
Concurrent wrist fracture in the opposite limb	12 (4.4)
Trans-scaphoid perilunate dislocation	8 (2.9)
Multiple injuries in the same limb	70 (25.7)
Patient not resident in trauma centre catchment area of a participating site	21 (7.7)
Previous injury or disease in the same wrist	2 (0.7)
Patient lacks mental capacity and is unable to understand the trial and instructions for treatment	11 (4.0)
Patient is pregnant	6 (2.2)
Other reasons (n=116)	
Patient did not meet inclusion criteria to be approached about trial: Presenting more than 2 weeks after injury No radiologically confirmed bicortical fracture Fracture includes proximal pole Aged <16 years and/or skeletally immature	29 (10.7) N=15 N=7 N=6 N=1
No fracture seen on CT prior to randomisation	8 (2.9)
Surgery not feasible within 2 weeks of injury	30 (11.0)
Patient not suitable for surgery	16 (5.9)
Study not discussed with patient (e.g. presented at weekend)	21 (7.7)
Other[a]	12 (4.4)

[a] no reason provided (n=6); patient currently in prison or young offenders institute (n=2); hospital records show 6 DNAs to visits so patient deemed unreliable (n=1); clinician deemed fracture 'would fix irrespective of study' (n=1); scapholunate disruption likely (n=1); patient previously approached about SWIFFT for right scaphoid fracture but declined as didn't want surgical intervention – patient not reapproached for left scaphoid fracture (n=1)

Patient consent

The percentage of eligible patients who consented to take part in the trial varied in the 31 sites that recruited a patient from 13.9 to 100% (median 63.2%). A reason was provided for 325 of the 336 (96.7%) patients who did not consent to the study despite being eligible: preference for non-operative treatment (n=206); preference for surgery (n=40); unable to commit to follow-ups (n=24); not wanting to take part in research and/or being unhappy with the concept of random treatment allocation (n=13); consent not taken in time to allow surgery (if allocated) to be conducted within two weeks of presentation at A&E or other clinic (n=13); patient circumstances would not allow for surgery (if allocated) to be conducted within two weeks of presentation at A&E or other clinic (e.g. planned holiday or exams) (n=7); and other miscellaneous reasons e.g. patient trying to become pregnant, has multiple comorbidities, etc. (n=22).

Treatment preference data were collected for 320 of the 336 eligible but non-consenting patients: 30 (9.4%) had no treatment preference; 57 (17.8%) had a preference for surgery; and 233 (72.8%) preferred not to have surgery. A response to the treatment the surgeon advised the patient to have was provided for 325 patients: no surgery n=191 (58.8%); surgery n=32 (9.9%); uncertain n=102 (31.4%). The agreed treatment for 328 of these patients was recorded: surgery (n=45, 13.7%); no surgery (n=283, 86.3%).

In total, the median time spent obtaining consent from participants to participate in the trial was 20 minutes. In general, approximately ten more minutes were spent with participants who went on to be randomised than those who did not (mean (SD) 31.6 (18.9) vs 19.5 (12.7), median 30 vs 20 minutes).

Participant flow

The flow of patients through the trial is summarised in a CONSORT flow diagram in Figure 5. Of the 439 randomised participants, 408 (92.9%) were eligible for inclusion in the primary analysis model (203/219, 92.7% in the surgery arm, and 205/220, 93.2% in the non-surgery arm). The trial was designed to allow for 20% attrition.

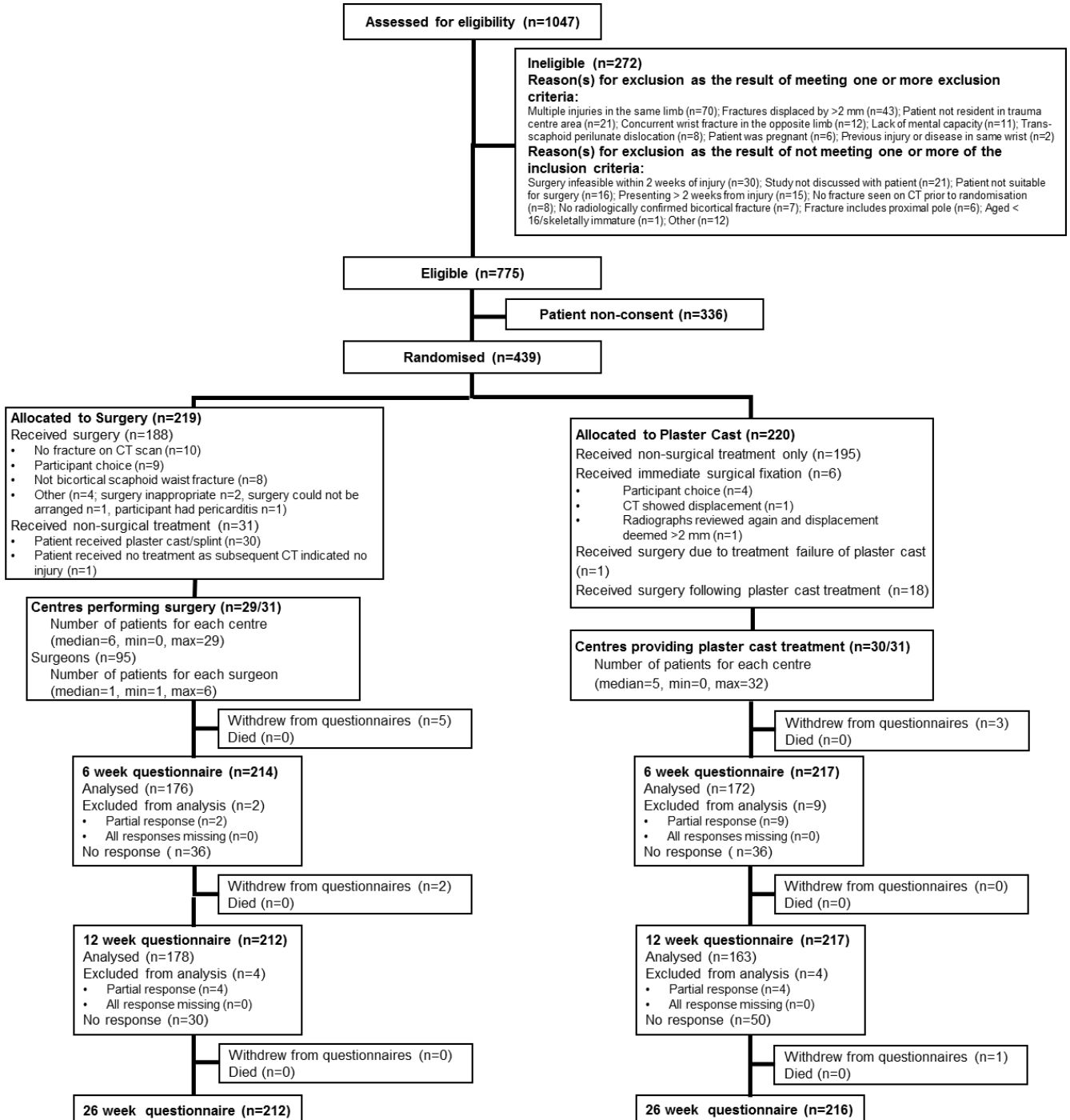

Assessed for eligibility (n=1047)
Ineligible (n=272)
Reason(s) for exclusion as the result of meeting one or more exclusion criteria:
Multiple injuries in the same limb (n=70); Fractures displaced by >2 mm (n=43); Patient not resident in trauma centre area (n=21); Concurrent wrist fracture in the opposite limb (n=12); Lack of mental capacity (n=11); Trans-scaphoid perilunate dislocation (n=8); Patient was pregnant (n=6); Previous injury or disease in same wrist (n=2)
Reason(s) for exclusion as the result of not meeting one or more of the inclusion criteria:
Surgery infeasible within 2 weeks of injury (n=30); Study not discussed with patient (n=21); Patient not suitable for surgery (n=16); Presenting > 2 weeks from injury (n=15); No fracture seen on CT prior to randomisation (n=8); No radiologically confirmed bicortical fracture (n=7); Fracture includes proximal pole (n=6); Aged < 16/skeletally immature (n=1); Other (n=12)
Eligible (n=775)
Patient non-consent (n=336)
Randomised (n=439)
Allocated to Surgery (n=219)
Received surgery (n=188)
• No fracture on CT scan (n=10)
• Participant choice (n=9)
• Not bicortical scaphoid waist fracture (n=8)
• Other (n=4; surgery inappropriate n=2, surgery could not be arranged n=1, participant had pericarditis n=1)
Received non-surgical treatment (n=31)
• Patient received plaster cast/splint (n=30)
• Patient received no treatment as subsequent CT indicated no injury (n=1)
Centres performing surgery (n=29/31)
Number of patients for each centre (median=6, min=0, max=29)
Surgeons (n=95)
Number of patients for each surgeon (median=1, min=1, max=6)
Withdrew from questionnaires (n=5)
Died (n=0)
6 week questionnaire (n=214)
Analysed (n=176)
Excluded from analysis (n=2)
• Partial response (n=2)
• All responses missing (n=0)
No response (n=36)
Withdrew from questionnaires (n=2)
Died (n=0)
12 week questionnaire (n=212)
Analysed (n=178)
Excluded from analysis (n=4)
• Partial response (n=4)
• All response missing (n=0)
No response (n=30)
Withdrew from questionnaires (n=0)
Died (n=0)
26 week questionnaire (n=212)
Allocated to Plaster Cast (n=220)
Received non-surgical treatment only (n=195)
Received immediate surgical fixation (n=6)
• Participant choice (n=4)
• CT showed displacement (n=1)
• Radiographs reviewed again and displacement deemed >2 mm (n=1)
Received surgery due to treatment failure of plaster cast (n=1)
Received surgery following plaster cast treatment (n=18)
Centres providing plaster cast treatment (n=30/31)
Number of patients for each centre (median=5, min=0, max=32)
Withdrew from questionnaires (n=3)
Died (n=0)
6 week questionnaire (n=217)
Analysed (n=172)
Excluded from analysis (n=9)
• Partial response (n=9)
• All responses missing (n=0)
No response (n=36)
Withdrew from questionnaires (n=0)
Died (n=0)
12 week questionnaire (n=217)
Analysed (n=163)
Excluded from analysis (n=4)
• Partial response (n=4)
• All response missing (n=0)
No response (n=50)
Withdrew from questionnaires (n=1)
Died (n=0)
26 week questionnaire (n=216)

Figure 5: SWIFFT CONSORT flow diagram

Baseline characteristics of randomised participants

The 439 participants were randomised using equal allocation to surgery (n=219) or plaster cast management (n=220) of their fractures. The allocation of participants was stratified by fracture displacement at enrolment (<1mm, 1 to 2 mm inclusive). On 24 occasions, the incorrect displacement stratum was used in the randomisation: 16 participants with no fracture displacement were randomised within the displacement stratum, and eight with displacement were randomised within the no displacement stratum (see *Methods*, *Primary outcome (Patient Rated Wrist Evaluation) analysis*). A baseline questionnaire was not received from two participants (both allocated to the surgery group). The recruited participants were predominantly male (82.7%), and the average age was 32 years (range 16 to 80). Just over half the participants (53.6%) had injured their left wrist, and their non-dominant side (56.8%). Nearly half the participants stated that they did not have a treatment preference at enrolment to the trial (47.6%), but of the other 230 most (84.3%) expressed a preference for surgery. This trend is substantially different to that observed in the population of eligible but non-consenting participant who predominantly stated a preference to not receive surgery. The treatment groups as randomised and as analysed appear to be balanced on all measured baseline participant characteristics and fracture details (*see Table 4 and Table 5*) with the exception of ethnicity, education and smoking status. Participants in the plaster cast group were more likely to have a degree or higher qualification and less likely to be a smoker and to be white, both as randomised and as analysed. No formal statistical comparisons were conducted and so we cannot see if these differences are statistically significant, but these differences are consistent with a chance imbalance. The trial team considered these imbalances post-hoc and it was decided to include a sensitivity analysis adjusting the primary analysis model additionally for smoking status as this is likely to be associated with outcome. It was not felt that ethnicity and education status were likely to be associated with outcome so no sensitivity analyses were conducted with these factors.

Table 4: Baseline characteristics of trial participants as randomised and as included in the primary analysis model

Characteristic	As randomised			As analysed		
	Surgery (n=219)	**Plaster cast (n=220)**	**Total (n=439)**	**Surgery (n=203)**	**Plaster cast (n=205)**	**Total (n=408)**
Gender, n (%)						
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)						
N	219	220	439	203	205	408
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 (min, max)	28 (16, 80)	29 (16, 76)	29 (16, 80)	29 (16, 80)	29 (16, 76)	29 (16, 80)
Ethnicity, n (%)						
White	205 (93.6)	195 (88.6)	400 (91.1)	191 (94.1)	180 (87.8)	371 (90.9)
Black	0 (0.0)	5 (2.3)	5 (1.1)	0 (0.0)	5 (2.4)	5 (1.2)
Asian	7 (3.2)	10 (4.5)	17 (3.9)	7 (3.4)	10 (4.9)	17 (4.2)
Other	5 (2.3)	10 (4.5)	15 (3.4)	5 (2.5)	10 (4.9)	15 (3.7)
Missing	2 (0.9)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
Education, n (%)						
No formal qualifications	24 (11.0)	27 (12.3)	51 (11.6)	22 (10.8)	25 (12.2)	47 (11.5)
Some qualifications/no degree	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, n (%)						
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)

Characteristic	As randomised			As analysed		
	Surgery (n=219)	**Plaster cast (n=220)**	**Total (n=439)**	**Surgery (n=203)**	**Plaster cast (n=205)**	**Total (n=408)**
Looking after family/home	1 (0.5)	6 (2.7)	7 (1.6)	0 (0.0)	5 (2.4)	5 (1.2)
Not employed but 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)	3 (0.7)	1 (0.5)	0 (0.0)	1 (0.2)
Type of employment, n (%)						
Unskilled manual	25 (11.4)	23 (10.5)	48 (10.9)	24 (11.8)	20 (9.8)	44 (10.8)
Skilled manual	63 (28.8)	60 (27.3)	123 (28.0)	56 (27.6)	56 (27.3)	112 (27.5)
Unskilled non-manual	19 (8.7)	12 (5.5)	31 (7.1)	19 (9.4)	11 (5.4)	30 (7.4)
Skilled non-manual	33 (15.1)	46 (20.9)	79 (18)	32 (15.8)	44 (21.5)	76 (18.6)
Professional	20 (9.1)	19 (8.6)	39 (8.9)	20 (9.9)	17 (8.3)	37 (9.1)
Other	19 (8.7)	30 (13.6)	49 (11.2)	18 (8.9)	28 (13.7)	46 (11.3)
Missing	40 (18.3)	30 (13.6)	70 (15.9)	34 (16.7)	29 (14.1)	63 (15.4)
Current smoker, n (%)						
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)
If Yes:						
How many cigarettes						
Median (min, max)	10 (1, 40)	10 (1, 30)	10 (1, 40)	10 (1, 40)	10 (1, 30)	10 (1, 40)
For how many years						
Median (min, max)	10 (1, 50)	10 (1, 36)	10 (1, 50)	10 (1, 50)	10 (1, 36)	10 (1, 50)

Characteristic	As randomised			As analysed		
	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)	Surgery (n=203)	Plaster cast (n=205)	Total (n=408)
Past smoker, n (%)						
Yes	116 (53.0)	109 (49.5)	225 (51.3)	110 (54.2)	99 (48.3)	209 (51.2)
No	85 (38.8)	101 (45.9)	186 (42.4)	81 (39.9)	96 (46.8)	177 (43.4)
Missing	18 (8.2)	10 (4.5)	28 (6.4)	12 (5.9)	10 (4.9)	22 (5.4)
Diabetes, n (%)						
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, n (%)						
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)

SD, standard deviation; min, minimum; max, maximum

Table 5: Baseline fracture details of trial participants as randomised and as included in the primary analysis model

Characteristic	As randomised			As analysed		
	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)	Surgery (n=203)	Plaster cast (n=205)	Total (n=408)
Time since injury (days)[a]						
N	219	220	439	203	205	408
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 (min, max)	5 (1, 14)	5 (0, 14)	5 (0, 14)	4 (1, 14)	5 (0, 14)	5 (0, 14)
Affected wrist, n (%)						
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)

Characteristic	As randomised			As analysed		
	Surgery (n=219)	**Plaster cast (n=220)**	**Total (n=439)**	**Surgery (n=203)**	**Plaster cast (n=205)**	**Total (n=408)**
Hand dominance, n (%)						
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)
Displacement (eligibility), n (%)						
No displacement	135 (61.6)	134 (60.9)	269 (61.3)	123 (60.6)	123 (60)	246 (60.3)
Displacement	84 (38.4)	86 (39.1)	170 (38.7)	80 (39.4)	82 (40)	162 (39.7)
Displacement (randomisation), n (%)						
No displacement	131 (59.8)	130 (59.1)	261 (59.5)	119 (58.6)	119 (58)	238 (58.3)
Displacement	88 (40.2)	90 (40.9)	178 (40.5)	84 (41.4)	86 (42)	170 (41.7)
Radiographs[b], n (%)						
Elongated scaphoid view	209 (95.4)	210 (95.5)	419 (95.4)	193 (95.1)	195 (95.1)	388 (95.1)
Posterior-anterior view	215 (98.2)	218 (99.1)	433 (98.6)	200 (98.5)	203 (99.0)	403 (98.8)
Semi 45° supine	159 (72.6)	166 (75.5)	325 (74.0)	144 (70.9)	156 (76.1)	300 (73.5)
Lateral	218 (99.5)	217 (98.6)	435 (99.1)	203 (100.0)	202 (98.5)	405 (99.3)
Semi 45° prone	198 (90.4)	196 (89.1)	394 (89.7)	184 (90.6)	183 (89.3)	367 (90.0)
Previous wrist problems on same side, n (%)						
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)

Characteristic	As randomised			As analysed		
	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)	Surgery (n=203)	Plaster cast (n=205)	Total (n=408)
If Yes, what injury, n (%)						
Previous fracture	23 (53.5)	28 (62.2)	51 (58.0)	23 (53.5)	25 (59.5)	48 (56.5)
Arthritis	2 (4.7)	1 (2.2)	3 (3.4)	2 (4.7)	1 (2.4)	3 (3.5)
Ligament, tendon or nerve injury	10 (23.3)	8 (17.8)	18 (20.5)	10 (23.3)	8 (19.1)	18 (21.2)
Other	6 (14.0)	8 (17.8)	14 (15.9)	6 (14.0)	8 (19.1)	14 (16.5)
Missing	2 (4.7)	0 (0.0)	2 (2.3)	2 (4.7)	0 (0.0)	2 (2.4)
Injury mechanism, n (%)						
Fall – standing	28 (12.8)	29 (13.2)	57 (13.0)	26 (12.8)	26 (12.7)	52 (12.7)
Fall – walking	24 (11.0)	24 (10.9)	48 (10.9)	22 (10.8)	23 (11.2)	45 (11.0)
Fall – running	40 (18.3)	38 (17.3)	78 (17.8)	37 (18.2)	33 (16.1)	70 (17.2)
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 – object striking palm	16 (7.3)	15 (6.8)	31 (7.1)	15 (7.4)	15 (7.3)	30 (7.4)
Hit on palm of hand – handle whipping back	9 (4.1)	11 (5.0)	20 (4.6)	8 (3.9)	11 (5.4)	19 (4.7)
Hit on palm of hand – other sudden extension	11 (5.0)	8 (3.6)	19 (4.3)	11 (5.4)	8 (3.9)	19 (4.7)
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)

Characteristic	As randomised			As analysed		
	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)	Surgery (n=203)	Plaster cast (n=205)	Total (n=408)
Place of injury[b], n (%)						
Sport	88 (40.2)	78 (35.5)	166 (37.8)	85 (41.9)	72 (35.1)	157 (38.5)
Home	27 (12.3)	43 (19.5)	70 (15.9)	24 (11.8)	38 (18.5)	62 (15.2)
Work	22 (10)	18 (8.2)	40 (9.1)	19 (9.4)	17 (8.3)	36 (8.8)
Road Traffic Accident	26 (11.9)	34 (15.5)	60 (13.7)	25 (12.3)	33 (16.1)	58 (14.2)
Public place	49 (22.4)	48 (21.8)	97 (22.1)	46 (22.7)	46 (22.4)	92 (22.5)
Other	3 (1.4)	0 (0)	3 (0.7)	3 (1.5)	0 (0.0)	3 (0.7)
Missing	4 (1.8)	2 (0.9)	6 (1.4)	3 (1.5)	2 (1.0)	5 (1.2)
Treatment preference, n (%)						
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)

SD, standard deviation; min, minimum; max, maximum
[a] time from injury to screening; [b] response categories not mutually exclusive

Follow-up

Participant questionnaires

In total, follow-up participant questionnaires were returned for 359 (81.8%), 349 (79.5%), 313 (71.3%) and 364 (82.9%) of the 439 randomised participants at six, 12, 26 and 52 weeks, respectively (*see Table 6*). Return rates were lower in the plaster cast group at all time-points, except at six weeks when they were similar between the two groups.

The participant questionnaires were primarily returned by post (50% or over at each time point). At six, 12 and 52 weeks, when participants were invited to attend for a hospital visit, there was the opportunity to complete the questionnaire in clinic. This occurred in 46.0%, 41.6% and 34.3% of cases at week six, 12 and 52, respectively. Questionnaire data was completed by telephone as a last resort for hard to reach participants in 84 instances.

The number of days from the date the questionnaire was due (e.g., for the six week questionnaire this was 42 days after randomisation) to the completion of the questionnaire as recorded by the patient ('Days to complete') and the return of the questionnaire to the YTU ('Days to return') is presented in Table 6. These were replaced with a 0 if the questionnaire was completed/returned before the due date (i.e., if completed during a clinic visit rather than having been posted out by the YTU on the due date). Median and interquartile range are presented as the data had a right-skewed distribution since most patients completed and returned their forms promptly. There was no obvious difference between the two groups in the time to completion or the time to return.

Table 6: Follow-up participant questionnaires return rates

Time point	**Surgery (n=219)**	**Plaster cast (n=220)**	**Total (n=439)**
6 weeks, n (%)			
Sent[a]	214 (97.7)	217 (98.6)	431 (98.2)
Returned[b]	178 (83.2)	181 (83.4)	359 (83.3)
Days to complete, median (IQR)	5 (1, 11)	2 (0, 9)	4 (0, 11)
Days to return, median (IQR)	13 (8, 24)	12 (5, 24)	13 (6, 24)
Completed within 1 week[c;d]	119 (66.9)	118 (65.2)	237 (66.0)
Mode of completion[d]			
Post	99 (55.6)	93 (51.4)	192 (53.5)
In clinic	78 (43.8)	87 (48.1)	165 (46.0)
Telephone	1 (0.6)	1 (0.6)	2 (0.6)

Time point	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)
12 weeks, n (%)			
Sent[a]	212 (96.8)	217 (98.6)	429 (97.7)
Returned[b]	182 (85.9)	167 (77.0)	349 (81.4)
Days to complete, median (IQR)	7 (2, 21)	5 (0, 19)	6 (0, 20)
Days to return, median (IQR)	15 (8, 31)	13 (7, 35)	14 (7, 33)
Completed within 2 weeks[c;d]	122 (67.0)	110 (65.9)	232 (66.5)
Mode of completion[d]			
Post	97 (53.3)	77 (46.1)	174 (49.9)
In clinic	70 (38.5)	75 (44.9)	145 (41.6)
Telephone	15 (8.2)	15 (9.0)	30 (8.6)
26 weeks, n (%)			
Sent[a]	212 (96.8)	216 (98.2)	428 (97.5)
Returned[b]	163 (76.9)	149 (69.0)	313 (72.9)
Days to complete, median (IQR)	10 (5, 27)	10 (4, 30)	10 (5, 28)
Days to return, median (IQR)	20 (10, 38)	19 (10, 37)	20 (10, 37)
Completed within 6 weeks[c;d]	136 (83.4)	131 (87.9)	267 (85.6)
Mode of completion[d]			
Post	165 (92.7)	165 (91.2)	330 (91.9)
Telephone	13 (7.3)	16 (8.8)	29 (8.1)
52 weeks, n (%)			
Sent[a]	212 (96.8)	213 (96.8)	425 (96.8)
Returned[b]	186 (87.7)	178 (83.6)	364 (85.7)
Days to complete, median (IQR)	5 (0, 16)	7 (2, 26)	6 (2, 22)
Days to return, median (IQR)	12 (7, 33)	17 (8, 36)	14 (7, 35)
Completed within 8 weeks[c;d]	170 (91.4)	157 (88.2)	327 (89.8)
Mode of completion[d]			
Post	103 (57.9)	110 (60.8)	213 (59.3)
In clinic	67 (37.6)	56 (30.9)	123 (34.3)
Telephone	8 (4.5)	15 (8.3)	23 (6.4)

IQR, interquartile range
[a] percentage of randomised participants; [b] percentage of sent; [c] of questionnaire due date; [d] percentage of returned

Hospital data collection forms

The return of hospital forms is summarised in Table 7. Treatment confirmation forms were collected at six and 12 weeks post-randomisation; at least one treatment confirmation form was completed for all but one participant (who was allocated to surgery but withdrew on the day of randomisation). A complications form was completed for over 84% of the randomised participants at each of the six, 12 and 52 week time points. Wrist range of movement and grip strength forms were received for 389 (88.6%), 336 (76.5%) and 309 (70.4%) participants at six, 12 and 52 weeks, respectively. At 52 weeks, there appears to be a difference in the percentage of grip and range forms returned between the two groups (Surgery 74.4%; Plaster cast 66.4%), otherwise there are no obvious differences between the two groups in the return rates of hospital forms. The return of treatment confirmation and complications forms is higher than for the grip and range forms as completion of these forms did not require the participant to attend the hospital visit.

Table 7: Follow-up hospital form return rates

Hospital form	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)
Wrist range of movement and grip strength form, n (%)			
6 weeks	189 (86.3)	200 (90.9)	389 (88.6)
12 weeks	172 (78.5)	164 (74.6)	336 (76.5)
52 weeks	163 (74.4)	146 (66.4)	309 (70.4)
Treatment confirmation form, n (%)			
6 weeks	200 (91.3)	211 (95.9)	411 (93.6)
12 weeks	202 (92.2)	195 (88.6)	397 (90.4)
At least one	219 (99.5)	220 (100.0)	438 (99.8)

Complications form, n (%)			
6 weeks	197 (90.0)	206 (93.6)	403 (91.8)
12 weeks	181 (82.7)	189 (85.9)	370 (84.3)
52 weeks	199 (90.9)	196 (89.1)	395 (90.0)

Patient withdrawals

Five participants (surgery n=2; plaster cast n=3) withdrew from hospital follow-up but agreed to continue completing participant questionnaires; three of these were before the six week visit (no hospital visits attended), and two were following the six week visit (12 and 26 week visits not attended). The reasons provided were: work commitments (surgery n=1; plaster cast n=1); participant moved away from trial catchment area (surgery n=1); participant too ill to commit to extra hospital visits (plaster cast n=1); and participant sought further opinion at alternative hospital, surgical fixation and follow-ups completed there instead of at recruiting site (plaster cast n=1).

A further 14 participants were withdrawn completely from the trial; eight before the 6 week time point (surgery n=5; plaster cast n=3); two between the six and 12 week time points (surgery n=2); one between 12 and 26 weeks (plaster cast n=1); and three between 26 and 52 weeks (plaster cast n=3). Reasons for these withdrawals were: participant no longer wants to take part in study e.g. too busy, sick of questionnaires (surgery n= 2; plaster cast n=3); no fracture present on CT scan (surgery n=4; plaster cast n=1); participant unhappy with treatment allocation (surgery n=1; plaster cast n=2); and participant emigrating (plaster cast n=1).

Hospital visits

Baseline participant and fracture data are summarised according to whether patients attended hospital visits at six, 12 and 52 weeks (*see*

Appendix 3*, Table 45 to Table 50*). Non-smokers and participants in employment were more likely to attend than smokers, and those not in employment, respectively at all time-points. Participants with fracture displacement at baseline were more likely to attend their six and 52 week hospital visits, but were equally likely to attend at 12 weeks.

Compliance with random allocation and treatment received

For all but four of the randomised participants, their affected wrist was recorded as being immobilised at enrolment, largely by a plaster cast (n=328, 74.7%), but alternatively by a splint (n=80, 18.2%), or a backslab (n=27, 6.2%). From the treatment confirmation and surgery forms, we were able to ascertain further treatment received for each participant within the 12 months following randomisation.

Allocated to receive surgery

Of the 219 patients allocated to surgery, 188 (85.8%) received treatment as allocated (*see Table 8*). Surgery took place, on average, 10.2 days (median 11, range 3 to 20) after injury, 9.5 days (median 10, range 1 to 20) after presenting at A&E or other clinic, and 4.5 days (median 5, range 0 to 15) after randomisation. Of the 188 participants who underwent surgery, 39 (20.7%) received routine treatment i.e., surgery and no subsequent plaster cast or splint; 141 (75%) had further routine treatment with plaster cast or splint only following surgery (not recorded as being due to a treatment failure); and 8 (4.3%) had at least one other surgery within the 12 months (seven had one other surgery, and one had two).

The reasons for repeat surgeries (for the seven patients with only one extra surgery within 12 months of randomisation) were: removal of screw due i) to protrusion (n=3), ii) experiencing pain and poor flexion of wrist (n=1), or iii) scaphoid screw breaching cortex of scaphoid at the capitate articulation due to mis-position of the screw (n=1); revision surgery due to pain/prominent metal work (n=1); or for persistent non-union (n=1). For the participant who underwent two further surgeries, the first was to remove the screw and perform iliac bone graft/k-wire stabilisation due to non-union of scaphoid fracture; the second was for persistent non-union.

The remaining 31 (14.2%) participants allocated to receive surgery were treated non-surgically[1] for the following reasons: no fracture observed on CT scan subsequent to randomisation (n=10); participant choice not to have surgery (n=9); not a bicortical scaphoid waist fracture (n=8; described as: waist plus distal pole fracture (n=2), radial styloid fracture (n=1), unicortical fracture (n=1), lunate fracture (n=1), Y-shaped waist fracture involving the tubercle (n=1), associated scaphoid tubercle fracture (n=1), incomplete fracture (n=1)); and other (n=4; surgeon felt surgery inappropriate/unnecessary following review of CT scan but no further information available (n=2), no appropriate time for surgery available for surgeon or patient (n=1), patient admitted to hospital with pericarditis (n=1)). Of these, 30 received plaster cast and/or splint following randomisation; while one did not receive any treatment due to the fact that the treating clinician deemed that their subsequent CT scan indicated no injury (*see Table 8*).

Following randomisation, 41 participants did not have any plaster cast/splint wear reported, and 65 were only reported to wear a splint (for a median of 40 days post-randomisation, range 4 to 97 – though upper range curtailed as final date of splint wear often not recorded/known and may be longer than 12 week reporting period of treatment confirmation forms). Of the remaining 113: 29 had a cast (with thumb incorporated) on for a median of 21 days (range 2 to 60) following randomisation, of which 2 then had a cast (with thumb free) applied for a median of 37 days; and 84 had a cast (with thumb free) on for a median of 18 days following randomisation (range 1 to 63), of which 2 then had a cast with thumb incorporated on for a median of 9 days. Overall, 103/219 (47.0%) participants allocated to the surgery group were still in a plaster cast or splint at 6 weeks post-randomisation, and 13 (5.9%) at 12 weeks.

Table 8: Treatment received - surgery group (n=219)

Treatment pathway	Definition of pathway	N (%)	Further details

[1] The participant with no treatment confirmation form was allocated to the surgery group but withdrew on the day of randomisation and provided no follow-up data. However, the reason provided for withdrawal included that the participant wanted conservative treatment; therefore, this patient is assumed not to have received surgery.

Crossover	Immediate switch 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 since no fracture was observed on CT.
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 subsequent evidence of non-union, so 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 the index surgery.

Allocated to receive plaster cast intervention

Of the 220 patients allocated to not receive immediate surgical fixation, the majority (n=195, 88.6%) were treated conservatively and did not receive surgery (*see Table 9*); though two of these were considered for surgical fixation due to non-union. Six (2.7%) participants immediately

crossed over to surgery following randomisation with no cast applied before this, for the following reasons: participant choice (n=4); CT showed displacement (n=1); and radiographs reviewed again at later date and displacement judged to be >2 mm (n=1). For these six participants, surgery took place, on average, 13.5 days (median 12, range 5 to 32) after injury, 12.8 days (median 11.5, range 5 to 31) after presenting at A&E or other clinic, and 8.8 days (median 8.5; range 0 to 24) after randomisation. None of these six participants underwent further surgery within 12 months from randomisation.

One (0.5%) participant had a plaster cast applied but received surgery 29 days after randomisation due to treatment failure as their fracture was displacing with plaster cast. This participant received a revision surgery, to remove the screw, three months following initial fixation.

One (0.5%) participant received surgery within 6 months of randomisation at a non-participating hospital to fix what the treating surgeon deemed to be a historic fracture. This was noted by the participant on a participant questionnaire. Limited other information is available for this participant as they withdrew from hospital follow-up at their recruiting site.

The remaining 17 (7.7%) participants received surgery as part of their expected treatment pathway when the treating surgeon judged that the bone had failed to unite with conservative treatment. Sixteen of these received only one surgery in the 12 months following randomisation, and one received three surgeries (second one for persistent non-union and third to remove the wires from the second operation). The initial surgery took place, on average, 159.0 days (median 161, range 68 to 358) after injury, 157.0 days (median 156, range 67 to 358) after presenting at A&E or other clinic, and 151.6 days (median 153; range 61 to 350) after randomisation. Fourteen participants met the protocol definition of the control condition by receiving early surgical fixation of their fractures following detection of persistent non-union after plaster cast management (defined here as surgery within 6 months of randomisation), while three had delayed surgical fixation, one of which opted to attend a private hospital for their fixation as told there would be a 4-5 month wait for surgery at treating centre.

There were two participants who were deemed to have a suspected non-union at 12 weeks and for whom surgical fixation was recommended, but who did not receive surgery. These participants did not fully comply with the anticipated control condition for the trial. The limited information we have about these participants is that for one, the operation was scheduled but then delayed, and the participant self-discharged after wait and declined all further treatment including offers of surgery. For the second, it was the surgeon's decision not to operate.

Following randomisation, two participants did not have any plaster cast/splint wear reported, and two were only reported to wear a splint (for a median of 44 days post-randomisation). Of the remaining 216: 45 had a cast (with thumb incorporated) on for a median of 42 days (range 7 to 84) following randomisation, of which 8 then had a cast (with thumb free) applied for a median of 25 days (range 14 to 42); and 171 had a cast (with thumb free) on for a median of 42 days (range 7 to 98) following randomisation, of which 5 then had a cast (with thumb incorporated) on for a median of 44 days (range 12 to 69). Overall, 187/220 (85.0%) participants allocated to the plaster cast group were still in a plaster cast or splint at 6 weeks post-randomisation, and 47 (21.4%) at 12 weeks.

Table 9: Treatment received – plaster cast group (n=220)

Treatment pathway	Definition of pathway	N (%)	Further details
Crossover	Immediate switch to surgery following randomisation	6 (2.7)	• Surgery took place a median of 9 days (range 0-24) post-randomisation. • Participants received plaster cast (n=3), 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 unknown, but was immobilised in plaster cast at enrolment to trial.
Treatment failure	Surgery undertaken to stabilise the fracture (before five weeks from randomisation). This is <u>not</u> 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; splint worn thereafter (unknown length of time). • Surgery undertaken to remove screw 96 days after initial fixation.
Further routine treatment – surgery (after five weeks post-randomisation)	Surgery undertaken beyond five weeks from randomisation – not due to failure to unite	1 (0.5)	• One received surgery within 6 months of randomisation at a non-participating hospital to fix historic fracture.

Further routine treatment – surgery recommended (after five weeks post-randomisation) as per specified treatment pathway because of failure to unite.	Surgery not received	2 (0.9)	• Operation scheduled but then delayed, participant self-discharged after wait and declined all further treatment/offers of surgery. • Non-union suspected at 12 weeks but surgeon's decision 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 received late fixation, between 6 and 12 months after randomisation. Reasons for two of these unknown; one participant opted to attend a private hospital for their fixation as was told there would be a 4-5 month wait for surgery at treating centre.
	Two or more surgeries performed within 12 months of randomisation	1 (0.5)	• Patient received initial surgical fixation within 3 months of randomisation, further surgery 6 months later for persistent non-union and surgery to remove the wires from the second operation a month later.

Surgical fixation details

A surgery form was received for 210 of the 213 participants in the trial who received surgical fixation of their fracture: surgery group n=187/188, (99.5%); and plaster cast group n=23/25 (92.0%). Surgery was performed by 102 surgeons across 30 sites. Each surgeon performed between 1 and 6 surgeries (median 1). Details of the operation, for initial surgical fixation procedures only, are provided in Table 10. Surgery lasted a median of 55 minutes (range 15 to 140) with a mean (SD) of 2 (0.9) surgeons in attendance. Most commonly, the main operating surgeon was a consultant (n=139, 66.2%), followed by a specialist trainee (n=49, 23.3%) and a staff grade/associate specialist (n=22, 10.5%). Where the main operating surgeon was a specialist trainee, an assisting consultant was recorded as being present in 33 (of 49, 67.4%) of the surgeries. Acutrak screws were the most frequently used type, and a second screw was used for 2 (1.0%) participants. There were no reported intraoperative complications, and most participants (n=113, 53.8%) were treated with a plaster cast post-operatively.

Table 10: Details of initial surgical fixation

Surgery details	**Surgery (n=210)**
Lead surgeon grade, n (%)	
Consultant	139 (66.2)
Staff grade/associate specialist	22 (10.5)
Specialist trainee	49 (23.3)
Total number of surgeons present in theatre	
N	210
Mean (SD)	2.0 (0.9)
Median (min, max)	2 (1, 9)
Duration of surgery (mins)	
N	197
Mean (SD)	59.0 (23.6)
Median (min, max)	55 (15, 140)

Surgery type, n (%)	
Percutaneous	164 (78.1)
Open	43 (20.5)
Both	1 (0.5)
Missing	2 (1.0)
Incision, n (%)	
Palmar	171 (81.4)
Dorsal	33 (15.7)
Both	2 (1.0)
Missing	4 (1.9)
Type of screw used, n (%)	
Acutrak	152 (72.4)
Medartis	33 (15.7)
Twinfix	10 (4.8)
Headless compression screw	10 (4.8)
Herbert™	1 (0.5)
Missing	4 (1.9)
Second screw, n (%)	
Yes	2 (1.0)
No	202 (96.2)
Missing	6 (2.9)
K-wire used, n (%)	
Yes	39 (18.6)
No	168 (80.0)
Missing	3 (1.4)
Placement of screw:	
Central position, n (%)	
Yes	148 (70.5)
No	55 (26.2)
Missing	7 (3.3)

Position less than perfect but acceptable, n (%)	
Yes	74 (35.2)
No	131 (62.4)
Missing	5 (2.4)
Uncertain bone hold, n (%)	
Yes	2 (1.0)
No	201 (95.7)
Missing	7 (3.3)
Intraoperative complications, n (%)	
Fracture around screw	0 (0.0)
Nerve injury	0 (0.0)
Vascular injury	0 (0.0)
Tendon injury	0 (0.0)
Post-operative management, n (%)	
Cast	113 (53.8)
Bandage	65 (31.0)
Splint	31 (14.8)
Missing	1 (0.5)
Unexpected procedure[a], n (%)	2 (1.0)
[a] trapezium trimmed	

Primary outcome (Patient Rated Wrist Evaluation) analysis

The PRWE was assessed at baseline (pre and post-injury) and at six, 12, 26 and 52 weeks post-randomisation. The PRWE total score is a value between 0 and 100, where a higher score indicates worse pain and functioning. Pain and function subscale scores are each out of a maximum of 50 (worst score). The trial was powered to detect an effect size of 0.3 (assuming a SD of 20); this is equivalent to a difference in total PRWE score of six points.

Primary end point analysis

There was no evidence of a difference in PRWE score between the surgery and plaster cast groups at the 52 week time-point, with an adjusted mean difference of -2.1 in favour of the surgery group (95% CI -5.8 to 1.6, p=0.27).

This result was extracted from a multilevel model in which participant was treated as a random effect and observations over time (six, 12, 26 and 52 weeks) were nested within participant. The effect of randomised treatment group was assessed while adjusting for time, group-by-time interaction, age, fracture displacement and hand dominance. The predicted means and associated 95% CIs for each group and time point are presented in Table 11 and displayed in Figure 6.

Different covariance structures were applied to the model. An unstructured pattern that models all variances and covariances separately resulted in the lowest AIC and so was used in the final model.

Diagnostics of model fit revealed that the standardised residuals demonstrated only a minor deviation from normality, and were uniform against fitted values; therefore, analyses were carried out on untransformed values. Model coefficients for the covariates with 95% CIs are provided as software output in Appendix **4** to aid understanding of the fitted model.

Table 11: Difference in adjusted mean PRWE scores over time by randomised group from primary analysis model (n=408; surgery, n= 203; plaster cast, n=205)

Time point	Surgery Mean (95% CI)	Plaster cast Mean (95% CI)	Difference (95% CI)	p-value
6 weeks	35.6 (32.6, 38.6)	39.8 (36.8, 42.8)	-4.2 (-8.5, 0.1)	0.06
12 weeks	21.0 (18.1, 24.0)	26.6 (23.6, 29.6)	-5.6 (-9.8, -1.4)	0.01
26 weeks	16.2 (13.5, 18.9)	16.5 (13.8, 19.2)	-0.3 (-4.1, 3.6)	0.89

52 weeks	11.9 (9.2, 14.5)	14.0 (11.3, 16.6)	-2.1 (-5.8, 1.6)	0.27
Overall	21.3 (18.9, 23.6)	24.4 (22.0, 26.7)	-3.0 (-6.3, 0.3)	0.07

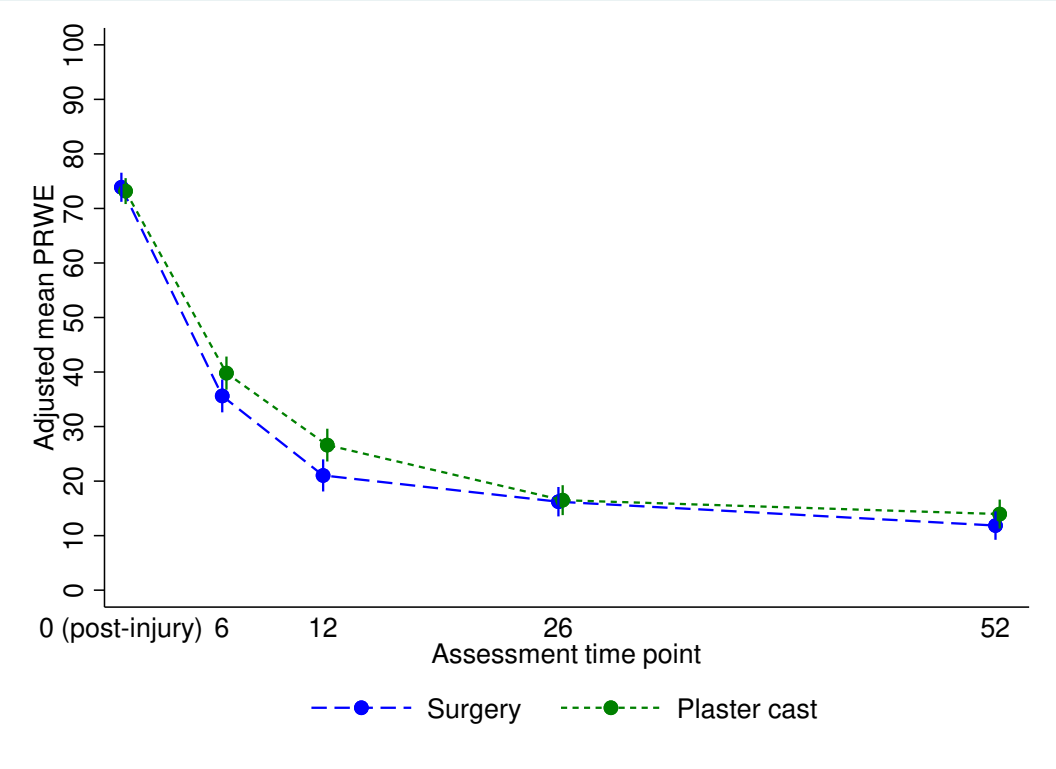


Figure 6: Adjusted mean PRWE scores (with 95% CIs) for primary analysis over time by randomised group

Valid data

The primary analysis included data from 408 patients (surgery n=203; plaster cast n=205) with a valid PRWE score for at least one follow-up time point and complete baseline covariates. A valid response is defined here as sufficient data (maximum of one missing PRWE item in each

of the two subscales) to allow the calculation of the total score. The number of participants with valid PRWE data at each time point is presented by randomised group in Table 12, with reasons for missing data.

The percentage of randomised participants with valid PRWE data ranged from 68.8% (26 weeks) to 82.5% (52 weeks) for the post-randomisation time points. Overall, 408 (surgery n=203, 92.7%; plaster cast n=205, 93.2%) had valid PRWE data for at least one post-randomisation time point and so were included in the primary analysis model.

Table 12: Valid PRWE data by randomised group and time point, with reasons for missing data

Follow-up	Response type	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)
Baseline (pre-injury)	Valid response	205 (93.6)	203 (92.3)	408 (92.9)
	No or partial response[a]:			
	Partial response	0 (0)	2 (0.9)	2 (0.5)
	All missing responses	12 (5.5)	15 (6.8)	27 (6.2)
	Did not return questionnaire	2 (0.9)	0 (0.0)	2 (0.5)
Baseline (post-injury)	Valid response	213 (97.3)	209 (95)	422 (96.1)
	No or partial response[a]:			
	Partial response	4 (1.8)	11 (5)	15 (3.4)
	All missing responses	0 (0.0)	0 (0.0)	0 (0.0)
	Did not return questionnaire	2 (0.9)	0 (0.0)	2 (0.5)
6 weeks	Valid response	176 (80.4)	172 (78.2)	348 (79.3)
	No or partial response[a]:			
	Partial response	2 (0.9)	9 (4.1)	11 (2.5)
	All missing responses	0 (0.0)	0 (0.0)	0 (0.0)
	Did not return questionnaire	36 (16.4)	36 (16.4)	72 (16.4)
	Withdrawn from questionnaires	5 (2.3)	3 (1.4)	8 (1.8)

12 weeks	Valid response	178 (81.3)	163 (74.1)	341 (77.7)
	No or partial response[a]:			
	Partial response	4 (1.8)	4 (1.8)	8 (1.8)
	All missing responses	0 (0.0)	0 (0.0)	0 (0.0)
	Did not return questionnaire	30 (13.7)	50 (22.7)	80 (18.2)
	Withdrawn from questionnaires	7 (3.2)	3 (1.4)	10 (2.3)
26 weeks	Valid response	156 (71.2)	146 (66.4)	302 (68.8)
	No or partial response[a]:			
	Partial response	6 (2.7)	3 (1.4)	9 (2.1)
	All missing responses	1 (0.5)	0 (0.0)	1 (0.2)
	Did not return questionnaire	49 (22.4)	67 (30.5)	116 (26.4)
	Withdrawn from questionnaires	7 (3.2)	4 (1.8)	11 (2.5)
52 weeks	Valid response	186 (84.9)	176 (80)	362 (82.5)
	No or partial response[a]:			
	Partial response	0 (0.0)	2 (0.9)	2 (0.5)
	All missing responses	0 (0.0)	0 (0.0)	0 (0.0)
	Did not return questionnaire	26 (11.9)	35 (15.9)	61 (13.9)
	Withdrawn from questionnaires	7 (3.2)	7 (3.2)	14 (3.2)

[a] questionnaire returned but missing response data to PRWE items

Demographic and injury characteristics at baseline for participants who provided valid PRWE data at each time point are presented by randomised group in

Appendix 3, Table 51 to Table 53.

Overall, 249 patients (56.7%) had a valid PRWE response at all post-randomisation follow-up time points (complete responders: surgery n=130, 59.4%; plaster cast n=119, 54.1%); and a further 159 (intermittent responders: surgery n=73, 33.3%; plaster cast n=86, 39.1%) had a valid PRWE response at one or more, but not all, post-randomisation time points. Table 13 provides the descriptive PRWE total scores for complete and intermittent responders, and the baseline PRWE scores for those who had no valid post-randomisation PRWE data. Complete responders had, on average, better PRWE outcomes (lower mean score) than intermittent responders pre-injury and at 52 weeks post-randomisation but similar outcomes at baseline (post-injury), and at six, 12 and 26 weeks post-randomisation.

Table 13: Unadjusted total PRWE scores for complete, intermittent and non-responders to post-randomisation follow-ups, by time point

Total PRWE		**Complete responders (n=249)**	**Intermittent responders (n=159)**	**Non-responders (n=31)**
Baseline (pre-injury)	Mean (SD)	2.7 (9.3)	4.8 (14.7)	1.1 (2.3)
	Median (IQR)	0 (0, 0)	0 (0, 0)	0 (0, 0)
	Min, max	(0, 85)	(0, 90.5)	(0, 8)
Baseline (post-injury)	Mean (SD)	74.4 (16.8)	72.4 (21.5)	72.1 (16.5)
	Median (IQR)	77.5 (65.3, 77.5)	76.8 (62, 76.8)	74.5 (63.8, 74.5)
	Min, max	(0, 100)	(0, 100)	(35, 96.5)
6 weeks	Mean (SD)	37.3 (19.7)	37.0 (24.6)	-
	Median (IQR)	37 (22.5, 37)	30.5 (17.5, 30.5)	-
	Min, max	(0, 85.9)	(0, 100)	-
12 weeks	Mean (SD)	22.9 (20.0)	23.9 (23.0)	-
	Median (IQR)	17. (8, 17.5)	17 (5, 17)	-
	Min, max	(0, 90)	(0, 80.5)	-
26 weeks	Mean (SD)	15.4 (17.1)	15.3 (21.7)	-

	Median (IQR)	10.5 (3.5, 10.5)	5 (0, 5)	-
	Min, max	(0, 84)	(0, 91.5)	-
52 weeks	Mean (SD)	11.7 (17.5)	15.0 (19.6)	-
	Median (IQR)	4.5 (0, 4.5)	4 (0, 4)	-
	Min, max	(0, 96)	(0, 88)	-

SD, standard deviation; IQR, interquartile range; min, minimum; max, maximum

Descriptive Patient Rated Wrist Evaluation statistics

Total mean PRWE scores for pre-injury and at enrolment (post-injury) were similar between the two groups (*see Table 14*). Total mean PRWE scores improved (decreased) over time following injury in both groups, but were higher (worse) in the plaster cast group than in the surgery group at all post-randomisation time points except at 26 weeks. At 52 weeks, the unadjusted mean difference was -2.8 points (95% CI -6.5 to 1.0), favouring the surgery group.

Table 14: Unadjusted PRWE total and subscale scores by randomised group and time point

PRWE		**Surgery**	**Plaster cast**	**Total**
Baseline (pre-injury)				
Pain subscale	Mean (SD)	2.2 (6.6)	2.5 (6.9)	2.4 (6.7)
	Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
	Min, max	(0, 50)	(0, 41)	(0, 50)
Function subscale	Mean (SD)	1.0 (5.1)	1.1 (5.7)	1.0 (5.4)
	Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, max	(0, 43)	(0, 49.5)	(0, 49.5)
Total	Mean (SD)	3.1 (10.8)	3.6 (11.8)	3.4 (11.3)
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
	Min, max	(0, 85)	(0, 90.5)	(0, 90.5)
Baseline (post-injury)				
Pain subscale	Mean (SD)	34.7 (10.8)	34.3 (9.7)	34.5 (10.2)
	Median (IQR)	36.0 (30.0, 42.0)	35.0 (28.4, 42.0)	36.0 (29.0, 42.0)

PRWE		**Surgery**	**Plaster cast**	**Total**
	Min, max	(0, 50)	(0, 50)	(0, 50)
Function subscale	Mean (SD)	39.1 (10.4)	38.5 (10.0)	38.8 (10.2)
	Median (IQR)	41.8 (34.0, 47.0)	40.5 (33.5, 46.0)	41.0 (33.5, 46.5)
	Min, max	(0, 50)	(0, 50)	(0, 50)
Total	Mean (SD)	73.9 (19.8)	73.2 (17.4)	73.5 (18.6)
	Median (IQR)	78.5 (65.5, 87.5)	76.0 (63.5, 86.5)	77.5 (64.0, 87.0)
	Min, max	(0, 100)	(0, 100)	(0, 100)
6 weeks				
Pain subscale	Mean (SD)	18.9 (10.5)	18.4 (10.7)	18.6 (10.6)
	Median (IQR)	19.0 (10.0, 27.0)	17.0 (10.0, 26.0)	18.0 (10.0, 26.3)
	Min, max	(0, 44)	(0, 50)	(0, 50)
Function subscale	Mean (SD)	16.8 (12.8)	20.1 (12.4)	18.5 (12.7)
	Median (IQR)	13.5 (6.5, 25.5)	19.0 (9.8, 27.3)	17.0 (8.0, 26.5)
	Min, max	(0, 47)	(0, 50)	(0, 50)
Total	Mean (SD)	35.7 (21.4)	38.8 (21.0)	37.2 (21.2)
	Median (IQR)	33.8 (18.8, 49.0)	38.3 (22.5, 52.3)	35.4 (19.5, 51.5)
	Min, max	(3, 85.5)	(0, 100)	(0, 100)
12 weeks				
Pain subscale	Mean (SD)	12.8 (11.0)	14.6 (11.2)	13.7 (11.1)
	Median (IQR)	10.0 (4.5, 18.0)	12.0 (6.0, 21.0)	11.0 (5.0, 19.0)
	Min, max	(0, 45)	(0, 47)	(0, 47)
Function subscale	Mean (SD)	7.9 (9.3)	11.2 (11.5)	9.5 (10.5)
	Median (IQR)	5.0 (1.0, 11.0)	7.5 (2.5, 16.0)	6.0 (1.5, 13.0)
	Min, max	(0, 44.5)	(0, 46.5)	(0, 46.5)
Total	Mean (SD)	20.7 (19.6)	25.9 (21.8)	23.2 (20.8)
	Median (IQR)	15.0 (6.0, 27.0)	20.0 (8.7, 35.5)	17.5 (7.0, 31.5)
	Min, max	(0, 89.5)	(0, 90)	(0, 90)
26 weeks				
Pain subscale	Mean (SD)	10.5 (10.6)	9.9 (10.0)	10.2 (10.3)
	Median (IQR)	7.0 (3.0, 15.0)	8.0 (2.0, 13.0)	8.0 (2.0, 15.0)
	Min, max	(0, 43)	(0, 44)	(0, 44)
Function subscale	Mean (SD)	5.3 (8.3)	5.4 (8.7)	5.4 (8.5)

PRWE		Surgery	Plaster cast	Total
	Median (IQR)	1.8 (0.0, 5.8)	2.0 (0.0, 6.0)	2.0 (0.0, 6.0)
	Min, max	(0, 41)	(0, 47.5)	(0, 47.5)
Total	Mean (SD)	15.7 (18.1)	15.1 (17.8)	15.4 (18.0)
	Median (IQR)	9.0 (3.5, 20.5)	10.5 (2.0, 18.0)	9.5 (3.0, 19.0)
	Min, max	(0, 84)	(0, 91.5)	(0, 91.5)
52 weeks				
Pain subscale	Mean (SD)	7.7 (10.1)	9.2 (11.3)	8.4 (10.7)
	Median (IQR)	4.0 (0.0, 10.0)	4.0 (0.0, 14.0)	4.0 (0.0, 12.0)
	Min, max	(0, 42)	(0, 48)	(0, 48)
Function subscale	Mean (SD)	3.7 (7.2)	4.9 (9.0)	4.3 (8.1)
	Median (IQR)	0.5 (0.0, 3.5)	0.5 (0.0, 5.0)	0.5 (0.0, 4.5)
	Min, max	(0, 43.5)	(0, 48)	(0, 48)
Total	Mean (SD)	11.4 (16.6)	14.2 (19.8)	12.8 (18.2)
	Median (IQR)	4.0 (0.0, 14.0)	4.5 (0.0, 19.3)	4.5 (0.0, 16.5)
	Min, max	(0, 85.5)	(0, 96)	(0, 96)

SD, standard deviation; IQR, interquartile range; min, minimum; max, maximum

PRWE at the secondary time points

Adjusted PRWE means and group differences for the primary analysis model are presented in Table 11 and displayed in Figure 6. The analysis showed a statistically significant difference between treatment groups at week 12 (p=0.01) and a borderline result at week six (p=0.06), but not at week 26 (p=0.89) or the primary end point of 52 weeks (p=0.27). There was no overall effect of treatment group (difference of 3.0 points in favour of the surgery group; p=0.07). Although statistically significant, the mean difference observed at 12 weeks was lower than our minimum clinically important difference of 6 points, though the confidence interval does include this difference.

Sensitivity analyses

Missing data

Adjusted PRWE means and group differences for the separate linear regression analysis models, for each time point, run on the multiply imputed dataset are presented in Table 15. Analyses showed very similar results to the primary analysis i.e., a statistically significant difference between treatment groups at weeks 6 (p=0.049) and 12 (p=0.01) but not at week 26 (p=0.93) or the primary end point of 52 weeks (p=0.28). The adjusted mean difference at 52 weeks was -2.0 (95% CI -5.7 to 1.6) in favour of the surgery group. Since separate linear regressions were performed for these analyses as opposed to a repeated measures model, there is no estimate for the overall treatment effect over time.

Handling multi-site data

Adjusted PRWE means and group differences are presented in Table 15 for the analysis in which the primary outcome model additionally included site as a random effect (within which participants were nested). An unstructured covariance pattern was specified for this model. The analysis showed no statistically significant differences between treatment groups post-randomisation, except at week 12 (p=0.01). The adjusted mean difference at 52 weeks was -1.9 (95% CI -5.6 to 1.8). There was no overall effect of treatment group (difference of 2.8 points in favour of the surgery group; p=0.09).

Timing of data collection

The primary analysis model was repeated only including data collected one week either side of the six week time point (surgery n=118; plaster cast n=112), 2 weeks either side of the 12 week time point (surgery n=121; plaster cast n=108), 6 weeks either side of the 26 week time point (surgery n=133; plaster cast n=128), and 8 weeks either side of the 52 week time point (surgery n=170; plaster cast n=155). A total of 380 participants were included in this analysis (190 in each group).

Adjusted PRWE means and group differences for the model as specified above are presented in Table 15. The analysis showed no statistically significant differences between treatment groups post-randomisation, except at week 12 (p=0.01). The adjusted mean difference at 52 weeks is

in this population was -3.1 (95% CI -6.7 to 0.6). There was no overall effect of treatment group (difference of 2.4 points in favour of the surgery group; p=0.16).

Post-hoc sensitivity analysis including smoking status

Smoking status (yes/no) was included as a covariate in the primary analysis model in a sensitivity check since this factor was found to be imbalanced by chance at baseline (smoker: surgery group: 33%; plaster cast group: 26%) and thought to be associated with poorer bone healing and complications. The analysis showed similar results to the primary analysis, that is a statistically significant difference between treatment groups at week 12 (p=0.01) but at neither week 26 (p=0.67) nor the primary end point of 52 weeks (p=0.14). Week six was now statistically significant at the 5% level (p=0.03). However, there was evidence of an overall effect of treatment group (difference of 3.6 points in favour of the surgery group; p=0.03). The magnitude of the effect at 52 weeks is increased compared to the primary analysis (from 2.1 to 2.8 points in favour of the surgery group), and the 95% confidence interval includes the minimum clinically important difference of six points (*see Table 15*).

Displacement and lack of fracture as assessed by independent review of baseline imaging data

The randomisation for the trial was stratified by presence or not of displacement of a scaphoid fracture (<1mm, or 1-2mm inclusive) as seen on the plain radiographic views taken at baseline and used by the treating clinician to determine eligibility (though note discrepancies discussed in section *Baseline characteristics of randomised participants*). This judgement of displacement is included as a covariate in the primary analysis model. Extent of fracture displacement was also subsequently assessed and agreed upon by three independent raters who reviewed all available participant baseline imaging data (CT scans and radiographs) throughout the trial.

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, 97.3%; plaster cast n=217, 99.1%). Both baseline and CT images were reviewed for 431 (98.2%) participants, radiographs only for 7 (1.6%) participants, and neither for one participant (0.2%). 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 (81.6%) 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 (14.9%) as displaced 1-2 mm, 8 (3.1%) as >2 mm, and 1 (0.4%) missing (see

Appendix 3, Table 54). Of the 178 fractures that were deemed to be displaced (1-2 mm) by the treating clinician at baseline, 112 (62.9%) were classified as not displaced (<1 mm) on review, 47 (26.4%) as displaced 1-2 mm, and 19 (10.7%) as >2 mm.

The primary analysis model was rerun replacing displacement as used in the randomisation as a covariate with the variable indicating extent of displacement agreed by the three raters (*see Table 15*) providing very similar results to the primary analysis (*see Table 11).*

Consensus was reached between the three raters that displacement of the fracture was greater than 2 mm, based on their assessment of the baseline radiography/CT scans, for 27 (6.2%) randomised participants. A fracture could be seen on radiographic imaging for all but one of the 438 participants (n=437, 99.8%) for whom these data were available, and on CT imaging for 426 (98.8%) 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 (*see Table 15*).

The quality of the radiographic imaging on which the one participant was deemed not to have a fracture was deemed to be 'good'. For the five participants for whom a fracture could not be seen on their CT images, the quality was deemed to be 'good' in three cases, and 'fair' in the other two.

In addition, for patients for whom raters thought there was no fracture on the CT later images were reviewed for evidence of bone healing to confirm whether there had been a fracture. For the participant for whom the baseline radiographic images also indicated there was no fracture, this was confirmed in all other images. In the four others, the radiographic images indicated a fracture: one only had baseline imaging so later images could not be reviewed; one had baseline and 52 weeks only, and at 52 weeks the appearances were interpreted as union;

one had baseline, 6 week and 52 week imaging and in all subsequent images the fracture was considered to be united; and one had only 6 week imaging in which the fracture was considered to have united. However, union cannot be said to confirm a fracture was initially present.

Table 15: Difference in adjusted mean PRWE scores over time by randomised group for sensitivity analyses

Time point	Surgery Mean (95% CI)	Plaster cast Mean (95% CI)	Difference (95% CI)	p-value
Missing data[a] (n=439; surgery, n= 219; plaster cast, n=220)				
6 weeks	35.1 (32.1, 38.1)	39.8 (36.7, 42.9)	-4.7 (-9.0, -0.5)	0.03
12 weeks	20.7 (17.9, 23.6)	26.6 (23.7, 29.5)	-5.9 (-9.9, -1.9)	<0.01
26 weeks	16.1 (13.4, 18.8)	16.4 (13.7, 19.2)	-0.3 (-4.2, 3.5)	0.87
52 weeks	12.0 (9.3, 14.6)	14.1 (11.4, 16.8)	-2.1 (-5.9, 1.6)	0.26
Handling multi-site data (n=408; surgery, n= 203; plaster cast, n=205)				
6 weeks	36.2 (32.6, 39.8)	40.2 (36.6, 43.8)	-4.0 (-8.2, 0.3)	0.07
12 weeks	21.6 (18.1, 25.1)	27.0 (23.4, 30.6)	-5.4 (-9.5, -1.2)	0.01
26 weeks	16.8 (13.5, 20.1)	16.9 (13.6, 20.3)	-0.1 (-3.9, 3.7)	0.96
52 weeks	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
Timing of data collection (n=380; surgery, n=190; plaster cast, n=190)				
6 weeks	37.3 (33.9, 40.7)	37.7 (34.2, 41.2)	-0.4 (-5.3, 4.4)	0.86
12 weeks	20.6 (17.5, 23.8)	26.4 (23.1, 29.7)	-5.7 (-10.3, -1.2)	0.01
26 weeks	15.2 (12.5, 17.9)	15.4 (12.7, 18.1)	-0.2 (-4.0, 3.6)	0.93
52 weeks	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
Adjusted for smoking status (n=406; surgery, n=202; plaster cast, n=204)				
6 weeks	35.3 (32.3, 38.3)	40.0 (36.9, 43.0)	-4.7 (-9.0, -0.4)	0.03
12 weeks	20.7 (17.8, 23.7)	26.8 (23.8, 29.8)	-6.0 (-10.2, -1.8)	0.01
26 weeks	15.9 (13.2, 18.6)	16.7 (14.0, 19.5)	-0.8 (-4.7, 3.0)	0.67

52 weeks	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
Including displacement as agreed by three independent raters (n=408; surgery, n= 203; plaster cast, n=205)				
6 weeks	35.5 (32.5, 38.5)	39.8 (36.8, 42.8)	-4.3 (-8.5, -0.0)	0.05
12 weeks	21.0 (18.0, 23.9)	26.6 (23.6, 29.6)	-5.6 (-9.8, -1.4)	0.01
26 weeks	16.2 (13.6, 18.9)	16.5 (13.8, 19.2)	-0.3 (-4.1, 3.6)	0.89
52 weeks	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 (n=407; surgery, n= 202; plaster cast, n=205)				
6 weeks	35.7 (32.6, 38.7)	39.8 (36.8, 42.8)	-4.1 (-8.4, 0.1)	0.06
12 weeks	21.1 (18.1, 24.0)	26.6 (23.6, 29.6)	-5.5 (-9.7, -1.3)	0.01
26 weeks	16.3 (13.6, 19.0)	16.5 (13.8, 19.2)	-0.2 (-4.1, 3.6)	0.91
52 weeks	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 >2 mm (n=383; surgery, n= 191; plaster cast, n=192)				
6 weeks	35.0 (31.9, 38.0)	39.8 (36.7, 42.9)	-4.8 (-9.2, -0.5)	0.03
12 weeks	20.7 (17.6, 23.7)	26.2 (23.1, 29.3)	-5.6 (-9.9, -1.3)	0.01
26 weeks	15.7 (13.0, 18.3)	16.3 (13.6, 19.0)	-0.6 (-4.4, 3.2)	0.76
52 weeks	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

Complier average causal effect (CACE) analysis

The CACE analysis considers the effect of receiving early surgical fixation compared with no surgical fixation of the fracture, and as such does not account for the 'partial' compliers in the plaster cast group (ie. the two participants for whom surgery was considered for non-union after a period of plaster cast management, and the three participants who received delayed surgical fixation (post 6 months after randomisation) of their

non-united fracture). We have considered these a pragmatic aspect of the 'control' condition. Six (2.7%) participants in the plaster cast group crossed over to the surgery group and received immediate surgical fixation of their fractures (contamination), while 31 (14.2%) participants in the surgery group did not receive surgery but instead were managed conservatively (non-compliance). The CACE estimate of the treatment effect with adjustment for non-compliance and contamination is a difference of -3.1 (95% CI -7.3 to 1.1, p=0.15) in 52 week total PRWE score. This difference is in favour of the surgery group and is larger than the ITT treatment effect estimate at 52 weeks, demonstrating a greater, but not statistically significant, benefit of surgery amongst participants who complied with their treatment allocation. The 95% CI is -7.3 to 1.1; therefore, we cannot rule out a clinically meaningful difference or no effect.

Subgroup analysis

Patient preference for treatment

The first subgroup analysis was undertaken to test the hypothesis that participants who expressed a preference for surgery at baseline would benefit more from surgery than participants who expressed a preference against surgery or who had no particular treatment preference.

Descriptive summary statistics for the PRWE total score are presented in

Appendix 3, Table 55 and displayed in

Appendix 3, Figure 14**Error! Reference source not found.** by treatment group stratified by baseline treatment preference. No notable differences between the two groups are observed at any time point within the subgroup who did not express a treatment preference at baseline. Unadjusted mean scores are lower (better) in the surgery group at all time-points except 26 weeks in the subgroup who expressed a preference for surgery. In the subgroup who preferred no surgery, unadjusted mean scores are lower (better) in the surgery group at all time-points except baseline (post-injury) in the subgroup who expressed a preference for surgery, and the differences between the groups are larger at six, 12 and 26 weeks than in the subgroup with a preference for surgery.

No significant interaction was observed between randomised allocation and treatment preference (surgery group and preference for surgery p=0.54; surgery group and preference for no surgery p=0.65). At 52 weeks, the adjusted mean difference in total PRWE score between the surgery and plaster cast groups was -0.9 (95% CI -6.0 to 4.2, p=0.72) in the no preference subgroup, -3.0 (95% CI -8.2 to 2.2, p=0.25) in the surgery preference subgroup, and -4.2 (95% CI -17.2 to 8.9, p=0.53) in the no surgery preference subgroup.

Fracture displacement (randomisation)

The second subgroup analysis tested the hypothesis that patients with a displaced fracture at baseline would benefit more from surgery than those with a non-displaced fracture. The relationship between fracture displacement (as stratified on in the randomisation) and randomised group in terms of PRWE is illustrated in

Appendix 3, Table 56 and

Appendix 3, Figure 15. Overall, participants with a displaced fracture tended to have higher post-randomisation PRWE scores than those with no or minimal displacement, and scores in the surgery group were lower than in the plaster cast group at six, 12, 26 and 52 weeks for this subgroup. There was no statistically significant interaction effect (p=0.35); at 52 weeks the adjusted mean difference between the surgery and plaster cast group was -0.8 (95% CI -5.4 to 3.8, p=0.73) in the no displacement subgroup, and -4.0 (95% CI -9.3 to 1.4, p=0.15) in the displaced subgroup, both favouring the surgery group.

Fracture displacement (study eligibility form)

A third subgroup analysis tested the hypothesis as above using displacement as recorded on the Study Eligibility Form. The relationship between fracture displacement (as recorded on the Study Eligibility Form) and randomised group in terms of PRWE is illustrated in

Appendix 3, Table 57 and

Appendix 3, Figure 16. Overall, participants with a displaced fracture tended to have higher post-randomisation PRWE scores than those with no or minimal displacement, and scores in the surgery group were lower than in the plaster cast group at six, 12, and 52 weeks for this subgroup. There was no statistically significant interaction effect (p=0.70); at 52 weeks the adjusted mean difference between the surgery and plaster cast group was -1.6 (95% CI -6.1 to 3.0, p=0.50) in the no displacement subgroup, and -2.9 (95% CI -8.4 to 2.6, p=0.30) in the displaced subgroup, both favouring the surgery group.

Surgery patients for whom the screw caused cartilage damage

A total of 188 (85.8%) participants allocated to the surgery group received treatment as allocated. For 142 (75.5%) of these, CT images at 52 weeks were assessed by three independent raters for surgical screw penetration. No screw penetration was observed for 49 (34.5%) participants. The extent of the penetration was measured for the remaining 93 participants (mean 1.6 mm, SD 0.95, range 0.2 to 4.7), and was categorised as: minor = <1 mm, unlikely to cause an effect on articular cartilage (n=25/93, 26.9%), moderate = 1-2 mm inclusive, probably will have an effect on cartilage causing damage (n=44, 47.3%); severe = >2 mm, definitely will cause lasting damage to articular cartilage (n=24, 25.8%). Descriptive summaries of baseline participant and fracture data and PRWE scores for these stratified by whether or not the surgical screw used was too long and caused cartilage damage (none+minor vs moderate+severe) as determined on the CT scans are provided in

Appendix 3, Table 58**Error! Reference source not found.**, Table 59**Error! Reference source not found.** and Table 60**Error! Reference source not found.**. Participants with displaced fractures at baseline were less likely to suffer from cartilage damage caused by the screw. At 52 weeks, those who did not have significant surgical screw protrusion tended to perform better on the PRWE (total unadjusted mean 8.9 vs 10.8).

Plaster cast patients who required surgery for non-union

Of the 220 participants allocated to the plaster cast group, six crossed over to receive immediate surgical fixation, while of the remaining 214, 19 (8.9%) were deemed to require surgical fixation of a non-united fracture following plaster cast management (though two participants did not receive the surgery, see *Allocated to receive plaster cast intervention*). Descriptive summaries of baseline participant and fracture data and PRWE scores for the 214 plaster cast participants stratified by whether or not they needed surgery due to non-union are presented in

Appendix 3, Table 58, Table 59**Error! Reference source not found.** and Table 60**Error! Reference source not found.**. Participants with displaced fractures at baseline were more likely to require surgery for non-union than those with <1 mm displacement. Other risk factors include being female and a smoker. Additionally, those that required surgery had had their injuries for slightly longer at enrolment to the trial than those who did not require surgery (median 6 vs 4 days). At 52 weeks, those who did not require surgery for non-union tended to perform better on the PRWE (total unadjusted mean 12.8 vs 29.1).

Feasibility requirements

There were two feasibility requirements for this trial: (i) that a CT scan was performed within two weeks (14 days) of a patient's injury (and before surgery if this occurred earlier); and (ii) for patients in the surgery arm, that surgery was performed within two weeks from presentation to A&E or other clinic.

The majority of participants had a CT scan within 2 weeks of their injury (and before surgery if this was earlier): surgery group n=216 (98.6%); and plaster cast group n=196 (89.1%) (*see*

Appendix 3*,* Table 61***Error! Reference source not found.****,* Table 62 *and* Table 63*).* Three participants in the surgery group did not meet this feasibility requirement: two crossed over treatment and received neither a CT scan nor surgery; and one had their CT scan 15 days after their injury, but this was before their surgery which occurred 5 days later. Twenty four participants in the plaster cast group did not meet this feasibility requirement: five received routine treatment and did not receive a CT scan; one immediately crossed over to surgery, which took place 7 days after injury, but did not receive a CT scan; and 18 had their CT scan between 15 and 47 days after injury (three of which received surgery at a later date as part of their further routine treatment for non-union).

Among participants allocated to the surgery group, 182 (83.1%) had surgical fixation of their fracture within 14 days of presenting at the A&E or other clinic. Of the remaining 37, 31 did not receive surgery, and six had their surgery between 15 and 20 days after presentation (*see*

Appendix 3, Table 61, Table 62***Error! Reference source not found.*** *and* Table 63). A linear regression for the surgery arm indicated that time from injury to surgery in days may be predictive of PRWE score at 52 weeks such that a one day delay in surgery is associated with a 0.78 points increase in PRWE score (95% CI -0.01 to 1.57, p=0.054).

Secondary analysis

PRWE subscales: pain and function

The PRWE subscale scores for pain and function are summarised in Table 14. Adjusted PRWE pain and function subscale means and group differences are presented in Table 16, and displayed

Appendix 3, Figure 17. The pain subscale analysis included data from 409 participants (surgery n=203, 92.7%; plaster cast n=206, 93.6%), and the function analysis from 408 participants (surgery n=203, 92.7%; plaster cast n=205, 93.2%). The analysis of the pain subscale showed no statistically significant difference between treatment groups overall or at any individual post-randomisation time point. The adjusted mean difference at 52 weeks was -1.1 (95% CI -3.3 to 1.0) in favour of the surgery group. However, a statistically significant difference in function subscale score, favouring the surgery group, was seen at six and 12 weeks. This difference did not persist to 26 or 52 weeks, but there is an overall statistically significant difference between the two groups over time.

Table 16: Difference in adjusted mean PRWE pain and function subscale scores over time by randomised group

Time point	Surgery Mean (95% CI)	Plaster cast Mean (95% CI)	Difference (95% CI)	p-value
PRWE Pain subscale (n=409; surgery, n= 203; plaster cast, n=206)				
6 weeks	18.8 (17.3, 20.4)	19.0 (17.5, 20.5)	-0.1 (-2.3, 2.0)	0.89
12 weeks	13.1 (11.5, 14.6)	15.0 (13.4, 16.6)	-2.0 (-4.2, 0.3)	0.09
26 weeks	11.0 (9.4, 12.5)	10.6 (9.0, 12.2)	0.4 (-1.8, 2.6)	0.75
52 weeks	7.9 (6.4, 9.5)	9.1 (7.5, 10.6)	-1.1 (-3.3, 1.0)	0.31
Overall	12.7 (11.5, 14.0)	13.5 (12.2, 14.8)	-0.7 (-2.5, 1.1)	0.44
PRWE Function subscale (n=408; surgery, n= 203; plaster cast, n=205)				
6 weeks	16.7 (14.9, 18.5)	20.5 (18.7, 22.3)	-3.8 (-6.3, -1.3)	<0.01
12 weeks	8.1 (6.6, 9.5)	11.5 (10.0, 13.0)	-3.4 (-5.6, -1.3)	<0.01
26 weeks	5.4 (4.1, 6.6)	6.0 (4.7, 7.3)	-0.6 (-2.4, 1.2)	0.52
52 weeks	3.9 (2.7, 5.1)	4.9 (3.7, 6.1)	-1.0 (-2.6, 0.7)	0.25
Overall	8.6 (7.5, 9.7)	10.8 (9.7, 12.0)	-2.2 (-3.8, -0.6)	0.01

SF-12: physical and mental health component scores

Mean mental and physical SF-12 component scores (MCS, PCS) improved (increased) over time following randomisation in both groups (except between 26 and 52 weeks in PCS in the plaster cast arm) (*see Table 17*). At 52 weeks, the unadjusted mean difference in MCS was -1.1 points (95% CI -3.2 to 1.0) favouring the plaster cast group, but in PCS was 1.8 (95% CI 0.2 to 3.3) favouring the surgery group.

Adjusted SF-12 means and group differences for the models are presented in Table 17, and displayed in

Appendix 3, Figure 18. Both analysis models included data from 408 participants (surgery n=202, 92.2%; plaster cast n=206, 93.6%). The analysis of the MCS subscale showed no statistically significant difference between treatment groups overall or at any individual post-randomisation time point. The adjusted mean difference at 52 weeks was -1.2 (95% CI -3.3 to 0.8) in favour of the plaster cast group. However, a statistically significant difference in PCS subscale score, favouring the surgery group, was seen at 12 and 52 weeks, but not at six or 26 weeks, nor overall (p=0.08). The adjusted mean difference at 52 weeks was 1.6 (95% CI 0.2 to 3.1) in favour of the surgery group.

Table 17: Summaries of, and differences in adjusted mean, SF-12 mental and physical component subscale scores over time by randomised group

SF-12		**Surgery**	**Plaster cast**	**Total**
6 weeks				
MCS	Mean (SD)	49.5 (11.4)	49.3 (10.8)	49.4 (11.1)
	Median (IQR)	52.4 (41.2, 58.1)	51.3 (43.9, 57.0)	51.5 (42.5, 57.3)
	Min, max	(12.8, 67.8)	(16.0, 68.8)	(12.8, 68.8)
PCS	Mean (SD)	43.7 (8.6)	43.9 (8.1)	43.8 (8.3)
	Median (IQR)	44.0 (38.6, 50.3)	43.9 (38.0, 49.9)	43.9 (38.3, 50.1)
	Min, max	(21.1, 62.1)	(23.6, 63.7)	(21.1, 63.7)
12 weeks				
MCS	Mean (SD)	50.9 (11.1)	51.5 (10.2)	51.2 (10.7)
	Median (IQR)	52.8 (44.7, 59.4)	53.2 (45.7, 59.3)	53.0 (45.3, 59.3)
	Min, max	(16.4, 67.9)	(15.6, 66.4)	(15.6, 67.9)
PCS	Mean (SD)	49.9 (7.5)	47.7 (8.5)	48.9 (8.1)
	Median (IQR)	51.9 (45.0, 55.9)	49.3 (42.6, 53.5)	50.2 (43.9, 54.8)
	Min, max	(21.5, 62.1)	(21.4, 64.6)	(21.4, 64.6)
26 weeks				
MCS	Mean (SD)	50.9 (12.1)	52.2 (9.9)	51.5 (11.1)
	Median (IQR)	54.2 (46.2, 58.4)	54.4 (47.9, 59.1)	54.2 (47.5, 59.1)
	Min, max	(8.2, 67.9)	(11.4, 68.2)	(8.2, 68.2)
PCS	Mean (SD)	51.8 (7.4)	52.0 (7.6)	51.9 (7.5)
	Median (IQR)	54.5 (48.9, 56.3)	54.2 (49.5, 56.7)	54.3 (49.1, 56.7)
	Min, max	(25.9, 63.0)	(17.8, 62.5)	(17.8, 63.0)
52 weeks				

MCS	Mean (SD)	51.4 (10.1)	52.5 (10.0)	51.9 (10.1)
	Median (IQR)	54.2 (46.8, 57.6)	55.8 (47.6, 59.3)	54.8 (47.5, 58.2)
	Min, max	(15.3, 64.7)	(13.0, 68.5)	(13.0, 68.5)
PCS	Mean (SD)	53.2 (6.3)	51.5 (8.1)	52.3 (7.3)
	Median (IQR)	55.9 (49.3, 57.2)	53.5 (48.4, 56.2)	54.8 (49.0, 56.7)
	Min, max	(33.6, 65.7)	(22.2, 69.4)	(22.2, 69.4)
Time point	**Surgery Mean (95% CI)**	**Plaster cast Mean (95% CI)**	**Difference (95% CI)**	**p-value**
SF-12 MCS subscale (n=408; surgery, n= 202; plaster cast, n=206)				
6 weeks	49.7 (48.1, 51.3)	49.1 (47.5, 50.7)	0.5 (-1.7, 2.8)	0.63
12 weeks	50.6 (49.0, 52.1)	50.7 (49.1, 52.3)	-0.2 (-2.4, 2.1)	0.88
26 weeks	51.0 (49.4, 52.6)	51.6 (49.9, 53.3)	-0.6 (-3.0, 1.7)	0.60
52 weeks	51.0 (49.6, 52.5)	52.3 (50.8, 53.7)	-1.2 (-3.3, 0.8)	0.24
Overall	50.6 (49.3, 51.8)	50.9 (49.7, 52.2)	-0.4 (-2.2, 1.4)	0.69
SF-12 PCS subscale (n=408; surgery, n= 202; plaster cast, n=206)				
6 weeks	43.9 (42.7, 45.1)	43.4 (42.2, 44.6)	0.5 (-1.2, 2.2)	0.59
12 weeks	49.8 (48.7, 50.9)	47.6 (46.5, 48.8)	2.2 (0.6, 3.8)	0.01
26 weeks	51.6 (50.5, 52.7)	51.6 (50.5, 52.8)	-0.0 (-1.6, 1.5)	0.95
52 weeks	53.1 (52.1, 54.2)	51.5 (50.5, 52.6)	1.6 (0.2, 3.1)	0.03
Overall	49.6 (48.8, 50.4)	48.5 (47.7, 49.3)	1.1 (-0.1, 2.2)	0.08

Wrist range of movement and grip strength – affected wrist

Measures of wrist range of movement and grip strength for the affected wrist are presented in Table 18. Similar mean values were observed across these variables in the two groups at baseline. These were assessed at hospital visits at baseline, and at six, 12 and 52 weeks post-randomisation.

Table 18: Grip and range measures by randomised group and time point

Wrist range of movement and grip strength – affected wrist	**Surgery**	**Plaster cast**	**Total**
Baseline			

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				
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				
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				
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)

Grip strength

On average, grip strength, in kilograms, increased over time in both groups and was higher in the surgery group than the plaster cast group at all post-randomisation time points except 52 weeks.

Adjusted grip strength means and group differences are presented in Table 19, and displayed in

Appendix 3, Figure 19. The analysis models included data from 407 participants (surgery n=201, 91.8%; plaster cast n=206, 93.6%) and showed a statistically significant difference between treatment groups at 6 weeks post-randomisation (p<0.001) favouring the surgery group, a borderline statistically significant result at 12 weeks (p=0.06), and no difference at 52 weeks. The adjusted mean difference at 52 weeks was -1.0 (95% CI -3.7, 1.8)) favouring the plaster cast group.

Table 19: Difference in adjusted mean grip strength over time by randomised group (n=407; surgery, n= 201; plaster cast, n=206)

Time point	Surgery Mean (95% CI)	Plaster cast Mean (95% CI)	Difference (95% CI)	p-value
6 weeks	23.8 (22.0, 25.6)	19.4 (17.6, 21.2)	4.4 (1.8, 6.9)	0.001
12 weeks	30.9 (29.0, 32.8)	28.3 (26.4, 30.2)	2.6 (-0.1, 5.3)	0.06
52 weeks	37.0 (35.1, 39.0)	38.0 (36.1, 40.0)	-1.0 (-3.7, 1.7)	0.48
Overall	30.1 (28.5, 31.7)	27.9 (26.3, 29.5)	2.0 (-0.3, 4.2)	0.08

Union

Assessment of union via radiographs was possible for 188 (85.8%) participants in the surgery group, and 201 (91.4%) in the plaster cast group at 6 weeks, of which 13 (6.9%) and 32 (15.9%), respectively, displayed non- or only slight-union (*see Table 20*). At week 12, radiographic images were available for assessment of union for fewer participants than at six weeks: 169 (77.2%) in the surgery group, and 163 (74.1%) in the plaster cast arm. A lower proportion of those reviewed were graded as having non- or slight-union at this time point in both groups (n=7, 4.1% and n=23, 14.1%).

The proportion of participants assessed for union decreased at each time point in both groups. At 52 weeks, the grading of union was based on CT images, or radiographic images where CT was not available, and was assessed for 314 participants (surgery n=164, 74.9%; plaster cast n=150, 68.2%) of which 13 (4.1%) were deemed to have non- or only slight union of their fracture (surgery n=4, 2.4%; plaster cast n=9, 6.0%).

In Table 20, the proportion of participants with full union in the surgery group appears to decrease between 12 and 52 weeks from 46.6% to 42.5%; however, when we consider the proportions from non-missing data only, these increase from 49.7% and 52.3%, respectively, as expected.

The 52-week PRWE scores, where available, are summarised for the two groups according to whether or not the participants had imaging available for union assessment at 52 weeks (*see Table 20*). Overall, there is little difference in the mean PRWE scores for those who attended and did not attend for imaging (12.7 vs 13.2); however, there are differences between the two randomised groups. In the surgery group, participants who did not attend for imaging tended to have higher (worse) scores than those who did attend for imaging (mean 16.4 vs 10.6), and so are perhaps less likely to have full union of their fractures. However, the trend reverses in the plaster cast group, with those not attending for imaging having lower (better) scores, and so more likely to have better union.

Participants in the surgery group were less likely to have non- or only slight union of their fracture at 52 weeks but this difference was not found to be statistically significant in a logistic regression model adjusting for age, fracture displacement and hand dominance (OR 0.40, 95% CI 0.12 to 1.33, p=0.13). Similarly, results following multiple imputation of the union variables at six, 12 and 52 weeks indicated that the likelihood of participants having non- or only slight union of their fracture at 52 weeks was lower for participants allocated to the surgery group (OR 0.51, 95% CI 0.17 to 1.57) but not statistically significantly so (p=0.24). In the surgery group, 4/219 participants were deemed to have non- or slight-union at 52 weeks (1.8%) and 9/220 in the plaster cast group (4.1%). Based on these figures, the number of participants needed to be offered surgery over plaster cast management (followed by fixation of fractures that fail to unite with cast immobilisation) in order to prevent one extra non- or slight union at 52 weeks is 44 (number needed to treat; NNT). However, over a quarter of participants have missing data, and this calculation, by default, assumes that all those with missing data have at least partial union. At the other extreme, assuming all missing have slight or non-union, the NNT is 11. For non-union alone, the NNT is 73 and 12 in the two scenarios respectively.

Table 20: Summary of union assessment by time point and randomised group

Time point[a]	Union	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)
6 weeks	Union	47 (21.5)	26 (11.8)	73 (16.6)
	Almost full union	81 (37)	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)
12 weeks	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)
52 weeks	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)
PRWE total[b]	Attend imaging	161, 10.6 (15.5)	145, 15.0 (20.1)	306, 12.7 (18.0)
	Did not attend	25, 16.4 (22.1)	31, 10.6 (17.7)	56, 13.2 (19.8)

[a] 6 and 12 weeks from radiographic images, 52 weeks from CT unless missing in which case radiographic imaging was considered

[b] Total 52 week PRWE score, where available, according to whether patients attended or not for imaging at 52 weeks; n, mean (SD)

The one participant in the plaster cast group with non-union assessed at 52 weeks by the three raters had surgical fixation of their fracture the day after randomisation, followed by wearing a splint for two weeks, and no concerns about non-union were raised and recorded in the treatment confirmation form at six or 12 weeks. Of the four participants in the plaster cast group with non-union assessed, one had surgery to fix non-union three months after randomisation, a further surgery for persistent non-union six months after that, and a month later surgery to remove the wires from the second operation. The remaining three received routine treatment with a plaster cast and were not offered surgery, two since non-union was not suspected by the treating clinician on review of radiography, while the third did not attend for radiography at six or 12 weeks.

Malunion

Malunion was determined by calculating the ratio of the scaphoid height to length, and determined using thresholds of both 0.6 and 0.7 (*see Table 21*). 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 six weeks, 175 (93.6%) participants in the surgery group and 180 (90.0%) in the plaster cast group had malunion based on the 0.6 threshold. At 0.7, the figures are 52 (27.8%) and 51 (25.5%), respectively. Malunion at both thresholds remained reasonably steady in both groups at six, 12 and 52 weeks as determined via radiographic images. However, at 52 weeks, on CT, the rate of malunion dramatically decreases to 60 (38.29%) participants in the surgery group and 45 (33.3%) in the plaster cast group at the 0.6 threshold, and 7 (4.5%) and 7 (5.2%), respectively, at 0.7.

Table 21: 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)	Plaster cast (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)

Complications

At least one surgical complication, up to and including 52 weeks post-randomisation, was experienced by 31 (14.2%) participants randomised to the surgery group, and 3 (1.4%) participants in the plaster cast group. The most common surgical complication was screw protrusion (*see Table 22*), reported for 10 participants in the surgery group and one in the plaster cast group at six, 12 or 52 weeks. A nerve event (of any kind) was reported for one participant in the plaster cast group (hypoaesthesia at 52 weeks) and for 10 unique participants in the surgery group. Table 22 only presents complications that were reported for at least one participant throughout the course of the study; however, we also explicitly asked about the following surgical complications, of which none were reported: superficial division of radial nerve, vessel events, and avascular necrosis.

Table 22: Surgery related complications as assessed by clinical examination by randomised group and time point. Figures are n (%), number of unique participants and percentage of those randomised

Surgery related complications	Time point	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)
Surgical site infection	6 weeks	1 (0.5)	0 (0.0)	1 (0.2)
	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	1 (0.5)	2 (0.9)	3 (0.7)
Delayed wound healing	6 weeks	2 (0.9)	0 (0.0)	2 (0.5)
	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	1 (0.5)	1 (0.5)	2 (0.5)
Regional pain syndrome	6 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	12 weeks	1 (0.5)	0 (0.0)	1 (0.2)
	52 weeks	1 (0.5)	0 (0.0)	1 (0.2)
Nerve event				

Hypoaesthesia	6 weeks	2 (0.9)	0 (0.0)	2 (0.5)
	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	1 (0.5)	1 (0.5)	2 (0.5)
Numbness	6 weeks	3 (1.4)	0 (0.0)	3 (0.7)
	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	0 (0.0)	0 (0.0)	0 (0.0)
Superficial division	6 weeks	3 (1.4)	0 (0.0)	3 (0.7)
of median nerve	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	0 (0.0)	0 (0.0)	0 (0.0)
Other nerve event	6 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	12 weeks	2 (0.9)	0 (0.0)	2 (0.5)
	52 weeks	1 (0.5)	0 (0.0)	1 (0.2)
Screw Related Complications				
Protrusion	6 weeks	2 (0.9)	0 (0.0)	2 (0.5)
	12 weeks	1 (0.5)	0 (0.0)	1 (0.2)
	52 weeks	7 (3.2)	1 (0.5)	8 (1.8)
Bending	6 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	1 (0.5)	0 (0.0)	1 (0.2)
Radiolucent halo	6 weeks	1 (0.5)	0 (0.0)	1 (0.2)
	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	2 (0.9)	0 (0.0)	2 (0.5)
Implant problem – movement	6 weeks	2 (0.9)	0 (0.0)	2 (0.5)
	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	3 (1.4)	0 (0.0)	3 (0.7)
Other[a]	6 weeks	3 (1.4)	0 (0.0)	3 (0.7)
	12 weeks	2 (0.9)	0 (0.0)	2 (0.5)
	52 weeks	1 (0.5)	1 (0.5)	2 (0.5)
≥1 surgical complication	6 weeks	14 (6.4)	0 (0.0)	14 (3.2)
	12 weeks	6 (2.7)	0 (0.0)	6 (1.4)
	52 weeks	15 (6.9)	3 (1.4)	18 (4.1)
	Any time point	31 (14.2)	3 (1.4)	34 (7.7)

[a] Other includes: 6 weeks (all surgery group) – painful, swollen, and stich sinus (n=1); stich still in situ (n=1); tingling sensation in fingers (n=1). 12 weeks (all surgery group) – pins and needles, and problems lifting

(n=1); pain, stiffness and swelling (n=1). 52 weeks – scar tenderness (surgery group, n=1); allergic reaction to dressing (plaster cast group, n=1)

At least one issue relating to the plaster cast, up to and including 52 weeks, was reported for five (2.3%) participants randomised to the surgery group, and 40 (18.2%) participants in the plaster cast group (*see Table 23*). The most commonly reported issue was that the cast caused soreness (this was generally minor rubbing of the skin), reported for three surgery participants and 23 plaster cast participants at six or 12 weeks.

Table 23: Plaster cast related complications as assessed by clinical examination by randomised group and time point. Figures are n (%), number of unique participants and percentage of those randomised

Plaster cast issues	Time point	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)
Cast broken	6 weeks	0 (0.0)	7 (3.2)	7 (1.6)
	12 weeks	1 (0.5)	1 (0.5)	1 (0.5)
	52 weeks	0 (0.0)	0 (0.0)	0 (0.0)
Cast too soft	6 weeks	1 (0.5)	9 (4.1)	10 (2.3)
	12 weeks	0 (0.0)	1 (0.5)	1 (0.2)
	52 weeks	0 (0.0)	1 (0.5)	1 (0.2)
Cast too tight	6 weeks	2 (0.9)	8 (3.6)	10 (2.3)
	12 weeks	0 (0.0)	1 (0.5)	1 (0.2)
	52 weeks	0 (0.0)	2 (0.9)	2 (0.5)
Cast caused soreness	6 weeks	3 (1.4)	20 (9.1)	23 (5.2)
	12 weeks	0 (0.0)	3 (1.4)	3 (0.7)
	52 weeks	0 (0.0)	0 (0.0)	0 (0.0)
Other[a]	6 weeks	0 (0.0)	5 (2.3)	5 (1.1)
	12 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	52 weeks	0 (0.0)	0 (0.0)	0 (0.0)
≥1 cast complication	6 weeks	5 (2.3)	40 (18.2)	45 (10.3)
	12 weeks	1 (0.5)	4 (1.8)	5 (1.1)
	52 weeks	0 (0.0)	3 (1.4)	3 (0.7)
	Any time point	6 (2.7)	45 (20.5)	51 (11.6)

[a] Other includes: 6 weeks (all Plaster cast group) - cast itchy (n=2); mild numbness of thumb (n=2); nerve event: hypoaesthesia left first branch at median nerve (n=1)

At least one medical complication, up to 52 weeks, was reported for 4 (1.8%) participants randomised to the surgery group, and 5 (2.3%) participants in the plaster cast group. These were either a chest infection or other issue (gastric upset; depression; or tenderness of affected wrist, *see Table 24*). We also explicitly asked about the following medical complications, of which none were reported: myocardial infarction, stroke, DVT requiring treatment, and pulmonary embolism requiring treatment.

Table 24: Other medical complications as assessed by clinical examination by randomised group and time point. Figures are n (%), number of unique participants and percentage of those randomised

Medical complications	Time point	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)
Chest infection	6 weeks	0 (0.0)	0 (0.0)	0 (0.0)
	12 weeks	1 (0.5)	2 (0.9)	3 (0.7)
	52 weeks	4 (1.8)	0 (0.0)	4 (0.9)
Other	6 weeks	0 (0.0)	2 (0.9)	2 (0.5)
	12 weeks	0 (0.0)	1 (0.5)	1 (0.2)
	52 weeks	0 (0.0)	0 (0.0)	0 (0.0)
≥1 medical complication	6 weeks	0 (0.0)	2 (0.9)	2 (0.5)
	12 weeks	1 (0.5)	3 (1.4)	4 (0.9)
	52 weeks	4 (1.8)	0 (0.0)	4 (0.9)
	Any time point	4 (1.8)	5 (2.3)	9 (2.1)

[a] Other includes: 6 weeks (all Plaster cast group) – gastric upset, possibly caused by ibuprofen (n=1); depression (n=1). 12 weeks (Plaster cast group) – tenderness of affected wrist (n=1)

There was no evidence of a difference in the likelihood of participants experiencing at least one surgical, medical or cast complication (as recorded on the Complications form and detailed in Table 22, Table 23 and Table 24) up to 52 weeks between the two groups (surgery group

n=39 (17.8%) vs plaster cast group n=51 (23.2%); OR 0.72, 95% CI 0.45 to 1.15, p=0.17). We must be careful in over interpreting this finding that the likelihood of experiencing a surgical, cast or medical complication is similar in both groups. Cast complications were observed more frequently among the plaster cast group, and surgical complications more frequently among the surgery group. Plaster cast related complications tended to be relatively minor and would not result in ongoing problems (see Table 23). However, surgery related complications are more severe and are more likely to have potentially long-lasting consequences for the individual (see Table 22). As an example, Table 23 shows in the plaster cast group that half (30 of 58 events) of the complications were from the cast being broken, soft or tight which are given the same importance as complex regional pain syndrome or an infection in the statistical analysis of the complications. There was recording of non-union symptoms (n=8) as an adverse event or complication when this was an expected part of the control pathway and how a non-union was identified. There are also some discrepancies between the reporting of events on the complications form compared with the reporting of adverse events in the following section. For example the adverse events log three participants as having complex regional pain syndrome but the complication form only records two. The three raters' review of the imaging identified further complications that were not accounted for in the adverse event forms or the complication forms, particularly after surgery. This could have been influenced by whether the problem had been recognised or the surgeon's decision on whether this needed to be reported or whether the complication was identified on imaging done solely for research purposes and hence not available to clinicians. The logistic regression included complications from the hospital forms only and did not include those from other data sources (i.e. adverse event reporting or imaging).

Cases when two out of the three raters agreed on imaging that there was a complication on review of imaging data are reported by randomised group and time point in Table 25.

Osteoarthritis (OA) was detected at baseline on either radiographic or CT images for 25 (11.4%) participants in the surgery group, and 31 (14.1%) in the plaster cast group. OA was more likely to be detected on CT images than plain radiographic views. Of these 25 in the surgery

group, 23 had radiographic or CT imaging at 52 weeks, and 17 were seen to have OA on either of these. OA was detected for a further 28 participants at 52 weeks in the surgery group. Of the 31 participants in the plaster cast group with OA at baseline, 22 had radiographic or CT imaging at 52 weeks, and 20 were seen to have OA on either of these. OA was detected for a further 22 participants at 52 weeks in the plaster cast group.

Penetration of the screw (used during surgical fixation) of the radio-scaphoid joint (RSJ), scapho-trapezium joint (STJ) or other joint was reported for a total of 104 unique participants at six, 12 or 52 weeks (surgery n=94, 42.9%; plaster cast n=10, 4.6%). At 52 weeks, the CT scans of 80 participants in the surgery group were reported to show screw penetration in one or more joints: RSJ n=44/80 (55.0%); STJ n=48/80 (60.0%), and other joint n=19/80 (23.8%). For the cast group, for which a smaller proportion underwent surgery, the CT scans of 9 participants were reported to show screw penetration in one or more joints: RSJ n=4/9, 44.4%; STJ n=6/9, 66.7%, and other joint n=0/9 (0.0%). On CT scans at 52 weeks, the maximum screw protrusion was measured and seen to be, on average, 1.7 mm (SD 0.9, range 0.4 to 4.7) and was similar between the two groups. Overall, maximum screw protrusion was categorised as <1 mm (20.7%), 1-2 mm (52.4%), and >2 mm (26.8%).

Lucency was assessed based on categories on follow up radiographic images (worst of each view available) and 52-week CT scan (worst of each of three multiplanar reconstructions (MPRs) available) agreed by three observers using agreement rules. This was only considered where an implant was present. Serious lucency (1-2 mm) was only observed, on radiography, for one participant in the surgery group at six weeks, two (including the one at six weeks) at 12 weeks and 4 (including the one at 12 weeks who did not display lucency at six weeks) at 52 weeks.

Prevalence of avascular necrosis (aka osteonecrosis) is summarised for the two groups in Table 25, and appears to be similar across the two group at baseline, but at later time points the plaster cast group has a higher proportion of more significant AVN cases.

Table 25: Complications reported on review of imaging data at six, 12 and 52 weeks by three independent raters by randomised group and time point. Figures are n (%), number of unique participants and percentage of those randomised

Complication observed on independent review of imaging data	Time point	Surgery (n=219)	Plaster cast (n=220)	Total (n=439)
Osteoarthritis[a]	Baseline (radiography)	N=218	N=220	N=438
		21 (9.6)	22 (10.0)	43 (9.8)
	Baseline (CT)	N=217	N=214	N=431
		22 (10.1)	26 (12.2)	48 (11.1)
	6 weeks	N=188	N=201	N=389
		15 (8.0)	21 (10.5)	36 (9.3)
	12 weeks	N=169	N=163	N=332
		21 (12.4)	28 (17.2)	49 (14.8)
	52 weeks (radiography)	N=157	N=142	N=299
		25 (15.9)	24 (16.9)	49 (16.4)
	52 weeks (CT)	N=157	N=135	N=292
		42 (26.8)	36 (26.7)	78 (26.7)
Avascular necrosis[a, b]	Baseline (radiography)	N=218	N=220	N=438
	None	204 (93.6)	204 (92.7)	408 (93.2)
	Just	14 (6.4)	15 (6.8)	29 (6.6)
	Missing	0 (0.0)	1 (0.5)	1 (0.2)
	Baseline (CT)	N=217	N=214	N=431
	None	197 (90.8)	187 (87.4)	384 (89.1)
	Just	20 (9.2)	27 (12.6)	47 (10.9)
	6 weeks	N=188	N=201	N=389
	None	141 (75.0)	131 (65.2)	272 (69.9)
	Just	46 (24.5)	61 (30.4)	107 (27.5)
	Marked 1	1 (0.5)	8 (4.0)	9 (2.3)
	Marked >1	0 (0.0)	1 (0.5)	1 (0.3)
	12 weeks	N=169	N=163	N=332
	None	130 (76.9)	109 (66.9)	239 (72.0)

	Just	39 (23.1)	51 (31.3)	90 (27.1)
	Marked 1	0 (0.0)	1 (0.6)	1 (0.3)
	Marked >1	0 (0.0)	2 (1.2)	2 (0.6)
	52 weeks (radiography)	N=157	N=142	N=299
	None	135 (86.0)	110 (77.5)	245 (81.9)
	Just	22 (14.0)	27 (19.0)	49 (16.4)
	Marked 1	0 (0.0)	4 (2.8)	4 (1.3)
	Missing	0 (0.0)	1 (0.7)	1 (0.3)
	52 weeks (CT)	N=157	N=135	N=292
	None	80 (51.0)	57 (42.2)	137 (46.9)
	Just	72 (45.9)	69 (51.1)	141 (48.3)
	Marked 1	5 (3.2)	5 (3.7)	10 (3.4)
	Marked >1	0 (0.0)	3 (2.2)	3 (1.0)
	Fragmented	0 (0.0)	1 (0.7)	1 (0.3)
Screw penetration[c]	6 weeks	N=172	N=6	N=178
		57 (33.1)	1 (16.7)	58 (32.6)
	12 weeks	N=156	N=6	N=162
		55 (35.3)	2 (33.3)	57 (35.2)
	52 weeks (radiography)	N=135	N=15	N=150
		52 (38.5)	5 (13.3)	57 (38.0)
	52 weeks (CT)	N=136	N=11	N=147
		75 (55.1)	8 (72.7)	83 (56.5)
Screw lucency[c]	6 weeks	N=172	N=6	N=178
	None	139 (80.8)	4 (66.7)	143 (80.3)
	<1 mm	32 (18.6)	2 (33.3)	34 (19.1)
	1-2 mm	1 (0.6)	0 (0.0)	1 (0.6)
	12 weeks	N=156	N=6	N=162
	None	113 (72.4)	6 (100.0)	119 (73.5)
	<1 mm	41 (26.3)	0 (0.0)	41 (25.3)
	1-2 mm	2 (1.3)	0 (0.0)	2 (1.2)
	52 weeks (radiography)	N=135	N=15	N=150

	None	99 (73.3)	7 (46.7)	106 (70.7)
	<1 mm	32 (23.7)	8 (53.3)	40 (26.7)
	1-2 mm	4 (3.0)	0 (0.0)	4 (2.7)
	52 weeks (CT)	N=136	N=11	N=147
	None	108 (79.4)	7 (63.6)	115 (78.2)
	<1mm	22 (16.2)	3 (27.3)	25 (17.0)
	>1mm	4 (2.9)	1 (9.1)	5 (3.4)
	Uneven	2 (1.5)	0 (0.0)	2 (1.4)

[a] N represents those with imaging; [b] >1 indicates density observed on more than one view or MPR; [c] N represents number for which screw was observed on imaging

Adverse events

At least one non-serious adverse event was reported for 24 (11.0%) participants in the surgery group, and 29 (13.2%) in the plaster cast group (difference in percentages -2.2%, 95% CI -8.3 to 3.9%) (*see Table 26*). Of those that experienced at least one event, most reported only one event (surgery group n=19, 79.2%; plaster cast group n=23, 79.3%) but participants reported up to three events each. In total, 30 [36] events were reported for participants in the surgery [plaster cast] group, of which 24 (80.0%) [4 (11.1%)] were related to receiving anaesthesia and/or surgery, 3 (3.0%) [23 (63.9%)] were related to cast treatment, and 3 (3.0%) [9 (25.0%)] were other events. Sixteen events (surgery group n=5, 16.7%; plaster cast group n=11, 30.6%) were deemed to be unexpected by the reporting clinician.

Table 26: Non-serious adverse events by randomised group

Non-serious adverse events	**Surgery (n=219)**	**Plaster cast (n=220)**	**Total (n=439)**
No. participants reporting ≥1 adverse events, n (%)	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, n (%)			
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], n (%)			
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], n (%)			
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], n (%)			
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], n (%)			
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], n (%)			
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], n (%)			

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

There were three reported serious adverse events, all for three (1.4%) participants in the surgery group (*see Table 27*). All three were related to anaesthesia and/or surgery, and two were deemed to be unexpected at the time of reporting.

Table 27: Serious adverse events by randomised group

Serious adverse events	**Surgery (n=219)**	**Plaster cast (n=220)**	**Total (n=439)**
No. participants reporting ≥1 adverse events, n (%)	3 (1.4)	0 (0.0)	0 (0.0)
Total number of serious adverse events	3	0	0
Number of serious events per participant, n (%)			
0	216 (98.6)	220 (100.0)	436 (99.3)
1	3 (1.4)	0 (0.0)	3 (0.7)
Type of event[b], n (%)			
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], n (%)			
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], n (%)			
Definitely related	3 (100.0)	0 (0.0)	3 (100.0)
Expectedness[b], n (%)			
Expected	1 (33.3)	0 (0.0)	1 (33.3)
Unexpected	2 (66.7)	0 (0.0)	2 (66.7)
Duration[b], n (%)			
≤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

Agreement analysis

Descriptive analyses of the agreement between the three independent raters on review of radiographic and CT imaging is presented in Appendix 5.

Participant use of home exercises to care for wrist

When entered into the study, participants should have been provided with written advice about home exercises to perform to care for their wrist. Participants were asked on the 12 week participant questionnaire how they found doing these exercises. Responses to these questions are provided in

Appendix 3, Table 64. Of those that provided a response to the question, 151/176 (85.8%) in the surgery group, and 123/155 (79.4%) in the plaster cast group reported that they found the exercises very or quite useful. Among those that performed the exercises, they were reported to have been performed on a median of 41 days (range 1 to 168) in the surgery group, and 35 (range 2 to 137) in the plaster cast group. On the 52-week complication form, data were collected on whether the participant was referred for physiotherapy for the treatment of their wrist injury during the previous year. Approximately twice as many participants allocated to the surgery group had been referred for physiotherapy than those in the plaster cast group (n=58, 26.5% vs n=30, 13.6%).

Participant perceptions of their wrist and treatment preference at 52 weeks

On the 52 week questionnaire, participants were asked about the state of their wrist now compared to a year ago (*see*

Appendix 3*,* Table 65***Error! Reference source not found.***). Of those that provided a response to the question, a very similar proportion in the two groups reported that their wrist felt much or slightly better (surgery group 166/181, 91.7%; plaster cast group 156/174, 89.7%). Participants were also asked, based upon their experiences of the treatment received as part of the trial, if they injured their wrist to the same extent as they did 52 weeks ago, which treatment they would prefer. Of those that provided a response to the question, three quarters in the surgery group reported that they would have surgery again (137/181, 75.7%), 36 (19.9%) did not have a preference, and 8 (4.4%) reported that they would not have surgery. In the plaster cast group, there was a reasonably equal split among the three categories: surgery n=59/175, 33.7%; no preference n=68, 38.9%, and not surgery n=48, 27.4%.

Chapter 4 Economic evaluation

The role of economic evaluation is to consider the relative merits of competing treatment alternatives weighed against their costs, using a consistent analytical perspective. This Chapter investigates the possible impact of available treatments for adults with bi-cortical, minimally displaced fractures of the scaphoid waist on the health of the patient and costs to the NHS and personal social services (PSS), both in the short and long-term.

This is achieved in two ways, firstly, the short-term health and costs to the NHS of the treatment are considered through a *within-trial analysis*, using direct results of the clinical trial up to 52 weeks of follow up. This analysis focusses on the short-term health implications of treatment and the immediate period of rehabilitation and the associated costs of this care. Secondly, as persistent non-union of the fracture and the development of osteoarthritis have potentially lifelong implications, it is necessary to consider the long-term implications of the treatments. This is achieved through an *extrapolated analysis*, where mathematical modelling of the expected future health of the patients is used to estimate the health and resource use implications beyond the timeframe of this SWIFFT report.

Within trial analysis - methods

The SWIFFT trial collected a rich array of information from both patients and clinicians on the health and resource use during and after treatment. This within trial analysis will consider the quality of life, as reported by the EQ-5D, and the level of NHS costs, estimated through the treatment received and the patient reported estimates of interaction with the NHS, at a per patient level for the 52 weeks after randomisation into the trial (the 'within analysis period'). This analysis was conducted using the Stata software package.[91]

The base-case is an intention to treat (ITT) analysis. An additional scenario of per protocol is presented, whereby any patients who were deemed to crossover from one treatment allocation to another are excluded from the analysis.

Missing data is imputed for both cost and quality of life components, as detailed later in this section. Relevant summary statistics and estimates of the quality of life and costs associated with patients are reported at both a complete case level (i.e. dropping all cases of missing data) and after imputation. Regression analyses are also conducted on total quality of life and costs in the within trial period to consider the impact of key patient characteristics on quality of life and costs, beyond the treatment allocation. The approach taken to missing data and the regression analyses conducted on quality of life and costs in this chapter are consistent with those outlined for the PRWE in statistical methods section of Chapter 2.

The primary clinical justification for surgical intervention is the reduced future risk of osteoarthritis and other long-term adverse events which may not become evident until after the within trial period, and as such consideration of the cost-effectiveness of the treatment options with only a within trial timeframe would be misleading. As a result, conclusions about the cost-effectiveness of the treatment options will be limited to the presentation of a within trial point estimate incremental cost-effectiveness ratio (ICER), the difference in average costs between two treatment pathways divided by the difference in average quality of life for the within trial period.

Quality of life – EQ-5D

The EQ-5D is a validated questionnaire to assess the generic health status or *quality of life* of a patient, consisting of questions covering five dimensions of health mobility, self-care, usual activity, pain/discomfort, and anxiety/depression.[92] It is the most widely used means of consistently estimating the general health of a patient, and is used by NICE as its preferred measure.[93] While other disease specific estimation questionnaires are available, such as the PRWE, they do not allow for comparison across disease areas, and cannot be used to determine the optimal allocation of limited NHS resources. A score of 0 is equivalent to death, and 1 represents perfect health, negative scores are considered worse than death. Under the UK preference weighting achievable scores range from -0.594 (worst response across all five dimensions) to 1 (best responses).

EQ-5D questionnaires were collected at baseline, and then at six, 12, 26, and 52 weeks after randomisation. In this section the combined EQ-5D score using the preference weighting are presented, such that each patient who completed a questionnaire at each time point has a single EQ-5D quality of life 'score' given to them based on their responses to the questionnaire. These scores are carried forward to the missing data analysis discussed later in this section and the within trial analyses.

After having imputed for any missing questionnaires (see later section) the quality of life scores are combined to estimate a score for the patient across the full within trial period, using the equation reported below, where t_i is the time in days at which questionnaire 'i' was conducted, and QoL_i is the quality of life score reported at time 'i'.

$$QoL_{within\ trial} = (QoL_{baseline} \times \frac{t_{6wk} - t_{baseline}}{2} + QoL_{6wk} \times (\frac{t_{6wk} - t_{baseline}}{2} + \frac{t_{12wk} - t_{6wk}}{2}) + QoL_{12wk} \times (\frac{t_{12wk} - t_{26wk}}{2} + \frac{t_{26wk} - t_{12wk}}{2}) + QoL_{26wk} \times (\frac{365 - t_{26wk}}{2} + \frac{t_{26wk} - t_{52wk}}{2}) + QoL_{52wk} \times \frac{365 - t_{26wk}}{2}) / 365$$

This combined quality of life score is used to inform the regression analysis conducted to estimate the impact of patient characteristics, including treatment allocation, on quality of life.

Resource Use and Unit Costs

Costs to the NHS are considered in two ways: those reported by clinical staff, and those reported by patients at six, 12, 26 and 52 weeks during the trial (*see trial CRFs in Supplementary File 15*). As the trial did not directly seek to report the costs of care, but the frequency of various interactions and care provision, all elements reported have to be linked with an appropriate unit cost to estimate total costs. We assumed that all interactions with the NHS were captured by the trial CRFs.

Relevant resource use is reported from the time of randomisation into the trial, and do not include the cost of initial presentation with the injury, nor care that might occur prior to randomly allocated treatment, typically immobilisation with a cast or splint. Randomisation

should ensure that these initial treatment options and costs are balanced between the two groups.

For the purpose of the costing of the within trial analysis only those interactions reported as being related to the patient's wrist are included. Unrelated interactions reported by the patients should not impact the incremental cost but risks introducing bias if patients had high cost but completely unrelated healthcare. An investigation into the level of NHS and PSS interactions for reasons other than the wrist injury confirmed that there was no statistically significant difference between the trial arms (mean number of interactions 5.65 for plaster immobilisation, 5.91 for surgical fixation, p-value of 0.828).

The unit costs associated with each component of the within trial analysis are presented in Table 28.

Table 28: Unit costs associated with within trial analysis

Stage	Cost item	Value	Source/assumption
Treatment and imaging	Cost of casts, both initial at diagnosis and additional casts	£10	*Consistent with NICE NG38.*[90] *Assumes costs of hospital attendance etc. are covered in patient reported activity.*
	Cost of primary surgery (patients randomised to surgical arm)	£1,632	Weighted average of adult HT44 (intermediate hand procedures for trauma, mapped from all open OPCS code), Reference Cost 2015/16[94]
	Cost of secondary surgery (repeat surgery for surgical arm and surgery for cast arm of trial)	£2,509	Weighted average of adult HT43 (Major hand procedures for trauma, mapped from all closed OPCS code), Reference Cost 2015/16[94]
	Cost of radiograph	£30	Reference Costs 15/16, DAPF, Direct Access Plain Film
	Cost of CT scans	£94	Reference Costs 15/16, RD20A, Computerised Tomography Scan of one area, without contrast, 19 years and over[94]
	Cost of MRI	£145	Reference Costs 15/16, RD01A, Magnetic Resonance Imaging Scan of one area, without contrast, 19 years and over[94]
Follow up care – from trial patient reported questionnaires, only for	GP – at practice	£37	Based on estimates from PSSRU (11.7 minute consultation)[95]
	GP – at home	£74	Based on estimates from PSSRU (11.4 minute consultation plus 12 minute of travel)[95]
	GP – by phone	£22	Based on estimates from PSSRU (7.1 minute consultation)[95]

	Physiotherapist – at GP practice	£49	Reference cost 2015/16 A08A1 (physiotherapist, adult, one to one, community)[94]
	Nurse – at GP practice	£12	Based on estimates of duration of contact and cost per hour of face to face time from PSSRU [95]
	District/community nurse	£38	Reference Costs 15/16 (N02AF, district nurse, adult, face to face, community) [94]
	Occupational therapist	£79	Reference Costs 15/16 (A06A1, occupational therapist, adult, one to one, community) [94]
	Hospital – physiotherapist	£46	Reference Costs 15/16, WF01A, Non-Admitted Face to Face Attendance, Physiotherapy[94]
	Hospital – occupational therapist	£58	Reference Costs 15/16, WF01A, Non-Admitted Face to Face Attendance, Occupational therapist[94]
	Hospital – A&E	£157	Reference Costs 15/16, WF01B, Non-Admitted Face to Face Attendance, First, Accident & Emergency [94]
	Hospital – fracture clinic	£110	Reference Costs 15/16, WF01A, Non-Admitted Face to Face Attendance, Trauma and orthopaedics[94]
	Hospital – pain management clinic	£131	Reference Costs 15/16, WF01A, Non-Admitted Face to Face Attendance, Pain Management[94]
	Hospital – in patient stay	£269 per day	Weighted average of Reference Costs 15/16 HE41 hand fracture without intervention excess bed days[94]

Patient reported costs are estimated at six, 12, 26, and 52 weeks for the purpose of the missing data analysis, and treatment and imaging costs estimated for the full within trial period.

After imputation for patient reported costs at the four time points and imaging costs, costs are combined into an estimate of the total patient level cost for the within trial period.
Patient reported medications, aids, and out of pocket costs such as private healthcare related to the initial injury are excluded from this analysis. In the case of medications, all reported cases were identified as being low cost pain killers which either cost less than the patient prescription cost or could have been purchased by patients over the counter. Aids are not routinely provided to patients on the NHS, as reflected by the trial data and as such reflect a private cost which, alongside out of pocket costs, fall outside of NHS and PSS perspective taken in this Chapter.

Missing data

Missing data was imputed across the patient reported questionnaires related to quality of life and resource use in addition to imaging. Using the framework described in Faria [96] the missing data was assumed to be missing at random (MAR). Imputation was conducted across all nine cost and quality of life variables identified as having missing data, i.e. costs at six, 12, 26, and 52 weeks, and quality of life at baseline, six, 12, 26, and 52 weeks.
Consistent with the missing data approach outlined in the PRWE analysis in the previous Chapter these missing variables were assumed to be correlated to each other as well as treatment allocation, age at randomisation, whether the patient's dominant hand was fractured, and displacement of the fracture. Number of imputations was set equal to the proportion of missing values in the variable with the largest level of missingness, presented in the results section. Imputation was conducted using the 'ICE' multiple imputation package in Stata, and reporting using the 'MIM' package.[97, 98]

Impact of lost employment and unpaid activities

In addition to consideration of costs to the NHS and PSS and quality of life to the patients, this within trial analysis reports the impact of treatment allocation on days of lost employment and unpaid activities. The method of this analysis are reported in Appendix 6, Section 1.

Extrapolated model - methods

As the implications, both in terms of NHS costs and patient health, of the different treatment options and associated adverse events can persist beyond the 52 week follow-up of the trial an extrapolation model is required to estimate cost-effectiveness over a lifetime. These beyond trial implications were discussed in Chapter 1 and can be broadly categorised by the future burden of osteoarthritis, SNAC and long-term pain or limited mobility, that occur as a direct result of the initial injury and its treatment.

Systematic review of existing cost-effectiveness evidence

A literature review was conducted to determine whether previous economic evaluations had sufficiently determined the cost-effectiveness of surgical fixation versus plaster cast immobilisation for bi-cortical, minimally displaced fractures of the scaphoid waist in adults. A secondary aim of the search was to determine if previous mathematical models could be adapted to estimate the long-term cost-effectiveness, and thus remove the need to construct a de novo mathematical model. Full details and results of the search strategy and results are in Appendix 6, Section 2.

The review found no suitably robust cost-effectiveness analysis. Therefore, we determined that a de novo mathematical model was required to investigate the long-term cost effectiveness of surgical fixation compared to cast immobilisation.

Cost-effectiveness analysis: analytical methods and model inputs

This section details the scope of the de novo extrapolated model and provides details on its structure, base-case inputs, and scenarios considered.

Analytical approach

The analysis presented here uses a methodology consistent with the NICE Guide to the Methods of Technological Appraisal,[93] and Decision Modelling for Health Economic Evaluation.[99] In brief, real world observations from trial data, published literature and expert opinion were used to estimate the expected lifetime health and resource use per patient for each treatment comparator.

Conventional outcomes of these models used to determine the cost-effectiveness of the different treatment pathways are lifetime cost, expected life years, and expected Quality

Adjusted Life Years (QALYs). These estimates are compared across treatment pathways by estimating the ICER. A cost-effectiveness threshold of £20,000/QALY is used as the base-case value to estimate the net health benefit (NHB) of each of the treatment options,[100] calculated by:
NHB = expected mean QALYs of intervention – (mean cost of treatment option / cost-effectiveness threshold)

To incorporate the uncertainty present in the estimation of such models, two approaches are used: 1) probabilistic sensitivity analysis (PSA) and 2) scenario analysis. PSA explicitly incorporates the uncertainty present in parameter estimates by using the range of values over which these estimates exist (characterised by an informative distribution), rather than single point estimates, as inputs into the mathematical models.[99]

Scenario analyses are used to test the structural uncertainty of the models, where the underlying structure and sources of evidence are changed to explore the impact of such uncertainty on the results of the models.

Value of information analysis explored the population expected value of perfect information (EVPI), an assessment of the benefit of resolving all uncertainty in the parameter estimates of the base case model.

Analytical perspective

Consistent with the within trial analysis, the full, extrapolated, analysis takes as its primary perspective the health outcomes to the patient, expressed in QALYs, and the costs to the NHS, expressed in UK pound sterling at 2017 prices. A lifetime time horizon is used in the base-case analysis to reflect the full duration of impact of potential adverse events including osteoarthritis and SNAC. Both costs and outcomes are discounted using a 3.5% annual discount rate consistent with current guidelines.[93] The model was developed using Microsoft Excel 2013.

Decision problem

Consistent with the SWIFFT trial protocol this analysis seeks to estimate the most cost-effective treatment pathway for adults presenting with an undisplaced (<1mm step or gap) and minimally displaced (1mm to 2mm inclusive) bicortical fracture of the scaphoid waist. An important element of any analysis that seeks to determine the cost-effective treatment is the full incorporation of all possible treatment alternatives, including those beyond the two considered in the SWIFFT. A brief review of the literature, using the framework outlined in Appendix 6, Section 2, and discussions with the SWIFFT Trial Management Group, highlighted that no active treatments beyond combinations of cast and surgical fixation were considered relevant to an NHS setting, with the only other treatment identified, pulsed electromagnetic fields, rarely used in the UK. To ensure the extrapolated model includes all possible treatment options the following four are considered; the first two are extensions of the SWIFFT trial:

1) No treatment – All patients who experience a scaphoid waist fracture are left untreated. While unlikely to happen in practice, and considered unethical to include in the SWIFFT trial, this is an important anchor point to ensure that all active treatments are well demonstrated to be effective and cost-effective compared to providing no intervention, and a means of model validation. Furthermore, the Trial Management Group confirmed some patients choose to not have treatment, often not attending for diagnosis or refusing recommended treatment. This arm therefore is important to explore the validity of patients decision.
2) Cast immobilisation only – All patients are treated with cast immobilisation alone, such that patients who are identified as having non-union are not able to progress to surgery. While not incorporated into the SWIFFT trial this allows the analysis to test whether the addition of surgical fixation for non-union patients is cost-effective compared to casting alone. Furthermore, it represents the historic treatment option in many cases, before fixation surgery was routinely offered. In this and all other similar cases ‘cast’ refers to all forms of non-surgical immobilisation, including casts with thumb incorporated and excluded, and splints.

3) Cast immobilisation followed by immediate surgery – In line with the SWIFFT trial population patients are initially treated with casting with immediate surgical fixation soon after cast removal offered to all patients who have non-union detected.

4) Surgical fixation – In line with the SWIFFT trial patients are initially treated with surgical fixation, if primary fixation is unsuccessful (either due to implant problems or failure of union) patients are offered additional surgery.

The assumptions related to each are considered later in this chapter.

Population

The population considered in the extrapolated model is consistent with the SWIFFT trial, as described in Chapter 2.

Inevitably, when an economic evaluation model has to use evidence from the existing literature to inform an extrapolation there are some differences between the analysed population and that considered in the relevant literature. These are identified and discussed later in this chapter, with biases explored where possible.

Model structure

The model itself has two components: 1) a short-term decision model, which characterises the first 52 weeks after initial presentation, consistent with the SWIFFT trial period,, and 2) a long-term element, over which the implications of the treatment and union status on long-term outcomes and costs are considered. These two components are presented separately below for clarity but are intricately linked.

The model takes as a starting point the time at which a treatment decision is made, such that patients have already experienced the injury and attended hospital for initial assessment. As a result, the nature of the fracture is known and the patient has been identified as within this population.

Short-term decision model

Covering the first year since treatment the short-term element closely matches the within-trial analysis by drawing directly from the findings of the SWIFFT trial with the additional treatment pathways of no treatment and primary cast immobilisation only. Figure 7 provides an overview of the short-term element of the model through this 52 week period, from the treatment decision to the 52 week time point, at which point patients enter the long-term 'Markov' model, symbolised by the M in the figure. The key features of each treatment arm in the short-term element are as follows:

No treatment – After having been identified as within the population considered in this analysis all patients receive no active treatment, i.e. neither cast nor surgery. As a result no short-term treatment costs are incurred but patients are assumed in the base-case analysis to never achieve union of the fracture. While it is expected that some untreated fractures would unite, as the literature provides examples of such,[101, 102] it is not possible to estimate this as a proportion of all cases and as such the base-case assumes no cases of union. This assumption is explored in a later scenario.

Cast immobilisation only – Primary cast immobilisation is assumed to be the only treatment available to patients, such that all are initially immobilised in a cast but should the fracture fail to unite no subsequent surgery is available. Treatment characteristics and rates of union are drawn directly from the SWIFFT trial primary cast immobilisation arm but all those offered post-cast surgery for non-union are assumed to remain as non-unions.

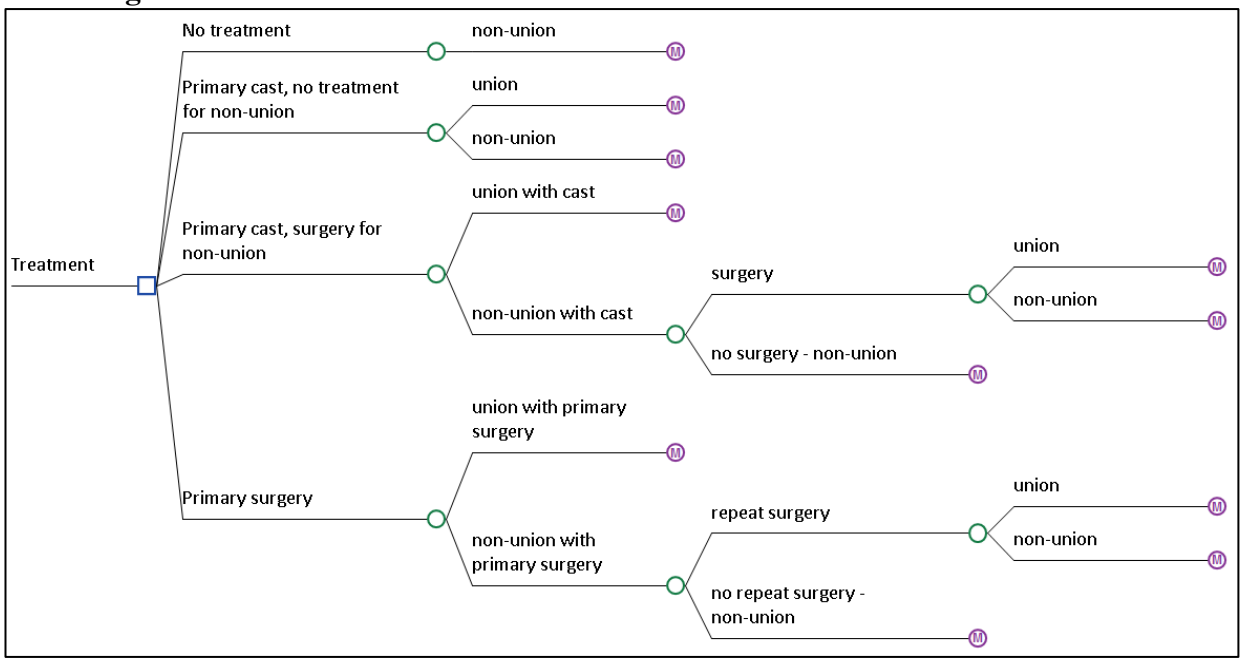
Cast immobilisation with immediate surgery for non-union – This treatment arm is consistent with the cast only arm except that patients who fail to achieve union are offered surgical fixation as in the SWIFFT trials, a proportion of who will opt for it. The patients who failed to achieve union with the cast and chose to not have surgery are assumed to end the short-term component still having non-union, while patients who opted for surgical fixation can achieve union or non-union at a rate determined by the SWIFFT trial results.

Primary surgery – As per the arm of the SWIFFT trial patients are treated with surgical fixation as their primary treatment, many patients initially receive a cast which is removed and surgery performed. After surgery patients can achieve union or non-union. A small

proportion determined by the SWIFFT trial have multiple rounds of surgery if the primary surgery is unsuccessful or there are complications. Furthermore, most patients are provided with a cast after surgery as part of routine therapy.

All cost and quality of life impacts that occur within this first year are included in the estimates presented later in this section. Mortality within the first year is not explicitly modelled as scaphoid related death is not expected to occur and the primary population is young, with no related or unrelated deaths observed in the SWIFFT trial.

Figure 7: schematic of the short-term element of the economic evaluation model



Long-term Markov model

The long-term cost and health outcomes extrapolated beyond the 52 weeks short-term model are estimated using two Markov models, presented in Figure 8 and Figure 9. In a Markov model, patients reside in one out of a set of mutually exclusive health states at particular points in time.[103] During discrete time intervals, these patients can either remain in a particular health state or move to a separate health state, typically because they have experienced a particular clinical event.

As shown in Figure 8 and Figure 9 the Markov model patients enter is dependent on their union status at the end of the short-term decision model, with patients achieving union entering the model outlined in Figure 8 and non-union patients the one in Figure 9. This is consistent with the very different long-term clinical expectations associated with the two groups, as discussed in Chapter 1, with union patients likely to regain usual health and function, but those with non-union likely to have long-term health concerns.

The treatment pathway a patient experienced to get to their union status is informative to their rate of transition through the respective model. In other words, while a patient's prior treatment is assumed to not impact the set of long-term health states they can achieve, it does impact the likelihood with which they achieve them.

Patients achieving successful union at the end of the short-term element are placed in one of two starting states in the union Markov: '*no osteoarthritis (OA) or other adverse events (AEs)'*, and '*no OA but long-term AEs'*. This distinction is made due to the prevailing evidence that a number of patients experience lifelong symptomatic adverse events associated with the original injury and treatment that are not related to the development of OA. Specifically, Lindström & Nyström[104] reported the presence of pain and weakness not associated with OA in their long-term follow-up study of patients treated with cast immobilisation. Limitations in the available evidence on the long-term transitions necessitated the assumption that these patients represent a separate group than those who will go on to develop OA.

Patients who experience permanent long-term symptomatic adverse events without OA remain in this state until they die of other causes, as the treatment or related events are unlikely to cause death. We also assumed that these non-OA AEs are fixed for the patient's remaining lifetime, with all time limited adverse-events being resolved within the short-term element of the model (i.e. within a year of injury).

Patients who enter the long-term model in the adverse event free state (i.e. *no OA nor other AEs*) can similarly stay in this state until they die of other causes, or they may develop OA, which is modelled as being either symptomatic or non-symptomatic, again informed by the literature. As is discussed later, limitations in the data mean we are unable to model the

potential development of OA from non-symptomatic to symptomatic, or the potential for different levels of symptomatic presentation. From each of the OA states patients stay in the state until they die of other causes.

The dearth of evidence relating to the development and transition between adverse events in this population necessitated the assumption that patients do not transit between the three adverse event states. As a result, the analysis assumes that patients only experience at most one lifelong adverse event. As there is no difference in the cost or utility difference in the two symptomatic states, discussed later in this section, and the asymptomatic OA state is based on long-term observational data, this model assumption does not impact the result of the analysis.

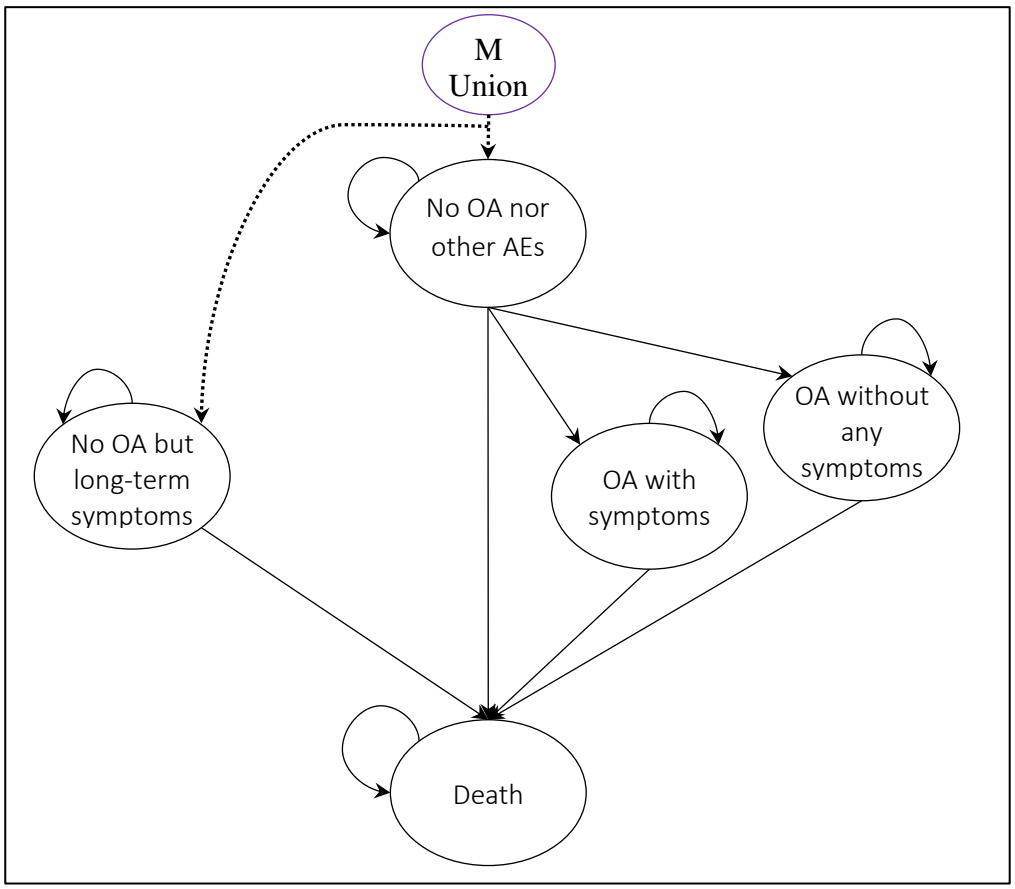


Figure 8: Long-term Markov model for successful union

In contrast, patients who end the short-term element in a non-union state are modelled based on their risk of developing SNAC, as shown in Figure 9. As discussed in Chapter 1, SNAC represents a serious adverse event which results from non-union, whereby the proximal

carpal row can no longer stabilise the distal carpal row, and hence the wrist. The resulting abnormal loading leads to carpal collapse, cartilage degeneration and arthritis. Due to a dearth of evidence relating to the natural history of events associated with non-union we were not able to model separate states reflecting the development of OA and other symptoms within the non-union Markov. Patients in this Markov model enter in the *no SNAC* state and throughout their lifetime face a risk of progressing to SNAC or dying from unrelated causes. As with OA in the union Markov, SNAC is modelled as being a binary disease state, but unlike OA is assumed to always be symptomatic due to the severity of the condition. Due to the challenging nature of treating SNAC, and lifetime implications even if treatment is successful, patients are modelled as remaining in the SNAC state for the rest of their life if it develops. Unlike the union model, patients are not modelled as separately having non-OA related long-term symptoms and non-symptomatic OA. This assumption is due to the observation by Dias[105] that almost all patients (9 of 10) had pain or stiffness after a mean of 2.1 years. Therefore, our base-case model assumes that all non-union patients had some quality of life decrement, incorporating a range of adverse events including low grade OA and non-OA adverse events.

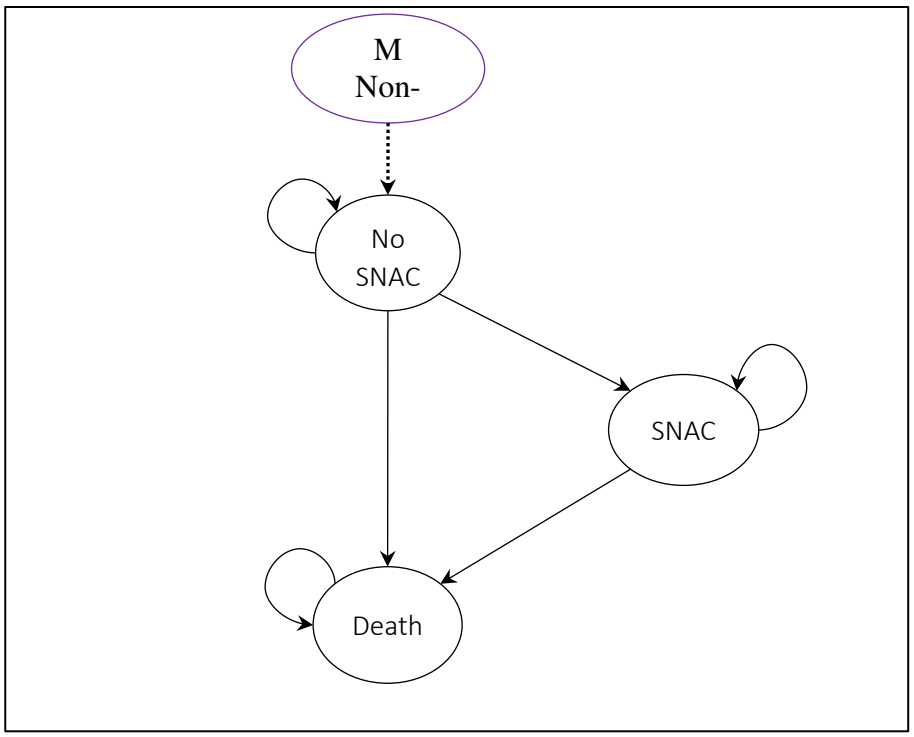


Figure 9: Long-term Markov model for non-union

Model inputs

Much of the evidence defining the patient cohort and the short-term element are sourced directly from the SWIFFT trial. As the SWIFFT trial currently only has 52 weeks of patient follow up, all long-term model inputs are informed by the wider literature. .

Consistent with the SWIFFT trial, the base-case patient cohort is modelled as being 33 years old, with 84% being male. A patient's age is assumed to only impact the rate of mortality, as while there is likely to be a correlation between age and OA and other adverse events, there was insufficient evidence to incorporate such a correlation. Similarly, the gender mix only impacts the mortality rate.

Short- and long-term element transition estimates

The short- and long-term model transitions estimates are reported in Table 29. The base case mean estimates are reported alongside the 95% confidence interval and the informative distribution used to inform the PSA. The distributions are reported in terms of the distribution selected, conforming to conventional approaches,[99] and the parameters required to describe the respective distribution.

Table 29: Probabilities applied in the model

Parameter		**Base case value (95% CI)**	**Distribution (informative parameters)**	**Source**
1. Short-term element of the model				
Probability of being identified as requiring surgery/repeat surgery after initial treatment	Cast immobilisation	0.090 (0.005 to 0.130)	Beta (alpha 20, beta 200)	SWIFFT trial, the 20 cases include those 17 who had surgery plus 3 who had not had surgery at 52 weeks but had an identification of non-union

	Surgery as initial treatment	0.037 (0.016 to 0.065)	Beta (alpha 8, beta 221)	SWIFFT trial, the 8 cases include the 8 who had secondary surgery
Probability of having surgery post cast non-union		0.948 (0.901 to 0.981)	Beta (alpha 110, beta 6)	Review of the existing literature
Probability of having repeat surgery post initial surgery non-union or issue		0.948 (0.901 to 0.981)	Beta (alpha 110, beta 6)	
Probability of non-union after second line surgery		0.059 (0.002 to 0.206)	Beta (alpha 1, beta 16)	SWIFFT trial, of 17 patients who underwent secondary surgery 1 had confirmed non-union
Probability of having non-union after no treatment		1	Fixed	Assumption
2.a. Long-term element of the model – Union Markov				
Probability of having long-term adverse symptoms that are not OA related				
Cast immobilisation		0.048 (0.024 to 0.079)	Beta (alpha 11, beta 218)	Lindström and Nyström[104]
Surgery as last treatment provided		0.048 (0.024 to 0.079)	Beta (alpha 11, beta 218)	Assumed same as cast
Probability of developing OA				
Cast immobilisation		Limiting value – 0.056 Time constant – 1.5 CI – 0.035 to 0.087	Exponential decay towards a limiting value, with limiting value characterised as a beta distribution, see Appendix 6, Section 3	Lindström and Nyström, [104] 5.6% of 218 patients had OA after primary healing with a minimum follow up of 7 years
Surgery as initial treatment		Limiting value – 0.056 Time constant – 1.5 CI – 0.035 to 0.087	Exponential decay towards a limiting value, with limiting value characterised as a beta distribution	Assumed same as cast
Probability that developed OA is symptomatic				

Cast	0.992 (0.918 to 1.00)	Beta (alpha 11.9, beta 0.1)	Lindström and Nyström[104]
Surgery	0.992 (0.918 to 1.00)	Beta (alpha 11.9, beta 0.1)	Assumed same as cast
Mortality from all causes	As per published tables	Fixed	ONS National Life Tables, England and Wales, 2014-16[106]
2.a. Long-term element of the model – Non-Union Markov			
Survival function of no SNAC to SNAC	Lambda 0.0069 Gamma 1.77	Weibull	Weibull function fitted to time to event data from Moritomo[107]
Mortality from all causes	As per published tables	Fixed	ONS National Life Tables, England and Wales, 2014-16[106]

The parameters required for the short-term element of the model are derived from the SWIFFT trial, with the exception of the assumption that all untreated patients have a non-union. This assumption biases against a no treatment scenario, and while some of the literature suggests rates of union in an untreated population,[101, 102] there is insufficient evidence to determine a rate of non-union in the population considered here.

The long-term Markov models are reliant on published literature until the five year follow-up of the SWIFFT trial is completed. In the base-case model, the choice and frequency of the different treatment options only impacts a patient's long-term health through its ability to effect union of the fracture, this core assumption is relaxed in a series of scenarios. The model parameters for which this assumption applies are presented in Table 29.

Base-case estimates of the probability of having long-term adverse symptoms that are not OA related are drawn from the study by Lindström & Nyström[104] who reported the presence of pain and weakness not associated with OA in their long-term follow-up study of patients treated with cast immobilisation, finding that 4.8% of patients had long-term non-OA adverse events.

The probability of developing OA as a result of the initial injury and treatment is modelled as an exponential decay. It is estimated by fitting an exponential function to three time points extracted from Lindström & Nyström:[104] time zero where no patients had developed related OA, year 1 where 2.6% had radiological OA, and year 7 when 5.6% had radiological OA, presented in more detail in Appendix 6, Section 3. We assume that no OA, which can directly be linked to the original fracture and treatment, occurs beyond 10 years. Authors such as Duppe[108] report prevalence of OA in union patients with greater follow-up, 36 years after the initial event, finding 15% had OA. However, they found no significant difference between the rate of OA in the injured and uninjured wrists assessed, suggesting much of the identified OA was unrelated to the original fracture. While literature does suggest that repeat intervention and surgery may exacerbate rates of OA,[109] we found insufficient evidence directly exploring these factors. Therefore, the probability of developing OA is assumed to be treatment independent, as discussed earlier. This assumption is justified by limited data on the rate of OA collected during the SWIFFT trial which showed no statistically significant difference in the rate of early OA between the two trial arms.

Once developed, the probability of OA being symptomatic is modelled as a time invariant probability applied at the point of development. In the base-case analysis the probability is estimated from Lindström and Nyström[104] who found that all those who developed OA (n=12 of 229 patients) were symptomatic. Scenarios exploring the treatment independence of this parameter and alternative estimates are explored.

For the non-union patients the probability of developing SNAC is modelled as a Weibull function fitted to time to event patient level data reported by Moritomo et al.,[107] using only those patients reported as having a fracture to the middle third. The Weibull function represented the best fitting function to the extracted Kaplan-Meier of those tried based on AIC, details of the regressions explored are detailed in Appendix 6, Section 4. The Cholesky decomposition method was used to reflect uncertainty in the analysis.[99] One major limitation of the Moritomo et al. study is that it considers a symptomatic population alone, albeit one where some non-union patients have symptoms but not radiologically detectable SNAC. The findings of Moritomo et al. are similar to elsewhere in the literature, for example Mack et al. [110] who, again looking at only patients presenting symptomatically, found that arthritis is likely to develop if sufficient time passes since the time of non-union development. Similarly

Dias et al.[105] identified that after only a 2.1 year mean review period 5 of 10 patients with non-union had signs of OA and dorsal intercalated segment instability, suggesting significant degeneration. Vender et al. [111] also conducted a retrospective radiological review of 64 symptomatic non-unions in an untreated population, finding a similar time to arthritis onset.

In both the union and non-union Markov models patients are subject to a mortality risk throughout, conditional on the cohort age and gender mix alone, such that non-union, OA, SNAC and all other modelled factors were assumed to have no impact on the rate of mortality. The required estimates were drawn from ONS National Life Tables, England and Wales, 2014-16.[106]

We assume that patients are only at risk of developing OA caused by the initial injury or subsequent treatment for 10 years, this assumption is to reduce the potential impact of conflation of OA caused by the injury with that occurring due to other causes. Additionally, we assume that all OA detected in the informative studies for 10 years since injury is a direct result of the initial injury and treatment.

In the base-case we assumed that the patient populations, treatments used, and clinical definitions (e.g. union and OA) evaluated in each of the informative studies match with those analysed in this study, or where they do vary do not introduce any bias so large as to make them uninformative or misleading. A review of the key characteristics and definitions including all studies pertinent to the base-case and scenario analyses is given in Appendix 6, Section 2. Table 67 shows that many of the characteristics appear consistent, with some limitations around insufficient detail, for example displacement of the original fracture. The potentially inconsistent definitions are relating to symptom, with some of the key studies only considering pain but others pain and weakness.

Resource use and cost estimates

The costs used in the mathematical model are presented in Table 30. Consistent with the model structure the costs incurred by the NHS during the first year, as described by the short-term model, are directly taken from the SWIFFT trial, with the additional two treatment arms (no treatment and cast immobilisation only). The short-term model costs are composed of the initial cost of each treatment alongside treatment specific costs incurred for the first year post injury, and any additional treatments within that period (i.e. secondary surgery). The no treatment option is assumed to have no costs in this first year, as no interactions with the NHS are expected until patients' progress into the extrapolated model. The casting without surgery arm is assumed to have the same cost as the SWIFFT casting with surgery for non-union arm with the exclusion of any surgical interventions.

The costs associated with the long-term model, also reported in Table 30, reflect the structure of the Markov model, shown in Figure 8, to reflect the occurrence of OA, symptomatic adverse events that are not related to OA, and non-union related events. In the base-case union model patients in the 'healthy group' of no adverse events including OA as well as the non-symptomatic OA group are assumed to not be associated with any costs to the NHS as both are categorised by the lack of symptoms with which they would present to an NHS setting for investigation and treatment. Similarly, the non-union base case assumes that patients in the non-SNAC state will be associated with no additional regular cost to the NHS, under the assumption that all suitable interventions would have been attempted, and thus costed, prior to the diagnosis of non-union. Once a patient progresses to SNAC a one-off treatment cost is applied to reflect any active interventions attempted to resolve or reduce the impact of the collapse. Little evidence was identified relating to the range and frequency of treatments for SNAC. Shah and Stern [112] describe highly personalised treatment of SNAC, including initial non-surgical treatment, wrist immobilisation with splints, anti-inflammatory medication, corticosteroid injections, coupled with surgical options for refractory cases. We assumed costs of half of the patients being treated with immobilisation, with the other half progressing to major surgery, in addition to the associated 52 week follow-up costs estimated from the trial data. A standard error equal to half of the mean SNAC cost is assumed to reflect the lack of certainty around the variable.

Table 30: Cost considered in short- and long-term sections of the mathematical model

Parameter	Base case value (95% CI)	Distribution	Source
Short-term costs modelled (first year)			
Follow up cost for cast as first treatment (not including any surgery costs)	£587 (£390 to £559)	Gamma	Estimated from the trial data,, includes the cost of all re-casting, NHS interactions, and imaging, but not surgery, using the ITT population, after imputation for missing values as detailed later
Cost of initial surgical treatment (not including follow-up)	£1,632	Fixed	As per within trial, see Table 28
Cost of secondary surgery (not including follow-up)	£2,509		
Follow up cost after surgery (not including any surgery costs)	£618 (£656 to £789)	Gamma	Estimated from the trial data, includes the cost of all re-casting, NHS interactions, and imaging, but not surgery, using the ITT population, after imputation for missing values as detailed later
Long-term costs modelled (52 week to end of analysis)			
Cost of diagnosis of symptomatic OA	£74	Fixed	Assumption of two GP visits with no radiological investigation, cost drawn from PSSRU 2015 (11.7 minute consultation)[95]

Annual cost of treating symptomatic OA	£38 (£10 to £83)	Gamma	Assumed mean one GP visit per year with no investigation or treatment cost (as treated with over the counter medication), SE assumed to be half of the mean.
Annual cost of treating non-OA symptomatic adverse events	£38 (£10 to £83)	Gamma	
Cost of SNAC	£2,551 (£695 to £5,592)	Gamma	Modelled as one off cost assuming half of patients receive very major surgery (£3,440, Reference Cost HN42A)[94] and half receive casting, both with associated cost per year of care from trial, SE assumed to be half of the mean.

Health related quality of life (QoL) inputs

As with the estimation of cost for the mathematical model, the health related quality of life (QoL) inputs into the short-term model are determined by the SWIFFT trial, such that patients have a QoL score for the first year of the analysis which is estimated from the trial data described earlier in this chapter. The base-case analysis assumes that the quality of life inputs section to reflect that in the base-case analysis patients in both the no treatment and cast immobilisation only arms are assumed to have the same quality of life as the cast plus surgery for non-union arm of the SWIFFT trial as a conservative estimate of their quality of life.

In the long-term model the QoL impact of being in a state associated with adverse health (e.g. symptomatic OA, SNAC, and non-union) are applied as decrements to the expected quality of life a 'normal' patient who is otherwise free of associated problems would expect to experience. These QoL norms are drawn from extensive surveys of the general public using the EQ-5D by Ara and Brazier[113] and are stratified by age and gender. Patients in the 'no OA

or other permanent adverse events' of the union Markov are assumed to achieve this QoL norm.

Evidence on the QoL of OA and SNAC relevant to this analysis is limited and diverse. Our review of the literature identified four relevant studies: Kovacs et al. ,[114] Neuprez et al.,[115] Slatkowsky-Christensen et al.,[116] and the economic evaluation by Davis et al..[117]The base-case analysis uses the Slatkowsky-Christensen et al. [116] estimated QoL decrement of OA to represent the QoL of patients in the symptomatic OA, non-OA related adverse events, and non-union 'no SNAC' states under the assumption that all represent, on average, a similar level of quality of life decrement. While we were unable to identify any evidence which explored the quality of life impact of non-union prior to the development of SNAC we believe this assumption is the most appropriate in the base-case as patients would not be expected to regain full quality of life with non-union. This is one of the many uncertainties that will be explored during the five-year follow up.

In contrast, the severe state of SNAC is estimated by applying the Kovacs et al. [114] QoL score as a decrement using the Slatkowsky-Christensen et al. [116] 'healthy' population baseline to ensure a consistent baseline. The Kovacs estimate is used here as it represents a more severe patient population which we believe to be the best fit to a SNAC outcome. While the use of QoL scores estimated using different tools (i.e. SF-6D and EQ-5D) is discouraged in current best guidance[93] due to risks of inconsistency, we believe that, given available evidence, this is the optimal approach. As with other parameters in the model these are subject to PSA and exploration through sensitivity analysis.

All QoL decrements are applied for the duration of a patient's time in each state, as while treatment may alleviate some symptoms, the progressive nature of many of these adverse events will have the opposite effect. As a result it was not possible, given existing evidence, to model changes in the QoL within each state over time, as reflected in the structural model assumptions discussed earlier in this chapter.

In order to reflect the QoL implications of additional surgery, patients who required surgery as a secondary line of treatment received an additional QoL decrement equal to that observed in the first year after surgery from the SWIFFT trial. This assumption is relaxed in a scenario.

The full set of informative QoL estimates are reported in Table 31. All uncertain QoL parameters are characterised as gamma distributions for the PSA to reflect the bounding of possible QoL scores.[99]

Table 31: Health-related quality of life model inputs

Parameter	Base case value (95% CI)	Distribution	Source
Short-term HRQoL modelled (first year)			
QoL for first year post cast	0.812 (0.780 to 0.844)	Gamma	Directly drawn from the trial data, using the ITT population, after imputation for missing values as detailed later
QoL for first year post surgery	0.834 (0.788 to 0.843)	Gamma	Directly drawn from the trial data, using the ITT population, after imputation for missing values as detailed later
QoL for first year for those who are untreated	0.812 (0.780 to 0.844)	Gamma	Assumed same as cast as the least invasive intervention
Long-term HRQoL modelled (52 week to end of analysis), all applied as **decrements** to population norms[113]			
Union and no OA or other adverse events decrement	0	Fixed	Assumption
symptomatic OA decrement	-0.130 (-0.120 to -0.140)	Gamma	decrement estimated from Slatkowsky-Christensen[116]

non-OA symptomatic adverse events decrement	-0.130 (-0.120 to -0.140)	Gamma	Assumed to be the same as decrement for OA
non-symptomatic OA decrement	0	Fixed	Assumption that lack of symptoms implies no HRQoL decrement
non-union (no SNAC state) decrement	-0.130 (-0.120 to -0.140)	Gamma	Assumed to be the same as decrement for OA
SNAC decrement	-0.275 (-0.0689 to -0.4811)	Gamma	Modelled as being from time of development to end of life. Estimated by comparing the response in Kovacs (0.495) to the [114] "healthy" control used in Slatkowsky-Christensen[116] (0.77)

Scenario analyses

In order to develop the mathematical model into the form presented above a number of simplifying assumptions and interpretations of the available evidence were necessary, as is true of all mathematical models.[99] While the assumptions made in the base-case analysis are considered to be the most reasonable given the evidence available it is important to test the impact of different approaches on the results of the analysis. A number of scenarios, detailed in Appendix 6, Section 5, have been constructed to conduct these tests, as far as possible other sources of evidence are used to inform the scenarios.

Results

Within trial analysis - results

In this section we present the results of the within trial analysis. The section is structured around four different scenarios relating to an ITT or per-protocol analysis and whether a complete case or after multiple imputation approach is taken. The ITT analysis is presented as the base-case, and the summary statistics relating to quality of life and costs are only reported for this analysis. The majority of within trial analyses results are presented in Appendix 6, Section 6, with the focus here on the regression analyses conducted across the QoL and cost outcomes.

Regression analyses

The dependent variable for both regressions are total cost, and average quality of life over the within trial period. Additional regressions are reported adjusting for quality of life at baseline (*Table 32 and Table 33*).

Table 32: Cost regression results for the four within trial scenarios, adjusted and unadjusted for baseline QoL

	Scenario	Regression constant	Surgical allocation	QoL at baseline	Fracture displacement	Dominant wrist injured	age
Unadjusted	**Complete case ITT**	589.96 (0.120)	1,580.27 (0.000)	N/A	180.06 (0.490)	-16.66 (0.934)	1.48 (0.833)
	With MI ITT	882.80 (0.002)	1,228.13 (0.000)	N/A	225.47 (0.168)	74.39 (0.622)	1.58 (0.767)
	Complete case PP	678.06 (0.072)	1,770.87 (0.000)	N/A	128.68 (0.595)	141.08 (0.467)	4.273 (0.535)
	With MI PP	799.81 (0.004)	1,549.14 (0.000)	N/A	190.84 (0.252)	86.87 (0.578)	2.716 (0.624)
Adjusted	**Complete case ITT**	939.86 (0.001)	1,308.11 (0.000)	-530.67 (0.022)	183.41 (0.223)	32.24 (0.804)	-0.08 (0.984)
	With MI ITT	1,160.66 (0.000)	1,294.53 (0.000)	-593.71 (0.015)	212.60 (0.164)	1.856 (0.989)	0.19 (0.964)

	Complete case PP	911.11 (0.002)	1.615.50 (0.000)	-519.08 (0.055)	143.33 (0.340)	-17.04 (0.904)	1.73 (0.692)
	With MI PP	1,091.85 (0.000)	1,594.40 (0.000)	-562.63 (0.036)	173.21 (0.255)	-28.19 (0.841)	1.39 (0.764)

ITT – intention to treat, MI – multiple imputation, PP – per protocol, QoL – quality of life

Values in brackets are the p values for each coefficient

Table 33: Quality of life regression output for the four within trial scenarios, unadjusted for baseline QoL

	Scenario	**Regression constant**	**Surgical allocation**	**QoL at baseline**	**Fracture displacement**	**Dominant wrist injured**	**age**
Unadjusted	**Complete case ITT**	0.8162 (0.000)	0.0208 (0.319)	N/A	-0.0283 (0.176)	-0.0285 (0.163)	-0.0011 (0.091)
	With MI ITT	0.8042 (0.000)	0.0182 (0.304)	N/A	-0.0350 (0.047)	-0.0399 (0.027)	-0.0016 (0.010)
	Complete case PP	0.8112 (0.000)	0.0257 (0.233)	N/A	-0.0342 (0.118)	-0.0348 (0.101)	-0.0012 (0.076)
	With MI PP	0.7984 (0.000)	0.0173 (0.331)	N/A	-0.0423 (0.021)	-0.0433 (0.018)	-0.0015 (0.026)
Adjusted	**Complete case ITT**	0.6947 (0.000)	0.0250 (0.289)	0.2895 (0.000)	-0.0202 (0.371)	0.0046 (0.826)	-0.0020 (0.020)
	With MI ITT	0.6733 (0.000)	0.0158 (0.379)	0.2732 (0.000)	-0.0261 (0.164)	0.0229 (0.203)	-0.0020 (0.005)
	Complete case PP	0.6761 (0.000)	0.0238 (0.315)	0.3272 (0.000)	-0.0168 (0.494)	0.0033 (0.884)	-0.0021 (0.018)
	With MI PP	0.6690 (0.000)	0.0118 (0.505)	0.2823 (0.000)	-0.0265 (0.175)	0.0218 (0.227)	-0.0019 (0.009)

ITT – intention to treat, MI – multiple imputation, PP – per protocol, QoL – quality of life

Values in brackets are the p values for each coefficient

The regression analyses highlight a number of interesting findings. Firstly, as expected, across all scenarios allocation to the surgical arm of the trial is associated with greater

incremental costs and greater quality of life. However, while the correlation with costs are found to be statistically significant the correlation with quality of life are not significant across any of the scenarios considered. The per protocol analyses find a larger impact on cost and quality of life as it removes the cross-over patients whose inclusion reduces the reported benefit of surgical allocation.

Also consistent to a-priori expectations increased fracture displacement (i.e. minimally (1mm to 2mm inclusive) compared to undisplaced (<1mm step or gap)) was associated with a lower quality of life (statistically significantly also in the two MI scenarios), and a higher cost. Age was also found to be associated with a decrease in quality of life and an increase in costs while those who had injured their non-dominant hand had increased quality of life but had no consistent impact on costs.

Adjusting for baseline quality of life using a regression approach only had a relatively small impact on the treatment allocation regression estimate, with no consistent direction across the different scenarios. The scale of this change, while surprising given the relative size of the incremental mean different in baseline reported in Table 34, is due to many of the differences being already explained by the existing explanatory variables in the unadjusted regressions, and the random component of the variable. The impact of quality of life at baseline on the cost regression is expected to be the result of adjusting for some level of co-morbidities or patients willingness to interact with the NHS.

Table 34: Incremental costs and quality of life estimates and ICER

Adjusted for baseline QoL	Scenario	Incremental cost (95% CI)	Incremental QALYs (95% CI)	ICER surgery versus cast
unadjusted	Complete case ITT	£1,580 (£1,282 to £1,879)	0.0208 (-0.0200 to 0.0616)	£75,962/QALY
	With MI ITT	£1,228 (£1,011 to £1,445)	0.0182 (-0.0165 to 0.0530)	£67,473/QALY
	Complete case PP	£1,771 (£1,490 to £2,052)	0.0257 (-0.0165 to 0.0678)	£68,910/QALY
	With MI PP	£1,549	0.0173	£89,538/QALY

		(£1,344 to £1,754)	(-0.0176 to 0.0522)	
adjusted	Complete case ITT	£1,308 (£1,063 to £1,609)	0.0250 (-0.0240 to 0.0694)	£52,320/QALY
	With MI ITT (base case)	£1,295 (£1,084 to £1,504)	0.0158 (-0.0221 to 0.0570)	£81,962/QALY
	Complete case PP	£1,616 (£1,314 to £1,988)	0.0238 (-0.0247 to 0.0649)	£67,899/QALY
	With MI PP	£1,594 (£1,296 to £1,961)	0.0118 (-0.0123 to 0.0529)	£135,085/QALY

Clearly, using the limited time scale of the within trial analysis, the use of surgical fixation is not cost-effective, especially if the difference in baseline quality of life is adjusted for. However, as discussed, such a limited timescale overlooks many of the outcomes correlated with the choice of treatment for scaphoid waist fractures, primarily the impact of non-union after this period of treatment on incidence of arthritis, SNAC and other related adverse events.

Impact of lost employment

The summary statistics of the patient reported days of lost employment are reported in Table 35. Primarily the table shows that the majority of patients experienced some days of lost employment in the first six weeks of the analysis period (with only 21.6% and 31.3% reporting no lost days over that period for surgery and cast respectively), but from 12 weeks onwards most were back to fulltime work (with medians of zero for all other periods). There did, however, remain a number of patients who were forced to continue missing work as a result of their wrist, characterised by the persistent mean number of days lost despite close to 90% reporting no lost days. A very few cases of patients having to miss work for most of if not all the period covered by the questionnaire were reported.

Table 35: Summary statistics for days of lost employment reported since last questionnaire

Questionnaire period	Treatment allocation	Number of responses	Mean	Median (95% percentile)	Percentage reporting 0 days
6 weeks	**Surgery**	148	12.07	6 (40)	21.6%
	Cast	150	12.13	4 (42)	31.3%
12 weeks	**Surgery**	159	2.38	0 (21)	76.7%
	Cast	145	3.90	0 (30)	69.0%
26 weeks	**Surgery**	140	1.34	0 (5)	91.4%
	Cast	135	3.72	0 (32)	88.9%
52 weeks	**Surgery**	164	1.51	0 (4)	91.5%
	Cast	160	1.94	0 (6)	91.8%
Total, compete case	**Surgery**	**102**	**16.62**	**9.5 (51)**	**13.7%**
	Cast	**91**	**17.57**	**5 (67)**	**28.6%**

Detailed description for this table and estimation methods are provided in Appendix 6 Section 1 which also includes details on impact on unpaid work.

Extrapolated model - results

In this section the results of the extrapolated mathematical model are reported. Firstly, we reported the headline cost-effectiveness results, i.e. the expected costs, QALYs and resultant ICER and NHB, alongside a consideration of how the NHB accumulate over time. We then go on to consider the decision uncertainty present in the decision model, this is reported in two ways: the probability of each of the four strategies being cost-effective at a given cost-effectiveness threshold represented by the CEAC, a series of scenario analysis exploring the impact of structural uncertainty on the result.

Base-case analysis

Table 36 reports the cost-effectiveness results for the base-case analysis in terms of each treatment options expected costs and QALYs alongside a range of ICERs and the NHB at threshold of £20,000 and £30,000/QALY.

Table 36: Discounted expected cost-effectiveness of all treatments per patient treated

Treatment	Cost (£)	QALYs	ICER (£/QALY), versus…		NHB at threshold of …	
			Lowest cost (cast only)	Next least effective non-dominated	£20,000/QALY	£30,000/QALY
Cast only	836	18.72	-	-	18.68	18.70
Cast + surgery	921	19.07	243	243	19.02	19.04
No treatment	1,749	14.75	Dominated	Dominated	14.67	14.70
Surgery	2,404	19.12	3,952	29,660	19.00	19.04

The results show that taking a lifetime perspective results in surgery being the most expensive option, followed by no treatment, cast plus surgery for non-union, and finally cast only. The high cost of the surgery arm is driven by the high upfront cost of the initial treatment, in contrast to the no treatment cost which is the result of high future costs. These different cost accumulations are shown in Figure 10 which shows the cumulative discount costs, clearly showing the large costs in the non-treatment arm after the initial treatment period, which result from high costs that result from the long-term implications of non-union. The total QALYs for the no treatment arm are much less than for any of the active treatment arms due to the lifetime impact of non-union related adverse events. The surgical arm was found to result in the highest total QALYs followed by cast plus surgery, and cast only. The ICERs and NHBs show that, at their expected values (i.e. not taking into account any uncertainty) cast plus surgery is the most cost-effective option, with the highest NHB at a conventional threshold of £20,000/QALY, followed by primary surgery, cast only, and finally no treatment.

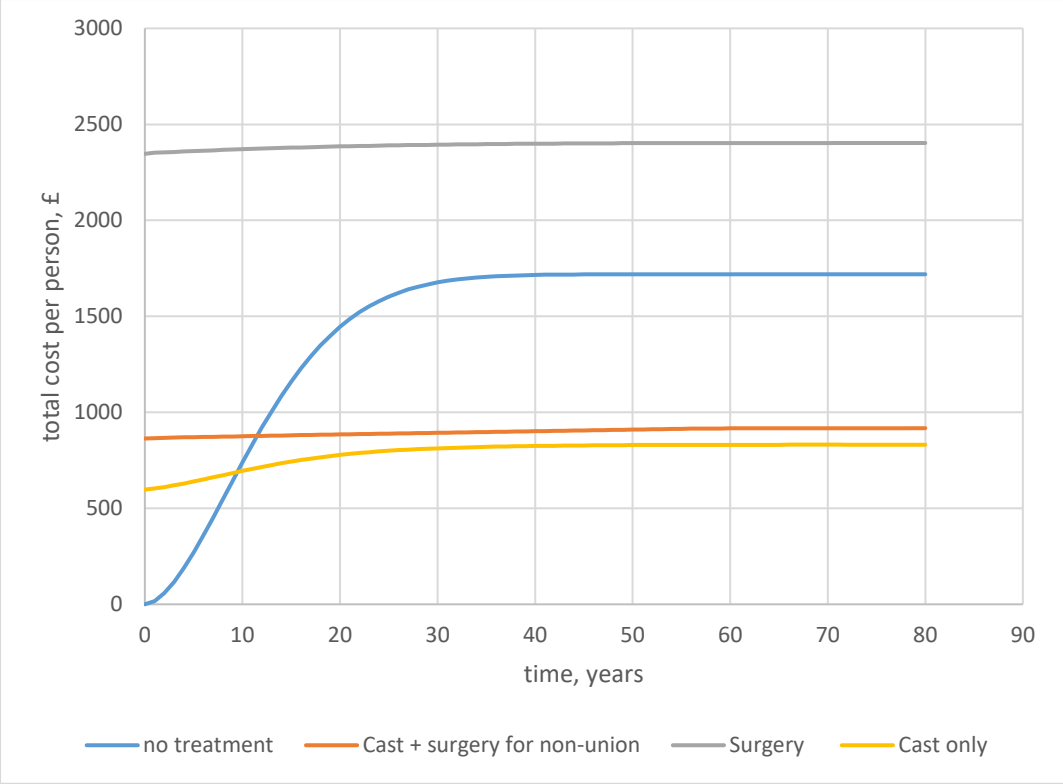


Figure 10: cumulative costs

The accumulation of NHB over time can be seen in Figure 11 which shows the cumulative incremental NHB over the analysis period at a threshold of £20,000/QALY, compared to no treatment. It shows that with the exception of the first year all three active treatment options have a positive cumulative incremental NHB throughout. The closeness of the primary surgery and cast plus surgery lines show that there is a very low absolute difference in the two over time, with the impact of the higher upfront cost in the surgery treatment never being overcome by future health or cost gains, such that at any time-point in the analysis cast plus surgery is the most cost effective when considering mean values at a threshold of £20,000/QALY.

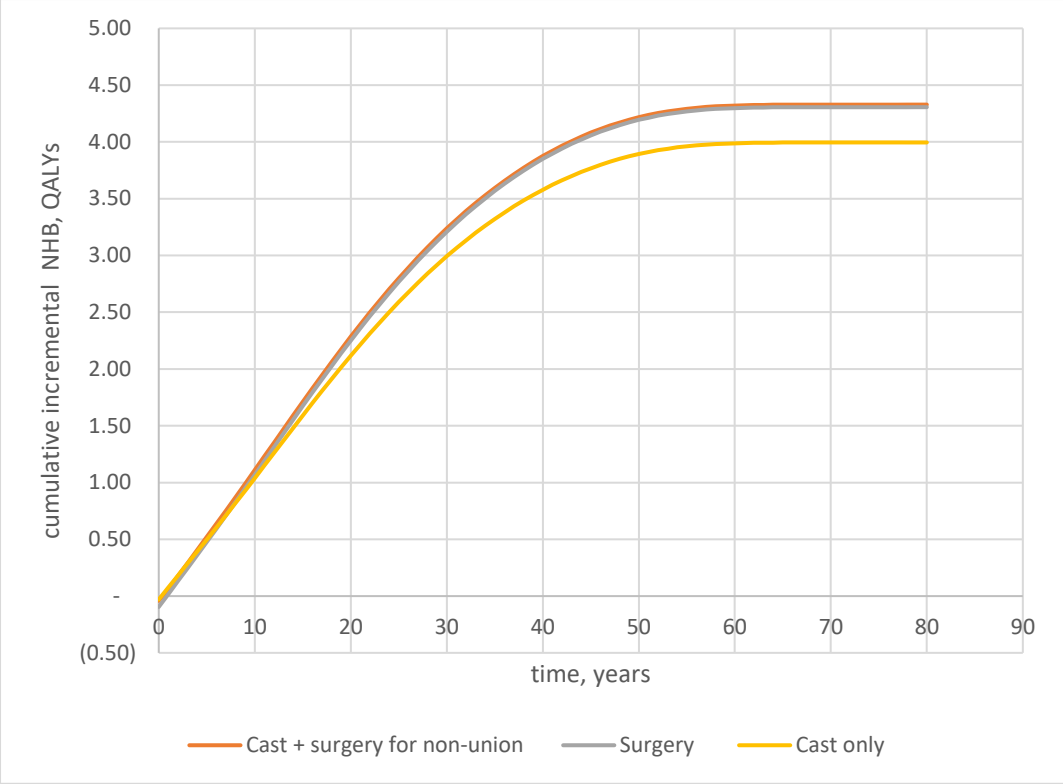


Figure 11: cumulative incremental NHB in relation to no treatment (QALY)

There are a number of ways of reporting the parametric uncertainty associated with the base-case analysis (i.e. how much the modelled uncertainty in each of the parameters impacts our decision), Figure 12 provides the conventional cost-effectiveness acceptability curve (CEAC), which reports the probability of each of the four arms being the most cost-effective option for a range of cost-effectiveness thresholds. The CEAC shows that at very low threshold values, below £300/QALY, the cast only treatment is the most cost-effective, this swaps to the cast plus surgery for thresholds between £300 and £29,660/QALY, after which surgery becomes the most cost-effective for all higher thresholds. As the threshold increases to extreme values primary surgery becomes the more cost-effective option due to its slightly higher estimated lifetime QALYs but there remains a large level of uncertainty in the decision.

The CEAC further shows that if a threshold of £13,000/QALY was used, as indicated by recent research,[118] cast plus surgery would remain the most cost-effective, with 79% of the simulations favouring it, with the expected incremental NHB when compared to primary surgery increasing to 0.07.

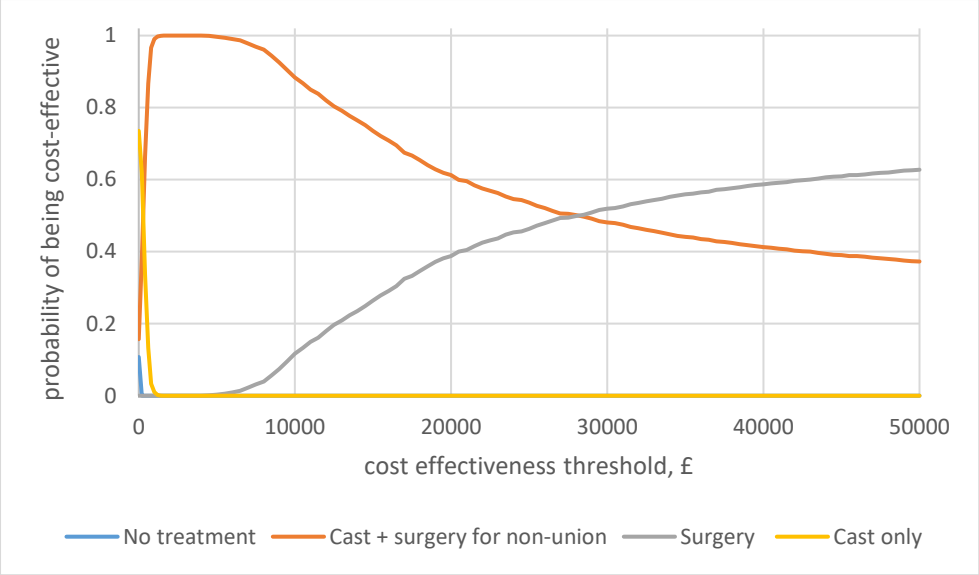


Figure 12: Cost-effectiveness acceptability curve (CEAC)

Another important factor to consider is the relative rank of each treatment option as it is important to understand the situation when a treatment option is not the most cost-effective. Table 37 provides the probability of each treatment option being ranked at each place at a cost-effectiveness threshold of £20,000/QALY. It shows that surgery and cast plus surgery are always the top two treatment options. Additionally, cast only is almost always third ranked and no treatment last. This distribution becomes more marked at higher threshold values. This combined with the base-case result and CEAC allow us to conclude that the cast plus surgical option results in the highest NHB and is the most likely to be cost-effective at a range of conventional threshold values, additionally, even in cases where it is not most cost-effective it is almost always the second most cost-effective option. The table also shows the large level of uncertainty in the decision at conventional thresholds, with the parametric uncertainty in our analysis resulting in two-thirds of simulations favouring cast plus surgery over initial surgical fixation.

Table 37: Probability of cost-effectiveness by rank, threshold of £20,000/QALY

Rank	No treatment	Cast + surgery for non-union	Surgery	Cast only
1	0.00	0.61	0.39	0.00
2	0.00	0.39	0.60	0.01
3	0.00	0.00	0.01	0.99
4	1.00	0.00	0.00	0.00

Furthermore, Appendix 6, Section 7, reports the cost-effectiveness scatter plots generated from the PSA analyses, alongside predictions made by the model for the rate of OA and SNAC at 1, 5, and 10 years to facilitate future validation of this analysis.

Value of information analysis

In addition to considering which treatment option is the most cost-effective and the probabilities of cost-effectiveness as we have done so far, it is also important to consider the implications of that decision uncertainty. For example, if a treatment is estimated as being the most cost-effective 80% of the time but when it is incorrect the resultant NHB are catastrophic, it may not be deemed the best option by decision makers until further research can be used to reduce this level of uncertainty.

To calculate the population EVPI an estimate of the population size and time frame is required. We assumed a ten year time frame and a per annum population of 4,650. The per annum population was estimated by using the 7,265 total scaphoid fractures reported by Garala[4], with 64% (ibid.) estimated as being located in the waist.

The population EVPI is presented in Figure 13, showing how the value of generating additional information varies as the threshold varies. In this case the figure shows that at lower threshold values there is a relatively low level of EVPI, associated with a high value of additional information, as there is a low level of uncertainty about the most cost-effective treatment option, as shown earlier in this section. However, the value of perfect information increases at an increasing rate as the threshold increases, as both the probability and the implications of an incorrect decision increase. The "kink" in the curve is the point at which primary surgery becomes the treatment most likely to be cost-effective, but as the level of uncertainty remains high the value of resolving it continues to increase. One approach to interpreting population EVPI is as a framework to measure conditions under which future research is potentially cost-effective.[99]

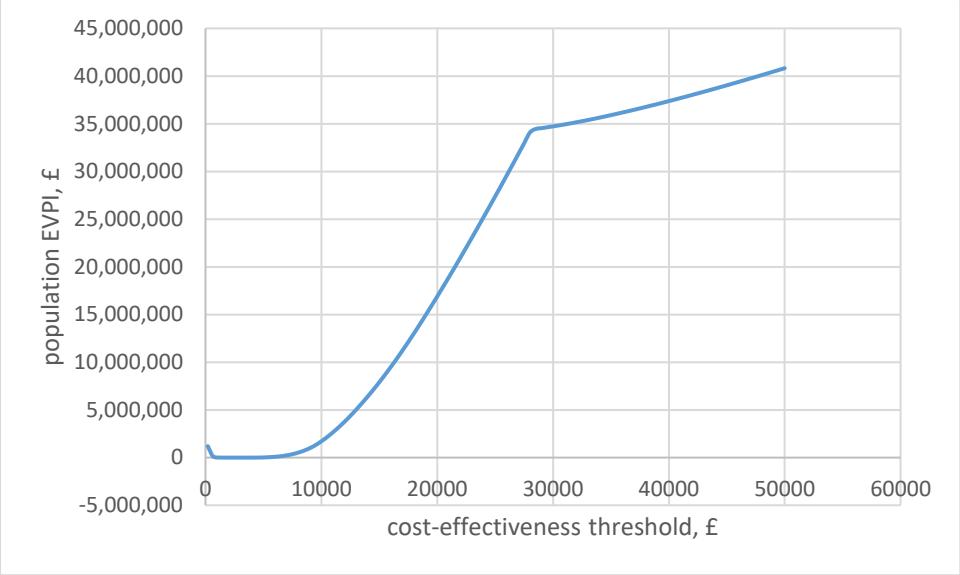


Figure 13: population EVPI across different threshold values

Scenario analyses

A number of scenarios were conducted to explore some of the elements of uncertainty not well captured by the PSA. The full methods and results of these scenarios are presented in Appendix 6, Section 5. In brief, the scenarios show that the headline result of the analysis is not sensitive to the majority of parameter changes but are to changes in how union is defined (scenario 1) and the assumption made regarding what happens to the patients who failed to achieve initial union with cast immobilisation only (scenario 2). These sensitivities are because the model result is almost completely driven by the rate of non-union between the treatment options, which were very similar in the SWIFFT trial at 52 weeks follow-up.

Chapter 5 Qualitative study

Introduction

Context of the qualitative study

A number of factors suggest the value of integrating qualitative research within the SWIFFT trial. That the fracture of the scaphoid waist is common in a younger, active (and economically active) population suggests that the impact of the injury may be wide-reaching and significant. A failure rate of 10-12% for plaster cast management, the potential for complications associated with surgery, and that cast and surgical treatments are of a different order (one invasive, one conservative) might suggest that patients will have opinions about the appropriateness of (and preference for) the treatment options available. Furthermore, a comparison of medical and surgical treatments creates its own challenge of trial delivery, in ensuring equipoise, managing expectations of treatment, and ensuring long-term engagement with trial procedures.

This nested study will seek to generate personalised, contextualised and specific insight about participants' experience of a scaphoid fracture and about their involvement in the SWIFFT trial. It will generate additional insight that will complement the findings of the main trial and will offer insight which will support the design and delivery of future surgical trials.

Aims and objectives

The aim of this study is to provide complementary, detailed and person-centred insight that will inform the interpretation of trial findings and which might support future clinical decision making.

Study objectives:

I. To explore participant experience of a fracture of the scaphoid waist.
II. To explore participant experience of treatment of a scaphoid waist fracture.
III. To consider preference for treatment options, and those factors which might be pertinent in this.
IV. To consider involvement in a surgical, randomised clinical trial.

Fracture and recovery – a patient's perspective

With the exception of hip fracture, qualitative investigation of patient experience of fracture is limited with only a small number of papers which address injury of the hand/wrist/arm.[119-126] Despite some variation ("wrist fracture", "wrist disorder", "hand injury", "hand disability", "finger fracture", "flexor tendon surgery") this body of work points to a number of common themes which are likely to be pertinent to a fracture of the scaphoid waist: functional ability; relationships with others; perceptions of treatment/recovery; and, recovery goals.

Functional ability

Functional ability was addressed in all studies.[119-126] "Wrist disorders" are described as impacting on all aspects of life (including domestic, recreational and economic) and spanning activities that require fine motor skills as well as those that require strength.[124] Employment was presented as an area where limitations might have significant impact, in changed roles, reliance upon others, and challenges to self-confidence.[119, 122, 126] The financial consequences of absence from work were a further potential consequence of a wrist injury.[124, 125] These and other limitations might lead individuals to feel anxious, frustrated, emotionally distressed or even depressed,[121, 123, 124, 126] some authors propose a holistic approach to managing injuries (which incorporates psychological as well as clinical therapy).[119, 121, 123, 125]

Watson et al. are alone in their assessment that the nature and extent of limitations might vary amongst a heterogeneous patient population, with factors such as single-parent status and self-employment associated with an increased impact.[125] They also propose that time spent in a cast might be associated with how limitations are perceived – a longer period in a cast increasing the experience of limitations associated with the injury.[125]

Relationships with others

Functional limitations associated with immobilised hand/wrists may lead individuals to become more reliant upon others for practical help and support,[124-126] husbands/wives, friends or family might all play an important role in helping an individual to maintain normal activities.[124] Such support, whilst generally perceived positively, might have some negative consequences for those that find a lack of independence or a reliance upon others emotionally challenging.[123] Schier and Chan describe that social roles (as a spouse, a caregiver, a worker)

might be fundamentally changed after a hand injury, and that a 'sense of loss' for 'previous social roles' is conceivable.[119]

A more positive perspective is offered by Chan and Spencer who identify that supportive relationships can be a motivator for patients making positive adaptive behaviours, e.g. adhering to rehabilitation programmes so as to resume parenting activities.[121] Supportive relationships might also provide moral (rather than practical) support at clinic appointments and in gathering information about injury and treatment.[125]

Perceptions of treatment/recovery

A potential disconnect between how an injury is perceived and the complexity/duration of treatment can have consequences for adherence to rehabilitation programmes[120] and for remaining optimistic about recovery.[126] That a treatment might *feel* excessive when compared to how the injury is *understood* (simple, uncomplicated, minor?) offers conceptual challenges in accepting treatment and imagining recovery.

Removal of a cast was associated with "a sense of relief, improved function and the *start of recovery*" [emphasis added];[125] this demonstrates the pertinence of lay conceptions of treatment and highlights that a patient's own sense of recovery might be at odds with their clinical recovery. That is, that perceptions of recovery might be more about regaining normality than about the clinical/physical repair of the fracture or injury. In the same study participants describe uncertainty and anxiety about the removal of a cast, concerned by the loss of protection and uncertainty about the status of the wrist repair.[125] A lack of feedback and information about recovery is a source of anxiety for some patients[126] and elsewhere patients describe the importance of feeling confident that they are receiving the *right care* and feeling certain about their recovery trajectory.[125]

It might seem that patient understanding of injury and recovery are influential in shaping their experience of treatment and satisfaction with it.

Recovery goals

Uncertainty about achievable levels of functionality,[123] acceptance about possible longer-term limitations,[121] and "*readjusting expectations and accepting limitations*" [126] all point to

some sense of uncertainty about what long-term recovery might look like. That such concerns are less manifest in this body of work, and less present in initial clinical consultations,[125] reinforces the assessment that "*wrist fracture is perceived too trivial to warrant* [detailed/longer term concern]".[125]

Amman et al. offer that patients "*had an inner drive to strive for normality*",[122] which mirrors a concern for "*regaining normality"* demonstrated in orthopaedic trauma patients (which includes wrist, elbow and shoulder injuries).[127] Pre-injury wrist status might be important in establishing some sense of what this might mean,[124] although to borrow from the hip fracture literature notions of *normality* will be shaped by broader conceptions of prior health and by what is considered acceptable with regard to natural deterioration (such as that associated with aging).[128]

Summary and assessment of literature

It is evident that hand/wrist injury can have wide-ranging impact upon functional abilities in domestic, leisure and employment environments; and that such difficulties can lead to a greater reliance upon other people. A lack of clarity about longer term goals, and the potential for dissonance between how injury (minor) and treatment (complex/long-term) are conceived, may lead to uncertainty about recovery. A patient's (subjective) 'sense of recovery' may thus be important in their level of satisfaction with treatment. That subjective experience is influenced by clinical, personal, social or even economic factors suggests a wide variation in how recovery might be managed.

It should be noted that this assessment is based upon a limited literature and that the existing evidence base varies in scope and method: from detailed reviews of two or three interviews [119, 121, 123] to more structured assessment of larger data sets.[124] Differences in focus (hand, wrist, finger) and reach (from one-off interviews to longitudinal studies) also make synthesis and confident extrapolation difficult. Little has been written about wrist fracture,[125, 126] and fracture of the scaphoid waist is not explicitly identified in these papers. Surgical treatment is not explicitly explored and an investigation of patient preference for treatment is lacking.

Randomised trials in surgery

Difficulties recruiting to randomised clinical trials are well documented [129-134] with issues of participant retention gaining increased consideration.[135-139] For clinical trials where surgery is compared to a non-surgical treatment these difficulties are recognised to be more pronounced [140] and McCulloch et al. identify a range of factors which they consider as inhibiting surgical trial delivery.[141] Amongst these are surgeons' equipoise, patients' equipoise, surgical learning curves, issues with blinding, life threatening and urgent conditions, definitions (of procedures) and quality control monitoring.[141]

More general assessment points to the relevance of contextual and specific characteristics in trial delivery; the setting of a study, the population of interest, and specific procedures may all pose challenges to the appeal or completion of a study.[135, 142] For SWIFFT a younger, active male population suggests some challenge to its delivery. Previous research has demonstrated that females are more likely to participate in research,[143] and that older people are more likely to fulfil their commitment to a study.[144] Insight generated in this qualitative research might provide further insight into the challenges of delivering a trial with this population; and might point to factors that enhance or inhibit success.

Methods

Study design

A nested interview study was conducted to explore participants' experience of the fracture of the scaphoid waist, its treatment and their experience (or opinion about) involvement in clinical research. This study involved both individuals recruited to the SWIFFT pragmatic RCT, as well as a small number of individuals who declined to participate in the trial. Interviews were conversational (semi-structured rather than structured) and analysed using an inductive, thematic approach.

Participants

A purposive sample [145] of those SWIFFT trial participants who indicated a willingness to be interviewed were recruited to this study. Interviewees were purposively selected to ensure that both men and women, experiencing different treatments, of different ages, and occupations were interviewed. A pre-defined sampling frame (*Table 38*) was constructed to guide participant selection and to ensure that the sample broadly reflects general patterns in

the incidence of scaphoid fractures, i.e. to prioritise younger people (under 30) and to prioritise male participants. The sampling frame also distinguishes manual and non-manual occupations to enable this comparison in analysis.

Table 38: Target sample – within trial

	Gender		Age		Occupation	
	Male	**Female**	**Under 30**	**Over 30**	**manual**	**non-manual**
Surgery	12	6	12	6	9	9
Cast	12	6	12	6	9	9
Total	24	12	24	12	18	18

Those who declined to participate in the SWIFFT trial were also invited to take part in this interview study. This second group was recruited to support a broader consideration of patient preference for treatment, i.e. to reflect that those who declined may have different attitudes about treatment. Again, a sampling frame was constructed to prioritise interviews with male participants and with those under 30 years of age (*Table 39*).

Table 39: Target sample – declined participation in SWIFFT trial

	Gender		Age		Occupation	
	Male	**Female**	**Under 30**	**Over 30**	**manual**	**non-manual**
Total	6	3	6	3	-	-

Recruitment to this element of the SWIFFT research was also informed by concerns for data saturation; that is, the point at which no new insight is generated in the undertaking of additional data collection.[146] Prior assessment has suggested that core topics and themes might be established with as few as 6 interviews and that more complete data saturation is

commonly achieved with 10-13.[147-149] Here, 18 in-trial interviews per treatment arm were proposed as sufficient to reach data saturation, and sufficient to be confident of interpretation of combinations such as *male/cast* (n=12) or *surgery/under 30* (n=12).

In total 36 in-trial interviewees and 9 interviews with those who declined to participate in SWIFFT were proposed.

All interviewees were separately consented for this element of the SWIFFT research.

Data collection

All participants were interviewed within 6 weeks of randomisation and those in the trial were interviewed again at 52 weeks. Both earlier and later interviews covered similar topics and were organised in three parts: i) *wrist fracture and its impact*, ii) *treatment of fracture*, and iii) *participation in clinical research*. Interviews at 6 weeks were intended to capture an immediate response to the scaphoid injury; interviews at 52 weeks were intended to reflect on treatment options and individual recovery. At both time-points, questions about clinical research were included to generate general (*understanding* and *perceptions of*) and specific (to support delivery of SWIFFT trial) insight.

The same interview schedule was used for all interviews at 6 weeks - with some adjustment in the prompts used and how questions were phrased for those who declined participation in the trial. Interview schedules are included here as Supplementary File 19.

Where possible interviews were undertaken face-to-face at a time and location convenient to the participant. In other cases, where the participant preferred or where geography made face-to-face meeting impractical, interviews were undertaken via telephone. Interview questions and prompts were used as a guide for discussion only (rather than as a strict script)[150-153] and interviewees were encouraged to develop issues that they felt important and to introduce new topics which had not otherwise been considered. In this way these interviews were intended to be discursive, generating personalised and contextualised accounts of injury and treatment. In this way the body of data generated was intended to capture the range of different individual experiences.

All interviews were digitally recorded and transcribed in full, transcripts were anonymised with all personally identifying data removed. Data was stored on a password protected, networked drive and handled using the N'Vivo (version 11) software package.

Data analysis

The discursive nature of the data generated (i.e. guided by but not restricted by an interview schedule) suggests a thematic approach to data analysis.[146, 154] Furthermore, the exploratory nature of the study would suggest an inductive, thematic approach as described by Braun and Clarke.[155] This approach describes a systematic and structured method undertaken in a series of iterative steps. It is a form of qualitative analysis which explores data on its own terms and which prioritises the organic insight generated therein.

Interview transcripts were read and re-read in an initial stage of *Data Familiarisation.* Next, open (inductive) coding was used to identify points of interest in a process of *Generating Initial Codes*. This process was managed independently by a study researcher, with the qualitative study lead ensuring consistency and validity of the coding.

In stage 3 these initial codes were merged and grouped according to topic or sentiment in the *Identification of Themes*. Here, themes and sub-themes were organised within three broad topic areas which reflect the aims and objectives of the study, i.e. focused upon *injury*, *treatment* and *research.* These early stages (1-3) were undertaken alongside data collection with emergent findings presented to the SWIFFT trial management group at its regular meetings.

Stage 4 saw *Themes Reviewed* and refined to ensure their internal and external coherence. At this stage themes were also interrogated to establish their utility in serving the aims and objectives of the research. Following this, themes were finalised in *Definition and Name* and connected to form broad narratives which provide insight into: *1. The injury and its impact*; *2. Cast treatment*; *3. Surgical treatment*; and, *4. Research*. Themes and thematic models were validated by the study CI and other members of the SWIFFT trial management group.

Braun and Clarke [155] offer *Producing the Report* as the final stage of thematic analysis, stressing that interpretation continues as data is organised in an authored form. The final

narratives (presented below) were validated by the SWIFFT trial management and author groups.

Results

Data overview and code book

A total of 64 interviews were undertaken with 49 individuals.

36 in-trial interviews were carried out at 6 weeks and 19 interviews at 52 weeks; 9 interviews with individuals who declined the main trial were carried out at 6 weeks (*Table 40, Table 41, Table 42 describe the demographics of the sample*). Of the 49 individuals interviewed, 36 in-trial participants were recruited at baseline, 9 who declined participation in SWIFFT were recruited at baseline, and 4 in-trial participants were recruited at 52 weeks (to compensate for drop out). Of these, 35 were male (14 female) and 26 under the age of 30. Approximately half of all interviews were with our key demographic - males under the age of 30 (17/36 at six weeks, 9/19 at 52 weeks, 5/9 declined trial).

Topics, themes and sub-themes were consistent across the sample; data collection ceased following the addition of 4 younger, male interviewees who were interviewed at 52 weeks only (to ensure data saturation for this key population).

Participants were recruited from 13 centres: Bath, Bolton, Cardiff, Coventry, Leicester, Newcastle, Nottingham, Oxford, Peterborough, Plymouth, Royal London, Southampton, and Teesside.

Interviews varied in length from 14–73 minutes at 6 weeks, and 13-41 minutes at 52 weeks. Interviews were typically 40-45 minutes at 6 weeks, and 20-25 minutes at 52 weeks.

Table 40: Interviews at 6wks with trial participants

	Gender		Age		Occupation	
	Male	**Female**	**Under 30**	**Over 30**	**manual**	**non-manual**
Surgery	13	4	9	8	7	10
Cast	12	7	10	9	7	12
	25	11	19	17	14	22

Total

Table 41: Interviews at 52wks with trial participants

	Gender		Age		Occupation	
	Male	**Female**	**Under 30**	**Over 30**	**manual**	**non-manual**
Surgery	8	1	6	3	5	4
Cast	5	5	4	6	6	4
Total	13	6	10	9	11	8

Table 42: Interviews with those declined participation in SWIFFT trial

Gender		**Age**	
Male	**Female**	**Under 30**	**Over 30**
6	3	5	4

Initial analysis was structured around three broad topics (*injury, treatment*, and *research*) with codes subsequently organised within 11 core themes and 37 sub-themes (*see Table 43a*). This represents stages 1–4 of the inductive thematic analysis.[155] Stages 5–6 are presented from the thematic analysis section onwards.

Table 43a: SWIFFT code book for qualitative data

Topic:	*Theme:*	*Sub-theme:*
Injury	A minor injury?	Delayed seeking medical help
		Not worthy of serious treatment
	Practical difficulties	Driving
		Leisure pursuits
		Washing
		Domestic chores
		Difficulties at work.
	Psycho-social difficulties	Loss of independence
		Mood
		Relationships with others
	Other difficulties	Employment
		Money and finances
Treatment	Plaster cast	Inconvenient and immobilising
		Passive
		Safe and natural
		Preference for plaster cast
	Surgery	Preference for surgery
		Active
		Quicker recovery

		Risks
	Factors in preference	The need for speed – employment and money
		The need for speed – familial responsibilities
		The need for speed – lifestyle and other events
		Access to practical support
		Prior clinical experience
	Recovery	Return to normal
		Progress made
		Long-term concerns
Research	Reasons for participating	Access to treatment options
		Clinical benefits
		Money as incentive
	Positive assessment of research	Research processes acceptable
		Research nurses
		Facilitators of research
	Negative assessment of research	Barriers to research processes
		Research processes unacceptable

Thematic analysis

Model 1 – the injury and its impact

Thematic model – Fracture of the scaphoid waist is often initially considered a relatively minor injury. It can, however, have wide-reaching impact in limiting function. Limited function may be associated with greater reliance upon other people and may have other psycho-social consequences.

An Inconsequential injury?

For many the fracture was the result of what they considered to be an inconsequential incident - a trip, a clash on the football pitch, a bang at work, falling off a bike. Few considered the injury serious and many continued what they were doing: "*Strapped it up, checked I could still catch and pass the ball, and then went back on*" [Plaster cast 1121, male, under 30, 6wk[2]]; "*I carried on working… I had to make the job safe before I walked away, so I worked for probably an hour after*" [Surgery 1008, male, under 30, 6wk]; "*oh yeah I carried on dancing, it didn't hurt at the time*" [P1245, female, under 30, 6wk]. Even an assessment that some damage might have been done did not necessarily mean that immediate action was taken:

> "*I knew as soon as I'd landed, it was obvious … I could tell it was more than a sprain … I thought I'd damaged it …* [but] *I did what I needed to do, I just finished the delivery, and drove the van to where it was needed … by the time I got back here it was 9 o'clock* [at night] *… So I went down the hospital first thing on Saturday morning*"
> [P1451, male, over 30, 6wk]

In the few cases where more immediate medical attention was sought it was often because of multiple injuries, with the wrist commonly considered the least of these: "*I went because of the blood gushing from my chin … I did my tooth, my chin, everything else as well*" [P1023, male, under 30, 6wk*]; "*the ladders slipped underneath me … it was my back … I didn't know I'd hurt my wrist*" [P1282, male, under 30, 6wk].

[2] The convention for identifying participants is as follows – "P(laster cast) Participant ID number, gender, age, 6/52wk interview" or "S(urgery) Participant ID number, gender, age, 6/52wk interview"; an * indicates an interview with someone who declined to participate in the main trial.

For most, swelling, pain or bruising prompted them to seek medical attention within 24 hours, although for some it was a number of days before they sought any treatment: P1823 [female, under 30, 6wk] went to A&E three days after her fall; P1161 [male, over 30, 6wk] went to hospital six days after a trip. Even when seeking medical attention some still suspected that they had only sprained their wrist, and a number were surprised at the fracture diagnosis. The severity of the consequences of the injury (and the potential for surgery) were surprising to some:

> "*I think when you initially do it, you always think well your wrists are nothing and it's not until somebody sits down and explains to you just exactly how complicated a wrist or a foot or hand is that you suddenly realise hang on a minute*"
> [S1175, male, over 30, 52wk]

> *"I was like well it didn't really hurt so how can it be that bad …* [the hospital] *said 'it could be six to ten weeks in a cast and then an operation' … I was like 'oh no, I don't want any of this! I only just went ice-skating and accidentally got pushed over'… I didn't realise the severity of it kind of thing, well I just didn't, I still can't quite believe it now to be fair"*
> [S1244, female, over 30, 6wk]

Practical difficulties associated with the injury

Despite any initial assessment that the fracture might be a minor injury, all interviewees described some degree of practical limitation, from *work* to *washing* and *dining* to *driving*.

The impact upon leisure pursuits was telling for some: "*the only real impact it's had is my leisure activities, so I haven't really felt that I'm comfortable going to play football just in case I fall again"* [P1201, male, under 30, 6wk]; "*my leisure time is somewhat disrupted, I'm a church bell-ringer, which involves my hands, and I can't really do that so much now"* [P1856, male, under 30, 6wk]; "*I do quite a bit of cycling. I haven't been on the bike since just because of grabbing the handlebar might be quite difficult, so I haven't been able to do that*" [P1360, male, under 30, 6wk].

The impact upon work more so for others, especially when pay is affected by an absence from work: "*the worse thing was knowing that I had to have time off work …* [I'm] *classed as self-employed so … it was just the thought of not being able to work really … knowing that there's kind of a month's pay that's going to be missing"* [P1327, male, under 30, 6wk]*; "Well I'd just gone self-employed, so I'm not going to be earning now. I'm out of pocket in*

that respect" [P1451, male, over 30, 6wk]. Driving was a common area of discussion with interviewees often concerned by advice not to drive, and about what this might mean for their independence:

> "*3 months of not driving for me would be 3 months of hell really … it would have affected my work so much, not being able to drive for 3 months*."
> [S2097, male, under 30, 52wk]

> *"I live right in the middle of nowhere really, so in terms of getting the bus to work that'd not be impossible … I was relying on my girlfriend for lifts and friends picking me up … But in terms of getting to places, yeah I was just really reliant on people giving me lifts which was awful"*
> [S1691, male, under 30, 6wk]

Psychological and social impact of the injury

This final quote points to the fact that practical difficulties often translated into reliance upon others and potential changes to relationships. Some (younger, often students) described becoming more reliant upon (or even moving back in with) parents or other family members. Others described being unable to contribute at home and to a reliance upon wives, husbands or partners for practical support:

> *"*[Interviewer - How did your wife cope?] *With great difficulty because I was someone who was very active and I turned into someone who … wasn't able just to take the mower out of the shed and mow the lawn or take my daughter to the park on the swings ... So I couldn't drive so it meant me not being able to take my son to sports. ... Everything was kind of left to her."*
> [P1020, male, over 30, 52wk]

Few suggested that this was problematic, although some indicated feeling *low* about the injury: "*I need to find other things to do with my time … I feel really bad, I feel depressed …*" [S2284, male, under 30, 52wk]; "*I started to get very depressed and it affected me badly. I wasn't coming out of my room*" [P1023, male, under 30, 6wk*]; "*Saturday was the day I felt a bit low … I was just a bit like I hate relying on everyone … I felt 'oh my God this is crap'*" [S1244, female, over 30, 6wk]. Less remarkable complaints about frustration and boredom were common:

> "*So I just had to sit there and watch TV and in the end it was getting boring to the point where I was just going out for a walk randomly, just to try and get out.* "
> [S1008, male, under 30, 6wk]

> *"I've definitely been frustrated with it yeah. Because it's just so well so silly falling off my bike. And then having like everything, everything changes you know just because of that really."*
> [S1691, male, under 30, 6wk]

Model 2 – plaster cast treatment

Thematic model – In comparison to surgery, initial treatment in a plaster cast is recognised as less risky and possibly more 'natural'. It is, however, perceived to be more limiting, and more limiting for a longer period of time. That repair beneath the cast is unseen is a concern for some.

A more natural option

For some interviewees plaster cast treatment was conceived as more natural and less risky. This assessment was of course informed by concerns about surgery – about anaesthesia, scarring, surgical error, etc. – but also seemed to reflect an attitude that there is benefit in allowing the body to heal naturally [P1986, female, over 30*; P1023, male, under 30*; P1360, male, under 30; amongst others].

Plaster cast was considered a convenient and straightforward option by some:

> *"*[when allocated to cast treatment] *I thought 'oh flipping heck'. But now, in hindsight, I'm so pleased I had the plaster because you've no scar or anything. You risk infection don't you if you have an operation? I've no scar or anything, it's perfectly healed, so no, I'm quite happy, I would have the plaster again I think."*
> [P1617, female, over 30, 52wk]

It is pertinent to note that these assessments reflect participants whose recovery was positive and straight-forward. Not all those who were interviewed experienced such outcomes and their assessment acknowledged that plaster cast treatment might be more or less attractive given the nature and severity of the injury, and different lifestyles and commitments:

> *"I prefer non-intervention if possible … my upfront view was never do surgical intervention if you don't need to…* [cast is better] *assuming that the bits are all in the right position … but I'm starting to wonder if I've done more damage* [than I thought]*"*
> [P1542, female, over 30, 6wk]

> *"And who's to say if I was entering a different situation in a different time, I'd be like oh I really do hope that I do get the surgery because I cannot be in a cast for more than two weeks, you know"*
> [P1030, male, over 30, 6wk]

An inconvenience

More common in the data were comments about the inconvenience of wearing a plaster cast:

> *"The worst thing … restricted movement. That's it you know. That's all it is. That's even worse than* [the original injury and pain] … *just being restricted from doing what you'd normally do. … I think just that, just being restricted you know… That to me, that's the main one, just the restriction of the cast."*
> [P1161, male, over 30, 6wk]

> "*when I had the cast on, being a bit limited for stuff you know. Which was a bit awkward, doing buttons up on shirts and stuff you know because it did used to hurt at the start. But because I used to do running and couldn't really run with the cast on, that was a bit of a pain.*"
> [P1161, male, over 30, 52wk]

An inability to work, difficulties at work, and difficulties driving were all associated with the restrictive nature of the cast; and whilst these complaints varied person to person the consequences for some were significant and long-term (for a few still evident at 52 weeks). Feelings of *being disabled* and about *losing independence* were associated this:

> *"I've become more reliant on other people …In a sense I've learnt how to sort of let people do more things … I try and do what I usually do and I get annoyed 'cause I can't do it, I sort of just sit back and faff about and then try and sort of relinquish that duty to someone else … err, so I've become more submissive I suppose in that sense, and sort of wait for someone to help out."*
> [P1485, male, under 30, 6wk]

Other complaints focused upon more mundane, personal, everyday activities. Difficulties going to the toilet, "*I couldn't flush the toilet normal, I couldn't wipe my backside*" [P1020, male, over 30, 6wk]. Difficulties using cutlery, "[eating] *would be a struggle, I can't use a knife and fork*" [P1245, female, under 30, 6wk]. Difficulties sleeping, "*I'm quite fidgety when I sleep, then I sleep on my side quite a bit so the arm gets in the way quite a lot*" [P1575, male, under 30, 6wk]. Issues with clothing were also mentioned, "*it's ruined so many clothes the plaster rubbing up against your dress or blouse*." [P1316, female, over 30, 52wk].

Difficulties washing might be added to this list, both with regard to keeping the cast dry as well as the dexterity required to wash with one hand and/or a non-dominant hand; "*I've got one nice smelling armpit, one less so*" [P1451, male, over 30, 6wk]. The itching associated with a plaster cast was distracting to some, and individuals described using knives, knitting-needles, pens, forks, amongst other things to scratch beneath the cast. The state of the cast and the potential for it to become "*manky"* [P1121, male, under 30, 6wk] was described by some who were concerned about hygiene, "*it's not the nicest smelling thing in the world – as much as you try wash your hands it really does smell like cheese*" [P1485, male, under 30, 6wk], "*I don't like the fact that there's one thing on my arm for 6 weeks you know. I'm a bit of a clean freak and it's quite annoying*". [P1823, female, under 30, 6wk]; and about how it might appear to others, "*I don't wear short sleeve when I've got the cast … like it's not exactly the most pleasant looking"* [P1575, male, under 30, 6wk].

Uncertain recovery

Around half of those treated in a plaster cast interviewed at 52 weeks expressed some on-going concerns about their recovery. P1020 [male, over 30, 52wk] described his recovery as being at 70%. Others described feeling some weakness in their wrist [P1560, female, over 30, 52wk; P1245, female, under 30, 52wk]; described wearing a wrist support [P1542, female, over 30, 52wk]; and described hoping for some further improvement, "*I'm hoping that it isn't going to be like this forever, I'm hoping that it's going to be one of those things that'll sort itself out one day*" [P1121, male, under 30, 52wk]. Of those describing a more positive recovery there was some disappointment at how they had been incapacitated:

> *"because it hadn't fully healed after the six weeks I had to have it on for another six weeks, and 12 weeks is kind of pushing it really, for how long I was to wear this thing for."*
> [P1807, male, under 30, 52wk]

> *"I was probably a bit surprised with how long it took to heal ...* [when the cast came off] *it wasn't completely healed. ... I do remember them saying it hadn't completely healed. I don't know, I think it was probably around 70% or something."*
> [P1161, male, over 30, 52wk]

A common observation was that cast treatment requires a long period for healing to take place: "*a bit of disappointment that I was going to have to be stuck in the cast for so much longer ... it's going to be on for a longer time than it would have been for surgery*" [P1856,

male, under 30, 6wk]. A less common, but perhaps equally pertinent, observation was that the period in a cast is an uncertain period, a time where improvement and outcome are unclear. These two elements combined (duration and uncertainty) might make cast treatment less attractive to some:

> *"being in a cast for maybe four to six weeks and then maybe another decision being made …. I think, you know, kind of six to 12 weeks of uncertainty"*
> [P1360, male, under 30, 6wk]

> *"*[it would be good] *if you could see the healing process before the six weeks* [when the cast is removed]*, because I think six weeks is a hell of a long time for somebody to kind of stop doing 50% of the things that they'd normally do to then still not be any better off. It's kind of a kick in the teeth. I mean if you was in the cast for three weeks and your healing* [could be checked] *or just to know something halfway through probably would have been a little bit better."*
> [P1020, male, over 30, 52wk]

Model 3 - surgical treatment

Thematic model – In comparison to cast treatment, initial surgery is perceived as a more active form of treatment. The benefits of a more quickly removed cast is important to those whose personal, economic or familial circumstances exaggerate the impact of limited functionality.

A preference for surgery

For a number of participants the opportunity for surgical treatment was an important factor in their willingness to participate in the trial. These individuals felt that surgery was the *right* option for them; for some this was an intuitive preference born of previous fractures, for others it was an assessment reached through discussion with their consultant and the nurses recruiting to the trial. Speed of recovery, strength of repair, and certainty of treatment were all factors in this; employment circumstances, family commitments, leisure pursuits and even holidays were also identified as being pertinent to surgery being more attractive:

> *"my mind was already sort of going towards the surgery side anyway ... me and a friend of mine we run an events catering business and June and July are the busiest months of the year … if I'd have been stuck in a cast you know I was able to come to work but my skill level dropped off when it comes to using knives"*
> [S1345, male, over 30, 6wk]

"I said to be honest, I'd just like to have the option of the operation if it will be quicker. … Because we were buying this house and we needed the money to be coming in. ... I've got no such thing as light duties. It's either all in or all out and I've had to put a few jobs off"
[S1008, male, under 30, 6wk]

A need for speed – a quicker recovery

At the most basic level the inconvenience of a cast was a push factor for favouring surgery:

"But for someone like me who is very independent and I have to work and drive and, you know, do all of these things, the thought of being in a cast for eight to ten weeks, maybe longer… that was quite scary."
[S1749, female, over 30, 6wk]

For others a slow, delayed recovery might lead them to do more than they should, potentially aggravating or re-injuring their fracture:

"[in a cast] *I would have wanted to become independent again and I would have done other stuff, you know, I wouldn't have been able to just sit around with a cast on, I would have been doing other stuff. So I would have probably have put myself at risk by wanting to become independent again."*
[S1658, female, over 30, 6wk]

"they said it could be six weeks but after those six weeks you could still need surgery… To be out of work for so long I'd then run the risk of, you know, trying to get back quicker and then ending up [hurting myself again] *and being twice as long. So you know, it seemed like a smarter option … I did feel as though it* [surgery] *was probably the best treatment for the injury."*
[S1759, male, under 30, 52wk]

The risk of the fracture not healing whilst in a cast was also present in other individual's assessments:

"Yeah that's what they said, if we just put the cast on it it could end up like having surgery later on, so I thought I might as well have the surgery done now … I thought oh well it's best to have the surgery done now and then avoid [more problems later]*"*
[S2097, male, under 30, 52wk]

" after six to ten weeks [in a cast] *you still might need an operation anyway because it might not have healed … I was thinking oh no I don't want that, well I don't want to go through doing that and then having the operation anyway, so that's the other*

reason, I thought well you're just better off going for the operation anyway."
[S1244, female, over 30, 6wk]

That surgery following the failure of cast treatment was perceived to be a more complex procedure reinforced the appeal of immediate surgical treatment; better to have straightforward surgery immediately than to risk a more challenging procedure later.

A need for speed – a more active form of treatment

Important in the assessment that surgery offers a quicker and more certain recovery was the perception that the more *invasive* and *interventional* nature of surgery offers benefits to the healing process. By this way of thinking surgery was doing something beneficial, rather than simply waiting for healing to take place. Surgery was seen as offering a more certain treatment pathway, was considered to involve a more active repair of the wrist, and was considered beneficial in kick-starting the healing process:

"I suppose you feel [it's a] *more involved healing process ... The fact that you're going to hospital and getting it treated rather than just waiting for it to heal in a cast."*
[S1339, male, under 30, 6wk]

"*Yeah. I think there's just a lot more certainty in the* [surgery] *treatment. … there's just some sense that the surgery would just feel like something's happening. It's happening now, I'm going to be getting better."*
[P1360, male, under 30, 6wk]

The insertion of a pin was intuitively appealing to some, adding strength to the fractured bone. This assessment was particularly important to those who were concerned about manual or physically demanding activities:

"*I was to knock it again it wasn't just going to break because the screw would hold it in place … The operation would be better in my circumstances* [self-employed joiner] *because it will be a stronger fix*."
[S1008, male, under 30, 6wk]

"*because it's got a screw in it, for me, mechanically minded* [motocross cyclist], *it's going to be stronger, so – I don't know – I think that's why I liked it a lot more.*"
[S1265, male, under 30, 6wk]

Assessment of surgical procedures

Those exposed to surgery expressed few concerns about the appropriateness of the procedure. That surgeons expressed confidence in the procedure was important, more so that the surgery was commonly offered within the NHS. All were generally content with their initial recovery and those interviewed at 52 weeks (n=9) indicated that their recovery had exceeded expectations (in both speed and completeness). Those interviewed at 52 weeks also indicated that they would recommend surgery to others.

> "*the fact that it is pretty much back to exactly the way it was, obviously there's just a pin in there, or a screw, whatever it is, you know, I mean there's no loss of movement, there's no stiffness in the movement, so I am quite surprised in the fact that I've had an injury like that and there's no, … you know, to be honest you kind of almost wouldn't really know it had happened in a way*."
> [S1345, male, over 30, 52wk]

There were some minor concerns about scarring and some comments about pain following surgery, but none of these were considered a barrier to the appeal of surgery. The only barrier identified by some was a reluctance to undergo surgery under a local (rather than general) anaesthetic.

> "[local anaesthetic] *I suppose it's more a bit modern and a bit … it just didn't appeal to me really … I know that you can't feel it or whatever and you probably couldn't see what's going on, I was just like 'oh no' and she said instantly in my face she could see how I weren't up for that!"*
> [S1244, female, over 30, 52wk]

> *"they said to me at first they was going to like knock me out, but then when they got there they said they wasn't, they was going to do it on the local anaesthetic. And that's when I started to get a bit worried. I didn't really want to hear it. I asked them straight away, well what about, would I be able to see it? And they said no, they'd put a screen up. And then eventually I asked for some sedative and I had it and went straight to sleep."*
> [S1452, male, under 30, 52wk]

Model 4 - research

Thematic model – Surgical treatment made participation more appealing to some, although for others surgery (and randomisation) were reasons for not taking part in the wider study. Study burden was considered acceptable and some felt that taking part in a clinical trial might improve clinical care.

The appeal of research

In both arms of the trial individuals expressed similar opinion about agreeing to participate because of the possibility of being randomised to the surgical treatment arm:

> *"I was approached to join the study and yeah I was fully willing to join and I thought it would probably be the best … I wanted surgery from the start, I know it was randomised, but I told them I wanted surgery"*
> [S1452, male, under 30, 52wk]

> *"I think she explained to me that with the operation it could heal quicker I think … I said to her "Look, OK, fair enough. Whatever's quicker" you know but I mean obviously it came that I've got to have the cast on"* [P1161, male, under 30, 6wk]

In contrast some of those who declined the main trial expressed uncertainty about the surgical procedure. At least one trial decliner indicated feeling "*scared of surgery*" [P1774, male, under 30, 6wk*]; another suggested that surgery felt quite serious for *a relatively minor injury*:

> *"I just felt* [surgery is] *a more drastic approach for something which is fairly common. … I was a little bit shocked, to be honest, when they offered me surgery … I think of surgery as something more, for more serious injuries I think I could probably heal without and, like I say, all the side effects put me off.*"
> [P1023, male, under 30, 6wk*]

In addition a number of interviewees speculated that participating in a major clinical study might bring with it other benefits, either with regard to improved clinical care or simply less waiting at appointments:

> *"you get seen quite quickly when you're doing it … Actually I think you get treated a bit better when you're doing it!"* [P1245, female, under 30, 52wk]

> "*and the other thing is because it's research, when it comes to the treatment, everything has to be within a certain period for that information to be relevant … So I thought everything will be pushed through quicker than just being on a waiting list as well"* [S1008, male, under 30, 6wk]

More commonly participants indicated altruistic reasons (benefiting other patients, contributing to the NHS) for taking part in the trial.

Research processes

A few of those who declined to participate pointed to study burden as a factor in their decision, although for those involved in the study this was rarely commented upon. More likely interviewees would confirm their commitment to fulfilling their involvement as a point of principle, *"you know it's just a mind-set really and I said I would do it, so I was quite happy to go ahead with it … I wouldn't have stopped"* [P1617, female, over 30, 52wk]. Some gripes about the questionnaires (long, repetitive) and about follow-up appointments (parking, timing, etc.) were mentioned, but these were rarely described as serious problems.

Continuity of contact and support from the research nurses was commended by some and described as a key factor in their fulfilment of the study requirements:

> *"I think that my experience of all the follow ups and stuff was absolutely spot on. I had the same nurse that I saw the first day … she kept in contact with me, she told me everything I need to know, always there if I needed to speak to someone … I think that I was very well looked after and always kept informed and very helpful at all times." [S1452, male, over 30, 52wk]*

> *"we've actually been treated really nicely and it was – obviously the research nurse that I went to in the hospital, or who I'd spoken to, she was lovely. She rings me about my appointments and stuff and…things like that. And I know what's going on." [P1245, female, under 30, 6wk]*

Most interviewees indicated that they had a reasonable comprehension of randomisation, although in some cases this included notions that individual circumstances would be considered [S1008, male, under 30, 6wk] and that the process might be modified according to the doctor's opinion [S1175, male, over 30, 6wk]. That both treatments were established and safe was important in accepting randomisation, and whilst many had an initial preference for one treatment or the other all demonstrated a willingness to adhere to the randomised treatment. Amongst those who declined the main trial an uncertainty about randomisation was the most clearly expressed reason for not wanting to take part. These individuals were unhappy with their clinical care being *compromised* by research procedures:

> *"I just didn't like the fact it was not the doctor giving me the best advice that he would normally give you … You know - they'd say this is what I recommend. I didn't at all like the fact* [that] *… something else would then decide which way to do it, and I didn't like that at all and it wasn't what I was expecting … I didn't think it's really*

appropriate. … I'd rather have the doctor telling me what he thought I should do." [P1464, female, under 30, 6wk*]

"I personally don't like the big question mark as to whether you're [getting surgery or plaster cast] *… Not with health issues, you know, I don't like the lottery effect… I like to know what is happening rather than a random number out of a hat."* [P1986, female, over 30, 6wk*]

Some of those who declined to participate in the main trial indicated that being provided with more information about the benefits of surgery might have changed their opinion about taking part: *"if someone then had taken time at that point and sit me down and say talk me through the benefits of what having a screw would give ... I would have been extremely open to go on the trial"* [P1263, male, over 30, 6wk*].

Discussion

Summary of key results

A number of points might be made about a scaphoid waist fracture:

- Initial assessment is often that this is a minor injury.
- Functional limitations associated with the fracture may impact across domestic, employment, familial and social activities.
- Individuals may become more reliant upon others due to these limitations.
- Individual circumstances may exaggerate or mitigate the impact of a fracture - personal, familial or other contextual circumstance (including severity of the fracture, dominant/non-dominant hand) may influence how limitations are experienced.

A number of points might be made about how treatment options are viewed:

- Cast treatment is recognised as conservative and less risky. It is, however, associated with an extended period of immobilisation.
- Uncertainty about healing may exaggerate concerns about the duration of immobilisation.
- Surgery is associated with a more active repair, and is perceived to offer a speedier recovery.
- Again, individual circumstances may inform treatment preference – where personal, familial or other contextual circumstances demand a quicker *recovery* surgery may be perceived advantageous.

A number of points might be made about the delivery of this trial:

- The potential for surgery was appealing to many of those interviewed. Conversely, amongst those who declined to take part in SWIFFT concerns were expressed about surgery.
- Trial procedures were not considered burdensome and there was recognition that trial processes may enhance navigation and experience of clinical processes.

Reflections upon the results

This work contributes to the limited literature upon patient experience of hand/wrist/arm injury. It reinforces and extends a number of themes in this literature – specifically, the wide-ranging functional impact of an injury,[119-126] the relevance of an individual's subjective "sense of recovery",[124-126] and the potential for personal or contextual factors to shape these.[125] It also adds insight about how treatments are perceived, and about personal and contextual characteristics which may shape this.

Fracture of the scaphoid waist

Data generated here reinforces that a wrist fracture can have far-reaching consequences [124-126] and that these might exceed any initial assessment that this is a *trivial injury*.[125] Impact upon functional limitations [119-126] were commonly reported, and interviewees described (to a greater or lesser degree) limitations in all aspects of their life. Impact in employment was common and concerns for the *financial distress*[125] were evident where interviewees described being self-employed. Changes to domestic and employment responsibilities suggest *social role* changes previously described.[119]

Moving in with parents, *relying on others for lifts*, *help tying shoe laces*, and *help cutting food* all illustrate a need for practical support that has been reported previously.[124-126] They also suggest a challenge to independence that Fitzpatrick and Finlay identify.[123] Complaints about boredom, frustration and depression mirror those concerns for the psychological consequences of a hand/wrist injury.[121, 123, 124, 126]

That individual reports of functional limitation varied significantly – from those continuing as normal, to those feeling significantly disabled – reminds us that this is a heterogeneous

population. This reinforces the importance of establishing what patients deem to be normal, [122, 128] reflection upon pre-injury wrist function[126] and consideration of those contextual factors which exaggerate or mediate disability.[125] In this, the data generated here takes us beyond a simple comparison of *men and women*, *manual and non-manual* and supports the relevance of specific circumstances, [125] such as *occupation*, *familial responsibilities*, access to *familial (or other social) support* and *leisure/lifestyle pursuits* (amongst many others).

Assessment of treatment options

That surgery is often uncritically assessed as a *quicker, stronger* and *a more active repair* overlooks important clinical facts – that cast is 90% successful, that surgery can be marked by complications (and risks non-union), that bone repair takes the same amount of time irrespective of treatment, etc.. Yet despite this the appeal of surgery is clear, a number of things might help us to understand this.

Firstly, it reiterates and reinforces Watson's recognition that an individual's "*sense of recovery*" might be distinct from the repair of the bone and actual (objective) recovery. That non-union following *conservative* treatment (plaster cast) is possible (irrespective of how likely) informs a subjective judgement that the relative risks/complications of surgery are consequently less important.

That, in Watson's work, the removal of the plaster cast represents the "*start of recovery*" also suggests a confusion between the *removal of a cast* with a more abstract sense of *personal recovery*.[125] This interpretation suggests that participants perceive an initial *remedial phase* (either in surgery or in a cast) as preceding a phase of more active *recovery* where normal function is regained. That this *remedial phase* takes longer in a plaster cast means that *returning to normal* [122, 127] is consequently perceived to take longer to achieve. That this overlooks the clinical reality would seem less important if we accept that understanding treatment is, in part at least, a subjective assessment.

As with functional limitations it is pertinent to reflect that individual assessment of treatment may also be influenced by contextual factors which demand a speedier return to *normality*. This might help us to understand why the student able to return to the parental home (P1023) found surgery less appealing than the self-employed caterer (S1345). Again, we should

reflect that our data has moved us beyond those simple dichotomies (*male/female*, *younger/older*) to recognise that the experience of, and preference for, a particular treatment will be shaped by a complex set of personal circumstances.

Concerns about clarity in treatment [125] were important to interviewees. A dislike about *not knowing* and about uncertainty [125, 126] may also help us to understand why some interviewees found plaster cast treatment challenging. Surgery may offer no more certain outcome, but that this outcome might be known more quickly better satisfies our impatience and [for some at least] lessens the likelihood that impetuous behaviour may lead to further injury.

One final set of circumstances should be highlighted. Due to participant drop-out our data is skewed towards interviews undertaken at 6 weeks. At this point the worst aspects of cast treatment and the best attributes of surgery might be manifest – on one side participants might be bored by on-going immobility or frustrated by a dirty plaster cast; on the other they might be surprised by their mobility and pleased at how quickly *normality* has been regained. Whilst we might expect these trends to even out over the longer term it is unfortunate that amongst those interviewed at 52 weeks 5 (of 10) treated in a plaster cast demonstrated some form of on-going concern.

Irrespective of this, it is evident that assessment of treatment (and consequent preference) is shaped by an individual's own *sense of recovery* and that this is in turn informed by their personal circumstances. That cast removal, and a return to more *normal* functioning, is conceived of as a significant threshold in this perhaps helps us to understand the appeal of surgery to those interviewed here.

Recruitment and retention in surgical, clinical trials

The challenge of recruiting to a surgical trial [140] is manifest here in an almost contradictory fashion – surgery both attracting and discouraging participation. Amongst those interviewed the appeal of surgery was often commented upon as a motivating factor; however, for those who declined the trial surgery was considered a reason not to take part. This of course points to the challenge of *patient equipoise* [141] and might suggest that the SWIFFT trial population favours those eager for surgery? Other elements of the SWIFFT data will address this issue more directly.

This of course also places pressure on *clinical equipoise* [141] and reinforces the importance of how a trial is introduced to a potential participant. That some of those who declined to take part in SWIFFT subsequently (when given more information about) suggested that they might have changed their mind, demonstrates the complexity of getting this right.

The challenge of retaining young male participants [143, 144] is manifest here with attrition in this population exceeding that for other demographics. For younger females, older males and older females approximately 50% declined or were unavailable for interview at 52 weeks, for younger males this proportion increased to 70%. We have commented about the challenge of this elsewhere [139] but it is worth reiterating that comments about a *positive experience*, *continuity of contact* and *accessibility of research nurses* suggest those *softer*, '*valuing a study'* type strategies that we have previously described.[139]

Closing comments and recommendations

Insight generated here points to the importance of a patient's subjective experience of scaphoid fracture and treatment, and points to the pertinence of their own *sense of recovery* in this. This has a number of implications for clinical practice.

- It suggests that clinical consultations might include a more detailed consideration of a patient's circumstances. We have argued here that a patient's experience is shaped (not simply by age, gender and occupation, but) by a range of specific personal, familial and economic circumstances which influence how immobilisation is experienced.

- It suggests that tailored information about a patient's fracture and recovery might be beneficial. Here we have argued that a participant's *sense of recovery* and treatment preference was often based on incomplete (possibly inaccurate) understanding of their injury.

- Finally, it suggests that earlier removal of a cast, supported by the use of alternative forms of immobilisation, might facilitate a stronger *sense of recovery* for patients. We have argued that functional limitation was a common complaint and that cast removal was perceived to be an important threshold in this.

This study has also offered insight into the delivery of the clinical trial, specifically highlighting issues of *patient* and *clinician equipoise*. For future trials, where medical and surgical treatments are being compared, recommendations might be suggested.

- That those who recruit participants should have knowledge of all treatments being investigated. This may mean that Research Nurses are drawn from pertinent specialities and/or that participants have access to clinicians who have experience of treatments. This will lessen the potential for stereotypical comparisons (*conservative/progressive*, *simple/complex*, *quicker/slower*) and support a more informed commentary on treatment options.

- That all information provided should demonstrate equipoise, both in fact and in impression. It is evident here that some participants *understood surgery to be a quicker solution* and that this impression shaped how they experienced their recovery.

- Where issues of retention might be difficult (such as with a young, male population) there is value in building in retention strategies from the outset. In this study the introduction of an *I-pad lottery* [139] might have had a greater effect had been established sooner.

Insight generated here points to a number of uncertainties which might benefit from further investigation.

- Further qualitative research with younger, male patients would respond to the high drop-out rate in this group here. Exploring whether this group has their own distinctive *sense of recovery*, or displays certain commonalities in treatment experience and expectation, would provide insight to shape clinical consultations. It may also help to reduce re-injury associated with impulsive or impatient behaviour that some predicted.

- Exploring the reasons for late clinical presentation of a scaphoid fracture would support awareness raising of this injury, and would complement prior work which has demonstrated gendered patterns in healthcare seeking behaviour.[156] Such research might challenge those initial assessments that this is an inconsequential injury and might also

offer insight into whether late presentation is significant in expectations for recovery and treatment experience.

- Research which considers the provision of information about the treatment a scaphoid fracture might similarly inform clinical consultations and inform a patient's *sense of recovery*. Research in this area might be two-fold: firstly in developing the information content and mechanisms for delivery; and secondly, in testing whether it improves experience of, and satisfaction with, treatment.

Chapter 6 Discussion and conclusion

Outcomes

This report is based on assessment of primary and secondary outcomes at 52 weeks (the primary time-point) after 439 participants with a clear bicortical scaphoid waist fracture were randomised to have the control treatment of immobilisation in a plaster cast and early identification of non-union followed by urgent surgical fixation (n=220) or to have early surgical fixation using CE marked headless screws (n=219).

Primary outcome

PRWE at 52 weeks

The main finding of this pragmatic trial is that there is no statistically significant difference in pain and function assessed by the PRWE at 52 weeks between participants randomised to receive initial cast treatment and those randomised to immediate fixation of clear and bicortical fractures of the scaphoid with 2mm or less displacement. The adjusted mean difference in the total PRWE score was -2.1 in favour of those in the surgical fixation group (95% CI -5.8 to 1.6, p=0.27). This difference is unlikely to be considered important by patients as the CIs of the adjusted mean difference excludes the clinically relevant difference of 6 points in PRWE scores.

In the early period at six and 12 weeks the difference, which favours surgery, is statistically significant and, although the mean difference is below the clinically relevant difference of 6 points, the lower CI is below -6 points is some analyses (indicating the possibility that the true treatment effect might be an increase of 6 points on the PRWE in the surgery group). Therefore, these differences are statistically significant but of borderline clinical importance. Importantly, 47% and 6% of participants in the surgery group respectively, were still in plaster cast or a splint at six and 12 weeks post-randomisation. This compares with 85% and 21% of patients still in plaster cast in the non-surgical group at these time-points. So participants in the plaster cast group were more likely to still be in a cast and have consequential functional limitations. This is corroborated when looking at the pain and function components of the PRWE: there is no difference between groups in pain but there is a difference in function at these early time points. After 12 weeks there is no statistically significant difference between groups.

Sensitivity analyses of the PRWE

The sensitivity analyses using multiple imputation, checking for an influence of the recruiting site, investigating those scores that were obtained within the time-point windows, adjusting for smoking status and displacement of the fracture, and a CACE analysis all broadly support the primary analysis. Subgroup analyses of baseline treatment preference, and displacement, also support the results of the primary analysis.

Secondary outcomes of bone union, grip strength and SF-12, support the primary analysis findings.

Immobilisation of the broken scaphoid in different types of casts has been compared to immediate fixation using a headless screw in at least eight reported trials[18, 23-28, 75] and one cohort study.[157] These studies (*Table 43*) have used different methods of assessing function and disability (three used DASH, one used PEM and another used PRWE, the other four studies used a variety of assessments including their own questionnaire, a satisfaction questionnaire and the modified Green & O'Brien score) and at different time-points (4 to 144 months). The studies reported are small, with different time-points and some reviews[29] and meta-analyses have also included case series.[24, 44, 158, 159] The data from these studies has been extracted systematically and meta-analysed on numerous occasions.[29-34, 36, 37]

One study reported PRWE at 10 years in 75 of 83 patients randomised to scaphoid cast treatment or surgical fixation with a Herbert headless screw and the mean score was 6 in each group.[28] No data was available for the 52 week time-point. Two studies reported a PROM score at 52 weeks. One[3] used the PEM score which ranges from 0-100, with 100 being worse and reported an unadjusted mean difference of -1.3 favouring surgery although the difference was not statistically significant. The second[18] reported on 60 patients randomised to either a below elbow cast leaving the thumb free or an Acutrac headless screw; authors used the Mayo modification of the Green and O'Brien score[160] to assess function (pain and function) and impairment (range of wrist movement and grip strength) and noted that this score was 13% better (higher) in those having surgery but this difference was not statistically significant. This finding is not reflected in our study.

As the non-union rate for displaced fractures is 14% compared with 10% for transverse undisplaced fractures,[8, 10, 39] randomisation was stratified by the presence or not of displacement (<1mm, or 1-2mm inclusive) of a scaphoid fracture as seen on radiographs [10, 39] and used by the treating clinician to determine eligibility. The three raters identified displacement of the fracture greater than 2 mm in 27 (6.2%) participants. When these patients were excluded, the PRWE difference between treatment groups at 52 weeks was -2.1 favouring surgery. The difference was not significant (p=0.07) and was below the clinically meaningful threshold.

Table 43: Randomised trials of treatments for fracture of the scaphoid bone

Author	Year	Participants			Follow up	PROM used	Non-union		Conclusion
		n	Surgery	Plaster cast	(months)		Surgery	Plaster cast	Summarised from text
Saedén	2001	62	32	30	144	Own Questionnaire, no difference	1	0	Surgery allows early return of function and is an alternative to conservative treatment
Bond	2001	25	11	14	25	Satisfaction no difference	0	0	Surgery for undisplaced fractures resulted in faster union and return to military duty compared with plaster cast
Adolfsson	2001	53	25	28	4	none	1	0	Surgery had better movement at 16 weeks but similar grip strength. Early surgery allows early mobilisation without adverse effects on fracture healing
Dias	2005	88	44	44	12	PEM no difference, at 8 weeks surgery better	0	2	Plaster cast treatment, carefully assessing fracture-healing with plain radiographs, and computed tomography scans, after six to eight weeks and recommending surgery at that time if non-union is confirmed achieved fracture union in over 95%
Dias	2008	88	44	44	93	PEM no difference at 8 weeks surgery better	0	2	No medium-term difference in function or radiological outcome between surgery and plaster cast.
Arora	2007	47	23	24	6	DASH, surgery better	1	0	Surgery for nondisplaced scaphoid fractures had faster union and quicker return to work . Although surgery is more expensive, the total cost was not higher.
Vinnars	2008	83	43	42	120	PRWE no difference	0	0	No long-term benefit of surgery, compared with plaster cast, for acute nondisplaced or minimally displaced fractures. The long-term risks of surgery should be considered.
McQueen	2008	60	30	30	12	Green/O'Brien score, no difference. Surgery better before 1 year	1	4	Surgery had a faster return of function, sport and work compared to plaster cast. Surgery had a low complication rate. All active patients should be offered surgery.
Clementson	2015	45	21	24	72	DASH no difference, at 6 and 10 weeks surgery better	0	0	Non- and minimally displaced scaphoid waist fractures are best treated in a plaster cast. Surgery may provide improved function in the short term but at an increased risk of arthritis in the long-term.

Complications

Surgical complications noted by the treating clinician at the recruiting site confirmed that 31 (14.2%) participants randomised to the surgery group had a complication while the rate was much lower in the plaster cast group (n=3, 1.4%). The review of radiographs identified penetration of joints by the screw in 94 participants in the surgery group (42.9%) compared to 10 (4.6%) in the plaster cast group. Half the penetrations had the screw protruding by 1-2mm in the joint and a quarter had significant protrusion of over 2 mms. The concern about such screw protrusion is that articular cartilage will be damaged irreversibly and lead to early degenerative arthritis within the involved joint.

Cast complications, in contrast, were minor, had no lasting consequence and were reported in six (2.7%) participants allocated to the surgery fixation group, probably reflecting the frequent changes of cast to inspect the wound and the cast initial application by the surgeon. Cast problems (soft, tight or broken cast, skin soreness) were reported for 45 (20.5%) participants in the plaster cast group which would usually be applied by experienced fracture clinic staff and not changed as frequently.

Malunion of the scaphoid was assessed using the height to length ratio on radiographs and the baseline and 52-week CT scan. ten Berg et al. noted that a ratio of 0.69 as the upper 95% CI of a normal population so we used this to define a malunion rather than the 0.6 we had proposed in our protocol. At 52 weeks, using the 0.7 threshold (i.e. ratio of the scaphoid height to length), malunion increased between baseline and 52 weeks on CT scans and was similar (3.2%) in both treatment groups. Radiographs had a higher rate but again demonstrated an increasing rate in time and a greater rate in those in the surgery group.

Re-operations

Eight participants in the surgery group had 11 re-operations, subsequent to their initial fixation; 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. One participant required re-operation for a persistent non-union following fixation of a non-union after initial cast fixation. The overall rate of re-operation for all causes (assuming that none who were not followed up required re-operation) was eight of 219 (3.7%) after early surgery and one of 220 (0.5%) after initial cast treatment and surgery to fix a non-union.

Secondary outcomes

Union

The aim of immobilising a broken scaphoid is to get it to unite. Failure of union, if left untreated, mostly results in wrist arthritis[12, 161, 162] as there is abnormal loading between the distal scaphoid and the radius.[163] So, an important outcome after treatment is to establish the state of fracture union on imaging. In clinical practice, union is commonly assessed on radiographs of the scaphoid in different projections. Bony continuity on all radiographic views is interpreted as trabeculae crossing the fracture line, and sometimes there may be sclerosis at the fracture line. Both these features suggest union especially if there are no adverse features of (a) a gap at the fracture line on any view, (b) progressive displacement of the fracture or (c) if implants are used then lucency around it may suggest failure of union[59]. The usual advice is that radiological union is only considered to have occurred when "bridging trabeculae" are seen across the whole cross-section of the scaphoid on radiographs or a CT scan[164] with the latter being more reliable.

The bone may unite partially with a gap seen across part of the fracture site and bony continuity identified across the remainder of the fracture. This can be identified on the scaphoid radiographic views but can be quantified on a CT scan.[61] Partial union has been reported in around 42% of scaphoid fractures and usually consolidates in time but the wrist may need protection for a while.[61]

Non-union is the absence of radiographic signs of healing with a clear gap on radiographs on any view and confirmed on a CT scan.[164-166] A high-quality CT scan (fine cut, bone window) helps establish that the fracture has not united. An ununited scaphoid fracture will eventually lead to collapse of the carpus and degenerative osteo-arthritis termed as SNAC.[161]

Clinically there would be a concern if union was <20% at 52 weeks and suggest treatment to bone-graft and stabilise the fracture although this partial union threshold has not been formally investigated. On radiographs, this extent of union is likely to be interpreted as a "non-union" by the treating clinician.

The rate of non-union recorded in this study is very low for both groups. In the 188 who had screw fixation in the surgery group there was one non-union. In the 198 in the plaster cast

group who fully complied with the control pathway (treated in a cast and surgery to fix a non-union) there was also just one non-union. This study has not identified evidence that the rate of non and slight union is statistically significantly different between surgical fixation and cast immobilisation in an ITT logistic regression model which adjusted for age, fracture displacement and hand dominance (OR 0.40, 95% CI 0.12 to 1.33, p=0.13). 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. Three meta-analyses[30, 36, 37] reported on union rates, two[36, 37] found no difference while one[30] reported a significant difference in favour of surgery. These meta-analyses reviewed four to seven small trials comparing surgical fixation to plaster cast treatment for scaphoid fractures.

The control treatment pathway in the SWIFFT trial was initial cast treatment with early identification of failure of union and early fixation of un-united fractures. Of 18 participants who had surgery for early identified non-union, 15 had it early within 6 months from randomisation and a further three were treated after six months. The reasons for this have been described in the Results chapter.

Union rate after early fixation of less than 20% after initial cast immobilisation is high. There are four papers[3, 157, 158, 167] reporting prospectively collected data and present results of early identification of non-union after cast treatment and early fixation of these. One is a RCT[3] and the other three are prospective comparative case series. These reported on 166 scaphoid fractures treated in a below elbow cast. Twenty non-unions were identified when the cast was discontinued. Seventeen of these had early surgery, 2 declined the offer of surgery and had a persisting non-union at 52 weeks. Of the 17 that were fixed all united (100%). Two retrospective studies[168, 169] also reported on 210 acute scaphoid fractures treated in a cast with 12 non-unions 11 of which were fixed early and all united (100%). One 80-year-old man was not offered surgery. There is only one retrospective case series[170] which reported on 308 acute fractures of which 27 did not unite. Of these 24 had fixation and 21 united, 3 did not join (87.5% union) two of these were re-operated and one healed. Overall the reported rate of union after early identification of failure to unite and fixation is very high. Our study confirms that it is unlikely that the risk of non-union following surgery for non-union after initial cast immobilisation is greater than if surgery is carried out in the first 14 days after the injury.

In SWIFFT, 18 patients in the plaster cast group were also offered and had surgery as clinicians treating them were concerned about the state of union after cast treatment. Only one had a persistent non-union at 52 weeks. In these patients the total PRWE was worse (mean 29.1 (SD 32.4)) compared to those who did not need surgery (mean 12.8 (SD 17.4)). This may reflect the delay in fixation of the non-union.

The numbers of scaphoid fractures we would need to fix in order to avoid one additional non-union or slight union is 44. All these patients would be exposed to the risks of surgery.

Range of wrist movement

One year after the fracture there is no difference between groups for range of wrist movement. This confirms that treatment method does not have a measurable effect on the range of wrist movement at 52 weeks. At six weeks, when participants treated in a plaster cast are likely still immobilised, the range is worse than those left out of a cast after surgery and screw fixation. Wrist movement returns to normal and most studies that compared cast with surgery were unable to establish a difference between groups at later time-points to 52 weeks.

One study [36] found that there was no difference between groups after six months and others[34, 171] found no difference between groups at any time point. Another meta-analyses[30] highlighted the observation that several trials[24, 27, 28] had noted a better range of wrist movement after treatment in a plaster cast.

Grip strength

The strength of the hand, assessed using a Jamar dynamometer, was similar between groups. Grip strength measured in kilograms was slightly worse in those treated in a cast at 6 weeks (by around 4 kg) and 12 weeks after injury (by around 2.6 kg) but better at 52 weeks (Cast 37.4 kg (SD 14.2) vs Surgery 36.2 kg (SD 12.7)). The cast is usually removed between 6 and 12 weeks so this is an expected difference at these time-points.

Five meta-analyses[30, 31, 34, 36, 171] have commented about the recovery of grip strength reporting on various combination of several small trials.[3, 18, 23-25, 27, 28] One[36] commented that patients having surgery had better grip strength up to a year after surgery. They also reported

that the difference between groups was greatest at 8 weeks combining results of two studies.[3, 18] Another[30] felt that they were unable to conduct a meta-analysis because of the different ways of recording this. This study collated the results from seven studies[3, 18, 23-25, 27, 28] in a table. They noted a consistent trend that those having early surgery had better strength but recommended caution in interpretation. Another meta-analysis found no difference between groups.[171]

Return to work and unpaid activities

This study, in contrast to most previous trials, found little difference in days of lost employment. On average the time that those treated in a cast were off work was for 21.7 days while those who had the broken scaphoid fixed were off work for 17.3 days. Of note was the time off work was the same in the first six weeks and was only 12 days.

Five meta-analyses[29, 31, 34, 36, 37] reviewed randomised controlled trials and reported on the time to return to work. One study[29] included a prospective comparative study[158] which was not randomised. All five, extracting data from different combinations of studies, noted that patients who had their scaphoid fracture fixed returned to work quicker (range 1.6 to 7 weeks earlier) than those treated in a cast.

This study finds little difference in time off work, especially in the early period and this may reflect the common practice of immobilising the operated fracture in a plaster cast or splint. One reason may be that around 77.7% were treated initially in a cast which did not include the thumb and therefore permitted early resumption of hand function. Another may be that patients may have felt more secure working in a cast. Finally, patients may have had direct reassurance regarding return to work in a cast and encouraged to do so.

The overall days of lost unpaid activity was also similar in the two groups. There was a larger impact on lost unpaid activity in the surgery group for the 6 weeks after randomisation. For all time points after this, patients allocated to the surgical arm report a smaller impact on unpaid activities which is consistent with the findings for days of lost employment.

SF-12

The SF-12 was completed to measure the potential broader consequences of a scaphoid fracture on both the participants' physical and mental health along with EQ5D. The analyses of the mental composite scores (MCS), reassuringly showed participants mental health improved in both treatment groups at each time-point and overall. The between-group differences in the MCS were not statistically different at any time-point with an adjusted mean difference at 52 weeks of -1.2 (95% CI -3.3 to 0.8) in favour of the plaster cast group. A statistically significant difference in the physical health composite score (PCS), favouring the surgery group was seen at 12 and 52 weeks, but not at 6 or 26 weeks, nor overall (p=0.08). The adjusted mean difference at 52 weeks was 1.6 (95% CI 0.2 to 3.1) in favour of the surgery group. These findings corroborate the overall PRWE results and its' function sub-scale but appear inconsistent across time-points and the differences are below that considered clinically meaningful (range 3.3 up to 12.6 points) in other musculoskeletal (spine and knee) disorders.[172-175]

Trial validity and minimising bias

Various measures were taken to ensure trial validity and minimise bias, or to explore the potential for bias, of which some are discussed here.

The secure randomisation method helped to ensure that there was comparability in the characteristics of the two treatment groups with the exception of ethnicity, education and smoking status, by chance. The imbalance in the number of smokers, with participants in the plaster cast group less likely to be a smoker, was examined in a post-hoc sensitivity analysis. Adjusting for smoking status (yes/no) found similar results to the primary analysis, except at 12 weeks when a clinically relevant six-point improvement in the PRWE in favour of the surgery group could not be ruled out. Also, at baseline, it was important that the series of five radiographic views were performed to ensure the correct diagnosis of the fracture for inclusion of a patient in the trial. Except for one view (semi 45° supine), nearly all randomised patients were enrolled based on these radiographs. The three raters agreed that 6% of randomised participants had displacement of the fracture at baseline that was greater than 2mm, which was a reason to exclude a patient. Only one participant was agreed to not have a fracture (in the surgery group). Sensitivity analyses of the primary outcome model that excluded these participants, supported findings of the primary analysis. A further sensitivity analysis also provided reassurance that the perceived threat to validity of low recruitment at

sites did not affect the results on the PRWE. Also, the subgroup analyses found participant treatment preferences at baseline, which if there was a preference it favoured surgery, did not affect the results of the PRWE at 52 weeks. However, this represented participants with a preference for surgery or in treatment equipoise as those preferring cast treatment were under-represented. This helps, in part, to mitigate against concerns that a lack of blinding can introduce bias in participant self-reported completion of the primary outcome.

Although it was not possible to blind assessing clinicians to the treatment allocations this multicentre study with its pragmatic design had multiple clinicians assessing objective outcomes. The statisticians and health economists were only presented with data after collection and cleaning was completed and the statistician undertaking the analyses was different to the one monitoring the study data collection processes. The DMEC and the TSC also provided independent advice and support throughout the conduct of this study.

To help ensure good standard of care, surgeons were advised to use techniques with which they were familiar, which also helped to avoid learning curve problems. The majority of operations were conducted by consultant surgeons, who were also present for the majority of operations when the main operating surgeon was a specialist trainee. Predominantly a percutaneous approach with a palmar incision was performed, which is consistent with current practice. No intra-operative complications were reported. All participants were provided with standardised, written physiotherapy advice detailing the exercises they needed to perform. At 12 weeks, the majority of participants in both treatment groups, self-reported that the written advice was quite or very useful and that they had performed home exercises.

The high rate of return of participant questionnaires at the primary end-point of the trial, reflects the success of the extensive measures taken to achieve the required retention rates. Critically, this included continuous engagement and advice from three involved groups (patients, research nurses and clinicians) as explained elsewhere.[139] The participant questionnaire return rates were lower in the plaster cast group, except at six weeks when they were similar. The baseline characteristics of participants who completed a valid primary outcome at 52 weeks were comparable between the two groups, except for the continued difference in ethnicity, education and smoking status. Any response bias that could be introduced from these imbalances in return rates and characteristics of a responder, was

minimised by using a mixed-effect, repeated measures model which included intermittent responders. Consequently only 7% of participants were not included in the primary analysis model with an almost identical numbers of participants included for each treatment group. The use of this statistical model had the benefit of increasing the statistical power of the analyses, compared with the use of a two sample -test for the sample size calculation. Multiple imputation analyses to explore the effect of this minimal missing data, helped to reassure that this did not have an effect on the results of the PRWE. There was, however, missing data on imaging for nearly 30% of participants at 52 weeks. There were quite marked differences in the PRWE in those participants who did or did not attend for imaging between groups. Participants in the surgery group who attended, tended to have better scores than those in the plaster group. This may have contributed to lower reporting of non-union in the surgery group. Furthermore, the lower than expected non-union reported for both groups, could be attributed to the participation of largely specialist hand units in this study and a more rigorous assessment of non-union than in previous studies.[3, 18, 23-28] The other finding on imaging that 43% of participants in the surgery group had penetration of the screw into the adjacent joint and this was 1mm or greater on 52 week CT scan in 68 participants and therefore considered to be likely to have an adverse effect on the joint cartilage and probably explains the worse PRWE in this participant group. This emphasises the need for imaging during surgery. In our study, imaging was reviewed by three independent raters, two senior radiologists and a surgeon not involved in the clinical care processes, with robust methods of identification and resolution of conflicts. The senior clinicians reviewing imaging could identify participants that had their fracture stabilised with a screw but did not know the allocation after randomisation. Also having three reviewers independently reviewing the imaging and performing measurements helped mitigate against any bias in measurements. Finally, a potential threat to study validity is non-compliance. This is when the treatment was not delivered as planned which can potentially dilute the treatment effect observed in the intention-to-treat (ITT) primary analysis. In the surgery group, 31 patients (14%) did not have surgery compared with six patients (3%) in the plaster cast group who immediately switched to surgery following randomisation. There were a combination of factors as to why participants did not get their allocated surgery. This included a fracture not being seen on the baseline CT scan, on further review of imaging/further imaging at baseline the surgeon deciding that the participant had a different type of fracture or the participant changed their mind. ITT analysis was used throughout, which includes all participants in the group to which

they were randomly assigned. This preserves the original random allocation and reflects the pragmatic nature of administering treatment in clinical practice. Complier Average Causal Effect (CACE) analysis was also conducted to explore the potential dilution of the treatment effect of the six participants (3%) who crossed over to surgery in the plaster cast group and the 31 participants (14%) in the surgery group who were managed conservatively. The CACE analysis reproduced a difference in favour of surgery amongst participants who complied with their treatment which was larger than the ITT treatment effect on the total PRWE at 52 weeks. Although it remained a non-statistically significant result nor a clinically important treatment effect, the upper confidence limit now included the clinically important effect. In terms of further non-compliance in the control pathway, of 17 participants in the plaster cast group who had surgery for early identified non-union in the plaster cast group, 14 had it within six months from randomisation and three were treated after six months. Three of the four participants in the plaster cast group who had a non- or slight union at 52 weeks were also not offered surgery. Therefore 6 of 21 participants did not have the expected immediate surgical fixation when there was non-union in the plaster cast group.

Applicability of results

Characteristics of the trial population

Review of the baseline characteristics of the trial participants and the fact that the three raters agreed on the baseline imaging that only one participant did not actually have a fracture at enrolment, helps to confirm the inclusion of appropriate participants in the SWIFFT trial.

The application of the eligibility criteria meant that a quarter of the population of patients considered for the trial were excluded for genuine clinical reasons, predominantly because the inclusion of these patients meant the surgeon would not be in equipoise about how to treat a patient. A further third of the population screened did not consent to take part. Therefore, just over 40% of the patients screened for participation were randomised. A comparison of the four key baseline characteristics revealed that eligible patients tended to be a few years younger than those excluded, and marginally more likely to be male and have a displaced fracture. Consenting and non-consenting patient characteristics were comparable, except that consenting patients were more likely to have a displaced fracture. As previously discussed, the statistical method used to analyse the primary outcome meant that only 7% of consenting participants were not included in the primary analysis. Multiple imputation analysis to

explore the effect of this minimal missing data, confirmed this did not bias the treatment effect in the PRWE.

Applicability of the trial findings

The pragmatic design of the SWIFFT trial helps to ensure that there is immediate application to the NHS. 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, as would be expected. The provision of standardised, written physiotherapy advice detailing the exercises participants needed to perform may not be entirely reflective of NHS practice. It did, however, help to ensure that a good standard of practice was applied consistently across both groups as was confirmed when participants self-reported this at 12 weeks. The follow-up clinics that were organised at six and 12 weeks were also to be 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 or minimally displaced fractures, with the sub-group analysis showing that participants with a displaced fracture did not statistically significantly benefit more from surgery than those with an undisplaced fracture.

Most of the previous small trials addressing this research question involved a single centre. In contrast, the SWIFFT trial recruited participants from 30 NHS hospitals in England, and one in Wales, which reflected a variety of geographical locations to improve the generalisability of results. There were also 95 surgeons who operated on participants. Whilst the large number of hospitals and surgeons involved improves generalisability, there could be concerns about how the limited number of participants operated on by a single surgeon can influence patient outcome. Including the adjustment of hospital site in the primary model, produced similar findings. Importantly, unlike previous RCTs, a thorough and detailed economic evaluation was undertaken to assess the relative cost-effectiveness of the two treatment options within the trial follow-up period and the lifetime implications of treatment decisions made. The primary analysis is that of the NHS and will therefore have direct applicability to informing future policy and commissioning decisions.

Cost effectiveness of early surgery compared to initial cast treatment

Incremental cost effectiveness ratio

The within study analysis, an assessment of the costs and quality of life associated with the patients for the first year post randomisation, found that up to 52 weeks early fixation was not cost-effective with an ICER of £67,473/QALY to £135,085/QALY. This range of values was based on the approach taken to trial population, missing data, and adjustment for baseline quality of life. The most reasonable scenario is considered to be 81,962 /QALY, a scenario of an intention to treat population with multiple imputation for missing values and baseline quality of life adjusted for.

Long-term model

"Initial use of cast with immediate fixation of confirmed non-union" was associated with a 61% probability of being cost-effective. The extrapolated model is driven by the relatively and absolutely small numbers of non-unions, alongside the uncertain long-term estimates.

Long-term model uncertainty

"Initial use of cast with immediate fixation of confirmed non-union" was associated with a 67% probability of being cost-effective. The extrapolated model is driven by the relatively and absolutely small numbers of non-unions, alongside the uncertain long-term estimates.

This result was influenced by the relatively low cost of initial cast immobilisation compared to surgery and the finding that if cast immobilisation was unsuccessful surgical fixation was offered, accepted by almost all, and then highly likely unite.

The long-term Markov model was based on data from small retrospective case series and was driven mainly by the very small difference in union rate at 52 weeks between the two groups- highlighting the considerable uncertainty surrounding the model. The uncertainty in this model will be addressed after the medium term five year review as this will help improve our assumptions and hence the confidence in such a model.

Health economic summary

The key finding is that if initial cast immobilisation is unsuccessful but surgical intervention is offered soon after confirming non-union, it is highly likely to be the most cost-effective, as it avoids the high upfront cost of fixing all broken scaphoids, but still avoids a long-term non-union and the risks of both high surgical rate and poor quality of life for patients who develop SNAC.

Health economics strengths and limitations

The economic evaluation of the treatment of these types of scaphoid fractures, described in Chapter 4, was associated with a number of strengths and weaknesses.

It was the first evaluation of this area to not only provide an analysis of the cost and quality of life implications of the treatments available using evidence from a RCT, but to combine these with a long-term model, using evidence from the literature to consider the lifetime implications of treatment decisions made. The 'within-trial' model provided a methodologically rigorous exploration of the cost and quality of life of patients in both arms of the SWIFFT trial, including extensive missing data estimation alongside a series of regression analyses seeking to explore the role of confounding factors. The mathematical model presented extends the findings of the SWIFFT trial by not only considering the lifetime implications of the two treatments, but also by incorporating treatment scenarios of cast immobilisation only and no treatment, not considered in the trial. This allows for a complete evaluation of all possible treatment options available and the long-term implications of each. This structure, alongside the PSA and extensive scenario analyses, allowed a detailed exploration and presentation of the significant role of uncertainty in this decision problem due to both the small incremental differences between the outcomes of the two arms of the trial alongside the limited long-term evidence available in the literature.

However, as with any such evaluation, there are additionally weaknesses of the analysis. Including those as a consequence of the available evidence and are detailed in Chapter 4. The primary weaknesses relate to the potential over-simplification of the mathematical model, and the limited connection between the trial data and the long-term model. The insensitivity of the decision-tree to the explicit role of the time lag between the observation of potential non-union after cast immobilisation and the occurrence of surgical fixation is one,

and while it would not be expected to change the base-case result, it limits our ability to explore the impact of changes to such a parameter. For example, it would be expected that there exists some time threshold at which unless surgery occurs before it, the cast plus surgery arm becomes less cost-effective than initial surgery for all patients. Similarly, the simplistic approach to OA, non-OA related AEs, and SNAC in the long-term model, while necessitated by the available evidence, risks incorrectly specifying the risks and benefits of each treatment arm. Finally, the use of the rate of non-union as the link between the short and long-term model, and the use of literature based estimates of adverse-event profiles, rather than from the trial, makes the result of the analysis highly sensitive to the rate of non-union estimates from the trial. This results in the model being highly sensitive to factors such as the assumption made about the three patients who had non-union at 52 weeks but were yet to have surgery, and the definition of slight union as indicative of non-union or not. However, given the available evidence and level of clinical understanding the models should represent the most robust base-case scenario.

The Markov Model was limited by the assumptions made and the data available. The latter were very small case series which were historic. We have addressed the uncertainty using many scenarios but feel that the five year study of SWIFFT participants will help resolve much of the uncertainty in the Markov model.

Nested qualitative study: what treatment patients prefer and their experience of treatment

The nested qualitative study explored the impact of a scaphoid fracture, as well as experience of treatment and treatment preference. The study offers detailed, contextualised insight with each interviewee offering a distinct and personalised narrative. This data complements the clinical and other data generated elsewhere in SWIFFT and provides an additional perspective to support the implementation of trial findings. The qualitative data generated here provides a valuable, subjective viewpoint that will aid clinicians in understanding their patients' experiences and in shaping their discussions about clinical options.

Sense of recovery

Insight generated here highlights that a patient's understanding of fracture and their *sense of recovery* is important in assessing treatment success. It also shows that an individual's *sense*

of recovery is shaped by specific personal, familial and economic circumstances; employment, social responsibilities or even hobbies and leisure pursuits will shape how they feel recovery is progressing. A broader consideration of a patient's personal circumstances might shape more productive clinical consultations and might enhance the management of recovery.

Certainty

The act of plaster cast removal is an important threshold in a patient's return to normal. Patients did not appreciate the uncertainty of the duration of immobilisation or the possible need for further treatment even though the rate of this was very low.

Preference

A broadly positive assessment of surgery amongst those interviewed reflects a more general trend amongst those recruited to the study: of 780 eligible patients only 12% of those preferring cast treatments consented to take part, compared to 77% of those preferring surgery and 87% of those with no preference. Consequently, it is difficult to assess treatment preference based on the comments and insights offered here.

Disability

One interesting observation was the feeling of some weakness, described by several of the women interviewed. This was experienced to an extent that some chose to use an external wrist support to help accommodate this. Some also experienced concern that this impairment may be permanent.

Return to normality while healing

Two elements of cast treatment concerned participants, the duration of immobilisation and the possibility that some (however small) could need further treatment.

Many suggestions were made: One participant suggested that clinicians check the state of healing halfway through immobilisation to identify failure earlier, although assessment of union is unreliable at earlier time-points especially on radiographs.[62] There was also a sense

that patients regarded surgery as “doing something” rather than “just waiting” and regarded it as more active and readily assumed that the risks and failures would not happen to them. A small number understood and verbalised that if the fracture is displaced, fixing it would reduce the displacement and make it heal in a better and reduced position.

The main reflection of this chapter is that considering this trial confirms the mode of initial treatment does not have significant impact on fracture union, clinicians should focus more on the impact of treatment choices on the patient’s day to day life and their work. There is a clear need to focus on becoming “normal” again. If external immobilisation is considered, then restoring independence and minimising the impacts on ADL by using removable splints at an earlier time-point in the pathway may help patients “recover”. This may need a careful and planned discussion at the outset when the injury is diagnosed. Another is the discussion about uncertainty in the recovery after both pathways as the control cast & fix non-union pathway required 1 re-operation up to 52 weeks while those having early surgery required 11 re-operations in 8 participants and the surgery pathway had one significant non-salvageable consequence and a high rate of screw penetration.

Qualitative interviews strengths and limitations

The qualitative substudy study offers detailed, contextualised insight into the experiences of a fracture of the scaphoid waist with each interviewee offering a distinct and personalised narrative about their injury and experience of treatment. This data complements the clinical and other data generated elsewhere in SWIFFT and provides an additional perspective to support the implementation of trial findings. The qualitative data generated here provides a valuable, subjective viewpoint which will aid clinicians in understanding their patients’ experiences and in shaping their discussions about clinical options.

That our sample broadly achieved its purposive aim – approximately half of all interviews were with males under the age of 30 - adds pertinence and credibility to the findings. That the sample is larger than other comparable qualitative investigations of patient experience of hand/wrist/arm injury also adds credibility to the findings reached. The findings add to the current literature with a more explicit focus upon how surgical and plaster cast treatments are perceived and experienced; and in extending those personal, contextual factors (domestic, social, economic) which might shape an individual’s experience of fracture and treatment.

It is, of course, important to reflect that this sub-study explores participant's subjective experience of fracture and their subjective understanding of treatment and recovery. It reflects how they think things are or should be; this does not always, or automatically, translate into how things actually are.

It should also be noted that interviewees are to some extent self-selected – restricted in the main to those who agreed to take part in the trial, and that amongst this group participants could opt out of the interview sub-study. Generalising is difficult across the different demographics included here (which includes both students and the retired) and differences in experience (both positive and negative) also make interpretation and generalisation difficult. It is perhaps, however, the taciturn and mono-syllabic responses of some young men that make interpretation most difficult.

A key limitation that must be acknowledged is that attrition between the 6 week and 52 week interviews exceeds that which had been predicted (50% rather than 30%) and that this limits the potential for direct comparison and building narrative accounts of fracture and recovery. Most often participants were not contactable – not responding to approach (on at least 3 occasions) via telephone call, SMS messaging or email – although some respondents explicitly indicated that they did not wish to take part in a second interview. That attrition was most pronounced in the younger male sample is pertinent and this led to new male interviewees (n=4) being added at the 52 week interview point. It should also be noted that older females are over-represented in the final interview sample - fewer younger females consented to the interview sub-study and consequently additional older females were recruited to achieve the target for female interviewees (n=11). That these female participants were least likely to drop-out means that older females are the second largest group interviewed at 52 weeks (n=5/19).

Recommendations for future research

Evidence from eight published meta-analyses[29-32, 34-37] to evaluate surgical fixation compared with conservative treatments for acute undisplaced or minimally displaced scaphoid fractures is based on 416 patients. The SWIFFT trial is therefore the largest study in the world and has doubled the existing evidence-base and should be used to update the meta-analyses in order to further address the uncertainty and to confirm whether no further trials are necessary.

The five year follow-up of SWIFFT participants will be important to investigate the outcome of the partial union of the scaphoid fracture and whether these unite over time and to explore the consequences of the progress of degenerative arthritis, malunion and screw problems (mal-position and penetration within joints) on participants' quality of life. This long-term follow-up will further inform the areas of uncertainty in the extrapolated model.
Findings from the qualitative study suggest in future trials that compare medical and surgical treatments, patients should have access to a clinician who can adequately explain the treatments to ensure both balance in the presentation of information and lessen the potential for stereotypical comparisons of the treatments that could affect recruitment. Extensive retention strategies should also be included from the outset for a difficult patient population such as predominantly young, males. Finally, research which considers the nature, form and delivery of information about a scaphoid fracture and its treatment might similarly inform future clinical consultations and inform a patient's sense of recovery. This could include providing the patient with a leaflet to encourage surgical fixation when non-union occurs, explaining that surgery will help reduce the rate of future arthritis. Further detailed qualitative, longitudinal research with younger, male scaphoid fracture patients would also be useful to explore their sense of recovery that may help to reduce re-injury associated with impulsive or impatient behaviour.

Conclusion

This prospective, pragmatic randomised controlled trial could not identify at the primary end-point of 52 weeks a statistically significant or clinically meaningful difference between the offer of cast treatment with early urgent fixation of non-unions compared with having all scaphoid fractures fixed surgically at the outset. The most cost-effective pathway is definitive cast treatment, with early fixation of only those fractures that do not unite with a cast. Patient treatment preferences following their injury, reflect their desire to have a "*sense of recovering*" and surgeons should address this at the outset.

The SWIFFT study results supports the treatment of all undisplaced and minimally displaced scaphoid waist fractures in a cast. Then to investigate for non-union at six to 12 weeks and fix all confirmed non-unions immediately.

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Contribution of authors

Professor Joe Dias (Professor of Orthopaedic and Hand Surgery, Chief Investigator) was lead co-applicant and Chief Investigator of the trial contributing widely to the design and conduct of the trial from inception, ongoing development and grant application, with overall management of the trial throughout its duration, co-ordinating and reviewing data collection on all imaging and overseeing analyses, in addition to writing and overseeing reports for publication.

Dr Stephen Brealey (Research Fellow, Trial Manager) was a co-applicant and trial manager who contributed to the design and conduct of the trial throughout the duration of the study and contributed to and commented on all drafts of the report.

Liz Cook (Research Fellow, Trial Coordinator) contributed to the conduct and coordination of the trial throughout the duration of the study and contributed to and commented on all drafts of the report.

Caroline Fairhurst (Research Fellow, Statistician) lead on the preparation of the statistical analysis plan, conducted the final analysis, and contributed to and commented on the final report.

Sebastian Hinde (Research Fellow, Health Economist) lead the write up of the chapter on the economic evaluation, developed the associated cost-effectiveness model, and commented on all drafts of the report.

Dr Paul Leighton (Senior Research Fellow) was a co-applicant who contributed to the design and conduct of the qualitative interview sub-study, participated in trial management systems, and contributed to and commented on all drafts of the report.

Dr Surabhi Choudhary (Consultant Radiologist) substantially contributed to the acquisition and analysis of data for the work and inputted into the writing of the report.

Professor Matthew Costa (Professor of Orthopaedic Trauma Surgery) was a co-applicant who contributed to the design and conduct of the trial throughout the duration of the study and contributed to and commented on all drafts of the report.

Professor Catherine Hewitt (Professor of Trials and Statistics/Deputy Director York Trials Unit) was a co-applicant and had overall responsibility for the statistical analyses of the trial data. She contributed to the design and analysis of the study and commented on all drafts of the report.

Mr Steve Hodgson (Consultant Orthopaedic Surgeon) was a co-applicant who contributed to the design and conduct of the trial and contributed to and commented on all drafts of the report.

Dr Laura Jefferson (Research Fellow) was a Trial Manager and Coordinator involved during the development of trial materials, setting up of sites and acquisition of data in the trial and has read and contributed to the trial report.

Dr Kanagaratnam Jeyapalan (Consultant Radiologist) contributed to the design and conduct of the trial, undertook the radiological assessment and review of all images throughout the duration of the study and inputted into the writing of the report.

Ada Keding (Research Fellow, Statistician) contributed to the reporting of data throughout the study, contributed to the planning and conduct of the statistical analysis and commented on all drafts of the report.

Dr Matthew Northgraves (Research Fellow, Trial Coordinator) contributed to the day-to-day running of the trial and the ongoing development of the study protocol and commented on all drafts of the report.

Jared Palmer (Research Assistant) was responsible for the reconstruction of the imaging data to trial specification and administration of imaging measurements for integrity, conflicts, subsequent re-reviewing, and preparation of imaging reports for management meetings and inputted into the writing of the report.

Professor Amar Rangan (Professor of Orthopaedic Surgery) contributed to the conception and design of the study; revising the work for important intellectual content; final approval of the work to be published; and agrees to be accountable for all aspects of the work

Professor Gerry Richardson (Professor of Health Economics) was a co-applicant who contributed to the design and conduct of the health economics sections of the trial throughout the duration of the study and contributed to and commented on all drafts of the report

Dr Nicholas Taub (Research Fellow) was a co-applicant and statistician who contributed to the statistical aspects of the trial design throughout the duration of the study and commented on drafts, including the final draft of the report.

Dr Garry Tew (Associate Professor) was a trial coordinator who contributed to the conduct of the trial from October 2013 to August 2015 and contributed to and commented on all drafts of the report.

Professor John Thompson (Professor of Genetic Epidemiology) contributed to the trial design and commented on the trial conduct, particularly on the development of the statistical analysis plan. He was actively involved in the analysis of the imaging data and the writing of that section of the report.

Professor David Torgerson (Director of York Trials Unit) helped to design the study and contributed to commenting on drafts, attending project meetings.

Collaborators: Principal Investigators

Mr Rouin Amirfeyz (University Hospitals Bristol NHS Foundation Trust); Mr Bhaskar Bhowal (University Hospitals of Leicester NHS Trust); Mr Neil Blewitt (North Bristol NHS Trust); Mr Mark Brewster (University Hospitals Birmingham NHS Foundation Trust); Mr Dan Brown (The Royal Liverpool and Broadgreen University Hospitals NHS Trust); Mr Chris Coapes (South Tees Hospitals NHS Foundation Trust); Prof Tim Davies (Nottingham University Hospitals NHS Trust); Mr Livio Di Mascio (Barts Health NHS Trust); Mr Rupert Eckersley (Chelsea and Westminster Hospital NHS Foundation Trust); Ms Sue Fullilove (Plymouth Hospitals NHS Trust); Mr Grey Giddins (Royal United Hospital Bath NHS Trust); Mr Rodney Hammett (Taunton and Somerset NHS Foundation Trust); Ms Helen Hedley (nee

Whalley) (University Hospitals Coventry & Warwickshire NHS Trust); Mr Jonathon Hobby (Hampshire Hospitals NHS Foundation Trust); Mr Stephen Hodgson (Bolton NHS Foundation Trust); Mr Phillip Johnston (Cambridge University Hospitals NHS Foundation Trust); Mr Jonathan Jones (Peterborough and Stamford Hospitals NHS Foundation Trust); Mr Andy Logan (Cardiff and Vale University Health Board); Mr William Loh (Southport & Ormskirk Hospitals NHS Trust); Mr Andrew Mahon (University Hospitals Coventry & Warwickshire NHS Trust); Mr Andrew Mahon (Worcestershire Acute Hospitals NHS Trust); Mr Will Mason (Gloucestershire Hospitals NHS Foundation Trust); Mr Andrew McAndrew (Royal Berkshire NHS Foundation Trust); Mr Ian McNab (Oxford University Hospitals NHS Trust); Mr Lindsay Muir (Salford Royal Hospital NHS Foundation Trust); Mr James Nicholl (Maidstone and Tunbridge Wells NHS Trust); Mrs Anna Noon (Worcestershire Acute Hospitals NHS Trust); Mr Rob Poulter (Royal Cornwall Hospitals NHS Trust); Mr Roland Pratt (Northumbria Healthcare NHS Foundation Trust); Mr Zulfi Rahimtoola (Royal Berkshire NHS Foundation Trust); Mr Daniel Redfern (Lancashire Teaching Hospitals NHS Foundation Trust); Mr Simon Richards (Poole Hospital NHS Foundation Trust); Mr Bijayendra Singh (Medway NHS Foundation Trust); Mr Paul Stuart (Newcastle upon Tyne Hospitals NHS Foundation Trust); Mr Adel Tavakkolizadeh (King's College Hospital NHS Foundation Trust); Mrs Lisa Tourret (Brighton and Sussex University Hospitals NHS Trust); Prof David Warwick (University Hospital Southampton NHS Foundation Trust).

Research Associates/Nurses at collaborating sites

Benita Adams, Emma Alderman, Caroline Andrews, Manjit Attwal, Kirsten Baddick, Emily Bannister, Michelle Bardgett, Steven Barnfield, Alison Barratt, Keira Beacham, Laura Behar, Jackie Berry, Georgina Bird, Colin Borgin, Charlotte Boustead, Sarah Brannigan, Sarah Brown, Charlotte Bryant, Deborah Butcher, Shirley Caldwell, Ronald Carrera, Rebecca Casey, Shirley Cawley, Julie Chadwick, Carol Chillmaid, Aisling Clarkson, Louise Clarkson, Rachel Clarkson, Jacqueline Claydon, Cheryl Cleary, Kate Coates, Shirley Cocks, Carolyn Colvin, Samantha Connell, Caroline Cowley, Heather Cripps, Andrew Cuff, Jean Cummings, Anwen Davies, Nicki Devooght-Johnson, Maria Dibua, Jackie Dingle, Christine Dobb, James Doolan, Alison Dude, Angela Dunne, Ruby Einosas, Eunice Emeakaraoha, Susan Farmer, Abigail Ford, Anna Fouracres, Julie Foxton, Sherron Furtado, Michelle George, Kirsty Gladas, Abdulkerim Gokturk, Christina Haines, Ruth Halliday, Simone Hargreaves, Christine Herriot, Joanne Hill, Lucille Hooper, Robert Hull, Irena Hutchins, Juliet James, Patricia

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Trial steering committee members

Prof Joseph Dias, Chief Investigator

Prof Wendy Baird, Chair

Prof Peter Burge, Independent member

Dr Jonathan Cook, Independent member

Mr Richard Palmer, Independent member

Mr Nick Welch, Independent member

Mrs Carolyn Maloney/Dr David Hetmanski, Sponsor representative (observing)

Data monitoring committee members

Prof Graeme MacLennan, Chair

Mr Timothy Hems, Independent member

Mr Adam Watts, Independent member

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Data sharing agreement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review with CI.

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Appendices

Appendix 1: Participating trusts

Barts Health NHS Trust

Bolton NHS Foundation Trust

Brighton and Sussex University Hospitals NHS Trust

Cambridge University Hospitals NHS Foundation Trust

Cardiff and Vale University Health Board

Chelsea and Westminster Hospital NHS Foundation Trust

Gloucestershire Hospitals NHS Foundation Trust

Hampshire Hospitals NHS Foundation Trust

King's College Hospital NHS Foundation Trust

Lancashire Teaching Hospitals NHS Foundation Trust

Maidstone and Tunbridge Wells NHS Trust

Medway NHS Foundation Trust

Newcastle upon Tyne Hospitals NHS Foundation Trust

North Bristol NHS Trust

Northumbria Healthcare NHS Foundation Trust

Nottingham University Hospitals NHS Trust

Oxford University Hospitals NHS Trust

Peterborough and Stamford Hospitals NHS Foundation Trust

Plymouth Hospitals NHS Trust

Poole Hospital NHS Foundation Trust

Royal Berkshire NHS Foundation Trust

Royal Cornwall Hospitals NHS Trust

Royal United Hospital Bath NHS Trust

Salford Royal Hospital NHS Foundation Trust

South Tees Hospitals NHS Foundation Trust

Southport and Ormskirk Hospitals NHS Trust

Taunton and Somerset NHS Foundation Trust

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

University Hospital Southampton NHS Foundation Trust

University Hospitals Birmingham NHS Foundation Trust

University Hospitals Bristol NHS Foundation Trust

University Hospitals Coventry & Warwickshire NHS Trust

University Hospitals of Leicester NHS Trust

Worcestershire Acute Hospitals NHS Trust

Appendix 2: Table of amendments

Table 44. Table of amendments

Type (Non-substantial or Substantial)	**Approved date**	**Documents amended**	**Brief Description of Amendment**
Non-substantial Amendment 1	13/06/13	Update to Trial Protocol (Version 1.1 date 05/06/13) Update to Main Trial Patient Information Leaflet (Version 1.1 date 05/06/13) Update to Main Trial Consent Form (Version 1.1 date 05/06/13) Update to Linked Interview Consent Form (Version 1.1 date 05/06/13) Update to Main Interview Consent Form (Version 1.1 date 05/06/13)	1. Clarification in the protocol regarding timing of baseline CT and surgery: • Baseline research Computed Tomography scan could be performed post-randomisation if not feasible on the day of consent. • Surgery should be performed within two weeks of presentation to A&E and not within two weeks of their injury as originally stated. 2. Minor changes to patient information leaflets in response to the Trial Steering Committee patient representative recommendations. Consequently Consent Form updated to reflect change in patient information leaflet version. 3. Change to Consent Status Form to capture time to consent as stated in the protocol.

Type (Non-substantial or Substantial)	Approved date	Documents amended	Brief Description of Amendment
		Update to Linked Interview Patient Information Leaflet (Version 1.1 date 05/06/13)	
Non-substantial Amendment 2	10/07/13	Hospital Poster Version 1.1 (02/07/13)	1. Update of eligibility criteria listed on the hospital poster to match those stated in the protocol.
Non-substantial Amendment 3	29/08/13	Update to Main Trial Patient Information Leaflet (Version 1.2 dated 16/08/13) Update to Main Trial Consent Form (Version 1.2 dated 16/08/13) Update to Interview Consent Form (Version 1.2 dated 16/08/13)	1. Correction of Birmingham site details. 2. Addition of new participating sites. 3. Addition of potential radiation risk from radiographs/Computed Tomography scan in the main trial patient information leaflet that was not previously explained.
Non-substantial Amendment 4	09/09/13	N/A	1. Change in Principal Investigator at Liverpool.
Non-substantial Amendment 5	08/10/13	N/A	1. Addition of new participating sites.

Type (Non-substantial or Substantial)	**Approved date**	**Documents amended**	**Brief Description of Amendment**
Substantial Amendment 1	03/12/13	Update to Trial Protocol (Version 2.0 date 20/10/13) Update to Main Trial Patient Information Leaflet (Version 2.0 date 20/10/13) Update to Main Trial Consent Form (Version 2.0 date 20/10/13) Update to Interview Consent Form (Version 2.0 date 20/10/13) Update to Hospital Poster (Version 2.0 date 20/10/13) Update to Consent Status Form (Version 2.0 date 06/11/13) Update to Baseline Form (Version 2.0 date 20/10/13)	1. Update to eligibility criteria in the protocol • 'Previous injury or disease in same wrist' removed as an exclusion criterion. • "of a participating site" added to the criterion about excluding patients who are not resident to the trauma catchment area. • Changed the phrase "cognitive impairment" to "lacks mental capacity". • Added pregnancy as an exclusion criterion because of radiation exposure from imaging. 2. Obtaining consent • Addition that consent can be performed not only by Research Nurses but also clinicians. 3. Timing of radiographs at baseline • Change to allow collection of missing baseline radiographs after consent, if necessary. 4. Collection of PRWE at baseline for both: • In the week since injury • In the week before injury 5. Adjustment for baseline covariates in the analyses plan • Removal of adjustment on baseline PRWE as a covariate, with grip strength and range as the latter allows for more variability as measured without the patient's wrist in plaster cast.

Type (Non-substantial or Substantial)	Approved date	Documents amended	Brief Description of Amendment
Non-substantial Amendment 6	14/01/14	Update to Trial Protocol (Version 2.1 date 06/01/14) Update to Hospital Poster (Version 2.1 date 06/01/14)	1. Change of Principal Investigator at Maidstone and Cardiff 2. Addition of new participating sites 3. Update the protocol about referral pathway to fracture clinic to include points of contact other than Accident and Emergency. 4. Changes to exclusion criteria in protocol: • Removal of fractures of the proximal pole as not applicable • Addition of concurrent wrist fracture 5. Addition of expected plaster cast adverse events to protocol (Soft/broken cast, pressure sores, Complex Regional Pain Syndrome, nerve compression, pain due to tight cast)
Non-substantial Amendment 7	19/06/14	N/A	1. Change of Principal Investigator at Royal London and Redditch.
Non-substantial Amendment 8	19/08/14	Update to Trial Protocol (Version 2.2 date 14/08/14)	1. Minor modifications to trial protocol • Clarification that adverse events are followed up at one month only if unresolved at initial reporting. • Primary analysis to be adjusted on grip strength in opposite wrist to the one fractured. • Primary analysis adjustment based on wrist range removed. • Correction of grip strength measurement instructions to reflect recommendations in Trampisch et al (2012).

Type (Non-substantial or Substantial)	Approved date	Documents amended	Brief Description of Amendment
			• Addition of Beighton Joint Laxity Score at baseline. 2. Submission of correct version of Consent Status Form 3. Change in Principal Investigator at Birmingham
Substantial Amendment 2	23/02/15	Update to Trial Protocol (Version 3.0 date 19/01/15)	1. Reinstatement of patients previously withdrawn due to equivocal Computed Tomography scan about the presence of a fracture • Letter to send to previously withdrawn 'Randomised in error' patients to agree to be reinstated and followed-up. 2. Verbal consent for qualitative sub-study • Permission to obtain verbal consent at time of telephone interview with written consent gained retrospectively 3. Outline of patient engagement activities (newsletter, video, website, postal envelope tagline) and example documents for approval. 4. Update to statistical analysis plan • Inclusion of greater detail about planned analyses and removal of one of the subgroup analyses that involved a three-way interaction. 5. Clarification regarding collection of patient questionnaires in clinic. • Removed ambiguity so that it is clear that a questionnaire is completed by a participant not the Research Nurse.

Type (Non-substantial or Substantial)	**Approved date**	**Documents amended**	**Brief Description of Amendment**
Substantial Amendment 3	26/11/15	Update to Trial Protocol (Version 4.0 date 20/10/15) Update to Main Trial Consent Form (Version 3.0 date 20/10/15) Update to Main Trial Patient Information Leaflet (Version 3.0 date 20/10/15)	1. Inclusion of letter and primary outcome only questionnaire at 6 weeks after initial 52 week follow-up questionnaire being sent. 2. Inclusion of prize draws at 26 weeks for participant completion of a returning questionnaire, and 52 weeks and five years for attending the hospital clinic visit. 3. Removal of adjustment on covariant 'baseline grip strength of opposite wrist' from analysis plan. 4. Clarification that there will be a five year follow-up.
Non-substantial Amendment 9	11/03/16	N/A	1. Extension to recruitment period.
Non-substantial Amendment 10	24/08/16	N/A	1. Change in Principal Investigator at Reading.
Substantial Amendment 4	17/10/16	Update to Trial Protocol (Version 5.0 date)	1. Permission to use email to contact patients for 52 week follow-up. 2. Inclusion of a patient letter from the hospital site to encourage attendance at 52 week clinic appointment. 3. Payment of travel expenses to patients attending 52 week clinic appointment. 4. Permission to retrieve imaging for participants attending other hospitals via Picture Archiving and Communications Systems.

Type (Non-substantial or Substantial)	**Approved date**	**Documents amended**	**Brief Description of Amendment**
			5. The use of the Summary Care Records to check contact details for patients who the trial team lose contact with. 6. Permission to contact the patient's GP to check whether they have had any further surgery for their scaphoid fracture. 7. Change to the categorisation of non-union, slight union etc. to remove cases of overlap.
Non-substantial Amendment 11	11/05/17	N/A	1. Change in Principal Investigator at Coventry.

Appendix 3: Tables and figures

Table 45: Baseline characteristics of trial participants according to whether or not they attended for the week 6 hospital clinic visit

Characteristic	Attended visit (n=388)			Did not attend visit (n=51)		
	Surgery (n=189)	Plaster cast (n=199)	Total (n=388)	Surgery (n=30)	Plaster cast (n=21)	Total (n=51)
Gender, n (%)						
Male	154 (81.5)	167 (83.9)	321 (82.7)	26 (86.7)	16 (76.2)	42 (82.4)
Female	35 (18.5)	32 (16.1)	67 (17.3)	4 (13.3)	5 (23.8)	9 (17.6)
Age (years)						
N	189	199	388	30	21	51
Mean (SD)	33.2 (13.3)	32.7 (12.4)	32.9 (12.8)	31.2 (12.6)	34.8 (10.9)	32.7 (11.9)
Median (min, max)	29 (16, 80)	29 (16, 76)	29 (16, 80)	25 (18, 57)	34 (21, 55)	28 (18, 57)
Ethnicity, n (%)						
White	179 (94.7)	174 (87.4)	353 (91.0)	26 (86.7)	21 (100.0)	47 (92.2)
Black	0 (0.0)	5 (2.5)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
Asian	7 (3.7)	10 (5.0)	17 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)
Other	3 (1.6)	10 (5.0)	13 (3.4)	2 (6.7)	0 (0.0)	2 (3.9)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	0 (0.0)	2 (3.9)
Education, n (%)						
No formal qualifications	18 (9.5)	24 (12.1)	42 (10.8)	6 (20.0)	3 (14.3)	9 (17.6)
Some qualifications/no degree	132 (69.8)	114 (57.3)	246 (63.4)	19 (63.3)	15 (71.4)	34 (66.7)
Degree or higher	38 (20.1)	61 (30.7)	99 (25.5)	3 (10.0)	3 (14.3)	6 (11.8)
Missing	1 (0.5)	0 (0.0)	1 (0.3)	2 (6.7)	0 (0.0)	2 (3.9)
Employment status, n (%)						
Part-time	20 (10.6)	16 (8.0)	36 (9.3)	0 (0.0)	2 (9.5)	2 (3.9)
Full-time	113 (59.8)	114 (57.3)	227 (58.5)	14 (46.7)	6 (28.6)	20 (39.2)
Self-employed	18 (9.5)	26 (13.1)	44 (11.3)	3 (10.0)	10 (47.6)	13 (25.5)
Student	17 (9.0)	21 (10.6)	38 (9.8)	3 (10.0)	0 (0.0)	3 (5.9)
Retired	7 (3.7)	5 (2.5)	12 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)
Looking after family/home	0 (0.0)	4 (2.0)	4 (1.0)	1 (3.3)	2 (9.5)	3 (5.9)
Not employed but seeking work	5 (2.6)	5 (2.5)	10 (2.6)	4 (13.3)	0 (0.0)	4 (7.8)

Characteristic	Attended visit (n=388)			Did not attend visit (n=51)		
	Surgery (n=189)	Plaster cast (n=199)	Total (n=388)	Surgery (n=30)	Plaster cast (n=21)	Total (n=51)
Other	8 (4.2)	8 (4.0)	16 (4.1)	3 (10.0)	1 (4.8)	4 (7.8)
Missing	1 (0.5)	0 (0.0)	1 (0.3)	2 (6.7)	0 (0.0)	2 (3.9)
Type of employment, n (%)						
Unskilled manual	23 (12.2)	17 (8.5)	40 (10.3)	2 (6.7)	6 (28.6)	8 (15.7)
Skilled manual	55 (29.1)	54 (27.1)	109 (28.1)	8 (26.7)	6 (28.6)	14 (27.5)
Unskilled non-manual	17 (9.0)	10 (5.0)	27 (7.0)	2 (6.7)	2 (9.5)	4 (7.8)
Skilled non-manual	30 (15.9)	44 (22.1)	74 (19.1)	3 (10.0)	2 (9.5)	5 (9.8)
Professional	19 (10.1)	15 (7.5)	34 (8.8)	1 (3.3)	4 (19.0)	5 (9.8)
Other	17 (9.0)	30 (15.1)	47 (12.1)	2 (6.7)	0 (0.0)	2 (3.9)
Missing	28 (14.8)	29 (14.6)	57 (14.7)	12 (40.0)	1 (4.8)	13 (25.5)
Current smoker, n (%)						
Yes	56 (29.6)	45 (22.6)	101 (26.0)	17 (56.7)	11 (52.4)	28 (54.9)
No	132 (69.8)	153 (76.9)	285 (73.5)	11 (36.7)	10 (47.6)	21 (41.2)
Missing	1 (0.5)	1 (0.5)	2 (0.5)	2 (6.7)	0 (0.0)	2 (3.9)
If Yes:						
How many cigarettes						
Median (min, max)	10 (1, 40)	10 (1, 30)	10 (1, 40)	10 (2, 20)	10 (5, 15)	10 (2, 20)
For how many years						
Median (min, max)	10 (1, 50)	10 (1, 36)	10 (1, 50)	9 (1, 44)	10 (4, 20)	10 (1, 44)
Past smoker, n (%)						
Yes	99 (52.4)	94 (47.2)	193 (49.7)	17 (56.7)	15 (71.4)	32 (62.7)
No	79 (41.8)	96 (48.2)	175 (45.1)	6 (20.0)	5 (23.8)	11 (21.6)
Missing	11 (5.8)	9 (4.5)	20 (5.2)	7 (23.3)	1 (4.8)	8 (15.7)
Diabetes, n (%)						
Yes	6 (3.2)	4 (2.0)	10 (2.6)	1 (3.3)	0 (0.0)	1 (2.0)
No	182 (96.3)	195 (98.0)	377 (97.2)	27 (90.0)	21 (100.0)	48 (94.1)
Missing	1 (0.5)	0 (0.0)	1 (0.3)	2 (6.7)	0 (0.0)	2 (3.9)
Steroid use, n (%)						
Yes	5 (2.6)	4 (2.0)	9 (2.3)	1 (3.3)	0 (0.0)	1 (2.0)
No	183 (96.8)	195 (98.0)	378 (97.4)	27 (90.0)	21 (100.0)	48 (94.1)
Missing	1 (0.5)	0 (0.0)	1 (0.3)	2 (6.7)	0 (0.0)	2 (3.9)

Characteristic	Attended visit (n=388)			Did not attend visit (n=51)		
	Surgery (n=189)	Plaster cast (n=199)	Total (n=388)	Surgery (n=30)	Plaster cast (n=21)	Total (n=51)

SD, standard deviation; min, minimum; max, maximum

Table 46: Baseline fracture details of trial participants according to whether or not they attended for the week 6 hospital clinic visit

Characteristic	Attended visit (n=388)			Did not attend visit (n=51)		
	Surgery (n=189)	Plaster cast (n=199)	Total (n=388)	Surgery (n=30)	Plaster cast (n=21)	Total (n=51)
Time since injury (days)[a]						
N	189	199	388	30	21	51
Mean (SD)	4.9 (3.1)	5.3 (3.4)	5.1 (3.3)	5.9 (2.7)	5.3 (3.2)	5.7 (2.9)
Median (min, max)	4 (1, 14)	5 (0, 14)	4 (0, 14)	6 (1, 12)	5 (1, 12)	5 (1, 12)
Affected wrist, n (%)						
Left	105 (55.6)	110 (55.3)	215 (55.4)	10 (33.3)	8 (38.1)	18 (35.3)
Right	84 (44.4)	89 (44.7)	173 (44.6)	20 (66.7)	13 (61.9)	33 (64.7)
Hand dominance, n (%)						
Yes	85 (45.0)	83 (41.7)	168 (43.3)	15 (50.0)	12 (57.1)	27 (52.9)
No	104 (55.0)	116 (58.3)	220 (56.7)	13 (43.3)	9 (42.9)	22 (43.1)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	0 (0.0)	2 (3.9)
Displacement (eligibility), n (%)						
No displacement	113 (59.8)	117 (58.8)	230 (59.3)	22 (73.3)	17 (81.0)	39 (76.5)
Displacement	76 (40.2)	82 (41.2)	158 (40.7)	8 (26.7)	4 (19.0)	12 (23.5)
Displacement (randomisation), n (%)						
No displacement	109 (57.7)	113 (56.8)	222 (57.2)	22 (73.3)	17 (81.0)	39 (76.5)
Displacement	80 (42.3)	86 (43.2)	166 (42.8)	8 (26.7)	4 (19.0)	12 (23.5)
Radiographs[b], n (%)						
Elongated scaphoid view	180 (95.2)	189 (95.0)	369 (95.1)	29 (96.7)	21 (100.0)	50 (98.0)
Posterior-anterior view	187 (98.9)	197 (99.0)	384 (99.0)	28 (93.3)	21 (100.0)	49 (96.1)
Semi 45° supine	134 (70.9)	151 (75.9)	285 (73.5)	25 (83.3)	15 (71.4)	40 (78.4)

Characteristic	Attended visit (n=388)			Did not attend visit (n=51)		
	Surgery (n=189)	Plaster cast (n=199)	Total (n=388)	Surgery (n=30)	Plaster cast (n=21)	Total (n=51)
Lateral	189 (100.0)	196 (98.5)	385 (99.2)	29 (96.7)	21 (100.0)	50 (98.0)
Semi 45° prone	170 (89.9)	179 (89.9)	349 (89.9)	28 (93.3)	17 (81.0)	45 (88.2)
Previous wrist problems on same side, n (%)						
Yes	40 (21.2)	41 (20.6)	81 (20.9)	3 (10.0)	4 (19.0)	7 (13.7)
No	148 (78.3)	158 (79.4)	306 (78.9)	25 (83.3)	15 (71.4)	40 (78.4)
Missing	1 (0.5)	0 (0.0)	1 (0.3)	2 (6.7)	2 (9.5)	4 (7.8)
If Yes, what injury, n (%)						
Previous fracture	21 (52.5)	26 (63.4)	47 (58.0)	2 (66.7)	2 (50.0)	4 (57.1)
Arthritis	1 (2.5)	1 (2.4)	2 (2.5)	1 (33.3)	0 (0.0)	1 (14.3)
Ligament, tendon or nerve injury	10 (25.0)	7 (17.1)	17 (21.0)	0 (0.0)	1 (25.0)	1 (14.3)
Other	6 (15.0)	7 (17.1)	13 (16.0)	0 (0.0)	1 (25.0)	1 (14.3)
Missing	2 (5.0)	0 (0.0)	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)
Injury mechanism, n (%)						
Fall – standing	24 (12.7)	27 (13.6)	51 (13.1)	4 (13.3)	2 (9.5)	6 (11.8)
Fall – walking	20 (10.6)	22 (11.1)	42 (10.8)	4 (13.3)	2 (9.5)	6 (11.8)
Fall – running	37 (19.6)	35 (17.6)	72 (18.6)	3 (10.0)	3 (14.3)	6 (11.8)
Fall – from height	24 (12.7)	31 (15.6)	55 (14.2)	4 (13.3)	3 (14.3)	7 (13.7)
Fall – from moving object	35 (18.5)	31 (15.6)	66 (17.0)	7 (23.3)	0 (0.0)	7 (13.7)
Hit on palm of hand – object striking palm	15 (7.9)	14 (7.0)	29 (7.5)	1 (3.3)	1 (4.8)	2 (3.9)
Hit on palm of hand – handle whipping back	7 (3.7)	10 (5.0)	17 (4.4)	2 (6.7)	1 (4.8)	3 (5.9)
Hit on palm of hand – other sudden extension	10 (5.3)	7 (3.5)	17 (4.4)	1 (3.3)	1 (4.8)	2 (3.9)
Punched something	4 (2.1)	9 (4.5)	13 (3.4)	0 (0.0)	3 (14.3)	3 (5.9)
Road traffic accident	9 (4.8)	6 (3.0)	15 (3.9)	0 (0.0)	2 (9.5)	2 (3.9)
Other	4 (2.1)	7 (3.5)	11 (2.8)	2 (6.7)	3 (14.3)	5 (9.8)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	0 (0.0)	2 (3.9)

Characteristic	Attended visit (n=388)			Did not attend visit (n=51)		
	Surgery (n=189)	Plaster cast (n=199)	Total (n=388)	Surgery (n=30)	Plaster cast (n=21)	Total (n=51)
Place of injury[b], n (%)						
Sport	79 (41.8)	72 (36.2)	151 (38.9)	9 (30.0)	6 (28.6)	15 (29.4)
Home	20 (10.6)	38 (19.1)	58 (14.9)	7 (23.3)	5 (23.8)	12 (23.5)
Work	18 (9.5)	17 (8.5)	35 (9.0)	4 (13.3)	1 (4.8)	5 (9.8)
Road Traffic Accident	24 (12.7)	32 (16.1)	56 (14.4)	2 (6.7)	2 (9.5)	4 (7.8)
Public place	44 (23.3)	42 (21.1)	86 (22.2)	5 (16.7)	6 (28.6)	11 (21.6)
Other	3 (1.6)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	3 (1.6)	1 (0.5)	4 (1.0)	1 (3.3)	1 (4.8)	2 (3.9)
Treatment preference, n (%)						
Surgery	80 (42.3)	92 (46.2)	172 (44.3)	13 (43.3)	9 (42.9)	22 (43.1)
No surgery	10 (5.3)	16 (8.0)	26 (6.7)	3 (10.0)	3 (14.3)	6 (11.8)
No preference	98 (51.9)	90 (45.2)	188 (48.5)	12 (40.0)	9 (42.9)	21 (41.2)
Missing	1 (0.5)	1 (0.5)	2 (0.5)	2 (6.7)	0 (0.0)	2 (3.9)

SD, standard deviation; min, minimum; max, maximum
[a] time from injury to screening; [b] response categories not mutually exclusive

Table 47: Baseline characteristics of trial participants according to whether or not they attended for the week 12 hospital clinic visit

Characteristic	Attended visit (n=338)			Did not attend visit (n=101)		
	Surgery (n=173)	Plaster cast (n=165)	Total (n=338)	Surgery (n=46)	Plaster cast (n=55)	Total (n=101)
Gender, n (%)						
Male	143 (82.7)	134 (81.2)	277 (82.0)	37 (80.4)	49 (89.1)	86 (85.1)
Female	30 (17.3)	31 (18.8)	61 (18.0)	9 (19.6)	6 (10.9)	15 (14.9)
Age (years)						
N	173	165	338	46	55	101
Mean (SD)	33.7 (13.5)	34.1 (12.8)	33.9 (13.1)	30.0 (11.9)	29.1 (9.6)	29.5 (10.6)
Median (min, max)	29 (16, 80)	31 (16, 76)	30 (16, 80)	26 (18, 57)	25 (17, 55)	25 (17, 57)
Ethnicity, n (%)						
White	163 (94.2)	144 (87.3)	307 (90.8)	42 (91.3)	51 (92.7)	93 (92.1)
Black	0 (0.0)	3 (1.8)	3 (0.9)	0 (0.0)	2 (3.6)	2 (2.0)
Asian	6 (3.5)	8 (4.8)	14 (4.1)	1 (2.2)	2 (3.6)	3 (3.0)
Other	4 (2.3)	10 (6.1)	14 (4.1)	1 (2.2)	0 (0.0)	1 (1.0)

Characteristic	Attended visit (n=338)			Did not attend visit (n=101)		
	Surgery (n=173)	Plaster cast (n=165)	Total (n=338)	Surgery (n=46)	Plaster cast (n=55)	Total (n=101)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.3)	0 (0.0)	2 (2.0)
Education, n (%)						
No formal qualifications	16 (9.2)	21 (12.7)	37 (10.9)	8 (17.4)	6 (10.9)	14 (13.9)
Some qualifications/no degree	120 (69.4)	91 (55.2)	211 (62.4)	31 (67.4)	38 (69.1)	69 (68.3)
Degree or higher	36 (20.8)	53 (32.1)	89 (26.3)	5 (10.9)	11 (20.0)	16 (15.8)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	2 (4.3)	0 (0.0)	2 (2.0)
Employment status, n (%)						
Part-time	19 (11.0)	15 (9.1)	34 (10.1)	1 (2.2)	3 (5.5)	4 (4.0)
Full-time	106 (61.3)	93 (56.4)	199 (58.9)	21 (45.7)	27 (49.1)	48 (47.5)
Self-employed	15 (8.7)	23 (13.9)	38 (11.2)	6 (13.0)	13 (23.6)	19 (18.8)
Student	14 (8.1)	16 (9.7)	30 (8.9)	6 (13.0)	5 (9.1)	11 (10.9)
Retired	7 (4.0)	5 (3.0)	12 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Looking after family/home	0 (0.0)	4 (2.4)	4 (1.2)	1 (2.2)	2 (3.6)	3 (3.0)
Not employed but seeking work	3 (1.7)	4 (2.4)	7 (2.1)	6 (13.0)	1 (1.8)	7 (6.9)
Other	8 (4.6)	5 (3.0)	13 (3.8)	3 (6.5)	4 (7.3)	7 (6.9)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	2 (4.3)	0 (0.0)	2 (2.0)
Type of employment, n (%)						
Unskilled manual	19 (11.0)	11 (6.7)	30 (8.9)	6 (13.0)	12 (21.8)	18 (17.8)
Skilled manual	51 (29.5)	44 (26.7)	95 (28.1)	12 (26.1)	16 (29.1)	28 (27.7)
Unskilled non-manual	18 (10.4)	9 (5.5)	27 (8.0)	1 (2.2)	3 (5.5)	4 (4.0)
Skilled non-manual	28 (16.2)	38 (23)	66 (19.5)	5 (10.9)	8 (14.5)	13 (12.9)
Professional	17 (9.8)	15 (9.1)	32 (9.5)	3 (6.5)	4 (7.3)	7 (6.9)
Other	16 (9.2)	23 (13.9)	39 (11.5)	3 (6.5)	7 (12.7)	10 (9.9)
Missing	24 (13.9)	25 (15.2)	49 (14.5)	16 (34.8)	5 (9.1)	21 (20.8)
Current smoker, n (%)						
Yes	49 (28.3)	31 (18.8)	80 (23.7)	24 (52.2)	25 (45.5)	49 (48.5)
No	123 (71.1)	133 (80.6)	256 (75.7)	20 (43.5)	30 (54.5)	50 (49.5)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	2 (4.3)	0 (0.0)	2 (2.0)
If Yes:						

Characteristic	Attended visit (n=338)			Did not attend visit (n=101)		
	Surgery (n=173)	Plaster cast (n=165)	Total (n=338)	Surgery (n=46)	Plaster cast (n=55)	Total (n=101)
How many cigarettes						
Median (min, max)	10 (1, 40)	11 (1, 36)	10 (1, 40)	10 (1, 20)	10 (4, 20)	10 (1, 20)
For how many years						
Median (min, max)	10 (1, 50)	10 (1, 40)	10 (1, 50)	10 (1, 44)	10 (2, 20)	10 (1, 44)
Past smoker, n (%)						
Yes	91 (52.6)	70 (42.4)	161 (47.6)	25 (54.3)	39 (70.9)	64 (63.4)
No	72 (41.6)	88 (53.3)	160 (47.3)	13 (28.3)	13 (23.6)	26 (25.7)
Missing	10 (5.8)	7 (4.2)	17 (5.0)	8 (17.4)	3 (5.5)	11 (10.9)
Diabetes, n (%)						
Yes	6 (3.5)	4 (2.4)	10 (3.0)	1 (2.2)	0 (0.0)	1 (1.0)
No	166 (96.0)	161 (97.6)	327 (96.7)	43 (93.5)	55 (100.0)	98 (97.0)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	2 (4.3)	0 (0.0)	2 (2.0)
Steroid use, n (%)						
Yes	4 (2.3)	4 (2.4)	8 (2.4)	2 (4.3)	0 (0.0)	2 (2.0)
No	168 (97.1)	161 (97.6)	329 (97.3)	42 (91.3)	55 (100.0)	97 (96.0)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	2 (4.3)	0 (0.0)	2 (2.0)

SD, standard deviation; min, minimum; max, maximum

Table 48: Baseline fracture details of trial participants according to whether or not they attended for the week 12 hospital clinic visit

Characteristic	Attended visit (n=338)			Did not attend visit (n=101)		
	Surgery (n=173)	Plaster cast (n=165)	Total (n=338)	Surgery (n=46)	Plaster cast (n=55)	Total (n=101)
Time since injury (days)[a]						
N	173	165	338	46	55	101
Mean (SD)	4.8 (3.1)	5.4 (3.5)	5.1 (3.3)	6.0 (3.0)	5.2 (2.9)	5.6 (3.0)
Median (min, max)	4 (1, 14)	4 (0, 14)	4 (0, 14)	6 (1, 14)	5 (0, 12)	6 (0, 14)
Affected wrist, n (%)						
Left	93 (53.8)	94 (57.0)	187 (55.3)	22 (47.8)	24 (43.6)	46 (45.5)
Right	80 (46.2)	71 (43.0)	151 (44.7)	24 (52.2)	31 (56.4)	55 (54.5)

Characteristic	Attended visit (n=338)			Did not attend visit (n=101)		
	Surgery (n=173)	Plaster cast (n=165)	Total (n=338)	Surgery (n=46)	Plaster cast (n=55)	Total (n=101)
Hand dominance, n (%)						
Yes	76 (43.9)	68 (41.2)	144 (42.6)	24 (52.2)	27 (49.1)	51 (50.5)
No	97 (56.1)	97 (58.8)	194 (57.4)	20 (43.5)	28 (50.9)	48 (47.5)
Missing				2 (4.3)	0 (0.0)	2 (2.0)
Displacement (eligibility), n (%)						
No displacement	107 (61.8)	101 (61.2)	208 (61.5)	28 (60.9)	33 (60.0)	61 (60.4)
Displacement	66 (38.2)	64 (38.8)	130 (38.5)	18 (39.1)	22 (40.0)	40 (39.6)
Displacement (randomisation), n (%)						
No displacement	104 (60.1)	97 (58.8)	201 (59.5)	27 (58.7)	33 (60.0)	60 (59.4)
Displacement	69 (39.9)	68 (41.2)	137 (40.5)	19 (41.3)	22 (40.0)	41 (40.6)
Radiographs[b], n (%)						
Elongated scaphoid view	164 (94.8)	158 (95.8)	322 (95.3)	45 (97.8)	52 (94.5)	97 (96.0)
Posterior-anterior view	171 (98.8)	165 (100.0)	336 (99.4)	44 (95.7)	53 (96.4)	97 (96.0)
Semi 45° supine	121 (69.9)	121 (73.3)	242 (71.6)	38 (82.6)	45 (81.8)	83 (82.2)
Lateral	173 (100.0)	164 (99.4)	337 (99.7)	45 (97.8)	53 (96.4)	98 (97.0)
Semi 45° prone	156 (90.2)	147 (89.1)	303 (89.6)	42 (91.3)	49 (89.1)	91 (90.1)
Previous wrist problems on same side, n (%)						
Yes	35 (20.2)	33 (20.0)	68 (20.1)	8 (17.4)	12 (21.8)	20 (19.8)
No	137 (79.2)	131 (79.4)	268 (79.3)	36 (78.3)	42 (76.4)	78 (77.2)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	2 (4.3)	1 (1.8)	3 (3.0)
If Yes, what injury, n (%)						
Previous fracture	18 (51.4)	20 (60.6)	38 (55.9)	5 (62.5)	8 (66.7)	13 (65.0)
Arthritis	2 (5.7)	1 (3.0)	3 (4.4)			
Ligament, tendon or nerve injury	8 (22.9)	7 (21.2)	15 (22.1)	2 (25)	1 (8.3)	3 (15.0)
Other	6 (17.1)	5 (15.2)	11 (16.2)	0 (0.0)	3 (25.0)	3 (15.0)
Missing	1 (2.9)	0 (0.0)	1 (1.5)	1 (12.5)	0 (0.0)	1 (5.0)
Injury mechanism, n (%)						

Characteristic	Attended visit (n=338)			Did not attend visit (n=101)		
	Surgery (n=173)	Plaster cast (n=165)	Total (n=338)	Surgery (n=46)	Plaster cast (n=55)	Total (n=101)
Fall – standing	22 (12.7)	21 (12.7)	43 (12.7)	6 (13.0)	8 (14.5)	14 (13.9)
Fall – walking	20 (11.6)	21 (12.7)	41 (12.1)	4 (8.7)	3 (5.5)	7 (6.9)
Fall – running	33 (19.1)	28 (17.0)	61 (18.0)	7 (15.2)	10 (18.2)	17 (16.8)
Fall – from height	25 (14.5)	25 (15.2)	50 (14.8)	3 (6.5)	9 (16.4)	12 (11.9)
Fall – from moving object	34 (19.7)	27 (16.4)	61 (18.0)	8 (17.4)	4 (7.3)	12 (11.9)
Hit on palm of hand – object striking palm	12 (6.9)	12 (7.3)	24 (7.1)	4 (8.7)	3 (5.5)	7 (6.9)
Hit on palm of hand – handle whipping back	5 (2.9)	8 (4.8)	13 (3.8)	4 (8.7)	3 (5.5)	7 (6.9)
Hit on palm of hand – other sudden extension	9 (5.2)	4 (2.4)	13 (3.8)	2 (4.3)	4 (7.3)	6 (5.9)
Punched something	4 (2.3)	7 (4.2)	11 (3.3)	0 (0.0)	5 (9.1)	5 (5.0)
Road traffic accident	7 (4.0)	5 (3.0)	12 (3.6)	2 (4.3)	3 (5.5)	5 (5.0)
Other	2 (1.2)	7 (4.2)	9 (2.7)	4 (8.7)	3 (5.5)	7 (6.9)
Missing				2 (4.3)	0 (0.0)	2 (2.0)
Place of injury[b], n (%)						
Sport	73 (42.2)	60 (36.4)	133 (39.3)	15 (32.6)	18 (32.7)	33 (32.7)
Home	17 (9.8)	29 (17.6)	46 (13.6)	10 (21.7)	14 (25.5)	24 (23.8)
Work	17 (9.8)	13 (7.9)	30 (8.9)	5 (10.9)	5 (9.1)	10 (9.9)
Road Traffic Accident	24 (13.9)	27 (16.4)	51 (15.1)	2 (4.3)	7 (12.7)	9 (8.9)
Public place	39 (22.5)	38 (23.0)	77 (22.8)	10 (21.7)	10 (18.2)	20 (19.8)
Other	2 (1.2)	0 (0.0)	2 (0.6)	1 (2.2)	0 (0.0)	1 (1.0)
Missing	3 (1.7)	1 (0.6)	4 (1.2)	1 (2.2)	1 (1.8)	2 (2.0)
Treatment preference, n (%)						
Surgery	72 (41.6)	76 (46.1)	148 (43.8)	21 (45.7)	25 (45.5)	46 (45.5)
No surgery	10 (5.8)	13 (7.9)	23 (6.8)	3 (6.5)	6 (10.9)	9 (8.9)
No preference	90 (52.0)	75 (45.5)	165 (48.8)	20 (43.5)	24 (43.6)	44 (43.6)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	2 (4.3)	0 (0.0)	2 (2.0)

SD, standard deviation; min, minimum; max, maximum

[a] time from injury to screening; [b] response categories not mutually exclusive

Table 49: Baseline characteristics of trial participants according to whether or not they attended for the week 52 hospital clinic visit

Characteristic	Attended visit (n=310)			Did not attend visit (n=129)		
	Surgery (n=164)	Plaster cast (n=146)	Total (n=310)	Surgery (n=55)	Plaster cast (n=74)	Total (n=129)
Gender, n (%)						
Male	137 (83.5)	122 (83.6)	259 (83.5)	43 (78.2)	61 (82.4)	104 (80.6)
Female	27 (16.5)	24 (16.4)	51 (16.5)	12 (21.8)	13 (17.6)	25 (19.4)
Age (years)						
N	164	146	310	55	74	129
Mean (SD)	34.6 (13.7)	34.6 (13.2)	34.6 (13.4)	27.8 (10.0)	29.5 (9.4)	28.7 (9.6)
Median (min, max)	31 (16, 80)	31 (16, 76)	31 (16, 80)	24 (18, 57)	26 (17, 55)	25 (17, 57)
Ethnicity, n (%)						
White	153 (93.3)	130 (89.0)	283 (91.3)	52 (94.5)	65 (87.8)	117 (90.7)
Black	0 (0.0)	2 (1.4)	2 (0.6)	0 (0.0)	3 (4.1)	3 (2.3)
Asian	7 (4.3)	8 (5.5)	15 (4.8)	0 (0.0)	2 (2.7)	2 (1.6)
Other	4 (2.4)	6 (4.1)	10 (3.2)	1 (1.8)	4 (5.4)	5 (3.9)
Missing				2 (3.6)	0 (0.0)	2 (1.6)
Education, n (%)						
No formal qualifications	14 (8.5)	21 (14.4)	35 (11.3)	10 (18.2)	6 (8.1)	16 (12.4)
Some qualifications/no degree	114 (69.5)	80 (54.8)	194 (62.6)	37 (67.3)	49 (66.2)	86 (66.7)
Degree or higher	35 (21.3)	45 (30.8)	80 (25.8)	6 (10.9)	19 (25.7)	25 (19.4)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	2 (3.6)	0 (0.0)	2 (1.6)
Employment status, n (%)						
Part-time	15 (9.1)	14 (9.6)	29 (9.4)	5 (9.1)	4 (5.4)	9 (7.0)
Full-time	105 (64.0)	86 (58.9)	191 (61.6)	22 (40.0)	34 (45.9)	56 (43.4)
Self-employed	14 (8.5)	19 (13.0)	33 (10.6)	7 (12.7)	17 (23.0)	24 (18.6)
Student	12 (7.3)	11 (7.5)	23 (7.4)	8 (14.5)	10 (13.5)	18 (14.0)
Retired	7 (4.3)	5 (3.4)	12 (3.9)			
Looking after family/home	0 (0.0)	4 (2.7)	4 (1.3)	1 (1.8)	2 (2.7)	3 (2.3)
Not employed but seeking work	3 (1.8)	3 (2.1)	6 (1.9)	6 (10.9)	2 (2.7)	8 (6.2)
Other	7 (4.3)	4 (2.7)	11 (3.5)	4 (7.3)	5 (6.8)	9 (7.0)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	2 (3.6)	0 (0.0)	2 (1.6)
Type of employment, n (%)						

Characteristic	Attended visit (n=310)			Did not attend visit (n=129)		
	Surgery (n=164)	Plaster cast (n=146)	Total (n=310)	Surgery (n=55)	Plaster cast (n=74)	Total (n=129)
Unskilled manual	17 (10.4)	10 (6.8)	27 (8.7)	8 (14.5)	13 (17.6)	21 (16.3)
Skilled manual	48 (29.3)	39 (26.7)	87 (28.1)	15 (27.3)	21 (28.4)	36 (27.9)
Unskilled non-manual	18 (11.0)	7 (4.8)	25 (8.1)	1 (1.8)	5 (6.8)	6 (4.7)
Skilled non-manual	27 (16.5)	37 (25.3)	64 (20.6)	6 (10.9)	9 (12.2)	15 (11.6)
Professional	17 (10.4)	13 (8.9)	30 (9.7)	3 (5.5)	6 (8.1)	9 (7.0)
Other	16 (9.8)	19 (13.0)	35 (11.3)	3 (5.5)	11 (14.9)	14 (10.9)
Missing	21 (12.8)	21 (14.4)	42 (13.5)	19 (34.5)	9 (12.2)	28 (21.7)
Current smoker, n (%)						
Yes	49 (29.9)	27 (18.5)	76 (24.5)	24 (43.6)	29 (39.2)	53 (41.1)
No	114 (69.5)	118 (80.8)	232 (74.8)	29 (52.7)	45 (60.8)	74 (57.4)
Missing	1 (0.6)	1 (0.7)	2 (0.6)	2 (3.6)	0 (0.0)	2 (1.6)
If Yes:						
How many cigarettes						
Median (min, max)	10 (1, 40)	10 (1, 30)	10 (1, 40)	10 (1, 20)	10 (4, 25)	10 (1, 25)
For how many years						
Median (min, max)	10 (1, 50)	11 (1, 36)	10 (1, 50)	9 (1, 40)	8 (2, 30)	8 (1, 40)
Past smoker, n (%)						
Yes	86 (52.4)	62 (42.5)	148 (47.7)	30 (54.5)	47 (63.5)	77 (59.7)
No	68 (41.5)	78 (53.4)	146 (47.1)	17 (30.9)	23 (31.1)	40 (31.0)
Missing	10 (6.1)	6 (4.1)	16 (5.2)	8 (14.5)	4 (5.4)	12 (9.3)
Diabetes, n (%)						
Yes	6 (3.7)	4 (2.7)	10 (3.2)	1 (1.8)	0 (0.0)	1 (0.8)
No	157 (95.7)	142 (97.3)	299 (96.5)	52 (94.5)	74 (100.0)	126 (97.7)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	2 (3.6)	0 (0.0)	2 (1.6)
Steroid use, n (%)						
Yes	5 (3.0)	2 (1.4)	7 (2.3)	1 (1.8)	2 (2.7)	3 (2.3)
No	158 (96.3)	144 (98.6)	302 (97.4)	52 (94.5)	72 (97.3)	124 (96.1)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	2 (3.6)	0 (0.0)	2 (1.6)

SD, standard deviation; min, minimum; max, maximum

Table 50: Baseline fracture details of trial participants according to whether or not they attended for the week 52 hospital clinic visit

Characteristic	Attended visit (n=310)			Did not attend visit (n=129)		
	Surgery (n=164)	**Plaster cast (n=146)**	**Total (n=310)**	**Surgery (n=55)**	**Plaster cast (n=74)**	**Total (n=129)**
Time since injury (days)[a]						
N	164	146	310	55	74	129
Mean (SD)	4.9 (3.1)	5.3 (3.4)	5.1 (3.3)	5.7 (3.1)	5.4 (3.2)	5.5 (3.1)
Median (min, max)	4 (1, 14)	4 (1, 14)	4 (1, 14)	5 (1, 14)	5 (0, 14)	5 (0, 14)
Affected wrist, n (%)						
Left	86 (52.4)	77 (52.7)	163 (52.6)	29 (52.7)	41 (55.4)	70 (54.3)
Right	78 (47.6)	69 (47.3)	147 (47.4)	26 (47.3)	33 (44.6)	59 (45.7)
Hand dominance, n (%)						
Yes	73 (44.5)	69 (47.3)	142 (45.8)	27 (49.1)	26 (35.1)	53 (41.1)
No	91 (55.5)	77 (52.7)	168 (54.2)	26 (47.3)	48 (64.9)	74 (57.4)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.6)	0 (0.0)	2 (1.6)
Displacement (eligibility), n (%)						
No displacement	96 (58.5)	86 (58.9)	182 (58.7)	39 (70.9)	48 (64.9)	87 (67.4)
Displacement	68 (41.5)	60 (41.1)	128 (41.3)	16 (29.1)	26 (35.1)	42 (32.6)
Displacement (randomisation), n (%)						
No displacement	94 (57.3)	83 (56.8)	177 (57.1)	37 (67.3)	47 (63.5)	84 (65.1)
Displacement	70 (42.7)	63 (43.2)	133 (42.9)	18 (32.7)	27 (36.5)	45 (34.9)
Radiographs[b], n (%)						
Elongated scaphoid view	157 (95.7)	138 (94.5)	295 (95.2)	52 (94.5)	72 (97.3)	124 (96.1)
Posterior-anterior view	161 (98.2)	145 (99.3)	306 (98.7)	54 (98.2)	73 (98.6)	127 (98.4)
Semi 45° supine	118 (72.0)	111 (76.0)	229 (73.9)	41 (74.5)	55 (74.3)	96 (74.4)
Lateral	164 (100.0)	144 (98.6)	308 (99.4)	54 (98.2)	73 (98.6)	127 (98.4)
Semi 45° prone	148 (90.2)	132 (90.4)	280 (90.3)	50 (90.9)	64 (86.5)	114 (88.4)
Previous wrist problems on same side, n (%)						
Yes	34 (20.7)	30 (20.5)	64 (20.6)	9 (16.4)	15 (20.3)	24 (18.6)
No	129 (78.7)	115 (78.8)	244 (78.7)	44 (80.0)	58 (78.4)	102 (79.1)
Missing	1 (0.6)	1 (0.7)	2 (0.6)	2 (3.6)	1 (1.4)	3 (2.3)

Characteristic	Attended visit (n=310)			Did not attend visit (n=129)		
	Surgery (n=164)	Plaster cast (n=146)	Total (n=310)	Surgery (n=55)	Plaster cast (n=74)	Total (n=129)
If Yes, what injury, n (%)						
Previous fracture	16 (47.1)	18 (60.0)	34 (53.1)	7 (77.8)	10 (66.7)	17 (70.8)
Arthritis	2 (5.9)	1 (3.3)	3 (4.7)			
Ligament, tendon or nerve injury	8 (23.5)	7 (23.3)	15 (23.4)	2 (22.2)	1 (6.7)	3 (12.5)
Other	6 (17.6)	4 (13.3)	10 (15.6)	0 (0.0)	4 (26.7)	4 (16.7)
Missing	2 (5.9)	0 (0.0)	2 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)
Injury mechanism, n (%)						
Fall – standing	21 (12.8)	19 (13.0)	40 (12.9)	7 (12.7)	10 (13.5)	17 (13.2)
Fall – walking	19 (11.6)	20 (13.7)	39 (12.6)	5 (9.1)	4 (5.4)	9 (7.0)
Fall – running	32 (19.5)	28 (19.2)	60 (19.4)	8 (14.5)	10 (13.5)	18 (14.0)
Fall – from height	24 (14.6)	20 (13.7)	44 (14.2)	4 (7.3)	14 (18.9)	18 (14.0)
Fall – from moving object	32 (19.5)	21 (14.4)	53 (17.1)	10 (18.2)	10 (13.5)	20 (15.5)
Hit on palm of hand – object striking palm	10 (6.1)	12 (8.2)	22 (7.1)	6 (10.9)	3 (4.1)	9 (7.0)
Hit on palm of hand – handle whipping back	6 (3.7)	9 (6.2)	15 (4.8)	3 (5.5)	2 (2.7)	5 (3.9)
Hit on palm of hand – other sudden extension	8 (4.9)	4 (2.7)	12 (3.9)	3 (5.5)	4 (5.4)	7 (5.4)
Punched something	2 (1.2)	6 (4.1)	8 (2.6)	2 (3.6)	6 (8.1)	8 (6.2)
Road traffic accident	7 (4.3)	3 (2.1)	10 (3.2)	2 (3.6)	5 (6.8)	7 (5.4)
Other	3 (1.8)	4 (2.7)	7 (2.3)	3 (5.5)	6 (8.1)	9 (7.0)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.6)	0 (0.0)	2 (1.6)
Place of injury[b], n (%)						
Sport	66 (40.2)	53 (36.3)	119 (38.4)	22 (40.0)	25 (33.8)	47 (36.4)
Home	20 (12.2)	28 (19.2)	48 (15.5)	7 (12.7)	15 (20.3)	22 (17.1)
Work	16 (9.8)	13 (8.9)	29 (9.4)	6 (10.9)	5 (6.8)	11 (8.5)
Road Traffic Accident	20 (12.2)	22 (15.1)	42 (13.5)	6 (10.9)	12 (16.2)	18 (14.0)
Public place	40 (24.4)	31 (21.2)	71 (22.9)	9 (16.4)	17 (23.0)	26 (20.2)
Other	1 (0.6)	0 (0.0)	1 (0.3)	2 (3.6)	0 (0.0)	2 (1.6)
Missing	3 (1.8)	2 (1.4)	5 (1.6)	1 (1.8)	0 (0.0)	1 (0.8)

Characteristic	Attended visit (n=310)			Did not attend visit (n=129)		
	Surgery (n=164)	Plaster cast (n=146)	Total (n=310)	Surgery (n=55)	Plaster cast (n=74)	Total (n=129)
Treatment preference, n (%)						
Surgery	71 (43.3)	67 (45.9)	138 (44.5)	22 (40.0)	34 (45.9)	56 (43.4)
No surgery	10 (6.1)	9 (6.2)	19 (6.1)	3 (5.5)	10 (13.5)	13 (10.1)
No preference	83 (50.6)	69 (47.3)	152 (49.0)	27 (49.1)	30 (40.5)	57 (44.2)
Missing	0 (0.0)	1 (0.7)	1 (0.3)	3 (5.5)	0 (0.0)	3 (2.3)

SD, standard deviation; min, minimum; max, maximum
[a] time from injury to screening; [b] response categories not mutually exclusive

Table 51: Baseline characteristics of trial participants with valid PRWE data by time point (6 and 12 weeks)

Characteristic	6 weeks			12 weeks		
	Surgery (n=176)	Plaster cast (n=172)	Total (n=348)	Surgery (n=178)	Plaster cast (n=163)	Total (n=341)
Gender, n (%)						
Male	143 (81.3)	141 (82.0)	284 (81.6)	150 (84.3)	134 (82.2)	284 (83.3)
Female	33 (18.8)	31 (18.0)	64 (18.4)	28 (15.7)	29 (17.8)	57 (16.7)
Age (years)						
N	176	172	348	178	163	341
Mean (SD)	33.5 (13.3)	33.3 (12.9)	33.4 (13.1)	33.4 (13.1)	33.4 (12.8)	33.4 (13.0)
Median (min, max)	30 (16, 80)	30 (16, 76)	30 (16, 80)	30 (16, 80)	30 (16, 76)	30 (16, 80)
Ethnicity, n (%)						
White	166 (94.3)	150 (87.2)	316 (90.8)	167 (93.8)	143 (87.7)	310 (90.9)
Black	0 (0.0)	5 (2.9)	5 (1.4)	0 (0.0)	3 (1.8)	3 (0.9)
Asian	6 (3.4)	7 (4.1)	13 (3.7)	7 (3.9)	7 (4.3)	14 (4.1)
Other	4 (2.3)	10 (5.8)	14 (4.0)	4 (2.2)	10 (6.1)	14 (4.1)
Education, n (%)						
No formal qualifications	19 (10.8)	21 (12.2)	40 (11.5)	17 (9.6)	21 (12.9)	38 (11.1)
Some qualifications/no degree	121 (68.8)	95 (55.2)	216 (62.1)	119 (66.9)	91 (55.8)	210 (61.6)
Degree or higher	35 (19.9)	56 (32.6)	91 (26.1)	41 (23.0)	51 (31.3)	92 (27.0)
Missing	1 (0.6)	0 (0)	1 (0.3)	1 (0.6)	0 (0.0)	1 (0.3)
Employment status, n (%)						
Part-time	17 (9.7)	15 (8.7)	32 (9.2)	18 (10.1)	14 (8.6)	32 (9.4)

Characteristic	6 weeks			12 weeks		
	Surgery (n=176)	**Plaster cast (n=172)**	**Total (n=348)**	**Surgery (n=178)**	**Plaster cast (n=163)**	**Total (n=341)**
Full-time	106 (60.2)	92 (53.5)	198 (56.9)	109 (61.2)	94 (57.7)	203 (59.5)
Self-employed	15 (8.5)	25 (14.5)	40 (11.5)	17 (9.6)	21 (12.9)	38 (11.1)
Student	16 (9.1)	19 (11.0)	35 (10.1)	14 (7.9)	18 (11.0)	32 (9.4)
Retired	6 (3.4)	5 (2.9)	11 (3.2)	7 (3.9)	5 (3.1)	12 (3.5)
Looking after family/home	0 (0.0)	5 (2.9)	5 (1.4)	0 (0.0)	4 (2.5)	4 (1.2)
Not employed but seeking work	5 (2.8)	5 (2.9)	10 (2.9)	6 (3.4)	3 (1.8)	9 (2.6)
Other	10 (5.7)	6 (3.5)	16 (4.6)	6 (3.4)	4 (2.5)	10 (2.9)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	1 (0.6)	0 (0.0)	1 (0.3)
Type of employment, n (%)						
Unskilled manual	20 (11.4)	13 (7.6)	33 (9.5)	19 (10.7)	12 (7.4)	31 (9.1)
Skilled manual	52 (29.5)	49 (28.5)	101 (29.0)	53 (29.8)	41 (25.2)	94 (27.6)
Unskilled non-manual	15 (8.5)	8 (4.7)	23 (6.6)	14 (7.9)	10 (6.1)	24 (7.0)
Skilled non-manual	28 (15.9)	34 (19.8)	62 (17.8)	30 (16.9)	37 (22.7)	67 (19.6)
Professional	18 (10.2)	15 (8.7)	33 (9.5)	19 (10.7)	14 (8.6)	33 (9.7)
Other	17 (9.7)	25 (14.5)	42 (12.1)	15 (8.4)	24 (14.7)	39 (11.4)
Missing	26 (14.8)	28 (16.3)	54 (15.5)	28 (15.7)	25 (15.3)	53 (15.5)
Current smoker, n (%)						
Yes	50 (28.4)	37 (21.5)	87 (25.0)	53 (29.8)	31 (19.0)	84 (24.6)
No	126 (71.6)	134 (77.9)	260 (74.7)	124 (69.7)	131 (80.4)	255 (74.8)
Missing	0 (0.0)	1 (0.6)	1 (0.3)	1 (0.6)	1 (0.6)	2 (0.6)
If Yes:						
How many cigarettes						
Median (min, max)	10 (1, 40)	10 (1, 30)	10 (1, 40)	10 (1, 20)	10 (1, 30)	10 (1, 30)
For how many years						
Median (min, max)	10 (1, 50)	10 (1, 30)	10 (1, 50)	10 (1, 50)	10 (1, 36)	10 (1, 50)
Past smoker, n (%)						
Yes	95 (54)	80 (46.5)	175 (50.3)	95 (53.4)	69 (42.3)	164 (48.1)
No	73 (41.5)	83 (48.3)	156 (44.8)	71 (39.9)	87 (53.4)	158 (46.3)
Missing	8 (4.5)	9 (5.2)	17 (4.9)	12 (6.7)	7 (4.3)	19 (5.6)
Diabetes, n (%)						

Characteristic	6 weeks			12 weeks		
	Surgery (n=176)	Plaster cast (n=172)	Total (n=348)	Surgery (n=178)	Plaster cast (n=163)	Total (n=341)
Yes	6 (3.4)	3 (1.7)	9 (2.6)	6 (3.4)	4 (2.5)	10 (2.9)
No	170 (96.6)	169 (98.3)	339 (97.4)	171 (96.1)	159 (97.5)	330 (96.8)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.3)
Steroid use, n (%)						
Yes	5 (2.8)	3 (1.7)	8 (2.3)	4 (2.2)	4 (2.5)	8 (2.3)
No	171 (97.2)	169 (98.3)	340 (97.7)	173 (97.2)	159 (97.5)	332 (97.4)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.3)

SD, standard deviation; min, minimum; max, maximum

Table 51: Baseline fracture details of trial participants with valid PRWE data by time point (6 and 12 weeks)

Characteristic	6 weeks			12 weeks		
	Surgery (n=176)	Plaster cast (n=172)	Total (n=348)	Surgery (n=178)	Plaster cast (n=163)	Total (n=341)
Time since injury (days)[a]						
N	176	172	348	178	163	341
Mean (SD)	4.8 (3.0)	5.4 (3.5)	5.1 (3.3)	4.9 (3.0)	5.5 (3.4)	5.2 (3.2)
Median (min, max)	4 (1, 4)	5 (0, 14)	4 (0, 14)	4 (1, 14)	5 (1, 14)	5 (1, 14)
Affected wrist, n (%)						
Left	95 (54.0)	96 (55.8)	191 (54.9)	97 (54.5)	89 (54.6)	186 (54.5)
Right	81 (46.0)	76 (44.2)	157 (45.1)	81 (45.5)	74 (45.4)	155 (45.5)
Hand dominance, n (%)						
Yes	80 (45.5)	73 (42.4)	153 (44)	80 (44.9)	69 (42.3)	149 (43.7)
No	96 (54.5)	99 (57.6)	195 (56)	98 (55.1)	94 (57.7)	192 (56.3)
Displacement (eligibility), n (%)						
No displacement	109 (61.9)	107 (62.2)	216 (62.1)	106 (59.6)	102 (62.6)	208 (61.0)
Displacement	67 (38.1)	65 (37.8)	132 (37.9)	72 (40.4)	61 (37.4)	133 (39.0)
Displacement (randomisation), n (%)						
No displacement	105 (59.7)	103 (59.9)	208 (59.8)	104 (58.4)	100 (61.3)	204 (59.8)
Displacement	71 (40.3)	69 (40.1)	140 (40.2)	74 (41.6)	63 (38.7)	137 (40.2)
Radiographs[b], n (%)						

Characteristic	6 weeks			12 weeks		
	Surgery (n=176)	**Plaster cast (n=172)**	**Total (n=348)**	**Surgery (n=178)**	**Plaster cast (n=163)**	**Total (n=341)**
Elongated scaphoid view	168 (95.5)	163 (94.8)	331 (95.1)	168 (94.4)	155 (95.1)	323 (94.7)
Posterior-anterior view	174 (98.9)	170 (98.8)	344 (98.9)	175 (98.3)	161 (98.8)	336 (98.5)
Semi 45° supine	124 (70.5)	129 (75.0)	253 (72.7)	123 (69.1)	121 (74.2)	244 (71.6)
Lateral	176 (100.0)	169 (98.3)	345 (99.1)	178 (100.0)	160 (98.2)	338 (99.1)
Semi 45° prone	158 (89.8)	154 (89.5)	312 (89.7)	161 (90.4)	145 (89.0)	306 (89.7)
Previous wrist problems on same side, n (%)						
Yes	36 (20.5)	35 (20.3)	71 (20.4)	37 (20.8)	35 (21.5)	72 (21.1)
No	139 (79.0)	135 (78.5)	274 (78.7)	140 (78.7)	128 (78.5)	268 (78.6)
Missing	1 (0.6)	2 (1.2)	3 (0.9)	1 (0.6)	0 (0.0)	1 (0.3)
If Yes, what injury, n (%)						
Previous fracture	21 (58.3)	20 (57.1)	41 (57.7)	20 (54.1)	21 (60.0)	41 (56.9)
Arthritis	1 (2.8)	1 (2.9)	2 (2.8)	1 (2.7)	1 (2.9)	2 (2.8)
Ligament, tendon or nerve injury	8 (22.2)	7 (20)	15 (21.1)	9 (24.3)	8 (22.9)	17 (23.6)
Other	6 (16.7)	7 (20)	13 (18.3)	6 (16.2)	5 (14.3)	11 (15.3)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)
Injury mechanism, n (%)						
Fall – standing	19 (10.8)	23 (13.4)	42 (12.1)	23 (12.9)	19 (11.7)	42 (12.3)
Fall – walking	21 (11.9)	20 (11.6)	41 (11.8)	22 (12.4)	17 (10.4)	39 (11.4)
Fall – running	32 (18.2)	28 (16.3)	60 (17.2)	35 (19.7)	28 (17.2)	63 (18.5)
Fall – from height	22 (12.5)	28 (16.3)	50 (14.4)	22 (12.4)	27 (16.6)	49 (14.4)
Fall – from moving object	37 (21.0)	27 (15.7)	64 (18.4)	35 (19.7)	29 (17.8)	64 (18.8)
Hit on palm of hand – object striking palm	14 (8.0)	11 (6.4)	25 (7.2)	12 (6.7)	13 (8.0)	25 (7.3)
Hit on palm of hand – handle whipping back	6 (3.4)	9 (5.2)	15 (4.3)	5 (2.8)	8 (4.9)	13 (3.8)
Hit on palm of hand – other sudden extension	10 (5.7)	5 (2.9)	15 (4.3)	9 (5.1)	3 (1.8)	12 (3.5)
Punched something	3 (1.7)	7 (4.1)	10 (2.9)	4 (2.2)	6 (3.7)	10 (2.9)

Characteristic	6 weeks			12 weeks		
	Surgery (n=176)	Plaster cast (n=172)	Total (n=348)	Surgery (n=178)	Plaster cast (n=163)	Total (n=341)
Road traffic accident	9 (5.1)	6 (3.5)	15 (4.3)	9 (5.1)	6 (3.7)	15 (4.4)
Other	3 (1.7)	8 (4.7)	11 (3.2)	2 (1.1)	7 (4.3)	9 (2.6)
Place of injury[b], n (%)						
Sport	74 (42.0)	61 (35.5)	135 (38.8)	77 (43.3)	61 (37.4)	138 (40.5)
Home	20 (11.4)	31 (18.0)	51 (14.7)	19 (10.7)	26 (16.0)	45 (13.2)
Work	17 (9.7)	16 (9.3)	33 (9.5)	18 (10.1)	14 (8.6)	32 (9.4)
Road Traffic Accident	23 (13.1)	27 (15.7)	50 (14.4)	21 (11.8)	29 (17.8)	50 (14.7)
Public place	39 (22.2)	38 (22.1)	77 (22.1)	39 (21.9)	36 (22.1)	75 (22.0)
Other	2 (1.1)	0 (0.0)	2 (0.6)	2 (1.1)	0 (0.0)	2 (0.6)
Missing	3 (1.7)	2 (1.2)	5 (1.4)	3 (1.7)	0 (0.0)	3 (0.9)
Treatment preference, n (%)						
Surgery	75 (42.6)	76 (44.2)	151 (43.4)	77 (43.3)	75 (46.0)	152 (44.6)
No surgery	10 (5.7)	14 (8.1)	24 (6.9)	10 (5.6)	15 (9.2)	25 (7.3)
No preference	90 (51.1)	81 (47.1)	171 (49.1)	91 (51.1)	72 (44.2)	163 (47.8)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	1 (0.6)	1 (0.3)

SD, standard deviation; min, minimum; max, maximum
[a] time from injury to screening; [b] response categories not mutually exclusive

Table 52: Baseline characteristics of trial participants with valid PRWE data by time point (26 and 52 weeks)

Characteristic	26 weeks			52 weeks		
	Surgery (n=156)	Plaster cast (n=146)	Total (n=302)	Surgery (n=186)	Plaster cast (n=176)	Total (n=362)
Gender, n (%)						
Male	129 (82.7)	119 (81.5)	248 (82.1)	153 (82.3)	140 (79.5)	293 (80.9)
Female	27 (17.3)	27 (18.5)	54 (17.9)	33 (17.7)	36 (20.5)	69 (19.1)
Age (years)						
N	156	146	302	186	176	362
Mean (SD)	33.2 (13.2)	34.0 (13.3)	33.6 (13.2)	33.9 (13.4)	33.9 (12.9)	33.9 (13.2)
Median (min, max)	30 (16, 80)	30 (16, 76)	30 (16, 80)	30 (16, 80)	30 (16, 76)	30 (16, 80)
Ethnicity, n (%)						
White	148 (94.9)	129 (88.4)	277 (91.7)	175 (94.1)	156 (88.6)	331 (91.4)
Black	0 (0)	3 (2.1)	3 (1)	0 (0.0)	3 (1.7)	3 (0.8)
Asian	6 (3.8)	7 (4.8)	13 (4.3)	7 (3.8)	9 (5.1)	16 (4.4)

Characteristic	26 weeks			52 weeks		
	Surgery (n=156)	Plaster cast (n=146)	Total (n=302)	Surgery (n=186)	Plaster cast (n=176)	Total (n=362)
Other	2 (1.3)	7 (4.8)	9 (3)	4 (2.2)	8 (4.5)	12 (3.3)
Education, n (%)						
No formal qualifications	15 (9.6)	18 (12.3)	33 (10.9)	17 (9.1)	23 (13.1)	40 (11.0)
Some qualifications/no degree	105 (67.3)	83 (56.8)	188 (62.3)	128 (68.8)	100 (56.8)	228 (63.0)
Degree or higher	35 (22.4)	45 (30.8)	80 (26.5)	40 (21.5)	53 (30.1)	93 (25.7)
Missing	1 (0.6)	0 (0)	1 (0.3)	1 (0.5)	0 (0.0)	1 (0.3)
Employment status, n (%)						
Part-time	16 (10.3)	15 (10.3)	31 (10.3)	19 (10.2)	16 (9.1)	35 (9.7)
Full-time	91 (58.3)	81 (55.5)	172 (57)	114 (61.3)	98 (55.7)	212 (58.6)
Self-employed	13 (8.3)	20 (13.7)	33 (10.9)	16 (8.6)	27 (15.3)	43 (11.9)
Student	15 (9.6)	15 (10.3)	30 (9.9)	16 (8.6)	17 (9.7)	33 (9.1)
Retired	6 (3.8)	5 (3.4)	11 (3.6)	7 (3.8)	5 (2.8)	12 (3.3)
Looking after family/home	0 (0)	4 (2.7)	4 (1.3)	0 (0.0)	5 (2.8)	5 (1.4)
Not employed but seeking work	7 (4.5)	2 (1.4)	9 (3)	5 (2.7)	4 (2.3)	9 (2.5)
Other	7 (4.5)	4 (2.7)	11 (3.6)	8 (4.3)	4 (2.3)	12 (3.3)
Missing	1 (0.6)	0 (0)	1 (0.3)	1 (0.5)	0 (0.0)	1 (0.3)
Type of employment, n (%)						
Unskilled manual	17 (10.9)	12 (8.2)	29 (9.6)	23 (12.4)	15 (8.5)	38 (10.5)
Skilled manual	45 (28.8)	39 (26.7)	84 (27.8)	51 (27.4)	43 (24.4)	94 (26.0)
Unskilled non-manual	13 (8.3)	9 (6.2)	22 (7.3)	19 (10.2)	10 (5.7)	29 (8.0)
Skilled non-manual	26 (16.7)	30 (20.5)	56 (18.5)	30 (16.1)	42 (23.9)	72 (19.9)
Professional	15 (9.6)	14 (9.6)	29 (9.6)	19 (10.2)	17 (9.7)	36 (9.9)
Other	13 (8.3)	19 (13)	32 (10.6)	18 (9.7)	23 (13.1)	41 (11.3)
Missing	27 (17.3)	23 (15.8)	50 (16.6)	26 (14.0)	26 (14.8)	52 (14.4)
Current smoker, n (%)						
Yes	43 (27.6)	25 (17.1)	68 (22.5)	56 (30.1)	35 (19.9)	91 (25.1)
No	112 (71.8)	120 (82.2)	232 (76.8)	129 (69.4)	140 (79.5)	269 (74.3)
Missing	1 (0.6)	1 (0.7)	2 (0.7)	1 (0.5)	1 (0.6)	2 (0.6)
If Yes:						

Characteristic	26 weeks			52 weeks		
	Surgery (n=156)	Plaster cast (n=146)	Total (n=302)	Surgery (n=186)	Plaster cast (n=176)	Total (n=362)
How many cigarettes						
Median (min, max)	10 (1, 40)	10 (1, 25)	10 (1, 40)	10 (1, 40)	10 (1, 30)	10 (1, 40)
For how many years						
Median (min, max)	10 (1, 40)	8 (1, 36)	10 (1, 40)	10 (1, 50)	10 (1, 36)	10 (1, 50)
Past smoker, n (%)						
Yes	78 (50)	60 (41.1)	138 (45.7)	98 (52.7)	77 (43.8)	175 (48.3)
No	66 (42.3)	80 (54.8)	146 (48.3)	76 (40.9)	92 (52.3)	168 (46.4)
Missing	12 (7.7)	6 (4.1)	18 (6)	12 (6.5)	7 (4.0)	19 (5.2)
Diabetes, n (%)						
Yes	5 (3.2)	4 (2.7)	9 (3)	6 (3.2)	4 (2.3)	10 (2.8)
No	150 (96.2)	142 (97.3)	292 (96.7)	179 (96.2)	172 (97.7)	351 (97.0)
Missing	1 (0.6)	0 (0)	1 (0.3)	1 (0.5)	0 (0.0)	1 (0.3)
Steroid use, n (%)						
Yes	4 (2.6)	3 (2.1)	7 (2.3)	6 (3.2)	4 (2.3)	10 (2.8)
No	151 (96.8)	143 (97.9)	294 (97.4)	179 (96.2)	172 (97.7)	351 (97.0)
Missing	1 (0.6)	0 (0)	1 (0.3)	1 (0.5)	0 (0.0)	1 (0.3)

SD, standard deviation; min, minimum; max, maximum

Table 53: Baseline fracture details of trial participants with valid PRWE data by time point (26 and 52 weeks)

Characteristic	26 weeks			52 weeks		
	Surgery (n=156)	Plaster cast (n=146)	Total (n=302)	Surgery (n=186)	Plaster cast (n=176)	Total (n=362)
Time since injury (days)[a]						
N	156	146	302	186	176	362
Mean (SD)	4.7 (3.0)	5.3 (3.4)	5.0 (3.2)	4.8 (3.0)	5.3 (3.4)	5.1 (3.2)
Median (min, max)	4 (1, 13)	4 (1, 14)	4 (1, 14)	4 (1, 14)	4 (0, 14)	4 (0, 14)
Affected wrist, n (%)						
Left	82 (52.6)	82 (56.2)	164 (54.3)	101 (54.3)	94 (53.4)	195 (53.9)
Right	74 (47.4)	64 (43.8)	138 (45.7)	85 (45.7)	82 (46.6)	167 (46.1)
Hand dominance, n (%)						
Yes	72 (46.2)	62 (42.5)	134 (44.4)	83 (44.6)	78 (44.3)	161 (44.5)

Characteristic	26 weeks			52 weeks		
	Surgery (n=156)	**Plaster cast (n=146)**	**Total (n=302)**	**Surgery (n=186)**	**Plaster cast (n=176)**	**Total (n=362)**
No	84 (53.8)	84 (57.5)	168 (55.6)	103 (55.4)	98 (55.7)	201 (55.5)
Displacement (eligibility), n (%)						
No displacement	96 (61.5)	89 (61.0)	185 (61.3)	114 (61.3)	106 (60.2)	220 (60.8)
Displacement	60 (38.5)	57 (39.0)	117 (38.7)	72 (38.7)	70 (39.8)	142 (39.2)
Displacement (randomisation), n (%)						
No displacement	92 (59.0)	88 (60.3)	180 (59.6)	110 (59.1)	103 (58.5)	213 (58.8)
Displacement	64 (41.0)	58 (39.7)	122 (40.4)	76 (40.9)	73 (41.5)	149 (41.2)
Radiographs[b], n (%)						
Elongated scaphoid view	147 (94.2)	138 (94.5)	285 (94.4)	177 (95.2)	167 (94.9)	344 (95.0)
Posterior-anterior view	154 (98.7)	145 (99.3)	299 (99.0)	183 (98.4)	174 (98.9)	357 (98.6)
Semi 45° supine	109 (69.9)	109 (74.7)	218 (72.2)	131 (70.4)	131 (74.4)	262 (72.4)
Lateral	156 (100.0)	144 (98.6)	300 (99.3)	186 (100.0)	173 (98.3)	359 (99.2)
Semi 45° prone	139 (89.1)	133 (91.1)	272 (90.1)	169 (90.9)	158 (89.8)	327 (90.3)
Previous wrist problems on same side, n (%)						
Yes	34 (21.8)	35 (24.0)	69 (22.8)	37 (19.9)	37 (21)	74 (20.4)
No	121 (77.6)	111 (76.0)	232 (76.8)	148 (79.6)	138 (78.4)	286 (79.0)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	1 (0.5)	1 (0.6)	2 (0.6)
If Yes, what injury, n (%)						
Previous fracture	20 (58.8)	22 (62.9)	42 (60.9)	21 (56.8)	23 (62.2)	44 (59.5)
Arthritis	2 (5.9)	1 (2.9)	3 (4.3)	1 (2.7)	1 (2.7)	2 (2.7)
Ligament, tendon or nerve injury	6 (17.6)	8 (22.9)	14 (20.3)	7 (18.9)	8 (21.6)	15 (20.3)
Other	5 (14.7)	4 (11.4)	9 (13.0)	6 (16.2)	5 (13.5)	11 (14.9)
Missing	1 (2.9)	0 (0.0)	1 (1.4)	2 (5.4)	0 (0)	2 (2.7)
Injury mechanism, n (%)						
Fall – standing	18 (11.5)	22 (15.1)	40 (13.2)	26 (14.0)	23 (13.1)	49 (13.5)
Fall – walking	16 (10.3)	18 (12.3)	34 (11.3)	20 (10.8)	20 (11.4)	40 (11.0)
Fall – running	32 (20.5)	26 (17.8)	58 (19.2)	36 (19.4)	28 (15.9)	64 (17.7)
Fall – from height	17 (10.9)	20 (13.7)	37 (12.3)	23 (12.4)	25 (14.2)	48 (13.3)

Characteristic	26 weeks			52 weeks		
	Surgery (n=156)	Plaster cast (n=146)	Total (n=302)	Surgery (n=186)	Plaster cast (n=176)	Total (n=362)
Fall – from moving object	35 (22.4)	26 (17.8)	61 (20.2)	36 (19.4)	29 (16.5)	65 (18.0)
Hit on palm of hand – object striking palm	13 (8.3)	8 (5.5)	21 (7.0)	12 (6.5)	13 (7.4)	25 (6.9)
Hit on palm of hand – handle whipping back	7 (4.5)	8 (5.5)	15 (5.0)	7 (3.8)	10 (5.7)	17 (4.7)
Hit on palm of hand – other sudden extension	7 (4.5)	2 (1.4)	9 (3.0)	10 (5.4)	6 (3.4)	16 (4.4)
Punched something	1 (0.6)	6 (4.1)	7 (2.3)	3 (1.6)	8 (4.5)	11 (3)
Road traffic accident	8 (5.1)	4 (2.7)	12 (4.0)	9 (4.8)	6 (3.4)	15 (4.1)
Other	2 (1.3)	6 (4.1)	8 (2.6)	4 (2.2)	8 (4.5)	12 (3.3)
Place of injury[b], n (%)						
Sport	70 (44.9)	55 (37.7)	125 (41.4)	76 (40.9)	63 (35.8)	139 (38.4)
Home	16 (10.3)	25 (17.1)	41 (13.6)	22 (11.8)	34 (19.3)	56 (15.5)
Work	15 (9.6)	12 (8.2)	27 (8.9)	19 (10.2)	15 (8.5)	34 (9.4)
Road Traffic Accident	21 (13.5)	23 (15.8)	44 (14.6)	22 (11.8)	30 (17.0)	52 (14.4)
Public place	31 (19.9)	34 (23.3)	65 (21.5)	44 (23.7)	35 (19.9)	79 (21.8)
Other	2 (1.3)	0 (0.0)	2 (0.7)	2 (1.1)	0 (0.0)	2 (0.6)
Missing	3 (1.9)	0 (0.0)	3 (1.0)	3 (1.6)	2 (1.1)	5 (1.4)
Treatment preference, n (%)						
Surgery	69 (44.2)	64 (43.8)	133 (44.0)	82 (44.1)	81 (46.0)	163 (45.0)
No surgery	8 (5.1)	12 (8.2)	20 (6.6)	10 (5.4)	14 (8.0)	24 (6.6)
No preference	79 (50.6)	70 (47.9)	149 (49.3)	94 (50.5)	80 (45.5)	174 (48.1)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.3)

SD, standard deviation; min, minimum; max, maximum

[a] time from injury to screening; [b] response categories not mutually exclusive

Table 54: Displacement of fractures as stratified on in the randomisation (based on radiographic images at time of enrolment), and as agreed by three independent reviews (based on baseline radiographs and CT imaging)

Displacement agreed by three raters from baseline CT and radiographic images	Surgery (n=219)		Plaster cast (n=220)	
	No displacement (n=131)	Displacement (n=88)	No displacement (n=130)	Displacement (n=90)
<1 mm	106 (80.9)	54 (61.4)	107 (82.3)	58 (64.4)
1-2 mm, inclusive	19 (14.5)	26 (29.6)	20 (15.4)	21 (23.3)
>2 mm	5 (3.8)	8 (9.1)	3 (2.3)	11 (12.2)
Missing	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)

Table 55: Descriptive PRWE statistics over time by randomised group and treatment preference at baseline

Time point		Surgery	Plaster cast	Total
No preference				
Pre-injury	Mean (SD)	4.5 (14.1)	3.1 (12.1)	3.8 (13.2)
	Median (IQR)	0.0 (0.0, 3.0)	0.0 (0.0, 1.0)	0.0 (0.0, 2.0)
	Min, max	(0, 85)	(0, 80.11111)	(0, 85)
Baseline (post-injury)	Mean (SD)	72.9 (20.9)	70.0 (19.7)	71.5 (20.3)
	Median (IQR)	78.5 (64.0, 88.0)	73.0 (59.5, 84.5)	75.0 (62.0, 86.5)
	Min, max	(0, 100)	(0, 100)	(0, 100)
6 weeks	Mean (SD)	33.8 (21.1)	35.9 (19.0)	34.8 (20.1)
	Median (IQR)	31.3 (18.0, 46.5)	35.5 (19.5, 49.0)	34.0 (19.0, 48.0)
	Min, max	(3, 82)	(0, 80)	(0, 82)
12 weeks	Mean (SD)	20.3 (20.5)	24.8 (21.5)	22.3 (21.0)
	Median (IQR)	11.5 (5.5, 28.5)	20.3 (8.0, 31.5)	16.5 (6.0, 30.5)
	Min, max	(0, 89.5)	(0, 90)	(0, 90)
26 weeks	Mean (SD)	16.1 (18.9)	15.3 (16.7)	15.7 (17.8)
	Median (IQR)	9.0 (4.0, 20.0)	10.5 (4.0, 18.0)	9.5 (4.0, 18.5)
	Min, max	(0, 84)	(0, 77)	(0, 84)
52 weeks	Mean (SD)	12.0 (18.1)	13.3 (18.7)	12.6 (18.3)
	Median (IQR)	4.0 (0.0, 13.0)	4.8 (0.3, 16.3)	4.3 (0.0, 15.0)
	Min, max	(0, 85.5)	(0, 80.5)	(0, 85.5)
Preference for surgery				
Pre-injury	Mean (SD)	1.7 (5.5)	4.4 (12.6)	3.1 (9.9)
	Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)
	Min, max	(0, 42)	(0, 90.5)	(0, 90.5)
Baseline (post-injury)	Mean (SD)	74.5 (19.1)	76.9 (14.5)	75.7 (16.9)
	Median (IQR)	77.8 (65.4, 88.0)	78.5 (70.0, 89.5)	78.5 (68.0, 89.0)
	Min, max	(0, 98)	(27, 96.5)	(0, 98)

6 weeks	Mean (SD)	37.0 (21.3)	40.7 (23.1)	38.8 (22.2)
	Median (IQR)	34.5 (19.0, 52.0)	38.8 (24.3, 55.3)	37.5 (22.0, 53.5)
	Min, max	(4, 85.5)	(0, 100)	(0, 100)
12 weeks	Mean (SD)	21.7 (19.1)	26.9 (22.8)	24.2 (21.1)
	Median (IQR)	17.0 (7.0, 30.0)	18.5 (10.0, 35.5)	18.0 (9.8, 33.0)
	Min, max	(0, 80.5)	(0, 84.5)	(0, 84.5)
26 weeks	Mean (SD)	16.0 (18.1)	13.7 (19.2)	14.9 (18.6)
	Median (IQR)	10.0 (3.0, 22.0)	8.0 (0.0, 16.7)	9.5 (1.0, 19.0)
	Min, max	(0, 74)	(0, 91.5)	(0, 91.5)
52 weeks	Mean (SD)	10.2 (14.4)	15.0 (21.1)	12.6 (18.1)
	Median (IQR)	4.5 (0.5, 14.0)	4.0 (0.0, 24.5)	4.5 (0.0, 17.5)
	Min, max	(0, 64)	(0, 96)	(0, 96)
Preference for no surgery				
Pre-injury	Mean (SD)	2.2 (5.3)	2.3 (4.9)	2.3 (5.0)
	Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 3.0)	0.0 (0.0, 2.0)
	Min, max	(0, 17)	(0, 19.5)	(0, 19.5)
Baseline (post-injury)	Mean (SD)	77.1 (15.2)	67.5 (15.2)	71.6 (15.7)
	Median (IQR)	78.8 (69.8, 86.0)	68.5 (62.3, 78.0)	72.8 (64.3, 81.5)
	Min, max	(43, 100)	(36, 94)	(36, 100)
6 weeks	Mean (SD)	42.1 (24.8)	46.2 (17.3)	44.5 (20.4)
	Median (IQR)	45.0 (23.5, 54.5)	48.5 (30.0, 58.5)	46.3 (28.5, 57.8)
	Min, max	(4, 78.5)	(16.5, 72.5)	(4, 78.5)
12 weeks	Mean (SD)	17.5 (16.3)	27.2 (19.0)	23.3 (18.3)
	Median (IQR)	14.8 (4.5, 25.0)	24.0 (8.0, 45.0)	23.0 (8.0, 43.5)
	Min, max	(0, 54.5)	(0, 57)	(0, 57)
26 weeks	Mean (SD)	9.1 (8.8)	21.6 (16.4)	16.6 (15.0)
	Median (IQR)	6.0 (2.5, 15.0)	16.8 (11.5, 30.5)	13.5 (5.0, 24.3)
	Min, max	(0, 25.5)	(0, 51)	(0, 51)
52 weeks	Mean (SD)	15.8 (19.5)	15.5 (18.7)	15.6 (18.6)
	Median (IQR)	8.0 (2.0, 24.5)	9.5 (2.0, 27.5)	9.5 (2.0, 26.0)
	Min, max	(0, 60)	(0, 66)	(0, 66)

Table 56: Descriptive PRWE statistics over time by randomised group and fracture displacement (as randomised) at baseline

Time point		Surgery	Plaster cast	Total
Fracture displaced <1mm				
Pre-injury	Mean (SD)	3.6 (12.3)	3.8 (12.8)	3.7 (12.5)
	Median (IQR)	0.0 (0.0, 1.1)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
	Min, max	(0, 85)	(0, 90.5)	(0, 90.5)
Baseline (post-injury)	Mean (SD)	73.3 (20.4)	73.3 (18.7)	73.3 (19.5)

	Median (IQR)	78.0 (69.0, 87.0)	76.3 (64.0, 87.0)	77.5 (65.9, 87.0)
	Min, max	(0, 98)	(0, 100)	(0, 100)
6 weeks	Mean (SD)	34.4 (21.1)	38.8 (21.3)	36.5 (21.2)
	Median (IQR)	32.5 (18.0, 49.0)	38.0 (23.0, 54.5)	35.0 (19.5, 52.0)
	Min, max	(3, 82)	(0, 100)	(0, 100)
12 weeks	Mean (SD)	18.8 (17.7)	23.0 (18.9)	20.8 (18.3)
	Median (IQR)	13.8 (5.8, 24.5)	18.8 (9.1, 30.8)	17.0 (6.8, 28.3)
	Min, max	(0, 73.3)	(0, 90)	(0, 90)
26 weeks	Mean (SD)	14.8 (16.8)	13.2 (16.3)	14.0 (16.5)
	Median (IQR)	9.4 (3.5, 19.5)	8.3 (0.5, 16.0)	9.1 (2.0, 17.8)
	Min, max	(0, 84)	(0, 77)	(0, 84)
52 weeks	Mean (SD)	11.0 (17.0)	13.0 (19.4)	12.0 (18.2)
	Median (IQR)	4.3 (0.0, 12.5)	4.0 (0.0, 18.0)	4.0 (0.0, 15.0)
	Min, max	(0, 85.5)	(0, 88)	(0, 88)
Fracture displaced ≥1 mm and ≤2 mm				
Pre-injury	Mean (SD)	2.4 (8.0)	3.3 (10.4)	2.8 (9.2)
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
	Min, max	(0, 64.7)	(0, 76)	(0, 76)
Baseline (post-injury)	Mean (SD)	74.7 (18.9)	73.1 (15.5)	73.9 (17.3)
	Median (IQR)	79.5 (61.5, 90.0)	75.0 (62.9, 85.0)	76.8 (62.0, 87.5)
	Min, max	(0, 100)	(34, 99)	(0, 100)
6 weeks	Mean (SD)	37.7 (21.8)	38.7 (20.6)	38.2 (21.1)
	Median (IQR)	34.5 (22.5, 51.5)	39.0 (19.5, 50.5)	36.0 (20.5, 51.0)
	Min, max	(4, 85.5)	(4, 90.5)	(4, 90.5)
12 weeks	Mean (SD)	23.4 (22.0)	30.5 (25.3)	26.7 (23.7)
	Median (IQR)	16.3 (6.5, 38.5)	22.5 (8.0, 49.5)	18.0 (8.0, 45.0)
	Min, max	(0, 89.5)	(0, 84.5)	(0, 89.5)
26 weeks	Mean (SD)	16.9 (19.9)	18.0 (19.7)	17.4 (19.8)
	Median (IQR)	8.2 (3.3, 23.5)	12.3 (4.0, 26.0)	10.5 (3.5, 25.5)
	Min, max	(0, 74)	(0, 91.5)	(0, 91.5)
52 weeks	Mean (SD)	12.0 (16.1)	15.8 (20.2)	13.9 (18.3)
	Median (IQR)	4.0 (0.3, 16.3)	8.5 (1.0, 21.5)	6.5 (0.5, 18.5)
	Min, max	(0, 64)	(0, 96)	(0, 96)

Table 57: Descriptive PRWE statistics over time by randomised group and fracture displacement (as recorded on Study Eligibility Form) at baseline

Time point		Surgery	Plaster cast	Total
Fracture displaced <1mm				
Pre-injury	Mean (SD)	3.6 (12.3)	3.2 (11.9)	3.4 (12.1)
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)

	Min, max	(0, 85)	(0, 90.5)	(0, 90.5)
Baseline (post-injury)	Mean (SD)	73.2 (20.1)	72.5 (18.8)	72.9 (19.4)
	Median (IQR)	78.0 (68.5, 87.0)	76.0 (63.0, 87.0)	77.0 (64.5, 87.0)
	Min, max	(0, 98)	(0, 100)	(0, 100)
6 weeks	Mean (SD)	33.6 (20.7)	38.2 (21.5)	35.9 (21.2)
	Median (IQR)	32.0 (18.0, 46.5)	36.0 (21.5, 54.5)	34.3 (18.8, 50.8)
	Min, max	(3, 82)	(0, 100)	(0, 100)
12 weeks	Mean (SD)	18.1 (16.9)	22.7 (19.4)	20.3 (18.3)
	Median (IQR)	13.3 (5.5, 24.0)	18.3 (8.0, 31.0)	16.0 (6.3, 27.8)
	Min, max	(0, 73.3)	(0, 90)	(0, 90)
26 weeks	Mean (SD)	14.0 (15.1)	13.0 (16.0)	13.5 (15.5)
	Median (IQR)	9.0 (3.5, 18.8)	8.5 (0.0, 16.0)	9.0 (2.0, 17.0)
	Min, max	(0, 60)	(0, 77)	(0, 77)
52 weeks	Mean (SD)	10.4 (15.9)	13.3 (19.5)	11.8 (17.8)
	Median (IQR)	4.0 (0.0, 12.5)	4.0 (0.0, 18.5)	4.0 (0.0, 15.0)
	Min, max	(0, 85.5)	(0, 88)	(0, 88)
Fracture displaced ≥1 mm and ≤2 mm				
Pre-injury	Mean (SD)	2.4 (8.0)	4.2 (11.8)	3.3 (10.1)
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.5)	0.0 (0.0, 1.3)
	Min, max	(0, 64.7)	(0, 76)	(0, 76)
Baseline (post-injury)	Mean (SD)	74.9 (19.3)	74.2 (14.9)	74.6 (17.2)
	Median (IQR)	79.5 (61.5, 90.0)	76.3 (65.0, 85.5)	78.5 (63.0, 88.0)
	Min, max	(0, 100)	(34, 99)	(0, 100)
6 weeks	Mean (SD)	39.1 (22.1)	39.7 (20.2)	39.4 (21.1)
	Median (IQR)	35.0 (22.5, 53.5)	39.5 (25.0, 50.5)	38.4 (23.3, 51.8)
	Min, max	(4, 85.5)	(4, 90.5)	(4, 90.5)
12 weeks	Mean (SD)	24.6 (22.6)	31.1 (24.6)	27.6 (23.7)
	Median (IQR)	16.8 (6.8, 38.8)	23.0 (11.5, 48.5)	18.5 (9.5, 45.4)
	Min, max	(0, 89.5)	(0, 84.5)	(0, 89.5)
26 weeks	Mean (SD)	18.4 (22.0)	18.4 (20.1)	18.4 (21.0)
	Median (IQR)	9.3 (3.3, 24.5)	12.0 (5.0, 26.0)	10.5 (3.5, 25.5)
	Min, max	(0, 84)	(0, 91.5)	(0, 91.5)
52 weeks	Mean (SD)	13.0 (17.6)	15.5 (20.2)	14.2 (18.9)
	Median (IQR)	4.3 (0.5, 17.5)	8.8 (1.0, 21.0)	7.3 (0.5, 18.5)
	Min, max	(0, 72.5)	(0, 96)	(0, 96)

Table 58: Baseline characteristics of trial participants according to whether or not they had surgical screw penetration likely to cause cartilage damage (surgery group only), and whether surgery was required for non-union (plaster cast group only)

Characteristic	Surgery (n=142)[a]		Plaster cast (n=214)[b]	
	No surgical screw complication (n=74)	Surgical screw complication (n=68)	Required surgery (n=19)	No surgery required (n=195)
Gender, n (%)				
Male	65 (87.8)	58 (85.3)	14 (73.7)	164 (84.1)
Female	9 (12.2)	10 (14.7)	5 (26.3)	31 (15.9)
Age (years)				
N	74	68	19	195
Mean (SD)	33.1 (13.6)	33.2 (13.4)	29.8 (10.3)	33.3 (12.4)
Median (min, max)	30 (16, 69)	30 (16, 80)	26 (18, 51)	29 (16, 76)
Ethnicity, n (%)				
White	69 (93.2)	64 (94.1)	13 (68.4)	177 (90.8)
Black	0 (0.0)	0 (0.0)	2 (10.5)	2 (1.0)
Asian	2 (2.7)	3 (4.4)	2 (10.5)	8 (4.1)
Other	3 (4.1)	1 (1.5)	2 (10.5)	8 (4.1)
Education, n (%)				
No formal qualifications	6 (8.1)	3 (4.4)	0 (0.0)	27 (13.8)
Some qualifications/no degree	47 (63.5)	53 (77.9)	17 (89.5)	109 (55.9)
Degree or higher	21 (28.4)	12 (17.6)	2 (10.5)	59 (30.3)
Employment status, n (%)				
Part-time	6 (8.1)	7 (10.3)	2 (10.5)	16 (8.2)
Full-time	52 (70.3)	39 (57.4)	9 (47.4)	110 (56.4)
Self-employed	5 (6.8)	6 (8.8)	2 (10.5)	32 (16.4)
Student	5 (6.8)	6 (8.8)	4 (21.1)	15 (7.7)
Retired	4 (5.4)	3 (4.4)	0 (0.0)	5 (2.6)
Looking after family/home	0 (0.0)	0 (0.0)	1 (5.3)	5 (2.6)
Not employed but seeking work	1 (1.4)	2 (2.9)	0 (0.0)	5 (2.6)
Other	0 (0.0)	5 (7.4)	1 (5.3)	7 (3.6)
Missing	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
Type of employment, n (%)				
Unskilled manual	6 (8.1)	8 (11.8)	4 (21.1)	19 (9.7)
Skilled manual	22 (29.7)	17 (25.0)	6 (31.6)	51 (26.2)
Unskilled non-manual	3 (4.1)	11 (16.2)	1 (5.3)	11 (5.6)
Skilled non-manual	17 (23)	7 (10.3)	2 (10.5)	43 (22.1)
Professional	9 (12.2)	8 (11.8)	1 (5.3)	18 (9.2)

Characteristic	Surgery (n=142)[a]		Plaster cast (n=214)[b]	
	No surgical screw complication (n=74)	Surgical screw complication (n=68)	Required surgery (n=19)	No surgery required (n=195)
Other	9 (12.2)	6 (8.8)	1 (5.3)	29 (14.9)
Missing	8 (10.8)	11 (16.2)	4 (21.1)	24 (12.3)
Current smoker, n (%)				
Yes	21 (28.4)	22 (32.4)	6 (31.6)	48 (24.6)
No	52 (70.3)	46 (67.6)	13 (68.4)	146 (74.9)
Missing	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.5)
If Yes:				
How many cigarettes				
Median (min, max)	10 (1, 20)	9 (2, 20)	10 (1, 12)	10 (1, 30)
For how many years				
Median (min, max)	10 (2, 50)	10 (4, 36)	20 (1, 30)	10 (1, 36)
Past smoker, n (%)				
Yes	38 (51.4)	37 (54.4)	11 (57.9)	94 (48.2)
No	32 (43.2)	27 (39.7)	7 (36.8)	92 (47.2)
Missing	4 (5.4)	4 (5.9)	1 (5.3)	9 (4.6)
Diabetes, n (%)				
Yes	2 (2.7)	3 (4.4)	0 (0.0)	4 (2.1)
No	71 (95.9)	65 (95.6)	19 (100.0)	191 (97.9)
Missing	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
Steroid use, n (%)				
Yes	3 (4.1)	1 (1.5)	1 (5.3)	3 (1.5)
No	70 (94.6)	67 (98.5)	18 (94.7)	192 (98.5)
Missing	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)

[a] allocated to surgery group, received surgery and had CT imaging reviewed at 52 weeks by independent raters

Table 59: Baseline fracture details of trial participants according to whether or not they had surgical screw penetration likely to cause cartilage damage (surgery group only), and whether surgery was required for non-union (plaster cast group only)

Characteristic	Surgery (n=142)[a]		Plaster cast (n=214)[b]	
	No surgical screw complication (n=74)	Surgical screw complication (n=68)	Required surgery (n=19)	No surgery required (n=195)
Time since injury (days)[a]				
N	74	68	19	195
Mean (SD)	5.1 (3.2)	4.6 (3.0)	6.8 (3.5)	5.2 (3.3)
Median (min, max)	4 (1, 14)	4 (1, 13)	6 (1, 14)	4 (0, 14)

Characteristic	Surgery (n=142)[a]		Plaster cast (n=214)[b]	
	No surgical screw complication (n=74)	Surgical screw complication (n=68)	Required surgery (n=19)	No surgery required (n=195)
Affected wrist, n (%)				
Left	37 (50.0)	34 (50.0)	11 (57.9)	103 (52.8)
Right	37 (50.0)	34 (50.0)	8 (42.1)	92 (47.2)
Hand dominance, n (%)				
Yes	34 (45.9)	32 (47.1)	8 (42.1)	85 (43.6)
No	40 (54.1)	36 (52.9)	11 (57.9)	110 (56.4)
Displacement (eligibility), n (%)				
No displacement	39 (52.7)	42 (61.8)	8 (42.1)	123 (63.1)
Displacement	35 (47.3)	26 (38.2)	11 (57.9)	72 (36.9)
Displacement (randomisation), n (%)				
No displacement	40 (54.1)	41 (60.3)	8 (42.1)	119 (61.0)
Displacement	34 (45.9)	27 (39.7)	11 (57.9)	76 (39.0)
Radiographs[b], n (%)				
Elongated scaphoid view	71 (95.9)	65 (95.6)	19 (100.0)	185 (94.9)
Posterior-anterior view	74 (100.0)	66 (97.1)	19 (100.0)	193 (99.0)
Semi 45° supine	54 (73.0)	45 (66.2)	15 (78.9)	146 (74.9)
Lateral	74 (100.0)	68 (100.0)	19 (100.0)	192 (98.5)
Semi 45° prone	70 (94.6)	57 (83.8)	15 (78.9)	176 (90.3)
Previous wrist problems on same side, n (%)				
Yes	12 (16.2)	18 (26.5)	6 (31.6)	38 (19.5)
No	62 (83.8)	49 (72.1)	12 (63.2)	157 (80.5)
Missing	0 (0.0)	1 (1.5)	1 (5.3)	0 (0.0)
If Yes, what injury, n (%)				
Previous fracture	5 (41.7)	10 (55.6)	3 (50.0)	24 (63.2)
Arthritis	1 (8.3)	0 (0.0)	0 (0.0)	1 (2.6)
Ligament, tendon or nerve injury	4 (33.3)	4 (22.2)	0 (0.0)	8 (21.1)
Other	1 (8.3)	3 (16.7)	3 (50.0)	5 (13.2)
Missing	1 (8.3)	1 (5.6)	0 (0.0)	0 (0.0)
Injury mechanism, n (%)				
Fall – standing	9 (12.2)	9 (13.2)	2 (10.5)	26 (13.3)
Fall – walking	6 (8.1)	7 (10.3)	0 (0.0)	23 (11.8)
Fall – running	11 (14.9)	18 (26.5)	1 (5.3)	35 (17.9)
Fall – from height	10 (13.5)	10 (14.7)	4 (21.1)	29 (14.9)

Characteristic	Surgery (n=142)[a]		Plaster cast (n=214)[b]	
	No surgical screw complication (n=74)	Surgical screw complication (n=68)	Required surgery (n=19)	No surgery required (n=195)
Fall – from moving object	19 (25.7)	11 (16.2)	1 (5.3)	30 (15.4)
Hit on palm of hand – object striking palm	4 (5.4)	3 (4.4)	3 (15.8)	12 (6.2)
Hit on palm of hand – handle whipping back	3 (4.1)	3 (4.4)	3 (15.8)	8 (4.1)
Hit on palm of hand – other sudden extension	5 (6.8)	3 (4.4)	0 (0.0)	7 (3.6)
Punched something	1 (1.4)	1 (1.5)	1 (5.3)	11 (5.6)
Road traffic accident	5 (6.8)	1 (1.5)	1 (5.3)	7 (3.6)
Other	1 (1.4)	2 (2.9)	3 (15.8)	7 (3.6)
Place of injury[b], n (%)				
Sport	31 (41.9)	32 (47.1)	7 (36.8)	68 (34.9)
Home	6 (8.1)	10 (14.7)	2 (10.5)	40 (20.5)
Work	7 (9.5)	4 (5.9)	1 (5.3)	17 (8.7)
Road Traffic Accident	12 (16.2)	5 (7.4)	3 (15.8)	30 (15.4)
Public place	18 (24.3)	16 (23.5)	5 (26.3)	42 (21.5)
Other	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)
Missing	1 (1.4)	1 (1.5)	1 (5.3)	1 (0.5)
Treatment preference, n (%)				
Surgery	31 (41.9)	25 (36.8)	10 (52.6)	85 (43.6)
No surgery	7 (9.5)	2 (2.9)	1 (5.3)	18 (9.2)
No preference	36 (48.6)	41 (60.3)	8 (42.1)	91 (46.7)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)

[a] allocated to surgery group, received surgery and had CT imaging reviewed at 52 weeks by independent raters

Table 60: PRWE total and subscale scores for the surgery group stratified by whether participants had a complication caused by their surgical screw; and for the plaster cast group over time stratified by whether participants had to have surgery due to non-union

PRWE		Surgery (n=142)[a]		Plaster cast (n=214)[b]	
		No surgical screw complication (n=74)	Surgical screw complication (n=68)	Required surgery (n=19)	No surgery required (n=195)
Baseline (pre-injury)					
Pain subscale	Mean (SD)	3.5 (9.9)	1.9 (4.6)	1.7 (4.7)	2.3 (6.3)
	Median (IQR)	0.0 (0.0, 2.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)
	Min, max	(0, 50)	(0, 24)	(0, 16.3)	(0, 39)
Function subscale	Mean (SD)	2.0 (8.2)	0.6 (2.6)	1.3 (4.4)	0.9 (4.6)
	Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, max	(0, 43)	(0, 18)	(0, 18.5)	(0, 41.1)
Total	Mean (SD)	5.5 (16.9)	2.5 (6.7)	3.0 (9.0)	3.1 (10.2)
	Median (IQR)	0.0 (0.0, 2.5)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)
	Min, max	(0, 85)	(0, 42)	(0, 34.8)	(0, 80.1)
Baseline (post-injury)					
Pain subscale	Mean (SD)	34.9 (11.4)	33.8 (11.7)	36.1 (8.2)	34.0 (9.8)
	Median (IQR)	39.5 (30.0, 43.0)	36.0 (28.0, 43.0)	39.0 (30.0, 43.0)	35.0 (28.0, 42.0)
	Min, max	(0, 50)	(0, 50)	(21, 46.25)	(0, 50)
Function subscale	Mean (SD)	38.7 (10.9)	38.2 (11.3)	38.0 (11.2)	38.6 (10.0)
	Median (IQR)	41.5 (32.5, 47.0)	41.3 (33.3, 46.5)	42.0 (32.0, 46.5)	40.3 (33.5, 46.0)
	Min, max	(0, 50)	(0, 50)	(8.5, 49)	(0, 50)
Total	Mean (SD)	73.8 (21.2)	72.0 (21.2)	74.1 (16.1)	73.0 (17.5)
	Median (IQR)	79.5 (69.0, 89.0)	77.0 (59.5, 87.4)	76.6 (58.0, 86.5)	75.5 (63.8, 86.3)

	Min, max	(0, 98)	(0, 100)	(48.5, 94.5)	(0, 100)
6 weeks					
Pain subscale	Mean (SD)	18.0 (10.1)	19.1 (10.9)	20.2 (13.1)	18.1 (10.2)
	Median (IQR)	17.0 (10.0, 25.0)	19.0 (10.5, 27.0)	18.0 (10.0, 22.0)	17.0 (10.0, 26.0)
	Min, max	(3, 39)	(0, 44)	(6, 48)	(0, 47)
Function subscale	Mean (SD)	17.1 (13.4)	16.2 (12.2)	23.0 (16.2)	19.9 (11.8)
	Median (IQR)	15.0 (4.3, 25.8)	12.5 (7.0, 22.5)	19.5 (9.0, 31.0)	19.0 (10.0, 26.5)
	Min, max	(0, 44)	(0, 47)	(4, 50)	(0, 46.5)
Total	Mean (SD)	35.1 (21.5)	35.2 (21.2)	43.1 (26.8)	38.2 (19.8)
	Median (IQR)	33.3 (17.5, 52.3)	32.0 (19.5, 46.5)	42.5 (19.0, 53.0)	38.0 (23.0, 51.5)
	Min, max	(4, 77)	(3, 85.5)	(11, 98)	(0, 90.5)
12 weeks					
Pain subscale	Mean (SD)	11.4 (10.3)	13.7 (10.6)	21.9 (13.0)	13.9 (10.8)
	Median (IQR)	8.0 (3.0, 17.0)	10.0 (6.0, 20.0)	22.5 (14.0, 34.0)	11.0 (5.0, 19.0)
	Min, max	(0, 41)	(0, 45)	(0, 41)	(0, 47)
Function subscale	Mean (SD)	6.7 (8.4)	8.7 (9.9)	23.0 (13.3)	10.1 (10.7)
	Median (IQR)	4.0 (0.5, 10.0)	4.8 (1.5, 12.0)	25.5 (12.3, 31.0)	6.5 (2.0, 15.0)
	Min, max	(0, 34.5)	(0, 44.5)	(0, 46.5)	(0, 45)
Total	Mean (SD)	17.8 (18.0)	22.6 (20.1)	45.0 (24.5)	24.0 (20.6)
	Median (IQR)	13.5 (4.0, 26.0)	15.8 (8.0, 36.8)	50.5 (26.3, 64.8)	18.3 (8.3, 31.0)
	Min, max	(0, 71.5)	(0, 89.5)	(0, 75.5)	(0, 90)
26 weeks					
Pain subscale	Mean (SD)	9.2 (10.0)	10.7 (10.1)	18.3 (10.1)	9.3 (9.7)
	Median (IQR)	5.0 (2.0, 13.0)	8.0 (4.0, 15.0)	16.0 (11.0, 23.0)	7.0 (1.0, 12.0)
	Min, max	(0, 43)	(0, 39)	(6, 44)	(0, 44)
Function subscale	Mean (SD)	3.8 (7.2)	5.7 (8.0)	14.7 (13.4)	4.6 (7.7)

	Median (IQR)	1.0 (0.0, 3.5)	2.0 (0.5, 7.5)	12.0 (4.0, 23.0)	1.5 (0.0, 5.0)
	Min, max	(0, 41)	(0, 35)	(1.5, 47.5)	(0, 40)
Total	Mean (SD)	13.1 (16.7)	16.4 (17.7)	33.0 (22.3)	13.6 (16.5)
	Median (IQR)	6.3 (2.0, 15.5)	9.5 (4.0, 20.5)	32.0 (15.0, 40.0)	9.8 (1.0, 17.0)
	Min, max	(0, 84)	(0, 74)	(9, 91.5)	(0, 83)
52 weeks					
Pain subscale	Mean (SD)	6.1 (8.9)	7.2 (8.5)	16.6 (16.0)	8.5 (10.5)
	Median (IQR)	3.0 (0.0, 9.0)	4.0 (1.0, 10.0)	10.0 (4.0, 28.0)	4.0 (0.0, 13.0)
	Min, max	(0, 42)	(0, 37)	(0, 48)	(0, 47.5)
Function subscale	Mean (SD)	2.8 (6.9)	3.6 (5.7)	12.5 (16.7)	4.2 (7.5)
	Median (IQR)	0.5 (0.0, 3.0)	1.0 (0.0, 4.5)	4.0 (0.5, 16.5)	0.5 (0.0, 4.5)
	Min, max	(0, 43.5)	(0, 26)	(0, 48)	(0, 33)
Total	Mean (SD)	8.9 (15.0)	10.8 (13.9)	29.1 (32.4)	12.8 (17.4)
	Median (IQR)	3.8 (0.0, 11.3)	5.0 (1.0, 14.5)	14.0 (4.5, 47.5)	4.5 (0.0, 17.8)
	Min, max	(0, 85.5)	(0, 58)	(1, 96)	(0, 76.5)

[a] allocated to surgery group, received surgery and had CT imaging reviewed at 52 weeks by independent raters

Table 61: Baseline characteristics of trial participants according to whether or not they had a CT scan taken within 2 weeks of injury, and for the surgery group whether their surgery was conducted within two weeks of presentation at A&E

Characteristic	All (n=439)		Surgery (n=219)	
	CT ≤2wks after injury (n=412)	CT >2wks after injury (n=27)	Surgery ≤2wks after A&E presentation (n=182)	Surgery >2wks after A&E presentation (n=37) (n=)
Gender, n (%)				
Male	342 (83.0)	21 (77.8)	156 (85.7)	24 (64.9)
Female	70 (17.0)	6 (22.2)	26 (14.3)	13 (35.1)
Age (years)				
n	412	27	182	37
Mean (SD)	32.9 (12.8)	32.3 (11.4)	32.2 (12.9)	36.2 (14.2)
Median (min, max)	29 (16, 80)	30 (17, 59)	27 (16, 80)	31 (17, 61)
Ethnicity, n (%)				
White	377 (91.5)	23 (85.2)	171 (94.0)	34 (91.9)
Black	3 (0.7)	2 (7.4)	0 (0.0)	0 (0.0)
Asian	16 (3.9)	1 (3.7)	6 (3.3)	1 (2.7)
Other	15 (3.6)	0 (0.0)	5 (2.7)	0 (0.0)
Missing	1 (0.2)	1 (3.7)	0 (0.0)	2 (5.4)
Education, n (%)				
No formal qualifications	49 (11.9)	2 (7.4)	17 (9.3)	7 (18.9)
Some qualifications/no degree	263 (63.8)	17 (63.0)	126 (69.2)	25 (67.6)
Degree or higher	98 (23.8)	7 (25.9)	38 (20.9)	3 (8.1)
Missing	2 (0.5)	1 (3.7)	1 (0.5)	2 (5.4)
Employment status, n (%)				
Part-time	34 (8.3)	4 (14.8)	15 (8.2)	5 (13.5)
Full-time	237 (57.5)	10 (37.0)	108 (59.3)	19 (51.4)
Self-employed	50 (12.1)	7 (25.9)	16 (8.8)	5 (13.5)
Student	37 (9.0)	4 (14.8)	18 (9.9)	2 (5.4)

Retired	12 (2.9)	0 (0.0)	7 (3.8)	0 (0.0)
Looking after family/home	7 (1.7)	0 (0.0)	1 (0.5)	0 (0.0)
Not employed but seeking work	14 (3.4)	0 (0.0)	7 (3.8)	2 (5.4)
Other	19 (4.6)	1 (3.7)	9 (4.9)	2 (5.4)
Missing	2 (0.5)	1 (3.7)	1 (0.5)	2 (5.4)
Type of employment, n (%)				
Unskilled manual	45 (10.9)	3 (11.1)	21 (11.5)	4 (10.8)
Skilled manual	115 (27.9)	8 (29.6)	54 (29.7)	9 (24.3)
Unskilled non-manual	29 (7.0)	2 (7.4)	15 (8.2)	4 (10.8)
Skilled non-manual	76 (18.4)	3 (11.1)	29 (15.9)	4 (10.8)
Professional	37 (9.0)	2 (7.4)	18 (9.9)	2 (5.4)
Other	44 (10.7)	5 (18.5)	14 (7.7)	5 (13.5)
Missing	66 (16.0)	4 (14.8)	31 (17.0)	9 (24.3)
Current smoker, n (%)				
Yes	120 (29.1)	9 (33.3)	56 (30.8)	17 (45.9)
No	289 (70.1)	17 (63)	125 (68.7)	18 (48.6)
Missing	3 (0.7)	1 (3.7)	1 (0.5)	2 (5.4)
If yes:				
How many cigarettes				
Median (min, max)	10 (1, 40)	10 (1, 25)	10 (1, 20)	10 (1, 40)
For how many years				
Median (min, max)	10 (1, 50)	6 (1, 30)	10 (2, 50)	10 (1, 44)
Past smoker, n (%)				
Yes	209 (50.7)	16 (59.3)	95 (52.2)	21 (56.8)
No	177 (43.0)	9 (33.3)	76 (41.8)	9 (24.3)
Missing	26 (6.3)	2 (7.4)	11 (6.0)	7 (18.9)
Diabetes, n (%)				
Yes	11 (2.7)	0 (0.0)	5 (2.7)	2 (5.4)
No	399 (96.8)	26 (96.3)	176 (96.7)	33 (89.2)
Missing	2 (0.5)	1 (3.7)	1 (0.5)	2 (5.4)

Steroid use, n (%)				
Yes	9 (2.2)	1 (3.7)	5 (2.7)	1 (2.7)
No	401 (97.3)	25 (92.6)	176 (96.7)	34 (91.9)
Missing	2 (0.5)	1 (3.7)	1 (0.5)	2 (5.4)

Table 62: Baseline fracture details of trial participants according to whether or not they had a CT scan taken within 2 weeks of injury, and for the surgery group whether their surgery was conducted within two weeks of presentation at A&E

Characteristic	All (n=439)		Surgery (n=219)	
	CT ≤2wks after injury (n=412)	CT >2wks after injury (n=27)	Surgery ≤2wks after A&E presentation (n=182)	Surgery >2wks after A&E presentation (n=37)
Time since injury (days)[a]				
N	412	27	182	37
Mean (SD)	5.2 (3.2)	5.3 (3.3)	4.8 (3.0)	6.3 (3.5)
Median (min, max)	5 (0, 14)	5 (1, 14)	4 (1, 13)	6 (1, 14)
Affected wrist, n (%)				
Left	221 (53.6)	12 (44.4)	98 (53.8)	17 (45.9)
Right	191 (46.4)	15 (55.6)	84 (46.2)	20 (54.1)
Hand dominance, n (%)				
Yes	184 (44.7)	11 (40.7)	85 (46.7)	15 (40.5)
No	227 (55.1)	15 (55.6)	97 (53.3)	20 (54.1)
Missing	1 (0.2)	1 (3.7)	0 (0.0)	2 (5.4)
Displacement (eligibility), n (%)				
No displacement	253 (61.4)	16 (59.3)	111 (61.0)	24 (64.9)
Displacement	159 (38.6)	11 (40.7)	71 (39.0)	13 (35.1)
Displacement (randomisation), n (%)				
No displacement	247 (60.0)	14 (51.9)	109 (59.9)	22 (59.5)
Displacement	165 (40.0)	13 (48.1)	73 (40.1)	15 (40.5)
Radiographs[b], n (%)				

Characteristic	All (n=439)		Surgery (n=219)	
	CT ≤2wks after injury (n=412)	CT >2wks after injury (n=27)	Surgery ≤2wks after A&E presentation (n=182)	Surgery >2wks after A&E presentation (n=37)
Elongated scaphoid view	392 (95.1)	27 (100.0)	173 (95.1)	36 (97.3)
Posterior-anterior view	406 (98.5)	27 (100.0)	181 (99.5)	34 (91.9)
Semi 45° supine	305 (74.0)	20 (74.1)	132 (72.5)	27 (73.0)
Lateral	408 (99.0)	27 (100.0)	182 (100.0)	36 (97.3)
Semi 45° prone	370 (89.8)	24 (88.9)	164 (90.1)	34 (91.9)
Previous wrist problems on same side, n (%)				
Yes	81 (19.7)	7 (25.9)	36 (19.8)	7 (18.9)
No	328 (79.6)	18 (66.7)	145 (79.7)	28 (75.7)
Missing	3 (0.7)	2 (7.4)	1 (0.5)	2 (5.4)
If Yes, what injury, n (%)				
Previous fracture	47 (58)	4 (57.1)	21 (58.3)	2 (28.6)
Arthritis	3 (3.7)	0 (0)	1 (2.8)	1 (14.3)
Ligament, tendon or nerve injury	17 (21)	1 (14.3)	9 (25.0)	1 (14.3)
Other	13 (16)	1 (14.3)	4 (11.1)	2 (28.6)
Missing	1 (1.2)	1 (14.3)	1 (2.8)	1 (14.3)
Injury mechanism, n (%)				
Fall – standing	53 (12.9)	4 (14.8)	21 (11.5)	7 (18.9)
Fall – walking	45 (10.9)	3 (11.1)	18 (9.9)	6 (16.2)
Fall – running	74 (18.0)	4 (14.8)	37 (20.3)	3 (8.1)
Fall – from height	60 (14.6)	2 (7.4)	25 (13.7)	3 (8.1)

Characteristic	All (n=439)		Surgery (n=219)	
	CT ≤2wks after injury (n=412)	CT >2wks after injury (n=27)	Surgery ≤2wks after A&E presentation (n=182)	Surgery >2wks after A&E presentation (n=37)
Fall – from moving object	69 (16.7)	4 (14.8)	40 (22.0)	2 (5.4)
Hit on palm of hand – object striking palm	30 (7.3)	1 (3.7)	9 (4.9)	7 (18.9)
Hit on palm of hand – handle whipping back	20 (4.9)	0 (0.0)	9 (4.9)	0 (0.0)
Hit on palm of hand – other sudden extension	16 (3.9)	3 (11.1)	8 (4.4)	3 (8.1)
Punched something	15 (3.6)	1 (3.7)	4 (2.2)	0 (0.0)
Road traffic accident	15 (3.6)	2 (7.4)	7 (3.8)	2 (5.4)
Other	14 (3.4)	2 (7.4)	4 (2.2)	2 (5.4)
Missing	1 (0.2)	1 (3.7)	0 (0.0)	2 (5.4)
Place of injury[b], n (%)				
Sport	156 (37.9)	10 (37.0)	77 (42.3)	11 (29.7)
Home	64 (15.5)	6 (22.2)	20 (11.0)	7 (18.9)
Work	38 (9.2)	2 (7.4)	14 (7.7)	8 (21.6)
Road Traffic Accident	57 (13.8)	3 (11.1)	24 (13.2)	2 (5.4)
Public place	93 (22.6)	4 (14.8)	43 (23.6)	6 (16.2)
Other	3 (0.7)	0 (0.0)	3 (1.6)	0 (0.0)
Missing	5 (1.2)	1 (3.7)	3 (1.6)	1 (2.7)
Treatment preference, n (%)				
Surgery	180 (43.7)	14 (51.9)	75 (41.2)	18 (48.6)

Characteristic	All (n=439)		Surgery (n=219)	
	CT ≤2wks after injury (n=412)	CT >2wks after injury (n=27)	Surgery ≤2wks after A&E presentation (n=182)	Surgery >2wks after A&E presentation (n=37)
No surgery	29 (7.0)	3 (11.1)	10 (5.5)	3 (8.1)
No preference	200 (48.5)	9 (33.3)	96 (52.7)	14 (37.8)
Missing	3 (0.7)	1 (3.7)	1 (0.5)	2 (5.4)

Table 63: PRWE total and subscale scores according to whether or not participants had a CT scan taken within 2 weeks of injury, and for the surgery group whether their surgery was conducted within two weeks of presentation at A&E

PRWE		All (n=439)		Surgery (n=219)	
		CT ≤2wks after injury (n=412)	CT >2wks after injury (n=27)	Surgery ≤2wks after A&E presentation (n=182)	Surgery >2wks after A&E presentation (n=37)
Baseline (pre-injury)					
Pain subscale	Mean (SD)	2.3 (6.6)	3.2 (9.3)	2.2 (6.6)	2.2 (6.3)
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)
	Min, max	(0, 50)	(0, 35)	(0, 50)	(0, 32.5)
Function subscale	Mean (SD)	1.0 (5.1)	2.4 (9.0)	0.9 (5.0)	1.3 (5.8)
	Median (IQR)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, max	(0, 49.5)	(0, 41)	(0, 43)	(0, 32.2)
Total	Mean (SD)	3.2 (10.9)	5.7 (17.9)	3.1 (10.7)	3.4 (11.8)
	Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)
	Min, max	(0, 90.5)	(0, 76)	(0, 85)	(0, 64.7)
Baseline (post-injury)					
Pain subscale	Mean (SD)	34.5 (10.2)	33.9 (10.8)	34.3 (11.1)	36.7 (8.8)
	Median (IQR)	36.0 (29.0, 42.0)	35.5 (25.0, 43.0)	36.0 (28.0, 42.0)	38.0 (31.0, 42.0)
	Min, max	(0, 50)	(8.75, 47)	(0, 50)	(2, 50)
Function subscale	Mean (SD)	39.0 (10.3)	36.7 (9.4)	38.7 (10.9)	41.3 (7.6)
	Median (IQR)	41.5 (33.5, 46.5)	40.0 (34.5, 42.5)	42.0 (33.0, 46.5)	41.0 (37.5, 48.5)
	Min, max	(0, 50)	(15, 49)	(0, 50)	(20, 50)
Total	Mean (SD)	73.7 (18.6)	71.6 (18.2)	73.1 (20.5)	78.0 (14.7)
	Median (IQR)	77.5 (64.0, 87.5)	75.5 (70.0, 85.0)	78.0 (62.0, 88.0)	79.0 (71.0, 87.5)
	Min, max	(0, 100)	(35, 96)	(0, 100)	(22, 100)

6 weeks					
Pain subscale	Mean (SD)	18.5 (10.6)	21.6 (9.3)	18.7 (10.3)	20.4 (12.1)
	Median (IQR)	18.0 (10.0, 26.0)	21.0 (14.5, 28.5)	19.0 (10.0, 26.0)	18.0 (10.0, 33.0)
	Min, max	(0, 50)	(6, 38)	(0, 44)	(2, 38)
Function subscale	Mean (SD)	18.3 (12.6)	22.5 (14.6)	16.2 (12.4)	21.1 (15.2)
	Median (IQR)	16.5 (8.0, 26.5)	23.5 (14.5, 32.5)	13.0 (6.1, 25.0)	16.0 (9.5, 32.0)
	Min, max	(0, 50)	(0, 46)	(0, 44.5)	(0, 47)
Total	Mean (SD)	36.8 (21.1)	45.4 (21.3)	34.9 (20.8)	41.5 (24.6)
	Median (IQR)	35.0 (19.5, 51.3)	43.3 (33.0, 63.3)	33.5 (18.5, 48.5)	39.5 (19.5, 62.0)
	Min, max	(0, 100)	(6, 84)	(3, 85.5)	(6, 82)
12 weeks					
Pain subscale	Mean (SD)	13.4 (10.9)	19.9 (13.3)	12.6 (10.9)	14.5 (11.6)
	Median (IQR)	11.0 (5.0, 18.0)	23.0 (7.5, 31.5)	9.0 (4.0, 17.5)	12.5 (5.0, 18.0)
	Min, max	(0, 47)	(0, 41)	(0, 45)	(0, 40)
Function subscale	Mean (SD)	9.1 (10.2)	17.8 (14.3)	7.7 (9.1)	9.7 (10.2)
	Median (IQR)	5.5 (1.5, 12.0)	17.8 (5.0, 27.5)	4.3 (1.0, 11.0)	7.4 (1.5, 12.0)
	Min, max	(0, 45)	(0, 46.5)	(0, 44.5)	(0, 34)
Total	Mean (SD)	22.5 (20.3)	37.8 (25.9)	20.2 (19.4)	24.2 (21.2)
	Median (IQR)	17.0 (7.0, 30.0)	38.8 (11.5, 60.0)	14.1 (6.0, 26.8)	18.8 (8.0, 28.5)
	Min, max	(0, 90)	(0, 78.5)	(0, 89.5)	(0, 73.3)
26 weeks					
Pain subscale	Mean (SD)	10.0 (10.3)	15.1 (9.8)	10.1 (10.4)	12.9 (12.4)
	Median (IQR)	7.0 (2.0, 13.0)	13.0 (7.0, 23.0)	7.0 (3.0, 15.0)	8.0 (2.0, 24.0)
	Min, max	(0, 44)	(0, 35)	(0, 43)	(0, 36)
Function subscale	Mean (SD)	5.3 (8.5)	7.5 (8.4)	5.0 (8.0)	7.9 (10.5)
	Median (IQR)	1.5 (0.0, 5.6)	4.4 (1.5, 10.5)	1.5 (0.3, 5.3)	4.0 (0.0, 13.0)

	Min, max	(0, 47.5)	(0, 24)	(0, 41)	(0, 41)
Total	Mean (SD)	15.1 (18.0)	21.0 (15.6)	15.2 (17.9)	19.4 (19.8)
	Median (IQR)	9.5 (2.5, 18.5)	15.5 (11.5, 36.5)	9.0 (3.5, 19.0)	12.0 (2.0, 37.5)
	Min, max	(0, 91.5)	(0, 45)	(0, 84)	(0, 55.5)
52 weeks					
Pain subscale	Mean (SD)	8.1 (10.4)	14.2 (14.0)	7.5 (9.9)	9.1 (11.4)
	Median (IQR)	4.0 (0.0, 11.0)	14.0 (2.0, 20.0)	4.0 (0.0, 10.0)	3.0 (0.0, 17.5)
	Min, max	(0, 47.5)	(0, 48)	(0, 42)	(0, 37)
Function subscale	Mean (SD)	4.0 (7.6)	9.8 (13.4)	3.5 (6.9)	5.3 (8.8)
	Median (IQR)	0.5 (0.0, 4.0)	4.0 (0.0, 14.5)	1.0 (0.0, 3.5)	0.5 (0.0, 10.3)
	Min, max	(0, 44)	(0, 48)	(0, 43.5)	(0, 31)
Total	Mean (SD)	12.1 (17.5)	24.0 (27.0)	11.0 (16.1)	14.4 (19.7)
	Median (IQR)	4.0 (0.0, 15.0)	17.5 (2.0, 32.5)	4.0 (0.5, 13.5)	4.3 (0.0, 27.8)
	Min, max	(0, 88)	(0, 96)	(0, 85.5)	(0, 60)

Table 64: Participant responses to questions relating to written advice about home exercises to perform to care for their wrist, asked on week 12 questionnaire

Returned 12 week questionnaire	**Surgery (n=182)**	**Plaster cast (n=167)**	**Total (n=349)**
How useful did you find the written advice about home exercises for your hand and wrist?, n (%)			
Very useful	59 (32.4)	38 (22.8)	97 (27.8)
Quite useful	92 (50.6)	85 (50.9)	177 (50.7)
Not very useful at all	15 (8.2)	21 (12.6)	36 (10.3)
Not at all useful	10 (5.5)	11 (6.6)	21 (6.0)
Missing	6 (3.3)	12 (7.2)	18 (5.2)
Have you done any of these home exercises?, n (%)			

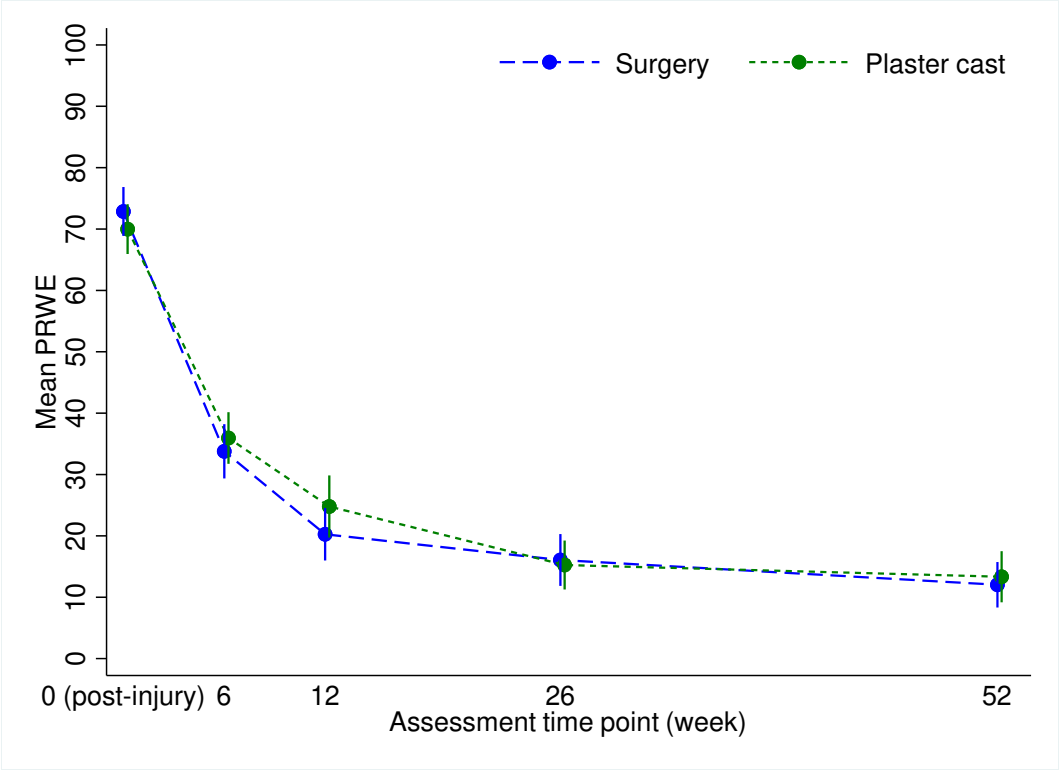
Yes	151 (83.0)	136 (81.4)	287 (82.2)
No	25 (13.7)	23 (13.8)	48 (13.8)
Missing	6 (3.3)	8 (4.8)	14 (4.0)
If 'Yes' on how many days over the past 12 weeks have you done these exercises?			
Mean (SD)	41.8 (28.5)	44.7 (28.6)	43.1 (28.5)
Median (min, max)	35 (2, 137)	41 (1, 168)	38 (1, 168)
Would you have preferred to have a formal referral to physiotherapy for your wrist injury?,n (%)			
Yes	67 (36.8)	56 (33.5)	123 (35.2)
No	102 (56.0)	98 (58.7)	200 (57.3)
Missing	13 (7.1)	13 (7.8)	26 (7.5)

Table 65: Participant responses to questions relating to the current state of their wrist, and treatment preference, asked on 52-week questionnaire

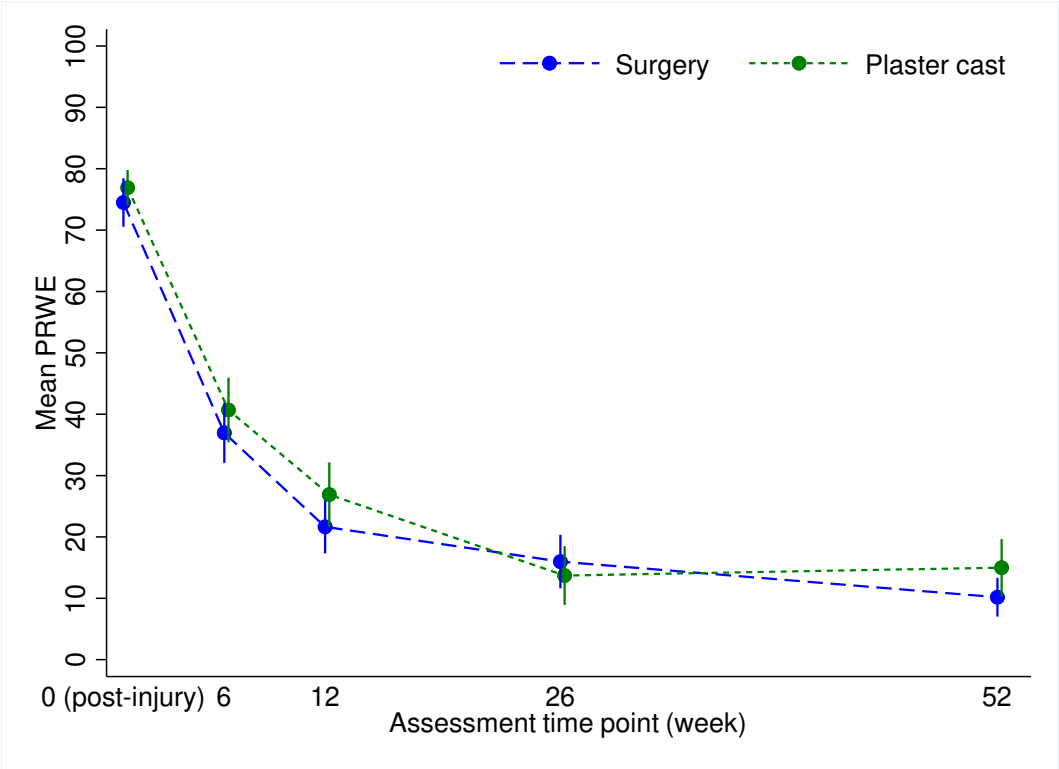
Returned 12 month questionnaire	**Surgery (n=186)**	**Plaster cast (n=178)**	**Total (n=364)**
Compared with one year ago how is your wrist now?, n (%)			
Much better now	149 (80.1)	139 (78.1)	288 (79.1)
Slightly better now	17 (9.1)	17 (9.6)	34 (9.3)
About the same now	9 (4.8)	11 (6.2)	20 (5.5)
Slightly worse now	5 (2.7)	4 (2.3)	9 (2.5)
Much worse now	1 (0.5)	3 (1.7)	4 (1.1)
Missing	5 (2.7)	4 (2.3)	9 (2.5)
Based upon your experiences of the treatment that you received as part of this trial, if you injured your wrist today to the same extent as you did one year ago, which treatment would you prefer?, n (%)			
No preference	36 (19.4)	68 (38.2)	104 (28.6)
Surgery	137 (73.7)	59 (33.2)	196 (53.9)

Not surgery	8 (4.3)	48 (27.0)	56 (15.4)
Missing	5 (2.7)	3 (1.7)	8 (2.2)

(a)


Surgery
Plaster cast
Mean PRWE
0
10
20
30
40
50
60
70
80
90
100
0 (post-injury)
6
12
26
52
Assessment time point (week)

(b)


Surgery
Plaster cast
Mean PRWE
0
10
20
30
40
50
60
70
80
90
100
0 (post-injury)
6
12
26
52
Assessment time point (week)

(c)

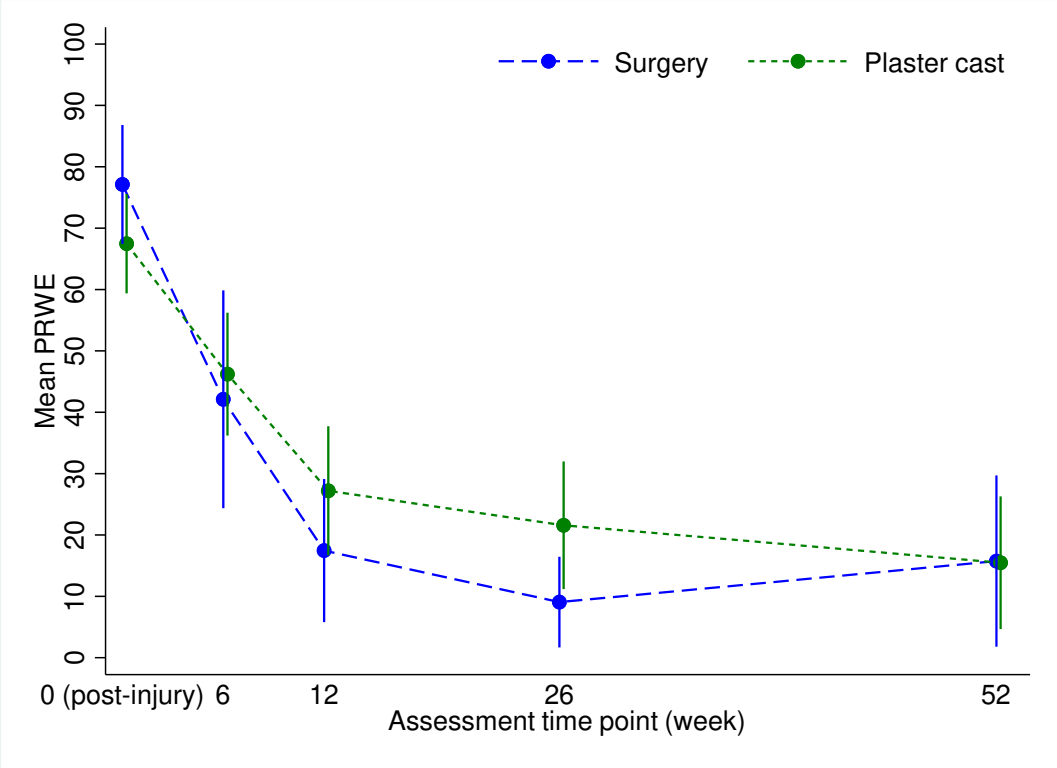
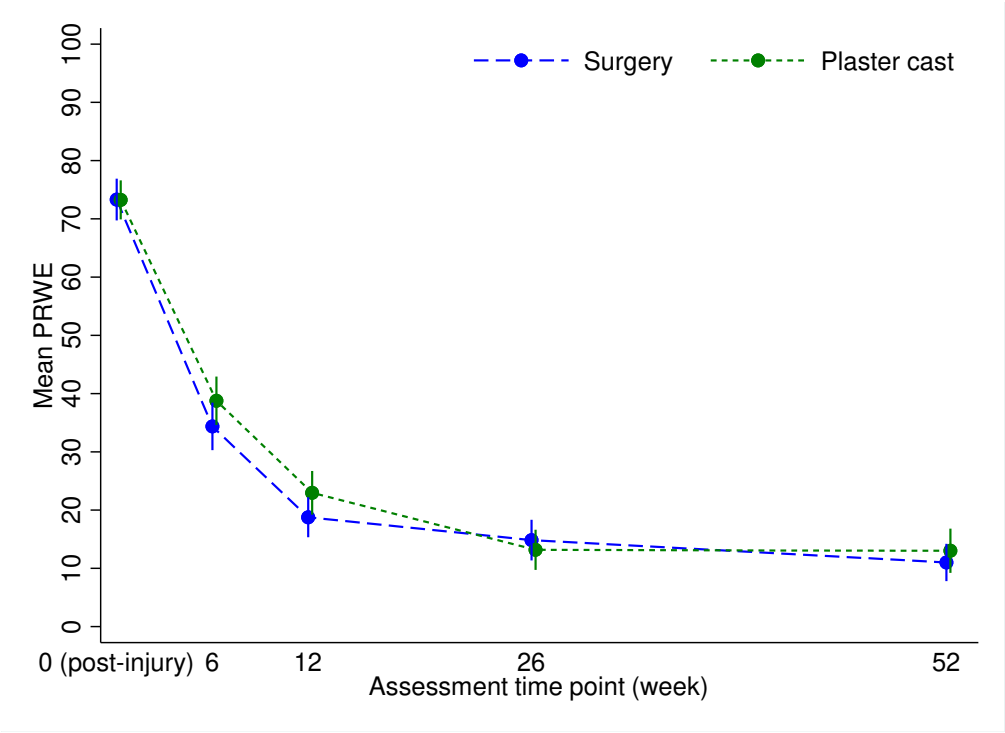


Figure 14: Unadjusted mean PRWE scores (with 95% CIs) over time by randomised group and patient treatment preference at baseline (a) No preference (b) Preference for surgery and (c) Preference for no surgery

(a)



(b)

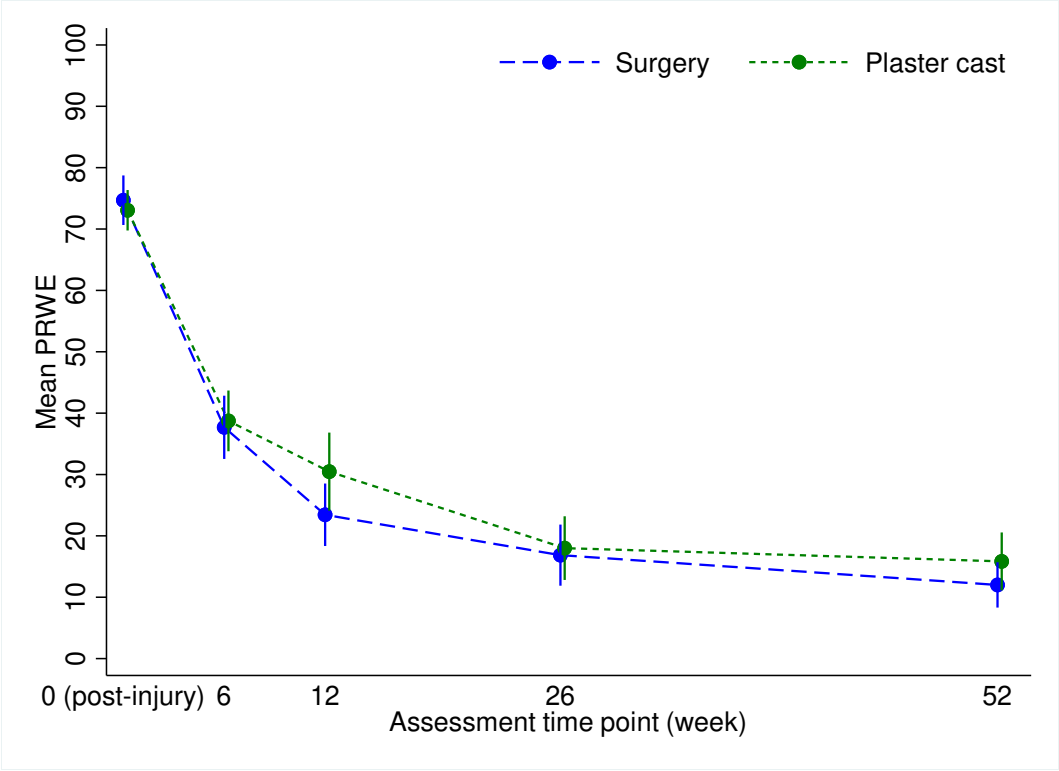
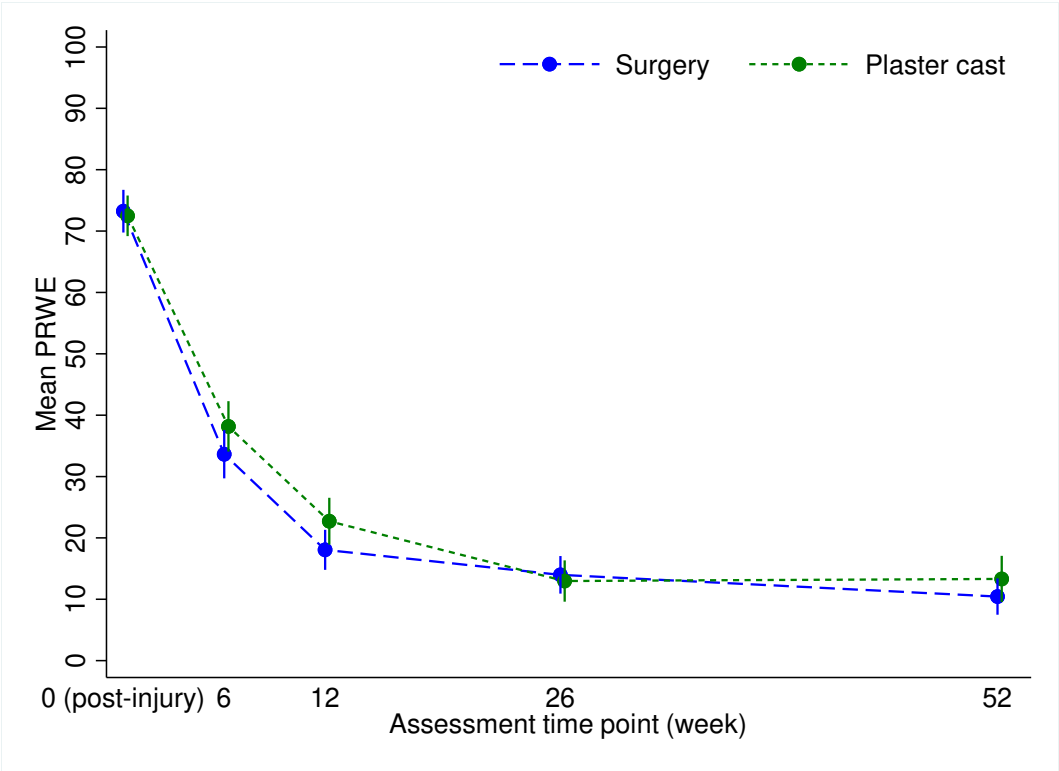


Figure 15: Unadjusted mean PRWE scores (with 95% CIs) over time by randomised group and fracture displacement (as randomised) at baseline (a) < 1 mm and (b) ≥1 mm and ≤2 mm

(a)



(b)

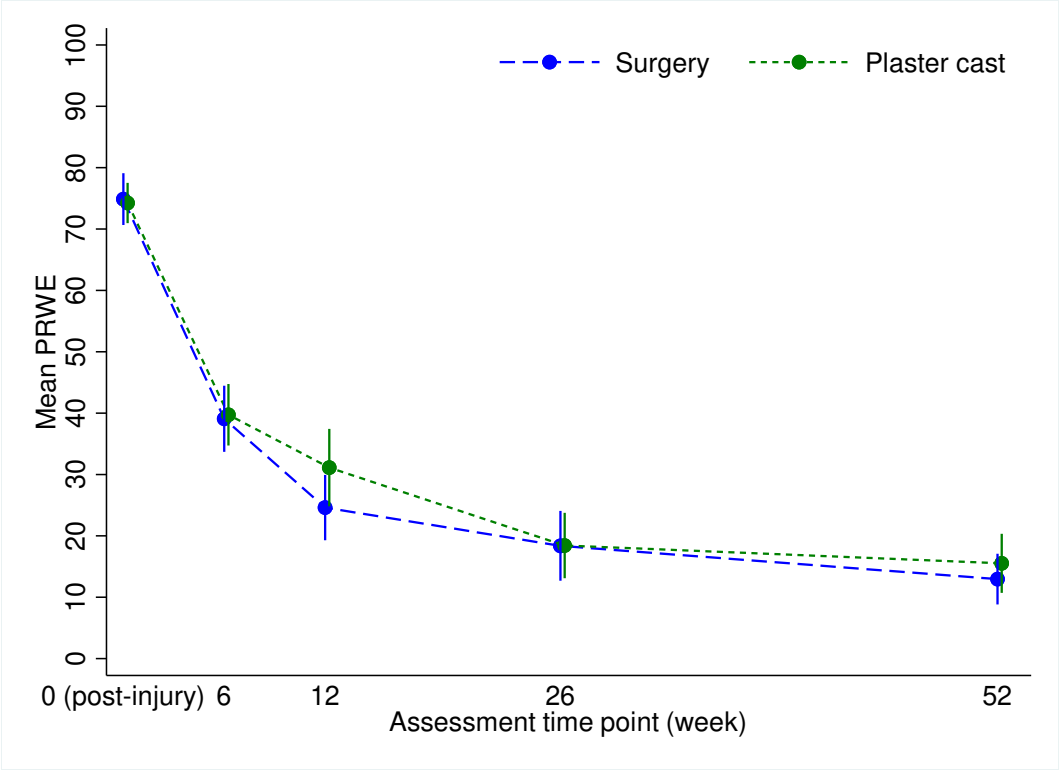
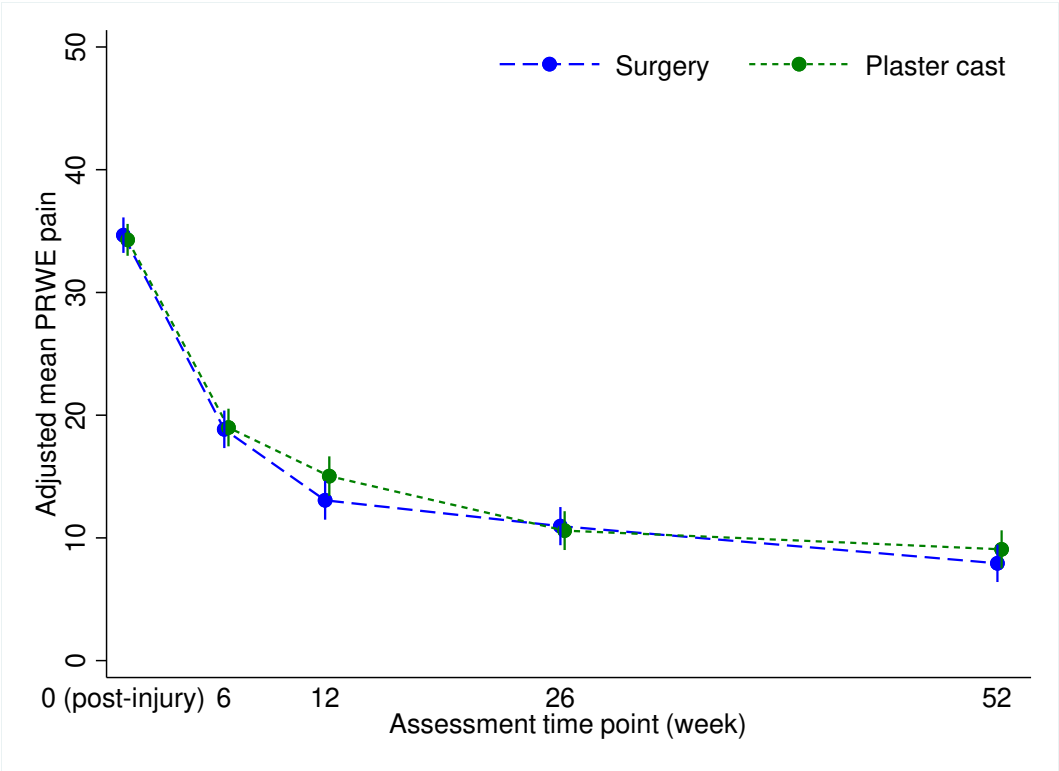


Figure 16: Unadjusted mean PRWE scores (with 95% CIs) over time by randomised group and fracture displacement (as recorded on Study Eligibility Form) at baseline (a) < 1 mm and (b) ≥1 mm and ≤2 mm

(a)



(b)

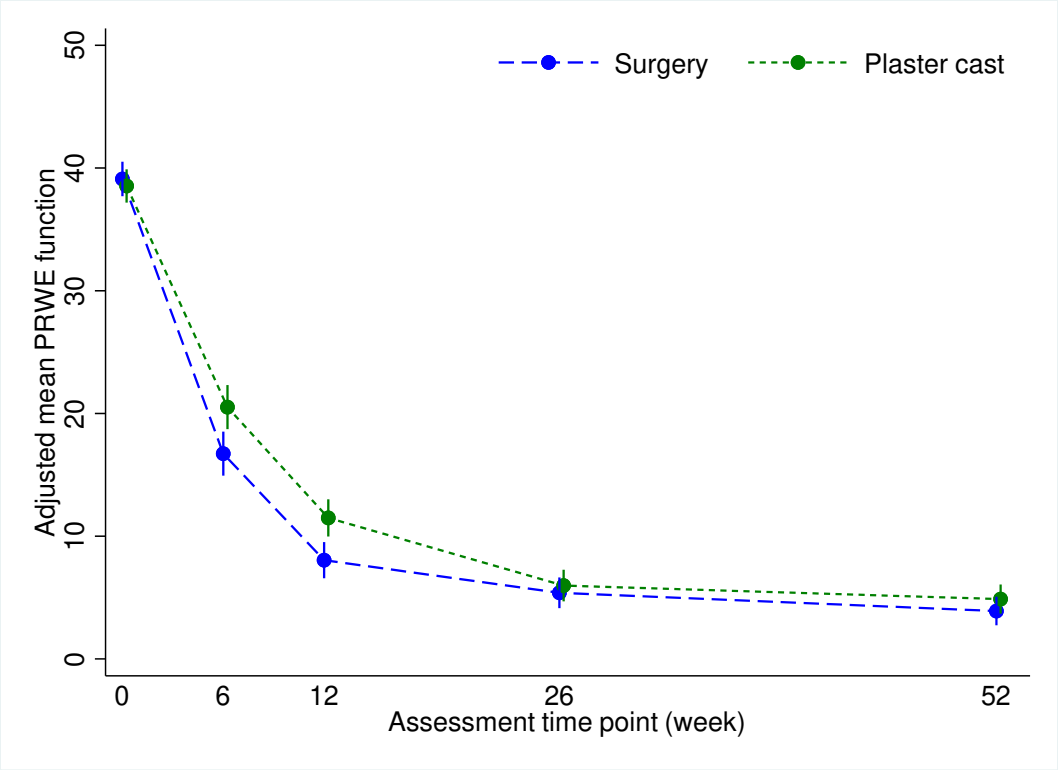
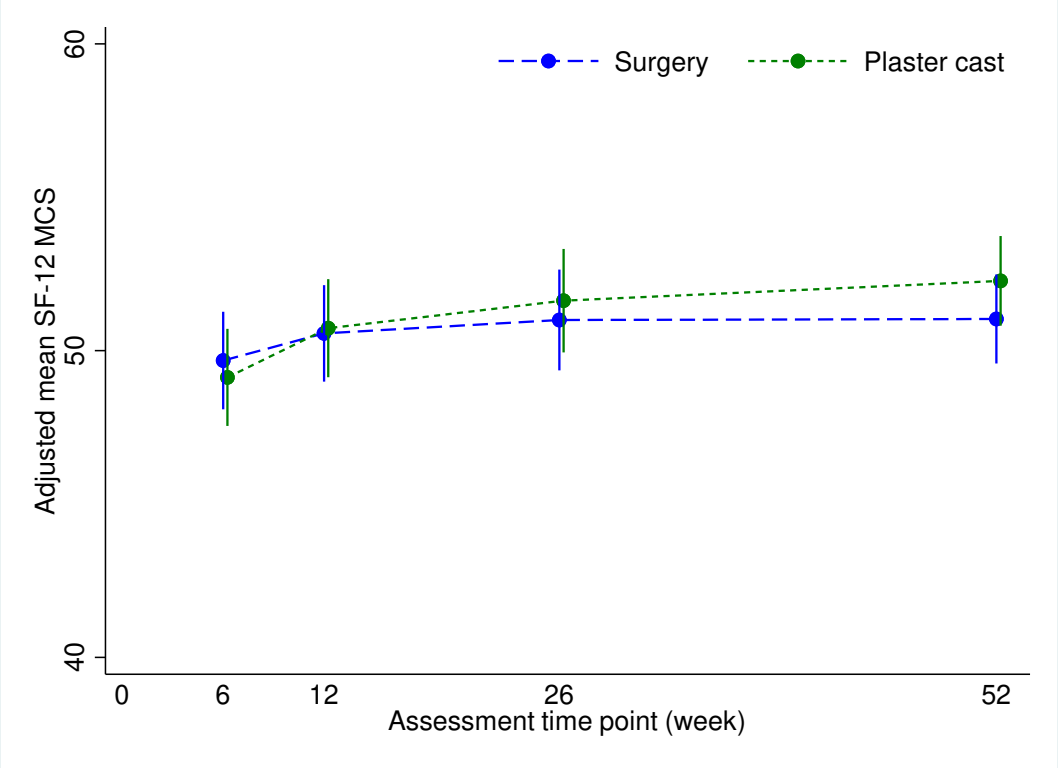


Figure 17: Adjusted mean PRWE subscale scores (with 95% CIs) over time by randomised group (a) pain and (b) function

(a)



(b)

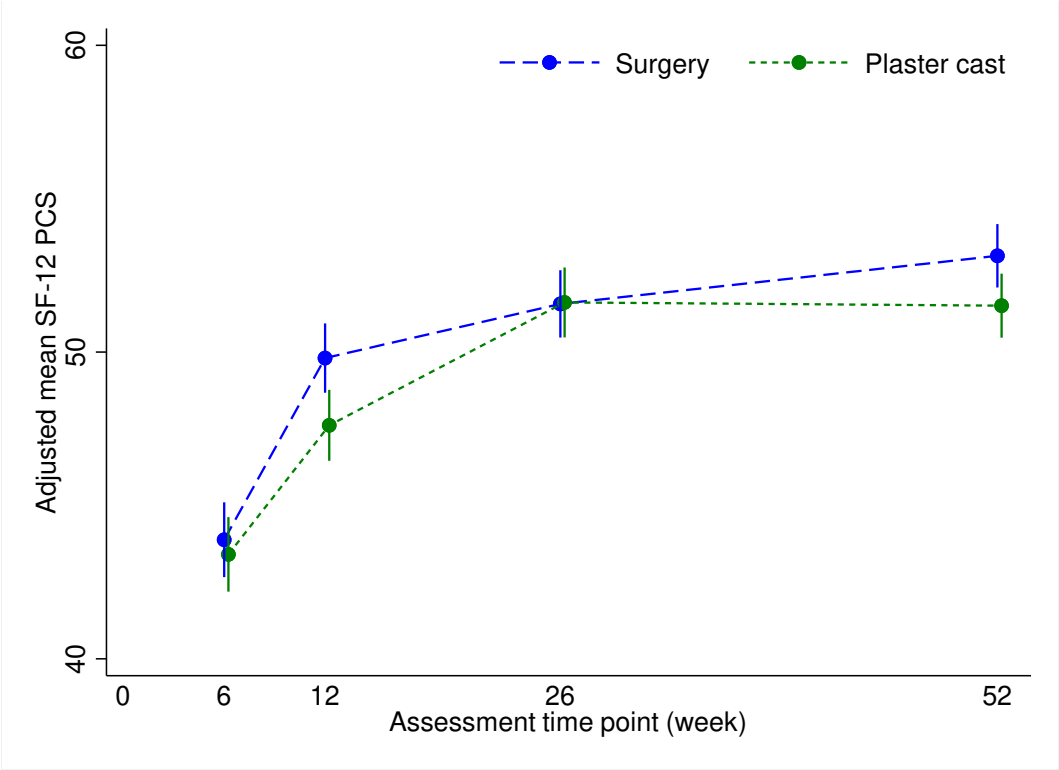


Figure 18: Adjusted mean SF-12 component subscale scores (with 95% CIs) over time by randomised group (a) MCS and (b) PCS

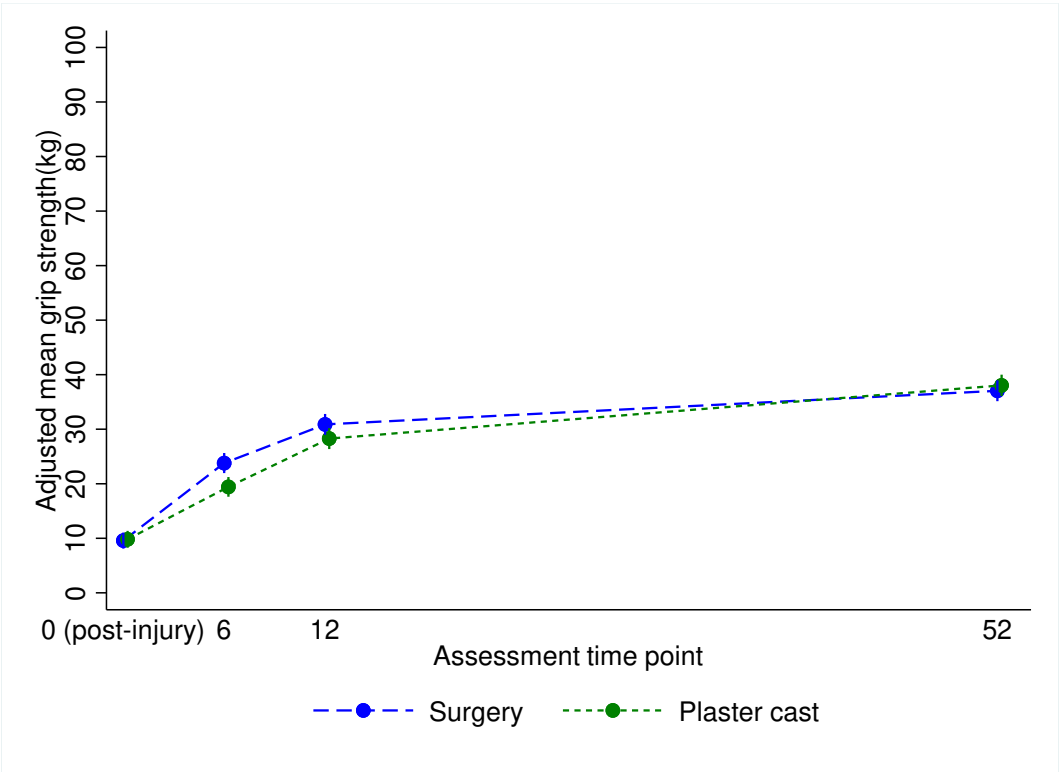


Figure 19: Adjusted mean grip strength (with 95% CIs) over time by randomised group

Appendix 4: Software output for primary analysis model

```
. mixed prwesum age i.fracturedisplacement i.injarm_M0 i.allocation##i.time || part:, noconstant
>  residuals(unstructured, t(time)) reml

Obtaining starting values by EM:

Performing gradient-based optimization:

Iteration 0:   log restricted-likelihood =  -5879.473  (not concave)
Iteration 1:   log restricted-likelihood = -5632.2982
Iteration 2:   log restricted-likelihood = -5611.4274
Iteration 3:   log restricted-likelihood = -5585.4815
Iteration 4:   log restricted-likelihood = -5584.6234
Iteration 5:   log restricted-likelihood = -5584.6207
Iteration 6:   log restricted-likelihood = -5584.6207

Computing standard errors:

Mixed-effects REML regression                   Number of obs     =      1,345
Group variable: participantid                   Number of groups  =        406

                                                Obs per group:
                                                              min =          1
                                                              avg =        3.3
                                                              max =          4

                                                Wald chi2(10)     =     545.12
Log restricted-likelihood = -5584.6207          Prob > chi2       =     0.0000
```

prwesum	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
age	.1913108	.0643396	2.97	0.003	.0652074	.3174142
fracturedisplacement						
Displacement	2.875526	1.693336	1.70	0.089	-.4433527	6.194404
injarm_M0						
No	-2.688593	1.677597	-1.60	0.109	-5.976623	.5994366
allocation						
Surgical fixation	-4.345097	2.191697	-1.98	0.047	-8.640744	-.0494512
time						
12	-13.31875	1.385872	-9.61	0.000	-16.03501	-10.60249
26	-23.35383	1.540652	-15.16	0.000	-26.37345	-20.33421
52	-25.92022	1.585252	-16.35	0.000	-29.02726	-22.81318
allocation#time						
Surgical fixation#12	-1.154507	1.922734	-0.60	0.548	-4.922997	2.613983
Surgical fixation#26	3.997146	2.148946	1.86	0.063	-.2147109	8.209004
Surgical fixation#52	2.247439	2.212047	1.02	0.310	-2.088092	6.582971
_cons	33.85504	2.862057	11.83	0.000	28.24551	39.46457

Random-effects Parameters	Estimate	Std. Err.	[95% Conf.	Interval]
participan~d: (empty)				
Residual: Unstructured				
var(e6)	439.5566	34.14463	377.4798	511.842
var(e12)	429.3117	33.16045	368.9989	499.4826
var(e26)	342.8587	27.64151	292.7458	401.55
var(e52)	342.5324	25.92882	295.303	397.3154
cov(e6,e12)	285.6388	28.50836	229.7634	341.5141
cov(e6,e26)	204.2326	25.65127	153.957	254.5081
cov(e6,e52)	180.8446	23.73652	134.3219	227.3673
cov(e12,e26)	273.1248	26.02855	222.1097	324.1398
cov(e12,e52)	228.317	24.05816	181.1638	275.4701
cov(e26,e52)	253.1665	23.24352	207.61	298.7229

```
LR test vs. linear model: chi2(9) = 589.70                Prob > chi2 = 0.0000
```

Appendix 5: Analysis of the agreement between raters on the imaging

Introduction

This report describes the agreement study that was conducted to validate the radiology assessments that were fed into the trial analysis. All X-rays and CT scans were assessed independently by three raters and where there was disagreement, the three met to discuss the assessment and a consensus was reached. This study looks at the agreement at the first stage, that is prior to the consensus meeting.

Methods

The assessments of the three raters were compared in pairs, i.e. A with B, A with C and B with C. When a categorical assessment was required, the measure of agreement was taken to be the percentage of X-rays or CT scans on which the two raters gave exactly the same grade. It was decided that 50% agreement was acceptable and that 80% or greater agreement was good. Percentage agreement is reported together with a 95% confidence interval.

When a continuous assessment was required, the measure of agreement was taken to be the 95% limits of agreement and the data were displayed as a Bland-Altman plot. The limits of agreement depend on the standard deviation of the differences between the two raters and an acceptable agreement was defined as a standard deviation that was less that 25% the range of the scale. A standard deviation that was less than 10% of the range was considered good. The range was taken to be the difference between the largest and smallest measurements made by either of the two raters.

Fracture

X-ray at Baseline

Rater A vs B

	Rater B				
Rater A	Clear	Seen	Just	No	(Missing)	All
Clear	180	72	10	0	50	312
Seen	21	33	27	4	16	101
Just	1	3	15	0	6	25
No	0	0	0	0	0	0

(Missing)	0	0	0	0	0	0
All	202	108	52	4	72	438

Both raters graded 366 X-rays with 62.3% agreement, 95%CI (57.3, 67.3).

Agreement was classified as acceptable.

Rater A vs C

	Rater C					
Rater A	Clear	Seen	Just	No	(Missing)	All
Clear	277	26	5	0	4	312
Seen	59	29	10	2	1	101
Just	5	6	6	8	0	25
No	0	0	0	0	0	0
(Missing)	0	0	0	0	0	0
All	341	61	21	10	5	438

Both raters graded 433 X-rays with 72.1% agreement, 95%CI (67.8, 76.3).

Agreement was classified as acceptable.

Rater B vs C

	Rater C					
Rater B	Clear	Seen	Just	No	(Missing)	All
Clear	188	13	1	0	0	202
Seen	84	18	5	1	0	108
Just	18	15	10	8	1	52
No	2	2	0	0	0	4
(Missing)	49	13	5	1	4	72
All	341	61	21	10	5	438

Both raters graded 365 X-rays with 59.2% agreement, 95%CI (54.1, 64.2).

Agreement was classified as acceptable.

CT at Baseline

Rater A vs B

	Rater B					
Rater A	Clear	Seen	Just	No	(Missing)	All
Clear	142	39	6	0	45	232
Seen	27	45	34	1	22	129
Just	2	17	31	6	12	68
No	0	0	1	0	1	2
(Missing)	0	0	0	0	0	0
All	171	101	72	7	80	431

Both raters graded 351 CT scans with 62.1% agreement, 95%CI (57, 67.2).

Agreement was classified as acceptable.

Rater A vs C

	Rater C					
Rater A	Clear	Seen	Just	No	(Missing)	All
Clear	227	5	0	0	0	232
Seen	84	25	18	1	1	129
Just	20	12	29	7	0	68
No	0	1	0	1	0	2
(Missing)	0	0	0	0	0	0
All	331	43	47	9	1	431

Both raters graded 430 CT scans with 65.6% agreement, 95%CI (61.1, 70.1).

Agreement was classified as acceptable.

Rater B vs C

	Rater C				
Rater B	Clear	Seen	Just	No	(Missing)	All
Clear	168	3	0	0	0	171
Seen	73	20	8	0	0	101
Just	26	13	26	6	1	72
No	0	1	5	1	0	7
(Missing)	64	6	8	2	0	80
All	331	43	47	9	1	431

Both raters graded 350 CT scans with 61.4% agreement, 95%CI (56.3, 66.5).

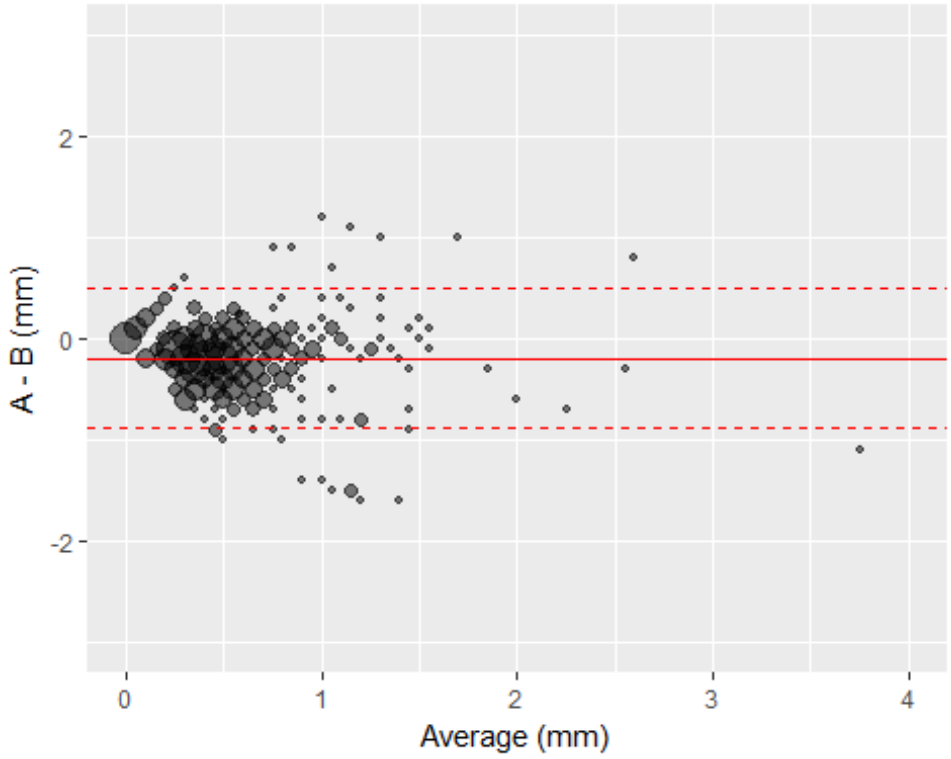
Agreement was classified as acceptable.

Displacement at Baseline

The Bland-Altman plots of displacement show the difference in the measurement between two raters against their average measurement. Horizontal lines show the average difference (solid) and the 95% limits of agreement (dashed).

Gap in X-ray

Rater A vs B

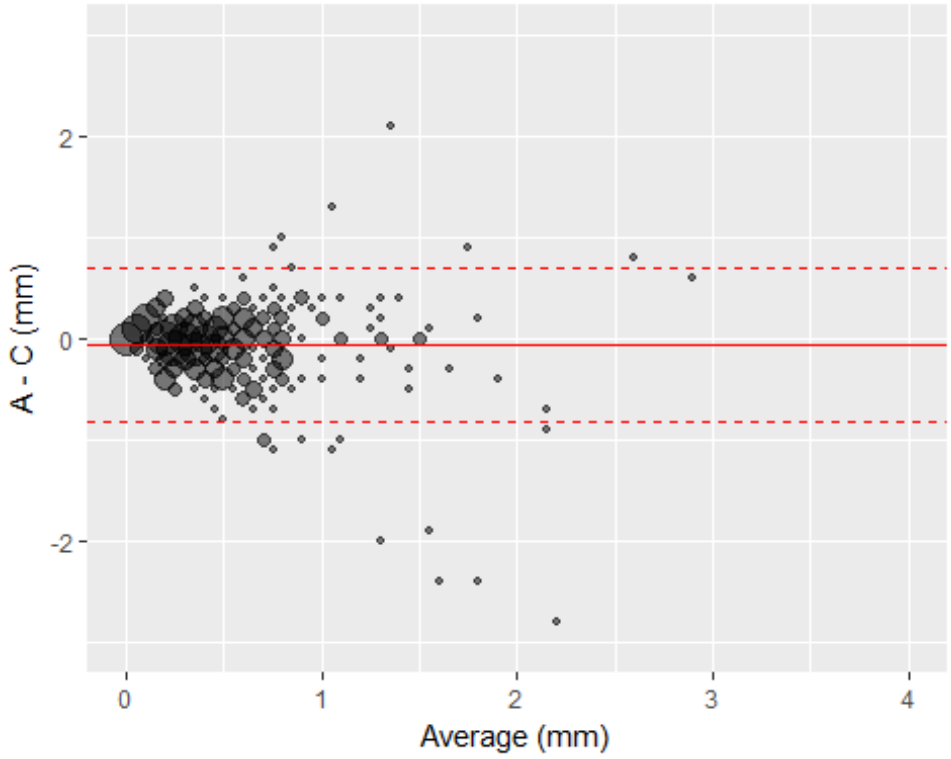


95% limits of agreement (-0.88mm, 0.5mm).

The standard deviation of the differences was 0.35 which is 11% of the range of 3.2.

Agreement was classified as acceptable.

Rater A vs C

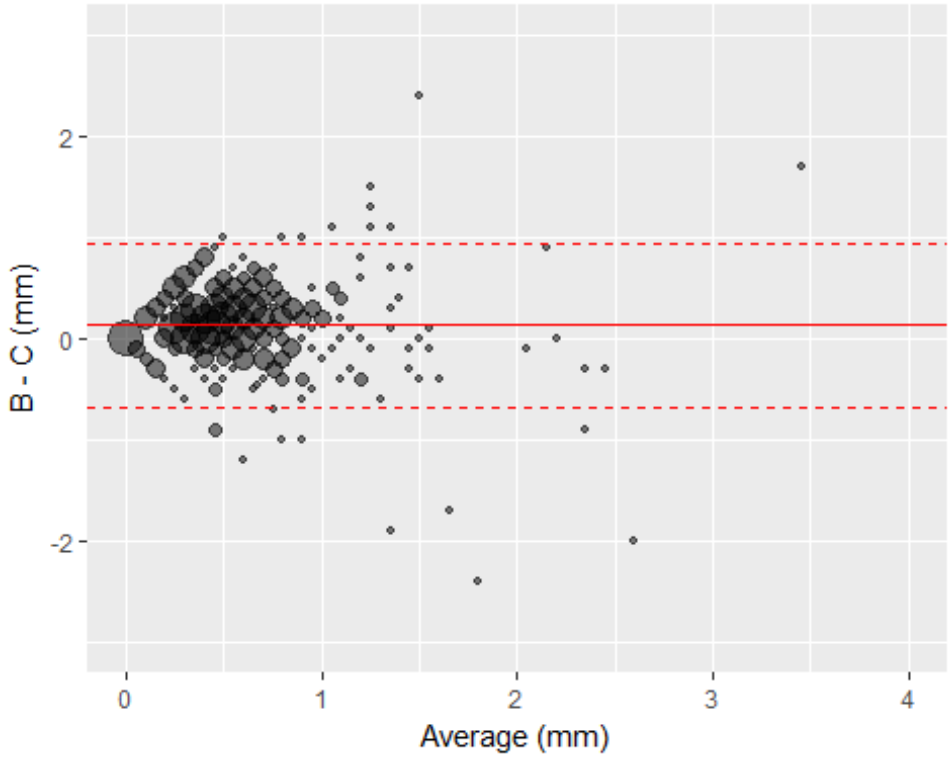


95% limits of agreement (-0.82mm, 0.7mm)

The standard deviation of the differences was 0.39 which is 12.2% of the range of 3.2.

Agreement was classified as acceptable.

Rater B vs C



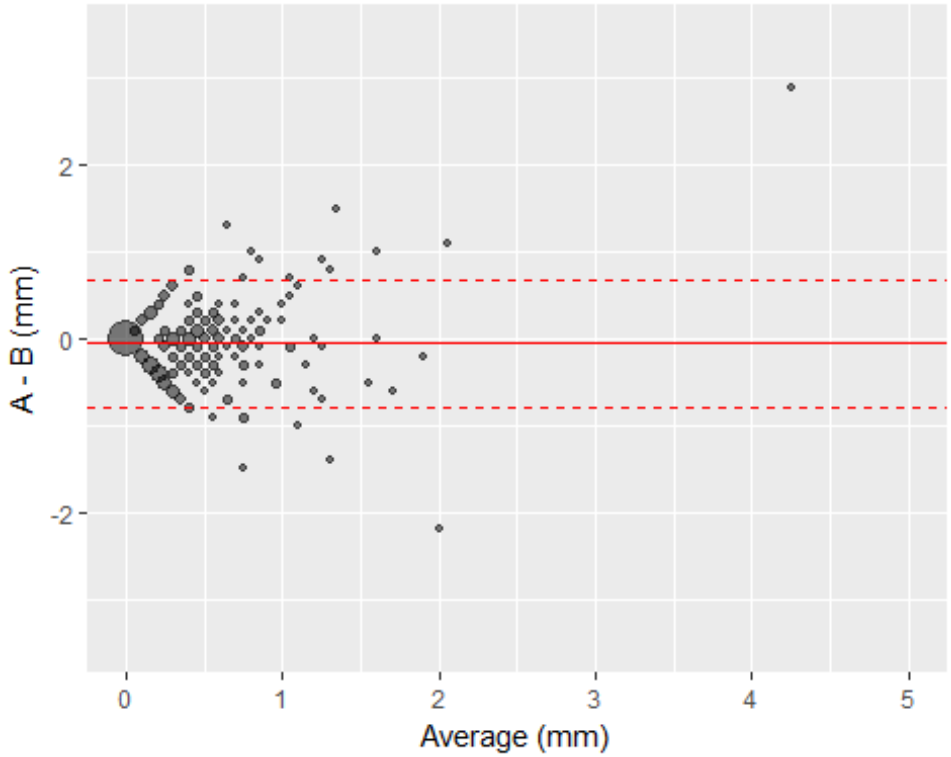
95% limits of agreement (-0.68mm, 0.95mm)

The standard deviation of the differences was 0.42 which is 9.7% of the range of 4.3.

Agreement was classified as good.

Step in X-ray

Rater A vs B

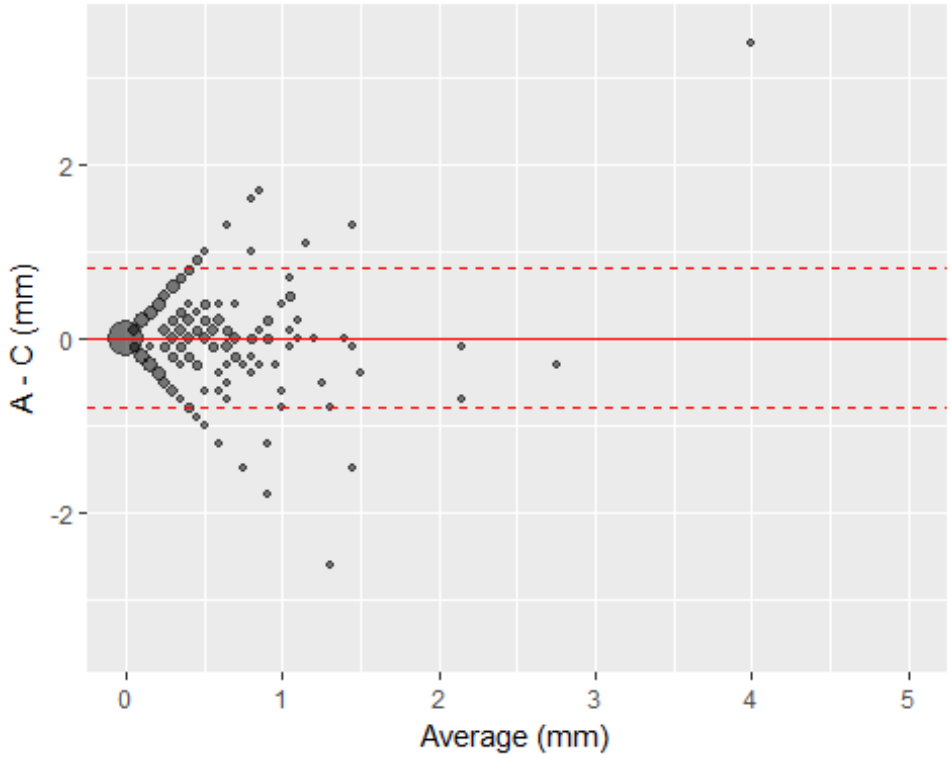


95% limits of agreement (-0.8mm, 0.69mm)

The standard deviation of the differences was 0.38 which is 6.7% of the range of 5.7.

Agreement was classified as good.

Rater A vs C

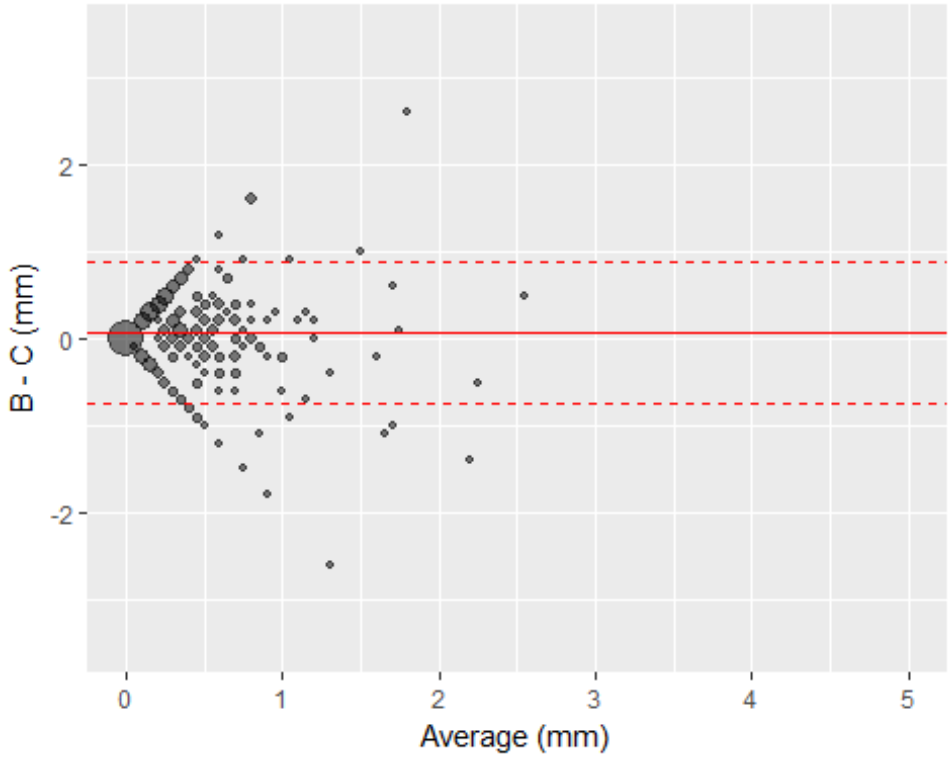


95% limits of agreement (-0.8mm, 0.82mm)

The standard deviation of the differences was 0.41 which is 7.2% of the range of 5.7.

Agreement was classified as good.

Rater B vs C



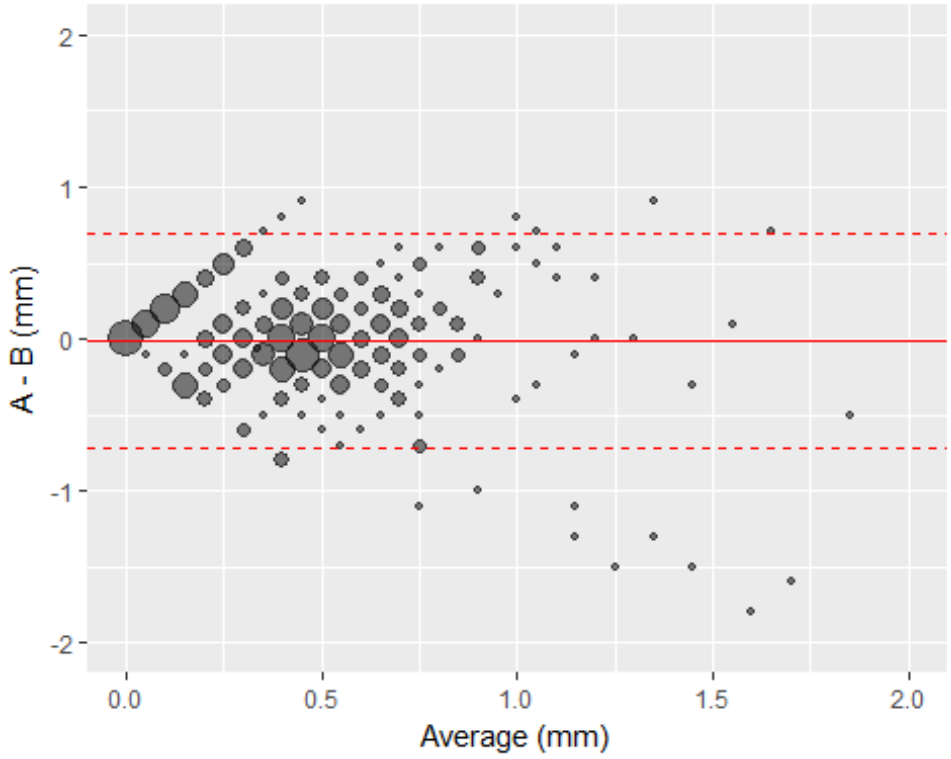
95% limits of agreement (-0.75mm, 0.89mm)

The standard deviation of the differences was 0.42 which is 13.5% of the range of 3.1.

Agreement was classified as acceptable.

Gap in CT scan: Coronal plane

Rater A vs B

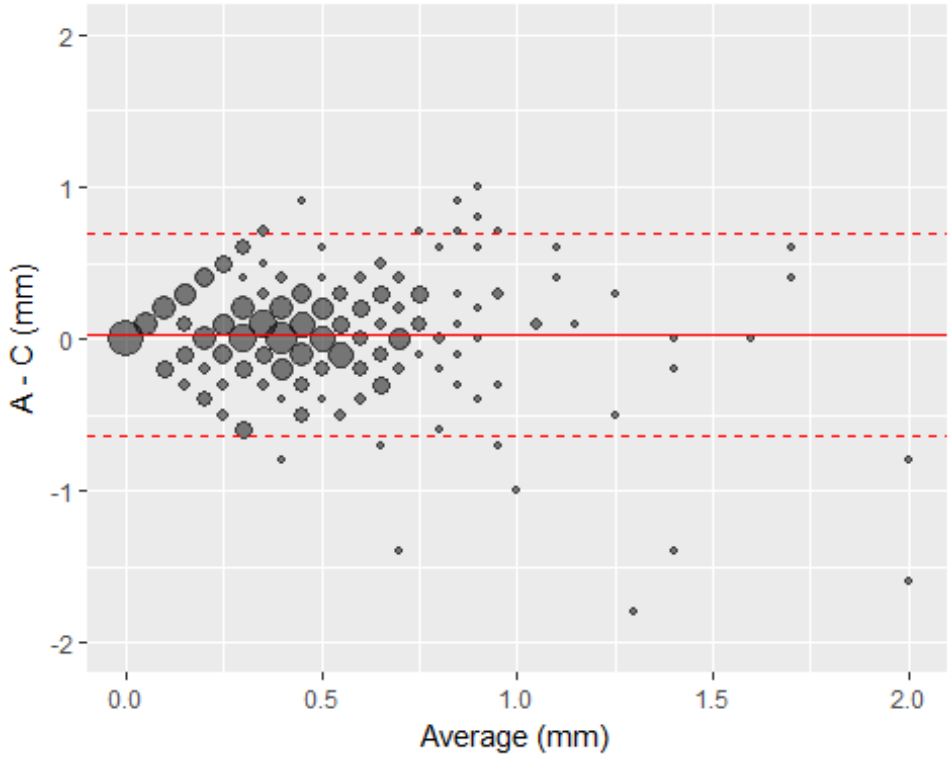


95% limits of agreement (-0.72mm, 0.7mm)

The standard deviation of the differences was 0.36 which is 11.3% of the range of 3.2.

Agreement was classified as acceptable.

Rater A vs C

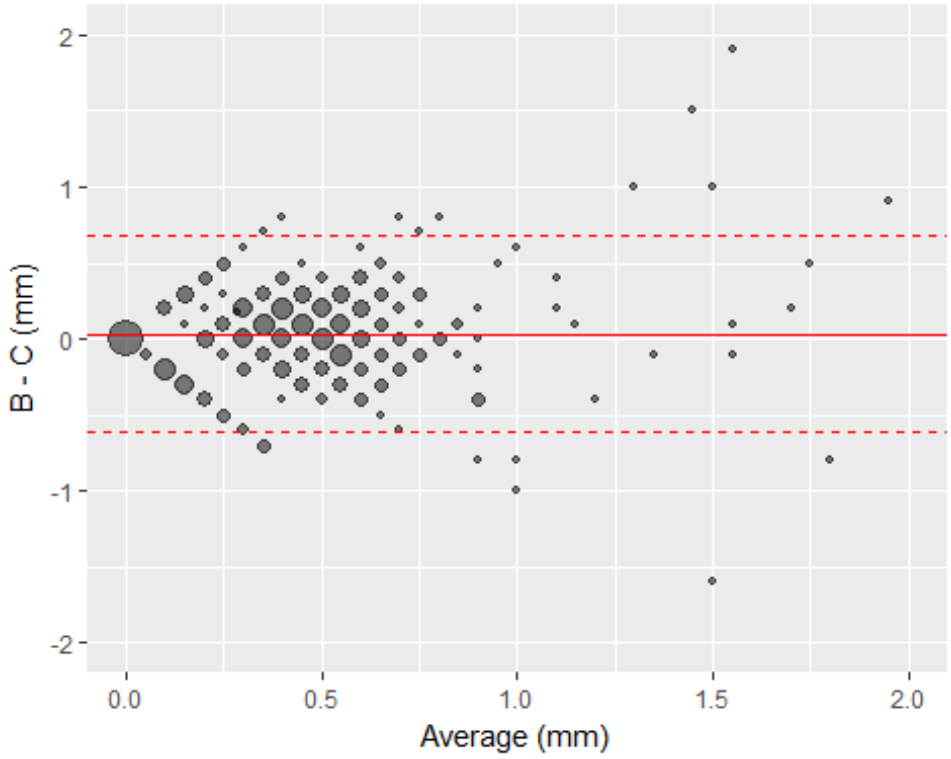


95% limits of agreement (-0.64mm, 0.69mm)

The standard deviation of the differences was 0.34 which is 10.6% of the range of 3.2.

Agreement was classified as acceptable.

Rater B vs C



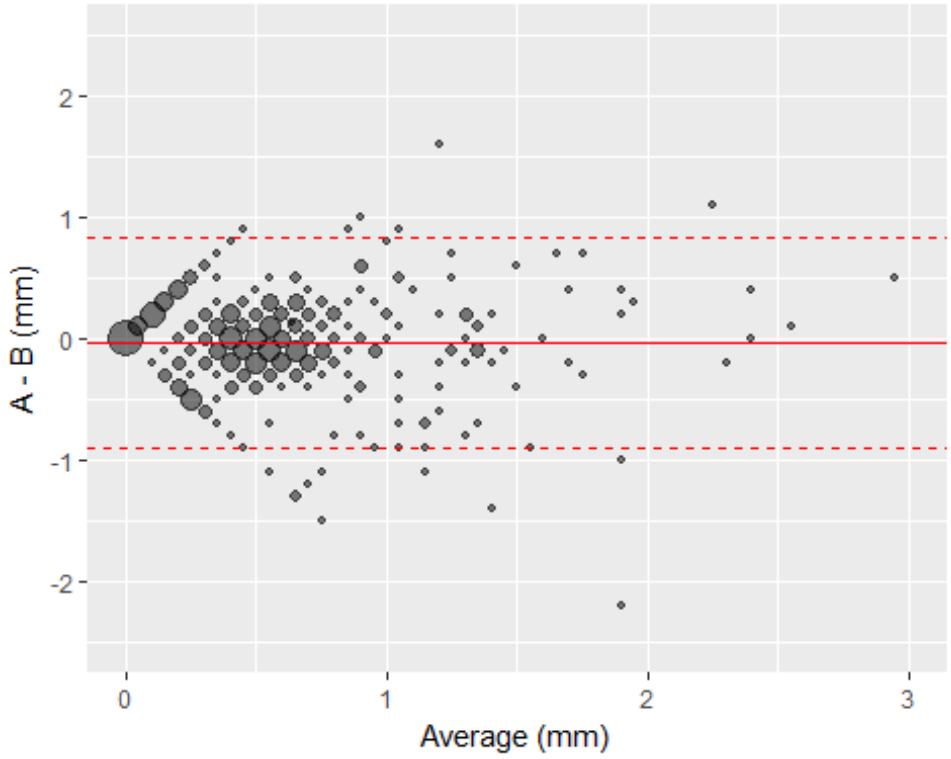
95% limits of agreement (-0.62mm, 0.68mm)

The standard deviation of the differences was 0.33 which is 9.2% of the range of 3.6.

Agreement was classified as good.

Gap in CT scan: Sagittal plane

Rater A vs B

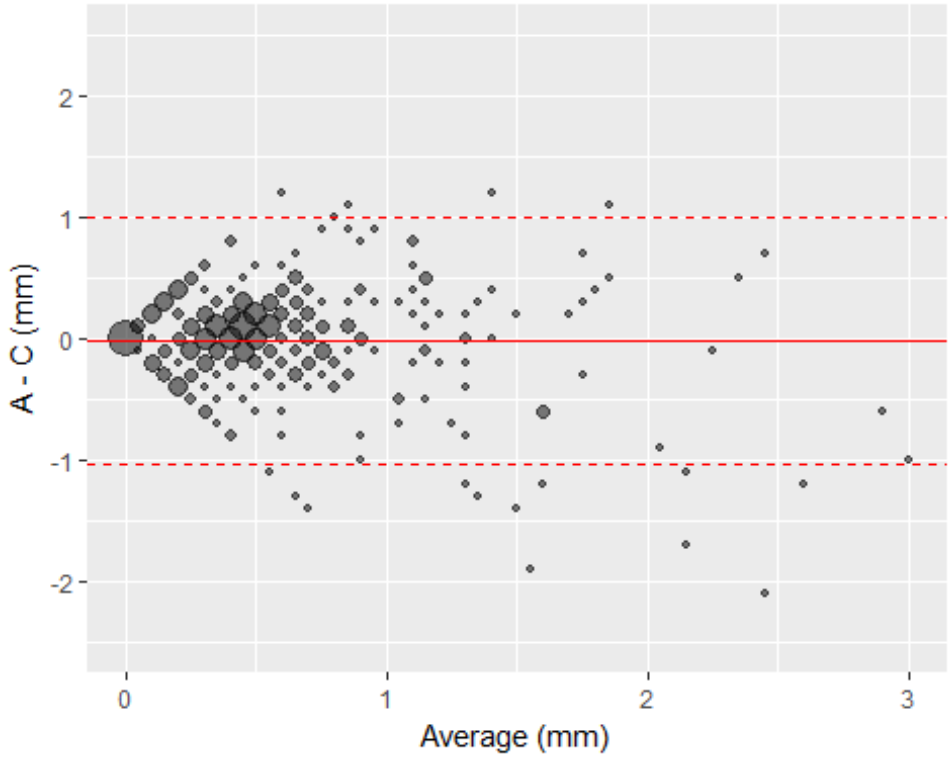


95% limits of agreement (-0.89mm, 0.84mm)

The standard deviation of the differences was 0.44 which is 7.9% of the range of 5.6.

Agreement was classified as good.

Rater A vs C

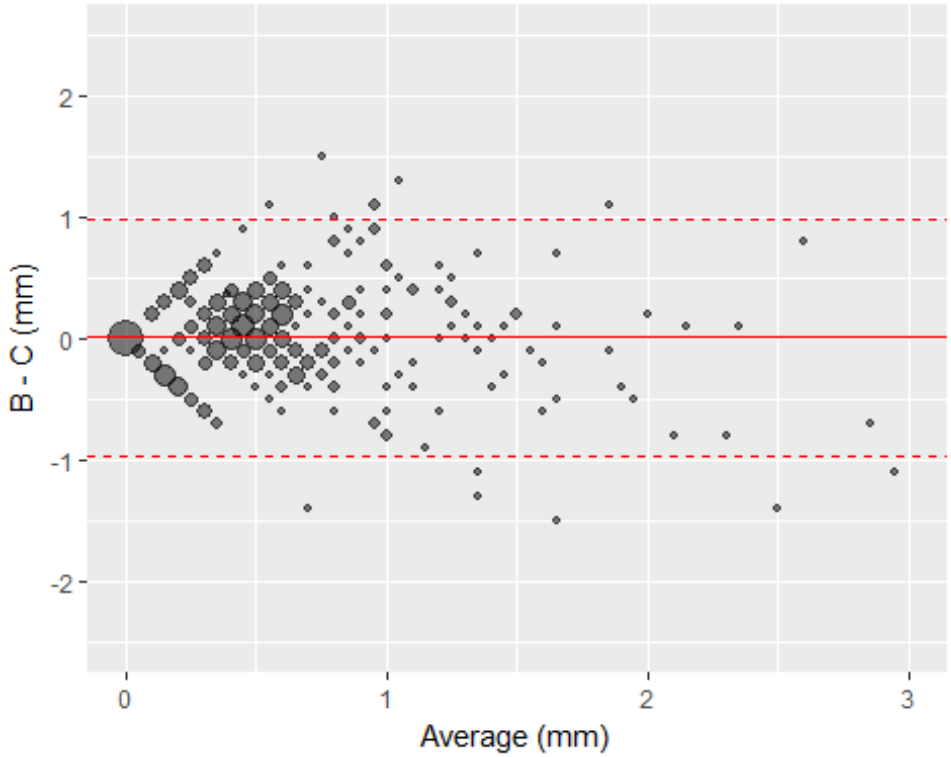


95% limits of agreement (-1.04mm, 1mm)

The standard deviation of the differences was 0.52 which is 9.3% of the range of 5.6.

Agreement was classified as good.

Rater B vs C



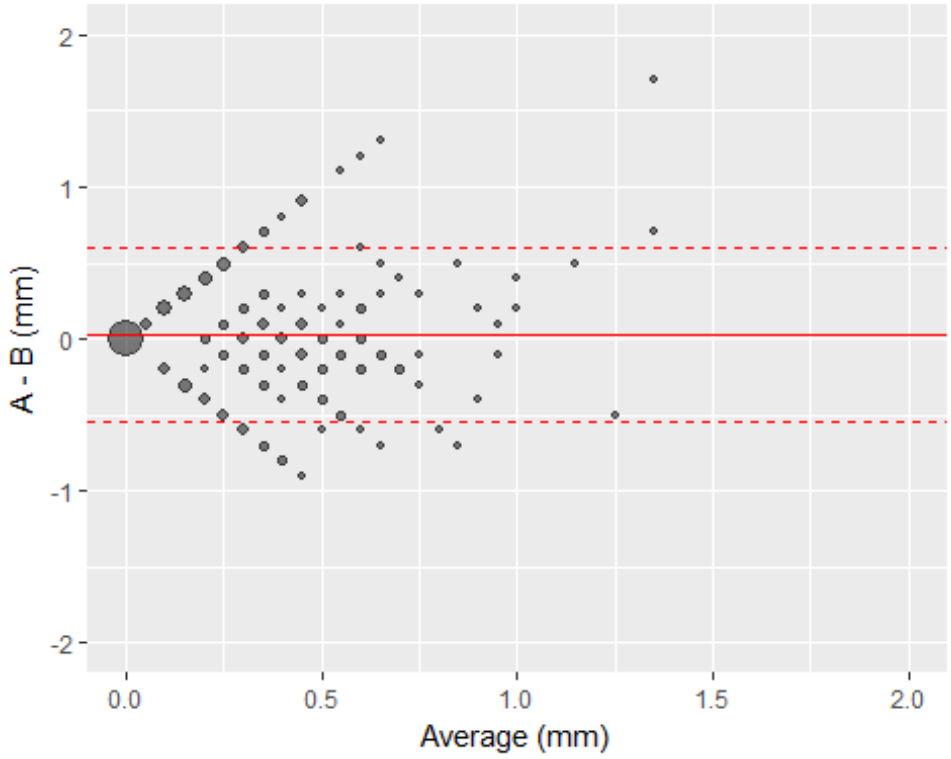
95% limits of agreement (-0.96mm, 0.98mm)

The standard deviation of the differences was 0.49 which is 9.9% of the range of 5.

Agreement was classified as good.

Step in CT scan: Coronal plane

Rater A vs B

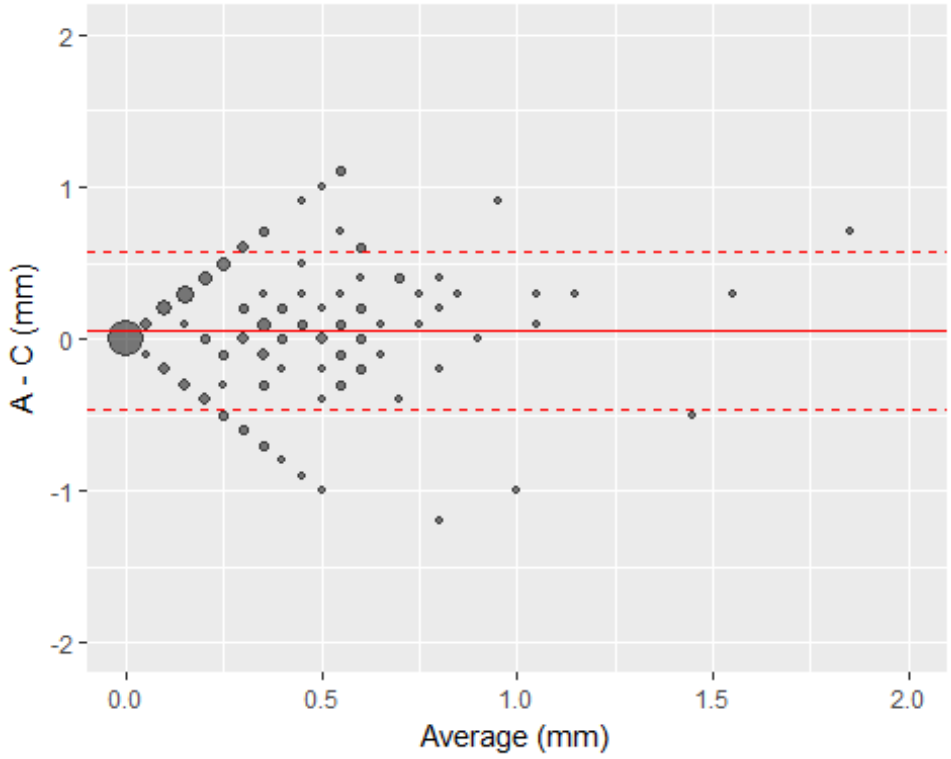


95% limits of agreement (-0.55mm, 0.61mm)

The standard deviation of the differences was 0.29 which is 13.4% of the range of 2.2.

Agreement was classified as acceptable.

Rater A vs C

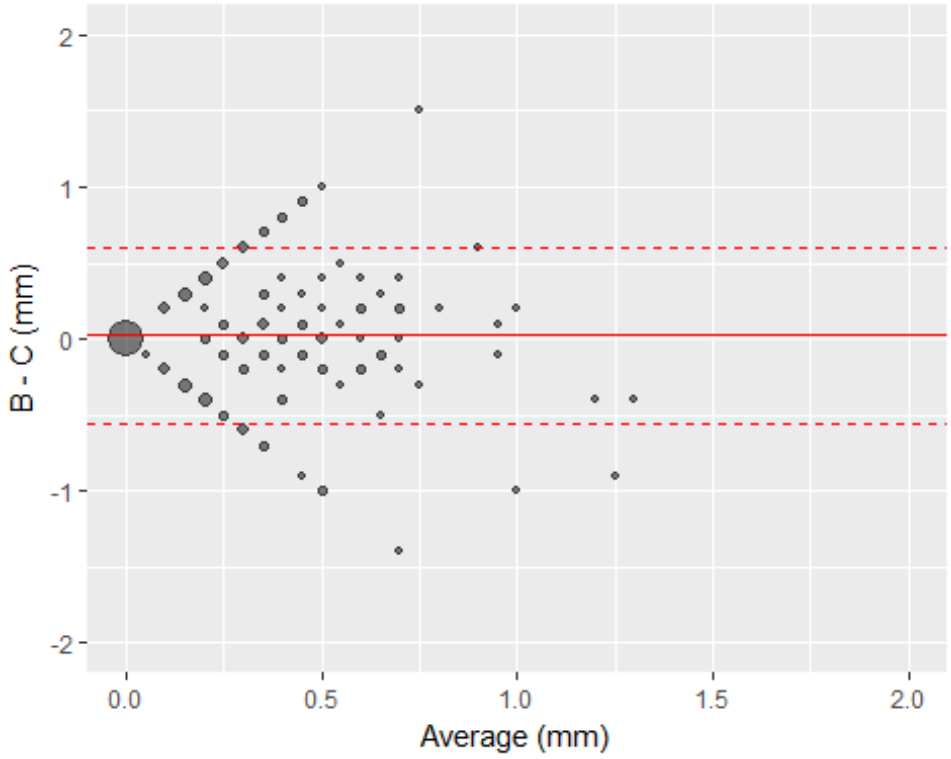


95% limits of agreement (-0.46mm, 0.57mm)

The standard deviation of the differences was 0.26 which is 11.9% of the range of 2.2.

Agreement was classified as acceptable.

Rater B vs C



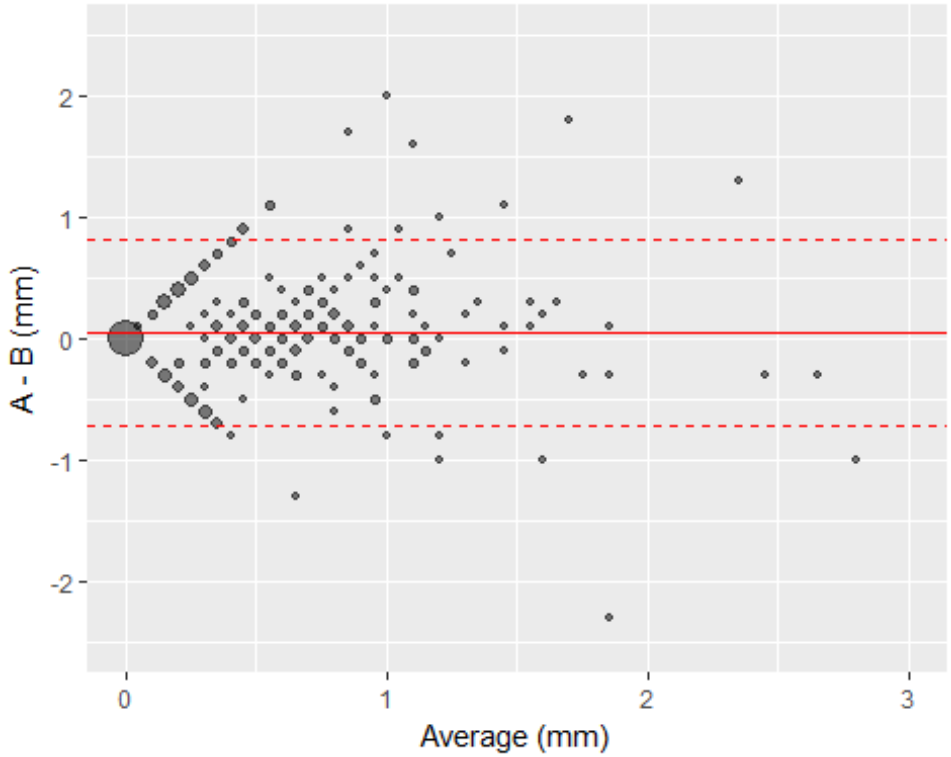
95% limits of agreement (-0.55mm, 0.61mm)

The standard deviation of the differences was 0.3 which is 19.7% of the range of 1.5.

Agreement was classified as acceptable.

Step in CT scan: Sagittal plane

Rater A vs B

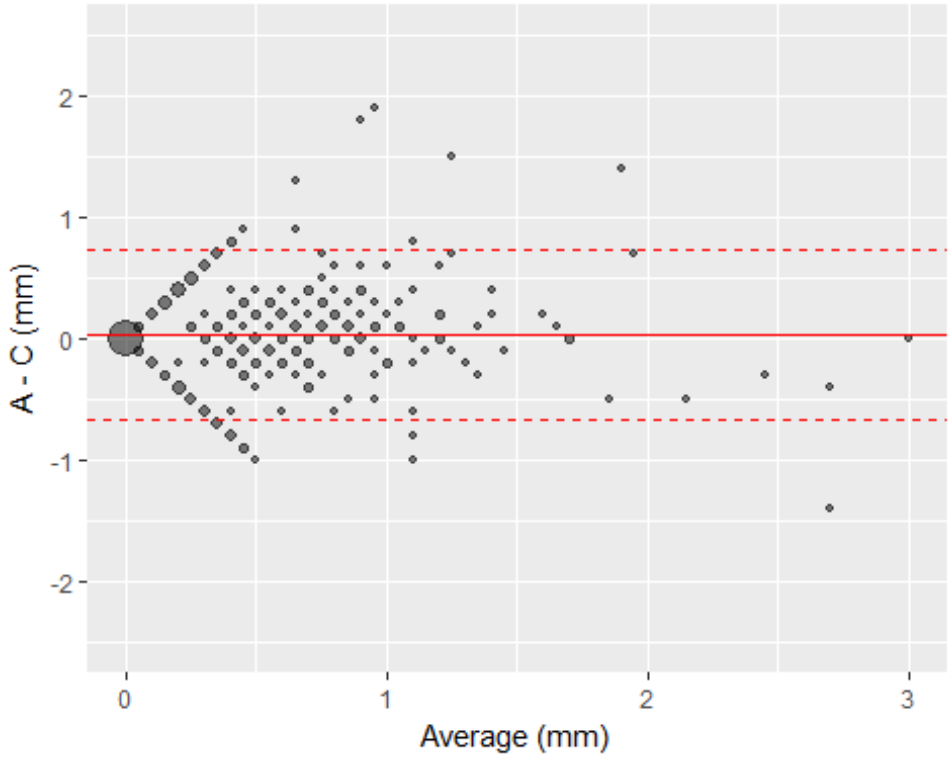


95% limits of agreement (-0.71mm, 0.82mm)

The standard deviation of the differences was 0.39 which is 13% of the range of 3.

Agreement was classified as acceptable.

Rater A vs C

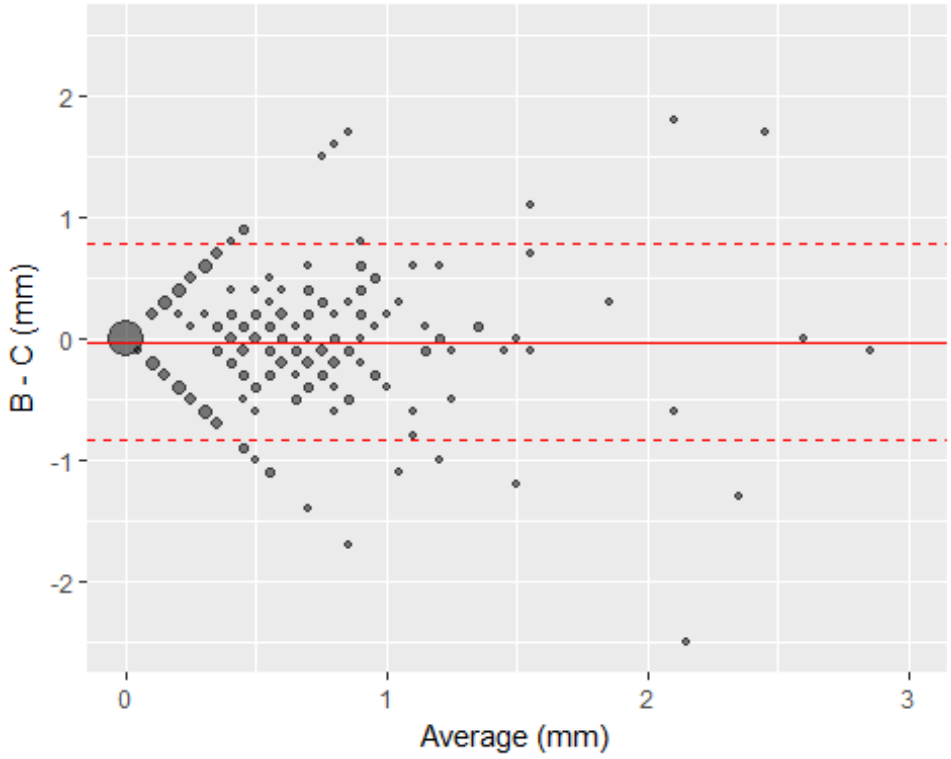


95% limits of agreement (-0.67mm, 0.73mm)

The standard deviation of the differences was 0.36 which is 11.9% of the range of 3.

Agreement was classified as acceptable.

Rater B vs C



95% limits of agreement (-0.84mm, 0.79mm)

The standard deviation of the differences was 0.41 which is 12.6% of the range of 3.3.

Agreement was classified as acceptable.

Union by X-ray at 52 weeks

Rater A vs B

	Rater B						
Rater A	United	Almost	Partial	Probably not	Not united	(Missing)	All
United	186	46	1	0	0	0	233
Almost	2	13	1	0	0	0	16
Partial	7	12	4	1	3	0	27
Probably not	0	2	3	2	2	0	10
Not united	0	0	1	1	10	0	12
(Missing)	0	0	0	0	0	0	0
All	195	73	10	4	15	0	299

Both raters graded 297 X-rays with 72.4% agreement, 95%CI (67.3, 77.5).

Agreement was classified as acceptable.

Rater A vs C

	Rater C						
Rater A	United	Almost	Partial	Probably not	Not united	(Missing)	All
United	224	6	0	0	0	3	233
Almost	14	2	0	0	0	0	16
Partial	13	13	1	0	0	0	27
Probably not	2	1	7	0	0	0	10
Not united	0	0	11	1	0	0	12
(Missing)	0	0	0	0	0	0	0
All	253	22	19	1	0	4	299

Both raters graded 295 X-rays with 76.9% agreement, 95%CI (72.1, 81.8).

Agreement was classified as acceptable.

Rater B vs C

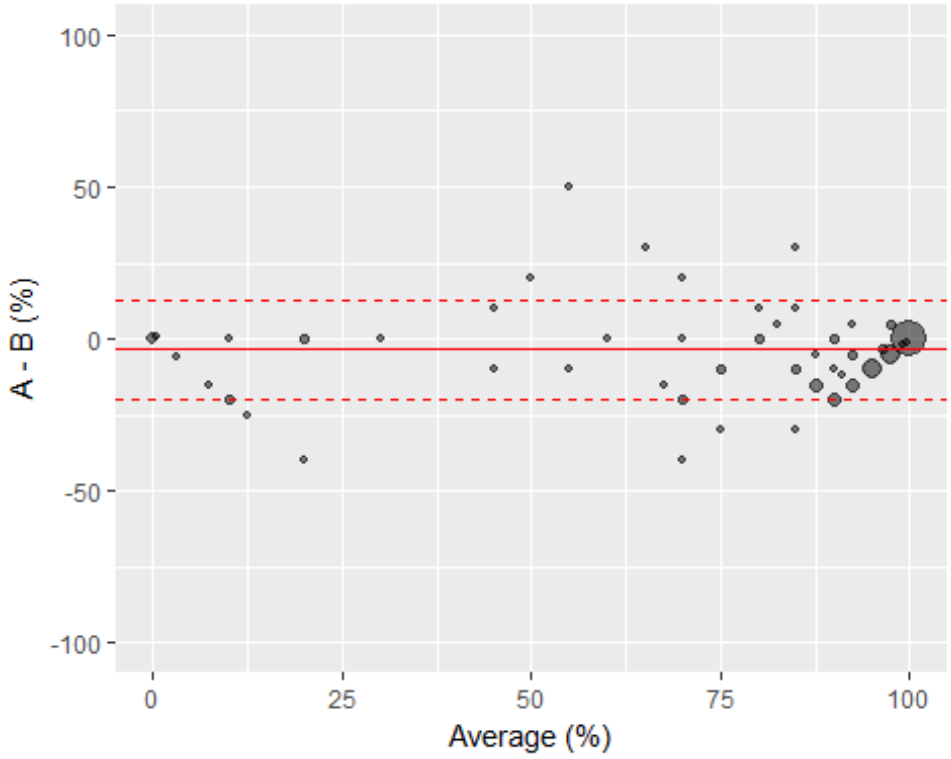
	Rater C						
Rater B	United	Almost	Partial	Probably not	Not united	(Missing)	All
United	188	5	0	0	0	2	195
Almost	62	9	1	0	0	1	73
Partial	2	4	4	0	0	0	10
Probably not	0	1	3	0	0	0	4
Not united	0	3	11	1	0	0	15
(Missing)	0	0	0	0	0	0	0
All	253	22	19	1	0	4	299

Both raters graded 294 X-rays with 68.4% agreement, 95%CI (63.1, 73.7).

Agreement was classified as acceptable.

Percent Union estimated from CT at 52 weeks

Rater A vs B

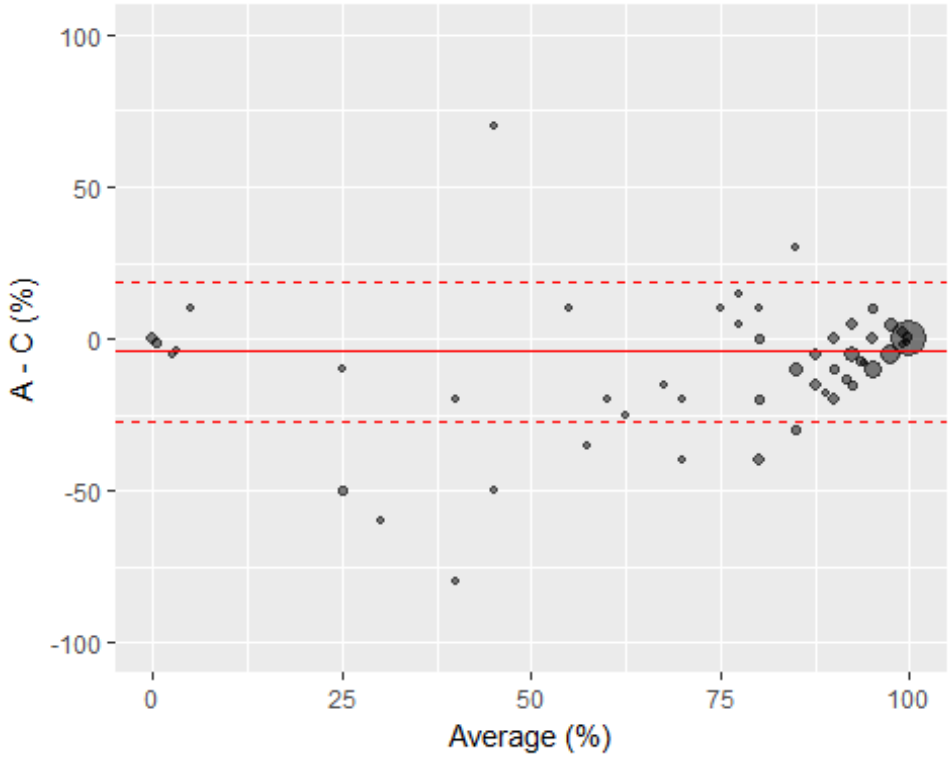


95% limits of agreement (-20.21%, 13.01%)

The standard deviation of the differences was 8.47 which is 8.5% of the range of 100.

Agreement was classified as good.

Rater A vs C

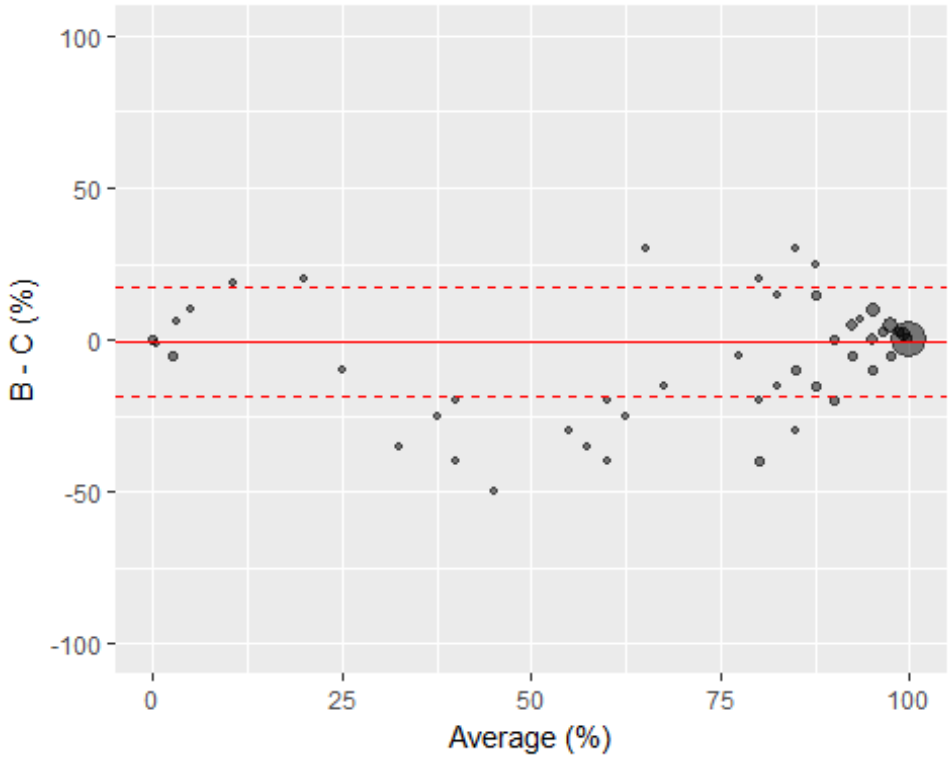


95% limits of agreement (-27.15%, 18.7%)

The standard deviation of the differences was 11.7 which is 11.7% of the range of 100.

Agreement was classified as acceptable.

Rater B vs C



95% limits of agreement (-18.67%, 17.43%)

The standard deviation of the differences was 9.21 which is 9.2% of the range of 100.

Agreement was classified as good.

X-ray Union at 52weeks: summary

A vs B

	Rater B				
Rater A	United	Partial	Not united	(Missing)	All
United	247	2	0	0	249
Partial	19	4	4	0	27
Not united	2	4	15	0	22

(Missing)	0	0	0	0	0
All	268	10	19	0	299

Both raters graded 297 CT scans with 89.6% agreement, 95%CI (86.1, 93).

Agreement was classified as good.

A vs C

	Rater C				
Rater A	United	Partial	Not united	(Missing)	All
United	246	0	0	3	249
Partial	26	1	0	0	27
Not united	3	18	1	0	22
(Missing)	0	0	0	0	0
All	275	19	1	4	299

Both raters graded 295 CT scans with 84.1% agreement, 95%CI (79.9, 88.2).

Agreement was classified as good.

B vs C

	Rater C				
Rater B	United	Partial	Not united	(Missing)	All
United	264	1	0	3	268
Partial	6	4	0	0	10
Not united	4	14	1	0	19
(Missing)	0	0	0	0	0
All	275	19	1	4	299

Both raters graded 294 CT scans with 91.5% agreement, 95%CI (88.3, 94.7).

Agreement was classified as good.

X-ray Union at 52weeks: views

A vs B

	Rater B				
Rater A	United	Partial	Not united	(Missing)	All
United	179	27	0	0	206
Partial	32	34	4	0	70
Not united	0	7	14	0	22
(Missing)	0	0	0	0	0
All	211	68	18	0	299

Both raters graded 297 CT scans with 76.4% agreement, 95%CI (71.6, 81.3).

Agreement was classified as acceptable.

A vs C

	Rater C				
Rater A	United	Partial	Not united	(Missing)	All
United	203	0	0	3	206
Partial	63	7	0	0	70
Not united	3	18	1	0	22
(Missing)	0	0	0	0	0
All	270	25	1	3	299

Both raters graded 295 CT scans with 71.5% agreement, 95%CI (66.4, 76.7).

Agreement was classified as acceptable.

B vs C

	Rater C				
Rater B	United	Partial	Not united	(Missing)	All

United	208	1	0	2	211
Partial	57	10	0	1	68
Not united	3	14	1	0	18
(Missing)	0	0	0	0	0
All	270	25	1	3	299

Both raters graded 294 CT scans with 74.5% agreement, 95%CI (69.5, 79.5).

Agreement was classified as acceptable.

CT Union at 52weeks: MPR

A vs B

	Rater B				
Rater A	United	Partial	Not united	(Missing)	All
United	161	1	0	0	162
Partial	86	32	1	0	119
Not united	0	3	8	0	11
(Missing)	0	0	0	0	0
All	247	36	9	0	292

Both raters graded 292 CT scans with 68.8% agreement, 95%CI (63.5, 74.1).

Agreement was classified as acceptable.

A vs C

	Rater C				
Rater A	United	Partial	Not united	(Missing)	All
United	155	6	0	1	162
Partial	60	56	2	1	119
Not united	0	1	9	1	11

(Missing)	0	0	0	0	0
All	215	63	11	3	292

Both raters graded 289 CT scans with 76.1% agreement, 95%CI (71.2, 81).

Agreement was classified as acceptable.

B vs C

	Rater C				
Rater B	United	Partial	Not united	(Missing)	All
United	209	36	0	2	247
Partial	6	27	3	0	36
Not united	0	0	8	1	9
(Missing)	0	0	0	0	0
All	215	63	11	3	292

Both raters graded 289 CT scans with 84.4% agreement, 95%CI (80.2, 88.6).

Agreement was classified as good.

CT Union at 52weeks: Estimated

A vs B

	Rater B			
Rater A	United	Partial	Not united	All
United	259	4	0	263
Partial	8	7	0	15
Not united	0	2	12	14
All	267	13	12	292

Both raters graded 292 CT scans with 95.2% agreement, 95%CI (92.8, 97.7).

Agreement was classified as good.

A vs C

	Rater C			
Rater A	United	Partial	Not united	All
United	259	3	1	263
Partial	12	3	0	15
Not united	1	5	8	14
All	272	11	9	292

Both raters graded 292 CT scans with 92.5% agreement, 95%CI (89.4, 95.5).

Agreement was classified as good.

B vs C

	Rater C			
Rater B	United	Partial	Not united	All
United	264	3	0	267
Partial	8	4	1	13
Not united	0	4	8	12
All	272	11	9	292

Both raters graded 292 CT scans with 94.5% agreement, 95%CI (91.9, 97.1).

Agreement was classified as good.

CT Union at 52weeks: Calculated

A vs B

	Rater B

Rater A	United	Partial	Not united	All
United	247	1	0	248
Partial	23	9	0	32
Not united	0	5	7	12
All	270	15	7	292

Both raters graded 292 CT scans with 90.1% agreement, 95%CI (86.6, 93.5).

Agreement was classified as good.

A vs C

	Rater C			
Rater A	United	Partial	Not united	All
United	246	2	0	248
Partial	21	10	1	32
Not united	0	4	8	12
All	267	16	9	292

Both raters graded 292 CT scans with 90.4% agreement, 95%CI (87, 93.8).

Agreement was classified as good.

B vs C

	Rater C			
Rater B	United	Partial	Not united	All
United	265	4	1	270
Partial	2	12	1	15
Not united	0	0	7	7
All	267	16	9	292

Both raters graded 292 CT scans with 97.3% agreement, 95%CI (95.4, 99.1).

Agreement was classified as good.

Discussion

Agreement was either acceptable or good on all scales.

Appendix 6: Health Economics

Section 1: Impact of lost employment and unpaid activities

In addition to consideration of costs to the NHS and PSS and quality of life to the patients, this within trial analysis reports the impact of treatment allocation on days of lost employment and unpaid activities. As part of the questionnaires patients were asked to report, if they were in paid employment, how many days over the period covered by the questionnaire they have missed as a result of their wrist injury, and how many days of unpaid activity they lost. While such outcomes are not conventionally incorporated into an economic evaluation in a UK setting[93] it can be helpful to inform decision makers who choose to take a broad definition of benefit, beyond patient quality of life and costs to the NHS, or patients who may choose to have the surgical procedure done through private healthcare provision to reduce the number of days of work lost. Brief summary statistics are reported for the four relevant time periods, stratified by treatment allocation.

Results

Impact of lost employment

The summary statistics of the patient reported days of lost employment are reported in Table 35. Primarily the table shows that the majority of patients experienced some days of lost employment in the first six weeks of the analysis period (with only 21.6% and 31.3% reporting no lost days over that period for surgery and cast respectively), but from 12 weeks onwards most were back to fulltime work (with medians of zero for all other periods). There did, however, remain a number of patients who were forced to continue missing work as a result of their wrist, characterised by the persistent mean number of days lost despite close to 90% reporting no lost days. A very few cases of patients having to miss work for most of if not all the period covered by the questionnaire were reported.

Over the entire within trial period for the compete case analysis surgical patients reported having lost a smaller mean number of days (16.62 compared to 17.57 respectively) but a larger median (9.5 compared to 5) and with fewer reporting no days of work lost (13.7% to 28.6%). Using the sum of the means for each time period, a larger difference is observed

between the two groups, with a mean lost days of employment of 17.30 and 21.69 reported, suggesting a biasing impact of the inconsistent level of missing data.

This distribution is best explained by the invasive nature of the surgery necessitating at least some days off work in more patients but the large impact of a few extreme cases where patients were absent from work for the majority of the year. These outliers appear to be more evident in the plaster cast arm, with 10 patients reporting more than 50 days off work, compared to 6 in the surgical arm. However, the high rate of missing data may be having a large biasing effect.

These findings appear inconsistent with other studies focussing on the impact of scaphoid fracture on fixation[176, 177] which have found much larger differences in days of work lost, favouring surgery, however, the source of this difference is not clear.

Using estimates of the average weekly earnings from the Office for National Statistics (£512)[178] allows us to crudely estimate the average societal impact of these lost days of employment of £1,702 per person for the surgical arm and £1,799 for the cast arm, a difference of £97 per person. However, it is important to note that without an estimate of the number of days of work a person would lose if no treatment was available it is not possible to interpret these results beyond their comparative value.

Impact on days of unpaid activity

Similar to the last section, Table 66 reports the impact of treatment allocation on lost unpaid activity (e.g. household chores, shopping, helping others) for reasons related to the wrist injury and subsequent treatment.

Table 66: Summary statistics for days of lost unpaid activity reported since last questionnaire

Questionnaire period	Treatment allocation	Number of responses	Mean	Median (95% percentile)	Percentage reporting 0 days
6 weeks	**Surgery**	167	12.41	10 (40)	28.1%
	Cast	162	10.13	6 (35)	35.8%

12 weeks	**Surgery**	163	2.21	0 (18)	83.4%
	Cast	151	5.03	0 (35)	66.9%
26 weeks	**Surgery**	150	1.77	0 (14)	89.3%
	Cast	140	3.51	0 (25)	85.7%
52 weeks	**Surgery**	169	1.08	0 (5)	91.7%
	Cast	163	2.73	0 (4)	91.4%
Total	**Surgery**	**118**	**16.15**	**11 (54)**	**21.2%**
	Cast	**103**	**15.90**	**8 (52)**	**26.2%**

The table shows a larger impact on lost unpaid activity of surgery than casting for the 6 weeks after randomisation, with larger mean and median values, and fewer patients reporting no days lost. However, for all time points after this, patients allocated to the surgical arm report a smaller impact on unpaid activities. As was seen in the responses to lost days of employment the results are highly skewed, with the majority of responders reporting no impact on unpaid activity after 6 weeks but a very small number continuing to report a large number of lost days throughout the trial period.

Section 2: Systematic review of previous cost-effectiveness studies

This Appendix details the literature review that was conducted to determine whether previous economic evaluations had sufficiently determined the cost-effectiveness of surgical fixation versus plaster cast immobilisation for treatment of bi-cortical, minimally displaced fractures of the scaphoid waist in adults. A secondary aim of the search was to determine if previous mathematical models could be adapted to estimate the long-term cost-effectiveness of the population, and thus remove the need to construct a de novo mathematical model.

Our strategy (detailed below) did not specify the form of treatment required, whether the evaluation considered the diagnosis or treatment of the fracture, or the extent of displacement of the fracture. The strategy was submitted to Ovid Medline in April 2017,[12] with all published, in process and other non-indexed citations in any language between 1946 and April 2017 allowed. The review was conducted by a single reviewer.

Systematic search strategy

Search conducted using Ovid Mediline through the University of York library, 04/04/2017
Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

1. Fracture Fixation/ (17279)
2. Fracturers, Bone/ (59494)
3. Orthopedic Fixation Devices/ (4975)
4. 1 or 2 or 3 (75839)
5. Scaphoid Bone/ (1850)
6. Wrist Joint/ (8976)
7. Wrist Injuries/ (5824)
8. 5 or 6 or 7 (14701)
9. Cost-Benefit Analysis/ (70573)
10. 4 or 8 or 9 (24)

In addition to the strategy submitted to Medline (above) a search of the grey literature was conducted. The search consisted of an iterative investigations of the literature identified using an internet search engine (Google Scholar), coupled with a targeted search of the National Institute for Health and Care Excellence's (NICE) website to explore any economic evaluations behind current best practice guidance.

The Medline search yielded 24 hits, 16 of which were deemed relevant upon review of their titles, only 3 of which were relevant after consideration of their abstracts[43, 179, 180]. The search of the grey literature only identified one fully relevant article from the NICE website and none from the internet search engine exploration. Consistent with the search strategy the relevance of the studies was defined by the existence of some form of economic evaluation at any point of the diagnostic or treatment pathway of a fracture of the wrist region. No further limits on the type of injury or point of care were placed to ensure all studies considering the cast immobilisation vs surgical fixation question were included. As a result, some of the studies deemed relevant considered the pre-treatment decision of how different diagnostic strategies compared, but as these implicitly included the consequences of the treatment used they were deemed relevant.

The four studies identified[43, 90, 179, 180] were reviewed using the Drummond Checklist for assessing the quality of economic evaluations,[103] the results of which are available later in this Appendix.

Of the four studies, two considered the cost-effectiveness of different diagnosis strategies for suspected scaphoid fractures.[90, 180] Karl et al.[180] explored the relative cost effectiveness of three strategies: empiric cast immobilisation for all patients followed by follow-up radiographs, immediate CT scan, and immediate MRI, in a population of patients deemed to have a possible scaphoid fracture after physical examination, but with a negative initial radiograph. The authors concluded that initial advanced imaging dominated empiric casting.

Similarly, the economic evaluation that accompanied NG38[90] primarily focussed on the cost effectiveness of imaging suspected scaphoid fractures rather than the appropriate treatment pathway, but contains valuable insights into the pathway. This analysis considered a slightly earlier problem than Karl et al., being prior to initial investigation. As a result the decision problem considered whether MRI or CT scans should be used as the first line diagnostic tool, and thus a broader population than Karl et al. by considering all those with suspected scaphoid fractures rather those with indeterminate initial radiology findings. The analysis included the possibility of patients having either cast immobilisation and/or surgical fixation, but these were considered to be accepted best practice depending on displacement and union, and as such no analysis of their respective cost-effectiveness was conducted. The evaluation concluded that the use of immediate MRI was the most cost-effective approach, dominating all other strategies except immediate CT scans.

As both Karl and NICE NG38 [90, 180] focussed on the cost-effectiveness of the diagnostic strategies prior to confirmed diagnosis, and considered the treatment options to be fixed decisions, they are not directly applicable to the SWIFFT trial evaluation.

The study by Hannemann et al. [179] considered the cost-effectiveness of pulsed electromagnetic fields in the treatment of acute undisplaced scaphoid fractures, compared to standard cast immobilisation. While relevant to the SWIFFT evaluation as an evaluation of treatment options in scaphoid fractures, Hannemann et al. consider a less severe population than SWIFFT, including patients with tuberosity fractures. Additionally, the study does not conduct a long-term mathematical model, instead being limited to a within trial analysis over 52 weeks of follow up.

Finally, Davis et al.[43] conducted an evaluation of the cost-effectiveness of open reduction and internal fixation surgery versus cast immobilisation for acute non-displaced scaphoid fractures. As a result, the study is relevant to this evaluation. The study is structured around a decision tree model which estimates the probability of a patient experiencing one of six possible outcomes after treatment with cast immobilisation (no complications, non-union, and delayed union, each with a normal and arthritis variant), and seven for surgical fixation (the same as the cast arm but with the addition of a risk of infection). The model estimates the cost per QALY gained of each treatment by combining the short term cost and health related quality of life of the different treatment outcomes with long-term estimates of the health related quality of life implications of each outcome, no long-term costs appear to be considered despite the existence of a long-term arthritis outcome.

As reflected in the review of the Davis study presented in the table later in this Appendix there are a number of areas of the model that were difficult to fully assess. The decision tree and related characterisation of the different possible post-treatment outcomes are good, considering the potential for non and delayed union, infection, misplaced screws, and arthritis. However, our review of the article raised a number of factors that limit the transferability of the model to the SWIFFT trial analysis. These factors included the lack of long-term cost associated with arthritis, a lack of clarity regarding which patients were associated with which resource use, the use of an unvalidated time trade off questionnaire completed by 50 medical students who had not experienced the fracture, a lack of clarity as to how the durations and probabilities that informed the model were derived from the literature, and the lack of correlation between non-union and the probability of arthritis. Furthermore, the lack of definition of non-displacement by Davis et al. makes the transferability of the model to the SWIFFT trial population difficult to determine.

Therefore, we determined that in addition to the planned within trial economic evaluation of the SWIFFT trial a de novo mathematical model was required to investigate the long-term cost effectiveness of surgical fixation compared to cast immobilisation. The de novo model is expected to draw from the Davis study, but this will be determined by the results of a series of targeted parameter specific literature reviews.

Drummond checklist review

Table 67: Drummond checklist[103] review of previous economic evaluations identified in the literature review (systematic and grey search)

Study	1. Was a well defined question posed in an answerable form?	2. Was a comprehensive description of the competing alternatives given?	3. Was the effectiveness of the programmes or services established?	4. Were all important & relevant costs & consequences for each alternative identified?	5. Were costs & consequences measured accurately in appropriate physical units?	6. Were costs & consequences valued credibly?	7. Were costs & consequences adjusted for differential timing?	8. Was an incremental analysis of costs & consequences of alternatives performed?	9. Was allowance made for uncertainty in the estimates of costs & consequences?	10. Did the presentation & discussion of results include all issues of concern to users?
Davis 2006 [117]	Yes, a clear focus from both a direct and indirect perspective	Yes, all options are considered, no explicit 'do nothing' but perhaps not appropriate. Limited detail on surgical option	Yes, had to rely on limited RCT data. Based on a systematic review but simple averages taken	Partial, short term direct and indirect costs were well handled but it is not clear how/if long-term costs of arthritis is modelled	Partial, not very clear as based on tariff payments so no clear breakdown. Outcomes in appropriate units	Partial, costs valued credibly but hard to test without trial and tariff details. Outcomes questionable as based on 50 medical students rather than patients	Unclear, No statement on discounting but the results would suggest it was applied.	Yes	Yes, through one and two way scenario analysis with some conceptualisation for values chosen.	No clear definition of non-displaced. Good consideration of the role of non-arthritis adverse events
Karl 2015 [181]	Yes, clear outline of three different options, and the aim and hypothesis of the study and patients	Yes, alternatives well defined. Not clear if all options are considered as possible repeat rests not	Yes, through limited meta-analysis, but only focus on diagnostic effectiveness, little on	Yes, appear to be sufficiently identified (given limitations of treatment modelling)	Yes, appear appropriate	Partial, based on limited evidence in the literature which is averaged. Questionable approach to	Partial, literature estimates adjusted to 2014 USD. Not clear if discounting is applied, scale	Yes	Yes, one and two way scenario analysis.	Yes, with exception of those raised elsewhere

		included or discussed	treatment post test			cost of surgery. Utility based on Davis so same limitations.	of results would suggest not.			
Hannemann 2015 [182]	Yes, clear outline of aims of analysis, although description of evaluation in abstract is a little misleading as study is just within trial report	Yes, good description although not clear if surgery would have been an option	Yes, using linked trial evidence only	Yes, identified as part of trial	Yes, costs and health outcomes well reported	Yes, costs from hospital and Dutch Guidelines and QoL from trial EQ5D. Some credible societal costs	N/A, only 1 year timeline but could argue should have been included	Yes	Yes, PSA presented but no scenario analysis	The study has limited scope as is only a within 1 year trial report with limited evaluation
NICE NG38 2016 [90]	Yes, clearly defined but a little unclear as to how the overall analysis links to the NICE Guidance so hard to comment on ability to answer primary aim	Yes, very well described and motivated, no 'do nothing' but as emergency medicine perhaps not reasonable option	Partial, the effectiveness of the diagnosis was well established but not the subsequent treatments (cast or surgical interventions)	Partial, short term costs were well considered but long-term costs and the consequences of different treatment options were not, however it is hard to determine if this had an impact on the results	Yes, costs and consequences were measured appropriately	Yes, based on a good literature search, and where no literature was available, reasonable assumptions.	Yes, all costs occurred in the first year but future QALYs were discounted appropriately.	Yes	Yes, through scenario analyses	Overall a good piece given the limitations of the evidence, but concerns around the failure to justify the simplistic approach to modelling the treatment options.

Drummond checklist review

	Age of population at injury	Male to female ratio	Characteristics of original injury	OA definition	Definition of union	Surgical intervention type	Definition of symptoms
This analysis, as defined by the SWIFFT trial (N=439)	Mean 33 (range 16 to 80)	84%	Unequivocal, bi-cortical, minimally displaced fracture (<2mm) of the scaphoid, presenting within two weeks of injury	Defined within trial period by radiography and CT scan	Disappearance of the fracture line on radiographs and complete bridging on CT scans from those taken at baseline	As per surgical preference (open or percutaneous fixation with standard CE marked headless compression screw)	Reported in terms of EQ-5D
Lindström and Nyström (1990) [104] (n=229)	Range 15 to 76 years	83.8%	Scaphoid fractures, fractures of the scaphoid tuberosity were excluded	One or more observations of: reduced joint space, osteophytes, or sclerosis of joint margins	N/A, only considers 'healed fractures' (not defined)	N/A, only cast patients	Patient reported weakness of grip, pain related to wrist motion and at rest, and impaired range of motion.
Saeden[109] (n=61)	29 +- 13 years for surgical group 37 +- 20 years cast group	84% surgical 73% cast	Acute fractures of the scaphoid visible at first radiological examination. Fractures of the scaphoid tuberosity were excluded.	narrowing of the joint or reactive changes around it compared with the uninjured side	radiological identified but not defined	Open fixation using Herbert screw	Symptoms reported as score out of 10 across 9 questions including pain at different times, wrist movement and manual work
Lindström and Nyström (1992) [102](n=33)	Mean 27.9, range 15 to 52 years	72.7%	Scaphoid fractures, fractures of the scaphoid tuberosity were excluded	One or more of: reduced joint space, osteophytes, or sclerosis of joint margins	Not defined	N/A as all untreated patients	Patient reported pain, stiffness, and weakness

Ruby [101] (n=56)	Mean 32, range 18 to 85 years	89.2%	Scaphoid fractures	At least presence of joint narrowing, severity determined by osteophytes and intraosseous cysts	Not defined	N/A as all untreated patients	Patient reported pain in the wrist
Moritomo [107] (n=33)	Mean 26.3, range at review of all patients 13 to 70	84.5%	Limited details given other than fracture of the scaphoid.	N/A	Not defined	N/A, no treatment details reported	Symptomatic population defined as seeking help for injury
Vender [111] (n=64)	Median 22	86%	Scaphoid fractures	Radial styloid pointing, radioscaphoid narrowing, and midcarpal joint narrowing	Displacement of the fragment cortices greater than 1 mrn.	N/A, excluded any patients who had previous operations	Patients who presented with clinical concerns related to the injured wrist

Section 3: Probability of developing OA

In the extrapolated model the probability of OA was modelled for all treatment arms as being an exponential decay towards a limiting value with the limiting value characterised as a beta distribution for the PSA. The functional form of the exponential function is:

$$y = y_{\infty} + a \times e^{\frac{-t}{\tau}}$$

Where y_{∞} is the limiting value, a is the constant, and τ is the time constant.

This formula is fitted to the evidence from Lindström and Nyström that at year 1 2.6% of patients had radiological OA, and at year 7 5.6% had radiological OA.[104] Figure 20 shows the goodness of fit of the fitted function to the observed data, with the bounds showing the 95% confidence interval taking account of the uncertainty of the time limiting value.

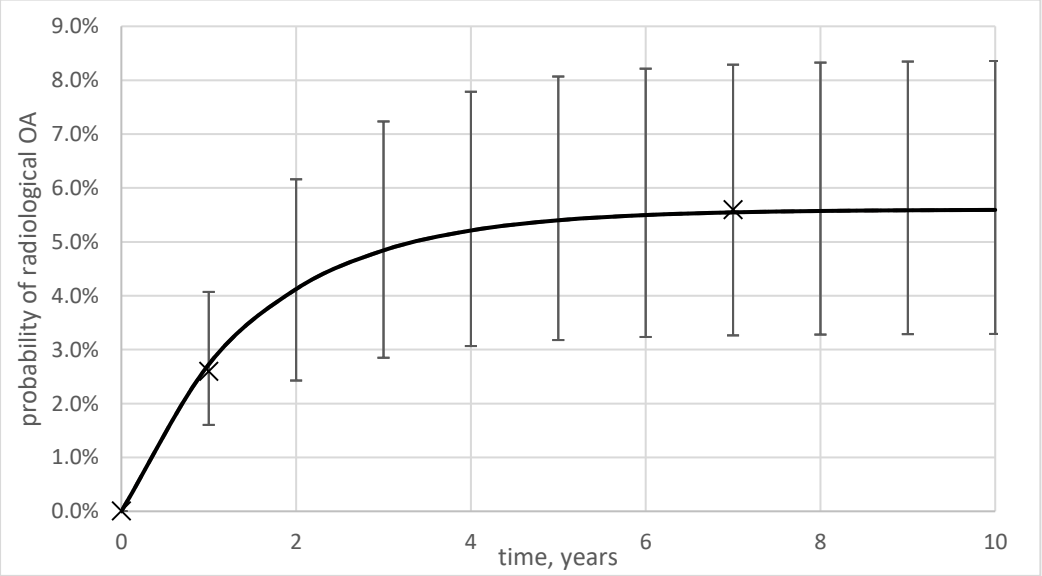


Figure 20: Goodness of fit of the exponential decay to the observed data

Section 4: Probability of developing SNAC

To estimate the probability of non-union patients developing SNAC we conducted a survival analysis to the patient level data reported in Moritomo.[107] The results of the survival analysis are reported below reporting the AIC and BIC of the seven regressions explored alongside the graphical goodness of fit of the Weibull, which was selected due to having the lowest AIC and BIC.

	AIC	BIC
exp	25.12107	26.11681
weibull	22.51636	24.50783
gomp	22.79423	24.7857
loglogistic	24.14154	26.133
lognormal	23.19027	25.18174
gamma	24.33022	27.31742

Figure 21: AIC and BIC estimates for the survival regressions fitted to the Moritomo patient level data

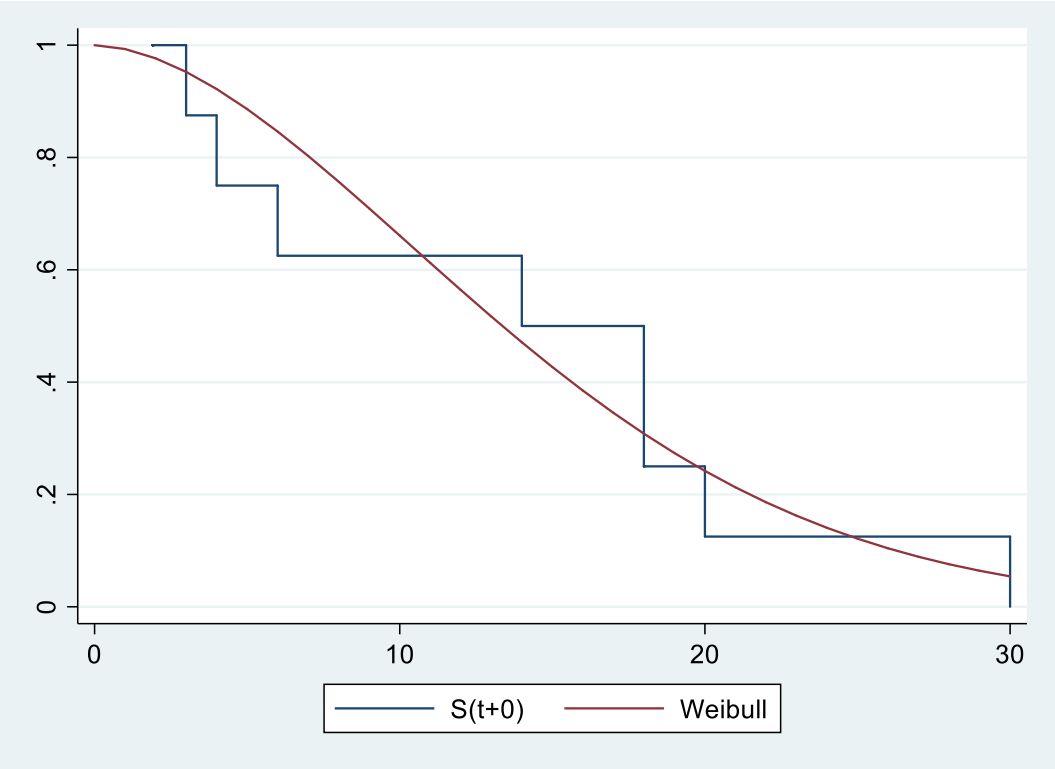


Figure 22: Weibull and Kaplan-Meier of the SNAC survival analysis

Section 5: Extrapolated model scenario analyses

In order to develop the mathematical model into the form presented above a number of simplifying assumptions and interpretations of the available evidence were necessary, as is true of all mathematical models.[99] While the assumptions made in the base-case analysis are considered to be the most reasonable given the evidence available it is important to test the impact of different approaches on the results of the analysis. The following scenarios have been constructed to conduct these tests, as far as possible other sources of evidence are used to inform the scenarios, however, often the uncertainty is driven not by contradictory sources but by a complete lack of evidence:

Scenario 1, Definition of non-union at 1 year

In the base case analysis we assume that the definition of non-union informative to the extrapolated model from the previous Chapter includes only those patients who are classified as having a non-union at 52 weeks, therefore all other diagnoses (union, almost full union, partial union, and slight union) are categorised as union for the sake of the model. If only this "pure" non-union definition is used there is one non-union in the surgical arm and four in the plaster cast arm (three of which we define as having surgical intervention at a later time). If a broader definition is used to include the slight unions then this increases to four in the surgical arm and nine in the plaster cast arm. The base-case assumption was made due to clinical guidance that there is no evidence to suggest that slight unions behave as non-unions, however there is uncertainty around this. Therefore, this scenario explores the sensitivity of the model to this assumption by only considering the "pure" non-unions as informative to the extrapolated model.

Scenario 2, no surgical treatment for those who fail to achieve union with cast

Our base-case analysis assumes that the three patients who failed to achieve union with cast fixation alone by 52 weeks in the cast plus surgery arm of the trial (i.e. did have an identified or suspected non-union after cast immobilisation but were not treated surgically) can be assumed to receive surgical intervention at a later time point. This scenario explores this assumption by assuming that these patients did not receive surgical intervention at a later date, and therefore are long-term non-unions.

Scenario 3, probability of non-union after secondary surgery

The base-case analysis uses evidence from the SWIFFT trial to estimate the probability of non-union for patients who underwent surgery after cast immobilisation (one patient of 17 who received surgery). This scenario explores the impact of this assumption by using an estimate from Filan and Herbert[183] to estimate the probability of non-union after secondary surgery (0.195, 95% CI 0.145 to 0.249).

Scenario 4, treatment specific adverse events

The base-case analysis assumed that the choice of treatment only impact the probability of achieving union, and not the subsequent risks of adverse event development. The base-case uses the large study by Lindström and Nyström[104] to inform the three parameters: the probability of having long-term non-OA adverse events, the probability of developing OA, and the probability that this OA is symptomatic. The major limitations of this approach are that the Lindström and Nyström[104] study solely considered patients treated with cast immobilisation. As observed by Saeden[109] the act of conducting surgery may result in the development of OA that may not have occurred with conservative treatment alone, and may be associated with a greater level of non-OA adverse events due to the invasive nature of surgery.

This scenario explores this assumption by using less robust, treatment specific estimates of adverse event rates from the literature. The primary source of evidence is Saeden,[109] a small (n=62) randomised study of cast versus Herbert screw fixation for acute scaphoid fracture. The small nature of this study, as well as the age of the surgical procedure (patients were randomised between 1984 and 1886), were the primary reasons for it being discounted as the primary source of the base-case analysis. Furthermore, there were concerns that the results of Saeden were inconsistent with clinical expectations, as it suggests a higher overall rate of adverse events in the cast immobilisation group. The use of this study changes the estimates reported in Table 29 in Chapter 4 to those reported in the condensed Table 68**Error! Reference source not found.** below, with the base-case estimates reported in the second line of each row. Estimates of the probability of developing SNAC post non-union remain unchanged from the base-case.

Table 68: Scenario 4 parameter values (shaded values report the base-case parameter estimates)

Parameter	Base case value (95% CI)	Distribution	Source
2.a. Long-term element of the model – Union Markov			
Probability of having long-term adverse symptoms that are not OA related			
Cast immobilisation	0.188 (0.043 to 0.405) 0.048 (0.024 to 0.079)	Beta (alpha-3, beta-13) (alpha-11, beta-218)	Saeden[109] Lindström and Nyström [104]
Surgery as last treatment	0.087 (0.011 to 0.228) Assumed same as cast	Beta (alpha-2, beta-21)	Saeden
Probability of developing OA			
Cast immobilisation	Limiting value – 0.308 Time constant – 1.5 CI – 0.123 to 0.527 Limiting value – 0.056 Time constant – 1.5 CI – 0.035 to 0.087	Exponential decay towards a limiting value, with limiting value characterised as a beta distribution	Saeden (only including scaphotrapezial joints) Lindström and Nyström
Surgery as initial treatment	Limiting value – 0.609 Time constant – 1.5 CI – 0.440 to 0.776	Exponential decay towards a limiting value, with limiting	Saeden

	Assumed same as cast	value characterised as a beta distribution	
Probability that developed OA is symptomatic			
Cast	0.750 (0.292 to 0.992) 0.992 (0.918 to 1.00)	Beta (alpha-3, beta-1) (alpha-11.9, beta-0.1)	Saeden Lindström and Nyström
Surgery	0.214 (0.050 to 0.454) Assumed same as cast	Beta (alpha-3, beta-11)	Saeden

Scenario 5, additional risk of OA development post non-union surgery

The base-case analysis assumes that there is no additional risk of developing OA as a result of multiple lines of treatment. This assumption implies that, in the case of surgery for non-union after cast immobilisation, there is no increase in the future risk of developing OA. However, Saeden[109] argues that surgery which opens the scaphotrapezial joint may result in the development of OA, but members of the trial TMG argue that surgery may in fact have a delaying effect on the progression of OA. This scenario will explore the sensitivity of the result to this assumption by assuming that patients undergoing surgery as a secondary treatment are firstly twice as likely to develop OA at any point than if surgery had been conducted as the primary treatment, and secondly if they are half as likely.

Scenario 6, non-OA permanent adverse event quality of life

The base-case model assumes that the HRQoL for non-OA permanent adverse event is the same as for OA, due to a lack of evidence. This scenarios tests the impact of this assumption by testing two extreme cases:

a. The HRQoL decrement for non-OA permanent adverse event is 50% less than for OA (mean decrement 0.065, CI 0.045 to 0.085) such that they have a greater quality of life than OA sufferers.

b. The HRQoL decrement for non-OA permanent adverse event is 50% greater that for OA (mean decrement 0.195, CI 0.175 to 0.215), such that they have a lesser quality of life than OA sufferers.

A third sub-scenario is additionally considered which attempts to separately model the role of rare but extremely impactful surgery related adverse events such as fusion, Chondrolysis, and infection. While previous analyses includes non-OA related AEs that are the same for both treatments (the base-case) and different (scenario 1), and the quality of decrement applied is lifelong (-0.130 each year) it is possible that this underestimates the impact of a small number of high impact and lifelong AEs that can occur after surgery. In the SWIFFT trial one patient was identified as having wrist fusion and reported a quality of life for the within trial period 0.31 less than the surgical arm average. This scenario explicitly incorporates this quality of life decrement occurring in 0.5% (roughly 1 in 219) of surgical patients for the rest of their lives.

Scenario 7, proportion of untreated patients who have union

The base-case analysis assumes that all patients in the untreated arm experience non-union, an assumption necessitated by the reality that it is impossible to estimate the rate in this treatment group. While in reality we know little about the prognosis and natural history of such a patient population, including whether any patients who did choose to not receive treatment would seek treatment later if symptoms persisted, we believe that the base case modelled provides a very important role in demonstrating the value of some form of active treatment. This scenario explores the sensitivity of the result to the assumption that all no treatment options result in non-union by using a threshold analysis to estimate the probability that the injury fails to unite without intervention at which point the no-treatment arm becomes the most-cost-effective treatment approach. This scenario can be used if future evidence emerges to reflect the validity of the base case assumption and therefore merits of active treatment.

Scenario 8, probability of SNAC post non-union

To explore the sensitivity of the model to changes in the probability of SNAC occurring at any time point after a non-union this scenario doubles and halves the base-case annual probabilities.

Scenario 9, proportion of patients who reject surgery post cast immobilization

In the base-case analysis the estimated probability of patients having surgery after a confirmed non-union after initial cast immobilisation is taken directly from the SWIFFT trial, with 4 of 18 patients did not have surgery. This scenario explores the sensitivity of the model to this parameter through a threshold analysis, identifying the rate at which patients would have to accept surgery after confirmed non-union after cast immobilisation for cast plus surgery to be the most cost-effective treatment.

Scenario 10, cost of first line surgical fixation

The base-case analysis estimates a cost per first line surgical fixation of £1,632 as informed by the relevant reference cost.[94] However, the trial TMG highlighted that this reference cost was widely considered to be a large underestimate of the true cost to the hospital of providing this procedure. Attempts were made to use data collected during the trial to conduct a bottom up costing of the procedure, but insufficient unit costs of the components and large variation in the level of reporting made it impossible to derive a meaningful estimate. This scenario therefore estimates the impact on the estimated result if the cost of surgical fixation were doubled to £3,264.

Scenario 11, No difference in quality of life in first year

The base-case analysis assumes a quality of life difference of 0.02 in favour of the surgical treatment arm in the first year of the model. This scenario explores the impact of incorporating the difference in baseline quality of life between the two arms by setting the quality of life of the two arms as the same (set to the cast value of 0.812).

Scenario 12, No quality of life decrement of non-union without SNAC

The base-case analysis assumes the quality of life decrement for patients with long-term non-union but no SNAC is the same as that used for OA (a decrement of 0.130). This scenario tests this assumption by assuming that non-union patients without SNAC have no quality of life decrement, experiencing the same quality of life as the general population.

Scenario Analyses Results

A number of scenarios were conducted to explore some of the elements of uncertainty not well captured by the PSA, as discussed in the main report and above. In this section the results presented of the different scenario analyses are reduced to reporting the NHB at a cost-effectiveness threshold of £20,000/QALY which gives a precise overview of which treatment option is the most cost-effective. The full list of NHB across the scenarios are reported in Table 69.

Table 69: Results of the scenario analyses, NHB at threshold of £20,000/QALY

Scenario	Surgery	Cast plus surgery	Cast only	No treatment
Base-case *Deterministic*	19.00	**19.02**	18.69	14.70
Scenario 1 *Definition of non-union at 1 year*	18.99	**19.02**	18.58	14.69
Scenario 2 *No surgical treatment for those who fail to achieve union with cast*	**19.00**	18.98	18.70	14.69
Scenario 3 *Probability of non-union after secondary surgery*	18.98	**18.99**	18.69	14.69

Scenario 4 *Treatment specific adverse events from Saeden*	**18.71**	18.40	18.06	14.69
Scenario 5a *Double risk of OA development post non-union surgery*	19.00	**19.03**	18.70	14.69
Scenario 5b *Half risk of OA development post non-union surgery*	19.01	**19.04**	18.68	14.69
Scenario 6a *50% less non-OA permanent adverse events QoL decrement*	19.07	**19.11**	18.75	14.69
Scenario 6b *50% greater non-OA permanent adverse events QoL decrement*	18.87	**18.90**	18.56	14.69
Scenario 6c *Explicit inclusion of additional fusion rate*	18.97	**19.04**	18.68	14.69
Scenario 7 *Proportion of untreated patients who have union*	*Would require 95.5% of untreated patients to achieve union for it to be the most cost-effective strategy*			
Scenario 8a *Double annual probability of*	19.00	***19.03***	*18.65*	*14.27*

SNAC post non-union				
Scenario 8b *Half annual probability of SNAC post non-union*	19.01	***19.04***	*18.75*	*15.17*
Scenario 9 *Proportion of patients who reject surgery post cast confirmed non-union*	*If the proportion of patients having surgery after confirmed non-union after cast immobilisation reduces from 0.948 to 0.852 primary surgery becomes cost-effective.*			
Scenario 10 *Doubling of cost of first line surgical fixation*	18.92	***19.04***	*18.68*	*14.72*
Scenario 11 *No difference in QoL in first year*	18.98	***19.03***	*18.68*	*14.69*
Scenario 12 *No QoL decrement for non-union no SNAC patients*	19.00	***19.03***	*18.81*	*16.01*

Table 69 shows that the cost-effectiveness results are sensitive to a number of key assumptions, while the headline result does not change in many of them, the incremental difference in NHB reduces in many. While scenario 4 is striking in that it results is a large change in the NHB and resultant decision, the small scale of the Saeden study which informs this scenario results in very large levels of uncertainty. Furthermore, it could be argued that the population used to inform this scenario from Saeden are not indicative of those considered here, with the cast population indicative of a more severe sub-set.

Scenarios 1 and 2 highlight the sensitivity of the model to the assumptions regarding the definition of slight union patients as union or non-union, and whether the three patients who are non-union at 52 weeks in the cast arm but have not received surgery can be assumed to be offered surgery at some point (as in the base case) or will remain non-unions (as in the scenario). These show the key finding of the analysis that if initial cast immobilisation is unsuccessful but surgical intervention is offered soon after it is highly likely to be cost-effective, as has avoided the high upfront cost implications of conducting surgery on all patients, but still avoids a high rate of long-term non-union and the adverse event risks of conducting a lot of surgical interventions.

Scenario 4 shows that the use of Saeden[109] to inform an estimate of treatment specific adverse events has a dramatic impact on the cost-effectiveness result. This result was flagged by the clinical advisors of this section as being contrary to clinical expectations as surgical intervention would be expected to be associated with a greater level of adverse events than cast immobilisation. However, as Saeden found a higher proportion of symptomatic adverse in the cast arm the model results responds accordingly. It is likely that the Saeden estimate suffers from small numbers and that the quality of life of those reporting symptoms in the surgical group is less than the cast group. However, given the evidence available it has not been possible to incorporate such factors without resorting to speculation. The results of this scenario justify the assumption of treatment independent adverse events made in the base case and highlight the need for further research into the nature of long-term adverse events in this clinical area.

Section 6: Within Trial Analysis Results

Summary statistics - costs

This section briefly considers the values observed in terms of costs to the NHS and PSS prior to imputation for missing values. These results provide a helpful overview of the results as reported by patients and prior to any assumptions being made about the nature of the missing data. The crude summary statistics and frequency histograms are reported in Table 70 and Figure 23.

As would be expected these compete case results show high levels of costs at the earlier stage of the trial, while patients are receiving treatment ($p<0.001$). With the exception of the first six weeks, when surgical patients will be having surgical related reviews, the time related costs are similar, as are imaging costs. While some surgical interventions did take place in the plaster cast arm (24 surgeries), resulting in a mean cost of £319, surgery costs are much greater in the surgery arm of the trials as would be expected.

In contrast, the average cost resulting from cast immobilisation is actually larger in the surgical arm. We believe this to be because many patients had casts fitted and re-fitted routinely after surgery to inspect healing, whereas the majority of patients randomised to cast immobilisation required fewer re-fittings. Overall, the average costs in the surgical arm were found to be statistically significantly greater than in the plaster cast arm, both in terms of the total costs for patients with complete data across all of the cost variables as well as the sum of the average costs, both reported in Table 70.

Table 70: Within trial cost summary statistics, complete case

Variable	Surgery mean (n, SE)	Plaster cast mean (n, SE)
6 weeks	£311 (168, 21.38)	£233 (169, 19.09)
12 weeks	£125 (165, 13.60)	£118 (162, 13.29)
26 weeks	£78 (153, 13.27)	£86 (140, 14.36)
52 weeks	£51 (174, 11.15)	£90 (163, 28.03)
Imaging	£42 (169, 4.72)	£43 (170, 4.92)
Surgery (no missing data)	£1,516 (219, 59.27)	£319 (220, 65.10)
Casting (no missing data)	£17 (219, 0.73)	£13 (220, 0.45)

Total costs, complete case	**£2,350 (83, 94.72)**	**£727 (65, 117.81)**
Sum of average costs	**£2,140**	**£901**

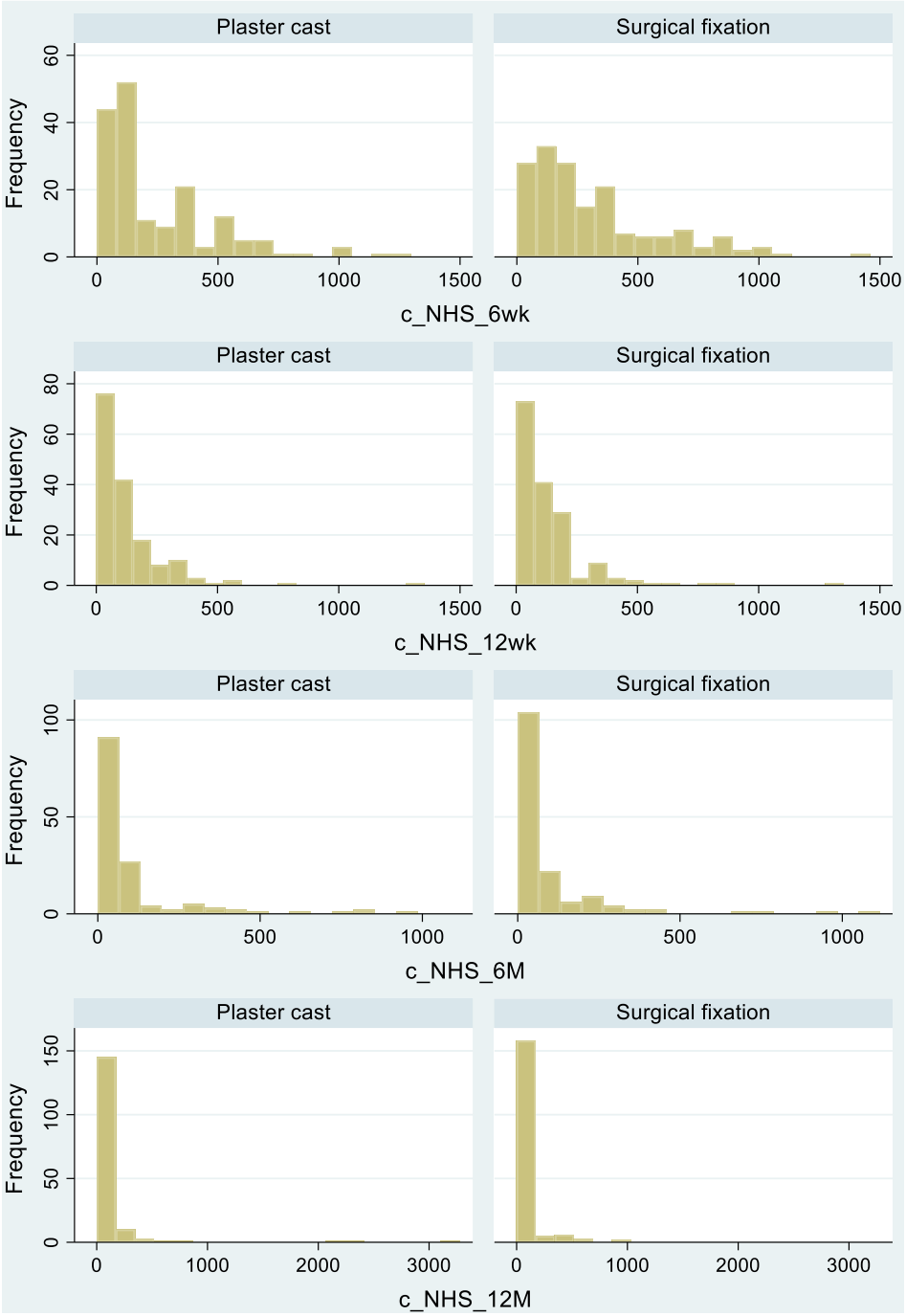


Figure 23: Histograms of patient interaction costs, complete case

Summary statistics - quality of life

This section briefly reports the within trial analysis results for the quality of life and cost estimates as complete case, i.e. prior to any imputation for missing data. The results are reported in Table 71 and Figure 24.

These crude analyses show that patients in both treatment strategies reported a bi-modal, highly skewed quality of life scores, with a high proportion reporting a perfect quality of life score of one, which increased as time since injury. However, there were also a small number of patients reporting very low quality of life score, including a proportion of negative scores throughout the follow up period, indicative of some patients experiencing very poor outcomes. This distribution is typical of such injuries where initial injury and treatment related impacts on quality of life reduce over time but some patients continue to experience adverse event related impacts. In addition, the average scores in the high 0.8 range are indicative of a 'normal' population of the age of the patients.[113]

While Figure 24 shows a similar spread of scores throughout the within trial period the mean results presented in Table 71 do appear to show that the plaster cast arm are have lower quality of life at all time points. The complete case average quality of life over the year (i.e. adjusted for the length represented by each questionnaire as given in the methods section) shows a slightly greater score for the surgical patients, alongside a smaller standard error. However, this difference may be the result of differences in the baseline score, which was 0.0287 higher in the surgical than the plaster cast arm.

Table 71: Quality of Life summary statistics, unadjusted mean complete case

Variable	Surgery mean (n, SE)	Plaster cast mean (n, SE)
Baseline	0.6260 (214, 0.0194)	0.5973 (219, 0.0201)
6 weeks	0.7522 (174, 0.0174)	0.7005 (179, 0.0181)
12 weeks	0.8290 (180, 0.0138)	0.7898 (164, 0.0173)
26 weeks	0.8361 (161, 0.0177)	0.8505 (146, 0.0183)
52 weeks	0.8820 (182, 0.0123)	0.8551 (176, 0.0176)
Average QoL, complete case	**0.8317 (134, 0.0131)**	**0.8140 (119, 0.0159)**

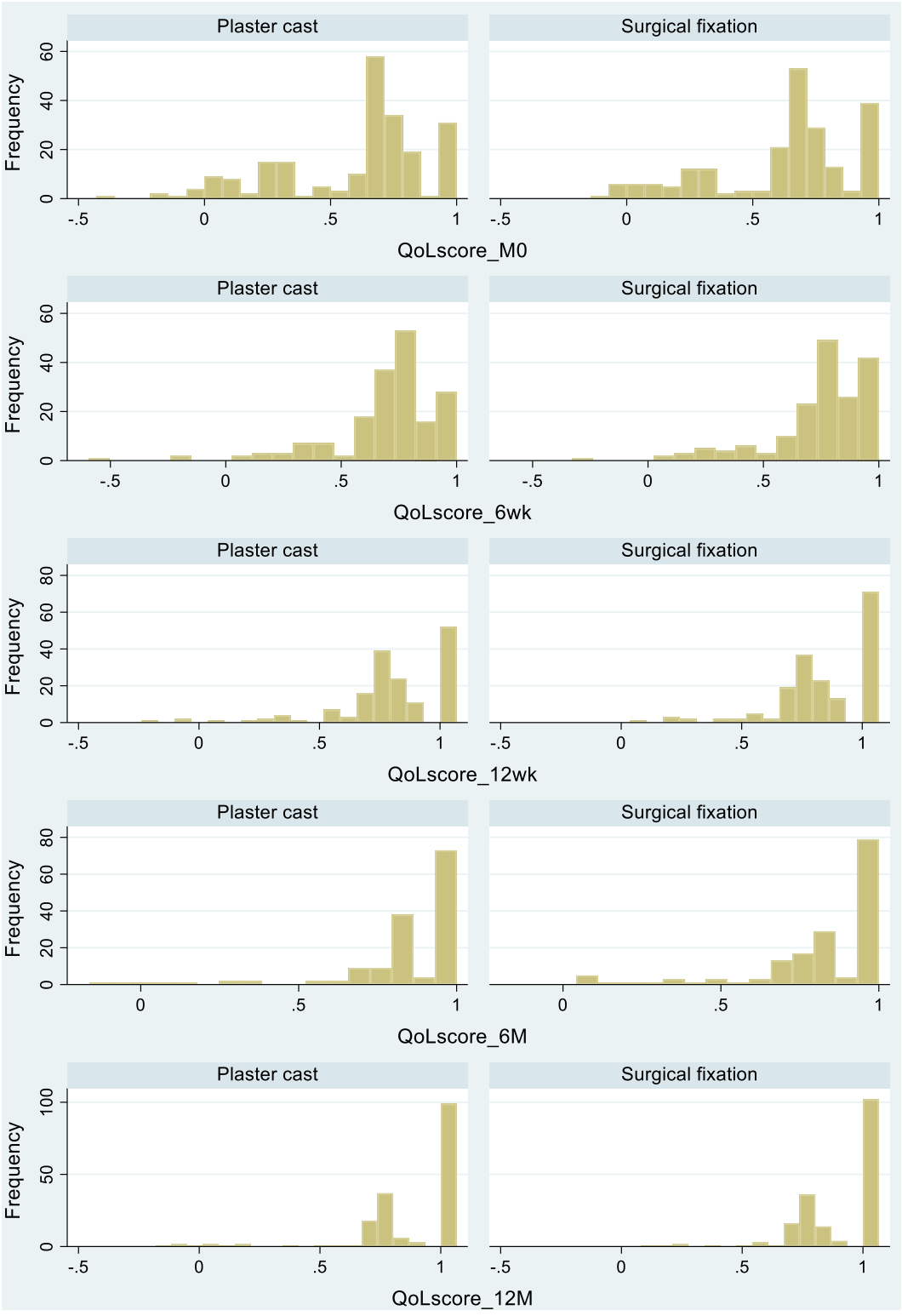


Figure 24: Complete case quality of life scores by time and treatment

Missing data results

Missing data was found to occur across the patient reported questionnaires related to quality of life and resource use at levels reported in Table 72. Overall the level of missing data was low but occurred at a greater level in the plaster cast arm, most likely due to a lower frequency of interaction and patient buy in with the treatment, potentially due to the perceived importance of the injury if cast immobilisation is deemed sufficient rather than the injury requiring surgical fixation.

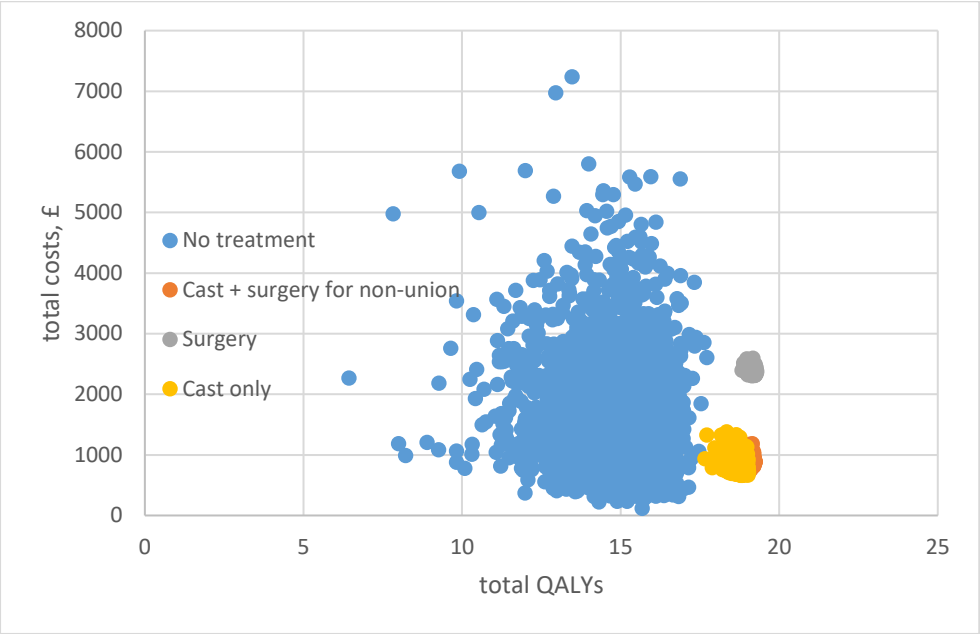
Table 72: Missing data observed in patient reported questionnaires

	Surgical fixation (n=219)	Plaster cast (n=220)
QoL score baseline	5 (2.3%)	1 (0.5%)
QoL score 6 weeks	45 (20.5%)	41 (18.6%)
QoL score 12 weeks	39 (17.8%)	56 (25.5%)
QoL score 26 weeks	58 (26.5%)	74 (33.6%)
QoL score 52 weeks	37 (16.9%)	44 (20.0%)
Cost 6 weeks	51 (23.3%)	51 (23.2%)
Cost 12 weeks	54 (24.7%)	58 (26.4%)
Cost 26 weeks	66 (30.1%)	80 (36.4%)
Cost 52 weeks	45 (20.5%)	57 (25.9%)
Imaging	50 (22.8%)	50 (22.7%)

Missing data was found to be non-monotonic and patients who were missing in one period were not necessarily missing in the next. Logistic regression in the quality of life and cost variables found many of the variables to be correlated with previously observed values, which, using the Faria[96] framework led to the assumption that the data was missing at random (MAR). As a result, in the multiple imputation framework missingness is assumed to depend on all other missing variables and baseline covariates, specifically gender, whether the injured arm was the patient's dominant, treatment allocation, and age. The variables selected are consistent with those used in the previous Chapter and the regression analyses presented in the next section. The imputation is run 36 times consistent with the largest proportion of missing data observed (36.0% in costs at 26 weeks in the plaster cast arm).[96]

Section 7: Extended model results

The figures below gives a scatter plot of the cost-effectiveness results first including all four treatment options and then only including the two SWIFFT trial options.



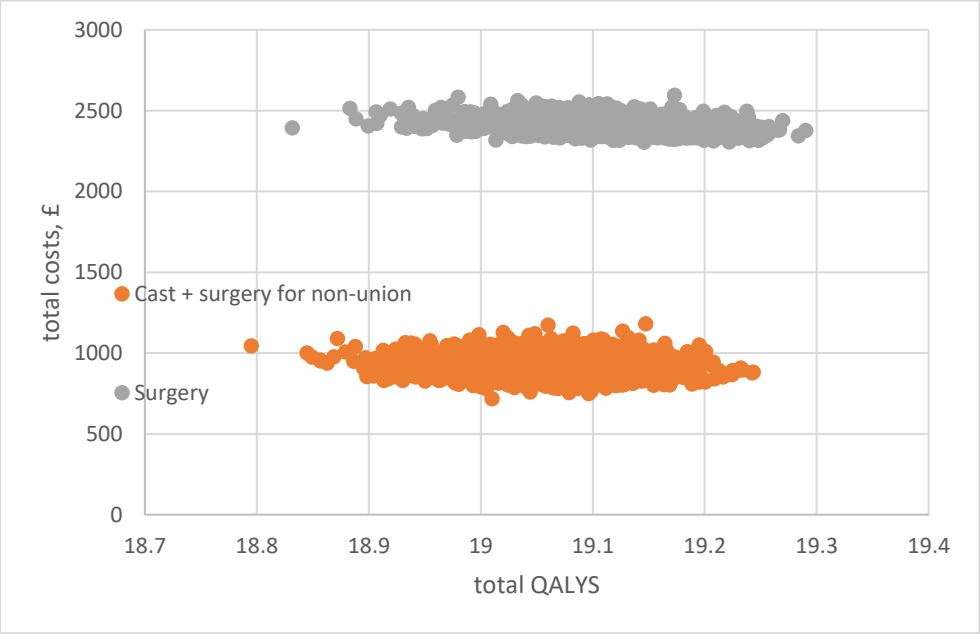


Figure 25: Scatter plot of the cost-effectiveness results for the 4 treatment options

The additional table below provides some of the clinical estimates of the model at three time points. The estimates allow this model to be validated as additional evidence emerges, specifically the five year SWIFFT update.

Table 73: Clinical estimates of the model at three time points

Time point	Percentage of initial population who have union with OA and are alive				Percentage of initial population who have SNAC and are alive			
	No treatment	Cast only	Cast + surgery	Surgery	No treatment	Cast only	Cast + surgery	Surgery
1	N/A	2.36%	2.58%	2.59%	0.69%	0.06%	0.00%	0.00%
5	N/A	4.66%	5.08%	5.11%	11.34%	1.02%	0.10%	0.04%
10	N/A	4.79%	5.23%	5.25%	33.53%	3.01%	0.31%	0.13%

Table 74: CHEERS checklist

Section/item	Item No	Recommendation	Reported on page No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	Page 113
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	Page 3 to 4
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study.	Page 28
		Present the study question and its relevance for health policy or practice decisions.	Page 28 to 32
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	Page 113 and 124
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	Page 113
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	Page 113 and 121

Section/item	Item No	Recommendation	Reported on page No
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	Page 125
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	Page 124
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	Page 124
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	Page 113
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	Page 4 and elsewhere in report
	11b	*Synthesis-based estimates*: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	Page 113
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	N/A
Estimating resources and costs	13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe	Page 113 to 121

Section/item	Item No	Recommendation	Reported on page No
		primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	Page 131 to 145
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	Page 124
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	Page 127 to 131
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	Page 127 to 131
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could	Page 120 and 128 to 131

Section/item	Item No	Recommendation	Reported on page No
		include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	Page 118 to 119, 135 to 137, 140 to 141, and 142 to 143
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	Page 151 to 153, and 157
Characterising uncertainty	20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	Page 153
	20b	*Model-based economic evaluation:*	Page 157 to 165

Section/item	Item No	Recommendation	Reported on page No
		Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	N/A
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	Page 165 to 167
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	Page 4
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with	Page 2

Section/item	Item No	Recommendation	Reported on page No
		International Committee of Medical Journal Editors recommendations.	