# Corrective osteotomy for malunited fractures of the distal radius: a follow-up study

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Ethical review	Approved WMO	
Status	Pending	
Health condition type	Fractures	
Study type	Observational invasive	

## Summary

### ID

NL-OMON34150

**Source** ToetsingOnline

**Brief title** Follow-up corrective osteotomy

### Condition

- Fractures
- Bone and joint therapeutic procedures

#### Synonym

correction of the position of the wrist (correction osteotomy), Wrong position of the bones in the wrist (malunited fracture of the distal radius)

#### **Research involving**

Human

### **Sponsors and support**

#### Primary sponsor: Academisch Medisch Centrum

#### Source(s) of monetary or material Support: AMC

#### Intervention

Keyword: Correction osteotomy, Distal radius fractures

#### **Outcome measures**

#### **Primary outcome**

CT scans of both forearms are obtained. Then the CT scans will be used to

obtain the position and orientation of the distal part of the radius, what will

be compared with three dimensional matching software. Also the patients have to

fill in questionnaires about their hand function, and function tests of the

wrist and forearm will be recorded.

#### Secondary outcome

Not applicable

## **Study description**

#### **Background summary**

Patients with malunited fractures of the distal radius often complain of weakness, pain, and reduced movement in the wrist and forearm. Corrective osteotomy may improve the alignment of the distal radius in relation to the carpus and the distal ulna. Restoration of the anatomical variables improves the biomechanics of the wrist, resulting in improved grip strength, movement of the wrist and forearm, and reduced pain. Several studies of acute distal radius fractures have shown that the radiological result is related to the clinical outcome, and that union in malalignment leads to a poorer outcome. The aims of our study are to evaluate the degree of anatomical correction and the functional outcome after corrective osteotomy of malunited distal radius fractures. We also want to compare the functional outcome of the osteotomised wrist with the function of the uninjured wrist.

#### **Study objective**

The aim of this study is to evaluate the results of corrective osteotomy for

distal radius malunion at our institution. We want to compare the pre-operative and post-operative CT scan-based three dimensional reconstructions for the comparison between the injured wrist and uninjured wrist. We hope to gain valuable anatomical information and to create a basis for further research in studies on various wrist pathology and surgical techniques.

#### Study design

A retrospective observational follow-up study. Anatomical study.

#### Study burden and risks

The radiation exposure of scans is estimated to be 0,6 mSv for each participant. This is comparable to 12-14 weeks background exposure to the natural radiation in The Netherlands.

## Contacts

#### Public

Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam NL **Scientific** Academisch Medisch Centrum

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- Patients included in this study have been treated by corrective lengthening osteotomy of extra-articular fractures of the distal radius at our institution in the years 2000-2010

- Patient has a pre-operative CT scan available
- Over the age of 18 years
- Contralateral wrist is unaffected

## **Exclusion criteria**

- Correction osteotomy of the ulna
- Madelung deformity of the wrist
- Not able to understand the written informed consent
- Pregnancy

## Study design

## Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	45
Туре:	Anticipated

## **Ethics review**

#### Approved WMO

Application type: Review commission:

## **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
 NL34264.018.10