Radiological outcomes following surgical fixation with wires versus moulded cast for patients with a dorsally displaced fracture of the distal radius: a radiographic analysis from the DRAFFT2 trial

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Aims
The primary aim of this study was to report the radiological outcomes of patients with a dorsally displaced distal radius fracture who were randomized to a moulded cast or surgical fixation with wires following manipulation and closed reduction of their fracture. The secondary aim was to correlate radiological outcomes with patient-reported outcome measures (PROMs) in the year following injury.

Methods
Participants were recruited as part of DRAFFT2, a UK multicentre clinical trial. Participants were aged 16 years or over with a dorsally displaced distal radius fracture, and were eligible for the trial if they needed a manipulation of their fracture, as recommended by their treating surgeon. Participants were randomly allocated on a 1:1 ratio to moulded cast or Kirschner wires after manipulation of the fracture in the operating theatre. Standard posteroanterior and lateral radiographs were performed in the radiology department of participating centres at the time of the patient's initial assessment in the emergency department and six weeks postoperatively. Intraoperative fluoroscopic images taken at the time of fracture reduction were also assessed.

Results
Patients treated with surgical fixation with wires had less dorsal angulation of the radius versus those treated in a moulded cast at six weeks after manipulation of the fracture; the mean difference of -4.13° was statistically significant (95% confidence interval 5.82 to -2.45). There was no evidence of a difference in radial shortening. However, there was no correlation between these radiological measurements and PROMs at any timepoint in the 12 months post-injury.

Conclusion
For patients with a dorsally displaced distal radius fracture treated with a closed manipulation, surgical fixation with wires leads to less dorsal angulation on radiographs at six weeks

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compared with patients treated in a moulded plaster cast alone. However, the difference in dorsal angulation was small and did not correlate with patient-reported pain and function.

Take home message

- For patients with a dorsally displaced fracture of the distal radius treated with a closed manipulation, surgical fixation with wires leads to less dorsal angulation on radiographs at six weeks compared with patients treated in a moulded plaster cast alone.
- However, the difference in dorsal angulation was small and did not correlate with patient-reported pain and function.

Introduction

Distal radius fractures are common injuries in both young and older adults.[1] Undisplaced fractures of the distal radius may be managed with a simple splint or cast. However, dorsally displaced fractures generally require manipulation and reduction of the fracture to restore the anatomy of the wrist.[2] Following manipulation, the reduction of the fracture may be supported by either a moulded cast or surgical fixation with wires or plates and screws. Previous investigations have demonstrated that surgical fixation provides reliable support for the healing bones with very little loss of the reduction before the fracture heals.[3,4] There is less data regarding the radiological outcomes following fracture manipulation and casting, but clinical outcomes suggests that a cast alone is not as reliable as surgical fixation in maintaining the fracture reduction, with a higher rate of loss of reduction in the first two weeks after the manipulation of the fracture.[5,6]

In previous studies of operatively managed patients, the quality of the initial fracture reduction has shown poor correlation with subsequent functional outcomes, although this may not be the case for patients treated with a manipulation and cast alone.[7-9]

The primary aim of this study was to report the radiological outcomes of patients with a dorsally displaced fracture of the distal radius who were randomized to either a moulded cast or surgical fixation with wires following a manipulation and closed reduction of their fracture. The secondary aim was to correlate radiological outcomes with patient-reported function in the year following injury.

Methods

Participants

Participants were recruited as part of the DRAFFT2 trial.[10] The analysis described here was pre-planned as part of the trial protocol. The protocol, analysis plan, and clinical and health economic data from the trial have been published previously.[3,11-13] In brief, DRAFFT2 was a multicentre clinical trial that was conducted at 36 NHS hospitals in the UK. Participants were screened for eligibility if aged 16 years or over with a dorsally displaced fracture of the distal radius, and were potentially eligible if they needed a manipulation of their fracture as recommended by their treating surgeon. Patients were excluded if they had an injury more than two weeks old, a fracture extending more than 3 cm from the radiocarpal joint, an open fracture, an articular surface of the fracture that could not be reduced by closed manipulation, or they were unable to complete follow-up questionnaires. Participants were randomly allocated on a 1:1 ratio to either a moulded cast or Kirschner (K)-wires after the successful closed manipulation of the fracture in the operating theatre.

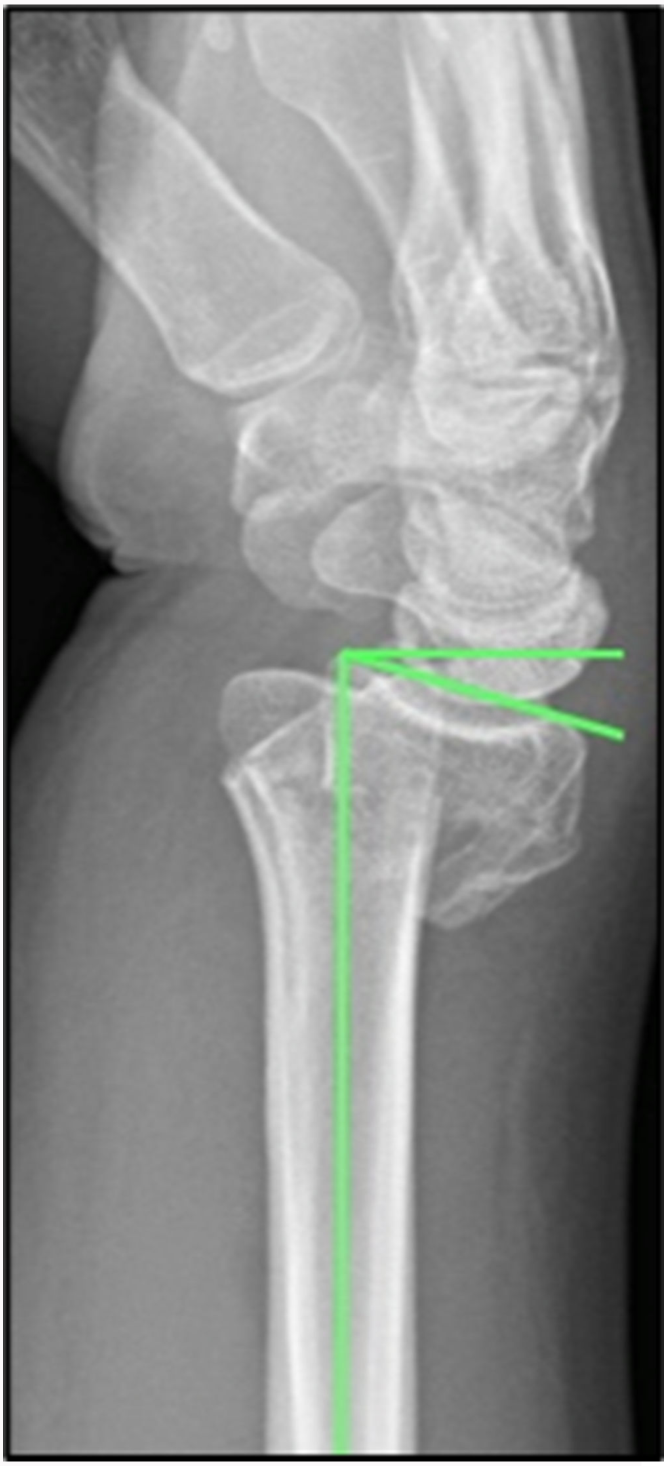

Fig. 1
Radial angulation: the angle between the articular surface of the radius and the perpendicular of the long axis of the radius measured on the lateral radiograph.

Table I. Estimates of intraclass correlation coefficient and 95% confidence intervals.

Variable	ICC	95% CI
Pre-reduction		
Dorsal angle, °	0.83	0.79 to 0.87
Ulnar variance, mm	0.84	0.79 to 0.87
Post-reduction		
Dorsal angle, °	0.63	0.55 to 0.70
Ulnar variance, mm	0.92	0.81 to 0.96
Six weeks		
Dorsal angle, °	0.84	0.79 to 0.88
Ulnar variance, mm	0.90	0.86 to 0.92

CI, confidence interval; ICC, intraclass correlation coefficient.

The DRAFFT2 trial was approved by the UK National Research Ethics Committee and registered with the clinical trials registry (16/SC/0462; ISRCTN11980540).

Radiological parameters

Standard posteroanterior and lateral radiographs were performed in the radiology department of participating centres at the time of the patient's initial assessment in the emergency department and six weeks postoperatively. In addition, intraoperative fluoroscopic images taken at the time of the fracture reduction were also assessed. The angulation of the radial articular surface on the lateral radiograph (radial tilt) and radial shortening on the posteroanterior radiograph (ulnar variance) were assessed from the calibrated digital images using the RadiAnt dicom reader (Medixant, Poland) primarily by the principal assessor (CEP) (Figure 1 and Figure 2).

Radial articular angulation (radial tilt) is defined as the angle between a line drawn perpendicular to the long axis of the radius and a line drawn between the anterior and posterior margins of the articular surface of the distal radius on the lateral radiograph. Radial shortening (ulnar variance) is defined as the distance between parallel lines drawn from the ulnar margin of the articular surface of the distal radius and the radial margin of the articular surface of the distal ulna, perpendicular to the axis of the radial shaft, on the posteroanterior radiograph.

The reliability of these measurements was verified using a second independent assessor (MCe; see Acknowledgements).

Patient-reported outcome measures

Participants' self-reported their wrist function and quality of life with the Patient-Reported Wrist Evaluation (PRWE), the EuroQol five-dimension five-level questionniare (EQ-5D-5L), and EuroQol visual analolgue (EQ-VAS) measures. The PRWE provides a ten-item assessment of wrist pain and function, which has been validated for use in patients following a distal radius fracture.[14,15] The EQ-5D-5L is a general health-related quality of life tool, including five dimensions assessing patients' mobility, pain, presence of anxiety/depression, and the ability to perform their usual activities and those

Fig. 2
Radial shortening: the distance between the radial and ulnar articular surfaces measured on the posteroanterior radiograph.

of self-care.[16] EQ-5D is responsive to change in function in the first 12 months of patients' recovery from a distal radius fracture.[17] Patients were asked to complete these measures pre-injury (retrospectively) and post-injury, and then at three, six, and 12 months post-injury.

Statistical analysis

Adjusted mean differences between treatment groups for the radiological parameters post- reduction and at six weeks post-injury were compared using a mixed effects model with articular extension of the fracture (intra- and extra-articular) and age of the patient (≥ 50 years or < 50 years) as fixed effects and recruiting centre as a random effect. Treatment by time point interactions were also included in the model to allow time specific treatment effects to be calculated. Time has been included as a discrete variable for the time points of post-reduction, at the time of the manipulation of the fracture in the operating theatre, and six weeks. Pre-reduction values are not included in the model and reported descriptively. The adjusted mean differences are reported with associated 95% confidence intervals (CIs) and p-values, with a two-sided significance level of 0.05.

Agreement between assessors was assessed through the intraclass correlation coefficient (ICC), along with 95% CIs. It is also assessed visually by Bland-Altman plots.

A correlation analysis was performed between the six-week radiological parameters and patient reported outcomes at three, six, and 12 months using Pearson correlation formula on all available data. The strength of the correlations was interpreted as: negligible (r = 0.00 to 0.30); weak (r = 0.31 to 0.50); moderate (r = 0.51 to 0.70); strong (r = 0.71 to 0.90); and almost perfect (r = 0.91 to 1.00). The significance threshold was adjusted using Bonferroni's correction to p < 0.003 for the correlation between the radiological and patient-reported outcome measures (PROMs) as a means of controlling the false positive rate.

Results

Estimated ICCs for both radiological measures at each time point are presented in Table I. Interobserver agreement was strong (ICC > 80) for all measurements taken, apart from the intraoperative dorsal angulation, where agreement was moderate (0.63).

Radiological parameters

The radiological outcomes for both treatment groups are detailed in Table II with the mean and adjusted mean differences at each timepoint.

There was no evidence of a difference in the angulation of the articular surface of the distal radius immediately after the manipulation of the fracture, but at six weeks there was a statistically significant adjusted mean difference of -4.13° (95% CI -5.82 to −2.45) (i.e. less dorsal angulation in the participants having wire fixation). There was no statistically significant difference in radial shortening.

Patient-reported outcomes

The PRWE, EQ-5D-5L questionnaire, and EQ-VAS scores improved up until 12 months post-randomization, with the greatest improvement within the first three months and a gradual levelling off from six to 12 months. Neither group returned to baseline pre-injury scores, with a mean deficit in the PRWE scores of 18.1 in the moulded cast group and 15.6 in the wire fixation group. No statistically significant difference was detected between the groups at any of the time points. Figure 1 depicts the change in each of the scores during the 12-month recovery period (see also Figure 3).

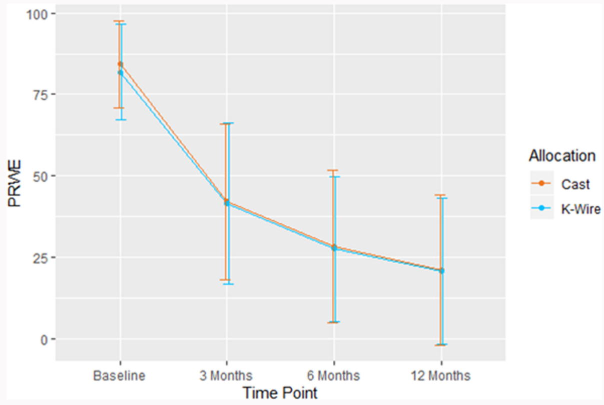

Fig. 3

Patient-Reported Wrist Evaluation (PRWE) score for patients managed with either manipulation and moulded cast or wire fixation during their 12-month recovery. The baseline depicts the post-injury level.

Correlation analysis

No significant correlation was detected between the radiological parameters and PROMs at any timepoint (Table III). The greatest correlation detected was between radial shortening and PRWE at 12 months, but even this showed only a negligible correlation (ICC -0.17). Table II details the correlation coefficients between the radiological outcomes at six weeks and the PROMs at all time points.

Discussion

This study showed a statistically significant increase in dorsal angulation in patients treated with a moulded plaster cast versus surgical fixation with wires at six weeks after the manipulation of a dorsally displaced fracture of the distal radius, with a mean difference of 4°. There was no evidence of a difference in radial shortening. However, there was no correlation between these radiological measurements and PROMs at any timepoint in the 12 months post-injury.

Our radiological results are in line with the finding of previous studies. Gutierrez-Monclus et al[18] assessed nonoperatively managed patients aged over 60 years. Radiographs taken at removal of cast demonstrated a residual dorsal angulation of 5° and radial shortening of 2 mm.[18] In patients treated with wire fixation, Kurup et al[19] found that there was less deformity, with an increase in dorsal angulation of only 2.6° and radial shortening of 1.3 mm on radiographs performed a month after the wires were removed. In a trial of patients aged over 70 years treated nonoperatively versus locking plate fixation, Sudow et al[20] also found that patients treated nonoperatively had greater dorsal angulation of the radius and more shortening than those treated with surgical fixation.[20]

While the difference in radiological measurements following surgical versus non-surgical management of fractures of the distal radius is clear, the clinical importance of these differences is questionable. The poor correlation between radiological and clinical outcomes following a fracture of the distal radius, has been reported in numerous studies of surgically and non-surgically managed patients[4,18,21] Paranaiba et al[15] demonstrated negligible correlation at 12 months post-injury with Spearman correlation coefficients

Table II. Radiological results.

Radiological outcomes	Cast n	Cast Mean (SD)	K-wire n	K-wire Mean (SD)	Mean difference Unadjusted	Mean difference Adjusted (95% CI)†	p-value†
Dorsal angle, °							
Pre-reduction	205	23.24 (12.48)	192	22.35 (13.08)	-0.89		
Post-reduction	148	-0.63 (5.96)	140	-1.28 (5.73)	-0.66	-0.83 (-2.62 to 0.96)	0.364
Six weeks	170	4.04 (9.68)	162	0.04 (9.39)	-4.01	-4.13 (-5.82 to -2.45)	< 0.001
Ulnar variance, mm							
Pre-reduction	213	-2.93 (2.97)	191	-3.04 (2.81)	-0.11		
Post-reduction*	31	0.27 (1.84)	43	-0.51 (2.39)	-0.78		
Six weeks	173	-2.01 (2.44)	162	-1.91 (2.46)	-0.10	0.14 (-0.36 to 0.63)	0.586

*No analysis of radial shortening was performed on the post-reduction images due to the difficulty of assessing this measurement on intraoperative fluoroscopy images. For this time point, only unadjusted mean differences are presented.
†Adjusted effects, confidence intervals, and p-values were from a mixed effects model described in the Methods section.
CI, confidence interval; K-wire, Kirschner wire; SD, standard deviation.

Table III. Correlation coefficients (with Bonferroni corrected 99.7% confidence intervals in brackets) between the six-week radiological parameters and the patient-reported outcome measures at three, six, and 12 months.

Correlation coefficients (Bonferroni corrected 99.7% CIs)	Dorsal angle, ° 3 mths	Dorsal angle, ° 6 mths	Dorsal angle, ° 12 mths	Ulnar variance, mm 3 mths	Ulnar variance, mm 6 mths	Ulnar variance, mm 12 mths
PRWE	-0.02 (-0.19 to 0.16)	0.08 (-0.10 to 0.26)	0.05 (-0.14 to 0.23)	-0.12 (-0.30 to 0.05)	-0.13 (-0.30 to 0.05)	-0.17 (-0.34 to 0.01)
EQ-5D-5L	0.00 (-0.17 to 0.18)	-0.14 (-0.31 to 0.04)	-0.08 (-0.26 to 0.10)	0.10 (-0.08 to 0.27)	0.10 (-0.08 to 0.28)	0.12 (-0.06 to 0.29)
EQ-VAS	0.02 (-0.15 to 0.20)	-0.07 (-0.25 to 0.11)	0.03 (-0.16 to 0.21)	0.06 (-0.11 to 0.24)	0.01 (-0.17 to 0.19)	0.08 (-0.10 to 0.26)

CI, confidence interval; EQ-5D-5L, EuroQol five-dimension five-level questionnaire; EQ-VAS, EuroQol visual analogue scale; PRWE, Patient-Reported Wrist Evaluation.

of -0.16 and -0.11 between the PRWE and dorsal angulation and radial shortening, respectively. In the longer term, Hevonkorpi et al[22] found no correlation between radiological parameters at ten weeks, and the PRWE score at four years in 201 patients undergoing predominately nonoperative management. Given the consistency of these findings, it appears that there is a threshold level of radiological deformity which needs to be reached before patients become symptomatic in terms of wrist pain and function. This is not to say that any deformity of the distal radius will be well tolerated by the patient. However, within the limits of what a treating surgeon believes is an acceptable radiological outcome following the manipulation of a fracture of the distal radius, there does not appear to be any functional deficit. Small residual radiological markers of malunion do not seem to matter from a patient perspective.

The strengths of this study include the large number of participants and the random allocation to either cast or surgical fixation following the closed reduction of their distal radius fracture. The limitations include some missing radiological data, most significantly the lack of data to inform the measurement of radial shortening at the time of the initial reduction of the fracture. This probably reflects the difficulties of obtaining reliable positioning and image quality using intraoperative fluoroscopy. The interobserver reliability of the measurement of dorsal angulation taken from the intraoperative imaging was only moderate, as opposed to the strong agreement demonstrated in the radiographs taken in the radiology dept after injury and at six weeks. The number of radiological measurements performed were also limited. Despite the availability of numerous radiological outcome measurements, correction of the radial angulation (radial tilt) and radial shortening (ulnar variance) have been shown to have most influence over functional outcomes and hence were measured in this study.[23] Another potential limitation is the lack of radiological data from later in the participants recovery. However, current guidelines dictate that routine imaging during follow-up is not required for patients following treatment for a fracture of the distal radius.[24] Furthermore, previous studies have shown that there are negligible changes in radiological measurements between six weeks and 12months following injury.[10] Therefore, it was not considered ethical to ask participants to have further radiographs taken after six weeks for the purposes of this study. A final important point of note is that one in eight participants treated with a moulded plaster cast as part of the DRAFFT2 trial lost fracture reduction in the first two weeks following their manipulation and required subsequent surgical fixation of their fracture.[3] The data presented in this study includes those participants who required a further intervention before their six week radiographs were taken. Although the mean difference in radiological parameters at six weeks was small and unlikely to be of clinical importance, some participants in the cast group would have had much greater deformity if a secondary procedure had not been performed. Therefore, while a moulded cast is a clinically and cost-effective intervention for patient with a dorsally displaced fracture that can be successfully reduced with a closed manipulation, patients treated in this way require routine radiological follow-up for at least two weeks after their injury.

In conclusion, for patients with a dorsally displaced fracture of the distal radius treated with a closed manipulation, surgical fixation with wires leads to less dorsal angulation on radiographs at six weeks compared with patients treated in a moulded plaster cast alone. However, the difference in angulation was small and did not correlate with patient-reported pain and function at any point during the one year following injury.

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Data sharing

The data form this study are publicly available at: https://www.fundingawards.nihr.ac.uk/award/15/27/01

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