# The kinematics and kinetics of walking using a forefoot offloading shoe in patients with diabetes and periferal neuropathy.

Published: 24-08-2006 Last updated: 20-05-2024

The goal of this study is to compare the kinematics and kinetics of walking in a FOS with a standard shoe in diabetic neuropathic patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational non invasive

# Summary

### ID

NL-OMON29941

**Source** ToetsingOnline

#### **Brief title**

Biomechanics of walking in a forefoot offloading shoe.

### Condition

- Diabetic complications
- Peripheral neuropathies

Synonym diabetes mellitus - diabetes

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Academisch Medisch Centrum

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

### Intervention

Keyword: biomechanics, diabetes mellitus, therapeutic shoes

### **Outcome measures**

#### **Primary outcome**

- Range of motion in the ankle, knee, and hip joint in the sagittale plane

during stance

- Joint moments in the ankle, knee, and hip joint in the sagittale plane during

ground contact.

- Vertical and horizontal ground reaction forces
- Walking speed, step length, step frequency

#### Secondary outcome

- Peak plantar pressure and pressure-time integral in the forefoot.

# **Study description**

#### **Background summary**

Forefoot offloading shoes are frequently used as offloading device for treatment of plantar forefoot ulcers in patients with diabetes. Earlier studies have show the significant pressure-relieving effect of FOS when compare with a standard shoe in this population (Bus et al., 2005). Due to the deviant sole construction of the FOS, in which the roll-over process over the forefoot does not take place, we believe that patient use a significantly different gait pattern when walking in these shoes. This may lead to compensating strategies that may result in complaints. Moreover, balance of walking, which is already affected because of the sensory neuropathy, may be further affected through these shoes which may increase the chance of falling incidents. Earlier research has shown that patients have a significantly reduced walking comfort in FOS. By measuring the lower-extremity dynamics of walking in diabetic neuropathic patients while walking in FOS we may be able to understand the mechanisms of forefoot pressure relief in these shoes. Moreover, it may be possible to assess changes in the gait pattern that may lead to complaints, falling incidents or reduced walking comfort.

#### **Study objective**

The goal of this study is to compare the kinematics and kinetics of walking in a FOS with a standard shoe in diabetic neuropathic patients.

#### Study design

The study has a cross-sectional design. Using three-dimensional movement analysis and in-shoe pressure measurement, the gait while wearing FOS and a standard shoe will be compared. Using reflective markers on the lower extremity, the movements of the segments of the lower extremity will be registered by eight camera\*s. Ground reaction forces will be measured using force plates that are set flush in the floor. In-shoe pressure measurements will be doe using flexible insoles that are placed between the foot and the insole and with which the pressure distribution is assessed.

Patients walk over a 12-meter walkway in two conditions per shoe: a self-selected walking speed and a constant walking speed. Per condition, 5 successful trials will be collected. Walking comfort in both shoe conditions will be assessed using a visual-analogue scale.

#### Study burden and risks

Patients will be asked to walk multiple times (minimal 15) across the gait lab while wearing a FOS and a standard shoe. The intensity of walking will not be different to the normal daily walking intensity. Moreover, patients will be given sufficient time to rest between conditions. The measurements (including subject preparation, questionnaire assessment and the actual walking) will take in total approximately 90 minutes.

The risk associated with participation in the study is neglectable. Patients at risk for which wearing a FOS is a contra-indication will be carefully excluded. Additionally, the FOS is already used widely in normal clinical diabetic foot practice for treatment of plantar ulcers.

# 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**

- a. Diabetes Mellitus and periferal neuropathy
- b. Age: 40-70 years old
- c. High risk of plantar ulceration in the forefoot

# **Exclusion criteria**

- a. Active ulcer
- b. Lower extremity Amputation
- c. Equinus deformity
- d. Charcot deformity
- e. Patient who can't walk unaided

# Study design

# Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	10
Туре:	Anticipated

### Medical products/devices used

Generic name:	Forefoot offloading shoe
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO	
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.

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# In other registers

# Register

ССМО

ID NL13084.018.06