Individually optimized rocker profile and self-adapting insole to reduce the plantar peak
pressure in Diabetic patients with loss of protective sensation

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25577

Bron
NTR

Verkorte titel
TBA

Aandoening

Diabetes Mellitus with loss of protective sensation

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: EIT Health

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In-shoe plantar pressures, measured with a pressure insole (Pedar-X):
1. Peak Pressures (PP)
2. Pressure Time Integral (PTI)

Balance with and without perturbations, measured with clinical tests and a force plate treadmill:
1. Time taken to stand up-walk- and sit (TUG)
2. Root Mean Square (RMS) of net anterior-posterior (AP) & medio-lateral (ML) Center of Pressure (COP) direction during eyes open and closed condition (static balance)
3. Margins of stability (MOS) during normal gait, AP & ML perturbations (dynamic balance)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: A common complication with Diabetes Mellitus is diabetes related neuropathy [1]. As a result, patients who developed neuropathy loose the 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]. In addition to ulceration, balance problems are also present due to the reduced plantar sensation.

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/orthopedic 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, adapted, rocker profiles and insoles.

In order to overcome these problems, two products will be used in this study. These are a self-adjusting insole and a 3D printed midsole of which the rocker shape is based on an algorithm that is intended to optimally offload peak plantar pressures. 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-element will drop down at that specific location, which results in immediate 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. This two way innovative solution needs further research in order to evaluate its efficacy. Therefore, the aim of this study is to investigate the efficacy of the self-adjusting insoles and the individually optimized rocker profiles to optimally offload peak plantar pressures.

Objective: Offloading the peak plantar pressure in Diabetic patients with loss of protective sensation by using the self-adjusting insoles and individually optimized rocker profiles. The secondary objective is to evaluate the effect of the self-adjusting insoles and individually optimized rocker profiles on balance.

Literature
[1]. Boulton AJM, Kirsner RS, Vileikyte L. Neuropathic Diabetic Foot Ulcers. N Engl J Med. 2004;351(1):48-55.
[2]. Bus SA, van Deursen RWM, Kanade R V., et al. Plantar pressure relief in the diabetic foot using forefoot offloading shoes. Gait Posture. 2009;29(4):618-622.
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[5]. Weijers RE, Walenkamp GHIM, Van Mameren H, Kessels AGH. The relationship of the position of the metatarsal heads and peak plantar pressure. Foot Ankle Int. 2003;24(4):349-353.
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Doel van het onderzoek

The objective of this study is offloading the peak plantar pressure in Diabetic patients with loss of protective sensation by using the self-adjusting insoles and individually optimized rocker profiles. The secondary objective is to evaluate the effect of the self-adjusting insoles and individually optimized rocker profiles on balance.

Onderzoeksopzet

Pre-test where the plantar pressure, balance, kinetics and kinematics will be measured with a reference shoe. After ± 2 weeks (post-test) the participants will wear rocker shoes, self-adjusting insoles in combination with reference shoes, and self-adjusting insoles in combination with rocker shoes. During these conditions the effect of the different conditions on the plantar pressure, balance, kinetics and kinematics will be measured. After the post-test, the participants will wear the rocker shoes (when plantar pressure during the second visit is lower than the first visit) for a period of 4 weeks. During that period the VAS comfort

and wearing time will be determined. At the end of the 4 week period, the plantar pressure will be measured for a last time.
For the participants who did not show a lower plantar pressure during the post-test compared to the pre-test, will not have a 4 week follow-up period and a third plantar pressure measurement.

Onderzoeksproduct en/of interventie

Each participant will walk on a treadmill during four conditions:
1) Unadapted reference shoe (Dr.Comfort, Mequon, WI, USA) + standard insole (visit 1)
2) Unadapted reference shoe + self-adjusting insole (visit 2)
3) Rocker shoe + standard insole (visit 2)
4) Rocker shoe + self-adjusting insole (visit 2)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

For the patients with Diabetes Mellitus:
- Adult
- Diabetes mellitus (type I or II)
- Loss of protective sensation (10 gr filament & 128Hz tunning fork)
- Ambulatory without use of walking aids (with the exception of the use of orthopaedic

footwear)
- Shoe size between 36 and 46

For the healthy reference group:
- Ambulatory without use of walking aids
- Age between 40-70 year
- Shoe size between 36-46

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

For the patients with Diabetes Mellitus:
- Current ulcer(s) and ulcer(s) in the past
- Use of walking aids (with the exception of the use of orthopaedic footwear)
- Extreme foot deformations (e.g. Charcot foot) or toe or foot amputations that do not allow participants to fit semi-ready-to-wear shoes
- Body weight >130kg

For the healthy reference group:
- Use of walking aids
- Foot complications (injuries that can influence gait) that do not allow participants to fit ready-to-wear shoes
- Body weight >130kg
- Any self-reported injury or disease that affects walking ability

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2021

Aantal proefpersonen:	35
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	02-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9384
Ander register	METC Groningen : METc 2020.683

Resultaten

Samenvatting resultaten
N/A