**Title:** Gait stability of diabetic patients is altered with the rigid rocker shoes

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*Background:* Rigid-rocker shoes may induce gait instability in diabetics, however, is not clearly investigated. The present study investigates if rigid-rocker shoes influence diabetic gait stability.

*Methods:* Fourteen non-neuropathic and nine neuropathic diabetics, plus eleven healthy young-adults were recruited. Full-body kinematic data was captured during walking tasks. Experimental conditions included barefoot and three rocker-shoe designs according to the rocker angle, apex angle and apex position (R10: 10°, 80°, 60%; R15: 15°, 95°, 52%; R20: 20°, 95°, 60%). Sagittal and frontal stability margin, plus fear of fall were main outcome measures.

*Findings:* Sagittal stability margin was not affected by health, however, was increased with R10 and R15 in non-neuropathic diabetics and healthy individuals (R2=0.16). Variability of sagittal stability margin was not altered in neuropathic diabetics, but was increased with R15 and R20 in healthy participants, with R15 in non-neuropathic diabetics (R2=0.12). Frontal stability margin (R2=0.46) and its variability (R2=0.39) were significantly increased in neuropathic and non-neuropathic diabetics compared to healthy individuals. Frontal stability margin was significantly higher with R15 in neuropathic diabetics, with R20 in non-neuropathic and healthy participants. Sagittal and frontal stability margin were strongly correlated with fear of fall in neuropathic diabetics.

*Interpretations:* R15 and R20 might challenge gait stability of diabetics cause them restrict centre of mass motion thereby imposing a tighter control over walking. However, neuropathic diabetics generally walk very cautious due to their neuropathy and higher fear of fall. Frontal stability margin, highly affected by health and experimental condition, is a more sensitive indicator of gait stability.

*Key words:* Diabetes; Neuropathy; Rocker shoe; Balance; Walking

**1. Introduction**

Diabetes mellitus is one of the most prevalent metabolic disorders worldwide [1], causing serious complications such as foot ulceration [2]. Peripheral neuropathy, prevalent in more than half of diabetic population, aggravates these complications [3]. Diabetic peripheral neuropathy increases the risk of foot ulceration and causes two-thirds of all non-traumatic lower limb amputations [4]. Due to the heavy physical and economic burdens of diabetic complications, prevention is the treatment priority [5,6].

To prevent plantar ulceration, offloading the critical areas such as forefoot is essential [7]. Rigid toe-only rocker outsoles are commonly used as a footwear modification to offload the forefoot region, and are effective in reducing peak plantar pressures up to 50% [8]. Plantar pressure reduction by different designs of the toe-only rocker outsole in terms of rocker angle, apex angle and apex position has been reported in the previous literature [9]. A toe-only rocker outsole with a rocker angle of 20° with an apex angle of 95° positioned at 60% of the shoe length, and a rocker angle of 15° with an apex angle of 95° positioned at 52% of the shoe length has been demonstrated to optimally offload the diabetic foot [9,10].

The Rigid rocker shoe (RRS) is clinically efficient in diabetics, however, the compliance in wearing is remarkably low [11]. Despite the proved clinical benefits of RRSs in offloading [12], there are evidence of destabilising potentials [13,14]. Postural stability with RRSs has been investigated in terms of postural reactions to a perturbed stance [15–17], static stance stability [18], and gait stability [19,20] with few studies on people with diabetes [17–20]. Gait stability in diabetics wearing RRSs was measured in two studies using dynamic gait index, gait variability index, and left-to-right ankle power asymmetry [19,20]. Yet, no study has directly inspected gait stability of diabetics with RRSs. Quantifying the instantaneous interaction between body centre of mass (CoM) movement and dynamic base of support (BoS) during walking by adopting the margin of stability (MoS) method, has been proved to be a valid measure of gait stability [21].

Previous studies have shown that diabetics walk with shorter and wider steps, and slower speed compared to healthy individuals [22,23]. Additionally, control of balance is impaired in diabetics with or without neuropathy [22–24] which is associated to their inherent fear of fall [25]. RRSs might impose more challenges to gait stability of diabetics whose postural control is substantially impaired. As most falls occur during walking, investigating the effect of RRSs on stability in walking seems essential [26]. However, adaptive walking strategies of people with diabetes might be substantially enough to cover the potential destabilising effects of the RRSs. Therefore, measuring dynamic stability during walking while wearing RRSs and its difference to barefoot in diabetics, along with healthy individuals could be informative in understanding the mechanisms of controlling stability in this population.

The present study thus aimed to investigate gait stability of diabetics with and without neuropathy, and healthy individuals using MoS in four experimental conditions including barefoot and three designs of RRSs. More specifically, this study investigated if mean and variability of MoS in sagittal and frontal planes of movement are altered by the experimental conditions or groups, and whether fear of fall has any relationship with these stability measures. Mean and variability of step length and step width, gait speed and cadence were additionally measured to understand possible gait adaptations.

**2. Methods**

*2.1. Participants*

Ethical approval was obtained from ethical review committee of the local university. A convenient sample of fourteen (78% females) diabetic patients without neuropathy (Non-NDPs) and nine (44% females) diabetic patients with neuropathy (NDPs) were recruited. Eleven healthy young-adults (63% females) were further experimented to provide a basis for comparisons. All participants voluntarily signed the written informed consent. Participant characteristics are presented in ***Table 1***.

Inclusion criteria were medically diagnosed type I or II diabetes with a maximum value of 10 for HbA1c (indicator of the average level of blood sugar over the past 3 months), aged between 35 and 65 years, and 5-years history of the disease. Exclusion criteria were a body mass index (BMI) of higher than 35 Kg/m2, gross foot deformity, a history of foot ulceration/amputation, any musculoskeletal/neuromuscular disease, and back or lower limb surgery. Diabetic peripheral neuropathy was assessed by Michigan Neuropathy Screening Instrument (MNSI) [27], along with nerve conduction velocity (NCV) [28]. Fasting blood glucose of less than 100 mg/dl was confirmed in healthy participants. The intact peripheral sensation of healthy participants was confirmed using a 10 g monofilament on six locations of each foot, receiving at least five verbal positive responses [29].

*2.2. Footwear*

A set of converse-style canvas shoes of various sizes from 36 to 44 was used. Canvas shoes allow precisely placement of reflective markers over bony prominences of interest, have a straight last with a firmed counter and a smoothly rounded toe box providing a sufficient toe space, and a stiff rubber sole with a nearly flat configuration. A 3-mm soft-foam layer was additionally inserted in shoes.

Toe-only rocker outsoles were made of micro-cellular rubber with measured standard hardness of 53 based on the shore A durometer scale. Three designs of the rocker outsole [9,30] were considered for the present study: R10, a rocker angle of 10° located at 60% of the shoe length with the apex angle of 80°; R15, a rocker angle of 15° located at 52% of the shoe length with the apex angle of 95°; and, R20, a rocker angle of 20° located at 60% of the shoe length with the apex angle of 95°. A 1-mm stainless steel shank with 25 mm width and a length normalized to each shoe size was embedded between the rubber sole and the rocker outsole in R15 and R20, to assure rocker angle consistency during walking. Steel shank was not applied for R10, which was supposed to resemble a typical shoe outsole. All the experimental rocker outsoles were manufactured manually by a nationally certified orthotist (***Fig. 1***).

*2.3. Data collection*

Participants filled out Fall Efficacy Scale International (FES-I) questionnaire prior to kinematic data-collection, as a measure of fear of falling [31].

Forty-four reflective markers (the plugin gait model [32]) were used to record full-body kinematics by a motion capture system with six calibrated infrared cameras at sampling frequency of 100 Hz (Qualisys Track Manager, QTM, Gothenburg, Sweden). Barefoot walking trials were recorded initially followed by walking with the three experimental shoes in a random order. For familiarisation, participants walked in a hand-railed walkway for 5 minutes per shoes [33]. For all experimental conditions (barefoot, R10, R15, and R20), participants were instructed to walk with their comfortable self-selected speed over a 10-meter walkway with a constant pace while looking forward. Overall, 18-30 steps were recorded over six consecutive trials per condition and per participant.

*2.4. Outcome measures and data processing*

Gait stability was quantified by MoS method which is defined as the instantaneous interaction of the velocity-adjusted CoM, termed as the extrapolated CoM (XcoM), and the boundaries of BoS [21]. Both the MoS mean which indicates the status of the overall gait stability, and MoS variability which reveals step-to-step anticipatory changes during walking were calculated to quantify gait stability [34].

A whole body CoM was computed based on a 15-segment model in Visual 3D software (C-motion Inc., USA). Heel-strike and toe-off time points were determined through the kinematic method developed by Zeni et. al (2008) [34]. MoS was calculated as [21]:

 $XcoM=COM+\frac{CȮM}{ω\_{0}}$, $ω\_{0}=\sqrt{^{g}/\_{l}}$ (1)

 $MoS=BoS-XcoM$ (2)

where *CoM* and *CȮM* are the position and velocity of CoM in either sagittal or frontal planes, *g* = 9.81 m/s2 is the gravitational constant and *l* is the distance between CoM and the lateral heel marker at heel strike (≈leg length).

The sagittal border of BoS was defined by the anterior-posterior position of the toe marker while the frontal border of BoS was considered as the medio-lateral position of a lateral marker placed exactly on the most lateral aspects of the rocker apex for shod conditions, and on 5th metatarsal head for barefoot condition. Sagittal and frontal margin of stability (SMoS and FMoS) of each step were calculated instantaneously over the stance phase. The stance phase was determined as the time points between each heel strike and the subsequent toe off. MoS mean was calculated as the average of instantaneous MoS values over each step for all steps. Standard deviation of MoS of consecutive steps was also calculated to measure MoS variability. All steps were time-normalized to 101 data points (0-100%) to remove the effect of walking speed on mean and variability measures. Mean and variability of SMoS and FMoS were the primary outcome measures of the study. Step length (SL), step length variability (SLV), step width (SW), step width variability (SWV), as well as walking speed and cadence were also measured as the secondary outcome measures in order to understand possible gait adaptations at each group.

*2.5. Statistics*

A linear mixed model (LMM) was applied with *Experimental Condition* (barefoot, R10, R15, and R20) as the first predictor variable, and *Group* as *the* second predictor variable to compare the effect between NDPs, Non-NDPs and healthy individuals. This model was implemented for each outcome variable separately. The model predictors were centred on barefoot condition for *Experimental Condition*, and healthy individuals for *Group,* therefore the estimates were the differences of other conditions to referenced level. *Experimental Condition* was allowed to have interaction with *Group*in all models. The participants’ ID (identifier) included as the random factor (random intercept model) in the model to control the variability of response factor caused by subjective differences. In a more complex model, age and BMI were included separately as the potential covariates to determine any possible interaction. In case of no interaction effects, covariates were removed from the model in favor to reach a most parsimonious model (model with no interaction). The calculation of the effect size and power for LMM are the areas of active development and still there are uncertainties about it. In this study we pragmatically calculate and report r-squared and Cohen’s f2. Marginal r-squared, as the measure of model’s fit strength, represents the variability of outcome explained by the fixed parts of the model and is defined as: (*σ\_f²*) / (*σ\_f² + σ\_α²*), where *σ\_f²* is the variance of the fixed effect components, *σ\_α²* is the variance of the random effects [35]. The R package MuMIn (Multi-Model Inference) version 1.42.1 by Kamil Barton´ used to facilitate the r-squared calculation. Additionally, Cohen’s f2 calculated as a measure of local effect size for each independent variable and defied as $f^{2}= (R\_{x1x2}^{2}-R\_{x1}^{2})/(1-R\_{x1x2}^{2})$, where $R\_{x1x2}^{2}$ is the r-squared for the model including both group and test condition as independent variable and $R\_{x1}^{2}$is the r-squared for the model including only one of the independent variables [36]. However, the estimated fixed terms (*beta* *coefficients*) which are in the metric of the response variable with their 95% confidence interval also presented in graphs which are a helpful visualisation on the comparative size of the effect. Spearman correlation analysis was also applied to measure the relationship between main outcome measures and the FES-I score. For linear mixed model analyses, the lme function of NLME package in R statistical software version 3.4.4 was used [37].

**3. Results**

No interaction of age or BMI with any of the predictor variables observed for any of the outcome variables (p>0.05). Therefore, to have the most parsimony, age and BMI, as covariates, were removed from the model. Summary of the results is reflected in ***Fig. 2***. Further details are presented in ***Table 2***, ***Table 3*** and ***Table 4***.

*3.1. Primary outcome measures: mean and variability of MoS*

The experimental condition (RRSs) was significantly different for SMoS (p<0.0001), SMoS variability (p=0.0002) and FMoS (p<0.0001). SMoS was greater with R10 and R15 in healthy participants (p=0.03 and p=0.01, respectively) and Non-NDPs (p=0.001 and p=0.0001, respectively) compared to barefoot, while there was no difference between conditions for NDPs (p>0.05). SMoS variability was greater with R15 (p=0.01) and R20 (p=0.023) compared to barefoot in healthy participants. SMoS variability was also greater with R15 compared to barefoot in Non-NDPs, while there was no difference between conditions for NDPs (p>0.05). FMoS was greater with R20 (p=0.005) in healthy participants, with R10 (p=0.01) and R20 (p=0.01) in Non-NDPs, and with R15 (p=0.01) in NDPs compared to barefoot.

Main effect of group was significant for frontal plane i.e. FMoS and FMoS variability (p<0.0001). NDPs showed higher FMoS compared to both Non-NDPs (p=0.001) and healthy participants (p<0.0001), and Non-NDPs compared to healthy individuals (p=0.044) irrespective of the experimental condition. FMoS variability was higher in NDPs compared to Non-NDPs (p=0.007) and healthy participants (p<0.0001), as well as Non-NDPs compared to healthy individuals (p=0.04) irrespective of the experimental condition. The interaction of the experimental condition and group was not significant for any of the primary outcome measures (p>0.05).

In addition, both SMoS (r=0.67) and FMoS (r= 0.73) were strongly correlated with fear of fall in NDPs (p<0.0001). A significant but weaker correlation was found for FMoS and FES-I scores in Non-NDPs (r= 0.23, p<0.01). No significant correlation of FES-I scores and stability measures was found in healthy individuals (P=0.89).

*3.2. Secondary outcome measures: SL, SLV, SW, SWV, speed, and cadence*

The experimental condition (RRSs) showed no significant effect on any of the secondary outcome measures (p>0.05). Main effect of group was significant for SL (p=0.003), SWV (p=0.029), speed (p=0.014), and cadence (p=0.019). Healthy participants walked with longer steps compared to both Non-NDPs and NDPs in all experimental conditions. The significant difference of SWV among groups was mainly due to a higher variability with R20 in NDPs compared to healthy participants (p=0.047).

Healthy participants walked faster compared to Non-NDPs with R10 (p=0.041), and compared to both Non-NDPs and NDPs with R15 (p=0.033 and p=0.027, respectively) and R20 (p=0.01 and p=0.027, respectively). Group contrast analysis showed that healthy participants walked significantly faster than both Non-NDPs (p=0.02) and NDPs (p=0.042) irrespective of the experimental condition, while there was no difference between Non-NDPs and NDPs (p=0.99). Cadence was greater in healthy participants compared to Non-NDPs with R15 (p=0.011) and R20 (p=0.004). Finally, the interaction of experimental condition and group was not significant for any of the secondary outcome measures (p>0.05).

**4. Discussion**

Despite the clinical efficiency of RRSs in offloading the diabetic foot, it is not clear how gait stability of diabetics is affected by RRSs. We investigated gait stability of NDPs and Non-NDPs along with healthy individuals in barefoot and RRS conditions. To our knowledge, this is the first study investigating the effect of RRSs on gait stability of diabetics using MoS. Our results showed that SMoS of walking was affected by neither diabetes nor diabetic neuropathy. However, RRSs could affect SMoS in healthy individuals and Non-NDPs. In contrast, FMoS of walking not only was affected by RRSs in all three groups of participants, but also by diabetes and diabetic neuropathy. These findings may show the sensitivity of FMoS to recognise any changes to the footwear or health status of the individuals.

Our findings indicated all participants walked with the same magnitude of SMoS irrespective of the footwear. In other words, NDPs, Non-NDPs and healthy individuals were equally stable in the anterior-posterior direction while walking during all experimental conditions. Shorter steps and slower walking speed of NDPs and Non-NDPs compared to healthy individuals helped them exhibit the same magnitude of SMoS. Higher SMoS of healthy individuals and Non-NDPs, with R10 and R15 compared to barefoot indicated more walking stability. However, unchanged SMoS of NDPs revealed that they walked with a relatively constant degree of stability irrespective of the footwear (***Table 3***). This, in addition to the slower speed and shorter steps shows a conservative walking strategy of NDPs which is not the case in healthy individuals and Non-NDPs [38]. This finding is well reflected on scores of their fear of falling much higher than that of the healthy participants and Non-NDPs.

All participants showed a relatively equal (i.e. not statistically different) SMoS variability irrespective of the footwear, however, SMoS variability was higher in healthy individuals and Non-NDPs with R15 and R20 compared to barefoot (***Fig. 2***). This may indicate more adaptive/corrective interaction of their CoM movement and sagittal BoS, as an effort to preserve a certain degree of SMoS with R15 and R20. Due to the constant step length variability, such variability has been most likely occurred through adjusting CoM motion rather than changing sagittal limits of BoS. In contrast, NDPs walked with a constant SMoS variability in all conditions which might be related to their higher fear of fall and conservative walking strategy.

NDPs showed a higher FMoS compared to Non-NDPs and healthy individuals irrespective of the footwear. FMoS of Non-NDPs also was higher than healthy participants in all conditions. In other words, NDPs and Non-NDPs offered a higher degree of FMoS and lateral walking stability. Interestingly, step width was relatively equal between groups indicating relatively comparable boundaries of frontal BoS among them. Thus, such a higher FMoS has been most likely caused by extremely restricting frontal CoM movement during walking in NDPs and Non-NDPs [38]. Overall, FMoS with RRSs was higher than barefoot in all three groups. However, it was more significant with R20 in healthy individuals and Non-NDPs, with R15 in NDPs compared to barefoot.

Higher FMoS variability and also stability of NDPs compared to healthy individuals and Non-NDPs, and also Non-NDPs compared to healthy individuals during walking, may indicate an active exertion of NDPs and Non-NDPs to preserve a certain degree of frontal stability. R20 caused a higher FMoS variability in NDPs compared to healthy individuals that can be explained by the greater step width variability of NDPs in R20. However, step width variability was almost equal between groups for other conditions showing regular adjustments of frontal CoM motion as a possible cause of higher FMoS variability of diabetics.

There would be some explanations to the key rationale of the study which was to answer if adaptive walking strategies found in diabetics are substantially enough to cover potential destabilising effects of the RRSs. Finding a significantly higher FMoS, and FMoS variability in barefoot condition for NDPs compared to healthy participants, might indicate that diabetic patients with neuropathy were ‘coping with’ their inherent instability caused by the disease during barefoot walking. Since they walked with the same step width of healthy participants in all four experimental conditions, their higher FMoS was the result of constraining frontal CoM movement as an adaptation to the perceived instability.

At the same time, FMoS was also significantly higher in diabetics during walking with RRSs compared to barefoot. Therefore, patients probably perceived the destabilising effects of the rocker shoes and thus further constrained their frontal CoM movement in order ‘to overcome’ this destabilising effect as well.

Healthy participants walked faster than both NDPs and Non-NDPs irrespective of the footwear. This is in a good agreement with previous studies [22,23]. Particularly, healthy participants walked faster with R15 and R20 compared to diabetics that can be explained by diabetic conservative walking strategy. Walking speed of NDPs and Non-NDPs was almost equal in all conditions and not affected by mild to moderate neuropathy. However, cadence was lower in Non-NDPs compared to healthy individuals with R15 and R20 that was mainly due to their much slower speed. NDPs walked with the same cadence of healthy participants most likely due to their slower speed and shorter steps, though the latter was not statistically significant.

*4.1. Study Limitations*

Participant groups were not balanced that can be a limitation to the study. However, our statistics showed that results were not significantly affected by the age or BMI. None of the participants were prior users of RRSs and study results might be influenced by the novelty of the shoes. Therefore, further studies are needed to investigate the long-term effects of RRSs on diabetic gait stability.

**5. Conclusions**

Our findings suggest that R15 and R20 might increase destabilising potentials to the gait of diabetic patients by restricting CoM motion and imposing a tighter control over walking. Nevertheless, none of participants experienced instability with RRSs in the present study. Such destabilising potentials are less obvious in NDPs rather than Non-NDPs, as their neuropathy and higher fear of fall force them walk very cautious irrespective of the footwear. Our study also showed that FMoS is a more sensitive indictor of gait stability in this population. This, in turn, is the result of active dynamics of walking in frontal plane where the central nervous system control has more contribution.

**Conflict of interest**

 The authors declare that they have no competing interest.

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**References**

[1] L. Guariguata, D.R. Whiting, I. Hambleton, J. Beagley, U. Linnenkamp, J.E. Shaw, Global estimates of diabetes prevalence for 2013 and projections for 2035, Diabetes Res. Clin. Pract. 103 (2014) 137–149. doi:10.1016/j.diabres.2013.11.002.

[2] K.G.M.M. Alberti, P.Z. Zimmet, Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus. Provisional report of a WHO Consultation, Diabet. Med. 15 (1998) 539–553. doi:10.1002/(SICI)1096-9136(199807)15:7<539::AID-DIA668>3.0.CO;2-S.

[3] K. Papatheodorou, M. Banach, M. Edmonds, N. Papanas, D. Papazoglou, Complications of Diabetes., J. Diabetes Res. 2015 (2015) 189525. doi:10.1155/2015/189525.

[4] A.J. Boulton, L. Vileikyte, G. Ragnarson-Tennvall, J. Apelqvist, The global burden of diabetic foot disease, Lancet. 366 (2005) 1719–1724. doi:10.1016/S0140-6736(05)67698-2.

[5] L. Prompers, M. Huijberts, N. Schaper, J. Apelqvist, K. Bakker, M. Edmonds, P. Holstein, E. Jude, A. Jirkovska, D. Mauricio, A. Piaggesi, H. Reike, M. Spraul, K. Van Acker, S. Van Baal, F. Van Merode, L. Uccioli, V. Urbancic, G.R. Tennvall, Resource utilisation and costs associated with the treatment of diabetic foot ulcers. Prospective data from the Eurodiale Study, Diabetologia. 51 (2008) 1826–1834. doi:10.1007/s00125-008-1089-6.

[6] S.A. Bus, J.J. van Netten, A shift in priority in diabetic foot care and research: 75% of foot ulcers are preventable, Diabetes. Metab. Res. Rev. (2016). doi:10.1002/dmrr.2738.

[7] S.A. Bus, R.W. van Deursen, D.G. Armstrong, J.E.A. Lewis, C.F. Caravaggi, P.R. Cavanagh, Footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes: A systematic review, Diabetes. Metab. Res. Rev. (2016). doi:10.1002/dmrr.2702.

[8] D. Brown, J.J. Wertsch, G.F. Harris, J. Klein, D. Janisse, Effect of rocker soles on plantar pressures, Arch. Phys. Med. Rehabil. 85 (2004) 81–86. doi:10.1016/S0003-9993(03)00374-5.

[9] J.D. Chapman, S. Preece, B. Braunstein, A. Höhne, C.J. Nester, P. Brueggemann, S. Hutchins, Effect of rocker shoe design features on forefoot plantar pressures in people with and without diabetes., Clin. Biomech. 28 (2013) 679–85. doi:10.1016/j.clinbiomech.2013.05.005.

[10] J.D. Chapman, S.J. Preece, C.J. Nester, B. Braunstein, A. Höhne, G.-P. Brüggermann, Evaluating the effect of apex position and rocker in curved rocker shoes, J. Foot Ankle Res. 7 (2014) A66. doi:10.1186/1757-1146-7-S1-A66.

[11] R. Waaijman, R. Keukenkamp, M. De Haart, W.P. Polomski, F. Nollet, S.A. Bus, Adherence to wearing prescription custom-made footwear in patients with diabetes at high risk for plantar foot ulceration, Diabetes Care. (2013). doi:10.2337/dc12-1330.

[12] S. Hutchins, P. Bowker, N. Geary, J. Richards, The biomechanics and clinical efficacy of footwear adapted with rocker profiles--evidence in the literature., Foot (Edinb). 19 (2009) 165–70. doi:10.1016/j.foot.2009.01.001.

[13] R. van Deursen, Footwear for the neuropathic patient: offloading and stability, Diabetes. Metab. Res. Rev. 24 (2008) S96–S100. doi:10.1002/dmrr.827.

[14] R. Ahmed, Effect of offloading footwear on postural stability and walking in healthy and diabetics with peripheral neuropathy, in: 142nd APHA Annu. Meet. Expo. (November 15 - Novemb. 19, 2014), APHA, 2014.

[15] B.C. Albright, W.M. Woodhull-Smith, Rocker bottom soles alter the postural response to backward translation during stance., Gait Posture. 30 (2009) 45–9. doi:10.1016/j.gaitpost.2009.02.012.

[16] D.R. Kimel-Scott, E.N. Gulledge, R.E. Bolena, B.C. Albright, Kinematic analysis of postural reactions to a posterior translation in rocker bottom shoes in younger and older adults., Gait Posture. 39 (2014) 86–90. doi:10.1016/j.gaitpost.2013.06.002.

[17] B. Ghomian, M. Kamyab, H. Jafari, M. Khamseh, A. Healy, Rocker outsole shoe is not a threat to postural stability in patients with diabetic neuropathy, Prosthet. Orthot. Int. 40 (2016). doi:10.1177/0309364614543549.

[18] M. Lumeau, M. Lempereur, O. Remy-Neris, Assessment of the rocker sole shoes on postural stability in diabetic patients with distal sensory neuropathy., Comput. Methods Biomech. Biomed. Engin. (2015). doi:10.1080/10255842.2015.1070588.

[19] M. Lumeau, M. Lempereur, E. Sonnet, O. Remy Neris, Assessment of the rocker sole shoes on postural stability in patients with type 2 diabetes and distal sensorimotor polyneuropathy, Ann. Phys. Rehabil. Med. 59 (2016) e123–e124. doi:10.1016/J.REHAB.2016.07.278.

[20] S.A. Bus, J.C. Maas, N.M. Otterman, Lower-extremity dynamics of walking in neuropathic diabetic patients who wear a forefoot-offloading shoe, Clin. Biomech. 50 (2017) 21–26. doi:10.1016/J.CLINBIOMECH.2017.10.003.

[21] A.L. Hof, The “extrapolated center of mass” concept suggests a simple control of balance in walking., Hum. Mov. Sci. 27 (2008) 112–25. doi:10.1016/j.humov.2007.08.003.

[22] A. Mustapa, M. Justine, N. Mohd Mustafah, N. Jamil, H. Manaf, Postural Control and Gait Performance in the Diabetic Peripheral Neuropathy: A Systematic Review, Biomed Res. Int. 2016 (2016) 1–14. doi:10.1155/2016/9305025.

[23] U. Alam, D.R. Riley, R.S. Jugdey, S. Azmi, S. Rajbhandari, K. D’Août, R.A. Malik, Diabetic Neuropathy and Gait: A Review, Diabetes Ther. (2017) 1–12. doi:10.1007/s13300-017-0295-y.

[24] P. Hewston, N. Deshpande, Falls and Balance Impairments in Older Adults with Type 2 Diabetes: Thinking Beyond Diabetic Peripheral Neuropathy, Can. J. Diabetes. 40 (2016) 6–9. doi:10.1016/j.jcjd.2015.08.005.

[25] C. Kelly, A. Fleischer, S. Yalla, G.S. Grewal, R. Albright, D. Berns, R. Crews, B. Najafi, Fear of falling is prevalent in older adults with diabetes mellitus but is unrelated to level of neuropathy., J. Am. Podiatr. Med. Assoc. 103 (2013) 480–8.

[26] S.J. Brown, J.C. Handsaker, F.L. Bowling, A.J.M. Boulton, N.D. Reeves, Diabetic peripheral neuropathy compromises balance during daily activities., Diabetes Care. 38 (2015) 1116–22. doi:10.2337/dc14-1982.

[27] A. Moghtaderi, A. Bakhshipour, H. Rashidi, Validation of Michigan neuropathy screening instrument for diabetic peripheral neuropathy, Clin. Neurol. Neurosurg. 108 (2006) 477–481. doi:10.1016/J.CLINEURO.2005.08.003.

[28] S. Tesfaye, A.J.M. Boulton, P.J. Dyck, R. Freeman, M. Horowitz, P. Kempler, G. Lauria, R.A. Malik, V. Spallone, A. Vinik, L. Bernardi, P. Valensi, on behalf of the T.D.N.E. Toronto Diabetic Neuropathy Expert Group, Diabetic neuropathies: update on definitions, diagnostic criteria, estimation of severity, and treatments., Diabetes Care. 33 (2010) 2285–93. doi:10.2337/dc10-1303.

[29] Y. Feng, F.J. Schlösser, B.E. Sumpio, The Semmes Weinstein monofilament examination as a screening tool for diabetic peripheral neuropathy, J. Vasc. Surg. 50 (2009) 675–682.e1. doi:10.1016/j.jvs.2009.05.017.

[30] S.J. Preece, J.D. Chapman, B. Braunstein, G.-P. Brüggemann, C.J. Nester, Optimisation of rocker sole footwear for prevention of first plantar ulcer: comparison of group-optimised and individually-selected footwear designs, J. Foot Ankle Res. (2017). doi:10.1186/s13047-017-0208-3.

[31] L. Yardley, N. Beyer, K. Hauer, G. Kempen, C. Piot-Ziegler, C. Todd, Development and initial validation of the Falls Efficacy Scale-International (FES-I), Age Ageing. 34 (2005) 614–619. doi:10.1093/ageing/afi196.

[32] Vicon®, Plug-in-Gait Marker Placement, Mocap. (2006) 1–4.

[33] J.M.A. Melvin, S. Preece, C.J. Nester, D. Howard, An investigation into plantar pressure measurement protocols for footwear research., Gait Posture. 40 (2014) 682–7. doi:10.1016/j.gaitpost.2014.07.026.

[34] P.M. McAndrew Young, J.B. Dingwell, Voluntary changes in step width and step length during human walking affect dynamic margins of stability., Gait Posture. 36 (2012) 219–24. doi:10.1016/j.gaitpost.2012.02.020.

[35] S. Nakagawa, H. Schielzeth, A general and simple method for obtaining *R* 2 from generalized linear mixed-effects models, Methods Ecol. Evol. 4 (2013) 133–142. doi:10.1111/j.2041-210x.2012.00261.x.

[36] A.S. Selya, J.S. Rose, L.C. Dierker, D. Hedeker, R.J. Mermelstein, A Practical Guide to Calculating Cohen’s f(2), a Measure of Local Effect Size, from PROC MIXED., Front. Psychol. 3 (2012) 111. doi:10.3389/fpsyg.2012.00111.

[37] R Core Team (2017), R: A language and environment for statistical computing, R Found. Stat. Comput. Vienna, Austria. (n.d.).

[38] J.B. Dingwell, J.P. Cusumano, D. Sternad, P.R. Cavanagh, Slower speeds in patients with diabetic neuropathy lead to improved local dynamic stability of continuous overground walking., J. Biomech. 33 (2000) 1269–77.



**Fig. 1.** Experimental shoes; A: R10 (rocker angle:10°, apex position: 60%, apex angle: 80°), B: R15 (rocker angle:15°, apex position: 55%, apex angle: 95°), and C: R20 (rocker angle:20°, apex position: 60%, apex angle: 95°).



**Fig. 2.** Mixed model results for each outcome variable. Error bars represent Confidence Intervals (CI). BF: Barefoot.

**Table 1**

Participant characteristics

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameters** | **Healthy participants**Mean (SD) | **Non-NDPs**Mean (SD) | **NDPs**Mean (SD) |
| **Age (years)** | 33.16 (9.3) | 54.39 (5.1) | 58.72 (4.7) |
| **BMI (kg/m2)** | 22.2 (2) | 27.9 (3.1) | 25.67(2.8) |
| **Duration of diabetes (years)** | - | 8.04 (3.52) | 10.46 (5.9) |
| **MNSI score** | - | 3.5 (4) | 5.5 (4.5) |
| **Motor NCV (m/s)****Sensory NCV (m/s)** | -- | 38.1 (2.1)24.14 (3.6) | 42.7 (8.7)33.65 (11.3) |
| **FES-I score** | 16 (0.1) | 29.7 (7) | 35.54 (9.6) |

**Table 2**

Comparisons of stability and spatiotemporal measures between experimental conditions and group participants

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Parameters** | **Healthy participants**(n = 11)Estimated Mean (SE) | **Non-NDP** (n = 14)Estimated Mean (SE) | **NDP** (n = 9)Estimated Mean (SE) | **Group effect**(p-value) | **Experimental condition**(p-value) | **Interaction**(p-value) |
| **(Cohen’s f2)** | **(Cohen’s f2)** | Marginal R-squared |
| **SMOS (mm)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 228.52 (7.5) | 215.17 (6.7) | 222.29 (8.3) | 0.262 | **<.0001** | 0.499 |
| R10 | 248.49 (7.5) | 239.6 (6.7) | 236.67 (8.6) |
| R15 | 251.24 (7.5) | 245.02 (6.8) | 229.45 (8.3) | 0.07 | 0.14 | 0.16 |
| R20 | 240.97 (7.5) | 227.4 (7.6) | 223.44 (8.3) |
| **SMOS Variability (mm)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 156.46 (7.9) | 139.93 (7.1) | 147.24 (8.8) | 0.146 | **0.0002** | 0.545 |
| R10 | 168.77 (7.9) | 151.99 (7.1) | 151.13 (8.9) |
| R15 | 173.26 (7.9) | 156.43 (7.1) | 149.62 (8.8) | 0.07 | 0.04 | 0.12 |
| R20 | 171.72 (7.9) | 151.12 (7.5) | 150.53 (8.8) |
| **FMOS (mm)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 99.15 (3.6) | 109.21 (3.2) | 124.61 (3.9) | **<.0001** | **<.0001** | 0.298 |
| R10 | 107.67 (3.7) | 118.86 (3.2) | 132.41 (4.1) |
| R15 | 103.98 (3.6) | 113.1 (3.2) | 136.31 (3.9) | 0.75 | 0.12 | 0.46 |
| R20 | 110.92 (3.6) | 119.72 (3.5) | 131.72 (3.9) |
| **FMOS Variability (mm)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 28.79 (2.2) | 35.69 (1.9) | 42.11 (2.4) | **<.0001** | 0.231 | 0.394 |
| R10 | 28.94 (2.2) | 33.25 (1.9) | 40.61 (2.5) |
| R15 | 27.64 (2.2) | 35.87 (1.9) | 46.27 (2.4) | 0.63 | 0.02 | 0.39 |
| R20 | 27.93 (2.2) | 33 (2.1) | 42.26 (2.4) |
| **SW (mm)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 83.28 (7.0) | 91.65 (6.2) | 95.1 (8.3) | 0.166 | 0.057 | 0.359 |
| R10 | 93.12 (7.1) | 101.08 (6.2) | 103 (8.3) |
| R15 | 90.49 (7.1) | 98.15 (6.3) | 109.35 (8.3) | 0.03 | 0.03 | 0.06 |
| R20 | 99.95 (7.2) | 102.42 (6.6) | 102.59 (8.2) |
| **SWV (mm)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 15.95 (2.6) | 26.64 (2.4) | 23.9 (2.9) | **0.029** | 0.271 | 0.424 |
| R10 | 21.03 (2.8) | 29.48 (2.3) | 23.48 (3.2) |
| R15 | 19.42 (2.7) | 30.42 (2.4) | 30.92 (3.1) | 0.15 | 0.04 | 0.15 |
| R20 | 16.07 (2.8) | 25.08 (2.5) | 28.29 (3) |
| **SL (mm)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 613.27 (14.4) | 556.23 (12.8) | 546.65 (15.9) | **0.003** | 0.180 | 0.729 |
| R10 | 630.22 (14.5) | 573.99 (12.8) | 559.56 (16) |
| R15 | 629.45 (14.5) | 569.71 (12.9) | 550.32 (16) | 0.39 | 0.02 | 0.29 |
| R20 | 642.12 (14.6) | 584.73 (13.2) | 551.52 (15.9) |
| **SLV (mm)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 30.03 (3.7) | 31.5 (3.3) | 32.22 (4.1) | 0.606 | 0.527 | 0.069 |
| R10 | 36.04 (3.9) | 29.52 (3.3) | 33.86 (4.2) |
| R15 | 30.43 (3.8) | 37.6 (3.4) | 39.48 (4.3) | 0.09 | 0.10 | 0.10 |
| R20 | 25.57 (3.9) | 36.38 (3.8) | 27.81 (4.2) |
| **Speed (m/s)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 0.97 (0.04) | 0.84 (0.03) | 0.85 (0.04) | **0.014** | 0.066 | 0.359 |
| R10 | 1.01 (0.04) | 0.89 (0.03) | 0.85 (0.04) |
| R15 | 1.007 (0.04) | 0.88 (0.03) | 0.82 (0.04) | 0.30 | 0.02 | 0.24 |
| R20 | 1.03 (0.04) | 0.91 (0.03) | 0.85 (0.04) |
| **Cadence (steps/min)** |  |  |  |  |  |  |
| Barefoot (Intercept) | 148.35 (5.5) | 133.41 (5.02) | 137.76 (6.04) | **0.019** | 0.127 | 0.253 |
| R10 | 153.07 (5.5) | 138.56 (5.02) | 140.88 (6.1) |
| R15 | 159.62 (5.5) | 135.69 (5.06) | 136.99 (6.04) | 0.20 | 0.03 | 0.18 |
| R20 | 160.79 (5.5) | 137.30 (5.3) | 145.08 (6.04) |
| P values < 0.05 was considered significant. |

**Table 3**

Pairwise contrasts between test conditions for outcome measures in which main effect of experimental condition was significant

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Outcome measure** | **Healthy participants**Estimate (SE) | **Pairwise contrast**(p-value) | **Non-NDP** Estimate (SE) | **Pairwise contrast**(p-value) | **NDP** Estimate (SE) | **Pairwise contrast**(p-value) |
| **SMOS (mm)** |  |  |  |  |  |  |
| Barefoot – R10 | -19.97 (7.1) | **0.030** | -24.43 (6.3) | **0.001** | -14.38 (8.1) | 0.290 |
| Barefoot – R15 | -22.72 (7.1) | **0.010** | -29.85 (6.4) | **0.0001** | -7.16 (7.8) | 0.790 |
| Barefoot – R20 | -12.45 (7.1) | 0.300 | -12.23 (7.3) | 0.340 | -1.16 (7.8) | 0.990 |
| R10 – R15 | -2.75 (7.1) | 0.980 | -5.41 (6.4) | 0.830 | 7.22 (8.1) | 0.810 |
| R10 – R20 | 7.51 (7.1) | 0.720 | 12.2 (7.3) | 0.350 | 13.23 (8.1) | 0.370 |
| R15 – R20 | 10.27 (7.1) | 0.480 | 17.61 (7.5) | 0.090 | 6.004 (7.8) | 0.870 |
| **SMOS Variability (mm)** |  |  |  |  |  |  |
| Barefoot – R10 | -12.31 (5.2) | 0.096 | -12.05 (4.6) | 0.054 | -3.89 (6) | 0.917 |
| Barefoot – R15 | -16.79 (5.2) | **0.010** | -16.50 (4.8) | **0.005** | -2.38 (5.8) | 0.977 |
| Barefoot – R20 | -15.25 (5.2) | **0.023** | -11.20 (5.2) | 0.149 | -3.29 (5.8) | 0.941 |
| R10 – R15 | -4.49 (5.2) | 0.828 | -4.44 (4.8) | 0.788 | 1.51 (6) | 0.994 |
| R10 – R20 | -2.94 (5.2) | 0.943 | 0.87 (5.2) | 0.998 | 0.6 (6) | 0.999 |
| R15 – R20 | 1.54 (5.2) | 0.991 | 5.31 (5.3) | 0.754 | -0.91 (5.8) | 0.999 |
| **FMOS (mm)** |  |  |  |  |  |  |
| Barefoot – R10 | -8.53 (3.5) | 0.080 | -9.65 (3.05) | **0.010** | -7.8 (3.9) | 0.200 |
| Barefoot – R15 | -4.83 (3.4) | 0.490 | -3.89 (3.1) | 0.590 | -11.7 (3.8) | **0.010** |
| Barefoot – R20 | -11.77 (3.4) | **0.005** | -10.51 (3.4) | **0.010** | -7.1 (3.8) | 0.250 |
| R10 – R15 | 3.69 (3.5) | 0.720 | 5.76 (3.1) | 0.260 | -3.9 (3.9) | 0.750 |
| R10 – R20 | -3.25 (3.5) | 0.790 | -0.86 (3.4) | 0.990 | 0.69 (3.9) | 0.990 |
| R15 – R20 | -6.94 (3.4) | 0.190 | -6.62 (3.5) | 0.240 | 4.59 (3.8) | 0.620 |
| P values < 0.05 was considered significant. |

**Table 4**

Pairwise contrasts between groups for outcome measures in which group main-effect was significant

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Outcome measure** | **Barefoot** Estimate (SE) | **R10**Estimate (SE) | **R15**Estimate (SE) | **R20**Estimate (SE) |
| **FMOS (mm)** |  |  |  |  |
| Healthy – NDP | -25.46 (5.3)\*\* | -24.74 (5.5)\*\* | -32.33 (5.3)\*\*\* | -20.79 (5.3)\*\* |
| Healthy – Non-NDP | -10.06 (4.8) | -11.19 (4.8) | -9.11 (4.8) | **-**8.8 (5) |
| NDP – Non-NDP | 15.4 (5.07)\* | 13.55 (5.2)\* | 23.22 (5.1)\*\* | 11.99 (5.3) |
| **FMOS Variability (mm)** |  |  |  |  |
| Healthy – NDP | -13.32 (3.3)\*\* | -11.67 (3.4)\*\* | -18.63 (3.3)\*\*\* | -14.33 (3.2)\*\* |
| Healthy – Non-NDP | -6.9 (2.9) | -4.31 (2.9) | -8.23 (2.9)\* | -5.07 (3.1) |
| NDP – Non-NDP | 6.42 (3.1) | 7.35 (3.2) | 10.39 (3.1)\*\* | 9.26 (3.2)\* |
| **SWV (mm)** |  |  |  |  |
| Healthy – NDP | -6.63 (5.9) | -4.85 (6.1) | -14.48 (5.9) | -15.15 (6.1)\* |
| Healthy – Non-NDP | -12.63 (5.3) | -5.5 (5.4) | -10.01 (5.4) | -8.64 (5.8) |
| NDP – Non-NDP | -6.0 (5.6) | -0.65 (5.7) | 4.46 (5.6) | 6.51 (5.9) |
| **SL (mm)** |  |  |  |  |
| Healthy – NDP | 66.17 (25.4)\* | 70.44 (25.8)\* | 81.65 (25.5)\*\* | 90.15 (25.8)\*\* |
| Healthy – Non-NDP | 58.67 (22.7)\* | 56.75 (22.9)\* | 64.81 (23.1)\* | 84.11 (23.8)\*\* |
| NDP – Non-NDP | -7.5 (24.1) | -13.69 (24.4) | -16.84 (24.2) | -6.04 (24.7) |
| **Speed (m/s)** |  |  |  |  |
| Healthy – NDP | 0.11 (0.06) | 0.16 (0.07) | 0.18 (0.07)\* | 0.18 (0.07)\* |
| Healthy – Non-NDP | 0.15 (0.06)\* | 0.15 (0.06)\* | 0.16 (0.06)\* | 0.19 (0.06)\* |
| NDP – Non-NDP | 0.03 (0.06) | -0.01 (0.06) | -0.02 (0.06) | 0.01 (0.06) |
| **Cadence (steps/min)** |  |  |  |  |
| Healthy – NDP | 10.6 (9.7) | 12.03 (9.8) | 22.64 (9.7) | 15.71 (9.7) |
| Healthy – Non-NDP | 17.98 (8.7) | 18.7 (8.7) | 27.2 (8.8)\* | 30.97 (8.9)\*\* |
| NDP – Non-NDP | 7.38 (9.3) | 6.67 (9.4) | 4.56 (9.3) | 15.26 (9.5) |
| p < 0.05: “\*”; p < 0.01: “\*\*”; p < 0.0001: “\*\*\*” |