Non-surgical casting versus surgical reduction for children with severely displaced distal radial fractures (the CRAFFT Study): a multicentre, randomised, controlled non-inferiority trial and economic evaluation

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Lancet 2026; 407: 1538–48

Published Online April 8, 2026 https://doi.org/10.1016/S0140-6736(26)00409-5

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See Online for appendix 1

Summary

Background Severely displaced distal radial fractures are among the most common and controversial injuries in children. Despite observational evidence of reliable remodelling with growth in younger children, their alarming radiographic appearance—particularly when completely displaced (off-ended)—has driven routine surgical reduction and fixation. The Children's Radius Acute Fracture Fixation Trial (CRAFFT) aimed to evaluate the clinical and cost-effectiveness of surgical reduction compared with non-surgical casting.

Methods This pragmatic, multicentre, randomised, non-inferiority trial included participants (aged 4–10 years) with a severely displaced distal radial fracture from 49 hospitals in the UK. Recruiting centres were secondary or tertiary care hospitals providing acute paediatric trauma care. Participants were randomly assigned to either non-surgical casting or surgical reduction, using a minimisation algorithm with a random element and stratification factors were centre, age group, fracture location, and displacement severity. Participants and their parents and carers could not be masked to treatment. Surgical reduction was performed under general anaesthesia or conscious sedation, to restore anatomical alignment, with fixation permitted at the discretion of the surgeon. Non-surgical care involved immobilisation of the fracture in a plaster cast without general anaesthesia or sedation, and without purposeful manipulation of the fracture position. Immobilisation of the fracture beyond 6 weeks post-randomisation was not recommended. The primary outcome was upper limb function at 3 months, measured using the Patient Report Outcomes Measurement System (PROMIS) Upper Extremity Score for Children in the intention-to-treat population, which included all participants in the groups to which they were randomly assigned, irrespective of treatment received. The non-inferiority margin was conservatively set at –2·5 points for the main trial population. A prespecified subgroup analysis was powered to assess whether non-surgical casting could exclude a larger more clinically relevant margin of –5 points among children with completely off-ended fractures. Complications and serious adverse events were summarised in a safety (as-treated) population defined by treatment received. A within-trial economic evaluation was undertaken from the perspective of the UK National Health Service (NHS) and Personal Social Services over a 12-month time period. The trial was registered with the ISRCTN registry, ISRCTN10931294, recruitment is complete and extended follow-up to 3-years post-randomisation is ongoing.

Findings Between Aug 11, 2020, and May 30, 2024, 1227 children were screened for eligibility across 49 UK hospitals. 477 children were excluded (54 met exclusion criteria and 423 did not enter the study, the majority for lack of clinical or parental equipoise). 750 participants were randomly assigned, 375 to the non-surgical casting group and 375 to the surgical reduction group. 456 (61%) participants were male, 294 (39%) were female, and the median age of participants was 7·9 years (IQR 6·5–9·5). 329 (44%) of the 750 participants had completely off-ended fractures. Primary outcome data were collected from 640 (85%) participants. At 3 months post-randomisation, the mean PROMIS Upper Extremity score was 44·9 (SD 8·7) in the non-surgical casting group and 46·6 (8·8) in the surgical reduction group (adjusted mean difference –1·64 [95% CI –2·84 to –0·44]), with the confidence interval favouring surgical reduction but extending beyond the prespecified non-inferiority margin of –2·5 points. In children with completely off-ended fractures, findings were consistent with non-inferiority against the wider, prespecified margin for this group. Most complications within 8 weeks occurred in the surgical reduction group, including pressure damage (n=2), wound infections (n=6), scarring (n=5), and nerve irritation (n=1). During the 12-months of follow-up, refracture occurred in 13 participants (nine after non-surgical casting and four after surgical reduction). From an NHS and Personal Social Services perspective, non-surgical casting was associated with a significant reduction in mean cost per patient of £1665 (95% CI 1487 to 1843) and a marginal incremental reduction in quality-adjusted life-years (QALYs; –0·023 [95% CI –0·037 to –0·009]). The probability of non-surgical casting being cost-effective at the £20 000 and £30 000 per QALY threshold was 100%, indicating that the small short-term functional advantage of surgical reduction was not cost-effective.

Interpretation The CRAFFT trial did not demonstrate non-inferiority of non-surgical casting at 3 months against a conservative margin; however, the observed difference in favour of surgical reduction was small, below thresholds that families considered meaningful, and did not persist beyond early recovery. Surgical reduction was associated with higher costs, early procedural complications, and only a modest improvement in cosmetic appearance, supporting consideration of a cast-first strategy for most children.

Funding National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (17/22/02) and the NIHR Oxford Biomedical Research Centre.

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Introduction

Distal radial fractures are the most common bony injury in children, accounting for about half of paediatric long-bone fractures.[1] Severely displaced injuries are typically treated by closed reduction under sedation or general anaesthesia, often followed by Kirschner wire or plate fixation.[2] This procedure restores immediate alignment, at the cost of anaesthesia, procedural pain, and frequent complications, including re-displacement and wire-related problems.[3,4] Despite this established practice, there is a growing uncertainty about whether surgical reduction is necessary.

Children's bones have a remarkable capacity to remodel, distinguishing them from adult bones. Through this process, deformity corrects as the child grows, with the greatest potential for remodelling found close to areas of active growth, particularly the growth plates (physes). Remodelling is greatest in younger children and close to active growth plates.

Observational studies of distal radial fractures in children up to age 10 years suggest that even completely displaced fractures—including those termed as completely off-ended fractures—can correct over time with restoration of function and little long-term deformity.[5,6] Although such fractures appear visibly bent and alarming to families and clinicians, these sometimes realign naturally without manipulation or fixation. A small UK comparative cohort found more complications in children undergoing surgical reduction than in those treated with simple casting.[7] The only randomised trial to date, published only as an abstract and based on radiographic outcomes, reported no advantage for surgical reduction in children younger than 11 years.[8]

This uncertainty led the British Society for Children's Orthopaedic Surgery to prioritise the treatment of these fractures for future research, resulting in the development of the Children's Radius Acute Fracture Fixation Trial (CRAFFT).[9] The trial was designed to determine whether

Research in context

Evidence before this study

We searched PubMed, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL) at the time of funding in May, 2017, and repeated the search iteratively throughout the trial, most recently on Dec 3, 2025, using combinations of the terms "distal radius fracture", "children", "paediatric", "pediatric", "surgery", "operative", "non-operative", and "randomised trial", with Boolean operators and truncation as appropriate. These searches identified no randomised controlled trials addressing the question, a Cochrane review highlighting the paucity of evidence for the treatment of children's wrist fractures, and only case series relevant to the comparison of interest. Although these case series suggested reliable remodelling with growth in younger children, the pronounced visual deformity and radiographic displacement of these injuries have continued to drive routine surgery. One small randomised trial, published only in abstract form, reported no benefit of surgery, leaving a persistent absence of robust evidence to guide practice.

Added value of this study

The CRAFFT trial is the first large, multicentre randomised study to address this long-standing uncertainty. The trial did not confirm non-inferiority of non-surgical casting at 3 months using a conservative margin set at the lower end of the minimally important difference. However, the observed difference was smaller than the threshold families considered meaningful to justify surgical reduction, and by 6 months and 12 months there was no evidence of any difference between treatments. Surgical reduction was associated with higher costs, early procedural complications, and only modestly better cosmetic appearance, which narrowed over time, highlighting the trade-off between early gains and longer-term outcomes.

Implications of all the available evidence

The CRAFFT trial provides the most robust evidence to date for the treatment of these injuries, adding to previous case series and an earlier small, randomised trial. This is a topic not addressed in any international guidelines. Although surgical reduction offered small early advantages, these fell below thresholds families considered clinically meaningful and did not persist. Given the higher costs and avoidable risks associated with surgical reduction, the findings support a cast-first strategy as the preferred initial approach for most children with severely displaced distal radial fractures.

non-surgical casting provides comparable functional outcomes to surgical reduction for severely displaced distal radial fractures in children, while reducing treatment-related harms and costs.

Methods

Study design

The CRAFFT study was a pragmatic, multicentre, randomised, controlled non-inferiority trial conducted in 49 UK hospitals. Recruiting centres were secondary or tertiary care hospitals providing acute paediatric trauma care. The trial was coordinated by the Oxford Clinical Trials Research Unit, sponsored by the University of Oxford. A trial steering committee and data and safety monitoring committee oversaw progress, conduct, and participant safety. The trial was approved by the UK National Health Service (NHS) Research Ethics Committee (West Midlands, Solihull, reference 20/WM/0054) and registered prospectively with the ISRCTN registry, ISRCTN10931294; recruitment is complete and extended follow-up until 3 years post-randomisation is ongoing. The protocol (appendix 2), statistical analysis plan (appendix 3), and health economics analysis plan (appendix 4) have been published.[10,11] In response to the COVID-19 pandemic, some participating centres temporarily paused recruitment during local restrictions. No significant changes were made to the trial protocol, design, outcomes, or analysis plan.

See Online for appendices 2–4

Patient and public involvement was embedded throughout the trial. Patient and public involvement contributors played a central role in the study's design, conduct, oversight, and dissemination. They informed the selection of outcomes most relevant to families, guided the definition of a meaningful treatment effect, and co-developed participant-facing materials, including animations used during recruitment. Patient and public involvement members also contributed to the design of the embedded qualitative study to optimise enrolment. Families continue to play a key role in dissemination efforts.

Participants

Children aged 4–10 years inclusive, with a severely displaced distal radial fracture (metaphyseal or Salter–Harris II), with or without an associated ulnar fracture, were eligible if the treating clinician considered that surgical reduction would usually be performed. The age range reflected the age for which both clinical equipoise and validated patient-reported outcome measurement were most appropriate. Eligible fractures included both completely off-ended fractures and those displaced but not completely off-ended, as both groups reflect common presentations in practice. Exclusion criteria were an injury more than 7 days old; a more complex wrist fracture (eg, open or extending into the joint); additional fractured bones elsewhere in the body; or factors preventing adherence to trial procedures or follow-up (eg, insufficient English comprehension, developmental delay or abnormality, or no access to mobile data or the internet).

Eligible children and their families were approached by a local researcher in either the emergency department or orthopaedic fracture clinic. A suite of digital information and animations that had been co-produced with families were used to explain the study. Families were asked to provide written informed consent (parents or carers) and assent (children). All trial procedures were administered electronically throughout the study, including consent, randomisation, and data collection. Sex was recorded as male or female from parental report at recruitment. Ethnicity was not recorded.

Randomisation and masking

Enrolment and randomisation was overseen by the local researcher in either the emergency department or orthopaedic fracture clinic. Participants were randomly assigned (1:1) to surgical reduction or non-surgical casting using a secure web-based system provided by the Oxford Clinical Trials Research Unit. Randomisation used a minimisation algorithm with a random element to ensure balanced allocation across treatment groups. Stratification factors were centre, age group (4–6 years *vs* 7–10 years), fracture location (metaphyseal *vs* physeal), and displacement severity (completely off-ended *vs* not completely off-ended). Stratification by age group and fracture location ensured balance across groups with reduced remodelling potential with increasing age and in fractures further from the growth plate.

Participants and their parents and carers could not be masked to treatment. The treating clinicians could not be masked to the treatments they were providing; however, the treating clinical team did not take part in the follow-up assessment of participants. Outcome data were collected directly from the participant or their parent or carer by the central trial team, using electronic data capture. The central trial team and statisticians were masked to treatment allocation during data cleaning. There were no independent clinician outcome assessors.

Procedures

Surgical reduction was performed under general anaesthesia or conscious sedation by surgical teams, according to local practice. The fracture was manipulated to restore anatomical alignment, and fixation was permitted at the discretion of the surgeon. The method of fixation was recorded. Non-surgical care involved immobilisation of the fracture in a plaster cast by either orthopaedic surgeons or emergency physicians without general anaesthesia or sedation, to hold the bones in the optimal position without purposeful manipulation of the fracture position. The choice of cast type (above-elbow or below-elbow) followed local practice guidelines. Details of non-surgical casting were recorded. Analgesia was

prescribed at the discretion of the treating clinician, following hospital guidelines, and details of analgesic use were recorded. Rehabilitation followed standard practice at the treating centre. Immobilisation beyond 6 weeks post-randomisation was not recommended. Details of rehabilitation, including physiotherapy sessions, were recorded. No artificial intelligence or machine learning tools were used in data collection, data management, or statistical analysis for this study.

Outcomes

Outcome data were collected using REDCap electronic data capture tools,[12] with data handling procedures prespecified in the trial protocol. Families were prompted by e-mail or SMS to complete follow-up questionnaires at 6 weeks, 3 months, 6 months, and 12 months post-randomisation. The primary outcome timepoint, outcome choices, and follow-up schedule were established in conjunction with families advising the study. If there was no response to the initial and reminder messages, families were contacted by telephone.

The primary outcome for this study was functional recovery assessed using the Patient Report Outcomes Measurement System (PROMIS Bank version 2.0) Upper Extremity Score for Children Computer Adaptive Test at 3-months post-randomisation. This is a validated patient-reported outcome system developed with the US National Institutes of Health.[13,14] Measures are reported as standardised T-scores derived using item response theory (mean 50 [SD 10]), with lower scores indicating worse upper-extremity function. In this study population, observed scores ranged from approximately 13·7 to 57·3. Given the age of participants, the parent-proxy version was used throughout.

A range of secondary outcomes were measured. Pain was measured using the Wong–Baker FACES Pain Rating Scale, a validated self-reported tool measuring pain intensity on a 0–10 scale.[15] Health-related quality of life was measured using EQ-5D-Y, a validated tool for assessing childhood health-related quality of life[16] (EQ-5D-Y consists of two components: a descriptive system which provides utility scores for economic evaluation, and a visual analogue scale [VAS]). An EQ-5D-Y value set for UK children is not yet available, therefore the reported analysis relates to the adult utility value set for the EQ-5D-3L.[17] All complications, including loss of reduction, infection, refracture, unplanned surgery, and adverse events related to cast or surgery, were recorded throughout the study. Health-care utilisation data, consisting of details of treatments received and interventions related to any complications, along with all health-care contacts related to the injury, were collected. Data were sourced from both families and hospital records. Parental work absence, out-of-pocket costs, and school absence were also recorded. Cosmesis was assessed using a parent-reported VAS. Further details of secondary outcomes and the timepoints at which they were assessed can be found in the protocol. This report presents outcomes to 12 months. Prespecified long-term outcomes at 2 years and 3 years will be reported separately.

Statistical analysis

The minimally important difference for PROMIS measures in children is typically about 3–4 points, based on paediatric anchor-based studies.[18,19] During study development, families advising the study team indicated that, in the context of surgery, a difference greater than this minimum would be required to justify operative intervention, identifying a threshold of approximately 5 points. The non-inferiority margin was therefore conservatively set at –2·5 points, representing half the value required by families and below published minimally important differences. Sample size estimation used a one-sided α of 0·025, reflecting the directional nature of the non-inferiority hypothesis. To achieve 90% power, with a one-sided α of 0·025, 674 participants providing primary outcome data at 3 months (337 per group) were required. Allowing for 10% loss to follow-up, the total planned recruitment was 750 participants.

The main trial population consisted of children with fractures that were either completely off-ended or those displaced but not completely off-ended. Completely off-ended fractures represent the most severe injuries and are those most likely to prompt invasive treatment, including internal fixation. We therefore prespecified a subgroup analysis powered to assess whether non-surgical casting could exclude a larger difference (5 points) that families considered meaningful in this context. Recruitment to the main population was planned to continue until at least 200 children with completely off-ended fractures were enrolled, providing adequate power to evaluate non-inferiority against this wider, clinically relevant margin of –5 points in this subgroup.

All primary and secondary clinical outcomes were analysed in the intention-to-treat population, with all participants analysed according to their randomised allocation, irrespective of the treatment received. The primary estimand reflected a treatment policy strategy, estimating the average treatment effect of surgical reduction versus non-surgical casting on upper limb function at 3 months, irrespective of adherence. A per-protocol analysis was also undertaken, excluding participants who did not receive their allocated intervention as intended. Safety outcomes were summarised descriptively according to the treatment received (as-treated population), in line with standard reporting guidance.

Prespecified subgroup analyses were undertaken by displacement severity (completely off-ended *vs* not off-ended), age group (4–6 *vs* 7–10 years), and fracture location (metaphyseal *vs* physeal), to examine consistency of treatment effects across key clinical groups. The trial was not powered to detect interaction effects.

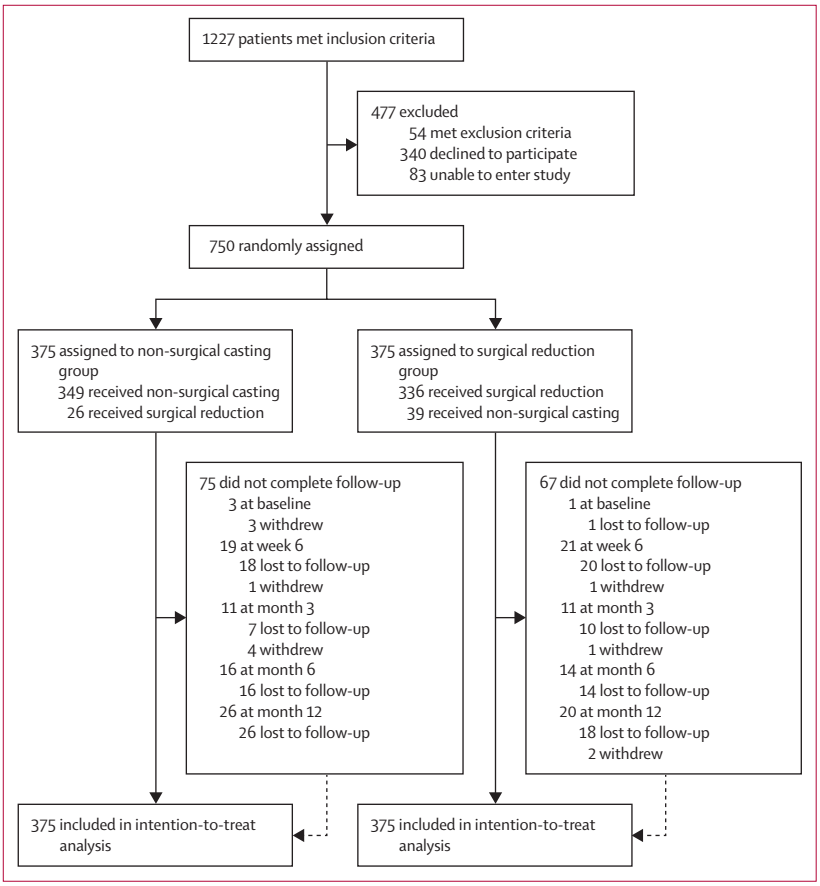

Figure 1: **Trial profile**
Withdrawal indicates that the participant actively declined further study participation from that point onwards.

	Non-surgical casting group (n=375)	Surgical reduction group (n=375)	Total (N=750)
Sex			
Male	225 (60%)	231 (62%)	456 (61%)
Female	150 (40%)	144 (38%)	294 (39%)
Age, years			
Median (IQR)	7·8 (6·5–9·5)	8·0 (6·5–9·6)	7·9 (6·5–9·5)
Age group			
7–10 years	249 (66%)	249 (66%)	498 (66%)
4–6 years	126 (34%)	126 (34%)	252 (34%)
Mechanism of injury*			
High energy fall	192 (51%)	202 (54%)	394 (53%)
Low energy fall	183 (49%)	173 (46%)	356 (47%)
Side of injury			
Left	213 (57%)	224 (60%)	437 (58%)
Right	162 (43%)	151 (40%)	313 (42%)
Injury to dominant arm			
No	195 (52%)	208 (55%)	403 (54%)
Yes	172 (46%)	160 (43%)	332 (44%)
Unsure or ambidextrous	7 (2%)	7 (2%)	14 (2%)
Missing	1 (<1%)	0	1 (<1%)
Displacement severity			
Completely off-ended	165 (44%)	164 (44%)	329 (44%)
Not completely off-ended	210 (56%)	211 (56%)	421 (56%)
Fracture location			
Metaphyseal fracture	303 (81%)	302 (81%)	605 (81%)
Physeal fracture	72 (19%)	73 (19%)	145 (19%)

Data are n (%). *The mechanism of injury was determined by the treating clinician for each participant.

Table 1: **Baseline characteristics**

The primary model was a three-level mixed-effects model, with repeated measures nested within individuals, and individuals nested within centres. The baseline score was included as part of the outcome. The model featured a full interaction between treatment and time, enabling estimation of treatment differences at each follow-up point. The model was adjusted for the randomisation stratification factors. A restricted maximum-likelihood-based repeated measures model with an unstructured covariance matrix was used. Full model specification was prespecified in the statistical analysis plan (appendix 3). A complier-average causal effect analysis was prespecified for the primary PROMIS Upper Extremity outcome at 3 months.

All randomly assigned participants contributed to the primary analyses using all available data across timepoints. The model operated as an implicit imputation model under missing at random assumptions, conditional on observed outcome data at other timepoints and adjustment factors included in the model. Sensitivity analyses for informative missingness of the primary outcome data at 3 months were undertaken using multiple imputation, incorporating treatment group, time, and randomisation stratification factors (age, displacement severity, and fracture location). A point estimate of the mean difference for each statistical test was presented with corresponding two-sided 95% CIs and p values.

A within-trial economic evaluation was conducted from the perspective of the UK NHS and Personal Social Services, over a 12-month time period, in line with the UK National Institute for Health and Care Excellence (NICE) reference case.[20] All participants were included in the economic analysis. Health-care resource use was costed in pounds sterling (£), using 2022 unit costs derived from national published sources (appendix 1 pp 2–4).[21,22] Quality-adjusted life-years (QALYs) were estimated using the area-under-the-curve method, adjusted for baseline imbalances.

A bivariate regression model of costs and QALYs, adjusted for relevant covariates and combined with non-parametric bootstrap sampling, was used to estimate total and incremental costs, QALYs, and net monetary

benefits, along with associated confidence intervals. Multiple imputation was employed to address missing data for both costs and EQ-5D utility scores.[10]

The primary analysis followed an intention-to-treat approach based on the economic analysis set, reporting net monetary benefits at willingness-to-pay thresholds of £20 000 and £30 000 per QALY gained. Sensitivity analyses considered scenarios including complete case data, use of the Dutch EQ-5D-Y-3L value set, and exploration of societal costs to include parental productivity losses, days of purchased childcare, private physiotherapy, and purchased medication. We prespecified our analysis in a health economics analysis plan (appendix 4) and report findings in accordance with the Consolidated Health Economic Evaluation Reporting Standards statement.[23]

All statistical analyses were undertaken using Stata and R (version 4.3.1). No formal interim efficacy analyses or stopping guidelines were specified; the Data Monitoring Committee reviewed unmasked safety data at prespecified intervals and could recommend modifications or early termination for safety concerns.

Role of the funding source

The funders had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Aug 11, 2020, and May, 30, 2024, 1227 children were screened for eligibility across 49 UK hospitals (appendix 1 pp 5–6). Of these, 477 were not randomised: 54 met exclusion criteria and 423 were eligible but did not enter the study (figure 1). The most frequent reasons for exclusion were an injury more than 7 days old (n=17) and inability to adhere to trial procedures or follow-up (n=16). Among eligible patients, the most common reasons for non-participation were lack of clinician equipoise (n=81; of which 12 were shown to have neurovascular compromise requiring urgent reduction), or families declining consent (n=340). Declined consent was most often due to a treatment preference (n=246), with 155 preferring surgical reduction and 91 preferring non-surgical casting (appendix 1 p 7). 750 participants were randomly assigned, 375 to the non-surgical casting group and 375 to the surgical reduction group (figure 1).

Baseline demographics (age, sex, and time from injury) were similar between those screened and those recruited (appendix 1 p 8). Baseline demographic characteristics by intervention group were similar and are summarised in table 1, and patient-reported outcome measures are presented in appendix 1 (p 9). 456 participants (61%) were male and 294 (39%) were female, and the median age of participants was 7·9 years (IQR 6·5–9·5). Overall, 329 (44%) of the 750 participants had completely off-ended fractures.

Primary outcome data at 3 months were available for 640 (85%) of the 750 randomly assigned participants. Across the 750 participants, there were 78 protocol deviations, of which 73 were considered important. Of these important protocol deviations, there were 65 intervention crossovers, three consent deviations, and five randomisation errors. The intention-to-treat population included all 750 participants and the per-protocol population excluded those with major protocol deviations and comprised 677 participants (344 in the non-surgical casting group and 333 in the surgical reduction group).

In the surgical reduction group, 336 (90%) of 375 underwent treatment as assigned. Almost all procedures were performed under general anaesthesia (291 [87%] of 336), with 45 (13%) under conscious or procedural sedation. Stabilisation was achieved with plaster cast application alone in 269 (72%) participants, Kirschner wires in 100 (27%) participants, plates in

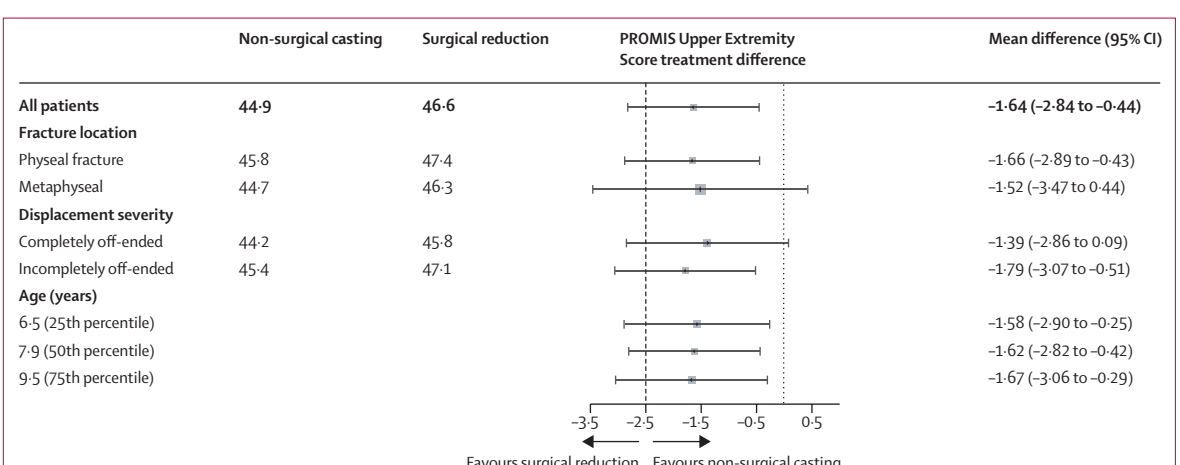

Figure 2: **PROMIS Upper Extremity Score treatment difference at 3 months by subgroups, including fracture location, displacement severity, and participant age at randomisation**

Surgical reduction is the reference group. PROMIS=Patient Report Outcomes Measurement System.

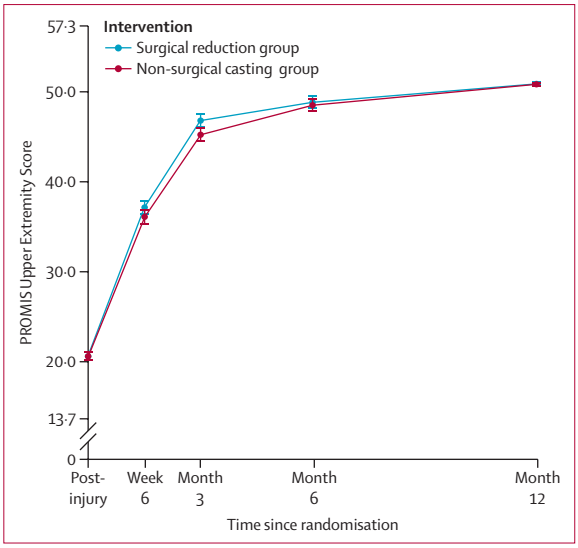

Figure 3: **PROMIS Upper Extremity Scale Scores at each trial timepoint in the surgical reduction and non-surgical casting groups**
Data are PROMIS Upper Extremity Scale Scores (95% CI). Higher scores indicate better upper extremity function. PROMIS=Patient Report Outcomes Measurement System.

five (1%) participants, and a TENS nail in one (<1%) participant. 39 (10%) participants received non-surgical casting despite allocation to surgical reduction, most commonly due to family decision (n=21), then clinician decision (n=16), or due to concurrent COVID-19 rendering anaesthesia unsafe (n=2).

In the non-surgical casting group, 349 (93%) of 375 underwent treatment as assigned. Most were immobilised in a full cast (198 [57%] of 349), with the remainder in backslabs. 26 (7%) participants received surgical reduction, most due to family preference (n=17), with others due to a clinician decision (n=9), which included loss of fracture position.

At 3 months (the primary endpoint), the mean PROMIS Upper Extremity score was 44·9 (SD 8·7) in the non-surgical casting group and 46·6 (8·8) in the surgical reduction group (appendix 1 pp 10–11). The adjusted mean difference was –1·64 (95% CI –2·84 to –0·44; p=0·0073), favouring surgical reduction (figure 2; appendix 1 p 12). As the confidence interval extended beyond the prespecified non-inferiority margin of –2·5 points, the primary intention-to-treat analysis did not demonstrate non-inferiority of non-surgical casting. The per-protocol analysis gave similar findings, with an adjusted mean difference of –2·07 (95% CI –3·32 to –0·81; p=0·0013), again extending beyond the –2·5-point margin (appendix 1 p 12). The complier-average causal effect analysis for the primary outcome yielded results consistent in direction and magnitude with the primary intention-to-treat estimand (appendix 1 p 12).

In the subgroup of children with completely off-ended fractures (n=329), the adjusted mean difference at 3 months was –1·39 (95% CI –2·86 to 0·09; p=0·066).

	Non-surgical casting (n=388)	Surgical reduction (n=362)	Total (N=750)
Unplanned surgery	0	31 (9%)	31 (4%)
Child or parent decision*	0	17 (5%)	17 (2%)
Clinician decision*	0	8 (2%)	8 (1%)
Fracture lost position, better-fitting cast required, or cast adjustment†	0	6 (2%)	6 (<1%)
Intra-operative complications			
Nerve injury	0	0	0
Vascular injury	0	0	0
Wire or screw breakage	0	0	0
Other	0	0	0
Cast complications			
Pressure areas	0	2 (1%)	2 (<1%)
Other	0	0	0
Other complications			
Wound infection	0	6 (2%)	6 (1%)
Scarring problems	0	5 (1%)	5 (1%)
Refracture after removal of cast	3 (1%)	1 (<1%)	4 (1%)
Nerve irritation	0	1 (<1%)	1 (<1%)

*Each of these participants were allocated to non-surgical casting but received surgical reduction within 2 weeks. †Five participants were randomly assigned to surgery, received surgery within 2 weeks, and then had an additional surgery owing to loss of fracture position or cast adjustment; one participant was initially randomly assigned to non-surgical casting and received surgical reduction within 2 weeks.

Table 2: **Complications up to 8 weeks, by treatment received**

	Non-surgical casting (n=388)	Surgical reduction (n=362)	Total (N=750)
Complications			
Refracture	6 (2%)	3 (1%)	9 (1%)
Adjacent to previous fracture location	1 (<1%)	1 (<1%)	2 (<1%)
Through old fracture site	5 (1%)	2 (1%)	7 (1%)
Wound infection with antibiotics prescription	0	1 (<1%)	1 (<1%)
Unplanned surgery			
Due to refracture	5 (1%)	2 (1%)	7 (1%)
Other	0	0	0

Table 3: **Complications between 8 weeks and 12 months, by treatment received**

Against the wider non-inferiority margin of –5 points, the lower bound of the confidence interval remained well above this threshold, supporting non-inferiority of non-surgical casting for this subgroup. Estimates of treatment effect across the other prespecified subgroups were similar in direction and magnitude to the primary analysis (figure 2).

By 6 months, observed mean scores had improved to 48·2 (SD 8·3) in the non-surgical casting group and

48·6 (8·0) in the surgical reduction group (appendix 1 p 17). The adjusted difference was –0·47 (95% CI –1·67 to 0·73; p=0·44) by 6 months, consistent with no difference between groups. At 12 months, scores were 50·5 (SD 7·3) in the non-surgical casting group and 50·6 (7·3) in the surgical reduction group, with an adjusted difference of –0·41 (95% CI –1·52 to 0·70; p=0·47), confirming no difference in longer-term recovery (figure 3).

Analyses adjusting for covariates associated with outcome and missingness did not materially alter the results, and sensitivity analyses in the intention-to-treat population exploring informative missingness under a range of plausible assumptions were consistent with the primary finding (appendix 1 p 18).

Pain, measured using the Wong–Baker FACES Pain Rating Scale, improved rapidly in both groups over the first 3 months and then plateaued (appendix 1 p 19). Using this scale, small differences favoured surgical reduction at 6 weeks, 3 months, 6 months, and 12 months (all <0·4 points) and below the 2-point difference considered clinically meaningful.

Quality of life (assessed via EQ-5D-Y) showed a difference at 3 months and 6 months favouring surgical reduction, but no difference at 6 weeks or 12 months (appendix 1 p 20). EQ-5D VAS scores were similar between groups throughout with a final treatment difference by 12 months of –0·18 (95% CI –2·04 to 1·69; p=0·854) on the 100-point VAS (appendix 1 p 21). Cosmesis scores were higher throughout follow-up in the surgical reduction group, with the largest differences observed at 6 weeks and 3 months. These differences narrowed over time, with a small mean difference of –6·8 points (95% CI –9·3 to –4·3) on the 100-point VAS by 12 months (appendix 1 p 22). School absence was slightly worse in the surgical reduction group (mean 3·6 days) than in the non-surgical casting group (mean 3·0 days), an absolute difference of 0·6 days. Parental satisfaction with both treatments was high at 12 months, with no meaningful difference observed (appendix 1 p 13). Results for secondary outcomes were consistent in the subgroup of completely off-ended fractures, with no systematic differences compared with the overall population.

Within 8 weeks, most complications occurred in the surgical reduction group, including pressure damage (n=2), wound infections (n=6), scarring (n=5), and nerve irritation (n=1). Refracture occurred in four participants (three after non-surgical casting and one after surgical reduction; table 2). Between 8 weeks and 12 months, complications were uncommon. Refracture occurred in nine participants (six after non-surgical casting and three after surgical reduction). Additional unplanned surgery was rare and related to new injuries in all cases (seven participants: five after non-surgical casting and two after surgical reduction; table 3).

All participants were included in the economic analysis. Complete EQ-5D data were available for 498 participants (255 for non-surgical casting and 243 for surgical reduction), and cost data were available for 492 participants (251 for non-surgical casting and 241 for surgical reduction). Missing data resulted from incomplete or partially completed participant questionnaires. There was a significant difference in QALYs, with a mean difference of –0·024 (95% CI –0·042 to –0·005), favouring surgical reduction. Mean per patient total and incremental costs and QALYs are provided in appendix 1 (pp 14–15). Following multiple imputation of missing values, non-surgical casting was associated with a significant mean per-patient cost saving of £1665 (95% CI 1487 to 1843) and a small incremental reduction in QALYs (–0·023 [95% CI –0·037 to –0·009]). Non-surgical casting was therefore substantially less costly but marginally less effective than surgical reduction. The results remained consistent across all sensitivity analyses (appendix 1 p 16). The incremental cost-effectiveness ratio plane, which depicts the bootstrap distribution, shows that

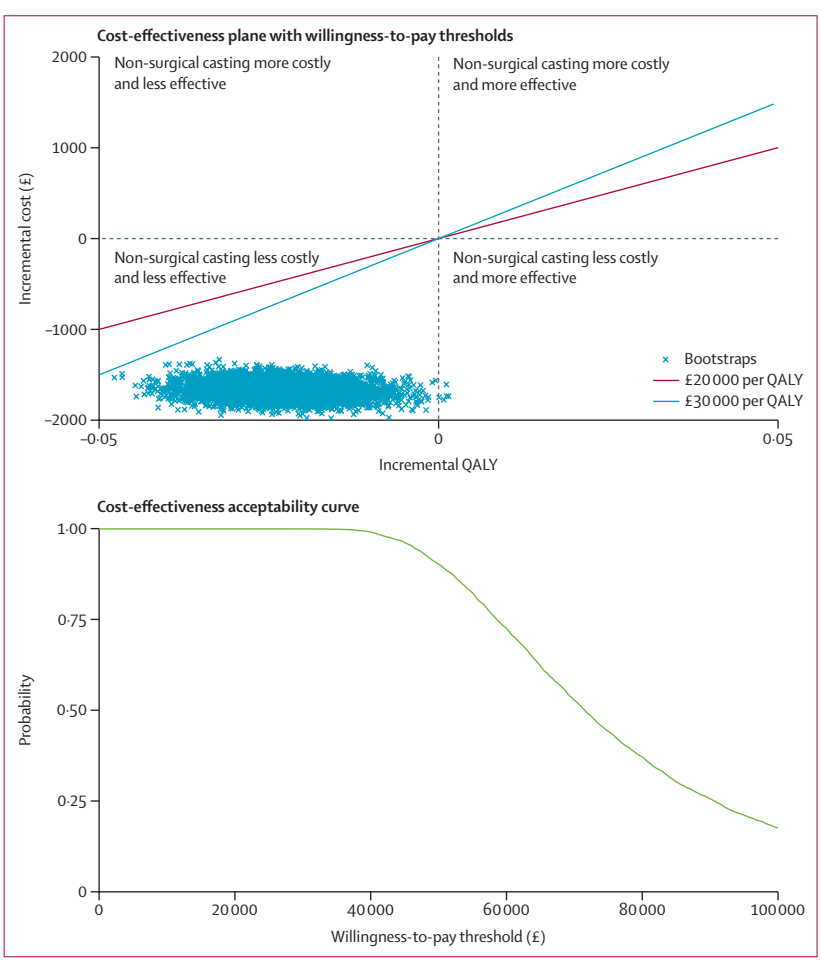

Figure 4: **Cost-effectiveness plane and cost-effectiveness acceptability curve**
The cost-effectiveness plane displays the distribution of incremental cost-effectiveness ratios from bootstrapped simulations comparing non-surgical casting with surgical reduction. The cost-effectiveness acceptability curve shows the probability that non-surgical casting is cost-effective across a range of willingness-to-pay thresholds, based on the proportion of simulations falling below each threshold. QALY=quality-adjusted life-years.

all cost and effect pairs lie below the £20 000 and £30 000 willingness-to-pay thresholds (to the right of the willingness-to-pay threshold lines; figure 4). This explains why the cost-effectiveness acceptability curve indicates that non-surgical casting has a 100% probability of being cost-effective at both the £20 000 and £30 000 willingness-to-pay thresholds.

Discussion

The CRAFFT trial did not demonstrate statistical non-inferiority of non-surgical casting compared with surgical reduction at the 3-month primary endpoint. However, the non-inferiority margin was deliberately conservative and set at the lower end of the minimally important difference for PROMIS scores. The observed treatment effect was small and below the threshold that families had indicated would be required to justify surgical reduction. Beyond 6 months there was no difference in function between treatments, suggesting that any early difference was transient and did not persist beyond the initial period of recovery. The same pattern of recovery was observed in the subgroup of children with completely off-ended fractures, indicating consistency among those with more severe injuries. The results of the complier-average causal effect analyses were similar to those from the per-protocol analyses, with both showing a slightly greater difference at 3 months in favour of surgical reduction. The intention-to-treat analysis was prioritised because it better reflects routine clinical practice where crossover and non-adherence are inevitable. From a health-system perspective, non-surgical casting offered substantial cost savings with only a very small and transient loss of health utility.

Cosmesis scores were higher in the surgical reduction group during early follow-up. However, this difference narrowed over time. Cosmetic appearance was not perfect in either group. Notably, no child was reported to have undergone a subsequent surgery for a corrective osteotomy, suggesting that any residual deformity was below the threshold for clinical concern. Minor residual deformity appears to be well tolerated, and cosmetic differences diminished with growth and remodelling. Longer-term follow-up to 3 years post-randomisation is ongoing and will provide further insight into whether these cosmetic differences continue to converge with time. Embedded qualitative studies supported these observations, by exploring parents' experiences of their child's recovery and participation in the trial.[24,25] Parents in both groups initially expressed concern about cosmesis, describing the arm as looking "bent" or abnormal, and some worried about whether the appearance would improve over time.[24] However, by 1 year, most reported being reassured and considered their child's recovery complete, even if the appearance was not perfect.[25] Families of children in the surgical reduction group sometimes reflected negatively on scars, while those in the non-surgical casting group valued avoiding them. Parents consistently emphasised function and return to activity over radiographic or cosmetic perfection and were often impressed by children's resilience. These findings provide important context to the quantitative outcomes, underscoring that families were broadly reassured by recovery trajectories regardless of initial treatment allocation.

Although the findings directly apply to children aged 4–10 years with fractures severe enough to prompt surgical reduction, consideration should be given to how the results can be extrapolated. Younger children were not included because the trial relied on validated patient-reported outcome measures appropriate to this age range; however, extrapolation to younger children is biologically plausible given their greater remodelling potential. By contrast, caution is warranted when extending these findings to older children, where remodelling potential is reduced.

Fractures that would not ordinarily prompt surgical reduction were not studied (ie, those managed with manipulation under analgesia or minimal sedation); however, the findings support a broader shift away from routine manipulation of distal radial fractures in the emergency setting, where potential harms might outweigh anticipated benefits.

Despite the trial's strengths, several limitations should be acknowledged. A small number of eligible children were not randomly assigned because neurovascular compromise led to loss of clinical equipoise requiring urgent reduction. Because transient pain and paraesthesia are common at presentation, neurological concern was not a formal exclusion criterion; instead, clinician judgement was used to identify cases in which randomisation was inappropriate, such as threatened skin integrity, dense neurological deficit, or vascular compromise.

Clinicians may seek clarification regarding the degree of radiographic angulation or displacement included in the study; however, the trial was deliberately pragmatic, reflecting thresholds that typically prompt intervention in routine practice. The subgroup of completely off-ended fractures provided a clear marker of more severe injury, and findings in this group were consistent with the main analysis. Although some variability in fracture severity and rehabilitation protocols across centres is inevitable, the large sample size, number of recruiting centres, and stratified randomisation make it unlikely that any residual imbalance materially influenced the results.

Additional outcomes such as range of motion might also be of interest; however, follow-up was deliberately aligned with routine care, without additional mandated assessments, to maximise completeness and prioritise validated, patient-centred functional outcomes. Radiographic alignment was not a prespecified outcome, because the trial focused on function and patient-centred outcomes; radiographic remodelling is being investigated separately as an exploratory analysis. Findings from the

embedded qualitative study support this approach, indicating that families generally prioritised function and appearance over radiographic appearance.

The interventions themselves were not standardised, but the techniques used are widely adopted, and the pragmatic multicentre design enhances generalisability. Adherence to allocated treatment was high overall, although crossover occurred slightly more often in the surgical reduction group, reflecting preferences at the point of care. Notably, equipoise was acceptable to families across both groups, as reflected by recruitment and the distribution of treatment preferences.

Finally, the trial was conducted within the UK, and clinical practice, pathways, and thresholds for intervention might differ globally. The economic evaluation reflects UK costs and willingness-to-pay thresholds within a state-funded health-care system. Nevertheless, the clinical findings are likely to be generalisable across settings, given the common nature of the injury, the routine techniques studied, and the pragmatic multicentre design.

The adoption of these findings into practice might be challenging. An embedded qualitative study of recruiting clinicians described anxiety about leaving severely displaced fractures to remodel, difficulty aligning the protocol with existing pathways, and so-called territorial tensions between orthopaedic and emergency teams, with some colleagues expected to resist change regardless of evidence.[26] This aligns with survey data showing that most surgeons still reduce off-ended distal radius fractures in children under anaesthesia, and few would accept non-surgical casting despite previous evidence of remodelling.[27]

Ongoing randomised trials in North America and Europe[28–30] suggest growing international equipoise but also suggest that the publication of CRAFFT will mark the beginning of the broader shift required to change practice. Successful implementation will require multidisciplinary agreement on indications for surgery, integration of non-surgical casting into local pathways, and careful management of clinician and families' expectations that a child's wrist must always be straightened immediately.

The CRAFFT trial did not demonstrate non-inferiority of non-surgical casting compared with surgical reduction at the 3-month primary endpoint, although the observed difference in upper limb function was small, below thresholds families considered clinically meaningful, and did not persist beyond early recovery. Surgical reduction was associated with modestly better cosmetic appearance, although this advantage diminished with longer follow-up from injury, and was associated with higher costs and early procedural complications. Non-surgical casting delivered substantial cost savings with only a small and transient reduction in health utility. Taken together, these findings support non-surgical casting as the preferred initial treatment strategy for most children with severely displaced distal radial fractures.

Contributors

DCP conceived the study and led the funding application. DCP led study oversight and manuscript preparation. JA coordinated the day-to-day management of the study and contributed to study design. NN, DM, and MDL provided clinical expertise in study design and interpretation. DA developed the data management and randomisation systems. SF, JM, and RK led the health economic analysis. AZ and DK did the statistical analyses. PG led patient and public involvement activities. MLC contributed to study design, oversight, and interpretation. All authors contributed to data interpretation, critically revised the manuscript for important intellectual content, and approved the final version for publication. AZ, DK, and DA had access to the study data and take responsibility for verifying the consistency of the underlying data. AZ and DK take responsibility for the accuracy of the data analysis. All authors had full access to all the data in the study and accept responsibility for the decision to submit for publication.

Declaration of interests

The University of Oxford received a grant from the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (17/22/02) on behalf of the authors for the conduct of the trial. DCP is an NIHR Research Professor and Chair of the NIHR Health Technology Assessment (HTA) Prioritisation Committee; both DCP and MLC were previously members of the NIHR HTA General Board and now serve on the NIHR HTA Prioritisation Committee. DCP was funded through an NIHR Research Professorship (NIHR301655). NN is a board member of the British Patellofemoral Society, the British Society for Children's Orthopaedics, and the British Orthopaedic Sports Trauma and Arthroscopy Association. NN has undertaken paid lectures for Smith and Nephew and Arthrex. All other authors declare no competing interests.

Data sharing

De-identified participant data will be made available on reasonable request to the corresponding author, subject to approval by the Trial Steering Committee and appropriate data sharing agreements.

Acknowledgments

This study was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (17/22/02) and supported by the NIHR Oxford Biomedical Research Centre. We would like to thank all those involved in making the CRAFFT trial possible, including the children and families who took part, the research associates and clinical teams at all participating hospitals, and the multidisciplinary staff (emergency clinicians, orthopaedic surgeons, radiographers, nurses, and physiotherapists) who contributed to the study across the UK. We are especially grateful to Kinzah Abbasi, Marta Campolier, Louise Spoors, and the broader Oxford Trauma and Emergency Care Team at the Kadoorie Institute for Trauma, Emergency and Critical Care, University of Oxford, for their commitment to trial delivery. We acknowledge the oversight provided by the Trial Steering Committee and by the Data Monitoring and Safety Committee: Joy Adamson, Lyndon Mason, Simon Scott, Jamie Kirkham, Richard Wilkin, Charlie Pearman, and Amy Moscrop. This trial has been conducted as part of a portfolio of trials in the UKCRC-registered Oxford Clinical Trials Research Unit at the University of Oxford. It has followed their standard operating procedures ensuring compliance with the principles of Good Clinical Practice and the Declaration of Helsinki and any applicable regulatory requirements. The views expressed in this report are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care. The authors used ChatGPT to improve the grammar and sentence structure during the preparation of this manuscript. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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