10 to 15 year follow-up after mallet finger fracture. A pilot study on the relation between anatomical 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 invasive

Summary

ID

NL-OMON42903

Source ToetsingOnline

Brief title

10 to 15 year follow-up after mallet finger 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 positon, Mallet finger fracture, Osteoarthritis

Outcome measures

Primary outcome

- The degree of OA in the fractured fingers and the same digit of the other

hand.

- The difference in degree of OA between the fractured and the non-fractured

fingers.

The degree of OA in the DIP-joints will be assessed using the standardised hand

radiographs from the Osteoarthritis Research Society International (OARSI).

Osteophytes and joint space narrowing (JSN) in the DIP-joints will be graded

0-3 points each, with total scores for the degree of OA ranging from 0 to 6.

Secondary outcome

- Finger (DIP-joint) function and pain.
- Health status
- Pinch grip strength.
- Relation between OA and functional outcome.
- Prevalence and degree of OA of the fractured and non-fractured fingers.

Study description

Background summary

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The mallet finger injury is the most frequently encountered closed tendon injury of the finger. These injuries involves avulsion of the extensor mechanism at the base of the distal phalanx and in case of a mallet finger fracture (MFF) the dorsal base of the phalanx is fractured as well. The treatment of MFF is usually conservatively with a splint and only in specific cases surgically. Several surgical techniques have been described in literature, some comparing outcome to splinting, but the efficacy of treatment modality has been shown to vary. There is an indication for operative treatment in cases where involvement of articular surface is greater than one-third and/or by palmar subluxation. Without accurate correction of the joint surface, the patient has an increased risk for early osteoarthritis (OA), swan-neck deformity, and persistent distal interphalangeal (DIP) joint-stiffness. Surgical procedures though, have a higher complication rate than splinting and a substantial part develops long-term disabilities.

To date, evidence is lacking to determine the best treatment for mallet finger fractures. In the last couple of years, there has been an increased tendency to perform surgery in case of a mallet finger fracture. A retrospective study with follow-up is planned to study the relation between radiological OA and the anatomical position.

Study objective

The primary objectives are to assess the degree of OA that patients develop 10 to 15 year after a mallet finger fracture, to find out whether there is a difference in degree of OA between conservatively treated patients with and without an indication for surgery according to the current guidelines and to compare the degree of OA between the fractured and non-fractured fingers.

The secondary objectives are to measure the functional outcome after treatment, to assess the prevalence of OA in our cohort and to study the difference in degree of OA between patients who had the same non-anatomical position of the fracture but received different treatment (operative versus conservative).

Study design

This is a retrospective pilot study, with a follow-up of 10 to 15 years. Out of all patients diagnosed with a MFF between 2001 and 2006, and attended the Reinier de Graaf Groep (RdGG) 100 patients will be included. The initial treatment and X-rays will be reassessed. The patients with an anatomical position of their MFF will be placed in group 1. The patients in this group would be treated conservatively under the current guidelines and were also treated conservatively at the time of trauma.

All other patients, those who did not have an anatomical position, will placed in be divided in group 2 en 3. Group 2 will consist of patients who would be operated under the current guidelines but were nevertheless treated conservatively at the time of trauma. Group 3 will consist of patients who would be operated under the current guidelines and were also operated at that time.

For control and to study the differences in OA, the same non-fractured digit of the other hand of all patients will be assessed as well. If this digit had a mallet finger fracture as well, patients will be excluded. Patients will have to visit the hospital once to complete questionnaires, to have an X-ray of the fractured and the non-fractured fingers, and for physical examination of these fingers.

Study burden and risks

The patients will have to come to the hospital once for the questionnaire, for X-rays of their fingers (four in total) and a physical examination of the fingers. The dosage of radiation exposure is approximately 4 x 0.001 mSv. This is a negligible dosage, as in contrast, the yearly exposure to radiation from natural sources is about 2 mSv. The radiation exposure due to the hand 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

Diagnosed with a mallet finger fracture between 2001 and 2006. Able to speak, read and write Dutch or English. Patient has to be 18 years or older

Exclusion criteria

Unable to understand or answer the questionnaires, irrespective of the reason Unwilling to participate Unable to find primary X-rays in the archive Mallet finger fracture in the same digit on both hands Mallet finger fracture in the same finger twice

Study design

Design

Study type: Observational invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2016
Enrollment:	100
Туре:	Actual

Ethics review

Approved WMO	
Date:	20-07-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	30-01-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	19-02-2018
Application type:	Amendment
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
ССМО	NL57723.098.16

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