Medium sized POSTerior fragments in AO Weber-B fractures, does open reduction and FIXation improve outcome? A multicenter randomized controlled trial.

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Compare 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) with no fixation of the posterior malleolar...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON47804

Source
ToetsingOnline

Brief title
POSTFIX

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: Aanvraag is gedaan bij AO-foundation;verdere aanvragen zullen eventueel gedaan worden bij Wetenschapscommissies van verschillende ziekenhuizen;ZonMW en het Emma-fonds.

Intervention

Keyword: Posterior fragments, Syndesmotic fixation, Trimalleolar fractures, Weber-B fractures

Outcome measures

Primary outcome

AAOS-questionaire after 1 year.

The functional outcome of the ankle will be evaluated 1 year after surgery

using the American Academy of Orthopaedic Surgeons foot and ankle score (AAOS).

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. The AAOS questionnaire will be answered 26 and 52 weeks after surgery.

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 worser the ankle function.The scoring system

is validated and patient-friendly.

Secondary outcome

1. VAS-pain

2. Olerud & Molander ankle score (short term)

3. AOFAS foot and ankle score (long term)

4. Range of motion

5. Euroqol-5D

6. Osteoarthritis (AO-scale)

7. Complications

8. Secondary interventions/reoperations

9. Tibiotalar gap or step-off (CT scan post-operatively)

Study description

Background summary

The optimal treatment of ankle fractures with involvement of the posterior malleolus remains a subject of debate. Despite a large amount of literature on the role of the posterior malleolus in a so-called trimalleolar fracture, there are no clear guidelines for its treatment. Its size is the leading indication whether fixation of the fragment is necessary or not. Most orthopedic surgeons consider a posterior malleolar fracture fragment larger than 25% to 33% an indication for fixation. Interestingly, after careful evaluation of the available literature, there does not seem to be hard evidence for these numbers.

It is generally accepted that restoration of a normal anatomic mortise and normal tibiotalar contact area are key elements for a good functional outcome. Inadequate reduction of the posterior fragment may alter the tibiotalar contact area and the joint biomechanics with altered stresses in parts of the joint, leading to the development of osteoarthritis and worse functional outcome.

Traditionally, reduction of these larger fragments is indirectly, followed by percutaneous screw fixation in anterior-posterior direction. Disadvantages are that it is hard to achieve an anatomical reduction, and that fixation of smaller fragments is very difficult. Recently, a direct exposure of the posterior tibia via a posterolateral approach in prone position, followed by open reduction and fixation with screws in posterior-anterior direction or antiglide plate is advocated by several authors. This approach allows perfect visualization of the fracture, articular anatomical reduction, and strong fixation. Another advantage is that even small posterior fragments can be addressed. Several case series are published, which describe minimal major wound complications, good functional outcomes, and minimal need for reoperation. Since 2 years, in our institution we perform an open, anatomical reduction and fixation of all medium-sized posterior fragments via this

approach. Although not thoroughly investigated yet, it seems to lead to better clinical outcomes than described in the literature and our retrospective cohort study.

Study objective

Compare 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) with no fixation of the posterior malleolar fragment on functional outcome assessed by the AAOS-score after 1 year.

Study design

Multicenter Randomized Controlled Trial

Participating Centers:
1. Haaglanden MC
2. Haga Hospital
3. Leiden University Medical Center

Patients presenting with an ankle fracture at the Emergency Department of the hospital will receive the usual treatment initially. Patients who met the inclusion criteria will be informed at the emergency department about the current study and will get the written patient information. Preoperatively, at the outpatients clinic or ward, the surgeon will discuss the study again with the patient and he or she is asked to participate. After Informed Consent, randomization will take place.

The first group will be treated according to the current directives. If present, medial and distal fibular shaft fractures are fixed according to AO principles. No additional posterior fragment will be fixed. The second group will also be treated according to AO-principles, however the posterior fragment will be reduced and fixed by a butress or antiglide plate using the posterolateral approach.

The postoperative treatment will be identical and according to the current local protocols. Patients will be seen at the outpatient clinics at 2 weeks, 6 weeks, 12 weeks, 26 weeks and 52 weeks postoperatively. Pre-operative and post-operative a CT-scan will be performed. In addition to the regular treatment, the patients will be asked to fill in a questionnaire during every visit and to perform a short functional test during the last 2 visits. The results between these two groups will be compared.

Intervention

The first group: Open reposition and fixation of the medial and lateral malleolus will take place. Additionally, closed reduction of the posterior malleolus will take place without internal fixation.
The second group: Open reposition and fixation of the medial, lateral and posterior malleolus will take place. (fixation of the lateral and posterior malleolus will take place using the posterolateral approach)

Study burden and risks

Additional to the regular treatment, the burden lies in the fact of several questionnaires which will be answered during the visits at the outpatient clinic. Also, post-operative an additional CT-scan of the ankle will be performed. The additional radiation is in our eyes negligible respected the normal, daily background radiation in the Netherlands.

There is no additional risk in the second intervention group compared to the intervention in the first group. Several case-series showed a comparable rate of woundinfections or reoperations in the posterolateral approach compared to the original approach.

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

AO-Weber B ankle fracture with involvement of a medium-sized posterior fragment (5-25% of the involved artricular surface) between the age of 18 and 75 years.

Exclusion criteria

multiple fractures
pre-existent impaired mobility
pre-existent impaired disability
Patients living in another region and follow-up will take place in another hospital
Inability to speak the dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-02-2014
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-12-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-05-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-06-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-08-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-03-2019
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	17-06-2020
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
CCMO	NL45763.098.13