ISRCTN27396017 https://doi.org/10.1186/ISRCTN27396017

# Clinical study of the volar locking plate for distal radial fractures

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 17/05/2009 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 08/09/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 07/10/2013 | Musculoskeletal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
07OR003

## Study information

**Scientific Title**
Unstable fractures of the distal radius: a randomised prospective clinical study comparing their treatment with volar locking plate and conventional method

## Study objectives
This study will compare the outcome of displaced distal radial fractures when treated with a volar locking plate (the Distal Volar Radius [DVR®]) or the conventional method which involves percutaneous wires +/- an external fixator.

Our primary research objective is to determine whether the use of volar locking plates improves functional outcome and allows for an earlier return to normal activities and work.

As a secondary objective, we aim to determine through economic evaluation, whether the use of volar locking plates for distal radial fractures is of financial benefit to the health service and society in general.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
North Nottinghamshire Research Ethics Committee approved on the 6th September 2007 (ref: 07 /H0407/39)

## Study design
Pragmatic randomised single centre controlled parallel group surgical trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Distal radius fracture

## Interventions
The intervention consists of surgical fixation of the distal radius fracture in a patient who fulfils the trial inclusion and exclusion criteria with a radial volar locking plate or the established conventional method involving percutaneous wires +/- an external fixator.

The health technology under assessment is the radial volar locking plate, a type of orthopaedic implant with locking screws which aid the reduction and stabilisation of distal radius fractures. We compare this to the established conventional methods (percutaneous wires and/or an external fixator device).

The plate chosen for this trial is the Distal Volar Radius or DVR® plate, which is in common use across the United Kingdom. Instrumentation also includes smooth 1.6 mm Kirschner wires and the standard AO external fixator, as appropriate. All are currently in use within the NHS, CME licensed and will not require MHRA authorisation.

The total duration of follow-up for each participant is one year post-surgery.

## Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Function of the limb following a surgically treated distal radius fracture. As a measure of function we selected the Hand Health Profile forming part of the Patient Evaluation Measure (PEM). Expected duration of patient participation will be one year. Follow up and data collection will be performed at 6 weeks, 12 weeks and 1 year.

### Key secondary outcome(s))
1. Clinical measurements: grip strength and range of motion
2. Radiographic parameters: radial length, palmar tilt, radial inclination and articular gaps/steps less or equal to 2 mm
3. Quality of life: as assessed via the EUROQUOL EQ-5D and 12-item short form health survey (SF-12) scores

Expected duration of patient participation will be one year. Follow up and data collection will be performed at 6 weeks, 12 weeks and 1 year.

### Completion date
30/08/2010

## Eligibility

### Key inclusion criteria
1. Fractures which the referring physician considers require operative intervention
2. Configuration is such that the fracture would be amenable to stabilisation via volar locking plate (not massively comminuted)
3. Adults (skeletally mature) with high demand requirements of their wrist in whom the radiological appearance of the bone suggests that it is robust enough to tolerate internal fixation; and in whom the fracture pattern at presentation fulfils the criteria as described below
4. Fractures of the distal radius which are:
4.1. Dorsally displaced extra-articular fractures (with or without an undisplaced intra-articular component) with dorsal cortical comminution as seen on the lateral radiograph
4.2. Displaced intra-articular fractures with an articular step or gap in the radio-carpal joint surface
5. Skeletally mature adults, minimum age 16 years and above, either sex

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Patients with concomitant systemic diseases (diabetes with vascular or neurological complications, advanced cardiac, pulmonary or neurological disease)
2. Proximal metaphyseal fractures (more than one inch or 2.5 centimetres from the articular surface)
3. Open fractures
4. Smith's and volar Barton's configuration
5. Previous fractures of the distal radius of the same or contra-lateral limb less than six months old
6. Significant pre-existing radiological abnormality
7. Multiply injured
8. Bilateral injuries
9. Patients who are unable to consent for themselves to treatment
10. Patients who may have difficulties in adequate understanding of English

### Date of first enrolment
11/02/2008

### Date of final enrolment
30/08/2010

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Academic Department of Orthopaedic & Accident Surgery**
Nottingham
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## Sponsor information

### Organisation
Nottingham University Hospitals NHS Trust (UK)

### ROR
https://ror.org/05y3qh794

## Funder(s)

**Funder type**
Government

**Funder Name**
Nottingham University Hospitals NHS Trust (UK)

**Funder Name**
Nottingham University Hospitals Charity via the Hand Research Fund (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? |
|---|---|---|---|---|---|
| Results article | results | 02/10/2013 | | Yes | No |