Long term outcome of posterior malleolar ankle fractures

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Aim of the project:1) The objective of this retrospective study is to compare a matched group (age, sex and ASA) of operatively treated patients with an ankle fracture including a posterior malleolar fragment with a group operatively treated...

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

Summary

ID

NL-OMON38840

Source
ToetsingOnline

Brief title
Posterior malleolar fractures. A Retrospective Case Series

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
Ankle fracture, posterior malleolar fragment

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ankle, Fractures, Outcome, Retrospective

Outcome measures

Primary outcome

Outcome of standardised questionnaires

Secondary outcome

Outcome X-Ray

Outcome CT-scan

Outcome range of motion

Outcome stability of the joint

Outcome VAS score

Outcome neurovasculaire status

Study description

Background summary

A posterior malleolar fracture can be treated surgically or conservatively. The latter is preferred as surgery is complicated because of the difficulties of the surgical approach and demanding surgical techniques to adequately reduce the fragment. Current treatment algorithms, based on level IV evidence, suggest that patients with posterior malleolus fractures that consist of 25% - 33% of the tibial plafond need anatomical surgical reduction. This algorithm seems arbitrary, not only because the lack of evidence, but moreover since the measurements have all been made on plain lateral radiographs. A variety of combinations from large fracture fragments with small articular involvement, to shell fragments with significant articular involvement including extension into the medial malleolus can be found based on computed tomograpy. It is unclear how these fractures appear on plain lateral radiographs.

Study objective

Aim of the project:

1) The objective of this retrospective study is to compare a matched group (age, sex and ASA) of operatively treated patients with an ankle fracture including a posterior malleolar fragment with a group operatively treated patients with an ankle fracture without a posterior malleolar fragment using standardized patient- and physician-based outcome instruments.
2) The objective of this retrospective study is to compare a matched group (age, sex, and ASA) of operatively treated patients with an ankle fracture including a posterior malleolar fragment with a group conservatively treated patients with an ankle fracture including a posterior malleolar fragment using standardized patient- and physician-based outcome instruments.
3) The objective of this study is to look what the reliability is of the post-op radiographs compared to our Q3DCT*s as gold standard.

Study design

Evaluate retrospective series of +/- 100 patients with ankle fractures with available rontgen scans. The Patients are treated at the AMC Amsterdam and the follow up is 10 to 30 years. The patients will be divided in groups with or without a posterior malleolair fragment and divided in groups where the posterior malleolair fragment is operatively treated or conservatively treated.

Visitors (tourists, exchange students) and patients who have died are excluded from the study. Furthermore patients with nerve damage, severe central nervous system injuries, patients who are mentally challenged, and patients who have musculoskeletal disorder (Paget disease, haemochromatosis).

Invitation letters are sent to possible candidates. An oppointment is arranged at a time of the subject's convenience. Informed consent is obtained prior to interview, examination, radiographs and tomographs. The invitations are send by 2 independent observers, Diederik Meijer and Barend Gevers Deynoot, on behalf of dr GMMJ Kerkhoffs.

First, a researcher interviews the subject about the history of their injury and about their current health status. The subject then completes a set of questionnaires about their health and about how their injured ankle feels.

Patients may skip any questions they choose not to answer.

The affected ankel will get an x-ray and a CT-scan as it would be done clinically. The healthy ankle will get an x-ray for comparison. After the x-ray and the ct-scan, the researcher examines the subjects injured ankle and performs relevant range-of-motion measurements.

Patients attend a 60-minute visit in our clinic

Statistical analysis will be done with SPSS.

Study burden and risks

The only risks associated with participation are the risks associated with the amount of ionizing radiation used to obtain tomographs of the injured ankle and a series of radiographs of both ankles. Dr. ir. G.J. Streekstra at the AMC calculated the risks and categorized it as 1 (<0,1 mSv) of the IRCP (international commission of radiological protection), which is qualified as a trivial risk. Therefore the medical ethical commission of the AMC gave dispensation for a special insurance for the patients.

Patients might feel some discomfort while answering the questionnaires.

Participation in the study is not likely to result in any direct benefit to the subjects. On the other hand, patients who elect to participate will get a free update on the status of their ankle, another chance to have all of their questions answered, and an initial evaluation of any curent problems. The major benefit of this study will be to patients who sustain these types of injuries in the future. A careful analysis of our results of treatment will lead to improved outcomes.

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

Subjects with a history of ankle fractures who have completed their normal care in the Orthopaedic Service will be invited to return for a long-term follow-up visit.

Exclusion criteria

Visitors (tourists, exchange students) are excluded from the study and patients who have died. Furthermore patients with nervedamage, severe central nervous system injuries, patients who has mentally challenged, and patients who have musculoskeletal disorder (Paget disease, haemochromatosis).

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):	02-12-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	02-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2014
Application type:	Amendment
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	NL45568.018.13