

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

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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...

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Fractures
<b>Study type</b>	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 worse 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 chronic 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. Additionally the posterior fragment will be reduced and fixed by a buttress 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