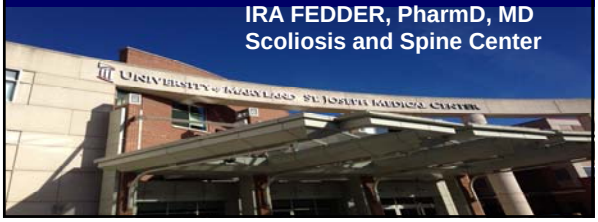
OSTEOPOROSIS AND SPINAL SURGERY

IRA FEDDER, PharmD, MD
Scoliosis and Spine Center



Clinical Reality

- Aging population
- Increased demand for surgery regardless of age
- Bone loss is universal
- Inactivity and Vitamin D deficiency
- Glucocorticoid use

OSTEOPOROSIS AND SPINE COMPLICATIONS

- DEWALD CJ ET AL. SPINE 2006;31(19 SUPPL):S144-51
- TOYONE T, ET AL. SPINE 2010;35:1915-18.

Surgical Strategies

- Modified instrumentation- e.g.osteoporosis screws
- Modified screw insertion techniques technique— e.g.cortical screws
- Anterior and posterior stabilization
- Cement augmentation

Medical strategies

- Calcium/Vitamin D
- Anti- resorptive agents-- bisphosphonates, denosumab (Prolia)
- Anabolic agents—Teriparatide (1-34 PTH)

Rat GC Treated Fusion Model – The Spine Journal 15(2015)298-306

Increased bone volume
Improved microstructural parameters
Improved fusion rates

N ENGL J MED 2007;357:2028-2039

- COMPARED TERIPARATIDE TO ALENDRONATE
- BMD WAS BETTER IN TERIPARATIDE GROUP
- FEWER FRACTURES

J Am Acad Orthop Surg 2015; 23(4):253-63

Teriparatide Fracture Prevention Trial Study Design

- Endpoints:
  - Vertebral and non-vertebral fracture, BMD
- Prospective, randomized, double-blind, multi-national trial in 1637 postmenopausal women with prior vertebral fracture
- Placebo, 20 mcg, or 40 mcg recombinant human PTH(1-34) (teriparatide, TPTD) (Eli Lilly and Company) by once daily self-injection SC for up to 2 years (median 19 months)
- Supplemental calcium 1,000 mg/day and vitamin D 400-1,200 IU/day

Neer et al. N Engl J Med 2001; 344:1434-41

Teriparatide Fracture Prevention Trial Inclusion Criteria

Ambulatory women ≥ 5 years postmenopausal with prior nontraumatic vertebral fractures, as follows:

≥ 2 moderate fractures

≥ 2 mild fractures + hip or spine BMD T-score ≤ -1.0

1 moderate fracture + hip or spine BMD T-score ≤ -1.0

Neer et al. N Engl J Med 2001; 344:1434-41

Teriparatide Fracture Prevention Trial Baseline Characteristics (mean ± SD)

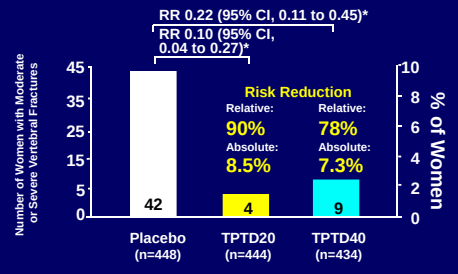
	Placebo	TPTD20	TPTD40
	N = 544	N = 541	N = 552
Age (years)	69 ± 7	70 ± 7	70 ± 7
Years postmenopausal	21 ± 9	21 ± 9	22 ± 8
Previous OP therapy (%)	15	16	13
Spine sBMD (mg/cm^2)	821 ± 172	820 ± 167	821 ± 172
Spine T-score	-2.6	-2.6	-2.6
Vertebral fractures			
1	28%	31%	32%
≥ 2	62%	60%	58%

sBMD = BMD standardized for machine differences

Neer et al. N Engl J Med 2001; 344:1434-41

Efficacy

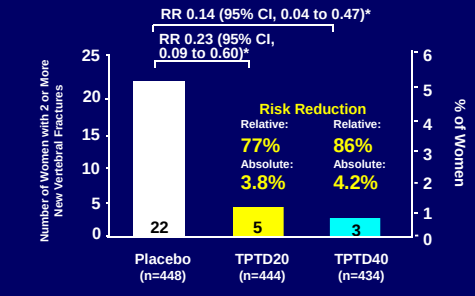
Effect of Teriparatide on the Risk of Moderate and Severe New Vertebral Fractures



Neer et al. N Engl J Med 2001; 344:1434-41

* P <0.001 vs. Placebo

Effect of Teriparatide on the Risk of Multiple New Vertebral Fractures



Neer et al. N Engl J Med 2001; 344:1434-41

*P <0.001 vs. Placebo

INSTRUMENTED FUSION OVER 50

- HISTORY OF FRAGILITY FRACTURE
- HISTORY OF TREATMENT OF OSTEOPOROSIS WITH BISPHOSPHONATES
- METABOLIC/PHARMACOLOGIC ISSUE
- PREMATURE MENOPAUSE

EVAL AND TREATMENT

- HISTORY-STEROIDS/METABOLIC/FRACTURES/EARLY MENOPAUSE
- DEXA
- VITAMIN D3 (MEASURE 25-OH VITAMIN D
- CALCIUM

TERIPARATIDE

PROS

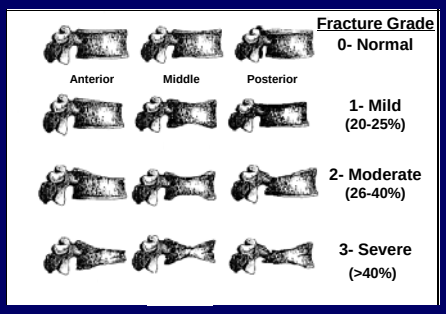
- ANABOLIC AGENT
- FEW REVERSABLE SIDE EFFECTS
- CREATES BONE/IMPROVED BONE MASS

CONS

- DAILY SELF INJECTION
- COST

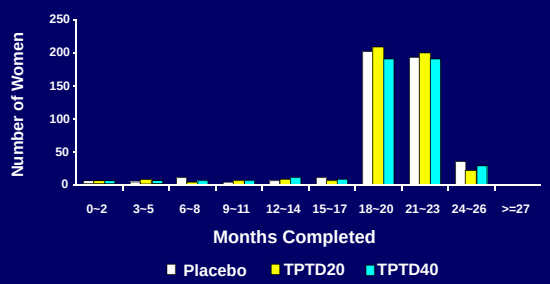
THANK YOU

Semiquantitative Evaluation of Vertebral Fracture Severity



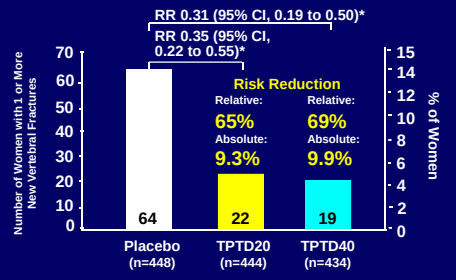
Adapted from J Bone Miner Res 1993; 8: 1137-1148 with permission of the American Society for Bone and Mineral Research

Teriparatide Fracture Prevention Trial Study Duration
(from randomization to last radiograph)



Data on File, Eli Lilly and Company

Effect of Teriparatide on the Risk of New Vertebral Fractures



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*P <0.001 vs. Placebo

Incidence of New or Worsening Back Pain[1]

	Placebo	TPTD20	TPTD40
No. of women (%)	123 (23)	91 (17)*	87 (16)**

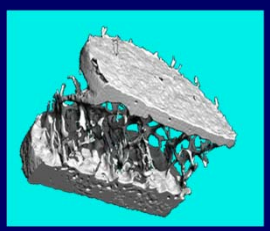
Fracture-Associated Height Loss

	Placebo	TPTD20	TPTD40
Centimeters lost	1.11	0.21**	0.31*

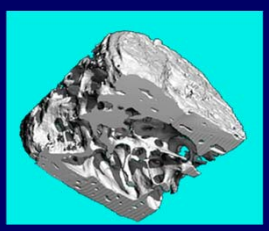
[1] Incidence of new or worsening back pain was recorded as adverse event
*P<0.05 vs. Placebo **P<0.01 vs. Placebo

Neer et al. N Engl J Med 2001; 344:1434-41

Effect of Teriparatide 20mcg



Baseline



Follow-up

Patient 1124

Female, age 65
Duration of therapy: 637 days (approx 21 mos)

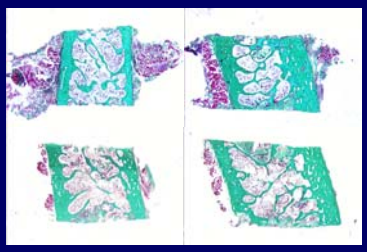
BMD Change:
⇒Lumbar Spine: +7.4% (group mean = 9.7 ± 7.4%)
⇒Total Hip: +5.2% (group mean = 2.6 ± 4.9%)

B3D-MC-GHAC
UCSF - Jiang

Effect of Teriparatide on Bone Histology

Patient 1131
20 mcg/day

Patient 1234
40 mcg/day



Baseline Endpoint

Data on File, Eli Lilly and Company