



**HAL**  
open science

# The effects of vibrating shoe insoles on standing balance, walking, and ankle-foot muscle activity in adults with diabetic peripheral neuropathy

Anna Hatton, Mark Chatfield, Thomas Cattagni, Bill Vicenzino

## ► To cite this version:

Anna Hatton, Mark Chatfield, Thomas Cattagni, Bill Vicenzino. The effects of vibrating shoe insoles on standing balance, walking, and ankle-foot muscle activity in adults with diabetic peripheral neuropathy. *Gait & Posture*, 2024, 111 (8-3), 10.1016/j.gaitpost.2024.04.008 . hal-04539954

**HAL Id: hal-04539954**

**<https://hal.science/hal-04539954>**

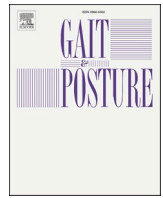
Submitted on 28 May 2024

**HAL** is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



Distributed under a Creative Commons Attribution 4.0 International License



# The effects of vibrating shoe insoles on standing balance, walking, and ankle-foot muscle activity in adults with diabetic peripheral neuropathy

Anna L. Hatton<sup>a,\*</sup>, Mark D. Chatfield<sup>b</sup>, Thomas Cattagni<sup>c</sup>, Bill Vicenzino<sup>a</sup>

<sup>a</sup> School of Health and Rehabilitation Sciences, The University of Queensland, Brisbane, Australia

<sup>b</sup> Centre for Health Sciences Research, The University of Queensland, Brisbane, Australia

<sup>c</sup> Nantes Université, Movement - Interactions - Performance, MIP, UR 4334, Nantes F-44000, France

## ARTICLE INFO

### Keywords:

Balance  
Gait  
Electromyography  
Orthotic devices  
Diabetes  
Peripheral neuropathy

## ABSTRACT

**Background:** Peripheral neuropathy is one of the most common complications of type 2 diabetes, which can lead to impaired balance and walking. Innovative footwear devices designed to stimulate foot sensory receptors, such as vibrating insoles, could offer a new route to improve motor impairments in people with diabetic peripheral neuropathy (DPN).

**Research question:** Does wearing vibrating insoles for the first time alter measures of balance, walking, and ankle-foot muscle activity, in people with DPN?

**Methods:** A randomised cross-over study was conducted with 18 ambulant men and women with a diagnosis of DPN. Participants performed tests of standing balance (Bertec® force platform) under four conditions (foam/firm surface, eyes open/closed) and level-ground walking (GAITrite® instrumented walkway), whilst wearing vibrating and non-vibrating (control) insoles on two separate occasions (one insole/session). Electromyography (EMG) was used to assess soleus, medial gastrocnemius, tibialis anterior, peroneus longus activity during balance tests. Outcomes included centre of pressure (CoP) sway, EMG amplitude, spatiotemporal gait patterns, and Timed Up and Go test. One sample t-tests were used to explore %differences in outcomes between insole conditions.

**Results:** Wearing vibrating insoles led to a reduction (improvement) in CoP elliptical area, when standing on a foam surface with eyes closed, relative to non-vibrating insoles ( $P=0.03$ ). Applying perceptible vibrations to the soles of the feet also reduced the EMG amplitude in soleus ( $P=0.01$  and  $P=0.04$ ) and medial gastrocnemius ( $P=0.03$  and  $P=0.09$ ) when standing with eyes closed on firm and foam surfaces.

**Significance:** Our findings of signs of improved balance and altered muscle activity with suprasensory vibrating insoles provides new insights into how these devices can be used to inform innovative rehabilitation approaches in individuals with DPN. This will be strengthened by further research into possible clinical benefits of these devices – given that the effects we detected were small with uncertain clinical meaning.

## 1. Introduction

Deteriorating balance is one of the earliest signs of foot sensory loss in diabetic peripheral neuropathy (DPN), associated with a high rate of trauma due to falls and fear of falling [1]. Existing treatments for DPN, such as footwear, insoles and orthoses, are routinely issued to prevent foot ulcers [2] or provide pain relief [3], associated with deteriorating foot sensory loss. However, there is an urgent need to develop rehabilitation interventions that better target early signs of sensory loss, to prevent the escalation of balance and walking impairments.

Vibrating shoe insoles, designed to augment sensory feedback at the

feet, are gaining momentum as a new route to help improve balance and walking in healthy [4–8] and clinical [5,9–15] populations. The principle behind vibrating insoles is that applying ‘noise’ to plantar mechanoreceptors can act as a pedestal to help amplify sensory signals that may be otherwise too weak to be detected [16]. For people with neuropathy, augmenting the sensory environment at the feet can offer major therapeutic benefit, leading to more efficient movement patterns and improved balance [9,11,14,15]. There are two forms of vibratory stimulation, with existing insoles delivering imperceptible (subsensory) [4–6,8–11,14,15] or perceptible (suprasensory) [12,13] noise; with varying effects on functional performance.

\* Correspondence to: School of Health and Rehabilitation Sciences, Therapies Building (84A), The University of Queensland, St Lucia, Brisbane, QLD 4072, Australia.

E-mail address: [a.hatton1@uq.edu.au](mailto:a.hatton1@uq.edu.au) (A.L. Hatton).

<https://doi.org/10.1016/j.gaitpost.2024.04.008>

Received 15 April 2023; Received in revised form 7 April 2024; Accepted 8 April 2024

Available online 9 April 2024

0966-6362/© 2024 The Authors. Published by Elsevier B.V. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Suprasensory vibrating insoles deliver perceptible haptic feedback that can provide a user with cues about their postural orientation and stability, leading to optimisation of movement and posture [7,12,13,17]. Of the few studies that have investigated suprasensory vibrating insoles, the primary focus has been on their potential to alter walking patterns in people without neuropathy [7,12,13,17]. Findings of increased toe clearance [7], ankle dorsiflexion [12], and reduced toe trajectory variability [17], suggest that suprasensory vibrating insoles could play a role in reducing the risk of trips and falls in older people. Stimulating the foot using perceptible vibration has also shown to improve spatiotemporal gait patterns in healthy young adults [18] and people with Parkinson's disease [13]. These initial studies in sensate populations provide the basis to now investigate suprasensory vibrating insoles in those with neuropathy, as a potential early intervention to help ameliorate balance and gait impairments.

Vibrating insoles that stimulate the feet either below or above a user's sensory threshold can have a positive influence on balance [19] and walking [18] in healthy adults. There is lack of understanding concerning the underlying mechanisms by which vibrating insoles influence balance and walking. Enhanced neuromuscular control is one possible option, whereby substitute tactile input may help to maintain the normal flow of sensory information at the feet [20]. In neuropathy, this is critical to help prevent any compensatory muscle activity (e.g., higher co-activation) across the ankle and knee joints [21] that occurs to counter sensory loss, yet exacerbates postural instability. Applying vibratory stimuli to the foot can lead to more controlled activation of ankle-foot muscles [4], which help to regulate balance. Greater understanding of how vibrating insoles work is essential to inform the development of efficacious footwear innovations for people with and without neuropathy.

The aim of this study was to determine whether immediate wear of suprasensory vibrating insoles alters measures of balance (centre of pressure sway) and walking (spatiotemporal gait patterns, Timed Up and Go test) in people with DPN. We hypothesised that wearing vibrating insoles would lead to reductions in centre of pressure measures (sway velocity and elliptical area), improvements in spatiotemporal gait patterns (increased gait velocity and stride length, and reduced double-limb support and base of support), and a faster time to complete the Timed Up and Go Test, compared to wearing non-vibrating insoles. Secondary aims were to investigate if vibrating insoles alter the amplitude of ankle-foot muscle activity, as a potential underlying mechanism to any changes in standing balance. Specifically, we hypothesised that the amplitude of ankle-foot muscle activity would be lower when wearing vibrating insoles versus non-vibrating insoles.

## 2. Methods

### 2.1. Design

A randomised, single-blind, cross-over study of adults with DPN was conducted. Participant recruitment and assessments took place between March 2019 and April 2020. The study was approved by The University of Queensland (#2018002272) Human Research Ethics Committee and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent prior to their enrolment.

### 2.2. Participants

Men and women living in Brisbane (Australia), with a diagnosis of DPN were recruited through volunteer databases held at The University of Queensland, community organisations (e.g., Diabetes Queensland), and social media (e.g., Facebook). Participants were screened via an online questionnaire (SurveyMonkey®) or telephone to determine if they met the inclusion criteria: aged  $\geq 18$  years; diagnosis of DPN secondary to type 2 diabetes; ambulant over 20 m (with/without use of an assistive device); willing to wear insoles during laboratory assessments; adequate

comprehension of the English language. A diagnosis of DPN was determined using one of two methods, described in previous work [22]. Exclusion criteria were: current foot ulcers or lower limb injury; current use of prefabricated or prescription foot orthoses/insoles; Charcot arthropathy; neurological disease; cardiorespiratory conditions that limit ambulation; impaired cognition (Short Form Mini-Mental State Examination Score  $< 24$  [23]).

### 2.3. Shoe insoles

The vibrating insoles (Walk With Path, London) were constructed from a combination of foam and harder materials, with three pressure sensors located at the heel, first and fifth metatarsals (Fig. 1). The heel counter (3D printed hard case) housed a printed circuit board and battery. During balance assessments, the motors delivered intermittent perceptible vibrations when participants swayed anteriorly and posteriorly, and in doing so, activated the sensors at the forefoot and heel. During gait assessments, the motors delivered step-synchronised perceptible vibrations at heel strike and forefoot contact. The non-vibrating (control) insoles were the vibrating insoles with the stimulation turned off, and so, the same material construction. Assessments of balance and gait were conducted with participants wearing standard shoes (Volley International Canvas, Volley, China), into which the insoles were fitted, to control for any shoe/insole interactions. Prior to data collection, participants walked for 5-min wearing the standard shoes only, to allow for familiarisation.

### 2.4. Randomisation and blinding

Participants attended the Gait Laboratory at The University of Queensland on two separate occasions (2-h/occasion) to complete assessments wearing vibrating and non-vibrating insoles (one insole/occasion, randomised). The two testing sessions took place over a 14-day period, at the same time of day, with at least one day off between sessions. This washout period was used to minimise cross-over, as any prolonged or latent effects of the vibration stimuli (for participants randomised to the vibrating insoles first) could have contaminated the control condition, if assessed within the same session/day. The insole randomisation schedule was determined and managed by a research assistant who was only responsible for administering the insoles during testing sessions. All other investigators involved in data acquisition, processing and analysis were blind to the conditions. As it was not possible to blind participants to the perceptible vibrations, the full aims of the study were concealed. Participants were informed that the study aimed to investigate the effects of different insoles on balance and gait; it



Fig. 1. Vibrating shoe insoles.

was not made explicit that the vibrating insoles were the intervention of primary interest. Debriefing occurred upon completion of the study.

## 2.5. Laboratory assessments

Participants completed questionnaires reporting their demographic details (e.g., sex, height), medical history, medications, time since diagnosis of diabetes, and number of falls in the previous 12-months. Patient-reported outcomes concerning foot health specific quality of life and fear of falling were assessed using the Foot Health Status Questionnaire (FHSQ) [24] and Falls Efficacy Scale-International (FES-I) [25], respectively.

## 2.6. Foot posture, sensation, and proprioception

Standing foot posture was evaluated using the 6-item Foot Posture Index (FPI-6) to quantify overall foot shape [26]. Foot sensory function was assessed bilaterally using published methods [22]. Light-touch pressure sense (Semmes-Weinstein monofilaments, 1.65–6.65 gauges) was determined by recording the smallest monofilament perceived ( $\geq 2/3$  applications) at the hallux, first and fifth metatarsal head, heel, and dorsal foot [27]. Vibration sense (neurothesiometer, frequency 100 Hz, amplitude 0–50 V), was assessed at the hallux and first metatarsophalangeal joint (normal:  $\leq 25$  V; average of 3 readings/per site) [28]. Foot position awareness (proprioception) was assessed using the ankle joint angle reproduction test (in plantarflexion and dorsiflexion directions) [29]. Accuracy in joint positioning was determined by measuring the difference between the target and actual angles using an internet-based goniometer (average of 3 recordings/foot). Measures of foot posture, sensation, and proprioception were only taken at the first testing session and used to characterise the sample.

## 2.7. Balance

Double-limb standing was assessed using a Bertec® force plate (sampling rate 1000 Hz). Participants maintained standardised positioning (heels placed at 1/10th participants height apart, angled at 14 degrees [30]; arms hanging by their sides [31]) for 30 seconds. Balance was assessed whilst standing on a foam and firm surface, with eyes open and closed (randomised). For each balance condition, the average of three trials was calculated for each CoP outcome.

## 2.8. Ankle-foot muscle activity

Ankle-foot muscle activity was collected during balance assessments using bipolar surface electrography (EMG) electrodes (Trigno, Delsys, LA, USA). Following skin preparation, EMG electrodes were placed on both legs over soleus, medial gastrocnemius, tibialis anterior, and peroneus longus, according to the SENIAM recommendations [32]. For each muscle, maximal voluntary isometric contractions were performed to normalise EMG signals. During the balance tests, EMG signals were recorded at a sampling frequency of 1.000 Hz and filtered with a 10–500 Hz bandpass filter. Average EMG amplitude for each ankle-foot muscle was calculated across three trials per balance test condition.

## 2.9. Gait

Level-ground gait performance was evaluated whilst walking over a 10-m instrumented walkway (GAITRite® CIR Systems, USA). Start and finish lines were marked on the floor 1 m in front and behind the walkway to allow for acceleration and deceleration outside the walkway [33]. Five walking trials were completed at participants' self-selected pace, whilst wearing vibrating insoles and non-vibrating insoles. Participants also performed the Timed Up and Go (TUG) test, which measures gait speed during functionally important tasks [34]. Participants performed one practice trial to ensure familiarity with the TUG test,

prior to the actual test (one trial/insole).

## 2.10. Outcome measures

Balance outcomes included the difference in CoP total sway velocity (mm/s), anteroposterior (AP) and mediolateral (ML) sway velocity (mm/s), and elliptical area (mm<sup>2</sup>) between insoles. Ankle-foot EMG activity was calculated as root mean square (RMS) values measured over 30 s during standing balance tests and over 0.3 s during the maximal voluntary contractions. For each ankle-foot muscle, the EMG RMS measured during balance tests was normalized to the highest peak EMG RMS value recorded during the maximal voluntary contractions. Spatiotemporal gait parameters included velocity (cm/s), stride length (cm), double-limb support (%), and base of support (cm). Time taken to perform the TUG test was recorded (seconds).

## 2.11. Data analysis

Data analyses were conducted in a blinded manner, using Stata 17.0 (StataCorp. 2021). Plots of within-subject differences in log-transformed outcomes versus average were examined for heteroscedasticity before deciding to analyse natural log-transformed data. Symmetric percentage differences were calculated [35]. One sample t-tests were performed. The significance level was set to 0.05, with no adjustments for multiple testing. Gait and foot sensory outcomes were averaged across the right and left lower limbs.

## 3. Results

141 people with DPN were screened for eligibility. Thereafter, 24 people with DPN were enrolled into the study, of whom 18 participants completed all assessments. Demographic and clinical characteristics of the sample are displayed in Table 1.

### 3.1. Balance

When standing on a foam surface with eyes closed there was a significant between-condition difference for CoP elliptical area ( $P=0.03$ ) (Table 2). On average, participants demonstrated a 23 % reduction in the amount of CoP movement when wearing vibrating insoles (versus control), indicative of better balance. No other significant differences (all  $P$  values  $>0.13$ ) were observed for any of the other CoP measures of interest across the balance tests.

### 3.2. Ankle-foot muscle activity

When standing on a firm surface with eyes closed there was a significant difference for the amplitude of soleus ( $P=0.01$ ) and medial gastrocnemius ( $P=0.03$ ) activity (Table 3). Wearing vibrating insoles led to reduced ankle-foot muscle activity by 19–20 % on average. Similarly, an 18 % reduction in soleus activity ( $P=0.04$ ) was observed when standing on foam with eyes closed whilst wearing vibrating insoles versus the control insoles (Table 3). There were no further significant between-condition differences (all  $P$  values  $>0.09$ ) for the lower limb muscle activity across the balance tests (Table 3).

### 3.3. Gait

There were no significant between-condition differences (all  $P$  values  $>0.36$ ) for any of the laboratory (spatiotemporal measures) or clinical (TUG) gait outcomes when walking with vibrating insoles and non-vibrating insoles (Table 4).

## 4. Discussion

This study provides novel evidence that suggests wearing

**Table 1**  
Demographics and clinical characteristics for people with diabetic peripheral neuropathy who completed the study.

| Characteristic                            | Total Participants (N=18) |
|---|---------------------------|
| Age, years                                | 58 (9)                    |
| Male                                      | 10 (56 %)                 |
| Body mass, kg                             | 102 (22)                  |
| Height, m                                 | 1.74 (0.10)               |
| Body mass index, kg/m <sup>2</sup>        | 34 (6)                    |
| Years since diabetes diagnosis            | 15 (6–20)                 |
| Mini mental state examination             | 29.6 (1.0)                |
| Number of medications                     | 5.2 (2.4)                 |
| Types of medications                      |                           |
| • Cardiovascular (e.g. anti-hypertensive) | 67 %                      |
| • Cholesterol                             | (44 %)                    |
| • Diabetes                                | 78 %                      |
| • Gastrointestinal                        | (39 %)                    |
| • Pain (e.g. anti-inflammatory, opioid)   | (33 %)                    |
| • Psychological (e.g. anti-depressant)    | (28 %)                    |
| • Respiratory (e.g. bronchodilator)       | (6 %)                     |
| • Other (e.g. thyroid hormones)           | 6 (33 %)                  |
| Number of falls in previous 12 months     |                           |
| • 0                                       | 78 %                      |
| • 1                                       | (6 %)                     |
| • 2                                       | 3 (17 %)                  |
| Falls efficacy scale international        | 23 (8)                    |
| Foot health status questionnaire          |                           |
| • Foot pain                               | 68 (23)                   |
| • Foot function                           | 82 (24)                   |
| • Footwear                                | 49 (24)                   |
| • General foot health                     | 47 (21)                   |
| • General health                          | 54 (18)                   |
| • Physical activity                       | 77 (19)                   |
| • Social capacity                         | 80 (24)                   |
| • Vigour                                  | 50 (17)                   |
| Foot posture index                        |                           |
| <i>Left foot</i>                          |                           |
| • Supinated                               | 1 (6 %)                   |
| • Neutral                                 | 13 (72 %)                 |
| • Pronated                                | 4 (22 %)                  |
| <i>Right foot</i>                         |                           |
| • Supinated                               | 3 (17 %)                  |
| • Neutral                                 | 12 (67 %)                 |
| • Pronated                                | 3 (17 %)                  |
| Light touch pressure sense                |                           |
| • Great toe                               | 4.6 (1.1)                 |
| • 1st metatarsal head                     | 4.8 (0.7)                 |
| • 5th metatarsal head                     | 4.8 (0.8)                 |
| • Heel                                    | 4.9 (0.7)                 |
| • Dorsum of foot                          | 4.4 (1.0)                 |
| Vibration sense (V)                       |                           |
| • 1st metatarsal head                     | 9.5 (5.6)                 |
| • Medial malleoli                         | 10.6 (4.7)                |
| Proprioception (error)                    |                           |
| • Ankle joint position sense              | 3.5 (2.1)                 |
| Insole comfort (VAS rating scale)         |                           |
| • Vibrating insole                        | 7.9 (2.4)                 |
| • Non-vibrating insole                    | 8.3 (2.1)                 |

Data are presented as mean (SD) or median (IQR) for continuous measures, and n (%) for categorical measures.

suprasensory vibrating insoles for the first time may have the capacity to reduce CoP sway and ankle-foot muscle activity during challenging balance tasks in people with DPN. We found that whilst standing under conditions where vision and proprioceptive inputs were removed or distorted, vibratory stimulation led to a reduction in CoP elliptical area. Smaller elliptical area represents less variability in the CoP sway trace and is interpreted to suggest greater postural stability. Yet, variability in CoP measures can also play an important role in balance, allowing for the detection and exploration of stability boundaries to achieve steady posture [36]; it is unclear if a reduction (or increase) in elliptical area infers greater stability. The current findings are congruent with previous work on vibrating insoles on two counts; the first being reduced CoP measures when people with DPN wear vibrating insoles for the first time

**Table 2**  
Centre of pressure measures for vibrating insoles and non-vibrating insoles, for people with diabetic peripheral neuropathy who completed all balance tests, including two surface and two vision conditions (N=18).

| Balance Measure                              | Vibrating Insole | Non-Vibrating Insole | % Difference (Vibrating vs Non-Vibrating) |           |         |
|--|------------------|----------------------|---|-----------|---------|
|  | Mean (SD)        | Mean (SD)            | Mean (SD)                                 | 95 % CI   | P value |
| <i>Firm Surface, Eyes Open</i>               |                  |                      |   |           |         |
| Total Sway Velocity (mm/s)                   | 14.3 (7.3)       | 12.8 (3.0)           | 4 (26)                                    | -9–17     | 0.54    |
| AP Sway Velocity (mm/s)                      | 11.9 (4.9)       | 11.5 (2.8)           | 0 (18)                                    | -9–9      | 0.97    |
| ML Sway Velocity (mm/s)                      | 5.2 (5.2)        | 4 (1.1)              | 11 (43)                                   | -11–32    | 0.31    |
| Elliptical Area (mm <sup>2</sup> )           | 267 (267)        | 199 (172)            | 21 (66)                                   | -11–54    | 0.19    |
| <i>Firm Surface, Eyes Closed</i>             |                  |                      |   |           |         |
| Total Sway Velocity (mm/s)                   | 23.6 (16.1)      | 23.8 (8.6)           | -8 (21)                                   | -18–3     | 0.14    |
| AP Sway Velocity (mm/s)                      | 21.7 (15.1)      | 21.9 (8.1)           | -8 (21)                                   | -18–3     | 0.13    |
| ML Sway Velocity (mm/s)                      | 6.2 (3.8)        | 6.3 (2.4)            | -7 (24)                                   | -19–5     | 0.23    |
| Elliptical Area (mm <sup>2</sup> )           | 332 (225)        | 333 (194)            | -3 (44)                                   | -24–19    | 0.80    |
| <i>Foam Surface, Eyes Open</i>               |                  |                      |   |           |         |
| Total Sway Velocity (mm/s)                   | 24.3 (10.3)      | 23.6 (7.0)           | 1 (20)                                    | -9–11     | 0.86    |
| AP Sway Velocity (mm/s)                      | 21.2 (9.7)       | 20 (6.3)             | 3 (20)                                    | -7–13     | 0.51    |
| ML Sway Velocity (mm/s)                      | 8.6 (3.1)        | 9.1 (2.9)            | -8 (21)                                   | -18–3     | 0.15    |
| Elliptical Area (mm <sup>2</sup> )           | 743 (346)        | 748 (218)            | -6 (36)                                   | -24–11    | 0.46    |
| <i>Foam Surface, Eyes Closed<sup>a</sup></i> |                  |                      |   |           |         |
| Total Sway Velocity (mm/s)                   | 48.5 (22.2)      | 49.3 (20.2)          | -4 (22)                                   | -16–7     | 0.42    |
| AP Sway Velocity (mm/s)                      | 40.7 (17.9)      | 41.8 (15.9)          | -5 (21)                                   | -16–5     | 0.31    |
| ML Sway Velocity (mm/s)                      | 19.2 (10.7)      | 18.9 (10.0)          | -3 (33)                                   | -20–14    | 0.74    |
| Elliptical Area (mm <sup>2</sup> )           | 1927 (1349)      | 2239 (1356)          | -23 (41)                                  | -44 to -2 | 0.03    |

<sup>a</sup> Data represents N=17, due to the removal of an outlier.

**Table 3**

Normalised EMG amplitude (mV) for lower limb muscles (average of right and left lower limbs) during balance tests wearing vibrating insoles and non-vibrating insoles, for people with diabetic peripheral neuropathy who completed all assessments (N=18).

| Muscle                                       | Vibrating Insole |              | Non-Vibrating Insole |           | % Difference (Vibrating vs Non-Vibrating) |         |
|--|------------------|--------------|----------------------|-----------|---|---------|
|  | Mean (SD)        | Mean (SD)    | Mean (SD)            | Mean (SD) | 95 % CI                                   | P value |
| <b>Firm Surface, Eyes Open</b>               |                  |              |                      |           |   |         |
| Soleus                                       | 21.7 (8.2)       | 22.6 (6.6)   | -8 (26)              | -21–5     | 0.19                                      |         |
| Medial Gastrocnemius                         | 11.1 (5.2)       | 12.2 (4.9)   | -12 (37)             | -30–6     | 0.19                                      |         |
| Tibialis Anterior                            | 2.4 (2.4)        | 2.3 (1.5)    | -5 (81)              | -45–36    | 0.81                                      |         |
| Peroneus Longus                              | 5.64 (3.08)      | 6.85 (4.47)  | -16 (50)             | -41–9     | 0.20                                      |         |
| <b>Firm Surface, Eyes Closed</b>             |                  |              |                      |           |   |         |
| Soleus                                       | 22.3 (9.3)       | 25.9 (8.6)   | -19 (29)             | -34 to -4 | 0.01                                      |         |
| Medial Gastrocnemius                         | 12.8 (5.3)       | 15.6 (6.3)   | -20 (35)             | -37 to -3 | 0.03                                      |         |
| Tibialis Anterior                            | 2.9 (2.1)        | 2.8 (2.4)    | 5 (49)               | -20–29    | 0.70                                      |         |
| Peroneus Longus                              | 6.82 (3.10)      | 8.15 (5.02)  | -13 (52)             | -39–13    | 0.32                                      |         |
| <b>Foam Surface, Eyes Open</b>               |                  |              |                      |           |   |         |
| Soleus                                       | 21.1 (8.8)       | 22.9 (9.0)   | -10 (36)             | -28–8     | 0.26                                      |         |
| Medial Gastrocnemius                         | 13.7 (4.9)       | 14.6 (5.8)   | -4 (35)              | -22–13    | 0.60                                      |         |
| Tibialis Anterior                            | 4.7 (3.3)        | 5.4 (5.3)    | -3 (63)              | -34–28    | 0.85                                      |         |
| Peroneus Longus                              | 9.77 (4.48)      | 9.79 (3.07)  | -8 (49)              | -32–16    | 0.50                                      |         |
| <b>Foam Surface, Eyes Closed<sup>a</sup></b> |                  |              |                      |           |   |         |
| Soleus                                       | 22.1 (11.4)      | 26.8 (16.5)  | -18 (35)             | -36 to -1 | 0.04                                      |         |
| Medial Gastrocnemius                         | 17 (5.3)         | 19.2 (5.7)   | -13 (30)             | -29–2     | 0.09                                      |         |
| Tibialis Anterior                            | 10.9 (7.0)       | 11.4 (9.4)   | 3 (44)               | -20–26    | 0.77                                      |         |
| Peroneus Longus                              | 12.14 (5.23)     | 11.91 (4.01) | -2 (38)              | -21–17    | 0.84                                      |         |

<sup>a</sup> Data represents N=17, due to the removal of an outlier.

**Table 4**

Laboratory and clinical gait measures for vibrating insoles and non-vibrating insoles, for people with diabetic peripheral neuropathy who completed all assessments (N=18).

| Gait Measure              | Vibrating Insole |            | Non-Vibrating Insole |         | % Difference (Vibrating vs Non-Vibrating) |  |
|---------------------------|------------------|------------|----------------------|---------|---|--|
|                           | Mean (SD)        | Mean (SD)  | Mean (SD)            | 95 % CI | P value                                   |  |
| Velocity (cm/s)           | 121 (16)         | 122 (17)   | -1 (8)               | -5–3    | 0.59                                      |  |
| Stride Length (cm)        | 135 (14)         | 135 (14)   | 0 (4)                | -2–2    | 0.83                                      |  |
| Double-Limb Support (%)   | 9.7 (2.2)        | 9.9 (2.3)  | -3 (12)              | -8–3    | 0.36                                      |  |
| Base of Support (cm)      | 30 (2.5)         | 29.9 (2.3) | 0 (5)                | -2–2    | 0.96                                      |  |
| Timed Up and Go (seconds) | 7.5 (1.4)        | 7.4 (1.4)  | 1 (11)               | -4–6    | 0.73                                      |  |

[4,11,14]. Second, the effects of vibrating insoles on CoP measures become most evident during higher-level balance tasks, for example by adding an unstable supporting surface or cognitive load [11]. Our finding of reduced elliptical area should be interpreted with caution, as it is only one of 16 CoP outcomes that reached significance and the p-value was not very small. Whilst a >20 % reduction in CoP elliptical area is clinically meaningful, only a little evidence of possible clinical benefit was found in this small study.

Contrary to our hypotheses, wearing vibrating insoles did not alter measures of walking in people with DPN. This finding conflicts with existing work that reports improved spatiotemporal gait measures in healthy young adults [18] and people with Parkinson’s disease [13], when wearing suprasensory vibrating insoles. Differences in gait assessment could explain this discrepancy; in this study participants walked a short distance (6–10 m) over level-ground, whilst others have implemented more demanding tasks, including walking on an inclined treadmill [18] and over a greater distance [13]. Therefore, we propose that the effects of vibrating insoles may only become apparent when the gait task is sufficiently demanding for ambulant populations. Further, suprasensory vibrating insoles have been shown to alter gait kinematics

(e.g., improved toe clearance) that could translate to a reduced risk of tripping [7,12,17]. It is possible that vibrating insoles may bring about changes in other measures of walking (e.g., joint kinetics) that were beyond the scope of this study.

Secondary aims were to explore underlying mechanisms by which vibrating insoles may bring about their effects on balance, specifically ankle-foot muscle control. When standing with eyes closed, we observed significant reductions in the amplitude of plantar flexor activity, when the vibrational stimuli was active. Delivering perceptible vibrations to the feet, specifically when vision is occluded, may facilitate sensory re-weighting towards the augmented proprioceptive cues, leading to more efficient control of lower limb muscles. Specifically, a lower amplitude of ankle-foot muscle activity may enhance balance, by reducing the mechanical contribution for postural control and excessive energy expenditure, which have previously been associated with postural instability in older people with a history of falls [37].

To date, only one other study [4] has explored the effects of vibrating insoles on lower limb muscle activity during balance in healthy adults who underwent an ice intervention designed to simulate diminished foot sensation. Applying subsensory noise to the feet appeared to help restore muscle activity to a level commensurate to that when foot sensation was intact [4]. Further studies suggest that altering sensory load to plantar cutaneous receptors, through ice interventions or sensory-stimulating devices, can regulate the intensity and timing of lower limb muscle activity for balance and gait [38–40].

**4.1. Study limitations**

There were several study limitations. First, participants performed assessments wearing vibrating and non-vibrating insoles on two separate occasions, with at least a one day washout period. However, it is unclear if, and for how long, latent sensory effects are experienced after exposure to vibrating insoles. Second, walking was not assessed under conditions that simulate free-living, which may be more sensitive to detect intervention effects. This is important to consider in the context of the sample who demonstrated minimal walking impairment. Third, participants wore the insoles during assessments only, allowing us to observe immediate effects. Yet, the beneficial effects of vibrating insoles may accrue, and additional benefits may emerge, with long-term wear. Fourth, vibrating insoles could improve measures that were beyond the scope of this work, e.g., reactive balance.

## 5. Conclusions

Wearing vibrating insoles may help to facilitate more efficient lower limb muscle activity during challenging balance tasks, which could enhance upright stability, in people with DPN. Specifically, insoles that deliver perceptible vibrations may have the capacity to alter plantar sensory loads that play a critical role in regulating neuromuscular control for balance. Changes in the amplitude of lower limb muscle activity may be one underlying mechanism by which vibrating insoles bring about their effects in people with diminished foot sensation. The current findings offer new insight into sensory-stimulating insole design features that can be used to help inform the development of innovative balance rehabilitation strategies. For people with DPN, a new evidence-based footwear device could help to facilitate safe, active, and independent living. Further exploration of the potential therapeutic effects of vibrating insoles following long-term wear in the community, across a wider range of functional, behavioural, and neurophysiological measures, is warranted.

## Funding

This work was supported by a Global Connections Fund Bridging Grant (#413816012) and Ascensia Diabetes Care.

## Declaration of Competing Interest

The authors have no conflicts to declare. This work was supported by a Global Connections Fund Bridging Grant (#413816012) and Ascensia Diabetes Care. Vibrating and non-vibrating insoles investigated in this study were supplied by Walk With Path (London, UK). The funding bodies and Walk With Path were not involved in any aspect of data acquisition, analysis, or interpretation, or preparation of this paper. Each of the authors has read and concurs with the content in the final manuscript. The material within has not been and will not be submitted for publication elsewhere except as an abstract.

## References

- P.R. Cavanagh, J.A. Derr, J.S. Ulbrecht, R.E. Maser, T.J. Orchard, Problems with gait and posture in neuropathic patients with insulin-dependent diabetes mellitus, *Diabet. Med.* 9 (5) (1992) 469–474.
- S. Ahmed, A. Barwick, P. Butterworth, S. Nancarrow, Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review, *J. Foot Ankle Res.* 13 (30) (2020).
- J. Burns, C. Wegener, L. Begg, M. Vicaretti, J. Fletcher, Randomized trial of custom orthoses and footwear on foot pain and plantar pressure in diabetic peripheral arterial disease, *Diabet. Med.* 26 (9) (2009) 893–899.
- W.M. Chen, J.W. Li, X. Geng, C. Wang, L. Chen, X. Ma, The potential influence of stochastic resonance vibrations on neuromuscular strategies and center of pressure sway during single-leg stance, *Clin. Biomech.* 77 (2020) 105069.
- A.M. Galica, H.G. Kang, A.A. Priplata, S.E. D'Andrea, O.V. Starobinets, F.A. Sorond, et al., Subsensory vibrations to the feet reduce gait variability in elderly fallers, *Gait Posture* 30 (3) (2009) 383–387.
- L.A. Lipsitz, M. Lough, J. Niemi, T. Trivison, H. Howlett, B. Manor, A shoe insole delivering subsensory vibratory noise improves balance and gait in healthy elderly people, *Arch. Phys. Med. Rehabil.* 96 (3) (2015) 432–439.
- P. Pathak, J. Moon, S.G. Roh, C. Roh, Y. Shim, J. Ahn, Application of vibration to the soles reduces minimum toe clearance variability during walking, *PLoS One* 17 (1) (2022) e0261732.
- A.A. Priplata, J.B. Niemi, J.D. Harry, L.A. Lipsitz, J.J. Collins, Vibrating insoles and balance control in elderly people, *Lancet* 362 (9390) (2003) 1123–1124.
- M. Bagherzadeh Cham, M.A. Mohseni-Bandpei, M. Bahramizadeh, B. Forogh, S. Kalbasi, A. Biglarian, Effects of vibro-medical insoles with and without vibrations on balance control in diabetic patients with mild-to-moderate peripheral neuropathy, *J. Biomech.* 103 (2020) 109656.
- I. Bourdel-Marchasson, S.C. Regueme, M. Kelson, J. Poustis, P. Barralon, O. Laosa, et al., A therapeutic vibrating insole device for postural instability in older people with type 2 diabetes: a randomized control study, *Diabetes Ther.* 13 (5) (2022) 995–1006.
- J.M. Hijmans, J.H. Geertzen, W. Zijlstra, A.L. Hof, K. Postema, Effects of vibrating insoles on standing balance in diabetic neuropathy, *J. Rehabil. Res. Dev.* 45 (9) (2008) 1441–1449.
- J.N. Liang, K.Y. Ho, V. Hung, A. Reilly, R. Wood, N. Yuskov, et al., Effects of augmented somatosensory input using vibratory insoles to improve walking in individuals with chronic post-stroke hemiparesis, *Gait Posture* 86 (2021) 77–82.
- P. Novak, V. Novak, Effect of step-synchronized vibration stimulation of soles on gait in Parkinson's disease: a pilot study, *J. Neuroeng. Rehabil.* 4 (3) (2006) 9.
- A.A. Priplata, B.L. Patritti, J.B. Niemi, R. Hughes, D.C. Gravelle, L.A. Lipsitz, et al., Noise-enhanced balance control in patients with diabetes and patients with stroke, *Ann. Neurol.* 59 (1) (2006) 4–12.
- S.C. Regueme, C. Cowtan, M.Y. Sedgelmaci, M. Kelson, J. Poustis, L. Rodriguez-Mañas, et al., A therapeutic insole device for postural stability in older people with type 2 diabetes. A feasibility study (SENSOLE Part I), *Front. Med.* 6 (2019) 127.
- A. Priplata, J. Niemi, M. Salen, J. Harry, L.A. Lipsitz, J.J. Collins, Noise-enhanced human balance control, *Phys. Rev. Lett.* 89 (23) (2002) 238101.
- S. Yamashita, K. Igarashi, N. Ogihara, Reducing the foot trajectory variabilities during walking through vibratory stimulation of the plantar surface of the foot, *Sci. Rep.* 11 (1) (2021) 7125.
- H. Xie, H. Liang, J.H. Chien, Different types of plantar vibration affect gait characteristics differently while walking on different inclines, *PeerJ* 11 (2023) e14619.
- G. Severini, E. Delahunt, Effect of noise stimulation below and above sensory threshold on postural sway during a mildly challenging balance task, *Gait Posture* 63 (2018) 27–32.
- E.P. Zehr, T. Nakajima, T. Barss, T. Klarnar, S. Miklosovic, R.A. Mezzarane, et al., Cutaneous stimulation of discrete regions of the sole during locomotion produces sensory steering of the foot, *BMC Sports Sci. Med. Rehabil.* 6 (33) (2014).
- O.Y. Kwon, S.D. Minor, K.S. Maluf, M.J. Mueller, Comparison of muscle activity during walking in subjects with and without diabetic neuropathy, *Gait Posture* 18 (1) (2003) 105–113.
- A.L. Hatton, E.M. Gane, J.N. Maharaj, J. Burns, J. Paton, G. Kerr, et al., Textured shoe insoles to improve balance performance in adults with diabetic peripheral neuropathy: study protocol for a randomised controlled trial, *BMJ Open* 9 (2019) e026240.
- M.F. Folstein, S.E. Folstein, P.R. McHugh, "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician, *J. Psychiatr. Res.* 12 (3) (1975) 189–198.
- P.J. Bennett, C. Patterson, S. Wearing, T. Baglioni, Development and validation of a questionnaire designed to measure foot-health status, *J. Am. Podiatr. Med. Assoc.* 88 (9) (1998) 419–428.
- 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 (6) (2005) 614–619.
- A.C. Redmond, J. Crosbie, R.A. Ouvrier, Development and validation of a novel rating system for scoring standing foot posture: The Foot Posture Index, *Clin. Biomech.* 21 (1) (2006) 89–98.
- D.G. Armstrong, L.A. Lavery, S.A. Vela, T.L. Quebedeaux, J.G. Fleischli, Choosing a practical screening instrument to identify patients at risk for diabetic foot ulceration, *Arch. Intern. Med.* 158 (3) (1998) 289–292.
- J.L. Richard, L. Reilhes, S. Buvry, M. Goletto, J.L. Faillie, Screening patients at risk for diabetic foot ulceration: a comparison between measurement of vibration perception threshold and 10-g monofilament test, *Int. Wound J.* 11 (2014) 147–151.
- J.L. Riskowski, A.E. Mikesky, R.E. Bahamonde, T.V. Alvey, D.B. Burr, Proprioception, gait kinematics, and rate of loading during walking: are they related? *J. Musculoskelet. Neuron Interact.* 5 (4) (2005) 379–387.
- W.E. McIlroy, B.E. Maki, Preferred placement of the feet during quiet stance: development of a standardized foot placement for balance testing, *Clin. Biomech.* 12 (1997) 66–70.
- A.L. Hatton, J. Dixon, K. Rome, D. Martin, Standing on textured surfaces: effects on standing balance in healthy older adults, *Age Ageing* 40 (2011) 363–368.
- H.J. Hermens, B. Freriks, C. Disselhorst-Klug, G. Rau, Development of recommendations for SEMG sensors and sensor placement procedures, *J. Electromyogr. Kinesiol.* 10 (5) (2000) 361–374.
- P. Batey, K. Rome, P. Finn, N. Hanchard, Assessing reliability of measurement of gait velocity, *Physiotherapy* 89 (5) (2003) 313–317.
- A. Shumway-Cook, S. Brauer, M. Woollacott, Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test, *Phys. Ther.* 80 (9) (2000) 896–903.
- T.J. Cole, Sympercents: symmetric percentage differences on the 100 log(e) scale simplify the presentation of log transformed data, *Stat. Med.* 19 (2000) 3109–3125.
- R.E.A. van Emmerik, E.E.H. van Wegen, On variability and stability in human movement, *J. Appl. Biomech.* 16 (4) (2000) 394–406.
- T. Cattagni, G. Scaglioni, D. Laroche, V. Gremaux, A. Martin, The involvement of ankle muscles in maintaining balance in the upright posture is higher in elderly fallers, *Exp. Gerontol.* 77 (2016) 38–45.
- M.A. Nurse, B.M. Nigg, The effect of changes in foot sensation on plantar pressure and muscle activity, *Clin. Biomech.* 16 (9) (2001) 719–727.
- K.J. Kelleher, W.D. Spence, S. Solomonidis, D. Apatsidis, The effect of textured insoles on gait patterns of people with multiple sclerosis, *Gait Posture* 32 (1) (2010) 67–71.
- K.A. Robb, J.D. Hyde, S.D. Perry, The role of enhanced plantar-surface sensory feedback on lower limb EMG during planned gait termination, *Somatosens. Mot. Res.* 38 (2) (2021) 146–156.