Maintaining Bone Health: Story of a Fragility Fracture Program

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How Does Osteoporosis Impact an Orthopaedic Surgeon?

• Ultimately, the patient has a higher risk for complications and a loss of quality of life and or mortality

• Longer more difficult surgery

• Higher risk for surgical failures

• Higher risk for periprosthetic fractures and longer delayed hospital stays

• Higher risk for post operative illnesses due to lack of mobility and stability of surgery

• CMS – 90 day observation of hips/knees – 5 year pilot

• Hospitals penalized for re-hospitalization
Acronyms You Will See Today

- NOF = National Osteoporosis Foundation
- FLS = Fracture Liaison Service
- NBHA = National Bone Health Alliance
- AAOS – American Academy of Orthopaedic Surgeons
- CMS = Center for Medicaid/Medicare Services
- ACE = American College of Endocrinology
What is a fragility fracture

= Fracture that occurs from a fall of 3 feet or less

• Standing height
• Stepped off a curb –
• Tripped over something
• Dizzy and fell
• Caused by very low energy
• Fracture pattern is different (splinter/spiral/chalk)
• Cast or metal (wrist/ankle)
A significant treatment gap exists for patients with osteoporosis who have sustained a fragility fracture.

- Osteoporosis remains undertreated in patients who suffer fragility fractures
- In one study, 3 out of 4 postmenopausal women in the US did not receive treatment during the year following an osteoporotic fracture
- Study from CMS (200,000 patients)
The Osteoporosis Treatment Gap

There is confusion and debate over which healthcare provider is responsible for treating osteoporosis.²

Call to Action and Why Orthopaedics

• AAOS asked Orthopaedics to get involved in osteoporosis treatment
• Realization of treatment gap in multiple studies
• Surgical treatment of secondary fractures
• Surgeons could be penalized by CMS for further complications due to osteoporosis not being treated when identified during surgery

• Treatment gap of when the surgery is done to treat the consequences of Osteoporosis and when patient gets back to see PCP
• PCP may not know of fractures that occurred in the past 12 months, and MOST importantly how SEVERE that fracture was
• Teachable moment and emotionally engaged at the time the fracture occurred
Orthopaedic Society Involvement

- AAOS Fracture liaison certification at national meetings
- Own the Bone (Hospital registry)
- Partnership with NOF
- Fracture Liaison Certification partnership with NOF
- NBHA.org (Fracture liaison support/resources, business proposals, webcasts, patient education)
Normal Bone Quality
Case Study of Poor Bone Quality
Evaluating Bone Strength

Osteoporosis is defined as a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture. Bone strength primarily reflects the integration of BMD and bone quality.  

Bone Strength

Obtain Through a DXA Test

BMD

Bone Characteristics
1. Rate of bone remodeling
2. Architecture
3. Degree of mineralization
4. Damage accumulation

Clinical Indicators
1. Increasing age
2. Previous fragility fractures

Bone Quality

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BMD=bone mineral density  DXA=dual-energy x-ray absorptiometry

1. NIH Consensus Development Panel on Osteoporosis Treatment. JAMA. 2001;285:785-795
Facts About BMD

**T-score = C/A**

Content of the bone/Area of the bone

Content of this bone is brought together and will read more dense. The area is also shrunk. This will falsely improve the t-score

Other complications that falsely improve a t-score=

- Calcifications
- Arthritis
- Fractures

**Summary = -2 Osteopenia**

How often do you see a hip t-score worse than the spine? Should that occur?

Consider doing a lateral x-ray of the lower lumbar and Thoracic (2 lateral views).

Many Vertebral Fractures are Hidden

Sometimes they do not feel pain until 40% height loss of a vertebrae.

Some radiologists will not report a fracture until moderate or severe.

**Types of fractures:**
- Wedge
- Biconcave
- Crush

Ankle, distal radius and vertebral tend to be the first fragility fractures that occur that are informing us there is a problem with bone quality.

**How to identify HIDDEN VERTEBRAL FRACTURES:**

- Back pain and over 50 do a lateral x-ray of thoracic and lumbar
- When doing chest x-rays in patients over 50 ask for the spine to also be evaluated

![Semiquantitative (SQ) Grading for Vertebral Fractures](image)
The World Health Organization defines a t score of $\leq -2.5$ as osteoporosis, and scores of $-1$ to $-2.5$ as osteopenia. Any patient with a fragility fracture (regardless of t score) is defined as having osteoporosis. Fragility fractures occur in bones with reduced bone quality and mineral density (ie, osteoporosis).
The Risk of Repeat Fracture

Nearly 20% of women who sustain a new vertebral fracture will experience a subsequent vertebral fracture within 12 months, as indicated by analysis of data from 4 osteoporosis treatment trials.

Women with a hip fracture are at a 4-fold greater risk of a second one.

Potential Impact of Hip Fractures Due to Osteoporosis

- Hip fractures due to osteoporosis are often associated with chronic pain and disability, loss of independence, decreased quality of life, and increased mortality

- Approximately 20% of patients with a hip fracture due to osteoporosis will require long-term or nursing home care

- Only 40% fully regain their pre-fracture level of independence a year after the fracture

- Hip fractures are followed by a 2.5-fold increased risk of future fractures

- Hip fractures are associated with a higher mortality in men than in women

5. International Osteoporosis Foundation. The Breaking Spine. 2010
Osteoporosis: The Silent Epidemic & the SENTINEL Event


Approximately **1 in 2** women over the age of 50 will have an osteoporosis-related fracture in their remaining lifetime.¹

In one study, **3 out of 4 postmenopausal women** in the US did not receive treatment during the year following an osteoporosis-related fracture.²

The number of fractures due to osteoporosis is expected to rise to more than **3 million** by 2025.³

Approximately **8.2 million** American women were estimated to have osteoporosis at the femoral neck or lumbar spine in 2010.⁴

Approximately **2.0 million** American men were estimated to have osteoporosis at the femoral neck or lumbar spine in 2010.⁴

As African American women age, their risk for hip fracture doubles approximately every 7 years, and they are more likely to die than white women following a hip fracture⁵

An estimated **10%** of Hispanic women age 50 and older have osteoporosis⁶
Osteoporosis-fracture
Occurrence vs. Other Disease

- Fractures cost: >$19 billion/year
  Increase expected if no action

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Attention Clinicians!

Much of the burden of bone disease can potentially be avoided if at risk individuals are identified. One of the most important flags.....a previous fracture!

ON EVERY OFFICE VISIT FOR PATIENTS OVER 50 OR ON STEROIDS, ASK IF THEY HAVE FRACTURED SINCE THEIR LAST VISIT OR IN THE LAST 12 MONTHS:

Surgeon General’s Report, 2004
Fracture Liaison Services
Establishing a Secondary Fracture Prevention Program

- Dedicated Fragility Fracture clinician
- All low energy hip and pelvis fractures
- Age 50+
- Males and Females
- Hospitalized or outpatient
- Establishment of Multidisciplinary team members (Ortho, Family Practice, Endocrine, Geriatrics, PT/OT/SAFR, Interventional radiology, Tobacco Consultation)
Identifying Patients at Risk

- Advancing age
- Previous fracture
- Parental history of hip fracture after the age of 50
- Low body weight /small frame
- Low calcium intake or hypercalciuria
- Vitamin D deficiency
- Excessive alcohol (3+ drinks daily)
- Sedentary life style
- Current smoking
- Oral glucocorticoid > 5 mg/d of prednisone for > 3 mo (ever) OR Steroid infusions (MS patients)
- Other meds: antiepileptic's, excess thyroxin, Aromatase inhibitors, GnRH agonists. Oral anticoagulants, PPI, TZD’s, SSRI (weak evidence)
- Secondary causes: RA, Autoimmune, Endocrine or Renal disease
FLS Models for Managing Fragility Fracture Patients
Fracture Patient Flow Through an Orthopedic FLS Clinic

Upon discharge from ER, scheduled to be seen in surgeon’s office for follow-up

Management of Fracture
- Surgeon follow-up care of fracture

Management of Osteoporosis
- Orthopedic PA/ANP responsible for the osteoporosis clinic evaluation and management*

Follow-up communication sent to all healthcare providers involved in the patient’s care

Disclaimer
The content on this slide depicts a hypothetical scenario intended for healthcare providers such as orthopaedic surgeons who perform procedures on osteoporotic patients at high risk for fracture. Lilly does not endorse the referral of any patient to or from any healthcare provider.

* Osteoporosis clinic is owned/managed by the orthopaedic practice. Referrals are made to appropriate medical subspecialist upon evaluation of standard labs and patient history.
NMMC Orthopaedic Trauma Fragility Fracture Program: Follow-up Plan

• 1 month
• 3 months
• 6 months
• 12 months
• Ordering labs at initial visits and follow-up visits if appropriate
• Establishing PT/OT evaluation and tx program
• Education
## Therapeutic Options

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<th>Antiresorptives (Maintenance)</th>
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<th>Anabolic (Formation – Volume added)</th>
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<tr>
<td>Fosamax</td>
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<td>Forteo (PTH)</td>
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<tr>
<td>Boniva</td>
<td></td>
<td>Not approved yet – Abaloparatide (PTH)</td>
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<td>Actonel</td>
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<td>Not approved yet - Sclerostin</td>
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<td>Reclast</td>
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<td>Prolia (Rank ligand)</td>
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<td>Evista (Serm)</td>
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<td>Miacalcin (Calcitonin-Salmon)</td>
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Bisphosphonates
Bone Turnover – Why should we be considering this more?

What is the fragility fracture telling us about the patients overall bone quality and structural integrity? Once a patient has fractured, the Mechanism of Action should be part of your decision on treatment plan.

Bone markers – used heavily in clinical trials and endocrinologist to evaluate if the patient is turning bone over, and used to evaluate how the medications are working/compliance/efficacy.

**Most Commonly used Bone Markers:**

**Osteoblastic activity – bone formation activity bone markers =**
- Serum type 1 Procollagen - P1NP
- Serum Osteocalcin
- Serum specific bone- alkaline phosphatase (BALP)

**Osteoclastic activity – bone resorption activity bone markers =**
- Urine N-telopeptide of type 1 collagen (NTX)
- Serum or Urine C-terminal telopeptide of type 1 collagen (CTX)
Bone Turnover Makes A Difference In Fracture Patients

**Forteo Versus Fosamax**

- P1NP = Bone formation/Osteoblastic Activity
- NTX/CTX = Bone resorption/Osteoclastic Activity

200% gain in formation
40% gain in resorption

Vs.

70-90% suppression of both formation & resorption

**Prolia Versus Fosamax**

**Resorption - CTX**

**Formation – P1NP**

"FIG. 4. Median (Q1, Q3) percent change from baseline in the bone turnover markers (A) sCTX1 and (B) P1NP through month 12 (*significantly different from alendronate, p ≤ 0.0001)."
## Pros & Cons of Different Options

### Antiresorptives (Maintenance)

**Pros:**
- Generic - Cost
- Simplistic dosing (yearly/2x year/monthly)
- Primary Fracture reduction
- Can be used in Padgets & Bone Met patients

**Cons:**
- Suppression complications (ONJ/Subtroch fractures)
- Delayed fracture healing
- GERD/Bone pain
- Long half life - Long term bone quality concerns (5 years & Holiday)
- Simplicity of dosing may have it being overused in high risk patients.
- Rebound effect of bone markers w/ discontinuation of Prolia
- If patient fracture while on it, delays anabolic effect (ACE recommends anabolic first in more severe patient)

### Anabolic (Formation – Volume)

**Pros:**
- Adds back bone volume in high risk patients – Rapid
- Secondary fracture reduction
- Short half life – 16 hours if discontinuation needed
- Broadly studied in Fragility fracture – poor bone quality issues
- RDNA of PTH – well tolerated
- Steroid induced indication – superior to fosamax in head to head study

**Cons:**
- Does not become cost effective until patient has a fracture
- Injection – train in house to get over fear
- Contraindicated in Padgets disease patients and any one with open growth plates.
- Can be difficult for insurance approval. In fracture patient, may need a reason they either failed or can not take generic.
Bisphosphonate/Prolia Associated Fracture

• May occur with long term bisphosphonate/Prolia use

• Relatively rare occurrence compared to fragility fractures

• Risk/benefit analysis still favors bisphosphonate/Prolia use for up to 5 years, then a drug holiday

• Consequence of long term SUPPRESSION of bone turnover

NMMC Orthopaedic Trauma Fragility Fracture Program: Goals

• Identify and evaluate patients 50yo and greater with fragility fracture
• Treatment of fragility fractures
• Follow treatment for one year
• Primary care physician continue osteoporosis treatment
• Prevention of future fragility fractures
• Reduction of morbidity, mortality, and improvement of quality of life
Thank you

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