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Shoe adaptation for patients with osteoarthritis in the ankle after ankle fracture

Submission date
24/03/2015

Recruitment status
No longer recruiting

Registration date
25/03/2015

Overall study status
Completed

Last Edited
25/03/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
More than 10% of the people who suffered from an ankle fracture develop early osteoarthritis, a condition that causes the joints to become painful and stiff. This can be treated either by surgery or conservatively. Conservative treatment is limited to pain medication or shoe modifications. The most commonly used shoe adaptation is the addition of a rocker profile under the shoe, which helps you to roll the shoe. We think this requires less motion in the ankle during walking and this could potentially reduce your pain. However, only limited evidence is available regarding whether this purpose is met. We will study the effect of such a shoe adaption on the motion in your ankle and on your pain.

Who can participate?
Patients aged 18 or over who have suffered an ankle fracture and have developed osteoarthritis.

What does the study involve?
First, you will be invited to the hospital to check if you can participate in the study. If you do, we will measure the size of your feet and order the shoes. When the shoes are ready, you will receive one pair of shoes, for which you will have to walk on for 2 weeks. Upon completion, you will return to the hospital and you will be asked to walk in front of a camera system that captures your gait. After this visit, you will walk on your own shoes for the next 2 weeks. Thereafter you will walk on a different pair of shoes. At the end, you will return to the hospital for the last time and we will ask you to walk for the cameras. During these 6 weeks you will be requested to complete a pain diary on a daily basis. At the end of the study, you are allowed to keep one pair of shoes at your choice.

What are the possible benefits and risks of participating?
We do not anticipate any risks, as these types of shoes are commonly prescribed in daily practice. You might possibly benefit from the study if one of the pairs of shoes reduces your pain.

Where is the study run from?
University Medical Centre Groningen, the Netherlands.

When is the study starting and how long is it expected to run for?
From August 2013 to February 2015.

Who is funding the study?
The study is partly funded by the hospital, partly by the shoe supplier, partly by the shoe technicians and partly by a foundation called OFOM.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
Protocol CvR/2012/PTAA

Study information

Scientific Title
The effect of rocker profile shoes on pain and range of motion in patients with post-traumatic ankle arthritis (PTAA), compared to standard shoes

Study objectives
To assess whether proximal rocker profiles significantly reduce pain, range of motion (ROM) and moments in the ankle in patients with PTAA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
METc (medical ethical committee) of the UMCG (University Medical Centre Groningen), date of first approval: 05/06/2013, date of approval of 1st amendment: 09/10/2013, ref: METc 2012/432

Primary study design
Interventional

Study design
Single-center randomised unblinded cross-over study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-traumatic ankle arthritis

Interventions
All patients test two types of shoes: one standard shoe, and the same shoes adapted with a rocker profile (including a proximally placed rocker, heel rounding and stiffened sole), with a wash-out period in between.

Patients will be invited to the hospital to check if they can participate in the study. If they do, we will measure the size of their feet and order the shoes. When the shoes are ready, they will receive one pair of shoes, for which they will have to walk on for 2 weeks. Upon completion, they will return to the hospital and they will be asked to walk in front of a camera system that captures their gait. After this visit, they will walk on their own shoes for the next 2 weeks. Thereafter they will walk on the other pair of shoes. At the end, they will return to the hospital for the last time and we will ask them to walk for the cameras. During these 6 weeks they will be requested to complete a pain diary on a daily basis. At the end of the study, they are allowed to keep one pair of shoes at their choice.

Intervention Type
Other

Primary outcome(s)
1. Primary biomechanical outcome: range of motion (sagittal) in ankle during stance phase. The ROM was calculated by adding the maximum dorsal flexion during stance phase to the maximum plantar flexion from the early stance phase
2. Primary clinical outcome: pain score, reported by patients using numeric rating scale scoring (0-10). Patients kept a diary for the whole 6 weeks (so including washout), for recording the daily average pain and the daily maximum pain

Key secondary outcome(s)
Secondary biomechanical outcomes: sagittal ankle moments (Nm/kg), step length (m), speed (m /s), cadence (steps/min) and stance time (s). The biomechanical parameters were measured using the VICON system. Sixteen reflective markers were placed bilaterally on anatomical landmarks according to the lower body Plug-in-Gait model of Vicon. The markers were tracked by an eight-camera motion capture system (Vicon, Oxford, UK, fs = 100 Hz) to measure the kinematics. Force data were measured by force plates (AMTI; Watertown, Massachusetts, fs = 1000 Hz). Joint kinematics and kinetics were computed using VICON Nexus software and further processed using MatLab.

Completion date
05/02/2015

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Fracture of tibia, fibula or talus in medical history
3. Daily ankle and/or foot pain with a NRS score at baseline > 3
4. Radiological evidence for osteoarthritis in tibial-talar joint
5. Being able to walk at least 100 meters without any support
6. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Concomitant conditions like cardiovascular disease or neuromuscular disease or musculo-skeletal problems in other joints that intervene with walking
2. Ankle arthrodesis or arthroplasty in place
3. Other forms of osteoarthritis (e.g., primary osteoarthritis, OA secondary to rheumatoid arthritis or haemophilia)
4. Leg length difference of more than 2 cm
5. Planned activities within the research period, like holiday, that influence the normal level of activity
6. Limited ankle motion in rest, defined as total passive ROM (range of motion) < 10°

Date of first enrolment
19/08/2013

Date of final enrolment
27/10/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Groningen
Netherlands

Sponsor information

Organisation
University Medical Centre Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Industry

Funder Name
OIM orthopedie

Funder Name
OFOM (ontwikkelingsfonds voor het Orthopedisch Maatschoentechnisch bedrijf; research funding for orthopedic technical companies)

Funder Name
DJO Global

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request