

# Retrospective evaluation of surgically treated unstable type C ankle fractures: long term functional and radiological outcomes.

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To evaluate the long term functional and radiological effects of surgical treatment of Weber type C (AO 44-C1/2/3) fibular fractures

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Approved WMO               |
| <b>Status</b>                | Pending                    |
| <b>Health condition type</b> | Fractures                  |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON57050

### Source

ToetsingOnline

### Brief title

RESULT study

### Condition

- Fractures
- Bone and joint therapeutic procedures

### Synonym

broken ankle, type C fibula fracture

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Haaglanden Medisch Centrum

**Source(s) of monetary or material Support:** aanvraag lokaal wetenschapsfonds

## Intervention

**Keyword:** Ankle fracture, osteoarthritis, trimalleolar ankle fracture, type C ankle fracture

## Outcome measures

### Primary outcome

Functional outcome of the ankle, assessed using the validated completely patient reported version of the PROM American Orthopaedic Foot and Ankle Score (PR-AOFAS), which provides a score ranging from 0 (worst possible functional outcome) to 100 0 (best possible functional outcome).

### Secondary outcome

- Functional outcome measured with the PROMIS Physical Function short form 8b.
- Pain measured with a visual analogue scale (VAS)
- The extent of osteoarthritis, assessed on anteroposterior, lateral and mortise view ra-diopgraph, using the Kellgren and Lawrence score for osteoarthritis, modified by Ki-jowski et al.
- Complications including secondary interventions/reoperations

## Study description

### Background summary

Despite the prominent position of ankle fractures in the daily practice of orthopaedic trauma surgery, relatively little is known about the long-term prognosis of operatively treated Weber C ankle fractures. It is suggested that Weber C fractures have a clinically less satisfactory outcome, however, large clinical studies evaluating long-term outcomes are lacking. The aim of this study is to evaluate the long-term functional and radiological outcome of surgically treated Weber C ankle fractures.

## Study objective

To evaluate the long term functional and radiological effects of surgical treatment of Weber type C (AO 44-C1/2/3) fibular fractures

## Study design

Multicenter 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 injury. The extra radiation exposure of the X-rays poses a negligible risk since it represents about 1/100th of the background radiation. The one-time visit to the outpatient clinic is considered a burden for the patients because it takes time. Filling out the two short questionnaires is considered to pose a minimal burden.

## Contacts

### Public

Haaglanden Medisch Centrum

Lijnbaan 32  
Den Haag 2511VA  
NL

### Scientific

Haaglanden Medisch Centrum

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Males or females aged 18 to 75 at the time of trauma and who are competent and capable to make medical decisions.
- Operated due to a Weber C fracture (AO type 44-C1/2/3) between January 1st 2012 and June 1st 2016.
- Sufficient understanding of the Dutch or English language in order to independently understand the patient information including informed consent and complete the follow-up questionnaires.
- Provision of informed consent by the patient.

### Exclusion criteria

- Unable to follow up (e.g. deceased, living abroad)
- Pathological fractures
- Multi-extremity fractures or other injuries at time of trauma.
- History of ankle fracture on the same ankle prior to the operation.
- Impaired function of the operated ankle prior to the operation.
- Patients with decreased use of the ankle due to disability of other cause
- Operated on prior to enrolment of the electronic hospital information system (no availability of digital initial trauma radiographs).

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

|                           |             |
|---------------------------|-------------|
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-11-2024  |
| Enrollment:               | 150         |
| Type:                     | Anticipated |

## Ethics review

|                    |                                     |
|--------------------|-------------------------------------|
| Approved WMO       |                                     |
| Date:              | 14-10-2024                          |
| Application type:  | First submission                    |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
|                    | metc-ldd@lumc.nl                    |

|                    |                                     |
|--------------------|-------------------------------------|
| Approved WMO       |                                     |
| Date:              | 18-02-2025                          |
| 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     | NL87654.058.24 |