10 to 15 year follow-up after distal radius fracture. A retrsospective study on the relation between anatmical position and radiological osteoarthritis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON43457

Source
ToetsingOnline

Brief title
10 to 15 year follow-up after distal radius fracture

Condition

- Bone and joint injuries
- Fractures
- Bone and joint therapeutic procedures

Synonym
degenerative joint disease, degenerative osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: vakgroep orthopedie

Intervention

Keyword: Anatomical position, Distal radius fracture, Elderly, Osteoarthritis

Outcome measures

Primary outcome

Difference in degree of osteoarthritis

Secondary outcome

- Wrist dysfunction/pain

- SLAC.

- Radial inclination

- Palmar tilt

- Radial length difference and loss

- Intra articular step off

- Distal radioulnar joint instability

- Intercarpal angles (DISI or VISI)

- Scapholunate distance.

- Signet ring sign

- Radiocarpal instability

- SLD

Study description

Background summary

Distal radius fractures (DRF) are common in emergency rooms and the incidence of DRFs is expected to increase with
the ageing of the population and the increased life expectancy. However there is still much controversy in the treatment
of DRFs. Since the development of volar plating with fixed angle screws the tendency to perform surgery as a primary
treatment has increased when a DRF is dislocated. It is generally thought that restoring the anatomical position will
lead to less osteoarthritis (OA). However, it is not complete clear if this is right.Through this retrospective study the relation between (the degree of) radiological OA and achieving an anatomical position will be studied.

Study objective

The primary objectives are to assess the degree of OA that patients develop 10 to15 year after a DRF, find out whether there is there is a difference in degree of osteoarthritis between conservative treated patients with and without an indication for surgery nowadays of the non-anatomical position of their distal radius fracture and compare the degree of OA between the fractured and contralateral wrist
Our secondary objective is to measure the functional outcome after treatment, assess the prevalence of OA in our cohort, study the difference in degree of OA between patients with the same non-anatomical position but different treatment (operative versus conservative) and assess the prevalence of SLD in our cohort.

Study design

This retrospective pilot study, with a follow-up of 10 to 15 years, is a continuation of a pilot study. All patients diagnosed with DRF between 2001 and 2005, who were between the age of 50-70 years at that time, will be included. Initial treatment and X-ray will be reassessed. The patients with an anatomical position of their wrist fracture will be in group 1. The second group will consist of all the other patients who did not have an anatomical position. Group 2 will then be subdivided in three groups. Group 2a will consist of patients who, under the current guidelines would have received the same conservative treatment. Group 2b will consist of patients who would be operated under the current guidelines but were nevertheless treated conservative at the time of trauma. Group 2c will consist of patients who would be operated under the current guidelines and were also operated at that time
To study the difference between OA of the fractured and contralateral wrist, the non-fractured wrist of all patients will be assessed as well.

Study burden and risks

The patients will have to come to the hospital once for the questionnaire, four X-rays of their wrists and a physical

examination of the wrists. The dosage of radiation exposure is approximately 4 x 0.001 mSv which is a negligible
dosage. In contrast: the yearly exposure to radiation from natural sources is about 2 mSv. The radiation exposure due
to the wrist X-rays represents about 1/500 of a normal yearly exposure.

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

Able to speak, read and write Dutch or English.
Diagnosed with a distal radius fracture between 2001 and 2005 at an age between 50 and 70 years.

Exclusion criteria

Deceased
Unable to understand or answer the questionnaires, irrespective of the reason
Unwilling to participate
Unable to find primary X-rays in the archive
Distal radius fracture both left and right
Fractured the same distal radius twice

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2016
Enrollment:	202
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL56566.098.16