

# New surgical treatment for sliding calcaneal osteotomy; retrospective case-series

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bone and joint therapeutic procedures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON37379

### Source

ToetsingOnline

### Brief title

New surgical treatment for CCO

### Condition

- Bone and joint therapeutic procedures

### Synonym

sliding calcaneal osteotomy

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Calcaneal osteotomy, Fixation, Operation technique, Plate

## Outcome measures

### Primary outcome

The main study parameters are the outcomes of the Foot and Ankle Outcome Score (FAOS), American Orthopaedic Foot and Ankle Society Hindfoot Score (AOFAS Hindfoot), Numeric Rating Scale (NRS) and Short Form (SF)-36 questionnaires.

### Secondary outcome

Secondary study parameters are assessment of radiographs of the ankle and calcaneus to evaluate the calcaneus displacement and fixation, and for malunion or nonunion of the calcaneus osteotomy.

## Study description

### Background summary

Sliding calcaneus osteotomy may be indicated to restore the natural congruency of the ankle joint and thereby preventing progression of symptoms and prevent progression of degenerative changes. The ankle joint has a high congruency. A decrease in joint congruence will increase contact pressure per area. More displacement corresponds to increasing contact pressure. Clinical and basic scientific investigations have shown that loading and motion of the joint can influence the healing of articular cartilage and joints. Malalignment may also increase the contact pressure of the ankle. Biomechanical experiments have demonstrated that in varus and supination the maximum pressure is located on the medial border of the talus, while in valgus and pronation the maximum pressure is located on the lateral talar border. It is therefore important to correct malalignment in patients with degenerative changes in the ankle. Sliding calcaneus osteotomy is an established procedure for treatment of an acquired adult flatfoot, correct hindfoot valgus after recurrent pronation trauma and deltoid ligament insufficiency, unicompartimental osteoarthritis, cavovarus foot deformity, osteochondral defects, and correction of a malaligned ankle. Currently, cannulated screw\*fixation is used for sliding calcaneus osteotomy.

This method fixation is achieved by inserting one or two compressive screws from posterior. The stability of the osteotomy allows a rapid mobilization of the ankle and weight bearing after 4 weeks. Radiographically, consolidation is complete after approximately 8 weeks. Nonunion of the osteotomy is rare because of the extensive spongy surface tissue which always remains in contact. However, fixation with screws has some disadvantages. Separate incisions have to be made for introduction of the screws. Patients may develop pain on walking when prominence of the screw heads on the plantar surface of the calcaneus. A fluoroscope has to be used during surgery, to determine the exact size and control the position of the screws. The osteomized area where screws can be placed is small. Furthermore, it is difficult to maintain and check the desired amount of calcaneal displacement since the screws are inserted from a different position. This may lead to over- and under-correction after calcaneus osteotomy. Recently, a stepplate-fixation technique was developed in order to overcome these problems. This study will be the first study to assess the results of this new surgical technique.

### **Study objective**

The primary objective of the study is to determine the patient satisfaction and assess objectively the clinical outcome at a minimum of one year follow-up after surgical intervention.

The secondary objective is to determine whether the osteotomy heals in the correct way and to evaluate the calcaneus displacement and fixation.

### **Study design**

This study is designed as a retrospective descriptive study with postoperative follow-up. All patients will be asked to come to our outpatient clinic for one visit. During this visit conventional radiographs of the ankle (lateral and AP) and of the calcaneus (axial) will be taken.

### **Study burden and risks**

All patients will receive three routine weight bearing radiographs, which is an exposure to radiation. This study does not provide immediate advantage for the participating patient. For future patients however this study is beneficial as it will evaluate the effectiveness of a new surgical procedure for sliding calcaneal osteotomies at the AMC.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

The study population consists from adult patients who underwent a sliding calcaneal osteotomy with plate-fixation in our clinic at the Academic Medical Centre in Amsterdam from 2010- April 2011

### **Exclusion criteria**

Pregnant or possibly pregnant patients and children will be excluded from study participation

## **Study design**

### **Design**

**Study type:** Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2012
Enrollment:	16
Type:	Actual

## Ethics review

Approved WMO	
Date:	16-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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	NL38569.018.11