10 to 15 years follow-up after mallet finger fracture. A pilot study on the relation between anatomical position and radiological osteoarthritis.

Gepubliceerd: 10-11-2017 Laatst bijgewerkt: 18-08-2022

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28857

Bron
Nationaal Trial Register

Verkorte titel
Mallet

Aandoening

Mallet finger fracture

Ondersteuning

Primaire sponsor: Department of orthopaedic surgery, Reinier de Graaf Groep
Overige ondersteuning: Department of orthopeadics, Reinier de Graaf Groep

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters are:

- 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.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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 isfractured 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. The objective of this retrospective study with follow-up is to study the
relation between radiological OA and the anatomical position. When this study hints at a difference in the degree of OA and/or functional outcome between the groups, a follow-up study can be planned with greater groups. When more patients are included, conclusions can be drawn about the relation between treatment modality and the development of OA.

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.

- 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 nonanatomical position of the fracture but received different treatment (operative versus conservative).

Study design:

This is a retrospective multicentre 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) or the HagaZiekenhuis 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, who did not have an anatomical position, will be divided between 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. 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 population:

For this pilot study, 100 patients who attended the emergency department of the RdGG or the HagaZiekenhuis between 2001 and 2006 with a diagnosed MFF will be included.

Patients need to be able to speak, read and write in Dutch or English and are willing to participate. They should not be mentally retarded or have any form of dementia and have to give informed consent. Patients will be excluded from the study if the primary X-rays are not

found in the archive, the same digit of the other hand endured a mallet finger fracture, the fractured distal phalanx had been fractured for a second time or if they are unable to understand and answer the questionnaires.

Main study parameters/endpoints:

The degree of OA in the fractured finger and in the same digit of the other hand in all patients will be assessed. Another main study endpoint will be the difference in degree of OA between the fractured and non-fractured fingers. The degree of OA will be measured using the Osteoarthritis Research Society International (OARSI) standardised hand radiographs.

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

The patients will have to come to the hospital once for the questionnaires, 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.

Onderzoeksopzet

Once after inclusion

Onderzoeksproduct en/of interventie

Patients will have to visit the hospital once to complete questionnaires, to have an X-ray of the fractured and non-fractured fingers, and for physical examination of these fingers.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Able to speak, read and write in Dutch or English.

- Diagnoses with a mallet finger fracture between 2001 and 2006.

- At the moment of inclusion, it has been at least 10 years after the diagnosis of mallet finger fracture.

- Patient is 18 years or older at the moment of inclusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- 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 of the same digit of the other hand.

- Mallet finger fracture in the same finger twice.

To check exclusion criteria, such as untraceable x-rays or a fracture of the same finger more than once, all patients' charts will be reviewed. during the recruitment on the telephone the researcher will reassess all inclusion and exclusion criteria. During this conversation the researcher will try to find out whether a patient is able to answer and understand the questionnaires or not.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2016
Aantal proefpersonen:	70
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6631
NTR-old	NTR6808
Ander register	METC Zuidwest Holland : 16-069

Resultaten