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ORIGINAL ARTICLE

Immediate effect of textured insoles on the balance in patients with diabetic neuropathy

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ABSTRACT

Aims/Introduction: Neuropathy is a common complication of diabetes that reduces balance by disrupting vision, and the sensory and vestibular systems. This is important in older adults who are more at risk of falling. Studies show that improving the sensory mechanisms through insoles can improve balance in people with balance disorders. As textured insoles have recently been considered for improving balance disorders, this study aimed to investigate the immediate effect of textured insoles on the balance of patients with diabetic neuropathy.

Materials and Methods: A total of 17 patients with diabetic neuropathy participated in this quasi-experimental study. The studied variables were the general balance index, posterior–anterior balance index and medial-lateral balance index, which were measured in three conditions: (i) soft textured insoles; (ii) hard textured insoles; and (iii) without textured insoles. A Biodex balance device was used for this purpose.

Results: In the general balance index, there was a significant difference between all the studied conditions. In the posterior–anterior balance index, there was a significant difference between without textured insole and hard textured insoles, and also soft and hard textured insoles. In the medial-lateral balance index, there was a significant difference between the hard textured insoles and without textured insoles, and also soft and hard textured insoles ($P < 0.05$).

Conclusions: Wearing textured insoles can increase the balance in patients with diabetic neuropathy. This can be due to its effect on the sensory feedback of the soles, improving the proprioception and tactile sensors that are the main sources of balance.

INTRODUCTION

Diabetes is a common metabolic disorder, and is defined as a chronic increase in blood sugar as a result of impaired production or function of insulin hormones[1]. According to a survey by the International Diabetes Association in 2013, approximately 382 million people suffer from diabetes worldwide, and this number is expected to reach >592 million by 2035[2].

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Peripheral neuropathy is reported as the most common complication in patients with diabetes, which gradually leads to postural instability by disrupting the peripheral nervous system and reducing sensory inputs[3–5]. In other words, as controlling balance is dependent on the somatosensory, vision and vestibular systems, an increased risk of falling is associated with diabetic neuropathy[6].

The first and most disturbance in patients with diabetic neuropathy is reported to be somatosensory system dysfunction, which is responsible for the perception of temperature change, pain, motion, touch and pressure[7]. Therefore, somatosensory damage leads to a decrease in environmental perception, a lack of timely postural response and decreasing stability[8].

Previously, reduction of postural control has been suggested as an important complication of diabetic neuropathy, which results from a delay or reduction of reflexes in response to postural perturbation[7]. Also, diabetes patients with neuropathy have a significant decrease in their balance compared with healthy people[9]. For instance, the center of pressure displacement in neuropathic patients is reported to be significantly higher compared with the non-neuropathic and control groups[4].

Previous studies show that increasing the somatosensory system's feedback through the soles with textured insoles can be effective in improving balance in healthy individuals[10]. The assumption is that these insoles change the discharge ratio of mechanoreceptors. In other words, their bulges increase sensory information from the soles by stimulating the mechanical receptors[11]. According to sensory reweighting theory, increasing input through mechanical receptors can partially compensate for the inefficiency of other balance sources[12].

Textured insoles might be used to improve balance in patients with diabetic neuropathy. However, to our knowledge, there seems to be no study on the effect of this type of intervention on balance in diabetes patients. Therefore, the present study was carried out to evaluate the immediate effect of textured insoles on the balance in patients with diabetic neuropathy.

MATERIALS AND METHODS

The present quasi-experimental study was carried out on 17 diabetic neuropathic patients (11 women and six men). The alpha and beta error rates were 0.05 and 0.02 in determining the sample size. Thus, the minimum sample size was 17 patients using G-power software (University of Dusseldorf, Germany) to achieve a statistical power of 0.08.

The inclusion criteria were: having diabetes for at least 5 years before entering the study; being diagnosed with diabetes neuropathy based on the Michigan neuropathy screening scale[13]; having a normal range of motion in the wrist, knee and hip joints; and ability to stand and walk independently. The exclusion criteria were: having foot ulcers; deformities in the lower extremities; a history of hypotension in the past 3 months; taking any medication that affects balance; any neurological disorder other than peripheral neuropathy; and any musculoskeletal disorder that affects balance. All participants signed an informed consent form before entering the study.

Intervention

The orthotic intervention included a pair of shoes, a pair of soft textured insoles and a pair of hard textured insoles (Figure 1). All insoles were prepared in standard sizes by a certified orthotist in an orthotics and prosthetics center. The characteristics of the textured insoles were: 5 mm total thickness, 5 mm diameter of bulges, 3 mm height of these bulges from the insole surface and 9 mm distance between the bulges (center to center). All insoles were made of ethyl vinyl acetate. The soft and hard textured insoles' densities were 270 and 320 mg/cm^3, respectively. Also, the same shoes were used for walking with the insoles to have the least effect on the results of this study (Figure 1).

Procedure

Biodex balance device (Biodex Medical Systems, Shirley, NY, USA) was used for testing. This device consists of a moveable platform that enables the participants to move anterior, posterior and sideways, besides standing still. The platform has locked and free modes. In the locked mode, the platform is fully stable and without movement. It has 12 stability levels, in which level 1 is the most volatile and level 12 is the most stable. In the present study, the level was set at 8 all the time[14].

The participants were instructed to walk for 5 min with and without the insoles inside their shoe, before carrying out the balance test. To carry out the balance test, the participants were asked to stand on the Biodex balance device, once with their eyes open and once with their eyes closed, while their hands were hanging to their sides (Figure 2). Each test lasted 30 s, during which the patient tried to keep the cursor in the middle of two concentrated circles. They carried out the tests in three conditions: (i) shoes without insoles; (ii) shoes with a soft textured insole; and (iii) shoes with a hard textured insole. The distance between the two heels was set constant during different conditions, to avoid the effects of adaptability on the stabilizing response due to different inter-heel distances.

The balance plate has three main outputs, including the anterior–posterior stability index (APSI), medial-lateral stability index (MLSI) and overall stability index (OSI). These outputs represent the fluctuations around the reference point. The MLSI denotes the center of the pressure fluctuations occurring on the *x*-axis (medial-lateral axis) for both feet concurrently. The APSI denotes the center of the pressure fluctuations occurring on the *y*-axis (anterior–posterior axis) for both feet concurrently. The OSI is a compound of the APSI and MLSI, and denotes the body displacements on both the *x*- and *y*-axes[15].

The Michigan neuropathy screening instrument that was designed in 1994 has two parts. The first part of this questionnaire has 15 items about the feet's general sensation, including pain, numbness and temperature sensitivity that are answered by the patient him/herself. It has a maximum score of 13, in which higher scores indicate more neuropathic symptoms. The second part is the patients' physical evaluation by a specialist, which includes: (i) foot examination in terms of any deformity, dry skin, hair and nails condition, callus, and infection; (ii) presence or absence of scar; (iii) evaluation of the slightly perceived tremble in the posterior of the toe; (iv) grading ankle reflexes; and (v) monofilament tests. This clinical trial

Figure 1 | The (a) textured insoles, the (b) textured tissue used to prepare the textured insoles and (c) the shoes.

can be scored up to 10, in which a score of >2 means having neuropathy[13,16].

Statistical analysis

The analysis was carried out using MS Excel 2013 (Microsoft, Redmond, WA, USA) and SPSS software version 21 (IBM Corp., Armonk, NY, USA). The Shapiro–Wilk test was used to assess the normal distribution of the data. Analysis of variance and least significant difference post-hoc test was used to determine the difference between each test. A P-value < 0.05 was considered significant.

RESULTS

A total of 83 eligible patients were considered to be included in the current study. Finally, 17 diabetic neuropathic patients with a mean age of 49.4 ± 7.1 years (range 41–58 years) participated in the present study. Their mean weight was 65.9 ± 7.09 kg (range 57–78 kg; Table 1).

Eyes-open condition

In the OSI, while the eyes were open, there were no significant differences between the soft textured insoles and no textured insoles, and also soft and hard textured insoles conditions

Figure 2 | The balance test using the Biodex balance device.

Table 1 | Demographic characteristics of the participants

Characteristic	Standard deviation	Mean
Age (years)	7.1	49.4
Weight (kg)	7.09	65.9
Height (m)	0.9	1.63
Body mass index (kg/m^2)	7	28.3

($P > 0.05$). However, there was a significant difference between the hard textured insoles and no textured insoles conditions ($P < 0.01$). Considering the APSI, there were no significant differences between a soft textured shoe and no textured insoles, and also hard and soft textured insoles ($P > 0.05$). However, there was a significant difference between the hard textured insoles and the no textured insoles ($P < 0.01$). Considering the MLSI, there were no significant differences between soft textured insoles and no textured insoles, and also hard and soft textured insoles ($P > 0.05$). However, there was a significant difference between the hard textured insoles and the no textured insoles (Table 2).

Eyes-closed condition

In the OSI, while the eyes were closed, there were no significant differences between the soft textured insoles and no textured insoles conditions ($P > 0.05$). However, there was a significant difference between the hard textured insoles and textured insoles conditions ($P < 0.001$), and soft and hard textured insoles conditions ($P < 0.05$). Considering the APSI, there were no significant differences between the soft textured insoles and no textured insoles conditions ($P > 0.05$). However, there was a significant difference between hard textured insoles and no textured insoles conditions ($P < 0.05$), and soft and hard textured insoles conditions ($P < 0.05$). Considering the MLSI, there were no significant differences between the soft textured insoles and no textured insoles conditions ($P > 0.05$). However, there was a significant difference between hard textured insoles and no textured insoles conditions ($P < 0.05$), and soft and hard textured insoles conditions (Table 3).

DISCUSSION

The present study evaluated the effect of textured insoles on the balance of patients with diabetic neuropathy. The results of the present study showed that increasing the somatosensory information input improves balance. The possible mechanism behind it can be that the bulges on the insoles stimulate the mechanical receptors, and this leads to a better understanding of the foot's position and joint displacement while standing.

Regarding the OSI, there was a significant difference between all conditions; that is, no textured insole versus soft textured tissue, no textured insole versus hard textured insole, and soft and hard tissue insoles. Also, the lowest mean was in the difference between no textured insoles and hard textured insoles conditions. The greatest effect on balance improvement was related to the hard textured insoles and then soft textured insoles conditions. This is in line with the results of previous studies, in which increasing somatosensory inputs reduces postural instabilities and improves balance[17,18]. The results of these two previous studies[17,18] showed that standing on a textured surface with small bulges reduces the fluctuations of the center of pressure in the medial-lateral direction in older adults. Instead of using an insole inside a shoe like ours, they used a textured surface with bulges and without shoes.

Also, in studies carried out by Corbin *et al.*[19] and Palluel *et al.*[20], there was a significant decrease in postural fluctuations in the standing position.

Regarding the APSI and MLSI, there was a significant difference between the no textured insoles and the soft textured

Table 2 | Mean overall stability index, anterior–posterior stability index and medial-lateral stability index for the eyes-open condition (*n* = 17)

Variables	Conditions			Significance		
	Condition 1 Shoe only	Condition 2 Hard insole	Condition 3 Soft insole	1 & 2	1 & 3	2 & 3
OSI	3.9 (1.5)	1.7 (0.9)	2.7 (1.9)	0.001*	0.151	0.190
APSI	2.9 (1.2)	1.3 (0.8)	2.1 (1.8)	0.006*	0.395	0.358
MLSI	2.5 (1.1)	1.1 (0.9)	1.7 (0.9)	0.049*	0.136	0.231

*Significant difference. APSI, anterior-posterior stability index; MLSI, medial-lateral stability index; OSI, overall stability index.

Table 3 | Mean overall stability index, anterior–posterior stability index and medial-lateral stability index for the eyes-close condition (*n* = 17)

Variables	Conditions			Significance		
	Condition 1 Shoe only	Condition 2 Hard insole	Condition 3 Soft insole	1 & 2	1 & 3	2 & 3
OSI	6.1 (1.7)	3.9 (0.9)	5.7 (1.5)	0.001*	0.143	0.015*
APSI	4.3 (1.4)	2.3 (0.7)	4.1 (1.3)	0.021*	0.561	0.049*
MLSI	4.6 (1.5)	2.8 (0.7)	3.8 (0.7)	0.013*	0.315	0.037*

*Significant difference. APSI, anterior-posterior stability index; MLSI, medial-lateral stability index; OSI, overall stability index.

insoles, and also the soft and hard textured insoles. The lowest balance was in wearing shoes without insoles. In other words, even the soft textured insole inside a shoe can improve balance in patients with diabetic neuropathy. Furthermore, using textured insoles might stimulate a larger number of mechanical receptors by applying pressure on the soles with the bulges, and lead to a better understanding of the feet's condition and ankle joint displacement, ultimately increasing nerve feedback from the skin receptors to the brain[21].

The use of textured insoles can improve the nervous system's ability to control movement and organize the motor responses required to maintain control and, thus, reduce changes in postural fluctuation parameters by increasing sensory symptoms of skin surface afferents[22]. The hard textured insole provides more balance improvement compared with the soft textured insole. This might be attributed to the stiffness of the insole. In other words, a hard textured insole might cause faster and stronger stimulation of sensory receptors on the foot's sole. This requires further research.

From a clinical perspective, people who are prone to falling, including people with diabetic neuropathy, have more postural fluctuations than healthy people[23]. Therefore, using textured insoles as a way to increase the sensory input of the body can reduce postural fluctuations and the likelihood of falling. The main limitation of the present study was the lack of investigation into the long-term effects of textured insoles. Another limitation was the impossibility of blinding the evaluators.

Textured insoles have a significant effect on the improvement of balance. It seems that the hard textured insole has the greatest effect on the senses, including proprioception and tactile senses. By stimulating the deep receptors in the soles, it increases the balance in patients with diabetic neuropathy. Using hard textured insoles can be recommended as a non-invasive, low-cost and easy-to-use intervention. Further research should investigate this method in the long term and its direct effect on falling. Also, the tolerance period of patients' adaptation to using the textured insoles can be an issue requiring further research.

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DISCLOSURE

The authors declare no conflict of interest.
Approval of the research protocol: The ethics committee of the medical university approved the study protocol.
Informed consent: All participants signed the informed consent.
Registry and the registration no. of the study/trial: IR.IUMS.-REC.1394.9211502205.
Animal studies: N/A.

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