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Effects of individually optimized rocker midsoles and self-adjusting insoles on dynamic stability in persons with diabetes mellitus and neuropathy

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ABSTRACT

Background: Persons with diabetic peripheral neuropathy (DPN) may face challenges such as balance issues due to reduced somatosensory feedback and an increased risk of developing diabetic foot ulcers (DFUs) due to increased plantar pressure. Pressure reducing footwear is thought to further impair balance. We introduced 3D-printed rocker midsoles and self-adjusting insoles that are able to reduce elevated plantar pressure values and aimed to prevent balance deterioration. However, their effect on the balance during walking (dynamic stability) is not analyzed yet.

Research question: Is dynamic stability of persons with DPN impaired compared to healthy individuals and what is the effect of the 3D-printed rocker midsoles and self-adjusting insoles on the dynamic stability in this population?

Methods: Dynamic stability, specifically the margins of stability (MOS) in the anterior-posterior (AP) and medio-lateral (ML) direction, was measured in ten healthy and nineteen persons with DPN. Independent-samples t-test was applied to analyze the difference in the MOS between groups. One-way repeated measures analyses of variance (ANOVA) was conducted to test the difference between the therapeutic footwear combinations within the DPN group.

Results: There is no significant difference between the healthy and DPN group in MOS-AP. MOS-ML is significantly larger in DPN compared to the healthy participants. Using the self-adjusting insole shows a significantly lower (negative) MOS-AP compared to when using a rocker shoe within the DPN group.

Significance: This study provides valuable information on whether DPN and our therapeutic footwear have a negative effect on the dynamic stability. DPN does not have a negative effect on dynamic stability in the AP direction. For the ML direction, DPN seems to cause larger MOS-ML by likely using a compensation strategy (e.g., wider steps) while our experimental footwear does not further impair the MOS-ML.

1. Introduction

Persons with diabetic peripheral neuropathy (DPN) have an increased risk to develop diabetic foot ulcers (DFUs) [1–3]. To prevent DFUs, pressure has to be reduced under the critical value of 200 kPa [4]. For this purpose we introduced individualized 3D-printed rocker midsoles and self-adjusting insoles to reduce the peak pressure (PP) in regions with high values ($\geq$ 200 kPa) and proved their effectiveness [5].

Persons with DPN are also susceptible to balance issues due to the reduced somatosensory feedback [6]. Moreover, (custom-made) rocker shoes and insoles may have additional adverse effects on the balance [7]. To avoid that therapeutic footwear deteriorates balance even further, we developed the individualized 3D-printed rocker midsoles and self-adjusting insoles (see Fig. 1 for their design) in such a way that the base of support was maximized for the shoes while a solid base of support was provided by avoiding highly resilient materials (that are known to negatively impact the balance) for the insoles [8].

Since persons with DPN are susceptible to balance deterioration (during walking), we will first analyze whether there is a difference in the dynamic stability, specifically the margins of stability (MOS) in the anterior-posterior (AP) and medio-lateral (ML) direction, compared to healthy persons . As mentioned earlier, we have shown the effectiveness in reduction of PP of individualized 3D-printed rocker midsoles and self-adjusting insoles in DPN [5]. In this study we will investigate their effect

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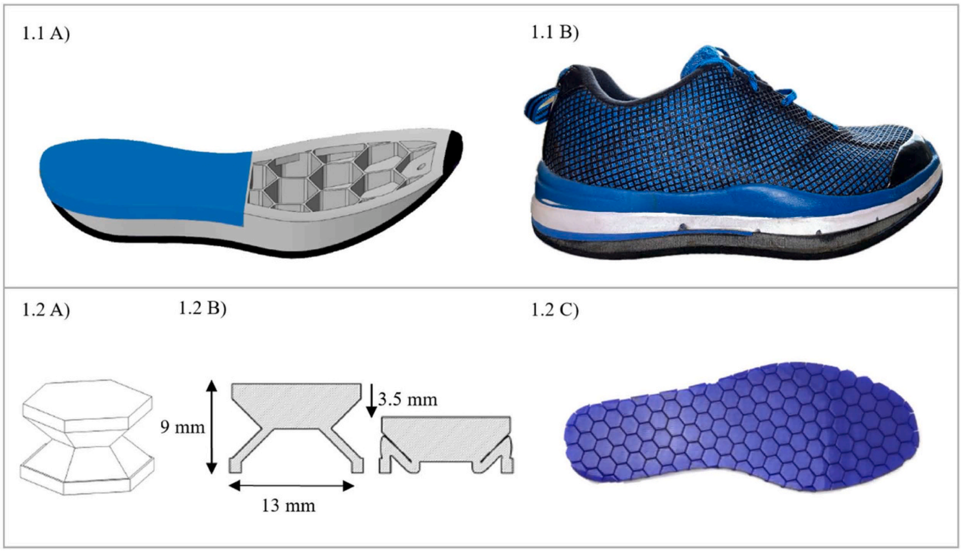

Fig. 1. Schematic design of the 3D-printed rigid midsole (1.1A) of the rocker shoe (1.1B) and the hexagonal shaped elements (1.2A & B) of the 3D-printed (FDM) self-adjusting insole (1.2C). The 3D-printed midsole of the rocker shoe has three layers: a 3, 5, 10 mm Multiform foam layer (Shore 30A) depicted as blue in figure 1.1A & B, a 3D-printed layer that is made of Polyamide 12 (Shore 80D, grey layer) and a final 8 mm outsole layer that consists of rubber material (Shore 40A, black layer). The height of the hexagonal elements (1.2A & B) of the self-adjusting insole (1.2C) is 9 mm, the width is 13 mm and they drop about 3.5 mm when a pressure of about 190 kPa is exceeded. Figure is adapted from [5].

on the dynamic stability.

2. Methods

2.1. Participants

A total of ten healthy adults and nineteen ambulatory persons (≥ 18 years) with DPN (shoe size 36 EU-46 EU) participated in this study. DPN was assessed with the Semmes-Weinstein 10 g monofilament, while vibration perception was measured with a 128 Hz tuning fork. For all participants individual information such as age, sex, body weight, body height, leg length, type of walking aid, balance problems and preferred walking speed was also reported. For the patients, the diabetes type and duration, dermal problems and foot deformities were also assessed. Excluded were patients who had current or prior ulcer(s) and all participants with severe foot deformities (incompatible with ready-to-wear shoes), who use walking aids, with a body weight exceeding 130 kg and self-reported injuries or pathologies (excluding DPN) that affect the gait. The Medical Ethics Review Board of the University Medical Center Groningen granted approval for the study (METc 2020/683). Prior to starting the experiments, participants provided written informed consent. This study was part of a larger study focusing on targeted offloading of PP ≥ 200 kPa [5].

2.2. Experimental procedure

Participants visited the Gait Realtime Analysis Interactive Lab (Motekforce Link, Amsterdam), University Medical Center Groningen, Center for Rehabilitation, location Beatrixoord, Haren, the Netherlands. First, they walked on an instrumented treadmill where their preferred walking speed was determined. The healthy individuals had one unperturbed walking condition, with a control shoe (Jason and Katy, Dr Comfort, Mequon, WI, USA) and insole (standard 6 mm Ethylene Vinyl Acetate insoles, Shore 25A). The patients had the following four different unperturbed walking conditions with different combinations of shoes and insoles:

- Control shoe & control insole (Control).
- Control shoe & self-adjusting insole (SAI).
- Individualized rocker shoe & control insole (Rocker).
- Individualized rocker shoe & self-adjusting insole (RockerSAI).

2.3. Data collection and analysis

Kinematic data of the markers attached to the pelvis (right and left anterior and posterior superior iliac spine) and heel was collected with the Vicon system (Vicon Bonita 10, Oxford, UK; $Fs = 100$ Hz). Marker data was filtered (2th order Butterworth, 6 Hz) and processed in the Gait Offline Analysis Tool (GOAT).

To assess dynamic stability, MOS was determined following the method introduced by Hof et al. [9]. The MOS is defined as the distance between the extrapolated center of mass (xCOM) and the boundaries of the individual's base of support (BOS), following this equation:

$$MOS = BOS - xCOM$$

The MOS is both calculated in AP (MOS-AP) and ML (MOS-ML) direction, in which both were calculated with respect to the BOS (defined by the heel marker) of the leading foot at heel strike. Heel strike is a key event during the gait cycle [10] and corresponds (approximately) to the point of minimum MOS (most unstable point), as shown by Hof et al. [9, 11]. Heel contact also determines foot placement during the stance phase, which is the primary mechanism in the control of gait stability (which is our focus) [10,12]. Using the heel marker as the boundary of the BOS at heel strike, provides a more accurate estimation of the true MOS compared to other markers [13]. Therefore, considering these factors, we opted for the heel strike (as many other studies [10,14–16]) as the timing for calculating the MOS while using the heel marker as the boundary of the BOS in both the AP and ML direction (as other recent studies [10,16]). The xCOM takes both the center of mass (COM) and the velocity into account. The position of the pelvis markers were used for the COM calculation and the xCOM was calculated according to the following equation:

$$xCOM = COM + \frac{vCOM}{\sqrt{\left(\frac{g}{l}\right)}}$$

where the vCOM is the velocity of the COM, $g = 9.8$ m/s^2 is the gravitational constant and l is the pendulum length, which is the distance from the left and right anterior superior iliac spine marker to the floor. The participants walked on a treadmill until around 100 steps were reached. The belt speed was accounted for during the calculation of the MOS-AP. The average across the total number of steps per condition for the MOS-AP and MOS-ML was calculated for each participant in Matlab (R2017b).

2.4. Statistical analysis

An independent-samples t-test was applied to analyze the difference in the MOS between the healthy and DPN group for the control condition. The level of significance for the independent-samples t-test is set at $p < 0.05$. An one-way repeated measures analyses of variance (ANOVA) was conducted with the shoe condition as within-subjects variable and the MOS as dependent variable for the DPN group. For pairwise comparison, a Bonferroni correction was applied, resulting in a level of significance set as $p < 0.008$. All statistical analyses were performed using SPSS statistics (26.0).

3. Results

The means and standard deviations to describe the study population are presented in Table 1. MOS-AP and MOS-ML of the ten healthy and nineteen participants with DPN for the four conditions, are presented in Table 2 and Fig. 2.

No significant differences between the healthy and DPN group in MOS-AP ($p = 0.238$) are found. Within the DPN group, a significantly lower (negative) MOS-AP is seen in the SAI condition compared to the Rocker condition ($p = 0.002$).

A significantly lower MOS-ML is seen in the healthy compared to the DPN group ($p = 0.004$). The repeated measures ANOVA shows no significant differences between the conditions for the MOS-ML in the DPN group.

Table 1
Characteristics of the participants.

	Healthy n = 10	DPN n = 19
Age (years ± SD)	59.8 ± 6.0	67.8 ± 7.2
Sex (male/female)	2/8	14/5
Diabetes type (1/2/both)	NA	6/12/1
Diabetes duration (years ± SD)	NA	17.6 ± 14.5
Body height (m ± SD)	1.66 ± 0.08	1.77 ± 0.10
Body weight (kg ± SD)	71.6 ± 10.1	91.1 ± 16.3
Walking speed (m/s ± SD)	1.06 ± 0.29	1.10 ± 0.19
Balance problems* (yes/no)	0/10	3/16
Type of walking aid none/insole/adaptation ready-to-wear shoe	10/0/0	8/11[a]/1[a]
	NoF = 20	NoF= 38
Dermal problem callus/corn/blister/discoloration	NA	5/2/0/0
Foot deformity hallux rigidus[b]/flat foot/pes cavus/hallux valgus	NA	11/10/4/5

DPN: Diabetic peripheral neuropathy. NA: Not applicable. NoF: Number of feet.

[*] Balance problems determined by Romberg test (and Timed Up & Go test)

[a] One participant used insoles and adaption to ready-to-wear shoes.

[b] hallux limitus

Table 2
Margins of stability in anterior-posterior (MOS-AP) and medio-lateral (MOS-ML) direction for the healthy (n = 10) and the DPN (n = 19) group.

	Healthy group (*Healthy*)	DPN group (Control)	DPN group (SAI)	DPN group (Rocker)	DPN group (RockerSAI)	*Healthy* vs. Control	Control vs. SAI	Control vs. Rocker	Control vs. RockerSAI	SAI vs. Rocker	SAI vs. RockerSAI	Rocker vs. RockerSAI
MOS_AP (m ± SD)	-0.100 ± 0.066	-0.127 ± 0.049	-0.114 ± 0.041	-0.124 ± 0.038	-0.119 ± 0.043	t(27) = 1.21 P = 0.238	F(1.99,35.8) = 4.25 P = 0.019	F(1.99,35.8) = 4.25 P = 0.694	F(1.99,35.8) = 4.25 P=0.076	F(1.99,35.8) = 4.25 **P = 0.002**	F(1.99,35.8) = 4.25 P = 0.081	F(1.99,35.8) = 4.25 P = 0.088
MOS_ML (m ± SD)	0.048 ± 0.016	0.072 ± 0.021	0.070 ± 0.015	0.067 ±0.014	0.070 ± 0.014	t(27) = − 3.16 **P = 0.004**	F(1.54,27.8) = 1.14 P = 0.552	F(1.54,27.8) = 1.14 P = 0.197	F(1.54,27.8) = 1.14 P = 0.660	F(1.54,27.8) = 1.14 P = 0.095	F(1.54,27.8) = 1.14 P = 0.916	F(1.54,27.8) = 1.14 P = 0.017

Significant difference between healthy and DPN group ($p < 0.05$). Significant difference between the conditions in DPN group ($p < 0.008$). The P-values in bold represent a significant difference.

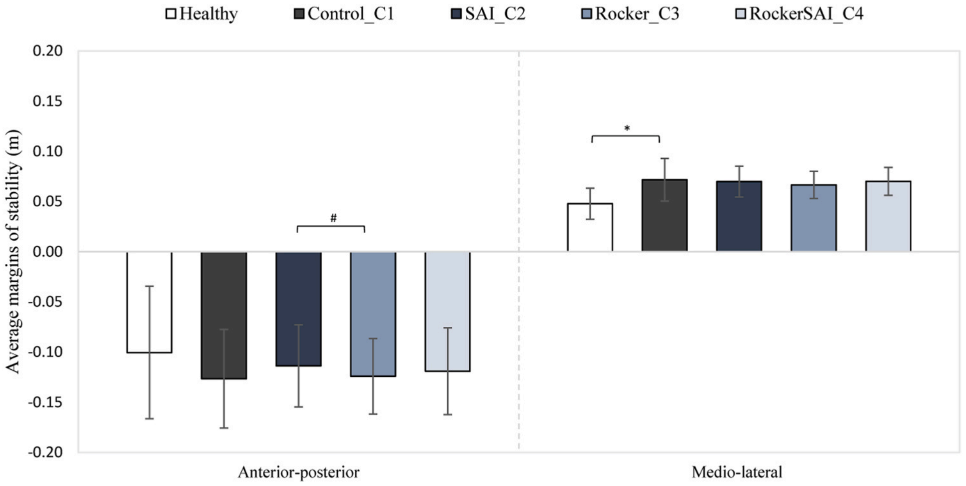

Fig. 2. Margins of stability in anterior-posterior (MOS-AP) and medio-lateral (MOS-ML) direction for the healthy ($n = 10$) and DPN ($n = 19$) group. The healthy group (represented as healthy using a control shoe and insole) and the DPN group with the control condition (represented as Control_C1 using control shoe and insole) and the experimental conditions with the abbreviations SAI_C2, Rocker_C3 and RockerSAI_C4: control shoe and self-adjusting insole, rocker shoe and control insole, rocker shoe and self-adjusting insole. The error bars represent the standard deviation. *: Significant difference between healthy and DPN group ($p < 0.05$). #: Significant difference between the conditions in DPN group ($p < 0.008$).

4. Discussion

While no significant differences in dynamic stability in the AP direction were observed between the DPN and the healthy group, a trend is seen where MOS-AP is more negative in the DPN compared to the healthy group. Variability in the MOS-AP in the healthy group, possibly due to the sample size, may have resulted in the lack of significant differences with the DPN group. Another factor to consider is that both groups possibly walked more cautiously (at slower speeds) on the treadmill compared to overground [17], likely bringing the xCOM closer to the BOS in the AP direction, resulting in a smaller negative MOS-AP [10,13]. Consequently, the difference in MOS-AP between both groups might not have been large enough to yield a significant difference. Significant results and trends show that individualized rocker shoes do not negatively affect MOS-AP and that self-adjusting insoles improve MOS-AP relative to standard insoles. This finding is promising since no other types of insoles in literature have shown a similar substantial beneficial effect on the gait stability [18,19]. Conversely, dynamic stability in the ML direction seems to be affected by DPN. The effect of DPN on MOS-ML might stem from the DPN group needing a larger step width (causing larger MOS-ML) on the treadmill to compensate for the different proprioceptive input compared to overground walking [10]. Given the reduced somatosensory feedback in persons with DPN [6], the change in proprioceptive input during treadmill walking could have more adverse effects on them compared to the healthy group. This could account for the difference in the MOS-ML between both groups. While DPN seems to affect dynamic stability in ML direction, footwear seems not to influence the MOS-ML. Finally, the difference in age and sex in both groups might have an effect on the MOS, however conflicting results are found in literature [20,21].

CRediT authorship contribution statement

Athra Malki: Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **María Baltasar Badaya:** Writing – review & editing, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Rienk Dekker:** Writing – review & editing, Visualization, Supervision, Methodology, Formal analysis, Conceptualization. **Gijsbertus Jacobus Verkerke:** Writing – review & editing, Visualization, Supervision, Methodology, Formal analysis, Conceptualization. **Juha Markus Hijmans:** Writing – review & editing, Visualization, Supervision, Methodology, Funding acquisition, Formal analysis, Conceptualization.

Declaration of Competing Interest

The authors declare no conflict of interest.

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