Effect of shoe adaptation on pain and ankle motion in patients with post traumatic ankle arthritis

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To investigate whether adding a rocker bar (including rounded heel, proximally placed fulcrum and stiffened sole) significantly reduces pain, the range of motion in the ankle and the ankle moments in patients with posttraumatic ankle arthritis.

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

Summary

ID

NL-OMON40032

Source
ToetsingOnline

Brief title
Shoe adaptation in post traumatic ankle arthritis

Condition

- Joint disorders

Synonym
posttraumatic artritis; artritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,DJO global (levert schoenen),OIM orthopedie Haren: maken de schoenaanpassing,Subsidie van Stichting OFOM

(Ontwikkelingsfonds voor het Orthopedisch Maatschoentechnischbedrijf)

Intervention

Keyword: pain, posttraumatic artritis, range of motion, rockerbar

Outcome measures

Primary outcome

Primary biomechanical outcome:

Range of Motion (the maximum motion in ankle joint) during stance phase.

Priamry clinical outcome:

Pain (daily average) around the ankle measured through Visual Analogue Scale

(VAS) .

Secondary outcome

Secondary biomechenical outcomes:

Joint moments of ankle and knee

Step rate/lenght and stance time

Secondary clinical outcome:

Pain (daily maximum) around the ankle measured through Visual Analogue Scale

(VAS) .

Study description

Background summary

The prevalence of posttraumatic osteoarthritis of the ankle is over 10%. This can be treated either surgically or conservatively. Conservative treatment is limited to pain medication, orthosis and footwear modifications. Footwear modifications have been widely prescribed, without any extensive evidence of efficacy7,8,9. It is assumed that by moving the fulcrum more proximally and by adding a heel rounding, less shifting of the body weight, hence the tibia, is required during the second rocker of the stance phase. Another consequence of these modifications is a reduction of the peak moments and integral of the moments on the ankle, theoretically meaning less pressure on the ankle joint surface. The main purpose of such an intervention is to alleviate pain. However, only limited scientific evidence is available if this purpose is met by shoe adaptation. We therefore designed this protocol in which we will study the effect of a shoe intervention on range of motion and ankle moments during stance phase and the effect on pain.

Study objective

To investigate whether adding a rocker bar (including rounded heel, proximally placed fulcrum and stiffened sole) significantly reduces pain, the range of motion in the ankle and the ankle moments in patients with posttraumatic ankle arthritis.

Study design

a randomized controlled crossover study.

Intervention

The intervention shoe, referred to as type B, is a standard shoe, of the brand Dr. Comfort, but modified with a proximally placed fulcrum, sole stiffening and a rounded heel, hereafter called together a *rocker bar*. The same shoe without these modifications will serve as control, hereafter called type A. All subjects, both the patients and the healthy subjects will walk on both shoe types. They will be randomized for the order of intervention, e.g. they will either start with intervention A or B.

Study burden and risks

The healthy volunteers will visit the clinic twice; first for screening and measuring shoe size (this will take about 30 min) and a second time for gait analyses (this will take about 1.5-2 hrs) while walking on 2 different types of shoes. The patients will be followed for 6 weeks. There will be 4 visits during this period. At the first visit, the protocol is explained and if consent is signed, the subjects will be examined and screened. During the other 3 visits at the hospital, a gait analysis and pain assessment will be performed. This will take about 45-60 minutes. During the 6 weeks the subjects are requested to

keep a diary to record their pain level, by documenting their maximum and average pain level at each day. The travel expenses (train class 2 and/or bus) will be reimbursed for all subjects. The patients may keep one pair of shoes, after completion of the trial.

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

For the patient group:
1. Age >= 18 years
2. Fracture of tibia, fibula or talus in medical history
3. Daily ankle and/or foot pain with a VAS 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;For the healthy volunteers:
1. Age >= 18 years
2. Signed Informed Consent

Exclusion criteria

For the patient group:
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 avtivity
6. Limited ankle motion in rest, defined as total passive ROM (range of motion) < 10°;For the healthy volunteers:
1. Foot or ankle pain
2. Other concomitant conditions like cardiovascular disease or neuromuscular disease or musculo-skeletal problems in other joints that intervene with walking
3. Ankle fracture in Medical History
4. Limited ankle motion in rest, defined as total passive ROM (range of motion) < 10°

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2013

Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	semi-orthopedic shoe in combination with shoe adaptation
Registration:	No

Ethics review

Approved WMO Date:	05-06-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL42481.042.12