Voetdruk bij het gebruik van een aanpasbare buitenzool en zelfaanpassende inlegzool

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21180

Source
Nationaal Trial Register

Brief title
Combination: adjustable rocker and self-adjusting insole

Health condition

Diabetes with neuropathy
Peak plantar pressures

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: NWO, symbionics programme, number 13528

Intervention

Outcome measures

Primary outcome

Peak Pressure

Secondary outcome

Max Mean Pressure

Force Time Integral

Spatio-temporal parameters

Comfort

Study description

Background summary

Rationale: A common complication with Diabetes Mellitus is diabetes related neuropathy[1]. As a result, patients who developed neuropathy get lower to no protective sensory feedback from their feet[1,2]. Combined with increased plantar pressures, this puts them at high risk of developing diabetic foot ulcers (DFU) that may eventually lead to amputation of the affected foot[3,4]. The metatarsal heads (MTH), and the first toe are considered high risk areas for DFU development as increased pressures mostly occur at these locations[5].

Owings et al 2009 proposed to aim for peak pressures (PP) lower than 200 kPa measured with Pedar-X sensors (Novel GMBH, Munich, Germany) to prevent DFU[6]. Custom made rocker profiles and insoles are commonly used to reduce pressures at the high risk areas[7,8]. However, the shape of the rocker profile and insoles are made through trial and error and experience of the prescriber/orthopaedic shoe technician. As a result, most prescribed rockers and insoles do not optimally offload the areas at risk for each individual. Apart from the way these products are designed/made there is another problem. Due to changes in foot structures the areas at risk may change over time, which would require new rocker profiles and insoles.

To overcome these problems two new products were designed and made at the UMCG; 1) an adjustable rocker profile, and 2) a self-adapting insole. The adjustable rocker profile allows for repeated changes in the rocker profile which can be made manually within seconds. The self-adjusting insole consists of hexagonal shaped elements that collapse when pressures are above a certain threshold. In other words, whenever the pressure is too high, the insole will drop down at that specific area, which results in offloading. The self-adapting insole is made entirely out of these hexagonal shapes, ensuring offloading even when the location of the high pressures change over time.

Both products have been tested in adult healthy volunteers and showed promising results. With different shape settings of the adjustable rocker profile it was possible to offload different areas of the foot. The (clinically) most important results were found in the medial (MTH1) and central (MTH2-4) forefoot, where pressures for all settings resulted in PP below the proposed 200 kPa, while the reference shoe was over 200 kPa (medial forefoot 208 kPa, central forefoot 230 kPa). In a pilot with the self-adapting insole PP reductions up to 53 kPa where found.

Even though the results look promising in healthy volunteers, it is not possible to directly transfer these results to patients with diabetes that have developed neuropathy, and thus are at high risk of developing DFU.

Objective: Therefore, we want to examine the effects of both the adjustable rocker profile and the self-adjusting insole on in-shoe pressure in this patient group. We expect to find similar reductions in pressure as previously found in healthy subjects. Also, the combination of both products will be tested to evaluate if this will result in even larger reduction of pressures, as it has been shown that the effect of rockers and custom insoles can be added[9].

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[3] N. Singh, D.G. Armstrong, B.A. Lipsky, Preventing foot ulcers in patients with diabetes, J. Am. Med. Assoc. 293 (2005) 94–96.

[4] S.D. Ramsey, K. Newton, D. Blough, D.K. McCulloch, N. Sandhu, G.E. Reiber, E.H. Wagner, Incidence, outcomes, and cost of foot ulcers in patients with diabetes, Diabetes Care. 22 (1999) 382–387. doi:10.2337/diacare.22.3.382.

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Lancet. 366 (2005) 1725–1735. doi:10.1016/S0140-6736(05)67699-4.

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Study objective

We want to examine the effects of both the adjustable rocker profile and the self-adjusting insole on in-shoe pressure in this patient group. We expect to find similar reductions in pressure as previously found in healthy subjects. Also, the combination of both products will be tested to evaluate if this will result in even larger reduction of pressures, as it has been shown that the effect of rockers and custom insoles can be added[9].

Study design

all interventions will be measured during a 1 hour session.

Intervention

- Walking with reference shoe

- Walking with self-adjusting insole

- Walking with adjustable rocker

- Walking with combination of self-adjustable insole and adjustable rocker

Contacts

Public
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Groningen
The Netherlands
Scientific
R Reints
Groningen
The Netherlands

Eligibility criteria

Inclusion criteria

- Aged ≥ 18 years

- Diabetes mellitus (type I or II)

- Neuropathy

- Ambulatory

- Shoe size between 36 and 45

Exclusion criteria

- Current ulcer

- Recently healed ulcer (< 2 months)

- Use of walking aids (with exception of inlays)

- Foot deformations

- Charcot foot

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-06-2018
Application type:	First submission

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
NTR-new	NL7057
NTR-old	NTR7262
Other	NL65662.042.18 / METC 2018/240 : ABR

Study results