

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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***National Institute for
Health Research***

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Abstract

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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Background: In high-income countries, 6% of all women will have sustained a fracture of the wrist (distal radius) by the age of 80 years and 9% by the age of 90 years. Advances in orthopaedic surgery have improved the outcome for patients: many such fractures can be treated in a plaster cast alone, but others require surgical fixation to hold the bone in place while they heal. The existing evidence suggests that modern locking-plate fixation provides improved functional outcomes, but costs more than traditional wire fixation.

Methods: In this multicentre trial, we randomly assigned 461 adult patients having surgery for an acute dorsally displaced fracture of the distal radius to either percutaneous Kirschner-wire fixation or locking-plate fixation. The primary outcome measure was the Patient-Rated Wrist Evaluation® (PRWE) questionnaire at 12 months after the fracture. In this surgical trial, neither the patients nor the surgeons could be blind to the intervention. We also collected information on complications and combined costs and quality-adjusted life-years (QALYs) to assess cost-effectiveness.

Results: The baseline characteristics of the two groups were well balanced and over 90% of patients completed follow-up. Both groups of patients recovered wrist function by 12 months. There was no clinically relevant difference in the PRWE questionnaire score at 3 months, 6 months or 12 months [difference at 12 months: -1.3; 95% confidence interval (CI) -4.5 to 1.8; $p = 0.398$]. There was no difference in the number of complications in each group and small differences in QALY gains (0.008; 95% CI -0.001 to 0.018); Kirschner-wire fixation represents a cost-saving intervention (-£727; 95% CI -£588 to -£865), particularly in younger patients.

Conclusions: Contrary to the existing literature, and against the increasing use of locking-plate fixation, this trial shows that there is no difference between Kirschner wires and volar locking plates for patients with dorsally displaced fractures of the distal radius. A Kirschner-wire fixation is less expensive and quicker to perform.

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BOX 1 Participating centres

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List of abbreviations

ANOVA	analysis of variance	MCID	minimal clinically important difference
BNF	<i>British National Formulary</i>		
CEAC	cost-effectiveness acceptability curve	NICE	National Institute for Health and Care Excellence
CI	confidence interval	NMB	net monetary benefit
CTU	Clinical Trials Unit	PRWE	Patient-Rated Wrist Evaluation® questionnaire
DASH	Disabilities of Arm, Shoulder and Hand questionnaire	PSSRU	Personal Social Services Research Unit
DMC	Data Monitoring Committee	QALY	quality-adjusted life-year
DRAFFT	Distal Radius Acute Fracture Fixation Trial	REC	Research Ethics Committee
EQ-5D	EuroQol – Five Dimensions	SAE	serious adverse event
GP	general practitioner	SD	standard deviation
ICC	intraclass correlation coefficient	TMG	Trial Management Group
ICER	incremental cost-effectiveness ratio	TSC	Trial Steering Committee
IQR	interquartile range	UHCW	University Hospital Coventry and Warwickshire
K-wire	Kirschner wire	WTP	willingness to pay
LOCF	last observation carried forward		
MCAR	missing completely at random		

Plain English summary

In high-income countries, 6% of all women will have sustained a fracture of the wrist (distal radius) by the age of 80 years and 9% by the age of 90 years. Advances in orthopaedic surgery have improved the outcome for patients; many such fractures can be treated in a plaster cast alone, but others require surgical fixation to hold the bone in place while they heal. The existing evidence suggests that a modern 'locking-plate' fixation provides improved wrist function but costs more than traditional 'wire' fixation.

In this study, we randomly assigned 461 adult patients having surgery for a fracture of the distal radius to either Kirschner-wire (K-wire) fixation or locking-plate fixation. The patients reported their own outcome in the 12 months after their fracture, using the Patient-Rated Wrist Evaluation. We also collected information on complications and costs.

Over 90% of the patients who took part completed the study. Both groups of patients recovered wrist function by 12 months, although their wrists were not quite back to normal. There was no difference in their wrist function at 3 months, 6 months or 12 months. Nor was there a difference in the number of complications in each group. K-wire fixation is 'cost saving', particularly in younger patients.

Contrary to the existing literature, and against the increasing use of locking-plate fixation, this study shows that there is no difference between K-wires and locking plates for patients with fractures of the distal radius. K-wire fixation is less expensive and quicker to perform.

Scientific summary

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.

Funding

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Chapter 1 Introduction

Background

Fractures of the distal radius are extremely common injuries. In the Western world, 6% of women will have sustained such a fracture by the age of 80 years and 9% by the age of 90 years.¹ As the population continues to age, these figures are likely to increase further. The optimal management of fractures of the distal radius in adults remains controversial. There is a bimodal distribution in terms of age. Younger patients frequently sustain complicated high-energy injuries involving the wrist joint. However, fractures of the distal radius are also common in older patients, who are more likely to sustain low-energy fractures, often related to osteoporosis.² This study is designed to address both groups of patients, as the key management issues pertain to all patients with a fracture of the distal radius.

In general, fractures of the distal radius are treated non-operatively if the bone fragments are not displaced or the fragments can be held in a good anatomical alignment (reduction) by a plaster cast or orthotic. However, if this is not possible then operative fixation is required. This carries inherent risks for the patient and considerable cost implications for the NHS; much of this cost is related to the choice of fixation.³

There are several operative options but the two most common in the UK are percutaneous Kirschner-wire (K-wire) fixation and volar locking-plate fixation using fixed-angle screws (locking plates). Each surgical method has its own advantages and disadvantages.

Kirschner-wire fixation is a long-standing and widely practised technique. During this procedure, smooth metal wires with a sharp point are passed across the fracture site through the skin. This is a relatively simple, quick and minimally invasive technique, which is cheap and requires limited operative hardware. However, as the fixation is not 'rigid' (the wires are inherently flexible) the wrist has to be immobilised in plaster cast; normally for 6 weeks or until the wires are removed. There is a risk of infection where the wires enter the skin. There is also a risk that the fracture will 'collapse' when the wires are removed, leading to deformity and loss of function.⁴

Locking-plate fixation, in the distal radius and for other fractures, has been facilitated by recent advances in implant technology, which allow the screws to be 'locked' into the plate. This produces a 'fixed-angle' bone-plate construct, (previously, plate-and-screw constructs relied on friction alone to maintain their position on the bone). Although originally designed for use in osteoporotic bone specifically, the theoretical advantages of the locking plates may equally be applied to high-energy (often multifragmentary) fractures in younger patients. The technique has become increasingly popular in the UK and across the developed world over the last 5 years. The procedure requires an incision over the volar (palm) side of the wrist. The plate and screws are then applied to the bone fragments under direct vision. This produces a rigid construct,⁵ and, therefore, the patients can be permitted to mobilise their wrist more quickly, potentially reducing future stiffness. As the plate and screws can remain inside the patient permanently, the risk of later collapse of the fracture is also smaller. However, this technique takes longer than a K-wire fixation and there is a greater risk of serious intraoperative complications such as injury to a nerve or blood vessel.⁵ There is also a risk of flexor and/or extensor tendon irritation and rupture.⁶ The locking-plate hardware itself is specialised and considerably more expensive; a cost-analysis of the total cost of each intervention (Plant *et al.*, University Hospital Coventry and Warwickshire NHS Trust, 2009, unpublished data) suggested that the use of a locking plate increased the cost of the operation itself (total operating department cost) threefold.

In 2003, Handoll and Madhok⁷ summarised the results of a series of Cochrane reviews of randomised controlled trials of the treatment of fractures of the distal radius and 'exposed the serious deficiency in the available evidence'. However, they were able to identify key areas for future research, including the area of 'when and what type of surgery is indicated'. An influential group of academic trauma surgeons (AO UK Research Committee chaired by Professor Keith Willett) recently identified our specific research question as a 'top priority' for urgent investigation.⁸

Relevance of project

The clinical management of any fracture depends on several factors including the severity of the fracture and the personal circumstances and comorbidity of the patient. These variables are generally out of the control of the treating surgeon. However, the type of operative intervention can be determined after the event. Although there will always be some variability in clinical practice, patients with a fracture of the distal radius may expect a reasonably consistent approach to the operative treatment of such a common fracture. However, for this particular injury there seems to be no consensus.² For fractures of the distal radius, perhaps more than any other fracture, the operative intervention varies enormously depending on the preference, training and experience of the treating surgeon and the policy, inventory and budget of the treating institution.

We recently performed a pilot study where the clinical details and radiological images of five patients with a displaced fracture of the distal radius were presented independently to 33 experienced trauma surgeons in the UK. The cases included younger patients with high-energy injuries and fragility fractures in older patients. The surgeons were asked to provide a treatment plan for each patient. There was < 50% agreement in the treatment regime for any individual patient. Across all of the cases, 44% of surgeons would use volar locking plates, 28% would use K-wire fixation, 7% would use volar non-locking plates, 5% would use external fixators and 15% would treat the patient with manipulation and a plaster cast alone.⁹

We intend to provide high-level evidence to inform the future management of adult patients with a displaced fracture of the distal radius by directly comparing the results of K-wire fixation and locking-plate fixation in a multicentre randomised controlled clinical trial.

Null hypothesis

There is no difference in the Patient-Rated Wrist Evaluation® (PRWE) questionnaire score 12 months post injury between adult patients with a dorsally displaced fracture of the distal radius treated with locking-plate fixation versus K-wire fixation.

Objectives

The primary objective is to quantify and draw inferences on observed differences in the PRWE questionnaire score (a validated assessment of wrist function) between the trial treatment groups at 12 months post injury.

The secondary objectives are to quantify and draw inferences on observed differences in the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire score (a validated assessment of general upper-limb function) between the trial treatment groups at 12 months post injury; to determine the complication rate of K-wire fixation versus locking-plate fixation at 12 months post injury; and to investigate, using appropriate statistical and economic analysis methods, the resource use, and comparative cost-effectiveness, of K-wire fixation versus locking-plate fixation.

Chapter 2 Methods

Trial design

This was a multicentre, stratified (by centre, intra-articular extension of the fracture and age of the patient, with balanced randomisation 1 : 1) double-blind, controlled trial.

Participants

Inclusion criteria

Patients were eligible for this study if:

- They sustained a dorsally displaced fracture of the distal radius, which was defined as a fracture within 3 cm of the radiocarpal joint.
- The treating consultant surgeon believed that they would benefit from operative fixation of the fracture.
- They were over the age of 18 years and able to give informed consent.
- The injury was < 2 weeks old.

Exclusion criteria

Patients were excluded from participation in this study if:

- The fracture extended > 3 cm from radiocarpal joint.
- The fracture was open with a Gustilo grading greater than 1.¹⁰
- The articular surface of the fracture could not be reduced by indirect techniques. (In a small number of 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.)
- There were contraindications to anaesthetic.
- There was evidence that the patient would be unable to adhere to trial procedures or complete questionnaires, such as cognitive impairment or intravenous drug abuse.

Patients who sustained other injuries, which could potentially affect the primary outcome measure at 1 year post injury, for example disruption of the carpal ligaments, were documented but included in the analysis.

Screening and recruitment

Patients were recruited from the emergency departments and fracture clinics at the trial centres. Any patient with a fracture of the distal radius who, in the opinion of the treating surgeon, required an operative intervention was referred to the local research associate for screening. The research associate then presented the eligible patient with the participant information sheet. Patients were given the opportunity to discuss any issues related to the trial with the research associate, as well as with members of their family and friends.

Consent

Informed consent was obtained by the local research associate. In general, patients who were admitted with a fracture of the distal radius had their surgery on the following day, so there was sufficient time for the patients to consider taking part in the trial. Any new information that arose during the trial that affected participants' willingness to take part was reviewed by the Trial Steering Committee (TSC); if necessary this was communicated to all participants by the trial co-ordinator. A revised consent form was completed if necessary.

Settings and locations

The trial was run in 18 trauma centres across the UK (Box 1).

Sample size

We performed an audit of the patients who had an operative fixation of their distal radius fracture at the University Hospital Coventry and Warwickshire (UHCW) over a 4-month period in 2007.¹¹ This revealed that 32 patients had either a K-wire fixation or a locking-plate fixation at our hospital during this period. Therefore, we anticipated that there would be 90–100 eligible patients per year. As each of the recruiting centres served a similar catchment area (c. 500,000 patients) we expected that there would be approximately 900–1000 eligible patients within the trial centres each year. All of the centres chosen to take part in this study regularly performed both locking-plate fixation and K-wire fixation for patients with a fracture of the distal radius.

In previous trials performed at the lead centre, recruitment rates of between 70% and 90% were achieved for trials comparing different surgical treatments (both elective and trauma procedures). At a conservative estimate of 35–40% recruitment for a multicentre study, we were, therefore, confident of achieving the recruitment target of 390 patients in 12–18 months.

BOX 1 Participating centres

Centre

1. Addenbrooke's Hospital.
2. Frenchay Hospital.
3. Ipswich Hospital.
4. James Cook University Hospital.
5. John Radcliffe Hospital.
6. Leicester General Hospital.
7. North Tyneside General Hospital.
8. Northampton General Hospital.
9. Peterborough City Hospital.
10. Poole Hospital.
11. Royal Blackburn Hospital.
12. Royal Victoria Infirmary.
13. St Thomas' Hospital.
14. University Hospital Coventry & Warwickshire.
15. University Hospital North Staffordshire.
16. University Hospital of North Tees.
17. Wansbeck General Hospital.
18. Wexham Park Hospital.

Randomisation

Those patients who consented to take part in the trial had their method of fixation allocated using a secure, centralised telephone randomisation service. The allocated treatment was then reported back to the research associate, who informed the patient and the treating surgeon. The surgeon then arranged the allocated surgery on the next available trauma operating list, as per standard practice at that institution. This ensured the integrity of the randomisation process.

Sequence generation

Randomisation was on a 1 : 1 basis, stratified by centre, intra-articular extension of the fracture and age of the patient (above or below 50 years).

Stratification by centre helped to ensure that any clustering effect related to the centre itself was equally distributed in the trial arms. The catchment area (the local population served by the hospital) was similar for all of the hospitals (c. 500,000), each hospital being a major orthopaedic unit dealing with these fractures on a daily basis. While it is possible that the surgeons at one centre may be more expert in one or other treatment than those at another centre, all of the recruiting hospitals were chosen on the basis that both techniques are currently routinely available at the centre, that is theatre staff and surgeons were already equally familiar with both forms of fixation. This could not eliminate the surgeon-specific effect of an individual at any one centre.¹² However, as the fixation of a fracture of the distal radius is a common procedure performed on routine trauma operating lists, many surgeons would be involved in the management of this group of patients: between 10 and 30 surgeons at each centre, including both consultants and trainees. Therefore, we expected that each individual surgeon would operate on only two or three patients enrolled in the trial, greatly reducing the risk of a surgeon-specific effect on the outcome in any one centre.

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.¹³ Recent evidence¹⁴ suggests that other associated features of fractures of the distal radius which commonly appear in the classification systems, such as involvement of the ulna styloid process and distal radio-ulnar joint involvement, do not actually affect the functional outcome of the injury. Therefore, we did not include any other variables in the stratification of the randomisation sequence.

Stratification on the basis of age was used to discriminate between younger patients with normal bone quality sustaining high-energy fractures and older patients with low-energy (fragility) fractures related to osteoporosis. Empirically, both of these groups of patients could benefit from the fixed-angle stability provided by locking-plate fixation. However, the stratification would help to identify any effect related to the quality of the patient's bone. The use of dual-energy X-ray absorptiometry (DEXA) is widely regarded as the gold standard for the assessment of bone density. However, such an investigation may be expensive and not routinely available at all centres. Therefore, we used age as a surrogate for bone density. In a large study in Norway involving 7600 participants, it was demonstrated that forearm bone mineral density remains stable up until the age of 50 years. After the age of 50 years, bone mineral density in males decreased steadily, while in females there was an initial decline between the ages of 50 and 65, with a further decline in the age groups thereafter.¹⁵ A recent study by Court-Brown and Caesar¹⁶ assessed over 1000 patients with a fracture of the distal radius. This study confirmed that there is a clear bimodal distribution for this type of fracture according to the age of the patient. The crossover of the two peaks of incidence was around 50 years of age. These studies provide strong evidence that patients over the age of 50 years become increasingly vulnerable to fragility fractures of the distal radius. Therefore, we chose the age of 50 years as the cut-off for this trial. Furthermore, the study by Court-Brown and Caesar¹⁶ demonstrated that in the UK approximately 60% of patients sustaining a fracture of the distal radius are over 50 years, while 40% are younger than 50 years. The number of patients above and below this stratification age would, therefore, be similar (see *Statistical analysis*).

Blinding

In this surgical trial, the patients could not be blinded to their treatment. The treating surgeons were, of course, not blind to the treatment, but took no part in the postoperative assessment of the patients. The statistical analyses were not performed blind.

Postrandomisation withdrawals

Participants could withdraw from the trial at any time without prejudice. If patients decided to have the treatment to which they were not randomised, they were followed up wherever possible and data collected as per the protocol until the end of the trial. The primary analysis was on an intention-to-treat basis with a secondary per-protocol analysis.

Interventions

All of the hospitals involved in this trial used both of the methods of fixation at the time of the trial and all of the surgeons involved were familiar with both techniques. Operative fixation of fractures of the distal radius usually took place under a general anaesthetic, but this decision was made by the attending anaesthetist. Patients undergoing surgical fixation for a fracture of the distal radius are placed in a supine (lying on their back) position with the affected arm on an 'arm-board' extension to the operating table, but the exact details of the positioning of the patient were left to the discretion of the treating surgeon. A copy of the 'operating record' formed part of the trial data set.

Each patient underwent the allocated surgery according to the preferred technique of the operating surgeon. Although the basic principles of percutaneous K-wire fixation and locking-plate fixation are inherent in the technique (see *Kirschner-wire fixation* and *Volar locking plate*), there are several different implant systems and several different options for the positioning of wires and screws. Similarly, each surgeon made minor modifications to their surgical technique according to preference and the specific pattern of each fracture. In this trial, the details of the surgery were left entirely 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.

Although all of the surgeons in the trial were familiar with both techniques, it is possible that an individual surgeon may have had more experience with one technique than the other. We expect that the proficiency of an individual surgeon to perform the procedure may change over time, as the surgeon gains experience and expertise. The term 'learning curve' is often used to describe this process. It was important to monitor the learning curve for all surgeons throughout the trial. The operating time recorded on the operative record for each surgery was used as a proxy to measure the task efficiency of the surgeons (quality assurance of the clinical process), and the number of complications (e.g. infections) at 6 weeks after surgery was also recorded as a patient-based outcome. Given the number of centres and surgeons taking part in this trial, no individual surgeon was likely to perform more than a small number of the procedures. However, where data were available for individual surgeons, temporal variations in operation times and complications at 1 week were modelled for each surgeon using a power curve,¹² for the trend with appropriate adjustment for confounding factors such as the age of the patients. In addition, as this study involved multiple surgeons, we expected that a more complex hierarchical model¹² that fully accounted for the structure of the data might prove to be useful; therefore, we expected fitting models of this class in addition to the simpler models. Results from the learning curve analysis for each surgeon would inform inferences regarding overall treatment differences and if necessary guide recommendations for implementation and training.

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 left entirely to the discretion of the surgeon. A plaster cast

was applied at the end of the procedure to supplement the wire fixation as per standard surgical practice. This cast holds the wrist still and is left on until the wires are removed at the 6-week follow-up appointment.

Volar locking plate

The locking plate is applied through an incision over the volar (palm) aspect of the wrist. Again, the details of the surgical approach, the type of plate, and the number and configuration of screws were left to the discretion of the surgeon. 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. The type of proximal screw was left to the discretion of the surgeon; these may be locking or non-locking screws, as the bone in this area provides a much better purchase for the screws. Some surgeons used a temporary plaster cast to hold the patients' wrist still but the fixed-angle stability provided by the locking plate was generally sufficient to allow early controlled range-of-movement exercises. The use of a cast or otherwise was again left to the discretion of the surgeon as per usual practice.

Radiographic evaluation

Patients were evaluated radiographically at presentation, and then at 6 weeks and 12 months post injury. The degree of palmar tilt, the ulnar variance and the presence of metaphyseal comminution were determined from the calibrated digital images of the posteroanterior and lateral radiographs using the OsiriX DICOM (Digital Imaging and Communications in Medicine) viewer (www.osirix-viewer.com).

The palmar tilt was measured as the angle between lines drawn perpendicular to the long axis and along the distal joint surface of the radius as described by Goldfarb *et al.*¹⁷ and Mann *et al.*¹⁸ (Figure 1). Dorsal angulation was denoted by a positive value and volar angulation by a negative value.¹⁹



FIGURE 1 Ulnar variance (the distance between the radial and ulnar articular surfaces).

The ulnar variance was determined using the method of perpendiculars described by Steyers and Blair²⁰ Lines were drawn along the distal ulnar aspect of the radius and the distal cortical rim of the ulnar parallel to the perpendicular of the long axis of the radius²⁰⁻²² (*Figure 2*). The distance between these lines measures the ulnar variance.²⁰

Rehabilitation

We ensured that all patients randomised into the two groups received standardised written physiotherapy advice detailing the exercises they needed to perform for rehabilitation following their injury. All of the patients in both groups were advised to move their shoulder, elbow and finger joints fully within the limits of their comfort. 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 at the 6-week follow-up appointment. Those patients in the locking-plate group could begin the exercises immediately if they did not have a plaster cast or as soon as the cast was removed. In this pragmatic trial, any other rehabilitation input beyond the written information sheet (including a formal referral to physiotherapy) was left to the discretion of the treating surgeon. However, a record of any additional rehabilitation input (type of input and number of additional appointments) together with a record of any other investigations/interventions was requested as part of the 3-month, 6-month and 12-month postal follow-ups and this formed part of the trial data set.

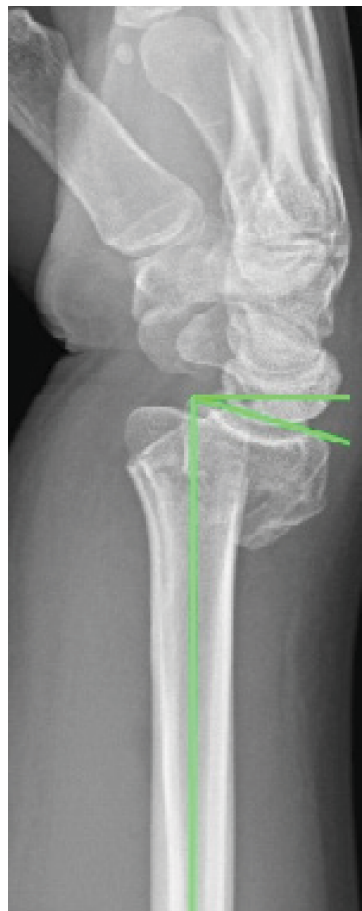


FIGURE 2 Palmar tilt (the angle between the articular surface of the radius and the perpendicular of the long axis of the radius).

Outcomes

The primary outcome measure for this study was the PRWE questionnaire score.²³ The PRWE is a validated questionnaire which is self-reported (filled out by the patient). It consists of 15 items specifically related to the function of the wrist. These data were collected at baseline and 3, 6 and 12 months postoperatively. The PRWE questionnaire score is the most sensitive outcome measure for patients sustaining this specific injury.²⁴

The secondary outcome measures in this trial were:

- DASH questionnaire score: the DASH outcome measure is a 30-item self-report questionnaire designed to provide a more general measure of physical function and symptoms in people with musculoskeletal disorders of the upper limb.²⁵
- EuroQol – Five Dimensions (EQ-5D): the EQ-5D is a validated, generic, quality of life questionnaire consisting of five domains related to daily activities with a three-level answer possibility. The combination of answers leads to a health profile of five digits that can then be converted into a utility that represents the overall quality of life of the patient.²⁶

Complications: all complications were recorded.

Resource use was monitored for the economic analysis. Patients retrospectively reported use of primary, secondary and community health-care use, medications and aids/instruments as well as social care, informal care, out-of-pocket expenses and lost productivity via a short questionnaire which was administered at 3, 6 and 12 months post surgery. Patient self-reported information on service use has been shown to be accurate in terms of the intensity of use of different services.^{27,28}

Follow-up measures

We used techniques common in long-term cohort studies to ensure minimum loss to follow-up, such as collection of multiple contact addresses and telephone numbers, mobile telephone numbers and e-mail addresses. Considerable efforts were made by the trial team to keep in touch with patients throughout the trial by means of newsletters, etc. Data were collected at baseline and at 6 weeks, 3 months, 6 months and 12 months post surgery (*Table 1*).

The PRWE²³ is a 15-item 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 disability. Scoring for all the questions is via a 10-point ordered categorical scale ranging from 'no pain' or 'no difficulty' (0) to 'worst possible pain' or

TABLE 1 Data collection

Time point	Data collection
Baseline	PRWE and DASH pre injury, EQ-5D pre injury and contemporary, radiographs
6 weeks	Complication records, radiographs and operative record
3 months	PRWE, DASH, EQ-5D, record of complications/rehabilitation or other interventions and economics questionnaire
6 months	PRWE, DASH, EQ-5D, record of complications/rehabilitation or other interventions and economics questionnaire
12 months	PRWE, DASH, EQ-5D, radiographs, record of complications/rehabilitation or other interventions and economics questionnaire

'unable to do' (10). Five questions relate to a patient's experience of pain and 10 relate to function and disability; the scores for the 10 function items are summed and divided by 2 and added to the scores of the five pain items to give a total score out of 100 (best score = 0 and worst score = 100).

We performed a retrospective pilot study²⁹ that obtained PRWE questionnaire scores for 84 patients (42 each receiving either a volar locking-plate fixation or a manipulation under anaesthetic and K-wire fixation) at 12 months after surgery. The mean PRWE questionnaire scores for the K-wire and locking-plate groups at 12 months were 33.2 and 27.5, respectively, with a pooled standard deviation (SD) of 19. The SD for the PRWE questionnaire score is similar to that reported for other studies of pain and disability after fracture of the distal radius,³⁰ which was in the range of 17–23 points.

We assumed a normal distribution for the PRWE questionnaire scores, which seemed appropriate given that our pilot study indicated that the 12-month group mean PRWE questionnaire score would be expected to be approximately 30 with a SD of 20. An appropriate sample size for detecting a six-point difference between groups at the 5% level with 80% power was, therefore, 175 patients in each group (power and sample size software, available at <http://medipe.psu.ac.th/episoft/pssamplesize/>). A six-point difference between groups equates to a standardised effect size of 0.3, for an assumed SD of 20 points. MacDermid *et al.*²⁴ found that the PRWE questionnaire is sensitive enough to detect subtle but clinically relevant changes in wrist function of this order of magnitude in patients sustaining a fracture of the distal radius, for example changes between 3 and 6 months (effect size 0.5). At the individual level, a change in the PRWE questionnaire score of 6 points reflects the difference between turning a doorknob or cutting a loaf of bread with mild pain versus no pain. We believed that such an improvement would be important to patients on an individual level and at population level and could lead to a change in clinical practice in the UK.

However, it is also helpful to consider the effect of choosing two alternative minimal clinically important difference (MCID) values of 5 and 7 points on the PRWE questionnaire score scale on the required sample size for 80% power at the 5% level (Table 2).

In summary, this study used the PRWE questionnaire score at 12 months after surgery as the primary outcome measure. The total number of patients required to obtain a power of 80% to detect a six-point difference between groups for the primary outcome measure was 350, that is 175 patients were required in each treatment group. In trials run previously at our institution comparing two different surgical techniques, we experienced a $\approx 5\%$ loss to follow-up. With an allowance for a conservative 10% loss to follow-up, we planned to recruit a minimum of 390 patients.

If recruitment proceeded at a faster rate than expected, for example if there were particularly adverse winter weather, which is known to be a primary causative factor for distal radius fractures, then there was the possibility of increasing the overall trial sample size within the defined recruitment period. Increasing the sample size would provide an increase in the power to detect a six-point difference between groups for the primary outcome measure above the set level of 80%. Recruitment was monitored and discussed at monthly Trial Management Group (TMG) meetings and, where appropriate, recruitment projections were undertaken to assess this possibility. See *Appendix 1* for details of recruitment projections and new sample sizes for increasing power.

TABLE 2 Effect of choosing alternative MCID values

MCID	Standardised effect size	Sample size per group
5	0.25	252
6	0.30	175
7	0.35	129

Adverse event management

Adverse events are defined as any untoward medical occurrence in a clinical trial subject and which do not necessarily have a causal relationship with the treatment. All adverse events were listed on the appropriate case report form for routine return to the Distal Radius Acute Fracture Fixation Trial (DRAFFT) central office.

Serious adverse events (SAEs) were defined as any untoward and unexpected medical occurrence that:

- results in death
- is life-threatening
- requires hospitalisation or prolongation of existing inpatients' hospitalisation
- results in persistent or significant disability or incapacity
- is a congenital anomaly or birth defect

or any other important medical condition which, although not included in the above, may require medical or surgical intervention to prevent one of the outcomes listed.

All SAEs were entered onto the serious adverse event reporting form and given to the DRAFFT central office within 24 hours of the investigator becoming aware of them. Once this was received, causality and expectedness were determined by the chief investigator. SAEs that were deemed to be unexpected and related to the trial were notified to the Research Ethics Committee (REC) within 15 days for a non-life-threatening event and within 7 days for a life-threatening event. All such events were reported to the TSC and Data Monitoring Committee (DMC) at their next meetings. SAEs that were expected as part of the surgical interventions, and that did not need to be reported to the main REC, were complications of anaesthesia or surgery (e.g. wound infection, delayed wound healing and thromboembolic events). All participants experiencing SAEs were followed up as per protocol until the end of the trial.

Risks and benefits

The risks associated with this study were predominantly the risks associated with the surgery: infection, bleeding and damage to the adjacent structures such as nerves, blood vessels and tendons. Participants in both groups underwent surgery and were potentially at risk from any/all of these complications. The application of the locking plates requires a surgical incision over the volar aspect of the wrist, which, empirically, may lead to a higher risk of injury to the adjacent structures. However, the evidence available to quantify this risk was limited.¹³ Late attrition and rupture of the extensor tendons have been associated with volar locking plates,³¹ but, equally, late collapse and secondary deformity have been associated with K-wire fixation.¹⁹ The risk of secondary (as a result of the injury) osteoarthritis of the wrist joint, particularly in those patients with intra-articular extensions of the fracture, is well recognised,¹³ but there were no data to suggest what that risk is or that the risk is greater in one group or another. We believed that the overall risk profile was similar for the two interventions but an assessment of the number of complications in each group was a secondary objective of this trial.

Statistical analysis

Analysis plan

The statistical analysis plan was agreed with the DMC at the start of the study. Any subsequent amendments to this initial plan are clearly stated and justified. Interim analyses were performed only where directed by the DMC. The trial registration details were updated soon after the start of the trial; this was not a change to the statistical analysis plan, but merely the inclusion of extra detail in the registration document, which was added at the suggestion of the DMC.

Software

The routine statistical analysis was carried out using R version 3.0.1 (The R Foundation for Statistical Computing, Vienna, Austria, www.r-project.org/). When any analyses were required, data were retrieved from the trial database by the trial statistician. The statistician imported data directly into the statistical package R for analysis and reporting. The version numbers of all software used, data files and all R scripts were made available to the DMC on request at any stage of the trial. Statistical results were reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines (www.consort-statement.org/).

Data validation

Prior to formal analysis, data were checked for outliers and missing values and validated using the defined score ranges for all outcome measures. Queries were reported to the trial co-ordinator and investigated. Standard statistical summaries (e.g. medians and ranges or means and variances, dependent on the distribution of the outcome) and graphical plots showing correlations were presented for the primary outcome measure and all secondary outcome measures. Baseline data were summarised to check comparability between treatment arms, and to highlight any characteristic differences between those individuals in the study, those ineligible for the study, and those eligible but withholding consent.

Missing data

As seemed likely at the outset, some data were not available because of the voluntary withdrawal of patients, lack of completion of individual data items or general loss to follow-up. Where possible, the reasons for data 'missingness' were ascertained and reported. Although missing data were not expected to be a problem for this study, the nature and pattern of the missingness were carefully considered – including, in particular, if data could be treated as missing completely at random (MCAR). If judged appropriate, we planned to impute missing data using the multiple imputation facilities (mice package) available in R. Any imputation methods used for scores and other derived variables were carefully considered and justified. We planned that if the degree of missingness was relatively low, as expected, the primary analysis would be based on complete cases only (complete case analysis), with analysis of imputed data sets used to assess the sensitivity of the analysis to the missing data. Reasons for ineligibility, non-compliance, withdrawal or other protocol violations would be stated and any patterns summarised. More formal analysis, for example using logistic regression with 'protocol violation' as a response, was also considered if appropriate and if it aided interpretation.

Interim analyses

Interim analyses were performed only where directed by the DMC. Any interim analyses would follow the same procedure as the final analyses.

Final statistical analyses

Null hypothesis

We considered that, while it may be of interest to the patient to know the time from surgery to returning to 'normal' function, our previous experience of collecting data related to this outcome has been very difficult. In addition, there is no clear formal definition of when a fracture can be considered to have fully healed and the patient is able to return to normal activity. This would be necessary if the time to this event were potentially to be used as the primary outcome measure in this trial. Therefore, for these reasons and as the practical difficulties and cost implications for a time-to-event analysis would be considerable, the main analysis investigated differences in the primary outcome measure, the PRWE questionnaire score at 12 months after surgery, between the two treatment groups (K-wire fixation and locking-plate fixation) on an intention-to-treat basis.

Null hypothesis: there is no difference in the PRWE questionnaire score 12 months post injury between adult patients with a dorsally displaced fracture of the distal radius treated with locking-plate fixation and those treated with K-wire fixation.

In addition to the analysis at 12 months post injury, early functional status was also assessed and reported at 3 months and 6 months.

Multilevel model

Differences between treatment groups were assessed, based on a normal approximation for the PRWE questionnaire score, at 12 months postoperatively, and at interim occasions. Tests were two-sided and considered to provide evidence for a significant difference if p -values are < 0.05 (5% significance level). Estimates of treatment effects were presented with 95% confidence intervals (CIs).

The stratified randomisation procedure should have ensured a balance in age, intra-articular extension and the recruiting centre between test treatments. Although generally we had no reason to expect that the clustering effects would be important for this study, in reality the data were likely to be hierarchical in nature, with patients naturally clustered into groups by recruiting centre and surgeon. Therefore, we proposed to account for this by generalising the conventional linear (fixed-effects) regression approach to a more general multilevel modelling approach; where patients are naturally grouped by surgeons and, likewise, surgeons are grouped by recruiting centres. This model would formally incorporate terms that allowed for possible heterogeneity in responses for patients owing to the recruiting centre and the surgeon, in addition to the fixed effects of the treatment groups, patient age and intra-articular extension. As discussed earlier, we expected that each individual surgeon would operate on only a small number (two or three) of the patients enrolled in the trial, which would greatly reduce the likelihood of a surgeon-specific effect on the outcome. Therefore, although we considered formally constructing a model with two levels of clustering (recruiting centre and surgeon), we expected that, if there were sparse data on individual surgeon effects, the final model would be simplified and consist of single random effect accounting for the recruiting centre only.

The main analyses were conducted using specialist multilevel modelling functions available in the software package R. PRWE questionnaire data were assumed to be normally distributed, although we considered the possibility of appropriate variance-stabilising transformation. The primary focus was the comparison of the two treatment groups of patients, and this was reflected in the analysis, which was reported together with appropriate diagnostic plots that check the underlying model assumptions. Although baseline PRWE questionnaire scores were recorded using a retrospective assessment by each patient post injury, these were not considered to be sufficiently reliable for formal baseline adjustment in the multilevel model. Mean baseline PRWE questionnaire scores together with other patient demographic data (e.g. age and gender) were reported for each treatment group to assess population comparability post randomisation.

The interactions between the stratifying variables (age and intra-articular extension) and the main treatment effect were not expected to be large; therefore, for practical reasons, the study was not powered with subgroup analysis in mind, as this would require a substantial and unrealistic increase in overall sample size. However, analyses were planned for each of the stratifying variables, particularly for participants aged over 50 years, who constitute a sizeable and important subgroup within the full study population. Formal tests of interaction between each stratifying variable and the treatment factor were reported together with appropriate 95% CIs and p -values. Significant results from this analysis were interpreted with due caution and reported as such, in line with recommendations for subgroup analysis made elsewhere.³²

Complications

The temporal patterns of any complications were presented graphically and if appropriate a time-to-event analysis (Kaplan–Meier survival analysis) was considered to assess the overall risk and risk within individual classes of complications (e.g. infection). This was to be the primary analysis for complications. However, if multiple complications proved to be widely reported then a Poisson regression model (or zero-inflated Poisson regression model) was planned to assess overall differences in counts of events between groups, adjusting for potential confounding factors such as age and gender. Multiple complications were defined

as two or more independent events, that is, not continuations of a previous complication, in the same patient and were identified only after discussion with the clinical team.

Reporting

Wherever possible, the results of all analyses were presented in a simple and easy-to-follow manner and related any observed differences to their clinical importance, so that they could be clearly understood by those with only rudimentary statistical knowledge. Open and confidential reports of the statistical analyses were planned, as required, by the trial statistician and, where appropriate, results were to be disseminated through peer-reviewed journals, conference presentations and local mechanisms.

Health economic analysis plan

Objectives

The economic evaluation was designed to estimate costs of distal radial fractures treated by locking-plate fixation and by K-wire fixation. If appropriate, the primary objective was to evaluate the incremental cost-effectiveness of distal radial fractures treated by locking-plate fixation versus K-wire fixation.

A within-trial analysis comparing the outcomes and costs up to 12 months' follow-up using trial data was undertaken for two age groups: (1) patients < 50 years of age and (2) patients \geq 50 years of age.

The evaluation followed the reference case guidance for technology appraisals set out by the National Institute for Health and Care Excellence (NICE).³³

In the longer term, we will develop a cost-effectiveness analysis modelling outcomes and costs up to 10 years post surgery. The methods for this second analysis will be presented in due course. However, the results for this analysis are not presented in the present report; this will require longer follow-up data, which are not currently available.

Measurement of outcomes

The economic analysis used quality-adjusted life-years (QALYs) to measure health outcomes. Health-related quality of life was estimated using responses from the EuroQol – Five Dimensions 3 Level.²⁶ Patients completed the EQ-5D questionnaire at baseline, 3 months, 6 months and 12 months after randomisation as secondary outcomes of the trial. Standard UK tariff values were applied to these responses at each time point to obtain utility. QALYs were calculated as an 'area under the curve' and formed the main outcome measure of the study. In addition, patients self-completed EQ-5D assessing their pre-injury quality of life retrospectively.

Measurement of costs

Patient-reported data on resource usage were collected within the trial at 3 months, 6 months and 12 months. For the 3-month data, the recall period was since discharge from hospital. For the other cases, it was since the last questionnaire was due to be completed. The questionnaires included number of further inpatient stays following the initial operation (including specialty and length of stay), number of outpatient, primary and community care visits, use of aids and adaptations, and medication use. Patients also reported the use of personal social services related to their treatment, as well as private costs such as treatments within private settings and time off work. Personal social services included number of weeks of frozen/hot meals on wheels, laundry services and number of visits of carers and social workers.

Costs were estimated combining patient-reported resource usage with unit cost data obtained from national databases such as the *British National Formulary* (BNF) and Personal Social Services Research Unit (PSSRU) Costs of Health and Social Care.³⁴ Any unit cost that was not available was estimated in consultation with the UHCW finance department.

The analyses initially took the perspective of the NHS including the costs of health and social care. Subsequent analyses adopted a societal perspective taking into account productivity costs (time away from work) and out-of-pocket expenditures incurred by patients in relation with their treatment. The currency used is pounds sterling (£).

Missing data

Although missing data were not expected to be a problem in this study, the economic analyses followed the nature and pattern of the missingness reported by the statisticians. This was illustrated as MCAR, missing at random or not missing at random.

A base-case analysis of the complete data set was conducted including only patients with complete cost and QALY data.

We then explored the use of the last observation carried forward (LOCF) approach to deal with missing values. Costs and EQ-5D values were carried forward for only one successive missing observation.

Finally, we imputed missing data through multiple imputations.^{35,36} This method, assuming that data are missing at random, replaces the missing values with plausible substitutes based on the distribution of observed data and, by using iterative multivariable regression techniques, includes randomness to reflect uncertainty. All baseline variables were used to impute missing data. This approach is recommended for economic analyses alongside clinical trials, as it reflects the uncertainty inherent in replacing missing data.¹² We considered the impact on the cost-effectiveness results using both imputation methods in the sensitivity analyses.

Within-trial analysis

Main characteristics of the analysis

The within-trial analysis aimed to determine the intervention that would maximise health outcomes (1) within the limited NHS budget and (2) within a societal perspective over the 12-month trial follow-up.

It adopted an intention-to-treat perspective and consisted of a cost–utility analysis over 12 months examining the cost per QALY gained for all patients. As the analysis uses a 1-year time horizon, discounting for the future cost and health outcome is not necessary in this analysis. We calculated the incremental cost-effectiveness ratios by dividing the average difference in cost between the two arms by the average difference in QALYs between the two arms as follows:

$$\text{ICER} = \frac{(\text{mean cost}_{\text{locking-plate}} - \text{mean cost}_{\text{K-wire}})}{(\text{mean QALY}_{\text{locking-plate}} - \text{mean QALY}_{\text{K-wire}})} \quad (1)$$

The incremental cost-effectiveness ratio (ICER) represents the additional cost per unit of outcome gained. This indicates the trade-off between total cost and effectiveness when choosing between volar locking-plate fixation and K-wire fixation. When compared against the marginal trade-off for the NHS as a whole – the cost-effectiveness threshold – this gives an indication of whether or not spending additional money on volar locking-plate fixation appears efficient. As a guideline rule, we used the NICE implicit cost per QALY threshold of £20,000–30,000 per QALY to determine cost-effectiveness. NICE accepts an intervention with an ICER of less than £20,000 per QALY as cost-effective and generally states that an intervention costing more than £30,000 per QALY is not considered cost-effective. The more expensive intervention was considered cost-effective as long as its ICER is within or below the £20,000–30,000 per QALY range.

Uncertainty

The non-parametric bootstrapping approach was used to determine the level of sampling uncertainty around the ICER by generating 10,000 estimates of incremental costs and benefits. We planned to present cost-effectiveness scatter plots illustrating the uncertainty surrounding the cost-effectiveness estimates.

The cost-effectiveness acceptability curves (CEACs) were derived by plotting the bootstrapped estimates. The bootstrap approach is a non-parametric method that considers the original sample as though it were the population and draws multiple random samples from the original sample. The CEACs illustrated the probability that a treatment is cost-effective in relation to a comparator, as a function of the threshold willingness to pay (WTP).¹² These were constructed using the net benefit approach. The standard non-parametric method for constructing CEACs is to bootstrap 10,000 samples from the original data, in order to plot the proportion of times each treatment represents the maximum average net benefit for a range of values of WTP values. Net monetary benefit (NMB) is calculated for each bootstrap estimate for a range of ceiling ratios as follows:

$$\text{NMB} = (\lambda \times \text{QALYs}) - \text{costs}, \quad (2)$$

where λ is the value a decision-maker would be willing to pay.

The intervention with $\text{NMB} > 0$ should be adopted taking into account the NHS WTP threshold. A series of net benefits were calculated for relevant λ values ranging from £0 to £50,000 (£5000 increments) to incorporate the £20,000–30,000 per QALY gain threshold range currently specified for NICE decision-making in England and Wales.³²

Mean incremental net benefits between the two arms were reported, with 95% bootstrap CIs calculated using the bias-corrected method.³⁷

Sensitivity

We planned to undertake univariate sensitivity analyses to explore key uncertainties in the scenarios considered.

The results for complete cost and quality of life data (i.e. those with no missing data) as well as a strict per-protocol analysis of the data were provided to identify the impact of missing data on the analysis and any sensitivity to protocol violations.

As patients might also recover function within the first 3 months (rather than continuously to 3 months), a quicker initial recovery was explored in QALY calculations, where each patient's quality of life was assumed to reach its observed 3-month level at 6 weeks postoperatively.

The cost assumptions in the analysis were modified if relevant (e.g. least expensive implant).

Sensitivity analyses were also planned to consider stratified analyses by factors such as age, gender, trial centre, baseline PRWE and DASH questionnaire scores, and intra-articular extension, if this was found to affect quality of life within the trial period.

Longer-term analysis

For the longer term, we will use decision-analytic modelling to compare locking-plate fixation and K-wire fixation for distal radial fractures over a longer time frame. We will use a 10-year Markov decision model based upon within clinical trial results to estimate the long-term effectiveness of fixations and the proportional hazards of complications and also revision in both people < 50 years of age and people ≥ 50 years of age.

The model will include four possible states: (1) successful fixation; (2) complications; (3) revised fixation/surgery; and (4) death and its structure (*Figure 3*).

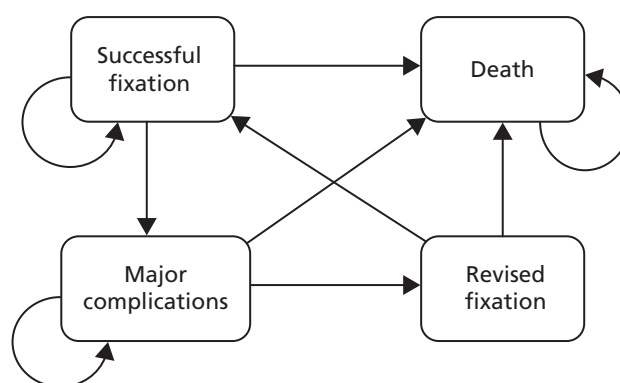


FIGURE 3 States and allowable state transitions corresponding to use of a distal radius acute fracture fixation.

The impact of complications and subsequent revision surgery will be assessed using information from various sources: the extrapolation of within-trial data and the longer complication follow-up data which is currently ongoing, the published literature and/or expert opinions to create the most accurate model to compare locking-plate fixation and K-wire fixation for distal radial fractures. We will conduct a systematic review of cost-effectiveness models in the treatment distal radius fracture. This will act as the main resource of transition probabilities for the model. Where possible, transition probabilities will be based on the latest UK studies reflecting current care pathways and associated expectations relating to long-term patient functioning.

Two different base case scenarios will be considered, < 50 years of age cohort and ≥ 50 years of age cohort, both followed for 10 years.

Following the NICE reference case,³³ costs and benefits will be discounted at 3.5% and a NHS perspective adopted.

Deterministic one-way sensitivity analysis will be performed to check the results over a plausible range of prior distributions placed on the time-varying model parameters. Multiway deterministic sensitivity analyses will be undertaken by modelling optimistic ('best case') and pessimistic ('worse case') scenarios.³⁸

Reporting

The results of the within-trial analyses are presented such that people with basic cost-effectiveness analysis knowledge can understand it.

It was planned that results would be disseminated through peer-reviewed journals, conference presentations and other types of research work dissemination. We expected to provide the within-trial analysis results for the trial main paper and we aimed at producing one extra paper focusing on the full health economics analysis with more mature data in the longer term.

Ethical approval and monitoring

Standard NHS cover for negligent harm was in place. There was no cover for non-negligent harm.

Ethics committee approval

The DRAFFT trial was approved by the Coventry Research Ethics Committee in February 2010 (REC reference 10/H1210/10) and by the research and development department of each participating centre. The final approved study protocol has been published.

Trial management group

The day-to-day management of the trial was the responsibility of the trial co-ordinator, based at Warwick Clinical Trials Unit (CTU) and supported by the CTU administrative staff. This was overseen by the TMG, which met monthly to assess progress. It was also the responsibility of the trial co-ordinator to undertake training of the research associates at each of the trial centres. The trial statistician and health economist were closely involved in the setting up of data capture systems and the design of databases and clinical reporting forms.

Trial Steering Committee

A TSC was responsible for monitoring and supervising the progress of the DRAFFT trial. The TSC consisted of four independent experts, a lay member and leading members of the TMG. Membership of the TSC is given in *Acknowledgements*.

Data Monitoring Committee

The DMC was independent of the trial and was tasked with monitoring ethical, safety and data integrity. The trial statistician provided data and analyses requested by the DMC at each of the meetings. Membership of the DMC is given in *Acknowledgements*.

Chapter 3 Results

Screening

Overall

The overall flow of patients in the trial is shown in *Figure 4*. The total number of patients screened was 12,162; *Table 3* shows the age and gender split.

The overall median age of screened patients, where data were available, was 53 years [interquartile range (IQR) 18–72 years]; for females it was 63 years (IQR 39–77 years) and for males 23 years (IQR 12–48 years).

There was clear bimodality in the age distributions for each gender (*Figure 5*), particularly for females. A Gamma mixture model, *gammamixEM* function in R package *mixtools*, was fitted to data from each gender to estimate the proportionate split and median ages in each group; bootstrapping ($n = 100$) was used to estimate 95% CIs for these statistics.

The modelling suggests that, for females, the 'young' group has a median age of 25.1 years (95% CI 24.1 to 25.8 years) and the 'old' group has a median age of 71.1 years (95% CI 70.6 to 71.5 years), with the split by group (young : old) given by 32.3% : 67.7% (95% CI 30.8 to 33.5). For males, the 'young' group has a median age of 19.7 years (95% CI 18.3 to 20.6 years) and the 'old' group has a median age of 63.7 years (95% CI 61.3 to 65.1 years), with the split by group (young : old) given by 73.5% : 26.5% (95% CI 69.3 to 76.0).

A recent study by Court-Brown and Caesar¹⁶ assessed over 1000 patients with a fracture of the distal radius. This study suggested that there is a clear bimodal distribution for this type of fracture according to the age of the patient; with a crossover of the two peaks of incidence at around 50 years of age. This was also the case for our data, for both males and females, with *Figure 5* showing that the approximate division between the two age groups was also at around 50 years. Stratification on the basis of age was used to discriminate between younger patients with normal bone quality sustaining high-energy fractures and older patients with low-energy (fragility) fractures related to osteoporosis.

Eligibility

Figure 4 shows that the total number eligible for the study was 639, that is the total number screened (12,162) minus the total number ineligible (11,523). The main reasons for patient ineligibility were that the fracture did not require fixation (32.1%), the fracture was dorsally displaced > 3 cm from the radiocarpal joint (26.1%) and the patient was aged < 18 years (27.8%).

Willingness

Of the 639 eligible patients, 461 (72.1%) were willing and 178 were unwilling to take part in the trial. The main reason for being unwilling to participate was a simple unwillingness to be part of a research project (55 patients; 30.9%). Of those patients who expressed a preference, there was a balance between the treatment groups, with 26 patients stating a preference for wires (14.6%) and 29 stating a preference for a plate (16.3%).

In total, 461 patients were willing to participate in the DRAFFT study. The gender and age of the individuals who were willing and unwilling to participate in the study are shown in *Table 4* and the distribution of ages by gender and group in *Figure 6*.

A *t*-test showed that ages did not differ significantly between groups ($p = 0.088$) and a chi-squared test showed no difference in gender split between groups ($p = 0.301$).

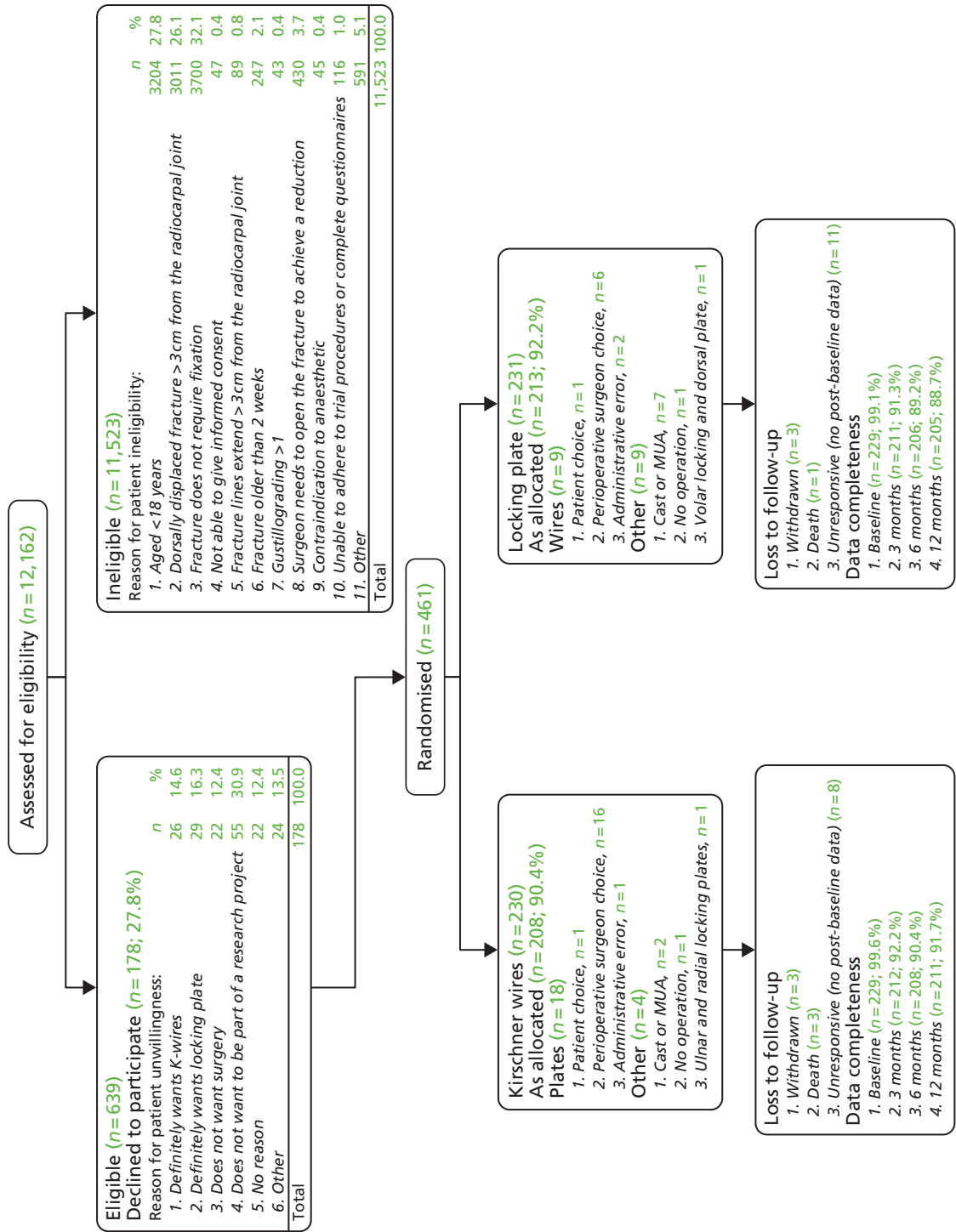
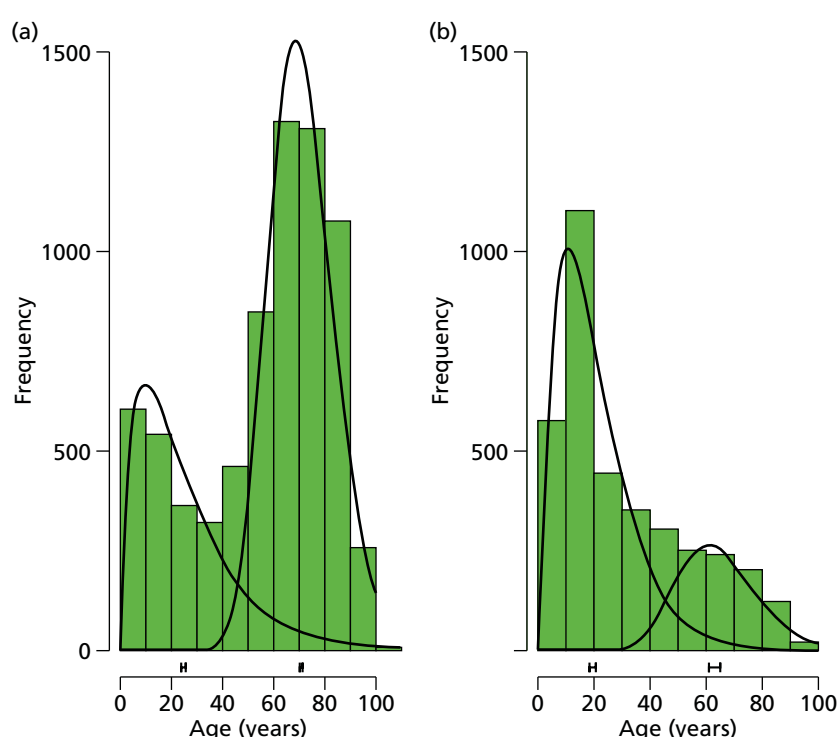


FIGURE 4 Consolidated Standards of Reporting Trials (CONSORT) plot: overall flow of patients in the study. MUA, manipulation under anaesthetic.

TABLE 3 Numbers and percentages of screened patients by gender and age group

Gender	Age group (years)		Total, <i>n</i> (%) ^a
	< 50, <i>n</i> (%)	≥ 50, <i>n</i> (%)	
Female	2317 (21.6)	4806 (44.7)	7123 (66.3)
Male	2798 (26.0)	830 (7.7)	3628 (33.7)
Total	5115 (47.6)	5636 (52.4)	10,751 (100.0)

a Total screened *n* = 12,162; missing only age *n* = 560, missing only gender *n* = 81 and missing both age and gender *n* = 770.

**FIGURE 5** Age distribution of screened patient bars and fitted distributions for (a) females (*n* = 7123) and (b) males (*n* = 3628).**TABLE 4** Age and gender of participants who were willing and unwilling

Characteristic	Willing (<i>n</i> = 461)	Unwilling (<i>n</i> = 178)
Age in years, mean (SD)	58.8 (15.9)	56.1 (18.8)
Gender (% female)	83.0	79.1

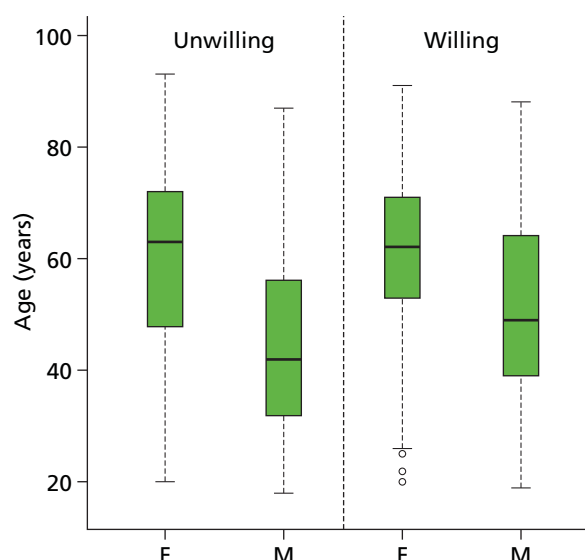


FIGURE 6 Box plot showing age distribution by gender and willingness to participate in trial. F, female; M, male.

Recruitment

The trial planned to recruit as a minimum 390 patients in total. Formal recruitment started on 1 January 2011 and finished on 30 June 2012. Recruitment took place at 18 centres (*Table 5*).

TABLE 5 Participating centres and centre codes

Centre	Code
1. Addenbrookes Hospital	ADH
2. Frenchay Hospital	FRH
3. Ipswich Hospital	IPH
4. James Cook University Hospital	JCH
5. John Radcliffe Hospital	JRH
6. Leicester General Hospital	LGH
7. North Tyneside General Hospital	NTG
8. Northampton General Hospital	NGH
9. Peterborough City Hospital	PCH
10. Poole Hospital	POH
11. Royal Blackburn Hospital	BBH
12. Royal Victoria Infirmary	RVI
13. St Thomas' Hospital	STH
14. University Hospital Coventry and Warwickshire	UHC
15. University Hospital North Staffordshire	UNS
16. University Hospital of North Tees	NTH
17. Wansbeck General Hospital	WGH
18. Wexham Park Hospital	WPH

Overall

Overall trends in recruitment are shown in *Figure 7*; the final number of participants recruited to the study was 461 (*Table 6*).

The final number of recruited participants was above the initial target of 390.

Recruitment proceeded at a faster rate than expected; therefore, the decision was taken to allow the sample size to increase above the target of 390 patients.

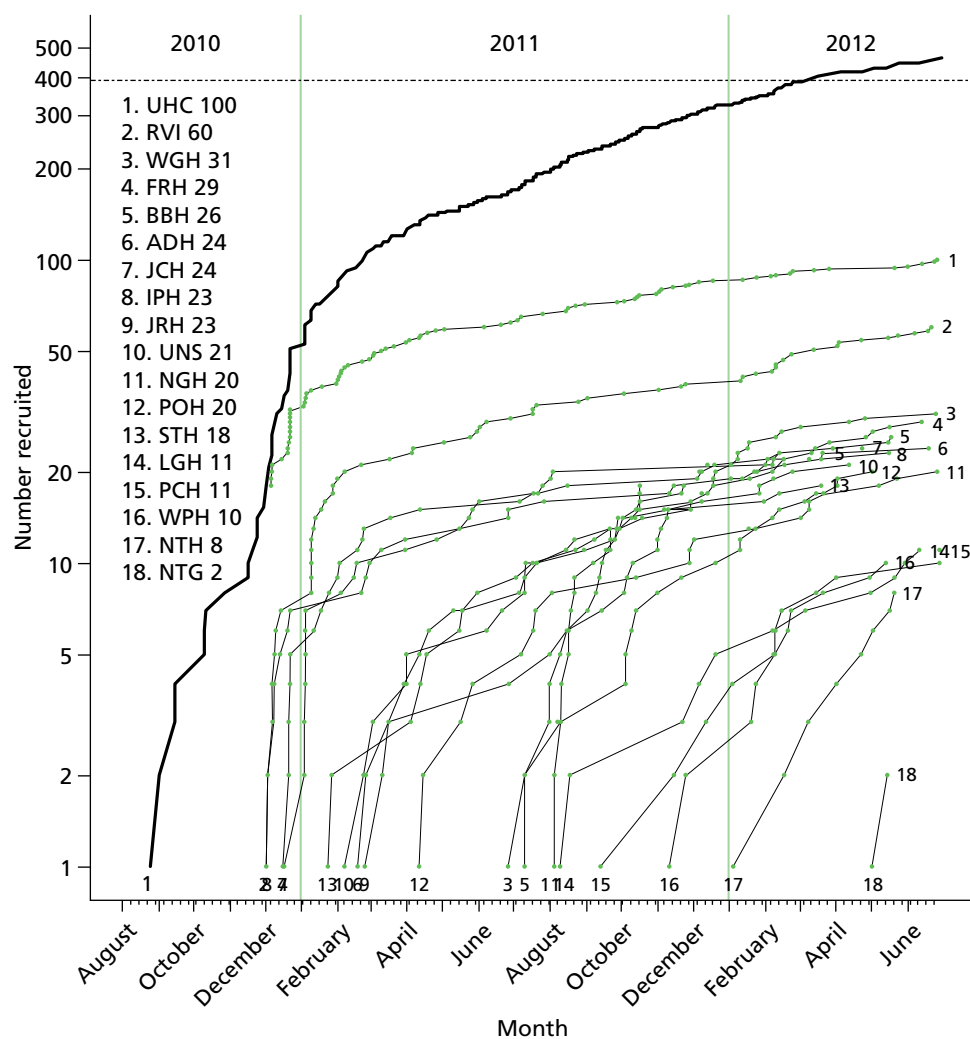


FIGURE 7 Overall DRAFT recruitment (thick black line) and recruitment by centre (January 2011 to June 2012); logarithmic scale used to enhance detail for individual centres. Original target = 390 patients.

TABLE 6 Recruitment by hospital and treatment group

Hospital	Treatment group		Total	Months open	Rate (per month)
	K-wire	Locking plate			
UHC	50	50	100	23	4.51
RVI	30	30	60	19	3.21
WGH	15	16	31	12	2.58
FRH	15	14	29	18	1.62
BBH	13	13	26	11	2.53
ADH	12	12	24	17	1.50
JCH	13	11	24	17	1.47
IPH	11	12	23	18	1.32
JRH	11	12	23	13	1.78
UNS	10	11	21	15	1.48
NGH	11	9	20	11	1.86
POH	9	11	20	13	1.58
STH	8	10	18	14	1.30
LGH	6	5	11	11	1.09
PCH	6	5	11	10	1.15
WPH	5	5	10	7	1.64
NTH	4	4	8	5	1.78
NTG	1	1	2	1	4.68
Average	–	–	–	13.05	1.96
Total	230	231	461	235	–

Population characteristics

The randomisation was stratified by hospital, age group and intra-articular extension. *Table 7* shows recruitment numbers by treatment group, age group and intra-articular extension.

The breakdown by age, gender and treatment group is shown in *Table 8*.

The majority (304 out of 461) of patients recruited to the trial were female and ≥ 50 years of age, as expected.

TABLE 7 Recruitment by treatment group, age group and intra-articular extension

Age group, years	Intra-articular extension	Treatment		Total
		K-wire	Locking plate	
< 50	No	31	33	64
	Yes	29	27	56
≥ 50	No	91	89	180
	Yes	79	82	161
Total		230	231	461

TABLE 8 Recruitment by treatment group, age group and gender

Age group, years	Gender	Treatment		Total
		K-wire	Locking plate	
< 50	Female	35	46	81
	Male	25	14	39
≥ 50	Female	156	148	304
	Male	14	23	37
Total		230	231	461

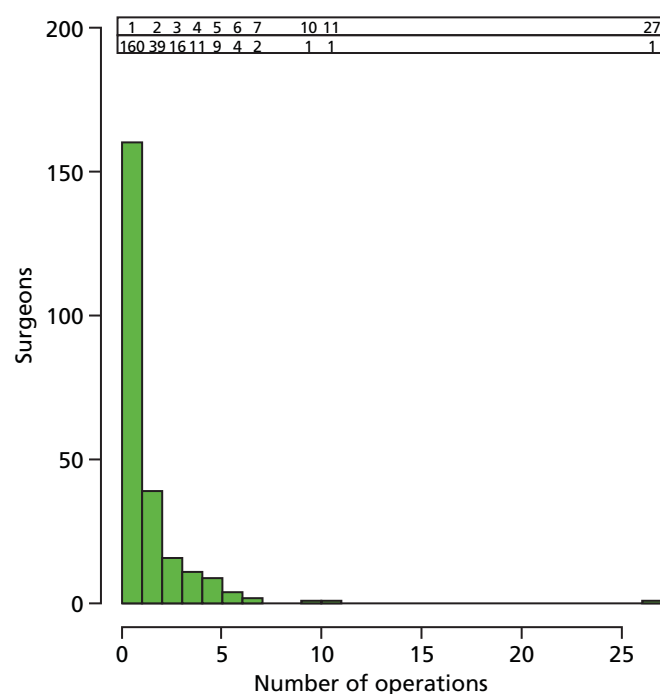
Surgeons and operations

Before proceeding to analyse the outcomes, it is informative to look at the details of the surgical procedures.

Surgeons

Treatments were undertaken by 244 different surgeons; the median number of operations per surgeon was 1 (IQR 1–2). *Figure 8* shows a histogram of the number of procedures undertaken by each surgeon.

As expected, any individual surgeon operated only on a small number of patients ($n = 2$ or 3) enrolled in the study; 88% of surgeons (215 out of 244) treated fewer than three study participants. This greatly reduces the likelihood of a surgeon-specific effect on the outcome at any one centre, that is one particularly good or bad surgeon dominating the other surgeons in the study.

**FIGURE 8** Histogram of numbers of operation for each surgeon.

Operations

Details of the surgeon grade and experience and methods employed for each procedure are shown in Table 9 and operation times by surgeon grade are shown in Figure 9.

There was no evidence to suggest that operation times differed between surgeon grades.

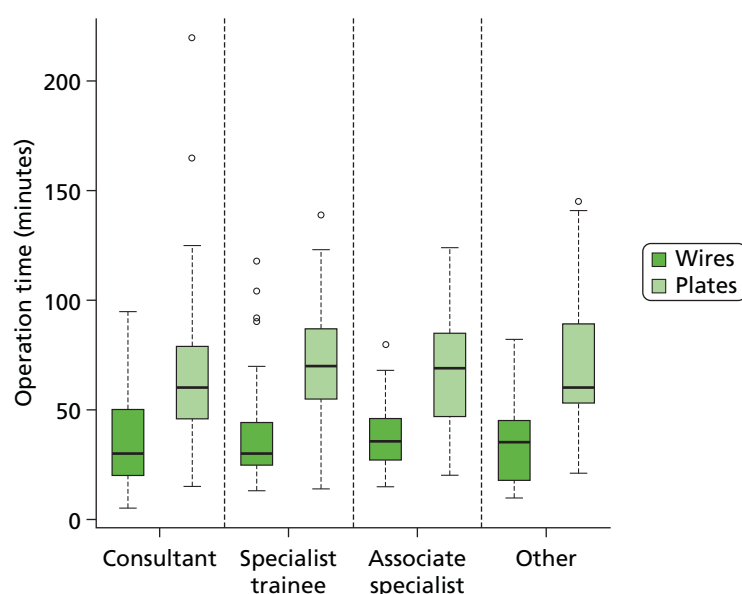
TABLE 9 Surgeon grade, experience and methods employed for each operation

Details of surgeons and surgery	K-wire (<i>n</i> = 230)	Locking plate (<i>n</i> = 231)
Perioperative antibiotic (no : yes)	58 : 164 (71%)	19 : 191 (83%)
Operated wrist (right : left)	101 : 24 (54%)	102 : 124 (54%)
Intraoperative problems (no : yes)	222 : 4 (2%)	219 : 4 (2%)
Surgeon grade, <i>n</i> (%)^a		
Consultant	60 (26)	71 (31)
Specialist trainee	102 (44)	106 (46)
Staff grade/associate specialist	30 (13)	29 (13)
Other	34 (15)	20 (9)
Surgeon experience (number of prior operations), <i>n</i> (%)^a		
0	0 (0)	1 (0)
< 5	11 (5)	8 (3)
5–10	16 (7)	23 (10)
11–20	25 (11)	30 (13)
> 20	171 (74)	158 (68)
Wires, <i>n</i> (%)		
<i>Number of wires used^b</i>		
1	1 (0)	–
2	96 (42)	–
3	105 (46)	–
> 3	5 (2)	–
Wire size^a		
1.6 mm	187 (81)	–
1.1 mm	1 (0)	–
Other	12 (5)	–
Technique^a		
Kapandji	54 (23)	–
Interfragmentary	78 (34)	–
Mixed technique	71 (31)	–

TABLE 9 Surgeon grade, experience and methods employed for each operation (*continued*)

Details of surgeons and surgery	K-wire (<i>n</i> = 230)	Locking plate (<i>n</i> = 231)
Plates, n (%)		
<i>Number of screws used^a</i>		
3	—	20 (9)
4	—	62 (27)
5	—	42 (18)
> 5	—	88 (38)
<i>Proximal screw^a</i>		
Locking	—	103 (45)
Non-locking	—	110 (48)
Operation time		
Minutes	31	66
Median (IQR)	24 (45)	50 (85)
Mean (SD)	37.2 (19.8)	69.9 (27.7)
Length of stay		
Days	1	1
Median (IQR)	0 (1)	0 (1)

^a Where numbers do not add to treatment group size, this indicates that there were some missing data.

**FIGURE 9** Operation times by surgeon grade and procedure.

Outcomes

Treatment allocation

Table 10 shows the treatment allocation and the treatments received by treatment group. In the K-wire group 90.4% of participants received their allocated intervention and in the locking-plate group 92.2% received their allocated intervention.

Unless stated otherwise, all analyses reported here will be on an intention-to-treat basis, that is by allocated treatment.

Baseline characteristics

The baseline characteristics are well balanced between treatment groups (Table 11).

Imaging outcomes

Dorsal angle (°) and ulnar variance (mm) data were extracted from available images from all study participants before their operation (pre-op), and 6 weeks and 12 months postoperatively. In addition to the principal clinician extracting these images (assessor 1), an additional clinician (assessor 2) also assessed and extracted data independently. Table 12 shows estimates of intraclass correlation coefficients (ICCs), with 95% CIs based on 1000 bootstrapped samples, for dorsal angle and ulnar variance data at the preoperative assessment, and at 6 weeks and 12 months postoperatively. The ICC provides a measure of agreement between the two assessors and can be interpreted as follows: 0 to 0.2 poor, 0.2 to 0.4 fair, 0.4 to 0.6 moderate, 0.6 to 0.8 substantial and 0.8 to 1.0 almost perfect.

TABLE 10 Treatment allocation

Received	Allocated		
	K-wire, <i>n</i>	Locking plate, <i>n</i>	Total, <i>n</i>
K-wire	208	9	217
Locking plate	18	213	231
Other	4	9	13
Total	230	231	461

TABLE 11 Baseline characteristics of 461 participants; data shown are mean (SD) unless indicated otherwise

Baseline characteristics	K-wire (n = 230)	Locking plate (n = 231)
Sex (female : male)	191 : 39 (17%)	194 : 37 (15%)
Intra-articular extension (no : yes)	122 : 108 (47%)	122 : 109 (47%)
Age (years)	59.7 (16.4)	58.3 (14.9)
Injury side (right : left)	101 : 123 (53%)	101 : 124 (54%)
Handedness (right : left)	196 : 32 (14%)	202 : 26 (11%)
Previous problem on injured side (no : yes)	197 : 33 (14%)	191 : 39 (17%)
BMI (kg/m ²)	24.8 (4.0)	26.5 (5.3)
Osteoporosis (no : yes)	208 : 22 (10%)	211 : 20 (9%)
Regular analgesia (no : yes)	160 : 70 (30%)	169 : 61 (26%)
Smoker (no : yes)	180 : 50 (22%)	189 : 42 (18%)
Mechanism of injury ^a		
Low-energy fall	190 (83%)	189 (82%)
High-energy fall	36 (16%)	36 (16%)
Road traffic collision	1 (0%)	4 (2%)
Crush	1 (0%)	0 (0%)
Other	2 (1%)	2 (1%)
Fracture classification ^{a,b}		
A1 : A2 : A3	0 (0%) : 73 (32%) : 84 (37%)	0 (0%) : 71 (31%) : 78 (34%)
B1 : B2 : B3	1 (0%) : 1 (0%) : 1 (0%)	4 (2%) : 1 (0%) : 0 (0%)
C1 : C2 : C3	33 (14%) : 26 (11%) : 7 (3%)	30 (13%) : 34 (15%) : 11 (5%)
Alcohol consumption (per week) ^a		
0–7 units	164 (71%)	164 (71%)
8–14 units	39 (17%)	45 (19%)
15–21 units	16 (7%)	14 (6%)
> 21 units	11 (5%)	8 (3%)
Pre-injury scores (retrospectively)		
PRWE	2.6 (8.4)	2.8 (8.7)
DASH	5.4 (12.7)	4.6 (10.8)
EQ-5D	0.92 (0.17)	0.94 (0.15)
Patient preference (after randomisation)		
K-wire	38 (17%)	39 (17%)
Locking plate	35 (15%)	42 (18%)
No preference	156 (68%)	150 (65%)

BMI, body mass index.

^a Where totals for categorical variables do not sum to treatment group totals, it indicates that some data were missing.

^b A1, extra-articular ulnar fracture with intact radius; A2, extra-articular radius fracture, simple or impacted; A3, extra-articular multiple fragmented fracture; B1, partially-articular fracture with trace at sagittal plane; B2, partially-articular fracture with dorsal fragment; B3, partially-articular fracture with volar fragment; C1, complete-articular simple metaphyseal trace; C2, complete-articular simple joint and multiple fragmented metaphyseal; C3, complete-articular multiple fragmented.

TABLE 12 Estimates of agreement (ICC) between assessors and 95% CIs (1000 bootstrap samples)

Occasion	Measure	<i>n</i>	ICC	95% CI
Preoperative	Dorsal angle (°)	279	0.94	0.91 to 0.96
	Ulnar variance (mm)	277	0.87	0.78 to 0.94
Week 6	Dorsal angle (°)	266	0.84	0.77 to 0.90
	Ulnar variance (mm)	266	0.82	0.70 to 0.92
12 months	Dorsal angle (°)	208	0.87	0.81 to 0.91
	Ulnar variance (mm)	209	0.89	0.82 to 0.93
ICC, intraclass correlation coefficient.				

It is clear from *Table 12* that for both measures there was almost perfect agreement between both assessors. This is displayed visually by the Bland–Altman plots in *Figure 10*, where the difference between data from the two assessors is plotted against the mean with 95% CIs. We conclude from the analysis presented in *Table 12* and *Figure 10* that there was excellent agreement between assessors, indicating a high level of confidence in the measurements made by the principal assessor (assessor 1). The following comparative analysis (between intervention groups) is based purely on the data extracted from the images by this assessor.

Image data were available from all 461 study participants before their operation (pre-op), and 6 weeks and 12 months postoperatively. However, some data were not available for analysis because of lack of collection, corrupted data files (which could not be opened) and poor-quality images that could not be analysed. In summary, only six study participants (1%) had no image data available at any occasion.

Metaphyseal comminution was reported at the preoperative assessment, in addition to dorsal angle and ulnar variance, and appeared to be well balanced across intervention groups, with 70.0% (152 out of 217) and 70.1% (155 out of 221) of study participants being assessed affirmatively for this characteristic for the K-wire and locking-plate groups respectively. *Table 13* shows the mean and SD for imaging outcomes at baseline, 6 weeks and 12 months postoperatively, and estimated treatment effects after adjustment at 6 weeks and 12 months. Adjusted effects were from mixed-effects regression analysis based on complete cases with treatment group, age group, sex and intra-articular extension as covariates (fixed effects) and recruiting centre as a random effect.

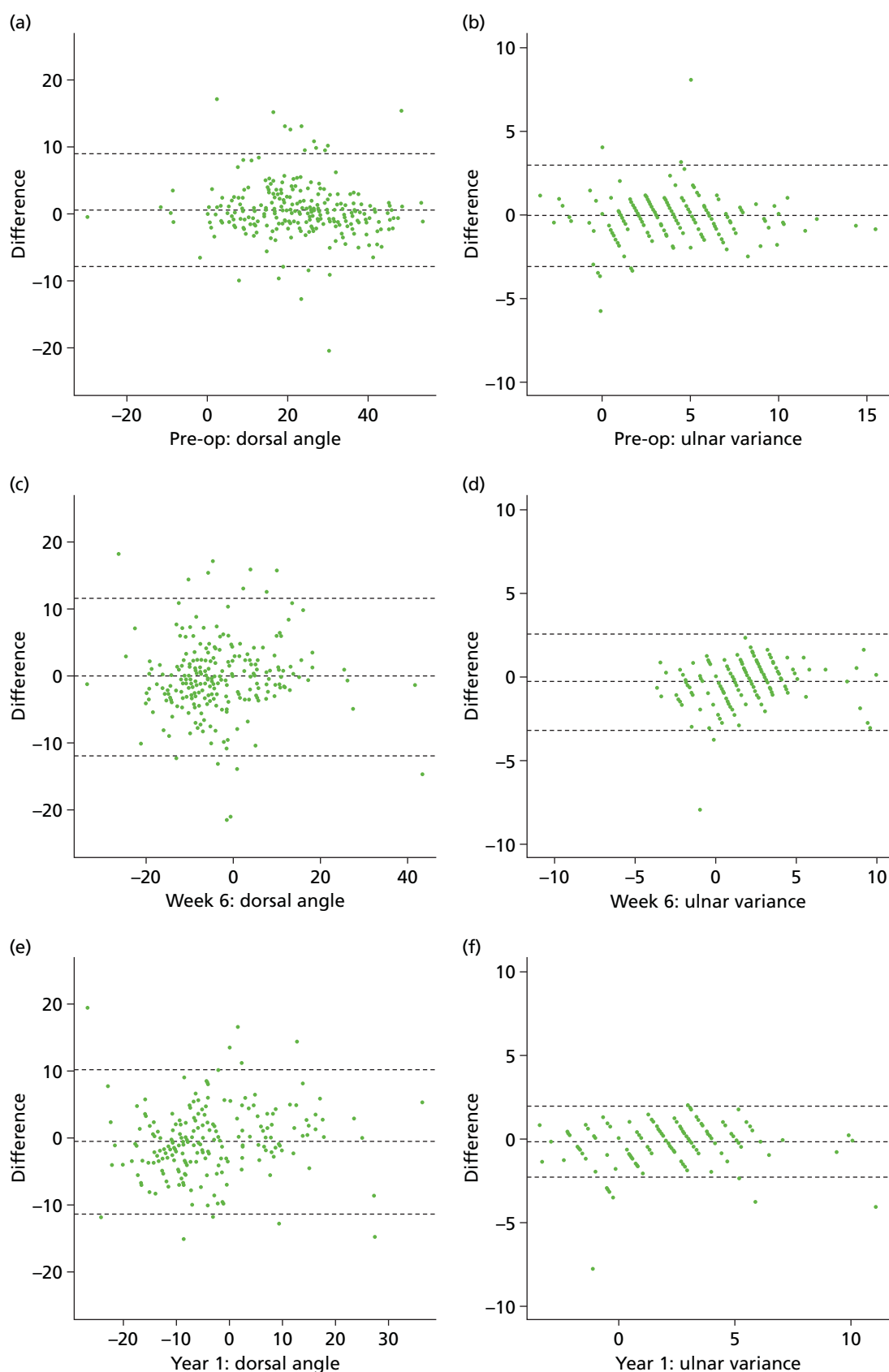


FIGURE 10 Bland–Altman plots showing agreement between assessors 1 and 2 for dorsal angle (°) preoperatively (a), 6 weeks (c) and 1 year (e); and for ulnar variance (mm) preoperatively (b), 6 weeks (d) and 1 year (f). Plots show differences plotted against mean data, with 95% CIs indicated by dashed lines.

TABLE 13 The mean and SD of imaging outcomes at baseline, 6 weeks and 12 months postoperatively and estimated treatment effects after adjustment at 6 weeks and 12 months

Imaging outcome		K-wire		Locking plate		Difference (95% CI)		p-value
		Mean (SD)	n	Mean (SD)	n	Raw	Adjusted ^a	
Dorsal angle (°)	Baseline	23.10 (12.57)	220	22.05 (13.85)	225	-1.05	–	–
	6 weeks	-1.16 (11.00)	215	-4.31 (9.39)	215	-3.15	-3.18 (-5.02 to -1.33)	< 0.001
	12 months	-0.49 (12.35)	178	-5.20 (8.24)	173	-4.70	-4.64 (-6.76 to -2.53)	< 0.001
Ulnar variance (mm)	Baseline	3.26 (2.62)	219	3.55 (3.24)	222	0.29	–	–
	6 weeks	1.95 (2.11)	215	1.20 (2.18)	215	-0.75	-0.75 (-1.15 to -0.35)	< 0.001
	12 months	2.43 (2.31)	179	1.32 (2.02)	173	-1.11	-1.08 (-1.53 to -0.63)	< 0.001

a Mixed-effects regression based on a complete-case analysis with treatment group, age group, sex and intra-articular extension as covariates (fixed effects) and recruiting centre as a random effect; p-values are from analysis of variance (ANOVA) F-test.

In summary, these results indicate that there was a significantly larger (more positive) dorsal angle in the K-wire group than the locking-plate group, at both 6 weeks and 12 months post operation. In addition, the variability in dorsal angle was significantly less in the locking-plate group than in the K-wire group at both 6 weeks and 12 months (*F*-test to compare the variances of two samples from normal populations; $p = 0.020$ and $p < 0.001$ and ratio of variances 0.73 and 0.45, at 6 weeks and 12 months, respectively). There was a significantly larger (more positive) ulnar variance in the K-wire group than in the locking-plate group, at both 6 weeks and 12 months post operation. However, there was no difference in variability between groups for ulnar variance at 6 weeks and 12 months ($p = 0.615$ and $p = 0.081$).

The image data are summarised further in the box plots of *Figure 11*, which clearly show the temporal trends in data and the difference in variance between dorsal angle data between groups at 12 months post operation.

Functional and quality of life outcomes

The primary outcome for this study is the PRWE questionnaire score²³ at 12 months after surgery. Early functional status was also assessed and reported at 3 months and 6 months. The DASH questionnaire²⁵ was used as a more general measure of physical function and symptoms in people with musculoskeletal disorders of the upper limb. Quality of life was assessed using EQ-5D. Data are summarised for each outcome measure, at each assessment occasion, in *Tables 14–16*. Baseline data are retrospective measurements made by study participants to assess pre-injury function and quality of life at recruitment. For EQ-5D, participants also made a post-injury assessment.

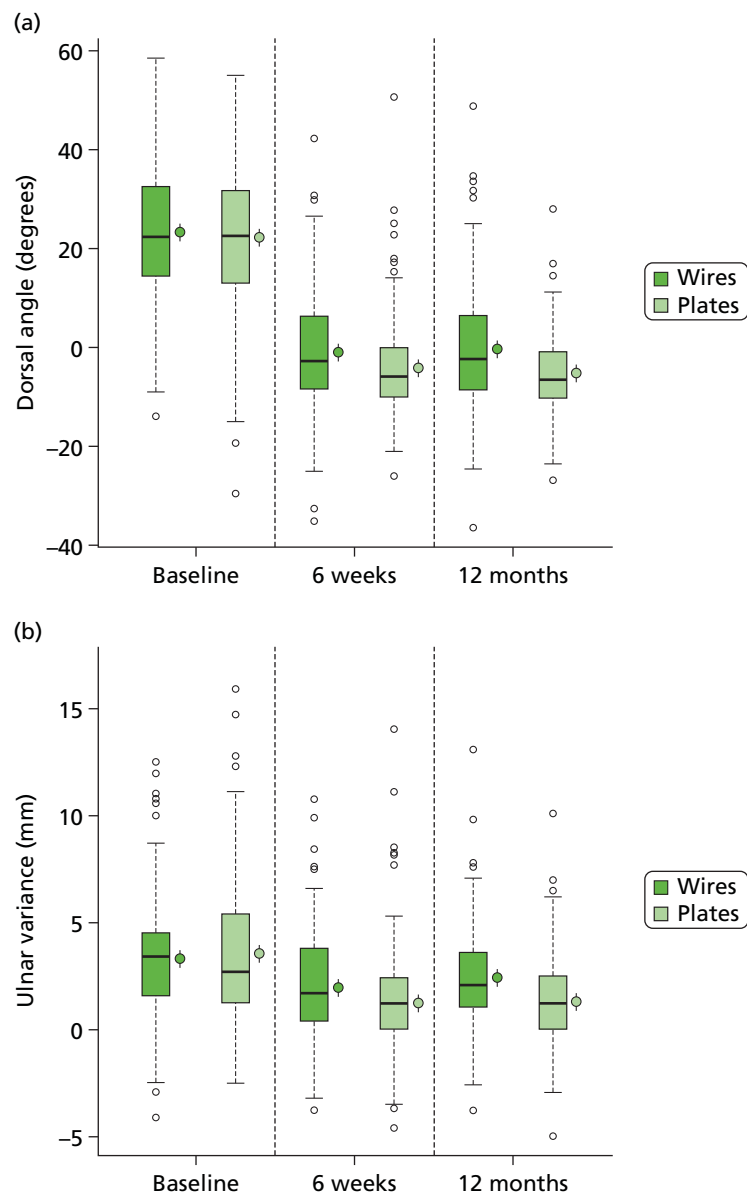


FIGURE 11 Box plots of baseline and postoperative scores and trends in means (filled circles) with 95% CIs for (a) dorsal angle and (b) ulnar variance.

TABLE 14 Numbers of measurements, minimum, mean, median, maximum and SD of PRWE questionnaire scores at baseline (pre injury), 3, 6 and 12 months

Treatment	Measure	Baseline	3 months	6 months	12 months
K-wire	<i>n</i>	229	212	208	211
	Minimum	0.0	0.0	0.0	0.0
	Mean	2.6	33.9	22.3	15.3
	Median	0.0	30.5	18.3	9.0
	Maximum	62.5	97.0	76.0	79.0
	SD	8.4	22.3	18.6	15.8
Locking plate	<i>n</i>	229	211	206	204
	Minimum	0.0	0.0	0.0	0.0
	Mean	2.8	31.5	20.6	13.9
	Median	0.0	27.5	16.0	7.5
	Maximum	75.5	97.5	91.0	79.5
	SD	8.7	22.4	17.7	17.1

TABLE 15 Number of measurements, minimum, mean, median, maximum and SD of DASH questionnaire scores at baseline (pre injury), 3, 6 and 12 months

Treatment	Measure	Baseline	3 months	6 months	12 months
K-wire	<i>n</i>	229	203	195	201
	Minimum	0.0	0.0	0.0	0.0
	Mean	5.4	31.1	21.1	16.2
	Median	0.8	27.6	15.8	8.3
	Maximum	80.0	84.2	87.5	86.1
	SD	12.7	20.6	18.5	17.9
Locking plate	<i>n</i>	227	207	199	195
	Minimum	0.0	0.0	0.0	0.0
	Mean	4.6	28.9	19.2	13.0
	Median	0.0	22.5	14.2	6.7
	Maximum	65.8	96.7	81.9	90.8
	SD	10.8	21.1	17.5	15.6

TABLE 16 Number of measurements, minimum, mean, median, maximum and SD of EQ-5D scores at baseline (pre injury), post injury, 3, 6 and 12 months

Treatment	Measure	Baseline	Post-injury	3 months	6 months	12 months
K-wire	<i>n</i>	229	223	205	200	204
	Minimum	0.1	−0.4	−0.3	−0.2	0.1
	Mean	0.9	0.4	0.7	0.8	0.8
	Median	1.0	0.3	0.8	0.8	0.9
	Maximum	1.0	0.8	1.0	1.0	1.0
	SD	0.2	0.3	0.2	0.2	0.2
Locking plate	<i>n</i>	229	225	207	194	194
	Minimum	0.0	−0.6	−0.2	0.1	−0.1
	Mean	0.9	0.4	0.7	0.8	0.9
	Median	1.0	0.3	0.8	0.8	0.9
	Maximum	1.0	1.0	1.0	1.0	1.0
	SD	0.2	0.3	0.2	0.2	0.2

Figures 12–14 show trends in means and box plots of distribution of scores for PRWE, DASH and EQ-5D by treatment group.

There appears to be, from a visual inspection of the plots, very little evidence for treatment group difference for the PRWE questionnaire score but some evidence for marginally better function in the locking-plate group than the K-wire group for the DASH questionnaire scores. Scores recover in the postoperative period in both groups but function is still worse than before the injury (based on retrospective assessment). Both PRWE and DASH questionnaire scores are left-skewed at the 12-month assessment, as they approach the score minimum. There is also very little evidence for treatment group difference for the EQ-5D score.

Table 17 shows means and SDs by treatment group. A mixed-effects linear regression model is used to estimate treatment differences (and 95% CIs). The full (planned) model incorporated terms that allowed for possible heterogeneity in responses for patients owing to the recruiting centre and the surgeon, in addition to the fixed effects of the treatment groups, sex, patient age and intra-articular extension. However, as we foresaw in the study protocol, the overwhelming majority of surgeons operated on fewer than three patients (see *Chapter 3, Surgeons and operations*), so a simplified model is used that implements a single random effect to account for the recruiting centre. Although baseline PRWE questionnaire scores were recorded using a retrospective assessment by each patient post injury, these were not considered sufficiently reliable for formal baseline adjustment in the multilevel model. The interactions between the stratifying variables (age and intra-articular extension) and the main treatment effect were not expected to be large; therefore, for practical reasons, the study was not powered with subgroup analysis in mind. However, formal tests of interaction between each stratifying variable and the treatment factor are reported together with appropriate 95% CIs and *p*-values in Table 17.

The adjusted estimate of the treatment effect for the PRWE questionnaire score for the full population is −1.3 (95% CI −4.5 to 1.8) in favour of the locking-plate group; the *p*-value of 0.398 indicates that there is no evidence for a statistically significant difference in PRWE questionnaire scores between the treatment groups at 12 months post operation. The MCID for the PRWE questionnaire score is 6 points; therefore, we conclude, based on our estimated CIs, that if there is a difference in functional scores between treatment groups it is likely to be sufficiently small as to be clinically unimportant.

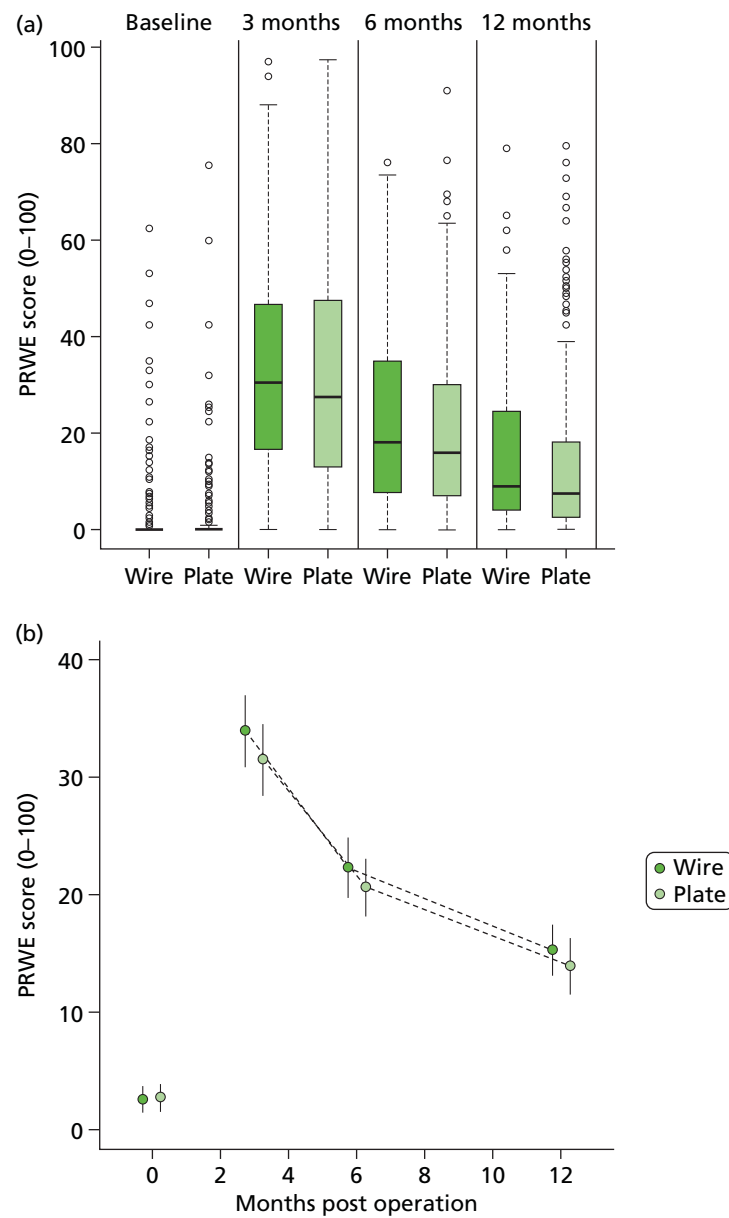


FIGURE 12 (a) Box plots of postoperative scores and (b) trends in means with 95% CIs for the PRWE questionnaire scores.

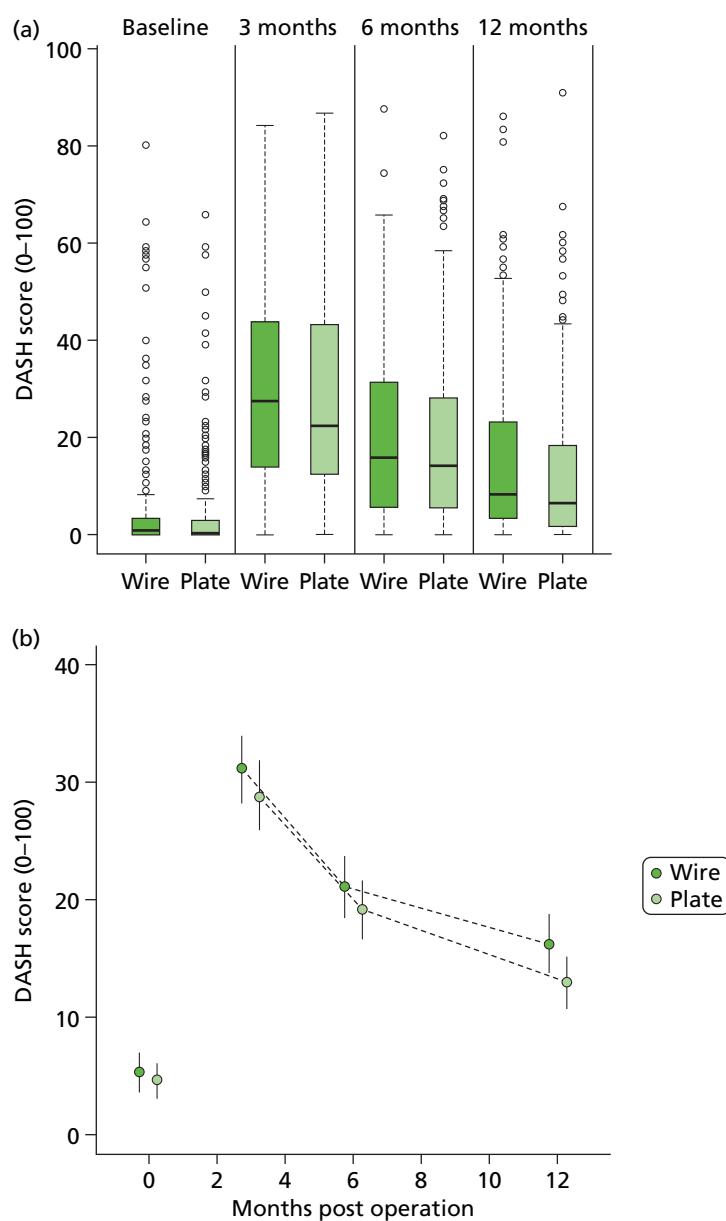


FIGURE 13 (a) Box plots of postoperative scores and (b) trends in means with 95% CIs for the DASH questionnaire scores.

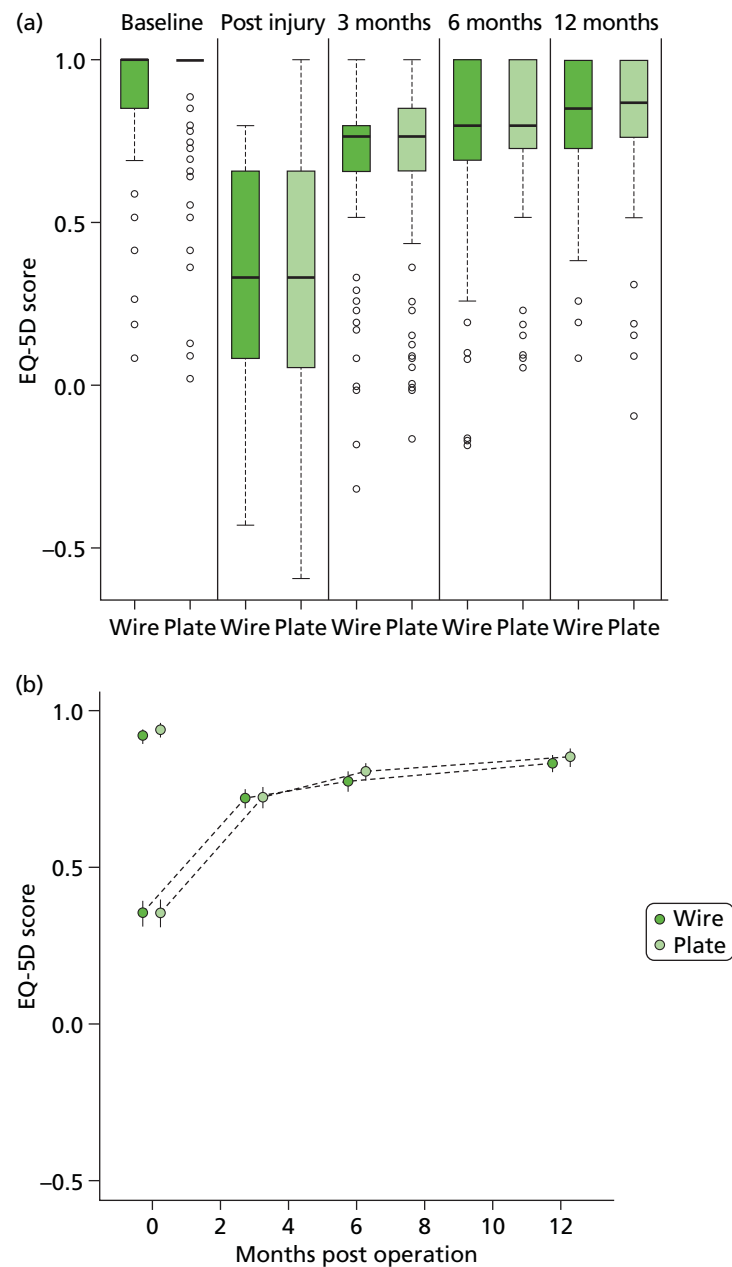


FIGURE 14 (a) Box plots of postoperative scores and (b) trends in means with 95% CIs for EQ-5D scores.

TABLE 17 Means and SDs of outcomes at 12 months postoperatively and estimated treatment effects after adjustment

Outcome	K-wire		Locking plate		Difference (95% CI)		p-value
	Mean (SD)	n	Mean (SD)	n	Raw	Adjusted ^a	
Primary outcome PRWE questionnaire score at 12 months in all participants							
All participants	15.3 (15.8)	211	13.9 (17.1)	204	−1.4	−1.3 (−4.5 to 1.8)	0.398
Primary outcome PRWE questionnaire score at 12 months in subgroups							
Aged < 50 years	13.2 (13.0)	52	15.3 (16.3)	49	2.0	1.4 (−5.0 to 7.8)	0.338
Aged ≥ 50 years	16.0 (16.5)	159	13.4 (17.4)	155	−2.6	−2.2 (−5.8 to 1.4)	
Intra-articular extension = no	16.7 (16.5)	110	13.2 (16.1)	105	−3.5	−3.3 (−7.6 to 1.1)	0.211
Intra-articular extension = yes	13.8 (14.9)	101	14.7(18.2)	99	0.9	0.7 (−3.8 to 5.2)	
Secondary outcomes at 12 months							
DASH	16.2 (17.9)	201	13.0 (15.6)	195	−3.3	−3.2 (−6.5 to 0.0)	0.051
EQ-5D	0.83 (0.19)	204	0.85 (0.19)	194	0.02	0.02 (−0.02 to 0.06)	0.353

^a Mixed effects regression based on a complete case analysis with treatment group, age group, sex and intra-articular extension as covariates (fixed effects) and recruiting centre as a random effect; *p*-values are from analysis of variance (ANOVA) *F*-test.

The ≥ 50 years age group formed a sizeable subgroup of patients; therefore, this was identified a priori as being of particular interest. The adjusted estimate of the treatment effect for the full population is -2.2 (95% CI -5.8 to 1.4) in favour of the locking-plate group; the *p*-value of 0.338 indicates there is no evidence for a significant interaction term between age group and treatment group.

There was some evidence for a small and marginally significant (*p* = 0.051) treatment effect for the DASH score at 12 months in favour of the locking-plate group, although the effect size was small, at -3.2 (95% CI -6.5 to 0.0). As for the PRWE questionnaire scores, an interaction test provided no evidence that the treatment effect for DASH differed between age groups (*p* = 0.309) and the small improvement in function for the plate group is evident in the over-50-years age group only. EQ-5D failed to show any significant differences between treatment groups.

A likelihood ratio test provided no strong evidence to support the inclusion of a random-effect to model hospital centre (*p* = 0.119; chi-squared test) for the primary outcome measure, PRWE questionnaire score. In addition, the effects of age group, sex and intra-articular extension were not significant (at the 5% level) in the fitted model for PRWE questionnaire scores [*p*-values 0.764, 0.090 and 0.462; *F*-tests from analysis of variance (ANOVA)]. Therefore, the inferences for the PRWE questionnaire scores would be approximately equivalent to the above if a simple *t*-test had been used to compare treatment groups (*t*-test; *p* = 0.396 and 95% CI for raw difference -4.5 to 1.8). The above analyses are based on assumed approximate normality of the residuals for the PRWE questionnaire score at 12 months; the box plots in *Figure 12* suggest that this approximation is poor. The median 12-month PRWE questionnaire scores were 9.0 for the K-wire group and 7.5 for the locking-plate group, and a Mann-Whitney test also provided no evidence to suggest that the treatment groups differed significantly (0.127). Inferences for the DASH questionnaire score were also equivalent between unadjusted and adjusted analysis (*t*-test; *p* = 0.055 and 95% CI for raw difference -6.6 to 0.1); median DASH questionnaire scores were 8.3 for the K-wire group and 6.7 for the locking-plate group, and a Mann-Whitney test also provided some evidence to suggest that the treatment groups differed significantly (0.071).

An adjusted per-protocol analysis of the PRWE questionnaire gave an adjusted treatment effect estimate of -1.0 (95% CI -4.2 to 2.2) and p -value equal to 0.530 . An adjusted per-protocol analysis of the DASH questionnaire gave an adjusted treatment effect estimate of -3.1 (95% CI -6.3 to 0.2) and p -value equal to 0.066 .

Missing data

There are 46 study participants with missing data at the 12-month study end point; the data are 90.0% (415 out of 461) complete. A summary of missing values, by age group and sex, for the PRWE questionnaire at 12 months is shown in *Table 18* and the full pattern of missing values is shown in *Tables 19* and *20* for K-wire and locking-plate groups, respectively. Baseline data, age group, hospital, treatment allocation, intra-articular extension and sex were all complete.

Tables 19 and *20* show that 336 study participants ($n = 168 + n = 168$) had complete score data on all occasions. There is no evidence that missingness patterns differed between treatment groups. Forty-five study participants did not provide PRWE questionnaire score data at 12 months: 19 in the K-wire group and 26 in the locking-plate group. The data were 90% complete for the primary outcome measure. In total, only 19 study participants had no post-baseline data: eight in the wire group and 11 in the plate group.

Logistic regression, with missing data coded as 1 and complete data as 0, indicated that age group and sex were predictive of the PRWE questionnaire score missingness at 12 months; p -values from chi-squared tests for including age and sex in the logistic regression model were 0.017 and 0.022 respectively. Males were more likely not to complete questionnaires than females, and those < 50 years were less likely to complete questionnaires than those ≥ 50 years of age. This is clearly apparent from an inspection of *Table 19*.

Study participants aged < 50 years and males were less likely to provide complete data; experience suggests this is not an unexpected result. Assuming that missingness is fully explained by these variables (for which we have complete data), that is assuming that data are missing at random, our approach to the analysis in which we adjust for the variables that are predictive of missingness is sensible and should yield unbiased estimates of the treatment effect.

Imputing the missing data and rerunning the analysis on fully complete data provides a useful sensitivity analysis. Missing data were imputed using the mice package in R (multiple imputation by chained equations; <http://cran.r-project.org/web/packages/mice/>) and pooled estimates³⁵ of model parameters based on 50 data imputations were obtained for the mixed-effects regression models reported in *Table 9*. The pooled estimates of the treatment group effect were -1.2 (95% CI -4.2 to 1.9) for the PRWE and -3.2 (95% CI -6.2 to -0.1) for the DASH questionnaire scores, with the percentage of the variability attributable to the uncertainty caused by the missing data estimated at 5.8% and 5.5% for the two outcome measures respectively. In summary, the inferences based on the complete data, after imputation, are not markedly different from those reported from the complete case analysis in *Table 18*.

TABLE 18 Data completeness for the PRWE questionnaire at 12 months by age group and sex

Age (years)	Sex	Data, n	Missing, n	Total, n	% data missing
< 50	Female	73	8	81	9.9
	Male	28	11	39	28.2
≥ 50	Female	281	23	304	7.6
	Male	33	4	37	10.8
Total		415	46	461	10.0

TABLE 19 Counts of missing and complete data for the wire group at baseline, injury (EQ-5D only), 3 months, 6 months and 12 months DASH, PRWE and EQ-5D scores

Treatment	n	Baseline		Injury		3 months		6 months		12 months	
		PRWE	DASH	EQ-5D	EQ-5D	PRWE	DASH	EQ-5D	PRWE	DASH	EQ-5D
K-wire	168	1	1	1	1	1	1	1	1	1	1
	3	1	1	1	1	1	0	1	1	1	1
	4	1	1	1	1	1	1	1	1	1	1
	3	1	1	1	1	1	1	1	1	0	1
	6	1	1	0	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	0	1	1	1
	1	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	0	1
	1	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	0	1	1	1	1
	2	1	1	1	1	1	1	0	1	1	1
	4	1	1	1	1	1	1	1	1	0	0
	1	1	1	1	1	1	1	0	1	1	0
	1	1	1	1	1	1	1	1	1	1	1
	4	1	1	1	1	1	0	1	1	1	1
	1	1	1	1	1	1	1	1	1	1	1
	3	1	1	1	1	1	1	1	1	0	0

continued

TABLE 19 Counts of missing and complete data for the wire group at baseline, injury (EQ-5D only), 3 months, 6 months and 12 months DASH, PRWE and EQ-5D scores (*continued*)

Treatment	n	Baseline			Injury			3 months			6 months			12 months		
		PRWE	DASH	EQ-5D	EQ-5D	DASH	PRWE	EQ-5D	DASH	PRWE	EQ-5D	DASH	PRWE	EQ-5D	DASH	EQ-5D
	1	1	1	1	1	0	1	0	0	1	0	0	1	0	1	1
	1	1	1	1	1	1	1	1	1	1	0	0	0	1	0	0
	1	1	1	1	1	0	1	0	0	0	0	0	1	0	1	1
	1	1	1	1	1	1	1	1	1	0	0	0	1	0	0	0
	2	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	6	1	1	1	1	0	0	0	0	0	0	0	1	0	1	1
	1	1	1	1	1	0	0	0	0	1	1	1	0	0	0	0
	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0
	1	1	1	1	1	0	0	0	0	1	0	0	0	0	0	0
	1	1	1	1	1	0	0	0	0	1	1	1	0	0	0	0
	1	1	1	1	1	0	0	0	0	1	0	0	0	0	0	0
	1	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	1	1	1	1	1	0	0	0	0	1	0	0	0	0	0	0
	1	1	1	1	1	0	1	0	0	0	0	0	0	0	0	0
	8	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
Total	230	1	1	1	7	27	18	25	35	22	30	29	19	26		

Missing data are indicated by 0 and complete data by 1.

TABLE 20 Counts of missing and complete data for the plate group at baseline, injury (EQ-5D only), 3 months, 6 months and 12 months DASH, PRWE and EQ-5D scores

Treatment	n	Baseline		Injury		3 months		6 months		12 months	
		PRWE	DASH	EQ-5D	EQ-5D	PRWE	DASH	EQ-5D	PRWE	DASH	EQ-5D
Locking plate	168	1	1	1	1	1	1	1	1	1	1
	2	1	0	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	0	1	1	1	1
	2	1	1	1	1	1	1	1	1	0	1
	2	1	1	0	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	0	1	1	1
	4	1	1	1	1	1	1	1	1	1	0
	3	1	1	1	1	1	1	1	1	1	1
	1	1	1	0	1	1	0	1	1	1	1
	3	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	0	0
	5	1	1	1	1	0	0	0	1	1	1
	2	1	1	1	1	1	1	1	0	0	0
	4	1	1	1	1	1	1	1	1	0	0
	2	1	1	1	1	1	1	1	1	1	1
	1	1	1	0	1	1	1	1	0	0	1

continued

TABLE 20 Counts of missing and complete data for the plate group at baseline, injury (EQ-5D only), 3 months, 6 months and 12 months DASH, PRWE and EQ-5D scores (*continued*)

Treatment	n	Baseline			Injury			3 months			6 months			12 months		
		PRWE	DASH	EQ-5D	EQ-5D	DASH	PRWE	PRWE	DASH	EQ-5D	PRWE	DASH	EQ-5D	PRWE	DASH	EQ-5D
	1	1	1	1	1	1	1	1	0	0	1	0	1	1	0	0
	1	1	1	1	1	1	1	1	1	1	1	0	0	1	0	0
	1	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	1	1	1	1	1	1	1	1	1	1	0	0	0	1	0	0
	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0
	1	1	1	1	1	1	0	0	0	0	0	0	0	1	1	1
	1	1	1	1	1	1	0	0	0	0	1	0	1	1	0	0
	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	0
	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0
	7	1	1	1	1	1	1	0	1	1	0	0	0	0	0	0
	1	1	1	1	1	1	1	0	0	0	1	1	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0
	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0
	2	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0
	10	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	231	2	4	2	6	24	20	24	24	24	25	32	37	27	36	37

Missing data are indicated by 0 and complete data by 1.

Complications

Complications were reported by participants at the 6-week follow-up assessment, and also at any point during the first 12 months of follow-up using the study adverse event reporting procedures. *Table 21* shows numbers of patients reporting complications by treatment group.

There was no evidence to suggest that rates for any of the reported complications (e.g. wound infections) differed between treatment groups, based on comparing counts in groups using Fisher's exact test. The proportion of participants given a cast after the operation differed between treatment groups, as expected, as did, consequently, the number of plaster changes required.

TABLE 21 Complications based on patient-reported events at the 6-week assessment and adverse events within 12 months of operation

Complication	K-wire (<i>n</i> = 230)		Locking plate (<i>n</i> = 231)		<i>p</i> -value ^a
	No, <i>n</i>	Yes, <i>n</i>	No, <i>n</i>	Yes, <i>n</i>	
Cast and dressing					
Cast after operation	5	224	57	171	<0.001
Dressing change	215	12	219	11	0.834
Plaster change	187	42	211	17	0.001
Postoperative complications					
Refracture	225	2	226	2	1.000
Neurological injury	215	14	210	20	0.373
Vascular injury	229	0	228	0	1.000
Tendon injury	225	4	223	6	0.751
Superficial wound infection	209	18	216	12	0.264
Deep wound infection	226	1	227	1	1.000
Treatment					
Antibiotics	217	13	220	11	0.682
Removal of metalwork	223	7	220	11	0.472
Debridement	228	2	230	1	0.623
Revision	222	5	226	2	0.285

a Fisher's exact test.

Chapter 4 Results of economic analysis

Introduction

The health economics analysis was designed to provide an economic evaluation of distal radial fractures treated by volar locking-plate fixation compared with K-wire fixation. The aim was to assess the cost-effectiveness of distal radial fractures treated by volar locking-plate fixation versus K-wire fixation from the NHS perspective. A societal perspective for costs was adopted for sensitivity analysis.

Unit cost data

Unit cost of resource use

Individual-level resource use was combined with unit costs to calculate the total health-care use cost for each patient. In order to convert resource usage figures into costs, unit cost figures were assigned from national databases such as the PSSRU Costs of Health and Social Care 2012³⁴ and the Department of Health's National Schedule of Reference Costs.³⁹ Further inpatient care following the initial operation was costed as Minimal Elbow and Lower Arm Procedures for Non-Trauma (HRG codes HB79Z and HB73Z) except if surgical hand complications such as metal removal or debridement were reported at 6-week follow-up, where inpatient stay was costed as Minor Elbow and Lower Arm Procedures for Trauma (HRG codes HA73B and HAB73C). All costs were adjusted to 2012 prices using the Campbell and Cochrane Economics Methods Group and Evidence for Policy and Practice Information and Coordinating Centre Cost Converter.⁴⁰ Table 22 presents the summary of unit costs.

TABLE 22 Summary of patient-reported health-care use and associated unit costs

Item	Unit cost (£)	Source
Initial operation		
Cost for average distal fracture surgery (≥ 19 years)	1983.39	National schedule of reference costs year 2011–2012 – Minor Elbow and Lower Arm Procedures for Trauma – HA73C ³⁹
Day case	1375.34	National schedule of reference costs year 2011–2012 – Minor Elbow and Lower Arm Procedures for Trauma – HA73C ³⁹
Adjustment per day \pm average LOS (≥ 19 years)	278.07	National schedule of reference costs year 2011–2012 – Elective Inpatient Excess day – HA73C ³⁹
Average LOS for distal fracture	0.95 days	Trial data
VLP: average LOS	0.98 days	Trial data, <i>t</i> -test, <i>p</i> = 0.696
K-wire: average LOS	0.92 days	Trial data
Average surgery time	53.57 minutes	Trial data
VLP: average surgery time	70.00 minutes	Trial data, <i>t</i> -test, <i>p</i> = 0.000
K-wire: average surgery time	37.18 minutes	Trial data
VLP: implant + consumables	818.26	UHCW
K-wires: implant + consumables	54.23	UHCW

continued

TABLE 22 Summary of patient-reported health-care use and associated unit costs (*continued*)

Item	Unit cost (£)	Source
Subsequent inpatient care		
<i>Inpatient (orthopaedics – wrist/arm)</i>		
Cost for average LOS	2064.71	National schedule of reference costs year 2011–2012 – HB79Z ³⁹
Day case	692.04	National schedule of reference costs year 2011–2012 – HB79Z ³⁹
Adjustment per day \pm average LOS	302.01	National schedule of reference costs year 2011–2012 – HB73Z ³⁹
<i>Inpatient (orthopaedics – other bones)</i>		
Cost for average LOS	3556.04	National schedule of reference costs year 2011–2012 – HB99Z ³⁹
Day case	928.36	National schedule of reference costs year 2011–2012 – HB99Z ³⁹
Adjustment per day \pm average LOS	293.08	National schedule of reference costs year 2011–2012 – HB99Z ³⁹
<i>Inpatient (other non-surgery)</i>		
Cost for average LOS	2688.10	National schedule of reference costs year 2011–2012 – HB91Z ³⁹
Day case	602.61	National schedule of reference costs year 2011–2012 – HB91Z ³⁹
Adjustment per day \pm average LOS	261.21	National schedule of reference costs year 2011–2012 – HB91Z ³⁹
<i>Inpatient (other)</i>		
Rehabilitation unit	985.00	PSSRU 2012, p. 114, weekly service costs per bed ³⁴
Outpatient care		
Orthopaedics ^a	103.72	National schedule of reference costs year 2011–2012 – 110T ³⁹
Pathology ^b (for blood tests)	60.74	National schedule of reference costs year 2011–2012 – 822 ³⁹
Radiology (for radiographs, per event)	153.21	National schedule of reference costs year 2011–2012 – 811 ³⁹
Physiotherapy (per session)	40.70	National schedule of reference costs year 2011–2012 – 650 ³⁹
Primary and community care		
GP surgery visit	40.00	PSSRU 2012, pp. 182–3, £3.40 per minute, average 11.7 minutes per visit ³⁴
GP clinic visit	58.00	PSSRU 2012, pp. 182–3, £4.3 per minute, 17.2 minutes per visit ³⁴
GP home visit	101.00	PSSRU 2012, pp. 182–3, £258 per hour, average 23.4 minutes per visit ³⁴
GP phone contact	24.00	PSSRU 2012, pp. 182–3, 7.1 minutes per contact ³⁴
Practice nurse surgery visit	11.63	PSSRU 2012, pp. 180–1, £45 per hour, average 15.5 minutes per visit ³⁴
Practice nurse home visit	18.75	PSSRU 2012, pp. 180–1, £45 per hour, average 25 minutes per visit ³⁴
Practice nurse phone contact	3.50	PSSRU 2012, pp. 180–1, £35 per hour, average 6 minutes per visit ³⁴
District nurse surgery visit	10.85	PSSRU 2012, p. 175, £42 per hour, average 15.5 minutes per visit ³⁴
District nurse home visit	21.83	PSSRU 2012, p. 175, £61 per hour, average 20 minutes per visit ³⁴
District nurse phone contact	4.20	PSSRU 2012, p. 175, £42 per hour, average 6 minutes per visit ³⁴
Physiotherapist surgery visit	15.00	PSSRU 2012, p. 167, £30 per hour, average 30 minutes per visit ³⁴
Physiotherapist home visit	44.16	PSSRU 2010, p. 151, £39 per hour, average 60 minutes per visit, inflated
Occupational therapist surgery visit	15.00	PSSRU 2012, p. 167, £30 per hour, average 30 minutes per visit ³⁴
Occupational therapist home visit	44.16	PSSRU 2010, p. 151, £39 per hour, average 60 minutes per visit ³⁴
GP, general practitioner; LOS, length of stay; VLP, volar locking plate.		
a This includes seeing a surgeon.		
b This is the standardised cost per event including the costs of activities relating to pathology testing; an average of 10 units of pathology testing can be required in each event.		

Unit cost of medications

Unit costs for medications were obtained from the BNF No. 67 (September 2013)⁴¹ and the NHS Electronic Drug Tariff (October 2013).⁴² Patients reported details for medications that were taken within the three budgetary periods (discharge to 3 months, 3–6 months, 6–12 months), including the quantity taken per day and the number of days. We calculated the total medication costs using the average cost per dose for each product and the mean quantity taken per day during the reported number of days. Where a dose range reported 'as required', we included the cost of one box of the drug. We assumed that all medications were in tablet form unless stated. If the dose of the drug was not recorded, we assumed the patient received the same dosage as other patients who reported the same drugs. If the quantity was not recorded, we applied the average quantity for that drug as reported in the data. *Table 23* shows all the unit costs for the drugs that were reported in the trial.

TABLE 23 Summary of patient-reported medication use and associated unit costs

Item	Unit cost (£) ^a	Source
Alendronic acid	1.44	10 mg (from pack of 28)
Alendronic acid	1.10	70 mg (from pack of 4)
Amitriptyline	0.84	10 mg (from pack of 28)
Amitriptyline	0.83	25 mg (from pack of 28)
Amoxicillin	0.95	250 mg (from pack of 21)
Aspirin	0.76	75 mg (from pack of 28)
Atenolol	0.83	100 mg (from pack of 28)
Atorvastatin	1.89	10 ml (from pack of 28)
Bendroflumethiazide	0.81	2.5 mg (from pack of 1)
Bisoprolol	1.02	5 mg (from pack of 28)
Calcium carbonate chewable	9.33	(From pack of 100)
Calcium salts (ADCAL®, ProStrakan)	7.25	(From pack of 100)
Calcium salts (Cacit®, Warner Chilcott)	11.81	(From pack of 76)
Citalopram	1.31	10 mg (from pack of 28)
Clarithromycin	2.52	250 mg (from pack of 14)
Co-amoxiclav	2.34	250 mg (from pack)
Cocodamol	3.54	30 mg (from pack of 100)
Cocodamol (Solphadol®, Sanofi-Aventis)	6.74	(From pack of 100)
Codeine	2.26	30 mg (from pack of 30)
Co-dydramol	1.06	500 mg (from pack of 30)
Cholecalciferol (ADCAL-D3®, ProStrakan)	3.84	1500 mg (from pack of 56)
Cholecalciferol (Calceos®, Innotech International)	3.62	(From pack of 60)
Cholecalciferol (Calcichew-D3®, Takeda)	4.24	(From pack of 60)
Cholecalciferol (Calfovit D3®, Menarini)	4.32	(From pack of 30)
Cholecalciferol (Fultium®, Internis)	8.44	(From pack of 84)
Diclofenac	1.42	50 mg (from pack of 84)
Diclofenac (Voltarol®, Novartis)	3.46	25 mg (from pack of 30)
Dihydrocodeine	5.18	60 mg (from pack of 56)
Enalapril maleate	0.95	10 mg (from pack of 28)

continued

TABLE 23 Summary of patient-reported medication use and associated unit costs (*continued*)

Item	Unit cost (£) ^a	Source
Ergocalciferol	30.34	1.25 mg (from pack of 50,000)
Esomeprazole (Nextum®, AstraZeneca)	25.19	40 mg (from pack of 28)
Eye drops	2.80	(From pack of 10)
Ferrous sulphate	1.01	(From pack of 28)
Flucloxacillin	1.77	250 mg (from pack of 1)
Flucloxacillin	2.89	500 mg (from pack of 28)
Furosemide	0.80	20 mg (from pack of 28)
Ibuprofen	1.44	200 mg (from pack of 84)
Ibuprofen	1.73	400 mg (from pack of 84)
Ibuprofen (gel)	2.13	50 g (from pack of 1)
Lansoprazole (Prevacid®, Takeda)	1.20	15 mg (from pack of 28)
Lercanidipine	4.98	10 mg (from pack of 28)
Meloxicam	1.54	15 mg (from pack of 30)
Meptazinol (Meptid®, Almirall Ltd)	22.11	200 mg (from pack of 112)
Mirtazapine	3.08	15 mg (from pack of 28)
Morphine	11.21	10 mg (from pack of 1)
Morphine salts (Oramorph®, Boehringer Ingelheim)	1.78	10 mg (from pack of 100)
Naproxen	1.25	250 mg (from pack of 28)
Naproxen	1.65	500 mg (from pack of 28)
Nefopam	10.54	30 mg (from pack of 90)
Nefopam hydrochloride (Acupan®, iNova Pharmaceuticals)	10.54	30 mg (from pack of 90)
Nifedipine (Adalat®, Bayer)	7.23	5 mg (from pack of 84)
Olanzapine	1.17	2.5 mg (from pack of 28)
Omeprazole	1.62	10 mg/20 mg (from pack of 28)
Oxycodone	8.70	5 ml (from pack of 50)
Oxycodone hydrochloride (OxyContin®, Purdue Pharma)	49.82	20 mg (from pack of 56)
Oxycodone hydrochloride (OxyContin®, Purdue Pharma)	74.81	30 mg (from pack of 56)
Paracetamol	0.16	500 mg (from pack of 16)
Polymyxins (Polyfax®, TEVA UK)	3.26	4 g (from pack of 1)
Pregabalin	2.77	400 mg (from pack of 84)
Risedronate	19.12	35 mg (from pack of 4)
Ramipril (capsules)	1.39	10 mg (from pack of 28)
Strontium ranelate (Protelos®, Servier)	25.60	2 g (from pack of 28)
Tibolone (Livial®, Merck Sharp and Dohme)	10.36	2.5 mg (from pack of 28)
Tamoxifen	5.71	10 mg (from pack of 30)
Tramadol	1.14	50 mg (from pack of 30)
Venlafaxine (Efexor®, Effexor® and Trevilor®, Pfizer)	2.62	37.5 mg (from pack of 56)
Topical NSAIDs (Voltarol Emulgel®, Novartis)	1.55	(From pack of 20)
Zopiclone	1.30	(From pack of 28)

^a It is defined as the cost of a given package of a product.

Unit cost of aids and adaptations

Patients reported any equipment that they had used to protect their injury or make their daily life easier to manage and the number of those. A number of aids and adaption tools were suggested and patients could add other equipment that was not in the list. Unit costs for aids and adaptations were taken from the website MobilitySmart (www.mobilitysmart.cc/), accessed in October 2013, which supplies the NHS and the PSSRU Costs of Health and Social Care 2012.³⁴ We calculated the total aids costs using the number of aids and the cost for each product. If the quantity was not recorded, we applied the average quantity for that aid as reported in the data. Reported aids and adaptations and unit prices are available in *Table 24*. Those costs were incurred by the NHS.

Intervention costs

The initial fixation surgery cost was based on the initial hospital stay and the operative cost (see *Table 22*). The cost of the initial distal radial fracture fixation surgery was assessed using NHS reference costs and HRG code HA73B (Minor Elbow and Lower Arm Procedures for Trauma). Costs for the initial operative period were identified for each patient using the average length of stay as reported in the patient records for the primary surgery. They were assumed to be £1375.34 for a day case or £1983.39 for overnight admission. We used excess bed-day costs when patient experience a length of stay beyond the average length of stay reported. For example, the cost to NHS was £1375.34 if a patient was discharged the same day, £1983.39 if the patient was referred to overnight hospital care at least one night but no more than the average length of stay; extra bed-day costs (based on a bed-day cost of £278.07) were added if a patient stayed more than the average length of stay. This cost was taken to include all expenditures incurred prior to discharge, including any items provided to patients before departure.

The operative costs for both volar locking-plate and K-wire fixations were provided by UHCW finance department; these included implant costs and consumables and are reported in *Table 25*.

The total cost of each arm of the trial was calculated combining the resource use and unit cost data along with the initial surgery cost.

Societal costs

Costs from the societal perspective were calculated by combining productivity loss and loss of earnings due to work absence, private costs such as treatments within private settings and out-of-pocket expenses incurred as a result of the wrist surgery, and reported use of Personal Social Services related to the treatment. We assumed that the Personal Social Services costs were unlikely to be directly supported by the NHS and this is why they were included in the societal perspective sensitivity analysis.

TABLE 24 Summary of patient-reported aids and adaptation equipment use and associated unit costs

Item	Unit cost (£)	Source
Wrist brace/splint	10.00	MobilitySmart
Grab rail	95.00	PSSRU 2012, p. 111, average total cost ³⁴
Dressing aids	5.95	MobilitySmart
Long-handle shoe horns	3.98	MobilitySmart
Bathing aids	23.35	MobilitySmart
Kitchen aids (jar/tin openers, etc.)	21.44	MobilitySmart

TABLE 25 Summary of the initial surgery theatre cost including consumables and prosthetic devices

Description of item	Code of item	Quantity used	Unit price (£)	Cost (£)
K-wire				
Reinforced gown XL	95224	2	3.74	7.48
Surgical visor masks	48247	2	1.01	2.03
Theatre masks	48100	2	0.06	0.11
Gammex gloves	351143	1	0.68	0.68
Biogel gloves	96180	2	1.14	2.28
Non-sterile gloves	8801	5	0.02	0.11
Image intensifier cover	39.00.02	3	2.49	7.47
Laceration pack	RMT9150	1	13.24	13.24
Surface wipes	CMW01X	6	0.03	0.18
Black bag		1	0.06	0.06
Yellow bag	UN3291	2	0.05	0.11
Polythene bag for extras		1	0.02	0.02
Inco pad	200995	2	0.13	0.26
K-wire	OS292160	3	2.94	8.82
Sterilisation of drill	TSU	1	10.00	10.00
Ethicon sutures	w319	1	1.22	1.22
Mepore 9 × 10 cm	r33334	1	0.16	0.16
Total for equipment used for K-wire surgery				54.23
Volar locking plate				
Surgical visor masks	48247	3	1.01	3.04
Theatre masks	48100	2	0.06	0.11
Gammex gloves	351143	1	0.68	0.68
Biogel gloves	96180	3	1.14	3.42
Non-sterile gloves	8801	6	0.02	0.14
Image intensifier cover	39.00.02	3	2.49	7.47
Upper limb pack	RMT9150	1	12.40	12.40
Surface wipes	CMW01X	6	0.03	0.18
Black bag		1	0.06	0.06
Yellow bag	UN3291	2	0.05	0.11
Polythene bag for extras		1	0.02	0.02
Inco pad	200995	2	0.13	0.26
Distal volar radius plate	DVRAW(L/R)	1	384.00	384.00
Shaft screws	CS(14)	3	27.00	81.00
Bar screws	FP(12)	6	44.00	264.00
Ethicon sutures	w319	1	1.22	1.22
Mepore 9 × 10 cm	r33334	1	0.16	0.16
Sterilisation of basic set	TSU	1	20.00	20.00
Sterilisation of drill	TSU	2	10.00	20.00
Sterilisation of distal volar radius set	TSU	1	20.00	20.00
Total for equipment used for volar locking plate surgery				818.26

Personal social services included number of weeks of frozen/hot meals on wheels, laundry services per load, and number of visits of carers and social workers. Unit costs were assigned using PSSRU and Information Centre of Personal Social Services in councils; they are reported in *Table 26*.

Patients reported their time off work in days or in terms of lost income because of their wrist fracture at every collection point. We employed a human capital approach using the gross median weekly pay rate for full-time employees from the Office for National Statistics (£506, April 2012)⁴⁴ and divided this by 5 to generate the cost of lost productivity per day.

Utility and quality-adjusted life-years

Patient health-related quality of life was assessed using the EQ-5D,⁴³ which was included along with the patient resource-use questionnaires. Changes in EQ-5D scores at baseline, 3 months, 6 months and 12 months were evaluated using two-sample *t*-tests to explore any important differences in these end points within the time frame of the trial. They are useful to understand the impact of the length of the follow-up on repeated measurements of the health outcome in which insufficiently long follow-up periods may potentially introduce biases in the subsequent cost-effectiveness analysis.

In line with the NICE reference case,³³ the primary outcome for the economic evaluation was QALY. Patient responses to the EQ-5D questionnaire at each time point were converted to QALYs using the standard UK tariff values⁴⁵ and an area under the curve approach. QALYs were calculated by multiplying these values with the time spent in each state, with quality of life linearly interpolated for the periods between the four observations provided in the trial data. QALYs represent a quality-weighted survival value in which 1 QALY is the equivalent of 1 year of full health. Average QALYs between adjacent time points were calculated to generate smoothed estimates between those time points.

Missing data

We calculated the mean total costs per patient from a NHS perspective adding the cost of inpatient stay, outpatient visit, consultations, medication, equipment, and applicable intervention costs for all patients where response data were available. Respondents who fail to complete individual items of the EQ-5D are not allocated a utility index score. From the overall sample, missing data represented 7.07%. Importantly, the health economics criteria for inclusion were slightly more restrictive than those for the statistical analysis. The complete data analysis was based on 278 patients.

For those cases in which neither resource usage nor quality-of-life data were available, these figures could not be calculated. We addressed missingness using two alternative methods.

TABLE 26 Summary of the reported personal social services and private costs and associated unit costs

Item	Unit cost (£)	Source
Personal social services		
Frozen meals on wheels (weekly)	41.40	Lewisham council, adult social care
Hot meals on wheels (weekly)	46.00	PSSRU 2012, p. 125 ³⁴
Laundry services (per load)	4.30	North Yorkshire social care
Care workers/help at home (per visit)	18.00	PSSRU 2012, p. 193 per weekday hour ³⁴
Social workers (per visit)	39.00	PSSRU 2012, p. 190 per hour ³⁴
Cost of lost productivity		
Days off work (per day)	101.20	Office for National Statistics – April 2012, median grossly week earning for full-time employees £506 ⁴⁴

We initially used the LOCF approach. Costs and EQ-5D values were carried forward for only one successive missing observation. Patients with more than one consecutive missing observation were omitted from the analyses. Observations were not carried backwards. The LOCF imputation analysis was then conducted on a sample of 367 patients. The advantage of the LOCF method is that it minimises the number of subjects who are eliminated from the analysis. However, the LOCF method has also been found to give a biased estimate of the treatment effect and underestimate the variability of the estimated result.^{46,47}

We then used multiple imputations via chained equations^{35,36} to complete missing data assuming missing at random and using Stata 12 (StataCorp LP, College Station, TX, USA). Missing cost data were predicted in terms of QALYs, treatment received, length of stay, age, gender, job status, patient's self-reported health status, PRWE questionnaire score and DASH questionnaire score. Missing QALY data were predicted in terms of this same list (excluding QALYs), plus each of the cost items. In order to remove implausible data, missing cost data were constrained to be positive. A total of 10 imputations were created to stabilise the result. The reported cost-effectiveness results were synthesised based on all imputed data sets.

Cost-effectiveness analysis

Our analysis was a cost-utility analysis over 12 months examining the cost per QALY gained for all patients. We initially undertook descriptive statistics of costs and EQ-5D scores and conducted parametric tests (Students' *t*-tests and ANOVA tests) to evaluate any important differences in the end points within the time frame of the trial. We then calculated ICERs by dividing the average difference in cost between the two arms by the average difference in QALYs between the two arms.

We also present cost-effectiveness scatter plots illustrating the uncertainty surrounding the cost-effectiveness estimates. The cost-effectiveness planes were derived using bootstrapping with replacement.

Sensitivity analyses were conducted to explore the impact of costs and missing data on the study results. First, the influence of outliers was evaluated; for this, participants with very large NHS health-care expenses were excluded from the analysis. These outliers may have a large effect on the mean cost and lead to different cost-effectiveness analysis results. Therefore, it is important, especially for policy-makers, to produce extreme scenarios to capture the worse and best cases. To evaluate the impact of missing data, the complete case analysis was conducted including only those participants with no missing data. The results of this analysis were compared with the results obtained through imputation using LOCF and then multiple imputations. We undertook the same analysis using costs from the societal perspective; this perspective includes the costs of use of personal social services, cost of lost productivity and private expenses in addition to the NHS costs. Finally, we carried out an adjusted analysis. To be consistent with the clinical analysis, we evaluated the cost-effectiveness by adjusting a set of characteristics at baseline such as gender, age, PRWE questionnaire score and DASH questionnaire score. Baseline EQ-5D score was also added to account for any possible baseline imbalance and to improve the precision of the estimates.

Cost-effectiveness results

Resource use and QALY data were available for 278 patients, with 137 patients receiving volar locking-plate fixation and 141 patients receiving K-wire fixation.

Health-care resource use

Table 27 presents the details of health-care resource used over the 12 months after discharge for complete case data. Resource use is broadly comparable between the two treatments. Patients were frequent users of physiotherapy outpatient visits (6.9 visits over the 12 months) and reported on average 3.6 radiology visits and 3.6 visits in orthopaedics outpatient visits. Use of general practitioner (GP) visits and nurse visits was infrequent. Patients reported using a wrist brace or splint. In terms of medications, we note that paracetamol tablets were the most reported medications in the questionnaires. No significant differences were observed between the two groups. Patients receiving K-wires appear to have used more bathing aids than patients receiving volar locking plates at a 10% significance level ($p = 0.087$).

TABLE 27 Use of health-care resources related to distal fracture fixation by each follow-up period and treatment arm (complete case)

Item	Dose	Mean usage (SD)		Difference: <i>p</i> -value of <i>t</i> -test
		K-wire (<i>n</i> = 141)	Volar locking plate (<i>n</i> = 137)	
Subsequent inpatient care				
Orthopaedics (wrist, arm, other bones)	–	0.383 (1.252)	0.343 (1.320)	0.796
Rehabilitation unit	–	0.007 (0.084)	0	0.325
Other surgery	–	0.170 (0.845)	0.117 (0.385)	0.500
Outpatient care				
Orthopaedics	–	3.340 (4.063)	3.788 (4.633)	0.392
Pathology	–	0.298 (1.423)	0.358 (1.464)	0.730
Radiology	–	1.801 (2.723)	2.197 (2.695)	0.225
Physiotherapy	–	6.128 (8.255)	7.584 (11.212)	0.218
Primary and community care				
In surgery				
GP	–	0.766 (2.144)	0.555 (1.212)	0.315
Practice nurse	–	0.113 (0.549)	0.080 (0.322)	0.541
Physiotherapist	–	0.879 (2.126)	0.854 (4.420)	0.951
Occupational therapist	–	0.071 (0.408)	0.088 (1.025)	0.858
In clinic				
GP	–	0	0.029 (0.241)	0.151
Practice nurse	–	0	0.007 (0.085)	0.311
District nurse	–	0	0	
Physiotherapist	–	0.241 (0.940)	0.409 (2.102)	0.389
Occupational therapist		0.014 (0.168)	0.051 (0.426)	0.340
At home				
Practice nurse	–	0.007 (0.084)	0	0.325
Physiotherapist	–	0.014 (0.168)	0	0.325
Occupational therapist	–	0.071 (0.842)	0	0.325
Aids and adaptation				
Wrist brace/splint	–	0.780 (1.076)	0.964 (1.239)	0.188
Grab rail	–	0.078 (0.464)	0.029 (0.270)	0.286
Dressing aids	–	0.071 (0.425)	0.109 (0.649)	0.557
Long-handle shoe horns	–	0.014 (0.168)	0.007 (0.085)	0.669
Bathing aids	–	0.021 (0.145)	0	0.087
Kitchen aids (jar/tin openers, etc.)	–	0.078 (0.687)	0.066 (0.406)	0.856
Medications				
Alendronic acid	10 mg	0.043 (0.235)	0.022 (0.147)	0.382
Alendronic acid	70 mg	0.220 (1.043)	0.0451 (0.3900)	0.077

continued

continued

TABLE 27 Use of health-care resources related to distal fracture fixation by each follow-up period and treatment arm (complete case) (*continued*)

Item	Dose	Mean usage (SD)		Difference: p-value of t-test
		K-wire (n = 141)	Volar locking plate (n = 137)	
Amitriptyline	10 mg	0.064 (0.600)	0.058 (0.683)	0.944
Amitriptyline	25 mg	0	0.029 (0.241)	0.151
Amoxicillin	250 mg	0	0.022 (0.256)	0.311
Aspirin	75 mg	0.028 (0.337)	0.073 (0.703)	0.499
Atenolol	100 mg	0	0.029 (0.342)	0.311
Atorvastatin	10 ml	0.028 (0.337)	0	0.325
Bendroflumethiazide	2.5 mg	0	0.657 (7.689)	0.311
Bisoprolol	5 mg	0.028 (0.337)	0	0.325
Calcium carbonate chewable	–	0.028 (0.205)	0.015 (0.171)	0.544
Calcium salts (ADCAL®, ProStrakan)	–	0.028 (0.205)	0.007 (0.085)	0.267
Calcium salts (Cacit®, Warner Chilcott)	–	0	0.007 (0.085)	0.311
Cholecalciferol (ADCAL-D3®, ProStrakan)	1500 mg	0.064 (0.418)	0.058 (0.482)	0.920
Cholecalciferol (Calceos®, Innotech International)	–	0.043 (0.376)	0.036 (0.307)	0.883
Cholecalciferol (Calcichew-D3®, Takeda)	–	0.035 (0.421)	0.066 (0.571)	0.615
Cholecalciferol (Calfovit D3®, Menarini)	–	0.007 (0.084)	0	0.325
Cholecalciferol (Fultium®, Internis)	–	0.014 (0.168)	0	0.325
Citalopram	10 mg	0.028 (0.337)	0	0.325
Clarithromycin	250 mg	0.007 (0.084)	0	0.325
Co-amoxiclav	250 mg	0	0.022 (0.256)	0.311
Cocodamol	30 mg	0.142 (0.661)	0.095 (0.541)	0.518
Cocodamol (Solphadol®, Sanofi-Aventis)	–	0	0.022 (0.256)	0.311
Codeine	30 mg	0.652 (3.408)	0.234 (1.208)	0.176
Co-dydramol	500 mg	0	0.044 (0.361)	0.151
Diclofenac	50 mg	0.043 (0.313)	0.051 (0.390)	0.840
Diclofenac (Voltarol®, Novartis)	25 mg	0	0.029 (0.208)	0.097
Dihydrocodeine	60 mg	0.121 (1.143)	0.095 (1.111)	0.850
Enalapril maleate	10 mg	0.007 (0.084)	0	0.325
Ergocalciferol	1.25 mg	0.007 (0.084)	0	0.325
Esomeprazole (Nextum®, AstraZeneca)	40 mg	0	0.029 (0.342)	0.311
Eye drops	–	0.128 (1.516)	0	0.325
Ferrous sulphate	–	0	1.020 (0.851)	0.155
Flucloxacillin	250 mg	0.794 (9.432)	0	0.325
Flucloxacillin	500 mg	0.014 (0.168)	0.015 (0.171)	0.984
Furosemide	20 mg	0.028 (0.337)	0	0.325
Ibuprofen	200 mg	0.092 (0.477)	0.102 (0.633)	0.882

TABLE 27 Use of health-care resources related to distal fracture fixation by each follow-up period and treatment arm (complete case) (*continued*)

Item	Dose	Mean usage (SD)		Difference: <i>p</i> -value of <i>t</i> -test
		K-wire (<i>n</i> = 141)	Volar locking plate (<i>n</i> = 137)	
Ibuprofen	400 mg	0.007 (0.084)	0.022 (0.190)	0.400
Ibuprofen (gel)	50 g	0.007 (0.084)	0	0.325
Lactulose	300 ml	0	1.314 (15.378)	0.311
Lansoprazole (Prevacid®, Takeda)	15 mg	0	0.029 (0.342)	0.311
Lercanidipine	10 mg	0	0.029 (0.342)	0.311
Meloxicam	15 mg	0	0.022 (0.256)	0.311
Meptazinol (Meptid®, Almirall Ltd)	200 mg	0	0.007 (0.085)	0.311
Mirtazapine	15 mg	0.014 (0.168)	0.029 (0.342)	0.641
Morphine	10 mg	0.397 (4.716)	0.044 (0.513)	0.384
Morphine salts (Oramorph®, Boehringer Ingelheim)	10 mg	0	0.007 (0.085)	0.311
Naproxen	250 mg	0.014 (0.168)	0.015 (0.171)	0.984
Naproxen	500 mg	0	0.015 (0.171)	0.311
Nefopam	30 mg	0	0.015 (0.171)	0.311
Nefopam hydrochloride (Acupan®, iNova Pharmaceuticals)	30 mg	0.007 (0.084)	0	0.325
Olanzapine	2.5 mg	0	0.029 (0.342)	0.311
Omeprazole	10 mg	0.007 (0.084)	0.029 (0.342)	0.457
Omeprazole	20 mg	0.035 (0.347)	0.029 (0.342)	0.880
Oxycodone	5 ml	0	0.007 (0.085)	0.311
Oxycodone hydrochloride (OxyContin®, Purdue Pharma)	20 mg	0.028 (0.337)	0	0.325
Oxycodone hydrochloride (OxyContin®, Purdue Pharma)	30 mg	0.028 (0.337)	0	0.325
Paracetamol	500 mg	2.702 (10.11)	1.285 (4.618)	0.136
Polymyxins (Polyfax®, TEVA UK)	4 g	0.298 (3.537)	0	0.325
Risedronate	35 mg	0.028 (0.337)	0.058 (0.482)	0.546
Ramipril (capsules)	10 mg	0	0.029 (0.240)	0.311
Strontium ranelate (Protelos®, Servier)	2 g	0	0.029 (0.342)	0.311
Tibolone (Livial®, Merck Sharp and Dohme)	2.5 mg	0.043 (0.505)	0	0.311
Tamoxifen	10 mg	0	0.022 (0.180)	0.311
Tramadol	50 mg	0.262 (1.850)	0.212 (1.160)	0.785
Zopiclone	–	0	0.007 (0.085)	0.311

Costs

The total costs associated with resource use during the trial among complete case data are shown in *Table 28*. The mean total NHS resource use costs are £3385 for K-wires and £4288 for volar locking plates and were significantly higher for volar locking plates (by £903). Lost earnings and productivity losses to employers through sickness absences appeared higher in the K-wire arm, but the difference does not appear to be significant. Overall, societal costs are on average £48 higher in the K-wire arm. However, there were no significant differences in NHS resource use costs and societal costs between the treatment arms according to the *t*-tests.

TABLE 28 Costs of resources used in relation to distal fracture fixation by treatment arms (not imputed)

Item	Parameter	K-wire (<i>n</i> = 141)	Volar locking plate (<i>n</i> = 137)	Difference: <i>p</i> -value of <i>t</i> -test
NHS resource use costs (£) ^a	Mean (SD)	3384.78 (2097.09)	4287.89 (2244.30)	
	Incremental (SE)	903.41 (260.43)		<0.001
Social care costs (£)	Mean (SD)	13.01 (105.37)	8.18 (57.97)	
	Incremental (SE)	−4.83 (10.24)		0.637
Private cost (£)	Mean (SD)	22.74 (123.57)	30.22 (158.78)	
	Incremental (SE)	7.48 (17.04)		0.372
Cost of lost productivity (£)	Mean (SD)	436.51 (1876.50)	316.06 (1481.78)	
	Incremental (SE)	−120.44 (203.16)		0.405
Societal costs (£, includes all the previous cost categories)	Mean (SD)	1984.10 (2679.43)	1936.48 (3299.80)	
	Incremental (SE)	−47.63 (360.04)		0.828

SE, standard error.
^a The costs also include implant costs and initial surgery costs.

Health outcomes

Table 29 details the EQ-5D scores at pre injury, baseline, 3 months, 6 months and 12 months in complete case data and when missing values are imputed. Both groups showed increasing EQ-5D scores from baseline to the last follow-up point; the most important increase is observed between baseline and 3-month follow-up point for both treatments, doubling the baseline EQ-5D score. It is noted that patients at 12 months have not recovered an EQ-5D score equivalent to their pre-injury, retrospectively reported, EQ-5D score.

On average, patients receiving a volar locking plate had higher EQ-5D index scores at baseline and at each follow-up point, but independent-sample *t*-tests indicated that the changes in EQ-5D score over time were not statistically significant. The average total number of QALYs over the 12 months was marginally higher in the volar locking-plate arm (0.745) than in the K-wire arm (0.731). Tables 30 and 31 provide the mean EQ-5D change scores between pre-injury and the follow-up points for the LOCF imputed analysis and multiple imputed data respectively. The same comments applied to the EQ-5D scores. The statistical tests indicated that there were no significant differences between EQ-5D scores at baseline for the two treatment arms, and, for this reason, adjustments on EQ-5D at baseline were not required.

TABLE 29 Mean EQ-5D index scores at the baseline and follow-up points and annual QALYs of distal fracture fixation by treatment arms (complete case data)

Time point	Parameter	K-wire (<i>n</i> = 141)	Volar locking plate (<i>n</i> = 137)	Difference: <i>p</i> -value of <i>t</i> -test
Retrospective pre injury	Mean (SD)	0.928 (0.170)	0.947 (0.149)	
	Incremental (SE)	0.019 (0.019)		0.320
Baseline	Mean (SD)	0.354 (0.303)	0.373 (0.317)	
	Incremental (SE)	0.019 (0.037)		0.611
3 months	Mean (SD)	0.725 (0.210)	0.739 (0.224)	
	Incremental (SE)	0.014 (0.026)		0.591
6 months	Mean (SD)	0.787 (0.193)	0.807 (0.183)	
	Incremental (SE)	0.020 (0.023)		0.366
12 months	Mean (SD)	0.842 (0.188)	0.845 (0.184)	
	Incremental (SE)	0.002 (0.022)		0.918
Total QALYs	Mean (SD)	0.731 (0.173)	0.745 (0.162)	
	Incremental (SE)	0.014 (0.020)		0.484

SE, standard error.

TABLE 30 Index scores for EQ-5D at the baseline and follow-up points and annual QALYs of distal fracture fixation by treatment arms (LOCF imputed data)

Time point	Parameter	K-wire (n = 187)	Volar locking plate (n = 180)	Difference: p-value of t-test
Retrospective pre injury	Mean (SD)	0.918 (0.176)	0.942 (0.142)	
	Incremental (SE)	0.024 (0.009)		0.149
Baseline	Mean (SD)	0.358 (0.307)	0.373 (0.323)	
	Incremental (SE)	0.015 (0.033)		0.641
3 months	Mean (SD)	0.714 (0.219)	0.722 (0.242)	
	Incremental (SE)	0.008 (0.024)		0.747
6 months	Mean (SD)	0.768 (0.216)	0.794 (0.195)	
	Incremental (SE)	0.026 (0.022)		0.225
12 months	Mean (SD)	0.824 (0.209)	0.841 (0.189)	
	Incremental (SE)	0.017 (0.021)		0.411
Total QALYs	Mean (SD)	0.717 (0.187)	0.735 (0.177)	
	Incremental (SE)	0.018 (0.019)		0.345

SE, standard error.

TABLE 31 Index scores for EQ-5D at the baseline and annual QALYs of distal fracture fixation by treatment arms (multiple imputed data)

Time point	Parameter	K-wire (n = 230)	Volar locking plate (n = 230)	Difference: p-value of t-test ^a
Retrospective pre injury	Mean (SD)	0.919 (0.169)	0.936 (0.154)	
	Incremental (SE)	0.075 (0.005)		0.259
Baseline	Mean (SD)	0.358 (0.305)	0.363 (0.323)	
	Incremental (SE)	0.070 (0.009)		0.856
Total QALYs	Mean (SD)	0.734 (0.167)	0.742 (0.160)	
	Incremental (SE)	0.013 (0.005)		0.649

SE, standard error.
^a The t-test reported for treatment is the multiple imputation version for the two-tailed t-test.

Cost-effectiveness results within the NHS perspective

Table 32 shows the total costs and QALY gains for each of the treatment arms. The differences in QALY gains between groups, 0.008 QALYs, were minimal and suggested only small health benefits of volar locking plates over K-wires. The volar locking-plate group had the highest QALY gains over the trial period. The mean total costs were higher for the volar locking-plate group; the high SD for the cost estimates indicates the presence of a few outlying individuals who incurred significant health service costs.

Table 33 provides the cost-effectiveness results, showing the incremental costs and benefits as well as the ICER. Interpretation should be tempered by considering the small between-group differences in QALY gains and the high level of uncertainty surrounding the QALY estimates. The results suggest that volar locking plates were more expensive than K-wires, with an incremental cost of £726.46, and had higher, albeit small, QALY gains.

TABLE 32 Total costs and QALY gains by treatment arm (NHS perspective, all patients)

Parameter	K-wires	Volar locking plate
<i>n</i>	230	230 ^a
Total QALY gain (SD)	0.734 (0.166)	0.742 (0.159)
Total cost (£) (SD)	3440.07 (2539.27)	4145.25 (2203.16)

a One patient was excluded from the health economic analysis as he did not complete the health economics questionnaire at any follow-up point.

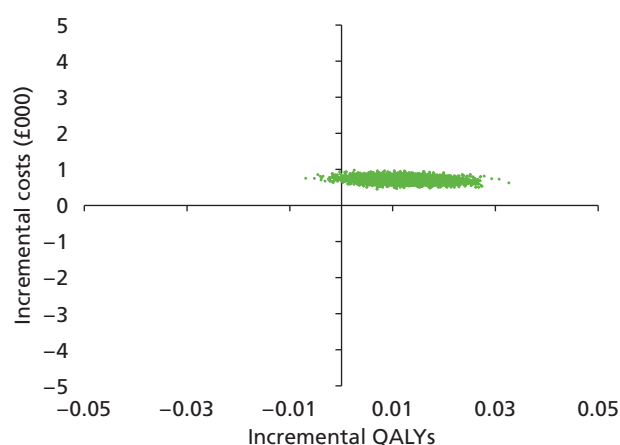
TABLE 33 Cost-effectiveness results (NHS perspective, all patients)

Treatment comparison	Incremental cost (£) (95% CI)	Incremental QALY gain (95% CI)	ICER (£)
Volar locking plate vs. K-wires	726.46 (588.44 to 864.48)	0.008 (−0.001 to 0.018)	89,322

We graphically represented the uncertainty of these cost-effectiveness estimates in a cost-effectiveness plane (*Figure 15*) using bootstrapping with 10,000 iterations. We sampled, at random with replacement, each of our 10 imputed data sets, producing 10,000 incremental cost and incremental QALY estimates. *Figure 15* shows that all the points are above the x-axis, indicating that the volar locking plate was more costly than K-wires, and more points are to the right of the y-axis, indicating that the volar locking plate produced more QALYs than K-wires.

The points lay in the north-east quadrant of the cost-effectiveness plane. In this area there is a trade-off between effect and cost: additional health benefit can be obtained but at a higher cost. The question that then arises is whether or not the trade-off is acceptable, that is if the health gain is worth the additional cost.⁴⁸ This decision is based on the ICER and what the decision-makers are willing to pay for the additional benefit. The guideline rule is the NICE threshold of £20,000–30,000 per QALY, and the ICER of volar locking plates versus K-wires equals £89,322 per QALY. Under these circumstances, volar locking plates cannot be considered cost-effective, as its ICER is above the £20,000–30,000 per QALY range.

The CEAC showing the probability that volar locking-plate fixation is cost-effective is presented in *Figure 16* with a range of cost-effectiveness WTP threshold values. The probability of being cost-effective at a WTP threshold of £20,000 per QALYs was nil and at a threshold of £30,000 was 3%.

**FIGURE 15** Cost-effectiveness plane generated from bootstrapped mean cost and QALY differences over 12 months (NHS perspective, all patients).

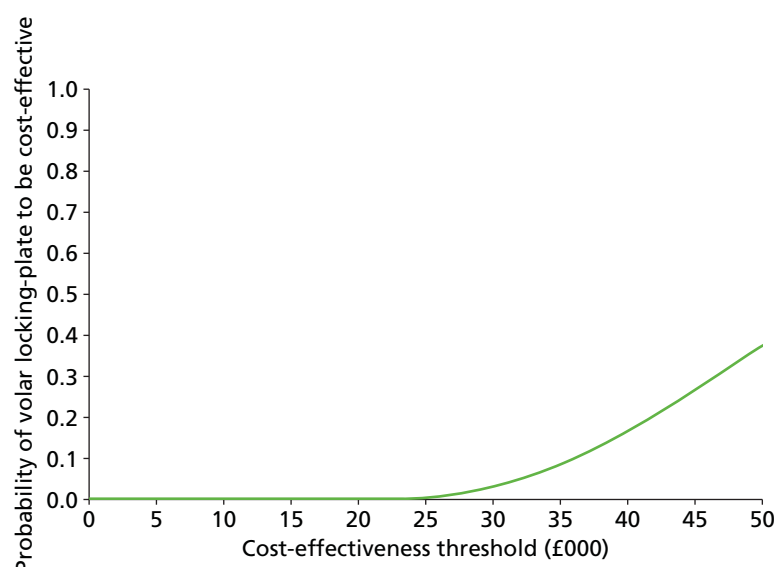


FIGURE 16 Cost-effectiveness acceptability curves at 12 months (NHS perspective, all patients).

Sensitivity analyses

We undertook a number of sensitivity analyses to test the robustness of the base-case results, which are presented in *Table 34*.

The first sensitivity analysis was based on complete-case data. This resulted in an incremental cost of £903 and an incremental QALY gain of 0.014, yielding an ICER of £64,026 per QALY.

The sensitivity analyses also expanded the cost-effectiveness analysis to the societal perspective. The incremental societal cost was £581 and the QALY gain was very comparable from the base-case analysis.

All the sensitivity analyses showed a higher mean cost and a higher but marginal QALY gain per patient receiving a volar locking plate. The ICERs of volar locking-plate fixation compared with K-wires were always more than £44,000 per QALY.

We also carried out cost-effectiveness analyses adjusting for the following baseline covariates including age, gender and EQ-5D scores. The adjusted analysis on the multiple imputations showed a lower incremental cost for a similar incremental QALYs gain both in the NHS and the societal perspectives; however, both ICERs remained above the cost-effectiveness threshold of £30,000 per QALY.

Subgroup analyses

The same analysis was then undertaken for patients < 50 years of age and patients ≥ 50 years of age, as the two age groups are assumed to present different types of fractures (high- and low-energy fractures) and so the impact of the fixation is expected to differ by age.

Table 35 shows the total costs and QALY gains for each of the treatment arms in each subgroup. Differences in QALY gains between groups were minimal in both age groups. The volar locking-plate group had the highest QALY gains in patients aged ≥ 50 years and K-wires had the highest QALY gains in younger patients. The mean total costs were higher for the volar locking-plate arm for both age subgroups. Older patients showed higher total costs than younger patients.

TABLE 34 Sensitivity analyses

Sensitivity analysis	Incremental cost (£) (95% CI)	Incremental QALY gain (95% CI)	ICER (£)
Unadjusted			
Complete-case data			
Volar locking plate vs. K-wires	903.41 (392.48 to 1414.34)	0.014 (−0.025 to 0.053)	64,026
LOCF imputed data			
Volar locking plate vs. K-wires	799.17 (284.07 to 1314.27)	0.018 (−0.019 to 0.055)	44,468
Societal perspective: multiple imputed data			
Volar locking plate vs. K-wires	581.00 (405.50 to 756.51)	0.010 (0.001 to 0.019)	58,852
Societal perspective: complete-case data			
Volar locking plate vs. K-wires	790.45 (59.54 to 1521.36)	0.014 (−0.025 to 0.053)	56,020
Adjusted			
Multiple imputations			
Volar locking plate vs. K-wires	285.93 (171.41 to 400.44)	0.009 (−0.015 to 0.032)	32,730.50
Complete-case data			
Volar locking plate vs. K-wires	907.44 (762.39 to 1052.50)	0.014 (−0.018 to 0.046)	64,662
LOCF imputed data			
Volar locking plate vs. K-wires	799.17 (692.15 to 906.19)	0.018 (−0.012 to 0.048)	44,468
Societal perspective: multiple imputed data			
Volar locking plate vs. K-wires	299.97 (157.68 to 442.26)	0.010 (−0.013 to 0.033)	30,385
Societal perspective: complete-case data			
Volar locking plate vs. K-wires	791.85 (567.72 to 1015.99)	0.014 (−0.018 to 0.046)	56,425
LOCF imputed data			
Volar locking plate vs. K-wires	799.17 (692.15 to 906.19)	0.018 (−0.012 to 0.048)	44,468

TABLE 35 Total costs and QALY gains by treatment arm (NHS perspective, all patients)

Parameter	K-wires	Volar locking plate
<i>n</i>	230	230
Patients aged ≥ 50 years		
Total QALY gain (SD)	0.72 (0.14)	0.74 (0.13)
Total cost (£) (SD)	3759.9 (538.8)	3972.8 (464.4)
Patients aged < 50 years		
Total QALY gain (SD)	0.77 (0.11)	0.75 (0.10)
Total cost (£) (SD)	2822.4 (499.9)	3218.6 (461.4)

Table 36 provides the cost-effectiveness results, showing the incremental costs and benefits as well as the ICER. Interpretation should be tempered by considering the small between-group differences in QALY gains and the high level of uncertainty surrounding the QALY estimates.

In the sample of patients aged ≥ 50 years, the evaluation suggests that patients treated with a volar locking-plate fixation gained 0.014 QALYs more than those treated with a K-wire fixation, at an increased cost of £752 per patient, yielding an ICER of £54,218 per QALY. Given a WTP of £20,000 for an additional QALY, the probability of volar locking plates being cost-effective is 46% based on the trial data, as shown in Figure 17.

In the sample of patients aged < 50 years, the evaluation suggests that volar locking-plate fixation is associated with both lower benefits and higher costs than if they are treated with K-wires. The K-wire fixation appears to dominate for this group of individuals.

Sensitivity analyses

We undertook a number of sensitivity analyses to test the robustness of the subgroup results, which are presented in Table 37.

The results based on the complete cases are the same as the main analysis for patients aged ≥ 50 years, showing an incremental QALY gain of approximately 0.02 and an incremental cost between £629 and £945, yielding ICERs higher than £35,323 per QALY. With regard to younger patients, the QALY gain was close to nil for patients aged < 50 years with an additional cost of £778, and K-wires would be a preferred option for cost-minimisation reasons.

TABLE 36 Subgroups cost-effectiveness results

Parameter	Incremental cost (£) (95% CI)	Incremental QALY gain (95% CI)	ICER (£ per QALY)
Patients aged ≥ 50 years			
Volar locking plate vs. K-wires	752.45 (538.88 to 921.03)	0.014 (0.002 to 0.025)	54,218
Patients aged < 50 years			
Volar locking plate vs. K-wires	652.81 (425.26 to 880.37)	-0.008 (-0.024 to 0.008)	-81,601 (K-wires dominates)

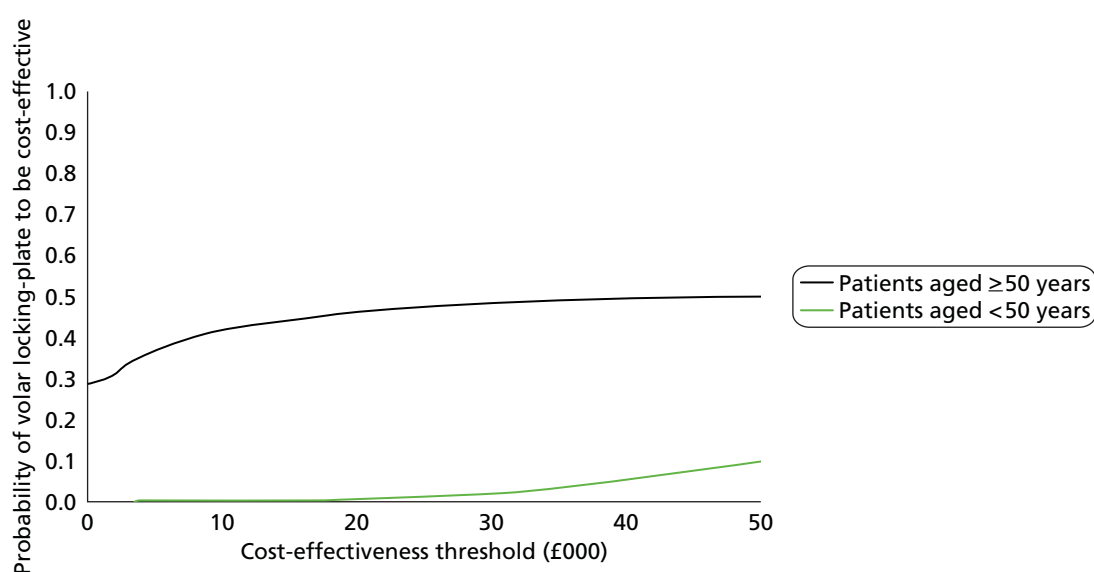


FIGURE 17 Cost-effectiveness acceptability curves by age subgroups at 12 months (NHS perspective).

TABLE 37 Subgroups sensitivity analyses

Parameter	Incremental cost (£) (95% CI)	Incremental QALY gain (95% CI)	ICER (£ per QALY)
Patients aged ≥ 50 years			
<i>Complete-case data</i>			
Volar locking plate vs. K-wires	944.93 (323.03 to 1566.83)	0.019 (−0.030 to 0.067)	50,959
<i>LOCF imputed data</i>			
Volar locking plate vs. K-wires	858.60 (227.88 to 1489.32)	0.021 (−0.025 to 0.067)	41,018
<i>Societal perspective: multiple imputed data</i>			
Volar locking plate vs. K-wires	628.57 (411.69 to 845.45)	0.018 (0.007 to 0.029)	35,323
Patients aged < 50 years			
<i>Complete-case data</i>			
Volar locking plate vs. K-wires	778.34 (−112.83 to 1669.52)	0.001 (−0.065 to 0.068)	590,973
<i>LOCF imputed data</i>			
Volar locking plate vs. K-wires	621.14 (−221.54 to 1463.83)	0.007 (−0.051 to 0.066)	83,114
<i>Societal perspective: multiple imputed data</i>			
Volar locking plate vs. K-wires	446.24 (172.32 to 720.15)	−0.013 (−0.028 to 0.003)	−34,326 (K-wires dominates)

Summary

The results showed that patients with distal radius fractures did not show differences in QALY gain when treated with the volar locking-plate fixation or the K-wires. However, volar locking-plate fixation presented positive incremental costs. This difference was driven by the higher cost of delivery of the volar locking-plate fixation (£818.26 vs. £54.23); this cost was not offset through decreases in health-care resource use during the 12-month follow-up after discharge. The incremental cost of volar locking-plate fixation was £726 (95% CI £588.44 to £864.48) from an NHS perspective and £581 (95% CI £405.50 to £756.51) from a societal perspective.

The base-case analysis based on imputed data found the incremental QALY gain to favour volar locking-plate fixation; the difference was small (0.008; 95% CI −0.001 to 0.018). The limits of the CIs did not include high QALY gain values where the study could have concluded that volar locking plates were cost-effective; a back-of-the-envelope calculation indicates that a net QALY gain of at least 0.036 would be required for the incremental cost of £726 to provide cost-effectiveness at a WTP of £30,000 per QALY. The high ICER and the low probability of volar locking plates being cost-effective at a WTP between £20,000 and £30,000 demonstrate that volar locking-plate fixation is not cost-effective. This result is robust to sensitivity analysis and stochastic bootstrapping.

The subgroup analysis showed small fluctuations in effectiveness as measured in QALYs, differing with patients' age group (≥ or < 50 years old). The incremental QALY gain of volar locking plates in patients aged ≥ 50 years was 0.014 (95% CI 0.002 to 0.025) whereas the incremental QALY gain of volar locking plates in patients < 50 years was −0.008 (95% CI −0.024 to 0.008). The right-hand limit of the CIs for QALY gains in younger patients shows that patients aged < 50 years are likely to experience an increased quality of life with K-wires. As volar locking-plate fixation is always associated with higher incremental costs than K-wires (£652.81; 95% CI £425.26 to £880.37), the evaluation suggests that K-wires fixation is

preferred in younger patients. For patients aged ≥ 50 years, the limits of the CIs did not include QALY gain values higher than 0.018 and so volar locking-plate fixation is unlikely to be not cost-effective (a back-of-the-envelope calculation indicates that a net QALY gain of at least 0.038 would be required for the incremental cost of £752.50 to provide cost-effectiveness at a WTP of £30,000 per QALY).

The results showed that EQ-5D score was a suitable measure of health utility for this population and was sensitive to distal radius fractures and fixation, as there were important changes in the score values over the follow-up points.

Chapter 5 Summary and discussion

Screening

Over 12,000 patients were screened during the course of the trial. There was a bimodal distribution. The first peak was in younger men, although there was a smaller peak in women; both of these groups most commonly suffer high-energy injuries associated with sport, etc. The second peak was predominantly in women with lower-energy fractures most likely related to osteoporosis.

As expected, the most common reasons for patients being ineligible were 'patient does not require fixation', 'patient is age less than 18 years' and 'fracture > 3 cm from the radiocarpal joint', that is the fracture was not of the distal radius. These criteria accounted for the exclusion of roughly 10,000 patients. The other ineligible patients were spread around the remaining eligibility criteria.

Of note, 430 patients with intra-articular fractures were excluded on the basis that the 'surgeon needed to open the fracture to achieve reduction of the joint surface'. Inevitably these fractures would be fixed with a plate, since the incision required to reduce the joint surface is essentially the same as that required for the insertion of the plate. There were 639 patients who fulfilled the eligibility criteria – some of whom did not wish to take part in the trial for the reasons described – so the majority of the patients who met the other eligibility criteria were considered by the surgeons to be eligible. Nonetheless, the number of patients excluded from the analysis on the basis of the 'surgeon needed to open the fracture to achieve reduction of the joint surface' eligibility criterion was perhaps greater than might have been expected given the proportion of complex intra-articular fractures, that is those who might be expected to fulfil this criteria, reported in the literature. Some surgeons may have taken a 'cautious' approach to the decision to include a patient in the trial, that is they excluded the patient if there was any doubt about their ability to subsequently reduce the joint surface without opening the joint. There was also some variability by trial centre in the number of patients excluded for this reason, but this was not unexpected and reflects variation in clinical practice and in particular the variation in surgeons' willingness to open the joint surface. To some degree, variation in the surgeons' preoperative assessment of their ability to reduce the fracture reflects such variation in clinical practice across the NHS.

Only a relatively small number of patients ($n = 116$) were excluded as being 'unable to adhere to trial procedures or complete questionnaires'. This most likely reflects the fact that the questionnaires were completed by post and hence patients with no fixed address could not take part, and also that translation services could not be provided for patients whose first language was not English.

Declined to participate

Only 178 potentially eligible patients (28%) declined to take part. This is reassuring in terms of the trial paperwork and in particular the state of equipoise presented in the patient information sheet, but also in terms of the generalisability of the trial to the broader population. The most common reason (55 patients, 31% of those who declined to participate) was the 'patient did not want to take part in a research project'.

Importantly, the number of patients declining to take part because they had a strong preference for one intervention was both small and equally divided between the treatment arms: 26 patients (15%) 'definitely wants K-wires' and 29 patients (16%) 'definitely wants plate'. Therefore, patients had equipoise and patient preference should not have influenced the result of the trial.

Treatment according to allocation

This was clearly an important issue because either surgeon or patient preference could have led to crossover from one group to the other post randomisation. However, > 90% of both patient groups had their allocated treatment according to protocol, 208 out of 231 patients allocated to K-wires (90%) and 213 out of 230 patients allocated to locking plates (92%). This ensured that the primary intention-to-treat analysis was not different from the planned secondary per-treatment analysis. Interestingly, in the case of nine patients, the surgeon decided not to use either form of fixation, that is the patient had a manipulation under anaesthetic and application of plaster cast without 'metalwork'.

Recruitment by centre

Each of the 18 centres successfully recruited to the trial. As expected, the centres that opened earliest in the trial recruited the most patients overall. Most centres achieved a recruitment rate of 1–2 patients per month, indicating that the pre-trial recruitment rate estimate was accurate.

The lead centre recruited the most patients, as may be expected. However, there was also a noticeable difference in the rate of recruitment in some other centres. This may reflect the size of the catchment area (number of patients seen) at that centre or the amount of snow and ice, and hence falls, in that area, for example Newcastle and North Tyneside, but may also reflect a different 'clinical threshold' for offering patients surgery following a fracture of the distal radius. This warrants further investigation.

Baseline characteristics of the two groups

The two groups were 'beautifully balanced in terms of baseline characteristics' (quote from the trial statistician).

In particular, the stratification by age, as a surrogate for bone density, and by intra-articular extension led to a good balance of these characteristics between treatment groups.

Patients

There were slightly more fractures of the left wrist than the right, but these were also evenly balanced between treatment groups, as were injuries to the 'dominant hand'. This may reflect the fact that people generally carry things in their dominant hand, and, therefore, may be more likely to put out their non-dominant hand if they fall.

The number of patients with 'pre-existing wrist problems' was low (14% K-wires, 17% locking plates) and this was reflected in the pre-injury wrist scores, which were near 'normal' in both groups (PRWE questionnaire 3/100, where 0 is the best score).

As expected, the most common mechanism of injury was 'low-energy fall' at 82% in the K-wire group and 83% in the locking-plate group. All other patient characteristics were also evenly balanced between groups.

Fractures

As expected, the great majority of fractures were either displaced extra-articular (AO type A) or complete articular (AO type C) fractures. Partial articular (AO type B) fractures are most commonly palmar fractures or styloid fractures and would, therefore, not be eligible for this trial of dorsally displaced fractures of the distal radius. The type of fracture was evenly distributed between groups.

The other feature of note is that the proportion of AO type C3 fractures – the most severe intra-articular fractures – was low in both groups. This was also expected as these are the fractures where the surgeon would most commonly need 'to open the fracture site to achieve reduction of the articular surface' and were also, therefore, not eligible for the trial.

Surgeons

In this pragmatic trial, we expected that a large number of surgeons, reflecting the true breadth of expertise and experience provided within the NHS, would deliver the trial interventions. This was indeed the case, with 244 surgeons delivering a median of one operation each. This greatly reduces the likelihood of a surgeon-specific effect on the outcome at any one centre, that is one particularly good or bad surgeon dominating the other surgeons in the study.

However, it was also important to look at the balance of surgeons delivering the two different interventions. Interestingly, this was also well balanced between the groups.

Before the trial, some senior surgeons may have considered the K-wire intervention 'simpler' and therefore allowed more junior colleagues to perform this operation while the more experienced surgeons performed the more 'complicated' locking-plate fixation. This may have led to a 'surgeon-effect' within the trial. However, only marginally more of the plate fixations were performed by consultant (attending) surgeons: 31% for locking plates compared with 26% for K-wires. Similarly, the surgeon's experience, as defined by the number of operations performed previously, was also well balanced between the groups. Therefore, a surgeon effect is very unlikely.

Just under half of the procedures in both groups (44% K-wires, 46% locking plates) were performed by 'specialist registrars', that is, trainees under supervision, which again reflects the reality of the delivery of trauma care in the NHS and is a testament to good training in this area.

Surgery

Although the principles of the fixation are inherent in the technique for both K-wires and locking plates, the details of the surgery were left to the discretion of the treating surgeon in this pragmatic trial.

Wires

As per traditional training, the great majority of wire fixations involved two or three wires. The most common size of wire used was 1.6 mm. The most common mode of insertion (34%) was 'inter-fragmentary', that is the wire was passed through the distal bone fragment and into the proximal. Twenty-four per cent of surgeons used the Kapandji technique alone, where the wire is inserted into the fracture site rather than the distal fragment and used as a buttress to hold the position of the bone. The remaining surgeries used a mixed technique, which may reflect a more recent trend.

Plates

The number of fixed-angle screws used in the distal bone fragment was variable but the largest single number used was '> 5' in 38% of surgeries. This is in keeping with the use of modern locking-plate systems, which provide multiple options for gaining fixation in the distal metaphyseal bone, particularly in intra-articular fractures. Surgeons may have chosen to use fewer distal locking screws in the extra-articular fractures.

The bone in the proximal part of the radius is much thicker 'cortical' bone, such that traditional 'non-locking' screws are thought to achieve adequate fixation in this area. However, locking screws were also used in the proximal fragment in nearly half (44%) of the surgeries. This variation in practice has cost implications, as the locking screws are generally more expensive.

Duration of surgery

A key finding of this trial is that the K-wire surgery took less than half the time of the locking-plate fixation, 31 minutes (24 to 45 minutes) for K-wires compared with 66 minutes (50 to 85 minutes) for locking plates. There was no evidence that there was a difference in the duration of surgery according to the seniority of the lead surgeon.

As access to trauma operating theatre space is a key limiting factor in the delivery of trauma care across the NHS, and indeed has secondary effects on the delivery of elective (planned) surgery as well, this finding is of particular importance to policy-makers and NHS managers. It also has financial implications, as theatre operating time is an expensive resource. However, it is difficult to 'cost' this time accurately, as many of the costs of theatre time – staff, cleaning, maintenance – are present even if the theatre is not being used at 100% capacity. Theatre time was, therefore, not included in the health economics analysis, which may have led to some underestimation of the cost-effectiveness of K-wire fixation.

Follow-up rate

The follow-up rate was excellent, with 90% complete follow-up at each time point in both groups of patients. This suggests that the follow-up protocol was satisfactory, and also contributes to the external validity of the trial.

Outcomes

Primary outcome

The main finding of this trial is that there is no difference in the primary outcome PRWE questionnaire score at 3 months, 6 months or 12 months (difference in PRWE questionnaire score at 12 months -1.3 , 95% CI -4.5 to 1.8 ; $p = 0.398$) between patients treated with K-wire fixation versus locking-plate fixation.

As the CIs exclude the MCID for the PRWE questionnaire, we conclude that any difference in functional scores between treatment groups is unlikely to be important to patients.

The size of the treatment effect seen in this trial is consistent with that seen in other studies of recovery following fracture of the distal radius. MacDermid *et al.*³⁰ conducted a prospective cohort study of 129 patients with a fracture of the distal radius; all patients completed the PRWE questionnaire at their baseline clinic visit and at 2 months, 3 months, 6 months and 12 months following their fracture. They reported a mean PRWE questionnaire score of 20.0 (SD 20.6) at 6 months and a score of 13.5 (SD 17.0) at 12 months. This is consistent with our reported values of 21.5 (SD 18.1) and 14.6 (SD 16.4) for the full population at 6 months and 12 months postoperatively.

Secondary outcomes

Patient-reported secondary outcomes

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 at one time point in favour of the locking plate, but this was well below the MCID.⁴⁹

Complications

There was no evidence to suggest that rates for any of the reported complications (e.g. wound infections) differed between treatment groups, based on comparing counts in groups. The number of complications was fortunately small and, again, it is important to note that the trial was not powered to look for differences in complications per se.

Although it is unlikely that there is a major difference in the overall rate of complications between K-wire fixation and locking-plate fixation, there may still be differences in the individual complications. This intuitively makes sense. One might expect the rate of superficial infection to be higher in the wire group (18 cases) versus the locking-plate group (12 cases), as the wires are generally applied directly through

the skin, which is colonised by bacteria. Similarly, the number of neurological injuries in the locking-plate group (20 cases) versus the K-wire group (14 cases) may also be expected, since the plates require a surgical approach to the bone close to the major nerves of the wrist.

In terms of the requirement for further surgery, there was also little difference between the groups. Five patients in the K-wire group and two in the locking-plate group required revision surgery for loss of reduction, that is the bone was not held in an acceptable position during healing, as determined by the treating surgeon, whereas nine patients in the plate group required removal of symptomatic metalwork (four for screw penetration of the joint) and one patient had a buried K-wire which also required removal in theatre.

Radiographic results

Dorsal angle (°) and ulnar variance (mm) data were extracted from available images from all study participants before their operation, and at 6 weeks and 12 months after their surgery. The dorsal angle is a measurement of how far the articulating surface of the distal radius is tilted away from the palm by the injury; a normal articular surface faces towards the palm by a few degrees. Ulnar variance is a measurement of how far the radius has shortened relative to the ulna; in the uninjured wrist they are usually the same length. The 6-week images were used to determine whether or not the initial reduction of the fracture was maintained, that is if the bone was held in the anatomical position by the fixation device. The 12-month images were used to look for 'late collapse' of the fracture, as discussed in the protocol.

Agreement between independent assessors (one radiologist and one orthopaedic surgeon), as determined by intraclass correlation, was above 0.8 for both measurements at each time point. This 'near perfect' agreement suggests that the measurements were reproducible, even if there was some error in individual measurements.

In terms of dorsal angulation, there was a mean 3° difference in the angulation in favour of the locking-plate group at 6 weeks. Similarly, there was a mean 0.75 mm less shortening of the radius in the locking-plate group.

These results are statistically significant. As noted in the introduction, most previous trials have suggested that locking-plate fixation provides improved radiographic outcomes, possibly because they can be used to aid the reduction of the bones into the correct (anatomic) position as well as holding that position when screwed to the bone surface. K-wires usually require the bone fragments to be reduced before the wires are inserted. However, the clinical relevance of such small differences is questionable. The long-term follow-up of the patients will hopefully provide some indication of whether or not radiographic measurements have a bearing on long-term clinical outcome.

At 12 months, the differences between the treatment groups persisted. The mean dorsal tilt in the wire group increased by 0.67° and the shortening by 0.33 mm between 6 weeks and 12 months. Therefore, 'late collapse' was minimal. This does not mean that late collapse did not occur in an individual patient but, on average, it was very unlikely to be clinically important.

It is difficult to explain why the mean dorsal tilt in the locking-plate group actually improved by 0.9° between 6 weeks and 12 months, other than measurement error.

Pre-planned subgroup and secondary analyses

At the beginning of the trial, three variables were identified as being of potential importance in terms of their influence on the recovery of patients following fracture of the distal radius. The randomisation sequence was therefore stratified on the basis of trial centre/hospital, age above and below 50 years as a surrogate for osteoporosis, and intra-articular extension of the fracture into the radiocarpal joint.

A single random effect was used to take account of the trial centre in the regression model used in the adjusted analysis; this made very little difference to the mean difference in PRWE questionnaire score between the groups (all participants: -1.3 adjusted, -1.4 raw).

The trial was not powered specifically for subgroup analysis. However, as three-quarters (314 out of 461) of the patients were in the 'over 50 years' subgroup, the estimate of the mean difference at 12 months is reasonably precise. The adjusted estimate of the mean difference between the treatments for the 'over 50 subgroup' is -2.2 points in favour of the plate fixation, but as the CIs exclude the MCID of 6 points on the PRWE questionnaire score (95% CI -5.8 to 1.4) this is unlikely to be clinically relevant.

The adjusted analysis for the 'under 50 years' subgroup was 1.4 in favour of the K-wire fixation. As the number of patients in this subgroup was smaller, the CIs are broader and do include the MCID (95% CI -5.0 to 7.8).

The number of patients analysed at 12 months with an intra-articular extension of the fracture ($n = 200$) was similar to those without ($n = 215$). Again, there was no evidence of a difference between the treatment groups. The mean difference was 0.7 (-3.8 to 5.2) for those patients with an intra-articular extension and -3.3 (-7.6 to 1.1) for those without.

Therefore, this trial provided no evidence of a clinically important difference between the effect of K-wire fixation and that of locking-plate fixation for patients under or over 50 years or for patients with and without an intra-articular extension of their distal radius fracture.

Finally, we also pre-planned a per-treatment (per protocol) secondary analysis of the data. As compliance with the trial was good, with > 90% of patients receiving their allocated treatment, the analysis by treatment given did not alter the result.

Health economic evaluation

Costs of initial surgery

The costs of the initial surgical interventions were markedly different; the total cost of the implants and theatre consumables was £54 for the K-wire fixation versus £818 for the locking-plate fixation. Therefore, K-wire fixation is a cost-saving intervention.

As noted above, this is a conservative estimate of the cost of initial surgery, as this does not take into account the extra theatre operating time required for the locking-plate fixation, which was 31 minutes for K-wires and 6 minutes for locking plates.

Other health resource use

The use of other health resource was broadly comparable between the treatment groups, as £1525 for K-wires and £1590 for volar locking plates. There was no statistically significant difference in the use of any individual service, orthotic or medication.

Both groups of patients were frequent users of physiotherapy services (seven visits over the 12 months) and reported on average 3.6 radiology visits for radiographs and 3.6 visits to the orthopaedic outpatient department. Use of GP visits and nurse visits was infrequent.

Societal costs

Cost from the societal perspective were calculated by combining productivity loss and loss of earnings due to work absence, private costs such as treatments within private settings and out-of-pocket expenses incurred as a result of the wrist surgery, and reported use of personal social services related to the treatment.

Again, there was very little difference between the treatment groups; overall societal costs were on average £70 higher for the patients having K-wire fixation.

Cost-effectiveness

There were no significant differences in health-related quality of life during the 12-month follow-up period and hence very little difference in average total QALY between the two groups: 0.08 difference, volar locking plate 0.745 versus K-wire 0.731.

As the locking-plate intervention was more expensive, with a total incremental cost of £726, the ICER of volar locking plates versus K-wires was £89,322 per QALY. Under these circumstances, volar locking plates cannot be considered cost-effective. The probability of being cost-effective at a WTP threshold of £20,000 per QALYs was nil and at a threshold of £30,000 was 3%.

Cost-effectiveness in pre-planned subgroups

There were small differences in QALY depending on the patients' age group. Therefore, there were small differences in cost-effectiveness according to age.

As patients aged < 50 years were likely to experience a marginal increase in quality of life with the cheaper K-wires, the health economic evaluation suggests that K-wire fixation is always preferred in younger patients.

In patients aged ≥ 50 years, there was a marginal increase in the unadjusted QALY gain with locking-plate fixation. Given a WTP for an additional QALY of £20,000, the probability of locking-plate fixation being cost-effective is 46% based on the trial data. Therefore, it is unlikely that locking-plate fixation would be cost-effective in older patients.

Limitations

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.⁵⁰

It should be noted that this study excluded patients whose fracture could not be reduced by indirect means, that is the results should not be generalised to the minority of patients whose fracture requires that the surgeon expose the individual bone fragments in order to restore the congruity of the wrist joint. The low number of patients in the trial with C3 fractures indicates that, as expected, the patients with the most complex intra-articular fractures were the ones who were excluded. None of the patients with extra-articular fractures should have been excluded, as this eligibility criterion refers only to the reduction of the 'joint surface'. While it is possible that a small number of patients were excluded in error, we think this unlikely given the high quality of the screening data which we collected throughout the trial. Of course, we have no way of checking the radiographs of those patients whom the surgeon considered to be ineligible, but variation in the interpretation of fractures and fracture patterns is inherent in clinical practice and is reflected in this trial.

Compliance with the trial was good, with > 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.

It is also important to underline that the health economics analysis used a conservative estimate of the cost of initial surgery. This did not take into account the extra theatre operating time required for the locking-plate fixation at 31 minutes for K-wires and 66 minutes for locking plates. It is likely that a microcosting analysis of the initial surgery in each arm could lead to even higher cost differences with regard to the cost of the initial surgery.

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 addition, this will provide us with data on the longer term that will allow a decision-analytic model where extrapolation will rely on more robust data on the benefits.

Chapter 6 Conclusion

This trial found no clinically relevant difference in PRWE questionnaire results in the 12 months following K-wire fixation versus volar locking-plate fixation. The health economic evaluation showed that K-wire fixation is cost saving.

The results of this trial will reverse the trend towards locking-plate fixation for this injury, and will, consequently, save time and money for health-care services around the world.

Acknowledgements

Contributions of authors

Matthew L Costa was chief investigator and led study conception and design, development of interventions, clinical responsibility, and the writing and reviewing of the report.

Juul Achten developed the protocol, is a member of the TMG and was involved in the writing and reviewing of the report.

Caroline Plant developed the protocol, is a member of the TMG and was involved in the writing and reviewing of the report.

Nick R Parsons developed the protocol, is a member of the TMG, was responsible for the statistical analysis of the trial and was involved in the writing and reviewing of the report.

Amar Rangan developed the protocol, was responsible for the recruitment of patients and was involved in the writing and reviewing of the report.

Sandy Tubeuf was responsible for the health economics analysis and was involved in the writing and reviewing of the report.

Ge Yu was responsible for empirical analyses for the health economic section.

Sarah E Lamb developed the protocol, is a member of the TMG and was involved in the writing and reviewing of the report.

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Publications

Costa ML, Achten J, Parsons NR, Rangan A, Edlin RP, Brown J, Lamb SE. 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. *BMC Musculoskeletal Disord* 2011;**12**:201.

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Appendix 1 Consent form

<<<TO BE PRINTED ON LOCAL HEADED PAPER>>>

Distal Radius Acute Fracture Fixation Trial

Chief investigator: Mr Matt Costa

PATIENT INFORMATION SHEET

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have.

Contacts for further information

If, at any time, you would like further information about this research project you may contact your local research lead <<insert name of local researcher>> telephone number <<insert telephone number>> or the overall trial coordinator << insert name of trail coordination>> by telephoning <<insert telephone number>> or Mr Matthew Costa, who is the overall lead of this study on 02476 869618.

For independent advice contact the PALS service (Patient Advice Liaison Service) at freephone 0800 0284203.

What is the purpose of this study

You have sustained a fracture of the distal radius, which is the largest of the bones that form the wrist joint. Some fractures of the distal radius can be treated in a plaster cast. However, other fractures of the distal radius are 'displaced' and need to be manipulated back into their original position and then held in that position until they have healed. The operation to hold the bone in its best position is called a 'fixation'.

There are several different forms of fixation for fractures of the distal radius. The two most common forms of fixation in the NHS are 'K-wire fixation' and 'plate and screw fixation'. Both types of fixation are used successfully in thousands of patients in the UK each year. However, we do not know which type of fixation provides the best wrist function for patients with a fracture such as yours. It is therefore important to perform a study in which the two methods are compared, so that in the future individuals with similar fractures will receive the best possible treatment.

This study aims to determine the best treatment for patients with a fracture of the distal radius. We are comparing two treatments – K-wire fixation with plate and screw fixation.

Why have I been chosen?

You have been chosen because you have sustained a displaced fracture of the distal radius which your surgeon feels would benefit from an operation to fix the bone back into position. Approximately 10 hospitals across the country will take part in this trial and a total of 390 patients will be recruited.

Do I have to take part?

It is up to you whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are free to withdraw at any time and without giving a reason. A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive.

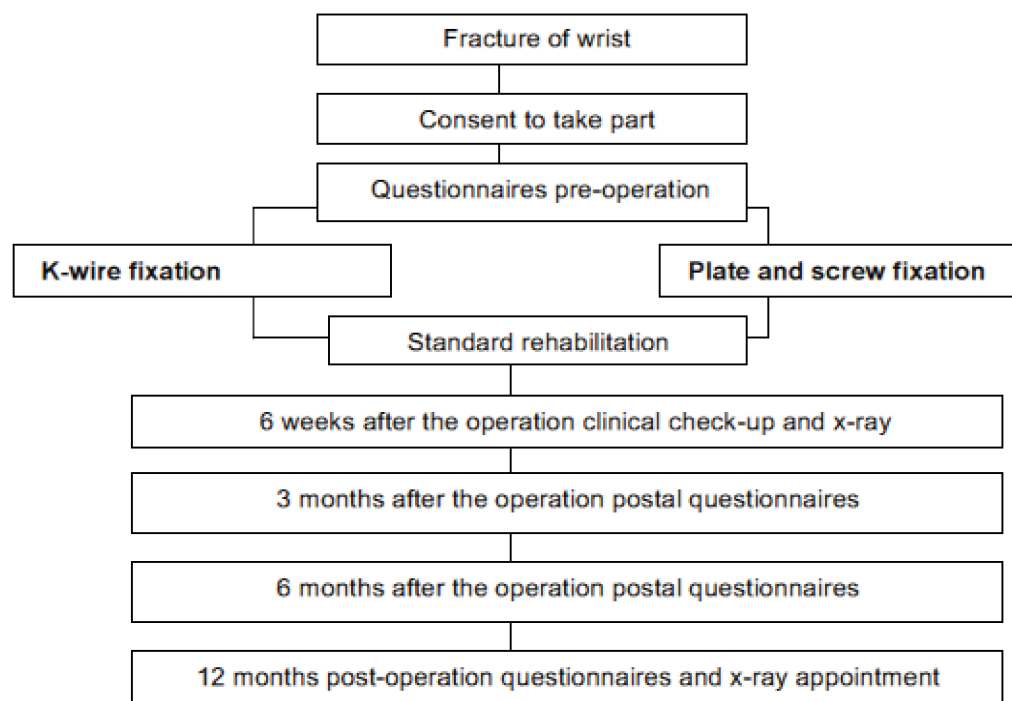
Which treatment will I get?

If you agree to take part, you will be allocated to either the K-wire group or the plate and screws group. The allocation process will be done by a computer and will be done purely by chance. There will be an equal chance of you receiving either K-wire fixation or plate and screw fixation.

To answer the question set out in the purpose of this study, we will compare the results we get from one treatment group with the results from the other group.

What will happen after I have been placed in one of the two groups?

In the flow-chart below you can see a schedule of the visits/assessments and what would happen at each time-point.



Once you have agreed to take part and given us your informed consent, you will be asked to fill out some questionnaires. The questionnaires will ask you about how well you are able to perform certain day-to-day tasks and how you feel. They will take 5 to 10 minutes to complete.

Your operation will be booked for you in the usual way. Both types of fixation require a general anaesthetic so you will be 'asleep' during the surgery. If you are allocated to the K-wire group the wires will be passed across the fracture on the back of your wrist. If you are allocated to the plate and screws group the plate will be screwed to the surface of the bone on the palm side of your wrist. Both types of operation are performed routinely in your hospital but the exact details of the surgery will be decided by your surgeon according to their preferred technique.

For the purpose of this study we would like to follow you up for one year after your operation. Your surgeon will arrange to see you at 6 weeks after the operation for a check up and an x-ray in the usual way. We will then send you some questionnaires in the post at 3 months, 6 months and 1 year after your operation: these will be the same questionnaires that you did before the operation and we will provide you with a stamped-addressed envelope to send them back to us once you have filled them out. All of the patients in the study will then be invited back to their hospital for a final x-ray one year after their injury. Your surgeon may of course arrange other visits to your hospital if he/she feels these are necessary.

What are the possible disadvantages and risks of taking part?

Both types of fixation in this study involve surgery. With any operation around the wrist there is a risk of infection, bleeding, failure of the fixation and damage to the nerves, blood vessels or tendons around the wrist. The risks of the surgery are the same for both groups of patients in the study and are the same as for patients who are not taking part in the study.

What are the possible benefits of taking part?

Both K-wire fixation and plate and screw fixation are used across the NHS for patients with a fracture of the distal radius so there is no specific advantage to you for taking part in the study. However, the information we get from this study may help us to treat future patients with similar fractures.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study you will be asked sign an updated consent form.

What happens when the research study ends?

You will be in the study for 12 months. If you are still having problems after this time, we will arrange for you to have an appointment with an appropriate specialist to continue your care.

What happens if something goes wrong?

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Warwick (Mr Peter Hedges, Director of Research Support Services, 02476523716) and/or UHCW NHS Trust (Mrs Ceri Jones, R&D services manager, 0247696196), but you may have to pay your legal costs.

The normal National Health Service complaints mechanisms will still be available to you

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the research centre will have your name and address removed so that you cannot be recognised from it. Your GP and other doctors who may treat you, but are not part of this study will be notified that you are taking part in this study.

What will happen to the results of the research study?

This study is expected to last 3 years. At the end of the study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. If you would like to obtain a copy of the published results, please ask your doctor.

What will happen if I decide not to participate in the research study?

If you decide not to participate in the research study your care will not be affected and you may discuss your further treatment with your doctor.

Who has reviewed this study?

This study has been reviewed by the Coventry Research Ethics Committee and approval was given on xxxth of xxx 2010.

Appendix 2 Patient information sheet

<<<TO BE PRINTED ON LOCAL HEADED PAPER>>>

Centre ID

Participant ID

Distal Radius Acute Fracture Fixation Trial

Chief Investigator: Mr Matt Costa

Initial box

- 1- I confirm that I have read and understand the information sheet dated 14th Jan 2010 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- 2- I understand that my participation is voluntary and that I am free to withdraw at anytime, without giving any reason, without my medical care or legal rights being affected.

- 3- I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from regulatory authorities, the NHS Trust or the research team, where it is relevant to my taking part in this research. I give my permission for these individual to have access to my records.

- 4- I agree for my contact details to be held at Warwick Clinical Trials Unit for the purpose of sending me questionnaires and other trial related material. These details will be held securely on password controlled computers and hard copies will be kept in secure, locked filing cabinets at the unit.

- 5- I agree to my GP being informed of my participation in the study.

- 6- I agree to take part in the above study.

Name of Patient

Date (dd/mm/yyyy)

Signature

Name of person taking consent

Date (dd/mm/yyyy)

Signature

Appendix 3 Background information

To be completed by the Research Associate once informed consent has been obtained

DRAFFT

Centre ID

Background Information

Patient Initials

SECTION 1 - CURRENT INJURY

1. Date of injury (dd/mm/yyyy):

2. Mechanism of injury (please select only one answer)

Low energy fall (e.g. while standing or walking) ☐

High energy fall (e.g. while running or from a height of more than 2 metres) ☐

Road traffic accident ☐

Crush injury ☐

Other details: ☐

3. Does the patient have any other injuries ☐ Yes ☐ No

If Yes, please give details:
.....

SECTION 2 - MEDICAL HISTORY

1. Height (cm) . Weight (kg) .

2. Is the patient right-handed or left-handed?

Right ☐

Left ☐

Not clearly one or the other ☐

Is the patient currently taking any of the following;

3. Osteoporosis medication e.g. Bisphosphonates Yes ☐ No ☐

4. Regular analgesia e.g. Paracetamol, anti-inflammatory Yes ☐ No ☐

5. Other Medication Yes ☐ No ☐

If Yes, please give details
.....

Centre ID Patient Initials

6. Is the patient currently a regular smoker? Yes ☐ No ☐
 If Yes, how many cigarettes per day? and for how many years?

7. How many units of alcohol does the patient drink in a normal week?

0-7 units ☐ 8-14 units ☐ 15-21 units ☐ More than 21 units ☐

8. Has the patient had previous wrist problems on the injured side? Yes ☐ No ☐

If Yes, Previous fracture Yes ☐ No ☐

Ligament, tendon or nerve injury Yes ☐ No ☐

Arthritis Yes ☐ No ☐

Other Yes ☐ No ☐

If Other please give details

9. In the last 12 months prior to this injury, how often did the patient have difficulties balancing whilst walking? (please select only one answer)

Never ☐
 Sometimes ☐
 Often ☐
 Very Often ☐
 Always ☐

10. In the last 12 months prior to this injury, how much difficulty did the patient have with the following activities without the help of another person? (please circle one number per line)

	No difficulty	A little difficulty	Some difficulty	A lot of difficulty	Unable to perform
a. Taking a bath	1	2	3	4	5
b. Moving from a bed to a chair	1	2	3	4	5
c. Getting to the toilet	1	2	3	4	5
d. Dressing	1	2	3	4	5
e. Eating	1	2	3	4	5

Centre ID Patient Initials

11. How many times has the patient fallen in the last 12 months (including this time if the cause of the injury was a fall)?

12. Please tick the box that most closely describes the patient's ethnic background

White	<input type="checkbox"/>	Pakistani	<input type="checkbox"/>
Black Caribbean	<input type="checkbox"/>	Bangladeshi	<input type="checkbox"/>
Black African	<input type="checkbox"/>	Chinese	<input type="checkbox"/>
Black Other	<input type="checkbox"/>	Other	<input type="checkbox"/>
Indian	<input type="checkbox"/>	(Please specify)	

13. What is the patient's current employment status? (please select only one answer)

Full-time employed	<input type="checkbox"/>	Unpaid work	<input type="checkbox"/>
Part-time employed	<input type="checkbox"/>	Unemployed	<input type="checkbox"/>
Self-employed	<input type="checkbox"/>	Full time student	<input type="checkbox"/>
Retired/looking after home/inactive	<input type="checkbox"/>		

If you selected 'unemployed' or 'retired', please go to Q15.

14. If the patient is employed which of the following categories best describes their employment? (please select only one answer)

Unskilled manual	<input type="checkbox"/>	Skilled non manual	<input type="checkbox"/>
Skilled manual	<input type="checkbox"/>	Professional	<input type="checkbox"/>
Unskilled non manual	<input type="checkbox"/>	Other	<input type="checkbox"/>
		(please describe)	

15. Although the patient will be given one of the treatment options by chance, if they could choose which treatment to have, which would be their preference? (please select only one answer)

K-wires	<input type="checkbox"/>
Locking plate	<input type="checkbox"/>
Participant does not mind which treatment they receive	<input type="checkbox"/>

Research Associate signature:

Date completed (dd/mm/yyyy):

Appendix 4 Baseline questionnaire

Centre ID Patient Initials

Section 1—Patient Rated Wrist Evaluation

Date completed (dd/mm/yyyy)

The questions below will help us understand how much difficulty you have had with your wrist in the week **BEFORE** you broke your wrist. You will be describing the average wrist symptoms over that week on a scale of 0-10. Please provide an answer for **ALL** questions. If you did not perform an activity, please **ESTIMATE** the pain or difficulty you would expect.

PAIN

Rate the **average** amount of pain in your wrist **BEFORE** you broke it by circling the number that best describes your pain on a scale from 0-10. A zero (0) means you did not have any pain and a ten (10) means that you had the worst pain you have ever experienced or that you could not do the activity because of pain.

	No pain										Worst ever	
	0	1	2	3	4	5	6	7	8	9	10	
At rest												
When doing a task with a repeated wrist movement												
When lifting a heavy object												
When it is at its worst												

	Never										Always	
	0	1	2	3	4	5	6	7	8	9	10	
How often do you have pain?												

FUNCTION

Specific Activities

Rate the amount of difficulty you experienced performing each of the items listed below in the week **BEFORE** you broke your wrist, by circling the number that describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do it at all.

	No difficulty										Unable to do	
	0	1	2	3	4	5	6	7	8	9	10	
Cut meat using a knife in my affected hand												
Turn a door knob using my affected hand												
Use my affected hand to push up from a chair												
Fasten buttons on my shirt												

Centre ID Patient Initials

	No difficulty						Unable to do					
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10	
Use a bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10	

Usual Activities

Rate the amount of difficulty you experienced performing your usual activities in each of the areas listed below in the week **BEFORE** you broke your wrist, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means that you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do any of your usual activities.

	No difficulty						Unable to do					
Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10	
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10	
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10	
Recreational activities	0	1	2	3	4	5	6	7	8	9	10	

Section 2—Disabilities of the Arm, Shoulder and Hand

These questions ask about your symptoms and ability to perform certain activities.

Please answer **ALL** questions, based on your condition in the week **BEFORE** you broke your wrist, by circling the appropriate number.

If you did not have the opportunity to perform an activity in that week, please make your best estimate of which response would be the most accurate.

It doesn't matter which hand you used to perform the activity; please answer based on your ability regardless of how you perform the task.

	No Difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Unable
Open a tight new jar	1	2	3	4	5
2. Write	1	2	3	4	5
3. Turn a key	1	2	3	4	5
Prepare a meal	1	2	3	4	5

Centre ID		Patient Initials		No Difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Unable
5.	Push open a heavy door			1	2	3	4	5
6.	Place an object on a shelf above your head			1	2	3	4	5
	Do heavy household chores (e.g., wash walls, wash floors)			1	2	3	4	5
	Garden or do yard work			1	2	3	4	5
8.	Make a bed			1	2	3	4	5
10.	Carry a shopping basket or briefcase			1	2	3	4	5
	Carry a heavy object (over 10lbs)			1	2	3	4	5
	Change a light bulb overhead			1	2	3	4	5
13.	Wash or blow dry your hair			1	2	3	4	5
14.	Wash your back			1	2	3	4	5
15.	Put on a pullover sweater			1	2	3	4	5
16.	Use a knife to cut food			1	2	3	4	5
17.	Recreational activities which require little effort (e.g. card playing, knitting etc)			1	2	3	4	5
18.	Recreational activities in which you take some force or impact through your hand (e.g. golf, hammering, tennis)			1	2	3	4	5
19.	Recreational activities in which you move your arm freely (e.g. playing Frisbee, badminton etc)			1	2	3	4	5
	Manage transportation needs (getting from one place to another)			1	2	3	4	5
	Sexual activities			1	2	3	4	5

Centre ID	<input type="text"/>	<input type="text"/>	<input type="text"/>	Patient Initials	<input type="text"/>	<input type="text"/>	<input type="text"/>
-----------	----------------------	----------------------	----------------------	------------------	----------------------	----------------------	----------------------

	Not at all	Slightly	Moderately	Quite a bit	Extremely
In the week before your injury, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	Not limited at all	Slightly limited	Moderately limited	Very limited	Unable
In the week before your injury, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the week BEFORE your injury

	None	Mild	Moderate	Severe	Extreme
Arm, shoulder or hand pain	1	2	3	4	5

Arm, shoulder or hand pain when you performed any specific activity	1	2	3	4	5
---	---	---	---	---	---

Tingling (pins and needles) in your arm, shoulder or hand	1	2	3	4	5
---	---	---	---	---	---

Weakness in your arm, shoulder or hand	1	2	3	4	5
--	---	---	---	---	---

Stiffness in your arm, shoulder or hand	1	2	3	4	5
---	---	---	---	---	---

	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	So much difficulty that I can't sleep
In the week before your injury, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand?	1	2	3	4	5

	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
I feel less capable, less confident or less useful because of my arm, shoulder or hand problem	1	2	3	4	5

Centre ID Patient Initials

Section 3—Quality of Life

These questions refer to your general health on the day **BEFORE** you broke your wrist. By placing a cross in **ONE** box in each group, please indicate which statement best describes your own health state on the day **BEFORE** you broke your wrist.

Mobility:

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care:

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

Pain/Discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety/Depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Centre ID: Patient Initials:

Your own health state on the day BEFORE your injury

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health was on the day BEFORE your injury, in your opinion.

Please do this by drawing a line from the box below, to whichever point on the scale indicates how good or bad your health state was before your injury.

<div style="border: 1px solid black; padding: 10px; width: fit-content; margin: 0 auto;"> <p>Your own health state on the day BEFORE your injury</p> </div>	
<p>Office use only</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div>	

Centre ID Patient Initials **Section 4****Other support from government benefits**Are you receiving any benefits Yes ☐ No ☐

If No, go to question 2

If Yes, please tick all benefits you currently receive and how much you currently receive in benefits each week.

Can you please estimate how much you receive altogether in benefits per week? £.....

Attendance Allowance	<input type="checkbox"/>	Income Support	<input type="checkbox"/>
Carer's Allowance	<input type="checkbox"/>	Jobseeker's Allowance	<input type="checkbox"/>
Child Tax Credit	<input type="checkbox"/>	Pension Credit	<input type="checkbox"/>
Council Tax Benefit	<input type="checkbox"/>	Statutory Sick Pay	<input type="checkbox"/>
Disability Living Allowance—caring	<input type="checkbox"/>	State Pension	<input type="checkbox"/>
Disability Living Allowance—mobility	<input type="checkbox"/>	Other:	<input type="checkbox"/>
Employment and Support Allowance	<input type="checkbox"/>	Other:	<input type="checkbox"/>
Housing Benefit	<input type="checkbox"/>	Other:	<input type="checkbox"/>

2. Where you live

As of today, do you live in:

A residential house, flat or bungalow	<input type="checkbox"/>
Assisted living/retirement village	<input type="checkbox"/>
A care home without 24 hour nursing	<input type="checkbox"/>
A care home with 24 hour nursing available	<input type="checkbox"/>

Centre ID Patient Initials

Quality of Life AFTER injury

These questions refer to your general health on the day **AFTER** you broke your wrist. By placing a cross in **ONE** box in each group, please indicate which statement best describes your own health state on the day **AFTER** you broke your wrist.

Mobility:

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care:

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

Pain/Discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety/Depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Centre ID Patient Initials

Your own health state on the day AFTER your injury

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health was on the day AFTER your injury, in your opinion.

Please do this by drawing a line from the box below, to whichever point on the scale indicates how good or bad your health state was after your injury.

**Your own health state
on the day AFTER
your injury**

Best imaginable health state

100

↑

↓

90

↑

↓

80

↑

↓

70

↑

↓

60

↑

↓

50

↑

↓

40

↑

↓

30

↑

↓

20

↑

↓

10

↑

↓

0

↑

↓

0

↑

↓

Worst imaginable health state

Appendix 5 Randomisation form

The Research Associate is to complete this form immediately before randomisation.
Phone 02476 150 402 between 9am-5pm Mon-Fri (excl bank hols)

DRAFFT—Randomisation Form

Hospital ID:

Name of Consultant who completed the eligibility form:.....

PATIENT DETAILS

Patient Initials

Gender

Male

☐

Female

☐

DOB (dd/mm/yyyy):

Date of injury (dd/mm/yyyy):

Must be no more than 2 weeks prior to randomisation

Is the patient eligible to enter the trial, as per the eligibility form? Yes ☐ No ☐

Date eligibility form signed (dd/mm/yyyy):

Has the patient signed the trial consent form? Yes ☐ No ☐

Date consent form signed (dd/mm/yyyy):

Age: Under 50 ☐ 50 and over ☐

Intra-articular extension: Yes ☐ No ☐

You will be given the treatment allocation and randomisation number in return which will become the participants ID number. The patient will be identified by their participant ID from now on. Please ensure that these are clearly recorded below. You may then inform the participant and the Principal Investigator of the treatment allocation.

Treatment Allocation (please cross one) Kirschner wires ☐ Volar Locking Plate ☐

Randomisation number (please note this will now become the participant ID)

Research Associate signature:

Date (dd/mm/yyyy):

Appendix 6 Operation note

To be completed following the operation

DRAFT

Centre ID

Operation Note

Participant ID

Surgeon's Name (please print)

Surgeon grade: Consultant ☐ Staff Grade/Associate Specialist ☐
Specialist Trainee ☐ Other

Date of operation (dd/mm/yyyy):

1. Peri-operative antibiotic cover Yes ☐ No ☐

2. Which wrist was operated on as part of the trial? Right ☐ Left ☐

3. Start time of operation (24hr clock)

4. Finish time of operation (24hr clock)

5. Any intra-operative problems? Yes ☐ No ☐
Nerve injury Yes ☐ No ☐
Vascular injury Yes ☐ No ☐
Tendon injury Yes ☐ No ☐
Extension of fracture Yes ☐ No ☐

6. If a wire fixation:

How many wires used: 1 ☐ 2 ☐ 3 ☐ More ☐

What size was used? 1.6mm ☐ 1.1mm ☐ 0.9mm ☐ Other ☐

What method was used? Kapandji ☐ Interfragmentary ☐ Mixed technique ☐

7. If a plate fixation:

How many screws/pegs in the distal fragment 3 ☐ 4 ☐ 5 ☐ More ☐

Were the screws that were used proximal to the fracture Locking ☐ Non-locking ☐

8. Regarding your (surgeon) previous experience of fixing fractures of the distal radius

How many have you treated, prior to today with:

K-wires 0 ☐ <5 ☐ 5-10 ☐ 11-20 ☐ >20 ☐

Plates and fixed angle screws 0 ☐ <5 ☐ 5-10 ☐ 11-20 ☐ >20 ☐

Signature of person completing this form:

Date (dd/mm/yyyy):

Appendix 7 Six-week follow-up clinic

This form is to be filled in by the Research Associate at the six week follow-up clinic

DRAFT

Centre ID

Six Week Follow-up Clinic

Participant ID

SECTION 1

Date of discharge from hospital (dd/mm/yyyy)

Which treatment did the patient receive?

Kirschner wires ☐ Volar Locking plate ☐ Other (please specify) _____ ☐

Was this different to randomisation?

Yes ☐ No ☐

If Yes, was this due to:

Patient choice	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Surgeon choice	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Lack of equipment	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Admin error	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Other _____	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Did the patient have a cast after the operation?

Yes ☐ No ☐

If Yes, for how long? weeks

SECTION 2—Wound complications

Following treatment did any of the following complications occur. Select all that apply

Erythema	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Persistent serous drainage longer than 5 days	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Purulent drainage	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Microbiological confirmation of infection	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Dehiscence	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Were complications treated with:

Antibiotics	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Metal removal, or at least routine removal of wires	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Surgical debridement	Yes <input type="checkbox"/>	No <input type="checkbox"/>

If wound complications were treated surgically, please give details

Date (dd/mm/yyyy)

Surgeon _____

Hospital _____

Details _____

Centre ID Participant ID **SECTION 3—Plaster complications**

Following scheduled wound checks (in the first one or two weeks) have there been any problems with the plaster cast/dressings?

Change of dressing Yes ☐ No ☐
 Change of plaster Yes ☐ No ☐

SECTION 4

As a result of the treatment received for the distal radius fracture has the patient had any of the following:

Neurological injury Yes ☐ No ☐

If Yes, please give details:

Vascular injury Yes ☐ No ☐

If Yes, please give details:

Tendon injury Yes ☐ No ☐

If Yes, please give details:

Since discharge from hospital has the patient had a diagnosis of:

Complex Regional Pain Syndrome Yes ☐ No ☐

If Yes, please give details:

DVT Yes ☐ No ☐

If Yes, please give details:

PE Yes ☐ No ☐

If Yes, please give details:

Other Yes ☐ No ☐

If Yes, please give details:

SECTION 5

1. After the patient broke their wrist they were probably put in plaster cast in the Emergency Department. Compared to then, does their wrist feel (please select one answer only)

The Same	<input type="checkbox"/>	A Lot Better	<input type="checkbox"/>
A Little Better	<input type="checkbox"/>	Almost Back to Normal	<input type="checkbox"/>
Moderately Better	<input type="checkbox"/>	Back to Normal	<input type="checkbox"/>

2. Has the patient changed or is likely to change any contact details over the next 3 months?

Yes ☐ No ☐

Research Associate signature:

Date (dd/mm/yyyy):

Appendix 8 Example follow-up questionnaire

3 Month Questionnaire

Centre ID:

Participant ID:

Date Completed:
(dd/mm/yyyy)



INSTRUCTIONS

Please read these instructions before completing the questionnaire.

Please **do not** sign this form or add your name.

Please follow the instructions for each section carefully.

Please answer ALL the questions. Although it may seem that the questions are asked more than once, it is still important that you answer every one.

Please use a **BLACK** or **BLUE** pen. Please do not use a pencil.

Please check that you have completed all sections.

Please write any notes you have for us on the back page.

For each section, if you are asked to circle a number, please **only** circle ONE. For example in the following question, if your answer to the question is never, you should place a circle around 0.

Example

Do you suffer from migraines? Never Rarely Occasionally Frequently

☐ 0 ☒ 1 ☒ 2 ☐ 3

If you are asked to put a cross in the box, please use a cross rather than a tick. For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Example

Do you drive a car? Yes ☒ No ☐

PTO >>>

Section 1—Patient Rated Wrist Evaluation

The following questions below will help us understand how much difficulty you have had with your wrist in the past week. You will be describing the average wrist symptoms over this week on a scale of 0-10.

Please provide an answer for ALL questions. If you did not perform an activity, please **ESTIMATE** the pain or difficulty you would expect.

1. PAIN

Rate the average amount of pain in your wrist over the past week by circling the number that best describes your pain on a scale from 0-10. A zero (0) means you did not have any pain and a ten (10) means that you had the worst pain you have ever experienced or that you could not do the activity because of pain.

	No pain										Worst ever
At rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with a repeated wrist movement	0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object	0	1	2	3	4	5	6	7	8	9	10
When it is at its worst	0	1	2	3	4	5	6	7	8	9	10

	Never										Always
How often do you have pain?	0	1	2	3	4	5	6	7	8	9	10

2. FUNCTION

A. Specific Activities

Rate the amount of difficulty you experienced performing each of the items listed below – over the past week, by circling the number that describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do it at all.

	No difficulty										Unable to do
Cut meat using a knife in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10

	No difficulty					Unable to do					
Carry a 10lb object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use a bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

B. Usual Activities

Rate the amount of difficulty you experienced performing your usual activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means that you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do any of your usual activities.

	No difficulty					Unable to do					
Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

Section 2—Disabilities of the Arm, Shoulder and Hand

These questions ask about your symptoms and ability to perform certain activities.

Please answer ALL questions, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your best estimate on which response would be the most accurate.

It doesn't matter which hand you use to perform the activity; please answer based on your ability regardless of how you perform the task.

	No Difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Unable
1. Open a tight new jar	1	2	3	4	5
2. Write	1	2	3	4	5
3. Turn a key	1	2	3	4	5
4. Prepare a meal	1	2	3	4	5

		No Difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Unable
5.	Push open a heavy door	1	2	3	4	5
6.	Place an object on a shelf above your head	1	2	3	4	5
7.	Do heavy household chores (e.g., wash walls, wash floors)	1	2	3	4	5
8.	Garden or do yard work	1	2	3	4	5
9.	Make a bed	1	2	3	4	5
10.	Carry a shopping basket or briefcase	1	2	3	4	5
11.	Carry a heavy object (over 10lbs)	1	2	3	4	5
12.	Change a light bulb overhead	1	2	3	4	5
13.	Wash or blow dry your hair	1	2	3	4	5
14.	Wash your back	1	2	3	4	5
15.	Put on a pullover sweater	1	2	3	4	5
16.	Use a knife to cut food	1	2	3	4	5
17.	Recreational activities which require little effort (e.g., cardplaying, knitting etc)	1	2	3	4	5
18.	Recreational activities in which you take some force or impact through your hand (e.g. golf, hammering, tennis)	1	2	3	4	5
19.	Recreational activities in which you move your arm freely (e.g. playing Frisbee, badminton etc)	1	2	3	4	5
20.	Manage transportation needs (getting from one place to another)	1	2	3	4	5
21.	Sexual activities	1	2	3	4	5

	Not at all	Slightly	Moderately	Quite a bit	Extremely
22. During the past week to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5
<hr/>					
	Not limited at all	Slightly limited	Moderately limited	Very limited	Unable
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem	1	2	3	4	5
<hr/>					
Please rate the severity of the following symptoms in the last week					
	None	Mild	Moderate	Severe	Extreme
24. Arm, shoulder or hand pain	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5
<hr/>					
	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	So much difficulty that I can't sleep
29. During the past week, how much difficulty have you had sleeping because of pain in your arm, shoulder or hand?	1	2	3	4	5
<hr/>					
	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem	1	2	3	4	5

Section 3—Quality of Life

These questions refer to your general health. By placing a cross in ONE box in each group, please indicate which statement best describes your own health state today.

1. Mobility:

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

2. Self-Care:

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

3. Usual activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

4. Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

5. Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

Your own health state TODAY.

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is TODAY, in your opinion.


Please do this by drawing a line from the box below, to whichever point on the scale indicates how good or bad your current health state is.

**Your own health state
TODAY**

Office use only:

Best imaginable health state

100



0

Worst imaginable health state

Section 4

1. Other support from government benefits

Are you receiving any of the below Yes ☐ No ☐

If No, go to question 2

If Yes, can you please tick all benefits you have received in the past 3 months and how much you currently receive in benefits each week.

Can you please estimate how much you receive altogether in benefits per week? £

Attendance Allowance	<input type="checkbox"/>	Income Support	<input type="checkbox"/>
Carer's Allowance	<input type="checkbox"/>	Jobseeker's Allowance	<input type="checkbox"/>
Child Tax Credit	<input type="checkbox"/>	Pension Credit	<input type="checkbox"/>
Council Tax Benefit	<input type="checkbox"/>	Statutory Sick Pay	<input type="checkbox"/>
Disability Living Allowance—caring	<input type="checkbox"/>	State Pension	<input type="checkbox"/>
Disability Living Allowance—mobility	<input type="checkbox"/>	Other:	<input type="checkbox"/>
Employment and Support Allowance	<input type="checkbox"/>	Other:	<input type="checkbox"/>
Housing Benefit	<input type="checkbox"/>	Other:	<input type="checkbox"/>

2. Where you live

As of today, do you live in:

A residential house, flat or bungalow	<input type="checkbox"/>
Assisted living/retirement village	<input type="checkbox"/>
A care home without 24 hour nursing	<input type="checkbox"/>
A care home with 24 hour nursing available	<input type="checkbox"/>

Section 5

Complications

In the past 3 months have you been treated for any of the following events?

- | | | | | |
|---|-----|--------------------------|----|--------------------------|
| 1. Wound complication | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Further surgery because of your wrist fracture | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. A regional pain syndrome | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 4. DVT (Deep Vein Thrombosis) | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| If yes, Did you see the DVT nurse | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| Were you prescribed medication | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 5. Any other complications | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

If yes, please specify

Have you had any other unscheduled appointment at hospital because for your wrist fracture

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
-----	--------------------------	----	--------------------------

If you are unsure about any of these questions, please cross here ☐ and someone from the research team will get in contact with you to help you answer these questions.

Physiotherapy Exercise

- | | | | | |
|---|-----|--------------------------|----|--------------------------|
| 1. Upon discharge from the hospital, did you receive exercise instruction sheets? | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 2. Were the exercise instruction sheets explained to you | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| 3. Did you perform the exercises as instructed | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |

If Yes, how often did you repeat the exercises?times/day

And for how many days did you repeat these exercisesdays

- | | | | | |
|---|-----------------|--------------------------|----|--------------------------|
| 4. Did you have any additional therapy for your wrist | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> |
| If Yes, who provided this therapy? | Physiotherapist | <input type="checkbox"/> | | |
| | Hand therapist | <input type="checkbox"/> | | |
| | Other | <input type="checkbox"/> | | |

And how often did you have this therapy?

Resource Use

Please think back over the times that you have used the NHS since being discharged. If you are unsure about any answer please write in your best recollection.

1. Inpatient care

Since being discharged following your operation, have you been admitted to hospital again?

Yes ☐

No ☐

If you can, please tell us which department of the hospital you went to (speciality) and whether or not you had to stay overnight. If you don't know which speciality it was or if it's not listed, then just write in the reason or part of your body as best you can.

	Did you stay overnight?		Total stay	
Orthopaedics (your wrist/arm)	Just the day <input type="checkbox"/>	Overnight <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	Days
Orthopaedics (any other bones)	Just the day <input type="checkbox"/>	Overnight <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	Days
Rehabilitation unit	Just the day <input type="checkbox"/>	Overnight <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	Days
For any other surgery? Details:	Just the day <input type="checkbox"/>	Overnight <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	Days
For any other non-surgical reason? Details:	Just the day <input type="checkbox"/>	Overnight <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>	Days

2. Outpatient care

Since being discharged following your operation, have you made any visits to the hospital or a clinic as an outpatient?

Yes ☐

No ☐

If you can, please indicate which part of the hospital you went to (speciality). If you don't know which speciality it was, or if it's not listed, then write in the reason or part of your body as best you can.

Speciality	Examples	Number of visits
Orthopaedics	Seeing a surgeon about your wrist fracture, changes to plaster or aids (e.g. splint/braces)	
Pathology	For blood tests	
Radiology	For X-rays	
Physiotherapy (NHS)	Physiotherapy appointment at the hospital to see an NHS physiotherapist	
Physiotherapy (Private)	Physiotherapy appointment to see a private physiotherapist (anywhere)	
Others: Details		
Others: Details		

3. Contacts with other health and social care professionals

In the last three months, have you seen any other professionals in the community because of your wrist fracture?

Yes ☐ No ☐

If you can, please indicate the person you saw, how often you saw them and where this was. If the person isn't listed then feel free to write this in.

	Total number of contacts with NHS and social services staff				Total time spent
	GP Surgery	Clinic (non-hospital)	By Phone	At home	
GPs	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> Visits	<input type="text"/> <input type="text"/> times	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> minutes
Practice nurse	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> Visits	<input type="text"/> <input type="text"/> times	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> minutes
District nurse	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> Visits	<input type="text"/> <input type="text"/> times	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> hours
Physiotherapist	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> Visits	<input type="text"/> <input type="text"/> times	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> hours
Occupational therapist	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> Visits	<input type="text"/> <input type="text"/> times	<input type="text"/> <input type="text"/> visits	<input type="text"/> <input type="text"/> hours
Other: details
Other: details

4. Medications

In the tables below, please note any medications (including pain relief) that you have been prescribed by a doctor or other health professional in relation to your wrist fracture in the past three months. Please ignore the medications you were provided at your discharge from hospital and anything that you bought without a prescription ("over the counter").

Medications (+ dosage)	Number of times daily	Number of days used

5. Other aids and adaptations

In the past three months, the NHS or local social services may have provided some equipment to protect your injury or make your day to day life easier to manage. In the following table, please indicate whether you have received the equipment stated. If an item you have received isn't listed then feel free to write this in.

Aids and adaptation	Used?		Number received
Wrist brace/splint	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Grab rail	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Dressing aids	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Long-handle shoe horns	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Bathing aids	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Kitchen aids (jar/tin openers, special cutlery etc)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Other	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Other	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>

6. Other support from personal social services

In the past three months, personal social services may have provided some other services to make your day to day life easier to manage. In the following table, please indicate whether you have received the service stated, how often you received it, and whether you are still receiving this support. If the type of support you have received isn't listed then feel free to write this in.

Have you used personal social services?

Yes ☐

No ☐

If Yes, please give details in the table below

Other support	How many times?	Is help ongoing?	
Meals on wheels (frozen, weekly)	<input type="text"/> <input type="text"/> <input type="text"/> weeks	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Meals on wheels (hot, daily)	<input type="text"/> <input type="text"/> <input type="text"/> weeks	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Laundry services	<input type="text"/> <input type="text"/> <input type="text"/> weeks	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Care workers/Help at home	<input type="text"/> <input type="text"/> <input type="text"/> visits	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Social workers	<input type="text"/> <input type="text"/> <input type="text"/> Visits	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Other: Details	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Other: Details	Yes <input type="checkbox"/>	No <input type="checkbox"/>

7. Time off work

Are you currently working?

Yes ☐

No ☐

If No, is this:

Because of your wrist fracture ☐

Because of other health reasons ☐

Because you are retired or unable to work for other reasons ☐

In the three months, have you taken time off work or lost any income because of your wrist fracture? If yes, please provide details below:

Days lost:

Income lost:

Section 6

1. Compared to when you attended your '6 week' follow up appointment does your wrist feel

Substantially Better	<input type="checkbox"/>
Moderately Better	<input type="checkbox"/>
No Different	<input type="checkbox"/>
Moderately Worse	<input type="checkbox"/>
Substantially Worse	<input type="checkbox"/>

2. How satisfied were you with the treatment you received ?

Extremely Satisfied	<input type="checkbox"/>
Very Satisfied	<input type="checkbox"/>
Somewhat Satisfied	<input type="checkbox"/>
Neither Satisfied nor Dissatisfied	<input type="checkbox"/>
Somewhat Dissatisfied	<input type="checkbox"/>
Very Dissatisfied	<input type="checkbox"/>
Extremely Dissatisfied	<input type="checkbox"/>

3. Have your contact details changed or likely to change in the next three months?

Yes ☐ No ☐

If Yes, please give your new details below:

House/Flat number:

Street Name:

Town/City:

Postcode:

Email:

Telephone

Home:

Work:

Mobile:

Preferred method/time of contact:

That is the end of the questionnaire.

Please check that you have completed all sections.

We will send you another questionnaire in three months. In the meantime, please keep a record of any days off work, hospital or GP visits, medication, use of special equipment or support you may receive as a result of your broken wrist.

Please write any notes you have for us in the space below and return the questionnaire in the reply-paid envelope provided.

Thank you very much for your time.

Notes

Appendix 9 Serious adverse event form

ONCE COMPLETE FAX IMMEDIATELY TO 02476 150 549

DRAFT—Serious Adverse Event Reporting Form

Centre ID: Participant ID: Participant Initials:

Initial Report Yes ☐ No ☐

Follow up report Yes ☐ No ☐

Date of Event (dd/mm/yyyy):

Reason for reporting:

Resulted in death ☐
 Is life threatening ☐
 Required hospitalisation or prolongation of existing hospitalisation ☐
 Resulted in persistent or significant disability or incapacity ☐
 Required medical intervention to prevent one of the above ☐
 Is otherwise considered medically significant by the investigator ☐

Details of event (please give as much information as possible, and if necessary attach a detailed report).
 Information must include incident, investigations and treatment given.

Outcome

Ongoing ☐ Resolved ☐ Resolved with sequelae ☐

In the opinion of the Principal Investigator.....

Is the event related to trial procedure? Yes ☐ No ☐
 Is the event Expected ☐ Unexpected ☐

PI Name:

PI Signature:

Date (dd/mm/yyyy):

In the opinion of the Chief Investigator

Is the event related to trial treatment? Yes ☐ No ☐
 Is the event Expected ☐ Unexpected ☐

CI Signature:

Date (dd/mm/yyyy):

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

EME
HS&DR
HTA
PGfAR
PHR

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