



Primary Clinical Science using the Juvent's Micro-Impact Platform®

The effect of whole body vibration therapy on bone density in patients with thalassemia: A pilot study

American Journal of Hematology, 2012

Patients with thalassemia (Thal) have low bone mass which can lead to fracture and decreased quality of life. There are no noninvasive anabolic therapies available to improve bone health in Thal.

A longitudinal cross-over pilot trial was conducted to evaluate the effectiveness of low magnitude whole body vibration (WBV) therapy on bone in 18 patients with Thal (9 adults, 10 male, 22.1 ± 10.7 years). Subjects were asked to stand on a vibrating platform (30 Hz, 0.3 g) for 20 min/day for 6 months. Areal bone mineral density (aBMD) by DXA and volumetric BMD by peripheral quantitative computed tomography (pQCT) was assessed at baseline, 6 and 12 months. Adherence in the first 3 months was greater when compared with the second 3 months (14 ± 6 vs. 10 ± 7 min/day, $P=0.007$). Intention to treat analysis revealed a significant increase in whole body BMC (2.6%; $P=0.021$), BMC/Ht (2.6%, $P=0.02$) and aBMD (1.3%; $P=0.036$), as well as a net increase in serum markers of bone formation (Osteocalcin/CTx, $P=0.027$) in the adult subjects.

These preliminary findings suggest that vibration therapy may be an effective non-pharmacological intervention in Thal. Future research is needed to confirm these findings in a larger sample for longer duration.

Effect of whole body vibration (WBV) therapy on bone density and bone quality in osteopenic girls with adolescent idiopathic scoliosis: a randomized, controlled trial

Osteoporos Int DOI 10.1007/s00198-012-2144-1

Effect of High Frequency, Low Magnitude Vibration on Bone and Muscle in Children with Cerebral Palsy

J Pediatr Orthop. 2010 ; 30(7): 732–738. doi:10.1097/BPO.0b013e3181efbab.

Background

Children with cerebral palsy (CP) have decreased strength, low bone mass, and an increased propensity to fracture. High frequency, low magnitude vibration might provide a non-invasive, non-pharmacologic, home-based treatment for these musculoskeletal deficits. The purpose of this study was to examine the effects of this intervention on bone and muscle in children with CP.

Methods

Thirty-one children with CP ages 6-12 years (mean 9.4, SD 1.4) stood on a vibrating platform (30 Hz, 0.3 g peak acceleration) at home for 10 min/day for 6 months and on the floor without the platform for another 6 months. The order of vibration and standing was randomized, and outcomes were measured at 0, 6, and 12 months. The outcome measures included computed tomography measurements of vertebral cancellous

bone density (CBD) and cross-sectional area, CBD of the proximal tibia, geometric properties of the tibial diaphysis, and dynamo meter measurements of plantar flexor strength. Outcomes were assessed using mixed model linear regression and Pearson's correlation.

Results

The main difference between vibration and standing was greater increases in the cortical bone properties (cortical bone area and moments of inertia) during the vibration period (all p 's ≤ 0.03). There was no difference in cancellous bone or muscle between vibration and standing (all p 's > 0.10) and no correlation between compliance and outcome (all r 's < 0.27 ; all p 's > 0.15). The results did not depend on the order of treatment ($p > 0.43$) and was similar for children in GMFCS 1-2 and GMFCS 3-4.

Conclusions

The primary benefit of the vibration intervention in children with CP was to cortical bone in the appendicular skeleton. Increased cortical bone area and structural (strength) properties could translate into a decreased risk of long bone fractures for some patients. More research is needed to corroborate these findings, to elucidate the mechanisms of the intervention, and to determine the most effective age and duration for the treatment.

Reversal of Lower-limb Edema by Calf Muscle Pump Stimulation.

J. Cardiopulmonary Rehab. & Prevention. 28:174-179. (2008)

Shows Juvent stimulation reverses fluid pooling in the lower limbs. It offers a simple counter-measure to address a problem affecting 40% of adult women.

Low-Level, High-Frequency Mechanical Signals Enhance Musculoskeletal Development of Young Women With Low BMD

J Bone Miner Res 2006; 21:1464–1474. Published online on June 26, 2006; doi: 10.1359/JBMR.060612

Abstract

The potential for brief periods of low-magnitude, high-frequency mechanical signals to enhance the musculoskeletal system was evaluated in young women with low BMD. Twelve months of this noninvasive signal, induced as whole body vibration for at least 2 minutes each day, increased bone and muscle mass in the axial skeleton and lower extremities compared with controls.

Introduction

The incidence of osteoporosis, a disease that manifests in the elderly, may be reduced by increasing peak bone mass in the young. Preliminary data indicate that extremely low-level mechanical signals are anabolic to bone tissue, and their ability to enhance bone and muscle mass in young women was investigated in this study.

Material and Methods

A 12-month trial was conducted in 48 young women (15–20 years) with low BMD and a history of at least one skeletal fracture. One half of the subjects underwent brief (10 minutes requested), daily, low-level whole body vibration (30 Hz, 0.3g); the remaining women served as controls. Quantitative CT performed at baseline and

at the end of study was used to establish changes in muscle and bone mass in the weight-bearing skeleton.

Results

Using an intention-to-treat (ITT) analysis, cancellous bone in the lumbar vertebrae and cortical bone in the femoral midshaft of the experimental group increased by 2.1% ($p = 0.025$) and 3.4% ($p < 0.001$), respectively, compared with 0.1% ($p = 0.74$) and 1.1% ($p = 0.14$), in controls. Increases in cancellous and cortical bone were 2.0% ($p = 0.06$) and 2.3% ($p = 0.04$) greater, respectively, in the experimental group compared with controls. Cross-sectional area of paraspinous musculature was 4.9% greater ($p = 0.002$) in the experimental group versus controls. When a per protocol analysis was considered, gains in both muscle and bone were strongly correlated to a threshold in compliance, where the benefit of the mechanical intervention compared with controls was realized once subjects used the device for at least 2 minute/day ($n = 18$), as reflected by a 3.9% increase in cancellous bone of the spine ($p = 0.007$), 2.9% increase in cortical bone of the femur ($p = 0.009$), and 7.2% increase in musculature of the spine ($p = 0.001$) compared with controls and low compliers ($n = 30$).

Conclusions

Short bouts of extremely low-level mechanical signals, several orders of magnitude below that associated with vigorous exercise, increased bone and muscle mass in the weight-bearing skeleton of young adult females with low BMD. Should these musculoskeletal enhancements be preserved through adulthood, this intervention may prove to be a deterrent to osteoporosis in the elderly.

Plantar vibration improves leg fluid flow in peri-menopausal women.

Am.J. Physiol. Regul. Integr. Comp. Physiol. 288:R623-R629 (2005)

Shows Juvent increases in peripheral, systemic blood flow, peripheral lymphatic flow and venous drainage from the lower limb, thereby providing an efficient, potential counter-measure for patients with inefficient calf muscle pump (most elderly or immobile people).

Prevention of Postmenopausal Bone Loss by a Low-Magnitude, High-Frequency Mechanical Stimuli: A Clinical Trial Assessing Compliance, Efficacy, and Safety.

(Journal of Bone and Mineral Research, Vol.19, Number 3, 2004)

Abstract

A 1-year, prospective, randomized, double-blind, and placebo-controlled trial of 70 post-menopausal women demonstrated that brief periods (<20 minutes) of low-level (0.2g, 30 Hz) vibration applied during quiet standing can effectively inhibit bone loss in the spine and femur, with efficacy increasing significantly with greater compliance, particularly in those subjects with lower body mass.

Introduction

Indicative of the anabolic potential of mechanical stimuli, animal models have demonstrated that short periods (<30 minutes) of low-magnitude vibration (<0.3g), applied at a relatively high frequency (20–90 Hz), will increase the number and width of trabeculae, as well as enhance stiffness and strength of cancellous bone. Here, a 1-year prospective, randomized, double-blind, and placebo-controlled clinical trial in 70 women, 3–8

years past the menopause, examined the ability of such high-frequency, low-magnitude mechanical signals to inhibit bone loss in the human.

Materials and Methods

Each day, one-half of the subjects were exposed to short-duration (two 10-minute treatments/day), low-magnitude (2.0 m/s² peak to peak), 30-Hz vertical accelerations (vibration), whereas the other half stood for the same duration on placebo devices. DXA was used to measure BMD at the spine, hip, and distal radius at baseline, and 3, 6, and 12 months. Fifty-six women completed the 1-year treatment.

Results and Conclusions

The detection threshold of the study design failed to show any changes in bone density using an intention-to-treat analysis for either the placebo or treatment group. Regression analysis on the a priori study group demonstrated a significant effect of compliance on efficacy of the intervention, particularly at the lumbar spine ($p = 0.004$). Posthoc testing was used to assist in identifying various subgroups that may have benefited from this treatment modality. Evaluating those in the highest quartile of compliance (86% compliant), placebo subjects lost 2.13% in the femoral neck over 1 year, whereas treatment was associated with a gain of 0.04%, reflecting a 2.17% relative benefit of treatment ($p = 0.06$). In the spine, the 1.6% decrease observed over 1 year in the placebo group was reduced to a 0.10% loss in the active group, indicating a 1.5% relative benefit of treatment ($p = 0.09$). Considering the interdependence of weight, the spine of lighter women (<65 kg), who were in the highest quartile of compliance, exhibited a relative benefit of active treatment of 3.35% greater BMD over 1 year ($p = 0.009$); for the mean compliance group, a 2.73% relative benefit in BMD was found ($p = 0.02$). These preliminary results indicate the potential for a noninvasive, mechanically mediated intervention for osteoporosis. This non-pharmacologic approach represents a physiologically based means of inhibiting the decline in BMD that follows menopause, perhaps most effectively in the spine of lighter women who are in the greatest need of intervention.

Low level, high frequency vibrational loading can be safely and efficiently applied to the human skeleton, with approximately 80% of the loads reaching the hip and spine in the standing or sitting human.

Transmissibility of 15-Hertz to 35-Hertz Vibrations to the Human Hip and Lumbar Spine: Determining the Physiologic Feasibility of Delivering Low-Level Anabolic Mechanical Stimuli to Skeletal Regions at Greatest Risk of Fracture Because of Osteoporosis. Spine, Vol. 28, No. 23, pp 2621-2627, 2003.

Significant improvements in muscle dynamics resulted from treatment with the Juvent DMT device. Postural stability was significantly improved in an eight week study; Type IIa muscle fiber activity was significantly increased in older (> 65 years) women; and neuro-muscular activity was significantly improved as reflected in the response of periand post-menopausal women to orthostatic stress.

The role of postural sway in the maintenance of bone mass. Trans. Am. Soc. Bone & Min. Res. 2002, Frequency dependent response of the cardiovascular system to foot based vibration while in the seated position. Trans. Biomed. Eng. Soc., 2002

The Juvent DMT device does effectively mimic the activity of Type IIa skeletal muscle fibers as determined by several recent investigations. In a study involving 15 adult women age 22-58 years, ten minutes per day of treatment for eight weeks with a 30 Hz, 0.2 g vibration was observed to produce a significant improvement in the postural stability. Vibromyography was used to measure the specific Type IIa muscle fiber activity in the 20

to 50 Hz range in a group of twelve elderly women (65-85 years) who self-treated for 30 minutes per day with a 30 Hz, 0.3g vibration during quiet standing. After two months, Type IIa fiber activity had increased significantly ($p=0.05$) by the Wilcoxon signed rank test.

Type IIa muscle fibers play a critical role in maintaining adequate venous and lymphatic return from the lower limbs, and therefore in the maintenance and growth of tissues in the lower extremities, including bone formation. The Juvent DMT device's role in replacing Type IIa muscle fiber activity in skeletal muscle pumping, and thereby modifying the cardiovascular response to orthostatic stress, was evaluated in a group of 32 women age 30-80 years. During upright posture, blood pressure falls in response to inadequate skeletal muscle pump activity, and a significant drop of approximately 15 mm Hg in mean arterial pressure was observed in this subject group. However, during treatment with the Juvent device, this blood pressure drop could be significantly inhibited, with the maximum benefit observed in the 30-60 Hz range. Additional testing at the NY Medical Center investigated the influence of Juvent vibration on lymphatic return using strain gage plethysmographic measurements. The Juvent DMT device was found to significantly improve lymphatic return.

A clinical trial on children with cerebral palsy demonstrated an 11% increase in trabecular bone density in the tibia following six months of treatment, in contrast to the 6% loss of bone mineral density in children standing on placebo devices.

Low Magnitude Mechanical Loading is Osteogenic in Children with Disabling Conditions. J Bone Min Res, accepted for publication, March, 2004.

In summary, this pilot RCT in children with disabling conditions provides evidence that short durations of extremely low magnitude high frequency mechanical loading can significantly increase vTBMD of the proximal tibia, with a positive trend observed in the spine. These data are indicative of the potential of this unique, biomechanically based intervention to offer a non-pharmacological, non-invasive method to increase low trabecular bone mineral density in humans.

A clinical trial on adolescent females (10-13yr) with osteoporosis showed a significant increase in BMD of both cortical and trabecular bone of the tibia, as well as an increase in muscle mass of the thigh, following two months of treatment.

Short Term Low Level Mechanical Stimulation Increases Cancellous and Cortical Bone Density and Muscles of Females with Osteoporosis: A Pilot Study. Endocrine Society Transactions in press. 2002.

This data indicates that the Juvent low amplitude, high frequency device is an effective, non-pharmacologic means of significantly increasing bone density in the cancellous bone of the lower appendicular spine (CaBD) and in the cortical bone of the femurs (CoBD) of children with osteopenia or osteoporosis as well as increasing muscle mass over the femurs in the short term period.

This clinical study assessed compliance with standing for 10 minutes/day on a Juvent DMT device. The compliance with the required daily use period and the satisfaction with the daily use of the device was assessed in the target population for osteoporosis therapy, elderly women.

Establishing the Compliance in Elderly Women for Use of a Low Level Mechanical Stress Device in a Clinical Osteoporosis Study