Precision Vibration Therapy Device to Treat Low Bone Density

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The Lack of a Comprehensive Treatment for Osteopenia

An estimated 52 million Americans have osteopenia, the precursor to osteoporosis.[1] Despite its prevalence and the fact that the majority of fractures occur in patients with osteopenia,[2] few treatment options exist for osteopenia. Current treatments are all lacking in effectiveness, patient compliance, or both. For patients with osteopenia, guidelines focus on diet and exercise.[3-4] While calcium and vitamin D are necessary for bone health, they are insufficient to significantly reduce fracture risk.[5] It is well known that resistance training and high-impact exercise can stimulate bones and maintain, or even improve, bone density.[6-7] However, the reality is that many older adults do not or cannot safely engage in weight-bearing exercise.[8-9] In addition, for those who do exercise consistently, most only engage in low-intensity types of exercise (e.g. walking, yoga, etc.) that are often not sufficient to prevent bone loss.[10-11]

Vibration as a Treatment for Low Bone Density

Like the response to mechanical stimulation provided by high-impact exercise, bones and bone cells also respond to the stimulation provided by vibration.[12-13] Vibration science is based on over 50 years of research, including work supported by NASA. This research inspired the invention of Osteoboost.

Osteoboost Device

Osteoboost is an FDA-cleared wearable vibration device (Figure 1) that delivers low energy (0.1 to 0.3 g of acceleration at the iliac crest), high frequency (20-40 Hz, sinusoidal waveform acting in the sagittal plane) vibration to the lumbar spine and hips. The device is worn around the hips, with the device's vibration pack secured against the patient's sacrum (the bone right above the tailbone). The device has a force sensor at the vibration pack that ensures proper fit and contact against the body. To further ensure that a therapeutic dose of vibration is delivered during every treatment session, the device has an embedded accelerometer located at the patient's iliac crest that measures the transmitted vibration and automatically adjusts/calibrates the vibration magnitude to be within the therapeutic range—no intervention is required by the physician or patient.

The Osteoboost therapy regimen consists of a daily 30-minute treatment session. The device's therapeutic vibration magnitude and daily treatment duration are based on results from a clinical study showing that these parameters were safe and provided an average reduction of 14.2% ($p < 0.001$ vs. sham) in serum type-I collagen crosslinked N-telopeptide (NTX), a biomarker of bone resorption activity.[14]

Osteoboost can be seamlessly incorporated into a patient's busy daily schedule. Patients can integrate their 30-minute treatment session into their activities of daily living that involve walking or standing—going for a walk, walking the dog, getting ready in the morning, cooking, and other household chores.

Figure 1. Osteoboost is a wearable medical device that provides mechanical stimulation to the central skeleton. Osteoboost is worn around the hips like a belt, and the vibration pack, which is positioned against the sacrum in the lower back, provides a daily 30-minute vibration therapy session. By mimicking the beneficial effects of high-impact exercise on bone density and strength, Osteoboost provides a safe, effective, and convenient treatment for osteopenia.

How is Osteoboost Different from Whole Body Vibration Platforms

Osteoboost (targeted vibration) and whole body vibration (WBV) platforms both deliver vibration to the body, but WBV platforms require the user to stand on a vibrating platform, delivering vibration to the bottom of the feet. Research has shown that vibration magnitude dissipates as you move away from the vibration source.[15] Thus, WBV platforms are great for providing mechanical stimulation to the feet and lower legs, but not for the hips and spine. WBV platforms also require the user to stand still on the platform for 20-30 minutes per day, which is inconvenient, and, accordingly, compliance is often low with these systems. Furthermore, no WBV platform has been cleared by the FDA, so no WBV platform has been judged by the FDA to be safe and effective for the treatment of low bone density.

In contrast, Osteoboost was designed to provide vibration targeted directly to the bones in the hips and spine, due to the severe consequences often associated with fractures in those areas. The patented calibration and pressure sensing features ensure that optimal vibration energy is delivered to the hips and lumber spine. As a wearable device OsteoBoost is convenient and easy to incorporate into a busy daily schedule. Finally, Osteoboost is the only device that has been cleared by the FDA as a safe and effective treatment for osteopenia.

Osteoboost Clinical Trial

Study Design and Methods

Researchers at the University of Nebraska Medical Center conducted a randomized, sham-controlled clinical trial to evaluate the safety and effectiveness of Osteoboost as a treatment for osteopenia in postmenopausal women. Participants, research staff, and outcomes assessors were blinded to treatment assignment.

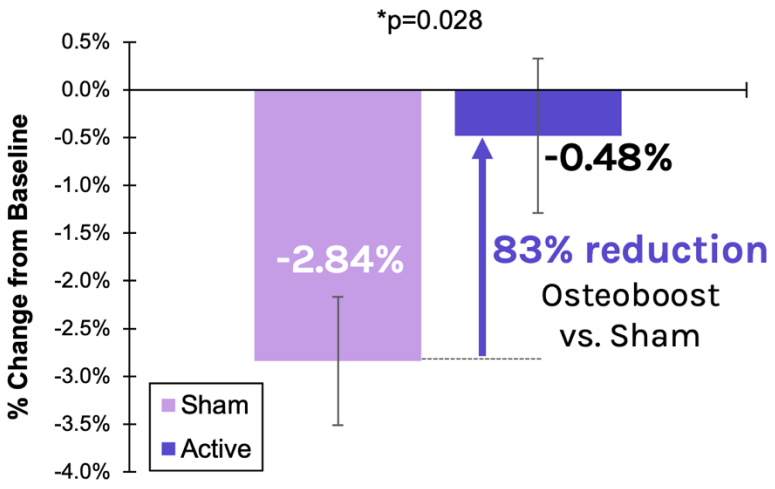
- Principal investigator: Laura Bilek, PhD, PT
- Center: University of Nebraska Medical Center
- Follow-up duration: 12 months
- Treatment groups:
  - Active treatment: Osteoboost device that delivered vibration therapy
  - Sham treatment: Inactive Osteoboost device that emitted an audible clicking sound instead of vibration
- Randomization: 1:1 (Active:Sham treatment)
- Sample size: n=126 women (n=64 Active treatment, n=62 Sham treatment)
- Key inclusion criteria:
  - Postmenopausal woman
  - ≥50 years old
  - Osteopenia of the lumbar spine, total hip, or femoral neck
- Key exclusion criteria:
  - Osteoporosis of the lumbar spine, total hip, or femoral neck
  - FRAX score >20% for major fracture or >3% for hip fracture
  - Taking osteoporosis medications or estrogen hormonal therapy
  - Diagnosed with a disease or medical condition that affects bone metabolism
  - Consistent engagement in high-impact exercise
- Therapy regimen: All participants were instructed to self-administer at least 5 sessions/week at home
- Dietary supplements: All participants were given daily supplements for calcium and vitamin D
- Bone scans: CT and DXA scans were used to evaluate changes in bone strength and bone density over the 12 months of follow-up
- Primary endpoint: Percentage change in vertebral bone strength of the L1 vertebral body (assessed from CT scans)
- Additional endpoints: Percentage change in BMD at the hips and lumbar spine

Effectiveness Results

As expected, women in the Sham group experienced large declines in bone strength and bone density. In contrast, Osteoboost's vibration therapy substantially mitigated the loss of bone strength and bone density in the Active treatment group. Benefits were observed across all outcomes and all study populations. At 12 months, statistically significant benefits for bone strength and bone density were observed for study participants who

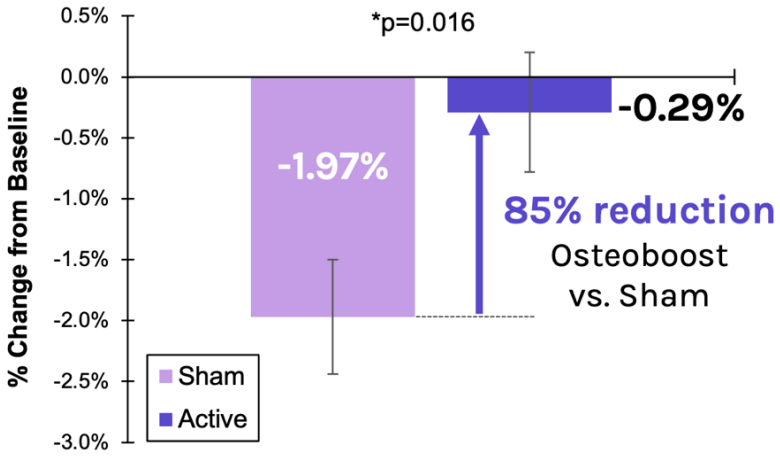
used the device at least 3 times per week, on average (this was the pre-specified Per Protocol population):

1. **83% reduction** in the loss of bone strength in the spine



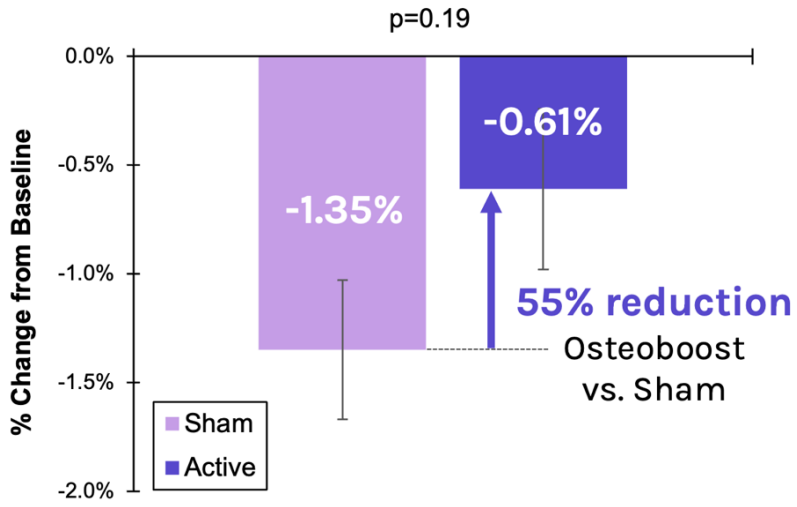
Per Protocol population of participants who averaged at least 3.0 sessions per week (n=73)
L1 vertebra analyzed from CT scans to determine % change in bone strength

2. **85% reduction** in the loss of bone density in the spine



Per Protocol population of participants who averaged at least 3.0 sessions per week (n=73)
L1 vertebra analyzed from CT scans to determine % change in volumetric BMD

3. **55% reduction** in the loss of bone density in the hip



Per Protocol population of participants who averaged at least 3.0 sessions per week (n=73)
Left and right hip BMD analyzed from DXA scans to determine % change in total hip BMD

Safety Results
Osteoboost demonstrated an excellent safety profile. There were no serious adverse events, or adverse effects, related to the device. Also, no participants experienced a bone fracture during study participation. There were some reports of back pain, pelvic pain, and leg pain, but these were experienced in both the Active and Sham groups. Generally, adverse/side effects that were noted were mild/moderate, commonly experienced conditions for older adults, transient, and resolved after temporarily stopping use of the device.

Compliance Results
Study participants reported that the device was easy to use and to incorporate into their daily routine. Study completers averaged 4.0 treatment sessions per week, providing 80% adherence to the test protocol over the 12-month study. When asked, “How easy was it to find time to use the belt 5 times per week?”, the average response was 7.8 out of 10. Many participants also commented that the Osteoboost treatment felt like a mini massage for their lower back.

Conclusions
The results from this randomized, sham-controlled study demonstrate that Osteoboost provides a safe, effective, and convenient treatment for postmenopausal women with osteopenia. The findings support that targeted vibration applied in a controlled dose directly to the spine/hips provides particular benefit for vertebral bone strength and density when treatment is administered at least 3 times per week. Participants’ compliance with the daily treatment regimen demonstrates that the wearable aspect of the device enables the incorporation of treatment sessions into daily schedules/activities.

Considering the prevalence of osteopenia (54% of postmenopausal women in the USA have osteopenia) and the limited treatment options, Osteoboost addresses an important, unmet clinical need for the prevention of bone loss in postmenopausal women.

A full journal manuscript of the clinical study methods and results will be published shortly.

FDA Breakthrough Device Designation
In 2020, Osteoboost was granted Breakthrough Device designation from the FDA. Breakthrough Device status is given to "medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions." The Breakthrough Device program "is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review." Accordingly, the FDA identified the importance of Osteoboost to provide an effective solution for an unmet medical need, the treatment of osteopenia in postmenopausal women.

FDA Regulatory Approval
Osteoboost is the first and only non-drug therapy to receive approval from the FDA for the treatment of low bone density. On January 12, 2024, Osteoboost received FDA clearance as a class II prescription medical device.

For each medical device, the FDA approval pathway is based on the classification of the device. The FDA determines the device's classification based on both the safety profile of the device and the condition it treats. While Osteoboost demonstrated an excellent safety profile, the FDA determined that Osteoboost is a class II device because it is designed to treat osteopenia, a serious health condition. The FDA also determined that Osteoboost requires a prescription because osteopenia is diagnosed by a clinician after review of a bone density scan.

De Novo Clearance - Class II devices are typically cleared by the FDA through the 510(k) pathway. However, with no similar medical device on the market (i.e. no predicate device), Osteoboost was cleared through the FDA's De Novo pathway where the FDA review team evaluates whether the device is safe and effective on its own merit (rather than relative to another device). After a thorough review of clinical trial and engineering test results, the FDA review team concluded that Osteoboost was safe and effective for the treatment of osteopenia in postmenopausal women.

Indications for Use - Osteoboost has the following indications for use:

> The Osteoboost Belt is indicated to reduce the decline in bone strength and volumetric bone density, as assessed via CT (computed tomography) scans that were analyzed using the O.N. Diagnostics VirtuOst estimate of vertebral bone strength and density in postmenopausal women with osteopenia of the lumbar

vertebrae or total hip as diagnosed via dual x-ray absorptiometry with a bone mineral density T-score between -1.0 and -2.49.

- The clinical effects have only been observed for the duration of the clinical study performed to support the indications for use (1 year).
- Fracture risk was not evaluated in the clinical study to support the indications for use, so it is not known how the treatment effects correlate with fracture risk.
- The clinical effects have been demonstrated only for those who used the device as indicated.

Prescribing Information

Osteoboost requires a prescription from a practitioner licensed in the United States. Please complete the prescription form and submit it to HealthWarehouse for fulfillment:

Fax: 1-888-870-2808
Phone: 1-800-748-7001
E-Prescribe: healthwarehouse.com (Florence, KY)
NPI: 1619252160
NCPDP#: 1832674

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