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Orthotic interventions to improve standing balance in somatosensory loss

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Properties of noise to improve
standing balance in people
with diabetic neuropathy.
A single case design.

6

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ABSTRACT

This study aims to determine the most effective properties of a mechanical noise signal, applied by vibrating insoles to the plantar surface of the feet, in order to improve standing balance in people with diabetic neuropathy. In a single case experimental approach (n=5) the effects on balance of mechanical noise with different properties were studied. Three different amplitudes and three different frequency bands (nine different interventions) were studied. Force plate measurements were used to calculate the mean velocity of the centre of pressure displacement, which was used as the measure for balance. The effects on standing balance of the nine different noise signals were compared to both the baseline interval before and after the intervention. Both the intervention and the baseline condition lasted for 30 s. This study confirmed that mechanical noise applied to the feet by vibrating insoles can improve balance in people with minor to moderate diabetic neuropathy. Noise, low pass filtered with an upper cut-off frequency of 200 Hz seems the most effective in improving balance; the applied amplitude with this cut-off frequency seems arbitrary.

INTRODUCTION

Diabetes Mellitus (DM) leads to the development of diabetic neuropathy (DN) in about 30% of the cases [1-3]. Prolonged disease duration, older age and poor glycemic control all increase the probability of developing DN [1-3]. The main cause of DN is axonal degeneration and demyelination due to a reduced nerve blood flow and therefore a reduced oxygenation [4]. Symptoms of DN include higher thresholds for tactile and vibrotactile sensation [5]. Impaired tactile sensation from the plantar surface of the feet may lead to deteriorated balance, because changes in pressure distribution are detected less accurately [5].

In normal stance, the body is not stationary. Rather, during quiet stance the body is constantly moving with the direction of the movement constantly changing. Postural control refers to maintaining the centre of gravity (CoG) within the base of support (BoS) [6]. Tactile sensation from the plantar surface of the foot is an important source of information for the control of balance [7;8]. When this tactile sensation is reduced balance is often impaired, which is the case in DN [5;9-11]. Improvement of this reduced tactile sensation of the plantar surface of the feet is thought to lead to improvement of balance [12].

Previously, it was shown that insoles providing mechanical noise to the plantar surface of the feet can improve tactile sensation and therefore improve standing balance in people with a deteriorated tactile sensation [13-15]. The rationale for improved balance from the application of mechanical noise to the plantar surface of the feet can be found in a mechanism called stochastic resonance (SR) [16]. SR can be described as a counterintuitive mechanism whereby the addition of noise to a non-linear system can enhance the detection of weak stimuli or enhance the information content of a signal [16]. In this study, the changing pressure under a certain part of the foot can be seen as the non-linear system. Based on the mechanism described earlier (SR) the noise, applied by vibrating insoles, is thought to have immediate effects on balance, which are thought to disappear immediately when the noise is turned off.

The positive effects on balance from insoles which apply mechanical noise to the plantar surface of the feet varied in magnitude [13-15]. In order to achieve clinically relevant effects and to use the insoles in daily life, improvement of the insoles leading to larger effects on balance is needed. One explanation for the limited effects may be that the optimal properties have not yet been applied. Therefore, the goal of this study was to determine the properties of the mechanical noise signal applied to the feet that lead to larger improvements in standing balance for those with reduced tactile sensation in the feet.

The effects of mechanical noise with different properties are studied in a single case experimental approach. This design is an experiment in which one entity is observed repeatedly during a certain period under different levels (treatments) of at least one independent variable [17]. Visual inspection of the graphs is used to explore the effects

of the intervention. It should not be confused with a case study in which there is often no experimental approach or manipulation of an independent variable [17]. Although this type of research is not often used in evaluating balance [18] the intervention in this study is well suited to a single case design. The intervention is thought to have an immediate effect on balance and the effects are thought to disappear instantaneously when the intervention is ended.

METHODS

In this study, five patients with DN aged between 42 and 52 years with various degrees of sensory loss of the plantar surface of the feet were included. Participants were selected where DN was mentioned in their medical records. The degree of sensory loss was assessed by a 10g Semmes Weinstein Monofilament (SWM) and a 128 Hz tuning fork [19]. Tactile sensation was tested at four locations on the plantar surface of each foot (heel, first metatarsophalangeal joint (MTP1), fifth metatarsophalangeal joint (MTP5) and first toe). Vibrotactile sensation was tested at the medial malleolus and the medial side of MTP1 of both feet. (Vibro)tactile sensitivity and other characteristics are presented in table 1. All participants signed informed consent. The procedures were approved and registered by the medical ethics committee of the University Medical Center Groningen (UMCG).

Balance was tested on a force plate. During each measurement, participants stood with their feet parallel (7 cm apart) and eyes closed. An AMTI force plate (BP 400600-1000) was used to measure ground reaction forces. Data were sampled at 1000 Hz and were low pass filtered (Butterworth) with a cut-off frequency of 6 Hz. The path length of the Center of

Table 1. Characteristics of the participants.

Subject number	1	2	3	4	5
Age in years	49	49	42	52	52
Gender	female	female	male	male	female
Mass in kg	82	59	94	98	102
Diabetes Mellitus type	I	I	I	I	II
Number of locations at which 10g SWM was perceived (max. 8)	0	8	0	2	8
Number of locations at which the tuning fork was perceived correctly (max. 4)	0	0	0	0	4
History of ulceration	no	yes	yes	no	no

SWM: Semmes Weinstein Monofilament

Pressure (COP) displacement was first calculated. Following the main outcome measure for balance, mean velocity of the COP displacement was calculated by dividing the path length by the sample duration. Data processing was completed with MatLab 7.1 (The MathWorks, Inc). In total, nine different trials were recorded. In some participants, the nine different trials were presented twice (both with eyes closed), once with and once without performing an attention demanding task (ADT). Because of fatigue and technical problems not all participants were able to complete the second set of measurements with an ADT. In previous research we showed an effect of vibrating insoles on balance only when an ADT had to be preformed [15]. The ADT consisted of a calculation task in which the participant had to continuously subtract 6 or 7 from a randomly chosen number between 300 and 500.

The participant stood on a pair of vibrating insoles, placed on the force plate during all measurements. The vibrating insoles were constructed as designed in a previous study [20], although rubber (Realux) was used instead of cork. Two rubber insoles with four piezoelectric actuators each, placed under the first toe (Noliac CMBR1; $\text{Ø}=20\text{mm}$), MTP1, MTP5, and the heel (Noliac CMBR7; $\text{Ø}=40\text{mm}$) covered with a fabric layer (Alantara) were used. The total thickness of the insoles (including actuators) was 4 mm.

The signal applied by the piezoelectric actuators consisted of white noise with a bandwidth from 10 Hz to 20 kHz which was low-pass filtered with a fifth order filter. The output was band limited white noise with an upper cut-off frequency of 50 Hz, 200 Hz or 1000 Hz. The amplitude of the output was adjustable between 0 V and 200 V (peak-to-peak) in 255 steps. The output of 200 V was the theoretical maximum (not reached because of the noisy character of the output signal). The amplitudes, were set on 150, 200 and 255 on a linear scale from 0 – 255, corresponding with a theoretically maximum output voltage of 118 V, 157 V and 200 V respectively. An output of 200 V matches a free stroke of 185 μm of the CMBR7 piezoelectric actuator (placed under the heel, MTP1, and MTP5) in both upward and downward direction, with a blocking force of 13 N. The maximum stroke of the CMBR1 actuator (placed under the first toe) was 47 μm , with a blocking force of 9 N. To define the most effective amplitude and bandwidth of the noise signal, nine different spectra of mechanical noise were tested; three different bandwidths (upper cut-off frequencies of 50 Hz, 200 Hz, and 1000 Hz), each with three different amplitudes (150, 200 and 255). The insoles were activated by a custom-made portable amplifier. The amplifier had a wireless connection to a notebook computer. Using LabView (version 8.0 National Instruments) based customised software, the upper cut-off frequency and amplitude of the noise signal were set.

During each trial of 60 s the vibrating insoles were turned on during the last 30 s. The outcomes were based on the interval between 2.5 s and 27.5 s (baseline) and the interval between 32.5 s and 57.5 s (intervention). This procedure was used because the exact point in time when the insoles were turned on was not recorded.

For each subject the effects of the nine interventions were compared to their baseline measure using a single case experimental design. Preceding each intervention, a baseline (control) condition was presented. Following this intervention a second interval of 25 s baseline was used to compare the intervention to. The study can be seen as an A_1 - B - A_2 - C - A_3 - D - A_4 - E - A_5 - F - A_6 - G - A_7 - H - A_8 - I - A_9 - J design in which A is the baseline condition (no vibration) and B to J are the nine different interventions. B was compared to both A_1 and A_2 , C was compared to both A_2 and A_3 and so forth. After three measurements of 60 s (intervention and preceding baseline measurement), the participants were allowed to rest for two minutes. This possibility was not used by any of the participants. The total duration of the measurements was almost one hour (when the nine different trials were presented twice). Interventions B to J were presented in a random order.

Since the order in each participant was different, it was chosen not to present the data of the five participants in one graph showing the outcomes (mean velocity of the COP displacement) of each participant chronologically, because in this way it is hard to interpret the different effects of the nine interventions, which were presented in random order. It was also chosen not to present the data clustered by intervention type, because in this way information about the changes in baseline over time was lost. Because in this study a single subject design was used, only descriptive statistics were presented.

RESULTS

As an example, XY plots of the COP of one participant (subject 5 ADT) during all nine interventions, combined with the preceding baseline measurements are presented in figure 1. This figure shows the behaviour of the COP during each trial.

Figure 2 presents the baseline conditions (A_1 - A_9) of the five participants chronologically, in order to explore the effects of time (e.g. learning or fatigue). Subject 1 completed only four of the nine trials. This participant was physically unable to stand for a longer duration. Two participants (subject 4 and 5) were measured twice, once with and once without ADT. The change in time of the two ADT measurements (subject 4 and 5) are in opposite direction. The largest change in baseline is present between A_1 and A_2 in most cases.

The difference between each intervention and both the preceding (figure 3) and the subsequent baseline measurement (figure 4) are presented as outcomes of this study. Differences in mean velocity of the COP displacement in terms of percentages are shown. By visual inspection of the scatter plots the most effective noise condition (amplitude and bandwidth) applied to the plantar surface of the feet was determined. Figure 3 demonstrates that most interventions resulted in a positive score. A positive difference in terms of percentages indicates a favourable effect of the intervention (increased stability) in mean velocity of the COP displacement (smaller velocity) compared to the preceding baseline measurement.

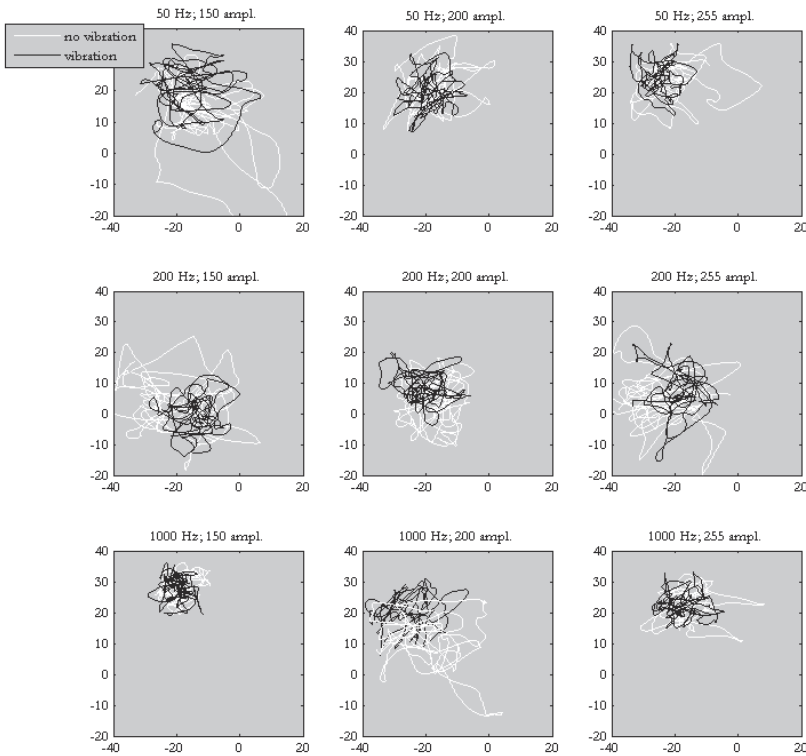


Figure 1. XY plots of the COP position (mm) during 55 s of subject 5 (with ADT); the first and last 2.5 s of the measurements are left out of consideration in this figure. The white lines represent the preceding baseline conditions. The black lines represent the COP during the nine different interventions.

The difference between the nine interventions and the subsequent baseline scores are presented in figure 4. Again, a positive score is indicative of a favourable effect of the application of mechanical noise on balance. The ninth intervention had no subsequent baseline measurements, therefore only eight differences are presented for the four participants that completed nine trials. This figure also demonstrates a favourable effect of the interventions compared to baseline. Both figure 3 and 4 display that largest improvements in terms of percentages compared to baseline can be found when noise with an upper cut-off frequency of 200 Hz is presented. When other upper cut-off frequencies are applied, larger amplitudes seem to be more effective than smaller.

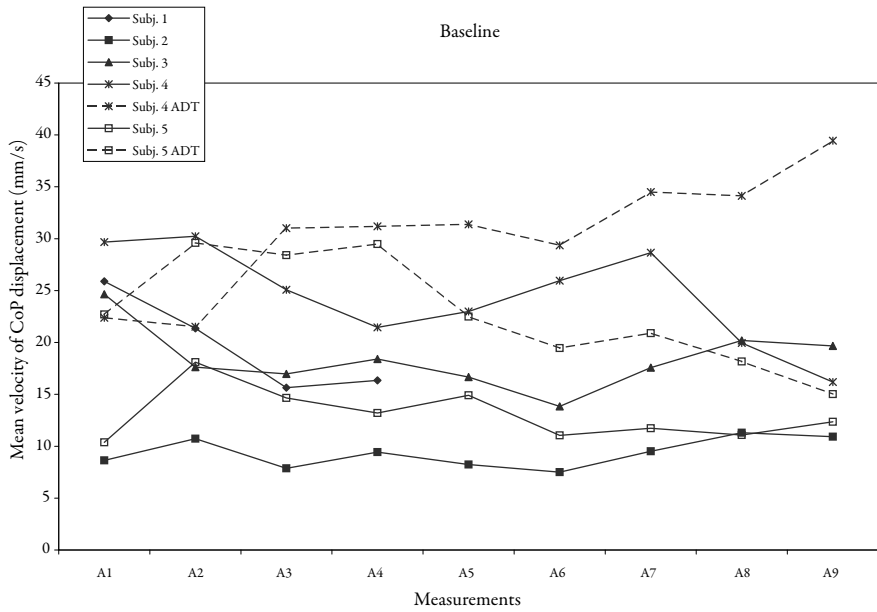


Figure 2. Repeated baseline measurements of the mean velocity of the COP displacement of the 5 participants in chronological order. The dashed lines represent the measurements when performing an attention demanding task (ADT).

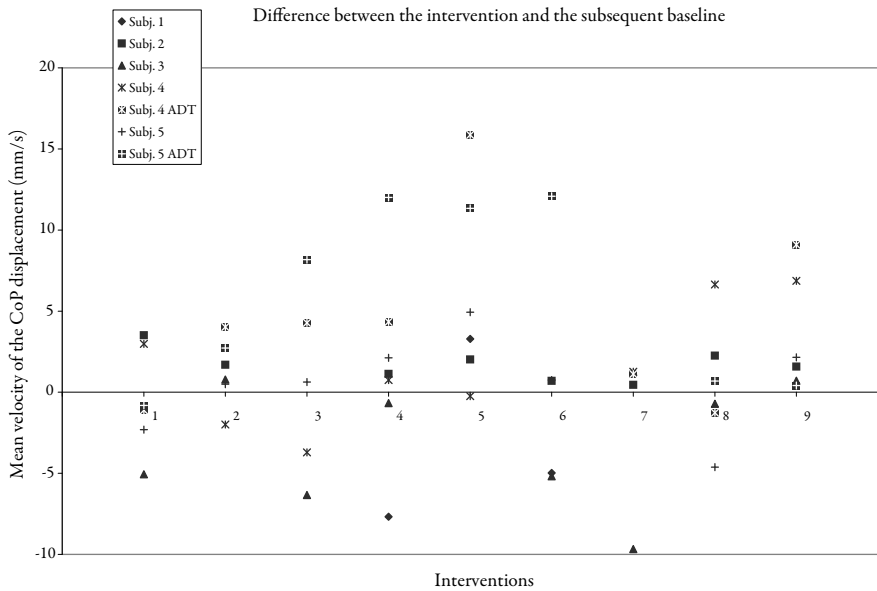


Figure 3. Difference between the preceding baseline measurement and the nine interventions in terms of percentages compared to baseline. A positive score indicates a favourable effect of the intervention. On the X-axis the upper cut-off frequency and amplitude of the nine different noise signals are presented. The dotted lines separate the different upper cut-off frequencies.

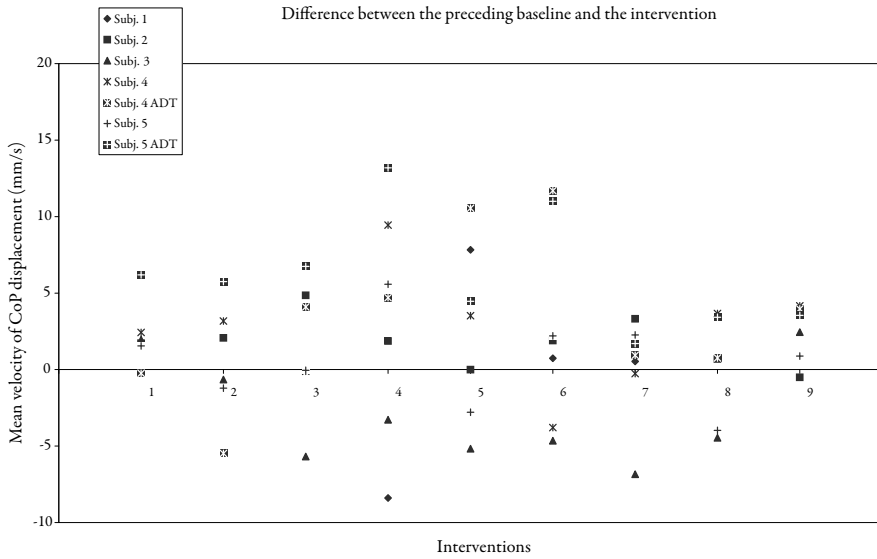


Figure 4. Difference between the nine interventions and the subsequent baseline measurement in percentage compared to baseline. A positive score indicates a favourable effect of the intervention. On the X-axis the upper cut-off frequency and amplitude of the noise signal are presented. The dotted lines separate the different upper cut-off frequencies.

DISCUSSION

In this study it was shown that the baseline of the participants was not steady (figure 2). However, the group of participants did not show a consistent in- or decrease over time in baseline mean velocity of COP displacement. Some of the participants did show a gradual in- or decrease, suggesting an effect of repeated measurements (fatigue or learning) and possibly an unexpected effect of the intervention on subsequent baseline outcomes. Because this effect was not shown in all participants and the direction of the change over time varied between participants, the vibrations applied are not thought to have either a positive or a negative effect on balance once the vibration is turned off. This is in line with theories about SR. In order to tackle the problem of the changing baseline over time, the interventions were compared to both the preceding and the subsequent measurement.

The figures showing the differences between the intervention and the preceding (figure 3) and the subsequent (figure 4) baseline measurement, generally demonstrate a favourable effect of the different interventions. Forty of the 58 (69%) interventions, resulted in a smaller mean velocity of the COP displacement compared to the preceding baseline, suggesting improved balance; two participants received 18 interventions, two participants received nine interventions and one participant received four interventions. Of all 51 interventions

with a subsequent baseline measurement, 32 (63%) showed a favourable effect of noise compared to this baseline. One participant (subject 3; triangles) seemed not to benefit from the mechanical noise. This participant had severe neuropathy with a long history of ulcerations. When his results are left out of consideration, the percentages increase to 78% and 74% respectively. Moreover, the percentages of improvement (score above 0) are larger than the deterioration percentages (score below 0), emphasising the favourable effects of the insoles. These results indicate that vibrating insoles seem to improve balance.

Not all interventions were thought to improve balance, rather the optimal noise properties were sought. Figures 3 and 4 demonstrate that noise when low pass filtered with an upper cut-off frequency of 200 Hz, seems more effective in decreasing the mean velocity of the COP displacement compared to an upper cut-off frequency of either 50 Hz or 1000 Hz. These graphs also display that when noise low-pass filtered with an upper cut-off frequency of 50 Hz or 1000 Hz is presented, larger amplitudes are more effective than smaller. With the application of an upper cut-off frequency of 200 Hz, an amplitude of 200, and compared to the subsequent baseline measurement, the largest average improvement was found (approximately 35%). Because of the design of this study (single case experimental approach), this study should be seen as a first step in the exploration of the most effective noise signal. In future the effects of the most suitable frequency bands and amplitude should be examined in a larger group.

In line with our previous research it was demonstrated that during the ADT condition, the favourable effects of the vibrating insoles were the largest (both in percentages as well as in absolute numbers) [15], in particular when an upper cut-off frequency of 200 Hz was applied. This suggests that when less processing capacity to control balance is available, the vibrating insoles are the most effective.

It was not possible to reach the threshold for sensing the vibration of the insoles in all participants (only subject 2 and 5 were able to feel the maximum vibration). Of the 9 presented interventions, maximally one intervention was consciously sensed by these two participants (upper cut-off frequency of 1000 Hz with an amplitude of 255). All other interventions were below the tactile threshold, therefore the participants can be considered as blinded for these interventions.

We suggested earlier that the amplitude for each of the eight actuators should be individually adjustable [20]. This feature was embedded in the system but not used. The reason was that in three participants the maximum amplitude was not sufficient to reach the threshold and in the two participants in whom the threshold could be reached it was near the maximum amplitude of the system. In the future a system which enables larger amplitudes might prove the value of this feature. The Noliac CMBR piezoelectric actuators used, have the ability to reach larger amplitudes, however the custom made portable insole system could not deliver

the required high voltages.

The piezoelectric actuators are quite fragile; it is important to build the actuators into a solid base, preventing any bending forces on actuators. The piezoelectric actuators require large voltages (up to 200 V peak-to-peak, in people with moderate DN) to reach the tactile threshold. This requires a large power and a heavy power source (battery). This raises the question of the potential of piezoelectric actuator based vibrating insoles in daily activity. Possibly in future, other actuators should be considered. However the possibilities are limited. Electromagnetic actuators heat up when activated, which is an undesirable side effect. All other actuators are rather thick and therefore difficult to build in an insole. Other actuators, however, seem to be more durable than piezoelectric ones.

The single case design is ideal in customizing treatments [17]. This study was designed to assess the optimal type of noise in order to improve balance in DN. This design was able to increase the knowledge about the most suitable noise signal. It should be mentioned that in this study the variation within one baseline measurement could not be studied. In order to report reliable COP based outcomes, the interval of 25 s cannot be subdivided. Usually, the within baseline variation is presented in a single case design in order to demonstrate that effects of the interventions are not based on chance, but are consistent. Because nine subsequent baselines were presented, and the idea that the intervention does not affect the subsequent baseline, this problem was handled.

In conclusion, mechanical noise applied to the feet by vibrating insoles may improve standing balance in people with minor to moderate DN. Where severe neuropathy is present, balance may be better addressed using other methods. Noise, low pass filtered with an upper cut-off frequency of 200 Hz, seems most effective. Using this upper cut-off frequency, the applied amplitude seems arbitrary; regardless of the amplitude, balance seems to improve. Where other upper cut-off frequencies are used, larger amplitudes seem to be more effective than smaller. This study provides further support to the potential role of vibrating insoles in improving standing balance where DN is present.

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