Functionele resultaten en complicaties bij patiënten die zijn behandeld voor polsbreuken met plaatfixatie.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23579

Source
Nationaal Trial Register

Health condition

Distal radius fractures are one of the most common fractures, representing 16% of all fractures treated by orthopaedic trauma surgeons. Most distal radius fractures can be treated with closed reduction (when it is displaced) and immobilization in a plaster cast. Indication for operative treatment is instability of the distal radius fracture leading to malunion with poor outcome. Various surgical interventions are available, in which open reduction and internal fixation by plates has gained widespread popularity. It is unknown which surgical treatment is considered as the most appropriate treatment for distal radius fractures.

Sponsors and support

Primary sponsor: Prof. dr. P.R.G. Brink

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Source(s) of monetary or material Support: government funding

Intervention

Outcome measures

Primary outcome

The first objective of this retrospective study is to compare dorsal and volar plate fixation for the treatment of distal radius fractures in a large patient group.

Secondary outcome

The second objective is to determine which one is the most appropriate treatment, meaning fewer complications and better functional outcome.

Study description

Background summary

Introduction:

Distal radius fractures are one of the most common fractures, representing 16% of all fractures treated by orthopaedic trauma surgeons. Most distal radius fractures can be treated with closed reduction (when it is displaced) and immobilization in a plaster cast. Indication for operative treatment is instability of the distal radius fracture leading to malunion with poor outcome. Various surgical interventions are available, in which open reduction and internal fixation by plates has gained widespread popularity. It is unknown which surgical treatment is considered as the most appropriate treatment for distal radius fractures.

Objectives:

The aim of this study is to compare dorsal plate fixation with volar plate fixation for the treatment of unstable distal radius fracture or malunion in a large patient group and determine which one is the most appropriate treatment, meaning fewer complications and better functional outcome.

Study design:

A retrospective comparison study.

Study population:

Patients of either sex from the age of 18 years or above who are been treated for their unstable distal radius fracture or malunion with open reduction and internal fixation, using dorsal or volar plate.

Main study outcomes:

Primary study outcomes: Disability of Arm, Shoulder and Hand (DASH) score, Patient Related Wrist Evaluation (PRWE) and complication rate.
Secondary study outcomes: range of motion, grip and pinch strength and radiographic analysis.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

All included patients have to undergo several examinations: filling out questionnaires, undergoing physical examination of both wrists and making radiographs of both wrists. The radiation exposure is almost negligible (< 1 mSv). The visit at MUMC will take in total 60 minutes. The patients will receive a bonus, if they complete all examinations.

Study objective

The newer dorsal locking plates will lead to comparable or improved outcomes in comparing with the volar locking plates in adult patients with unstable distal radius fracture or malunion.

Study design

All study outcomes will be measured at one time point.

Primary study outcome:

The functional outcome will be measured with the use of the DASH score and PRWE. The DASH score is a self-reporting questionnaire which is the best scoring system to evaluate patients with disorders involving multiple joints of the upper limb. The DASH score ranges from 0 to 100, with lower numbers indicating a lower level of disability. PRWE score is also a

self-reporting questionnaire and is the most responsive instrument for evaluating the outcome in patients with distal radius fractures. The total function on the PRWE scale ranges from 0 (normal wrist) to 150 (worst possible score).

Complications are categorized as major or minor. Minor complications include tendon irritation, superficial infections, and finger stiffness which were treated nonoperatively on an outpatient basis. Major complications include loss of reduction, malunion, nonunion, deep infection, neuropathy and tendon rupture which required hospitalization or reoperation.

Secondary study outcome:

Functional outcome:

1. Range of motion of the wrist will be evaluated by recording flexion-extension, pronation-supination, and radioulnar deviation with a standard goniometer;

2. Grip and pinch strength are going to be measured with a dynamometer and the values will be compared with those for the contralateral extremity.

Radiographic analysis:

Anteroposterior and lateral radiographs of the fractured and uninjured distal radius are going to be made for measurement of volar tilt, radial inclination, radial length, ulnar variance, and steps and gaps for intra-articular fractures. These radiographs of both wrists will be compared to each other, but also the first radiographs after the reduction will be compared.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients of either sex from the age of 18 years or above;

2. Operative treatment for uunstable distal radius fracture or malunion by open reduction and internal fixation with dorsal or volar plate fixation;

3. At least 24 months of postoperative follow-up.

Exclusion criteria

1. Open or bilateral fractures, previous fractures of the wrist at the ipsilateral or contralateral arm, wrist fractures in polytraumatized patients, other fractures at the ipsilateral arm, fractures associated with neurovascular injury;

2. Local disorders (e.g., tumors, Paget’s disease);

3. Motor function disorders (e.g., central motor disorder, myasthenia gravis).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-11-2011
Enrollment:	120
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 35181
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2967
NTR-old	NTR3114
CCMO	NL37589.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35181

Study results

Summary results
N/A