Vertebral Body Compression Fracture Treatment Options
Why have we been content to leave the spine in a physiologically and biomechanically compromised condition?
Fracture Treatment Objectives

Four AO principles

- Fracture reduction and fixation to restore anatomical relationships
- Stability by fixation or splintage, as the nature of the fracture and the injury requires
- Preservation of blood supply to soft tissues and bone by careful handling and gentle reduction techniques
- Early and safe mobilization of the part and the patient

*Arbeitsgemeinschaft Osteosynthesefragen (English translation: Association for the Study of Internal Fixation - ASIF)
1 Ruedi & Murphy, AO Principles of Fracture Management, Thieme, Stuttgart, New York, 2000
Vertebral Body Compression Fracture (VCF)

Normal

Fractured

Wedge-shaped

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\(^1,2,4,5,6,7,8,9,10\))
    - High pressure injection
    - Uncontrolled fill
    - High complication rate (1-20% reported\(^3,4,5\))
  - 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?

- **What is orthopedic reduction?**
  - The restoration, by surgical or manipulative procedures, of a part to its normal anatomical relation\(^1\)

- **What is the goal?**
  - To produce optimal outcomes with early diagnosis and treatment\(^2\)
  - To accommodate the frail physical status and co-morbidities of geriatric patients\(^2\)

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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
Minimally Invasive Fracture Reduction

KyphX® Inflatable Bone Tamp has been developed for patients with symptomatic VCFs
Possible causes of VCFs

- Primary osteoporosis
- Secondary osteoporosis
  - Drug-induced (corticosteroids, tobacco, barbituates, heparin)
  - Endocrine (hyperparathyroidism, diabetes)
  - Miscellaneous (renal failure, COPD, rheumatoid arthritis, hepatic disease or transplant)

Possible causes of VCFs

- Osteolytic lesions
  - Multiple Myeloma
  - Bone metastases
  - Paget’s disease
- Trauma
  - ½ of all trauma cases are misclassified
Summary

- The general goal for fracture treatment is restoration of anatomy and early return to function
- Conventional therapy not always effective
- KyphX® IBT is a new option for VCFs designed to:
  - reduce the fracture
  - move cancellous bone (elevate endplates)
  - create void inside vertebral body
- As with hip fracture surgery, early diagnosis and intervention are important for fracture reduction
KyphX Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneus.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See device Instructions for Use for complete indications, precautions, and method of use.

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