Research Article

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Improvement in Balance and Stability Using a Novel Sensory Application: Haptic Vibrotactile Trigger Technology

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ABSTRACT

Introduction: Posture and balance are predominantly controlled by intricate mechanisms fluctuating between sensory and motor modules located in the spinal cord, brain stem and cerebellum. They rely upon the ongoing cycle of synchronization of the sensory system (i.e., vestibular, visual, somatosensory), the cognitive system (central nervous system), and musculoskeletal system. As we age, physiological changes occur in each one of the sensory systems resulting in an increased risk of falling primarily due to the difficulties of maintaining postural control and balance.

Peripheral and central nervous system (PNS/CNS) communications are crucial in determining sensory input and motor output in response to various external and internal stimuli. Understanding the neuronal pathways and networks associated in balance control is crucial in neuropathology and how they are influenced by and respond to external stimuli.

There have been several therapeutic approaches identified and shown to be effective to assist with improving balance and stability in addition to possibly preventing, delaying, and reversing frailty. Some of these approaches may not be a realistic option as they require a high level of mobility. Alternative strategies, including new technologies focusing on improving balance and stability may provide promise for those with decreased or limited mobility.

The neuromuscular system along with the neural pathways are constantly engaged as the body must continuously adjust to ongoing environmental stimuli for successful movement and fall prevention. Synchronization of the visual, vestibular, and tactile senses should be working together with the neuromuscular system in order to control body alignment and to promote the proper motor output.

Haptic vibrotactile trigger technology (VTT) targets the neural pathways and was designed and developed to assist with improving balance, stability, pain, sleep, and other areas of health and wellness. The technology has been incorporated into apparel and other non-invasive routes of delivery such as non-pharmacological patches, braces, wrist bands, and compression sleeves.

The purpose of this minimal risk study was to explore the effects of haptic vibrotactile trigger technology (VTT) enhanced socks and its effect on balance and stability with those patients that wore regular cloth socks that were not embedded with the technology.

Methods: This Institutional Review Board-approved study compared the efficacy of haptic vibrotactile trigger technology (Superneuro VTT Enhanced Socks (Srysty Holding Co., Toronto, Canada)) and its effect on balance and stability with those subjects that wore regular cloth socks that were not embedded with the technology. Sixty-nine (69) subjects (n=44 males, 25 females) were enrolled in the study after providing consent. A Sway Medical Balance Assessment was taken on each subject while wearing the VTT Enhanced Socks and while wearing regular socks not embedded with the VTT technology. Overall Sway Medical Balance Assessment Scores were obtained, evaluated, and compared for each subject. A one-way ANOVA F test was performed to compare and identify change in means in VTT enhanced socks and regular socks.

Results: The results showed a distinct and statistically significant difference in the Sway Medical Balance Assessment Scores between those subjects wearing regular socks and the haptic vibrotactile trigger technology (VTT) enhanced socks. The mean difference in Sway Medical Balance Assessment Scores between the regular socks and the VTT enhanced socks was 31%, with the increase and positive subject response to the VTT enhanced socks being significantly higher than with the regular sock type.

Conclusions: Study results indicate that subjects wearing socks embedded with haptic vibrotactile trigger technology (VTT) demonstrated an improvement in overall Balance and Stability Scores. VTT Enhanced Socks appeared to influence neuromuscular balance and stability control centers and sensory, cognitive, and musculoskeletal areas of the brain. It has the potential to become a beneficial treatment option and solution for clinicians, their patients, and those suffering from various ailments while limiting risks associated with conventional treatments. The results support further research into the use of this haptic vibrotactile trigger technology (VTT) to confirm the impact on balance and stability, Activities of Daily Living (ADL), and Quality of Life (QoL) components.

Keywords
Haptic vibrotactile trigger technology, Balance and stability, Neuromatrix, Superneuro, VTT enhanced socks.

Introduction
Sensation and tactual perception by skin is an innate mechanism for human survival and represents our evolved and adaptive somatosensorial ability to apprehend information via haptics – the active touch for object recognition and perception by higher centers of the brain [1,2]. The somatosensation that is identified by a set of molecular receptors sensitive to a variety of stimuli (thermal, tactile, and mechanical) is critical to survival, balance control, and pain modulation.

Peripheral and central nervous system (PNS/CNS) communications are crucial in determining sensory input and motor output in response to various external and internal stimuli [3]. The cerebral cortex, in addition to the brain stem and cerebellum, in particular, play a critical role in sensory, motor and association mechanisms, including human balance control.

There is an increased risk of falling in older adults primarily due to the difficulties of maintaining postural control and balance while performing activities of daily living (ADL) [4,5]. Postural control and balance rely upon the ongoing cycle of synchronization of several systems: the sensory (i.e., vestibular, visual, somatosensory), the cognitive (central nervous system), and musculoskeletal. As one ages, physiological changes occur in each one of the sensory systems [4,6,7].

There have been several therapeutic approaches identified and shown to be effective to prevent falls in older adults. Evidence includes physical training regimens, including aerobic and resistance exercises, to assist in restoring, maintaining function, in addition to possibly preventing, delaying, and reversing frailty [8,9]. Because some of these approaches require that participants be highly mobile, those with low mobility may be restricted from benefiting from these treatments. Thus, alternatives to exercise for those who have low mobility, including balance or coordination exercises or incorporating newly identified technologies, may provide similar benefits [10,11].

Research has confirmed that by improving the ADL in those with mobility issues, there is a direct association with a high quality of life (QoL) [12]. Understanding the various systems (sensory, cognitive, and musculoskeletal) and how they may impact ADL and QoL components, will assist researchers in identifying alternative strategies and approaches to improve those with balance and stability and other mobility challenges.

As people go about their normal daily activities, they are susceptible to changes in both dynamic and static balance. The automatic postural responses sustaining stability in posture and balance control, whether static or dynamic, as basic physiological motor activities emanating from either polysynaptic spinal or transcortical loops, are neurobiologically regulated by an intricate network of mechanisms [13]. Controlling those changes is challenging for the neuromuscular system as the body must continuously adjust to ongoing environmental stimuli for successful movement and fall prevention. Synchronization of the visual, vestibular, and tactile senses should be working together with the neuromuscular system in order to control body alignment and to promote the proper motor output [6,14,15]. As people age, their balance and stability is impaired, due to the physiological and cognitive changes noted above. Researchers are continuing to work in identifying balance and stability control approaches for those with these challenges [16].

Essentially, posture and balance are predominantly controlled by intricate mechanisms fluctuating between sensory and motor modules located in the spinal cord, brain stem and cerebellum [7]. (Recently, evidence has shown that the cerebral cortex plays a crucial role in regulating those neural pathways implicated with balance and posture, such as in the fronto-central and centro-parietal cortical regions. This, subsequently, contributes to the optimization of balance control mechanisms via time-variant, directed functional connectivity [7].

Unraveling the neuronal pathways and networks involved in balance control is crucial in neuropathology [2]. In addition, the impact of external stimulations or experimental interventions are likely to modulate those webs of pathways [11].

With neuroimaging and advanced signal processing technologies, the optimization of balance control requires a topographically situated time-variant, waveform frequency-selective and directed functional connectivity modules measurable by the electroencephalogram (EEG) [17]. Recording brain activity by the EEG due to mechanical, cognitive and sensory mechanisms related to static or dynamic balance control, has unraveled intricate pathways and cortical networks that correlate with temporal and spatial paradigms [13,18].

A potential correlation is established between EEG modulations and subsequent interference with neuronal activities that are likely to be involved with human balance control, as this may have neuropathological dimensions in the treatment of neurodegenerative diseases and debilitating conditions [7].

Researchers have shown that interference between external stimulations and EEG fluctuations are likely involved with neuronal activities relating to human balance control, and based on the fact that exogenous neuronal stimuli can affect and change the patterns of EEG waveforms that create fluctuations and responses that are likely coordinated mechanically, sensorially and cognitively, in maintaining static and dynamic balance control [7,11].

Haptic vibrotactile trigger technology (VTT) targets the neural pathways and is theorized to disrupt the neuromatrix. The technology has been incorporated into apparel and other non-invasive routes of delivery such as non-pharmacological patches, braces, wrist bands, and compression sleeves [19].

Dhaliwal et al. (2022) specifically examined neural mechanisms associated with the effects of foot stimulation on the EEG patterns by evaluating VTT and how it may impact and influence the neuromatrix. Since those patterns are closely related to human balance control, there is compelling evidence indicating that the manipulation of neural circuits can affect the oscillations of EEG waveforms and, subsequently, motor-dependent balance control [11]. Further, it has been theorized that when a somatosensory pattern of stimulation is applied to the metatarsal region of the foot through the incorporation of haptic vibrotactile trigger technology, then improved balance and movement coordination may occur due to the influence this stimulation has on the sensory, cognitive, and musculoskeletal systems [11]. As a consequence, the somatosensory pattern of stimulation (haptic vibrotactile trigger technology) was woven and incorporated into socks and worn on one's feet to facilitate the effects of the somatosensory stimulation of the metatarsal region of the bottom of the feet on the peripheral and central nervous system. The purpose of this minimal risk study was to explore the effects of haptic vibrotactile trigger technology enhanced socks and its effect on balance and stability with those patients that wore regular cloth socks that were not embedded with the technology.

Methods

Study Design

This study was an Institutional Review Board-approved trial aimed at comparing the efficacy of haptic vibrotactile trigger technology (Superneuro VTT Enhanced Socks (Srysty Holding Co., Toronto, Canada) and its effect on balance and stability with those patients that wore regular cloth socks that were not embedded with the technology. (See Photos 1 and 2) A priori sample size estimation indicated a desired population of 36 for an effect size of 0.25. Sixty-nine (69) subjects (n=44 males, 25 females) were enrolled in the study after providing consent. Inclusion criteria included: (a) no current pain limiting movement, and (b) no foot or knee condition that would limit the ability to wear the socks, taking a Sway Medical Balance Assessment with regular socks and then the subject replacing the regular socks with the VTT enhanced socks and completing the Sway Medical Balance assessment again.

Enrolled subjects were given 2 pairs of socks (VTT enhanced socks and regular socks) and instructed to choose one pair of either type of sock first. They were not instructed to choose one over other for the first assessment. After placing one pair on their feet, the subjects were given the Sway Medical Balance Assessment. This assessment takes approximately 15 minutes to complete. After the first assessment was completed, subjects had a 5-10 minute interval where they rested, removed the first pair of socks, and then placed the second pair of socks in their feet. The Sway Medical Balance Assessment was then taken again. Data was collected and recorded during each of these assessments.

The Sway Balance System is and FDA-cleared mobile balance testing system that measures and scores an individual's balance and stability and can be used to monitor for signs of balance-related dysfunction [20].

The Sway Medical Balance System measures stability using the built-in motion sensors of any iOS mobile device to quantify postural sway. While the device is pressed against the chest, a proprietary motion analysis algorithm calculates stability and provides an easy-to-understand value on a 100-point scale with 100 being completely stable and 0 being unstable.

The Overall Score is comprised of the statistical mean of all previous test scores and serves as a baseline or control that can be compared against the latest score to detect change.

A Sway Medical Balance Overall Score of between 80 and 85 is in the 50th percentile. Overall Scores between <80 the 25th percentile and Overall Scores between >85 and 95 are in the 75th percentile.

One-way ANOVA F test was performed to compare and identify change in means in VTT enhanced socks and regular socks Overall Scores: (ANOVAN, Matlab, MathWorks, Inc.), with post-hoc Tukey's HSD comparisons to identify differences between the 2 sock types (Superneuro VTT Enhanced Socks and Regular Socks) and between sides (MULTCOMPARE, Matlab, MathWorks, Inc.). An a priori significance level of =0.05 was used for all tests.

Paired t-tests between the regular/standard socks and Superneuro VTT enhanced socks were computed for each subject as well as group paired t-tests.

The study protocol was approved by an institutional review board and was performed in full accordance with the rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the principles of the declaration of Helsinki and the international council of Harmonisation/GCP. All patients gave informed and written consent.

Haptic Vibrotactile Trigger Technology (VTT) Intervention

Photo 1: The Superneuro VTT enhanced sock.

Photo 2: The Superneuro VTT enhanced sock.

Study Procedures and Assessments

Statistical Analysis

For all variables, descriptive statistics were calculated, including frequencies and percent for categorical variables and means with standard deviation (SD) for continuous variables. The maximum sample size available was used for each statistical analysis. Paired t-tests between the regular/standard socks and Superneuro VTT enhanced socks were computed for each subject as well as group paired t-tests.

A two-tailed alpha was set to 0.05 for all statistical comparisons. SPSS v. 27 was used for all analyses.

Results

The results showed a distinct and statistically significant difference in the Sway Medical Balance Assessment Scores between those subjects wearing regular socks and the VTT enhanced socks. Data analysis showed that the overall Sway Medical Balance Assessment Score was significantly higher for the VTT enhanced socks (mean = 89.470; $p<0.005$) with a 95% Confidence Interval (CI) [87.769,91.171] compared to the regular socks (mean = 68.573) (Figures 1-3).

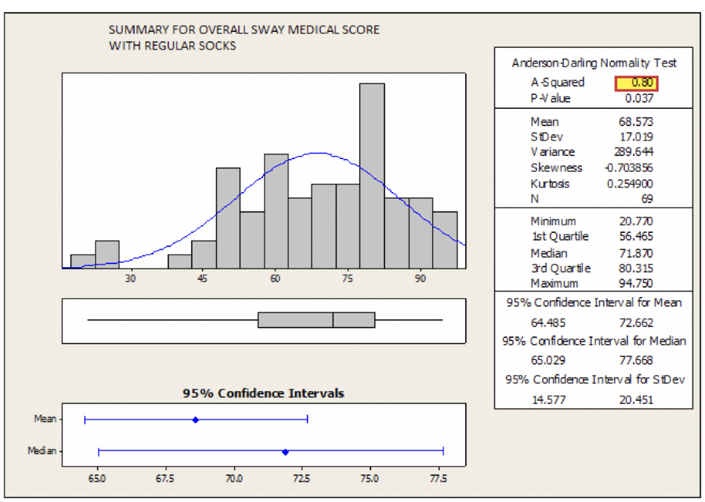


Figure 1

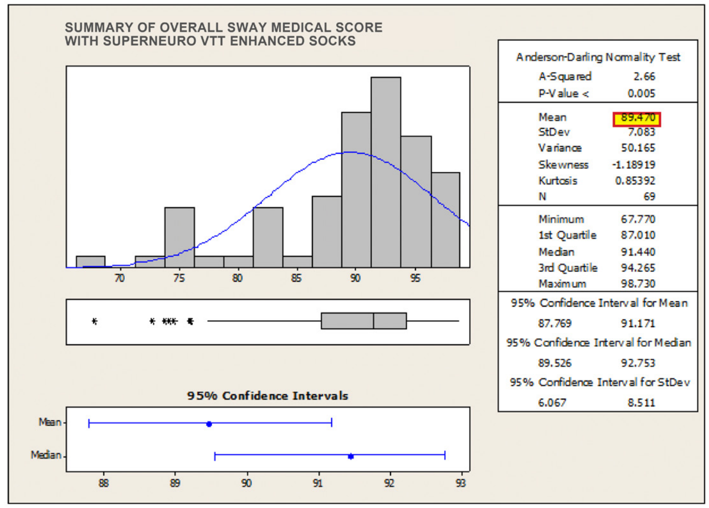


Figure 2

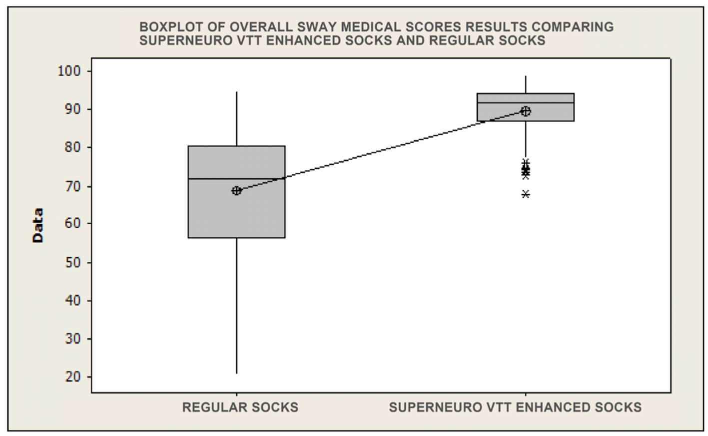


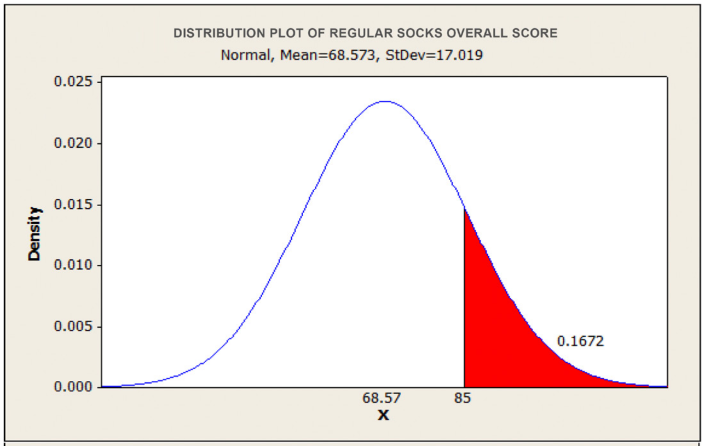
Figure 3

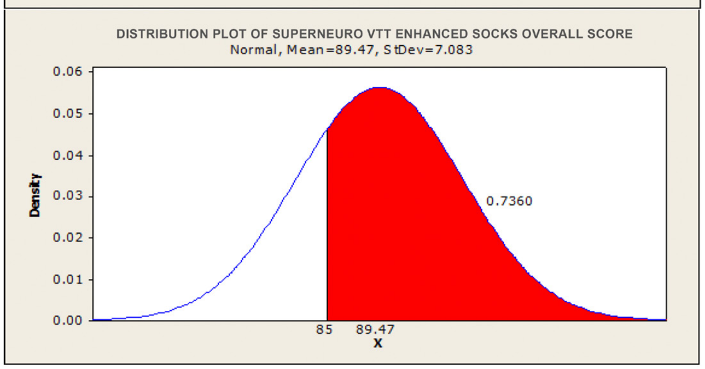
The VTT Enhanced Socks appeared to influence neuromuscular balance and stability control during the Sway Medical Balance testing by increasing the Overall Score relative to the Regular Socks (RS). The mean difference in Sway Medical Balance Assessment score between the regular socks and the VTT enhanced socks was 31%, with the increase being significantly higher with the enhanced sock type, resulting in a higher level of balance and stability for those wearing the VTT enhanced socks.

It was also noted that sock type showed a significant difference in the Overall Sway Medical Balance Assessment Score distribution. Whereas the Regular Socks (RS) condition yielded only a data set of subjects that recorded 16.72% with an Overall Sway Medical Balance Assessment Score of greater than 85%. The VTT enhanced socks, on the other hand, showed a much larger overall Sway Medical Balance Assessment Score distribution, with 73.6% of subjects having a score of greater than 85% (see Figures 4 and 5).

Safety

Patients reported no adverse skin reactions, adverse or serious adverse events while wearing the socks embedded with the haptic vibrotactile trigger technology or the regular socks.





Figures 4 and 5

Discussion

There is mounting evidence that innovative technology-based therapies, such as haptic vibrotactile trigger technology (VTT) supports enhanced brain activation mechanisms in "balance control tasks," irrespective of sensory, cognitive or mechanical occurrences [21,22]. The results from this study show that VTT technology increases balance and stability among those subjects wearing VTT enhanced socks compared to those who are not wearing the socks embedded with the technology. These "balance control tasks" are dual in nature given the fact that they are both sensory (visual, somatosensory, and vestibular), and mechanical (support surface translations) perturbations that correlatively circumvent motor responses emanating from balance deficits. Another key discovery identified neural networks in the midline of the posterior somatosensory association cortex (SAC), which is located within the parietal cortex that is linked with the pre-motor cortex. The SAC is engaged in somatosensory integration via the theta waveforms. In particular, EEG mapping has revealed engaged theta activity within the SAC, corroborating the hypothesis that higher cognitive centers engage in balance control [2,3,7,23]. The mapping technology that has been develop by Srysty Holdings (Toronto. Canada) and that is incorporated into VTT enhanced socks has revealed influence in patterns in neuropathways that are critical in identifying the challenges and limitations of current approaches in the treatment of conditions associated with posture, balance, and mobility.

Further research of cortical networks has shown the involvement of the primary motor cortex region, comprising of a network that emanates from SAC, thereby representing somatotopic control of both static and dynamic balance situations. This mapping has also identified a dimension of motor sequencing and planning, in addition to movement initiation and inhibition [18,24,25]. Interestingly, both mechanisms implicated alpha waves in inhibited cortical areas, suggesting that this drop is a loss of inhibition necessary to promote cognitive decisions in maintaining balance control and stability. Haptic vibrotactile trigger stimulation correlates with this reasoning given the observation that there was statistically significant inhibition of EEG coherence, indicating enhanced neuronal network complexity and potential cognitive ability in participants [11]. This technology has been shown to influence those areas in the brain that are associated with balance and mobility, energy, and pain, by modulating different neural pathways.

The VTT technology is theorized to facilitate somatosensory information processing during balance control, in addition to the integration, planning, and execution of motor-related responses [11,21,26,27]. On the other hand, the alpha network, presumably involving ventral and dorsal pathways, promotes visual processing necessary in maintaining optimal stability [21,28].

Anatomy of EEG Waveforms in Static and Dynamic Balance Control Paradigms – Solving the EEG Conundrum of Neuronal Networks

The EEG network sequence can be regarded as a set of modules that comprise of temporal and spatial networks spanning frontal, central, and parietal cortical regions. Understanding static and dynamic control paradigms across mechanical, cognitive and sensory modules, is critical in determining the dynamicity of EEG in assessing balance control networks [7,26].

The results from this study corroborate the role of somatosensory patterns of stimulation on human balance control. To verify the consequences of somatosensory activation on human balance control, a pattern resembling somatosensory activation was woven and incorporated into socks (VTT enhanced socks) and worn on one's feet to better facilitate the effects of the somatosensory stimulation of the metatarsal region of the bottom of the feet on the PNS and CNS systems, corroborating previous observations [7,23,29].

Identifying the neuropathways activated by VTT enhanced socks is critical to understanding the outcomes of balance and posture control. Here, the anatomy of this dimension is presented in support of potentially promising projections for enhancing neural circuits associated with posture and balance, backed up by evidence provided by published studies in scientifically relevant fields [7].

The somatosensory component of the VTT enhanced socks revealed patterns that are consistent with the haptic sensation and tactical perception theory [1,2]. Briefly, Reed and Ziat (2018) states the following: "The haptic system is designed for processing the material properties of objects and surfaces via the mediation of cutaneous and kinesthetic afferent subsystems. The passive aspect of haptic perception is often called tactile perception, and it refers to sensations gleaned from being touched by items in the outside world. Mechanoreceptors and thermoreceptors in the skin (e.g., cutaneous inputs) contribute largely to this tactile aspect of haptic perception. However, haptic perception also includes active touch and the sensations that result from the stimulation of receptors in muscles, tendons, and joints (e.g., proprioceptive and kinesthetic inputs). Our understanding of the neural bases of haptic perception from the skin to the brain is based on the study of perceptual and neurophysiological responses in animals and humans". Evidently, the haptic perception has components that are strongly associated with sensory, spatial, proprioceptive, and motor elements [2], all of which are integral components of the haptic vibrotactile trigger technology (VTT), thereby having a potential benefit for applying the concept of haptic/tactual sensation to neuronal development, plasticity, and circuitry involved with human balance control, and perhaps other mechanisms as well [30,31].

Previous research has supported that EEG alpha band frequency falls as balance difficulty increases in central and parietal areas [28,32]. Recent peer-reviewed literature [11] showed that VTT enhanced socks caused oscillations in the alpha frequency in an analogous manner.

Published research has unequivocally shown that the somatosensory system, as a complex system of sensory neurons and intricate pathways that respond to external or internal changes, is also involved in maintaining postural balance by relaying information about body position to the brain, allowing it to activate the appropriate motor responses controlling movement [2,13].

When compared to non-VTT enhanced socks, this study shows that VTT enhanced socks create a response that is indicative of improved balance and stability among those subjects taking part in this study. Potential reasoning for this response includes that the haptic vibrotactile trigger technology triggers a form or cascade of neuronal network that putatively connected with the somatosensory module of the brain, and therefore is likely to be involved in mediating posture and balance control mechanisms under carefully controlled conditions, consistent with earlier, scientifically backed observations [7,13].

Further research on haptic vibrotactile trigger technology (VTT) is encouraged to confirm these results. If the data on this technology continues to show positive results in the balance and stability, pain management, energy, or other areas of study, then this VTT enhanced technology may have the potential to have a large impact on activities of daily living (ADL), quality of life (QoL) components, and overall functionality and wellness among the population.

The results of this study showed that a significant difference in the Sway Medical Balance Assessment Scores of those wearing Superneuro VTT enhanced socks compared to when those same subjects wore regular/standard socks without the embedded technology. As with other published research, the exact mechanisms of action of the haptic vibrotactile trigger technology enhanced socks on the somatosensory system are currently unknown. Identifying alternative treatment options and approaches, such as VTT, that have minimal adverse effects, reduced risks, lack limitations for those who can utilize the technology, when compared to conventional treatment approaches (e.g., physical training regimens that incorporate aerobic/anerobic exercise), are needed in order to provide better options to clinicians and those with reduced functionality and who have balance and stability challenges. A better understanding of the neuromatrix and identifying and incorporating novel, non-pharmacological treatments will add important safe and effective options to a clinician's armamentarium in support of enhanced patient care.

Conclusion

This study demonstrated an improvement in Overall Balance and Stability Scores in subjects wearing Superneuro VTT Enhanced Socks compared to Regular Socks (RS). VTT Enhanced Socks appeared to influence neuromuscular balance and stability control. Incorporating haptic vibrotactile trigger technology into apparel and other non-invasive routes of delivery has the potential to become a beneficial treatment option and solution for clinicians, their patients, and those suffering from various ailments while limiting risks associated with conventional treatments. The results support further research into the use of this haptic vibrotactile trigger technology (VTT) to confirm the impact on balance and stability, Activities of Daily Living (ADL) and Quality of Life (QoL) components.

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Disclosure

John Haddad, PhD received compensation for study interpretation. Baldeep Dhaliwal, MD was not compensated. Manny S Dhaliwal was not compensated. Peter L Hurwitz was compensated for data review and study interpretation.

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