■ WRIST & HAND

Percutaneous fixation with Kirschner wires versus volar locking-plate fixation in adults with dorsally displaced fracture of distal radius: five-year follow-up of a randomized controlled trial

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Aims

The aim of this study was to compare the clinical effectiveness of Kirschner wire (K-wire) fixation with locking-plate fixation for patients with a dorsally displaced fracture of the distal radius in the five years after injury.

Patients and Methods

We report the five-year follow-up of a multicentre, two-arm, parallel-group randomized controlled trial. A total of 461 adults with a dorsally displaced fracture of the distal radius within 3 cm of the radiocarpal joint that required surgical fixation were recruited from 18 trauma centres in the United Kingdom. Patients were excluded if the surface of the wrist joint was so badly displaced it required open reduction. In all, 448 patients were randomized to receive either K-wire fixation or locking-plate fixation. In the K-wire group, there were 179 female and 38 male patients with a mean age of 59.1 years (19 to 89). In the locking-plate group, there were 194 female and 37 male patients with a mean age of 58.3 years (20 to 89). The primary outcome measure was the patient-rated wrist evaluation (PRWE). Secondary outcomes were health-related quality of life using the EuroQol five-dimension three-level (EQ-5D-3L) assessment, and further surgery related to the index fracture.

Results

At 12 months, 402/448 participants (90%) recruited into the main study provided PRWE scores. At year two, 294 participants (66%) provided scores; at year five, 198 participants (44%) provided scores. There was no clinically relevant difference in the PRWE at any point during the five-year follow-up; at five years, the PRWE score was 8.3 (12.5) in the wire group and 11.3 (15.6) in the plate group (95% confidence interval -6.99 to 0.99; p = 0.139). Nor was there a clinically relevant difference in health-related quality of life. Only three participants had further surgery in the five years after their injury (one in the wire group and two in the plate group).

Conclusion

This follow-up study continues to show no evidence of a difference in wrist pain, wrist function, or quality of life for patients treated with wires *versus* locking plates in the five years following a dorsally displaced fracture of the distal radius.

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In 2014, we published the Distal Radius Acute Fracture Fixation Trial (DRAFFT).[1] This compared percutaneous Kirschner wire (K-wire) fixation with volar locking-plate fixation for patients with a dorsally displaced fracture of the distal radius (wrist fracture). The trial showed no evidence of a difference in functional outcome or quality of life for patients at any time during the first year after the injury. The associated health economic evaluation demonstrated that that locking-plate fixation is very unlikely to be cost effective.[2,3] These findings contradicted much of

Table I. Population characteristics at recruitment (baseline)

Variable	Wire (n = 217)	Plate (n = 231)	p-value
Mean age, (SD); range	59.1 (16.5); 19 to 89	58.3 (14.3); 20 to 89	0.599*
Sex, female:male (%)	179:38 (*82.4*)	194:37 (*84.0*)	0.705†
Intra-articular extension, no:yes (%)	115:102 (*53.0*)	121:110 (*52.4*)	0.925†
Pre-injury baseline scores			
Mean PRWE, (SD); range	2.3 (7.4); 0 to 53	2.9 (9.5); 0 to 76	0.460*
Mean DASH, (SD); range	4.9 (11.9); 0 to 80	4.9 (11.3); 0 to 66	0.999*
Mean EQ-5D-3L, (SD); range	0.93 (0.16); 0.1 to 1.0	0.93 (0.17); 0.0 to 1.0	0.806*

*Student's *t*-test

†Fisher's exact test

PRWE, patient-rated wrist evaluation; DASH, Disabilities of Arm, Shoulder, And Hand; EQ-5D-3L, EuroQol five-dimension three-level health-related quality-of-life assessment

the existing literature and led to a rapid and substantial change in clinical practice in the United Kingdom.[4]

However, a major criticism of the original DRAFFT report was that it only included one year of follow-up.[5] What if patients developed persistent symptoms that affected their wrist function in the longer-term? What if patients required revision surgery after one year, or required extensive salvage surgery for arthritis?

We therefore present the outcomes at five years of the original DRAFFT trial cohort. The primary objective was to estimate differences in the patient-rated wrist evaluation (PRWE) between those patients treated with K-wire fixation and those treated with locking-plate fixation. Secondary objectives were to estimate differences in health-related quality of life and the need for further surgery related to the fracture.

Patients and Methods

Synopsis of the DRAFFT trial. DRAFFT was a two-arm, parallel-group randomized controlled trial (RCT) that recruited from 18 trauma centres in the United Kingdom. Adults with a dorsally displaced fracture of the distal radius within 3 cm of the radiocarpal joint were eligible for inclusion if their treating surgeon believed that they would benefit from surgical fixation. Patients were excluded if the surgeon thought that the surface of the wrist joint was so badly displaced that it required open reduction. Half of the patients were randomized to receive K-wire fixation and the other half locking-plate fixation. Following the completion of the first 12 months of clinical review, participants were approached to provide consent to be included in the five-year long-term follow-up. Participants were contacted yearly by post, to complete the PRWE (which was the primary outcome measure) and the EuroQol five-dimension three-level (EQ-5D-3L) health-related quality of life assessment, and to report any additional surgery related to the index wrist fracture. The PRWE score[6] is a questionnaire designed specifically for assessment of distal radial fractures and wrist injuries that rates wrist function using a range of questions in two (equally weighted) sections concerning the patient's experience of pain and function. Scoring for all the questions is via an 11-point, ordered, categorical scale ranging from 'no pain' or 'no difficulty' (0) to 'worst possible pain' or 'unable to do' (10). The EQ-5D is a validated generalized quality of life questionnaire consisting of five domains of health; patients' responses can be converted to health state utility values,[7] anchored at 1 (perfect health) and 0 (death).[8]

Statistical analysis. Mixed-effects linear regression analysis was used for longitudinal analysis of PRWE and EQ-5D scores using data from years one to five postoperation, with sex, age group (dichotomized into patients younger and older than 50 years of age), intra-articular extension, and year of follow-up (log-transformed) as explanatory variables. The significance of terms in the fitted models were assessed using likelihood ratio tests (LRT), with significance set at the 5% level. Cross-sectional analysis of scores was also undertaken using Student's *t*-tests to assess differences between treatment groups at each assessment occasion. Mixed-effect logistic regression analysis was used to assess patterns of missing PRWE data during follow-up with participant as the random effect, and with sex, age group, and intra-articular extension added as explanatory variables. A complete-case analysis was used for consistency with previous reporting of data from the DRAFFT study. No adjustments were made for multiple testing. All analyses were implemented in R (version 3.3.0; R Foundation for Statistical Computing, Vienna, Austria) using the package lme4.[9]

Results

Population. For the DRAFFT RCT, 461 patients were recruited and followed to one year. Of these, 230 were allocated to the wire arm and 231 to the plate arm of the study. In the wire arm, 208 participants received the allocated intervention and 18 went on to receive the plate intervention; in the plate group, 213 participants received the allocated intervention and nine received the wire intervention. In all, 13 patients did not receive either of the treatments under investigation; the majority (85%) were treated with a cast. For the purposes of this follow-up study, patients are analyzed according to the treatment they received. Therefore, in total, 217 participants received the wire intervention and 231 participants received the plate intervention.

Table I shows the main characteristics of the population. There was no evidence that the participants differed between intervention arms.

Follow-up patterns. At the 12-month assessment, 402/448 participants (90%) recruited into the main study provided PRWE scores. A total of 301 patients provided consent for the

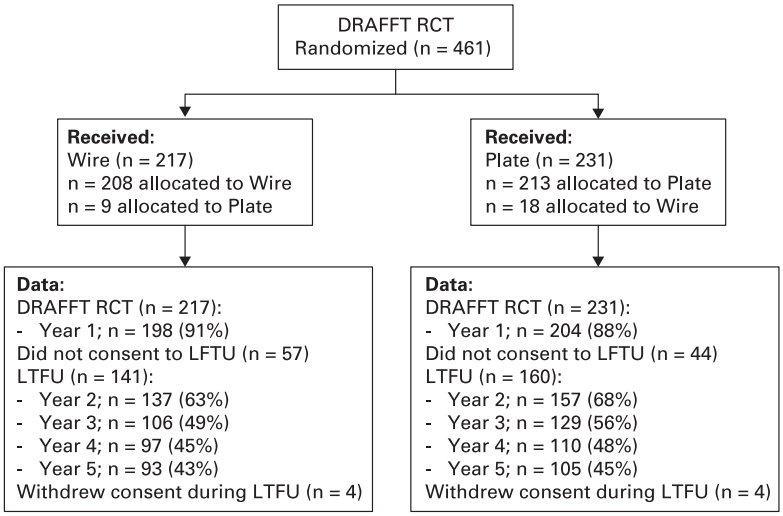


Fig. 1

Overall flow of participants and follow-up for the long-term follow-up (LTFU) study. DRAFFT, Distal Radius Acute Fracture Fixation Trial; RCT, randomized controlled trial.

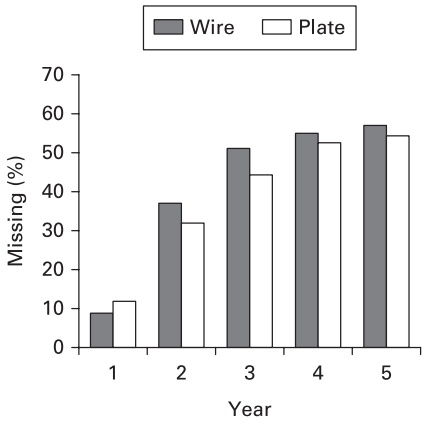


Fig. 2a

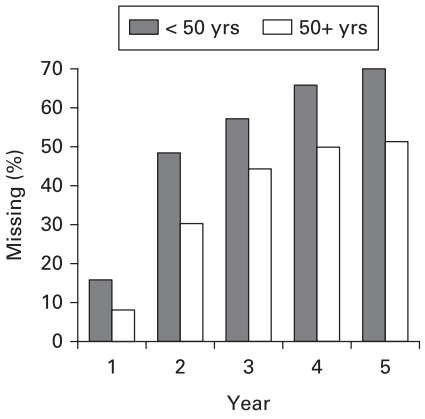
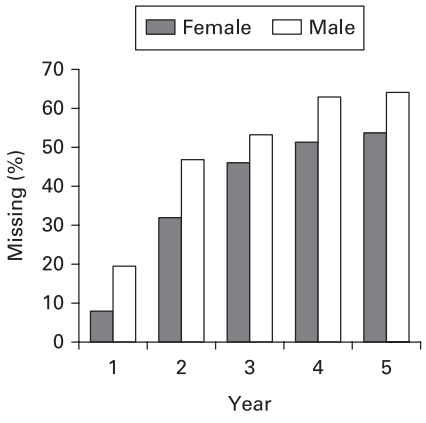


Fig. 2b



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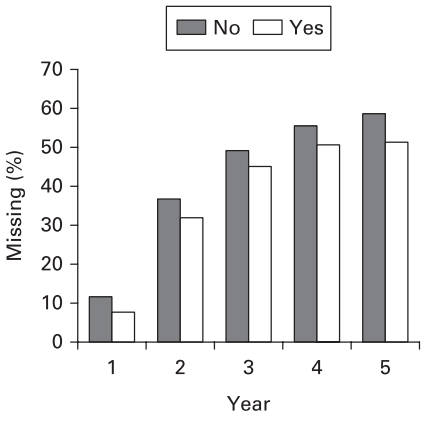

Fig. 2d

Percentage of the missing data for long-term follow-up (LTFU) study population by year of follow-up for: a) treatment; b) age; c) sex; and d) intra-articular extension. Population size from years one to five was 415, 300, 241, 213, and 203, respectively.

long-term follow-up phase of the trial. At year two, 294 participants (66%) provided scores; by year five, 198 (44%) of the original cohort provided scores (Fig. 1).

Response rates declined significantly during the data collection period from year two to year five (Figure 2), and were lower for those participants under 50 years of age than for those over

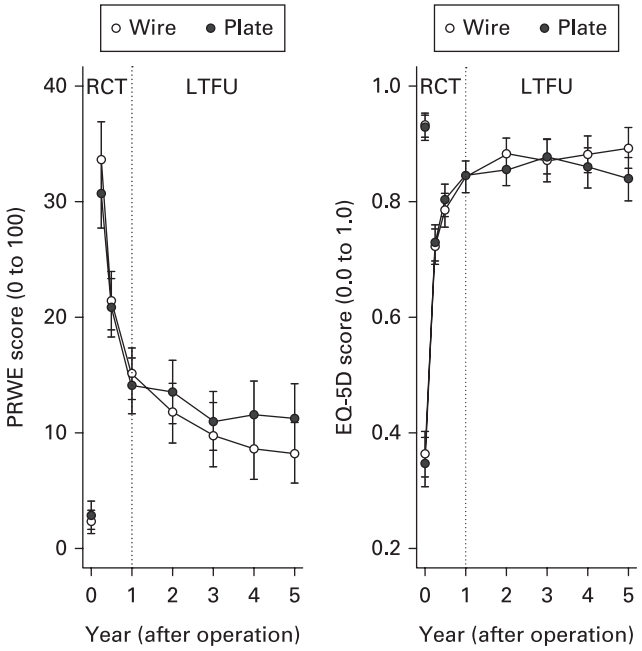

Fig. 3a

Fig. 3b

Temporal trends in mean (95% confidence interval (CI)) for a) patient-rated wrist evaluation (PRWE) scores, and b) EuroQol five-dimension three-level (EQ-5D) assessment scores during the randomized controlled trial (RCT) and long-term follow-up (LTFU) study.

Table II. Treatment differences on a yearly cross-sectional basis for PRWE and EQ-5D scores

Outcome/year	Wire (n = 217)		Plate (n = 231)		Raw difference (95% CI)	Adjusted difference (95% CI)	p-value*
	n	Mean (SD)	n	Mean (SD)			
PRWE							
1	198	15.1 (15.7)	204	14.1 (17.3)	1.04 (-2.20 to 4.29)	1.06 (-2.19 to 4.31)	0.521
2	137	11.7 (15.0)	157	13.6 (16.9)	-1.84 (-5.54 to 1.85)	-1.84 (-5.53 to 1.86)	0.328
3	106	9.9 (14.4)	129	11.1 (14.2)	-1.22 (-4.93 to 2.48)	-1.12 (-4.81 to 2.56)	0.549
4	97	8.7 (13.0)	110	11.6 (15.1)	-2.87 (-6.76 to 1.02)	-2.75 (-6.63 to 1.13)	0.164
5	93	8.3 (12.5)	105	11.3 (15.6)	-3.00 (-6.99 to 0.99)	-2.91 (-6.91 to 1.08)	0.152
EQ-5D							
1	191	0.84 (0.19)	195	0.84 (0.20)	0.00 (-0.04 to 0.04)	0.00 (-0.04 to 0.04)	0.999
2	135	0.88 (0.15)	155	0.86 (0.18)	0.03 (-0.01 to 0.07)	0.03 (-0.01 to 0.06)	0.185
3	105	0.87 (0.19)	129	0.88 (0.17)	-0.01 (-0.05 to 0.04)	-0.01 (-0.05 to 0.04)	0.769
4	96	0.88 (0.16)	110	0.86 (0.18)	0.02 (-0.02 to 0.07)	0.02 (-0.02 to 0.07)	0.339
5	93	0.89 (0.17)	105	0.84 (0.20)	0.05 (0.00 to 0.10)	0.05 (0.00 to 0.10)	0.055

*p-value from regression analysis after adjusting for age group and intra-articular extension
PRWE, patient-rated wrist evaluation; EQ-5D, EuroQol EQ-5D; CI, confidence interval

50 years of age. However, there was no evidence that response rates were different between treatment groups.

Outcomes. Figure 3 shows the changes in PRWE and EQ-5D scores during the five-year follow-up study, and Table II shows means, differences, and unadjusted tests of treatment differences calculated on a cross-sectional basis.

There was no evidence to support differences between groups in the primary outcome measure of PRWE. There was no evidence of a difference in health-related quality of life, other than some weak evidence in favour of wire fixation at five years; this difference was of borderline statistical significance (p = 0.055) and the difference was below the level of clinical significance prespecified in the DRAFFT trial.

Longitudinal analysis of the PRWE scores showed that treatment (LRT p = 0.550), age group (LRT p = 0.856), and intra-articular extension (LRT p = 0.449) did not exert a significant effect on outcome. However, year of follow-up (LRT p < 0.001) and sex (LRT p = 0.009) were significant. That is, participant wrist function continued to improve during the follow-up period (PRWE scores became lower) and men had better wrist function than women. Participants with poor function in the first 12 months after their injury tended to improve more during long-term follow-up than those participants with initially better function.

Longitudinal analysis of the EQ-5D scores showed that treatment (LRT p = 0.470), year of follow-up (LRT p = 0.429), sex (LRT p = 0.067), and intra-articular extension (LRT; p = 0.930)

were not significant. However, age (LRT p = 0.023) was marginally significant, with health-related quality of life being lower in the over 50-year age group than in the under 50-year age group, although the model estimate of -0.05 (95% confidence interval -0.09 to -0.01) indicated that the difference was unlikely to be clinically important.

In terms of further surgery, only three participants reported having additional surgery in years two to five. In year two, one patient in the wire group reported having an ulna shortening osteotomy for restricted wrist movement. In the plate group, there was one late tendon rupture four years after the index fracture, and one other patient reported having further surgery to remove a retained suture following a previous repair of a tendon rupture that occurred in the first year after the fracture.

Discussion

This five-year follow-up study showed no evidence of a difference in wrist pain or function as indicated by the PRWE between patients randomized to K-wire fixation and those randomized to locking-plate fixation for a dorsally displaced fracture of the distal radius. Secondary analyses showed no evidence of a difference in health-related quality of life in years two, three, and four. There was weak evidence of a difference in quality of life at five years in favour of wire fixation, although the absolute difference was small and less than the prespecified clinically important difference in the DRAFFT trial. In general, patients recover well after this injury, with good wrist function and quality of life even after a wrist fracture that requires surgical fixation.

One of the concerns raised by clinicians when the DRAFFT trial was published was that patients may develop post-traumatic arthritis in the wrist joint, leading to reduced function in the longer term and further surgery, including extensive salvage operations such as wrist fusion. Although there is now strong evidence that radiological parameters do not correlate with functional outcome in the short term,[10] the worry was that problems related to arthritis may not manifest until after the 12-month follow-up period of the first trial report. Furthermore, since wire fixation has previously been associated with worse radiological outcomes than locking-plate fixation,[11] the rate of wrist arthritis and the need for salvage surgery may be greater in the group treated with wire fixation. This study, however, found that further surgery was very uncommon, with only three operations between years two and five, albeit with lower rates of follow-up as the study progressed.

Other findings of note were that PRWE scores declined during follow-up, meaning that function continued to improve from years one to five, albeit more slowly than in the first year after their injury. This is reassuring information and should be helpful to clinicians when counselling patients with regard to the longer-term outcome of their injury. Despite the continued improvement in wrist function, there was no significant change in health-related quality of life scores during the follow-up period.

The major limitation of this study is the loss to follow-up during the five years after participants agreed to take part in the DRAFFT trial. Other large-scale randomized trials in orthopaedic trauma have reported higher rates of follow-up, albeit in different populations of patients.[12,13] The sponsor of the study required that patients reconsent to take part in the longer-term follow-up of the trial. This, along with the fact that many patients had returned to near normal function at the end of the 12-month follow-up period, led to some patients declining to take part in the longer-term follow-up. This was particularly the case for younger patients; response rates were lower for those participants aged under 50 years than for those participants aged over 50 years. However, there was no evidence to support differences in response rates between treatment groups. Therefore, although the loss to follow-up does limit the external validity of the study, we can be reasonably confident when making comparisons between treatment groups.

In conclusion, and contrary to concerns raised after the DRAFFT trial, this study shows no evidence of a difference in wrist function or quality of life at five years for patients randomized to wire fixation *versus* locking-plate fixation for a dorsally displaced fracture of the distal radius. Patients may be reassured that their wrist function is likely to continue to improve in the five years following their injury.

Take home message

- Patients may be reassured that their wrist function is likely to continue to improve in the five years following their injury.
- Most patients can expect very good function with little pain from their wrist, albeit not quite back to their preinjury level.
- There is no evidence of a difference in outcome for patients treated with wire fixation *versus* locking plate fixation.

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N. R. Parsons: Responsible for concept and design, Acquired, analyzed, and interpreted the data, Wrote and revised the manuscript, Statistical analysis, Had full access to all of the data in the study, Took responsibility for the integrity of the data and the accuracy of the data analysis.

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Ethical approval for this study was given by the Coventry and Warwickshire NHS Research Ethics Committee on the 24 April 2010 under reference number 10/H1210/10.

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