

Perioperative Bone Health Care



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Disclosures

- Consultant: Amgen, Radius, Solerea Bio
- Speakers Bureau: Radius
- Board Member: Orthopaedic Research Society (ORS), AAOS Board of Specialty Societies

Silver Tsunami in Orthopaedics

- Aging population with osteoporosis and low bone mass
- Aging population with osteoarthritis and spinal stenosis
- Patients desiring independence and high levels of physical function well into their geriatric years
- Improvements in instrumentation make surgical candidates of patients who historically would not have been surgical candidates
 - Wider age range
 - Health issues
 - Lives full of chronic diseases that are being managed
- Wide acceptance of the success of spine and total joint surgery
 - Expectations of success

Silver Tsunami in Orthopaedics

- Many procedures now outpatient or short stay
 - Preop classes and surgery preparation protocols
 - Smoking cessation
 - Nutrition enhancement
 - Diabetes management (A1c levels <7)
 - ERAS (enhanced recover after surgery) protocols
 - Expectations of the patient rapid return to some normal activities
 - Time from decision for surgery to actual procedure can vary
 - A few days if urgent problem
 - 3-4 months for total joints if a busy surgeon
 - Most somewhere around 4-6 weeks

Making bone health assessment a part of perioperative care

- Becoming a highly structured protocol driven environment for preoperative prep
- Some patients first see the surgeon/care team a few years before procedure knowing they are likely headed toward surgery
- Postoperative protocol driven care for
 - Physical therapy
 - Nutrition
 - Wound management
 - Return to activities
- Opportunity for bone health intervention?

Perioperative Bone Health: Lessons from our fracture patients

- Talked for years about post fragility fracture bone health care
 - Some progress over 20 years
 - Making the connection in rapid, short stay environment
 - Dementia and delirium after surgery
 - Patient's acceptance of diagnosis of osteoporosis and medications
 - Lack of access to testing
 - Lack of providers to do assessment and recommendation
 - Getting primary care to think of bone health as a part of standard of care
- Best improvements in systems and countries that went to protocol driven care

Saturday night
transfer...

And, yes, its
infected, too



So what do I do with these patients?

- Surgeons sending patients for bone optimization
 - Preop
 - Postop
 - Postop after trouble
 - Postop after disasters

NO CLEAR EVIDENCE OR PROTOCOL TO FOLLOW

WE TEND TO GET IN OUR OWN WAY AND MAKE THINGS TOO DIFFICULT WITH
BONE HEALTH

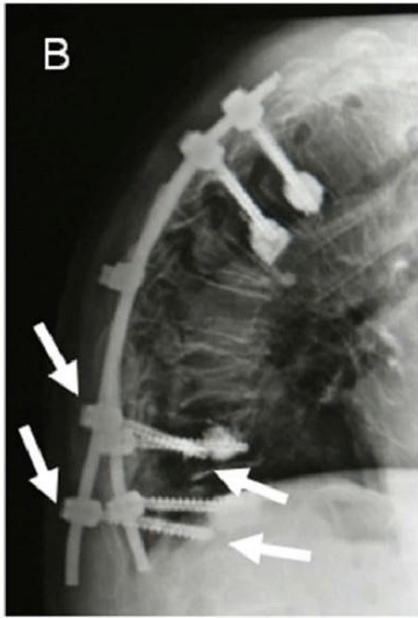
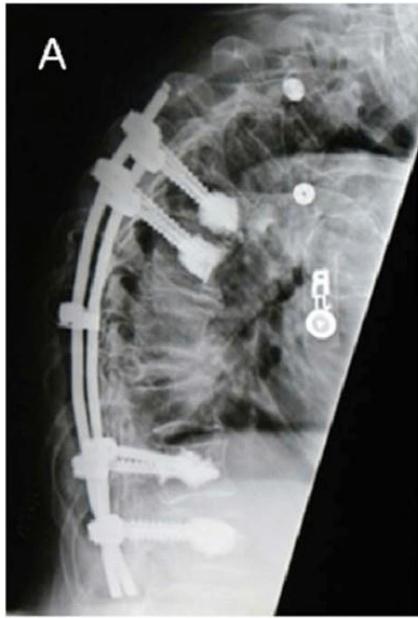
What types of things are on the minds of surgeons?

- Joints

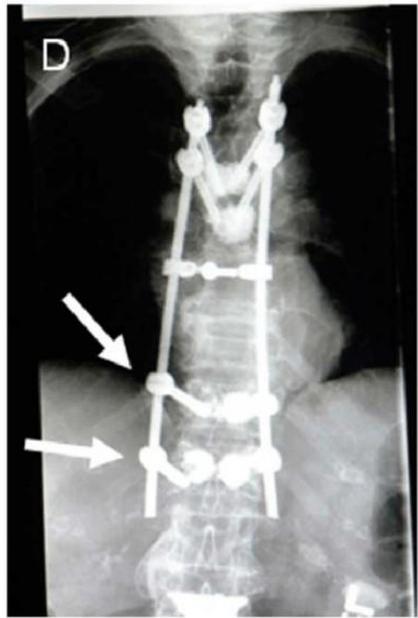
- Intraoperative fracture
- Implant subsidence
- Periprosthetic fracture

- Spine

- Adjacent segment fracture
- Screw pull out
- Cage subsidence

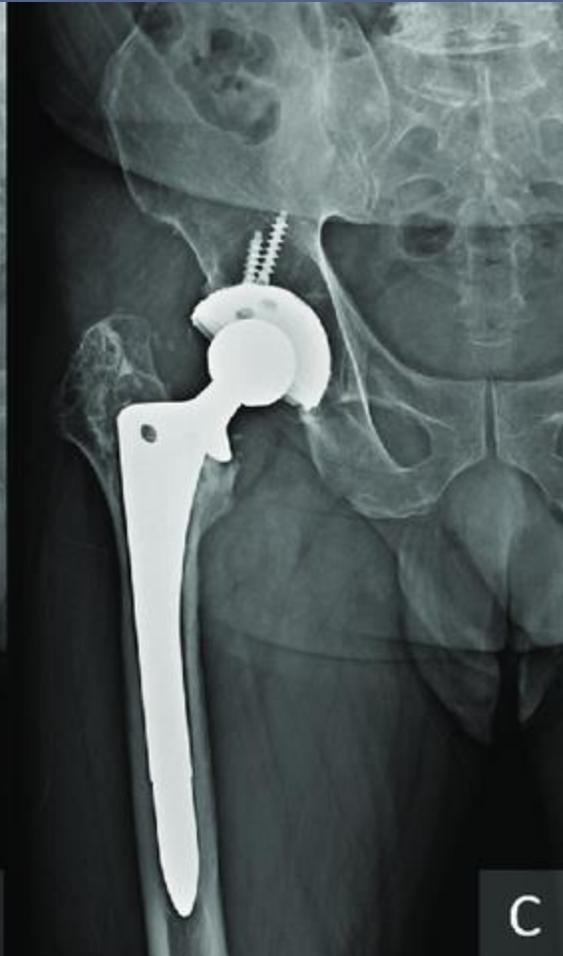


Pedicle screw pull out



Cage Subsidence



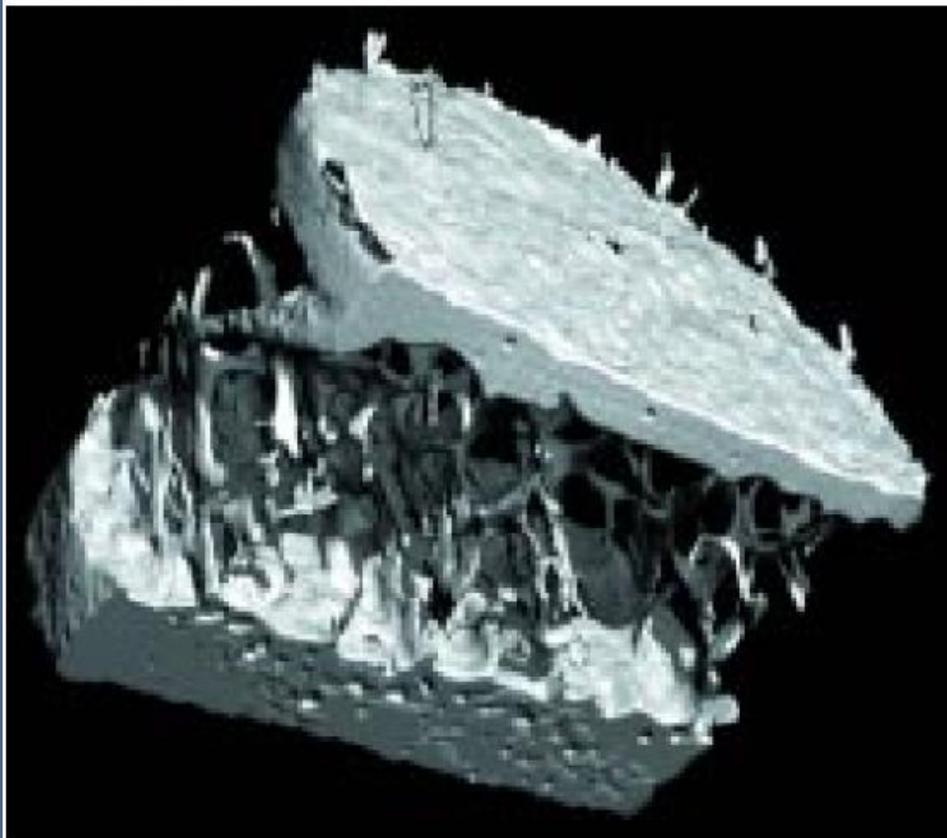


Rising tide of periprosthetic fracture

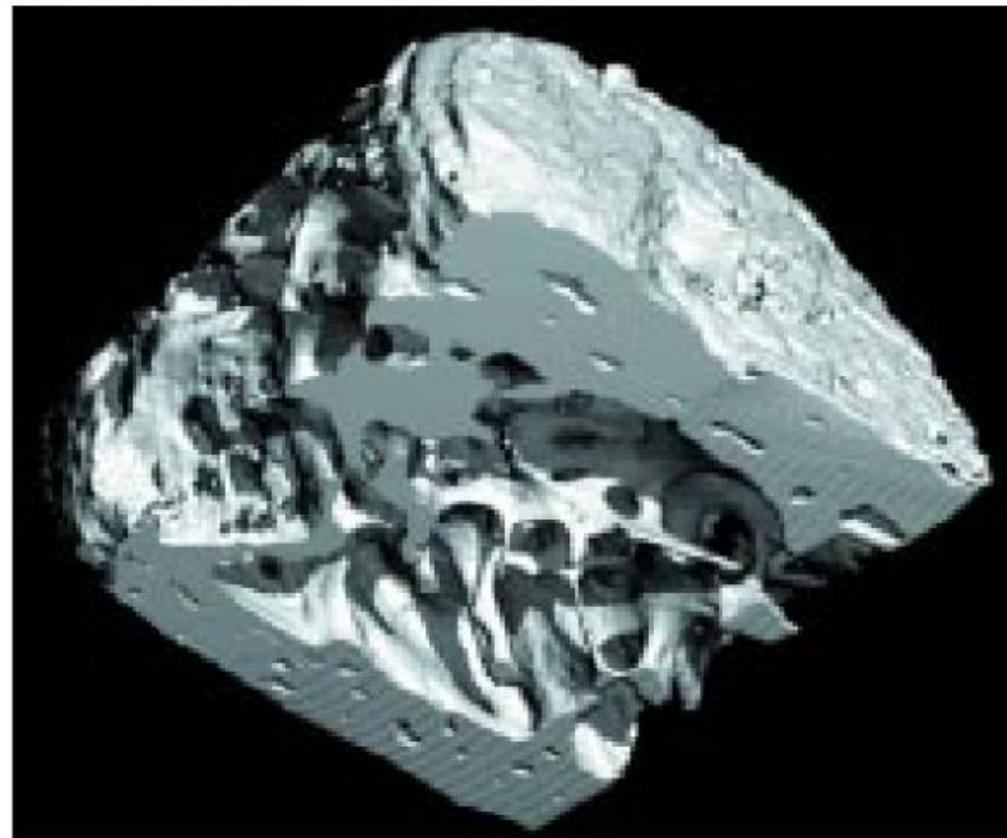


What are we trying to accomplish?

Baseline

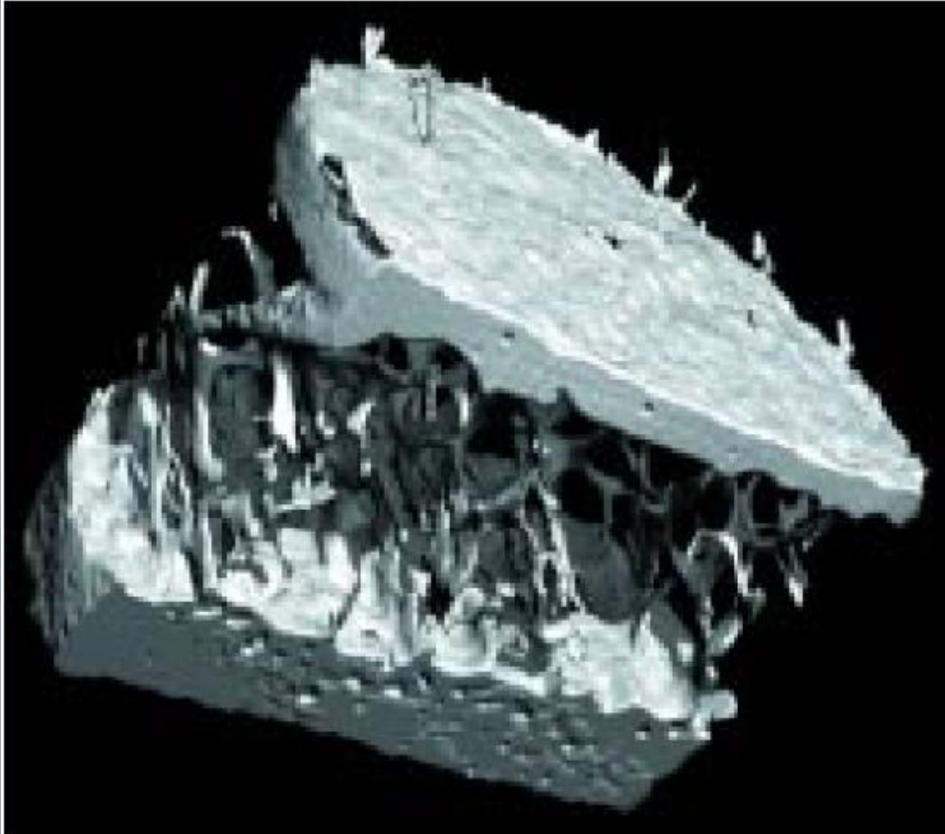


Follow-up

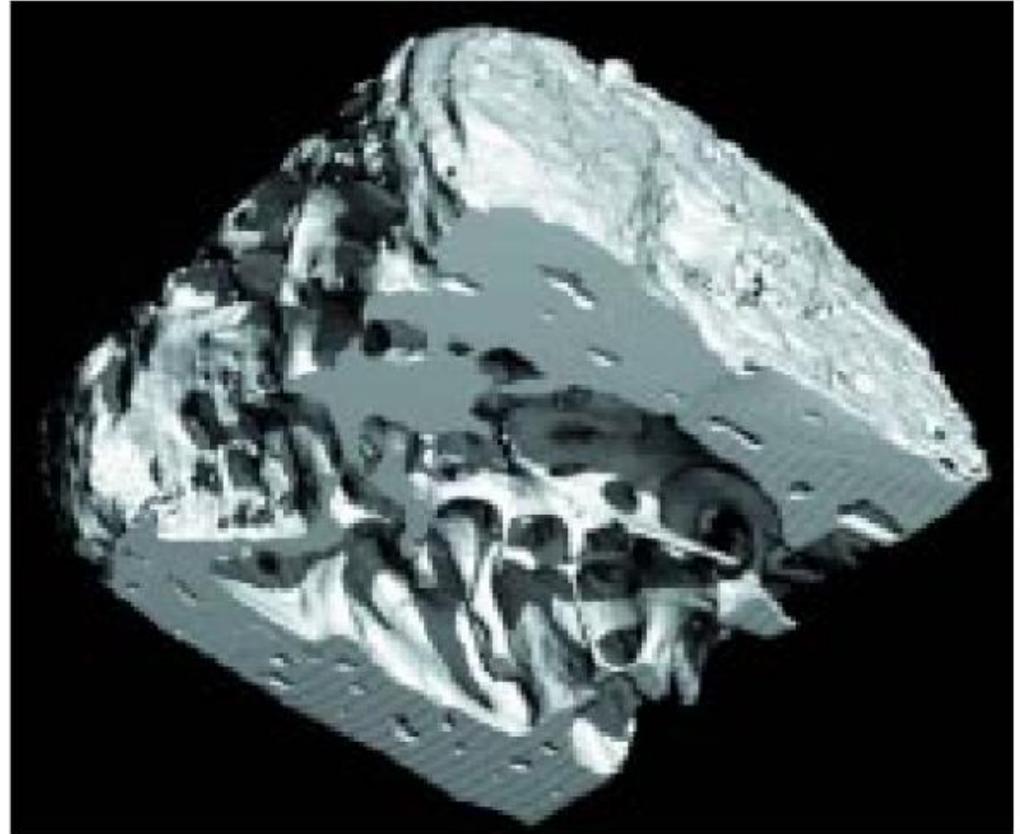


What are we trying to accomplish?

Baseline



Follow-up



This took 21 months on an anabolic to accomplish

So really what should our goal be?

- Change the dialogue from preoperative miracles to getting the patient on track for a lifetime of success
- Making both the patient and the surgeon aware of the diagnosis of osteoporosis and some sense of the severity
 - Surgeon making instrumentation and operative technique choices
 - Patient wanting the elective surgery, wanting to enjoy the results for a long time
 - Getting everyone to recognize this is a long term investment

Let's talk about arthroplasty

- Reality of an arthroplasty patient
 - Most osteoarthritis patients present with symptoms years before reaching the surgical stage
 - joint pain complaint given to the PCP
 - Conservative management starts
 - Physical therapy
 - Lifestyle modifications
 - Weight loss
 - Use of NSAIDs and anti-inflammatory meds/supplements
 - First presentation to the surgeon or the arthroplasty team
 - 40% visit conversion rate to surgery in highly refined protocolled practices
 - Physician extenders/advanced practice providers/non-operative joints physicians
 - Joint injections
 - More common with knees and shoulders than hips and ankles

Let's talk about arthroplasty

- Reality of an arthroplasty patient
 - Some patients have prior injuries that dramatically increase the chances of needing a joint replacement
 - ACL injury (50% rate of joint replacement at 25 years post injury)
 - Hip dysplasia
 - Avascular necrosis
 - Auto immune inflammatory diseases
- From surgical booking to metal to recovery
 - Time on the surgical runway 1-3 months in US (can be much longer outside of US)
 - Immediate start in the quality protocol pathways (smoking, diabetes, nutrition)
- Longevity investments
 - Knees, even older generation styles, anticipated 25 year life before wear revision
 - Hips, estimated 15 year life before wear revision
 - Many much longer
 - Materials changes (ceramic, highly crosslinked polyethylene liners) changing the discussion to once in a lifetime

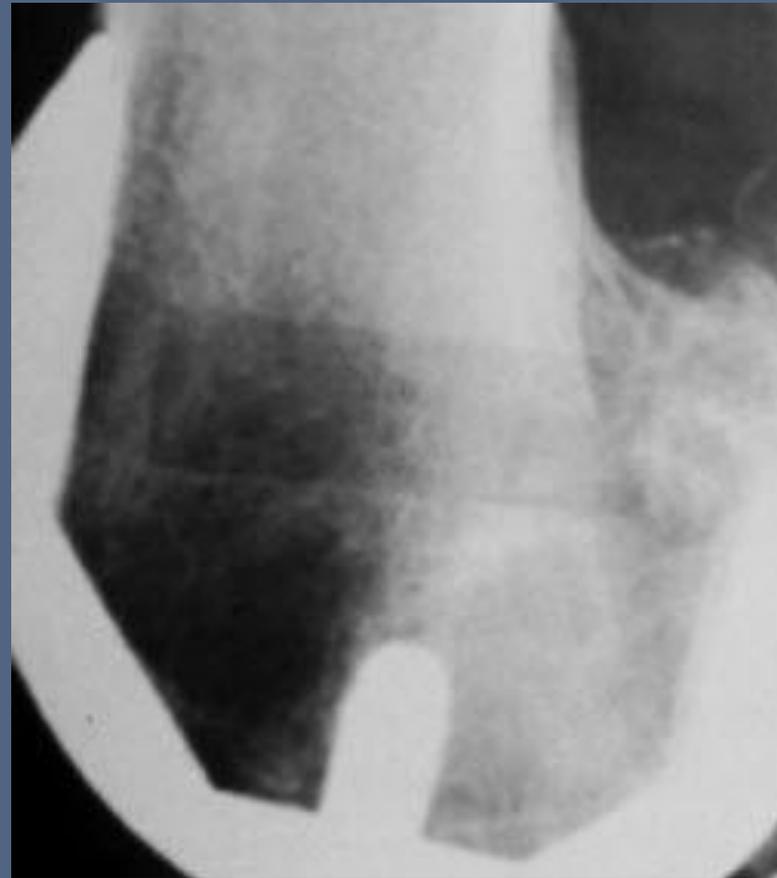
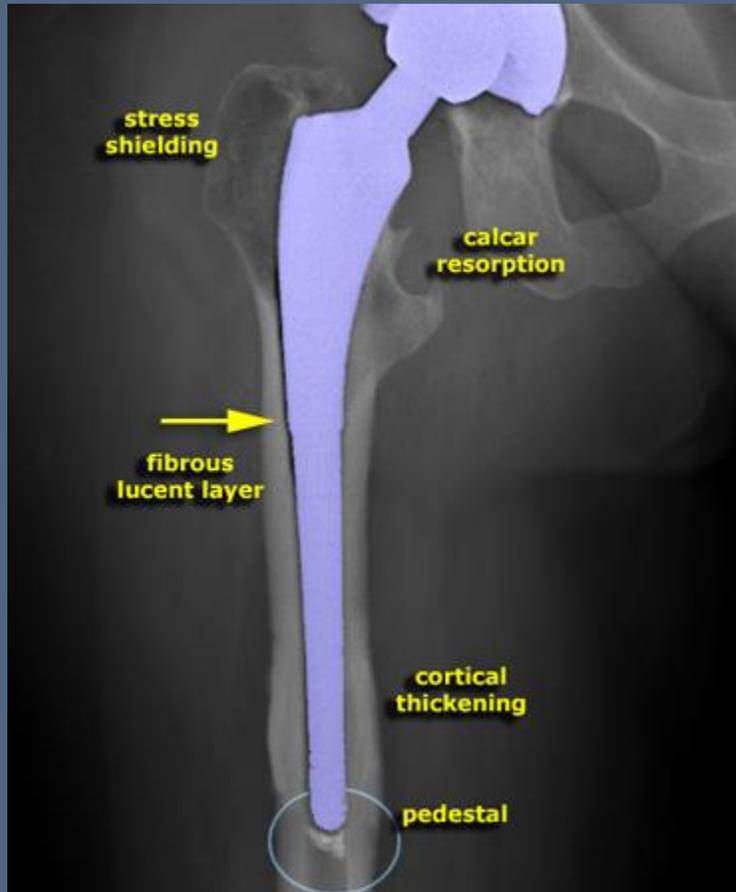
Total Joint Arthroplasty

- Prevalent disease even just on DXA
 - Two studies, but small patient populations (199 and 53)
 - Rate of osteoporosis 23% /28%
 - Rate of osteopenia (low bone mass) 43% /45%
 - Either way that is 2/3 of the patients!
- Can we give guidance to the surgeon regarding
 - Implant fixation choice
 - Cemented vs uncemented
 - Fracture risk
 - Any prep that can optimize outcomes

Joint related problems

- Periprosthetic fracture
 - In first 5 years after joint replacement
 - 0.9% primary/ 4.2% revision for THA
 - 0.6% primary/ 1.7% revision for TKR
 - Females over age 70 at highest risk
 - Fracture through guidepin holes from navigated knees
 - Now seeing bisphosphonate associated periprosthetic fractures
 - Difficult to get to heal
 - Stress shielding
 - Decreased bone mass adjacent to TKR at 4 years

This is stress shielding



Joint related problems

- Ingrowth of bone into porous coated implants
 - Worry about implant subsidence
 - General concept to cement for poor quality/quantity bone
 - Most hemiarthroplasty in patients over 80 now cemented
 - Intraop biopsy study showed only minor relationship between quality of cancellous bone and implant subsidence
 - Its may be all about the fit and the technique

Patient related problems

- Increased cortical porosity with
 - Type 2 diabetes
 - Even mild hyperparathyroidism
 - Hyperthyroidism
- Fall risk increased after surgery
- Decreased bone architecture with
 - Steroids
 - Chemo
 - Menopause
 - Low testosterone in men

Let's talk spine surgery

If at first you don't succeed...



SURGERY

Teriparatide Accelerates Lumbar Posterolateral Fusion in Women With Postmenopausal Osteoporosis

Prospective Study

Seiji Ohtori, MD, PhD, Gen Inoue, MD, PhD, Sumihisa Orita, MD, PhD, Kazuyo Yamauchi, MD, PhD, Yawara Eguchi, MD, PhD, Nobuyasu Ochiai, MD, PhD, Shunji Kishida, MD, PhD, Kazuki Kuniyoshi, MD, PhD, Yasuchika Aoki, MD, PhD, Junichi Nakamura, MD, PhD, Tetsuhiro Ishikawa, MD, PhD, Masayuki Miyagi, MD, PhD, Hiroto Kamoda, MD, PhD, Miyako Suzuki, MD, Gou Kubota, MD, Yoshihiro Sakuma, MD, Yasuhiro Oikawa, MD, Kazuhide Inage, MD, Takeshi Sainoh, MD, Masashi Takaso, MD, PhD, Tomoyuki Ozawa, MD, PhD, Kazuhisa Takahashi, MD, PhD, and Tomoaki Toyone, MD, PhD

- 57 postmenopausal women underwent decompression and fusion at one to two levels
- 29 received daily TPTD 20 mcg/d and 28 received risedronate weekly 17.5 mg/d. Medications were started 2 months prior to surgery and continued for 8 months post-operatively.
- The rate of bone union was 82% in the TPTD group and 68% in the risedronate group
- Bone union was achieved on average at 8 months in the TPTD group and 10 months in the risedronate group
- Symptoms were more improved in the TPTD group but not statistically different

Conclusion: Teriparatide showed better results for the rate of bone union and average duration of bone union compared an with oral bisphosphonate

SURGERY

Comparison of Teriparatide and Bisphosphonate Treatment to Reduce Pedicle Screw Loosening After Lumbar Spinal Fusion Surgery in Postmenopausal Women With Osteoporosis From a Bone Quality Perspective

Seiji Ohtori, MD, PhD, Gen Inoue, MD, PhD, Sumihisa Orita, MD, PhD, Kazuyo Yamauchi, MD, PhD, Yawara Eguchi, MD, PhD, Nobuyasu Ochiai, MD, PhD, Shunji Kishida, MD, PhD, Kazuki Kuniyoshi, MD, PhD, Yasuchika Aoki, MD, PhD, Junichi Nakamura, MD, PhD, Tetsuhiro Ishikawa, MD, PhD, Masayuki Miyagi, MD, PhD, Hiroto Kamoda, MD, PhD, Miyako Suzuki, MD, PhD, Gou Kubota, MD, Yoshihiro Sakuma, MD, Yasuhiro Oikawa, MD, Kazuhide Inage, MD, Takeshi Sainoh, MD, Masashi Takaso, MD, PhD, Tomoaki Toyone, MD, PhD, and Kazuhisa Takahashi, MD, PhD

- 62 postmenopausal women undergoing decompression and 1-2 level fusion were given either risedronate 2.5 mg/d, TPTD 20 mcg/d or no medication for osteoporosis. OP medications were given 2 months prior to surgery and 10 months post-operatively
- The incidence of pedicle screw loosening in the teriparatide group was significantly lower than that in the risedronate or the control group ($P < 0.05$). In contrast, the extent of pedicle screw loosening in the risedronate group was not significantly different from that in the control group ($P > 0.05$).

Conclusion: Our findings suggest that teriparatide increased the quality of the lumbar spine pedicle bone.

Teriparatide increases the insertional torque of pedicle screws during fusion surgery in patients with postmenopausal osteoporosis.

Inoue G¹, Ueno M, Nakazawa T, Imura T, Saito W, Uchida K, Ohtori S, Toyone T, Takahira N, Takaso M.

- Fusion surgery for the thoracic and/or lumbar spine was performed in 29 postmenopausal women with osteoporosis
- Patients were treated with teriparatide (n = 13) or not (n = 16) before the surgery
- Patients received preoperative teriparatide therapy as either a daily (20 µg/day, n = 7) or a weekly (56.5 µg/week, n = 6) injection for a mean of 61.4 days and a minimum of 31 days
- The mean insertional torque value in the teriparatide group was 1.28 ± 0.42 Nm, which was significantly higher than in the control group (1.08 ± 0.52 Nm, $p < 0.01$).
- There was no significant difference between the daily and the weekly teriparatide groups with respect to mean insertional torque value (1.34 ± 0.50 Nm and 1.18 ± 0.43 Nm, respectively, $p = 0.07$).

Conclusion: Teriparatide injections beginning at least 1 month prior to surgery were effective in increasing the insertional torque of pedicle screws during surgery in patients with postmenopausal osteoporosis



Taking advantage of partnerships and protocols

- Even if the surgeon thinks about it, access to a bone health provider is challenging
- Patients are in a unique window focused on preparation for surgery and wanting success
- CMS gave us a head start on forcing perioperative pathways
 - Bundles
 - Gold Star rating
 - US News and World Report Rankings
 - JCAHO joint replacement center accreditation

Taking advantage of partnerships and protocols

- Start small with real conversations with other providers person to person
 - A joints or spine team with an engaged surgeon champion
 - Creating the sense that this is part of the team care just like
 - Smoking cessation
 - preop anesthesia assessment
 - medication management
 - physical therapy
 - preop class
 - Postop pathway care (PT, meds, wound care)

Taking advantage of partnerships and protocols

- Nurses and administrators in charge of the protocol paths can be our best allies
 - Great patient educators
 - Help develop media for the patient
 - Already have the trust of the patient
 - How can you leverage the patient education that is already required for surgery
- How can you leverage an EMR
 - Order sets
 - Empowering the pcp or arthroplasty APP to make decisions on meds
- Playing for the long haul

Taking advantage of partnerships and protocols

- Playing for the long haul
 - Start the conversation early
 - Realize the patient is nervous and focused on the surgery
 - It may have taken forever to get tests and get to you
 - Reassurance that this is a long term investment in success

What to do?

- Postoperative bone health evaluation
 - Often triggered by a complication or intraop realization that the bone is terrible quality or quantity
 - Same as preop but may have other factors from complications or fracture that need to be considered in treatment choices and rapidity of response

What to do?

- Preoperative evaluation of bone health
 - Keep it simple
 - Standard labs (CMP, intact PTH, 25 Vitamin D)
 - Calcium and Vitamin D optimization
 - DXA
 - FRAX
 - Start meds for osteoporosis as indicated

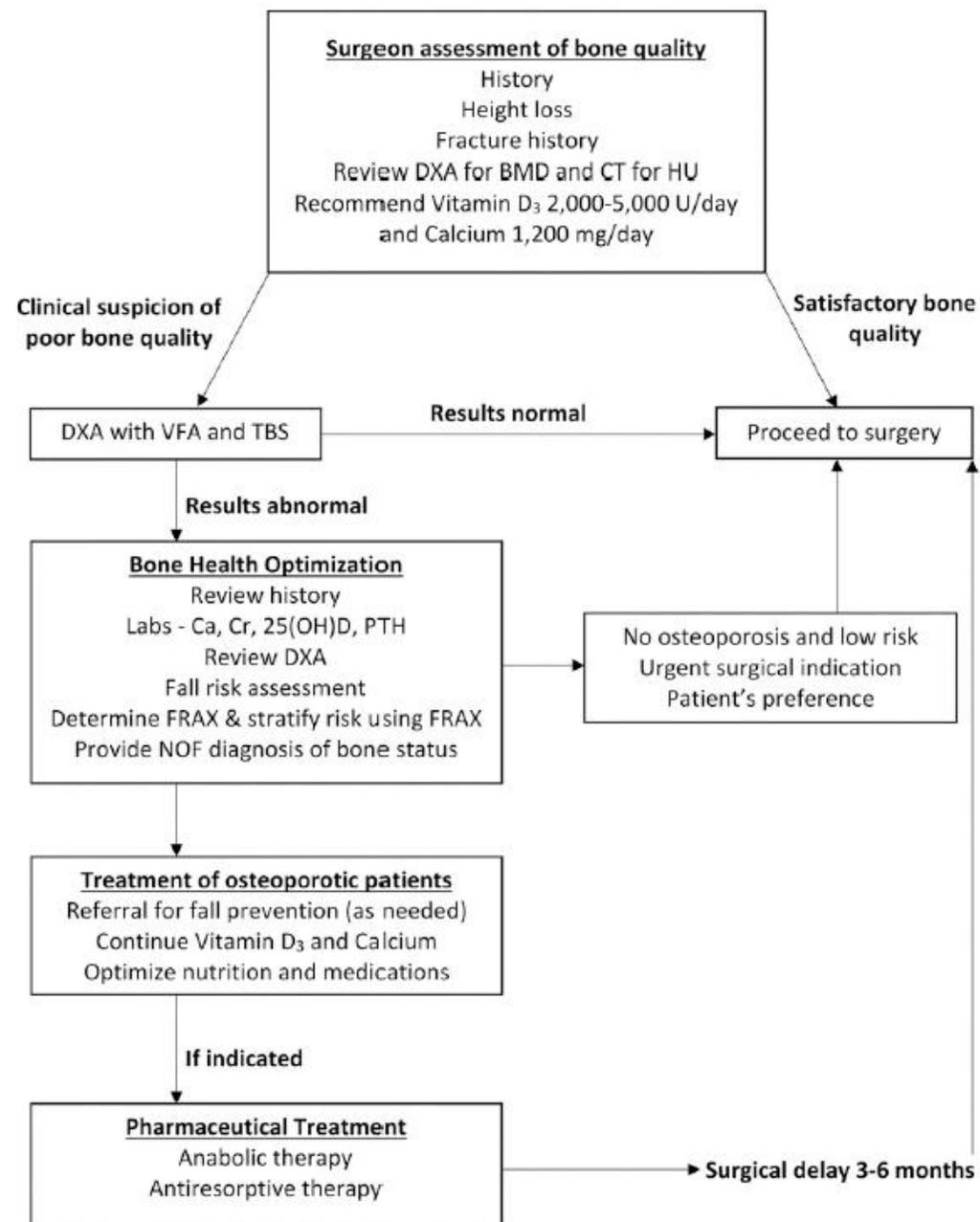


Fig. 1

Flowchart showing the patient referral process and evaluation conducted during bone health optimization. BMD = bone mineral density, VFA = vertebral fracture assessment, TBS = trabecular bone score, Ca = calcium, Cr = creatinine, and PTH = parathyroid hormone.

FRAX can be really helpful in a pinch

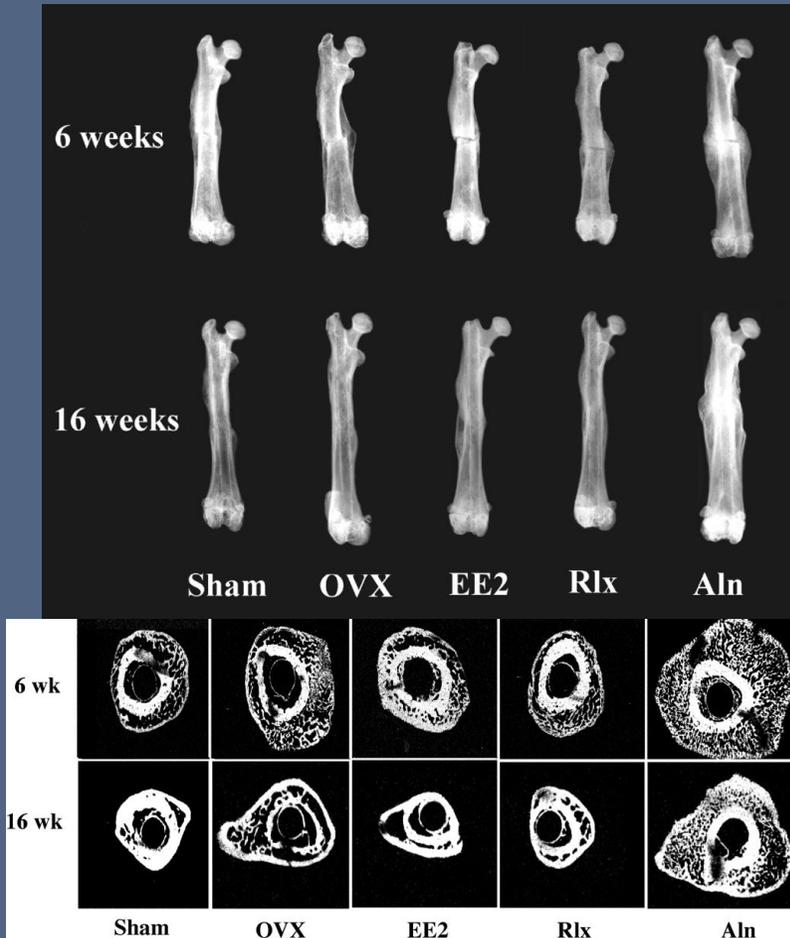
TABLE II FRAX Scores with and without Bone Mineral Density			
	Female Group	Male Group	Total Group
With bone mineral density			
No. of patients	102	20	122
Major osteoporotic fracture risk of $\geq 20\%$	56%	40%	53%
Hip fracture risk of $\geq 3\%$	78%	85%	80%
Either major osteoporotic fracture risk of $\geq 20\%$ or hip fracture risk of $\geq 3\%$	81%	85%	82%
Without bone mineral density			
No. of patients	103	21	124
Major osteoporotic fracture risk of $\geq 20\%$	49%	19%	44%
Hip fracture risk of $\geq 3\%$	70%	57%	69%
Either major osteoporotic fracture risk of $\geq 20\%$ or hip fracture risk of $\geq 3\%$	71%	62%	70%

- High Frax risk in 82% of patients when included DXA and 70% without DXA
- Small study, but correlation without DXA slightly better in women

Treatment choices

- There is a place for everything
 - Bisphosphonate
 - Denosumab
 - Anabolics
 - PTH
 - PTHrP
 - Anti-sclerostin antibody

Reassure the surgeon about healing



Callus formation comparisons in rat femur fracture model

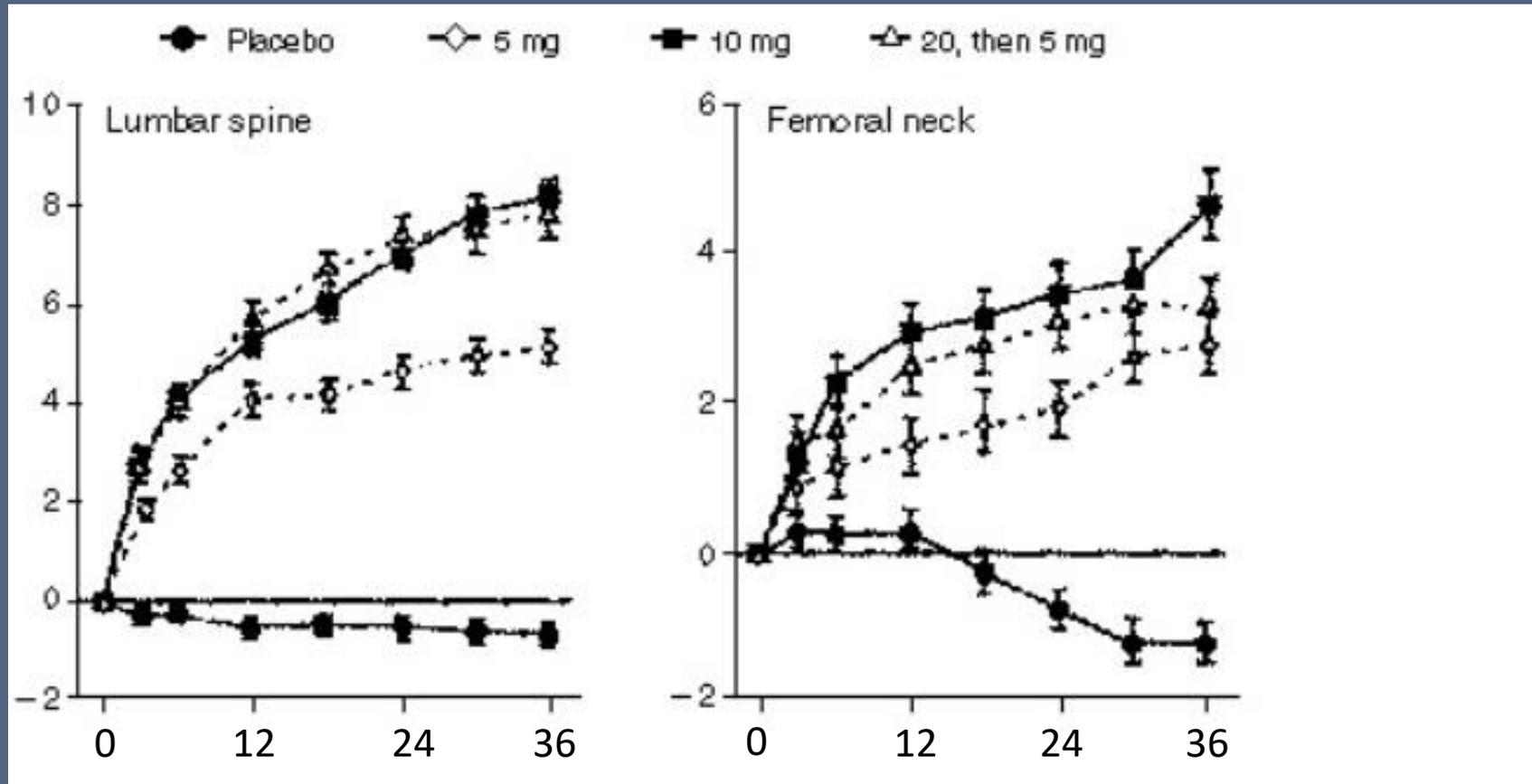
They all heal, just the pattern is different

So it becomes a question about goals

- Need to think about the severity of the osteoporosis
- Bad bone builder, big bone loser, or both?
- Are they already on treatment?
- Are steroids, chemo, or immunotherapy in the mix increasing inflammation?
- Short term small gains with long term big gains

Bisphosphonates

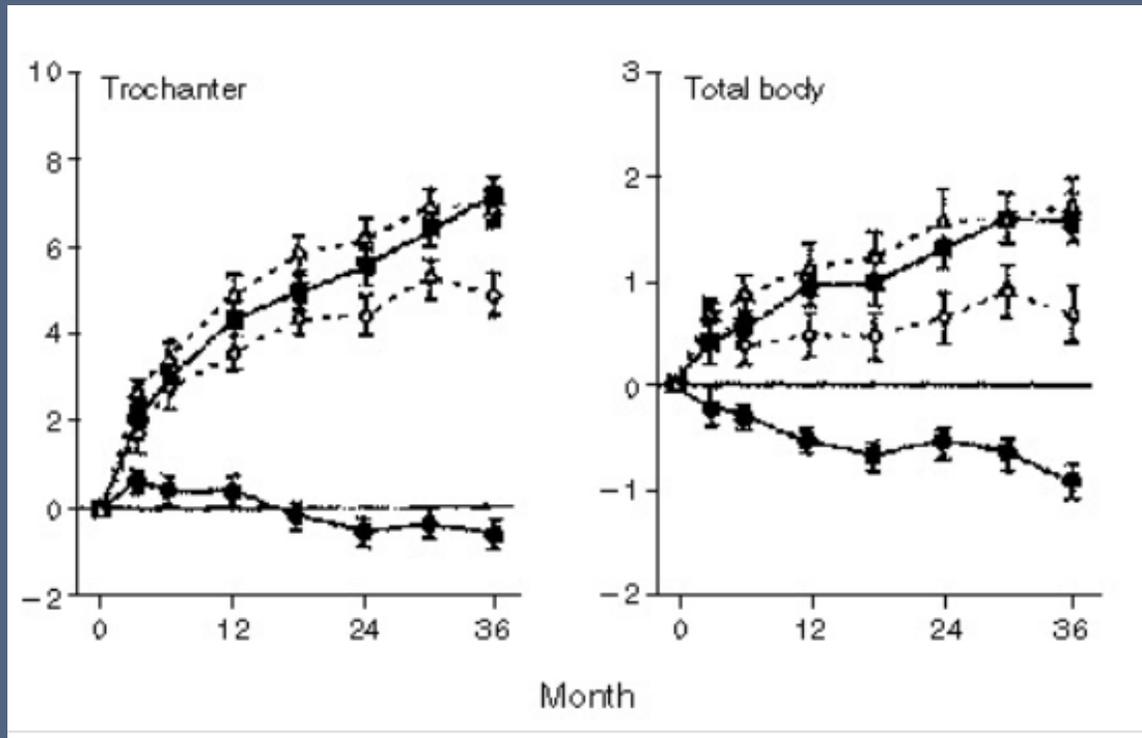
Oral alendronate



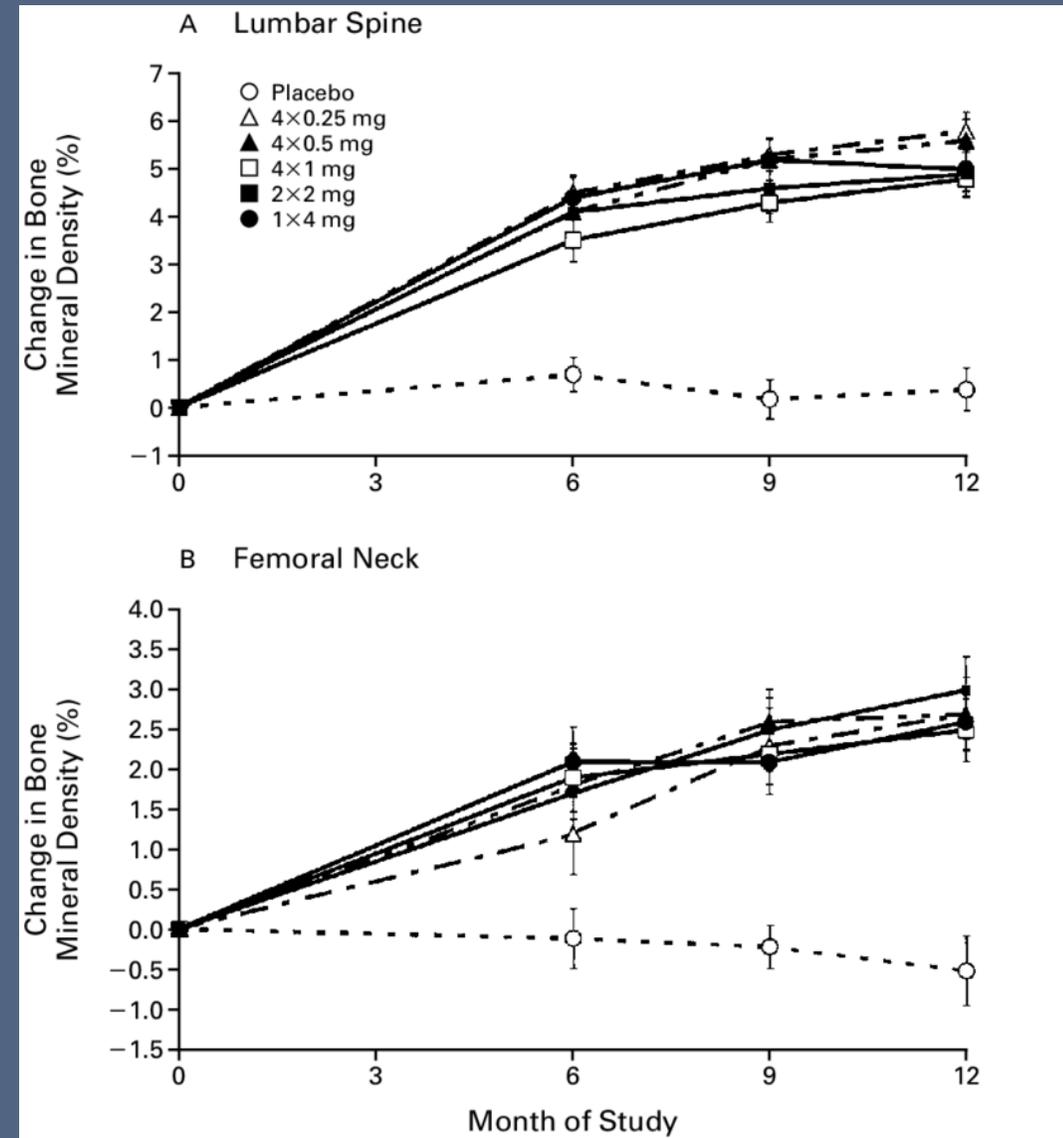
Mean change in bone mineral density by months

Bisphosphonates

alendronate



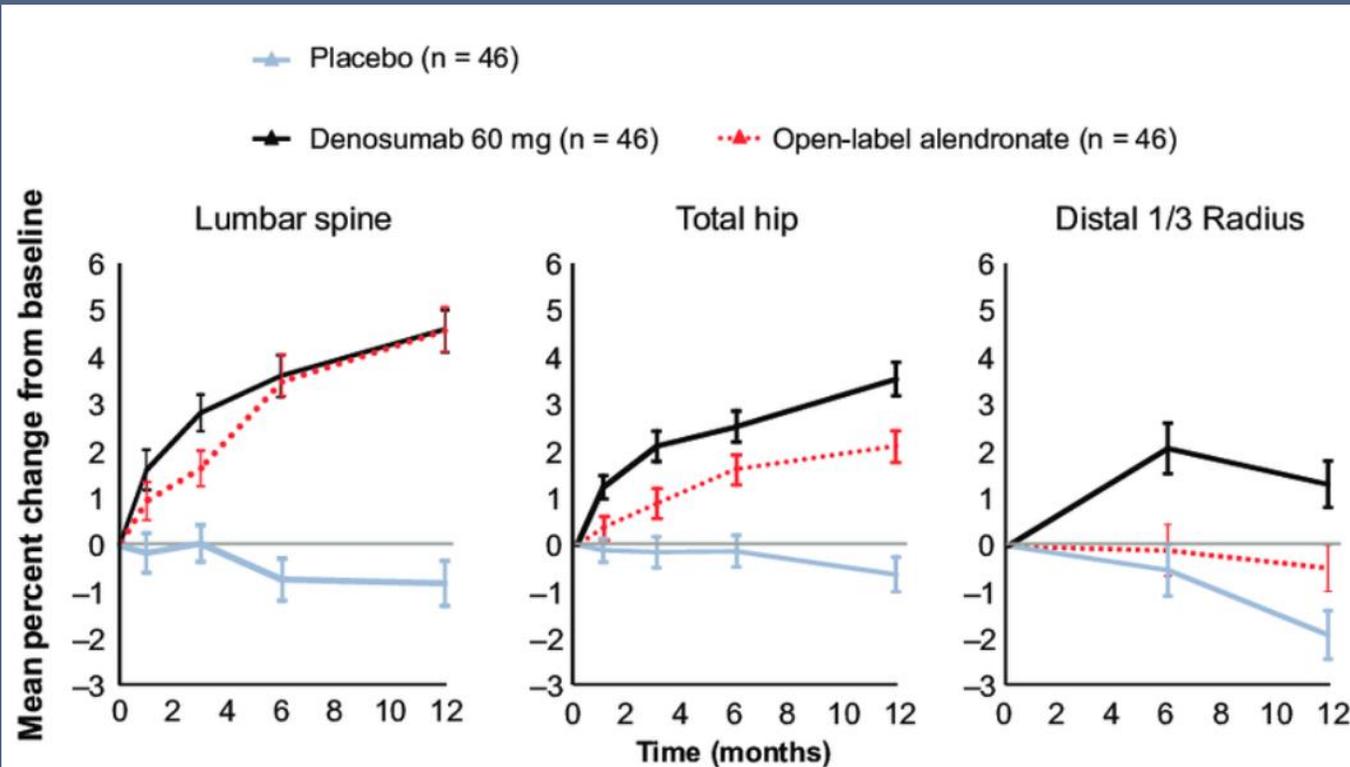
Zoledronic acid



A little caution about zoledronic acid if you love your surgeon and your patient

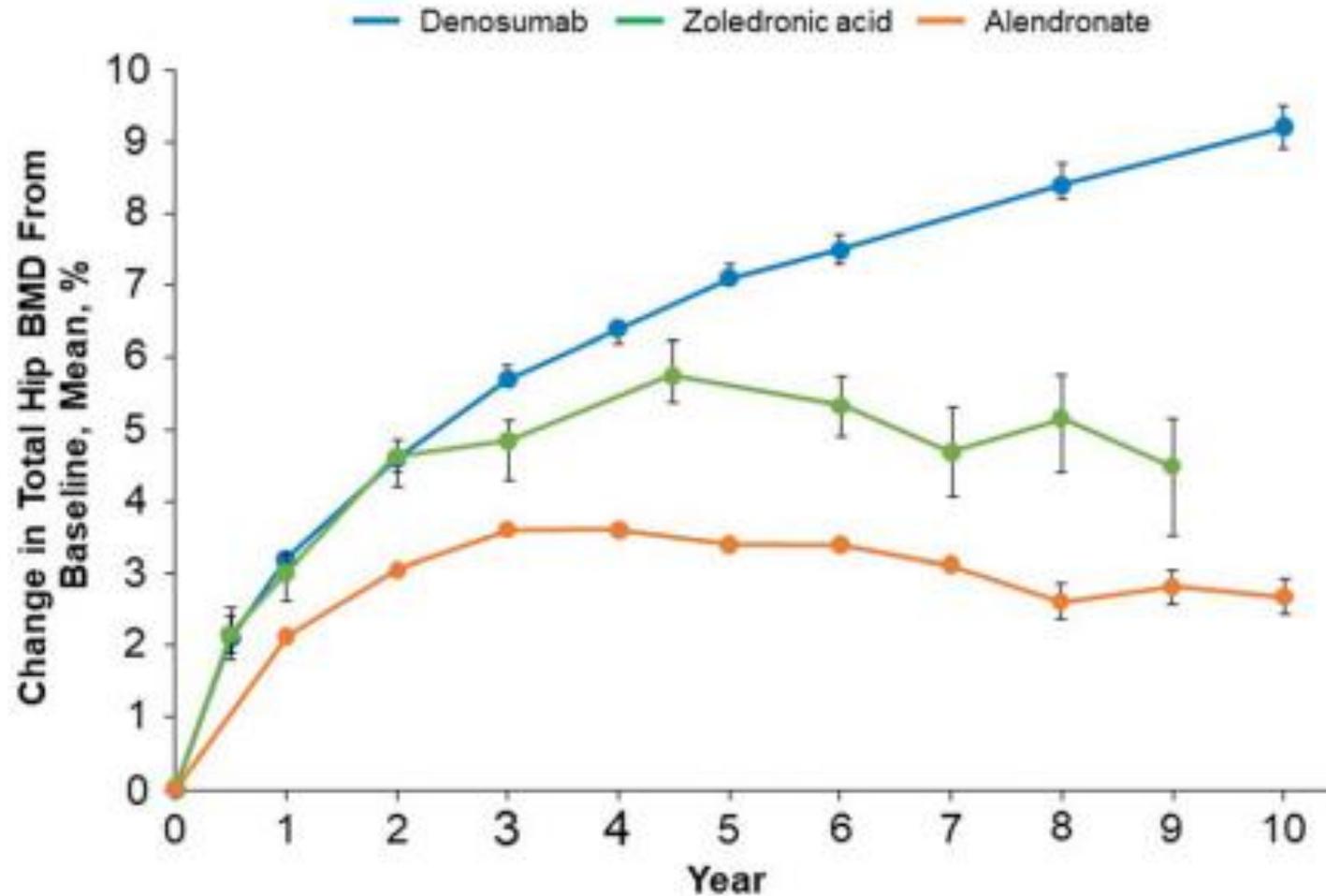
- Acute phase reaction is real and happens with first dose
 - Muscle aches
 - Fever
 - Flu like symptoms
- Dosing just before surgery
 - often the patient does not feel great going into a procedure
- Dosing right after surgery
 - a fever will trigger a 'code sepsis' in the post op period and actually count against the surgeon's quality scores

Denosumab



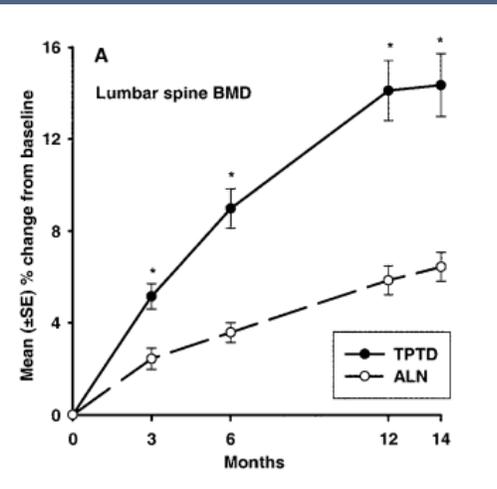
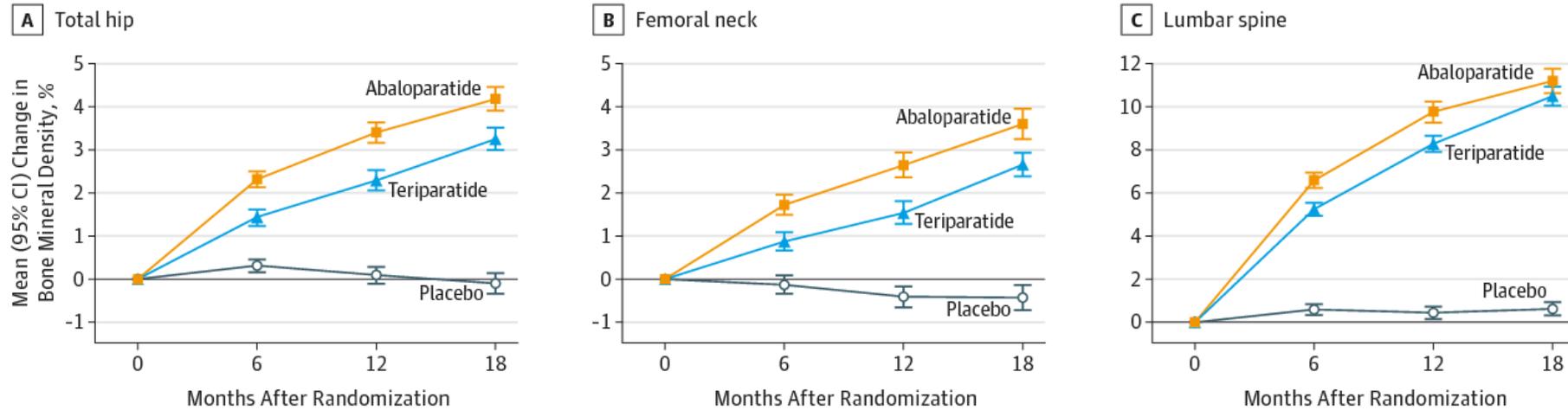
Phase 2 study of denosumab every 6 months in postmenopausal women with low (bone mineral density) BMD: lumbar spine, total hip, and distal 1/3 radius BMD at 12 months. Adapted from *J Bone Miner Res.* 2007;22:1832-1841, 30 with permission of the American Society for Bone and Mineral research; and from *N Engl J Med.* 2006;354:821-831. 29

Antiresorptives over the long haul



Abaloparatide and Teriparatide

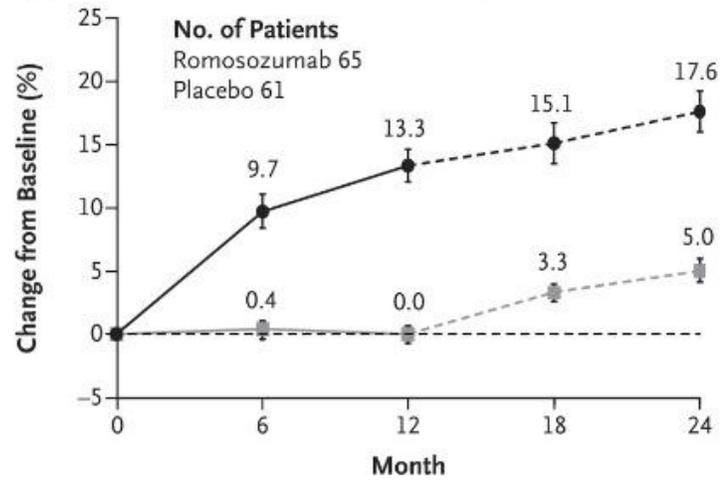
Figure 2. Change From Baseline in Bone Mineral Density



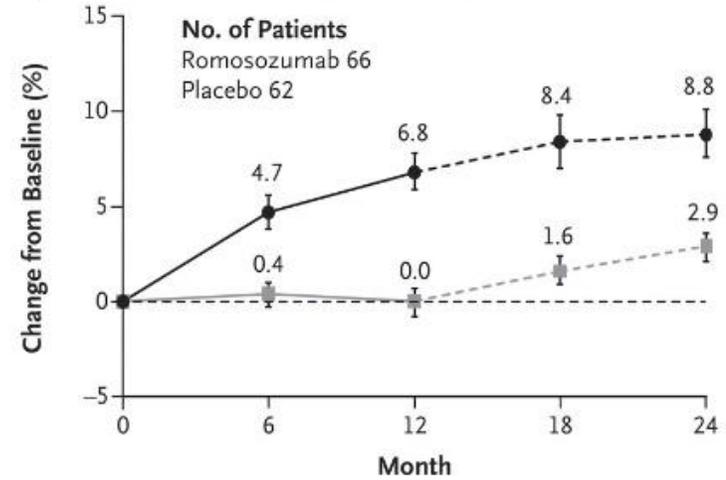
Romosozumab

— Placebo - - - Placebo → Denosumab — Romosozumab - - - Romosozumab → Denosumab

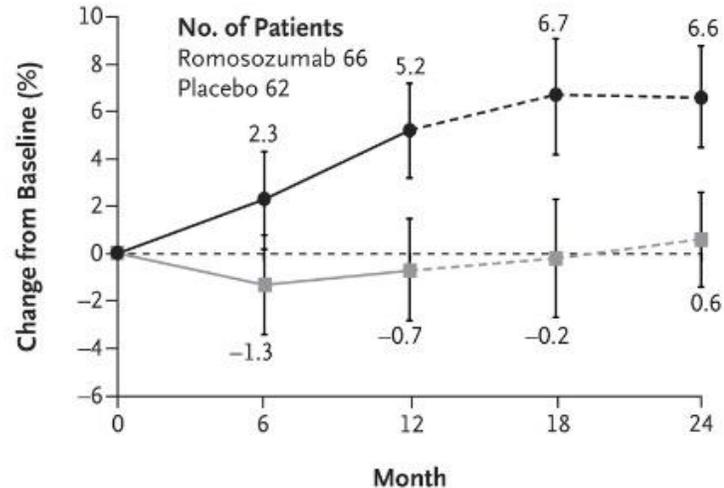
A Change in Bone Mineral Density at Lumbar Spine



B Change in Bone Mineral Density at Total Hip

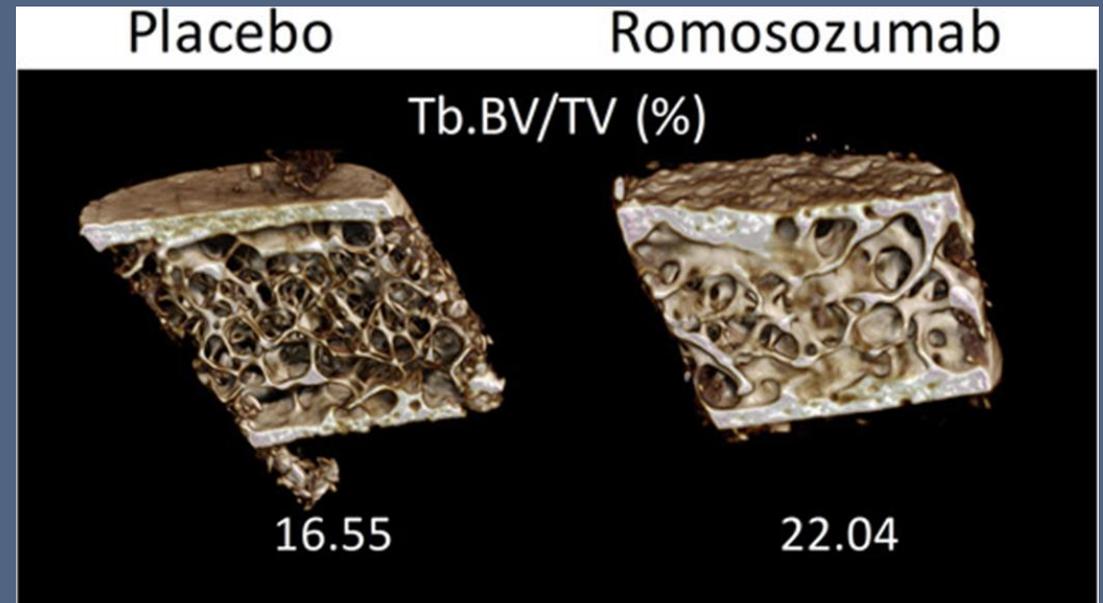
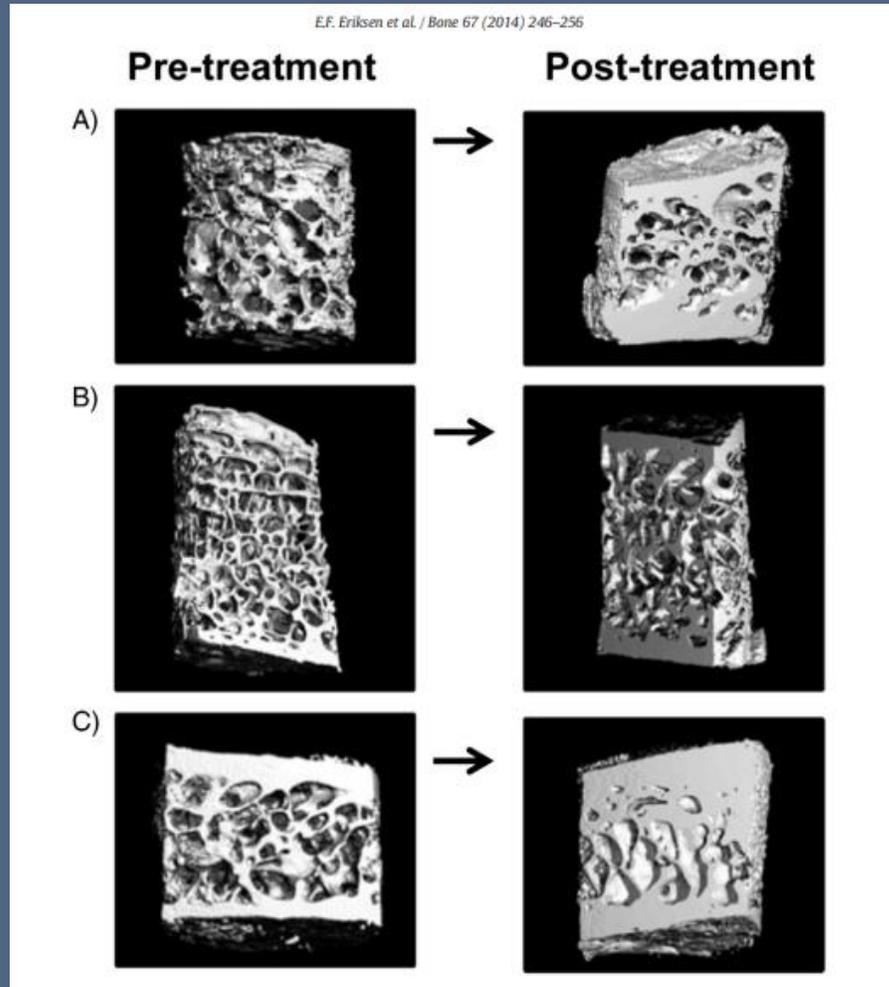


C Change in Bone Mineral Density at Femoral Neck



A picture is worth a thousand words

Teriparatide 21 months



Remember the importance of Vitamin D

- Three studies now have shown decreased rate ACUTE periprosthetic joint infection with normal Vitamin D levels
 - Infected patients Vitamin D in low 20s compared to high 30s in controls
 - On average infected patients had lower calcium levels and lower albumin levels

So, what to do

- Anything you do helps
- Even the best anabolic will not rescue most patients in 3-6 months
- Identify patients early in the sometimes long time frame before elective surgery
- Remind the surgeons to still think osteoporosis with technique and instrumentation
- Play the long game

What Do I do?

- Short term usually an anabolic
 - High risk patient undergoing a major surgery
 - Early complications with bone rarely results in good things long term
- Long term consider the patient
 - Antiresorptive if not too bad but need to stop bone loss (lock it down)
 - Anabolic if already low bone mass
 - Anabolic if a bad bone builder or other high risk

Thank you

