

# Comparison of surgical procedures for patients with a fracture of the wrist

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/04/2016	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Fractures of the wrist are extremely common injuries. If the broken bones have stayed in their original place, then the fracture can usually be treated in a plaster cast or splint. However, some 'unstable' fractures (where the broken bones have been displaced) might need to be fixed back into place with an operation. The two most commonly used techniques in the UK are fixation with wires inserted through the skin (a simple and well-established method), and fixation with a plate which is applied to the surface of the bone with special screws (a very modern, potentially advantageous but expensive method). The aim of this study is to compare these two techniques.

### Who can participate?

Patients aged over 18 with a wrist fracture

### What does the study involve?

Participants are randomly allocated to be treated with either the wire fixation or the plate fixation technique. Before the operation and at three occasions after the operation (3 months, 6 months and 1 year), the patients' wrist function and quality of life are assessed. X-rays are taken at 6 weeks and 1 year to check if healing has occurred. A record is kept of any complications which occur after the operation. The patients are also asked to provide information about any out-of-pocket expenses they might have had in the period after the operation as a result of the injury (for instance whether they had to see a physiotherapist or had a cleaner for a while). The results of all these measurements are then used in two ways: to determine if there is a difference in effectiveness of the two fixation methods and what the most cost-effective method is, bearing in mind the quality of life of the patients.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

University of Warwick (UK)

### When is the study starting and how long is it expected to run for?

July 2010 to December 2013

Who is funding the study?  
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?  
Mr Matthew Costa  
Matthew.costa@warwick.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Matthew Costa

**Contact details**  
Clinical Sciences Research Institute  
Clifford Bridge Road  
Coventry  
United Kingdom  
CV2 2DX  
+44 (0)2476 968 618  
Matthew.costa@warwick.ac.uk

## Additional identifiers

**Protocol serial number**  
HTA 08/116/97

## Study information

**Scientific Title**  
A randomised controlled trial of percutaneous fixation with Kirschner wires versus volar locking-plate fixation in the treatment of adult patients with a displaced fracture of the distal radius

**Acronym**  
DRAFFT

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

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/0811697>  
Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0012/52041/PRO-08-116-97.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0012/52041/PRO-08-116-97.pdf)

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Coventry Research Ethics Committee, 24/02/2010, ref: 10/H1210/10

**Study design**

Multicentre randomised double-blind clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Dorsally displaced fracture of the distal radius

**Interventions**

K-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 will be left entirely to the discretion of the surgeon. A plaster cast will be 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 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 will be left to the discretion of the surgeon. The screws in the distal portion of the bone will be fixed-angle, i.e. screwed into the plate, but this is standard technique for the use of these plates. The type of proximal screw will be 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 use a temporary plaster cast to hold the patients wrist still but the fixed-angle stability provided by the locking-plate is generally sufficient to allow early controlled range-of-movement exercises. The use or otherwise of a cast will again be left to the discretion of the surgeon as per usual practice.

The treatment takes approximately 1 hour. All patients will be followed-up for 12 months.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Primary outcome measure as of 24/01/2012:

Patient Rated Wrist Evaluation (PWRE). The PRWE score 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. This data will be collected at baseline, 3, 6 and 12 months post-operatively. The PRWE is the most sensitive outcome measure for patients sustaining this specific injury. Analysis will be performed on the complete data set as well as on the subgroup of patients over the age of 50 years.

Previous primary outcome measure:

Patient Rated Wrist Evaluation (PWRE). The PRWE score 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. This data will be collected at baseline, 3, 6 and 12 months post-operatively. The PRWE is the most sensitive outcome measure for patients sustaining this specific injury.

### **Key secondary outcome(s)**

1. Disabilities of Arm, Shoulder and Hand score (DASH) - 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
2. EQ-5D - a validated, generalised, quality of life questionnaire consisting of 5 domains related to daily activities with a 3-level answer possibility. The combination of answers leads to the QoL score.
3. Complications - all complications will be recorded
4. Radiographic evaluation - standard posterior-anterior and lateral radiographs will be taken at baseline, 6 weeks and 12 months after the injury. These radiographs are those routinely used for the investigation of patients with a suspected fracture of the distal radius and for the follow-up of such patients following any intervention, so there will be no need to request any additional or special investigations. Although the technique for taking these radiographs is well-established, each centre will be provided with a written protocol to ensure that exactly the same views are obtained at each hospital. An assessment of the quality of the reduction, and the risk of subsequent loss of reduction, will be made using the criteria recommended by Mackenney et al.
5. Resource use will be monitored for the economic analysis. Unit cost data will be obtained from national databases such as the BNF and PSSRU Costs of Health and Social Care. Where these are not available the unit cost will be estimated in consultation with the UHCW finance department. The cost consequences following discharge, including NHS costs and patients' out-of-pocket expenses will be recorded via a short questionnaire which will be 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.

### **Completion date**

31/12/2013

## **Eligibility**

### **Key inclusion criteria**

1. Sustained a dorsally displaced fracture of the distal radius, which is defined as a fracture within 3 cm of the radio-carpal joint
2. The treating Consultant Surgeon believes that they would benefit from operative fixation of the fracture
3. Aged over 18 years (either sex) and able to give informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

## **Lower age limit**

18 years

## **Sex**

All

## **Key exclusion criteria**

1. The fracture extends more than 3 cm from radio-carpal joint
2. The fracture is open with a Gustillo grading greater than 1
3. The articular surface of the fracture cannot 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)
4. There are contra-indications to surgery, defined as:
  - 4.1. Severe cardiac impairment, e.g. heart or valve replacement, arrhythmia, previous myocardial infarction
  - 4.2. Severe respiratory impairment, e.g. chronic obstructive pulmonary disease, asthma that has required hospital admission
  - 4.3. Any other systemic medical condition that would produce a specific contraindication to a general anaesthetic
5. There is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires, such as cognitive impairment or intravenous drug abuse

## **Date of first enrolment**

01/07/2010

## **Date of final enrolment**

31/12/2013

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**Clinical Sciences Research Institute**

Coventry

United Kingdom

CV2 2DX

## **Sponsor information**

### **Organisation**

University of Warwick (UK)

## Organisation

University Hospitals Coventry and Warwickshire NHS Trust (UK)

## Organisation

University of Warwick

## ROR

<https://ror.org/01a77tt86>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	05/08/2014		Yes	No
<a href="#">Results article</a>	results	01/02/2015		Yes	No
<a href="#">Protocol article</a>	protocol	13/09/2011		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes