The effect of a heel-unloading orthosis in short-term treatment of calcaneus fractures on physical function, quality of life and return to work – study protocol for a randomized controlled trial

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Study protocol

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Abstract

Background Neither for operative nor non-operative therapy standardized guidelines for rehabilitation of calcaneus fractures are existing. While there is consensus for non- or partial weight bearing, the use of supporting devices such as specific foot ankle orthosis is still a matter of debate. Recently, a heel-unloading orthosis (‘Settner shoe’) was introduced for aftercare of these fractures, allowing walking by shifting the load to the middle- and forefoot. This orthosis enables early mobilization of patients suffering from both one-and two-sided fractures. The ‘Settner shoe’ can be applied in non-operative therapy and following operations. Specifically in calcaneus fractures, early regain of physical activity has been highlighted as one of the key factors for quality of life and the ability to return to work. Thus, we hypothesize that mobilization with the ‘Settner shoe’ results in higher physical activity within the first 3 months, which is the primary outcome criterion. Methods This is going to be analyzed by a randomized controlled study comparing treatment with and without this specific orthosis. The secondary outcome measures are the time point of return to work in calcaneus fracture patients aged between 18 and 60 years. Furthermore, the American Orthopaedic Foot and Ankle Society's (AOFAS) ankle-hindfoot score, a 3-dimensional gait analysis, and the EQ-5D-3L questionnaire for quality of life are assessed. Discussion It is the first trail applying a standardized rehabilitation protocol in patients suffering from calcaneus fractures aiming to improve the non-operative part of treatment by the use of an orthosis. Trial registration: NCT03572816

Background

In the past decades, the scientific focus regarding treatment of calcaneus fractures was the choice of operative or non-operative treatment modality. Although the evidence is ambiguous (1), recent meta-analyses suggest that operative therapy is associated with a higher likelihood to resume pre-injury work, to reach a higher level of physical function and fewer problems when wearing shoes. However, non-operative therapy has significant less complications and infections (2,3). Typically, aftercare includes non- or partial weight bearing, but protocols are different and often not very specific. In fact, there are no published studies comparing different procedures or special supporting devices. Recently, a heel-unloading orthosis (‘Settner shoe’ (4)) was introduced in aftercare for calcaneus fractures, allowing walking by shifting the load to the middle- and forefoot. This orthosis does not only enable early mobilization of patients suffering from one-sided fractures, but also permits going following two-sided fractures, avoiding the otherwise necessary wheel-chair mobilization. The ‘Settner shoe’ can be applied in non-operative therapy and following operations. Specifically in calcaneus fractures, early regain of physical activity has been highlighted as one of the key factors for quality of life and the ability to return to work (2,3). Thus, we hypothesize that mobilization with the ‘Settner shoe’ results in higher physical activity within the first 3 months and secondly improves ability to return to work in calcaneus fracture patients aged 18-60 years. Further outcome criteria are the American Orthopaedic Foot and Ankle Society's (AOFAS) ankle-hindfoot assessment, a 3-dimensional gait analysis, and the EQ-5D-3L questionnaire. It is the first trail applying a standardized aftercare in patients suffering from calcaneus

fractures aiming to improve the non-operative part of treatment. Furthermore, the trial clarifies, whether the economical effort for the equipment acquisition is scientifically justified.

Objectives

We hypothesize that mobilization with the 'Settner shoe' results in higher physical activity within the first 3 months after calcaneus fractures.

Research questions

Does the application of a heel-unloading orthosis ('Settner shoe') independent of operative or non-operative therapy of a calcaneus fracture improve:

1.) the physical activity (active minutes per day)?

2.) the quality of life (EQ-5D-3L)?

3.) the foot function (AOFAS)?

4.) the time necessary for return to work in patients between 18 and 60 years?

Trial design

The study design is a parallel group, randomized controlled trial with open allocation including all patients with calcaneus fractures independent of kind of initial therapy. It is an investigator initiated trial.

Methods

Study setting

All patients treated for calcaneus fracture (DS920* 'Fraktur af hælben' according to the Danish SKS-browser) at the University Hospital Odense are prospectively screened for eligibility and included in the trial, if they fulfil the inclusion criteria as listed below. The follow-up period is 6 months.

Eligibility criteria

In Denmark, the treatment of calcaneus fractures is regarded as highly specialized, wherefore both decision-making and operations are done for the whole Region of Southern Denmark in the Department of Orthopaedics and Traumatology at the University Hospital Odense. Therefore, patients are screened by consultants of the local trauma section.

Inclusion criteria:

· Fracture of the calcaneus, which is classifiable according to the Sanders' classification (excludes avulsion fractures)

· Being able to understand Danish or English and answer the questionnaires

· Informed consent

· Age between 18 and 65 years

Exclusion criteria:

· Pathological fractures including fractures associated with a Charcot foot

· Immature skeletal system

· Other fractures with influence on weight-bearing

· A soft-tissue situation not allowing the equipment with a 'Settner shoe' within 3 weeks after treatment (either decision-making for non-operative therapy or open reduction and internal fixation)

Interventions

After operation or decision for non-operative therapy, the schedule for the 2 groups are defined as follows:

Group 1 (treatment without 'Settner shoe'):
- mobilization without weight bearing for 6 weeks starting with the day of either decision-making for non-operative therapy or open reduction and internal fixation, if needed a cast or another kind of orthosis such as a Static Walker are applied; after the first 6 weeks weight-bearing is increased to 15-20 kg for another 4 weeks, then followed by 2 weeks with 35-45 kg; after that transition to full-weight bearing (always only if possible)

- X-ray after 6 and 12 weeks; depending on the results, the schedule for weight bearing may be adjusted to the need in case of delayed healing or complications related to implants

Group 2 (treatment with 'Settner shoe'):

- mobilization with the custom-made heel-unloading orthosis ('Settner shoe') without pads for 6 weeks, then 2 weeks one pad, 2 weeks 2 pads, 2 weeks 3 pads, after that full-weight bearing without any support (always only if possible)

- X-ray after 6 and 12 weeks; depending on the results, the schedule for weight bearing may be adjusted to the need in case of delayed healing or complications related to implants

The patients of both groups are informed about the aftercare at the time point of inclusion.

Outcomes

Overview about assessments

The schedule of enrolment, interventions, and assessments for the different variables is summarized in table 1.

Primary outcome criterion

The EuroQol 5D-3L questionnaire (5) following 3 months (time point 3) is the primary outcome criterion.

Secondary outcome criteria

· active minutes per day at time point 1

· portion of highly active periods per day at time point 1 and 3

· active minutes per day following 3 months after fracture or decision for non-operative treatment (time point 3)

Explorative outcome criteria

· AOFAS (time point 3) (6)

· 3-dimensional gait analysis (time point 2 if possible, and 4)

· time point of return to work of patients between 18 and 60 years

· Range of motion (ROM): Pro- and supination (percent of healthy side or assumed normal mobility) are analyzed as part of the clinical examination.

· Pain: The evaluation includes the medication and a visual-analogue scale (VAS).

· Comparison between patients with and without operation

Patient characteristics beside outcome criteria

Epidemiology

· age

· sex

· body mass index

· ASA (American Society of Anesthesiologists) physical status classification system

Injury characteristics

· classification according to Sanders (7)

· classification of open/closed tissue damage (8)

· polytrauma (ISS≥16, multiple injuries, monotrauma)

· indication for operation (dislocation, broadening, flattening of Böhler angle etc.) or conservative therapy (comorbidity, smoking etc.)

· the time between the fracture occurred and operation or decision making for non-operative therapy

Healing and treatment characteristics

· bone healing after 3 months: union or delayed healing The decision is made based on conventional radiographs including the clinical description of complains.

· weight bearing after 3 months Is it possible or not?

· hindfoot axis (varus/valgus-deformity, Böhler angle, subtalar osteoarthritis) The decision is made based on conventional radiographs and a clinical evaluation.

· type of operation (approach, fixation method, graft)

Complications

· infection (I)

· deep venous thrombosis (DVT)

· nerve paresis/palsy/disturbed sensibility (N)

· subtalar posttraumatic osteoarthritis (PTOA) assessed using the Kellgren Lawrence score (9)

· subtalar instability (SI), clinically assessed

· local mechanical irritation by plate/screws (LI)

· wound irritations (WI) as superficial healing problems or skin edge necrosis

· irritations associated to the use of the custom-made heel-unloading orthosis (‘Settner shoe’)

Participant timeline

An overview about the timeline is provided in table 1. The clinical and radiological controls correlate with the usual guidelines for treating calcaneus fractures at the Odense University Hospital.

Sample size and power analysis

The sample size calculation was based on data of a pilot study suggesting a 33% difference in quality of life (QoL) and activity, correlating with a clinically relevant difference. However, the 95% confidence interval was less for the EuroQol 5D-3L questionnaire compared to all activity measurements. Therefore, QoL was chosen as the primary outcome measure. Desired ratio of sample size of Group 2 to Group 1 was set as ‘1’ (sample sizes are equal), the power to 80% and the 2-sided confidence interval to 95%. The calculation was done using the following equations (10):

n1 = sample size of Group 1

n2 = sample size of Group 2

σ1 = standard deviation of Group 1

σ2 = standard deviation of Group 2

Δ = difference in group means

κ = ratio = n2/n1

Z1-α/2 = two-sided Z value (e.g. Z=1.96 for 95% confidence interval).

Z1-β = power

The calculation resulted in 28 patients in each group. Considering 10% drop-outs, 31 patients will be included in each group.

Recruitment

All consultants of the trauma section of the Department of Orthopaedics and Traumatology at the University Hospital Odense are involved in the recruitment process of the study.

Methods: Assignment of interventions (for controlled trials)

Allocation

In the period between treatment (either decision-making for non-operative therapy or open reduction and internal fixation) and consolidation of the soft-tissue situation, the patients are randomized for the aftercare with or without the custom-made heel-unloading orthosis ('Settner shoe'). As soon as the soft-tissue situation allows the adjustment, the patients are referred to an orthopaedic shoemaker, who equips the patient accordingly. The randomization is done using the tool provided by OPEN.

Blinding (masking)

The allocation is not blinded, because it will be obvious to the patient, whether a special shoe is worn or not. Furthermore, the treating trauma surgeon needs to initiate the prescription.

Methods: Data collection, management, and analysis

Management and collection

REDCap™ (Research Electronic Data Capture), a secure application for online surveys and databases, facilitates data management. The University Hospital Odense is an institutional partner of REDCap™, which was especially designed for biomedical research and fulfills all necessary safety features. This is supported by the OPEN initiative (Odense Patient data Explorative Network). REDCap™ used with the OPEN-platform supports also a randomization function, which is used for the study. This agreement was approved by OPEN (project nr. 656, 18/29801).

Statistical methods

Normally distributed numeric data sets are compared using the paired Student's t–test. Otherwise or in case of non-numeric data, nonparametric tests such as the Mann-Whitney U-test for two and the Kruskal-Wallis H-test for multiple variables determine the significance of difference. For correlations, Spearman ρ

is calculated. Incidences are compared using the chi square test. For the binary outcomes, a logistic regression is calculated at least including the a-priori confounders age and sex. Considering the fact that the ability of patients to mobilize after injury is highly dependent upon pain and swelling, which in turn is partly dependent on fracture type and treatment modality, special attention is paid to the classification according to Sanders, which will be tested as one of the most influential confounders just as the type of treatment. For continuous variables, a multiple regression is used, while both regression analyses include confounders identified by dichotomous calculations. Variables to include cover besides epidemiological parameters classification, and treatment modality. The analysis will be done using the Intention-to-treat approach, which means that the patients are considered as using the orthosis when they were randomized in this group.

Methods: Monitoring

Data monitoring

After exception from OPEN, a data manager was assigned to the study, who supports the data coherence. Furthermore, a yearly data monitoring will be done by a study nurse, who is assigned to the project.

Harms

Any adverse or severe adverse events will be registered during the trial. Expected are especially local mechanical irritations, which are listed in the chapter for registration of patient characteristics beside outcome criteria.

Ethics and dissemination

Ethics

The study was approved by the ethical board of the Region of Southern Denmark (https://komite.regionsyddanmark.dk/wm258128, S-20170219).

Patient law/privacy

All data collected from patients are protected by the Act on Processing of Personal Data and Health Act according to Danish Data Protection Agency. The project was reported to the local data safety authorities (Datatilsynet under “Regionens Paraply 2012-58-0018”, 17/44501). The database was established with OPEN, however, other possible related files are stored in a secure Sharepoint (https://secure.regionsyddanmark.dk/projektrum/ProTibExPla/SitePages/Startside.aspx).

Publication

Reporting will be conducted according to Consolidated Standards of Reporting Trials (CONSORT guidelines (http://www.consort-statement.org/) and published in a peer reviewed journal. The authorships are granted according to the ICMJE (International Committee of Medical Journal Editors) guidelines.

Trial registration

The project was registered and approved by the Ethical Board Region Southern Denmark (Project-ID S-20170219). Furthermore, the project was approved according to the Act on Processing of Personal Data (Journal no. 17/44501). Moreover, the trial was registered at Clinicaltrials.gov (Identifier NCT03572816).

Access to data

The final analysis is done by LP and HS, who will have access to the final trial dataset. This is monitored by the assigned data manager (OPEN). The access to the data is regulated by the contract with OPEN.

Appendices

Measurement of physical activity

For monitoring of activity, the patients are equipped with an Axivity™ AX3 (Newcastle upon Tyne, UK) at the lateral femur of the unaffected side. If there is a fracture at both sides, the trackers are attached to the side with the less complicated fracture. The wear time is 7 days. At day 7±14 (discharge, time point 1) and after 3+1 months (time point 3) patients are equipped, and activity signals are analyzed by calculating the mean of all acquired 24-hour-data during these two periods. Regarding the Axivity™ AX3, the portion of highly active periods per day and the number of active minutes, correlating with walking activity, have shown to be most discriminating in the validation study (11). Therefore, these parameters are selected. Reliability is checked using a wear-time analysis based on change of signal vector magnitudes and temperature monitoring. Correlating with these two data points, the EuroQol 5D-3L questionnaire (5) and the AOFAS (6) are monitored.

Orthosis

The heel-unloading orthosis (‘Settner shoe’ (4)) can be used for conservative treatment and aftercare following surgery. It needs to be assembled out of pre-formed and size-adjusted parts. This is done by an orthopaedic shoemaker. The increase of weight bearing is achieved by pads. The first 6 weeks the shoe is worn without pads. Then, the first pad is applied. Every 2 weeks a further pad is put in the shoe, which is

removed after 3 months. Preliminary data suggest that this heel-unloading orthosis reduce days of inability to work.

3-dimensional gait analysis

All outcome calculations will be based on measurements taken during gait using a 3D Vicon MX movement analysis system with eight cameras operating at 100 Hz (Vicon, Oxford, UK) and two AMTI force-plates (AMTI, OR6-7, Watertown, MA, USA) embedded at floor level, operating at 1,000 Hz. A technician experienced in gait analysis and the Vicon system will attach reflective markers that reflect infrared light according to the Vicon Plug-in-Gait marker set and model (12).

Patient involvement

The patients give feedback about the actual use of the orthosis including the possible benefit associate with its application. Furthermore, activity measurements provide objective data about patient mobility during early aftercare and signals feedback to the patient. By this, the patients themselves can control their postoperatively increasing activity. This includes a scientifically supported evaluation by the study investigators at the defined follow-up time points at 6 weeks and 3 months after therapy start.

Consent form

The consent form used during the trial is provided as supplementary material.

Discussion

This manuscript presents a protocol for a standardized rehabilitation protocol in patients suffering from calcaneus fractures aiming to improve the non-operative part of treatment using an orthosis.

Aftercare in fracture treatment appears to be as important as the operation itself and stands in case of non-operative treatment for the main part of treatment. Recently, it could be shown that early functional exercise and weight bearing activity can smooth and shape the subtalar joint following intraarticular calcaneus fractures “and reduce the residual displacement of the articular surface, improving functional recovery of the affected foot” (13). Therefore, early rehabilitation should be optimized and implemented in clinical practice. There are a lot of different factors and parameters, which can be influential and were not yet evaluated in a standardized manner. An article appreciating the different rehabilitation possibilities of a single injury compared to calcaneus fractures in multiple injured patients surprisingly concluded that there were no differences in outcome measures between these two groups (14). While orthoses are in the focus of non-operative therapy in foot-related diseases (15), the use of aids and supporting devices in the treatment of fractures are often totally neglected. Usually short rehabilitation protocols are provided without going too much into details (16). Therefore, reliable protocols evaluating

the use of often applied orthotic devices appear to be just as necessary as a standardized procedure for the operation.

Pain, disability, and instability in the joint are the most important symptoms in patients with osteoarthritis or fractures causing distress to many people (17). Considering this, a quality of life score (EuroQol 5D-3L questionnaire) was chosen as the primary outcome measure. Although we have good experiences with our objective parameter, physical activity, which correlated with quality of life after proximal femur fractures, proximal tibia fractures and ankle fractures, the spread of data exceeded the one obtained with the EuroQol 5D-3L questionnaire.
A major concern of the study is heterogeneity, including intra-articular fractures of all types and severity, and both operative and non-operative treatments. However, independent of the injury and the treatment, one group will start with weight bearing (just a free-hanging calcaneus) and the other one without. The expectation is that weight bearing is the factor that will make the difference in clinical outcome and not the intervention. Furthermore, the allocation is randomized, which hopefully secures even distribution of the influential factors. Moreover, special attention is paid to the classification according to Sanders, which will be tested as one of the most influential confounders just as the type of treatment.

Summarizing, the trial will contribute to elucidate the value of orthosis treatment in aftercare of calcaneus fractures. Considering the fact that quite some hospitals regularly use this equipment, the study can help to evaluate, whether this economic effort is justified.

Trial Status

Protocol version: 2.6 from 12/17/2018

The recruitment has not yet begun and starts in March 2019. Recruitment will presumably be completed in January 2021.

Declarations

Ethics approval and consent to participate

The study was approved by the ethical board of the Region of Southern Denmark (S-20170219). The participants will be introduced to the study by the medical personnel in a room, where they will not be disturbed. It will be assured that patients are allowed (if they wish) to be introduced to the study accompanied by a family member or any other person(s) selected by the patient. Patients will be given an oral overview of the purpose of the study, a participant information document describing the study and potential risk together with a patient consent form, which the patients will sign if they decide to participate in the study. The patient can resign from participating in the study without giving a reason and without any consequences. Patients are included after the operation or after decision for non-operative therapy, but before discharge.

Consent for publication

Not applicable.

Availability of data and material

Original data will be provided in an anonymized form together with the publication

Competing interests

The authors declare that no competing interests exist.

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Authors' contributions

HS: principal investigator, sponsor, patient recruitment, data analysis.

LP: investigator, study design, patient recruitment, data analysis.

AHL: study design, gait analysis.

LF: study design, patient acquisition.

JLE: investigator, patient recruitment, data analysis.

CFM: advisor, patient acquisition.

All participants are affiliated with the Odense University Hospital and have substantially contributed to the design of study and protocol. They all approved the final manuscript.

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Not applicable.

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Table 1

Due to technical limitations, Table 1 is only available as a download in the supplemental files section.

Supplementary Files

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- supplement1.doc
- supplement2.jpg