

Long-term functional outcomes of extraarticular distal radius osteotomy for the treatment of extraarticular distal radius malunion

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The aim of this project is to do an objective and subjective functional long-term outcome assessment of patients with distal radius malunions, treated with intraarticular osteotomy and therefore evaluate factors that are good outcome predictors for...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON30172

Source

ToetsingOnline

Brief title

Long term functional outcomes EDRO for the treatment of EDRM

Condition

- Bone disorders (excl congenital and fractures)
- Bone and joint therapeutic procedures

Synonym

Carpal malunion, Deformed wrist

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Extra-articular, Malunion, Osteotomy, Radius

Outcome measures

Primary outcome

Objectieve uitkomst maten: Polsfunctie onderzoeksuitkosten (scores) en rontgenfoto beoordeling.

Subjectieve uitkomstmatenL tevredenheid en beperkingen/oijn van de patient (scores)

Objective study parameters: Writs function assesement results (scores) and X-ray assessment.

Subjective study parameters: patient satisfaction and disability/pain (score)

Secondary outcome

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Study description

Background summary

Union with defomity is the most common complication following a distal radial fracture. Thes deformity can be extra articular affecting either the raiocondral or the radioulnar jointsl characterized by metaphyseal angulation and loss of

function, or a combination of both.

Malunion of the distal radius can affect the kinematics of the wrist and its function, causing pain, restriction of movement and arthritis for the patient. Corrective osteotomies have been proven to be an effective treatment for symptomatic malunion. Even though it is a difficult procedure that has many pitfalls in order to achieve a good result.

There is short and medium term outcome evaluation in the published literature. However, there is a lack of evidence of the subjective and objective functional and radiological long-term outcomes in patients with EDRM treated with EDRO. This is a retrospective non-comparative cohort review of patients from the AO AMC database with EDRO in terms of long-term functional outcomes.

Study objective

The aim of this project is to do an objective and subjective functional long-term outcome assessment of patients with distal radius malunions, treated with intraarticular osteotomy and therefore evaluate factors that are good outcome predictors for the population. Additional subjective functional assessment also will be addressed.

Study design

All patients treated operatively for extraarticular distal radius malunion through EDRO in the Academic Medical Centre in Amsterdam from the first available year of registry in the AO AMC database until 2004, will be invited to return to our out-patient clinic for a long term follow up (IRB approved) DASH questionnaire and Modified Gartland and Werley and Modified Mayo Wrist Scores are the instruments used for the evaluation. Furthermore we will use a range of motion and grip strength measurement which will be analysed independently.

Follow up standard wrist radiographies will be taken to evaluate postoperative alignment, percentage of correction compared to preoperative X rays and the presence of radiocarpal and/or radioulnar arthritis.

Study burden and risks

Burden: one time visit to the AMC in Amsterdam

Risk: Very low risk classified as trivial risk for X-photography of the wrist.

Contacts

Public

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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 an extra-articular distal radius malunion and who were treated with extra articular distal radius osteotomy

Exclusion criteria

Patients younger than 18 years old. Patient with an intraarticular distal radius malunion.
Patienten with systemic diseases of the muscular-skeletal system (i.e. Rheumatoid Arthritis)

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):	15-07-2006
Enrollment:	30
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	NL13537.018.06