Operative treatment of AO Weber C fibular fractures with additional posterior malleolar fragment: functional outcome after SYNdesmotic positioning screws or POSTerior fragment fixation. POSTFIX-C trial: a prospective comparative observational study.

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

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON50689

Source
ToetsingOnline

Brief title
POSTFIX-C

Condition

- Fractures

Synonym
ankle fracture, Trimalleolar fracture

Research involving
Human

Sponsors and support

Primary sponsor: Heelkunde
Source(s) of monetary or material Support: Wetenschapsfonds

Intervention

Keyword: AO Weber C fracture, Posterior fragment, Syndesmotic Stabilization, Trimalleolar ankle fracture

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 Prospective cohort study,
Participating Centers:
1. Haaglanden MC
2. 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. The choice will be between placement of syndesmotic screws (group 1) or Open Reduction and 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. The syndesmosis will be reduced by 1 or 2 transsyndesmotic screws. The second group will be treated by open reduction and fixation of the posterior malleolar fragment using the posterolateral approach. If the ankle shows stability after fixation, no transsyndesmotic screws will be placed.

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

Public
Selecteer

Lijnbaan 32
Den Haag 2512 VA
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Scientific
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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 larger than 5% 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:	Recruiting
Start date (anticipated):	11-02-2016
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	14-03-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-04-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	18-06-2020
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	NL50169.098.15