# The treatment of stable ankle fractures: Brace versus Cast immobilization

Published: 28-11-2012 Last updated: 15-05-2024

To examine if a functional brace in the treatment of Unimalleolar Weber-B fracture results in a higher Olerud and Molander Score, less pain, better comfort, greater range of motion.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

### **Summary**

### ID

NL-OMON39792

**Source** ToetsingOnline

**Brief title** GIBRA

### Condition

• Fractures

**Synonym** ankle fracture, Fibula fracture, Stable ankle fracture

#### **Research involving**

Human

### **Sponsors and support**

Primary sponsor: Medisch Centrum Haaglanden

**Source(s) of monetary or material Support:** De brace wordt gratis geleverd door de producent 'Bauerfeind'. Overige kosten zullen voornamelijk liggen in adminstratie- en personeelskosten. Een aanvraag voor subsidiëring van deze kosten is nog in behandeling (AO Foundation en Wetenschapsfonds MC Haaglanden)

#### Intervention

Keyword: Brace, Cast immobilization, Weber-B fracture

#### **Outcome measures**

#### **Primary outcome**

The function of the ankle will be assessed by using a questionnaire, the Olerud & Molander Ankle Score, which the patient will be asked to fill in9. This scoring system is specifically designed to demonstrate the function of the ankle after an ankle injury, mainly for short term evaluation. The scoring system is well-recognized, is validated and patient-friendly9. Nine questions combine the aspects of pain, swelling, stiffness and ability to perform certain activities to one overall score of 0-100 points, the higher the score, the better the function of the ankle. Primary outcome is the Olerud & Molander Score at 6 weeks.

#### Secondary outcome

The level of pain will be assessed using a 10-point Visual Analogue Scale (VAS), in which 0 implies no pain and 10 implies the worst possible pain.

Patient comfort with regard to the type of immobilization (cast or brace) will also be assessed using a 10-point Visual Analogue Scale (VAS), in which 0 implies not comfortable at all and 10 implies very comfortable.

By measuring the maximum active dorsiflexion and maximum active plantar flexion with a goniometer the Range of Motion will be assessed.

The degree of fracture dislocation will be determined using radiographs.

De American Academy of Orthopaedic Surgeons Foot and Ankle score (AAOS-score) will be completed by the patient as from 26 weeks post fracture, this score reflects the function of the ankle in the long term10. This scoring system combines 25 items for pain, function, stiffness, swelling and giving way, which generates a single score of 0-100 points, the higher the score, the better the function of the ankle.

Euroqol-5D (EQ-5D) is a validated questionnaire for health-related quality of life.

The presence of osteoarthritis at 1 year post fracture will be determined using radiographs which will be staged according to the Ankle Osteoarthritis Scale13.

The time to return to work will be documented for all patients.

## **Study description**

#### **Background summary**

Ankle fractures are commonly seen on emergency departments of hospitals. They represent about 10% of all fractures and the incidence is expected to increase in the following years.

In the case of an ankle fracture, the fibula (lateral malleolus) and/or the tibia (medial and/or posterior malleolus) can be injured. Furthermore, there can be ligament injury (mainly the syndesmosis between tibia and fibula en the deltoid ligament are of important value). The degree of osseous and/or ligament injury determines if the fracture is stable or unstable. In general, stable

fractures are treated non-operatively (conservatively) and unstable fractures are treated operatively.

Ankle fractures can be subdivided according to different classification systems. A system that is practical in use divides ankle fractures in unimalleolar (fibular fracture solely or medial malleolar fracture solely), bimalleolar (fibular fracture and medial malleolar fracture) or trimalleolar fracture (fibular fracture, medial malleolar fracture and posterior malleolar fracture). The most commonly used classification system is the AO-Weber system, which classifies the fracture based upon the level of the fibular fracture. Weber-A fractures are located distal to the syndesmosis, Weber-B fractures are located at the level of the syndesmosis and Weber-C fractures are located proximal to the syndesmosis.

Weber-A fractures are stable fractures and are therefore treated as ankle sprains (usually 1 week cast immobilization, followed by tape). In general, Weber-C fractures are stable for which they are treated operatively. In case of a Weber-B fracture, the presence of osseous and/or ligament injury additional to the fibular fracture is relevant in deciding how to treat the fracture. Biand trimalleolar fractures are practically always unstable and are treated operatively. Weber-B fractures without signs of medial ligament injury (deltoid ligament) are stable and do not need to be treated operatively. This group represents about 50% of all ankle fractures.

The current treatment of stable ankle fractures in the Netherlands and most other Western European countries consist of 6 weeks cast immobilization: a below-the-knee plaster cast for 1-2 weeks non-weight bearing, followed by a fiberglass short leg walking cast for the next 4-5 weeks, bearing weight within the limits of pain. Disadvantages of this treatment are that after cast immobilization some stiffness in the ankle joint may develop, atrophy of the calf muscle occurs and there might be an increased risk of developing osteoporosis.

In some countries, including Switzerland, stable ankle fractures are often treated with a functional brace. Some previous studies indicate that this functional treatment prevents fracture dislocation as well as cast immobilization does, although it results in better clinical outcome and more comfort. In 1989 Stuart examined the treatment of stable ankle fractures with a functional brace compared to 6 weeks cast immobilization6. He reported a more rapid decrease of swelling because of use of the calf muscle and more comfort in the functional treated group and no significant difference in functional outcome between both groups. Pitfalls of this study are the small sample sizes, poorly defined endpoints and the fact that no standardized Outcome Scores were used. In addition, the outcome measures were assessed at one point and not evaluated for a period of time. Brink published a study which compared two different ankle braces as treatment for stable ankle fractures3. Both braces provided accurate fracture healing with good results; there were no significant differences between the braces. However, this does not indicate whether a functional brace or cast immobilization provides the best result. Furthermore, there have been studies in the past that compare these two types of treatment, although in these studies the ankle fractures were treated operatively after which they were treated with a brace or cast.

In general they showed that the group treated with a functional brace reported less pain, better function and a greater range of motion on short term. As for long term, no significant differences were found.

A well designed randomized controlled trial performed by Lehtonen (2003) comparing the two types of treatment in operatively treated ankle fractures showed more wound infection in the group treated with a functional brace, due to the movement of the ankle. Vioreanu (2007) ruled this out by starting with the functional treatment after wound healing, 2 weeks postoperatively. He found a significantly better outcome at 6 weeks postoperatively in the functional brace group compared to the cast immobilization group. This difference was not significant at long-term follow up.

A recent Cochrane Review (2009) described that there is limited evidence that the use of a removable type of immobilization and performing exercises during the immobilization period result in a better outcome. They also indicate that more clinical studies are necessary to support the current evidence. Future trials need to be adequately designed, outcome measures and endpoints need to be clear and they need to be adequately powered so that the results can be conclusive.

#### **Study objective**

To examine if a functional brace in the treatment of Unimalleolar Weber-B fracture results in a higher Olerud and Molander Score, less pain, better comfort, greater range of motion.

#### Study design

Multicenter, prospective clinical trial in Medical Center Haaglanden (The Hague) and Bronovo Hospital (The Hague). All patients presenting at the emergency department with a stable ankle fracture will initially be treated with cast immobilization, the current treatment. Patients that meet the inclusion criteria will be informed about the study at the emergency department and they get an information letter. They will be asked by telephone to participate in the trial, a few days after their visit to the emergency department. By telephone they will be asked for any questions about the study and the procedures. One week after visit to the emergency department there will be a check by the trauma-surgeon of the fracture by an ankle X-ray. If the fracture shows to be stable, they will be included in the study and randomization takes place under patients who are willing to participate in the trial. Group 1 will receive the current treatment with cast immobilization for a period of 5 weeks (non-weight bearing for 2 weeks and 3 weeks bearing weight within the limits of pain).

Patients will be reviewed at 1 week, 3 weeks, 6 weeks, 12 weeks, 26 weeks and 52 weeks to assess some parameters (see section 5 Assessment). After which these parameters will be analyzed between both groups.

#### Intervention

At 1 week post fracture the patient will return to the clinic. If he/she is willing to participate in the trial the randomization will take place. Group 1 consists of patients treated with cast immobilization for a period of 5 weeks.

Group 2 consists of patients treated with a functional ankle brace for a period of 5 weeks.

Week 1:

Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Patient comfort using a Visual Analogue Scale Dislocation of the fracture using radiographs Eurogol-5D questionnaire

Week 3:

Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Patient comfort using a Visual Analogue Scale Dislocation of the fracture using radiographs Eurogol-5D questionnaire

Week 6: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Patient comfort using a Visual Analogue Scale Range of Motion Dislocation of the fracture using radiographs Eurogol-5D questionnaire

Week 12: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Range of Motion Eurogol-5D questionnaire

Week 26: Olerud & Molander Ankle Score

6 - The treatment of stable ankle fractures: Brace versus Cast immobilization 10-05-2025

Pain level using a Visual Analogue Scale Range of motion Euroqol-5D questionnaire AAOS-score

Week 52: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Range of motion Euroqol-5D questionnaire AAOS-score The presence of arthrosis using radiographs (Ankle Osteoarthritis Scale)

#### Study burden and risks

The treatment will not differ from regular treatment, the number of outpatient visits and the number of X-rays will be the same. Extra is that the patient will be asked to fill in a questionnaire. During the review visits the function of the ankle will be examined and an X-ray will be made. In addition, the group of patients who are treated with an ankle brace will be asked to perform a number of daily exercises with the ankle.

## Contacts

**Public** Medisch Centrum Haaglanden

Lijnbaan 32 Den Haag 2512 VA NL **Scientific** Medisch Centrum Haaglanden

Lijnbaan 32 Den Haag 2512 VA NL

## **Trial sites**

### **Listed location countries**

Netherlands

7 - The treatment of stable ankle fractures: Brace versus Cast immobilization 10-05-2025

## **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Patients with a stable ankle fracture (type Weber B and less than 2 mm dislocation), between the age of 18 and 65 years old

### **Exclusion criteria**

Multiple fractures Patients with an mental handicap Patients not living in the right region, follow up takes place in a different medical centre. Patients who do not speak Dutch fluently

## 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:	Recruitment stopped
Start date (anticipated):	14-01-2013
Enrollment:	100
Туре:	Actual

### Medical products/devices used

Generic name:	MalleoLoc
Registration:	Yes - CE intended use

## **Ethics review**

Approved WMO	
Date:	28-11-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	09-07-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	06-06-2014
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

ID: 23875

9 - The treatment of stable ankle fractures: Brace versus Cast immobilization 10-05-2025

Source: NTR Title:

### In other registers

### Register

CCMO OMON ID NL41177.098.12 NL-OMON23875