A comparison of the efficacy of textured insoles on balance performance in older people with versus without plantar callosities

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1. Introduction

The plantar surface of the foot has direct contact with the ground when in the upright position and plays an essential role in regulating sensory feedback, which is required to control human balance [1]. The mechanical receptors embedded in the plantar tissues provide a necessary feedback mechanism to regulate postural control [2]. Previous research has shown that changing the plantar surface feedback mechanism alters postural stability. For instance, balance performance is impaired when the plantar receptors' sensory feedback has been reduced [3]. In contrast, if the plantar surface is mechanically stimulated, the postural stability can be improved [4].
It is known that the foot undergoes structural and functional decline with the aging process [5]. The foot's age-related changes are associated with a reduced plantar sensation and a higher risk of balance disability [6]. Hence, additional feedback to the skin mechanoreceptors can compensate for reduced plantar sensitivity to improve older people's balance control [7], [8]. Although textured insoles are likely to be useful for people with age-related reduced plantar sensitivity [9], [10], there is some evidence that using thick and soft material under the foot has a detrimental impact on balance control [11], [12]. While most literature has focused on the efficacy of the material interface between the foot and the ground, less attention has been paid to the plantar skin's interaction with external material in regulating sensory feedback to the plantar mechanoreceptors.

Callosity is a common dermatologic condition developed to compensate for prolonged pressure on the skin [13]. Plantar callosity frequently occurs in older people [14] and is usually formed due to soft tissue atrophy or foot deformity [15]. Plantar callosities increase skin thickness, reduce plantar sensitivity, and increase the risk of falls in older people [16]. Plantar callosity can inhibit sensory feedback in the area they develop; hence plantar pressure is driven from these zones to a site with normal skin sensitivity [2], [17].

Therefore, plantar callosity is thought to alter the efficacy of textured insoles in providing sensory feedback to the plantar mechanoreceptors. To the authors' knowledge, no previous study has investigated the efficacy of textured material on the balance performance of older people with plantar callosity. The study of the possible interaction between the sensory facilitatory insoles and plantar callosity would give us insight into developing customized insoles to improve balance in older people and may help to explain the cause of discrepancies in previous studies' results. The first objective of this study was to compare the efficacy of textured insoles on balance performance and foot position sense between older people with and without plantar callosity. The second aim was to investigate the efficacy of textured insoles within each study group.

2. Methods

2.1. Participants

This study recruited 30 participants aged over 60 years who had a history of falls within the last six months. The participants were recruited using a convenience sampling method in the geriatric clinic, Alzahra Hospital, Isfahan, Iran. All participants could walk independently without the assistance of a walking aid and provided informed consent. Exclusion criteria were neurological conditions, diabetes mellitus, a history of surgery, fracture(s) in their lower limbs or spine, vestibular or visual defects. Participants with plantar callosity were included if they had a moderate or marked (Grade 2 or 3 out of 6) thickened keratin layer on their sole [18]. Participants who had a callosity with a hematoma, ulcer, or infection (grades 4, 5, and 5, respectively) were excluded. Participants without plantar callosity were tested to have a normal plantar sensation using a 10 gr monofilament over four sites of the sole [19]. The participants with plantar callosity and without plantar callosity were entered into two groups. Ethical approval was obtained from the ethical committee of Isfahan University of Medical Sciences, Isfahan, Iran, before participants' recruitment. All participants were informed about the details of the research before participation.

All testing was completed in a single session at the university's clinical lab. After informed consent was obtained, demographic characteristics were recorded. All participants were given the same type of casual, lace-up walking shoes. Each participant was given a pair of shoes in their appropriate size. Each pair of shoes was fitted with one of three kinds of insoles (study interventions) in random order: 1) textured insoles, 2) smooth (control) insoles, and 3) placebo insoles (insoles are presented in Fig. 1). The randomization order was determined by drawing a concealed envelope from a hat. The textured insoles were manufactured in 3 mm semi-rigid Poly-Vinyl-Chloride, using 3-dimensional printing technology. The textured insoles had a convex circular pattern (2 mm raised circles, 5 mm diameter of rings, 10 mm peak-to-peak distance of adjacent processes) covering the entire insole's surface. A flat insole pair with a smooth surface was used as the control condition and manufactured in 3 mm semi-rigid Ethylene-Vinyl-Acetate (EVA). The placebo condition was the same as the control condition (3 mm flat and smooth EVA sheet cut into insoles) but had a thin vinyl film with a printed pattern covering the surface. The printed design on the covering of the surface resembled the circles on the textured insoles and attempted to blind the participants to the condition they received during testing. Participants were given a few minutes to rest and accommodate their new insoles.

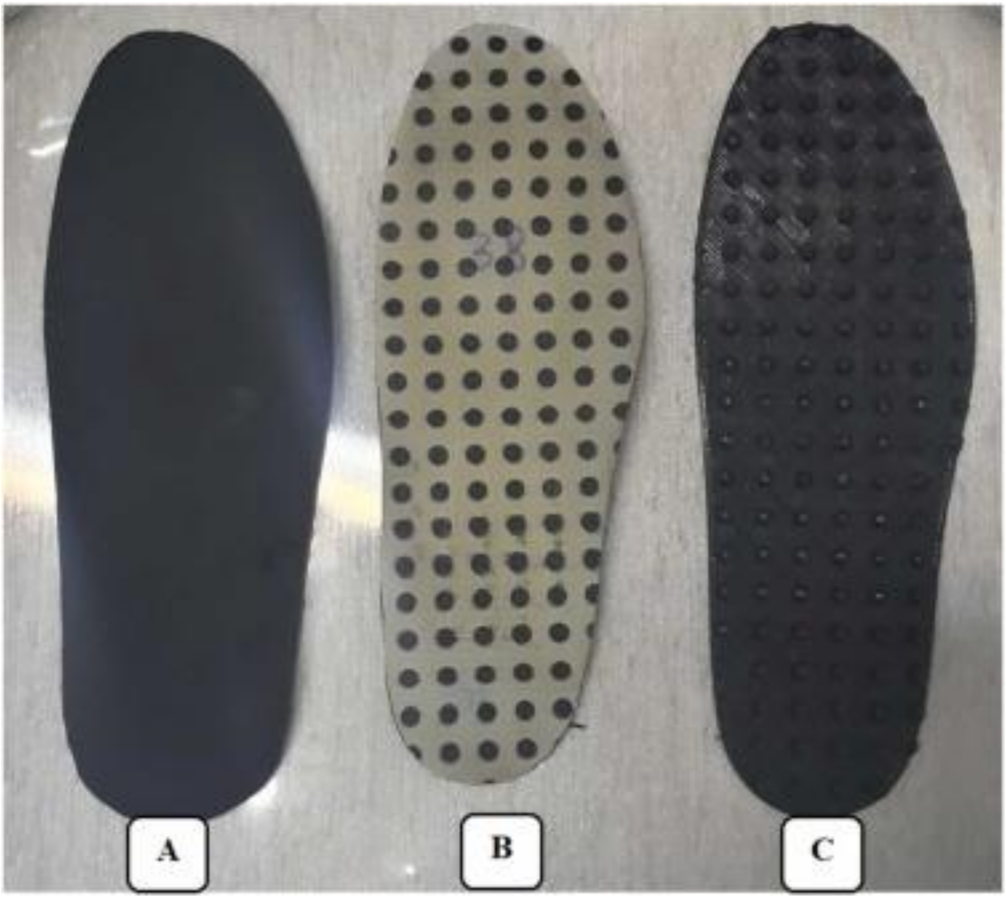

Fig. 1. The study interventions: A) smooth insole (control); B) placebo insole, and C) textured insole.

The primary outcome measures were ankle joint position sense (JPS), postural sway, and the Timed Up & Go (TUG) test. The JPS was defined as the ability to estimate the inclination of the supporting surface under the foot. An adjustable slope box was used, as described in a previous study [20]. This slope box had two parts: a fixed horizontal surface and a sloped surface that could tilt in steps of 2.5°. Participants were asked to stand with their dominant foot on the scaled surface and score the slope's inclination on a − 9 (plantar flexion) to 9 (dorsiflexion) scale. Before the actual testing, the slope with Score − 6 (15° plantar flexion), zero (level surface), and 6 (15° dorsiflexion) were presented as reference scores to be memorized by each participant. Ten different slopes were determined randomly for testing the JPS, varying from − 22.5–22.5°. The absolute errors expressed were averaged and used as the error of the JPS. The slope surface was placed back at the neutral angle between each measurement to control the impact of thixotropic properties of the leg muscles on the ankle JPS [21]. Participants had to complete the JPS measurements with closed eyes, however they could touch the wall for safety during testing. The TUG test was used to assess participants' mobility. In the TUG, participants were asked to sit on an armchair and stand up with the word “go” then walk a 3-meter distance at a comfortable and safe pace until they reach a marked line, returning to the initial position and resting back against the chair. The time to complete the TUG was recorded using a stopwatch. Postural sway was recorded during bipedal standing on a force platform (Advanced Medical Technologies Inc., Watertown, USA) with a sampling rate of 100 Hz. Participants were asked to take an upright stance on the force platform (wearing their shoes, an intermalleolar distance of 8 cm, and a 30° foot angle) and to keep looking straight forward to a reference point placed on the wall in front of them at their sight level. Participants had to stand as still as possible with arms relaxed at their side for the 70 s. The recorded signals were processed to calculate the center of pressure (CoP) over the force platform. The CoP signal was filtered using a 10 Hz cut-off threshold with a second-degree curve. The first and last 5 s were trimmed (leaving 60 s remaining) to obtain more reliable data. The recorded CoP had two anteroposterior (AP) and mediolateral (ML) displacement components. Mean velocity (MV) was calculated to give postural sway features during the AP or ML components during the recording time.

All measurements were carried out in a single session. Each participant had one practice session to become familiar with the process before the actual testing. The TUG and postural sway tests were repeated three times, and mean values were calculated. Participants were given a 2 min break between each trial to prevent fatigue. Two-way analyses of variance (ANOVA) were used to compare outcomes measured in the two study groups and the three study conditions for participants. Tukey HSD posthoc analyses were conducted to explore pairwise differences between study conditions. The statistical analyses were carried out using SPSS software (SPSS Inc., Chicago, IL, USA) version 18, and the level of significance was set at 0.05.

3. Results

The participants with plantar callosity (n = 15, female=6, age: 65.7 ± 5.1 years, and BMI: 26 ± 11) and participants without plantar callosity (n = 15, female=6, age: 67.3 ± 3.1 years, and BMI: 24 ± 10) had no significant difference in demographic parameters ($p > 0.05$). Table 1 summarizes the two groups' mean (SD) scores for the primary outcome measures. All participants completed all testing procedures. No adverse events were reported.

Table 1. The outcomes in two groups and across the study conditions.

Outcome Measures		With plantar callosity (n = 15)			Without plantar callosity (n = 15)			Total (n = 30)		
		Control insole	Placebo insoles	Textured insole	Control insoles	Placebo insoles	Textured insoles	Control insole	Placebo insoles	Textured insole
Error of ankle JPS (Degrees)		6.1 ± 1.7 (3.66–9.63)	4.97 ± 1.13 (2.77 – 7.29)	3.07 ± 1.08 (1.11 – 5.29)	4.33 ± 1.48 (1.88 – 7.08)	4.06 ± 1.41 (1.88 – 6.7)	2.42 ± 1.04 (1.22 – 4.54)	5.28 ± 1.81 (1.88 – 9.6)	4.54 ± 1.33 (1.88 – 7.29)	2.76 ± 1.09 (1.11 – 5.29)
Timed Up & Go (Seconds)		11.28 ± 1.64 (8.14 – 14.2)	11.48 ± 1.64 (9.5 – 15.7)	10.1 ± 1.23 (7.79 – 11.96)	10.98 ± 1.9 (8.06 – 14.7)	11.12 ± 1.88 (8.4 – 14.9)	9.95 ± 1.76 (7.5 – 13.27)	11.13 ± 1.75 (8.06 – 14.7)	11.3 ± 1.74 (8.4 –15.7)	10.02 ± 1.49 (7.5 – 13.27)
MV of CoP (mm/s)	*AP*	8.47 ± 1.88 (5.8 – 12.83)	8.32 ± 1.8 (4.89 – 12.57)	9.65 ± 2.03 (6.49 – 13.66)	11.02 ± 1.8 (7.29 – 13.97)	11 ± 1.77 (8 – 13.59)	11.05 ± 1.83 (7.38 – 13.79)	9.7 ± 2.22 (5.8 – 13.97)	9.61 ± 2.29 (4.89 – 13.59)	10.32 ± 2.02 (6.49 – 13.79)
	ML	10.34 ± 1.97 (7.94 – 13.28)	10.3 ± 2.06 (7.9–13.95)	11.5 ± 2.21 (7.9 – 15.77)	11.83 ± 2.72 (7.4 – 16.99)	12.16 ± 2.72 (7.86 – 16.9)	12.41 ± 3.64 (7.18 – 20.35)	11.06 ± 2.43 (7.4 – 16.99)	11.19 ± 2.54 (7.86 – 16.9)	11.94 ± 2.96 (7.18 – 20.35)

Descriptive values for study conditions are presented as mean±SD and (Minimum - Maximum).
JPS: joint position sensation; MV: mean velocity; CoP: center of pressure; AP: antero-posterior; and ML: mediolateral.

A two-way analysis of variance (ANOVA) showed a statistically significant impact of plantar callosity [(group factor) $f(1,78) = 1.35$, $p < 0.001$] on the ankle JPS. The error of JPS for participants with plantar callosity was significantly greater than for participants without plantar callosity. The main effect for the textured insole [(intervention factor) $f(1,78) = 25.47$, $p < 0.001$] was significant. Post-hoc comparisons using the Tukey HSD test indicated that the error of ankle JPS for the textured insoles was significantly different from placebo insoles and smooth (control) insoles (Fig. 2). The interaction between group and intervention was not significant ($p = 0.26$).

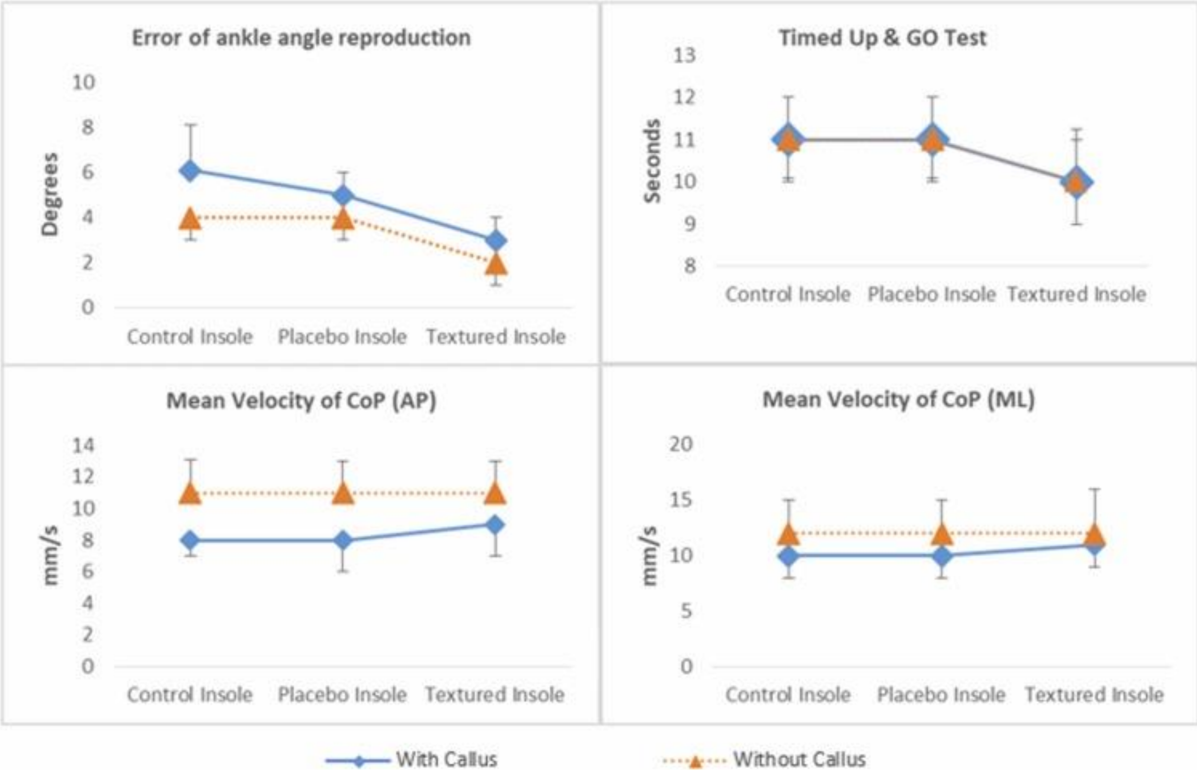

Fig. 2. The change in study outcomes with control, placebo, and textured insoles (Lines are added for interpretation only; the dot points indicate mean values, error bars represent +/- 1 standard deviation of mean values).

There was a statistically significant impact of the intervention factor [f(1,84)= 14.42, p =0.009] on the participant's mobility measured by the TUG test. Post-hoc comparisons using the Tukey HSD test indicated that the recorded time for the textured insole was significantly shorter than the placebo insole and control condition (Fig. 2). The impact of the group factor on the TUG was not significant (p = 0.57) (Table 2). The interaction between the group and intervention was not significant (p = 0.97).

Table 2. The summary of ANOVA analysis on the effects of intervention, group, and their interaction factors on the study outcomes.

Source	df	Mean squares	F	p	partial η2
Variable: ankle JPS					
group	1	25.93	1.35	< 0.001[a]	0.16
Intervention	2	45.26	25.47	< 0.001[a]	0.39
Group × Intervention	2	2.4	1.35	0.26	0.03
Error	78	1.77			
Variable: Timed Up & Go					
group	1	1.63	0.57	0.57	0.007
Intervention	2	14.42	5.03	0.009[a]	0.11
Group × Intervention	2	0.08	0.03	0.97	0.001
Error	84	2.86			
Variable: MV of CoP-AP					
group	1	98.69	27.65	< 0.001[a]	0.27
Intervention	2	3.75	1.05	0.35	0.03
Group × Intervention	2	3.31	0.93	0.4	0.02
Error	75	3.57			
Variable: MV of CoP-ML					
group	1	40.49	5.99	0.017[a]	0.074
Intervention	2	5.84	0.86	0.42	0.023
Group × Intervention	2	1.53	0.23	0.8	0.006
Error	75	6.75			

JPS: joint position sensation; MV: mean velocity; CoP: center of pressure; AP: antero-posterior; and ML: mediolateral.

[a] Indicates a statistically significant difference.

There was a statistically significant impact of the group factor on the postural sway measured by the forceplate [AP component: f (1,75)= 98.69, p < 0.001; ML component: f (1,75)= 40.49, p = 0.017] (Table 2). The mean velocity of CoP for participants with plantar callosity was significantly smaller than for participants without plantar callosity with control and placebo insoles (Fig. 2). The impact of group factor on the AP CoP velocity (p = 0.35) and ML CoP velocity (p = 0.42) was not significant (Table 2).

The details of factor analyses for the primary outcome measures are presented in Table 2. The between-group comparisons for the study's outcomes are shown in Fig. 2.

4. Discussion

The main findings from this study revealed a significant impact of insole type on the ankle JPS and TUG test. This study showed that the textured insole immediately improved ankle joint position sensation and mobility of older people in the two groups. Furthermore, older people with plantar callosity showed a greater average error of ankle JPS and slower AP and ML CoP velocity than those without plantar callosity. No significant callosity-insole interaction was found for any study outcome.

Foot insoles have been suggested as a therapeutic intervention to stimulate the plantar sensory receptors, produce additional somatosensory inputs, improve balance control, and prevent falls [4], [7], [8], [22], [23], [24], [25], [26], [27]. Mechanical stimulation of the plantar receptors includes vibration [8], [26], changes in the contact surface [22], [23], [25], and using a textured surface [7], [24], [27]. Applying a textured surface under the foot could be a more straightforward strategy to stimulate the plantar receptors than to modify the insole’s geometry or embed the vibrating cells in foot insoles. Many scales are used to assess the balance performance in the literature. In this study, we used the mean velocity of CoP for bipedal standing over a force plate. We recorded time to complete the TUG test to assess participants' static balance and mobility, respectively. The literature indicated these are good instruments to estimate the risk of falls in older people with high reliability (33,34).

As in our study, others measured the balance parameters soon after using textured insoles. In one study, Qiu et al. [7] observed the reduced displacement of CoP in using small granulations over the foot insoles while standing on a firm or soft surface. However, they presented no information on participants' plantar sensitivity; therefore, we cannot elaborate on the possible mechanisms for these differences. In another study, a significant decrease of the mean velocity of CoP was reported by Palluel et al. [24] after 5 min of using sandals equipped with spiked insoles in older people. The participants' plantar sensation was assessed with Semmes-Weinstein monofilaments, where it was observed that participants had a relatively normal cutaneous sensation. In accordance with the observed results in our study, Palluel and colleagues [24] have shown that using a textured surface under older people’s feet does not cause an immediate change in their postural sway. Our study participants were given an acclimatization time; although it was shorter than 5 min, it showed the early effects in the reported study [24]. However, the wearing time to obtain the best efficacy of textured insoles is still unclear and needs to be investigated in future studies. Hatton et al. [28] reported no difference in postural sway in older people with normal plantar sensation using textured or smooth insoles, although gait velocity reduced with textured insoles. Also, Qu [29] did not observe any difference in static stability but reported that rigidity of the insole could improve the participant's mobility. De Morias Barbosa et al. [30] have shown that using both textured and smooth insoles in older people with normal plantar sensation could immediately improve the dynamic balance measured with TUG. The results of the literature mentioned above are in line with the findings of our study and indicate that the textured insoles do not immediately change the postural sway of older people with normal plantar sensation (although they could improve the mobility of the users). There are two elements that could explain the lack of significant effects of textured insoles in older people without a callused sole. Firstly, the application time was too short to induce the benefits of the intervention. Secondly, the testing position (i.e., bipedal stance with open eyes over a stable surface) may have been a too simple task to make a challenging condition for the sensory reweighting required to maintain balance [2]. The role of foot sensation in balance control is more important while testing in a challenging condition such as unilateral standing [31].

In the current study, participants with callosity demonstrated a smaller CoP velocity than those without callosity. The impact of plantar callosity on postural stability was supported in previous literature [32], [33]. This finding could imply that people with plantar callosity choose a more cautious strategy to control body sway in standing. This justification can be supported with the average errors of ankle JPS which showed greater values in participants with plantar callosity than those without callosity. It is not clear if the textured insoles worked by providing additional sensory information about the stability limits under the feet [2] or if this was due to a distracting effect of the convex prominence under the callosity. Further studies with muscle activity records can shed light on the balance strategies of people with callosity to show if they use more co-activation patterns of muscle recruitment for cautious standing. The electromyographic studies can also help explore the underlying mechanisms that textured insoles could influence the balance.

There are several limitations in this investigation that need to be mentioned. The sample size was small, and participants were recruited through a convenience sampling method; this could affect the generalizability of our findings. The assessor was not blinded to the insole conditions, and the risk of "bias assessment" should be taken into account, although this may be less relevant as some objective data was measured with automated types of equipment (e.g., recording postural stability with force plate system). Mean differences in TUG performance were small, as low as 1.1–1.38 s between conditions within groups. The clinical significance of these findings therefore needs to be interpreted with caution given that these stopwatch recorded time differences could reflect measurement errors. This was an investigation of the immediate effects of textured insoles, and the impact of longer-term use is the subject of further studies.

5. Conclusion

This study provides evidence that the textured insoles improve ankle joint position sense and mobility (TUG) of older people with history of falls regardless of their plantar callosity status. The insole-callosity interaction effect was not seen in this study.

Ethics committee approval

The work completed here was a research project approved by the Isfahan University of Medical Sciences Ethics committee (Registration No: IR.MUI.REC.1396.3.252).

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Conflict of interest

The authors have no conflicts of interest to disclose.

Data availability

The study data (excluding the personal details) can be shared with other researchers upon their request by email.

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