Break Free!
Non Medical Innovation in
Bone Health and Restoration
LeadingAge MO Institute & Expo

Presenters
Barb Christensen, OT
Milwaukee, WI – Aegis Therapies
National Director of Clinical Services
Barb.Christensen@aegistherapies.com

Lynn Freeman, PT, PhD, DPT, GCS, CWS
Sammamish, WA – Aegis Therapies and
PATH Clinical Research Institute (501c3)
Vice President of Clinical Research
Lynn.Freeman@aegistherapies.com

Disclosure of Commercial Interests
We DO have commercial interests in the following organization(s): (or I consult for the following organizations)

Name: Aegis Therapies
Type: Healthcare across post-acute healthcare continuum

We DO NOT have commercial interests in the following organization(s): (or I consult for the following organizations)

Name: bioDensity™ or Performance Health Systems
Type: Biomedical equipment manufacturers
Session Objectives

1. Understand existing evidence on bone remodeling through non-medical interventions for bone restoration and fracture prevention including new knowledge of “osteogenic loading” (bone loading) principles to build bone density.

2. Explain the process of developing an individualized wellness program that promotes bone health and understand if interventions with and without bone-loading exercise equipment, impacts controllable risk factors for Osteoporosis.

3. Learn if a wellness program of high intensity bone loading exercise is safe and effective in reducing adverse events in institutionalized and community-dwelling older adults with Osteopenia and Osteoporosis.

Content shared today……..

Introduction and Epidemiology
Review of Literature
Translating Research into Clinical Practice
Barriers, Best Practices and Outcomes
Case Reviews
Q & A
Decrease in bone mass and density

Osteoporosis

Bone mineral density (BMD) is the standard for testing

Osteoporosis – Technically

Osteoporosis: A chronic, progressive disease characterized by:
- Low bone mass,
- Microarchitectural deterioration of bone tissue
- Decreased bone strength,
- Bone fragility,
- And a consequent increase in fracture risk

Osteoporosis

T-score of > -2.5

Bone Mineral Density (BMD) test is a snapshot of bone health and can identify osteoporosis, determine risk for fractures, and measure response to osteoporosis treatment.

The most widely recognized BMD test is called a central dual-energy x-ray absorptiometry, or central DXA test.

Given as T-scores, a score of 0 means BMD is equal to the norm for a healthy young adult. Differences between BMD and that of the healthy young adult norm are measured in standard deviations (SDs). The more SDs below 0 (negative number) the lower BMD and the higher risk of fracture.
Osteopenia

Low mass/density = Osteopenia

Bone density between 1.0 and 2.5 standard deviations below the mean BMD of a young-adult reference population

(T-score between -1.0 and -2.4).

T-score relationship to mean bone density

Based on information from the World Health Organization

<table>
<thead>
<tr>
<th>T Score in Deviations from Norm</th>
<th>Bone Density</th>
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</thead>
<tbody>
<tr>
<td>0 to -1</td>
<td>Normal Density</td>
</tr>
<tr>
<td>-1 to -2.4</td>
<td>Osteopenia</td>
</tr>
<tr>
<td>-2.5 and Below</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>&gt; - 2.5 with fx.</td>
<td>Severe Osteoporosis</td>
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Dual-Energy X-ray Absorptiometry (DXA)

Dual-energy X-ray absorptiometry (DXA):

A diagnostic test used to assess bone density at various skeletal sites using radiation exposure about one-tenth that of a standard chest X-ray.
Fracture Risk Assessment Tool (FRAX)


World Health Organization developed and provides this assessment tool:
- Computer and paper driven tools available
- Evaluates fracture risk
- Gives 10-year probability of fracture at hip AND 10-year probability of major osteoporotic fractures (spine, forearm, hip, or shoulder)

Osteoporosis: Bottom Line

Osteoporosis causes weak bones.

Poor bone health is common and costly.

Images available from Office of the Surgeon General, 2012, NIH publication No.12-7827
Physiology of bone formation

The remodeling cycle consists of three consecutive phases:
1) Reabsorption - osteoclasts digest old bone;
2) Reversal - mononuclear cells appear on the surface of the bone
3) Formation - osteoblasts lay down new bone until the reabsorbed bone is completely replaced.

(Hadjidakis and Androulakis 2006)

Bone formation over the years

Influence of aging and hormonal changes

- Peak bone mass is attained between 25-30 yrs of age; ~ 50% gained in our teen years
- Slow bone loss occurs between 30-50 yrs
  - (rate of loss is 1-1.5 % per year)
- Rapid bone loss occurs between 30-50 yrs
  - Rate of loss 3-5% per year for 1st-5th year post menopause
  - Less rapid bone loss occurs > age 60-65

Bone Cycle

Rate of bone loss 1 – 1 ½ % /yr from mid 30’s to 50’s.
Rate of loss 3-5 % for First 5 yrs after menopause

Image available from Office of the Surgeon General, 2012, NIH publication No.12-7827
## Pathophysiology of Osteoporosis

### Secondary Osteoporosis (or Type III)

**Possible Causes:**
- Rheumatoid arthritis
- COPD
- Anorexia / bulimia
- Liver and / or kidney impairments
- Hormonal causes from diabetes
  - Hyperparathyroidism / hyperthyroidism
- Cancers (multiple myeloma, leukemia, metastatic bone)
- And….others

### RISK FACTORS

<table>
<thead>
<tr>
<th>Uncontrollable</th>
<th>Controllable</th>
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<tbody>
<tr>
<td>Gender—↑ female</td>
<td><em>Inadequate intake</em> of calcium, vitamin D, fruits and vegetables</td>
</tr>
<tr>
<td>Race—↑ in Asian and European nationalities</td>
<td><em>Excessive intake</em> of protein, sodium, caffeine, and carbonated beverages</td>
</tr>
<tr>
<td>Menopause</td>
<td><em>Inactivity</em></td>
</tr>
<tr>
<td>Age—↑ &gt; 50 years of age</td>
<td><em>Smoking</em></td>
</tr>
<tr>
<td>Family history of osteoporosis</td>
<td><em>Excessive alcohol</em></td>
</tr>
<tr>
<td>Small/thin stature</td>
<td></td>
</tr>
<tr>
<td>Broken bones or loss of bone height</td>
<td><em>Weight loss</em> (planned excessive)</td>
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</table>
Osteoporosis in Men

For men, the lifetime risk of fracture is greater than that of developing prostate cancer.

1 out of 5 will experience a fracture.

Men are more likely to suffer serious consequences related to their first fracture, primarily since the age of onset in men is ≥70 years.

Increased risk with:
- Testosterone deficiency
- Androgen deprivation therapy

AGING → ↓bone health → Fall

- Insufficient bone mass in teen to Early adult yrs
- Clinical complexities leading to early rapid bone loss
- Menopause ↓ hormones
- ↓ rapid bone loss
- Loss of fall protective reactions
- Clinical complexities ↑ Fall risk
- Impaired safety ↑↑ fall risk
- Impact of fall on fragile skeleton

Prevention of Osteoporosis

Physical activities - work against gravity.
Examples of weight bearing physical activities include:

- Walking (brisk), jogging, or running
- Stair climbing
- Hiking
- Jumping rope (50-100 times)

Adults
3-5x/week at least 30 minutes

Children
daily at least 60 minutes
Examples of muscle strengthening

- Weight lifting (free weights)
- Weight (resistive) machines
- Elastic bands
- Body weight (resistance: squats, toe raises)

At least 2 times/wk

Treatment

- Who
- When
- What type

Who should receive treatment?

Major Recommendations—Level A (good and consistent scientific evidence)

Treatment should be recommended for:

- Women with a T-score of -2.5 or <
- Women who have had low-trauma fracture(s)
- Women with a T-score from -1 to -2.5 AND a fracture risk assessment tool (FRAX) score ≥ 3% for risk of hip fracture.
  OR FRAX score ≥ 20% for risk of major osteoporotic fracture
  OR both in the next 10 years

Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov
Therapy Intervention

Strengthening the Support Muscles

- Diaphragm
- Intercostals
- Back extensors
- Abdominals
- Pelvic floor
- Gluteus medius and maximus

Osteoporosis and Physical Activity

Appropriate exercise slows the rate of bone loss.

- Meta-analysis (14 RCTs) demonstrated high intensity strength training → significant ↑ BMD at the LS and a non-significant ↑ total hip\(^1,42\)

- Moderate intensity PA: average 1-3x week, 45 minutes, 1 year.

- Sedentary lifestyles and immobility: ↓ BMD

- Effects of PA improved when combined with proper nutrition and medication.
Introduction to Impact

Remember Wolff's Law?
- Impact and Mechanotransduction
- A bone grows or remodels in response to forces or demands placed on it
- High-Impact sport: example, gymnastics

Julius Wolff, Wolff's Law (1892)

Impact and Bone

Differences in loading moments, ranged movement vs. impact

Impact yield: The two conditions, positioning & Multiples of Bodyweight (MOB) force/loading

Impact and Soft Tissues

More than Just Bone
- Tendons and Ligaments (Benjamin & Ralphs, 1998)
- Cartilage quality via MRI (Koli et al, 2015)
- Myofibril protein syntheses (Welle et al, 1993)
- Impact level loading and GLUT4 signaling (Holten et al, 2004)

Impact: More than Just Bone

Decoupling Function vs. BMD
- Fracture probabilities, 10 year


Functional Bone Performance

Deceleration
- Average cadaver hip failures ~ 450 Joules (Lots & Hayes, 1990)
- Foxhound kinetic chain* (Yoshikawa et al, 1994)

* National Institutes of Health guidelines for the care and use of laboratory animals were observed in all phases of the research. All phases of the protocol were approved by the Indiana University School of Medicine Animal Care and Use Committee (protocol MD-1209).
Functional Bone Performance

Osteogenic Loading (OL) Therapy

- Analysis of loading through the kinetic chain
- The MOB force/loading levels DXA subset correlated to the MOB forces seen with the larger population (N=2380) showing spine and lower extremity loading with 2.89 +/- 1.02 SD and 9.67 +/- 3.68 SD MOB respectively.
- New metric of functional bone performance
- DXA subset (N=14) showed bone density gains that averaged 7% in the hip and 7.7% in the spine over one year.


Traditional “Solutions”

- Bisphosphonate drugs
- Calcium Supplements
- Weight bearing strength training

“...there is no clinical trial evidence that increasing calcium intake from dietary sources prevents fractures. Evidence that calcium supplements prevent fractures is weak and inconsistent.”


Bone Age Reduction

Is routine treatment worth it?

- By improving a 75 year old woman’s average bone density to a 55 year old level we statistically reduce fractures 6 fold

Economic and Outcomes Analysis of Bisphosphonate Use after Distal Radius Fracture for Prevention of Hip Fracture

Traditional OL in Clinical Practice

Safe…but efficacy?
- History of loading with deconditioned and elderly patients.
- 2kg dumbbell, when the human head weighs 7kg.
- The ongoing dilemma: We want to treat with physical medicine intervention, but do not want to put the patient at risk of injury.


Traditional OL in Clinical Practice

Safe…but effective?
- Traditional exercise loading insufficient to bone density development beyond nominal levels. Loading of impact level, as well as some high-intensity programs have been promising, but not necessarily practical
- There is a need for more focused intervention targeting bone and fracture prevention.


Traditional OL in Clinical Practice

Safe…but value-based?
The Cost of Inaction
- $81,300 lifetime cost for a hip fracture (44% r/t SNF)
- $205,000 attempts to avoid
OR
The Cost of action
- ~$24,000 20 years of non-medical treatment

AAOS paper- “The cost of bisphosphonate treatments”
Innovative OL in Clinical Practice

Simple to Complex
- Fitness apparatus, or attempting to control impact moments.
- Specialized osteogenic loading apparatus.

4 Exercises
- Chest Press
- Leg Press
- Core Pull
- Vertical Lift

Increased patient awareness
Understanding of osteogenesis, and fracture prevention
Visual biofeedback

OL & Functional Bone Performance

Keeping Patients Safe
- Multi-site analysis of safety and potentiation with over 4,300 subjects using OL therapy. (isolating, and allowing for compression in the impact ranges of motion, 5cm measured kinetic chain compression)
- No adverse reaction or injury in over 68,000 instances

See handout appendix - Sample bioDensity Performance Report

Innovative OL in Clinical Practice

**Safe...but Patient-Centered?**
- Neural Potentiation - Training an impact protective neural firing event with multiple progressive increasing loads.
- Neural Inhibition - Self imposed force loading and comfort.


**Brain Health Solutions**

Traditional Therapy + Innovative Technologies
- Proven bone density gains
- 1,000,000+ session- no reported injuries
- Exercise can be performed in street clothes
- SAAS database and patient performance metrics- HIPPA compliant

See handouts appendix – bioDensity norms
Recent DEXA studies have shown a 14.9-16.6% increase in bone density in six months in the hip and spine with bioDensity.


**Value-Based Solutions?**

**Put into Perspective**

<table>
<thead>
<tr>
<th>bioDensity</th>
<th>14.9% hip, 16.6% Spine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional strength</td>
<td>1-3% hip and spine</td>
</tr>
<tr>
<td>(4-24 months- ACSM)</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>3.1% hip, 6.4% spine</td>
</tr>
<tr>
<td>(3 years- webMD)</td>
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**Provider Issues**

**Common Barriers**
- Lack of skill AND Knowledge
- Practice-based opposition

**Opportunities**
- Education grounded in evidence – “Based on??”
- Foster a positive culture of “defensive clinical practice”
Research & Education Issues

Common Barriers
- Research Evidence: Perceived vs. Real
- Lack of PAC translational research

Opportunities
- Strengthen academic-acute-PAC partnerships
- Collaborative research and education
- Funding opportunities – Grants and Contracts
- Clinical education grounded in ethics
- Professional Codes of Ethics

Research & Education Issues

Common Solution – Payers AND Providers AND Industry
- MN CSSD GRANT Aegis and Galeon of Osakis (CCRC)
- Program Evaluation Grant

Bone Health: What’s the “how to”?
Donna Diedrich and Lynn Freeman
Practice-Based Evidence Clinical Practice Guided by ICF

Health Condition
E.g. Osteoporosis & Associated Conditions

<table>
<thead>
<tr>
<th>Body Function/Structure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impairment:</td>
</tr>
<tr>
<td>- Muscle</td>
</tr>
<tr>
<td>- Tendon</td>
</tr>
<tr>
<td>- Bone/Cartilage</td>
</tr>
<tr>
<td>- Ligaments</td>
</tr>
<tr>
<td>- High Intensity (Muscle)</td>
</tr>
<tr>
<td>- High Intensity (Bone)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activity Limitation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Essential Tasks</td>
</tr>
<tr>
<td>- ADLs/M AIDS</td>
</tr>
<tr>
<td>- Walking to kitchen</td>
</tr>
<tr>
<td>- Standing to cook meal</td>
</tr>
<tr>
<td>- High Intensity (Muscle)</td>
</tr>
<tr>
<td>- High Intensity (Bone)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participation Restriction:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Essential Roles</td>
</tr>
<tr>
<td>- ADLs/M AIDS</td>
</tr>
<tr>
<td>- Employment</td>
</tr>
<tr>
<td>- Parenting/Grandparenting</td>
</tr>
<tr>
<td>- High Intensity (Muscle)</td>
</tr>
<tr>
<td>- High Intensity (Bone)</td>
</tr>
</tbody>
</table>

WHO. International Classification of Functioning, Disability and Health (ICF)

Program Development – Case Reviews

Bone Health Wellness Programs

- Without high-intensity bone-loading equipment

See handouts appendix – Research Posters (2)

Program Development – Case Reviews

Bone Health Wellness Programs

- With high intensity bone-loading equipment

See handouts appendix – Research Posters (2) Used with permission, bioDensity™
Case Report, Subject #6

Female
- Age at time of second DXA: 59
- Height: 5'4"
- Weight: 125lbs

Medications and supplements taken during OL usage:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormone replacement therapy</td>
<td>Yes</td>
</tr>
<tr>
<td>Testosterone</td>
<td>No</td>
</tr>
<tr>
<td>Growth hormone</td>
<td>No</td>
</tr>
<tr>
<td>Medication to prevent bone loss</td>
<td>No</td>
</tr>
<tr>
<td>Multivitamin</td>
<td>Yes</td>
</tr>
<tr>
<td>Calcium supplements</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Jaquish et al. (2012). Napa Valley Test Facility

“...My bone density increased 6%! After years of measurable bone density decline I was desperate to find an answer.”