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A combined randomised and observational study of surgery for fractures in the distal radius in the elderly (CROSSFIRE)—a study protocol

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ABSTRACTINTRODUCTION

Fractures of the distal radius are common and occur in all age groups. The incidence is high in older populations due to osteoporosis and increased falls risk. Considerable practice variation exists in the management of distal radius fractures in older patients ranging from closed reduction with cast immobilisation to open reduction with plate fixation. Plating is currently the most common surgical treatment. While there is evidence showing no significant advantage for some forms of surgical fixation over conservative treatment, and no difference between different surgical techniques, there is a lack of evidence comparing two of the most common treatments used: closed reduction and casting versus plating. Surgical management involves significant costs and risks compared with conservative management. High-level evidence is required to address practice variation, justify costs and to provide the best clinical outcomes for patients.

Methods and analysis This pragmatic, multicentre randomised comparative effectiveness trial aims to determine whether plating leads to better pain and function and is more cost-effective than closed reduction and casting of displaced distal radius fractures in adults aged 60 years and older. The trial will compare the two techniques but will also follow consenting patients who are unwilling to be randomised in a separate, observational cohort. Inclusion of non-randomised patients addresses selection bias, provides practice and outcome insights about standard care, and improves the generalisability of the results from the randomised trial.

Ethics and dissemination CROSSFIRE(Combined Randomised and Observational Study of Surgery for Fractures In the distal Radius in the Elderly) was reviewed and approved by The Hunter New England HREC (HNEHREC Reference No: 16/02/17/3.04). The results of the trial will be published in a peer-reviewed journal and will be disseminated via various forms of media. Results will be incorporated in clinical recommendations and practice guidelines produced by professional bodies.

Strengths and limitations of this study

- The combined randomised and observational study design will address selection bias and increase generalisability. The use of many centres with varying demographics and the pragmatic nature of the study (allowing surgeons to use their preferred, standard techniques) will also increase generalisability.
- A limitation of the study is the lack of blinding of surgeons and participants to the treatment allocation. This may bias the results depending on differences in preference and expectations between the treatment groups.

Registration CROSSFIRE has been registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR: ACTRN12616000969460).

INTRODUCTION

Distal radial fractures (DRFs) are the the most common fractures seen in an hospital setting.[1] They are particularly common in the elderly due to higher rates of falls and prevalence of osteoporosis. In Australia, it is estimated that the number of osteoporotic wrist fractures (in people aged 50 years and over) will increase over 25% from approximately 20 000 in 2013 to over 25 000 in 2022, and most of these will be aged 65 years and over.[2] Direct costs from osteoporotic wrist fractures have been estimated to be over 130 million dollars (AUD) per year in Australia.[2] In the European Union in 2010, it was estimated that there were 560 000 osteoporotic forearm fractures sustained, at a cost

of almost €1 billion.[3] With increasing use of surgical fixation, the cost is expected to increase disproportionately.[2]

Considerable practice variation exists in the management of distal radius fractures in the elderly.[4] Historically, these fractures have been treated by closed reduction (manipulation of the fracture) and plaster cast immobilisation. Over the last 10–20 years, the use of internal fixation for these fractures has increased more than fivefold[5] due to the frequent loss of alignment seen with plaster fixation, despite a lack of any clear association between alignment and function in this population.[6] Open reduction and (volar locking) plate fixation is currently the most common surgical treatment provided. In 2011, a survey of Australian orthopaedic surgeons showed that nearly half (47%) of surgeons preferred surgical (plate) fixation for the case example used (typical distal radius fracture in a female aged 75 years).[4]

What the evidence says

Comparative trials have not shown clear superiority of pain and function with plate fixation compared with plaster fixation, despite better radiographic appearance with operative (plate) fixation. The improved radiographic and clinical alignment noted with surgical (plate) fixation is a driver of the preference for surgical fixation among surgeons, despite evidence that the residual alignment (or malalignment) is not correlated with pain or function in these fractures.[7]

In 2009, a Cochrane review involving 3371 mainly elderly female patients concluded that there was a 'lack of clear evidence for the surgical management of these fractures'.[8] The Cochrane review did not contain any studies comparing plate fixation to closed reduction and cast immobilisation. Surgery has also been associated with significant complications otherwise not seen with non-surgical approaches.[9 10]

In 2011, a high-quality randomised controlled trial (RCT) involving 73 participants aged 65 years and older found no difference in patient-reported outcomes when volar plating was compared with plaster fixation for unstable distal radius fractures that had redisplaced after initial closed reduction.[11] However, this was a single-centre study, limiting generalisability, and it did not report changes in quality of life. Furthermore, this study only included patients in whom the initial closed reduction had failed on first review, a practice not followed in Australia, where the decision to operate is made on initial presentation. In many countries, including Australia, a treatment decision is made on the initial radiographs (degree of displacement) with no trial of closed treatment first. Therefore, the current study reflects that practice by randomising based on the initial radiographs. It is the consideration of many (particularly in Australia and the USA) that 'stability' is decided on the initial radiographs (displacement, comminution) and 'reducibility' decided on the postreduction radiographs.

In 2014, a second randomised trial involving 185 participants aged 65 years and older also showed no significant benefit to volar locked plating over closed reduction for displaced distal radius fractures, but this paper had a high rate of crossover and only included the less common intra-articular fracture type, making interpretation and generalisation difficult.[12]

We initially considered using an age cut-off of 65 years in order to align with other studies. However, the frequency of these fractures increases from age 50. Investigators were surveyed to consider lowering the age cut-off. Age 60 was the lowest age cut-off accepted by all investigators.

Table 1 Comparison of previous randomised controlled trials and proposed study, comparing volar plate fixation with casting for distal radius fractures in the elderly

	Arora *et al*[11]	Bartl *et al*[12]	Current study
All dorsally angulated distal radius fractures	Yes	No	Yes
Low crossover	Yes	No	Not known
Treatment assigned on initial presentation	No	Yes	Yes
Multicentre	No	Yes	Yes
Include general health outcome	No	Yes	Yes

Justification for, and aims of, a new trial

Given the increased resource utilisation and risks associated with surgery, a clear benefit is required to make this treatment cost-effective. No clear benefit to surgery has yet been established. Our aim is to definitively quantify the true benefit (if any) and harms of the current standard surgical treatment, and to determine its cost-effectiveness, in comparison with closed reduction and cast immobilisation. Our trial will address the methodological shortcomings of previous trials as outlined in table 1.

Given the risk associated with surgery, particularly in older people, who are more prone to comorbidities that may lead to complications and longer hospital stays, there is an important need for a definitive trial to guide practice, reduce unwarranted practice variation, optimise health outcomes and justify use of valuable resources. The results of this trial will guide care in Australia and New Zealand and will have major relevance internationally.

METHODS AND ANALYSIS

Study design

We will conduct a multicentre RCT with an accompanying economic evaluation. The study will include a concurrent prospective observational study including eligible patients who decline participation in the randomised trial and will therefore receive standard care (either plate fixation or closed reduction according to patient preference and usual care for each institution) and consent to be followed-up. All institutions have agreed to use only these two common techniques. Participants from the

parallel observational cohort will be followed-up at the same time intervals using the same outcomes measures as the randomised trial. Surgeons and participants will not be blinded. The primary outcome (patient-reported outcome) will be collected by a blinded assessor.

The use of a parallel observational 'preference' cohort in addition to the core RCT addresses criticisms of selection bias in the RCT by following non-randomised patients, and increases generalisability by following a large cohort of patients receiving the same treatment options as the RCT, as part of usual care.[13] This study type has been used in surgical trials[14] and has been recommended as a model for trials of surgery versus non-operative treatment where recruitment rates are expected to be lower than for other RCTs.[15] Our experience from our recently completed, similar multicentre fracture trial[16] is that a third of patients accept randomisation with almost 100% of the remainding eligible patients consenting to be part of the observational cohort.

Participants

The study will recruit from up to 32 institutions and over 30 clinician investigators. The study population will include non-institutionalised individuals aged 60 years or older presenting to participating institutions with an isolated, displaced, dorsally angulated distal radius fracture, within 1 week of injury.

Inclusion criteria

- Age 60 years or older
- Displaced distal radius fracture (fracture classification AO/OTA 23A or 23C with more than 10° dorsal angulation, referenced off a line perpendicular to the shaft of the radius or >3 mm shortening or >2 mm articular step) prior to reduction
- Medically fit for surgery
- Independent living (including hostel accommodation)
- Low energy injury (fall from <1 m)
- Available for follow-up for 12 months

Exclusion criteria

- Patient unable to provide consent (due to cognitive capacity or English proficiency)
- Volar angulation
- Diaphyseal extension
- Partial articular fractures, for example, Chauffeur or Bartons' fractures (AO/OTA 23B)
- Associated fracture or dislocation in any other body part that will affect the use of the involved wrist (ulna styloid fracture will be permitted, as these are usually associated with the fracture under investigation)
- Open injury
- Previous wrist fracture on the same side
- Medical condition precluding anaesthetic

Potential participants will be screened and those eligible will be approached by members of the orthopaedic team. Eligible patients will be provided with the Participant Information Sheet, invited to participate and given the opportunity to ask questions. Eligible patients who are unwilling to be included in the randomised cohort of the study will be invited to participate in the observational cohort. Written consent will be obtained prior to inclusion in either the randomised or observational cohorts.

Randomisation will occur immediately after consent has been gained by the recruiting orthopaedic team, within 1 week of the date of the injury. This will occur by the orthopaedic team member contacting a central computer-based randomisation service by telephone. Participants will be randomised using the method of minimisation. Randomisation will be stratified by site, and minimisation, adjusting for gender and age (60–74 years and >74 years), will be employed as recommended by the National Health and Medical Research Council Clinical Trials Centre, who will provide the randomisation service. Minimisation (adaptive stratified sampling) aims to reduce imbalance between the groups on prognostic factors which can occur despite random allocation of treatment. Here, age and gender will be included in the minimisation algorithm for randomisation.

Interventions

Intervention group (plate group)

Surgical fixation using a volar locking plate will be performed within 2 weeks of initial injury according to usual care of the participating institution, with an orthopaedic surgeon in attendance. This is a commonly performed procedure. Surgical technique and type of plate (make and length) will be surgeon preference. A plaster cast may be applied postoperatively but for no longer than 2 weeks. Active finger movement will be encouraged postoperatively. Participants will be reviewed 2 weeks (10–17 days) after surgery; the wound will be reviewed and sutures removed where necessary. Participants will be provided with a home-exercise programme (see online supplementary file 1) postoperatively. Referral for outpatient rehabilitation will not be routinely provided but will be permitted. See the 'Physiotherapy' section for more information on post-treatment rehabilitation.

Control group (cast group)

Participants in this group will be treated with a closed reduction and cast immobilisation, avoiding wrist flexion, within 2 weeks of the initial injury. This method of casting is consistent with standard casting practice in Australia. Immobilisation of a DRF in flexion has been associated with an increased risk of fracture displacement as well as finger and MCPJ (metacarpophalangeal joint) stiffness.[17] Also, immobilisation in a cast that is too restrictive and excessively flexed has been associated with an increased risk of CRPS (complex regional pain syndrome).[18 19]

The reduction may be performed in the emergency department under sedation and local anaesthetic infiltration into the fracture (haematoma block) where possible, but may also be performed in an operating

room (according to availability and local practice). The procedure will be performed by the treating team. Postreduction radiographs will be taken to assess the fracture alignment after the reduction. The best reduction achievable will be accepted.

The cast will be removed at 6 (±1) weeks from the initial reduction. Active finger movement and light use of the hand will be encouraged immediately. Participants will be provided with a home-exercise programme (see online supplementary file 1). Referral for outpatient rehabilitation will not be routinely provided but will be permitted (as above).

Observational arm

Patients who do not consent to be randomised will be offered participation in the observational arm of the study. Their treatment will consist of either closed reduction and cast immobilisation or operative fixation using a volar locking plate (the same two treatment options as the RCT arm). Treatment will be decided by patient preference as per usual practice at each institution. Postoperative treatment protocols, follow-up and outcome measures will be the same as the randomised arms.

Physiotherapy

A home-exercise programme (see online supplementary file 1) will be provided to all groups. Outpatient physiotherapy will be allowed according to local practice, but not controlled.

Outcomes

Baseline variables will include age, gender, pre-injury difficulty using arm (yes/no), fracture type (AO/OTA 23A or 23C), radiographic features (see the 'Inclusion criteria' section), diabetes (yes/no), smoking status (current smoker: yes/no), current glucocorticoid treatment: yes/no, osteoporosis treatment. Outcome scores (quality of life) and radiographic measures will be recorded at baseline. We will also collect treatment preference at baseline, as this may have an independent effect on outcome.

The primary outcome will be The Patient Rated Wrist Evaluation (PRWE)[20 21] at 12 (±1) months. The PRWE is a 15-item patient-reported measure of pain and function, specific to the wrist. It is a continuous score on a scale from 0 to 100 with higher scores being worse. It is commonly used, was developed with patient-input and has been validated for use in patients with distal radius fractures.

Secondary outcomes will include:

- PRWE at 3 months and 2, 5 and 10 years,
- Disability of the Arm Shoulder and Hand (DASH)[22] at 12 months,
- EQ-5D-5L (EuroQol five dimension health-related quality of life questionnaire) at 3 and 12 months and 2, 5 and 10 years,
- pain (numerical rating scale, 0–10) at 3 and 12 months and 2, 5 and 10 years,
- patient-reported treatment success (at 12 months, 5-point Likert scale),
- patient rated bother with appearance (at 12 months and 2, 5 and 10 years, 5-point Likert scale),
- complications (including deep infection, reoperation, neuropathy, tendon irritation requiring treatment, tendon rupture, fracture non-union at minimum 6 months, implant failure, complex regional pain syndrome, death) at 3 months, 12 months, 2, 5 and 10 years,
- radiographic measures (shortening (ulnar variance), dorsal angulation, radial tilt, articular step) measured at presentation, postreduction and between 6 weeks and 12 months),
- physiotherapy utilisation up to 3 months post-treatment.

Sample size

The recent RCT by Arora *et al*[11] used a 1:1 allocation, 5% significance and 80% power to detect a difference of 10 points on the PRWE, calculating a sample size of 68 participants for both groups. Based on a SD for the PRWE of 23 in the study by Arora *et al*, a 10-point threshold would be less than the commonly used threshold of 0.5 SD for a clinically important difference[23] and less than the MCID (minimum clinically important difference) of 12 points for the PRWE determined by Walenkamp *et al*.[24] Using a 14-point cut-off represents 0.6 SD and is in line with another estimate of the minimum clinically important difference of the PRWE.[25] We consider 14 points to be the (MCID) necessary to justify the additional costs of surgery compared with non-operative treatment.

A total of 128 patients (64 in each group) will provide 90% power to detect a difference of 14 points on the PRWE scale at a significance level of 0.05. We aim to recruit 160 patients to allow for 20% loss to follow-up. The previous RCTs each reported loss to follow-up rates of 19%.[11 12]

The observational cohort will be a convenience sample of patients not consenting to randomisation. In our experience, this group will comprise approximately two participants for every one randomised. We will therefore recruit 160 patients into the randomised trial and approximately 300 patients into the parallel observational cohort.

Data collection

Primary data collection from site investigators will be paper-based but direct electronic data entry will also be allowed. Participant follow-up will be by telephone, but the option of electronic data capture by participants (incorporating electronic reminders) will be available.

Data analysis

The primary outcome is the PRWE score at 12 months. An analysis of covariance will be used to compare the mean PRWE between the two independent groups. Intention-to-treat analysis will be performed in the primary analysis. A per-protocol analysis (including participants according

to treatment received) will be added as a secondary analysis. Analysis of secondary outcomes will include mixed model analyses, comparing secondary outcomes between timepoints. Non-operative treatment will be defined as a minimum of 28 days in the plaster splint for the purposes of the per-protocol analysis.

The observational cohort will be analysed separately, comparing the same two treatment groups against the same outcomes using multivariable linear regression to adjust for potential confounders. Repeated measures analysis will be performed as a secondary analysis.

Attempts will be made to minimise missing data, such as obtaining multiple contact details at recruitment and using telephone follow-up rather than mail. Missing data will be dealt with according to the instructions on the use of the outcome tools (PRWE, DASH and EQ-5D-5L). If >10% of data is missing from the randomised sample, then missing data will be imputed.

Cost-effectiveness

The costs of both treatment cohorts, and health service utilisation will be calculated for the cost-effectiveness analysis. A cost-effectiveness analysis will be performed from the hospital perspective and an healthcare funder perspective, and limited to clearly defined costs. Costs will be calculated from: (1) length of stay (if admitted), (2) theatre costs (based on standard fees for public hospitals in each state), (3) implant costs and (4) outpatient rehabilitation-related costs. Using the mean costs and the mean health outcomes in each trial cohort, the incremental cost per quality-adjusted life-year (QALY) of the plate group compared with cast group will be calculated; results will be plotted on a cost-effectiveness plane. Bootstrapping will be used to estimate a distribution around costs and health outcomes, and to calculate the CIs around the incremental cost-effectiveness ratios. One-way sensitivity analysis will be conducted around key variables and a probabilistic sensitivity analysis to estimate the joint uncertainty in all parameters. A cost-effectiveness acceptability curve will be plotted to provide information about the probability that the intervention is cost-effective, given willingness to pay for each additional QALY gained.

ETHICS AND DISSEMINATION

Safety considerations

The study compares two treatments that comprise usual care. It is not anticipated that either treatment cohort will be associated with adverse events beyond what is experienced normally with these therapies. An independent data safety monitoring board (DSMB) will be established at the commencement of the trial. The board will convene 4 months after trial commencement to review study progress and, where appropriate, provide advice on issues regarding the scientific aspects of study conduct (eligibility, recruitment rates, compliance) and any emerging evidence as it relates to the trial. The DSMB will reconvene subsequently to review progress if any recommendations were made after the initial review. If not, the DSMB will only meet as required, that is, if any adverse event (defined below) occurs. The DSMB will be required to decide whether the adverse event is related to the trial interventions or not. If there appears to be an atypical trend in adverse events, trial suspension will be considered. The DSMB will comprise three members who are not investigators (an orthopaedic surgeon, a physical therapist and a statistician /epidemiologist), as well as one investigator.

Adverse events will be defined as:

- symptomatic fracture non-union (three of four cortices not united radiographically at minimum 6 months),
- infection (local infection requiring any treatment),
- neuropathy,
- tendon irritation (requiring treatment),
- tendon rupture,
- complex regional pain syndrome (diagnosed on the basis of presence of dysaesthetic pain, hyperaesthesia extending into the hand of the injured limb, vasomotor changes, skin atrophy and diffuse osteopenia).

Site agreements include provisions for liability and insurance, requiring each site to maintain insurance for indemnity relating to activities in the conduct of the study. Participants are informed in the patient information and consent form as to what they should do if they suffer any injuries or complications as a result of participation in the study.

Ethics

The study was granted ethics committee approval by the Hunter New England human research ethics committee (HREC): HREC/16/HNE/10.

The study was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12616000969460). Registration can be viewed at http://www.ANZCTR.org.au/ACTRN12616000969460.aspx. The study satisfies the requirements of the National Statement on Ethical Conduct in Human Research (updated March 2014). No financial or other competing interests have been identified or declared. The protocol was presented to, reviewed and endorsed by The Australian and New Zealand Musculoskeletal Clinical Trials Network.

The investigators consider randomised trials of operative versus non-operative treatment to be ethical, provided that the requirements of ethical research have been satisfied, and the potential benefits of the study to society outweigh the potential risks to individuals involved in the study. Two of the investigators have previously published on ethics in surgical research.[26 27] As operative treatment is currently a common treatment, we see no increased harm from surgery than would exist without the presence of the study.

In this case, we consider the risks of continued operative treatment of distal radius fractures without supporting

evidence of a clinical advantage over non-operative treatment to be unjustified. Risks associated with this study are the risks associated with each of the treatments.

Participants will not be paid. Institutions will receive reimbursement per participant for the randomised group and AUD100 per participant for patients declining randomisation (who are included in the observational cohort) to compensate for the time given by local research support staff in recruitment and data collection.

Data management

Data will be collected by local site investigators and study documents will be submitted securely (scanned and emailed) to the project manager at the administering institution. Data will be stored in password protected computers and locked filing cabinets within the administering institution.

Dissemination

The protocol will be published in accordance with The SPIRIT Statement.[28 29] Reporting will be according to the CONSORT Statement (Consolidated Standards of Reporting Trials).[30]

The results of the study will be presented at national and international orthopaedic scientific meetings such as the Australian Orthopaedic Association Annual Scientific Meeting and the American Academy of Orthopaedic Surgeons Annual Scientific Meeting. Results will be published in an high impact general medical or surgical journal and will be disseminated via various forms of media. The results of the trial will be incorporated in clinical recommendations and practice guidelines. A medical education programme will include direct feedback of the results to participating institutions, including orthopaedic departments, emergency departments, general practitioners and physiotherapists.

Authorship will be under the name of 'The CROSSFIRE Study Group'. This group will comprise all investigators, including at least one investigator from each contributing institution. Aggregated, deidentified results will also be made available to participants and participating institutions via the study website. The deidentified participant-level dataset and statistical code will be made available for collaborative research projects.

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Correction notice This paper has been amended since it was published Online First. Owing to a scripting error, some of the publisher names in the references were replaced with 'BMJ Publishing Group'. This only affected the full text version, not the PDF. We have since corrected these errors and the correct publishers have been inserted into the references.

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Contributors Authorship belongs to The CROSSFIRE Study Group. All members of the study group have and will substantially contribute to the study by way of study design and/or acquisition of data and/or analysis of data. All members of the study group have been consulted on and approved of the final version of the study protocol. The trial was designed by IH, JN, RB, RI, ZB and PS with contributions from RM and AL. AL is the project manager and AV is the study coordinator. Specific advice was provided by KH on health economics and WX on statistics. All other members of the study group – PY, BR, GS, IE, WK, MC, JS, KL, JW, SV, MR, KS, HD, PT, JL, RP, RH, RB, JM and II—reviewed the protocol and will coordinate data collection at respective sites.

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Competing interests All authors have completed the ICMJE COI form. Completed forms are held by the corresponding author. There were no COIs declared by any of the authors.

Ethics approval Hunter New England HREC (HNEHREC Reference No: 16/02/17/3.04).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Aggregated, deidentified results will also be made available to participants and participating institutions via the study website, accessed via the Whitlam Orthopaedic Research Centre website. The deidentified participant-level dataset and statistical code will be made available for collaborative research projects, on request of the chief investigator.

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