

# Marodyne LiV

## Product and scientific information



# Scope of document

- Provides an overview of vibration therapy; mechanism of action for low and high intensity variants, human whole body vibration safety, indications for use of low intensity vibration, the scientific data to support this modality.
- The document is aimed at physical medicine/therapist and can be adapted for discussion with a physician or general public audience

# Marodyne LiV – Low intensity Vibration device

## Indications for use

- ✓ Bone health
- ✓ Muscle health
- ✓ Postural control, balance and mobility



# The Marodyne LiV device

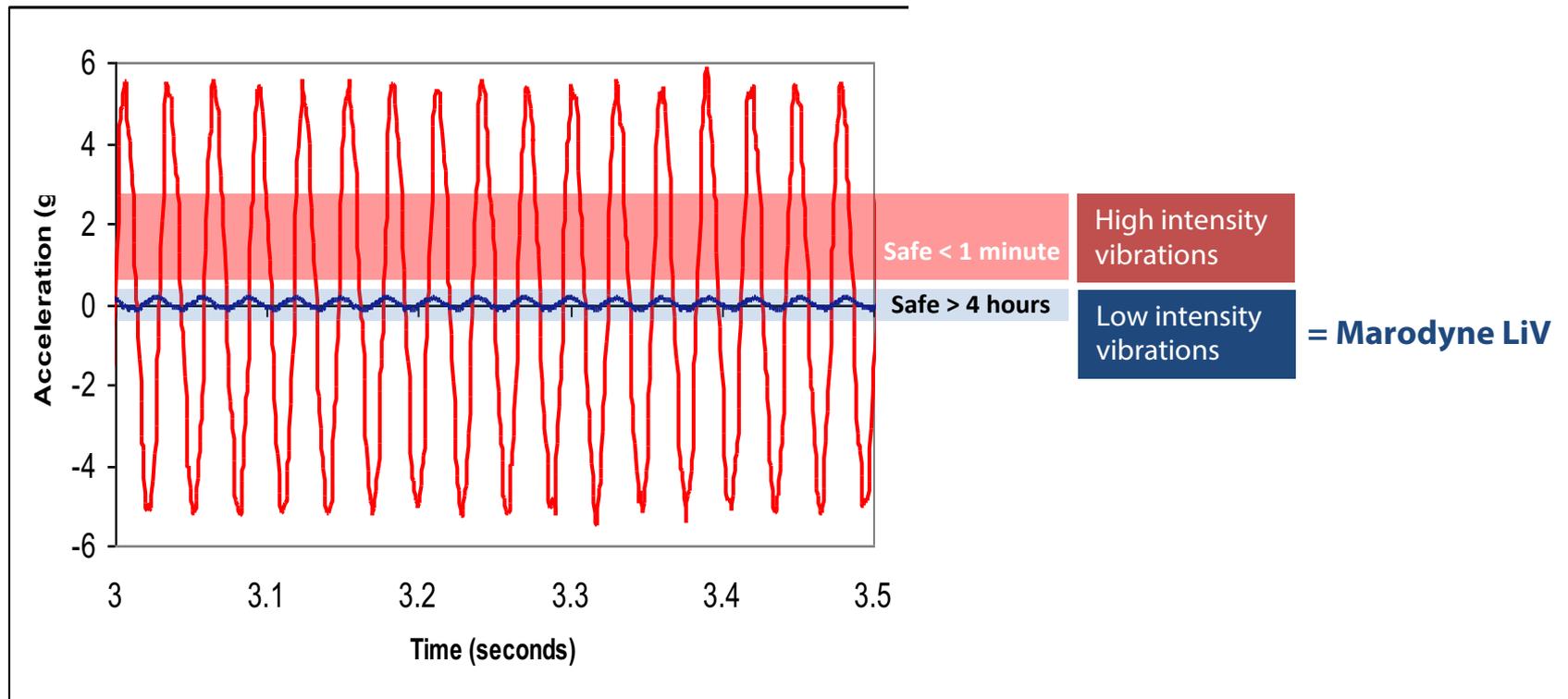
- System Weight: 8.1 kg (17.85 lb)
- Dimensions:
  - Height 7.7 cm (3.03 in)
  - Width 45.7 cm (17.99 in)
  - Depth 35.6 cm (14.01 in)
- Electrical Power Supply 100-240 V / 50-60 Hz
- Micro processor controlled sound wave that outputs 0.4 g acceleration to any\* user on constant basis
- 10 minutes session time



\* User within accepted weight range from 23 kg (50 lb) up to 125 kg (275 lb)

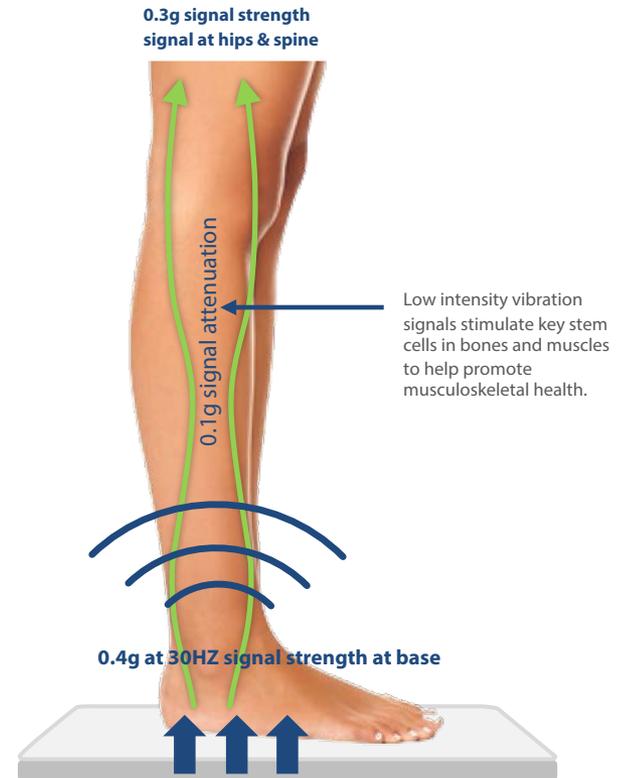
# Safety for the acceleration of humans

- ISO-2631 Human tolerance limits for vibration



# Safety for the acceleration of humans

- Stimulate key stem cells in bone marrow in specific way to help promote skeletal health
- Fat formation is suppressed and bone, muscle, skin, cartilage formation stimulated
- Act as surrogate for fast firing muscle fibers



Standing 10 minutes per day on low-intensity vibration provides maximal benefits to bone, muscle and stem cell health.

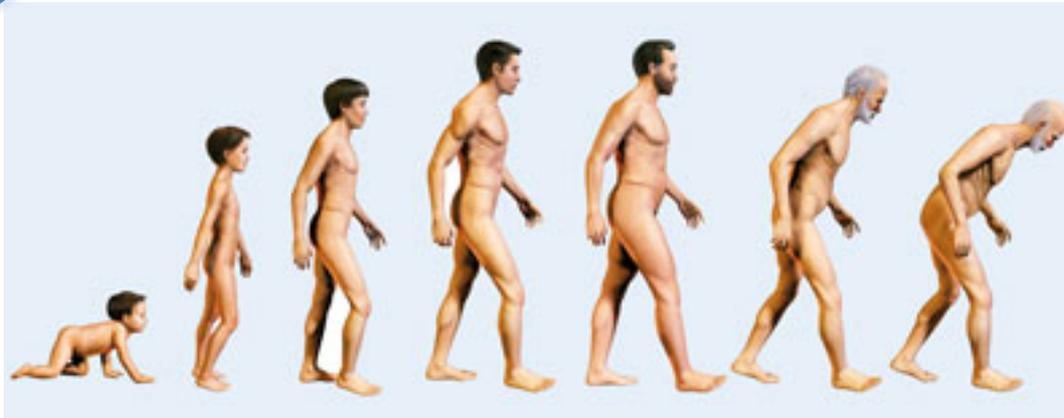
# How does high intensity vibration work?

1. Muscle is stretched
2. Neuromuscular spindle is stimulated
3. Information gets to the spinal cord
4. Motor neuron fires quick impulses
5. Muscle contraction of the stretched muscle

## Reflexive muscle contraction



# Low and high intensity vibrations: Where do they fit?



No vibrations

Low intensity  
vibrations (LiV)

High intensity  
vibrations (WBV)

Low intensity  
vibrations (LiV)

# Summary low vs high

- Low acceleration
  - below 0.5 g force
- Low risk
- Safe & easy home use
- Passive stands
- Therapy for elderly, frail or recovery – rehabilitation



- High acceleration
  - above 1 g force
- High risk
- Supervised or instructed use only
- Active exercises
- Exercise for fit and health



# Marodyne LiV is a safe and scientific based solution for musculoskeletal health

## With benefits for

- Health & Fitness
- Medical Rehabilitation
- Active Aging



# Forces and bone

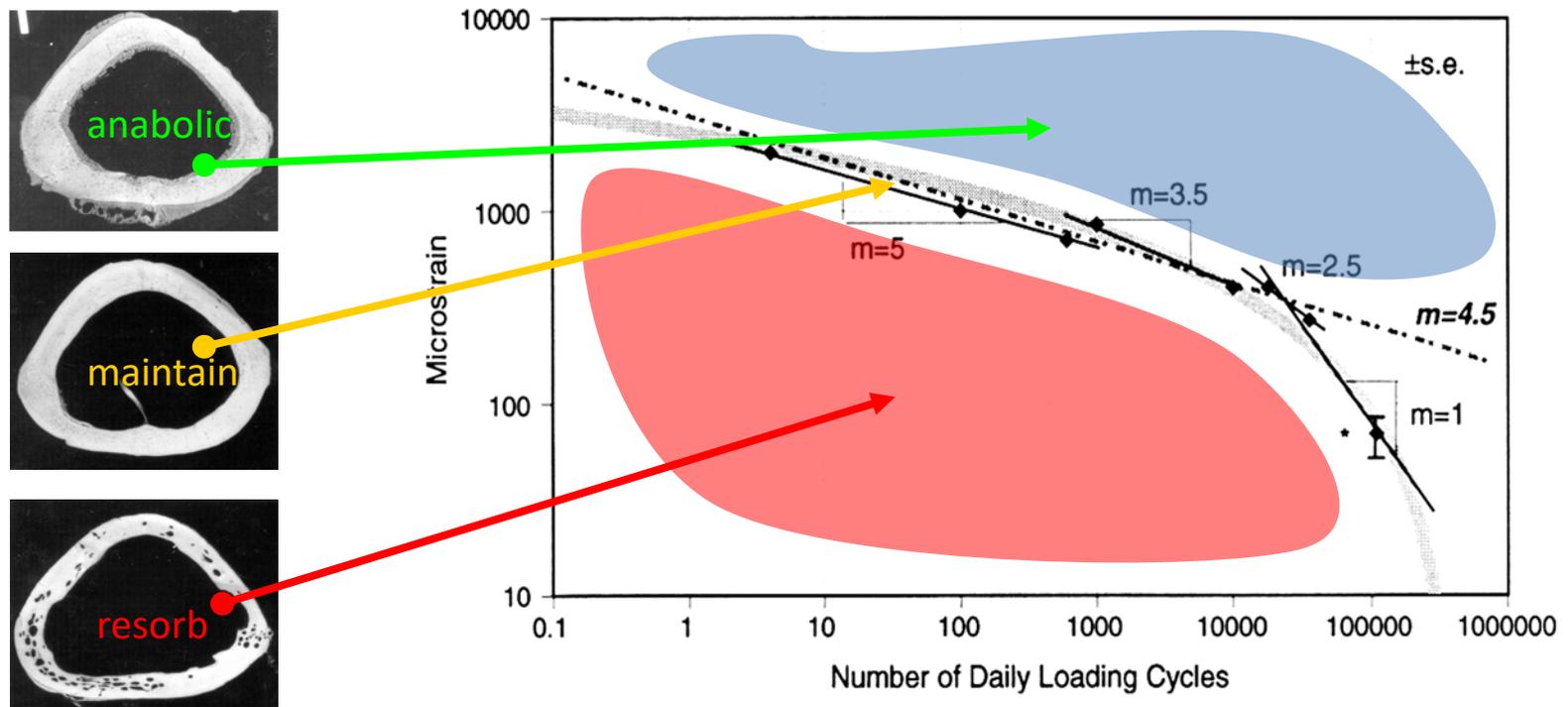
- Ground-reaction forces move through your bones and stimulate them to “remodel” themselves and add density and strength
- Muscular contractions that tug at and slightly bend attached bones
- Forces or other mechanical signals are converted to biochemical signals in cellular signaling

**Wolff’s law: ‘Changes in form and function of bone are followed by changes in its internal structure’**



# Mechanical signals into bone

Bone can be maintained with a few large loading cycles, or thousands of extremely small ones.



Qin et al. 1998

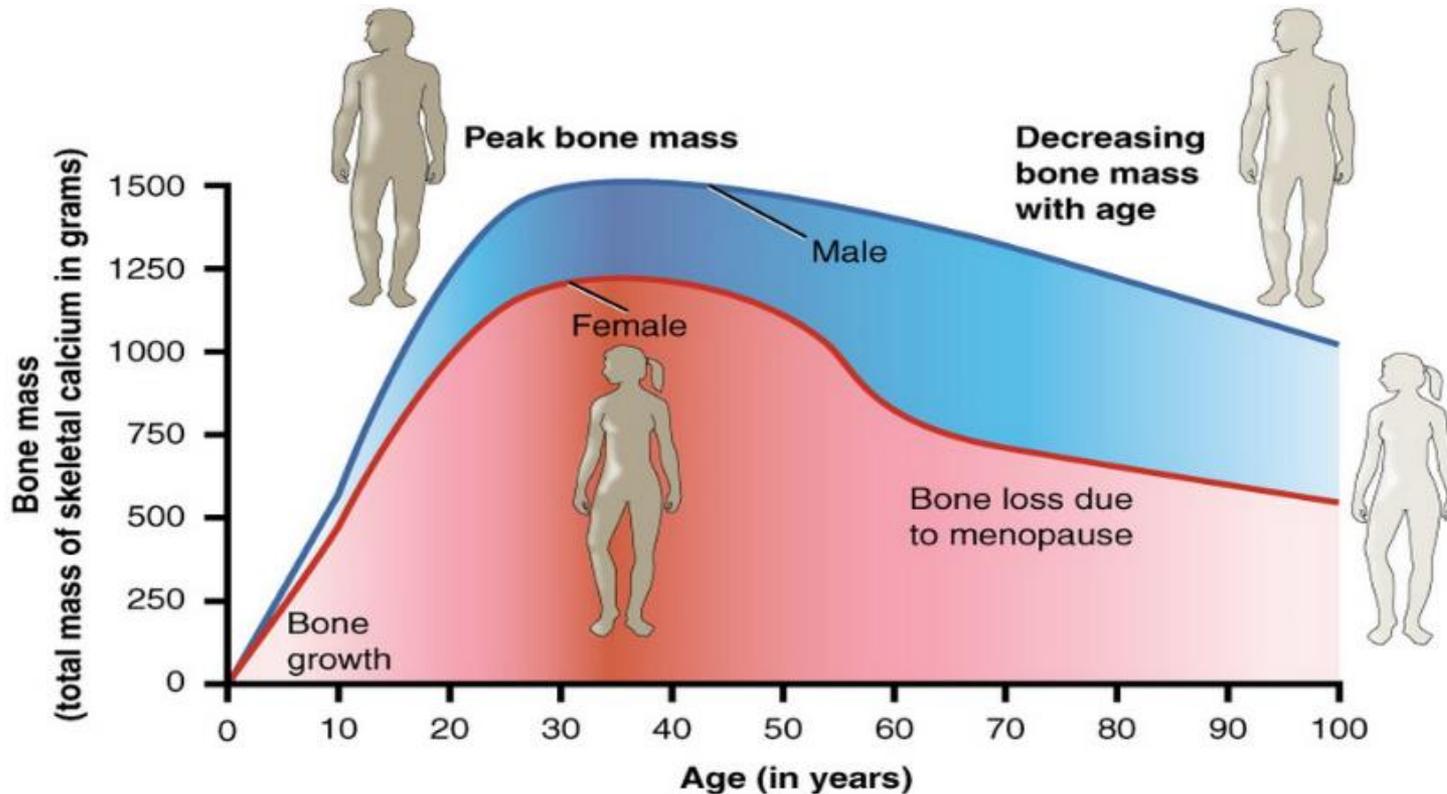
# Marodyne LiV impact on bone as we age

Bone accrual in young

Recover bone in adult maladies

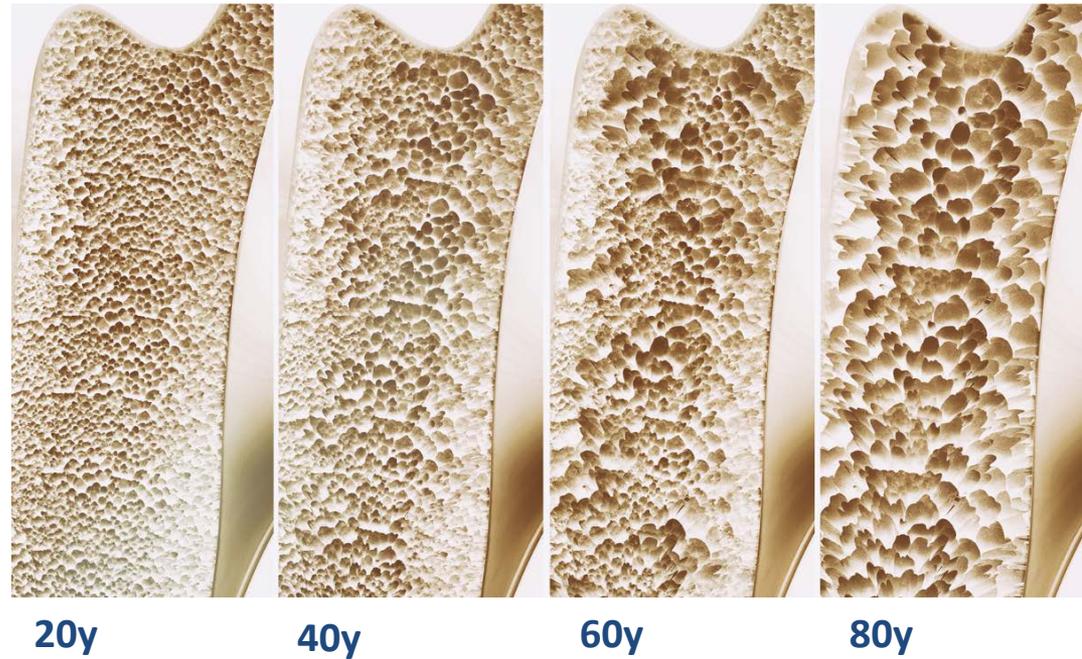
Slows bone loss in older adult

Reduces fractures from falls in elderly



# Osteoporosis

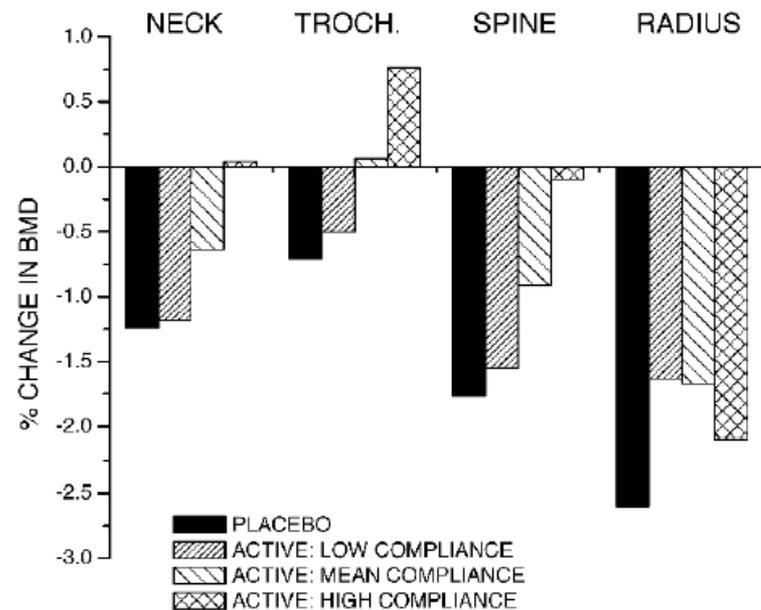
- Reduced bone quality & quantity elevates fracture risk
- Expansion of the marrow space by fat



# Scientific research – Rubin et al. 2004

## Rubin et al. 2004

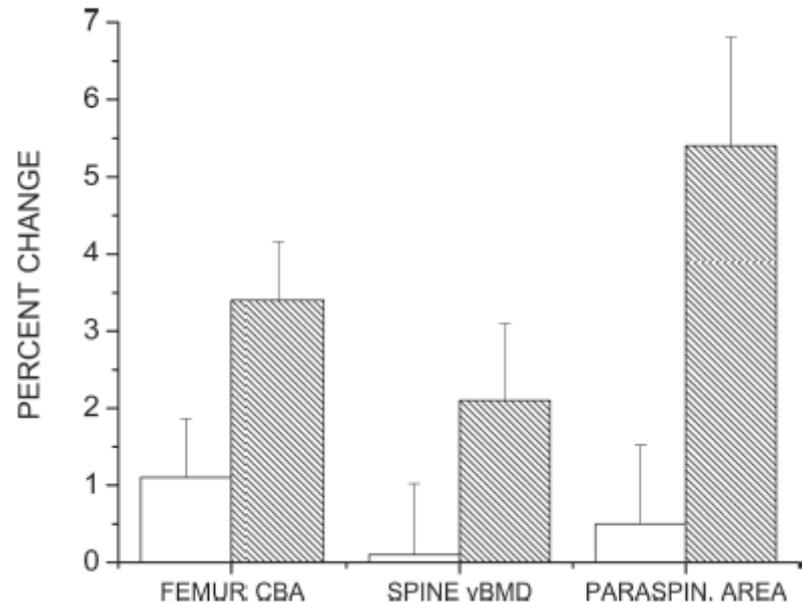
A 1-year prospective, randomized, double-blind, and placebo-controlled trial of 70 postmenopausal women demonstrated that brief periods (<20 minutes) of a low-level (0.2g, 30 Hz) vibration applied during quiet standing can effectively inhibit bone loss in the spine and femur, with efficacy increasing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



# Scientific research

## Gilsanz et al. 2006

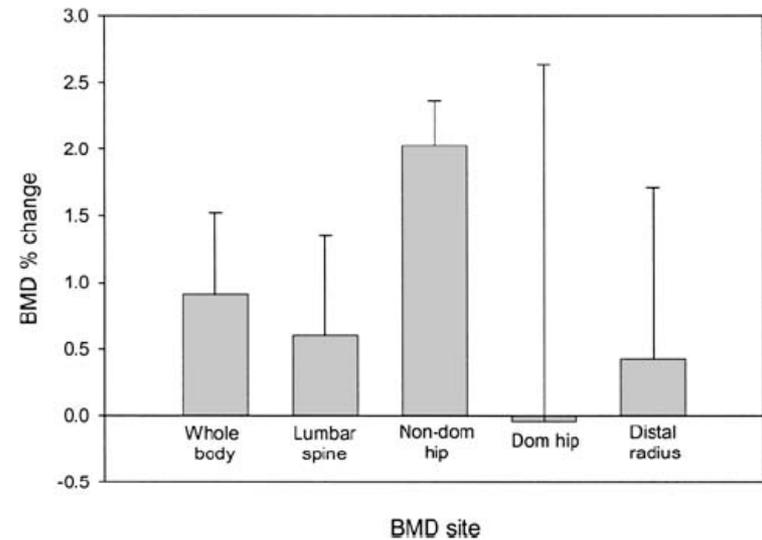
Short bouts of extremely low-level mechanical signals, several orders of magnitude below that associated with vigorous exercise, increased bone and muscle mass in the weight-bearing skeleton of young adult females with low BMD.



# Scientific research

## Beck et al. 2006

Preliminary findings provide evidence of a possible positive response of regions of low bone mass to brief daily bouts of in-home, passive, noninvasive, low-strain, high-frequency, mechanical loading.



# Scientific research

## Leung et al. 2014

- A large study in 710 women over 60 years using LiV for 18 months, showed reductions in falls and fractures in the group using LiV compared to controls.
- There were significant benefits in muscle strength and balance and in high compliance LiV users 1.4 % hip and 1.12% spine BMD benefit.

	Vibration group	Control group
Fall or fracture—no. of subjects (%) <sup>b</sup>	62 (18.6)	94 (28.7)
Fracture—no. of subjects (%) <sup>c</sup>	4 (1.1)	8 (2.3)

# Scientific research – Bone loss in children

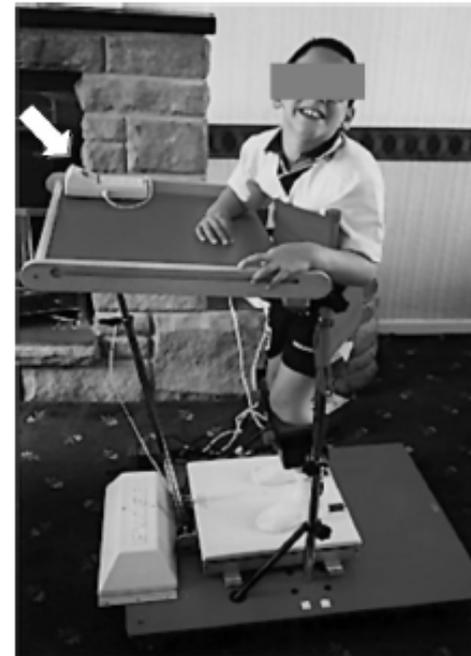
- Ward et al. 2004
- Wren et al. 2010
- Lam et al. 2012
- Leonard et al. 2012
- Bianchi et al. 2013
- Ness et al. 2015



# Scientific research

## Ward et al. 2004

The mean change in tibia was +6.3% in the intervention group compared with -11.9% in the control group. This pilot randomized controlled trial provides preliminary evidence that low-level mechanical stimuli represent a noninvasive, non-pharmacological treatment of low BMD in children with disabling conditions.



# Scientific research

## Wren et al. 2010

The primary benefit of the vibration intervention in children with Cerebral Palsy was to the cortical bone in the appendicular skeleton. Increased cortical bone area and the structural (strength) properties could translate into a decreased risk of long bone fractures in some patients.

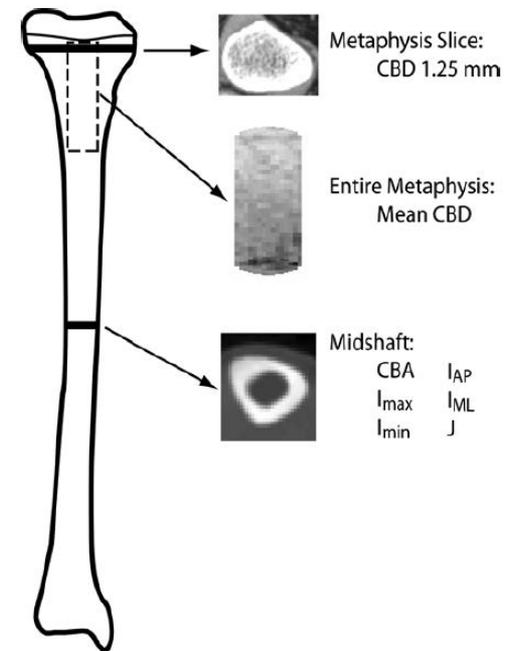
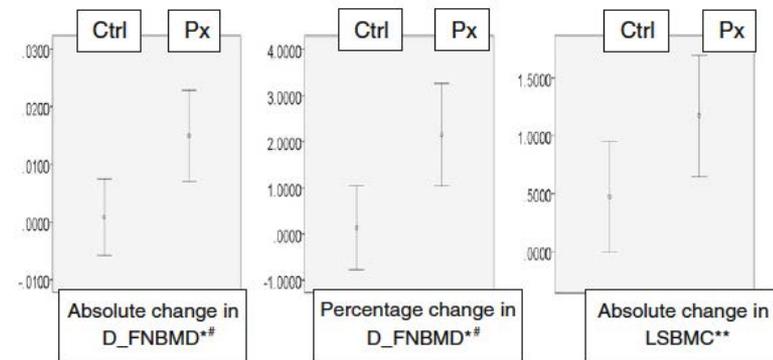


FIGURE 1. Location of CT scans from the tibia.

# Scientific research

## Lam et al. 2013

Low-magnitude high-frequency WBV was effective for improving areal BMD at the femoral neck of the dominant side and lumbar spine BMC in adolescent idiopathic scoliosis subjects.



Ctrl = Control group

Px = Treatment group

D\_FNBMD = Dominant femoral neck aBMD ( $\text{g}/\text{cm}^2$ )

LSBMC = Lumbar spine BMC (g)

The mean and 95% confidence interval are shown

\* :  $p < 0.05$

\*\* :  $p = 0.05$

# : Difference remains statistically significant after analysis with the Benjamini-Hochberg procedure

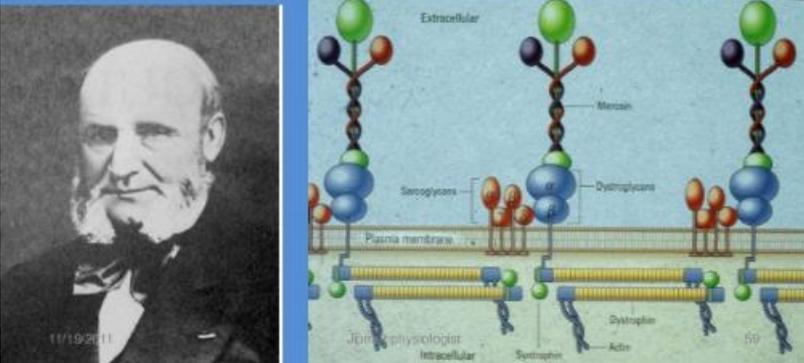
# Scientific research

## Bianchi et al. 2013

- 21 males 6 – 13 yrs  
Benefit: spine BMAD 7.9%, TB 6.8%, Femoral neck 9.8% Bianchi et al. 2013
- These data suggest that Low Magnitude High Frequency Vibration can effectively improve BMD and bone turnover in ambulant boys with Duchenne Muscular Dystrophy

### Duchenne muscular dystrophy

- First described in 1881- dystrophin gene discovered in the early 1980's



# Scientific research

## Ness 2015

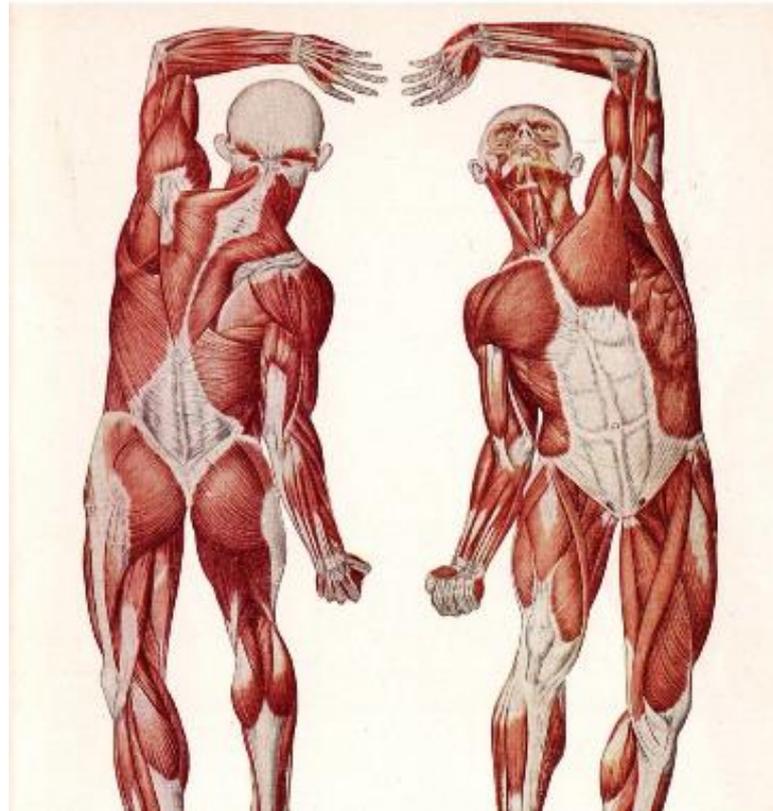
- Bone density decreases during chemotherapy
- Marodyne LiV intervention twice daily, 10 minutes
- 7 – 17 years old childhood cancer survivors

	Intervention		Placebo		p-value*
	Mean*	SD	Mean*	SD	
	(N=22)		(N=26)		
Total body BMD Z-score	0.25	0.78	-0.19	0.79	0.05
Lumbar BMD Z-score	0.15	0.51	0.08	0.51	0.82
% tibial cortical bone	3.00	4.69	1.77	4.90	0.16
% tibial trabecular bone	4.86	16.58	-3.68	16.92	0.08
% lumbar bone volume	5.64	10.83	5.30	11.06	0.91

*\*Adjusted for sex and Tanner stage*

# Muscle health

- Redevelops muscles
- Restores dynamic action of muscle fibers

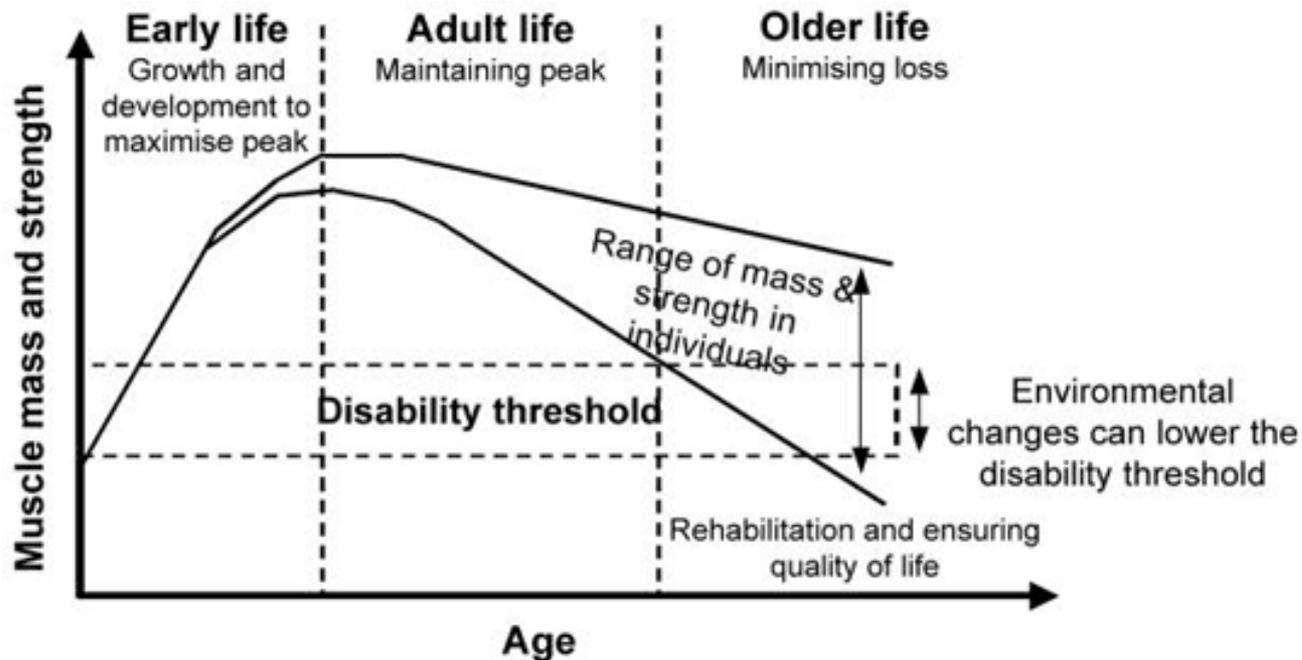


# Marodyne LiV impact on muscle through age

Building muscle and functionality in young

Maintain muscle health in adults

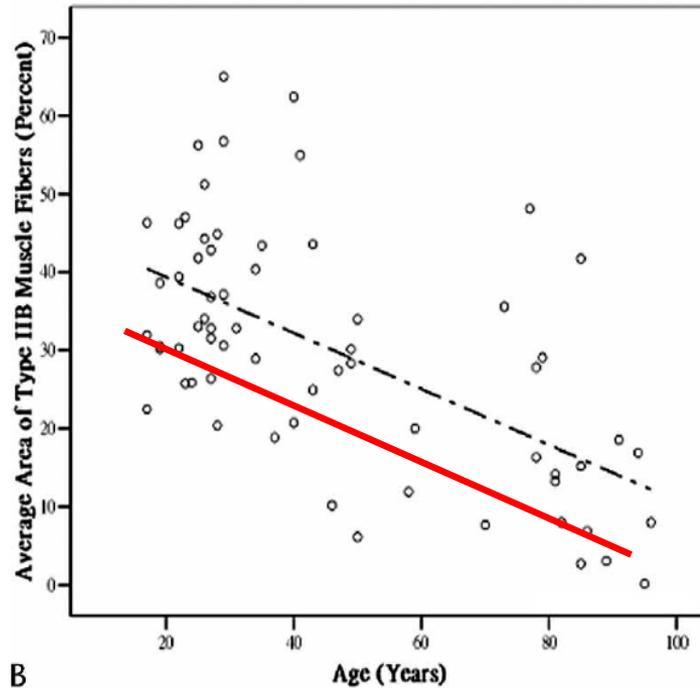
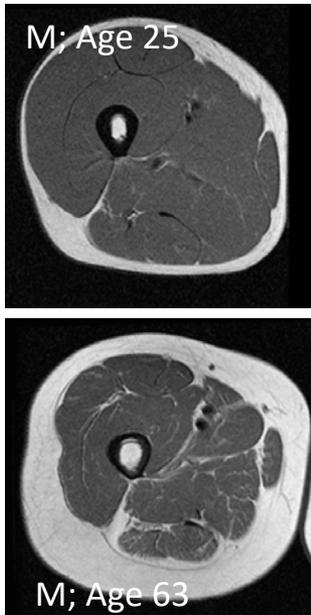
Minimize muscle loss in elderly



Modified WHO/HPS, Geneva 2000

# Age-associated decrease of type IIA/B human skeletal muscle fibers

Lee et al. 2006

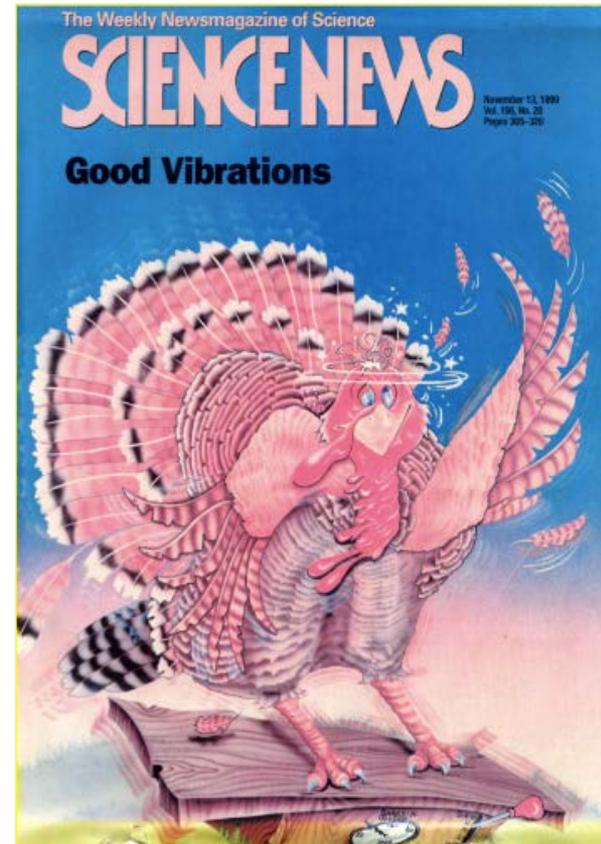


Type IIb

Wing-Sze Lee, Bsc; Wing-Hoi Cheung, PhD; Ling Qin, PhD; Ning Tang, FRCSEd(Orth); and Kwok Sui Leung, MD

# Scientific research – Muscle health

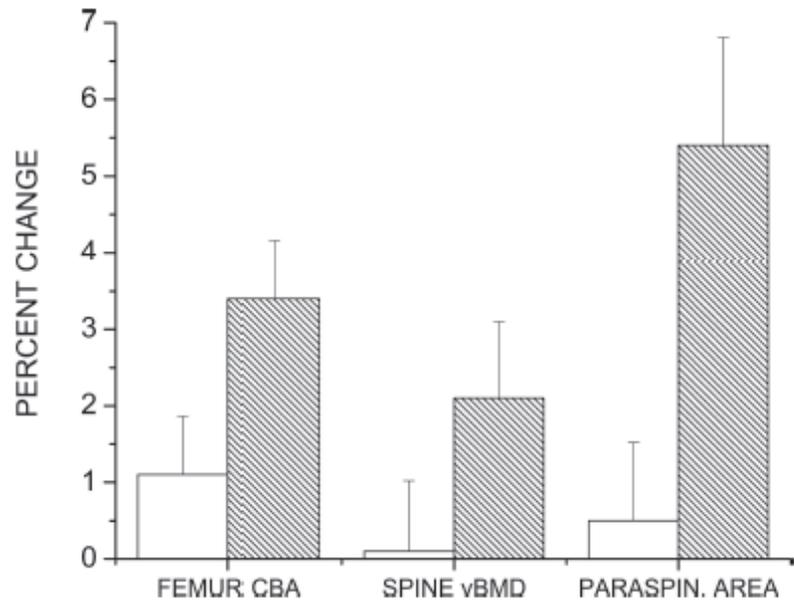
- Gilsanz et al. 2006
- Muir et al. 2011
- Leung et al. 2014



# Scientific research

## Gilsanz et al. 2006

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.



# Scientific research

## Muir et al. 2011

Chronic bed rest resulted in decrements to muscle strength and endurance, thus biasing several critical control systems towards instability and falling. This decline in stability and strength was significantly attenuated by brief daily exposure to extremely low magnitude mechanical signals, delivered to the plantar surface of the foot of the supine subject by Low Intensity Vibration (LIV).

	Control baseline	LMMS baseline	Control 90 days	LMMS 90 days	Benefit of LMMS	<i>p</i>
<b>Knee concentric strength</b>						
Extension at 60°/s	109 ± 43	120 ± 31	81 ± 39	90 ± 24	+2.7%	0.33
Extension at 180°/s	80 ± 33	88 ± 28	63 ± 28	70 ± 23	+3.7%	0.48
Flexion at 60°/s	64 ± 25	63 ± 17	51 ± 19	53 ± 14	+21.9%	0.13
Flexion at 180°/s	48 ± 19	51 ± 15	41 ± 16	47 ± 13	+46.2%	0.01
<b>Knee concentric endurance</b>						
Extension at 180°/s	1158 ± 511	1028 ± 339	945 ± 442	881 ± 296	+22.3%	0.17
Flexion at 180°/s	624 ± 306	510 ± 130	521 ± 279	493 ± 171	+79.8%	0.02
<b>Ankle concentric strength</b>						
Extension at 30°/s	72.5 ± 22.8	80.4 ± 16.5	52.9 ± 23.7	59 ± 16	+1.5%	0.32
Flexion at 30°/s	22.1 ± 8.8	24.0 ± 6.6	20.5 ± 8.3	21.8 ± 6.5	-26.6%	0.28
<b>Ankle eccentric strength</b>						
Extension at 30°/s	108 ± 28.0	121 ± 29.5	74.8 ± 34.1	83.2 ± 25.3	-1.6%	0.39
Flexion at 30°/s	36 ± 12.4	38.9 ± 10.2	30.1 ± 13.3	34.9 ± 8.8	+37.3%	0.07
<b>Back concentric strength</b>						
Extension at 60°/s	249 ± 97	222 ± 72	218 ± 96	202 ± 72	+27.6%	0.44
Flexion at 60°/s	132 ± 23	133 ± 46	119 ± 31	127 ± 44	+54.2%	0.10

# Scientific research

## Leung et al. 2014

Low Mechanical High Frequency Vibration (LMHFV) is effective in fall prevention with improved muscle strength and balancing ability in the elderly. We recommend its use in the community as an effective fall prevention program and to decrease related injuries.

Osteoporos Int

**Table 4** Difference in secondary outcomes between vibration and control groups (cluster-adjusted 2 sample *t* test analysis)

	Cluster-adjusted mean (95 % CI) (vibration group)	Cluster-adjusted mean (95 % CI) (control group)	Cluster-adjusted difference between groups (V-C) (95 % CI)	<i>p</i> value <sup>a</sup>	Intracluster correlation coefficient
Muscle strength: dominant leg (kg)					
18-month-baseline	1.61 (1.10, 2.12)	-0.85 (-1.48, -0.22)	2.46 (1.70, 3.22)	<0.001*	0.095
9-month-baseline	1.35 (0.82, 1.87)	-0.74 (-1.40, -0.07)	2.08 (1.29, 2.87)	<0.001*	0.125
Nondominant leg					
18-month-baseline	1.54 (0.99, 2.10)	-0.89 (-1.59, -0.19)	2.43 (1.59, 3.27)	<0.001*	0.110
9-month-baseline	1.33 (0.80, 1.86)	-0.72 (-1.40, -0.05)	2.06 (1.25, 2.86)	<0.001*	0.134

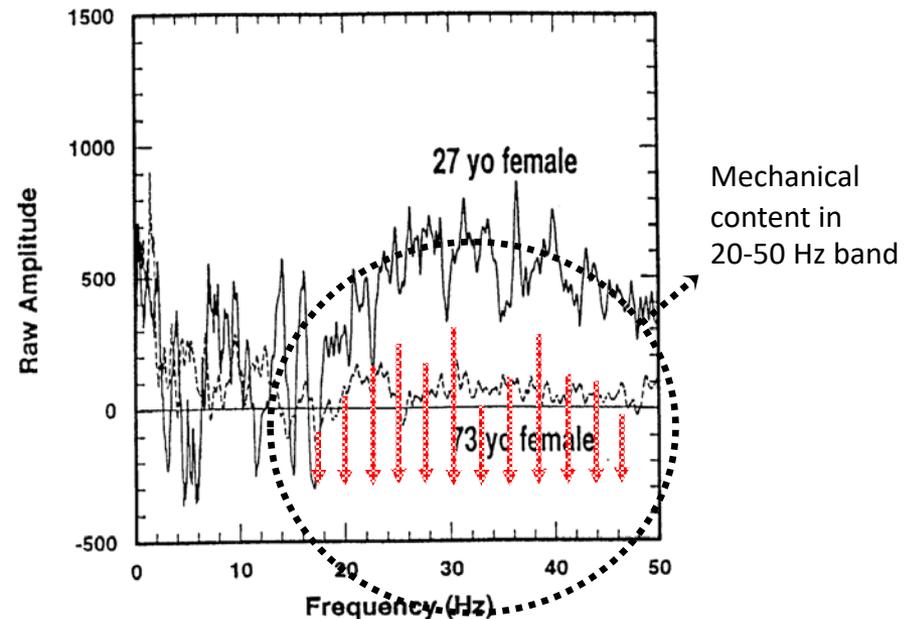
# Postural Control

- Restores motion to joints
- Restores fast twitch muscle fibers



# Contractile spectra of postural muscle deteriorates as a function of age

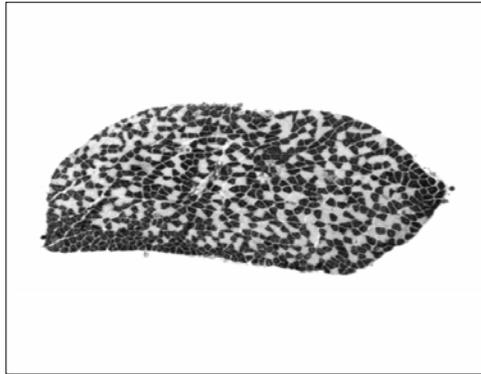
- Does fibre-type specific sarcopenia suppress regulatory signals to bone?
- Can Marodyne LiV mimic muscle contraction at 30Hz and maintain muscle mass and function?



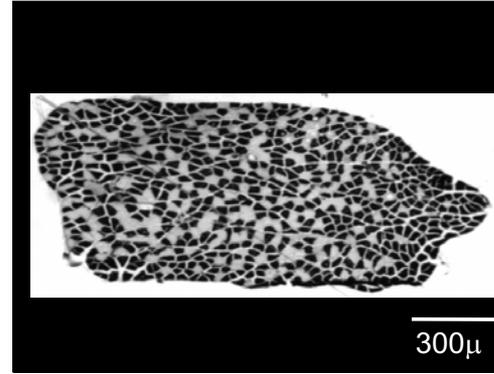
Huang et al. 1999

# LiV influences on the musculoskeletal system

AC

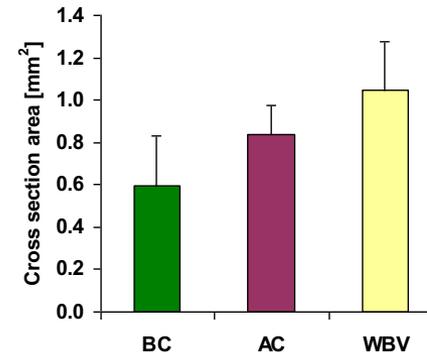
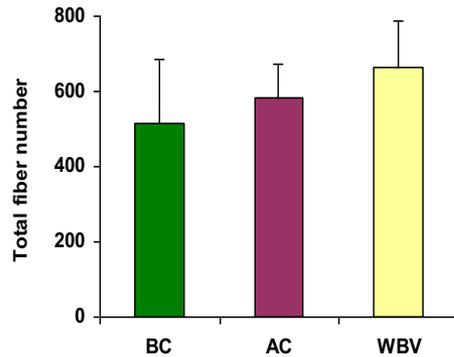


ATPase staining (pH10.4)



WBV

w/ Type II as black



(mean±SD, n=12)

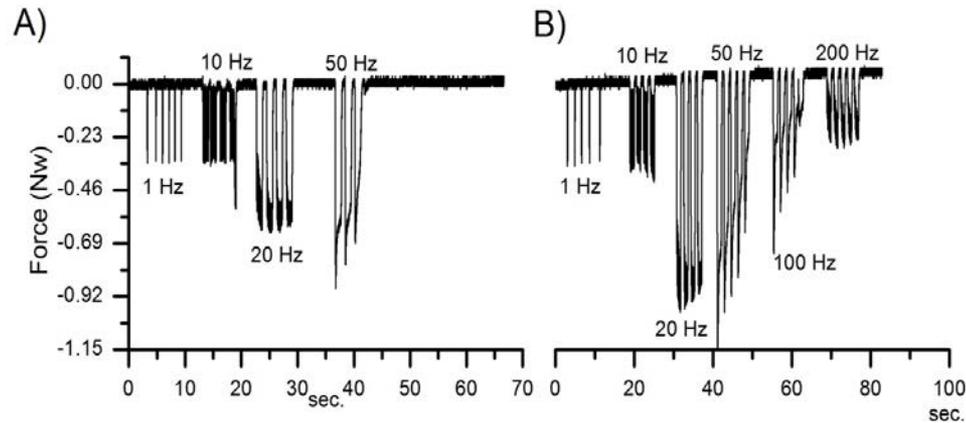
>30% increase in cross-sectional area of muscle ( $p < 0.05$ ), trend of increase in fiber # and area

Xie et Al. 2008

# Marodyne LiV promotes force: Muscle activity

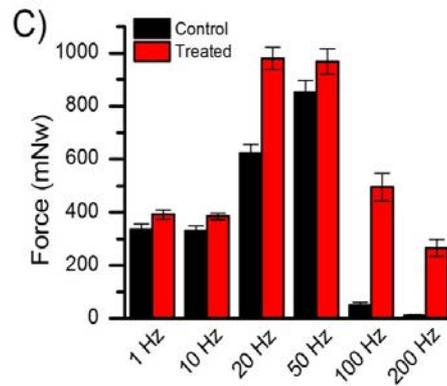
*In collaboration with Dr. James Bibb, UTSW*

Control

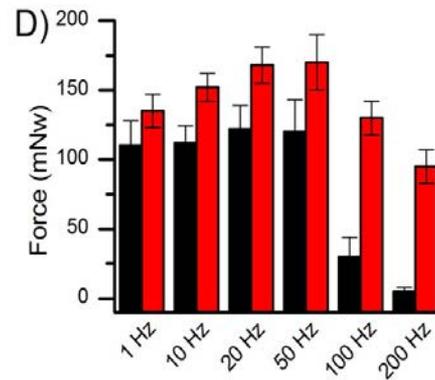


Marodyne LiV

Young Mice



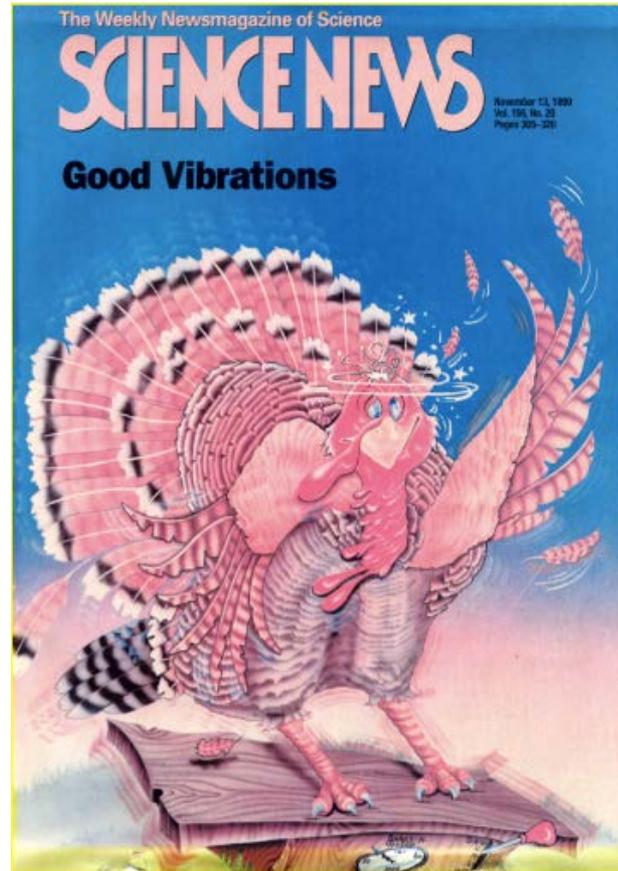
Old Mice



Mettlach et al. 2013

# Scientific research – Postural control

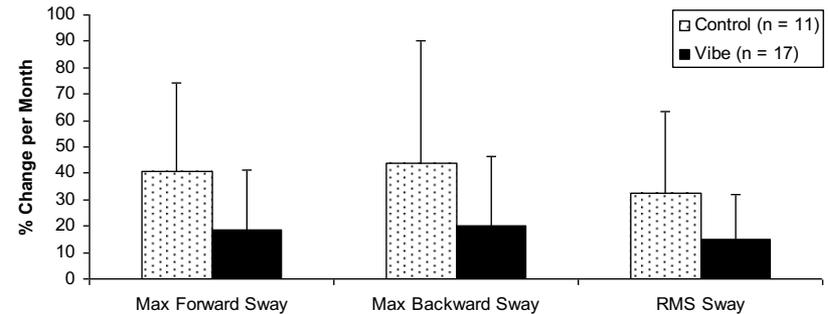
- Muir et al. 2011
- Leung et al. 2014



# Scientific research

## Muir et al. 2011

In summary, chronic bed rest severely compromised several critical indices of postural control. This degree of deterioration in postural stability was significantly alleviated by brief, daily treatment of LMMS delivered through a low intensity (<1g) vibrating (LiV) platform.



# Scientific research

## Leung et al. 2014

Low Mechanical High Frequency Vibration (LMHFV) is effective in fall prevention with improved muscle strength and balancing ability in the elderly. We recommend its use in the community as an effective fall prevention program and to decrease related injuries.

**Table 3** Total number of falls during the study period (18 months)

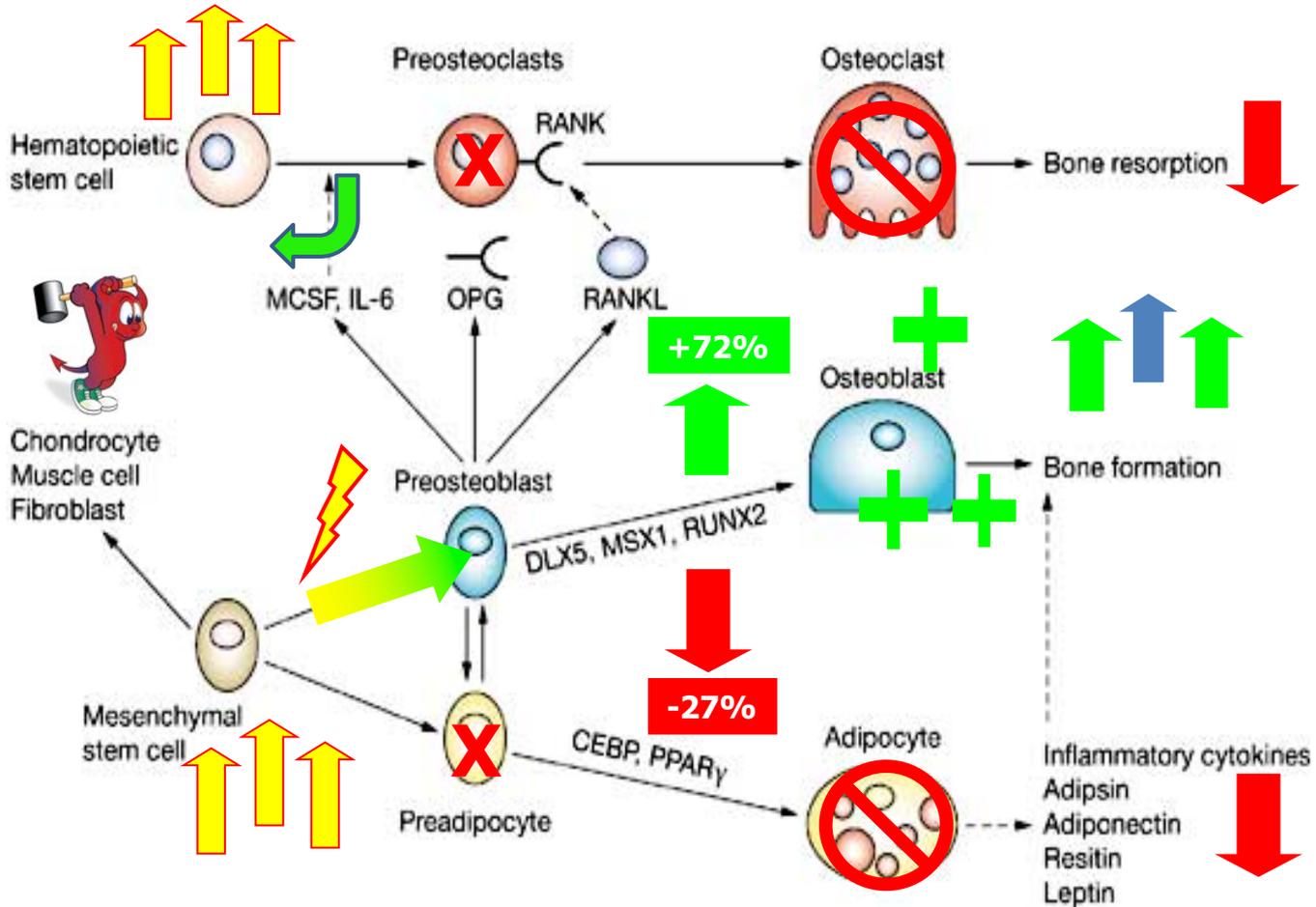
Total no. of falls—no. of subjects (%) <sup>a</sup>	Vibration group (n=334) <sup>b</sup>	Control group (n=327) <sup>b</sup>
0	272 (81.4)	233 (71.3)
1	55 (16.5)	73 (22.3)
2	6 (1.8)	14 (4.3)
3	1 (0.3)	7 (2.1)

# Impact of Marodyne LiV at cellular level

- Promotes RUNX 2 (bone forming) and suppresses PPAR $\gamma$  (fat forming)
  - Luu et al. 2009
- Changes cell structure during use to promote intracellular signaling
  - Sen et al. 2012
- Daily exposure to LIV (single or multiple episodes) to maintain the cellular effect
  - Sen et al. 2011



# Marodyne LiV therapy biasing of stem cell fate selection



Towards a stronger and healthier musculoskeletal system

# Testimonials

## Ingrid (78), Vienna/Austria

*“My friend Klaus from Berlin (Germany) told me the best about the device. After using that I confirm that. My history: I have two artificial hips (1999 and 2008), four bypasses (2012), a cardiac pacemaker (2013), osteoporosis. And I broke my sacrum twice (2012). Till 2012 I went active skiing (cross country and slope skiing). Till 2012 I went by bicycle regularly. Till nowadays I try to make gym regularly.*

*I have pain all over my body, especially in the region of my sacral bone. I got pain killers with cortisone – but it didn't work. By the moment I got physiotherapy and balneo therapy. Against my osteoporosis I got every three months an injection.*

*I discontinued my pain killers, because they didn't work. Last week I couldn't leave my bed for two days – because of pain. In the evening the device arrived. Immediately I went on the device. And the first night after a long time I slept without pain! In the morning I went again on the device. Afterwards I made a little walk and I went once more on the device. Because the back pain started again. And – a little wonder: The pain got less and less – only by standing on the device! By the moment I use the device every day (if my pain begins). But especially in the morning after rising and in the evening before I went to bed. The last months it was only possible for me to went through my apartment with a walking stick. But now it is possible for me to go without my walking stick.*

*If I use the device I use the time for making a little physiotherapy. Mostly I like the gentle vibrations in my whole body.*

*Normally if I went to bed in the evening I need a hot-water bottle for my cold feet. And it needs a long time till my feet are warm. But since I use the device I go with warm feet in my bed!”*

# Testimonials

## Belinda. PT in Australia

*"I can happily report that participants in my previous small trial experienced a 70% improvement in wall squat performance (an index of lower extremity strength and muscular endurance) in their non-dominant limb, and improved their ability to rise from a chair multiple time (an index of balance and mobility) after 8 months of twice weekly 15 minutes low intensity whole body vibration exposure."*

# Testimonials

## Jane (USA)

*"I bought my mom a Marodyne LiV last year. Her bone scans have improved significantly by nearly 8% "*

## Madeline (USA)

*"I have been using the Marodyne LiV low intensity vibration plate for ~ a year now and this week I had my follow up DEXA exam.*

*I wanted to let you know that my bone density statistics have increased significantly since my last exam in 2012! My overall T-score is -2.4 and the bone density in the lumbar spine has increased by 6.5% and in the right femur it has increased by 8.3% "*

# References

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