Author Response to 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*

Running Head: Vibrating Insoles and Gait Quality

Giorgio Orlando[1], Steven Brown[1], Edward Jude[2], Frank L. Bowling[3], Andrew J. M. Boulton[3,4], Neil D. Reeves[5.]

[1]Department of Sport and Exercise Sciences, Institute of Sport, Faculty of Science and Engineering, Manchester Metropolitan University, Manchester, U.K. [2]Tameside and Glossop Integrated Care NHS Foundation Trust, Ashton under Lyne, Manchester, UK. [3]Department of Medicine, Manchester Royal Infirmary, Manchester, UK. [4]Diabetes Research Institute, University of Miami, Miami, FL, USA. [5]Medical School, Faculty of Health and Medicine, Lancaster University, UK.

Corresponding Author:

Giorgio Orlando, PhD, Department of Sport and Exercise Sciences, Institute of Sport, Faculty of Science and Engineering, Manchester Metropolitan University, Manchester, U.K. E-mail: G.Orlando@mmu.ac.uk. Phone number: +44 (0)161 247 2000

Words: 500/500

Wang et al. recently questioned one aspect of our statistical analysis and commented on conclusions drawn in our recent study exploring the acute effects of sole vibration on gait and balance in people with diabetic peripheral neuropathy (DPN) (1). We value their feedback and intend to clarify several points.

Following their concerns, the data were meticulously re-analysed and verified using *Matlab* and *SPSS*, and we confirmed that the original results were correct. Wang et al. asserted that larger group average differences and smaller standard deviations often indicate a higher likelihood of significant differences. However, for a paired t-test, the critical values are the mean of paired differences within each participant (Xdiff), and standard deviation of differences (Sdiff), rather than the group means and standard deviations. The formula for the paired samples Student's t-test is $t = Xdiff / (Sdiff/\sqrt{n})$. Wang et al. focused on the group means and standard deviations, which although indicative, do not directly reflect the variability of paired responses to each condition. The vibratory conditions (Vc) identified as significantly different for stair ascent were Vc2, Vc4, and Vc7, for which the Sdiff for gait speed were 0.17, 0.07, and 0.15 m/s, respectively. These Sdiff values were lower than those of non-significant conditions Vc1, Vc3, Vc5, and Vc6, with Sdiff values of 0.19, 0.21, 0.23, and 0.19 m/s, respectively. Therefore, despite higher Xdiff values in some non-significant conditions, higher Sdiff values (indicating greater variability in differences within the group) resulted in lower t-values, demonstrating a lower probability of significant differences among groups (this finding is also consistent with the descent data). This higher variability in paired differences, despite lower overall group variability, explains Wang et al.'s observations and validates our statistical outcomes as initially reported. The differing responses among individuals remain consistent with the interpretation of our findings in the manuscript that sole vibration has positive effects on several gait variables.

Additionally, Wang et al. commented on some conclusions on gait speed improvement following vibration. We re-emphasise here (as was made clear in the manuscript) that our findings do not identify a relationship between acute gait speed improvement with vibration and the risk of falling. Within the discussion, we state that prior studies have identified gait speed as a well-established predictor of fall risk. Then, later, discuss the need for future clinical trials to investigate the long-term effects of vibrating insoles on fall risk.

While we establish the acute effects of vibration in people with DPN, we agree that the long-term effects on peripheral sensation and physical function remain unknown, as does the mechanism(s) by which vibration

benefits postural control, including the common finding that sub-sensory frequencies are beneficial, highlighting it is not 'perception' of the vibration itself that is beneficial. We agree with Wang et al. that further studies are required; our research group is conducting a clinical trial to test the long-term effects of vibration on neuropathic signs and symptoms and physical function in people with DPN, and we will report on this study in due course.

Funding:

This research was funded by EU small- and medium-sized enterprises instrument grant 879948.

Conflict of interest:

No potential conflicts of interest were reported by the authors.

Reference:

1. Orlando G, Brown S, Jude E, Bowling FL, Boulton JM, Reeves ND. 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(6):1004-1011.