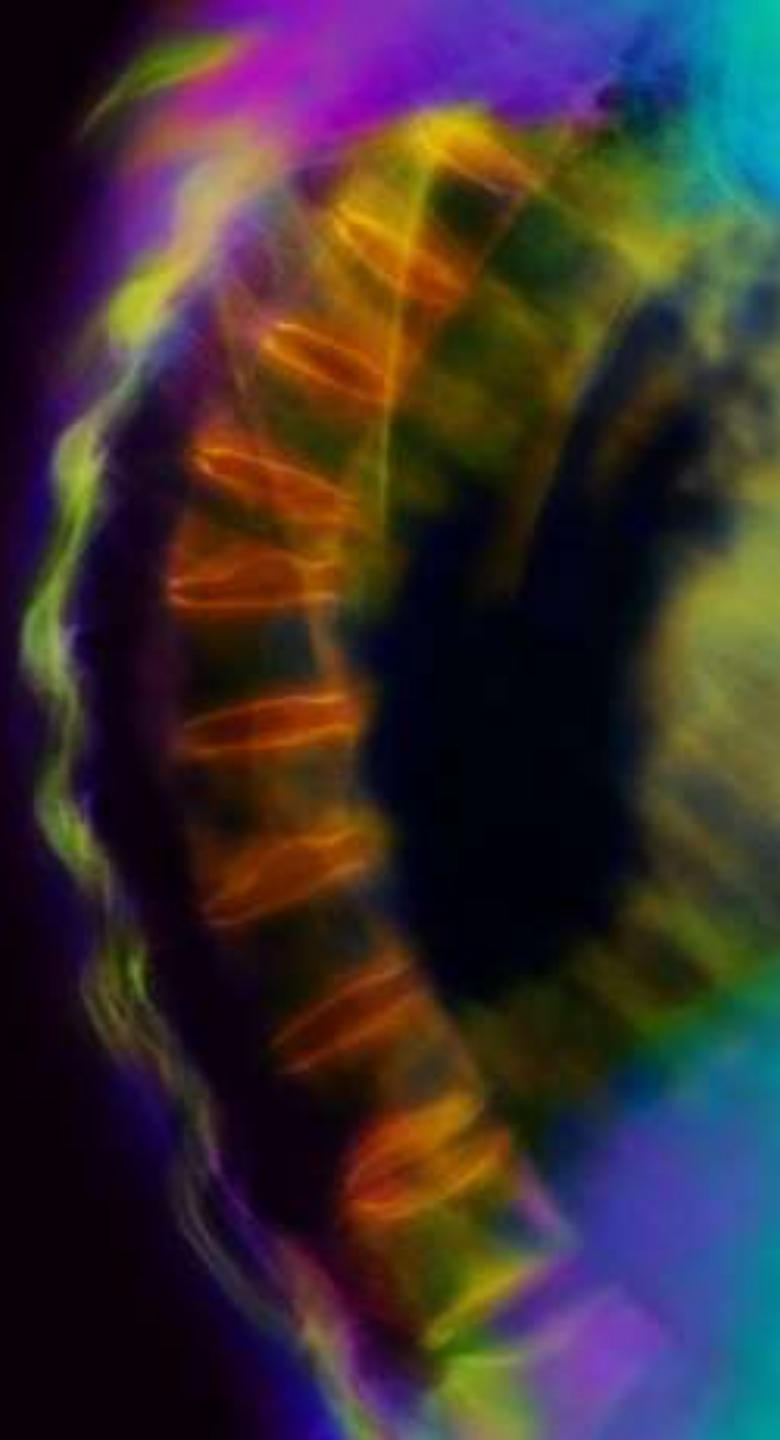


The
Downward
Spiral:
*Impact of
Vertebral Body
Compression
Fractures*



Osteoporosis

A Public Health Problem

- Worldwide, 1 in 3 women and 1 in 8 men over 50 are affected by osteoporosis¹
- 44 Million People U.S. at Risk²
- 1.5 Million Fragility Fractures in US²
 - **700,000 spine**
 - 300,000 hip
 - 250,000 wrist
 - 300,000 other

¹ *International Osteoporosis Foundation*

² *National Osteoporosis Foundation*

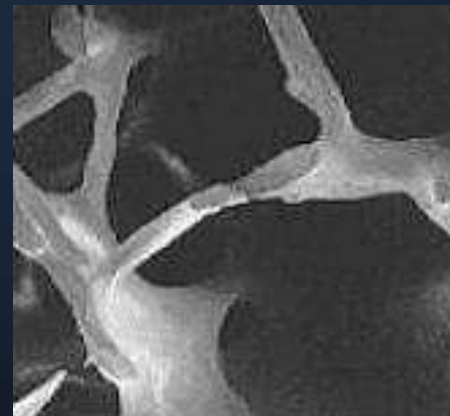
Osteoporosis

Osteoporosis is defined as a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture.

NIH Consensus Development Conference, March 2000

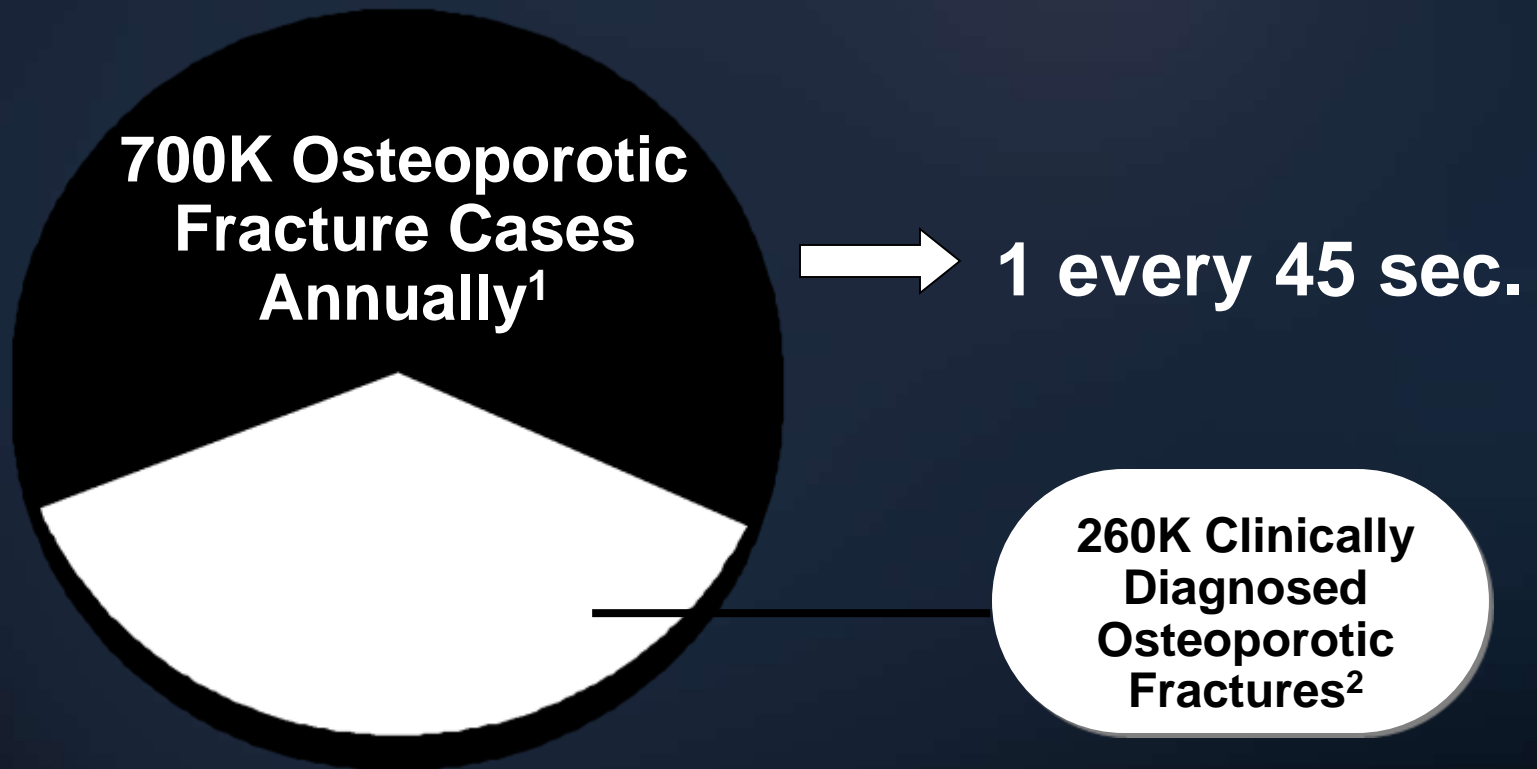


Normal Bone



Osteoporotic Bone

Incidence of VCFs

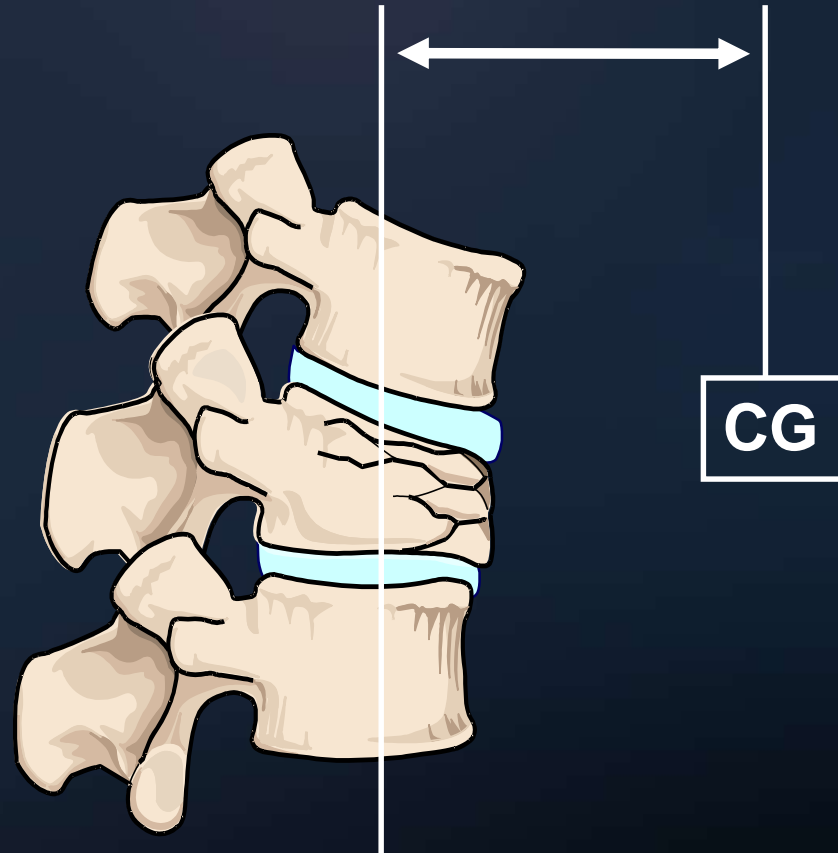


1 National Osteoporosis Foundation

2 Cooper et al., J Bone Min Research 1992

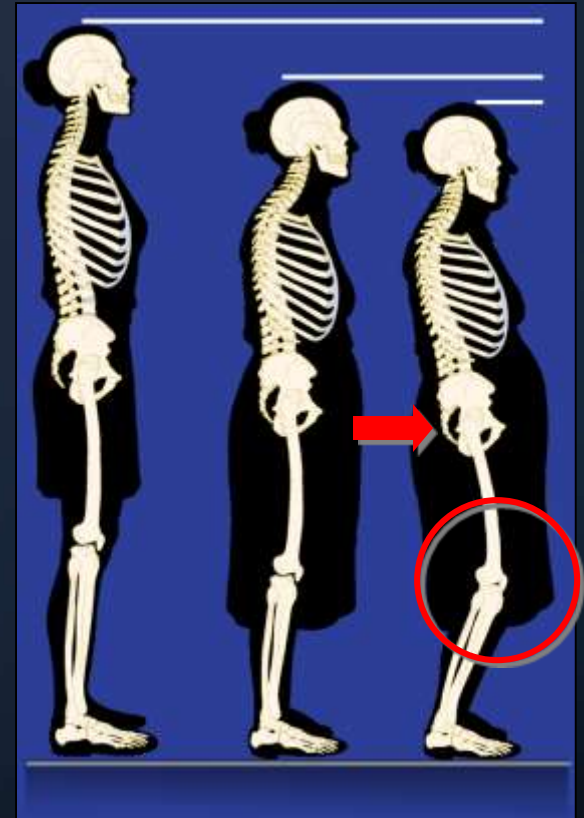
Biomechanics of VCF

- Center of gravity (CG) moves forward
- Large bending moment created
- Posterior muscles and ligaments must counterbalance increased bending
- Osteoporotic anterior spine must resist larger compressive stresses



Biomechanics of VCF

- Knees bend, pelvis tilts forward to counteract forward bending
 - Change in balance¹
 - Decrease in gait velocity¹
 - Increased muscle fatigue¹
 - Increased risk of falls and additional fractures²



¹ Gold et al., *Osteoporosis* 2001

² Ross et al., *Annals Int Med* 1991

Physical Impact of VCF



Age 50



Age 75

Signs of VCF

Acute Event:

- Sudden onset of back pain with little or no trauma

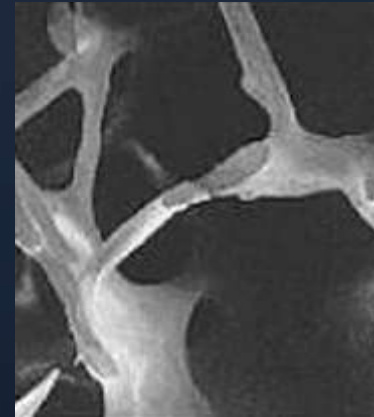
Chronic Manifestation(s):

- Loss of height
- Spinal deformity ("Dowager's hump")
- Protuberant abdomen



Symptomatic VCFs

- 260,000 pts/yr refractory to medical therapy¹
- Only fracture not treated in an orthopedic manner
 - Open surgical repair too invasive
 - Poor outcomes (osteopenic bone)
- No orthopedic treatment may lead to long-term increased morbidity, mortality



¹ Cooper et al., *J Bone Min Research* 1992

THE HUMAN COST

Impaired Function

- Spinal deformity and pain impair function, decrease mobility^{1,2,3}
- Decreased activity leads to more bone loss¹
- Compressed abdomen decreases appetite^{1,3}
- Sleep disorders develop^{1,3}



1 Silverman, Bone 1992

2 Lyles et al., Am J Med 1993

3 Gold et al., Osteoporosis 2001

Increased Pulmonary Disorders

VCF reduces pulmonary function¹

- One thoracic VCF causes 9% loss of forced vital capacity²
- Lung function (FVC, FEV1) is significantly reduced in patients with thoracic and lumbar fracture compared to patients with low back pain¹
- **Degree of kyphosis is significantly related to risk of pulmonary death ($p=0.005$)³**

1 Schlaich et al., Osteoporosis Int 1998

2 Leech et al., Am Rev Respir Dis 1990

3 Kado et al., Arch Intern Med 1999

Decreased Quality of Life

- Decreased activity
- Increased depression
- Lower self-esteem
- Increased anxiety
- Diminished social roles
- Increased dependence on others



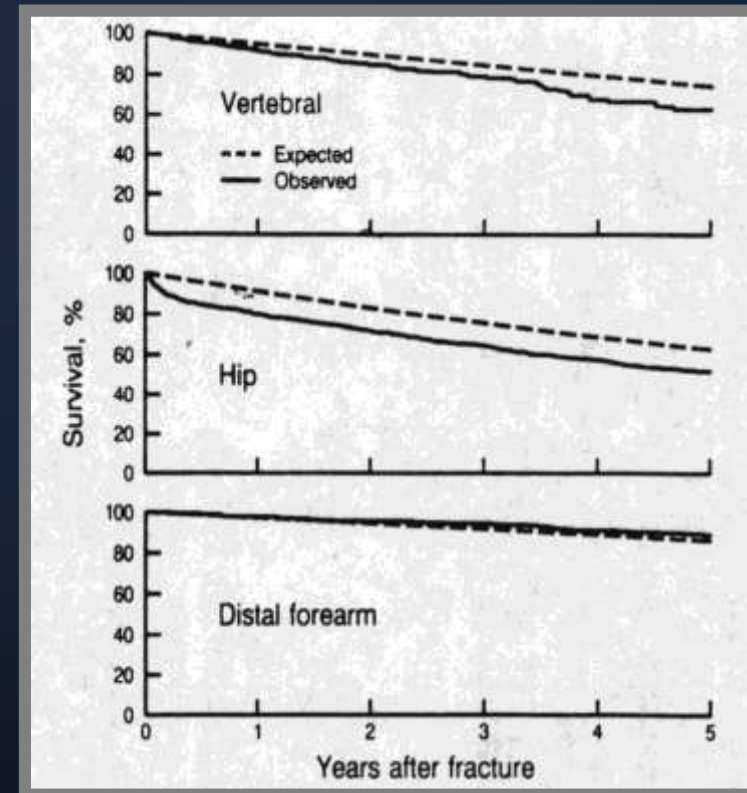
Increased Fracture Risk

- After first VCF, risk of subsequent VCF is increased
 - **5 fold** after first VCF
 - **12 fold** after 2 or more VCFs
 - **75 fold** after 2 or more VCFs and low bone mass (below the 33rd percentile)

Increased Mortality

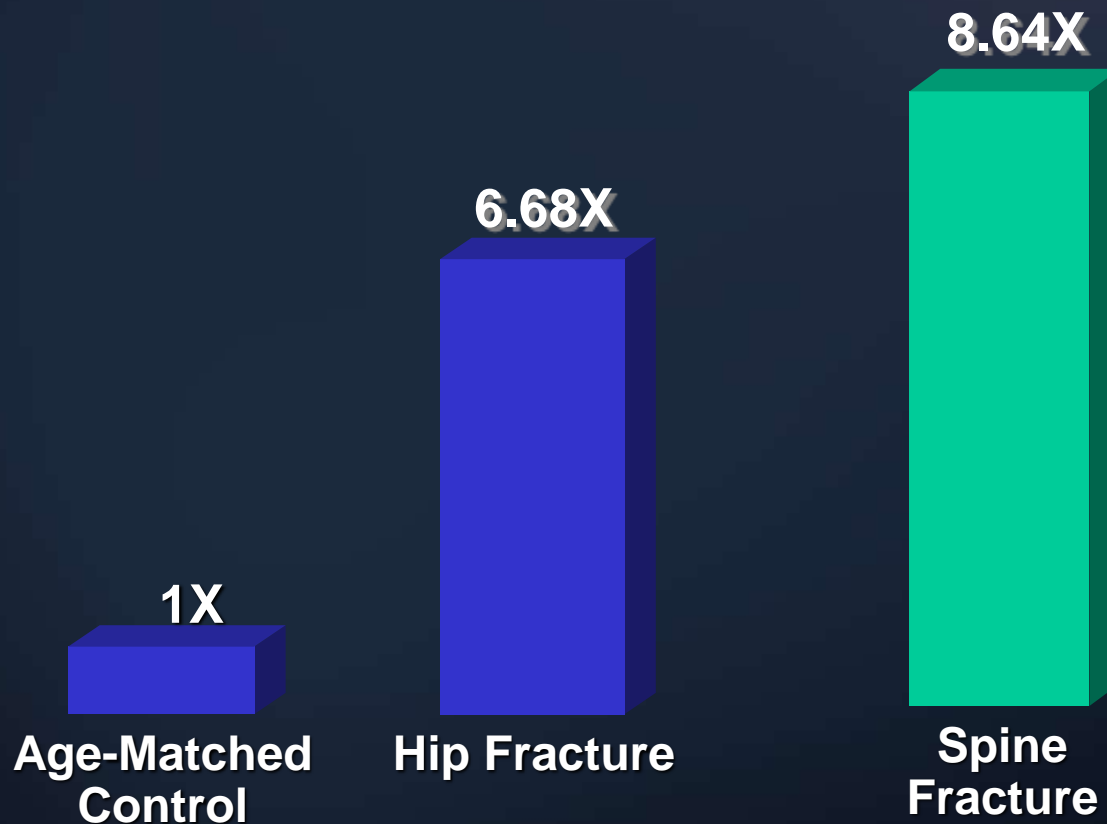
Retrospective analysis of Rochester, MN patients demonstrated the 5 year survival rate after VCF is:

- Significantly worse than expected (61% vs 76%)
- Comparable to hip fx at 5 yrs
- Steadily declines compared to excess mortality in first 6 months after hip fx



Increased Mortality

Relative Risk of Death in 3.8 yrs



Increased Mortality

Prospective study of 9,575 women followed > 8 years demonstrated:

- Patients with VCF have a 23-34% increased mortality rate compared to patients without VCF
- VCF patients are 2-3xs more likely to die of pulmonary causes
- Most common cause of death was pulmonary disease, including COPD and pneumonia

Osteoporotic Fractures

Economic Cost



- 2001 U.S. Hospital and Nursing Home Direct Expenditures > \$17 Billion
 - \$47 Million Daily
- 2030 Projected Cost > \$60 Billion
 - \$164 Million Daily

Vertebral Compression Fractures

Economic Cost



- 161,000 PCP office visits per year¹
- 150,000 hospitalizations per year¹
- Mean length of stay (LOS) is 10.1 days²
- VCFs are among the top 3 conditions accounting for LOS²
- \$12,300 average hospital charge³

1 Riggs and Melton, Bone 1995

2 Papaioannou et al., Osteoporosis Int'l 2001

3 MedPAR 1996

Vertebral Compression Fractures

Economic Cost

- Long-term increased morbidity and mortality
- Bone loss up to 2% per week reported after prolonged bed rest¹

THE HUMAN COST

Downward Spiral

