Surgical fixation compared with cast immobilisation for adults with a bicortical fracture of the scaphoid waist: the SWIFFT RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The SWIFFT RCT

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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 immobilising the wrist in a cast and then fixing only those that fail to unite.

Objectives

The objective was to evaluate the clinical effectiveness 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. A qualitative study was also conducted to explore 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 with an economic evaluation (within-trial and extrapolated analyses) 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 of 1–2 mm inclusive, as seen on any radiographic view. Random block sizes of 6 and 12 were used. Follow-up was at 6, 12, 26 and 52 weeks. Data collection included imaging (radiographs and computed tomography scans) at baseline and at 6, 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 owing 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 participants who indicated a willingness to be interviewed within 6 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 semistructured and, where possible, were undertaken face to face at a time and location convenient to the participant.

Setting

Trial recruitment was undertaken from the orthopaedic departments of 30 NHS hospitals in England and one hospital in Wales. Patients were recruited from fracture clinics from 23 July 2013 to 26 July 2016.

Participants

Adults (aged ≥ 16 years) presenting at a participating site within 2 weeks of their injury and in whom surgery could be undertaken within 2 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 > 2-mm displacement, as these are likely to be unstable and require surgical intervention; if they had a concurrent wrist fracture in the opposite limb; if they had a trans-scaphoid perilunate dislocation; if they had multiple injuries in the same limb; if they lacked the mental capacity to comply with treatment or data collection; if they were pregnant, as radiation exposure would be contraindicated; or if they were not a resident in the trauma catchment area of the participating site to allow follow-up.

Interventions

The intervention involved early percutaneous or open surgical fixation using standard Conformité Européenne-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 6–10 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 total score (scale 0–100, with lower scores indicating better outcomes) at 52 weeks. It was also completed at 6, 12 and 26 weeks. The trial was powered to detect a clinically relevant difference in the Patient-Rated Wrist Evaluation of 6 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 Patient-Rated Wrist Evaluation; the physical component summary and mental component summary scores of the Short Form questionnaire 12-items; bone union; range of movement and grip strength; complications; and return to work and unpaid recreational activities. In addition, resource use and the EuroQol-5 Dimensions, three-level version, were collected and a literature review was performed to inform the health economic evaluation.

All patient-reported outcomes (i.e. Patient-Rated Wrist Evaluation; Short Form questionnaire 12-items; EuroQol-5 Dimensions, three-level version; return to work; and unpaid recreational activities) were collected by post, in hospital clinics or occasionally over the telephone, at 6, 12, 26 and 52 weeks. Bone union was assessed on radiographs at 6, 12 and 52 weeks and computed tomography scans at 52 weeks. The other outcomes (i.e. range of movement and grip strength, as well as complications) were collected in routine hospital clinics at 6 and 12 weeks, and additionally at 52 weeks.

Statistical analysis

Analyses were conducted using the principles of intention to treat, 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 Patient-Rated Wrist Evaluation scores) was compared between the two randomised 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 was included as a random effect (to account for the repeated observations per participant). This analysis included any participant with valid Patient-Rated Wrist Evaluation 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 Patient-Rated Wrist Evaluation data. An estimate of the difference between treatment groups in total Patient-Rated Wrist Evaluation score was extracted for each time point and overall, with a 95% confidence interval and *p*-value. The treatment effect estimate for the 52-week time point served as the primary outcome. The treatment effects for the 6-, 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 multisite data [including site as a random effect (within which participants were nested) in the model as described for the analyses of the primary outcome]; the timing of the data collection by repeating the analysis of the primary outcome including only data collected within agreed time frames around each time point; separately excluding participants who three raters agreed based on the baseline images that (1) there was no fracture or (2) the displacement of the fracture was > 2 mm; and non-compliance using a complier-average causal effect analysis. 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 the pain and function subscales of the Patient-Rated Wrist Evaluation, the physical component summary and mental component summary of the Short Form questionnaire 12-items, 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 extent of union was presented at 6, 12 and 52 weeks by randomised group. Regression methods were used to analyse the union data only at 52 weeks, dichotomising participants as 'probably need surgery' and 'probably do not need surgery' and also using the repeated measures of dichotomised union at 6, 12 and 52 weeks. Rates of malunion (based on the ratio of the scaphoid height to length at thresholds of 0.6 and 0.7) were presented overall and for each treatment group at 6, 12 and 52 weeks. Complications that were defined as medical, surgical or plaster cast were presented for each treatment group at 6, 12 and 52 weeks using only data collected at the hospital and 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 or any of the complications identified elsewhere. All serious and non-serious adverse events and complications noted on review of the imaging were summarised by treatment group.

Economic analysis

The perspective of the economic analysis was that of the UK NHS and Personal Social Services. For the within-trial analysis, the EuroQol-5 Dimensions, three-level version, was collected from patient questionnaires to permit the estimation of quality-adjusted life-years 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 Great British pounds at 2017 prices. Differences in mean costs and quality-adjusted life-years at 52 weeks were used to estimate the incremental cost-effectiveness ratio of surgery compared with cast for a 'within-trial' analysis. Multiple imputation of missing data was used with an intention-to-treat analysis to estimate a base-case incremental cost-effectiveness ratio, 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 time frame 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 incremental cost-effectiveness ratio and net health benefit 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, as well as a series of scenario analyses to explore the impact of structural uncertainty on the results.

Qualitative analysis

The discursive, exploratory and semistructured 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 their own terms and to prioritise the insight generated therein.

Clinical effectiveness results

Of the 1047 patients who met the inclusion criteria, 775 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 the 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 the 17 participants in the plaster cast group who had surgery for early identified non-union, 14 had this surgery within 6 months from randomisation and three were treated after 6 months. Three of the four participants in the plaster cast group who had non-union identified at 52 weeks had not been offered surgery during the 52-week follow-up.

The primary analysis was on the 408 participants providing valid Patient-Rated Wrist Evaluation 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 were 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 Patient-Rated Wrist Evaluation score at 52 weeks: the cast group mean score was 14.0 (95% confidence interval 11.3 to 16.6) and the surgery group mean score was 11.9 (95% confidence interval 9.2 to 14.5), with an adjusted mean difference of –2.1 in favour of surgery (95% confidence interval –5.8 to 1.6; $p = 0.27$). A complier-average causal effect analysis to take non-compliance into account found, at 52 weeks, an increased difference in favour of surgery in the total Patient-Rated Wrist Evaluation score of –3.1 (95% confidence interval –7.3 to 1.1; $p = 0.15$). The adjusted mean difference in total Patient-Rated Wrist Evaluation score in favour of surgery at 6 weeks was –4.2 (95% confidence interval –8.5 to 0.1; $p = 0.06$), at 12 weeks was –5.6 (95% confidence interval –9.8 to –1.4; $p = 0.01$), at 26 weeks was –0.3 (95% confidence interval –4.1 to 3.6; $p = 0.89$) and overall was –3.0 (95% confidence interval –6.3 to 0.3; $p = 0.07$). The sensitivity analyses that have been described produced similar results on the total Patient-Rated Wrist Evaluation score 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 or fracture displacement on the total Patient-Rated Wrist Evaluation score.

For secondary outcomes, the adjusted mean difference at 52 weeks in favour of surgery in the Patient-Rated Wrist Evaluation pain subscale was –1.1 (95% confidence interval –3.3 to 1.0; $p = 0.31$) and for the function subscale was –1.0 (95% confidence interval –2.6 to 0.7; $p = 0.25$). For the Short Form questionnaire 12-items mental component summary at 52 weeks, the adjusted mean difference was –1.2 points (95% confidence interval –3.3 to 0.8 points; $p = 0.24$) favouring the plaster cast group. In the Short Form questionnaire 12-items physical component summary, the adjusted mean difference was 1.6 points (95% confidence interval 0.2 to 3.1 points; $p = 0.03$) 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%) were less likely than those in the plaster cast group (9 of 220, 4.1%) to have non- or only slight union of their fracture at 52 weeks (i.e. probably needing surgery versus probably not needing surgery), but this difference was not statistically significant. Based on these figures, 44 patients would need to be offered surgery instead of a cast to prevent one extra non-union 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 computed tomography 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 reoperations and one participant in the cast group required a reoperation for non-union. There were no intraoperative complications. Surgical complications occurred in 14.2% of participants in the surgery group and 1.4% of participants in the plaster cast group. Cast issues, which were usually minor, occurred in 2.7% and 20.5% of the surgery and plaster cast group, respectively. There were inconsistencies in reporting complications between the complications form 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%) participants in the plaster cast group. All three serious adverse events were in the surgery group. Furthermore, 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, £1295 more per patient (95% confidence interval £1084 to £1504) 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 incremental cost per quality-adjusted life-year at 52 weeks for surgery compared with cast immobilisation with early fixation of confirmed non-union was £81,962 per quality-adjusted life-year.

The economic evaluation base-case analysis of the extrapolated long-term model established that the initial use of a 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 per quality-adjusted life-year. The net health benefit 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 among 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 a 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 evidence suggests that patients should be immobilised in a cast and that all suspected non-unions be immediately investigated and those that are confirmed urgently fixed. Surgeons should address, at the outset, patients' desire to have a 'sense of recovering'.

Recommendation for future research

The planned 5-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 (malposition and penetration within joints) on quality of life. This will further inform the areas of uncertainty in the extrapolated model.

Trial registration

This trial is registered as ISRCTN67901257.

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