Moulded cast compared with K-wire fixation after manipulation of an acute dorsally displaced distal radius fracture: the DRAFFT 2 RCT

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Scientific summary

The DRAFFT 2 RCT

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Scientific summary

Background

Patients with a displaced fracture of the distal radius are frequently offered surgical fixation following a manipulation of their fracture. A moulded plaster cast is an alternative treatment that avoids metal implants, but evidence of its effectiveness is lacking.

Objectives

The primary objective of this randomised controlled trial was to compare the Patient-Rated Wrist Evaluation score in the 12 months following randomisation among patients with a dorsally displaced fracture of the distal radius who were treated with manipulation and surgical fixation with Kirschner wires (K-wires) and those treated with manipulation and a moulded cast

The secondary objectives were to compare quality-of-life outcomes, complications, resource use and cost-effectiveness between the treatments in the first 12 months after randomisation.

Methods

All adult patients presenting at the recruitment centres with an acute dorsally displaced fracture of the distal radius who would benefit from manipulation were potentially eligible to take part in the trial. These broad eligibility criteria ensure that the results of the study can be readily generalised to the wider patient population.

Prior to the manipulation, a member of the local research team collected baseline demographic information. The participants were asked to complete a questionnaire to ascertain both their current (injured) and their typical (pre-injury) status.

A randomisation sequence, stratified by recruitment centre, intra-articular extension of the fracture and age of the participant (aged < 50 or ≥ 50 years), was produced and administered independently. Each participant had their fracture manipulated in the operating theatre and was then randomly allocated to either 'manipulation and surgical fixation with K-wires' (the K-wire group) or 'manipulation and moulded casting' (the cast group). Both of these interventions are widely used in the NHS and all of the surgeons were familiar with both techniques. Post manipulation, each participant was issued with standardised written rehabilitation instructions.

Outcome

The primary outcome measure for this study was the Patient-Rated Wrist Evaluation. The Patient-Rated Wrist Evaluation is a 15-item questionnaire designed specifically for assessment of distal radial fractures and wrist injuries and comprises a range of questions in two (equally weighted) sections concerning the patient's experience of pain and function. All questions are scored on an 11-point, ordered, categorical scale ranging from 'no pain' or 'no difficulty' (0) to 'worst ever pain' or 'unable to do' (10). Five questions relate to the patient's experience of pain and 10 questions relate to function and disability; scores for the 10 function items are summed and divided by 2 and added to the total score for the five pain items to give a score out of 100 (best score = 0 and worst score = 100).

Health-related quality of life was recorded using the EuroQol-5 Dimensions, five-level version, and resource use was recorded from a health and personal social care perspective. A within-trial cost–utility analysis was computed from an NHS and Personal Social Services perspective.

A member of the local research team performed a clinical assessment and made a record of any early complications at 6 weeks, including the need for any further surgery. Outcome data were collected by the central research team using the Patient-Rated Wrist Evaluation and EuroQol-5 Dimensions, five-level version, at 3, 6 and 12 months post randomisation. These questionnaires were administered centrally. The participants were also asked to complete a health-care resource use questionnaire and to provide details of any complications or interventions related to their injury.

Results

Between January 2017 and March 2019, 500 participants (mean age 60 years, 83% women) were randomly allocated to the cast group ($n = 255$) or the K-wire group ($n = 245$) after a closed fracture manipulation. A total of 395 participants (80%) were included in the primary analysis at 12 months.

Patients' wrist function improved in the year following randomisation as measured by the Patient-Rated Wrist Evaluation score, but there was no evidence of a difference between the two treatments at 12 months [cast group: $n = 200$, mean score 21.2 (standard deviation 23.1); K-wire group: $n = 195$, mean score 20.7 (standard deviation 22.3); adjusted mean difference −0.34 (95% confidence interval −4.33 to 3.66); $p = 0.87$]. Nor was there evidence of a difference in Patient-Rated Wrist Evaluation scores at 3 or 6 months post randomisation.

Health-related quality of life, measured by the EuroQol-5 Dimensions, five-level version, also showed an improvement over time from injury until 12 months post randomisation, but there was no difference between the treatments at any time point, with a 12-month adjusted mean difference of −0.03 (95% confidence interval −0.07 to 0.02). Thirty-three participants (12.94%) in the cast group required surgery for loss of fracture reduction in the first 6 weeks post randomisation, compared with one participant (0.41%) in the K-wire group (odds ratio 0.02, 95% confidence interval 0.001 to 0.10; $p < 0.001$). The base-case cost-effectiveness analysis showed that surgical fixation with K-wires was dominated, in that it provided similar outcomes for slightly higher costs. The use of K-wires is unlikely to be cost-effective, and sensitivity analyses found this result to be robust.

Conclusions

Surgical fixation with K-wires was not found to be superior to moulded casting, as measured by Patient-Rated Wrist Evaluation score following manipulation of a dorsally displaced fracture of the distal radius. However, one in eight patients treated with the moulded cast later required surgery for loss of fracture reduction in the first 6 weeks post randomisation. If a closed reduction of the fracture can be achieved, clinicians may consider the application of a moulded cast as a safe and cost-effective alternative to surgical fixation with K-wires.

Trial registration

This trial is registered as ISRCTN11980540 and UKCRN Portfolio 208830.

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This report

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