FACTS study: Functional outcome assessment after Calcaneal Trauma Surgery

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON34227

Source
ToetsingOnline

Brief title
FACTS-study

Condition

- Bone and joint injuries
- Fractures
- Bone and joint therapeutic procedures

Synonym
calcaneal break, calcaneusfracture

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

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

Intervention

Keyword: calcaneus fracture, functional outcome, trauma surgery

Outcome measures

Primary outcome

To study the biomechanical and anatomical characteristics in patients treated surgically after traumatic calcaneal fracture, and compare these data to healthy subjects, patients after arthrodesis of the subtalar and talar joint.

- Is there a relation between the postoperative functional subtalar axis and the clinical functional outcome?

- Is there a relation between the functional subtalar axis and the anatomical subtalar axis?

Secondary outcome

To investigate whether the changes in biomechanical and anatomical characteristics determines the post-operative outcome and patient satisfaction.

Research questions:

- What are the changes in biomechanics after surgery for calcaneal fractures if compared to healthy persons?

- What are the changes in biomechanics after calcaneus surgery if compared to patients after arthrodesis of the subtalar joint?

- What are the changes in biomechanics after calcaneus surgery if compared to patients after arthrodesis of the talar joint?

- Does patient satisfaction after operative treatment correlate with changes in

biomechanics?

- Have the changes in biomechanics and difference in treatment an effect in the

patient satisfaction?

Study description

Background summary

In the Netherlands the number of patients that are treated in the emergency room with an ankle- or foot injury is valued on approximately 190,000. The fractures of the calcaneus comprise 60% of the tarsal fractures, but only 4% of all foot-ankle fractures. The most common mechanism of injury is a high energy axial load: fall from height.
The fractures can be treated conservatively or with ORIF (open reduction and internal fixation). Functional outcome after conservative or ORIF is frequently tampered. Improved understanding of biomechanical changes after calcaneal fractures and surgery for calcaneal fractures may alter the functional outcome.

Study objective

The aim of this study is to assess biomechanical properties after a calcaneal fracture, and compare these data tot the radiological and functional outcome parameters. Hereby comparing healthy subjects to patients who were treated with ORIF (open reduction internal fixation), with arthrodesis of the talar joint or arthrodesis of the subtalar joint. The methods used for the assessment are the VICON-system with the *Oxford foot model*, radiological characteristics (computed tomography) and questionnaires. The VICON-system comprises of six cameras and markers. The markers are placed on specific points on the subjects with tape. The camera system then makes a recording and calculates specific changes/vectors of the markers. By using this system the gait of the subject can be analyzed and a comparison can be made between healthy and treated subjects. The outcome of this part of the investigation is to assess the biomechanical changes of the ankle-joint and to determine the *subtalar joint-axis* (STJ-axis).
The VICON system is validated for the testing of the lower extremity in combination with other programs, the oxford foot model has been validated by other authors. This system has been used in multiple trials by the department of movement sciences of Maastricht University, but previsously not regarding the STJ-axis. Recently, the department of movement sciences has validated with the VICON-system the Oxford foot model.
Earlier investigations have given us more insight in the relationship between the function of the ankle-joint and the STJ-axis. It is known that this axis,

between the calcaneal bone and the talus bone, has great influence on the function of the ankle.
The aim of this study is to determine the influence of deviations in the STJ-axis on the (postoperative) outcome.
Also there will be a footprint-analysis to get an impression of the pressure partitioning.
The outcomes of the biomechanical analyses are compared in the patients group with the radiological findings on CT (Böhler, Ghislaine angle, subtalar joint congruency). Furthermore the patients* satisfaction is analyzed by health questionnaires (The foot and ankle disability score (FADI), Visual Analog Scale of Hildebrand and RAND-36).
By analyzing these outcomes there can be overall, objective, assessment of the postoperative outcome after the trauma ankle-surgery. At present there is no evidence comparing biomechanical analyses of the VICON-system with radiological and patient reported outcome scores. The outcome of this study can contribute in the knowledge about the foot biomechanics and the decision for the treatment of a calcaneal fracture. Intra-operative pedobarography has been shown to improve outcome in patients undergoing ankle arthrodesis and may be also applicable in acute fracture surgery.

Study design

The experimental design of the study is a prospective observational study comparing healthy and operated patients regarding foot biomechanical and anatomical abnormalities, and outcome satisfaction.

Study burden and risks

There will be no benefits or extra risks for the participants during this study.

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

Group 1: Primary (non-pathological) displaced unilateral fracture of the calcaneus (open fractures are included)
1. Age: 18-65 years old
2. Independent for activities of daily living (yes/no question).
3. All patients must be >1 year after operation/fracture;Group 2: Healthy subjects
1. Age: 18-65 years old
2. Independent for activities of daily living (yes/no question).;Group 3: Patients after subtalar arthrodesis for posterior facet posttraumatic arthritis
1. Age: 18-65 years old
2. Independent for activities of daily living (yes/no question).
3. All patients must be >1 year after operation/fracture;Group 4: Patients after talar arthrodesis for posttraumatic arthritis of the ankle joint, with no signs of subtalar arthritis
1. Age: 18-65 years old
2. Independent for activities of daily living (yes/no question).
3. All patients must be >1 year after operation/fracture

Exclusion criteria

Group 1: Primary (non-pathological) displaced unilateral fracture of the calcaneus (open fractures are included)
1. Fracture of contra lateral leg/ankle
2. Neurotrauma
3. Spinal or neurological injury
4. Pathologic fractures (metastasis, secondary osteoporosis)
5. Dependent in activities of daily living.;Group 2: Healthy subjects

1. History of operations or fractures of the legs.
2. Dependent in activities of daily living.;Group 3: Patients after subtalar arthrodesis for posterior facet posttraumatic arthritis
1. Fracture of contra lateral leg/ankle
2. Neurotrauma
3. Spinal or neurological injury
4. Pathologic fractures (metastasis, secondary osteoporosis)
5. Dependent in activities of daily living.;Group 4: Patients after talar arthrodesis for posttraumatic arthritis of the ankle joint, with no signs of subtalar arthritis
1. Fracture of contra lateral leg/ankle
2. Neurotrauma
3. Spinal or neurological injury
4. Pathologic fractures (metastasis, secondary osteoporosis)
5. Dependent in activities of daily living.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-02-2011
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	06-12-2010

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL34131.068.10