Corrective osteotomy of the distal radius: evaluation of a patient-tailored positioning and fixation plate.

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To investigate clinical outcome, functional outcome and accuracy of patient-tailored plating in corrective osteotomy procedures and compare this to the standard osteotomy procedures based on 2D imaging and standard fixation plates. Additionally we...

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

Summary

ID

NL-OMON43538

Source
ToetsingOnline

Brief title
Patient-tailored Corrective Osteotomy (PCO)

Condition

- Fractures

Synonym
abnormal bone healing after wrist fracture, distal radius fracture malunion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bone Plates, Fracture Fixation, Internal, Radius Fractures

Outcome measures

Primary outcome

Functional outcome of the wrist is assessed through physical examination, measuring: flexion, extension, pronation, supination, radial deviation and ulnar deviation.

Secondary outcome

Accuracy is calculated using computed tomography imaging, providing us with: dorsal collapse, radial collapse and rotational deformation.

Total costs are assessed using direct medical costs, operation time, indirect costs (aftercare) and workplace absenteeism. Self-assessed quality-of-life is assessed using the EuroQol EQ-5D-5L questionnaire.irect medical costs, operation time, indirect costs (aftercare), workplace absenteeism, self-assessed quality-of-life (using EuroQol EQ-5D-5L questionnaire).

Other study parameters: age, gender, body weight, smoking, alcohol, diabetes, NSAID usage.

Study description

Background summary

Distal radius fractures are among the most common types of fractures, accounting for 25% of pediatric fractures and up to 18% of fractures in elderly

persons. Usually, the mechanism of injury is a fall on the outstretched arm from standing position. Complications include malunion of the distal radius, occurring in approximately 5% of patients with complaints of significant pain, deformity and decreased functional ranges of motion.

Treatment of malunited distal radial fractures is centered on accurately re-establishing normal anatomy, especially since the precision of the realignment has shown to be significantly associated with better functional outcomes. In order to provide stable fixation following osteotomy, surgeons use anatomical plates, pre-shaped to optimally fit the contour of the undeformed distal radius.

In malunion cases, however, the bone is generally deformed. Using a standard fixation plate in these cases may result in substantial residual positioning errors and reduced functional outcome. Novel techniques describe the use of preoperative 3D imaging to design patient-tailored fixation plates, fitting the bone geometry more precisely and resulting in accurate restoration of bone alignment.

To further investigate the potential benefits of this new technique, it is necessary to analyze the results in a larger group of patients. Additionally, this provides a unique opportunity to compare using custom fixation plates with conventional anatomical plates.

Study objective

To investigate clinical outcome, functional outcome and accuracy of patient-tailored plating in corrective osteotomy procedures and compare this to the standard osteotomy procedures based on 2D imaging and standard fixation plates. Additionally we will investigate cost and quality-of-life differences between the new and old technique.

Study design

Randomised controlled trial, single-blinded, to study the difference between 3D-printed patient-tailored plating and default anatomical plating.

Intervention

One group (n=24) will undergo a corrective osteotomy procedure, in which standard anatomical plating will be used for bone fixation. The other group (n=24) will undergo corrective osteotomy using patient-tailored plating, printed three-dimensionally to optimally fit the bone contour. All participants will undergo computed tomography (CT) scans of the wrist both pre-operatively and 6 months after the surgical procedure.

Study burden and risks

not applicable

Contacts

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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 are adults aged 18 years or over with a symptomatic malunion after distal radius fracture.

Exclusion criteria

- Bony deformities in the contralateral distal forearm.
- Congenital skeletal disorders (Madelung deformity).
- Not able to understand the written informed consent.
- Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2017
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	12-08-2016
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	NL56144.018.16