ผลกระทบของแผ่นรองฝ่าเท้าชนิดพื้นผิวไม่เรียบต่อการทรงตัวในผู้สูงอายุ

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Abstract: Influence of Textured Surface Insoles on Postural Control in Older Adults

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Background: The loss of plantar cutaneous sensation in the feet is one of the age-related deteriorations associated with impaired balance control, increased postural sway, and an increased risk of falling. About 33% of adults over 65 undergo falls, resulting in serious injuries. Textured insoles are a simple and low-cost intervention that could improve balance in older adults. **Objective:** This study evaluated and compared the influence of three textured surface insoles on postural control and gait parameters in older adults with either a history of falls within the last three months or a moderate risk of falls. **Method:** Fifteen participants above 65 years old participated in this study. All participants were tested under four conditions (using a within-session repeated-measures design) for static balance assessment with eyes closed, functional mobility assessment, and spatiotemporal gait assessment: barefoot (control), Textured Insole A, Textured Insole B, and Textured Insole C. **Result:** The results revealed that wearing Texture Insole A significantly improved the static balance assessment, but not the functional mobility and spatiotemporal gait parameters. The textured surface insole significantly influenced postural control, especially when using filled polymer used as 12V wire insulation, with hardness Shore A 55.1, a density of 354.84 g/cm^3, a diameter of 6 mm, a height of 3 mm, and a center-to-center distance of the protrusions of 9.5 mm. This was defined as Textured Insole A. **Conclusion:** Using a textured insole was a simple and low-cost intervention that could decrease postural sway and improve postural control.

Keywords: Textured insole, Older adults, Postural control, Wii Balance Board, BTS G-sensor

บทคัดย่อ

ภูมิหลัง: การสูญเสียความรู้สึกทางผิวหนังที่ฝ่าเท้าเป็นหนึ่งในการเสื่อมสภาพที่เชื่อมโยงกับอายุที่เพิ่มขึ้นเกี่ยวข้องกับการทรงตัวที่แย่ลง, เพิ่มการแกว่งของร่างกาย, และเพิ่มความเสี่ยงของการพลัดตกหกล้ม ประมาณร้อยละ 30 ของบุคคลที่อายุเกินกว่า 65 ปี ประสบกับการพลัดตกหกล้มแล้วเป็นผลให้เกิดการบาดเจ็บที่ร้ายแรง แผ่นรองฝ่าเท้าชนิดพื้นผิวไม่เรียบเป็นวิธีการที่เรียบง่ายและมีราคาไม่สูง ที่จะสามารถปรับปรุงความสมดุลในผู้สูงอายุ **วัตถุประสงค์:** การศึกษานี้เป็นการประเมินและเปรียบเทียบผลกระทบของแผ่นรองฝ่าเท้าชนิดพื้นผิวไม่เรียบ 3 รูปแบบในการควบคุมการทรงตัว และการเดินในผู้สูงอายุที่มีประวัติการพลัดตกหกล้มในสามเดือนที่ผ่านมา หรือมีความเสี่ยงของการพลัดตกหกล้มในระดับปานกลาง **วิธีการ:** ผู้เข้าร่วมวิจัยที่อายุมากกว่า 65 ปี จำนวน 15 คนเข้าร่วมการวิจัย ทุกคนจะได้รับการทดสอบ

ทั้งหมด 4 เงื่อนไขการทดลอง สำหรับการทดสอบการทรงตัวขณะหลับตายืนนิ่ง, การทดสอบความสามารถด้านการเคลื่อนไหว, และการทดสอบท่าทางการเดิน ได้แก่ แผ่นรองฝ่าเท้าชนิดเรียบ (เพื่อเป็นมาตรฐานเปรียบเทียบ) และแผ่นรองฝ่าเท้าชนิดพื้นผิวไม่เรียบที่มีลักษณะแตกต่างกันทั้งสามรูปแบบ **ผล:** แผ่นรองฝ่าเท้าชนิดพื้นผิวไม่เรียบมีผลกระทบต่อการทรงตัว อย่างมีนัยสำคัญ โดยเฉพาะอย่างยิ่งเมื่อทดสอบกับ Filled Polymer used as 12V wire insulation, ความแข็งของยางซิลิโคนที่ 55.1, ความหนาแน่นที่ 354.84 กรัม/ซม3 และมีลักษณะของตุ่มนูนที่เส้นผ่านศูนย์กลาง 6 มม., ความสูง 3 มม., ระยะห่างระหว่างตรงกลางของปุ่มนูน 9.5 มม. ที่ได้กำหนดเป็น Textured insole A (TI-A) **สรุป:** แผ่นรองฝ่าเท้าชนิดพื้นผิวไม่เรียบ เป็นอุปกรณ์ที่เรียบง่ายและมีราคาไม่สูง สามารถลดการแกว่งของร่างกายและเพิ่มการทรงตัวให้ดีขึ้น

คำสำคัญ: แผ่นรองฝ่าเท้าชนิดพื้นผิวไม่เรียบ, ผู้สูงอายุ, การควบคุมการทรงตัว , Wii Balance Board, BTS G-sensor

Introduction

One-quarter of older adults experience unexpected falls every year[1]. Consequently, falls are the principal cause of death and injury among older adults, with approximately 33% of individuals above 65 years old experiencing falls[2]. In addition, approximately 20% to 30% of these falls result in severe injuries, such as a hip fractures or head injuries[3].

Moreover, older adults present a progressive loss of cutaneous afferent axons that alter cutaneous receptors[4]. The loss of plantar cutaneous sensation in the feet has been associated with impaired balance control, increased postural sway, and an elevated risk of falling[5].

Postural control is influenced by a variety of inputs, from visual to vestibular information, and somatosensory systems. The somatosensory system is a part of the sensory system, which processes information from the cutaneous afferent receptors[6]. The afferent input of the foot or the plantar mechanoreceptor responds to the force of the footas it makes direct contact with the ground. Thus, the central nervous system (CNS) regulates sensory information about the position of the body to provide postural balance. Consequently, the plantar surface of the foot is essential for maintaining balance and postural control[7].Numerous previous studies have suggested that footwear interventions can alter the mechanical and sensory effects on posture. The effects included applying a vibratory device[8-10], non-electrical stimulation of plantar mechanoreceptors as skin indentation[11-12], customized Foot Orthoses (FOs)[13-14], and textured insole[15-18]. These interventions all serve a role in affecting posture. One possible mechanism of using a textured surface insole is the ability to produce higher plantar pressure at elevated areas, providing stronger sensory stimulation to the mechanoreceptors of the limbs[16]. Several studies have investigated the effect of textured insoles in a specific foot area[19-20]. For example, Ritchie et al[20] showed that textured surface insoles equidistantly placed on the medial side of the sole could reduce mid-foot pronation during the loading and propulsive phases of the gait cycle. Vibratory devices are expensive, complex and may not be a feasible solution for clinical practice. Therefore, a simple mechanical stimulus in the form of textured surface insoles may improve postural stability.

Currently, the ideal material properties and geometric patterns of the indentations or protrusions that compose the textured insoles are unknown, and their effectiveness on postural control needs further investigation. Moreover, many previous studies selected textured materials based on commercially available to the researchers. This study aims to compare different types of locally available textured material properties used to fabricate insoles.

Materials and Methods

Three different locally available materials were obtained from a popular foam material shop. Regarding the control condition, a 3 mm smooth surface Pe-lite insole with a Shore A hardness of 24.02 was used to compensate for shoe’s depth and make it equal to the other conditions. However, it was difficult to determine whether the effect of the intervention was through the mechanical or sensory system, so a flat textured surface was used as the intervention instead of a form of custom-made foot orthosis (FO) to exclude the mechanical system. The properties and geometry of the protrusion are shown in Figure 1 and Table 1, respectively. The objective for this study is to investigate whether wearing textured surface insoles alters or improves static balance, functional mobility, and spatiotemporal gait parameters, the efficacy of different textured surface insoles was compared.

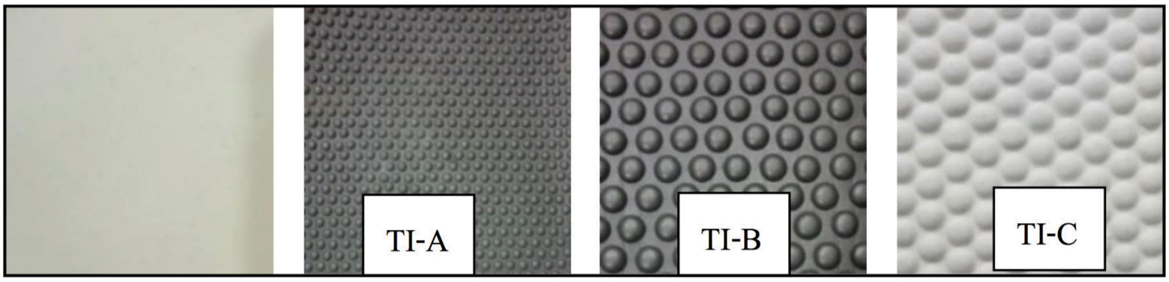

Figure 1 Control condition, Textured Insole A, Textured Insole B, and Textured Insole C.

Table 1 Characteristics and descriptions of the tested textured insoles 3 mm in thickness with a semi-circular pattern distributed evenly across the surface.

Characteristics / Textured type	Material	Hardness (Shore A)	Density (g/cm^3)	Texture descriptions (mm)		
				Diameter	Height	Center distance
Textured Insole A (TI-A)	Filled polymer	55.1	354.84	6	3	9.5
Textured Insole B (TI-B)	White rubber	37.3	189.40	12	2.5	15
Textured Insole C (TI-C)	Asphalt	33	315.06	13	3	15

This study was conducted at the Sirindhorn School of Prosthetics and Orthotics (SSPO) from February 2021 to April 2021. Participants were recruited through an invitation poster displayed in the SSPO clinic, geriatric clinic, and rehabilitation clinic at Siriraj Hospital. No previous study has evaluated the textured materials available in Thailand to make insoles as a reference. The sample size estimation was based on the most similar study design and outcome measurements from two previous studies as references. First, the study by Qiu et al.[16] used a sample size of 8, and Nurse et al.[21] used a sample size of 15. Therefore, it was considered that 15 participants might be enough for this preliminary study.

This study involved a within-subject experimental design, in which participants were exposed to all the different conditions for assessing the independent variables in this study. Consequently, all the participants were tested under four conditions, namely the control condition (3 mm smooth insole), Textured Insole A (TI-A), Textured Insole B (TI-B), and Textured Insole C (TI-C), for static balance assessment, functional mobility assessment, and spatiotemporal gait assessment.

All the participants provided written informed consent before participating in the study. Ethical approval was approved by Siriraj Institutional Review Board, Faculty of Medicine Siriraj Hospital, Mahidol University with protocol number 9652563/(IRB1).

The inclusion criteria were as follows: age greater than or equal to 65 years old (with an average of 70 years), healthy weight range (BMI: 18.524.9-), an ability to walk independently for at least 15 meters on a level surface without using any gait aids, and a history of falls within the last three months, or a score between 25 to 55 on the Morse Fall Scale, thus indicating a moderate risk of falling.

The exclusion criteria were participants who had undergone any lower limb extremities surgery during the previous year, had leg length discrepancy (LLD), used of medications that may affect balance or had taken any substance such as alcohol within 24 hours before testing, having a clinical diagnosis of peripheral neuropathy or cerebrovascular disease (Stroke), have lower limb or foot pain, and no history of limb amputation or partial limb amputation, such as toe amputation or partial foot amputation.

Participants attended testing on two visits, in which they were tested in two conditions per visit, with at least one day apart between visits to minimize any fatigue that could impact another assessment condition. Before initiating the testing procedures, the participants were asked to stand and walk with the textured insoles for 5 minutes.

Preparation session

All three different textured surfaces, including one smooth control surface (Pe-lite, 3 mm thickness) were trimmed according to each participant's shoe size. To minimize the confounding effects of different shoe construction, all participants received the standardized control footwear with open-toe shoes and soft false leather lining (Cordoma International Co., Ltd., Bangkok, Thailand). It had three Velcro straps, 11 cm collar height, 1 cm heel high, and Shore C 60 sole hardness (stiff sole). Additionally, the principal investigator modified a posterior 10-degree heel bevel (a little beveled area on the heel that contacts the ground) following the recommended shoe design for older adults from the previous systematic review[22]. The test sequence of 4 testing conditions was randomized for each participant via the Research randomizer website (https://www.randomizer.org/), and participants did not know which conditions they are assigned in (Single-Blind Study).

The testing session was performed in three modes: static balance testing using a Wii Balance Board (WBB; Nintendo, Japan), functional mobility testing, and spatiotemporal gait assessment using the G-Sensor® (BTS Bioengineering, S.p.A., Italy). All data were interpreted and collected using the software program «Ross Clark–WBB sway program» (Ross Clark, copyright 2015). The Wii Balance Board and the BTS G-Sensor® were connected to a personal computer (PC) via Bluetooth.).

Static balance assessment

Participants were instructed to stand bipedally with their trunks erect, arms by their sides, and lower limbs extended in a barefoot condition for 20 seconds. One practice trial with eyes open condition was first provided by asking the participants to look straight ahead at an eye-level target on a wall 3 meters away to familiarize themselves with the systems. Subsequently, three trials per condition were performed, involving 10 seconds for preparation and 20 seconds of actual testing (6 trials in total for each visit) with eyes closed. Participants were instructed to stand still as much as possible. Between each trial, the participants rested for 2 minutes while seated to avoid fatigue.

Functional mobility assessment

All participants performed Timed Up and Go (TUG) tests when wearing a wireless sensing unit (70 × 40 × 18 mm; 37 g; G-Sensor)[23] attached to an elastic belt at the L2 level of the spine over their clothes. The timing was initiated by the BTS® G- Studio software when the researcher said the word "go" and was stopped when the participants were seated again. One practice trial was provided for acclimation to the test followed by three testing trials. A shorter total TUG time was considered to indicate better functional mobility.

Spatiotemporal gait assessment

For the spatiotemporal gait assessment session, the BTS G-Sensor® was used to measure the spatiotemporal parameters, which consisted of walking speed, step length, stride length, and cadence during a 10-meter walk test. The device was attached to an elastic belt at the S1 level of the spine over participants' clothes. Participants were asked to walk from a standing position at a comfortable and safe speed along a 15-metre pathway for three trials.

Overall comfort subjective assessment

Participants were asked to rate the overall comfort of wearing their allocated intervention using a visual analog scale (VAS) by marking a 100 mm linear scale. The scale ranged from 0 (not comfortable at all) to 100 (extremely comfortable), and any adverse effect was recorded in the case record form.

Statistical analysis

Data were analyzed using Statistical Package for the Social Sciences Version 21.0 (IBM Corp., New York, NY, USA). A repeated-measures ANOVA was used to identify statistical differences among the four conditions with an alpha level set at 0.05. If ANOVA found any significant difference, Bonferroni-adjusted post-tests were used to compare the main effects of each condition.

Results

Overall, 15 elderly participants were recruited for this study. The participants were identified as in the normal weight range with a body mass index of 18.5–24.9. None of the participants presented any adverse effects from wearing the textured insole material.

For the static balance assessment, there was a statistically significant difference in the Center of Pressure (COP) path range ($F_{3,42}$ = 11.63, p = .003), COP path velocity ($F_{3,42}$ = 5.26, p = .014), mediolateral (ML) path velocity ($F_{3,42}$ = 10.99, p = .017), ML range ($F_{3,42}$ = 5.92, p = .006), anterior–posterior (AP) path velocity ($F_{3,42}$ = 11.44, p = .002), and AP range ($F_{3,42}$ = 8.20, p = .003). Textured Insole A (TI-A) showed the best measures among the four conditions, as shown in Figure 2. Bonferroni-adjusted comparisons revealed that TI-A was the only condition that significantly decreased postural sway in all the static balance measurements when comparing the control condition with the other conditions. ML path velocity and ML range showed statistically significant differences ($p < .01$). Whereas no significant difference was observed with Textured Insole C (TI-C) compared to the control condition. This result indicates that TI-A was effective at reducing postural sway.

Table 2 Functional mobility assessment results (n = 15)

Outcomes	Control	TI-A	TI-B	TI-C	p-value
Total duration (s); mean(SD)	13.39(1.84)	13.15(1.68)	13.08(1.90)	13.07(1.39)	.663

Abbreviations: SD = standard deviation.

Table 3 Spatiotemporal gait assessment results (n = 15)

Outcomes	Control	TI-A	TI-B	TI-C	p-value
Walking speed (m/sec.)	1.03(0.29)	1.01(0.17)	1.06(0.26)	1.01(0.21)	.062
Step length (%st length)	50.42(2.89)	50.02(2.02)	51.05(3.51)	50.59(3.23)	.274
Stride length (m)	1.12(0.27)	1.12(0.18)	1.16(0.30)	1.12(0.16)	.641
Cadence (step/min.)	111.44(7.35)	110.04(9.14)	111.53(9.1)	111.08(7.17)	.079

Data are presented as mean(SD)

The functional mobility and spatiotemporal gait assessment are shown in Tables 2 and 3. There were no significant differences in the total duration of functional mobility and the spatiotemporal gait parameters observed among the four conditions. Lastly, after three testing sessions were completed, the participants reported their level of comfort, and the mean (SD) visual analog scale (VAS) for the control conditions was 69.53 (8.11), indicating the lowest mean overall comfort. There was a significant difference among the four conditions. Moreover, 5 participants reported minor adverse effects from the textured surface insolesexperiencing some discomfort with Textured Insole A (TI-A) during the test. Still, no redness or irritation was present after the test was completed. Contrary to the rest of the participants (10 participants), these 5 participants could sense their foot while standing and walking during the test with TI-A more than with the other types but did not feel discomfort. Accordingly, the level of overall comfort was arranged from uncomfortable to the most comfortable as the control condition, TI-A, TI-C, and TI-B, respectively.

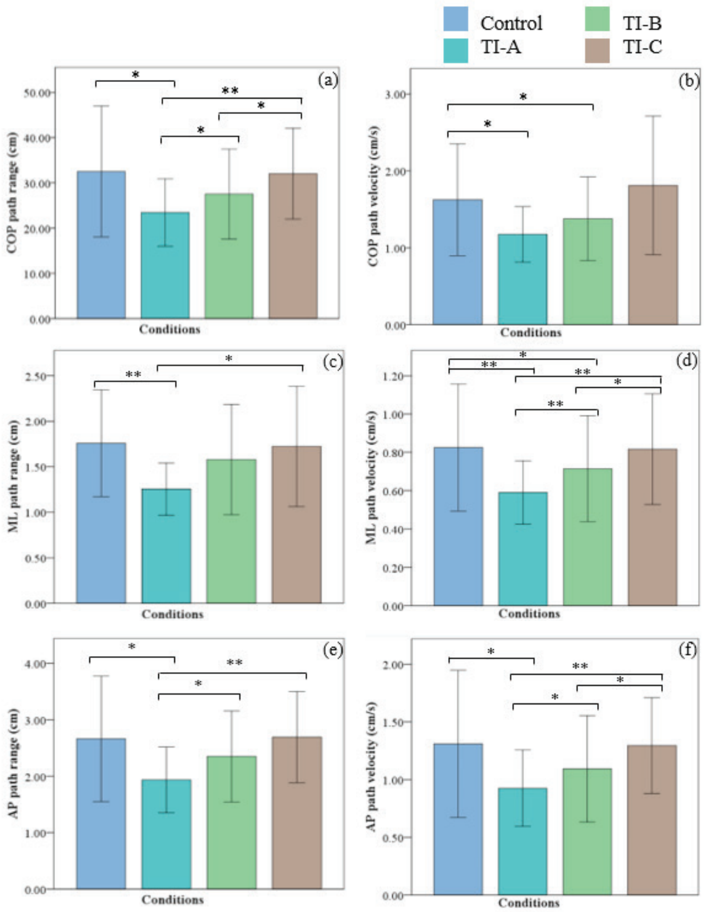

Figure 2 Mean and standard deviation (± 1 SD) for the COP path range (a), COP Path velocity (b), ML path range (c), ML path velocity (d), AP path range (e), AP path velocity (f). Significant differences between conditions are displayed with * ($p < .05$) and ** ($p < .01$)

Discussion

The primary objective of this study was to evaluate and compare the effectiveness of different types of textured insoles on static balance, functional mobility, and spatiotemporal gait parameter in older adults with a moderate risk of fall. The result from this study showed that the textured surface insole (filled polymer), referred to as Textured Insole A (TI-A), gave an optimal reduction of postural sway among the four conditions. Moreover, TI-A caused a significant reduction of all the static balance parameters compared to the control condition. This suggests that the geometry and properties of Textured Insole A (TI-A) provide strongest sensory stimulation to the mechanoreceptors compared to other conditions.

According to the static balance assessment result, essential information on each direction of postural sway and static balance ability is proposed. Postural sway in the medial-lateral direction or lateral instability is common in older adults and is associated with a future risk of falls. Moreover, serious injury, such as a hip fracture, is usually associated with lateral falls[24]. Postural sway in the anterior–posterior direction, also known as A–P stepping, is defined as the instability of taking an additional step in both the forward and backward directions during walking[25]. Static balance is the ability to sustain postural stability by keeping our center of gravity (COG) within a fixed base of support (BOS). Static balance stability is a foundation of postural stability that is important to use to initiate dynamic balance stability and for maintaining stability while the base of support (BOS) is moving. Moreover, the improvement of static balance is beneficial to real-life circumstances; for example, cycling and yoga exercise. Similarly, in the previous investigation by Maki and Maclloy[25], a lack of lateral stability was found to be concerned with an increased risk of falling; thus, the reduction of the ML path velocity (cm/s) and ML path range (cm) may benefit fall prevention.

Several limitations should be noted in this study. Firstly, this study only focused on immediate effects, so the effect of prolonged wear in the long term remains unknown. Secondly, other balance assessments, such as dynamic balance assessment or balance performance with a cognitive task, should be investigated to ensure the validity of this finding. Thirdly, the sample size of 15 was relatively small, and a larger sample size might cause different results. Fourthly, the standard deviation for the static balance assessment was relatively high, which indicates that the data had a broader range. The recruitment selection should then scope down by setting a baseline balance ability (for example, physical activity and muscle strength), which might result in more accurate results. Finally, using textured surface insoles in other population groups, such as Parkinson's disease patients and multiple sclerosis patients, with asymmetry gait and poor walking ability should be investigated in future studies.

Conclusion

The results from this study contribute preliminary evidence suggesting that wearing textured surface insoles could immediately influence static balance stability. In contrast, wearing such insoles did not influence functional mobility and spatiotemporal gait parameters. This study's findings provide a rationale that textured surfaced insoles with similar properties to the filled, 55.1 Shore A hardness, a density of 354.84 g/cm^3 and diameter of 6 mm, the height of 3 mm, a center-to-center distance of 9.5 mm of the protrusions could provide an improvement in static balance posture by providing substitute sensory cues at the feet in older adults with a history of fall within the last three months. Lastly, using textured surface insoles in other population groups, such as Parkinson's disease patients and multiple sclerosis patients, with asymmetry gait and poor walking ability should be investigated in future studies.

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