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Acute Effects of Vibrating Insoles on Dynamic Balance and Gait Quality in Individuals With Diabetic Peripheral Neuropathy: A Randomized Crossover Study

Giorgio Orlando, Steven Brown, Edward Jude, Frank L. Bowling, Andrew J.M. Boulton, and Neil D. Reeves

Abstract

Objective

This study investigated the effects of vibrating insoles on dynamic balance and gait quality during level and stair walking and explored the influence of vibration type and frequency in individuals with diabetic peripheral neuropathy (DPN).

Research design and methods

Twenty-two men with DPN were assessed for gait quality and postural and dynamic balance during walking and stair negotiation using a motion capture system and force plates across seven vibratory insole conditions (Vcs) versus a control (Ctrl) condition (insole without vibration). Vibration was applied during standing and walking tasks, and 15-min rest-stop periods without vibration were interposed between conditions. Repeated measures test conditions were randomized. The primary outcomes were gait speed and dynamic balance.

Results

Gait speed during walking significantly improved in all Vcs compared with Ctrl ($P < 0.005$), with Vc2, Vc4, and Vc6 identified as the most effective. Gait speed increased (reflecting faster walking) during stair ascent and descent in Vc2 (Ctrl vs. Vc2 for ascent 0.447 ± 0.180 vs. 0.517 ± 0.127 m/s; $P = 0.037$ and descent 0.394 ± 0.170 vs. 0.487 ± 0.125 m/s; $P = 0.016$), Vc4 (Ctrl vs. Vc4 for ascent 0.447 ± 0.180

vs. 0.482 ± 0.197 m/s; P = 0.047 and descent 0.394 ± 0.170 vs. 0.438 ± 0.181 m/s; P = 0.017), and Vc6 (Ctrl vs. Vc6 for ascent 0.447 ± 0.180 vs. 0.506 ± 0.179 m/s; P = 0.043 and descent 0.394 ± 0.170 vs. 0.463 ± 0.159 m/s; P = 0.026). Postural balance improved during quiet standing with eyes closed in Vc2, Vc4, Vc6, and Vc7 (P < 0.005).

Conclusions

Vibrating insoles are an effective acute strategy for improving postural balance and gait quality during level walking and stair descent in individuals with DPN. These benefits are particularly evident when the entire plantar foot surface is stimulated.

Introduction

Diabetic peripheral neuropathy (DPN) is the commonest neuropathy worldwide, affecting up to 50% of individuals with diabetes (1), and is linked to high levels of disability, poor quality of life, and increased mortality (2). On the basis of a recent estimate from the International Diabetes Federation, it is possible that as many as 270 million people with diabetes worldwide are affected by DPN (3).

DPN results in a progressive deterioration of the peripheral sensory and motor nerves, which affects the distal segments of the upper and, predominantly, lower limbs (2). Loss of sensory feedback and alterations in motor control and function (i.e., loss of muscle power) are typical features of DPN (4). Consequently, patients with DPN are predisposed not only to foot ulceration and amputation (5) but also to a 20-fold greater risk of falling than individuals without DPN as a result of an altered gait pattern and impaired balance (6,7). Typically, patients with DPN are characterized by a slower self-selected walking speed (range 0.7–1.2 m/s) than that of their age-matched control participants without diabetes (range 1.0–1.5 m/s) (8). Changes in gait pattern are accompanied by impaired balance, which is particularly pronounced during daily tasks, such as level walking and stair climbing

(9). The importance of balance problems in this population is underpinned by unsteadiness being identified as one of the main predictors of depressive symptoms (10).

Because we live in an era of rapidly evolving technologies, smart wearable devices are being developed to monitor the risk factors for foot ulceration (e.g., pressure and skin temperature) and improve some aspects of physical function (11). Specifically, smart insoles that provide short periods of mechanical vibration to the plantar surface of the feet have been shown to enhance gait quality and balance in adults with and without chronic diseases (12–14). There is also evidence that mechanical vibration improves vibrotactile foot sensation in individuals with mild to moderate DPN (15–17). These acute effects of vibration have also been linked to a significant decrease in postural sway, especially when visual feedback is removed, thus highlighting vibration as a potent tool for improving proprioception in those with DPN (18–20). Stochastic resonance has been proposed as a determinant underpinning the improvements in peripheral sensation induced by specific types of vibration (e.g., random and subsensory vibrations). This phenomenon improves the ability of cutaneous mechanoreceptors to detect mechanical stimuli that cannot be identified under normal circumstances (21). Currently, the long-term effects of vibrating insoles are poorly understood in individuals with DPN, with only one study reporting no effects on gait performance after 1 month of sole vibration applied for a short daily duration (22 min) (22).

Although vibrating insoles may induce acute beneficial effects on some aspects of peripheral sensation and standing/postural balance, their capacity to improve gait quality and balance during daily tasks, such as level walking and stair climbing (i.e., dynamic balance), has not previously been investigated. This is important because the main challenges to balance and a majority of falls occur during gait rather than while standing (7). Furthermore, because the type and frequency of vibration can translate into changes in mechanical stimuli, there is also a need to examine the acute impact of these variables on modulating improvements in balance and gait.

Therefore, we undertook this study to investigate the effects of a vibrating insole system on gait quality and balance during walking and stair negotiation and explored the influence of the type and frequency of vibration in individuals with DPN. We hypothesized that mechanical vibration applied to the plantar surface of the feet would improve gait quality and balance and that these effects could be optimized by modulating the type and frequency of the vibration stimuli.

Research Design and Methods

Participants

Twenty-two adults with type 2 diabetes were identified and recruited across two hospitals in the U.K. between 2020 and 2022. Major inclusion criteria included age >18 years and a diagnosis of mild to severe DPN based on a vibration perception threshold (VPT) at the halluces of ≥15 V and/or a modified neuropathy disability score (mNDS) of ≥3 and at least one palpable pedal pulse on each foot (23–25).

Major exclusion criteria were presence of an active foot ulcer, lower limb amputation of more than two toes on either foot, National Health Service prescription footwear, Charcot deformities, and use of a pacemaker. The study was conducted in accordance with the 1964 Declaration of Helsinki and its subsequent amendments, and the Ethics Committee of the U.K. National Health Service and the Medicines and Healthcare Products Regulatory Agency approved the protocol. All participants provided written informed consent.

Study Design and Procedures

A randomized controlled crossover design was adopted to test the effects of seven vibrating insole conditions (Vcs) on improving gait and balance. During the biomechanical assessment, participants with DPN were randomly exposed to seven different vibratory stimuli and one placebo control condition (insole without vibration). Each condition lasted ~10 min. In between conditions, there were 15 min of rest without vibration and a 5-min acclimatization period during which participants

grew accustomed to the new vibration settings. Data on gait kinematics and balance were collected during standing tests, walking, and stair negotiation. The primary outcomes of interest were changes in gait speed and dynamic balance. Dynamic balance was assessed by the extrapolated center of mass (XCoM), whereas postural balance was assessed by the center of pressure (CoP) velocity measured under the feet. Medical history, anthropometric data, neurological evaluation, questionnaires, and gait analysis were conducted during a single daily experimental session.

Insole System and Vibratory Conditions

Vibrating insoles were prototypes designed and produced by Walk With Path (PathFeel; Waltham Abbey, U.K.). This device comprised two vibratory motors located under the forefoot and the heel and three piezoelectric actuators, one positioned under the heel and two at the medial and lateral forefoot (between first and second and fourth and fifth metatarsal heads). Motors were responsible for the vibratory stimulation, with actuators generating white noise and measuring foot pressure. A printed circuit board and battery were housed in a rigid plastic box attached to the laces of the shoes using Velcro. Vcs were selected using a mobile app and transmitted via Bluetooth to the insoles.

The seven conditions varied in terms of vibration frequency (0–240 Hz), type of activation and delivery, and addition or otherwise of white noise. The type of vibrational stimuli was determined by a binary or linear activation algorithm developed by the company behind the smart insole, Walk With Path. Through the algorithm, the linear activation modulated vibration (within a range of frequencies) based on the pressure sensor data, whereas, in binary activation, vibration was applied at a specific frequency. The type of vibration delivery varied across the different conditions (i.e., single site or whole foot). Motors under the heel and/or forefoot were thus activated based on pressure provided by each foot in the single-site setting. In contrast, both motors were active simultaneously in the whole-foot stimulation upon detection of weight bearing. Vibration was, therefore, released only during the weight-bearing stance phase (i.e., when the foot was on the ground) of gait in both settings. White noise was generated by the piezoelectric actuators at an

amplitude set to 80% of the individual's perception threshold, which was established as part of the calibration of the insoles at the start of the session.

The following Vcs were tested: Vc1, mechanical vibration inactive, white noise active; Vc2, vibration frequency ranging from 100 to 240 Hz, linear activation, white noise active, whole foot; Vc3, vibration frequency of 150 Hz, binary activation, white noise inactive, whole foot; Vc4, vibration frequency ranging from 100 to 240 Hz, linear activation, white noise inactive, whole foot; Vc5, vibration frequency of 240 Hz, binary activation, white noise inactive, single site; Vc6, vibration frequency of 240 Hz, binary activation, white noise inactive, whole foot; and Vc7, vibration frequency ranging from 100 to 240 Hz, linear activation, white noise inactive, single site.

Clinical Characteristics

Demographic and anthropometric data and medical history were gathered during a semistructured interview. Body mass and height were measured using a digital scale and stadiometer; BMI was then calculated. Fear of falling was assessed using an internationally validated questionnaire, the Falls Self-Efficacy Scale.

Participants underwent neurological evaluation, which included an assessment of small and large sensory functions via a combination of VPT and mNDS. VPT was assessed using a neurothesiometer (Horwell Ltd, Nottingham, U.K.); the mean of three results with variable speeds of voltage increase from each hallux was taken as the VPT result (2). The mNDS is a semiquantitative composite score that evaluates pain sensitivity using a Neurotip, vibration sensation using a 128-Hz tuning fork, dorsal temperature using warm and cool rods, and Achilles reflex using a tendon hammer. The assessment provides a score ranging from 0 to 10, with a score of 3–5, 6–8, or 9–10 indicating mild, moderate, or severe neuropathy, respectively (23). Finally, the pedal pulses in both feet were examined via palpation and recorded as dichotomous variables (present or absent).

Gait Analysis

Whole-body kinematics and balance were recorded using a 10-camera optoelectronic motion capture system (Vicon, Oxford, U.K.) in combination with force platforms (Kistler, Winterthur, Switzerland) during standing tests, level walking, and stair climbing. Motion and force data were recorded simultaneously at 100 and 1,000 Hz, respectively. Fifty-six reflective markers were placed at key anatomical positions on the participants to track the movement of all body segments according to a full-body marker set including medial and lateral ankle and knee markers, four-marker clusters on the foot, shank, and thigh, a CODA-style pelvis model, and a plug-in gait–style upper-body torso and arms model. Participants were asked to wear tight-fitting shorts, tight-fitting T-shirts, standardized socks, and standardized footwear (within which the vibrating insoles were fitted).

Two standing balance assessments were performed, which included quiet standing with eyes open and eyes closed. Participants stood comfortably on a force plate, with their arms down at their sides and their feet side by side (approximately shoulder width apart) while facing straight ahead. For each test, motion and force data were collected for 30 s.

Level walking was evaluated while the participant walked on an 8-m-long walkway equipped with two embedded force plates. This evaluation was performed at the participant's self-selected comfortable walking speed three times. Participants were instructed to stand behind a mark on the level walkway and, when required, to walk to the other end of the walkway.

Stair negotiation was assessed on a seven-step instrumented staircase equipped with four force plates embedded in the middle four steps. Each step had a width of 1,050 mm, a depth of 275 mm, and a step riser height of 175 mm. For safety, a full-body harness was worn by each participant for the entire duration of the assessment. Participants were asked to start at the foot of the staircase, ascend the stairs, turn around on reaching the platform at the top, and then descend the staircase. They ascended and descended the staircase three times at a speed at which they were comfortable without using the handrails. However, participants were permitted to use the handrails minimally if they felt they could not complete the task safely.

Data Processing

Motion and force data were labeled using Vicon Nexus and then exported to Visual 3D (C-Motion, Germantown, MD). Raw kinematic and kinetic data were filtered using 6- and 25-Hz low-pass Butterworth filters, respectively. Filtered data were then used to model and calculate body position, spatiotemporal parameters, CoP velocity under the feet (i.e., measure of postural balance while standing), and XCoM (i.e., measure of dynamic balance, walking, and stair walking). The XCoM was measured in the mediolateral plane, because previous work has shown individuals with DPN have impaired sway control during walking and stair walking in the mediallateral plane (9,26). The XCoM considers the position and velocity of the CoM and the mean length of left and right legs multiplied by 1.34 (i.e., length of the pendulum) (27). Dynamic balance throughout a gait cycle was then quantified as the deviation from the path the XCoM would follow if traveling in a straight line throughout the gait cycle (28,29).

Where multiple gait cycles were recorded per participant (three per walking trial and stair ascent and descent), average values per participant were calculated for variables calculated per gait cycle. Variables calculated per side of the body (left/right) were also averaged to provide overall values per participant, per Vc.

Statistical Analysis

Data are expressed as mean ± SD for parametric variables, median and interquartile range for nonparametric data, and percentages for categorical variables. All parameters were tested for normal distribution by visual inspection and using the Shapiro-Wilk test. As an exploratory investigation, the seven Vcs were assessed using a dose-response analysis for best improvement in the primary outcomes (dynamic balance and walking speed). This yielded three key Vcs with similar response levels as the optimum at improving the primary outcomes. These conditions were then further analyzed statistically as follows. Differences among vibratory and placebo control conditions were tested using paired Student *t* tests. ANCOVA was used to test the difference in dynamic balance

among Vcs and placebo control, including as covariate gait speed. All statistical tests were performed via Matlab (version 2022a; MathWorks, Natick, MA), with significance set at $P < 0.05$.

Sample Size Calculation

Because the impact of vibration on dynamic balance in individuals with DPN has not been previously explored, a power analysis was performed using the CoM velocity (m/s) during standing derived from previous investigations exploring the effects of sole vibration on postural balance (19). A minimum group sample size of 22 participants with an effect size of 0.720 ($\beta = 0.1$; $\alpha = 5\%$) was identified based on a conservative population SD of 3.3 m/s[1] and a between-group difference of 0.5 m/s.

Data and Resource Availability

The data sets generated during and/or analyzed in the current study are available from the corresponding author upon reasonable request.

Results

Clinical Characteristics and Demographics

The clinical characteristics of the study population are listed in **Table 1**. Our cohort included 22 participants with DPN with a mean age of 68 ± 8 years, diabetes duration of 17 ± 10 years, and mNDS and VPT values of 8 ± 2 points (range 4–10) and 27 ± 10 V, respectively. A score of 29 ± 10.6 was recorded on the Falls Self-Efficacy Scale, indicating that participants were moderately concerned about falling. Four (18.2%) participants had a history of foot ulcers (right foot $n = 3$; left foot $n = 1$): one on the heel, one on the metatarsal head, and two on the toes. There were no cases of amputation. Pedal pulses were present on both feet in 86.4% of the cohort, whereas 13.6% had only one pedal pulse.

Table 1

Clinical characteristics of study participants

Variable	DPN
Participants, *n*	22
Age, years	68 ± 7.8
Diabetes duration, years	17 ± 10
Body mass, kg	89 ± 13
BMI, kg/m^2	30.2 ± 6
mNDS score (0/10)	8 ± 2
VPT halluces, V	27 ± 10
FES-I score (16/64)	29 ± 10.6
History of diabetic foot ulcer, %	
Yes	18.2
No	81.8

FES-I, Falls Self-Efficacy Scale; mNDS, modified neuropathy disability score; VPT, vibration perception threshold.

Gait Quality

Table 2 summarizes the comparison between the seven Vcs and the placebo control condition in relation to gait quality and dynamic balance. Figures 1 and and22 present the comparison of the seven conditions in relation to gait speed and dynamic balance during level walking and stair descent, respectively. Significant differences were identified between the placebo condition and Vc2,

Vc4, and Vc6 in gait speed during level and stair walking. These insole conditions were identified as the most effective because they significantly increased gait speed in all three walking settings (i.e., level and stair walking [ascent and descent]) compared with control. Gait speed and stride length significantly increased and stance and step times were reduced (reflecting faster gait speed) during level walking in Vc2 (gait speed $P = 0.005$; stride length $P = 0.019$; stance time $P = 0.006$; step time $P = 0.007$) and Vc6 (gait speed $P = 0.007$; stride length $P = 0.039$; stance time $P = 0.005$; step time $P = 0.005$) compared with the placebo condition. Similarly, Vc4 increased gait speed ($P = 0.021$) and reduced step ($P = 0.035$) and stance ($P = 0.033$) times (reflecting faster gait speed), whereas only a nonsignificant increase in stride length was observed ($P = 0.053$). During stair ascent, gait speed increased and step time, stance time, and swing time decreased (reflecting faster gait speed) in Vc2 (gait speed $P = 0.037$; step time $P = 0.011$; stance time $P = 0.026$; swing time $P = 0.030$), Vc4 (gait speed $P = 0.047$; step time $P = 0.044$; stance time $P = 0.038$; swing time $P = 0.031$), and Vc6 (gait speed $P = 0.043$; step time $P = 0.005$; stance time $P = 0.010$; swing time $P = 0.007$). Gait speed increased and step time decreased during stair descent (reflecting faster gait speed) in Vc4 (gait speed $P = 0.017$; step time $P = 0.021$) and Vc6 (gait speed $P = 0.026$; step time $P = 0.022$), whereas only gait speed improved in Vc2 ($P = 0.016$).

Table 2

Gait and dynamic balance (measured by XCoM) changes during level and stair walking across vibratory and control (without vibration) conditions

Variable	**Ctrl**	**Vc1**	***P***	**Vc2**	***P***	**Vc3**	***P***	**Vc4**	***P***	**Vc5**	***P***	**Vc6**	***P***	**Vc7**	***P***
Walking															

Variable	**Ctrl**	**Vc 1**	***P***	**Vc 2**	***P***	**Vc 3**	***P***	**Vc 4**	***P***	**Vc 5**	***P***	**Vc 6**	***P***	**Vc 7**	***P***
Speed, m/s	1.031 ± 0.183	1.132 ± 0.167	**0.004**	1.119 ± 0.150	**0.005**	1.102 ± 0.174	**0.014**	1.100 ± 0.165	**0.021**	1.121 ± 0.149	**0.001**	1.129 ± 0.152	**0.007**	1.101 ± 0.184	**0.005**
Stride length, m	1.226 ± 0.018	1.292 ± 0.156	**0.004**	1.277 ± 0.155	**0.019**	1.269 ± 0.164	0.059	1.268 ± 0.153	0.053	1.280 ± 0.152	**0.003**	1.272 ± 0.155	**0.039**	1.265 ± 0.184	**0.020**
Stride width, m	0.150 ± 0.034	0.144 ± 0.029	0.206	0.144 ± 0.033	0.274	0.143 ± 0.028	0.291	0.153 ± 0.028	0.692	0.152 ± 0.027	0.131	0.143 ± 0.033	0.185	0.147 ± 0.026	0.722
Step time, s	0.598 ± 0.034	0.575 ± 0.045	**0.024**	0.572 ± 0.034	**0.007**	0.579 ± 0.045	**0.011**	0.044 ± 0.035	**0.035**	0.574 ± 0.042	**0.005**	0.531 ± 0.05	**0.005**	0.579 ± 0.038	**0.008**

Variable	**Ctrl**	**Vc 1**	***P***	**Vc 2**	***P***	**Vc 3**	***P***	**Vc 4**	***P***	**Vc 5**	***P***	**Vc 6**	***P***	**Vc 7**	***P***
Stance time, s	0.728 ± 0.071	0.680 ± 0.077	**0.014**	0.679 ± 0.062	**0.006**	0.693 ± 0.080	**0.014**	0.085 ± 0.033	**0.033**	0.680 ± 0.073	**0.004**	0.670 ± 0.061	**0.005**	0.690 ± 0.072	**0.008**
Swing time, s	0.466 ± 0.035	0.468 ± 0.032	0.511	0.465 ± 0.031	0.260	0.466 ± 0.031	0.195	0.030 ± 0.010	0.310	0.466 ± 0.032	0.189	0.460 ± 0.029	0.053	0.464 ± 0.036	0.073
Dynamic balance, m	0.027 ± 0.008	0.028 ± 0.008	0.616	0.030 ± 0.009	0.149	0.028 ± 0.009	0.616	0.030 ± 0.008	0.277	0.028 ± 0.009	0.702	0.029 ± 0.008	0.602	0.028 ± 0.007	0.556
Stair ascent															

Variable	**Ctrl**	**Vc 1**	***P***	**Vc 2**	***P***	**Vc 3**	***P***	**Vc 4**	***P***	**Vc 5**	***P***	**Vc 6**	***P***	**Vc 7**	***P***
Speed, m/s	0.447 ± 0.180	0.515 ± 0.107	0.100	0.517 ± 0.127	**0.037**	0.494 ± 0.159	0.272	0.482 ± 0.197	**0.047**	0.481 ± 0.166	0.443	0.506 ± 0.179	**0.043**	0.519 ± 0.107	0.081
Step time, s	0.668 ± 0.121	0.622 ± 0.086	0.237	0.631 ± 0.127	**0.011**	0.627 ± 0.086	0.197	0.612 ± 0.101	**0.044**	0.639 ± 0.087	0.146	0.601 ± 0.109	**0.005**	0.632 ± 0.070	0.194
Stance time, s	0.836 ± 0.163	0.789 ± 0.126	0.375	0.799 ± 0.191	**0.026**	0.778 ± 0.131	0.118	0.764 ± 0.149	**0.038**	0.804 ± 0.146	0.113	0.749 ± 0.166	**0.010**	0.799 ± 0.113	0.189
Swing time, s	0.527 ± 0.060	0.497 ± 0.047	0.133	0.506 ± 0.063	**0.030**	0.501 ± 0.045	0.156	0.494 ± 0.044	**0.031**	0.503 ± 0.051	0.153	0.489 ± 0.054	**0.007**	0.501 ± 0.047	0.143

Variable	**Ctrl**	**Vc 1**	***P***	**Vc 2**	***P***	**Vc 3**	***P***	**Vc 4**	***P***	**Vc 5**	***P***	**Vc 6**	***P***	**Vc 7**	***P***
Dynamic balance, m	0.121 ± 0.026	0.131 ± 0.032	0.165	0.132 ± 0.033	**0.017**	0.133 ± 0.024	**0.041**	0.133 ± 0.026	0.184	0.132 ± 0.038	0.128	0.128 ± 0.033	0.056	0.136 ± 0.041	**0.035**
Stair descent															
Speed, m/s	0.394 ± 0.170	0.483 ± 0.101	0.058	0.487 ± 0.125	**0.016**	0.472 ± 0.147	0.099	0.438 ± 0.181	**0.017**	0.448 ± 0.153	0.323	0.463 ± 0.159	**0.026**	0.493 ± 0.101	**0.038**
Step time, s	0.753 ± 0.122	0.692 ± 0.114	0.242	0.714 ± 0.178	0.173	0.658 ± 0.078	**0.001**	0.690 ± 0.128	**0.021**	0.693 ± 0.103	**0.047**	0.676 ± 0.142	**0.022**	0.679 ± 0.079	**0.008**

Variable	**Ctrl**	**Vc 1**	***P***	**Vc 2**	***P***	**Vc 3**	***P***	**Vc 4**	***P***	**Vc 5**	***P***	**Vc 6**	***P***	**Vc 7**	***P***
Stance time, s	0.059 ± 0.015	0.063 ± 0.036	0.476	0.067 ± 0.036	0.322	0.084 ± 0.063	0.273	0.070 ± 0.035	0.215	0.066 ± 0.034	0.191	0.076 ± 0.039	0.268	0.067 ± 0.034	0.705
Swing time, s	1.429 ± 0.232	1.304 ± 0.231	0.230	1.332 ± 0.317	0.216	1.220 ± 0.136	**0.001**	1.308 ± 0.280	0.065	1.314 ± 0.224	**0.027**	1.281 ± 0.290	0.059	1.276 ± 0.168	**0.023**
Dynamic balance, m	0.153 ± 0.017	0.153 ± 0.017	0.918	0.152 ± 0.019	0.296	0.153 ± 0.021	0.738	0.160 ± 0.011	0.242	0.145 ± 0.035	0.377	0.152 ± 0.018	0.490	0.143 ± 0.035	0.228

Bold font indicates significance.

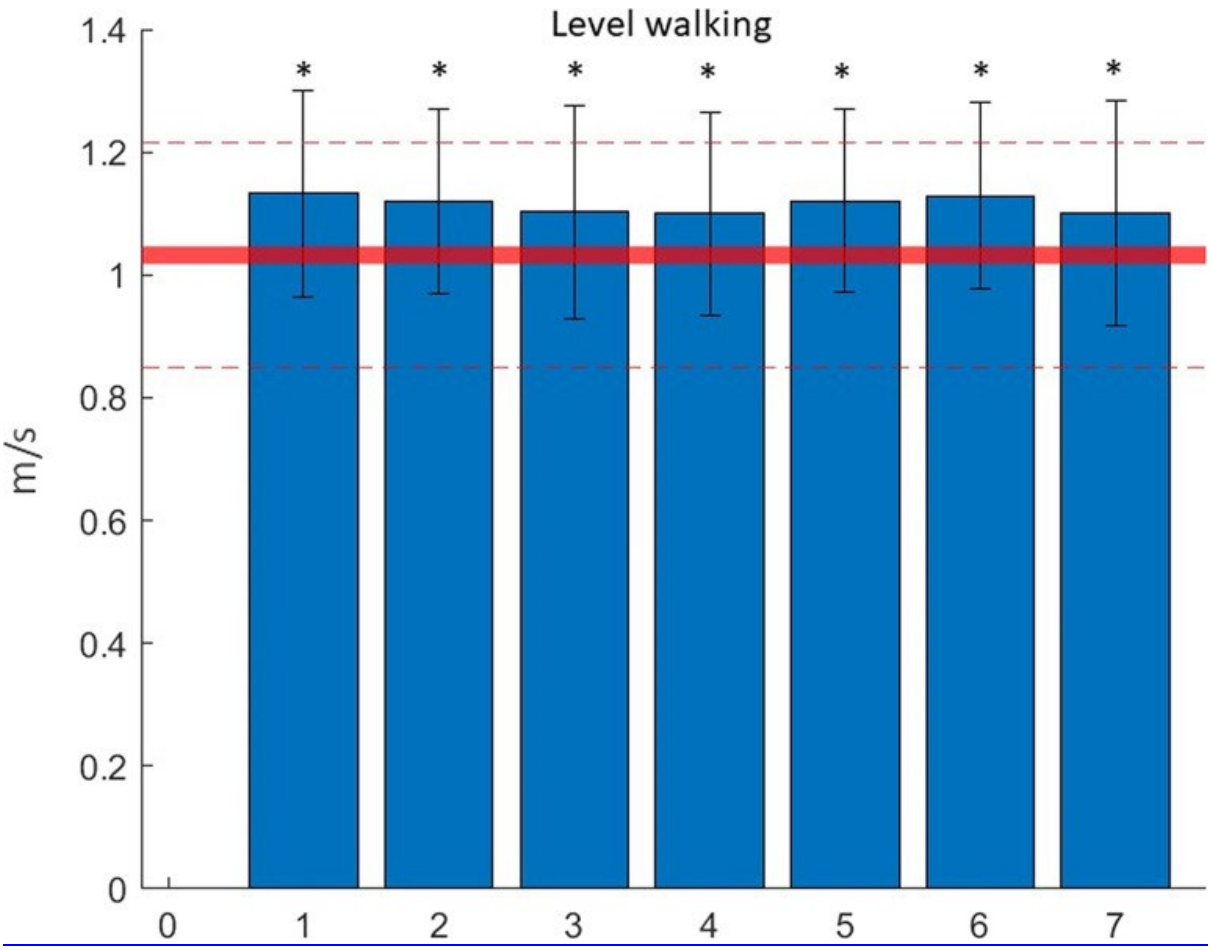

Figure 1

Gait speed (mean ± SD) during level walking across the different vibratory conditions (bars). Red line shows gait speed for control condition (gean [solid red line] ± SD [dotted lines]). *P value <0.05.

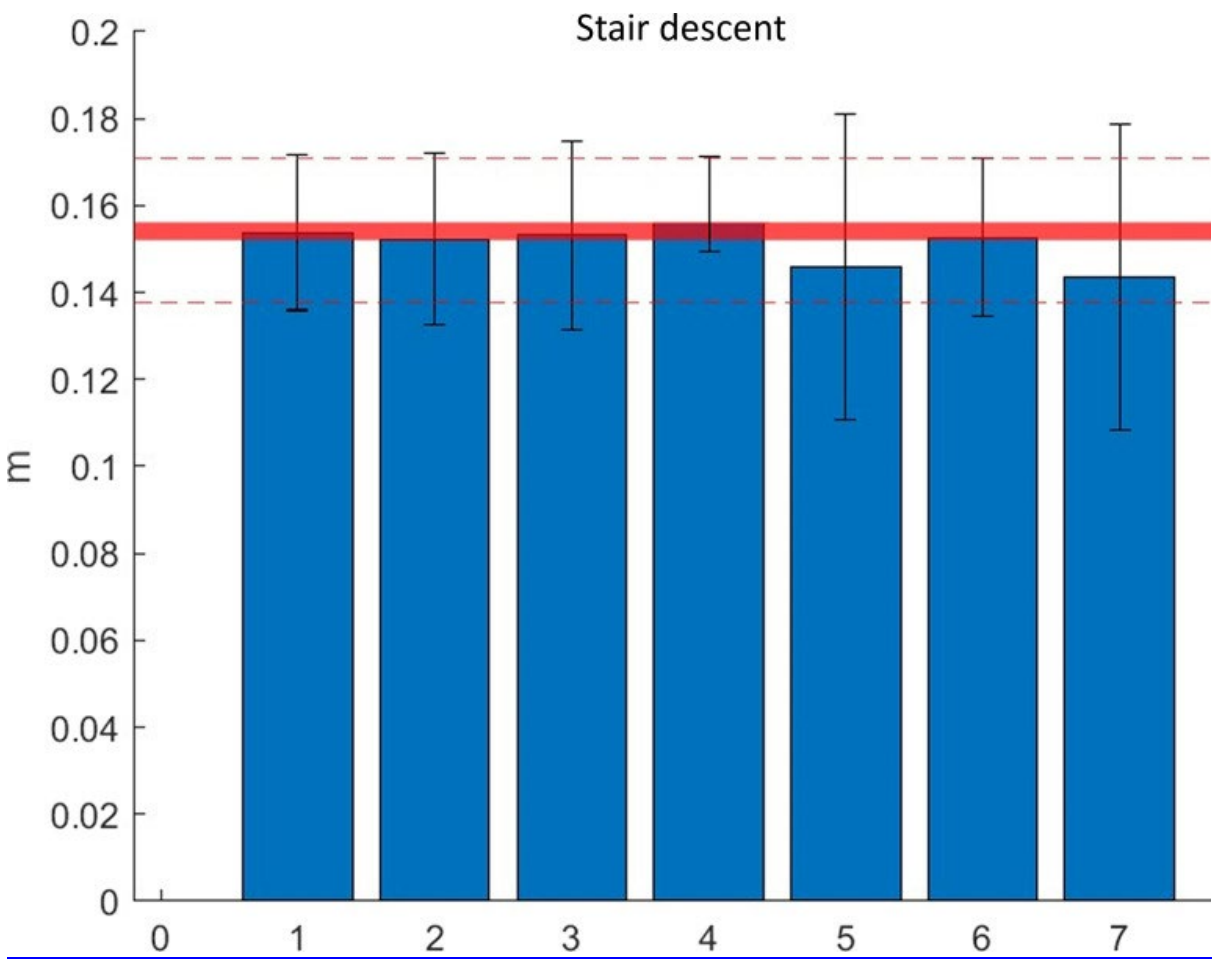

Figure 2

Dynamic balance (measured by XCoM [mean ± SD]) during stair descent in relation to the seven vibratory conditions (bars). Red line shows dynamic balance for control condition (mean [solid red line] ± SD [dotted lines]).

Postural and Dynamic Balance

There was no significant difference in dynamic balance across the seven conditions during level walking and stair descent. A significant increase in dynamic balance (**Table 2**), indicating a poorer control of balance, was observed during stair ascent in Vc2 (P = 0.016), whereas no changes were detected in Vc4 or Vc6 after adjusting for gait speed. Postural balance measured by CoP velocity improved significantly during quiet standing with eyes closed in Vc2 (Vc2 vs. Ctrl 0.013 ± 0.004 vs.

0.017 ± 0.008 m/s; *P* = 0.041), Vc4 (Vc4 vs. Ctrl 0.012 ± 0.003 vs. 0.017 ± 0.008 m/s; *P* = 0.01), Vc6 (Vc6 vs. Ctrl 0.013 ± 0.005 vs. 0.017 ± 0.008 m/s; *P* = 0.044), and Vc7 (Vc7 vs. Ctrl 0.013 ± 0.006 vs. 0.017 ± 0.008 m/s; *P* = 0.038), whereas a nonsignificant decrease was detected in Vc1 (Vc1 vs. Ctrl 0.014 ± 0.006 vs. 0.017 ± 0.008 m/s; *P* = 0.257), Vc3 (Vc3 vs. Ctrl 0.014 ± 0.005 vs. 0.017 ± 0.008 m/s; *P* = 0.254), and Vc5 (Vc5 vs. Ctrl 0.015 ± 0.006 vs. 0.017 ± 0.008 m/s; *P* = 0.296). No significant differences were observed across the balance parameters during quiet standing with eyes open (Vc1 vs. Ctrl 0.016 ± 0.018 vs. 0.013 ± 0.009 m/s; *P* = 0.472; Vc2 vs. Ctrl 0.014 ± 0.009 vs. 0.013 ± 0.009 m/s; *P* = 0.989; Vc3 vs. Ctrl 0.014 ± 0.008 vs. 0.013 ± 0.009 m/s; *P* = 0.667; Vc4 vs. Ctrl 0.012 ± 0.006 vs. 0.013 ± 0.009 m/s; *P* = 0.502; Vc5 vs. Ctrl 0.014 ± 0.008 vs. 0.013 ± 0.009 m/s; *P* = 0.525; Vc6 vs. Ctrl 0.013 ± 0.006 vs. 0.013 ± 0.009 m/s; *P* = 0.748; and Vc7 vs. Ctrl 0.013 ± 0.008 vs. 0.013 ± 0.009 m/s; *P* = 0.884).

Conclusions

This is the first study to show the beneficial effects of a vibrating insole system on gait quality and postural balance in individuals with DPN. The most salient results show that mechanical vibration applied through a smart insole system improves gait speed (i.e., one of the main determinants of gait quality) in those with DPN. Vibration was responsible for a 7–10% increase in self-selected gait speed during level walking, 8–16% increase in gait speed during stair ascent, 11–25% increase in gait speed during stair descent, and a modest improvement in postural balance. These findings indicate that the vibrating insole system is an effective acute therapeutic strategy for improving postural balance and gait quality, particularly during extremely challenging locomotor tasks, such as stair walking (9).

We recruited patients with mild to severe DPN, with a group mean VPT of 27 V; this suggests that most of our participants had moderate to severe neuropathy. Therefore, our results show that vibrating insoles were effective in individuals with marked deterioration of sensory function and almost total peripheral sensory loss. Because postural sway was reduced and gait speed increased during level walking across the seven Vcs, our findings suggest that mechanical vibration is itself a

stimulus that promotes beneficial effects on gait and balance in individuals with DPN. On the basis of our secondary analysis encompassing specific factors that influence the effects of vibration on gait and balance, our findings also indicate that benefits for gait and balance are optimized when the entire plantar surface of the feet is stimulated, and modulation of the type of activation, change of frequency (range vs. fixed stimulation), and addition of white noise do not have a significant impact on maximizing the beneficial effects of foot sole vibration.

Gait speed is one of the main determinants of gait quality and a predictor of fall risk, physical disabilities, quality of life, and mortality in elderly individuals (30,31). In those with DPN, gait speed is markedly reduced, and it is associated with diminished lower-limb joint strength and reduced range of motion, predisposing patients to instability and risk of falls (7). Among the available strategies for counteracting the functional consequences of DPN, exercise-based solutions are widely recognized as optimal for improving gait speed in individuals with and without diabetes (32). In studies conducted in patients with diabetes with or without DPN, those with neuropathy reported an increase in gait speed during level walking, ranging from 0.06 to 0.14 m/s, after short-term exercise programs (33–35). There is also evidence that an increase of 0.10 m/s in self-selected speed over a 1-year period decreased the risk of mortality in older individuals, after adjusting for multiple risk factors (30). In our study, we detected immediate increases in gait speed ranging from 0.07 to 0.10 m/s after the application of Vcs, indicating that this acute therapeutic strategy induced a marked increase in gait speed comparable to those obtained by multiple months (3–6 months) of specific exercise programs (33–35). These effects do not require training or supervision, potentially promoting the vibrating insole system as a more feasible strategy for improving gait and balance in individuals with DPN compared with the exercise-based solution, where compliance with exercise is very low (36). It is important to note, however, that we tested the acute effects of vibration. Therefore, whether these benefits will be maintained or exacerbated by the chronic use of vibration and whether these effects translate into increased physical activity and better general health remain to be addressed by a long-term clinical trial.

Our findings are in line with previous investigations indicating improvements in standing balance after the use of a vibrating insole system in individuals with DPN (18,19). Foot sole vibration has previously been demonstrated to decrease postural sway, particularly during standing with eyes closed, in those with DPN (18). We found similar effects in our cohort, with a decrease in CoP velocity during standing tasks without visual feedback indicating improved balance. This is likely explained as follows: without visual feedback, maintenance of postural control relies exclusively on sensations underneath the feet and joint proprioception, thus making the beneficial effects on proprioception induced by vibration more apparent. Indeed, vibration has been associated with a reduction in VPT (i.e., improved peripheral sensation) and pressure perception at different locations of the foot in individuals with DPN (16,17). It has been suggested that mechanical vibration affects balance by improving the peripheral vibrotactile sensation (17). Although the mechanisms underlying the effect of vibration are not yet clear, it has been hypothesized that stochastic resonance enhances sensation by making cutaneous mechanoreceptors more sensitive to mechanical stimulation (21). Similarly, because of the prior improvements in balance seen during standing, we hypothesized that we would observe similar improvements in dynamic balance during level walking and stair walking. We did not detect any significant improvements here. This may be associated with the increased walking speed in the Vc, which, although representing functional improvements, required greater muscular effort, thereby increasing the challenge to the participant's balance control and obscuring any benefit to balance control provided by the vibration. To confirm any potential beneficial effects on dynamic balance, a longitudinal study would be required to allow participants time to adapt to their new gait speed and potentially realize improvement in dynamic balance.

Our study presents several limitations. Our sample size was determined to allow for statistical comparison between vibration and control conditions, which prevents us from detecting some statistical differences across the Vc beyond a dose-response analysis. Also, it is worth noting all participants were male because of the size of the devices used in the study, which may limit the generalizability of our findings. Our study also explored the acute effects of vibration in a laboratory

setting, and therefore, new prospective clinical trials are necessary to test the effects of longer-term use of the vibrating insole device on gait and balance, as well as to determine whether these improvements will translate to a lower incidence of falling. To mitigate any residual effects of vibration, our study included the randomization of the Vcs, a placebo control condition, and a rest-stop period of 15 min between conditions.

In conclusion, our study shows that vibrating insoles are an effective acute therapeutic strategy for improving postural balance and gait speed during stair negotiation in individuals with mild to severe DPN. These effects appear immediately as a result of the application of vibration and are intensified when the entire plantar surface of the feet is stimulated.

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References

1. Pop-Busui R, Boulton AJM, Feldman EL, et al. . Diabetic neuropathy: a position statement by the American Diabetes Association. Diabetes Care 2017;40:136–154

2. Boulton AJM, Malik RA, Arezzo JC, Sosenko JM.. Diabetic somatic neuropathies. Diabetes Care 2004;27:1458–1486

3. Sun H, Saeedi P, Karuranga S, et al. . IDF Diabetes Atlas: global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045. Diabetes Res Clin Pract 2022;183:109119.

4. Orlando G, Balducci S, Boulton AJM, Degens H, Reeves ND.. Neuromuscular dysfunction and exercise training in people with diabetic peripheral neuropathy: a narrative review. Diabetes Res Clin Pract 2022;183:109183.

5. Armstrong DG, Boulton AJM, Bus SA.. Diabetic foot ulcers and their recurrence. N Engl J Med 2017;376:2367–2375

6. Richardson JK, Hurvitz EA.. Peripheral neuropathy: a true risk factor for falls. J Gerontol A Biol Sci Med Sci 1995;50:M211–M215

7. Reeves ND, Orlando G, Brown SJ.. Sensory-motor mechanisms increasing falls risk in diabetic peripheral neuropathy. Medicina (Kaunas) 2021;57:457.

8. Fernando M, Crowther R, Lazzarini P, et al. . Biomechanical characteristics of peripheral diabetic neuropathy: a systematic review and meta-analysis of findings from the gait cycle, muscle activity and dynamic barefoot plantar pressure. Clin Biomech (Bristol, Avon) 2013;28:831–845

9. Brown SJ, Handsaker JC, Bowling FL, Boulton AJM, Reeves ND.. Diabetic peripheral neuropathy compromises balance during daily activities. Diabetes Care 2015;38:1116–1122

10. Vileikyte L, Peyrot M, Gonzalez JS, et al. . Predictors of depressive symptoms in persons with diabetic peripheral neuropathy: a longitudinal study. Diabetologia 2009;52:1265–1273

11. Najafi B, Reeves ND, Armstrong DG.. Leveraging smart technologies to improve the management of diabetic foot ulcers and extend ulcer-free days in remission. Diabetes Metab Res Rev 2020;36(Suppl. 1):e3239.

12. Xie H, Song H, Schmidt C, Chang W-P, Chien JH.. The effect of mechanical vibration-based stimulation on dynamic balance control and gait characteristics in healthy young and older adults: a systematic review of cross-sectional study. Gait Posture 2023;102:18–38

13. Viseux FJF, Delval A, Defebvre L, Simoneau M.. Postural instability in Parkinson's disease: review and bottom-up rehabilitative approaches. Neurophysiol Clin 2020;50:479–487

14. Önal B, Sertel M, Karaca G.. Effect of plantar vibration on static and dynamic balance in stroke patients: a randomised controlled study. Physiotherapy 2022;116:1–8

15. Khaodhiar L, Niemi JB, Earnest R, Lima C, Harry JD, Veves A.. Enhancing sensation in diabetic neuropathic foot with mechanical noise. Diabetes Care 2003;26:3280–3283

16. Bagherzadeh Cham M, Mohseni-Bandpei MA, Bahramizadeh M, Kalbasi S, Biglarian A.. The effects of vibro-medical insole on sensation and plantar pressure distribution in diabetic patients with mild-to-moderate peripheral neuropathy. Clin Biomech (Bristol, Avon) 2018;59:34–39

17. Bagherzadeh Cham M, Mohseni-Bandpei MA, Bahramizadeh M, Kalbasi S, Biglarian A.. The effects of vibro-medical insole on vibrotactile sensation in diabetic patients with mild-to-moderate peripheral neuropathy. Neurol Sci 2018;39:1079–1084

18. Bagherzadeh Cham M, Mohseni-Bandpei MA, Bahramizadeh M, Forogh B, Kalbasi S, Biglarian A.. Effects of vibro-medical insoles with and without vibrations on balance control in diabetic patients with mild-to-moderate peripheral neuropathy. J Biomech 2020;103:109656.

19. Hijmans JM, Geertzen JHB, Zijlstra W, Hof AL, Postema K.. Effects of vibrating insoles on standing balance in diabetic neuropathy. J Rehabil Res Dev 2008;45:1441–1449

20. Regueme SC, Cowtan C, Sedgelmaci MY, et al. . A therapeutic insole device for postural stability in older people with type 2 diabetes. A feasibility study (SENSOLE part I). Front Med (Lausanne) 2019;6:127.

21. Moss F, Ward LM, Sannita WG.. Stochastic resonance and sensory information processing: a tutorial and review of application. Clin Neurophysiol 2004;115:267–281

22. Bourdel-Marchasson I, Regueme SC, Kelson M, et al. . A therapeutic vibrating insole device for postural instability in older people with type 2 diabetes: a randomized control study. Diabetes Ther 2022;13:995–1006

23. Young MJ, Boulton AJM, MacLeod AF, Williams DRR, Sonksen PH.. A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. Diabetologia 1993;36:150–154

24. Young MJ, Breddy JL, Veves A, Boulton AJM.. The prediction of diabetic neuropathic foot ulceration using vibration perception thresholds. A prospective study. Diabetes Care 1994;17:557–560

25. Abbott CA, Vileikyte L, Williamson S, Carrington AL, Boulton AJM.. Multicenter study of the incidence of and predictive risk factors for diabetic neuropathic foot ulceration. Diabetes Care 1998;21:1071–1075

26. Almurdhi MM, Brown SJ, Bowling FL, et al. . Altered walking strategy and increased unsteadiness in participants with impaired glucose tolerance and type 2 diabetes relates to small-fibre neuropathy but not vitamin D deficiency. Diabet Med 2017;34:839–845

27. Hof AL, Gazendam MGJ, Sinke WE.. The condition for dynamic stability. J Biomech 2005;38:1–8

28. Weinert-Aplin RA, Twiste M, Jarvis HL, Bennett AN, Baker RJ.. Medial-lateral centre of mass displacement and base of support are equally good predictors of metabolic cost in amputee walking. Gait Posture 2017;51:41–46

29. Eames MH, Cosgrove A, Baker R.. Comparing methods of estimating the total body centre of mass in three-dimensions in normal and pathological gaits. Hum Mov Sci 1999;18:637–646

30. Studenski S, Perera S, Patel K, et al. . Gait speed and survival in older adults. JAMA 2011;305:50–58

31. Guralnik JM, Ferrucci L, Simonsick EM, Salive ME, Wallace RB.. Lower-extremity function in persons over the age of 70 years as a predictor of subsequent disability. N Engl J Med 1995;332:556–561

32. Gu Y, Dennis SM.. Are falls prevention programs effective at reducing the risk factors for falls in people with type-2 diabetes mellitus and peripheral neuropathy: a systematic review with narrative synthesis. J Diabetes Complications 2017;31:504–516

33. Melai T, Schaper NC, IJzerman TH, et al. . Strength training affects lower extremity gait kinematics, not kinetics, in people with diabetic polyneuropathy. J Appl Biomech 2014;30:221–230

34. Allet L, Armand S, Aminian K, et al. . An exercise intervention to improve diabetic patients' gait in a real-life environment. Gait Posture 2010;32:185–190

35. Morrison S, Colberg SR, Parson HK, Vinik AI.. Exercise improves gait, reaction time and postural stability in older adults with type 2 diabetes and neuropathy. J Diabetes Complications 2014;28:715–722

36. Colberg SR, Sigal RJ, Yardley JE, et al. . Physical activity/exercise and diabetes: a position statement of the American Diabetes Association. Diabetes Care 2016;39:2065–2079