

Operative treatment of AO Weber B fibular fractures with additional posterior malleolar fragment: reduction and functional outcome after prolonged follow up

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To asses if there is a difference in functional outcome between open reduction and fixation of the posterior fragment in trimalleolar AO-Weber B fractures with additional medium-sized posterior fragment (5-25% of the involved articular surface, AO...

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

Summary

ID

NL-OMON51230

Source

ToetsingOnline

Brief title

POSTFIX-midterm

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym

ankle fracture., Trimalleolar fracture

Research involving

Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ankle fracture, ORIF, osteoarthritis, posterior malleolus

Outcome measures

Primary outcome

The functional outcome of the ankle will be evaluated using the American Orthopaedic Foot and Ankle Society score (AOFAS).

This scoring system is exclusively developed for injury of the ankle and is worldwide the most used and best scoring system for long-term functional outcome. In this questionnaire the aspects of pain, function, stiffness, swelling and the rate of giving way of the ankle will be evaluated in 25 questions. After completion of this questionnaire the obtained score will be between 0 and 100. The lower the obtained score, the worse the ankle function. The scoring system is validated and patient-friendly.

Secondary outcome

- VAS-pain
- Olerud & Molander ankle score (short term)
- AOFAS foot and ankle score (long term)
- Range of motion
- Osteoarthritis (AO-scale)
- Complications

- Secondary interventions/reoperations
- Tibiotalar gap or step-off (CT scan postoperatively)

Study description

Background summary

Ankle fractures are frequently (incidence 2 in 1000 people per year) seen in the emergency department of hospitals. In most cases (67%) there is a fracture of the lateral or medial malleolus (unimalleolar), in a quarter of the cases of a bimalleolar fracture and in the remaining 7% of the ankle fractures there is also a fracture at the posterior side of the distal tibia (tertius fragment), a trimalleolar fracture.

Despite the prominent place that ankle fractures occupy within (orthopedic) trauma surgery, relatively little is known about the long-term prognosis of these injuries. Trimalleolar fractures may have a worse prognosis for function and pain than uni- / bimalleolar fractures, with an important predictive role for the tertius fragment. There is still no consensus about the influence of the size of the fragment, the degree of dislocation and the best treatment.

Theories about the influence of tertius fragments on the clinical prognosis come from, among other things, biomechanical studies. The central idea here is that long-term development of osteoarthritis is dependent on the size of the contact surface in the tibiotalar joint. Macko investigated the influence of the size of the tertius fragment on the contact surface in 1991 by means of a cadaver study with 8 ankles. He described that a larger tertius fragment resulted in a smaller contact surface. Hartford also confirmed this in a study of 16 cadavers. Macko assumes a relevant reduced contact surface for a tertius fragment larger than 25% of the tibiotalar joint surface, while Hartford shows that this is only the case at a size of 33%. On the basis of these studies, they argue that obtaining the largest possible contact surface in the tibiotalar joint reduces the risk of osteoarthritis. That is why they advise striving for the largest possible contact surface and thus the best possible anatomical position.

Recent studies indicate that a postoperative step-off is a superior predictor of functional outcome and the development of osteoarthritis. Therefore, fixation via a direct exposure of the posterior tibia via a posterolateral approach in the prone position, followed by open reduction and fixation with screws in the posterior-anterior direction or antiglide plate has gained popularity. It is unclear whether this approach leads to less development of osteoarthritis and a better functional outcome.

The multicentre POSTFIX study (RCT) has been set up at the HMC to answer this question (intended end date summer 2021). This is a continuation of that study.

Study objective

To assess if there is a difference in functional outcome between open reduction and fixation of the posterior fragment in trimalleolar AO-Weber B fractures with additional medium-sized posterior fragment (5-25% of the involved articular surface, AO type 44-B3) and no fixation of the posterior malleolar fragment assessed by the AOFAS-score after 4-7 years.

Study design

Retrospective cohort study.

Study burden and risks

Participants of this study will not benefit directly by participating, other than the opportunity to receive extra information if they experience any problems or have any questions regarding their operated ankles during the visit to the outpatient clinic. The extra radiation exposure of the X-rays is about 1/100th of the background radiation and does not outweigh the benefits of this study.

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

- 1) Age between 18 and 75 years at time of trauma
- 2) First ankle fracture of the affected side
- 3) Trimalleolar AO-Weber B fracture with additional medium-sized posterior fragment (5-25% of the involved articular surface, AO type 44-B3)

Exclusion criteria

- 1) Severe traumatized patients
- 2) Multiple fractures during visit emergency department
- 3) Ankle fracture of the same ankle in the history
- 4) Patients with pre-existent mobility problems
- 5) Pre-existent disability
- 6) Patients living in another region and follow-up will take place in another hospital
- 7) Inability to speak the Dutch language

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 10-01-2023
Enrollment: 120
Type: Actual

Ethics review

Approved WMO
Date: 18-11-2021
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	NL77804.058.21