Kyphoplasty

Richard M. Spiro, MD
Michael Horowitz, MD
Painful Osteoporotic Compression Fractures

Treatment Objectives & Options
Why have we been content to leave the spine in a physiologically and biomechanically compromised condition?
VCF Treatment Objectives

- Restoration of anatomy
- Early diagnosis and treatment for optimal outcomes
- Special care for geriatric patients
  - frail physical status and comorbidities

1 Colton, CL. Ch. 1 in Skeletal Trauma. 1998
2 Brakoniecki et al. Ch. 7 in Skeletal Trauma. 1998
VCF Treatment Options
Management for Pain

**Medical Management**
- Bed rest
- Narcotic analgesics
- Braces

**Open Surgical Treatment**
- Vertebroplasty
Balloon Kyphoplasty

Overview of Treatment Steps

1) The balloon is inserted into the fractured vertebral body
Balloon Kyphoplasty

Overview of Treatment Steps

2) The balloon is inflated, reducing the fracture and elevating the endplates
3) The balloon is deflated and withdrawn, leaving a cavity within the vertebra
Balloon Kyphoplasty

Overview of Treatment Steps

4) The void is filled with KyphX® HV-R™ Bone Cement, creating an internal cast.
Case Study

Patient: 73 YO Female
Diagnosis: Primary Osteoporosis
Fracture Reduced: L1, 6 months old

Courtesy of Mohammad Majd, M.D., Jeffersonville, IN
## Case Study

<table>
<thead>
<tr>
<th>Patient:</th>
<th>55 YO Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis:</td>
<td>Secondary osteoporosis</td>
</tr>
<tr>
<td>Fracture Reduced:</td>
<td>L-1, 3 day old</td>
</tr>
</tbody>
</table>

*Courtesy of Ulrich Berlemann, M.D., Germany*
Patient Selection and Work-Up
Diagnosis

Identify painful level
Define fracture configuration
Define fracture age
Osteoporotic Fracture?
History and Physical Exam

- Has there been a recent event, prior to onset of pain?
- Does direct pressure on suspect vertebral bodies elicit pain?
- Pain findings on physical exam should be concordant with radiographic findings.
- Some patients will have multiple painful vertebral bodies.
X-Ray

Older films (if available) may be useful to assess fracture progression
Case Study

Patient: 80 YO Male  
Diagnosis: Steroid-induced osteoporosis  
Fracture Reduced: T-8, 10 weeks old  

Courtesy of Eeric Truumees, M.D., Southfield, MI
Case Study

Patient: 75 YO Female
Diagnosis: Primary osteoporosis
Fracture Reduced: L-3, 4 week old

Courtesy of Jonathan Hyde, M.D., Miami Beach, FL
MRI

- $T_1$ weighted shows high intensity for fat, subacute hematomas and Gadolinium enhanced substances
- $T_2$ weighted shows high intensity for conditions that increase free water, such as acute fracture
- STIR MRI sequence is most sensitive for water content when assessing fractures
MRI

Notice the high signal intensity around the fracture

T1

T2
CT and Bone Scan

- CT Scan
  - Differentiates fat from other soft tissue
  - Shows structure of bone
  - Extremely high contrast between calcified structures (cortical and trabecular bone) and soft tissue
  - Effectively limited to axial plane

- Use CT plus Bone Scan to determine fracture when MRI cannot be used
  - Implantable metal devices
Balloon Kyphoplasty
Surgical Approaches and Technique
Balloon Kyphoplasty Approaches

Transpedicular

Extrapedicular

Both approaches are intended to be bilateral
TRANSPEDICULAR APPROACH

Access

- Use fluoroscopy to locate the pedicle cutaneously
- Place a small incision lateral and superior to the cutaneous pedicle location
- This will allow proper convergence through the tissues to the pedicle entry point
TRANSPEDICULAR APPROACH

Inflatable Bone Tamp Inflation

- Place contralateral tools and IBT

- Increase the volume in both IBTs in small (0.25-0.5 cc) increments

- Assess tamp size and position in lateral and AP views

- Sequentially inflate until an inflation endpoint is reached
VCF Treatment

Cementing

- Deflate and remove IBTs

- Insert BFD to within 3-5mm of anterior cortex

- Under continuous fluoroscopy slowly inject the cement mix

- Leave the bone void filler device anterior
VCF Treatment
Cementing AP

- Final A-P view of cement fill
- Cement fills in interstices of fractured bone
Balloon Kyphoplasty Experience
Balloon Kyphoplasty

Since 1998

Approximately 95,000 fractures have been treated worldwide
Patient Outcomes

- Correction of Vertebral Body Deformity
- Reduction in Pain
- Improvement in Quality of Life
- Improvement in Ability to Perform Activities of Daily Living
- High rates of Patient Satisfaction
- Low Complication Rate
Percent Lost Height Restored

- Based on the mean height measurement of the closest, unfractured vertebrae above and below the treated level

- Anterior, midline, and sometimes posterior measurements are taken
Example: Percent Lost Height Restored

Avg. 30 mm

% Lost Height Restored = \(\frac{(24 - 20)}{(30 - 20)}\) or \(\frac{4}{10} = 40\%\)
Vertebral Body Height Restoration

Percent of Lost Vertebral Body Height Restored

- In a U.S. Multicenter, Prospective Single Arm Study
  - 65 patients treated – 30.2% of the average lost midline height was restored for all fractures
  - Among reducible fx §*, (78% of all fx §), an average of 58% of lost midline height was restored
  - Mean fracture age was 4.3 months
  - No evidence of loss of improvement at two year follow-up

* §Reducible § refers to measurable fractures where at least 15% of predicted height was lost due to fracture.

Kyphon U.S. Study; Data on file at Kyphon Inc.
Vertebral Body Height Restoration
Percent of Lost Vertebral Body Height Restored

- Lieberman et al (2001) states of 70 fractures treated, average lost midline height restored was 35%
  - In the group of fx $\$ that were reducible (70% of all fx $\$ treated), lost midline height restored was 47%*
  - Mean fracture age was 5.9 months

*A reducible fracture is defined by Lieberman as having restored at least 10% of lost vertebral body height at the midline with kyphoplasty.

Lieberman et al. (2001) Spine 26: 2, 1631-1638
Vertebral Body Height Restoration

Percent of Lost Vertebral Body Height Restored

- Theodorou et al (2002) reported that among 24 fractures average lost height restored was 52%
  - Average lost anterior height restored was 52%
  - Average lost midline height restored was 66%
  - Mean fracture age was 3.2 months
Significant Pain Reduction

- Following Balloon Kyphoplasty, Ledlie, et. al. (2003) Reports the mean pre-operative pain VAS score was 8.6 (96 cases). The post-operative mean VAS scores were 2.7 (89 cases) at 1 week and 1.4 (29) at 1 year follow-up

- In a retrospective analysis, Garfin, et. al. (2001) reported most patients have gone from narcotic analgesics to over the counter medication

Significant Pain Reduction

- Multi-center prospective single-arm U.S. study
  - Average of 60% reduction in pain
  - Pre-operative VAS score = 7.5, one-week post-op follow-up VAS = 3 (p<0.01)
  - Results persisted for two years. (n=100)
- Ledlie et al. (2002) reported similar results, pain reduction was noted at one week follow-up, with a continuation in improvement at one year

2. Ledlie et al. (2003) J Neurosurg (Spine 1) 98: 36-42
Improvement in Quality of Life

- Coumans et al (2003) report on 78 patients and 188 procedures,
  - Patient quality of life is reflected by marked improvement in seven measures of SF-36 scores

![Graph showing pre and postoperative SF-36 scores](image)

Black bar = pre-op
Gray bar = post-op

Higher score indicates better performance
PF= Physical Functioning,  V= Vitality,  RF=Role Functioning,  SF= Social Functioning
BP= Bodily Pain,  RE= Role Emotional,  GH =General Health,  MH=Mental Health

Coumans et al. (2003) J Neurosurg (Spine 1) 99:44-50
Activities of Daily Living

- **Ambulatory Status**
  - Studies indicate that ambulatory status is quickly improved after Balloon Kyphoplasty and persists at one year.
  - In a retrospective analysis following 79 patients treated (Ledlie et al),
    - 80% of all patients fully ambulatory at one week follow-up and 27 of the patients followed for one year maintained full ambulatory status.
    - 90% of patients (10 out of 12) who were wheelchair-bound preoperatively were ambulatory at one week follow-up.

Ledlie et al. (2003) J Neurosurg (Spine 1) 98: 36-42
Improved Activities of Daily Living

*Function*

- Coumans et al report 15% improvement in function as shown by Oswestry Disability Index (ODI)
  - Measurements in the early post-operative period and continuing through long term follow-up (12-18 month f/u)

---

Coumans et al. (2003) J Neurosurg (Spine 1) 99:44-50
A multicenter, prospective single-arm U.S. study measured back function:
- Evaluated the ability to bend forward, lift 10 pounds and stand for one hour both pre and post-operatively.
- Significant improvement was noted at one month and persisted at two-year follow-up in all three areas.
Patient Satisfaction

- In a prospective U.S. study, patients were asked to rate their level of satisfaction with the outcome of their kyphoplasty procedure
  - Scale of 1-20
    - 1 = Completely dissatisfied
    - 20 = Completely satisfied

- The mean score at one week post-operative was **17.5** and persisted throughout two year follow-up (n=100 patients)

Kyphon U.S. Study, Data on file at Kyphon Inc.
Low Complication Rate

- In a literature review of 1342 vertebrae treated with balloon kyphoplasty
  - Total adverse events are 1% per fracture (2% per patient)
  - Bone cement leaks associated with injury are < 0.2% per fracture (<0.3% per patient)

- Balloon kyphoplasty can compact cancellous bone and create a cavity

- The low complication rate is also related to the way in which viscous bone cement is delivered into the cavity under fine manual control
Conclusions

- Kyphoplasty is a safe and effective treatment for osteoporotic compression fractures
- Safe and effective for pathological fractures
- Usually 1 night stay in hospital and can be done as an outpatient
## Case Study

<table>
<thead>
<tr>
<th>Patient:</th>
<th>61 YO Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis:</td>
<td>Multiple Myeloma</td>
</tr>
<tr>
<td>Fracture Reduced:</td>
<td>T11-L2, 1 ½ yrs old</td>
</tr>
</tbody>
</table>

_Courtesy of Kent Grewe, M.D., Portland, OR_
Case Study

Patient: 76 YO Female
Diagnosis: Metastatic Lung Cancer
Fracture Reduced: T8, 8 weeks old

Courtesy of Henry Small, M.D., Houston, TX
## Case Study

<table>
<thead>
<tr>
<th>Patient:</th>
<th>80 YO Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis:</td>
<td>Primary Osteoporosis</td>
</tr>
<tr>
<td>Fracture Reduced:</td>
<td>L1, 2 months old</td>
</tr>
</tbody>
</table>

*Courtesy of James Hazel, M.D., Richland, WA*
# Case Study

<table>
<thead>
<tr>
<th>Patient:</th>
<th>65 YO Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis:</td>
<td>Primary Osteoporosis</td>
</tr>
<tr>
<td>Fracture Reduced:</td>
<td>L2, 9 weeks old</td>
</tr>
</tbody>
</table>

_Courtesy of Vito Loguidice, M.D., Phillipsberg, NJ_
Case Study

Patient: 61 YO Male
Diagnosis: Multiple Myeloma
Fracture Reduced: T11, 5 weeks old

Courtesy of Paul Pagano, M.D., Houston, TX
# Case Study

<table>
<thead>
<tr>
<th>Patient:</th>
<th>79 YO Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis:</td>
<td>Primary osteoporosis</td>
</tr>
<tr>
<td>Fracture Reduced:</td>
<td>T-11, 7 weeks old</td>
</tr>
</tbody>
</table>

Courtesy of James Hamada, M.D., Torrance, CA
# Case Study

<table>
<thead>
<tr>
<th>Patient:</th>
<th>61 YO Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis:</td>
<td>Multiple Myeloma</td>
</tr>
<tr>
<td>Fracture Reduced:</td>
<td>T-11, 5 weeks old</td>
</tr>
</tbody>
</table>

*Courtesy of Donald Schomer, M.D., Houston, TX*
Case Study

<table>
<thead>
<tr>
<th>Patient:</th>
<th>81 YO Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis:</td>
<td>Primary osteoporosis</td>
</tr>
<tr>
<td>Fracture Reduced:</td>
<td>L-1, 10 days old</td>
</tr>
</tbody>
</table>

*Courtesy of Bruce Orisek, M.D., Santa Cruz, CA*
Case Study

Patient: 89 YO Female
Diagnosis: Primary osteoporosis
Fracture Reduced: T-7, 1 year old Fx (2 Stage Inflation)

*Courtesy of Wade Wong, DO, La Jolla, CA*


Literature Review References


