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 osteoporosis\(^1\)
- 44 Million People U.S. at Risk\(^2\)
- 1.5 Million Fragility Fractures in US\(^2\)
  - 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

700K Osteoporotic Fracture Cases Annually\(^1\)

1 every 45 sec.

260K Clinically Diagnosed Osteoporotic Fractures\(^2\)

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1 National Osteoporosis Foundation
2 Cooper et al., J Bone Min Resarch 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

White III and Panjabi 1990
Biomechanics of VCF

- Knees bend, pelvis tilts forward to counteract forward bending
  - Change in balance\(^1\)
  - Decrease in gait velocity\(^1\)
  - Increased muscle fatigue\(^1\)
  - Increased risk of falls and additional fractures\(^2\)

1 Gold et al., Osteoporosis 2001
2 Ross et al., Annals Int Med 1991
Physical Impact of VCF

Age 50

Age 75

National Osteoporosis Foundation
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

Gold et al., Osteoporosis 1996, 2001
Symptomatic VCFs

- 260,000 pts/yr refractory to medical therapy
- 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 Resarch 1992
THE HUMAN COST
Impaired Function

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

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

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

Gold, Bone 1996
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)

Ross et al., Ann Inter Med 1991
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

Cooper et al., Am J Epidemiology 1993
Increased Mortality

Relative Risk of Death in 3.8 yrs

- Age-Matched Control: 1X
- Hip Fracture: 6.68X
- Spine Fracture: 8.64X

Cauley et al., Osteoporosis International 2000
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

Kado et al., Arch Intern Med 1999
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 year\(^1\)
- 150,000 hospitalizations per year\(^1\)
- Mean length of stay (LOS) is 10.1 days\(^2\)
- VCFs are among the top 3 conditions accounting for LOS\(^2\)
- $12,300 average hospital charge\(^3\)

\(^1\) 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 rest\(^1\)

\(^1\) Johnell et al., Osteoporosis Int 2000
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

Aug 31, 2000

16° kyphosis

Sept 3, 2000

25° kyphosis

Lieberman et al., Spine 2001
VCF Treatment Options

Medical Management

- **Treatment Protocol**
  - Bed rest
  - Narcotic analgesics
  - Braces

- **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

Open Surgical Treatment

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

- **Shortcomings**
  - Invasive
  - Poor outcomes in osteopenic bone
VCF Treatment Options

Vertebroplasty

- Designed to stabilize painful VCFs

- Shortcomings
  - Risk of filler leaks (27-74% reported\textsuperscript{1,2,4,5,6,7,8,9,10})
    - High pressure injection
    - Uncontrolled fill
    - High complication rate (1-20% reported\textsuperscript{3,4,5})
  - Freezes spinal deformity
    - Does not reduce fracture or restore anatomy
    - Not designed to reposition bone

\textsuperscript{1} Cortet et al., J Rheum 1999  \textsuperscript{5} Jensen et al., AJNR 1997  \textsuperscript{8} Grados et al., Rheumatology 2000
\textsuperscript{2} Alvarez et al., Eurospine 2001  \textsuperscript{6} Cotten et al. Radiology 1996  \textsuperscript{9} Peh et al., Radiology 2002
\textsuperscript{3} Padovani et al., AJNR 1997  \textsuperscript{7} Gaughen et al., AJNR 2002  \textsuperscript{10} Ryu et al., J Neurosurgery 2002
\textsuperscript{4} Weill et al., Radiology 1996
Why Fracture Reduction?

• What is orthopedic reduction?
  – The restoration, by surgical or manipulative procedures, of a part to its normal anatomical relation\textsuperscript{1}

• What is the goal?
  – To produce optimal outcomes with early diagnosis and treatment\textsuperscript{2}
  – To accommodate the frail physical status and co-morbidities of geriatric patients\textsuperscript{2}

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

Minimally Invasive Fracture Reduction
Minimally Invasive Fracture Reduction

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® Introducer Tool Kit

Allows precise, minimally invasive access to the vertebral body and provides a working channel
KyphX® IBT Inflation

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

- Osteolytic lesions
  - Multiple Myeloma
  - Bone metastases
  - Paget’s disease

- Trauma
  - $\frac{1}{2}$ of all trauma cases are misclassified
Case Study

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

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