

Long-term functional outcomes of ORIF for Intra-Articular Distal Radius Fractures

Published: 17-04-2008

Last updated: 10-05-2024

The aim of this project is to assess objective and subjective functional long-term outcome of patients with intra-articular distal radius fractures treated with open reduction and internal fixation (ORIF). This will be done by standardized...

Ethical review	Approved WMO
Status	Pending
Health condition type	Connective tissue disorders (excl congenital)
Study type	Observational invasive

Summary

ID

NL-OMON31634

Source

ToetsingOnline

Brief title

Long-term functional outcome of ORIF for IADR fractures

Condition

- Connective tissue disorders (excl congenital)
- Bone and joint therapeutic procedures

Synonym

intra-articular distal radius fracture, polsfracture

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Distal, Intra-articular, ORIF, Radius

Outcome measures

Primary outcome

Objective study parameters: Wrist function assesment results and X-ray assesment

Subjective study parameters: Patients satisfaction level and disability/pain level (scores)

Secondary outcome

-

Study description

Background summary

Fractures of the distal radius is the most common fracture in the orthopaedic practice. It is well established that instable fractures of the distal part of the radius may require operative treatment to restore alignment and that failure to restore alignment often leads to wrist and forearm dysfunction. Although sometimes stated otherwise, the outcome of these fractures is not uniformly good regardless the treatment instituted. There is ongoing debate in the literature whether or not there is a strict relationship between the quality of anatomical reconstruction and functional outcome.

There are several theories of how malalignment will cause problems in the long term. However, the literature on the relationship between anatomy and function of the distal radius is inconsistent and incomplete. There is no long-term data on intra-articular distal radius fractures in the orthopaedic literature. Most of it is 10 years or fewer outcomes and nearly all is after non-operative treatment.

There is a abundance of short-term retrospective studies on various plating techniques for operative treatment of intra-articular distal radius fractures in the orthopaedic literature. Most of these studies are industry driven to evaluate the results of a new fixation techniques.

There is a short of long-term objective and subjective functional outcome.
This is a retrospective non-comparative cohort review of patients from the "AO AMC database" with ORIF treatment treated for a intra-articular distal radius fracture with at least 10 year of follow-up.

Study objective

The aim of this project is to assess objective and subjective functional long-term outcome of patients with intra-articulair distal radius fractures treated with open reduction and internal fixation (ORIF). This will be done by standardized objective and subjective scales. We will evaluate factors that are predictors of good outcome.

Study design

All patiets treated for a IADR fracture with ORIF treatment who are registrated in the AO-AMC database will be invited to take part of the study. They will be asked to return to the Academic Medical Centre to take part in a long-term follow-up research.

The DASH questionnaire and the Modiefied Gartland and Werley and Modified Mayo Wrist Scores will be filled out by the patients at their long-term follow up appointment. Range of motion in the radio-ulnar deviation, pronation-supination and flexion-extension arcs will be measured with a hand held goniometer. Lastly, objective evaluation for grip strengthwill be performed by authors not involved in the patient care.

Finally there will be taken 3 X-rays to evaluete objectieve state of the wrist

Study burden and risks

Except for a one time visit to the AMC Amsterdam, there is no futher burden for the patient.

There is very low risk, classified as tricial, for the X-rays of the wrist.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9

1100 DD Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Males and females; older than 18 years, who suffered in the past from an intra-articular distal radius fracture and where treated by open reduction with internal fixation

Exclusion criteria

Patients younger than 18 years old. Patients with a extra-articulair distale radius fracure.
Patients with systemic diseases of the muscular-skeletal system

Study design

Design

Study phase: 4

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	04-10-2007
Enrollment:	108
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL19424.018.07