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ORIGINAL ARTICLE

A Shoe Insole Delivering Subsensory Vibratory Noise Improves Balance and Gait in Healthy Elderly People

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Abstract

Objectives: To test whether subsensory vibratory noise applied to the sole of the foot using a novel piezoelectric vibratory insole can significantly improve sensation, enhance balance, and reduce gait variability in elderly people, as well as to determine the optimal level of vibratory noise and whether the therapeutic effect would endure and the user's sensory threshold would remain constant during the course of a day.

Design: A randomized, single-blind, crossover study of 3 subsensory noise stimulation levels on 3 days.

Setting: Balance and gait laboratory.

Participants: Healthy community-dwelling elderly volunteers (N=12; age, 65–90y) who could feel the maximum insole vibration.

Interventions: A urethane foam insole with the piezoelectric actuators delivering subsensory vibratory noise stimulation to the soles of the feet.

Main Outcome Measures: Balance, gait, and timed Up and Go (TUG) test.

Results: The vibratory insoles significantly improved performance on the TUG test, reduced the area of postural sway, and reduced the temporal variability of walking at both 70% and 85% of the sensory threshold and during the course of a day. Vibratory sensation thresholds remained relatively stable within and across study days.

Conclusions: This study provides proof of concept that the application of the principle of stochastic resonance to the foot sole sensory system using a new low-voltage piezoelectric technology can improve measures of balance and gait that are associated with falls. Effective vibratory noise amplitudes range from 70% to 85% of the sensory threshold and can be set once daily.

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Falls and mobility disorders are common, dangerous, and expensive conditions in older people.[1] Their causes are multifactorial, including impairments in vision, gait, balance, muscle strength, and cognition. Loss of peripheral somatosensory function, which is common in aging, diabetes, and other causes of peripheral neuropathy, is also a risk factor for falls.[2-5] There were no proven methods to improve somatosensory function in humans until recently when the physical principle of stochastic resonance (SR) was applied to the human somatosensory system. The principle asserts that the presence of a particular low level of white noise can be used to enhance the detection of a weak signal.[6,7] Although we usually think of noise as something that interferes with the transmission of information, experiments in various biological systems, including ion channels and sensory neurons, have demonstrated that low levels of white noise superimposed on a stimulus can actually improve its detection.[7] Therefore, we hypothesized that a noise-based device, such as a shoe insole, might be effective in enhancing somatosensory function in the feet and thereby enable those with reduced plantar sole sensation to overcome associated impairments in balance and gait.

We and others have shown that imperceptible (subsensory) vibratory noise applied to the feet can improve balance in healthy young and elderly subjects[8] and patients with diabetic neuropathy and stroke.[9] We have also shown that this approach can significantly reduce stride, stance, and swing time variability during walking in elderly people with recurrent falls.[10] These studies

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suggested that SR is a potentially viable technology to improve balance and gait if subsensory vibratory noise can be delivered via a shoe insole. However, these early studies used a vibrating tactor that required such a large energy source that it could not be embedded into a shoe. Furthermore, the amplitude of vibratory noise was set 10% below the level that each subject could feel (90% of the sensory detection threshold), which was determined through extensive laboratory testing at the beginning of the experiment. It is not known whether less precise noise levels between 70% and 90% of the sensory threshold would yield similar results or whether the thresholds change throughout a day and therefore require repeated noise settings at different amplitudes to remain effective during prolonged use.

After the experiments with these early devices, a new insole stimulation device using piezoelectric actuators was developed. The actuators were inserted into a typical insole using a standard manufacturing process. These actuators can be driven by a circuit and supplied by a battery, which are inserted in a small encasing and attached to the tongue of a shoe. Still, many questions remain before an insole using this technology can be developed for therapeutic use. We asked whether (1) this device could achieve improvements in mobility, balance, and locomotor control as previously observed in elderly subjects; (2) the therapeutic effect would endure during the course of a day; (3) the user's sensory threshold would remain constant throughout the day; and (4) the stimulation amplitude could still achieve a beneficial effect at other subsensory threshold levels. The present study addresses these important questions.

Methods

Design

We conducted a randomized, single-blind, crossover study of 3 subsensory noise stimulation levels on 3 days in 12 healthy elderly participants aged 65 to 90 years.

Subject recruitment

Subjects were recruited from the community, local senior centers, and independent living housing sites by posting flyers and giving brief presentations about the study. Potential subjects were first screened for eligibility over the phone via a brief questionnaire. Those who passed this initial screening were then evaluated for their ability to feel the vibrations delivered by insoles. These screening visits took place at the potential subject's home or in the Clinical Research Laboratory at the Hebrew SeniorLife's Institute for Aging Research. Informed consent was obtained before vibration screening. Subjects who could feel the vibration from the insoles in both feet were enrolled in the study. The 3 subsequent study visits took place at the Clinical Research Laboratory. All study visits were completed within a 14-day period with at least a day off in between. The study was approved by the Hebrew SeniorLife Institutional Review Board.

List of abbreviations:

COP	**center of pressure**
CV	**coefficient of variation**
ICC	**intraclass correlation coefficient**
SR	**stochastic resonance**
TUG	**timed Up and Go**

Inclusion criteria

To be included in this study, participants needed to be between 65 and 90 years old, feel the maximum insole vibrations, be fluent in English, be capable of understanding and providing written informed consent, and be willing to follow study instructions.

Exclusion criteria

Potential participants were excluded if they had active ulcers on their feet, Parkinson disease or other neurodegenerative conditions, or moderate to severe chronic pain in their lower extremities that interfered with standing and walking (eg, due to arthritis, plantar fasciitis, or painful peripheral neuropathy); used any type of lower extremity orthotic device; could not walk unsupported around their home; could not stand and balance unsupported for at least 1 minute; could not feel the insole vibration when the insoles were set to maximum; did not feel comfortable wearing the insoles; used an investigational new drug within the past 30 days; were active participants in another clinical product performance study within the past 30 days; or had any condition that would make study participation inappropriate in the judgment of the investigators.

Randomization

Participants were randomized by a computerized algorithm to 3 vibratory noise levels on 3 days of testing. These levels were 0%, 70%, and 85% of the baseline sensory threshold measured during the first session of each day. The stimulation level remained constant for each day of testing.

Vibratory insole description

The insole, its control box, and placement in a shoe are shown in figure 1. Two piezoelectric actuators (2.5cm diameter each) were placed 2cm apart in the medial arch region of each three-quarter-length insole to deliver vibratory stimulation. The insole was made of urethane foam and double insulated to avoid contact with the piezoelectric actuators delivering the stimulation. Electrical circuit components for setting the threshold values were attached to the insole via a single cable. The battery lasts approximately 8 hours on a full charge, sufficient for the 6-hour duration of each study visit.

When worn for the study, the insoles were inserted into the subject's footwear and the control box was secured to the shoelaces or the top of the shoe. Research staff ensured that the participant was comfortable before beginning any study procedures. Each control box has an indicator light to show that the insole is turned on, adequately charged, and working correctly. There were no instances of a malfunction or discomfort to the participant. The same pair of shoes and insoles was used for each test day for each subject. Each pair of insoles was used in only 1 subject, and they were cleaned with an antiseptic spray for each day of testing.

Study procedures

Participants were asked to bring their own sneakers and walking shoes to the first study visit, and the shoe and insoles that fit most comfortably were used for all studies. All study participants were provided with normal-thickness socks to wear at all study visits to ensure a consistent sock thickness across all participants and all visits.