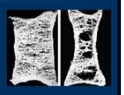
Transforming The Skeleton Osteoporosis: What has changed in 2020?



AAPA 2020 Annual Conference

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Founder and Past President Society of PAs in Rheumatology
"Rheum To Know"
Professor, Author, Speaker
Workshop Leader

1

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Disclosures

Nothing to disclose

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Learning Objectives

1. Apply accepted criteria to make the diagnosis of osteoporosis.
2. Use directed history, physical, labs and other validated tools that are helpful in assessing individual patient risk for fracture.
3. Develop strategies to manage your patient's skeletal health and decrease their risk of fracture.
4. Compare and critique different mechanisms of action for FDA approved OP medications.

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Expanded diagnostic Criteria for PMP women and men aged 50 and older

Initiate therapy with low trauma fracture in postmenopausal women and men over age 50 with

1. Low-trauma fracture of the hip regardless of BMD DXA score
2. T-score of ≤2.5 or lower by DXA
   a. lumbar spine
   b. femoral neck
   c. total hip
   d. 33% distal radius

1. Siris ES, Adler R, Bilzekian J, et al. The clinical diagnosis of Osteoporosis: A position statement from the NBHA Working Group. *Osteoporosis Int.* 2014;25(5):1439-43
2. Schousboe JT, Shepherd JA, Bilzekian JT, et al. Executive summary of the 2013 ISCD Position Development Conference on Bone Densitometry.*J Clin Densitom.* 2013Oct-Dec;16(4):455-66

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Expanded diagnostic criteria for PMP women and men aged 50 and older

Initiate therapy with low trauma fracture in postmenopausal women and men over age 50 with

3. Low bone mass/osteopenia with a fragility fracture of vertebrae, proximal humerus, pelvis, or wrist.
4. Low bone mass/osteopenia with T-score between -1.0 and -2.5 at the femoral neck or total hip and a 10 yr probability of major OP fracture related fracture of ≥20%
   Or a hip fracture probability ≥3%

1. Siris ES, Adler R, Bilzekian J, et al. The clinical diagnosis of Osteoporosis: A position statement from the NBHA Working Group. *Osteoporosis Int.* 2014;25(5):1439-43
2. Schousboe JT, Shepherd JA, Bilzekian JT, et al. Executive summary of the 2013 ISCD Position Development Conference on Bone Densitometry.*J Clin Densitom.* 2013Oct-Dec;16(4):455-66

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Risk of Subsequent Fracture after prior fracture in older women

- In 65-year-old females who sustained a fracture what is the risk of future fracture?
  - Year 1 post fracture is 10%
  - Year 2 post fracture is 18%
  - Year 5 post fracture is 31%[1]
- Conclusion: early risk of subsequent fracture following a broad array of initial fractures.
- Timely management with consideration of pharmacotherapy is warranted in older women following all fracture types evaluated.[1]

Balasubramanian A, Zhang J, Chen L, et al, Risk of subsequent. Fracture after prior fracture among older women. *Osteopor Int.* (2019)30:79-92

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Clinical Evaluation History

- Evaluate risk factors by history
  - Personal history
  - Family history
  - Surgical history
  - Dietary history e.g. supplements Ca+ Vit D?
- Fall History
- Review medications that increase fracture risk e.g.
  - Steroids, how often in the last year
  - Anticonvulsants
  - Cancer chemotherapy agents
  - Aromatase inhibitors
  - GnRH agonists
- Prior History of treatments for osteoporosis for how long and when.

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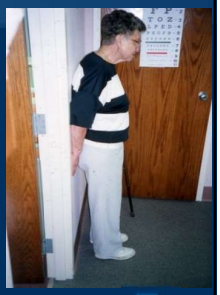
Clinical Evaluation



- Evaluate risk of falling and test gait
  - Tests to determine gait stability, e,g.TUG test
  - Balance and muscle strength (heel to toe, tandem gait, one legged standing. DTR's in LE, muscle tone, etc.)
- **Measure for height loss** wall mounted stadiometer

- Look for kyphosis

See STEADI algorithm at https://www.cdc.gov/steadi/

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Primary risk factors for osteoporosis and fracture

1. Age
2. Sex ♀>♂

Women > Men

3. Prior fracture over the age of 50

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Other Risk Factors for Fracture

- Family history of osteoporosis
- Low body weight under 127 lbs.
- Early menopause including surgical
- Height loss or kyphosis 1.5” women, 2.5” men ~
- Risk for falling
- Pt’s reliability, ability to understand and adhere to meds

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Lab Tests for workup of Osteoporosis Suggested and adaptable

1. CBC
2. Comprehensive chemistry panel
   - Serum calcium (hypocalcemia, hypercalcemia)
   - Alkaline phosphatase (e.g. Paget's disease of bone)
   - Renal functions- bisphosphonates renally cleared
   - Liver functions tests
   - 25 (OH) Vit D
   - Parathyroid hormone (PTH)
   - Total testosterone and gonadotropin in men age 50-69
- 24-hour urinary calcium and creatinine

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Caveats on lab tests in OP

1. iPTH and serum Ca+ - caveat--PTH  results from Vit. D deficiency – normalize and re-check

2. 24 hr. urine Ca+- 10-25% of treated PMP OP population as 2° cause (idiopathic hypercalciuria[1])

1. Giannini, S. et al; Hypercalciuria is a common and important finding In postmenopausal women with osteoporosis. *Eur J Endocrinol 149 209-213, Sept 1, 2003*

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Dual Energy X-ray Absorptiometry DXA

AP SPINE BONE DENSITY

Facility:
70 years 01/29/1930
61 in 140 lbs White Female

Acquired: 01/24/2001 (4.7a)
Analyzed: 01/24/2001 (4.7a)
Printed: 01/24/2001 (4.7a)
schilm03.s23

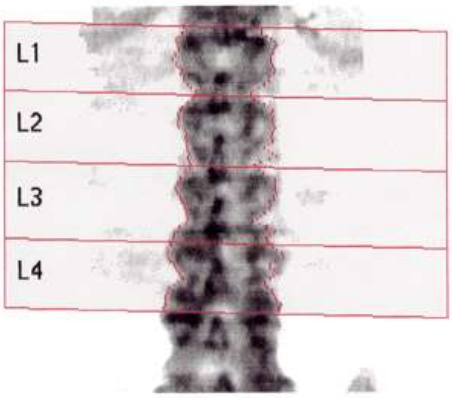

Image not for diagnosis
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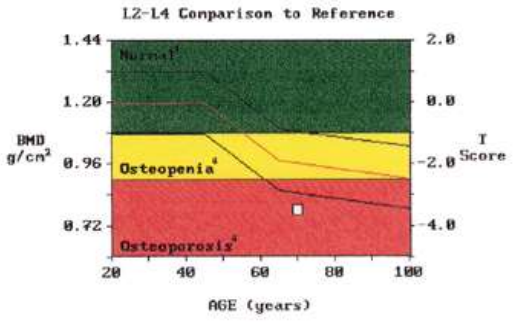
723764:435210 272.36:203.66:144.32
%Fat = 22.2(1.348)



Region	BMD g/cm²	Young-Adult %	Young-Adult T	Age-Matched %	Age-Matched Z
L2-L4	0.783	65	-3.5	81	-1.5

T-score establishes diagnosis

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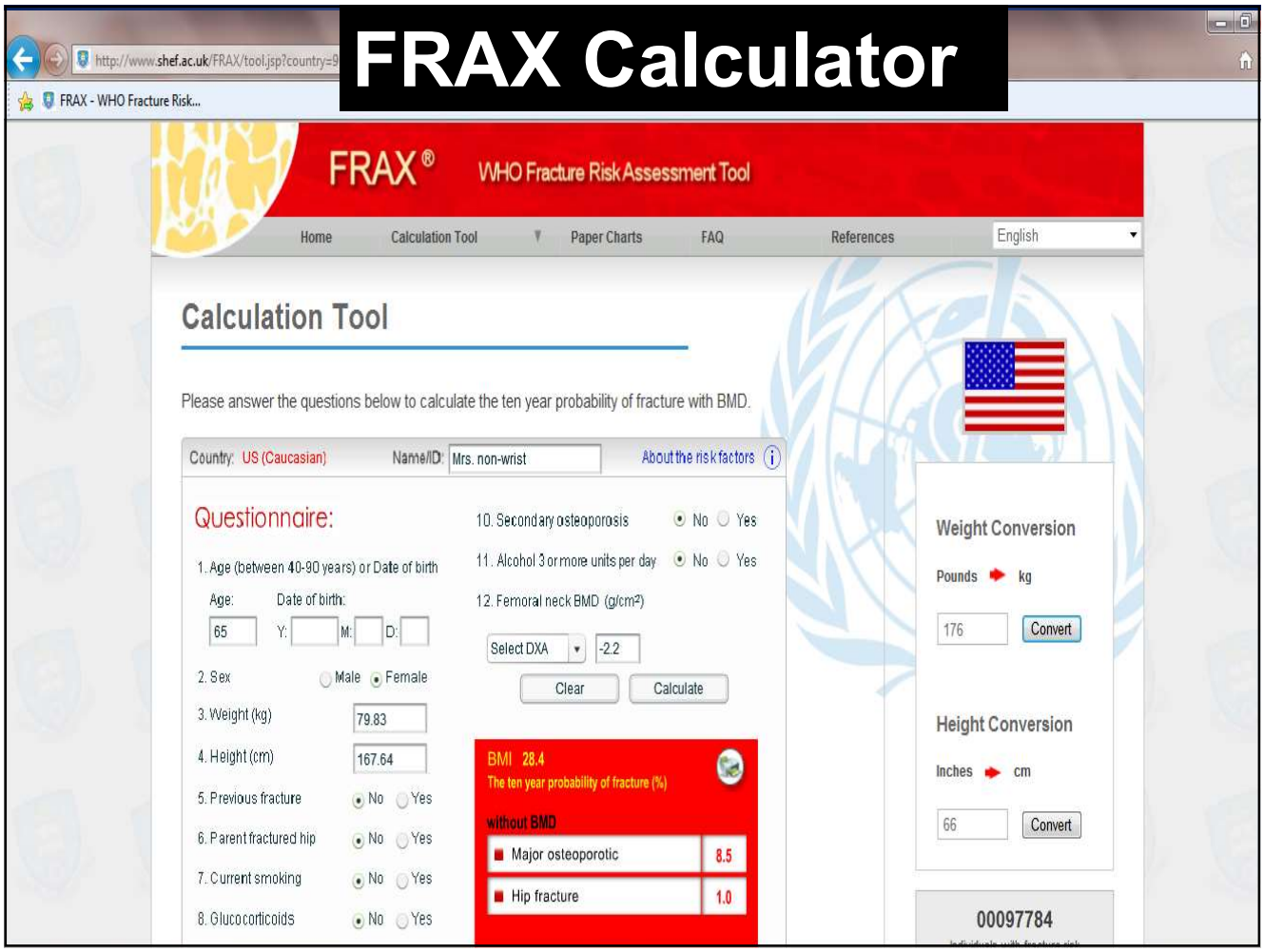
FRAX Calculator



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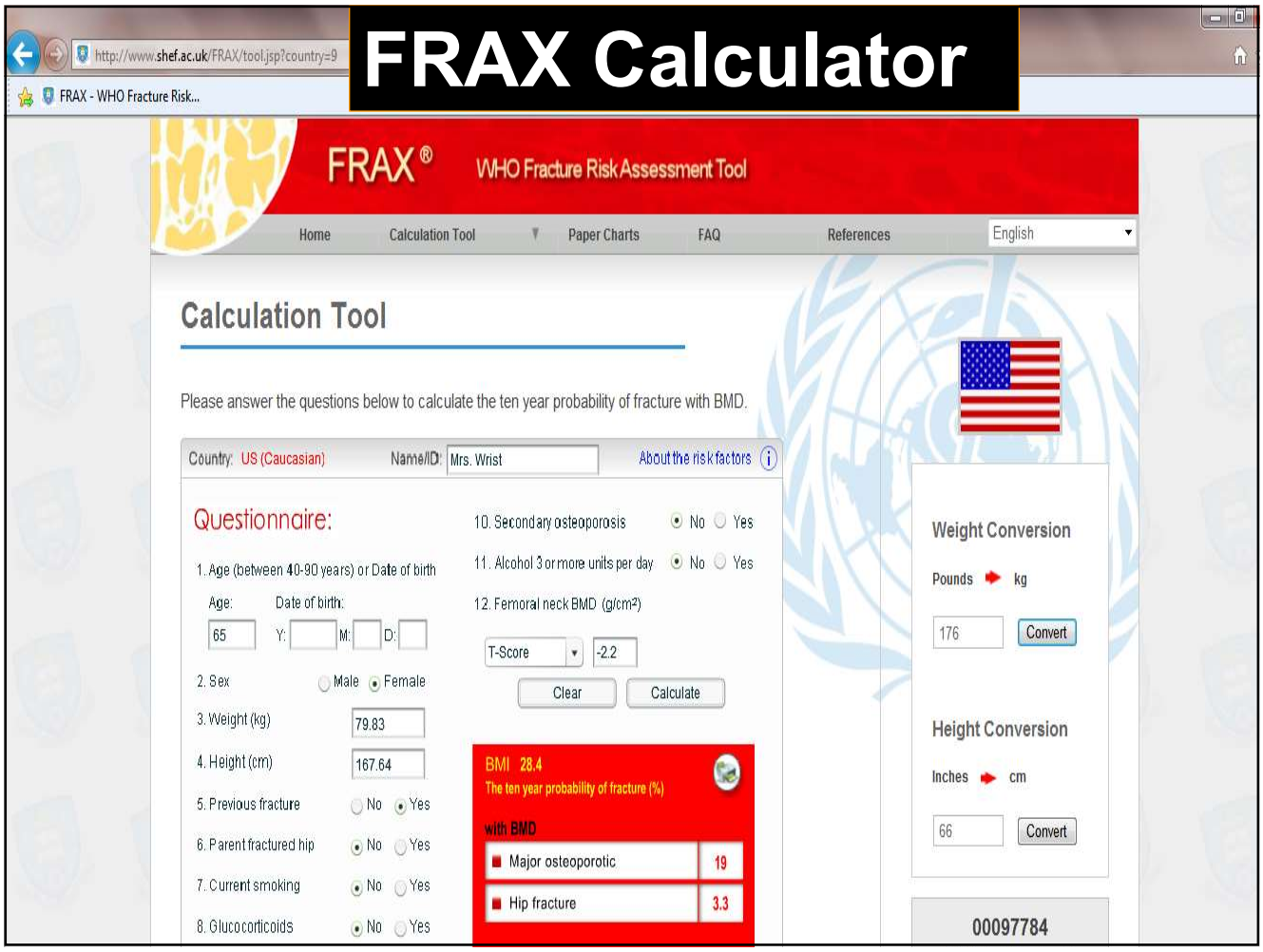
FRAX Calculator



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Validated Tools that are helpful VFA, TBS, BTMs

- Vertebral Fracture Assay. Looks for spinal compressions
- Can be ordered at the time of DXA
- Indicated for height loss in women (1.5”)
- Indicated for height loss in men (2.5”)
- Insurance reimbursable
- Alternative is lateral spine x-ray (Thoracic and/or LS-spine)

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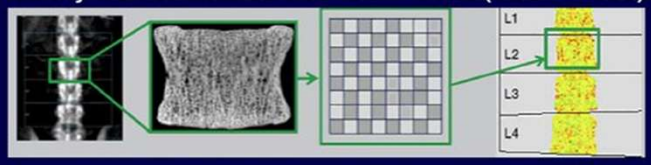
Trabecular Bone Score TBS

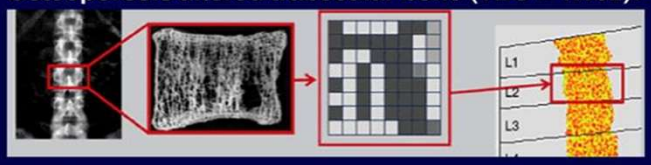
Trabecular Bone Score as Noninvasive Measure of Bone Microstructure

- TBS is an indirect measure of bone microstructure: higher score = better microstructure
- Derived from standard LS DXA images
  - Bone texture inhomogeneity determined by pixel variations (ie, trabecular textural index)
  - Software installed on existing DXA scanner, so no extra scan time or radiation exposure
  - Archived LS DXA images can be assessed retrospectively
- FRAX can adjust for TBS

Healthy well-structured trabecular bone (TBS = 1.360):



Osteoporosis altered trabecular bone (TBS = 1.102):



TBS Value	Bone Microstructure Status
≥ 1.35	Normal
> 1.20 to < 1.35	Intermediate
≤ 1.20	Degraded

Sharma A, et al. International Comorbidities WS 2016. Abstract O04. New tools to predict fracture risk. http://www.mayoclinic.org. Reproduced with permission.

Slide credit: clinicaloptions.com

Used with permission of Mayo Foundation for Medical Education and Research. All rights reserved.
https://www.mayoclinic.org/medical-professionals/clinical-updates/endocrinology/new-tools-to-predict-fracture-risk

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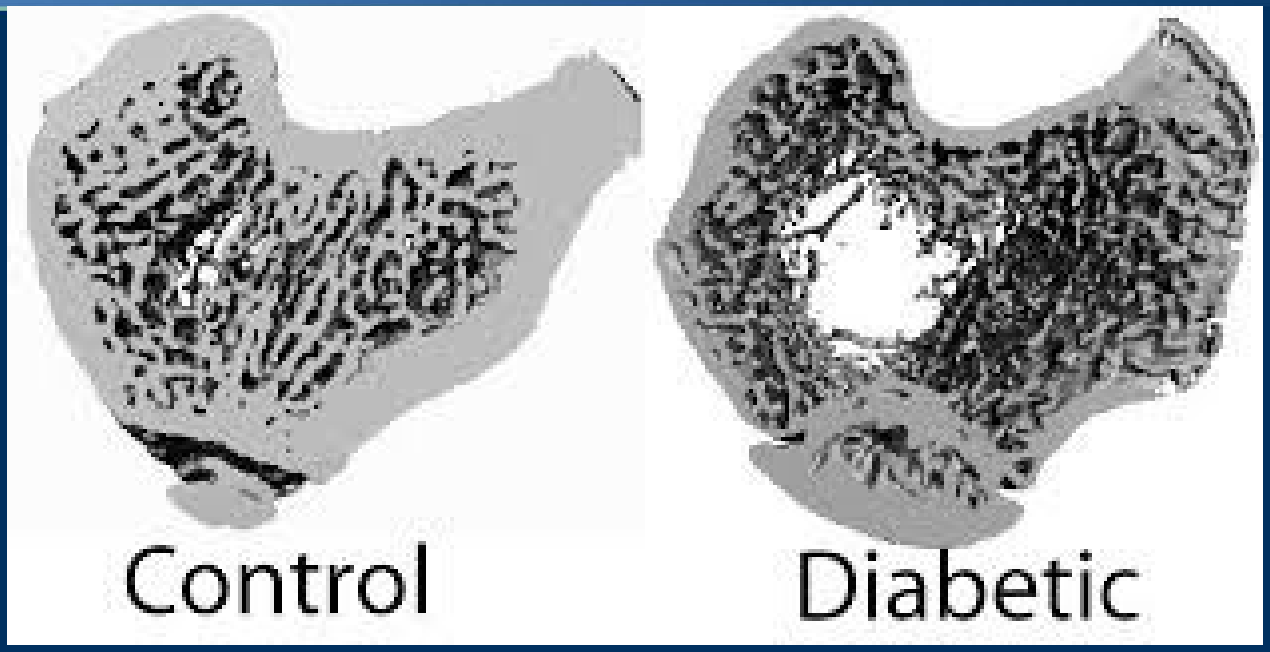
TBS
Identical T-scores
Independent Risk from BMD



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Can We Measure Bone Quality? Bone Turnover Markers BTMs

- **sCTX for antiresorptives** (LSC 40% reduction in CTX)
- **PINP for anabolic Rx**

(In my lab ordered as beta cross-links)

1. May predict rapidity of bone loss in untreated PMP women
2. Predict extent of fracture risk reductions when repeated after 3-6 months of Rx with FDA approved meds
3. Predict magnitude of BMD increases with FDA-approved Rx
4. Characterize compliance and persistence with OP Rx

Potential for use in bisphosphonate holiday to suggest when and if medication should be restarted

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Universal Bone Health Recommendations

Exercises: Weight bearing, balance, resistive exercises, Tai Chi, stair climbing, dancing and tennis exercises in adulthood[1]

In childhood and adolescence consistent weight bearing and high-impact activities contribute to acquisition of peak bone mass[2]

Foot strike is important

1. NOF Clinician's Guide to Prevention and Treatment of Osteoporosis 2019
2. Burrows M. Exercise and bone mineral accrual in children and adolescents. *J Sports Sci Med.* 2007 Sep 1;6(3) 305-12. PMID:24149416;PMCID:PMC3787280.

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Universal Bone Health Recommendations

- Smoking cessation
- Avoid excess alcohol intake >2 drinks/day♀
- ♂ > 3 drinks/day MAY be detrimental to bone[5]
- Calcium intake
- Vitamin D intake[1234]
- Avoidance of sedating medications

1. NIH Consensus Development Panel on Optimal Calcium Intake. www.consensus.nih.gov;
2. NOF Clinician's Guide to Prevention and Treatment of Osteoporosis 2019 www.nof.org;
3. FORE. www.fore.org/patients/eating_right.html. 2
4.AACE OP guidelines 2016 Recommendation 16
5. Mikosch P. Alcohol and bone. *Wiener Medizinisched Wachenschrift*. 2014;164(1-2):15-24

25

Exercise in OP

- It can be ordered as gait and balance training, overall muscle strengthening

In research settings, structured exercise has been demonstrated to modestly improve bone density[1,2]

1. Watson SL et al, Heavy resistance training is safe and improves bone function and structure in postmenopausal women with low to very low bone mass: novel early findings from the LIFTMOR trial. *Osteoporosis Int.* 2015 Dec;26(12):2889-94
2. Greenway KG et al, Impact exercise and bone density in premenopausal Women with below average bone density for age. *Eur J Appl Physiol.* 2015 Nov;115(11):2457-69

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How Much Calcium?

- **Varies for age**
  - 1,200 mg every day after age 50
  - 1,000 mg for younger women + men
- From diet first and/or supplement (most need some)
- Calcium citrate for patients on PPIs

Estimating Sources of Calcium

- Milk-300 mg/glass (4 glasses per day)
- Cheese 1 oz. 200 mg (6 servings per day)
- Almond/soy-milk 450mg/glass (~3 glasses per day)
- Yogurt-300 mg/cup (4 cups per day)
- Broccoli-172 mg/cup (7+ cups per day)
- Tofu, firm-8 oz 250mg (~5 servings per day)

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Vitamin D

Most organizations and societies recommend 25 (OH) Vit D levels in OP patients to be 30ng/ml

Supplement for bone health at least 1,000 ius daily and up to 2,000 ius is often recommended

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More on Vitamin D

- Vitamin D facilitates calcium absorption
- May play a role in preventing falls.
- 50 and older NOF Vit D 800-1000 ius daily
- Higher 25(OH) of >30 ng/mL is associated with optimal calcium absorption and is preferred by NOF, Endocrine Society, AACE, others

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More on Vitamin D

- Serum levels up to 50ng/ml are considered safe
- An upper limit of 40,000 ius once monthly is considered safe
- Research suggests that excessive intake of vitamin D may have adverse impacts on bone through increased risk for falls and fractures.[1],[2]
- Dietary sources of Vitamin D:
  - Fortified milk (400 ius/quart)
  - Breakfast cereals (40-50 ius/serving)
  - Salt-water fish-salmon, mackerel, tuna and liver

1. Bischoff-Ferrari HA et al. Monthly high dose vitamin D Treatment for the prevention of Functional Decline: A Randomized Clinical Trial. *JAMA Intern Med*. 2016 Feb;176(2):175-83.
2. Sander KM et al, Annual high-dose oral vitamin D and falls and fractures In older women: a randomized controlled trial. *JAMA* 2010 Mar 12;303(18):1815-22

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Antiresorptive Agents: Clinical Trial Results

Trials of Different Agents Cannot Be Compared Directly

Agent	Effect on fracture risk		
	Spine	Non-spine	Hip
Estrogen	+	+	+
Raloxifene	+	-	-
Calcitonin	Not recommended	Not recommended	Not recommended
Alendronate	+	+	+
Risedronate	+	+	+
Ibandronate	+	§	-
Denosumab	+	+	+
Zoledronic acid	+	+	+

+ documented in randomized, controlled trial; – effect not documented

§ effect documented only in a post hoc analysis of a high-risk sub-group (femoral neck T score < -3) and in a meta-analysis of clinical trials (Harris ST, et al. *Curr Med Res Opin* 2008;24:237-2

4**American Association of Clinical Endocrinology (AACE) 2010 summary of evidence for fracture risk reduction by drug.**5)

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Estrogen/Hormone Therapies

- **ET brands** e.g. Climara, Estrace, Estraderm, Estratab, Ogen, Premarin, Vivelle

- **HT brands** e.g. Activella, FemHRT, Premphase, Prempro

FDA approved for prevention of osteoporosis, and relief of vasomotor symptoms

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Estrogen/Hormone Therapies

- Drug efficacy-WHI 5 yrs of HT (Prempro)
  - Decreased incidence of clinical vertebral and hip fractures by 34% and other OP fxs by 23%[1]
- Side effects/safety:
  - Increased risk of MI and stroke, invasive breast cancer, pulmonary emboli, and DVT
- NAMS AACE ACE recommend tailoring ET/HT to individual risk benefit ratios.
- Endocrine Society suggests:

  Age <60 and <10 years past menopause who cannot take bisphosphonates and have vasomotor symptoms

Roussouw JE et al, Writing group for the WHI Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: Principle results from the WHI randomized controlled trial. *JAMA*. 2002;288(3):321-33

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How Antiresorptives Increase Bone Strength

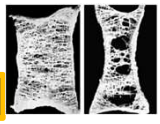
Bisphosphonates/denosumab

Reduce bone turnover

Reduce stress risers

Fill resorption cavities

Preserve microarchitecture



Increase mineralization

Increase collagen cross linking

Increase bone density

Increase bone strength

Reduce fracture risk

Adapted from McClung et al. Endocrinol Metab Clin N Am. 2003

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Bisphosphonate efficacy in PM OP

- Vertebral fracture reduction 40-77%
- Hip fracture reduction 40-60%
- Non-vertebral fracture 30-40%

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Following BMD Estimated improvement in fracture reduction despite small changes in BMD

	Vertebral Fracture	Hip Fracture
Δ Total hip BMD		
2%	28%	16%
4%	51%	29%
6%	66%	40%
Δ Femoral neck BMD		
2%	28%	15%
4%	55%	32%
6%	72%	46%
Δ Lumbar spine BMD		
	28%	22%
	62%	38%
	79%	51%

Reprinted with permission from the NOF.1.Lenchik L, Rogers LF, Delmas PD, et al. Diagnosis of osteoporotic vertebral fractures; Importance of recognition and description by radiologists. *Am J Roetgenology*. 2004;183(4):949-58

[#]Note: Larger improvements in DXA-based BMD are associated with greater reductions in fracture risk, particularly for vertebral and hip fractures. (Note changes in nonvertebral fractures are not significant.)[67]

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Issues Regarding Bisphosphonates

- Osteonecrosis of the jaw- (ONJ) a rare issue
- Atypical Femoral Fractures- (AFF) a valid but rare consideration
- How long to treat- Drug Holiday

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ONJ Risks

A. All bisphosphonates, denosumab
B. 90% cancer patients high dose BPs
C. Osteoporosis 1/10,000 to 1/100,00
D. Risks:
    - Highest zoledronic acid
    - Dental extractions or surgery
    - Periodontal disease
    - Long duration of Rx

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Atypical Femoral Fractures
AFF

- <1% are atypical and look different than "typical" femoral shaft fractures
- They will often occur in older women with low velocity trauma

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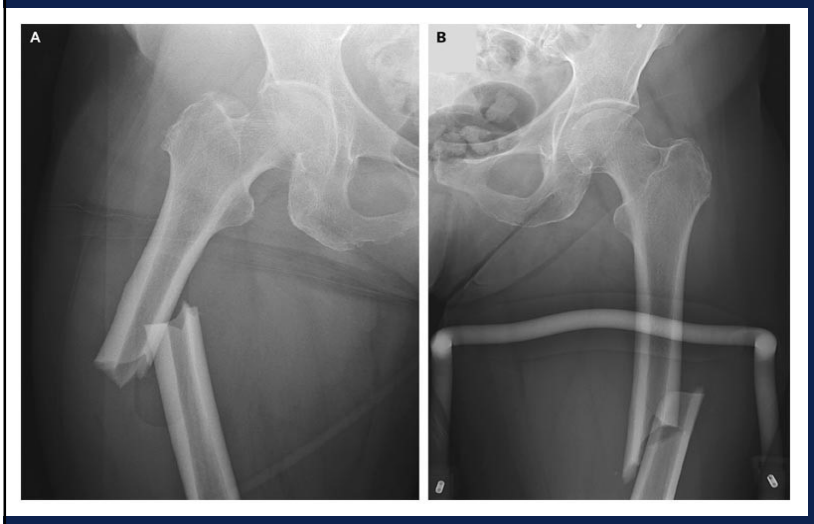
AFF
Radiographs of Fractures of the Femoral Shaft Showing the "Simple with Thick Cortices" Pattern



Major:
Transverse

1. **No trauma**
2. **Non-comminuted**
3. **Both cortices**
4. **Medial spike**
5. **Periosteal reaction lateral cortex**

Shane, E. JBMR 2014; 29-1:

Lenart B et al. N Engl J Med 2008;358:1304-1306

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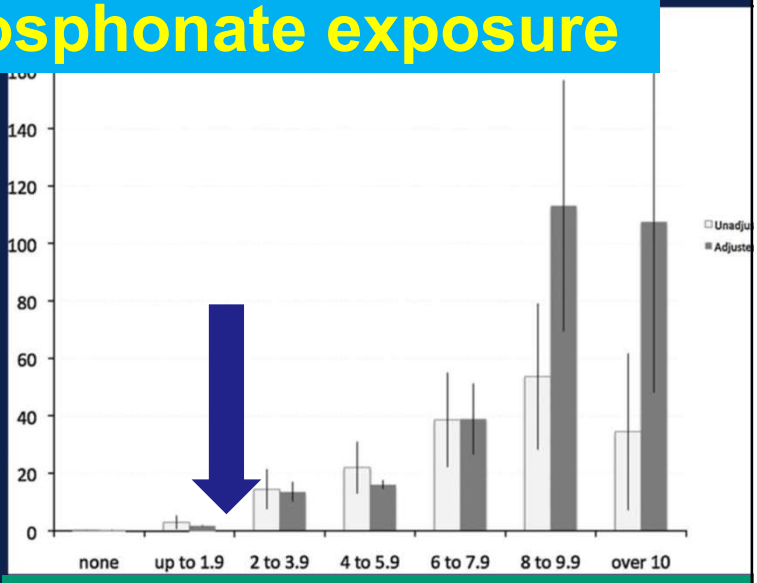
Age-adjusted AFF Incidence by Duration of BP Exposure (Kaiser Permanente)
(Incidence per 100,000 persons/year of BP treatment)

Atypical Fractures increase with longer bisphosphonate exposure

Cohort study of **~1.8 million** > 45 with ~12,000 femur fractures between 2007 & 2011
• With radiograph review
From **0.1 to 1.9** yrs BP exposure
• **1.78/100,000** persons/year (95% CI, 1.5–2.0)
Increasing to from **8 to 9.9** yrs BP exposure
• **113/100,000** persons/year (95% CI, 69.3–156.8)



Dell et al., J Bone Miner Res, 2012

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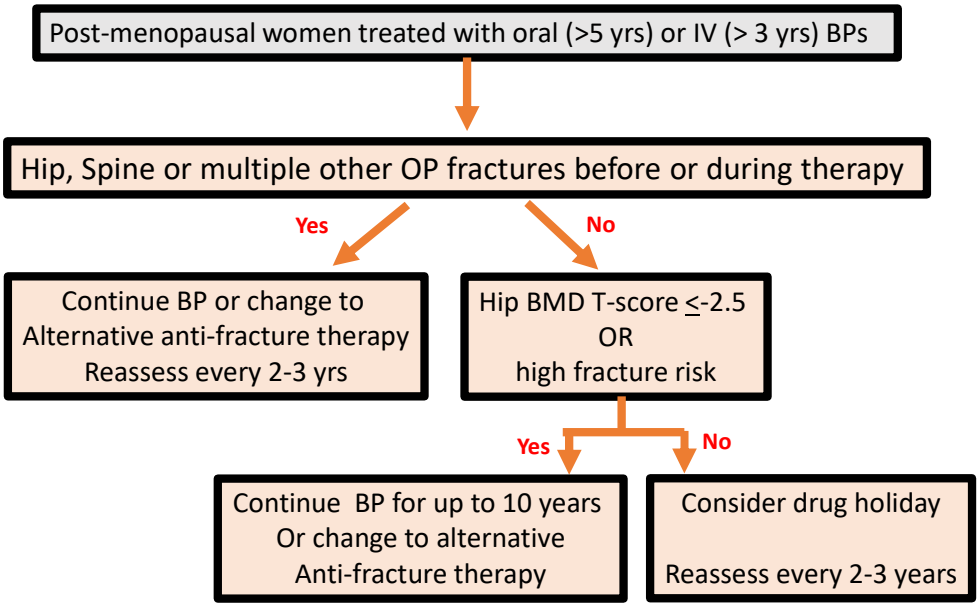
Drug Holiday?



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Denosumab (Prolia)
RankL inhibitor

Monoclonal antibody to rankL that decreases osteoclast maturation, function and number

1. Vertebral fracture reduced 60%
2. Hip fracture reduced 40%
3. Non-vertebral fracture 20%

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Indications

- Postmenopausal osteoporosis
- Prevention of bone loss with aromatase inhibitor therapy in breast cancer
- Prevention of bone loss androgen deprivation therapy in prostate cancer
- Men high fracture risk

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Denosumab vs. Bisphosphonates

- Spine and hip BMD continue to increase for up to 10 years
- Not incorporated in bone matrix
- Effect wears off rapidly approximately 6 months
- No creatinine clearance limitations, no renal elimination and therefore less renal concerns
- Must continue Rx **(No Drug Holiday)**

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Denosumab Discontinuation

- Denosumab discontinuation associated with rapid increase in bone turnover and potential **increase risk** of **multiple vertebral fractures**.
- Patients at high risk should either continue denosumab for up to 10 years or be switched to an alternative treatment.
- Patients and practitioners should be aware that denosumab should not be stopped without considering an alternative treatment[1]

1. *Bone.* Accepted manuscript Aug 4, 2017. Discontinuation of denosumab therapy for osteoporosis: A systematic review and position statement by ECTS

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Anabolic Therapies

Teriparatide and Abaloparatide

Romosozumab

Indications for women (men)

at high risk for fracture

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How do Anabolic Agents Work

- Anabolic agents improve cancellous and cortical bone microarchitecture
- PTH-1 agonists (teriparatide and abaloparatide) stimulate formation more than resorption.
- Sclerostin antibodies (romosozumab) stimulate bone formation and simultaneously inhibit bone resorption.

- Recent head to head fracture trials (teriparatide vs. residronate, Romosozumab vs. alendronate) indicate that anabolic drugs offer superior fracture protection over antiresorptive drugs.

The fundamentally different mechanisms of action and recent fracture trials support the sequential use of anabolic and antiresorptive drugs.

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Teriparatide (Forteo™)

- 1-34 Amino Acid Chain of Parathyroid Hormone
- Once Daily Injectable for 18 To 24 Months

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Teriparatide Indications

- Postmenopausal ***women*** and ***men*** with osteoporosis who are at **high risk** for fracture.
- To increase bone mass in ***men*** with primary or hypogonadal osteoporosis who are at high risk for fracture.
- ***Men*** and ***women*** with osteoporosis Rxed with glucocorticoid therapy who are at high risk for fracture
- Individuals include those who meet one of the following criteria:
  - Have a history of osteoporotic fracture
  - Have multiple risk factors for fracture
  - Failed previous osteoporosis therapy
  - Are intolerant to previous osteoporosis therapy

FORTEO (teriparatide (rDNA origin) injection Prescribing information Eli Lilly and Company, 2010

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Teriparatide

- Vertebral Fracture 65% Reduction
- Non-vertebral Fracture 53% Reduction
- Hip Fracture Not Enough Events To Calculate
- Used for High risk pts

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Definitions of Very High Risk for OP

- Multiple spine fractures/hip fracture ***and***
- T-score of ≤-2.5 at spine or hip

Endocrine Society Guidelines 2019

1. Teriparatide or abaloparatide for up to 2 years, then
2. Followed by anti-resorptive therapies to maintain BMD gains

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Safety Concerns

- Hypercalcemia
- Paget's Disease
- Unexplained increase in alk phos
- Previous skeletal radiation
- Other metabolic bone diseases
- ? Higher risk of urolithiasis
- Osteogenic sarcoma
- Bone cancer or metastatic disease to bone

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Abaloparatide Tymlos™

- Anabolic PTHrp 1-34
- Indication: Postmenopausal ***women*** with osteoporosis who are at high risk for fracture.

- Slight molecular difference to teriparatide
- Women only who are at high risk for fracture
- Duration of treatment 18 months and can be given up to 2 years
- Black box warning-Osteosarcoma
- SQ 80 mcg/daily
- Vertebral fracture RR reduction at 18 months was
  - Vertebral 86%
  - Non-vert fractures 43%
- Hip data (not powered for hip due to low numbers)

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Safety Concerns

- Hypercalcemia, hypercalciuria, ? risk of urolithiasis
- Dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo.
- Previous skeletal radiation
- Other metabolic bone diseases e.g. Paget's Dx
- Osteogenic sarcoma
- Bone cancer or metastatic disease to bone

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April 2019
Romosozumab Evenity™

- MAB against sclerostin
- For moderate to severe OP in women
- MOA-works as antibody against sclerostin
  - This stimulates both bone formation simultaneously inhibiting resorptive mechanisms
- WNT signaling pathway has both osteoclastic and osteoblastic effects.
- Sclerostin antibodies (romosozumab) stimulate bone formation and simultaneously inhibit bone resorption.

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12 Months of Romosozumab vs. Placebo

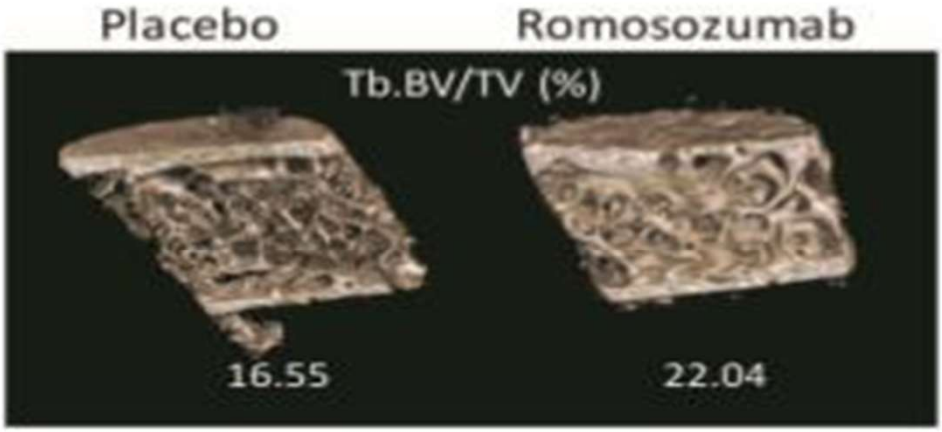

Fig. 3. Effects of romosozumab at month 12 on bone mass and microarchitecture assessed by μCT. Tb.BV/TV = trabecular bone volume per tissue volume

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April 2019 Romosozumab Evenity™

Indications

- Postmenopausal OP at high risk for Fracture.
- History of osteoporotic fracture.
- Multiple risk factors for fracture.
- Pts who have failed or intolerant to other osteoporosis therapy.

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi.ashx

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Romosozumab Evenity™

- Boxed warning of CVS risks-caution with prior CVD history.
- Rx by injection monthly for 12 months.
- Two injections 210 mg given monthly Xs 12.

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi.ashx

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Boxed Warning Evenity™

WARNING: POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE AND CARDIOVASCULAR DEATH

- EVENITY may increase the risk of myocardial infarction, stroke and cardiovascular death.
- EVENITY should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors.
- If a patient experiences a myocardial infarction or stroke during therapy, EVENITY should be discontinued.

https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/evenity/evenity_pi.ashx

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Treatment Summary

- BMD, FRAX®, VFA, TBS, BTMs, are all validated tools
- **Age**, sex, and previous fractures are strong, independent predictors of fracture risk
- Treatments significantly decrease fracture risk:
  - "Antiresorptive" therapy produces a modest BMD increase
  - an unmeasured improvement in bone "quality"
  - Anabolic therapies increase BMD more than antiresorptive treatment, but it is not yet obvious that fracture protection is greater
  - Romosozumab for high risk OP and is both simultaneously anti-resorptive and anabolic

Patient factors determine the most appropriate drug to use

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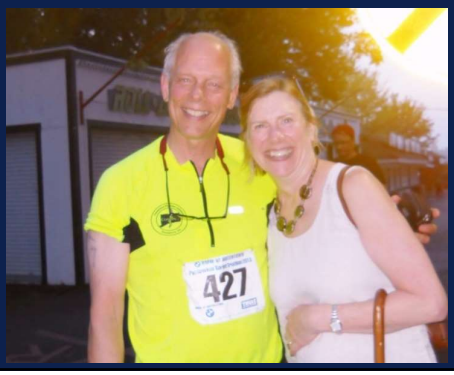
Summary

Think about osteoporosis in all your patients
Measure height with a wall mounted stadiometer
Look for kyphosis, evaluate fall risk
Order DXA scans for ≥65 ♀ and ≥70 ♂
Use FRAX for osteopenic BMD pts and use algorithms
Remember to ask for VFA and TBS when ordering BMD
Use FDA approved meds-consider drug holidays as/pt.
Healthy life-style exercise, Ca+ Vit D keep it going
Refer for severe OP



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Valuable Resources

- Clinician's Guide to Prevention and Treatment of Osteoporosis-Position paper of the National Osteoporosis Foundation-2014/2019
- Controversies in Osteoporosis Care 2: How long to Treat? How should We Monitor Patients? Miller P, Silverman S, NOF Clinical Updates 2015 available at nof.org
- AACE/ACE Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis-2016. Endocrine Practice Vol 22 (suppl 4) Sept. 2016
- Endocrine Society – Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, May 2019, 104(5):1595-1622

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Valuable Resources

- Journal of the ADA Executive summary of the recommendations from the ADA Council on Scientific Affairs. *JADA* 142 (11) Nov. 2011 pg 1243-1251
- Discontinuation of Denosumab therapy for osteoporosis: A systematic review and position statement by European Calcified Tissue Society (ECTS). *Bone* Vol 105, Dec. 2017, pgs 11-17
- Sclerostin antibodies in osteoporosis: Latest evidence and therapeutic potential. *Ther Adv Musculoskelet Dis* 2017 Oct; 9(10):263-270

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Valuable Resources

- Evenity® PI available at www.evenityhcp.com/
- Medication Guide Fosamax® (alendronate sodium).www.accessdata.fda.gov.drugsatfda_docs/label/2012/021575s017lbl.pdf
- Horizon-Pivotal Fracture Trial. Black DM, Reid IR, Boonen S, et al. *JBMR* vol 27 No. 2, Feb. 2012 pp 243-254. The effect of 3 vs 6 years of ZA treatment of Osteoporosis. A Randomized Extension to the Horizon-Pivotal Fracture Trial (PFT)
- Prolia® PI available at www.proliahcp.com/
- FIT Trial. The effect of alendronate on Risk of fracture in Women with Low Bone Density but Without Vertebral Fractures. Cummings, SR et al *JAMA* Dec. 23, 1998 vol 280 No 24
- FLEX Trial. *JAMA* 2006 Dec 27;296(24):2927-38. Effects of continuing or stopping alendronate after 5 years of treatment: the Fracture Intervention Trial Long-term Extension (FLEX): a randomized trial
- NICE Clinical Guidelines, No 146. Osteoporosis: Fragility Fracture Risk: Osteoporosis: Assessing the Risk of Fragility Fracture. National Clinical Guideline Centre (UK). London: Royal College of Physicians (UK);2012 Aug.
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Practice Tools and Resources Available at NOF.ORG

- Osteoporosis International – free to NOF members
- NOF.org Clinical Updates on the Bone Source drop down (many valuable resources of which some require membership)
- Education materials for your patients at NOF.ORG
  - How Strong are your bones (May is National Osteoporosis Month)
  - Osteoporosis Medication and Medication Guidelines
  - Boning up on Osteoporosis: A guide to prevention and Treatment. an excellent resource to have available in your office for pt. education however is 92 pages long.
- NOF Clinical Updates available on Bone Source via nof.org https://www.cme.nof.org/Education.aspx

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Thank You

Questions?

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