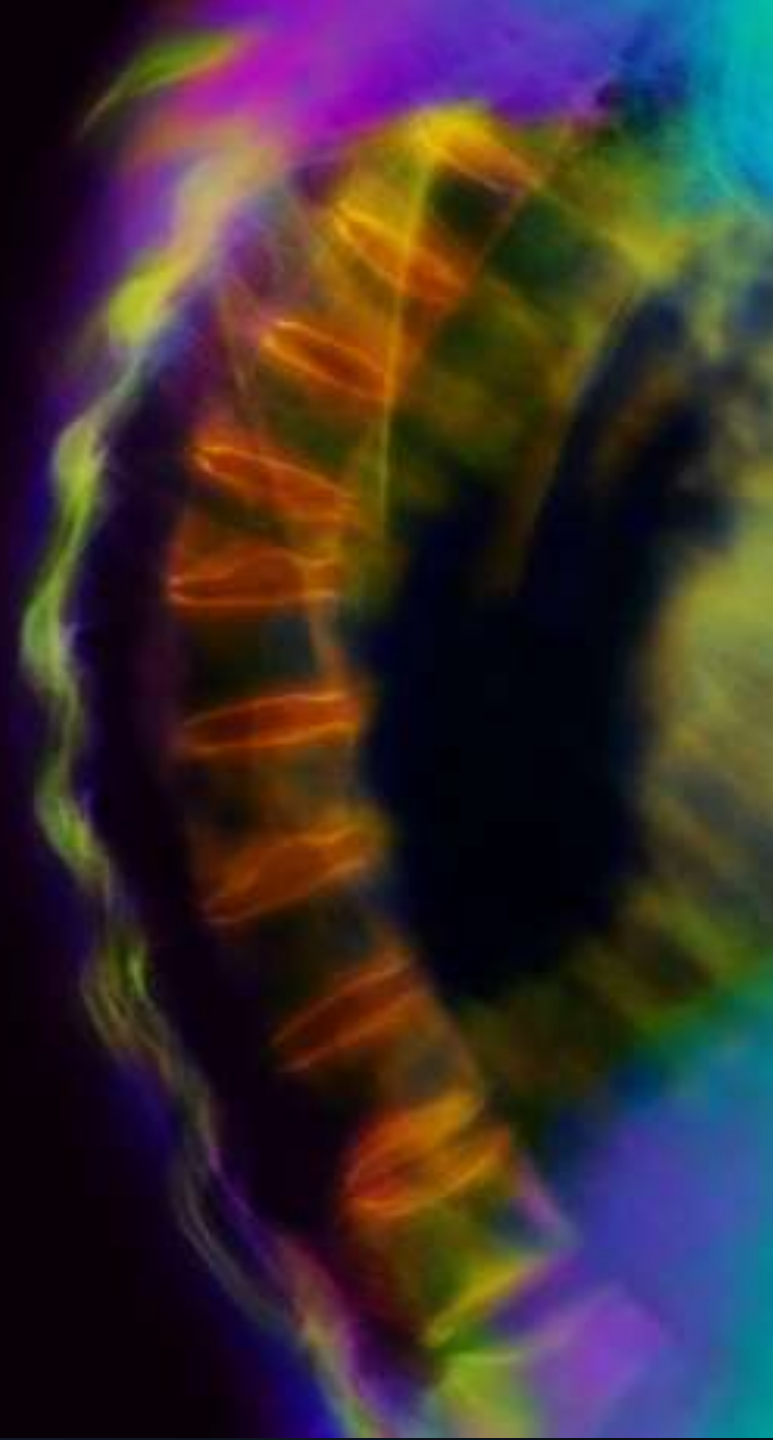


The  
Downward  
Spiral:  
*Impact of  
Vertebral Body  
Compression  
Fractures*



# Osteoporosis

## *A Public Health Problem*

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- Worldwide, 1 in 3 women and 1 in 8 men over 50 are affected by osteoporosis<sup>1</sup>
- 44 Million People U.S. at Risk<sup>2</sup>
- 1.5 Million Fragility Fractures in US<sup>2</sup>
  - **700,000 spine**
  - 300,000 hip
  - 250,000 wrist
  - 300,000 other

<sup>1</sup> *International Osteoporosis Foundation*

<sup>2</sup> *National Osteoporosis Foundation*

# Osteoporosis

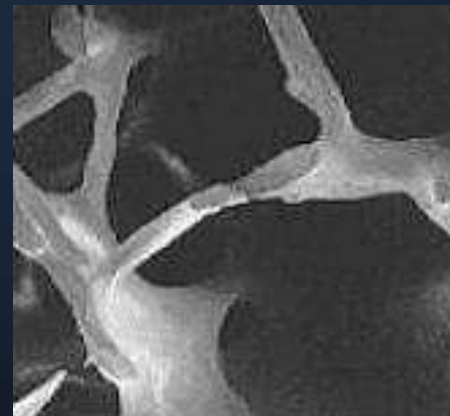
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Osteoporosis is defined as a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture.

NIH Consensus Development Conference, March 2000



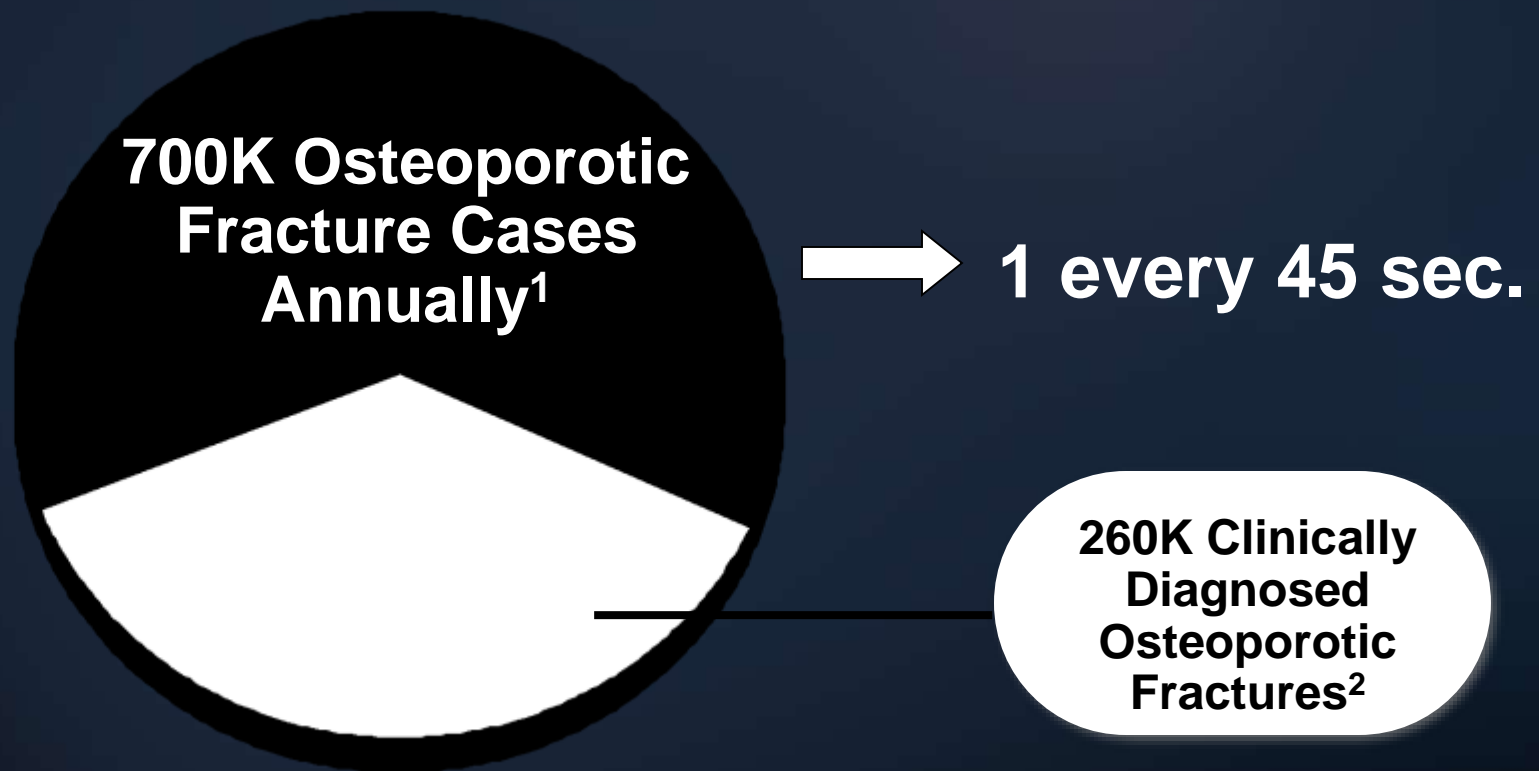
Normal Bone



Osteoporotic Bone

# Incidence of VCFs

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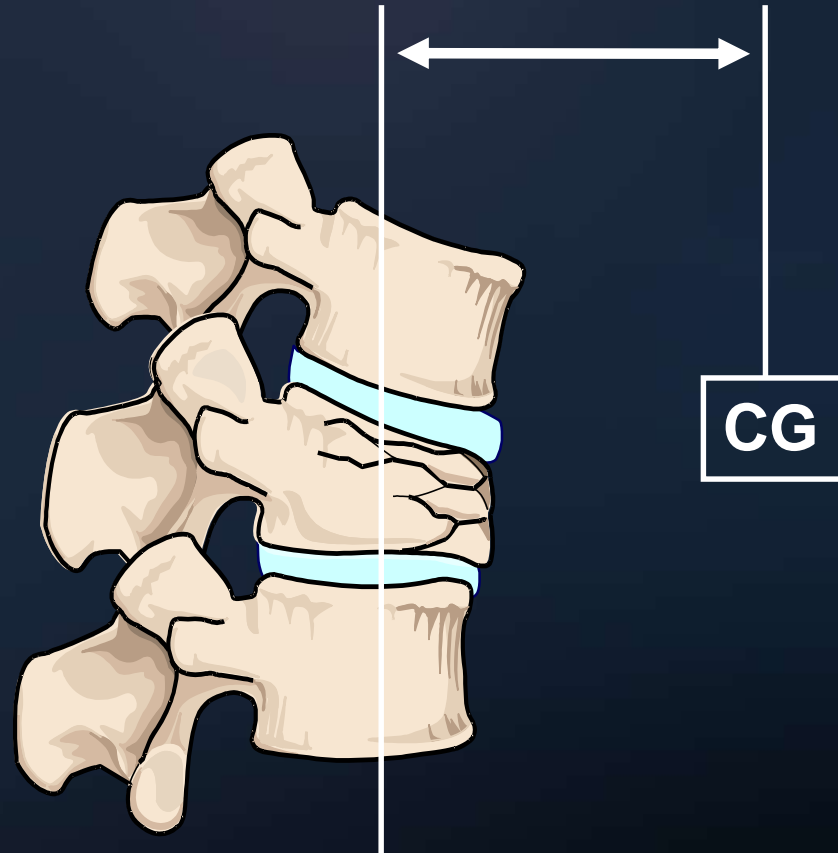


*1 National Osteoporosis Foundation*

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

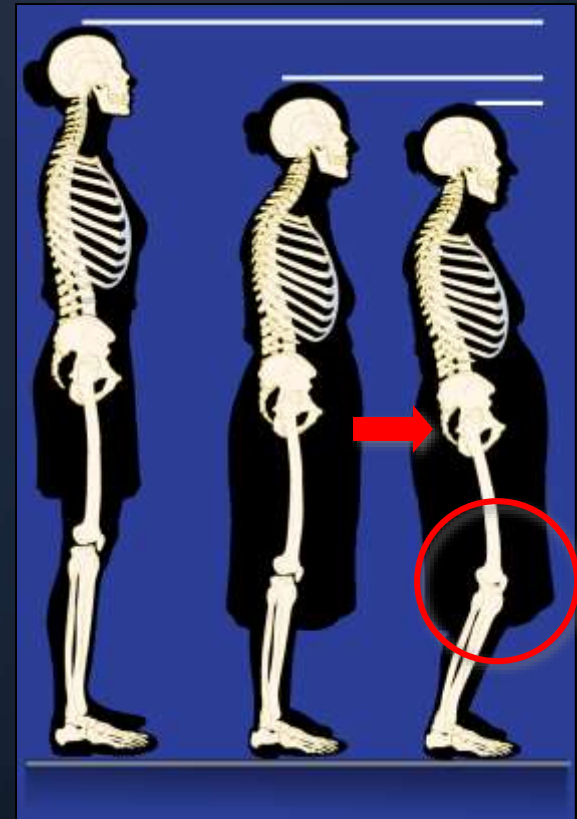
# Biomechanics of VCF

- 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 balance<sup>1</sup>
  - Decrease in gait velocity<sup>1</sup>
  - Increased muscle fatigue<sup>1</sup>
  - Increased risk of falls and additional fractures<sup>2</sup>



<sup>1</sup> Gold et al., *Osteoporosis* 2001

<sup>2</sup> 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

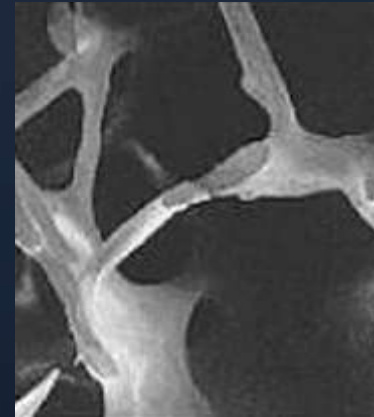




# Symptomatic VCFs

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- n 260,000 pts/yr refractory to medical therapy<sup>1</sup>
- n Only fracture not treated in an orthopedic manner
  - Open surgical repair too invasive
  - Poor outcomes (osteopenic bone)
- n No orthopedic treatment may lead to long-term increased morbidity, mortality



<sup>1</sup> Cooper et al., *J Bone Min Research* 1992

# THE HUMAN COST

## *Impaired Function*

- n Spinal deformity and pain impair function, decrease mobility<sup>1,2,3</sup>
- n Decreased activity leads to more bone loss<sup>1</sup>
- n Compressed abdomen decreases appetite<sup>1,3</sup>
- n Sleep disorders develop<sup>1,3</sup>



1 Silverman, Bone 1992

2 Lyles et al., Am J Med 1993

3 Gold et al., Osteoporosis 2001

# *Increased Pulmonary Disorders*

---

## **VCF reduces pulmonary function<sup>1</sup>**

- n One thoracic VCF causes 9% loss of forced vital capacity<sup>2</sup>
- n Lung function (FVC, FEV1) is significantly reduced in patients with thoracic and lumbar fracture compared to patients with low back pain<sup>1</sup>
- n **Degree of kyphosis is significantly related to risk of pulmonary death ( $p=0.005$ )<sup>3</sup>**

*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*

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



# *Increased Fracture Risk*

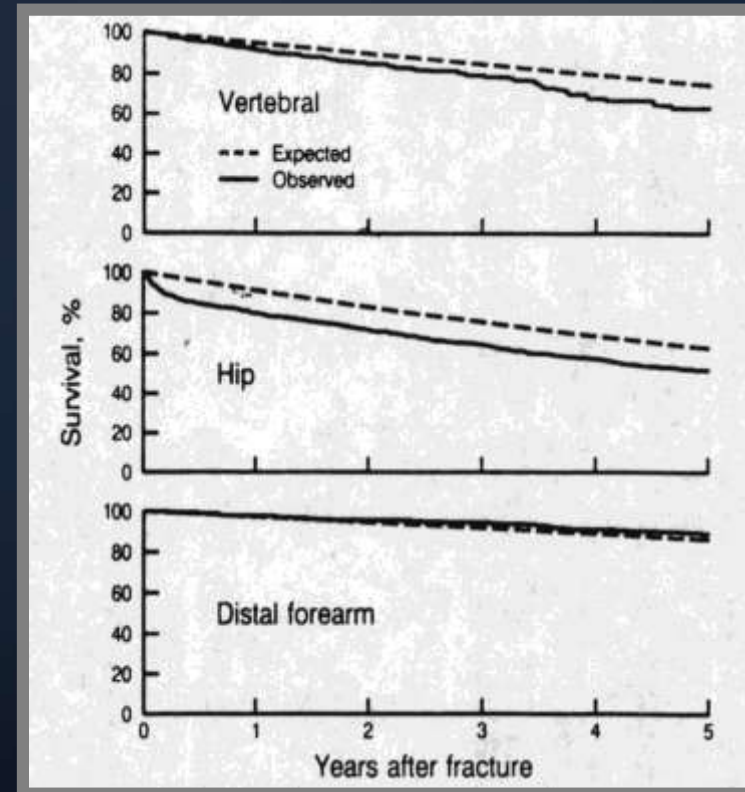
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- After first VCF, risk of subsequent VCF is increased
  - **5 fold** after first VCF
  - **12 fold** after 2 or more VCFs
  - **75 fold** after 2 or more VCFs and low bone mass (below the 33<sup>rd</sup> percentile)

# Increased Mortality

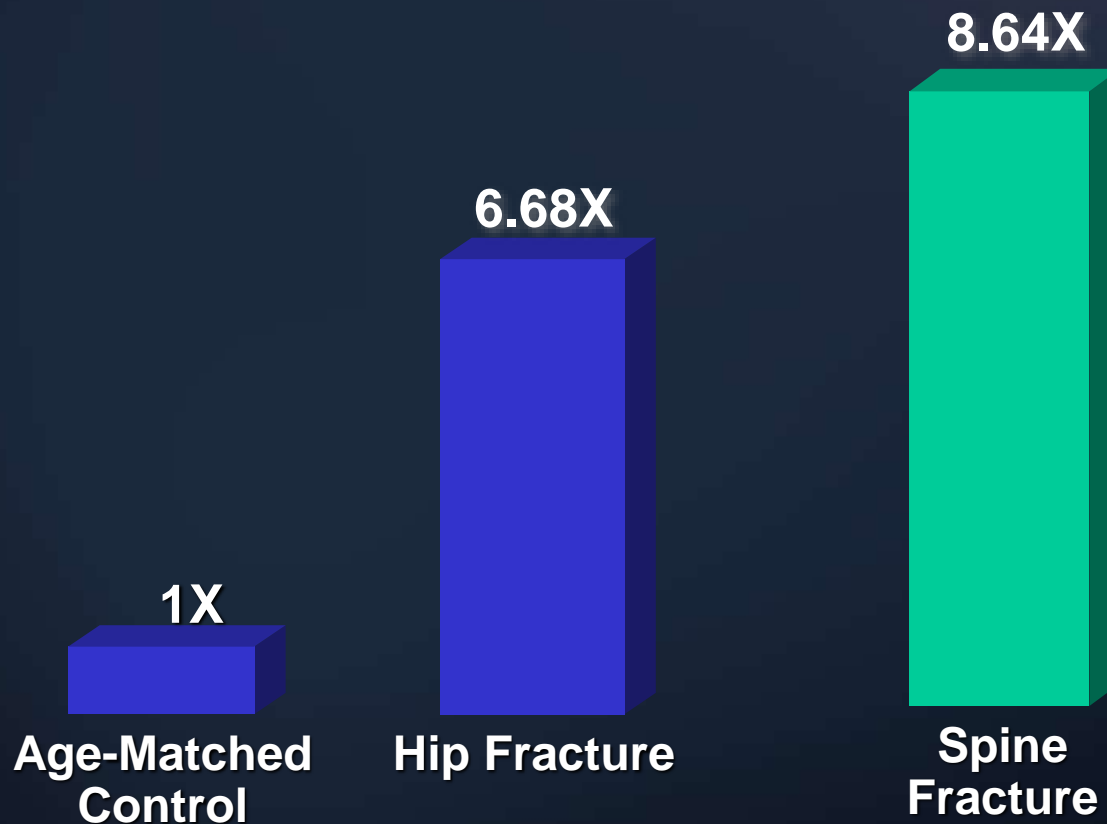
Retrospective analysis of Rochester, MN patients demonstrated the 5 year survival rate after VCF is:

- 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:

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



# Osteoporotic Fractures

## *Economic Cost*

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

# Vertebral Compression Fractures

## *Economic Cost*

---

- 161,000 PCP office visits per year<sup>1</sup>
- 150,000 hospitalizations per year<sup>1</sup>
- Mean length of stay (LOS) is 10.1 days<sup>2</sup>
- VCFs are among the top 3 conditions accounting for LOS<sup>2</sup>
- \$12,300 average hospital charge<sup>3</sup>

*1 Riggs and Melton, Bone 1995*

*2 Papaioannou et al., Osteoporosis Int'l 2001*

*3 MedPAR 1996*

# Vertebral Compression Fractures

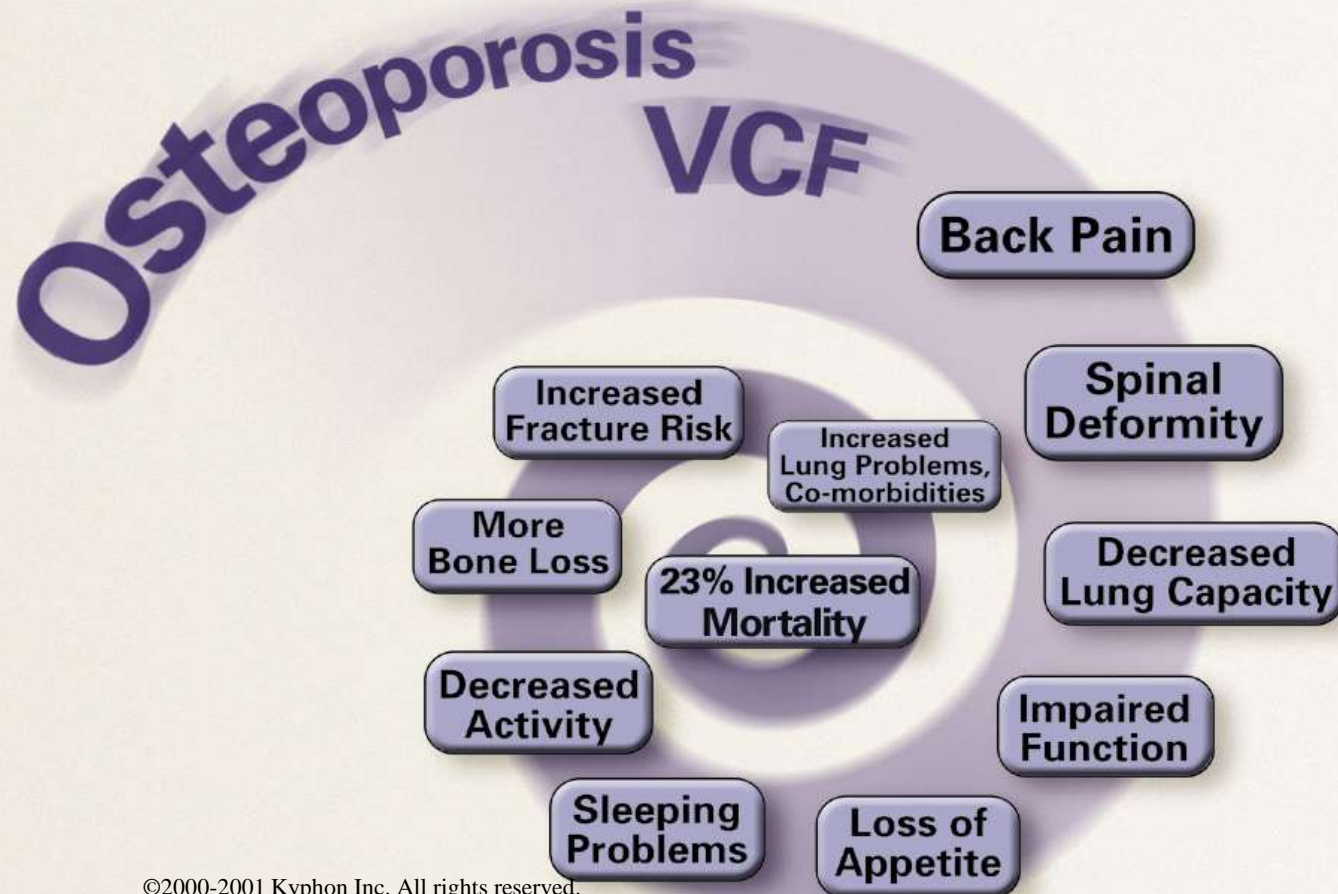
## *Economic Cost*

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- Long-term increased morbidity and mortality
- Bone loss up to 2% per week reported after prolonged bed rest<sup>1</sup>

# THE HUMAN COST

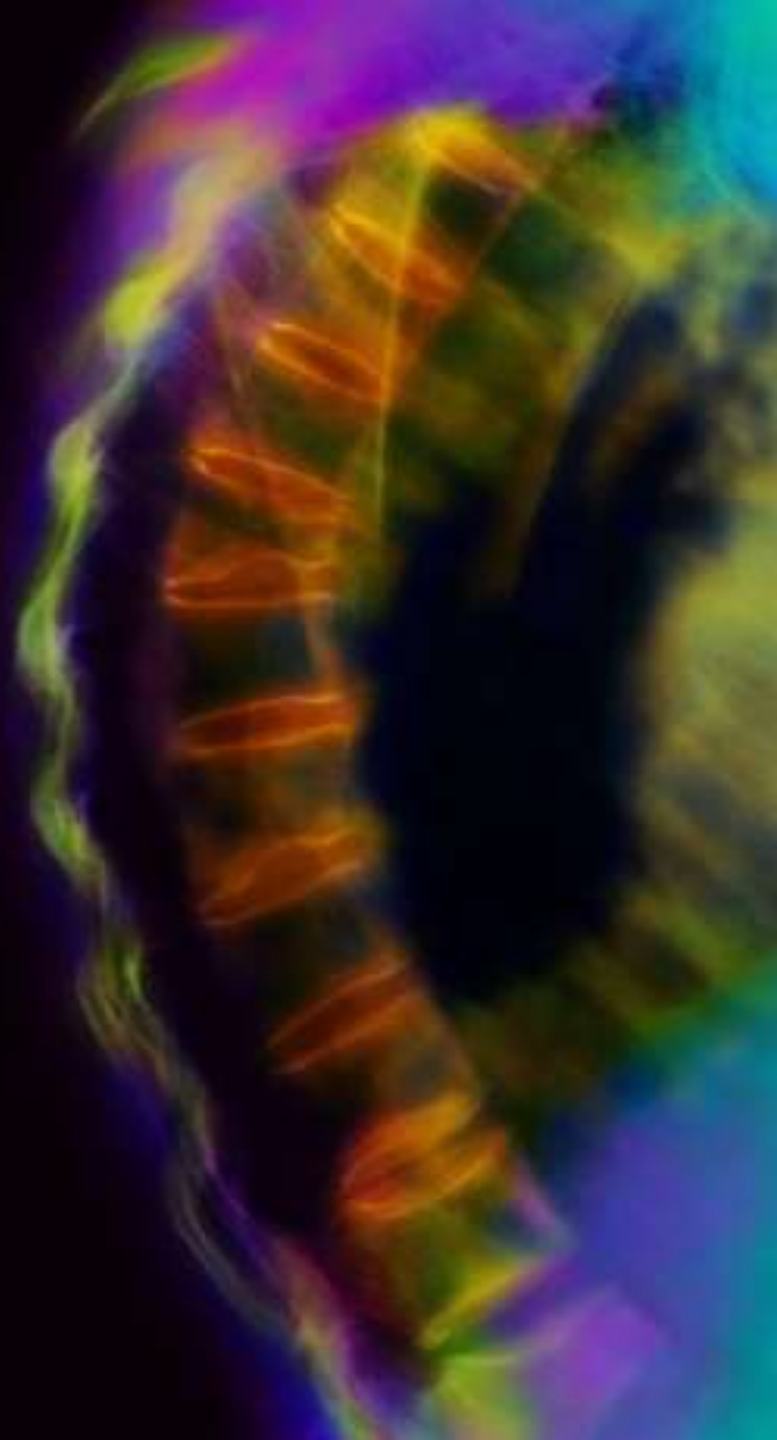
## *Downward Spiral*



# INDICATION & TIMING FOR SURGERY

- Neurologic deficit
- Severe deformity?
- Severe pain?

# Vertebral Body Compression Fracture Treatment Options

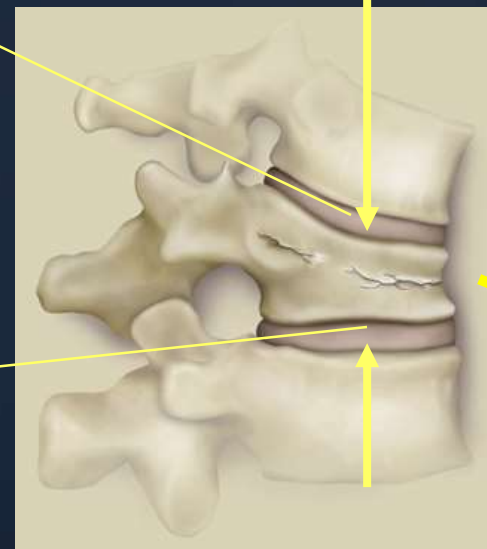


# Vertebral Body Compression Fracture (VCF)



Normal

Wedge-shaped

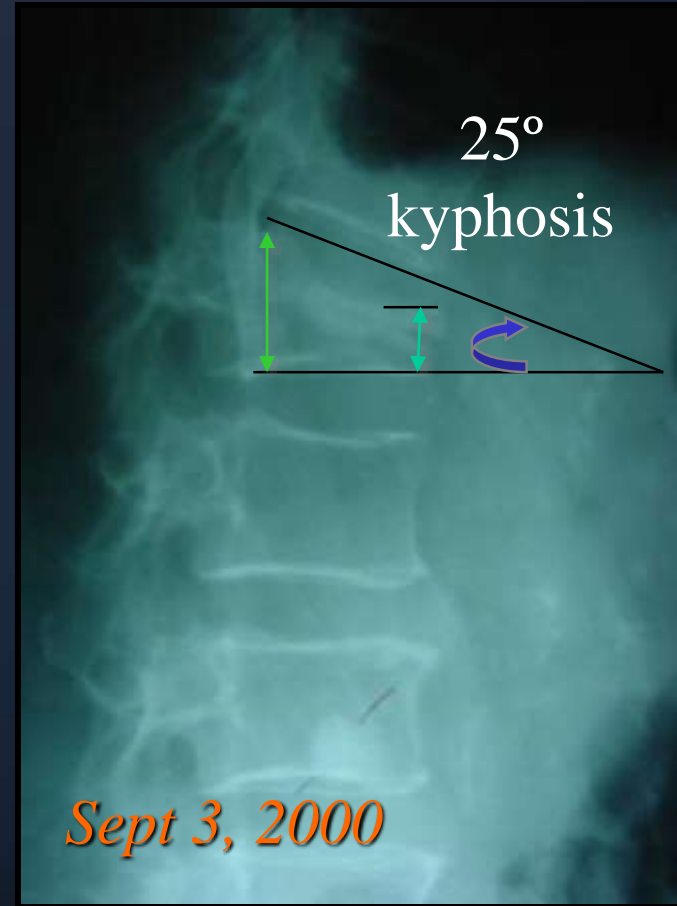
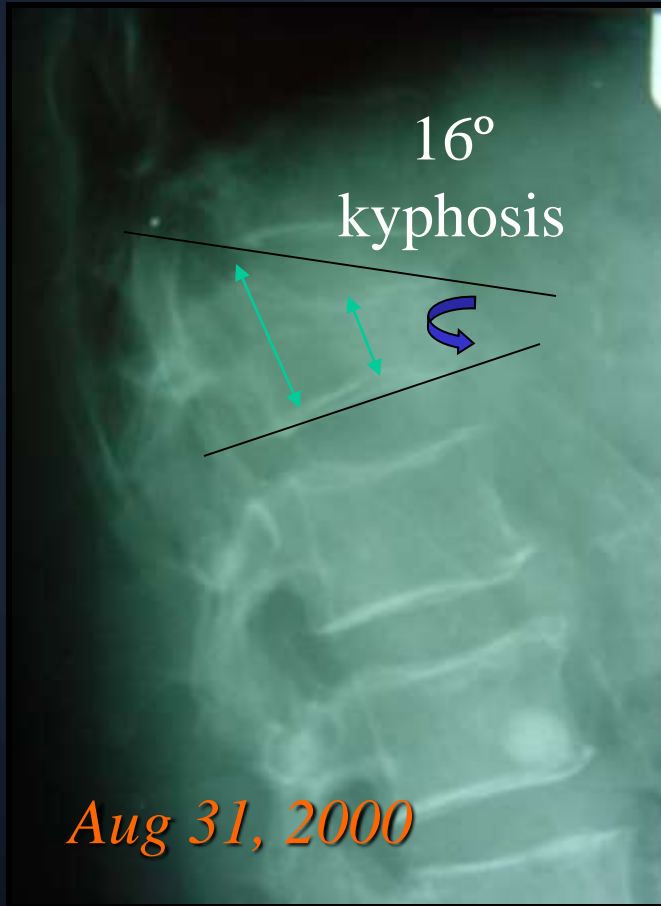


Fractured

Depressed  
endplate(s)

Spine  
shorter,  
tilted  
forward

# Deformity Progression





# VCF Treatment Options

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## Medical Management

### n Treatment Protocol

- Bed rest
- Narcotic analgesics
- Braces

### n Shortcomings

- May fail to relieve pain
- Does not provide long-term functional improvement
- May exacerbate bone loss
- Does not attempt to restore the anatomy

# VCF Treatment Options

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## Open Surgical Treatment

### n Indication

- Only if neurologic deficit (very rare, only 0.05%)
- Instrumented fusion, anterior or posterior

### n Shortcomings

- Invasive
- Poor outcomes in osteopenic bone

# VCF Treatment Options

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## Vertebroplasty

- n Designed to stabilize painful VCFs
- n Shortcomings
  - Risk of filler leaks (27-74% reported<sup>1,2,4,5,6,7,8,9,10</sup>)
    - High pressure injection
    - Uncontrolled fill
    - High complication rate (1-20% reported<sup>3,4,5</sup>)
  - Freezes spinal deformity
    - Does not reduce fracture or restore anatomy
    - Not designed to reposition bone

1 Cortet et al., J Rheum 1999

2 Alvarez et al., Eurospine 2001

3 Padovani et al., AJNR 1997

4 Weill et al., Radiology 1996

5 Jensen et al., AJNR 1997

6 Cotten et al. Radiology 1996

7 Gaughen et al., AJNR 2002

8 Grados et al., Rheumatology 2000

9 Peh et al., Radiology 2002

10 Ryu et al., J Neurosurgery 2002

# Why Fracture Reduction?

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- What is orthopedic reduction?
  - The restoration, by surgical or manipulative procedures, of a part to its normal anatomical relation<sup>1</sup>
- What is the goal?
  - To produce optimal outcomes with early diagnosis and treatment<sup>2</sup>
  - To accommodate the frail physical status and co-morbidities of geriatric patients<sup>2</sup>

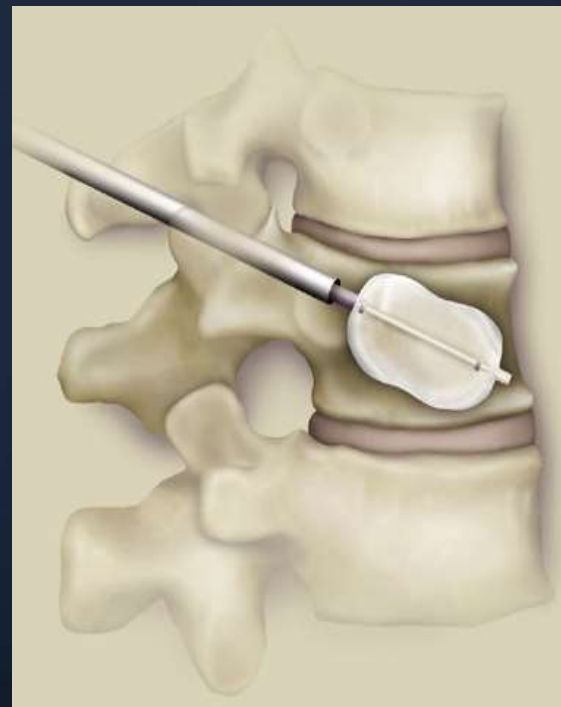
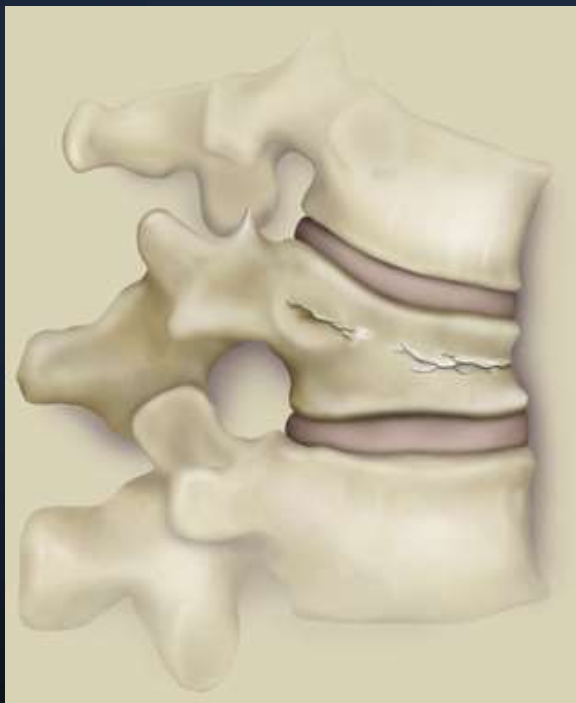
*1 Stedman 's Concise Medical Dictionary. 1997. Williams and Wilkins.*

*2 Brakoniecki, Anesthetic Management of the Trauma Patient with Skeletal Injuries, Skeletal Trauma, W.B. Saunders Company, 1998, 1:7:171-172*

# New VCF Treatment Option

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## Minimally Invasive Fracture Reduction

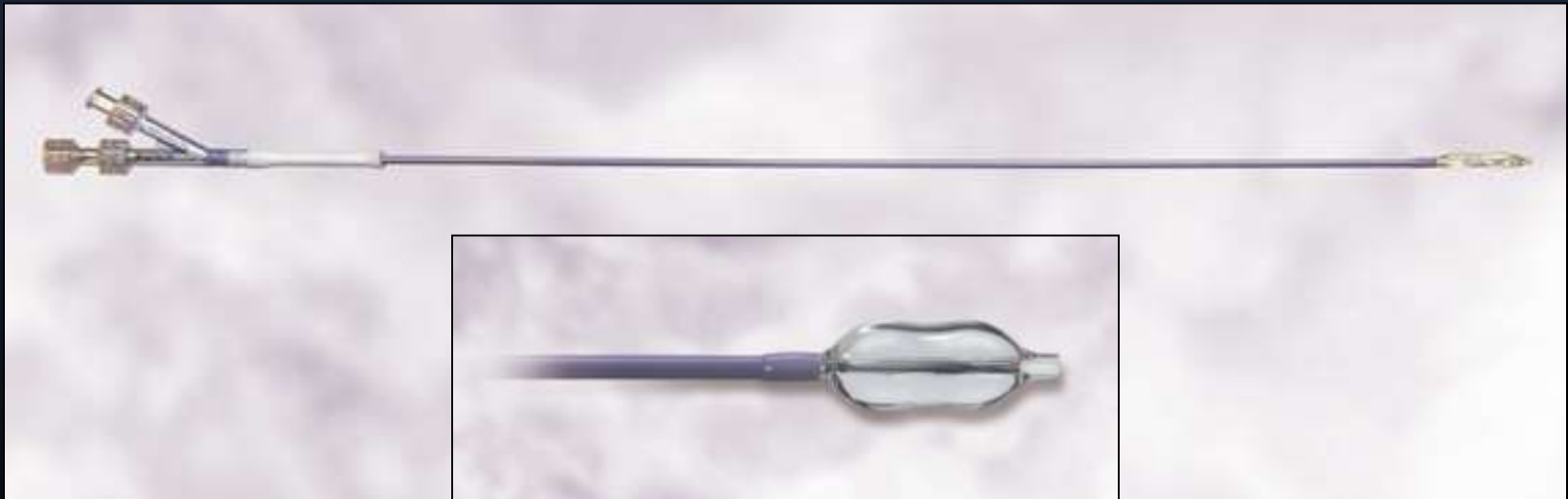


# Minimally Invasive Fracture Reduction

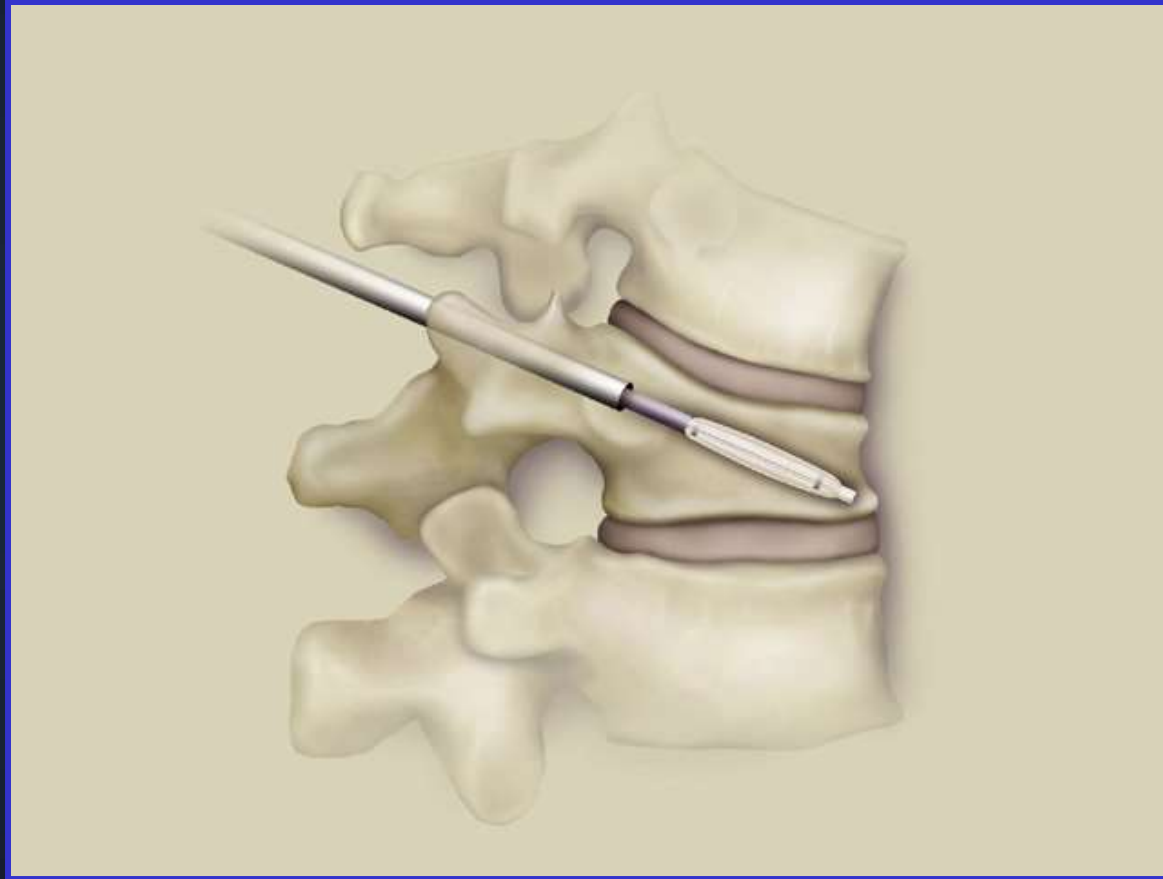
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## KyphX® Inflatable Bone Tamp (IBT)

For use as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneus.

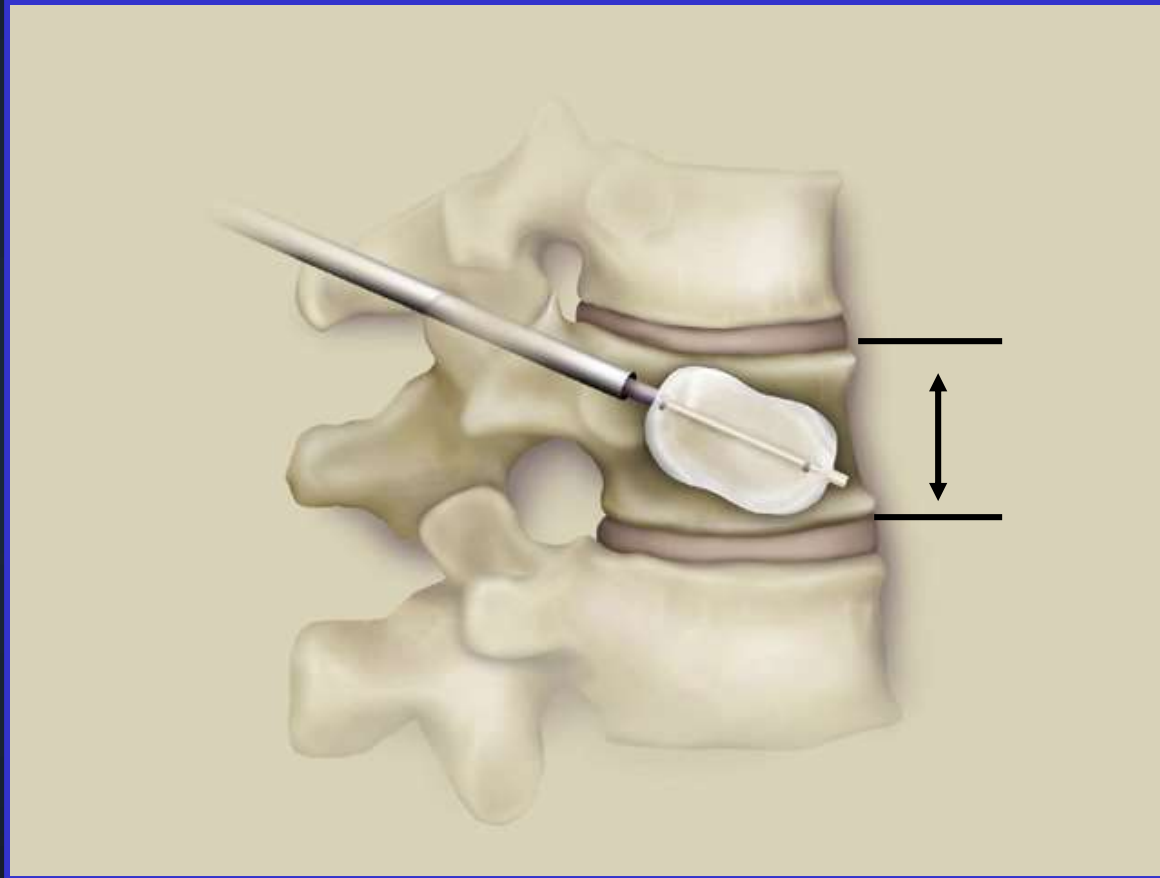


# KyphX<sup>®</sup> Introducer Tool Kit



Allows precise, minimally invasive access to the vertebral body and provides a working channel

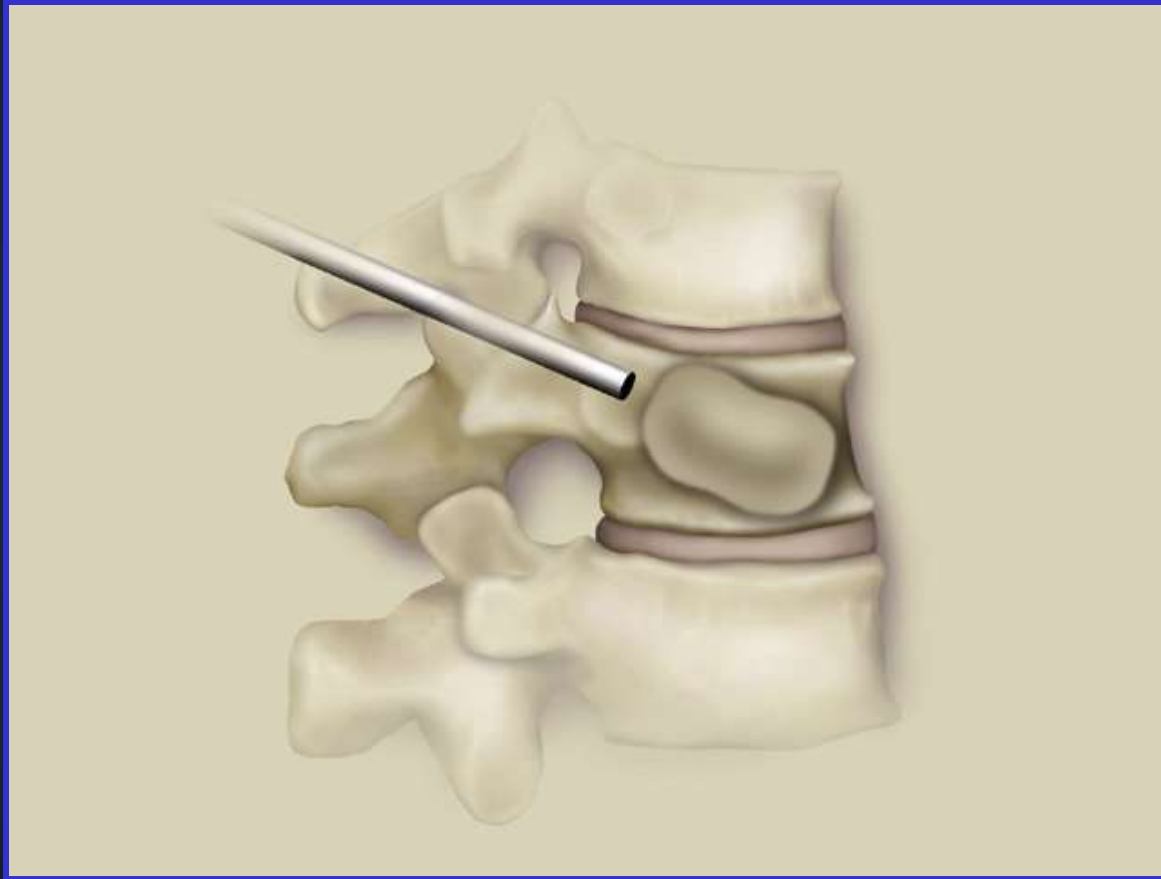
# KyphX<sup>®</sup> IBT Inflation



Reduces the fracture, compacts the bone,  
and may elevate the endplates



# KyphX<sup>®</sup> IBT Removal



Leaves a defined cavity within the  
vertebral body

# Minimally Invasive Fracture Reduction

## *Clinical Experience*

---

- Over 3 years of orthopedic fracture reduction
- As of June 30, 2002
  - Fractures reduced > 22,000
  - Patients > 17,000

# Possible causes of VCFs

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- Osteolytic lesions
  - Multiple Myeloma
  - Bone metastases
  - Paget's disease
- Trauma
  - 1/2 of all trauma cases are misclassified

# Case Study

Patient: 55 YO Male  
Diagnosis: Secondary osteoporosis  
Fracture Reduced: L-1, 3 day old



# Case Study

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Patient: 89 YO Female  
Diagnosis: Primary osteoporosis  
Fracture Reduced: T-7, 1 year old

