JBMR Plus, 2025, **9**, ziaf050
https://doi.org/10.1093/jbmrpl/ziaf050
Advance access publication: April 1, 2025
Reply to Letter to the Editor

Response to Letter to the Editor for "Benefits of targeted vibration for bone strength and bone density in postmenopausal women with osteopenia: a randomized, sham-controlled trial"

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Keywords: Osteopenia, osteoporosis, low bone mass, bone strength, bone density, female, menopause, targeted vibration, mechanical stimulation

Dear JBMR Plus Editor,

We thank the authors for their interest in our study on the use of targeted vibration therapy for the treatment of low bone density. In our study, we evaluated the safety and effectiveness of a wearable vibration device, the Osteoboost Belt, in postmenopausal women with osteopenia.

We agree with the authors' support of exercise as an important tool in combating age-related bone loss. In fact, several of our co-authors have recently published a study on the benefits of a resistance training and high-impact exercise program on bone structure.[1] Exercise has numerous benefits for bone and overall health, and we also encourage all older adults to engage in regular exercise in addition to using Osteoboost. However, the reality is that many older adults do not or cannot safely engage in weight-bearing exercise.[2–4] In addition, for those who do exercise consistently, many only engage in low-intensity types of exercise (eg, walking, yoga, etc.) that are often not sufficient to prevent bone loss.[5,6] Furthermore, many women are unable to participate in resistance training and high-impact exercise due to lack of access to the equipment, facilities, and trainers.[7]

We see vibration therapy devices, like the Osteoboost Belt, as complementary to exercise, particularly for patients who are not able to engage in regular exercise that is intense enough to stimulate bones in the hips and spine. Furthermore, the authors state: "The investigators' conclusion that such a focal treatment could be prescribed as a treatment strategy for osteopenia, a systemic – not a local – disease, is not supported by the study results." However, we stated in the manuscript: "The Osteoboost Belt (Bone Health Technologies, Inc., Redwood City, CA) is an FDA-cleared wearable device that delivers targeted vibration to the lumbar spine and hips." It is clear that the manuscript did not claim treatment of systemic osteopenia throughout the body. Osteoboost was designed to provide targeted vibration focused at the lumbar spine and hips, the bones for which fractures can have the most serious consequences.

Regarding the authors' comments about the study endpoints and results, we would like to clarify a few points. First, the primary endpoint of the study was percentage change in vertebral strength of the L1 vertebral body (or L2 if L1 was not analyzable) as determined from CT scans. When comparing the Active and Sham treatment groups, a trend of a benefit was observed for the mITT population ($p = .17$), which achieved statistical significance for both the study completer population ($p = .040$) and the pre-specified per-protocol (PP) population ($p = .028$), where PP was defined as subjects who used the device at least 3 times per week. Use at 3 d per week is a modest level of compliance and a meaningful benefit for a device that is intended to be used 7 d per week, and treatment benefit increased with higher compliance. It is important to note that the PP population is clinically practical and relevant since benefit cannot be achieved if the therapy is not used consistently, which is also true for exercise.

Second, after 12 mo, the PP population experienced a relative benefit from Osteoboost therapy of +2.36% ($p = .028$) for vertebral strength and +1.68% ($p = .016$) for vertebral volumetric BMD (vBMD), levels of benefit that are rarely matched by high-intensity exercise programs. While our study did not show a significant treatment effect for DXA-based lumbar spine BMD, as noted in the manuscript, the limitations of DXA scans at the lumbar spine must be considered: "The lack of statistical significance in the DXA-based results is likely due to the higher noise inherent in DXA measures, particularly of the lumbar spine.[8–10] This noise results in lower sensitivity to detect changes that occur over 12 mo. Indeed, clinical studies have shown that bone loss in the spine for control groups can be detected earlier and is statistically more significant by BCT than by DXA."[8] The Osteoboost Belt applies vibration to the sacrum, which is located five vertebral

Received: March 19, 2025. **Revised:** March 24, 2025. **Accepted:** March 27, 2025

bodies away from L1. We, therefore, expect similar benefits to strength and vBMD for L2-L5, which are closer to the vibration source, although this must be confirmed in a future study with these CT-based assessments.

Third, as the authors stated and we acknowledged in the manuscript, our study was underpowered for the DXA-based secondary endpoints. For the hip, we believe it is noteworthy that trends were observed across all study populations for percentage change in total hip BMD ($p = .13$, $p = .07$, and $p = .19$ for the mITT, completer, and PP populations, respectively). While not statistically conclusive in this study, additional data will further elucidate the effect on hip BMD. In this vein, the conclusions in the manuscript were focused and aligned with the study results.

As clinicians and researchers in the ASBMR community, we take quite seriously how intensely patients are actively seeking safe and effective treatments for their low bone density. This provides our motivation, and we encourage the community to view it in the same way. We see this as a mandate to develop and evaluate novel treatment options so that we can provide each patient with the best solution that meets her or his individual needs.

Author contributions

Laura D. Bilek (Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Writing—original draft, Writing—review & editing) and Michael J. Jaasma (Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Visualization, Writing—original draft, Writing—review & editing).

Conflicts of interest

L.D.B. has received research support and stock options from Bone Health Technologies and is a clinical advisor to Bone Health Technologies. M.J.J. is an employee and has stock ownership of Bone Health Technologies.

References

1. Blay R, Flores LE, Kupzyk K, et al. Twelve-month resistance and impact exercise program or risedronate provides a relative benefit to hip bone structure in postmenopausal women: results from a randomized controlled trial. *Osteoporos Int*. 2024;35:877-891. https://doi.org/10.1007/s00198-023-07008-x
2. Booth FW, Roberts CK, Laye MJ. Lack of exercise is a major cause of chronic diseases. *Compr Physiol*. 2012;2:1143-1211. https://doi.org/10.1002/cphy.c110025
3. Crombie IK, Irvine L, Williams B, et al. Why older people do not participate in leisure time physical activity: a survey of activity levels, beliefs, and deterrents. *Age Ageing*. 2004;33:287-292. https://doi.org/10.1093/ageing/afh089
4. Yang Y, Gao Y, An R, Wan Q. Barriers and facilitators to exercise adherence in community-dwelling older adults: a mixed-methods systematic review using the COM-B model and theoretical domains framework. *Int J Nurs Stud*. 2024;157:104808. https://doi.org/10.1016/j.ijnurstu.2024.104808
5. Fernandez-Rodriguez R, Alvarez-Bueno C, Reina-Gutierrez S, et al. Effectiveness of Pilates and yoga to improve bone density in adult women: a systematic review and meta-analysis. *PLoS One*. 2021;16:e0251391. https://doi.org/10.1371/journal.pone.0251391
6. Martyn-St. M, Carroll S. Meta-analysis of walking for preservation of bone mineral density in postmenopausal women. *Bone*. 2008;43:521-531. https://doi.org/10.1016/j.bone.2008.05.012
7. Kruger J, Carlson SA, Kohl HW III. Fitness facilities for adults: differences in perceived access and usage. *Am J Prev Med*. 2007;32:500-505. https://doi.org/10.1016/j.amepre.2007.02.003
8. Keaveny TM, Clarke BL, Cosman F, et al. Biomechanical computed tomography analysis (BCT) for clinical assessment of osteoporosis. *Osteoporos Int*. 2020;31:1025-1048. https://doi.org/10.1007/s00198-020-05384-2
9. Keaveny TM. Biomechanical computed tomography-noninvasive bone strength analysis using clinical computed tomography scans. *Ann N Y Acad Sci*. 2010;1192:57-65. https://doi.org/10.1111/j.1749-6632.2009.05348.x
10. Adams AL, Fischer H, Kopperdahl DL, et al. Osteoporosis and hip fracture risk from routine computed tomography scans: the fracture, osteoporosis, and CT utilization study (FOCUS). *J Bone Miner Res*. 2018;33:1291-1301. https://doi.org/10.1002/jbmr.3423

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