

Effects of vibrating insoles on standing balance in diabetic neuropathy

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Abstract—This study investigated the effects on standing balance of random vibrations applied to the plantar side of the feet by vibrating insoles in subjects with neuropathy and nondisabled subjects. In four different conditions (eyes open or closed and with or without an attention-demanding task [ATD]), subjects with neuropathy secondary to diabetes mellitus ($n = 17$) and nondisabled subjects ($n = 15$) stood for 60 s on vibrating insoles placed on a force plate. During each condition, the insoles were turned on for 30 s and off for 30 s (random order). The calculated balance measures were mean velocity of the center of pressure displacements and root-mean-square of the velocity of these displacements in the anteroposterior and mediolateral directions. In subjects with neuropathy, an interaction effect between vibration and an ADT was found for balance. No effects of vibration on balance were found in nondisabled subjects. Vibrating insoles improved standing balance in subjects with neuropathy only when attention was distracted. Improvement of the insoles and their activation is needed to make their implementation in daily living possible and effective.

Key words: balance, center of pressure displacement, diabetes mellitus, neuropathy, noise, postural instability, rehabilitation, standing balance, stochastic resonance, vibrating insoles.

INTRODUCTION

In nondisabled humans, balance is under constant control. Several sensory mechanisms play a role in the control of balance. Information from the somatosensory, visual, and vestibular systems is used for the detection of postural

changes [1–3], and attention plays a crucial part as well [4]. The somatosensory system can be subdivided into the tactile and the proprioceptive systems. Feedback from both these systems plays a part in the control of balance [3,5–6].

The tactile system provides the central nervous system (CNS) with information concerning the sense of touch. Mechanoreceptors such as Meissner's corpuscles, Pacinian corpuscles, Merkel's disks, and Ruffini endings are responsible for the detection of tactile input. Mechanoreceptors situated on the plantar side of the feet provide the CNS with information concerning the pressure distribution under the feet [3]. During stance, shear stresses and changes in pressure are related to changes in the center of mass position, which are mediated by the plantar mechanoreceptors. Feedback concerning these changes is important for the maintenance of balance during standing.

Abbreviations: ADT = attention-demanding task, ANOVA = analysis of variance, AP = anteroposterior, CNS = central nervous system, COP = center of pressure, DM = diabetes mellitus, ML = mediolateral, MTP = metatarsophalangeal joint, RMS = root-mean-square, SR = stochastic resonance, SWM = Semmes-Weinstein monofilament, UMCG = University Medical Center Groningen.

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The proprioceptive system can be seen as the system that provides the CNS with information concerning angles and angular changes of the joints. Muscle spindles, Golgi tendon organs, and joint afferents play a part in the detection of joint angles and angular velocities during both the stance and swing phases of walking [6]. In nondisabled people, the proprioceptive system seems to play only a minor role in balance control [7].

When problems arise in the conduction of somatosensory information to the CNS, problems in balance control are likely to occur, especially when the availability of compensatory mechanisms is limited. In persons with neuropathy, neither tactile nor proprioceptive information is conducted to the CNS with as much intensity as in persons without neuropathy. This reduction in somatosensory perception has detrimental effects on postural stability, resulting in an increased risk for falling [8–10]. Appliances for the foot (which do or do not encompass the ankle) may compensate for these detrimental effects [7].

Peripheral neuropathy is a common problem in persons with diabetes mellitus (DM). About one-third of persons with DM have peripheral neuropathy. Longer disease duration is one of the factors associated with a higher incidence of neuropathy [11]. In diabetic neuropathy, both large fibers and small fibers may be affected. In people with impaired tactile sensation, the large fibers are affected [12]. Therefore, in this study, we focus on large-fiber neuropathy only.

A new technique that may improve tactile, and possibly proprioceptive, feedback is the application of noise to the plantar surface of the feet [13–16]. By adding subthreshold electrical [13] or mechanical noise (vibration with a randomly varying frequency) [14–16] to a subthreshold sensory input, the sensory threshold may be crossed. In this way, a signal that is not detected during normal circumstances can be detected. The subthreshold noise signal can enhance the tactile sensation of changes in pressure under the foot, resulting in more sensitive detection of these pressure changes. More sensitive detection may result in an earlier reaction to the change in pressure, which may result in better balance performance. The mechanism by which signal detection is improved by noise is called stochastic resonance (SR) [17]. A few studies have shown that the application of noise can improve tactile sensitivity [18] and balance in nondisabled adolescents, elderly adults, people with diabetic neuropathy, and those with stroke [13–16]. In **Figure 1**, the mechanism of SR is explained.

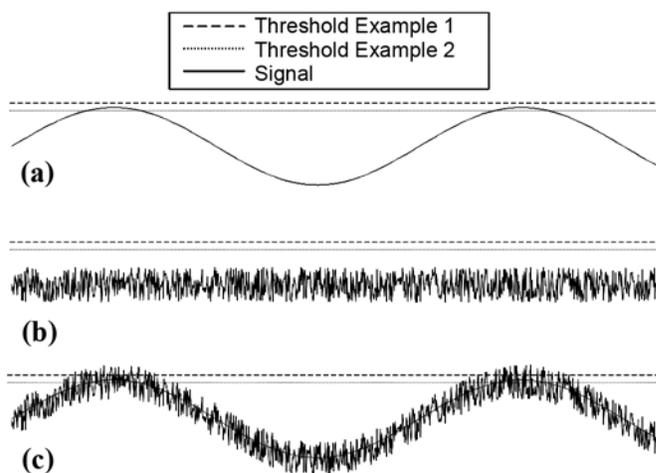


Figure 1.

Stochastic resonance. (a) Sinusoid signal (solid line) with two examples of threshold (dashed line which is not reached and dotted line which is reached). (b) Noise signal below both examples of thresholds. (c) Mechanism of stochastic resonance. When the noise signal is added to the sinusoid signal, two important phenomena are noticed: (1) signal reaches threshold example 1 (dashed line), which is not reached under normal circumstances, and (2) signal reaches threshold example 2 (dotted line) earlier than under normal circumstances.

In the present study, we assessed the effects of vibrating insoles on balance in persons with peripheral neuropathy secondary to DM and in nondisabled subjects. Vibrating insoles were designed in which random vibrations are applied to the plantar surface of the feet by piezoelectric elements [19]. Piezoelectric elements are thin and relatively cheap and therefore ideal for application in an insole without appreciably increasing its thickness.

METHODS

Subjects

We screened the medical records of all persons with DM (type 1 and 2) between 40 and 60 years of age who visited the outpatient clinics of the Diabetes Center of the University Medical Center Groningen (UMCG) between June 2006 and April 2007. This age range was chosen because persons with DM usually do not develop neuropathy before 40 years of age. Older people without DM may develop plantar surface insensitivity [20]. We expected that in a control group with a maximum age of 60 years, sensory problems would be uncommon and the sensory

problems in the study group would be secondary to DM. When the presence of neuropathy was mentioned in the medical record, the individual was invited to participate if he or she met the other inclusion criteria. All participants signed an informed consent. The procedures were approved and registered by the medical ethics committee of the UMCG.

To include or exclude a patient, we tested for the presence of neuropathy by pressing a 10 g Semmes-Weinstein monofilament (SWM) (North Coast Medical, Inc; Morgan Hill, California) [21] three times at each test location (first toe, first metatarsophalangeal joint [MTP1], MTP5, and heel) [20]. Neuropathy was defined as inability to feel the SWM (for all three test trials) at four or more of the eight test locations [21]. Exclusion criteria for both groups were (1) ulcerations and/or infections on the plantar surface of the feet, (2) (partial) foot or toe amputation, (3) inability to stand without aid, (4) inability to understand the instructions of the examiner, (5) disorder of the musculoskeletal system (unrelated to DM, e.g., rheumatoid arthritis), and (6) severe visual impairment. Exclusion criteria for the nondisabled subjects were (1) DM, (2) inability to feel the 10 g SWM on more than two test locations [21], and (3) inability to report correctly whether a tuning fork positioned at the medial side of MTP1 of both feet was vibrating [21]. Vibrotactile sensitivity was part of the inclusion criteria for nondisabled people in order to be sure that the control group had no sensory problems.

A total of 45 persons with DM was selected based on their medical record. Of these, 18 did not participate for various reasons (e.g., physician reported an exclusion criterion, patient did not want to participate). The other 27 persons with DM were tested. We excluded 10 for various reasons (no neuropathy $n = 6$, inability to stand without aid with the eyes closed $n = 2$, toe amputation $n = 1$, severe visual impairment $n = 1$). In addition to the included subjects with neuropathy ($n = 17$), we included 15 nondisabled subjects, matched by age and sex.

Procedures

After inclusion, all subjects' vibrotactile sensitivity was tested. To test the tactile sensitivity of the plantar surface of the feet in both nondisabled subjects and subjects with neuropathy, we used a set of 20 SWMs that varied between 0.008 g and 300 g [22]. The SWM was pressed to the skin three times at each location (first toe, MTP1, and MTP5). The SWM with the smallest buckling

force that could be located correctly at least two of the three times was noted. To test vibrotactile sensitivity of the subjects, we used a 128 Hz tuning fork positioned at MTP1 [23]. The subjects had to report whether the tuning fork was vibrating or not. Vibrotactile sensitivity was tested so we could describe additional characteristics of the subjects with neuropathy.

After the sensitivity tests, subjects were asked to stand on a pair of vibrating insoles that were attached to a force plate (Bertec 4060, Bertec Corporation; Columbus, Ohio) with double-sided tape. The insoles were made in five sizes, and the best fitting pair of insoles for each subject was chosen. The distance between the heels was 5 cm, and the insoles were positioned in 15° external rotation. This is the foot position used in platform stabilometry [24]. While the subject was standing on the insoles, we separately determined the perception thresholds for the noise signal for both feet. The amplitude of the noise was gradually increased by the examiner, and the subject had to report when the noise signal was perceived. Then, the amplitude was set at 90 percent of the tactile threshold for each individual subject (therefore, the vibrations were not perceptible). Previous research reported on a 90 percent threshold [15–16]. In this way, subjects were blinded to the intervention. When the threshold could not be reached, the maximum amplitude that could be applied to the piezoelectric elements (120 V) was chosen. Subject characteristics, including vibrotactile sensitivity and amplitude of the insole vibrations, are reported in **Table 1**.

The measurement protocol consisted of five trials in which the subjects were asked to stand on the vibrating insoles for 60 s. During the first and fifth trial, the subjects stood with their eyes open looking straight ahead. The other three trials consisted of subjects standing with their eyes closed, performing an attention-demanding task (ADT), and completing a combination of both. These three trials were presented in random order. The ADT was a calculation task, consisting of continuously subtracting six from a random number. Throughout each 60 s trial, the vibrating insoles were turned on during either the first or second 30 s (randomly chosen). During the other 30 s, the insoles were turned off. Because the vibrations of the insoles were audible to the subjects, we applied a sound to both ears using earphones to ensure the subjects were unaware of whether the vibrations were turned on or off. The subjects were allowed to rest after every trial for a maximum of 2 minutes.

Table 1.

Characteristics and test results of subjects.

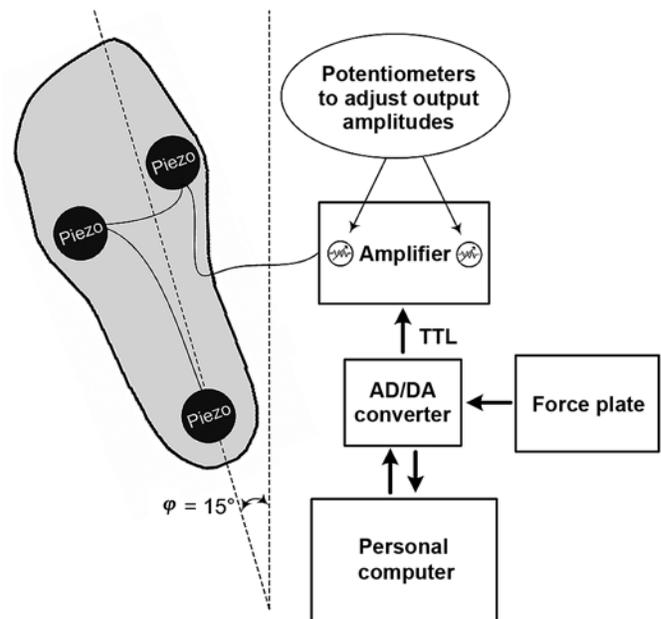
Variable	Neuropathy (<i>n</i> = 17)		Nondisabled (<i>n</i> = 15)	
	Left	Right	Left	Right
Age (yr), Mean ± SD	52.1 ± 6.0		51.8 ± 5.6	
Female, % (<i>n</i>)	53 (9)		53 (8)	
Weight (kg), Mean ± SD	92.6 ± 23.1		78.0 ± 12.1	
DM Type 1, % (<i>n</i> type 1; <i>n</i> type 2)	65 (11 type 1; 6 type 2)		—	
Correctly Located 5.07/10 g SWM 1st Toe, % (<i>n</i>)	12 (2)	6 (1)	100 (15)	100 (15)
Correctly Located 5.07/10 g SWM MTP1, % (<i>n</i>)	0 (0)	6 (1)	100 (15)	100 (15)
Correctly Located 5.07/10 g SWM MTP5, % (<i>n</i>)	18 (3)	6 (1)	100 (15)	100 (15)
Correctly Located 5.07/10 g SWM Heel, % (<i>n</i>)	12 (2)	22 (4)	93 (14)	93 (14)
Thinnest Detected SWM 1st Toe (g), Median (range)	60 (6–xx)	60 (6–xx)	1.4 (0.16–4)	1.4 (0.16–4)
Thinnest Detected SWM MTP1 (g), Median (range)	100 (15–xx)	60 (10–xx)	2 (0.6–8)	1.4 (0.16–6)
Thinnest Detected SWM MTP5 (g), Median (range)	60 (6–300)	26 (10–xx)	2 (0.6–8)	2 (0.6–4)
Thinnest Detected SWM Heel (g), Median (range)	60 (8–xx)	26 (2–xx)	4 (1.4–15)	4 (1–15)
Correctly Reported 128 Hz Tuning Fork MTP1, % (<i>n</i>)	24 (4)	12 (2)	100 (15)	87 (13)
Vibration Amplitude (V), Median (range)	120 (42–120)	120 (42–120)	47 (22–120)	48 (24–120)

DM = diabetes mellitus, MTP = metatarsophalangeal joint, SD = standard deviation, SWM = Semmes-Weinstein monofilaments, xx = thickest (6.67/300 g) SWM could not be detected.

Vibrating Insoles

The vibrating insoles consisted of a cork sole with three built-in piezoelectric elements (piezo element EPZ35-MS29, 35 mm diameter, Karl/Heinz Mauz GMBH; Ostfildern, Germany) at MTP1, MTP5, and the heel; the sole was covered with a thin leather layer. We chose the position of the actuators in order to apply the noise to the anterior and posterior supporting areas. The total thickness of the insole was 6 mm. The piezoelectric elements were driven by a custom-built amplifier. Input to the amplifier was an on/off signal, changing between 0 and 5 V at random intervals between 2 and 40 ms. This signal was generated on a personal computer and output to the amplifier via the digital output of a USB-DAQ AD/DA card (USB-6008, National Instruments, Corp; Austin, Texas). The amplitude of the amplifier output signal could be manually adjusted from 0 to 120 V for each insole individually, but the input for the three actuators in a single insole was identical. Taking into account the limited frequency response of the actuators (not specified by the manufacturer), we found that this resulted in a random noise signal with a nominal bandwidth from 25 to 500 Hz and adjustable amplitude. The vibrating insole configuration is described in **Figure 2**.

The analog signals from the force plate (Berotec 4060) were acquired by the AD/DA channels of the USB-DAQ card. Signal generation and data acquisition were done with custom LabVIEW software (version 8.0, National

**Figure 2.**

Schematic representation of vibrating insoles and their activation. Via portable USB-DAQ AD/DA card, a transistor-to-transistor logic (TTL) input signal of varying frequency was provided to the amplifier by a personal computer. The amplifier provided the piezoelectric elements (Piezo) in the insoles with input with a manually adjustable amplitude. The amplitude of the output signal to both insoles could be adjusted separately. Same personal computer and USB-DAQ AD/DA card were used to record force plate data.

Instruments, Corp). Force plate data were sampled at 100 Hz and low-pass filtered (Butterworth) with a cut off frequency of 6 Hz. Data processing was done in MATLAB (version 7.1, The MathWorks, Inc; Natick, Massachusetts).

Outcome Measures and Statistics

The primary outcome measure was the mean velocity of the center of pressure (COP) displacements in millimeters per second. The total path length of the COP displacements was measured over a period of 25 s, and the mean velocity was calculated. During each measurement (60 s), two intervals of 25 s were used to collect outcome data (vibration-on and vibration-off condition). Data from the first 5 s of both conditions were left out of consideration. Secondary outcomes were the root-mean-square (RMS) of the anteroposterior (AP) and mediolateral (ML) COP velocity.

In a repeated measures analysis of variance (ANOVA) model, the effects of vibrating insoles on balance, defined by previously described outcome measures, were tested. Main effects of vibration (on or off), vision (eyes open or closed), and ADT (calculation task or not) and interaction effects of vibration \times vision and vibration \times ADT were tested. Differences between the neuropathy group and the nondisabled group were tested with a two-way ANOVA. A *t*-test was used to test the differences between the first and the fifth measurement. We used SPSS (version 14.0, SPSS, Inc; Chicago, Illinois) for all statistical analyses.

RESULTS

Mean Velocity of COP Displacements

Both the nondisabled and the neuropathy groups showed significant main effects of vision and ADT (eyes closed and an ADT increased mean velocity of COP displacements) on mean velocity of COP displacements (main effect of vision: $p = 0.01$, main effect of ADT: $p < 0.01$ in neuropathy group, main effects of both vision and ADT: $p < 0.01$ in nondisabled group) (**Figure 3**). Compared with the nondisabled controls, subjects with neuropathy showed a significant increase in the mean velocity of COP displacements ($p < 0.01$). No main effect of vibration was found for either the neuropathy group (**Figure 3(a)**) or the nondisabled group (**Figure 3(b)**) ($p = 0.07$ neuropathy group, $p = 0.37$ nondisabled group). The neuropathy group showed a significant favorable interaction effect of vibration \times ADT ($p = 0.05$). No interaction between vision and vibration was found in the neuropathy group ($p = 0.17$). In the nondisabled group, no interaction effects were found between

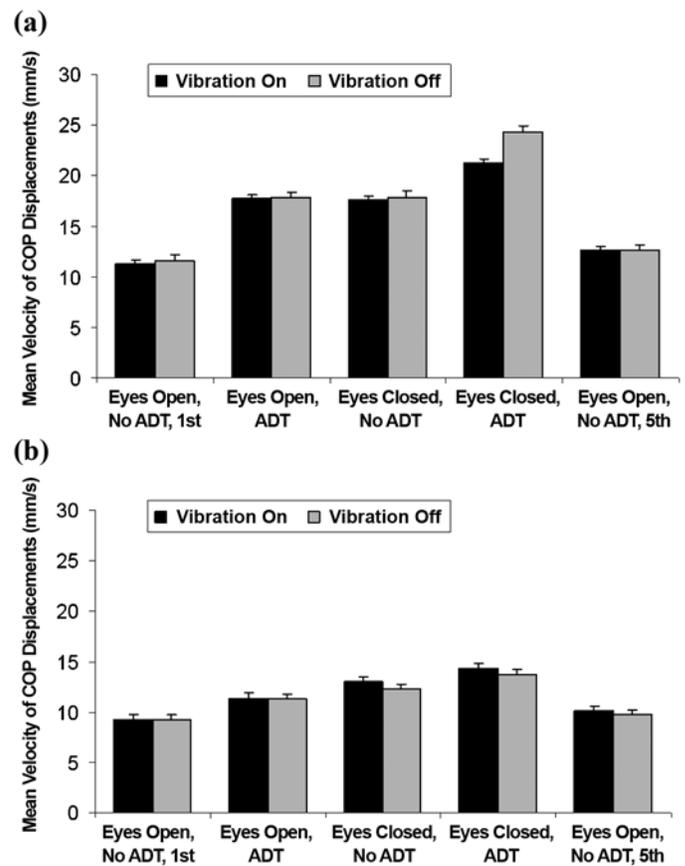


Figure 3.

Mean velocity of center of pressure (COP) displacements with vibrating insoles turned on (black bars) and off (gray bars) in (a) subjects with neuropathy and (b) nondisabled subjects during five different trials. ADT = attention-demanding task. Error bars = standard error of the mean.

vibration and either vision or ADT ($p = 0.79$ and $p = 0.28$, respectively).

No significant differences between the identical first and fifth condition (both conditions consisted of eyes open without an ADT) on mean velocity of COP displacements were found ($p = 0.11$ and $p = 0.29$ in the neuropathy group and $p = 0.24$ and $p = 0.52$ in the nondisabled group for the vibration-on and vibration-off condition, respectively). Therefore, the fifth measurement was omitted. Data from both the first and the fifth measurements are shown in **Figure 3** and **Tables 2** and **3** in order to show the absence of fatigue.

RMS of COP Velocity in AP and ML Direction

As the data presented in **Tables 2** and **3** show, no main effects of vibration on RMS of the COP velocity in

Table 2.

Mean \pm standard error of mean of root-mean-square of center of pressure velocity in anteroposterior direction with vibrating insoles turned on and off in subjects with neuropathy and nondisabled control subjects during five different trials.

Trial	Neuropathy		Nondisabled	
	Vibration On	Vibration Off	Vibration On	Vibration Off
Eyes Open, No ADT, 1st Measurement	9.6 \pm 0.5	10.0 \pm 0.6	7.5 \pm 0.5	7.5 \pm 0.5
Eyes Open, ADT	17.1 \pm 2.5	17.1 \pm 1.7	12.0 \pm 1.5	10.7 \pm 0.7
Eyes Closed, No ADT	17.5 \pm 2.5	16.9 \pm 2.7	9.7 \pm 0.8	9.6 \pm 0.9
Eyes Closed, ADT	20.4 \pm 2.5	24.3 \pm 3.3	14.2 \pm 1.5	12.6 \pm 1.1
Eyes Open, No ADT, 5th Measurement	11.3 \pm 0.9	11.2 \pm 1.1	8.7 \pm 0.8	8.0 \pm 0.6

ADT = attention-demanding task.

Table 3.

Mean \pm standard error of mean of root-mean-square of center of pressure velocity in mediolateral direction with vibrating insoles turned on and off in subjects with neuropathy and nondisabled control subjects during five different trials.

Trial	Neuropathy		Nondisabled	
	Vibration On	Vibration Off	Vibration On	Vibration Off
Eyes Open, No ADT, 1st Measurement	8.6 \pm 0.4	8.7 \pm 0.4	7.4 \pm 0.5	7.5 \pm 0.4
Eyes Open, ADT	12.1 \pm 1.0	12.4 \pm 0.8	9.6 \pm 0.8	9.2 \pm 0.7
Eyes Closed, No ADT	11.3 \pm 0.8	12.1 \pm 1.0	8.8 \pm 0.6	8.6 \pm 0.6
Eyes Closed, ADT	14.5 \pm 1.4	14.9 \pm 1.2	10.2 \pm 0.9	9.9 \pm 0.8
Eyes Open, No ADT, 5th Measurement	9.3 \pm 0.5	9.2 \pm 0.5	7.6 \pm 0.3	7.6 \pm 0.5

ADT = attention-demanding task.

the AP or ML direction were found for either group (neuropathy group: $p = 0.12$ in AP direction and $p = 0.35$ in ML direction, nondisabled group: $p = 0.30$ in AP direction and $p = 0.43$ in ML direction). Significant main effects of vision and ADT (eyes closed and an ADT increased RMS in the AP direction) on RMS of the COP velocity in the AP direction were found in both groups (main effect of vision $p = 0.01$ and $p = 0.01$; main effect of ADT $p = 0.01$ and $p < 0.01$ in the neuropathy group and nondisabled group, respectively). Significant main effects of vision and ADT (eyes closed and an ADT increased RMS in the ML direction) on RMS of the COP velocity in the ML direction were found in both groups as well (main effect of vision $p = 0.01$ and $p < 0.01$; main effect of ADT $p < 0.01$ and $p < 0.01$ in the neuropathy group and nondisabled group, respectively).

The neuropathy group showed a significant favorable interaction effect of vibration \times ADT on RMS of the COP velocity in the AP direction ($p = 0.05$), whereas this interaction effect was not present in the ML direction ($p = 0.76$). In the nondisabled group, no interaction effects of vibration and either vision or ADT on the RMS of the COP velocity were found in either the AP or ML direction.

DISCUSSION

In line with other research [9–10,25], we found that in subjects with neuropathy, balance was impaired and worsened when the balance task became more difficult. Moreover, when an ADT was presented, vibrating insoles improved balance in subjects with neuropathy, suggesting that when attention is distracted from the standing task, random vibrations applied to the feet improve balance. In contrast to earlier research [15–16], we found no effects of vibrating insoles in nondisabled subjects. The interaction effect in persons with neuropathy can mainly be explained by the improvement in balance as a result of vibrating insoles during the most difficult balance task: standing with the eyes closed and performing an ADT (**Figure 3**). The results from our study show that when vision is occluded and attention is distracted, the destabilizing effect of these interventions seems to diminish when random vibrations are applied to the plantar surface of the feet. During the condition with the eyes closed and an ADT, subjects have fewer compensatory options for balance control. Therefore, subjects have to rely more on the remaining information sources, of which mechanoreceptors on the plantar side of

the feet are the most important, to control their standing balance. Improvement of the sensation of plantar surface pressure by vibrating insoles may lead to improved balance when subjects cannot use compensatory strategies.

The interaction between vibration and attention in subjects with neuropathy can mainly be explained by a decrease in COP velocity in the AP direction and not the ML direction. One possible explanation is that COP velocity in the AP direction was relatively more affected by the additional ADT (without vibration) than the COP velocity in the ML direction and, therefore, more improvement was possible in the AP direction. A second and more important explanation could be that plantar cutaneous mechanoreceptors play a more important role in the control of COP in the AP direction than in the ML direction [26]. This study showed deteriorated COP control in the AP direction after plantar hypoesthesia. Improving plantar sensation of people with reduced plantar sensation (neuropathy) by vibrating insoles may therefore lead to improvement in balance control in the AP rather than the ML direction.

The findings of this study seem to be less pronounced compared with earlier research on vibrating insoles and application of noise to the feet [13–16]. The effects in persons with neuropathy seemed smaller, and in contrast with previous research, no effects in nondisabled people were found. Several explanations may account for these less pronounced effects. In our study, different measures and a different measuring device for balance were used. The first studies concerning vibrating insoles used excursions of a single shoulder marker to determine balance [15–16]. These shoulder-marker excursions are not commonly used as outcome measures for balance [27]. For example, rotation about the longitudinal axis will result in excursions of a single shoulder marker but is not a balance mechanism. However, according to Priplata et al., excursions of a shoulder marker used in their studies on vibrating insoles [15–16] correlated with COP displacements measured by a force plate [28]. This can only be the case when the human body acts completely as an inverted pendulum and no bending at the hip takes place. A possible explanation, although not very plausible, for the less pronounced findings in our study may be that vibrating insoles have a larger effect on hip strategy and less on ankle strategy, which may explain larger shoulder excursions measured by cameras and smaller effects on COP measured by a force plate.

The physical properties of the insoles differed from those used in the work of Priplata et al. as well [15–16]. In our study, we used insoles of 5 mm-thick cork with three built-in piezoelectric elements that were covered with a thin leather layer, whereas the first vibrating insole studies used gel-based insoles that were 16 mm thick and had electromagnetic actuators. We chose to use this insole configuration for several reasons. First, in this study, piezoelectric activators were used because these are much thinner than electromagnetic actuators. Therefore, it was possible to develop 6 mm-thick insoles that could be more easily implemented in clinical practice. Second, we decided to use rather hard insoles, because soft insoles may deteriorate balance due to deteriorated feedback concerning plantar pressure distribution. Differences in effects between the current study and previous work could be a result of these differences in insole configuration.

A weakness of our study is the applied amplitude of the vibrations. In the majority of the included subjects with neuropathy (71%), the maximum amplitude that could be applied by our vibrating insole system (120 V) was not sufficient to reach the sensory detection threshold. Therefore, in 71 percent of the included subjects with neuropathy, the amplitude of the vibrations was probably below 90 percent of the sensory detection threshold. On the other hand, in 93 percent of the nondisabled subjects, the threshold was reached. However, in the nondisabled group, no effects of vibration were found. This result suggests that the ability to detect the maximum amplitude of the vibrations, as was found in 93 percent of the nondisabled subjects, does not imply improvement of balance by vibrating insoles.

The weight of the people with neuropathy in our study was almost 15 kg more than the nondisabled subjects. This difference might influence the differences in balance between the two groups. However, because in this study the effects of mechanical noise were tested in a crossover design in which the subjects served as their own controls, we did not expect that the weight of the subjects would influence the results.

The noise type used in this study was a transistor-to-transistor logic signal with a randomly varying frequency band of 25 to 500 Hz. In previous research, digitized white noise, low-pass filtered to 100 Hz, with uniformly distributed amplitude was used. Research is needed to optimize the input signal to the insoles. Application of a fourth piezoelectric element under the big toe, where

many mechanoreceptors are located, and an individually controllable amplitude of each piezoelectric element may contribute to improvement of the effects of the vibrating insoles [19].

CONCLUSIONS

The findings from this study are encouraging. The use of vibrating insoles in which the vibration is applied by piezoelectric elements seems to be an option for increasing stability in persons with neuropathy when compensatory strategies to control balance are limited. These insoles are thin (6 mm) and can therefore easily be worn in regular shoes. The absence of effects of vibrating insoles in nondisabled subjects and in persons with neuropathy when attention is not distracted requires extension of current research and development. The next step is to optimize the properties of the random vibrations applied to the feet, followed by research concerning the effects of these insoles on balance during walking and ultimately on fall frequency. To make the latter research possible, researchers must develop a wearable device that provides input to the plantar surface of the feet.

Finally, random vibrations applied to the plantar surface of the feet improved balance of persons with neuropathy only when attention was distracted and vision was occluded. The balance improvement can mainly be explained by improvement of the COP displacement velocity in the AP and not the ML direction. Assessment of the effects of vibrating insoles on a more functional level, such as research on the effects on balance during walking, is essential before implementation in daily living is recommended. Moreover, improvement of the insoles and their activation is necessary to make the use of these medical aids in daily living possible and effective.

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