Efficacy and Effectiveness of a Balance-Enhancing Insole

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Background. Age-related loss of foot-sole cutaneous sensation is very common and is associated with impaired balance control. This study investigated the effect of a balance-enhancing insole (designed to facilitate foot-sole sensation) on lateral gait stability and evaluated its effectiveness in daily life.

Methods. Forty community-dwelling older adults (age 65–75) with moderate loss of foot-sole sensation (unrelated to neuropathy) were fitted with the same model of walking shoes. Half of the participants were assigned, at random, to wear the shoes with a facilitatory insole for 12 weeks; the other participants wore a conventional insole. A gait perturbation protocol, simulating uneven terrain, was performed at baseline and after wearing the assigned insoles for 12 weeks. Participants were tested with both types of insoles during each gait-testing session and sent in weekly postcards with information pertaining to insole comfort, hours of wear, and falls.

Results. The facilitatory insole improved lateral stability during gait, and this benefit did not habituate after 12 weeks of wearing the insole in daily life. Nine participants who wore conventional insoles experienced one or more falls, whereas only five of the facilitatory group fell. Although there were initial reports of mild discomfort in 10 cases, all but one participant tolerated the facilitatory insole, and most indicated that they would like to continue wearing the insole on a long-term basis.

Conclusions. A relatively simple change in insole design can help to counter effects of age-related (non-neuropathic) decline in foot-sole sensitivity, and is a viable intervention to enhance balance control.

Key Words: Cutaneous sensation—Gait—Footwear—Falls prevention—Postural balance.

One of the most pervasive effects of aging is a loss of cutaneous touch and pressure sensation (1). The loss of cutaneous sensation in the plantar surface (sole) of the feet has been correlated with impaired balance control and increased risk of falling (2,3). To maintain stable upright stance, the center of mass (COM) of the body must be positioned over the base of support (BOS) established by the feet. Cutaneous sensation from the plantar mechanoreceptors helps to provide the central nervous system (CNS) with critical stability information about the proximity of the COM to the BOS limits and the degree to which loss of balance may be imminent. Numerous studies support the important contribution of plantar cutaneous sensation in the control of balance (4–9) and gait (10–12). In addition, it has been shown that vibratory insoles designed to reduce cutaneous sensory thresholds (through the phenomenon of stochastic resonance) can improve control of balance during unperturbed stance (13,14).

Plantar pressure sensation appears to play a particularly important role in controlling balancing reactions that involve rapid compensatory stepping movements (8,15). Age-related loss of this sensation can lead to impaired control of these reactions; however, a previous study has demonstrated that it is possible to compensate for this impairment by means of footwear insoles that have a raised ridge around the perimeter (15). The ridge is designed to enhance stimulation of cutaneous mechanoreceptors located near the periphery of the sole, in situations where loss of balance may be imminent (i.e., as the COM approaches the BOS limits). The ridge is intended to cause a small degree of skin indentation in such situations, thereby increasing stimulation of the receptors located in the vicinity of the ridge and increasing the likelihood of exceeding the threshold of these receptors to elicit activity in the associated sensory neurons. The increased stimulation is intended primarily to compensate for reduction in sensitivity due to age-related loss of cutaneous mechanoreceptors, changes in receptor morphology, and/or decreases in skin elasticity (16), but could also possibly help to counter loss of sensation related to impaired sensory-nerve conduction (e.g., due to peripheral neuropathy). To prevent skin irritation or discomfort and reduce any potential for habituation to the stimulus, the ridge is constructed of compliant elastomeric material, with the intent that substantive skin indentation and associated mechanoreceptor stimulation occur only when the COM nears the BOS limits.

The present study examined whether such an insole improves lateral balance control during gait, and whether the
peripheral neuropathy contributed to the loss of sensitivity. Vibration-detection thresholds were determined at four vibration frequencies (3, 25, 100, and 250 Hz) at each of four locations on the sole of the right foot [heel, heads of 1st and 5th metatarsals, and great toe; see (19) for more details]. The intent was to include participants with moderate loss of sensitivity, i.e., with at least 1 of the 16 measured vibration-detection thresholds exceeding the mean thresholds previously reported for healthy young adults (7 to 28 μm, depending on the test location and frequency) (19). Five volunteers were excluded because their loss of sensation was much more severe (i.e., thresholds more than 1 standard deviation higher than the group mean in 50% or more of the 16 vibration-detection tests that were performed). The average threshold was 112 ± 22 μm for these five individuals, whereas the average for the other 46 volunteers was 45 ± 25 μm. Six of these 46 volunteers did not complete the study due to death (n = 1), illness (n = 1), unavailability (n = 2), a perception that the Rockport shoe was too heavy and bulky (n = 1), or inflammation of the heel (cause not reported) (n = 1).

benefits persist after 12 weeks of wearing the insole in daily life. A second objective was to determine whether there are any practical problems associated with wearing such footwear, for example, due to discomfort or skin irritation. A third objective was to gather preliminary evidence regarding potential benefits in reducing risk of falling.

We elected to focus on lateral stability in this study due to its importance in preventing hip fractures (17). The ability to maintain lateral stability during gait is particularly important because lateral balance recovery may require a complex crossover step [which can lead to collisions and/or entangling of the limbs (18)], whereas loss of balance in other directions can potentially be countered via simpler adjustments to step length or step width.

**Methods**

Fifty-one participants completed a medical screening questionnaire and participated in foot-sole vibration-sensation testing (see Table 1 for screening details). The targeted population was healthy older adults (age 65–75) who had moderate insensitivity of the foot-soles, as compared to published norms for young adults (9,19). To avoid the possibility of soft-tissue injury, participants with a clinical diagnosis of diabetes or peripheral neuropathy were excluded; however, it is possible that subclinical levels of peripheral neuropathy contributed to the loss of sensitivity in some of the participants. Of an initial 51 volunteers, five were excluded because they had much higher sensory thresholds. Of the remaining 46 volunteers, 40 completed all components of the study. Failure to complete the study was unrelated to the facilitatory insole, with one possible exception: a participant who dropped out after reporting heel inflammation. Each participant provided written informed consent in compliance with ethics approval granted by the Institutional Review Board.

Each participant was fitted with walking shoes (Rockport World Tour Classic Model; Canton, MA) and both facilitatory and conventional insoles. The facilitatory insoles had a raised ridge around the perimeter (Figure 1A), but were otherwise identical to the conventional insoles in terms of shape, thickness, and material properties. Each participant performed the gait-perturbation protocol described below with both types of insoles, and was then randomly assigned to either the test or control group. The test group wore the facilitatory insoles for 12 consecutive weeks while the control group wore the conventional insoles. During the 12-week period, participants sent in postcards weekly with information pertaining to insole comfort, hours of wear, and falls. They then returned to the laboratory where they repeated the gait-perturbation protocol with both types of insoles.

The gait-perturbation protocol simulated walking over uneven terrain. Six small inclined platforms were located on a walkway so that the foot contacted a different platform at each step (Figure 1B). The analysis focused on the two platforms (#3 and #4) that were located centrally within the viewing volume of a motion-analysis (Optotrak 3020; Northern Digital Inc., Waterloo, Ontario, Canada) system. Prior to each trial, the orientation of these two inclined platforms was changed (to one of four walkway configurations, Figure 1C) in a randomized sequence. Participants were instructed to walk at a comfortable pace, while looking straight ahead at an “X” marked on the wall, and were not allowed to view the walkway prior to the start of each trial. The intent of the random variation in platform orientation was to limit ability to control lateral stability in a predictive manner and to instead force increased reliance on cutaneous feedback.

During each testing session, each participant performed one block of trials while wearing the facilitatory insoles and one while wearing the conventional insoles. The order of testing the two types of insoles was counterbalanced across participants. Each trial block comprised 12 trials (3 trials × 4 walkway configurations). For each trial, kinematic data were collected (5 seconds at 100 Hz) and then used to calculate the total-body COM using a 13-segment model as described previously (20).

The primary focus of the analysis was the lateral displacement of the COM in relation to the BOS (Figure 2). Stability was characterized in terms of the minimum lateral COM–BOS distance occurring during single-support phase. When this distance is at a minimum, the lateral COM velocity is zero; hence, the minimum lateral COM–BOS distance can be interpreted as a lateral “stability margin” (21), which indicates the degree to which the COM approached the limits of stability defined by the BOS (larger values indicate greater stability). Smaller values of this stability

<table>
<thead>
<tr>
<th>Participant Characteristic</th>
<th>Test Group (Wore Facilitatory Insoles for 12 Weeks)</th>
<th>Control Group (Wore Conventional Insoles for 12 Weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>11 men, 9 women</td>
<td>10 men, 10 women</td>
</tr>
<tr>
<td>Age, y*</td>
<td>69 ± 3.6 (65–75)</td>
<td>69 ± 3.1 (65–75)</td>
</tr>
<tr>
<td>Total body mass, kg*</td>
<td>75.9 ± 12.5 (56.7–102.1)</td>
<td>72.9 ± 10.8 (54.4–102.1)</td>
</tr>
<tr>
<td>Height, cm*</td>
<td>1.71 ± 0.11 (1.52–1.88)</td>
<td>1.69 ± 0.08 (1.55–1.83)</td>
</tr>
<tr>
<td>Average vibratory threshold for foot sole, μm*</td>
<td>45.4 ± 24.7 (18–90)</td>
<td>43.8 ± 23.5 (14–84)</td>
</tr>
</tbody>
</table>

Notes: Volunteers were recruited by placing advertisements in local newspapers and putting up posters in community centers, churches, golf courses, and physician offices. Each volunteer completed a medical screening questionnaire. Volunteers who reported any neurological or musculoskeletal problems or use of medications that could affect balance control were excluded. Participants who required footwear orthotics were also excluded.*Reported values represent the mean (± standard deviation) and range.

*Each volunteer completed a testing protocol to determine foot-sole sensitivity. Vibration-detection thresholds were determined at four vibration frequencies (3, 25, 100, and 250 Hz) at each of four locations on the sole of the right foot [heel, heads of 1st and 5th metatarsals, and great toe; see (19) for more details]. The intent was to include participants with moderate loss of sensitivity, i.e., with at least 1 of the 16 measured vibration-detection thresholds exceeding the mean thresholds previously reported for healthy young adults (7 to 28 μm, depending on the test location and frequency) (19). Five volunteers were excluded because their loss of sensation was much more severe (i.e., thresholds more than 1 standard deviation higher than the group mean in 50% or more of the 16 vibration-detection tests that were performed). The average threshold was 112 ± 22 μm for these five individuals, whereas the average for the other 46 volunteers was 45 ± 25 μm. Six of these 46 volunteers did not complete the study due to death (n = 1), illness (n = 1), unavailability (n = 2), a perception that the Rockport shoe was too heavy and bulky (n = 1), or inflammation of the heel (cause not reported) (n = 1).
Figure 1. A, Facilitatory insole used in this study ("SoleSensor"; www.hartmobility.com; U.S. patent #6,237,256 issued May 29, 2001). The conventional insole was of identical style and material but without the raised ridge. B, Experimental setup for studying dynamic balance control during gait over uneven terrain. C, Overhead view of the orientation of the inclined platforms used to simulate the uneven terrain. Arrow: rise of each platform (low end to high end). Note that the participant’s starting position and the spacing of the platforms were adjusted to match the preferred step length of the participants as determined during initial familiarization trials, to ensure that each step landed on a platform when participants walked without looking down during the experimental trials.
margin, as defined above. The statistical model comprised one between-participant factor (participant group, i.e., type of insole worn during the 12 weeks: facilitatory vs conventional) and two within-participant factors: (i) testing session (baseline vs 12 weeks later), and (ii) type of insole worn during testing (tested insole: facilitatory vs conventional).

RESULTS

Lateral stability during gait over uneven terrain increased when participants wore the facilitatory insoles during the testing, in comparison to wearing the conventional insoles. Main effects due to the tested insole were statistically significant for two of the four platform orientations (Table 2). For the lateral orientation, the mean lateral stability margin increased when wearing the facilitatory insoles, in comparison to the conventional insoles (6.0 vs 5.4 cm; F_{1,38} = 7.92, p = .007). For the anterior platform orientation, the facilitatory insole caused the stability margin to increase to a similar degree (6.3 vs 5.8 cm; F_{1, 38} = 4.81, p = .035). An increase in stability margin due to the facilitatory insole occurred in approximately two thirds (26) of the 40 participants, for both the lateral and anterior platform orientations.

None of the analyses showed significant two- or three-way interactions (p values < .11). As illustrated in Figure 3, the facilitatory insole consistently increased the lateral stability margin in both participant groups and in both testing sessions (three-way interaction between tested-insole, session, and group; p values > .46). The consistent effect in the control group across both sessions indicates that there were no significant changes in test performance due to “learning effects” or other time-dependent changes. The fact that the facilitatory insole had a similarly consistent effect in both sessions for the test group indicates that the stabilizing benefits did not habituate to a significant degree as a consequence of wearing the facilitatory insole on a daily basis.

The effect of the facilitatory insole on the stability margin was not associated with any systematic changes in the spatial and temporal characteristics of the gait (p values > .4). For the lateral platform orientation, comparison of facilitatory versus conventional insoles showed nearly identical mean values in terms of stance time (659 vs 661 ms), step width (10.3 vs 10.3 cm), and step length (46.3 vs 46.0 cm). The same was true for the anterior platform orientation: stance time (641 vs 641 ms), step width (11.1 vs 11.1 cm), and step length (46.4 vs 46.5 cm).

There was 100% compliance in completing the weekly reports. These reports indicated that 14 participants experienced one or more falls during the 12 weeks of wearing the footwear/insole. Nine of the fallers were in the group that wore the conventional insoles in daily life, whereas only five of the fallers were in the facilitatory-insole group; hence, wearing the facilitatory insole appeared to reduce the fall rate from 45% (9/20) to 25% (5/20). It should be emphasized, however, that the falls data were collected purely for exploratory purposes; a larger sample would be required to confirm that these trends are statistically significant.

Participants reported no discomfort during gait testing. The weekly reports indicated some minor discomfort associated with wearing the facilitatory insoles in daily life;
however, this was not a common problem after participants became accustomed to wearing these insoles. In the first week, 10 of 20 participants indicated that the facilitatory insoles were mildly uncomfortable; however, there were only four such reports in the second week, three over the next 9 weeks, and none during the final week. After completing the 12-week trial, 17 of 20 participants reported that they would like to continue wearing the facilitatory insole on a long-term basis; the remaining three participants were indifferent. Weekly reports regarding hours of use indicated that both types of insoles were worn to a very similar degree. The average weekly hours of wear were 37.6 (standard deviation \(\text{SD} \) 5.37) and 38.1 (\(\text{SD} \) 5.44) in the facilitatory- and conventional-insole groups, respectively. All but three participants averaged >18 hours of wear per week.

**DISCUSSION**

The facilitatory insole influenced the ability to control body motion when walking over uneven terrain in a manner that reduced the likelihood that the COM motion would exceed the BOS limits in the lateral direction. Moreover, this stabilizing effect was shown to occur during the most unstable (single-support) phase of the gait cycle, with statistically significant effects in two of the four inclined-platform orientations that were tested. The magnitude of the effect was not significantly diminished after 12 weeks of wearing the facilitatory insole in daily life, indicating that the CNS did not habituate to the heightened cutaneous stimulation provided by the insole. These results reinforce the evidence that foot-sole sensation plays an important role in controlling dynamic balance (8,10,11) and support the potential clinical application of the facilitatory insole as a balance-enhancing assistive device.

Although the two groups of participants both showed the same trends, the effect of the insole in increasing the stability margin appeared to be less pronounced (both at baseline and after 12 weeks) in the group that wore the facilitatory insole during the 12 weeks. Possibly, this was the result of inter-group differences in cutaneous sensitivity that were not detected by the vibration-detection tests, or other inter-group differences (e.g., in CNS processing of cutaneous information). The absence of a stabilizing insole effect in two of the four platform orientations could be due to alterations in foot-pressure distribution: The “posterior” platform may cause an anterior pressure shift that could increase stimulation of toe proprioceptors (and thereby reduce reliance on cutaneous receptors) (8,15), whereas the “medial” platform may cause a lateral pressure shift that provides increased stimulation of the cutaneous receptors located near the lateral foot boundary (and thereby obviates the need for the insole ridge).

On average, the facilitatory insole reduced the degree to which the COM approached the lateral BOS limit by approximately 0.5 cm. In absolute terms, the magnitude of the effect may seem small. However, very tight regulation of the COM–BOS relationship is required to maintain lateral stability during gait (22). In the present study, the lateral stability margins (i.e., the proximity of the COM to the lateral margin of the stance foot) were, on average, only 5–6 cm. Moreover, these stability margins were calculated with respect to the edge of the shoe, which corresponds...
approximately to the anatomical margin of the foot, whereas the actual functional limits of the BOS are smaller than the anatomical limits (23). It is also relevant to note that natural variability in lateral foot placement during gait (stride-to-stride SD of stride width) is approximately 2–2.5 cm in older adults (24,25). Such variation may further reduce the stability margin. Moreover, small changes in stride width variability (~1 cm) have been shown to be associated with increased fall risk in older adults (25,26). When considered in relation to these factors, the magnitude of the facilitatory effect is not insubstantial. The insole may well help to reduce the likelihood that errors in motor control or perturbation of balance will lead to loss of balance and falling by causing the COM to be displaced beyond the lateral stability limits. The potential functional benefit of the facilitatory insole is supported by the trends in the
preliminary falls data that were collected. The insole appeared to reduce the incidence of falling from 45% to 25%; however, there is a need for a larger sample to verify this outcome.

Upon returning for testing after completing the 12-week trial, none of the participants reported any discomfort, and most indicated that they would like to continue wearing the facilitatory insole on a long-term basis. These findings indicate a high degree of user acceptance. To further promote acceptance, users could be forewarned that they may experience an initial short period of mild discomfort. However, further research is needed to establish the suitability of this type of footwear in persons who may have increased risk of soft-tissue injury (e.g., due to diabetes). In this context, it is noteworthy that one participant did drop out of the study due to heel inflammation; however, we were unable to confirm whether this was a direct result of wearing the insole.

The tested cohort appears to be representative of a relatively young (age 65–75) community-dwelling senior population. Although we deliberately restricted the study to older adults with moderate loss of plantar cutaneous sensation, only 5 of 51 volunteers were excluded because their loss of sensation was severe. Such individuals were excluded out of concern that a severe reduction in the density of functional cutaneous mecanoreceptors could largely preclude the ability to detect the added stimulation provided by the insole. Further work is needed to determine the minimum level of cutaneous sensitivity required for the insole to be effective. It also remains to be determined whether the insole can provide any benefit in persons with diagnosed peripheral neuropathy. The degree to which the insole is beneficial for older persons with little or no loss of cutaneous sensation has not been examined directly; however, our previous study did show some improvements in balance reactions, even in healthy young adults (15).

In addition, studies of young adult athletes have suggested that the increased sensory feedback provided by a textured insole may enhance performance and reduce risk of injury during sports (27).

Use of vibration as a method for facilitating foot sensation has recently received much publicity (6,14); however, this approach requires a power supply, electronic circuitry, and transducers, and is likely to be much more expensive and complicated than the simple passive insoles tested here. It should also be noted that the vibrating insoles have only been tested during quiet unperturbed standing; hence, their effectiveness in enhancing ability to recover from loss of balance, in potential falling situations, has not been established. The passive mechanical facilitation used here has previously been shown to be effective in enhancing ability to recover balance via compensatory stepping reactions (15), and the present results now demonstrate that it may also improve control of dynamic lateral stability during gait. The previous study (15) clearly indicated that facilitation contributed to reactive control of balance, and reactive mechanisms may have also contributed to the present findings (i.e., use of “online” cutaneous feedback to regulate the lateral excursion of the COM during the singlestance phase of gait). However, the present results may also reflect a contribution to predictive control mechanisms (e.g., use of the augmented sensory information to aid in planning subsequent steps).

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FINANCIAL DISCLOSURE

A patent for the balance-enhancing insole is held jointly by Brian Maki, Stephen Perry, and William McIlroy. Royalties or licensing fees associated with the product mentioned in this article (SoleSensor) may be used to support the authors’ research.

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