Operative treatment of AO Weber C fibular fractures with additional posterior malleolar fragment: Does anatomical reduction and fixation improve syndesmotic reduction? POSTFIX-C trial.

Published: 11-07-2014
Last updated: 20-04-2024

To compare the accuracy of syndesmotic reduction on an axial CT-scan postoperatively (reflecting syndesmotic malreduction) after anatomical open reduction and fixation of the posterior malleolar fragment versus no fixation of the posterior fragment...

Ethical review	Not approved
Status	Will not start
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON40169

Source
ToetsingOnline

Brief title
POSTFIX-C

Condition

- Fractures

Synonym
ankle fracture, trimalleolar fracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Wetenschapsfondsen;andere fondsen zoals EMMA-fonds;ZonMW en OCT zullen om een bijdrage worden gevraagd.

Intervention

Keyword: AO Weber C fractures, Posterior fragment, Syndesmotic stabilization, Trimalleolar fractures

Outcome measures

Primary outcome

1. The accuracy of syndesmotic reduction on an axial CT-scan postoperatively.

2. 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

In AO Weber type C fractures, there is a combination of a proximal fibular fracture, a medial fracture or ruptured deltoid ligament, and a syndesmotic injury. Anatomical repair and reduction of the syndesmosis is essential to prevent diastasis in the ankle-joint. Widening and chronical instability of the syndesmosis is related to worse functional outcome and development of posttraumatic osteoarthritis in the ankle. There is limited biomechanical and clinical evidence that syndesmotic stability in AO Weber type C fractures with an additional posterior malleolar fracture can also be reached by fixation of the posterior malleolar fragment. Maybe, this is even superior to the usual treatment with syndesmotic positioning screws. Some authors concluded that stability of the syndesmosis in these fractures can be much more achieved by fixation of the posterior malleolar fragment than by placement of syndesmotic positioning screws alone. Another additional benefit of open reduction and fixation of the posterior malleolar fragment is that this will lead to an anatomical reconstruction of the syndesmosis. Although there is no current evidence, it is likely that a malreduction of the fibula in the tibial incisura will lead to a worse functional outcome on the long-term. No clear consensus in the literature is found as to which fragment size of the posterior malleolus should be internally fixed. The general opinion is that displaced fragments that involve more than 25% of the distal articular tibia should be fixed. 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 percutaneous 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.

Study objective

To compare the accuracy of syndesmotic reduction on an axial CT-scan postoperatively (reflecting syndesmotic malreduction) after anatomical open reduction and fixation of the posterior malleolar fragment versus no fixation of the posterior fragment in AO Weber-C ankle fractures with involvement of the posterior malleolus.

Study design

Multicenter Randomized Clinical Trial.

Participating Centers:
1. MC Haaglanden
2. Haga Hospital
3. Bronovo Hospital
4. 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. Before visit of the outpatient clinics a CT-scan of the ankle will be performed. 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. In case of participation, Informed Consent will be taken and patients will be included and scheduled for the operation. After inclusion, randomization will take place between additional Open Reduction and Fixation of the posterior fragment (group 1) or no additional fixation of the posterior fragment (group 2).

Patients in 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. Treatment of syndesmotic injury will take place by 1 or 2 transsyndesmotic screws. Additional the posterior fragment will be reduced and fixed by a butress or antiglide plate using the posterolateral approach. The second group will also be treated according to AO-principles: medial and distal fibular shaft fractures are fixed and syndesmotic injury will be treated by 1 or 2 transsyndesmotic screws. The posterior fragment will not be fixated.

Post-operatively, a CT-scan of both ankles will be performed in order to evaluate the success of reposition of the fibula in the tibial incisura and the posterior fragment. 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. 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.

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, postoperative a 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.
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

1. Age between 18 and 70 years 2. First ankle fracture of the affected side 3. Fibular fracture proximal to the syndesmosis with a posterior malleolar fragment between 5% and 25% of the involved articular surface(AO type 44-C1, 44-C2, 44-C3)

Exclusion criteria

multiple fractures
multi-traumatized patients
history of fracture of the same ankle
Patients with pre-existent mobility problems
pre-existent 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:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	54
Type:	Anticipated

Ethics review

Not approved

Date:	11-07-2014
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	NL46802.098.14