

Effects of Neuromuscular Gait Training on:

Vestibular Disorders

Prepared By:

Ashley Williams, PhD(c), CHPSE

Medical Device Commercialization Consultant & Ethicist

Executive Summary:

KC Product Development DBA Vizziq, is a developer of a patented, breakthrough, neuromuscular gait (manner of walking) training device, leading the charge towards gait training education, improved gait dynamics, and health. Vizziq improves gait health and provides dynamic stability for adults with chronic conditions, illness, injury, or those with the desire to improve or maintain their gait. Vizziq is utilizing strategic partnerships to increase community engagement programs positioning us at the forefront of the industry. This white paper examines the impact of neuromuscular gait training on adults with Vestibular disorders.

Background and Industry Overview

Our gait is modulated by three interconnected internal systems: Vestibular, Visual, and Somatosensory – when all three function properly, inherent fall defense mechanisms improve.¹ Our vestibular (inner ear) system controls our balance, posture, and modulates our gait. Vestibular changes occur as we age and due to specific inner ear changes or anomalies. Vestibular disorders traditionally cause the individual to walk with a normal gait speed but longer, slower steps, and a declination in gait cycle timing occurs to improve postural control. These changes lead to degeneration of gait cycle spatial (Proprioception) and temporal aspects, causing decreased confidence therefore increasing fear of falling.

Gait health is a cornerstone of overall well-being, and translates into maintaining independence in living conditions, safe mobility, and improved quality of life. Gait velocity, or walking speed, is the 6th vital sign which correlates with functional ability, balance, and confidence (fear of falling).² Gait velocity can reflect both functional and physiological changes. The assessment of gait velocity provides the ability to predict future health status and functional decline including potential risk for falls, hospitalization and mortality.³ Treatment options are limited for gait training and rehabilitation. The challenges increase with a chronic condition, injury, or illness, such as vestibular disorders.

Vestibular changes have a significant impact on treatment of gait and/or balance dysfunction and vestibular exercise integration should be incorporated.⁴ Over-the-ground gait training options are limited, expensive, or outdated. Additionally, the ubiquity of low quality mobility aids or minimally available highly technological products has compounded the existing problems of constrained, inefficient, and cost-effective gait training options. The rising use of complex, clinic-only based technology is not just a logistical issue; it represents a significant socioeconomic threat, leaving those without insurance and/or the financial means

the inability to receive proper treatment. Without proper treatment, those with any decline in gait health have a significant risk for falls, leading to further economic challenges.

Moreover, the economic implications of falls are staggering. The cost of fall injuries continues to climb as our geriatric population increases in numbers. As consumers grow more conscious of the impact on daily life and importance of gait health, there is a call for more sustainable, usable, cost-effective gait training offerings. Current gait training frameworks are mired in traditional unsuccessful methods that are financially, logistically, and operationally unsustainable. In this context, the estimated spend of over \$101 billion in falls alone, annually, by 2030, is not just a challenge—it's a call for a radical transformation in the industry.

Vizziq's Mission and Vision

Vizziq emerged as a response to the need for innovative, cost-effective, over-the-ground, gait training technology. Our mission is rooted in the belief that the challenges of today's gait training limitations can be met with Vizziq Neuromuscular Trainer technology. We are committed to redefining perception, stereotypes, and standard of care of over-the-ground gait training and mobility aids, transforming Vizziq from a concept to a sustainable, affordable training tool. By leveraging breakthrough technologies, education, and fostering functional-level based training practices, we aim to realize a vision where every person has the ability to improve their gait health, and utilize gait health as a valuable resource poised for improved quality of life.

We see a future where Vizziq is synonymous with quality gait training and dynamic stability—a future where our name reflects our drive towards improved gait health, therefore enhanced quality of life for everyone. We aim to be a driving force for change, education, influencing standard of care, shaping consumer behavior & perception, and catalyzing industry-wide shifts toward improved over-the-ground gait training opportunities. Quality, Repetition, and Form; One Step at a time!

Problem Statement

Vestibular system deficit is one component of balance and gait dysfunction, causing dizziness, loss of balance, and increased fall risk.⁵ In 2015, the annual spend on falls was \$50B. It is projected that by 2030, if a transformation does not occur, the US will spend \$101B annually, with 75% being paid for by CMS. Even as we produce high-tech consumer goods and advanced devices, our gait training infrastructure lags woefully behind.

As a result, a thorough Physical Therapy evaluation should be completed, followed by prescription of home exercises. To continue advancement, progressively challenging the vestibulocochlear reflex in static and dynamic environments in the clinic is essential. Challenging balance by walking on uneven surfaces (perturbation) or incorporating noisy/busy surroundings are a training opportunity for those with vestibular disorders.⁶ Vizziq can be used to safely allow people to perform these exercises and provide support if necessary. Existing over-the-ground gait training systems struggle with complexity, cost, and consumer perception, all of which contribute to lower adoption rates of at home gait training devices.

These limitations have considerable consequences that are significant: economically, the value embedded in gait training is lost due to lack of consistency and follow through; logistically, the continued reliance on expensive, large, clinic-based treatment options causes a decline in usability; socially, the perception of using a mobility aid causes a lack of adoption. The US beckons for a complete overhaul of the gait training paradigm—one that integrates technological innovation, education and changes in standard of care, with societal engagement.

Vizziq's Innovative Solutions

In the face of these challenges, Vizziq has not only invented & patented but also implemented a transformative solution that addresses the multifaceted dimensions of neuromuscular gait training.

- Spring-Loaded Pivoting Frame with Resistive Technology: Our sophisticated technology-driven device enables pelvic & trunk rotation. The frame provides spring-loaded resistance that enables supplementary support and strengthening for the users. The frame can be used with additional weights or resistance bands for further support and/or strength & aerobic training opportunities. The frame can be placed in pivot/non-pivot mode to meet the user at their particular functional level. The ripple effects are profound: by providing spring-loaded resistance, we not only enhance the pelvic and trunk rotation of the user, but with consistent Vizziq training, the reliance on devices for support is reduced, driving both physical and psychological benefits.
- **Dynamic Stability:** Posture and balance are central to healthy gait mechanics. Vizziq has both upright and parallel bar hand placements to enable the user to receive as much support as necessary for safe and efficient ambulation. These hand placements enable users to maintain a straight

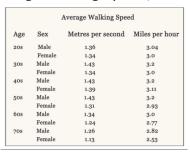
forward, upright posture and gaze. We've pioneered a gait training tool that enables the utility of training opportunities that were once deemed appropriate for clinical environments only. Our proprietary training tool reinstills the fundamental properties of gait health, imbuing users with a new lease on life. This breakthrough approach not only expands the range of gait training opportunities but also training locale where users can continue to train, after being discharged from their current clinical environment, at a lower-level or outpatient clinical environment, at home, or in a fitness center.

• Community & Educational Programs: Our commitment extends beyond the boundaries of our device. We employ Success Coaches that engage the clinicians and consumers through initiatives designed to enlighten, inspire, and educate. Our programs demystify the gait training process, empower individuals to make informed decisions based on their functional level and support, and drive home the impact of gait training. Success Coaches work with clinicians and fitness staff to provide Vizziq specific gait training opportunities and programs based on the needs of the particular user and their functional level.

Impact Assessment:

The effectiveness of neuromuscular training with Vizziq can be measured through several key performance indicators:

• **Increased Gait Speed:** Vizziq users have increased the speed in which they walk, some back to the average walking speed, or even above average.



- **Increase Stride/Step Length:** Vizziq users have seen an improvement in the length of their stride/steps. The average stride length for males is 2.5 feet while for females is around 2.2 feet.
- **Increased Pelvic/Trunk Rotation:** Vizziq users have regained a standard pelvic and trunk rotation of 4 degrees, during ambulation.

- **Improved Balance & Posture:** Vizziq enables users to keep their gaze upwards and straightforward, enabling proper posture, through core muscle activation. Vizziq trains for better performance vs. the traditional stoop-over-and-shuffle posture, which over time causes weakness and increases fall risk.
- **No Dependency to Device:** Vizziq is intended as a training tool but can be used as a mobility aid, without the potential for dependency.
- **Muscle Strengthening:** Vizziq leads to an improvement in muscle strength and proper use of toe push-off and heel strike during ambulation. Vizziq does not cause dependency nor does it cause changes in the center of gravity, which decreases muscle strength, especially in gluteal and calf muscles.
- **Limits Double Stance:** Vizziq decreases the time a user stands on both feet during ambulation, and increases the single stance aspects of the gait cycle including mid-stance, terminal stance, toe push-off, and swing phase.
- **Improved Confidence:** Vizziq users have seen a decrease in fear of falling, due to their improved confidence, as seen in the Fear or Falling Survey (FES-1) completed during case studies.

Case Studies/Testimonials:

1. Stacey, severe vertigo: "This is the first time in over 8 years that I have had trunk rotation. I finally can walk with my friends and feel stable. I can walk and talk at the same time, shifting my gaze back and forth to my friends, while walking down the street."

Future Outlook and Innovation Roadmap

Vizziq recognizes that the journey toward a new standard of care in gait training & gait health requires innovation. As our gaze focuses towards the horizon, our commitment is anchored in a clear vision of progress and a dedication to spearheading transformative initiatives. By the year 2030, we have set ambitious goals to establish the new standard of care, to decrease the risk of falls, thereby enabling a new paradigm shift in gait training. Our plans also include scaling our operations and laying the groundwork for a connected community network of clinical, fitness, durable medical equipment distributors, and consumers, working together.

The road ahead involves strategic milestones that will see us exploring novel gait training technologies, expanding our patent portfolio, and adopting a new standard of care for gait training. Central to our roadmap is the assignment of a new HCPCs code for insurance (CMS) billing, educating stakeholders regarding the importance of gait health and the impact it has on overall well-being, and reducing stigma of using a device like Vizziq. Our research and development teams are already engaged in partnerships with leading academic institutions to pioneer these next-generation training methodologies.

Moreover, the commercialization of Vizziq is an integral part of our vision. We aim to transcend socioeconomic boundaries to deliver our proven, cost-effective device on a national scale. This expansion will not only amplify our impact but will also foster knowledge exchange, cultural acceptance, and the diffusion of best practices in gait health.

Recommendations for Industry Leaders

To realize the potential of **The Movement_Movement** revolution, we urge industry leaders to embrace an open-minded and forward-looking stance. Our recommendations are threefold:

- Investment in Gait Training Equipment: To transition from outdated gait training systems to the future of gait health, investments are essential. We advocate for the allocation of funds, incentives for return on investments, and the development of financial strategies specifically designed to bolster gait health infrastructure. Modernizing facilities with innovative technologies such as over-the-ground gait training devices will create a foundation for a resilient and sustainable gait health program.
- Partnerships & Referral Network: We recommend the formation of partnerships and referral systems that can mobilize resources, streamline standards of care, and accelerate the adoption of advanced gait training technologies. These collaborations should aim to balance clinical gait training programs with the usability for any setting (clinical or non-clinical), creating opportunities for improved gait health despite functional level, financial status, and clinician availability.
- **Education and Outreach:** A well-informed community is the bedrock of positive health outcomes. It is imperative that ongoing educational initiatives are implemented to cultivate a standard of care in gait health that uses new

training technologies, like Vizziq. We encourage clinical key opinion leaders to integrate gait training into physical therapy protocols, support communitybased referral programs, and launch awareness campaigns, like **The Movement-Movement**, that elucidate the tangible benefits of gait health practices to improve overall well-being.

Conclusion:

Vizzig showcases the transformative potential of innovative over-the-ground gait training technology. Through our efforts, we demonstrate that with the right technology, clinician support, and community engagement can evolve the standard of care into a dynamic, education-based training program.

Call to Action:

We invite all stakeholders to join us in creating a new standard of care in gait health. Let's innovate together to improve gait health and gait training standard of care. There is an urgent need for action beyond traditional rehabilitation to normalize gait patterns and avoid long term consequential damage to the vestibular system. Visit Vizzig.com or email info@vizzig.com to learn more.

References:

A comprehensive list of academic articles, industry reports, and independent studies validating the methodologies and findings presented by Vizzig.

Fritz, Stacy & Lusardi, Michelle. "White Paper: "Walking Speed: The Sixth Vital Sign"." Journal of Geriatric Physical Therapy 32, no. 02 (2009): 5. Kauffman, Beth. "The Vestibular Component in Gait and Balance Dysfunction." Rehab Management. (July 11, 2013 2013): 1.

¹ Beth Kauffman, "The Vestibular Component in Gait and Balance Dysfunction," Rehab Management (July 11, 2013 2013). Page 1.

² Stacy & Lusardi Fritz, Michelle, "White Paper: "Walking Speed: the Sixth Vital Sign"," Journal of Geriatric Physical Therapy 32, no. 02 (2009). Page 1.

³ Fritz, "White Paper: "Walking Speed: the Sixth Vital Sign"." Page 1.

Kauffman, "The Vestibular Component in Gait and Balance Dysfunction." Page 1.
Kauffman, "The Vestibular Component in Gait and Balance Dysfunction." Page 1.
Kauffman, "The Vestibular Component in Gait and Balance Dysfunction." Page 1.