

Malunited Radius: Computer-Assisted Corrective Osteotomies

Published: 04-03-2013

Last updated: 24-04-2024

The aim of this study is to provide an overview of this novel technique and to present the preliminary clinical results in a series of patients.

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

Summary

ID

NL-OMON36993

Source

ToetsingOnline

Brief title

MR CACAO

Condition

- Fractures

Synonym

Malunion of the radius; malaligned bone healing following wrist fracture

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: AMC

Intervention

Keyword: Corrective osteotomy, Fracture, Malunion, Radius

Outcome measures

Primary outcome

Postoperative residual deformation evaluated using CT scans

Secondary outcome

Wrist function as measured on the DASH score and PRWE score, pain, prehensile gripstrength, Range of Motion, patient satisfaction.

Study description

Background summary

Corrective osteotomy for patients with a malunited radius fracture may improve wrist function and reduce other symptoms such as pain. Since functional outcome is susceptible to the accurateness of the anatomic reconstruction, detailed preoperative planning is essential. However, malunions often involve complex deformations which are not recognized during conventional preoperative planning. Computer-assisted navigation techniques with 3D images address three-dimensional deformity and may optimise functional and radiological results of corrective osteotomies of the radius.

Study objective

The aim of this study is to provide an overview of this novel technique and to present the preliminary clinical results in a series of patients.

Study design

A prospective observational follow up study which will be conducted in the Academic Medical Center Amsterdam for an estimated period of six months.

Study burden and risks

Patients will be asked to return to the hospital once. During this visit patients will be asked about any complaints/pain/contentment. These procedures are all part of standard care. The two questionnaires (DASH and PRWE) provide a tool to assess wrist function in a validated and standardized manner and will take an estimated 10 minutes each. Physical examination of the wrist including range of motion and prehensile grip strength are also part of standard follow

up. A post operative CT scan provides information on the position of the bone and osteosynthesis material, fracture healing and residual deformation. The radiation exposure is minimal (0.6mSV), however, this examination is also often part of usual care.

For this study, patients will be asked to return to the hospital for follow up only once. The risks are comparable to those that the standard follow up visits involve. The burden experienced regarding time spent will not exceed 50 minutes.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Patients with a symptomatic malunion of a distal radius or midshaft fracture which was treated with a computer-assisted planned osteotomy

Exclusion criteria

1. Not able to understand the written informed consent
2. Pregnant

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): 04-03-2013

Enrollment: 5

Type: Actual

Ethics review

Approved WMO

Date: 04-03-2013

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	NL42760.018.12