

# Long term results of distal radius fractures treated with Open Reduction and Internal fixation with a volar Locking Compression Plate

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What are the clinical and radiological results of ORIF with a volar LCP in distal radius fractures?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Fractures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON35346

### Source

ToetsingOnline

### Brief title

long term results of DRF after ORIF with volar LCP

### Condition

- Fractures
- Bone and joint therapeutic procedures

### Synonym

broken wrist, Distal radius fracture

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Deventer Ziekenhuis

**Source(s) of monetary or material Support:** Deventer Ziekenhuis

## Intervention

**Keyword:** distal radius, Long term results, ORIF, volar LCP

## Outcome measures

### Primary outcome

Disabilities of Arm, Shoulder and Hand (DASH)

score.

### Secondary outcome

Range of movement, squeezing power, radiological parameters, complications,

implant removal

## Study description

### Background summary

Although very common (1/6 fractures) the most effective treatment of distal radius fractures still isn't clear. Recent investigations gave promising results of Open Reduction with Internal Fixation (ORIF) with a volar placed Locking Compression Plate (LCP) in the treatment of distal radius fractures. The majority of these studies are limited by a short follow up (12-24 months average 18,8) and small numbers of patients (34-305 average 105,8). The long term results of ORIF with a volar LCP remain a question up until this day. This is the reason why

we want to investigate long term functional and radiological results after ORIF with a volar

LCP. At the Deventer Ziekenhuis (Netherlands) from 2004-2010 a minimum of 150 patients were treated with a volar LCP. We will ask patients to return to our hospital for a one time follow-up visit which includes clinical and radiological investigations.

### Study objective

What are the clinical and radiological results of ORIF with a volar LCP in distal radius fractures?

## Study design

Observational study; cohort study.

## Study burden and risks

Patiënts are invited for a one time visit to the Deventer Ziekenhuis outpatient clinic. An advance they wil fill in the DASH and general questionnaire. During their visit both wrists will be examined for range of movement and squeezing power. The investigator will take a short history. Patiënts will receive conventional x-ray photo's in two directions of their wrist. Radiation used is minimal ( $<0.1\text{mS}$ ). Protocol by the radiologists at the Deventer Ziekenhuis is used. Physical and mental burden are minimal. Except for the radiation, there are no study related risks involved.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- distal radius fractuur AO-type A2-C3
- treated with open reduction and internal fixation with a volar locking compression plate
- age > 18jr
- Informed Consent

## Exclusion criteria

- bi-lateral distal radius fracture
- Treatment with volar and dorsal LCP at the same time
- death
- follow-up <24 months
- antebrachii fracture

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 27-01-2012

Enrollment: 150

Type: Actual

## Ethics review

Approved WMO

Date: 12-01-2012  
Application type: First submission  
Review commission: METC Isala Klinieken (Zwolle)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL38835.075.11