

UK DRAFFT: a randomised controlled trial of percutaneous fixation with Kirschner wires versus volar locking-plate fixation in the treatment of adult patients with a dorsally displaced fracture of the distal radius

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Scientific summary

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Background

Fractures of the distal radius are extremely common injuries. In high-income countries, 6% of women will have sustained such a fracture by the age of 80 years and 9% by the age of 90 years. All age groups are affected; younger patients frequently sustain complicated, high-energy injuries involving the wrist joint but fractures of the distal radius are also common in older patients, who are more likely to sustain low-energy fractures, related to osteoporosis.

Fractures of the distal radius are treated non-operatively if the bone fragments can be held in anatomical alignment (reduction) by a plaster cast or orthotic. However, if this is not possible then surgical fixation is performed. This carries inherent risks for the patient and considerable cost implications; much of this cost is related to the choice of fixation.

The two most common forms of surgical fixation are percutaneous Kirschner-wire (K-wire) fixation and locking-plate fixation.

Kirschner-wire fixation is a long-standing technique in which smooth metal wires with a sharp point are passed across the fracture site through the skin. However, this technique is rapidly being superseded by locking-plate fixation, in which a plate is attached to the bone with fixed-angle screws. To date, studies comparing K-wire fixation and volar locking-plate fixation have indicated that locking plates provide improved radiological and/or functional outcomes.

In this multicentre randomised trial, the Distal Radius Acute Fracture Fixation Trial (DRAFFT), we compared K-wire fixation with locking-plate fixation for patients with a dorsally displaced fracture of the distal radius.

Methods

Patients

We enrolled patients from 18 centres in the UK.

Patients were aged ≥ 18 years with a dorsally displaced fracture of the distal radius within 3 cm of the radiocarpal joint. The other inclusion criteria were that the treating surgeon believed that the patient would benefit from surgical fixation of the fracture and that the injury was < 2 weeks old.

Patients were excluded if the fracture extended > 3 cm from the radiocarpal joint, if the fracture was open (with a Gustilo grading greater than 1), if the articular surface of the radiocarpal joint could not be reduced by indirect techniques (in some fractures, the joint surface is so badly disrupted that the surgeon will have to open up the fracture in order to restore the anatomy under direct vision), if there was a contra-indication to anaesthesia or if the patient was unable to complete questionnaires.

Measures

Patient characteristics and baseline (pre-injury) functional status were self-reported after consent to take part in the trial. The primary outcome measure was the validated Patient-Rated Wrist Evaluation® (PRWE) questionnaire. The secondary outcome measures were the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire score, the EuroQol – Five Dimensions (EQ-5D), complications related to the surgery and resource use. The primary and secondary measures were collected by postal questionnaire at baseline, 3, 6 and 12 months after surgery.

Study treatments

All of the hospitals and the surgeons involved in the trial were familiar with both fixation techniques. Although the basic principles of percutaneous K-wire fixation and locking-plate fixation are inherent in the design of the implants, the details of the surgery were left to the discretion of the surgeon to ensure that the results of the trial could be generalised to as wide a group of patients as possible.

Kirschner-wire fixation: the wires are passed through the skin over the dorsal aspect of the distal radius and into the bone in order to hold the fracture in the correct (anatomical) position. The size and number of wires, the insertion technique and the configuration of wires were decided by the surgeon. A plaster cast was applied to supplement the wire fixation as per usual surgical practice.

Locking-plate fixation: the locking plate is applied through an incision over the volar (palm) aspect of the wrist. The details of the surgical approach, the type of plate, and the number and configuration of screws were decided by the surgeon. The only stipulation was that the screws in the distal portion of the bone were 'fixed-angle', that is screwed into the plate, but this is standard technique for the use of these plates. Some surgeons use a temporary plaster cast after the procedure, but the fixed-angle stability provided by the locking plate is generally sufficient to allow early controlled range-of-movement exercises.

Rehabilitation: all patients received the same standardised written physiotherapy advice. Those patients in the K-wire group were encouraged to perform range-of-movement exercises at the wrist as soon as their plaster cast was removed. Those patients in the locking-plate group were encouraged to begin the exercises immediately if they did not have a plaster cast, or as soon as the cast was removed.

Randomisation

Following informed consent, the method of fixation was allocated using a secure, centralised telephone randomisation service. The randomisation sequence was generated and administered at an independent clinical trials unit (York, UK) to ensure that allocation was concealed. Randomisation was on a 1 : 1 basis, stratified by centre, intra-articular extension of the fracture and age of the patient.

Stratification by centre ensured that any clustering effect related to the centre itself was equally distributed in the trial arms. Stratification on the basis of intra-articular extension of the fracture (specifically involvement of the articular surface of the radiocarpal joint) eliminated a major potential confounder, since disruption of this articular surface may predispose to secondary osteoarthritis of the wrist. Stratification on the basis of age (\geq or $<$ 50 years) was used to balance, between the groups, the number of younger patients with normal bone quality sustaining high-energy fractures and older patients with low-energy (fragility) fractures related to osteoporosis. Age was, therefore, used as a surrogate for bone density.

Blinding

The operating surgeon could not be blind in the trial, and, as the K-wires protrude on the back of the wrist and the locking plate requires an incision, neither could the patient. However, all staff involved in checking, entering and analysing questionnaire responses were blinded.

Statistical analysis

The PRWE questionnaire score at 12 months was the primary outcome measure. A six-point difference in the PRWE questionnaire score equates to a standardised effect size of 0.3, for an assumed standard deviation of 20 points. At the individual level, a change in the PRWE questionnaire score of 6 points reflects the difference between turning a doorknob with mild pain and no pain.

A six-point difference between groups at the 5% level with 80% power required 175 patients in each group, that is 350 patients in total. With an allowance for a conservative 10% loss to follow-up,

we planned to recruit 390 patients. However, as a result of faster than expected recruitment to the trial, and with the permission of the Review Board, we were able to recruit 461 patients.

Differences between treatment groups were assessed on an intention-to-treat basis, using a normal approximation for the PRWE questionnaire score, at 3 months, 6 months and 12 months. Pre-planned subgroup analyses of the PRWE questionnaire scores were based on the stratification by intra-articular extension and age \geq or $<$ 50 years. A secondary analysis based on the type of fixation provided (per-treatment analysis) was also pre-planned. Tests were two-sided and considered to provide evidence for a significant difference if p -values were less than 0.05 (5% significance level).

The statistical analysis plan was agreed with the independent Data Management Committee at the start of the study.

Health economic analysis

The economic evaluation was designed to estimate costs of both treatments, and the incremental cost-effectiveness of distal radial fractures treated by locking-plate fixation versus K-wire fixation. The primary outcome for the economic evaluation was the number of quality-adjusted life-years (QALYs) gained, using the EQ-5D. Primary, secondary, community and social care service usage, medications and aid usage were retrospectively collected using a short patient questionnaire administered at 3, 6 and 12 months post surgery. Patients also reported out-of-pocket expenditure related to their treatment, lost productivity and support from personal services.

We compared costs and QALYs, calculated incremental cost-effectiveness ratios (ICERs) and examined the probability of cost-effectiveness by constructing cost-effectiveness acceptability curves.

Results

Patients

During the recruitment period, 178 potentially eligible patients were unwilling to take part. From January 2011 to the end of July 2012, 461 patients were randomised. Of the 230 patients assigned to K-wires, 208 (90%) had the allocated treatment and, of the 231 patients assigned to locking-plate fixation, 213 (92%) were treated as allocated. The baseline characteristics of the two groups were very similar.

Treatments were undertaken by 244 different surgeons; the median number of operations per surgeon was 1 (interquartile range 1–2). Of note, the surgical time for the K-wire fixation was less than for a locking plate with a mean difference of 33 minutes [95% confidence interval (CI) 28 to 37, $p < 0.001$ (t -test)].

Also of note was the greater rate of perioperative antibiotic use in the locking-plate group than the K-wire group; 83% versus 71% of study participants required antibiotics (estimated odds ratio 3.5, 95% CI 2.0 to 6.5; Fisher's exact test, $p < 0.001$).

Primary outcome

Wrist scores improved in the postoperative period in both groups, although function at 12 months was still approximately 15% worse than before the injury.

There was no evidence of a statistically significant difference in PRWE questionnaire scores between the treatment groups at any time point. The adjusted estimate of the treatment effect for the PRWE questionnaire score at 12 months after surgery was -1.3 [95% CI -4.5 to 1.8 ; $p = 0.398$; F -test for treatment factor from model analysis of variance (ANOVA)].

Patients ≥ 50 years of age formed a sizeable subgroup (74%, 341 out of 461); therefore, this was identified a priori as being of particular interest. The adjusted estimate of the treatment effect in this age group was -2.2 (95% CI -5.8 to 1.4) in favour of the plate group; the p -value of 0.338 (F -test from ANOVA) indicates that there is no evidence of a significant interaction term between age group and treatment.

Secondary analyses

There was evidence for a marginally significant ($p = 0.051$) treatment effect in favour of the locking-plate group for the DASH questionnaire score at 12 months only, although the effect size was small (-3.2 ; 95% CI -6.5 to 0.0). EQ-5D did not show any significant differences between treatment groups.

The per-treatment analysis (according to the fixation performed) for PRWE questionnaire scores gave an adjusted treatment effect estimate of -1.0 (95% CI -4.2 to 2.2 ; $p = 0.530$).

There are 46 study participants with missing primary outcome data at the 12-month study end point; the data are 90.0% (415/461) complete. The inferences based on the complete data, after imputation, were not markedly different from those reported from the complete case analysis.

There was no evidence to suggest that rates of any complications differed between study groups, based on comparing counts in groups. As expected, more patients were given a cast after the operation in the K-wire group, and subsequently that group had a greater number of plaster changes.

Resource use

The mean cost associated with the surgical fixation of the fracture was higher in the locking-plate group: £818 for the locking-plate fixation and consumables versus £54 for the K-wires and consumables. Total NHS costs were significantly higher, £903, in the locking-plate group and consumables (95% CI 393 to 1414; $p < 0.001$) and societal costs were marginally higher, £45, in the K-wires and consumables group. The incremental cost-effectiveness ratios of volar locking-plate fixation compared with K-wire fixation were always more than £30,000 per QALY.

Probabilities of the cost-effectiveness of volar locking plates at a willingness to pay £20,000 per QALY are near nil in both perspectives for all patients. The results indicate that effectiveness, as measured in QALYs, differs with patients' age group. In the subgroup of older patients, cost-effectiveness peaks at 46% in the NHS perspective and 48% in the societal perspective. However, in patients aged < 50 years, K-wire fixation always dominates (more gain at cheaper cost).

Discussion

Despite the expense associated with locking-plate fixation of distal radius fractures, millions of patients have been treated with locking plates around the world. In this trial, we have shown that locking plates offer no advantage over the older and cheaper method of K-wire fixation.

As the CIs exclude the minimum clinically important difference for the PRWE questionnaire scores, we conclude that any difference in functional scores between treatment groups is unlikely to be important to patients. Furthermore, secondary clinical outcomes show that there is no difference between the groups in terms of health-related quality of life or the risk of complications. There was a borderline significant difference in the DASH questionnaire score at one time point in favour of the locking plate, but this was well below the minimum clinically important difference.

Kirschner-wire fixation requires significantly less surgical operating time than locking-plate fixation and a reduced use of peri-operative antibiotics. The health economic evaluation suggests that locking-plate fixation is unlikely to be cost-effective overall and that K-wire fixation is preferred.

This large multicentre trial contradicts both the increasing trend towards the use of locking plates in the treatment of distal radius fractures and the findings of previous trials, which indicated that locking plates provide improved functional outcomes compared with K-wire fixation. The previous trials were smaller single-centre studies.

The main limitation of the trial is that it was not possible to blind either the surgeons or the patients to the study treatments. However, it could be argued that this is a positive feature in a pragmatic trial, as patients would know about their proposed treatment before surgery during routine care. It should be noted that this study excluded patients whose fracture could not be reduced by indirect means, i.e. the results should not be generalised to the minority of patients whose fracture requires that the surgeon expose the surface of the radiocarpal joint in order to restore the congruity of the wrist joint.

Compliance with the trial was good, with over 90% of patients receiving their allocated treatment. Some patients did cross over to have a different form of fixation, but an analysis by treatment given did not alter the result. The long-term outcome of patients with a fracture of the distal radius is not known. Our data suggest that patients' wrist function and quality of life improve over the 12 months following their surgery but do not return to pre-injury levels. The patients in this trial will be followed up annually to determine the prevalence of late complications such as arthritis.

In conclusion, and in contrast to both the trend in surgical practice and the previous literature, this trial found no difference in PRWE questionnaire scores in the 12 months following K-wire fixation versus volar locking-plate fixation. The health economic evaluation showed that the volar locking plate is not cost-effective.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN31379280.

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