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1 **Title:**

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

5

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103 **Abstract**

104

105 **Background**

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

111

112 **Methods**

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

120

121 **Findings**

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130 **Interpretation**

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

134

135 **Funding**

136 This project was funded by the National Institute for Health Research Health Technology
137 Assessment Programme (project number 11/36/37).

138

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

140

141 **Research in Context:**

142

143 *Evidence Before this study:*

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

154

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

166

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

171

172 *Added value of this study:*

173 To our knowledge, SWIFFT is the largest randomised trial (439 participants) to compare
174 surgery with cast immobilisation in the treatment of adults with slight or no displacement of
175 scaphoid waist fractures. It has doubled the evidence from previous small trials of variable
176 quality. There was no evidence of a difference in overall patient-reported outcome at 52
177 weeks, nor for the pain or function sub-scales of the patient-reported outcome, grip strength,
178 or range of movement. Time off work was similar between the two groups. While fewer
179 participants in the surgery group (n=4, 2%) compared with cast immobilization (n=9, 4%)
180 had non- or slight union at 52 weeks (p=0.13), surgery was more likely to lead to potentially
181 serious complications.

182

183 *Implications of all the available evidence:*

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

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203 **Introduction**

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

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

212

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

222

223 Immediate surgical fixation is said to avoid the need for a cast and accelerate return to
224 function, work, and sport⁷ but exposes patients to surgical risks. Eight small randomised
225 clinical trials in United Kingdom, United States of America (USA) and Sweden,⁸ of variable
226 quality, reporting on undisplaced or minimally displaced fractures of the scaphoid waist,
227 provide unclear evidence on whether surgical fixation gives better outcomes than cast
228 immobilization. Despite insufficient evidence there is an increasing trend⁹ to immediately fix
229 this fracture for perceived short-term benefits, but concerns remain about the lack of evidence
230 on long-term benefits and additional risks from surgery, such as malunion, infection, and
231 implant related problems.

232

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

235

236

237 **Methods**

238 *Study design and participants*

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

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

243

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

255

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

261

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

266

267 ***Randomisation and blinding***

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

271

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

274

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

277

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

284

285 ***Interventions***

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

289

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

296

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

299

300 ***Data collection and outcome measures***

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

304

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

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

312

313 Bone union was determined using the plain radiographs and a CT scan performed for
314 research purposes at baseline and 52 weeks. Routine radiographs taken at six and 12-week
315 hospital clinic visits were also collected. Union was defined as complete disappearance of the
316 fracture line⁵ on radiographs and complete bridging on CT scans.¹³ Partial union was
317 recorded as the proportion of the fracture plane traversed by bridging trabeculae on CT
318 sagittal and coronal multiplanar scaphoid reconstructions and union was categorised as none
319 (0%), slight (>0-20%), partial (>20-70%), almost full (70-<100%) and full (100%). Malunion
320 was assessed on the 52-week CT scan, as the ratio of Scaphoid height to length ≥ 0.6 or ≥ 0.7
321 in the scaphoid sagittal plane.¹⁴

322

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

326

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

330

331 **Statistical methods**

332 A six-point improvement in PRWE score was deemed a conservative¹⁵ minimum clinically
333 important difference. Using a SD of 20,¹¹ this gave an effect size of 0.3. To observe this
334 effect size with 80% power using a two-sided 5% significance level requires 350 participants.
335 Allowing for 20% attrition, the recruitment target was 438 participants.

336

337 Analyses strictly followed a prespecified analysis plan, endorsed by the independent
338 oversight committees. Analyses were on an intention-to-treat basis, and were performed in
339 Stata v15¹⁶ using two-sided statistical tests at the 5% significance level. Baseline and
340 outcome data are summarized descriptively by treatment group. The primary analysis
341 compared total PRWE scores between the two groups using a covariance pattern, mixed-
342 effect linear regression model incorporating all post-randomisation time points (six, 12, 26

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

352

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

356

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

364

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

369

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

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

378

379 **Role of the funding source**

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

384

385 **Results**

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

392

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

399

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

402

403 Of the 219 patients allocated to surgery, 188 (86%) received surgery, on average 10·2 days
404 (range 3-20) after injury, and performed by 95 surgeons across 29 sites. Data on operating
405 surgeon were available for 187 of the 188 operations; 163 were either performed (n=120,
406 64%) or assisted/supervised (n=43, 23%, assisted 40, supervised 3) by consultants. The
407 remaining 24 were performed by a specialist trainee (n=13) or staff grade/associate specialist
408 (n=11). Of the 220 patients allocated to cast immobilization, 214 (97%) had a cast initially
409 and six (3%) received surgery (mean 13·5 days after injury, range 5-32) shortly after

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

416

417 Following randomisation, participants in the cast immobilization group wore a cast for an
418 average of 44.8 days (SD 15.2); 91 (41%) then were given a splint for an average of a further
419 26.4 days (SD 15.1). Of the 188 participants allocated to the surgical fixation arm who
420 underwent surgery 86% had minimal or no immobilisation: 26 (14%) had a bandage applied
421 (duration not available); 62 (33%) had a splint only (mean 28.4 [SD 19.6] days); and 73
422 (39%) had a cast on for a short period immediately after surgery (mean 15.6 [SD 9.8] days)
423 followed by a splint (24.7 [SD 13.9] days). The remaining (14%) were immobilised in a cast:
424 24 (13%) had a cast only (mean 30.9 [SD 16.7] days); and three had a splint for a mean of
425 12.7 days [SD 2.5] then a cast for a mean of 27.7 days [SD 0.6].

426

427 ***Primary outcome and sensitivity analyses***

428 Valid PRWE data were provided by 348 participants (79%) at six weeks, 341 (78%) at 12
429 weeks, 302 (69%) at 26 weeks, and 362 (82%) at 52 weeks. The primary analysis included
430 408 (93%) participants (203 surgery; 205 cast immobilization) with a valid PRWE score for
431 at least one follow-up time point and complete covariate data. At 52 weeks, the unadjusted
432 mean PRWE score was 11.4 (SD 16.6) in the surgery group and 14.2 (SD 19.8) in the cast
433 immobilization group for which there was no evidence of a ceiling effect. There was no
434 evidence of a statistically significant or clinically important difference in PRWE score
435 between groups at 52 weeks (adjusted mean difference -2.1 favouring the surgery group,
436 95% CI -5.8 to 1.6, $p=0.27$), at 26 weeks nor over the whole 52 weeks (Table 2; Figure 2).
437 There was a statistically significant difference at week 12 ($p=0.01$) and weak evidence of a
438 difference at six weeks ($p=0.06$) favouring surgery. While the point estimates of the
439 difference do not exceed 6 points (the threshold of clinical importance we are using in this
440 study), the confidence intervals do include this difference.

441

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

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

446

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

451

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

455

456 *Subgroup analyses*

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

460

461 *Secondary outcomes*

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

467

468 Participants in the surgery group were less likely to have non- or slight union of their fracture
469 at 52 weeks (Table 3) but this difference was not statistically significant (four vs nine
470 participants, adjusted odds ratio 0·40, 95% CI 0·12 to 1·33, p=0·13). Supplementary Table 7
471 presents the malunion assessed at different thresholds of ratio of scaphoid height to length
472 (0·6 and 0·7). For both thresholds there were no marked differences between groups in
473 malunion at all time-points on the radiographic and CT images.

474

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

478 (numbness in the region of the scar, n=3 and decreased sensation over the scar and distally
479 with tenderness, n=1), two had infection, and three developed Complex Regional Pain
480 Syndrome (CRPS); while in the cast group, one developed transient nerve problems, two had
481 infection, and none had CRPS (Supplementary Table 8). The number experiencing a medical
482 complication (n=4, 2% vs n=5, 2%) was similar in the two groups. CT images at 52 weeks
483 were assessed for screw penetration from the surface of the bones in mm for 142 of the 188
484 participants who received surgery; screw penetration was identified in 93 (65%) participants
485 (<1 mm, n=25 [27%]; 1-2 mm inclusive, n=44 [47%]; and >2 mm, n=24 [26%]). For these
486 142 participants the unadjusted mean PRWE at 52 weeks for those who had screw
487 penetration <1mm was 8.9 (SD 15.0) and for those ≥1mm was 10.8 (SD 13.9).

488

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

494

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

498

499 Over the 52 week period, surgery group participants reported an average of 15.6 days of lost
500 employment compared to 18.2 days in the cast immobilization group (Table 4). This
501 difference is not statistically significant.

502

503 **Discussion**

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

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

514

515 Early on, when more participants in the cast group were still in a cast, differences in pain and
516 function were statistically significant, favouring surgery, but below six points on the PRWE
517 and so of uncertain clinical relevance. Beyond 12 weeks there was no difference between
518 groups, nor did this study identify evidence that the rate of non- and slight union was
519 statistically significantly different between surgical fixation and cast immobilisation. We
520 observed this state in four (three slight union and one non-union) participants in the surgery
521 group and nine (five slight union and four non-union) of those who were treated in a plaster
522 cast. Complications of infection, nerve problems and CRPS were ten-times more likely after
523 early fixation (14.2%) than in the cast group (1.4%). The screw penetrated joints in far more
524 participants than anticipated, in half the screw protruded by 1-2 mm and in a quarter by over
525 2 mms risking irreversible articular cartilage damage and early degenerative arthritis but only
526 six had penetrating screws removed. In most, screw penetration was seen because we did CT
527 scans at one year. This emphasises the need for careful imaging during surgery. Cast
528 complications (soft, tight or broken cast, skin soreness) were minor, resolved early and had
529 no lasting consequence. Reoperations were more frequent after early screw fixation (4% vs
530 <1%) for six of these participants the re-operations were for implant related problems and for
531 two they were for non-union, with one requiring scaphoid excision and a four-corner fusion.
532 The longer-term consequences of arthritis, malunion, injury, and screw penetration will be
533 investigated in a five-year review of these participants.

534

535 Over the last few decades the use of surgery has increased as clinicians and patients
536 anticipated better union rate and quicker return to work. We reviewed Hospital Episode
537 Statistics (HES) for National Health Service (NHS) hospitals in England. These recorded a
538 two-thirds increase (1534, 1720 and 2582) of acute scaphoid fracture fixations for the years
539 2007/8, 2008/9 and 2009/10 before this study was commissioned. The rate of surgical
540 fixation²⁰ rose very slightly from 37% to 41% from 2007/8 to 2008/9 but then increased
541 sharply to 62% in 2009/10. The rate of surgical treatment of acute scaphoid fractures has also
542 increased significantly in the USA from 22.1% in 2006 to 34.1% in 2012. The incidence of
543 primary surgical treatment has increased more than threefold in Finland between 1997 and
544 2014. Achieving union is particularly important since untreated non-union causes wrist
545 arthritis. The difference in union rate between those fractures initially treated in a cast and

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

553

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

566

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

579

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

587

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

597

598 **Conclusion**

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

604

605 **Contributors**

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

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

615

616 **Trial Steering Committee**

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

622

623 **Data Monitoring Ethics Committee**

624 Graeme MacLennan (independent chair), Timothy Hems (independent member, orthopaedic
625 surgeon), Adam Watts (independent member, orthopaedic surgeon).

626

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644

645

646

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650

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652 The views expressed are those of the authors and do not necessarily reflect those of the
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654 Department of Health and Social Care.

655

656 **Data sharing agreement**

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

662

663 **Declaration of interests**

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

670

671

672 **Table 1. Baseline characteristics for all randomised participants and those included in**
673 **the primary analysis, by treatment group**

| | All Randomised Patients | | | Patients in Primary Analysis ^a | | |
|---|-------------------------|--|------------------|---|--|------------------|
| | Surgery (n=219) | Cast immobilization ^b (n=220) | Total (n=439) | Surgery (n=203) | Cast immobilization ^b (n=205) | Total (n=408) |
| Sex, No. (%) | | | | | | |
| Male | 180 (82.2) | 183 (83.2) | 363 (82.7) | 168 (82.8) | 169 (82.4) | 337 (82.6) |
| Female | 39 (17.8) | 37 (16.8) | 76 (17.3) | 35 (17.2) | 36 (17.6) | 71 (17.4) |
| Age, years | | | | | | |
| Mean (SD) | 32.9 (13.2) | 32.9 (12.2) | 32.9 (12.7) | 33.2 (13.2) | 32.9 (12.4) | 33.1 (12.8) |
| Median (IQR) | 28 (22, 39) | 29 (23, 41) | 29 (23, 40) | 29 (23, 39) | 29 (23, 41) | 29 (23, 40) |
| Ethnicity, No. (%) | | | | | | |
| White | 205 (93.6) | 195 (88.6) | 400 (91.1) | 191 (94.1) | 180 (87.8) | 371 (90.9) |
| Other | 12 (5.5) | 25 (11.4) | 37 (8.4) | 12 (5.9) | 25 (12.2) | 37 (9.1) |
| Missing | 2 (0.9) | 0 (0.0) | 2 (0.5) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Education, No. (%) | | | | | | |
| No formal qualifications | 24 (11.0) | 27 (12.3) | 51 (11.6) | 22 (10.8) | 25 (12.2) | 47 (11.5) |
| Some qualifications | 151 (68.9) | 129 (58.6) | 280 (63.8) | 139 (68.5) | 120 (58.5) | 259 (63.5) |
| Degree or higher | 41 (18.7) | 64 (29.1) | 105 (23.9) | 41 (20.2) | 60 (29.3) | 101 (24.8) |
| Missing | 3 (1.4) | 0 (0.0) | 3 (0.7) | 1 (0.5) | 0 (0.0) | 1 (0.2) |
| Employment status, No. (%) | | | | | | |
| Part-time | 20 (9.1) | 18 (8.2) | 38 (8.7) | 20 (9.9) | 18 (8.8) | 38 (9.3) |
| Full-time | 127 (58.0) | 120 (54.5) | 247 (56.3) | 119 (58.6) | 111 (54.1) | 230 (56.4) |
| Self-employed | 21 (9.6) | 36 (16.4) | 57 (13.0) | 19 (9.4) | 31 (15.1) | 50 (12.3) |
| Student | 20 (9.1) | 21 (9.5) | 41 (9.3) | 19 (9.4) | 21 (10.2) | 40 (9.8) |
| Retired | 7 (3.2) | 5 (2.3) | 12 (2.7) | 7 (3.4) | 5 (2.4) | 12 (2.9) |
| Looking after family/home | 1 (0.5) | 6 (2.7) | 7 (1.6) | 0 (0.0) | 5 (2.4) | 5 (1.2) |
| Seeking work | 9 (4.1) | 5 (2.3) | 14 (3.2) | 8 (3.9) | 5 (2.4) | 13 (3.2) |
| Other | 11 (5.0) | 9 (4.1) | 20 (4.6) | 10 (4.9) | 9 (4.4) | 19 (4.7) |
| Missing | 3 (1.4) | 0 (0.0) | 3 (0.7) | 1 (0.5) | 0 (0.0) | 1 (0.2) |

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

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

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

SD, standard deviation; PRWE, Patient Rated Wrist Evaluation

674

675

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

| | Mean (95% CI) ^a | | Mean Difference (95% CI) | p-value |
|--|----------------------------|-------------------------------------|-----------------------------|---------|
| | Surgery | Cast immobilization ^b | | |
| <i>Primary outcome: PRWE total score^c</i> | | | | |
| No. of | 203 | 205 | | |
| At 6 wk | 35.6 (32.6, 38.6) | 39.8 (36.8, 42.8) | -4.2 (-8.5, 0.1) | 0.06 |
| At 12 wk | 21.0 (18.1, 24.0) | 26.6 (23.6, 29.6) | -5.6 (-9.8, -1.4) | 0.01 |
| At 26 wk | 16.2 (13.5, 18.9) | 16.5 (13.8, 19.2) | -0.3 (-4.1, 3.6) | 0.89 |
| At 52 wk | 11.9 (9.2, 14.5) | 14.0 (11.3, 16.6) | -2.1 (-5.8, 1.6) | 0.27 |
| Over 52 | 21.3 (18.9, 23.6) | 24.4 (22.0, 26.7) | -3.0 (-6.3, 0.3) | 0.07 |
| <i>Secondary outcome: PRWE pain subscale score^d</i> | | | | |
| No. of | 203 | 206 | | |
| At 6 wk | 18.8 (17.3, 20.4) | 19.0 (17.5, 20.5) | -0.1 (-2.3, 2.0) | 0.89 |
| At 12 wk | 13.1 (11.5, 14.6) | 15.0 (13.4, 16.6) | -2.0 (-4.2, 0.3) | 0.09 |
| At 26 wk | 11.0 (9.4, 12.5) | 10.6 (9.0, 12.2) | 0.4 (-1.8, 2.6) | 0.75 |
| At 52 wk | 7.9 (6.4, 9.5) | 9.1 (7.5, 10.6) | -1.1 (-3.3, 1.0) | 0.31 |
| Over 52 | 12.7 (11.5, 14.0) | 13.5 (12.2, 14.8) | -0.7 (-2.5, 1.1) | 0.44 |
| <i>Secondary outcome: PRWE function subscale score^d</i> | | | | |
| No. of | 203 | 205 | | |
| At 6 wk | 16.7 (14.9, 18.5) | 20.5 (18.7, 22.3) | -3.8 (-6.3, -1.3) | 0.003 |
| At 12 wk | 8.1 (6.6, 9.5) | 11.5 (10.0, 13.0) | -3.4 (-5.6, -1.3) | 0.001 |
| At 26 wk | 5.4 (4.1, 6.6) | 6.0 (4.7, 7.3) | -0.6 (-2.4, 1.2) | 0.52 |
| At 52 wk | 3.9 (2.7, 5.1) | 4.9 (3.7, 6.1) | -1.0 (-2.6, 0.7) | 0.25 |
| Over 52 | 8.6 (7.5, 9.7) | 10.8 (9.7, 12.0) | -2.2 (-3.8, -0.6) | 0.01 |
| <i>Secondary outcome: SF-12 mental component score^e</i> | | | | |
| No. of | 202 | 206 | | |
| At 6 wk | 49.7 (48.1, 51.3) | 49.1 (47.5, 50.7) | 0.5 (-1.7, 2.8) | 0.63 |
| At 12 wk | 50.6 (49.0, 52.1) | 50.7 (49.1, 52.3) | -0.2 (-2.4, 2.1) | 0.88 |
| At 26 wk | 51.0 (49.4, 52.6) | 51.6 (49.9, 53.3) | -0.6 (-3.0, 1.7) | 0.60 |
| At 52 wk | 51.0 (49.6, 52.5) | 52.3 (50.8, 53.7) | -1.2 (-3.3, 0.8) | 0.24 |
| Over 52 | 50.6 (49.3, 51.8) | 50.9 (49.7, 52.2) | -0.4 (-2.2, 1.4) | 0.69 |
| <i>Secondary outcome: SF-12 physical component score^e</i> | | | | |
| No. of | 202 | 206 | | |
| At 6 wk | 43.9 (42.7, 45.1) | 43.4 (42.2, 44.6) | 0.5 (-1.2, 2.2) | 0.59 |
| At 12 wk | 49.8 (48.7, 50.9) | 47.6 (46.5, 48.8) | 2.2 (0.6, 3.8) | 0.01 |
| At 26 wk | 51.6 (50.5, 52.7) | 51.6 (50.5, 52.8) | -0.0 (-1.6, 1.5) | 0.95 |
| At 52 wk | 53.1 (52.1, 54.2) | 51.5 (50.5, 52.6) | 1.6 (0.2, 3.1) | 0.03 |
| Over 52 | 49.6 (48.8, 50.4) | 48.5 (47.7, 49.3) | 1.1 (-0.1, 2.2) | 0.08 |
| <i>Secondary outcome: grip strength (kg) for affected wrist</i> | | | | |

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

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

681 ^b The “Cast immobilization” group was the standard clinical pathway using cast immobilisation initially and
682 expecting suspected non-unions to be confirmed on imaging and immediately fixed.

683 ^c Score range 0-100; lower score indicates better outcome

684 ^dScore range 0-50; lower score indicates better outcome

685 ^e 0 (lowest level of health) to 100 (highest level of health)

686

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

| Time point ^a | Union ^b | Surgery (n=219) | Cast immobilization ^c (n=220) | Total (n=439) |
|-------------------------|--------------------|--------------------|--|------------------|
| At 6 wk, No. (%) | Union | 47 (21.5) | 26 (11.8) | 73 (16.6) |
| | Almost full union | 81 (37.0) | 73 (33.2) | 154 (35.1) |
| | Partial union | 47 (21.5) | 70 (31.8) | 117 (26.7) |
| | Slight union | 11 (5.0) | 23 (10.5) | 34 (7.7) |
| | Non-union | 2 (0.9) | 9 (4.1) | 11 (2.5) |
| | Missing | 31 (14.2) | 19 (8.6) | 50 (11.4) |
| At 12 wk, No. (%) | Union | 102 (46.6) | 63 (28.6) | 165 (37.6) |
| | Almost full union | 45 (20.5) | 44 (20.0) | 89 (20.3) |
| | Partial union | 15 (6.8) | 33 (15.0) | 48 (10.9) |
| | Slight union | 7 (3.2) | 13 (5.9) | 20 (4.6) |
| | Non-union | 0 (0.0) | 10 (4.5) | 10 (2.3) |
| | Missing | 50 (22.8) | 57 (25.9) | 107 (24.4) |
| At 52 wk, No. (%) | Union | 93 (42.5) | 72 (32.7) | 165 (37.6) |
| | Almost full union | 64 (29.2) | 59 (26.8) | 123 (28) |
| | Partial union | 3 (1.4) | 10 (4.5) | 13 (3) |
| | Slight union | 3 (1.4) | 5 (2.3) | 8 (1.8) |
| | Non-union | 1 (0.5) | 4 (1.8) | 5 (1.1) |
| | Missing | 55 (25.1) | 70 (31.8) | 125 (28.5) |

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

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

688

689

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

| | Surgery | | | Cast immobilization ^a | | | Total | | |
|------------------------------------|----------|-----------------------------------|-----------------------------------|----------------------------------|---------------------------------------|-----------------------------------|----------|---------------------------------------|-----------------------------------|
| | <i>n</i> | <i>Mean (SD) Median (IQR)</i> | <i>% reporting 0 days</i> | <i>n</i> | <i>Mean (SD) Median (IQR)</i> | <i>% reporting 0 days</i> | <i>n</i> | <i>Mean (SD) Median (IQR)</i> | <i>% reporting 0 days</i> |
| <i>Baseline to 6 weeks</i> | 156 | 13.6 (14.4) 7 (1, 25.5) | 20.5 | 158 | 13.4 (15.6) 5 (0, 30) | 29.8 | 314 | 13.5 (15.0) 6 (0, 30) | 25.2 |
| <i>6-12 weeks</i> | 161 | 2.6 (7.5) 0 (0, 0) | 75.8 | 149 | 4.9 (10.9) 0 (0, 2) | 67.1 | 310 | 3.7 (9.4) 0 (0, 1) | 71.6 |
| <i>12-26 weeks</i> | 142 | 2.0 (10.2) 0 (0, 0) | 90.1 | 135 | 3.7 (14.9) 0 (0, 0) | 88.9 | 277 | 2.8 (12.7) 0 (0, 0) | 89.5 |
| <i>26-52 weeks</i> | 164 | 1.5 (10.7) 0 (0, 0) | 91.5 | 160 | 1.9 (14.7) 0 (0, 0) | 91.3 | 324 | 1.7 (12.8) 0 (0, 0) | 91.4 |
| <i>Total</i> | 197 | 15.6 (26.7) 5 (0, 21) | 30.5 | 201 | 18.2 (29.1) 4 (0, 30) | 35.8 | 398 | 16.9 (27.9) 5 (0, 25) | 33.2 |

691 ^aThe “Cast immobilization” group was the standard clinical pathway using cast immobilisation initially and
692 expecting suspected non-unions to be confirmed on imaging and immediately fixed.
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Figure 1. SWIFFT trial profile

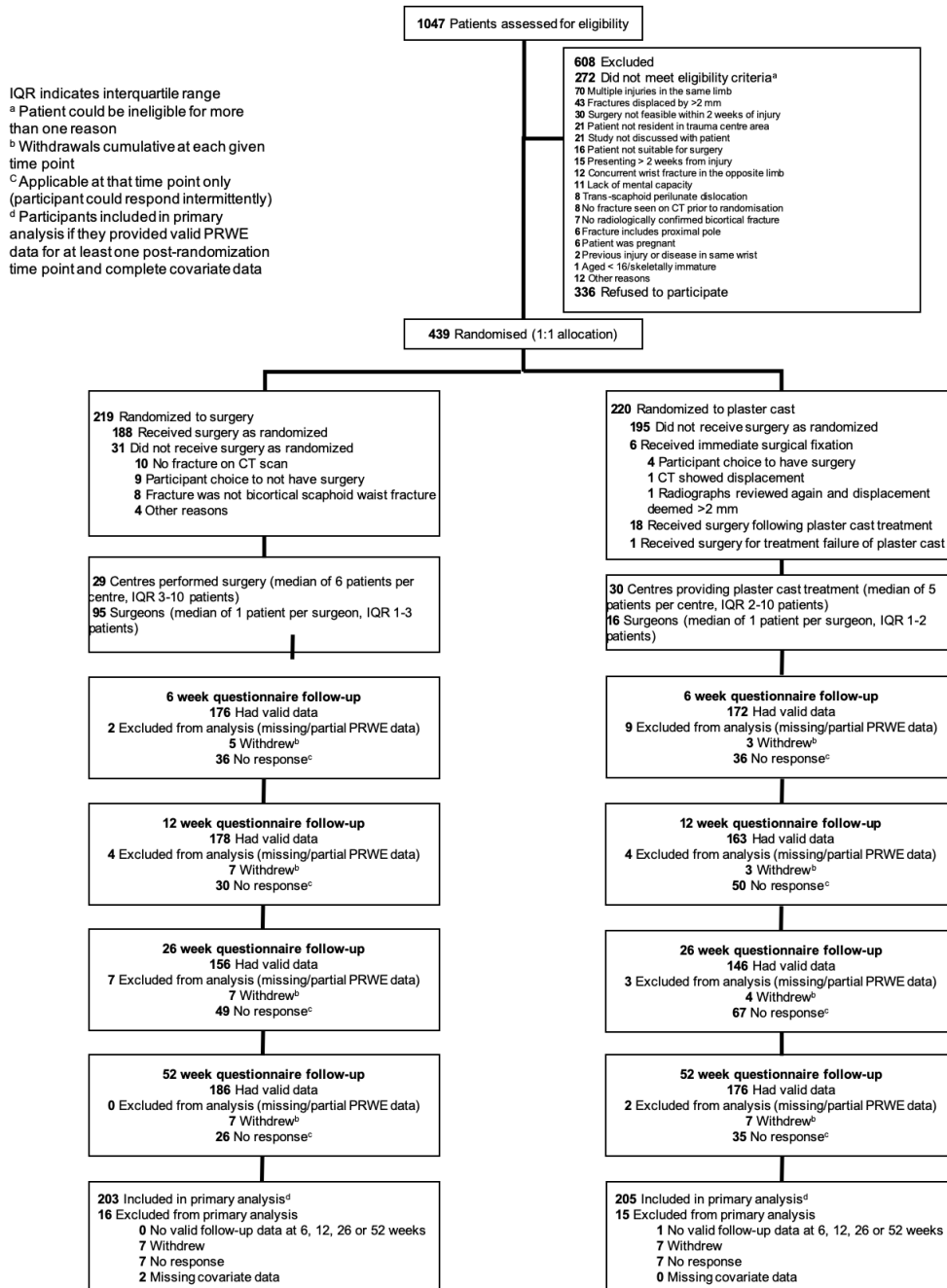
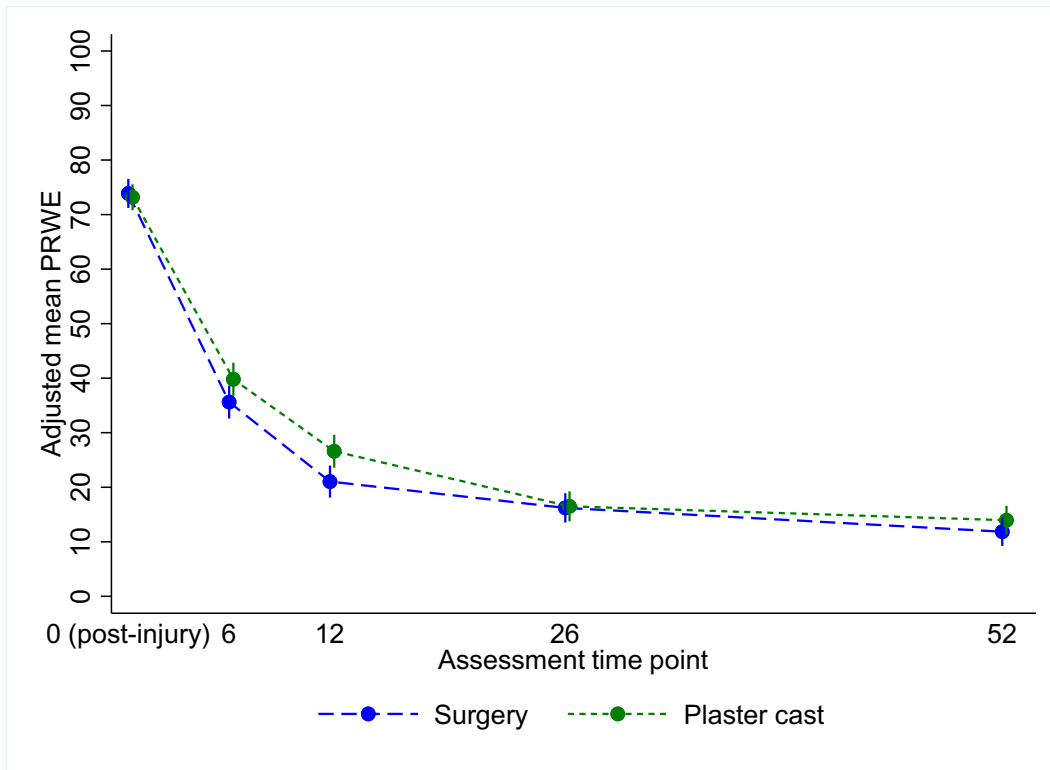


Figure 2: Adjusted mean PRWE scores (with 95% CIs) for primary analysis over time by randomised group



Web extra material

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

| | All Randomised Patients | | | Patients in Primary Analysis ^a | | |
|--|-------------------------|--|-------------------|---|--|-------------------|
| | Surgery (n=219) | Cast immobilization ^b (n=220) | Total (n=439) | Surgery (n=203) | Cast immobilization ^b (n=205) | Total (n=408) |
| Baseline (pre-injury) PRWE score | | | | | | |
| Mean (SD) | 3.1 (10.8) | 3.6 (11.8) | 3.4 (11.3) | 3.3 (11.2) | 3.8 (12.2) | 3.5 (11.7) |
| Median (IQR) | 0 (0, 1) | 0 (0, 1) | 0 (0, 1) | 0 (0, 1) | 0 (0, 1) | 0 (0, 1) |
| Baseline (post-injury) PRWE score | | | | | | |
| Mean (SD) | 73.9 (19.8) | 73.2 (17.4) | 73.5 (18.6) | 73.8 (20.1) | 73.4 (17.3) | 73.6 (18.8) |
| Median (IQR) | 78.5 (65.5, 87.5) | 76 (63.5, 86.5) | 77.5 (64.0, 87.0) | 78.5 (63.5, 88.0) | 76 (64.0, 70.0) | 77.5 (64.0, 87.5) |
| Days since injury^c | | | | | | |
| Mean (SD) | 5.1 (3.1) | 5.3 (3.3) | 5.2 (3.2) | 4.9 (3.0) | 5.4 (3.3) | 5.2 (3.2) |
| Median (IQR) | 5 (3, 7) | 5 (3, 8) | 5 (3, 7) | 4 (2, 7) | 5 (3, 8) | 5 (3, 7) |
| Affected wrist, No. (%) | | | | | | |
| Left | 115 (52.5) | 118 (53.6) | 233 (53.1) | 110 (54.2) | 110 (53.7) | 220 (53.9) |
| Right | 104 (47.5) | 102 (46.4) | 206 (46.9) | 93 (45.8) | 95 (46.3) | 188 (46.1) |
| Missing | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Dominant Hand, No. (%) | | | | | | |
| Yes | 100 (45.7) | 95 (43.2) | 195 (44.4) | 92 (45.3) | 89 (43.4) | 181 (44.4) |
| No | 117 (53.4) | 125 (56.8) | 242 (55.1) | 111 (54.7) | 116 (56.6) | 227 (55.6) |
| Missing | 2 (0.9) | 0 (0.0) | 2 (0.5) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Fracture displacement, No. (%) | | | | | | |
| No displacement (<1mm) | 135 (61.6) | 134 (60.9) | 269 (61.3) | 123 (60.6) | 123 (60.0) | 246 (60.3) |
| Displacement (≥1mm, ≤2mm) | 84 (38.4) | 86 (39.1) | 170 (38.7) | 80 (39.4) | 82 (40.0) | 162 (39.7) |
| Previous wrist problems on | | | | | | |

| | All Randomised Patients | | | Patients in Primary Analysis ^a | | |
|--|-------------------------|--|------------------|---|--|------------------|
| | Surgery (n=219) | Cast immobilization ^b (n=220) | Total (n=439) | Surgery (n=203) | Cast immobilization ^b (n=205) | Total (n=408) |
| same side, No. (%) | | | | | | |
| Yes | 43 (19.6) | 45 (20.5) | 88 (20.0) | 43 (21.2) | 42 (20.5) | 85 (20.8) |
| No | 173 (79.0) | 173 (78.6) | 346 (78.8) | 159 (78.3) | 161 (78.5) | 320 (78.4) |
| Missing | 3 (1.4) | 2 (0.9) | 5 (1.1) | 1 (0.5) | 2 (1.0) | 3 (0.7) |
| Injury mechanism, No. (%) | | | | | | |
| Fall from standing, walking or running | 92 (42.0) | 91 (41.4) | 183 (41.7) | 85 (41.9) | 82 (40.0) | 167 (40.9) |
| Fall from height | 28 (12.8) | 34 (15.5) | 62 (14.1) | 26 (12.8) | 31 (15.1) | 57 (14.0) |
| Fall from moving object | 42 (19.2) | 31 (14.1) | 73 (16.6) | 41 (20.2) | 31 (15.1) | 72 (17.6) |
| Hit on palm of hand | 36 (16.4) | 34 (15.5) | 70 (15.9) | 34 (16.7) | 34 (16.6) | 68 (16.7) |
| Punched something | 4 (1.8) | 12 (5.5) | 16 (3.6) | 4 (2.0) | 10 (4.9) | 14 (3.4) |
| Road traffic accident | 9 (4.1) | 8 (3.6) | 17 (3.9) | 9 (4.4) | 7 (3.4) | 16 (3.9) |
| Other | 6 (2.7) | 10 (4.5) | 16 (3.6) | 4 (2.0) | 10 (4.9) | 14 (3.4) |
| Missing | 2 (0.9) | 0 (0.0) | 2 (0.5) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Treatment preference, No. (%) | | | | | | |
| Surgery | 93 (42.5) | 101 (45.9) | 194 (44.2) | 89 (43.8) | 96 (46.8) | 185 (45.3) |
| No surgery | 13 (5.9) | 19 (8.6) | 32 (7.3) | 11 (5.4) | 16 (7.8) | 27 (6.6) |
| No preference | 110 (50.2) | 99 (45.0) | 209 (47.6) | 102 (50.2) | 92 (44.9) | 194 (47.5) |
| Missing | 3 (1.4) | 1 (0.5) | 4 (0.9) | 1 (0.5) | 1 (0.5) | 2 (0.5) |

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

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

^c time from injury to screening; ^d response categories not mutually exclusive
SD, standard deviation; PRWE, Patient Rated Wrist Evaluation

Supplementary Table 2. Patient baseline characteristics of different populations

| | Screened (n=1047) | Ineligible (n=272) | Eligible (n=775) | |
|--|----------------------|-----------------------|---------------------------|-----------------------|
| | | | Non-consenting (n=336) | Consenting (n=439) |
| Sex, No. (%) | | | | |
| Male | 834 (79.7) | 203 (74.6) | 268 (79.8) | 363 (82.7) |
| Female | 210 (20.1) | 66 (24.3) | 68 (20.2) | 76 (17.3) |
| Missing | 3 (0.3) | 3 (1.1) | 0 (0.0) | 0 (0.0) |
| Age, y | | | | |
| N | 1040 | 266 | 335 | 439 |
| Mean (SD) | 33.7 (14.8) | 36.6 (17.5) | 32.5 (14.6) | 32.9 (12.7) |
| Median (IQR) | 29.2 (22.5, 41.6) | 30.0 (23.4, 47.4) | 28.2 (21.1, 39.8) | 29.3 (23.1, 40.4) |
| Days since injury^a | | | | |
| N | 1044 | 269 | 336 | 439 |
| Mean (SD) | 1.0 (1.8) | 1.2 (2.5) | 1.0 (1.5) | 0.8 (1.4) |
| Median (IQR) | 0 (0, 1) | 0 (0, 1) | 1 (0, 1) | 1 (0, 1) |
| Displacement involvement^b, No. (%) | | | | |
| Displacement | 342 (32.7) | 61 (22.4) | 111 (33.0) | 170 (38.7) |
| No displacement | 651 (62.2) | 160 (58.8) | 222 (66.1) | 269 (61.3) |
| Missing | 54 (5.2) | 51 (18.8) | 3 (0.9) | 0 (0.0) |

SD, standard deviation

^a time from injury to first contact with NHS (presentation at A&E or other); this is consistent with the inclusion criterion for patients to present at a participating site within two weeks of injury^b as recorded on the Study Eligibility Form**Supplementary Table 3: Treatment received - surgery group (n=219)**

| Treatment pathway | Definition of pathway | N (%) | Further details |
|--------------------------|---|-----------|---|
| <i>Crossover</i> | Participant immediately switched to plaster cast following consent and randomisation, no surgery | 31 (14.2) | <ul style="list-style-type: none"> Thirty participants received plaster cast (n=16), splint (n=3), or combination both (n=11), for a median of 52 days (range 9-84) post-randomisation. One participant did not receive any treatment as no fracture was observed on CT scan. |
| <i>Routine treatment</i> | Participant had one surgery within the 12 months from randomisation and no subsequent plaster cast and/or splint | 24 (11.0) | <ul style="list-style-type: none"> Surgery took place a median of 4 days (range 0-9) post-randomisation, no subsequent treatment recorded except bandaging. |
| <i>Treatment failure</i> | Participant had surgery and subsequent plaster cast and/or splint due to treatment failure e.g. poor stability from surgery | 0 (0.0) | - |

| | | | |
|----------------------------------|--|------------|--|
| <i>Further routine treatment</i> | Participant had surgery and subsequent plaster cast and/or splint following routine practice | 156 (71.2) | <ul style="list-style-type: none"> • Surgery took place a median of 4 days (range 0-15) post-randomisation. • All received plaster cast (n=23), splint (n=40) or a combination of both (n=93) for a median of 37 days (range 2-89) following surgery. |
| | Participant had index surgery but there was subsequent evidence of non-union, so was offered further surgery | 2 (0.9) | <ul style="list-style-type: none"> • 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) | <ul style="list-style-type: none"> • Revision surgery (n=1), or for removal of screw (n=5) • All received a splint (n=2) or a combination of plaster cast and splint (n=4) for a median of 44 days (range 22-105) following their index surgery. • All underwent only one further surgery within 12 months from randomisation; this took place a median of 235 days (range 97-347) after index surgery. |

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

| Treatment pathway | Definition of pathway | N (%) | Further details |
|--------------------------|---|--------------|--|
| <i>Crossover</i> | Participant immediately switched to surgery following randomisation | 6 (2.7) | <ul style="list-style-type: none"> • Surgery took place a median of 9 days (range 0-24) post-randomisation. • Participants received a plaster cast (n=3), a splint (n=1) or a combination of both (n=2) for a median of 41 days (range 35-74) following surgery. |
| <i>Routine treatment</i> | Participant treated conservatively – no surgery | 193 (87.7) | <ul style="list-style-type: none"> • 192 participants received a plaster cast (n=109) or a combination of plaster cast and splint (n=83) for a median of 43 days (range 7-101) post-randomisation. • One participant was followed up at a different hospital so |

| | | | |
|--|--|----------|---|
| | | | treatment was unknown, but was immobilised in plaster cast at enrolment to the trial. |
| <i>Treatment failure</i> | Surgery undertaken to stabilise the fracture (before five weeks from randomisation). This is not a cross-over because the patient did have a plaster cast applied. | 1 (0·5) | <ul style="list-style-type: none"> Plaster cast worn following randomisation but fracture seen to be displacing so surgical fixation undertaken 29 days post-randomisation and a splint was worn thereafter (unknown length of time). Surgery was undertaken to remove the screw 96 days after initial fixation. |
| <i>Further routine treatment – surgery (after five weeks post-randomisation)</i> | Surgery was undertaken after five weeks from randomisation – not owing to a failure to unite | 1 (0·5) | <ul style="list-style-type: none"> One participant received surgery within 6 months of randomisation at a non-participating hospital to fix a historic fracture. |
| <i>Further routine treatment – surgery recommended (after five weeks post-randomisation) as per specified treatment pathway because of failure to unite.</i> | Surgery was not received | 2 (0·9) | <ul style="list-style-type: none"> Operation was scheduled but then delayed, participant self-discharged after wait and declined all further treatment/offers of surgery. Non-union suspected at 12 weeks but the surgeon decided not to operate. |
| | One surgery performed within 12 months of randomisation | 16 (7·3) | <ul style="list-style-type: none"> 13 received urgent fixation of non-union (within 6 months of randomisation). Three participants received late fixation, between 6 and 12 months after randomisation. The reasons for two of these are unknown; one participant opted to attend a private hospital for their fixation as they were told there would be a 4-5 month wait for surgery at treating centre. |
| | Two or more surgeries were performed within 12 months of randomisation | 1 (0·5) | <ul style="list-style-type: none"> Participant received initial surgical fixation within 3 months of randomisation, a further surgery 6 months later for persistent non-union and surgery to remove the wires |

| | | | |
|--|--|--|--|
| | | | from the second operation a month later. |
|--|--|--|--|

Sensitivity analyses for the primary outcome

Timing of data collection

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

Displacement and absence of fracture assessed by independent review of baseline imaging data

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

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

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

Supplementary Table 5. Sensitivity analyses for the primary outcome

| | Mean (95% CI) ^a | | Mean Difference (95% CI) | p-value |
|--|----------------------------|---------------------|--------------------------|---------|
| | Surgery | Cast immobilization | | |
| Data derived by multiple imputation^a | | | | |
| No. of patients | 219 | 220 | | |
| At 6 wk | 35.1 (32.1, 38.1) | 39.8 (36.7, 42.9) | -4.7 (-9.0, -0.5) | 0.03 |
| At 12 wk | 20.7 (17.9, 23.6) | 26.6 (23.7, 29.5) | -5.9 (-9.9, -1.9) | 0.007 |
| At 26 wk | 16.1 (13.4, 18.8) | 16.4 (13.7, 19.2) | -0.3 (-4.2, 3.5) | 0.87 |
| At 52 wk | 12.0 (9.3, 14.6) | 14.1 (11.4, 16.8) | -2.1 (-5.9, 1.6) | 0.26 |
| Adjusting for clustering by site | | | | |
| No. of patients | 203 | 205 | | |
| At 6 wk | 36.2 (32.6, 39.8) | 40.2 (36.6, 43.8) | -4.0 (-8.2, 0.3) | 0.07 |

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

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

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

| Wrist range of movement and grip strength – affected wrist | | Surgery | Cast immobilization | Total |
|--|--------------|-------------------|---------------------|-------------------|
| Baseline | | N=216 | N=218 | N=434 |
| <i>Beighton Laxity Score</i> | Mean (SD) | 1.1 (2.0) | 0.9 (1.7) | 1.0 (1.8) |
| | 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) |
| <i>Extension (°)</i> | 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) |
| <i>Flexion (°)</i> | 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) |
| <i>Radial Deviation (°)</i> | 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) |
| <i>Ulnar Deviation (°)</i> | 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) |
| <i>Forearm Rotation Supination (°)</i> | Mean (SD) | 66.9 (26.7) | 63.6 (27.8) | 65.3 (27.3) |
| | 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) |
| <i>Forearm Rotation Pronation (°)</i> | Mean (SD) | 72.2 (23.1) | 71.2 (25.0) | 71.7 (24.0) |
| | 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) |
| <i>Grip Strength (kg)</i> | Mean (SD) | 9.6 (10.0) | 9.8 (10.6) | 9.7 (10.3) |
| | Median (IQR) | 6.0 (2.0, 15.3) | 7.0 (2.0, 12.7) | 6.7 (2.0, 14.4) |
| | Min, max | (0.0, 61.7) | (0.0, 58.0) | (0.0, 61.7) |
| 6 weeks | | N=189 | N=200 | N=389 |
| <i>Extension (°)</i> | 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) |
| <i>Flexion (°)</i> | 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) |
| <i>Radial Deviation (°)</i> | 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) |
| <i>Ulnar Deviation (°)</i> | 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) |
| <i>Forearm Rotation Supination (°)</i> | Mean (SD) | 82.4 (15.7) | 74.9 (20.3) | 78.5 (18.6) |
| | 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) |
| <i>Forearm Rotation Pronation (°)</i> | Mean (SD) | 82.8 (14.4) | 80.1 (15.5) | 81.4 (15.0) |
| | 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) |
| <i>Grip Strength (kg)</i> | Mean (SD) | 24.1 (12.7) | 20.1 (14.0) | 22.0 (13.5) |
| | Median (IQR) | 23.3 (15.3, 32.7) | 18.2 (9.3, 28.7) | 20.0 (11.3, 30.7) |
| | Min, max | (0.0, 77.3) | (0.0, 81.7) | (0.0, 81.7) |
| 12 weeks | | N=172 | N=164 | N=336 |
| <i>Extension (°)</i> | 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) |
| <i>Flexion (°)</i> | 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) |

| | | | | |
|--|--------------|-------------------|-------------------|-------------------|
| <i>Radial Deviation (°)</i> | 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) |
| <i>Ulnar Deviation (°)</i> | 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) |
| <i>Forearm Rotation Supination (°)</i> | Mean (SD) | 87.1 (13.8) | 82.3 (18.2) | 84.7 (16.3) |
| | 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) |
| <i>Forearm Rotation Pronation (°)</i> | Mean (SD) | 86.5 (8.5) | 83.4 (13.8) | 85.0 (11.5) |
| | 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) |
| <i>Grip Strength (kg)</i> | Mean (SD) | 30.8 (12.5) | 28.2 (14.4) | 29.5 (13.5) |
| | Median (IQR) | 29.3 (22.3, 39.3) | 28.5 (18.7, 37.8) | 28.7 (20.0, 38.7) |
| | Min, max | (0.0, 82.0) | (0.0, 89.0) | (0.0, 89.0) |
| 52 weeks | | N=163 | N=146 | N=309 |
| <i>Extension (°)</i> | 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) |
| <i>Flexion (°)</i> | 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) |
| <i>Radial Deviation (°)</i> | 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) |
| <i>Ulnar Deviation (°)</i> | 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) |
| <i>Forearm Rotation Supination (°)</i> | Mean (SD) | 88.3 (13.3) | 85.2 (13.9) | 86.8 (13.6) |
| | 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) |
| <i>Forearm Rotation Pronation (°)</i> | Mean (SD) | 86.8 (10.5) | 86.2 (9.5) | 86.5 (10.0) |
| | 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) |
| <i>Grip Strength (kg)</i> | Mean (SD) | 36.9 (12.7) | 37.4 (14.2) | 37.2 (13.4) |
| | Median (IQR) | 36.2 (28.7, 44.8) | 38.5 (28.7, 46.2) | 37.3 (28.7, 45.2) |
| | Min, max | (10.3, 109.7) | (4.7, 88.3) | (4.7, 109.7) |

Malunion

Scaphoid height and length was measured by the three independent raters of the CT and plain radiographs. Malunion was determined by calculating the ratio of the scaphoid height to length, and determined using thresholds of both 0.6 and 0.7 (Supplementary Table 4). ten Berg et al.¹⁴ noted a ratio of 0.69 as the upper 95% CI of a normal population so we used this (0.7) to define malunion in addition to the 0.6 we proposed in our protocol. By default, more participants are classified as having malunion using the 0.6 threshold than 0.7. Considering those with non-missing data only, at 6 weeks, 175 (94%) participants in the surgery group and 180 (90%) in the cast immobilization group had malunion based on the 0.6 threshold. At 0.7, the figures are 52 (28%) and 51 (26%), respectively. Malunion at both thresholds remained reasonably steady in both groups at 6, 12 and 52 weeks on radiographic images. However, at 52 weeks, on CT, the rate of malunion occurred in 60 (38%) participants in the surgery group and 45 (33%) in the cast immobilization group at the 0.6 threshold, and increased to 7 (5%) and 7 (5%), respectively, at 0.7.

Supplementary Table 7. Malunion assessed at thresholds of scaphoid ratio height to length of 0.6 and 0.7 by randomised group and time point

| Time point | Union | Surgery (n=219) | Cast immobilization (n=220) | Total (n=439) |
|----------------------|-------------|--------------------|-----------------------------------|------------------|
| 0.6 threshold | | | | |
| Baseline | No malunion | 30 (13.7) | 28 (12.7) | 58 (13.2) |
| (Radiographs) | Malunion | 182 (83.1) | 190 (86.4) | 372 (84.7) |
| | Missing | 7 (3.2) | 2 (0.9) | 9 (2.1) |
| Baseline | No malunion | 154 (70.3) | 160 (72.7) | 314 (71.5) |
| (CT) | Malunion | 63 (28.8) | 54 (24.5) | 117 (26.7) |
| | Missing | 2 (0.9) | 6 (2.7) | 8 (1.8) |
| 6 weeks | No malunion | 12 (5.5) | 20 (9.1) | 32 (7.3) |
| | Malunion | 175 (79.9) | 180 (81.8) | 355 (80.9) |
| | Missing | 32 (14.6) | 20 (9.1) | 52 (11.8) |
| 12 weeks | No malunion | 10 (4.6) | 12 (5.5) | 22 (5.0) |
| | Malunion | 159 (72.6) | 151 (68.6) | 310 (70.6) |
| | Missing | 50 (22.8) | 57 (25.9) | 107 (24.4) |
| 52 weeks | No malunion | 9 (4.1) | 13 (5.9) | 22 (5.0) |
| (Radiographs) | Malunion | 148 (67.6) | 128 (58.2) | 276 (62.9) |
| | Missing | 62 (28.3) | 79 (35.9) | 141 (32.1) |
| 52 weeks | No malunion | 97 (44.3) | 90 (40.9) | 187 (42.6) |
| (CT) | Malunion | 60 (27.4) | 45 (20.5) | 105 (23.9) |
| | Missing | 62 (28.3) | 85 (38.6) | 147 (33.5) |
| 0.7 threshold | | | | |
| Baseline | No malunion | 167 (76.3) | 173 (78.6) | 340 (77.4) |
| (Radiographs) | Malunion | 45 (20.5) | 45 (20.5) | 90 (20.5) |
| | Missing | 7 (3.2) | 2 (0.9) | 9 (2.1) |
| Baseline | No malunion | 214 (97.7) | 212 (96.4) | 426 (97) |
| (CT) | Malunion | 3 (1.4) | 2 (0.9) | 5 (1.1) |
| | Missing | 2 (0.9) | 6 (2.7) | 8 (1.8) |
| 6 weeks | No malunion | 135 (61.6) | 149 (67.7) | 284 (64.7) |
| | Malunion | 52 (23.7) | 51 (23.2) | 103 (23.5) |
| | Missing | 32 (14.6) | 20 (9.1) | 52 (11.8) |
| 12 weeks | No malunion | 117 (53.4) | 118 (53.6) | 235 (53.5) |
| | Malunion | 52 (23.7) | 45 (20.5) | 97 (22.1) |
| | Missing | 50 (22.8) | 57 (25.9) | 107 (24.4) |
| 52 weeks | No malunion | 96 (43.8) | 101 (45.9) | 197 (44.9) |
| (Radiographs) | Malunion | 61 (27.9) | 40 (18.2) | 101 (23.0) |
| | Missing | 62 (28.3) | 79 (35.9) | 141 (32.1) |
| 52 weeks | No malunion | 150 (68.5) | 128 (58.2) | 278 (63.3) |
| (CT) | Malunion | 7 (3.2) | 7 (3.2) | 14 (3.2) |
| | Missing | 62 (28.3) | 85 (38.6) | 147 (33.5) |

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

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

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

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

Supplementary Table 9. Serious adverse events by randomised group

| Serious adverse events | Surgery (n=219) | Cast immobilization (n=220) | Total (n=439) |
|---|--------------------|-----------------------------------|------------------|
| No. participants reporting ≥ 1 adverse events, No. (%)[^] | 3 (1.4) | 0 (0.0) | 0 (0.0) |
| Total number of serious adverse events | 3 | 0 | 0 |
| Number of serious events per participant, No. (%)[^] | | | |
| 0 | 216 (98.6) | 220 (100.0) | 436 (99.3) |
| 1 | 3 (1.4) | 0 (0.0) | 3 (0.7) |
| Type of event^b, No. (%)[‡] | | | |
| Hospitalisation | 2 (66.7) | 0 (0.0) | 2 (66.7) |
| Persistent or significant disability/incapacity | 1 (33.3) | 0 (0.0) | 3 (33.3) |
| Adverse events of anaesthesia and/or surgery^a, No. (%)[‡] | | | |
| Anaesthetic complication | 2 (66.7) | 0 (0.0) | 2 (66.7) |
| Symptoms consistent with non-union | 1 (33.3) | 0 (0.0) | 1 (33.3) |
| Causality^b, No. (%)[‡] | | | |
| Definitely related | 3 (100.0) | 0 (0.0) | 3 (100.0) |
| Expectedness^b, No. (%)[‡] | | | |
| Expected | 1 (33.3) | 0 (0.0) | 1 (33.3) |
| Unexpected | 2 (66.7) | 0 (0.0) | 2 (66.7) |
| Duration^b, No. (%)[‡] | | | |
| ≤ 24 hours | 2 (66.7) | 0 (0.0) | 2 (66.7) |
| >24 hours | 1 (33.3) | 0 (0.0) | 1 (33.3) |

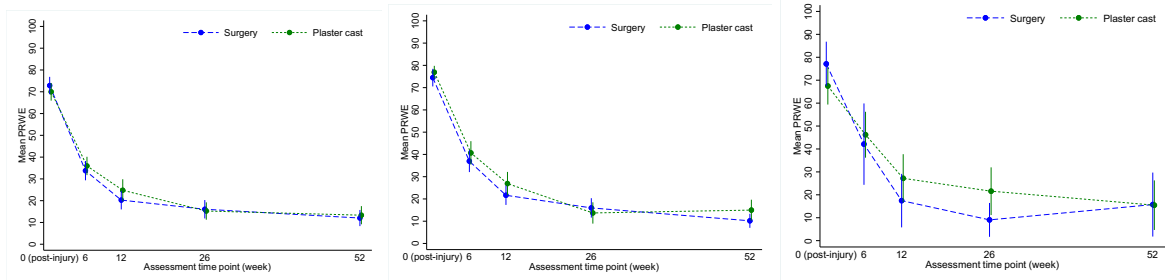
^a retrospectively and independently classified by two clinicians, disagreements discussed and resolved; ^b classifications as provided on Adverse Event Initial Report Form by reporting clinician

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

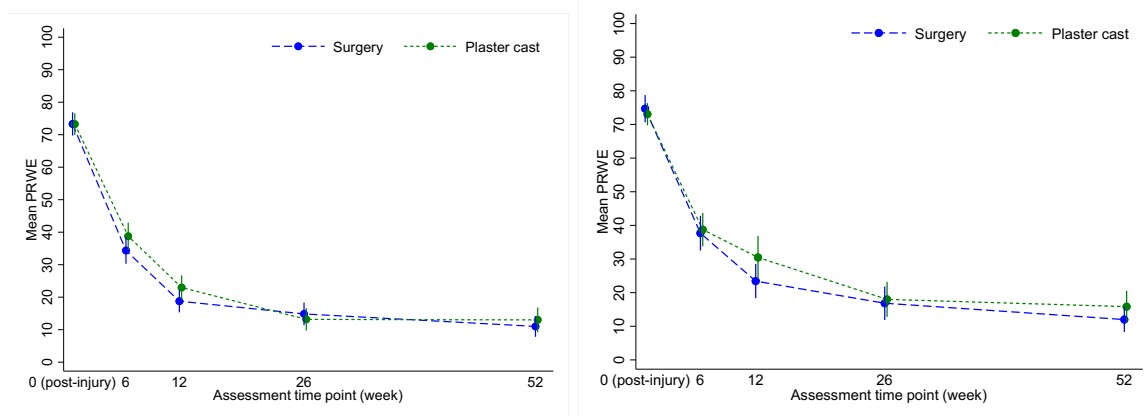
There was no evidence of a difference between the two groups in the overall rate of participants experiencing at least one surgical, medical or cast complication regardless of severity or impact up to 52 weeks (surgery group, n=39, 18%; plaster cast group, n=51, 23%, OR 0.72, 95% CI 0.45 to 1.15; p=0.17).

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

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



(d) <1 mm and (e) ≥1 mm and ≤ 2 mm



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