



COMMENT ON ORLANDO ET AL.

Acute Effects of Vibrating Insoles on Dynamic Balance and Gait Quality in Individuals With Diabetic Peripheral Neuropathy: A Randomized Crossover Study. *Diabetes Care* 2024;47:1004–1011

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Diabetes Care 2024;47:e80–e81 | <https://doi.org/10.2337/dc24-1090>

We read with interest the paper by Orlando et al. (1), in which they reported on a randomized crossover study that evaluated the effects of vibrating insoles on dynamic balance and gait quality during level walking and stair walking and explored the influence of vibration type and frequency in individuals with type 2 diabetes who had diabetic peripheral neuropathy (DPN). The authors concluded that vibrating insoles are an effective acute strategy for improving postural balance and gait quality during level walking and stair descent in individuals with DPN; these benefits are particularly evident when the entire plantar foot surface is stimulated (1). This is a well-done crossover study on the correlation between vibrating insoles and postural balance and gait quality in individuals with diabetes. However, we have two concerns about this study.

The first concern is about the analysis of gait speed between vibratory insole conditions (Vcs) and control conditions (Ctrl). The authors reported in Table 2 that gait speed increased during stair ascent and descent in Vc2, Vc4, and Vc6 but not in Vc1, Vc3, Vc5, and Vc7: Vc4, Ctrl vs. Vc4 for ascent 0.447 ± 0.180 vs. 0.482 ± 0.197 m/s, $P = 0.047$, and descent 0.394 ± 0.170 vs. 0.438 ± 0.181 m/s, $P = 0.017$; Vc1, Ctrl vs. Vc1 for ascent 0.447 ± 0.180 vs. 0.515 ± 0.107 m/s, $P = 0.100$, and descent 0.394 ± 0.170 vs. $0.483 \pm$

0.101 m/s, $P = 0.058$; Vc3, Ctrl vs. Vc3 for ascent 0.447 ± 0.180 vs. 0.494 ± 0.159 m/s, $P = 0.272$, and descent 0.394 ± 0.170 vs. 0.472 ± 0.147 m/s, $P = 0.099$; and Vc5, Ctrl vs. Vc5 for ascent 0.447 ± 0.180 vs. 0.481 ± 0.166 m/s, $P = 0.443$, and descent 0.394 ± 0.170 vs. 0.448 ± 0.153 m/s, $P = 0.323$. We used a statistical formula for paired t test, namely, $t = X_{diff}/(S_{diff}/\sqrt{n})$, where X_{diff} represents sample mean of the differences, S_{diff} represents sample SD of the differences, and n is sample size (i.e., number of pairs). Compared with the control group, for larger average values and smaller SD for the experimental group, the possibility that a significant difference existed was higher. Because the average gait speed in Vc1, Vc3, and Vc7 was numerically greater than that in Vc4, even with a smaller SD, we suggest the authors analyze the data in Table 2 again.

The second concern is about the study intervention. DPN is characterized by progressive dysfunction of the peripheral sensory and motor nerves, loss of sensory feedback, and alterations in motor control and function. It can alter gait pattern and impair balance, which predisposes the individual to a greater risk of falling than that for individuals without DPN (2). Although the authors pointed out the limitation that further clinical trials were needed to confirm whether long-term vibrating insoles could improve

postural balance and gait performance and reduce the risk of falls, the authors mentioned repeatedly the relationship between gait speed and fall risk in individuals with DPN, which could induce readers to believe that acute-phase improvement can reduce the risk of falls. Indeed, vibrating insole systems improve motion sensing not because of improved sensory threshold but rather by adding an additional vibration to the foot during walking. Moreover, the chronic effects of the treatment still need to be studied, because the human nervous system may develop tolerance to such stimuli (3). Patients may not be able to perceive sensitively the 100- to 200-Hz stimulation used in the entire sole of the foot after long-term intervention, thereby reducing the effects on gait quality and posture balance and ultimately failing to reduce the risk of falls. Furthermore, the gait impairment observed with diabetes is multifactorial. Vibrating insoles are not expected to correct sarcopenia or ischemic arterial peripheral disease, for instance. The only study evaluating the long-term effects of vibrating insoles reported no effects on gait quality in individuals with diabetes and with DPN after 1 month of sole vibration applied (4). Larger studies with longer-term stimulation protocols are required

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to test this beneficial hypothesis more carefully.

Funding. P.F.S. has received research grants from the National Natural Science Foundation of China (81870564) and Huadong Medicine Joint Funds of the Zhejiang Provincial Natural Science Foundation of China (LHDMD24H030001).

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Handling Editors. The journal editors responsible for overseeing the review of the manuscript were Steven E. Kahn and Jennifer B. Green.

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