

Vertebral Augmentation (Kyphoplasty) for Vertebral Compression Fractures

An Evidence-Based Approach for Clinical Practice

Nathan Sneddon MD
Interventional Spine and Pain Management
Spokane WA

Disclaimers

- None

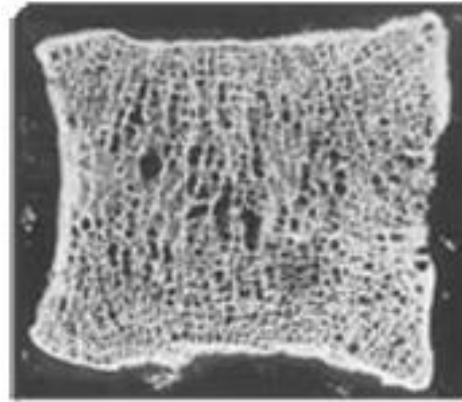
Presentation Overview

- Clinical Background on Osteoporosis and VCFs
- Diagnosis Techniques and Imaging
- Evidence-Based Practice and Patient Selection
- Treatment Options and Comparison
- Vertebral Augmentation Techniques
- Procedural Steps and Considerations
- Clinical Outcomes and Complications

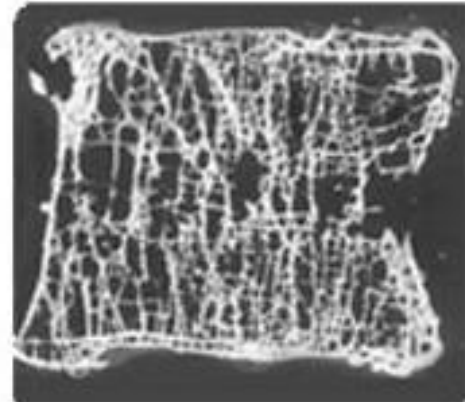
Clinical Background

Osteoporosis Overview

- Age-related condition affecting bone density and strength [10]
- Affects approximately 20% of women over age 50 [10,11]
- Risk factors include age, gender, family history, smoking, alcohol [10,11]
- Results in compromised bone strength and increased fracture risk [10,11]



Normal Bone



Osteoporotic Bone

Osteoporosis Statistics

- 1 in 2 women and 1 in 4 men over age 50 will experience osteoporotic fractures [\[10\]](#)
- 10 million Americans have osteoporosis [\[11\]](#)
- 44 million Americans have low bone density [\[11\]](#)
- Osteoporosis causes 2 million fractures annually [\[11\]](#)
- Healthcare costs exceed \$19 billion annually [\[11\]](#)



Osteoporotic Vertebral Compression Fractures

- Most common osteoporotic fracture [11]
- Approximately 700,000 VCFs occur annually in the US [11]
- Most commonly located in midthoracic region and thoracolumbar junction [16]
- Often presents with acute pain that may become chronic [16]
- Can lead to progressive kyphosis and height loss [16]



Clinical Significance of VCFs

- Significant impact on quality of life [\[16\]](#)
- Associated with 23-34% increased mortality risk [\[14,15\]](#)
- Leads to decreased pulmonary function [\[16\]](#)
- Causes impaired mobility and activities of daily living [\[16\]](#)
- Results in increased dependence and healthcare utilization [\[11\]](#)

Diagnosis

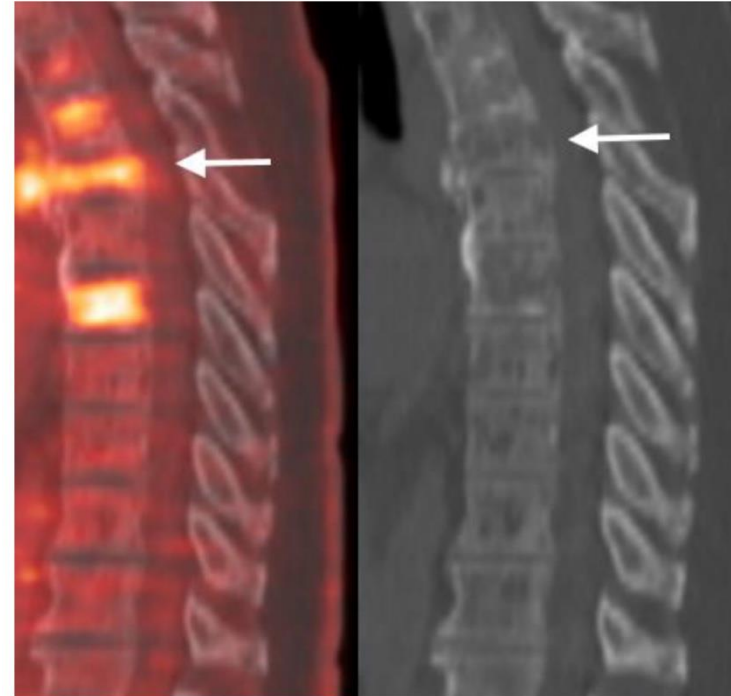
Diagnosis Techniques

- X-rays: Initial assessment and follow-up
Quick screening, identifies fracture location and severity [\[18\]](#)
- CT Scan: Detailed bone anatomy, fracture pattern assessment [\[18\]](#)
- CT: Pre-procedural planning for complex cases



Diagnostic Applications

- MRI: Detects edema, determines fracture age, neural compression [18]
- Bone Scan: Identifying symptomatic level and multiple fractures [18]
- MRI: Determining fracture acuity and neural involvement [18]



MRI Applications

- T1 sequences show vertebral body morphology
- T2 sequences show neural compression
- STIR sequences show edema in acute fractures [\[18\]](#)
- Critical for determining fracture age and treatment planning [\[18\]](#)



Treatment Options and Outcomes

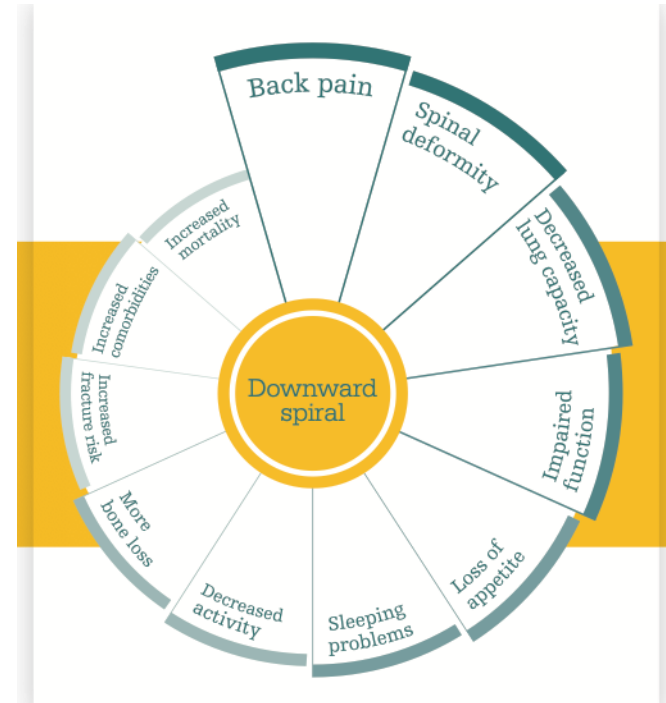
VCF Treatment Options

Non-surgical Management:

- Bed rest and activity modification [16]
- Analgesics and anti-inflammatory medications [16]
- Bracing [16]

Interventional Management:

- Vertebral augmentation (vertebroplasty, kyphoplasty) [18,19]
- Spinal fixation (for unstable fractures) [9]



Treatment Comparison

Conservative Management:

- Limited pain relief [3,4]
- Prolonged recovery time [16]
- Risk of progressive deformity [16]

VS



Vertebral Augmentation:

- Immediate pain relief [1,2,3,4]
- Improved functional outcomes [1,2,7]
- Potential height restoration [19,20]
- Reduced mortality risk [5,6]

VCF treatment

Clinical support

Reduce the risk of mortality

A series of studies compared the mortality risk between non-surgical management (NSM), vertebral augmentation (VA), and vertebroplasty (VP). Five of the six studies were consistent in their findings.¹⁸⁻²⁴

Significantly higher mortality risk with NSM vs BKP/VP

n

Years follow-up

Key findings

Ong et al.*
(Osteo Int 2017)⁷



2,077,944
BKP (n=261,756)
VP (n=117,232)
NSM (n=1,698,956)

10+

NSM: 55% and 24% higher mortality risk at 1 year and 10 years than BKP (Propensity adjusted: 95% CI: 23-24%; p<0.001).
NSM: 30% and 8% higher mortality risk at 1 year and 10 years than VP. (Propensity adjusted: 95% CI: 8%-9%; p<0.001).



Mortality Risk Reduction

- **Multiple studies show reduced mortality with vertebral augmentation** [5,6]
- Edidin et al: 37% relative risk reduction at 4 years [5]
- Chen et al: 44% relative risk reduction at 1 year [6]
 - NNT = 15 (vertebroplasty N = 22)
 - Angioplasty? NNT = 30-50 [33]
- **Mechanism likely related to:**
 - - Reduced immobility-related complications [5,6]
 - - Improved pulmonary function [16]
 - - Reduced analgesic medication requirements [5,6]

Evidence for Vertebral Augmentation

Evidence-Based Practice for Vertebral Augmentation

- **Multiple randomized controlled trials support efficacy [1,2,3,4]**
- FREE trial: Significant pain reduction and quality of life improvement [1,2]
- VERTOS II: Immediate pain relief and improved function [3]
- EVOLVE: Sustained benefits at 12 months [7]
- Meta-analyses confirm safety and effectiveness [22,23,24,25]

FREE Study, (the Lancet 2009)¹³

Meta-Analysis of Vertebral
Augmentation Compared
with Conservative
Treatment, (JBMR 2013)¹⁴

Vertos I, (AJNR 2007)¹⁵

Vertos II, (the Lancet 2009)¹⁶

VAPOUR, (the Lancet 2016)¹⁷

Vertebral augmentation
compared to non-surgical
management

Vertebroplasty
compared to non-surgical
management

Vertebroplasty
compared to sham

Pain
relief

Over 20%
greater at
1 week
Significantly
greater up to
6 months



Significantly
greater up to
12 months



4.5 times
greater at
1 day
Significantly
greater up to
2 weeks



25%
greater at
1 month
Significantly
greater up to
12 months



Significantly
greater up to
6 months



Physical
function

60 more days of
unrestricted activity at
12 months



Significantly
greater up to
12 months



Significantly
greater up to
2 weeks



120 pain free
days gained at
12 months



Greater
improvement up to
6 months



Quality
of life
(QOL)

4 times
greater at
1 month
Significantly
greater up to
12 months



Nearly 40%
greater at
3 months
Significantly
greater up to
12 months



Significantly
greater at
2 weeks



Significantly
greater up to
12 months



Scores favored
VP up to
6 months



Patient Selection for Vertebral Augmentation

- Proper patient selection is critical for optimal outcomes [9]
- Consider fracture age, pain severity, and response to conservative care [9]
- MRI confirmation of acute/subacute fracture [18]
- Correlation of clinical symptoms with imaging findings [9]
- Assessment of patient's overall health status [9]

Indications for Vertebral Augmentation

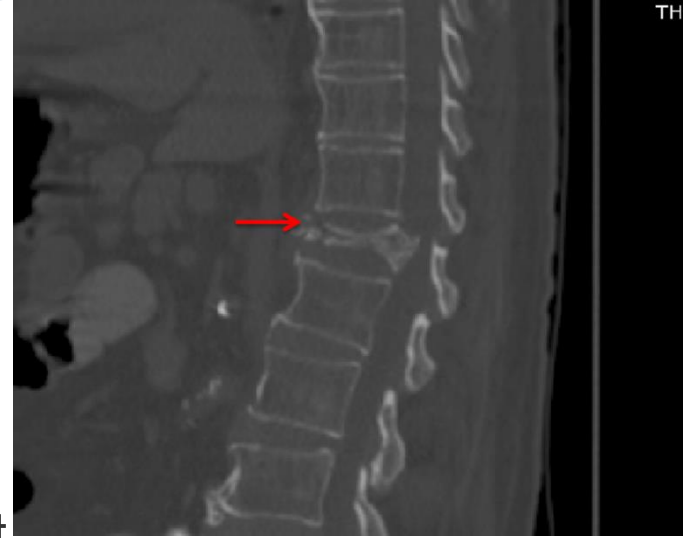
- Painful osteoporotic VCF refractory to conservative management [9]
- Acute to subacute fractures (< 6 weeks) [9]
 - Zhao et al showed fractures treated after 6 months had better pain and ODI scores [34]
- MRI showing edema or 'fresh' fracture [18]
- Pain localized to fracture level [9]
- Painful VCF with progressive height loss (>25%) [9]
- Hospitalized patients with painful VCF [9]



Contraindications for Vertebral Augmentation

Absolute Contraindications:

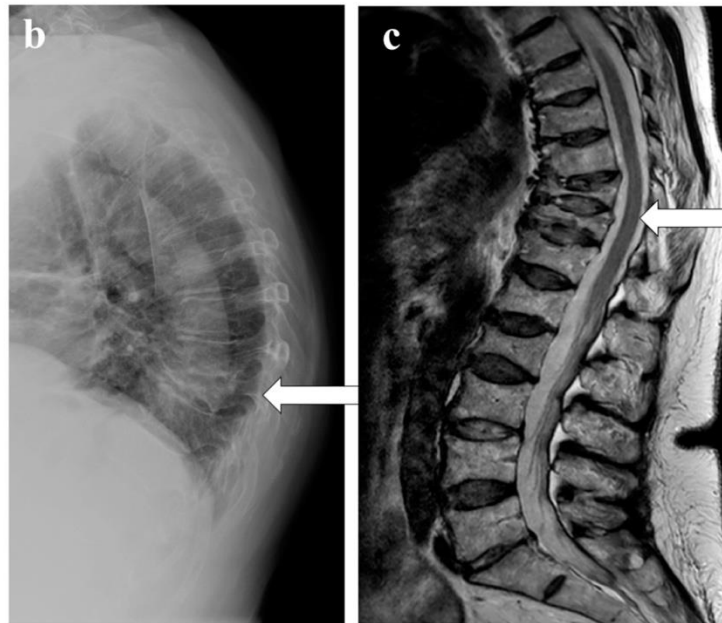
- Active systemic infection [9]
- Local infection at surgical site [9]
- Uncorrectable coagulopathy [9]
- Allergy to bone cement components [9]
- Unstable fracture with posterior element involvement [9]
- Spinal cord compression with neurological deficit [9]



Contraindications for Vertebral Augmentation (cont.)

Relative Contraindications:

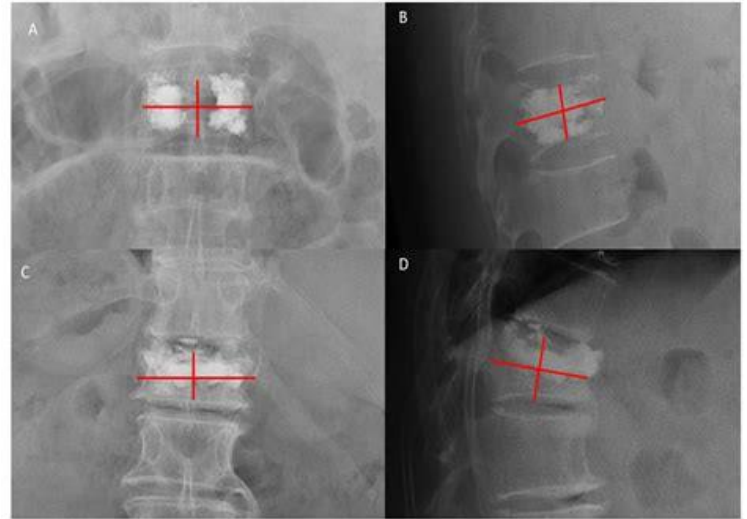
- Asymptomatic stable fractures [9]
- Fractures >1 year old without edema on MRI [9,18]
- Severe cardiopulmonary disease [9]
- Radiculopathy in excess of vertebral pain [9]
- Pregnancy (due to radiation exposure) [9]
- Vertebra plana (>70% collapse) [9]



Increased Fracture Risk?

Does Vertebral Augmentation Increase Subsequent Fracture Risk?

- Clinical evidence does not support increased risk [28,29]
- Natural history of osteoporosis is the primary driver of subsequent fractures [12,13]
- Proper cement volume and distribution (interdigitation) minimizes biomechanical alterations [27]
- Patient-specific factors are the main determinants of future fracture risk [26,27,28,29,30]
- Proper medical management of osteoporosis is essential [17]



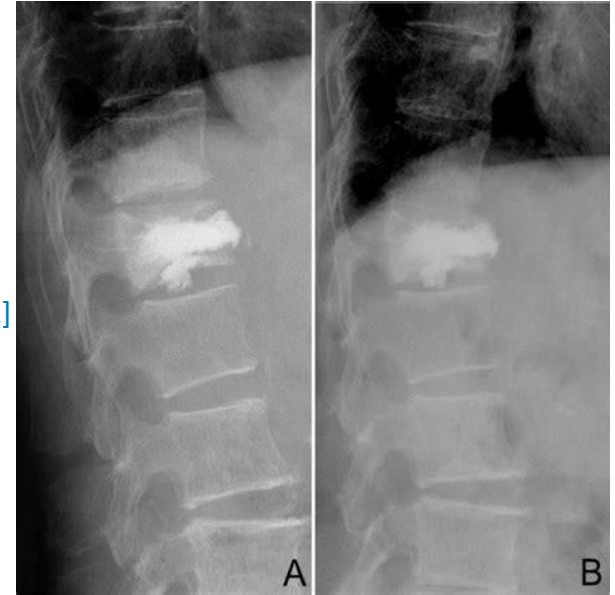
Risk Factors for Subsequent Vertebral Fractures

Patient-Related Factors:

- Advanced age (>75 years) [12,13]
- Female sex [10]
- Low bone mineral density (T-score < -2.5) [10,11]
- History of multiple previous fractures [12,13]

Procedure-Related Factors:

- Cement leakage into adjacent disc [27]
- Excessive height restoration [19,20]



Expert Consensus on Subsequent Fracture Risk

Multi-Society Consensus Statement (2014): [9]

"The incidence of new vertebral fractures following kyphoplasty approximates the baseline risk seen in untreated patients, and there is minimal, if any, impact on new fracture rates attributable to the procedure itself." [9]

Supporting Organizations:

- Society of Interventional Radiology (SIR) [9]
- American Association of Neurological Surgeons (AANS) [9]
- American College of Radiology (ACR) [9]
- American Society of Neuroradiology (ASNR) [9]
- This was confirmed in 2025 study by Lian et al (n> 6500)

Vertebral Augmentation

Vertebral Augmentation Overview

Minimally invasive procedures to stabilize VCFs [\[18,19\]](#)

Benefits include:

- Pain relief [\[1,2,3,4\]](#)
- Fracture stabilization [\[19\]](#)
- Potential height restoration [\[19,20\]](#)
- Improved sagittal alignment [\[19,20\]](#)
- Enhanced mobility and function [\[7\]](#)



Vertebral Augmentation Techniques

- Vertebroplasty: Direct cement injection [3,4]
- Balloon Kyphoplasty: Cavity creation with inflatable balloon [1,2]
- Mechanical Vertebral Augmentation: Implantable device for controlled expansion [8]
- Each technique has specific advantages and applications [22,23,24,25]

Augmentation Techniques Comparison

Vertebroplasty:

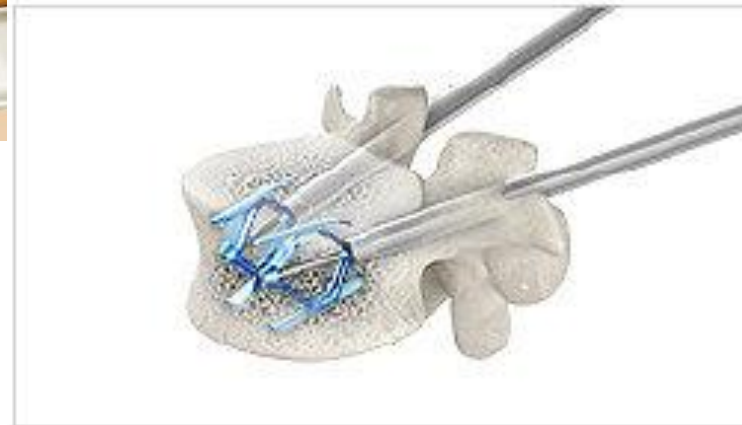
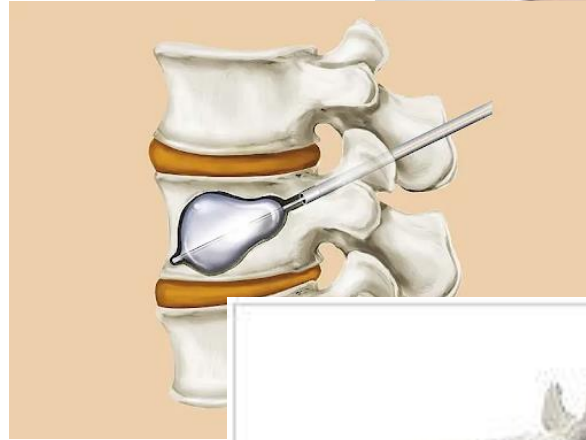
- Simple technique, lower cost [24]
- Limited height restoration [24]

Balloon Kyphoplasty:

- Moderate height restoration [19,20]
- Lower cement leakage rates [24]

Mechanical Vertebral Augmentation:

- Superior height restoration [8]
- Controlled anatomical restoration [8]



Procedural Techniques

Balloon Kyphoplasty: Procedural Overview

- Minimally invasive procedure performed under fluoroscopic guidance [\[18,19\]](#)
- Typically performed under conscious sedation or general anesthesia [\[19\]](#)
- Bipedicular or unipedicular approach [\[19\]](#)
- Step-by-step process with balloon inflation and cement delivery [\[19\]](#)
- Usually completed in 30-60 minutes per level [\[19\]](#)

Bipedicular balloon kyphoplasty

Step-by-step

Needle is inserted through the pedicle of the fractured vertebra for VA procedures (including balloon kyphoplasty)²⁶



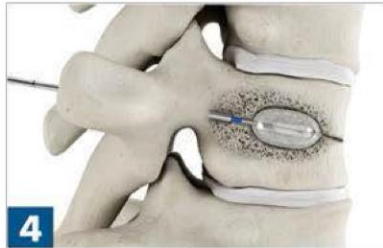
Needle to posterior 1/3rd



Drill to anterior 1/3rd



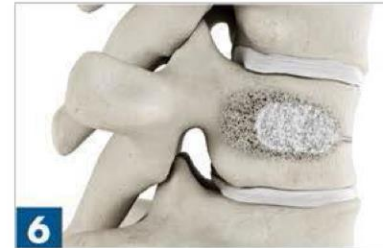
Insert balloon



Inflate balloon



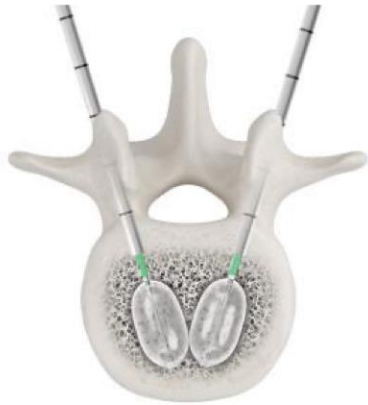
Inject cement



Cement interdigitates

**Bipedicular balloon
kyphoplasty:**

Straight balloons



**Unipedicular balloon
kyphoplasty:**

Curved balloon



**Mechanical vertebral
augmentation:**

SpineJack system



Bipedicular Approach

Bipedicular Approach

- Needles inserted through both pedicles [19]
- Provides symmetric access to vertebral body [19]
- Allows balanced cavity creation and cement distribution [19]
- **Preferred for severely collapsed vertebrae [19]**
- Historically, Standard approach for most kyphoplasty procedures [19]

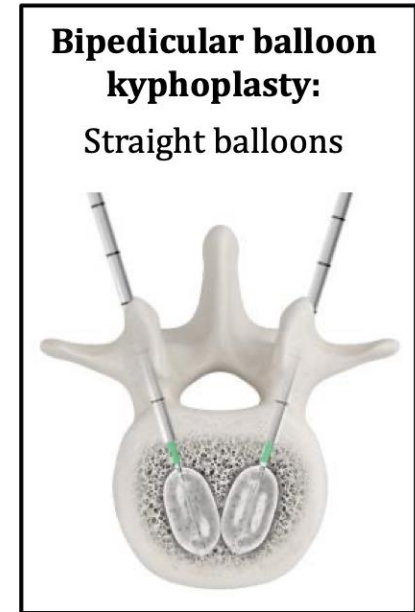
Transpedicular Approach

Needles inserted through the pedicles [19]

Anatomical considerations:

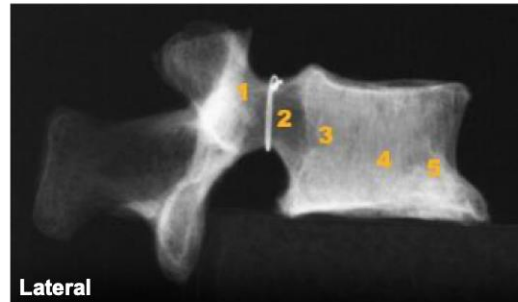
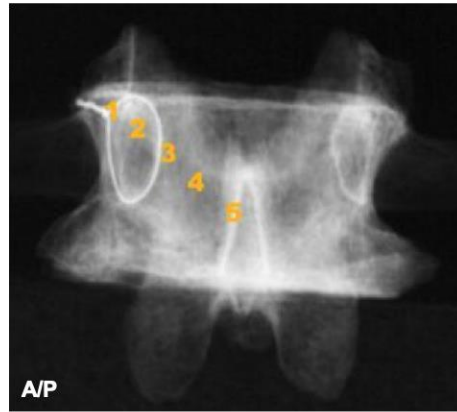
- Pedicle diameter and orientation [18,19]
- Vertebral body size and shape [18,19]
- Fracture pattern [18,19]

Extrapedicular approach is an alternative when standard approach is not possible [19]



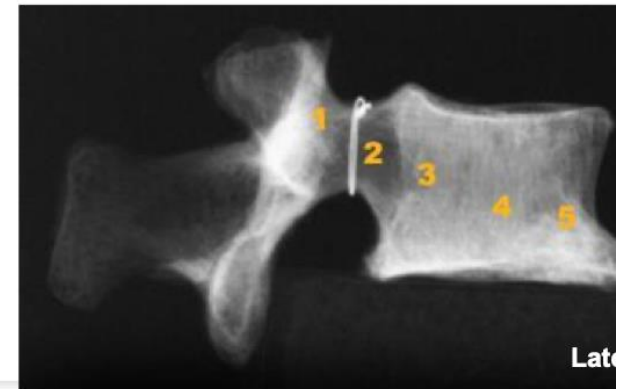
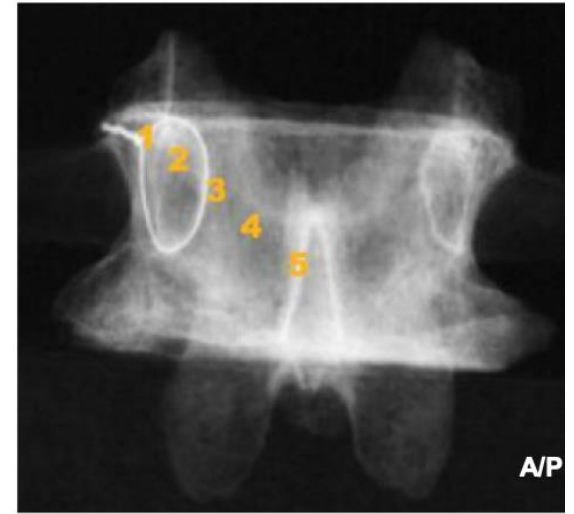
Transpedicular approach

Trajectory



Vertebral body entrance

- When needle arrives at medial border of pedicle (#3 in A-P), ensure needle tip is inside of vertebral wall (#3 in lateral)
- Advance needle past the posterior cortical wall



Optional Step: Obtain Bone Sample

Using biopsy for bone sample

Insert biopsy needle through working cannula [\[18,19\]](#)

Obtain bone sample for pathological analysis [\[18,19\]](#)

Particularly important for:

- Atypical fracture patterns [\[9\]](#)
- Suspected pathological fractures [\[9\]](#)
- History of malignancy [\[9\]](#)

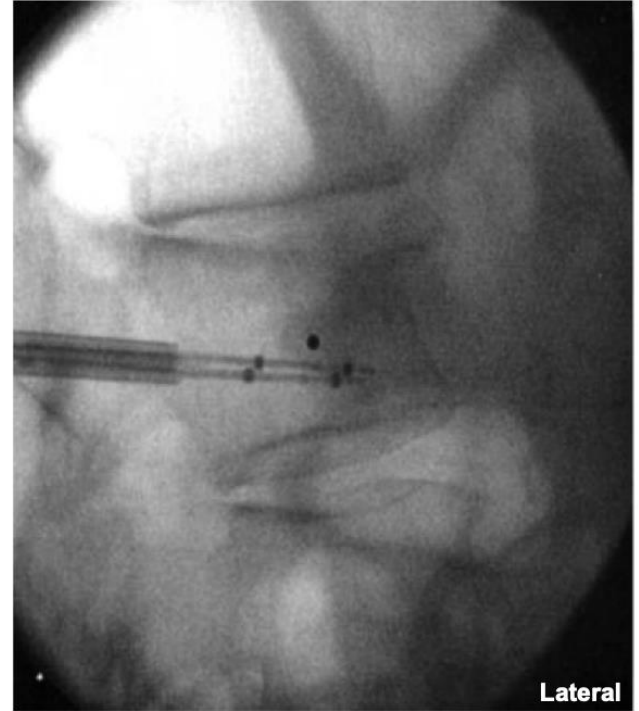


Optional: Curette to displace hard bone prior to balloon

Drill to Anterior 1/3rd



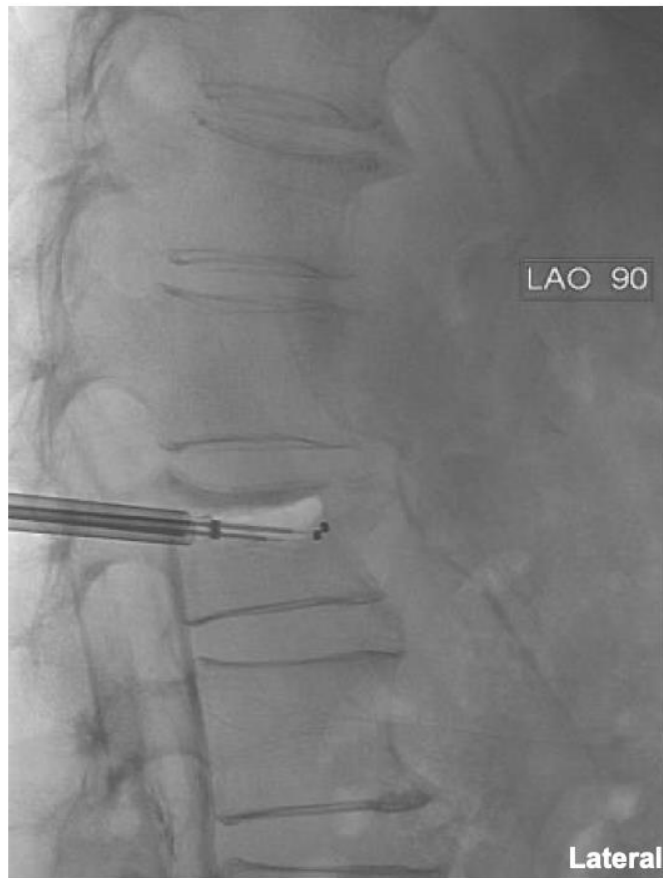
Insert balloon



Contrast in balloon allows for visualization under flouro



Balloon cavity remains



Cement will fill cavity and interdigitate with trabecular bone



Unipedicular Approach

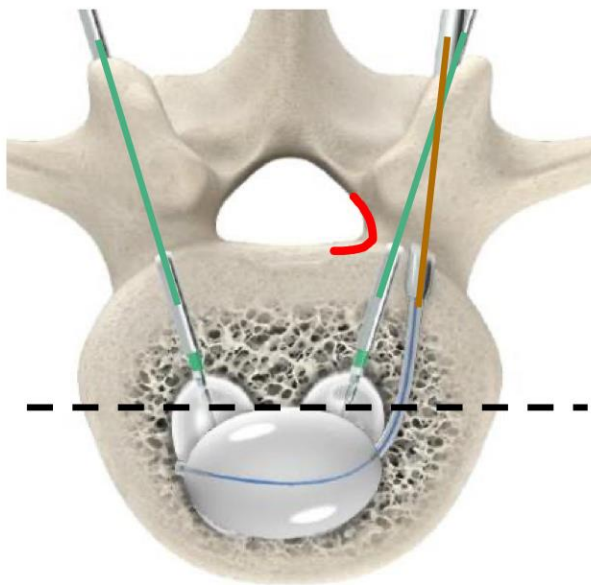
Unipedicular Balloon Kyphoplasty - Overview

- Single pedicle approach [\[19\]](#)
- More diagonal trajectory across midline [\[19\]](#)
- Complete procedural sequence similar to bipedicular approach [\[19\]](#)
- Requires specific technical considerations [\[19\]](#)

Unipedicular Balloon Kyphoplasty - Features

Benefits:

- Less operation time and lower cement dosage [\[37\]](#)
- Reduced radiation exposure [\[37\]](#)
- Improved procedural analytics [\[37\]](#)
- Procedurally simpler if one pedicle is compromised [\[37\]](#)
- Comparable height restoration and stability [\[36\]](#)
- Reduced cost with only one needle [\[37\]](#)



Unipedicular vs Bipedicular Kyphoplasty: Clinical Outcomes

- Equal efficacy in pain relief (VAS scores) [\[4,7\]](#)
- Comparable functional improvement (ODI scores) [\[4,7\]](#)
- Similar vertebral height restoration [\[4,7\]](#)
- Equivalent kyphotic angle correction [\[4,7\]](#)
- Consistent results across short and long-term follow-up [\[4,7\]](#)



Unipedicular vs Bipedicular Kyphoplasty: Evidence-Based Recommendations

Meta-analyses and systematic reviews support unipedicular approach as:

- At least equal in clinical outcomes [\[4,7\]](#)
- Preferable for procedural efficiency [\[4,7\]](#)
- Non-inferior in radiological outcomes [\[4,7\]](#)

Approach selection should be individualized based on:

- Patient anatomy
- Fracture characteristics
- Surgeon experience and preference



Mechanical Vertebral Augmentation

Technological Advances: Spine Jack System

- Titanium implantable device that provides controlled expansion
- Designed for precise height restoration and endplate reduction

Clinical Advantages:

- Controlled anatomical restoration [8]
- Targeted height restoration [8]
- Reduced bone fracture during expansion [8]

SpineJack® system



Mechanical Vertebral Augmentation - Restoration

- Controlled anatomical restoration through mechanical device deployment [8]
- Step-by-step expansion process [8]
- Precise control of height restoration [8]
- Designed to reduce endplate damage during expansion [8]

SpineJack® system



Mechanical vertebral augmentation

Procedure

Controlled anatomical restoration

1 Access cannula



2 Guidewire



3 Reamer



4 Template



5 Cannula plug



6 Closed SpineJack Implant



7 Expanded SpineJack Implant



8 Cement fill



Mechanical Vertebral Augmentation - Fluoroscopy

Real-time visualization of device deployment [8]

Monitoring of height restoration [8]

Assessment of endplate reduction [8]

Guidance for cement delivery [8]



Mechanical vertebral augmentation

SAKOS clinical study³¹

5 countries | 13 sites | 15 investigators

- Prospective, multicenter, randomized, comparative study
- N=141 (SpineJack system n=68; KyphX Xpander BKP n=73)
- Non-inferiority study
- 12-month follow up



Superior mid-vertebral height restoration

- Significantly greater midline VB height restoration with SJ system at 6 and 12 months

6 mo. $p=0.0246$
12 mo. $p=0.0035$

Significantly fewer adjacent level fractures

- Reduction in clinically significant AEs
 - BKP compared to SJ system had more than double the rate of ALFs

12.9% v. 27.3%
 $p=0.043$

- Fewer hospital and physician visits
- Decrease in future interventions

Greater pain score reduction

- Less pain medication usage including opioid analgesics at 5 days after surgery (SJ group 7.4% vs. BKP group 21.9%)
- Decreased pain intensity vs. baseline more pronounced in the SJ group at 1 and 6 months

1 mo. $p=0.029$
6 mo. $p=0.021$

Spine Jack System: Clinical Outcomes

SAKOS Study: International, randomized, non-inferiority trial [\[8\]](#)

Superior anterior vertebral body height restoration [\[8\]](#)

Significantly better midline height restoration [\[8\]](#)

Significant VAS pain score reduction [\[8\]](#)

Greater reduction in analgesic consumption [\[8\]](#)

Comparable safety profile to balloon kyphoplasty [\[8\]](#)

Lower rate of cement leakage (27.8% vs 30.0%) [\[8\]](#)

Mechanical Vertebral Augmentation - Outcomes

Clinical studies show:

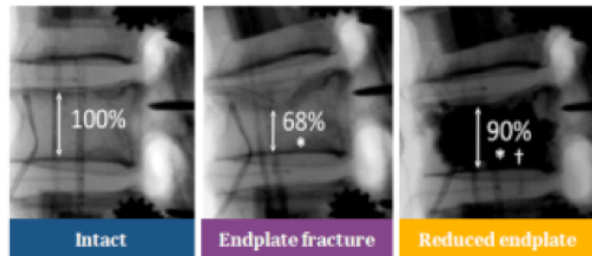
- Significant anterior height restoration [\[8\]](#)
- Effective pain reduction (VAS score) [\[8\]](#)
- Functional improvement (ODI score) [\[8\]](#)
- Radiographic evidence of sustained height restoration [\[8\]](#)
- Progressive improvement over time [\[8\]](#)

Mechanical vertebral augmentation

Vertebral fractures cascade

Endplate reduction

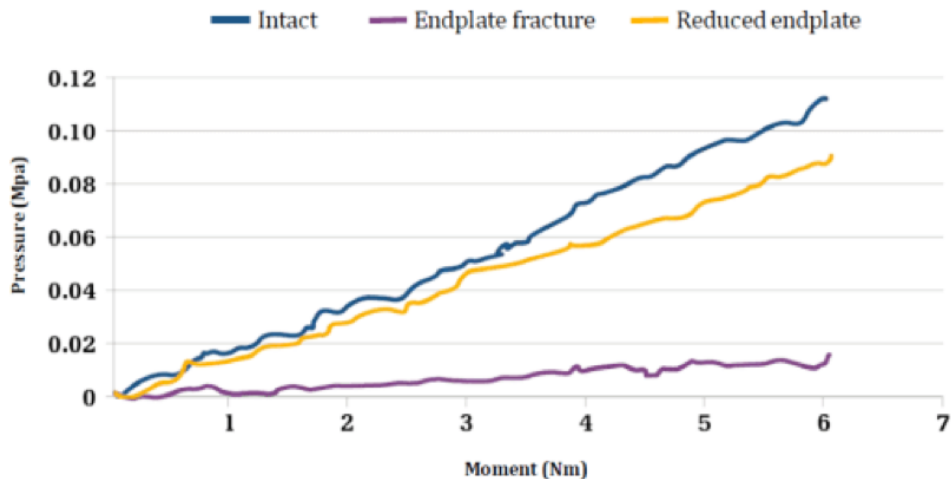
Realignment of the endplates recreated disc biomechanics and allowed load to be transferred throughout the spine.³²



* compared to Intact.

† compared to VCF.

Flexion pressure in disc adjacent to fractured endplates T11-T12





CT showing T12 Fracture

Cement Bits

PMMA (Bone Cement): Overview

Ideal Characteristics:

- High vs low viscosity polymethylmethacrylate (PMMA) cement
- Specifically designed for vertebral augmentation procedures
- Predictable handling characteristics

Typical injection volumes: 3-5 mL per vertebral body

Ideal Advantages

- Significantly lower cement leakage rates compared to low-viscosity cements
- Better control during injection
- Reduced risk of extravasation complications
- Equivalent clinical efficacy to other PMMA cements



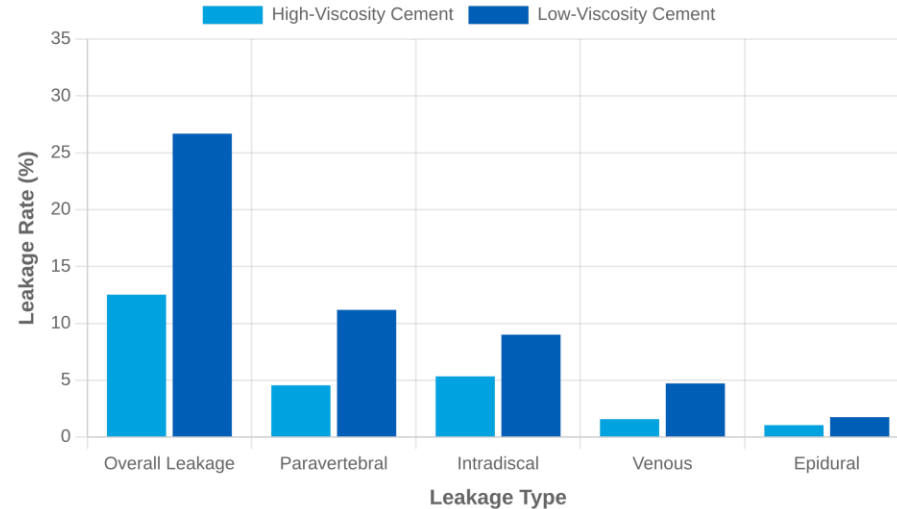
PMAA (Bone Cement): Clinical Evidence

Meta-Analysis Findings:

- Significantly lower cement leakage rates compared to low-viscosity cements⁴⁰⁻⁴³
- Equivalent improvements in pain scores (VAS)⁴⁰⁻⁴⁴
- Similar disability index improvements (ODI)⁴⁰⁻⁴⁴
- No difference in adjacent vertebral fracture rates⁴⁰⁻⁴³
- Comparable vertebral height restoration⁴⁰⁻⁴⁴

Clinical Implications:

- Reduced leakage risk without compromising efficacy⁴⁰⁻⁴³
- Particularly beneficial in paravertebral and venous spaces⁴⁰⁻⁴³
- Reduced risk of extravasation complications
- Equivalent clinical efficacy to other PMMA cements



Cement leakage rates: High vs. Low-viscosity PMMA (Data from Wang Q, et al. 2022)

PMAA (Bone Cement): Practical Considerations

Dosing and Administration:

- Typical injection volumes: 3-5 mL per vertebral body^{45,47}
- Volume tailored to fracture morphology and patient anatomy^{45,47}
- No specific dosing recommendations established in literature^{45,47}

Technical Considerations:

- More predictable working time compared to low-viscosity cements⁴⁶
- Requires higher injection pressure⁴⁵
- Reduced risk of cement extravasation⁴⁰⁻⁴³
- Continuous fluoroscopic monitoring still recommended

Parameter	Viscosity	Low-Viscosity
Working Time	More predictable	Variable
Injection Pressure	Higher	Lower
Leakage Risk	Lower	Higher
Control During Injection	Better	Less precise
Filling Pattern	More controlled	More diffuse
Clinical Outcomes	Equivalent	Equivalent

Clinical Outcomes

Is Vertebral Augmentation Effective for Patients?

Multiple randomized controlled trials demonstrate significant clinical benefits [\[1,2,3,4,7\]](#)

Pain Reduction:

- Significant reduction in VAS pain scores [\[1,2,3,4,7\]](#)
- Rapid pain relief within days of procedure [\[1,2,3,4\]](#)

Functional Improvement:

- Significant improvement in ODI scores [\[7\]](#)
- Improved quality of life measures (SF-36, EQ-5D) [\[1,2\]](#)

Mortality Benefit:

- Reduced mortality compared to non-surgical management [\[5,6\]](#)



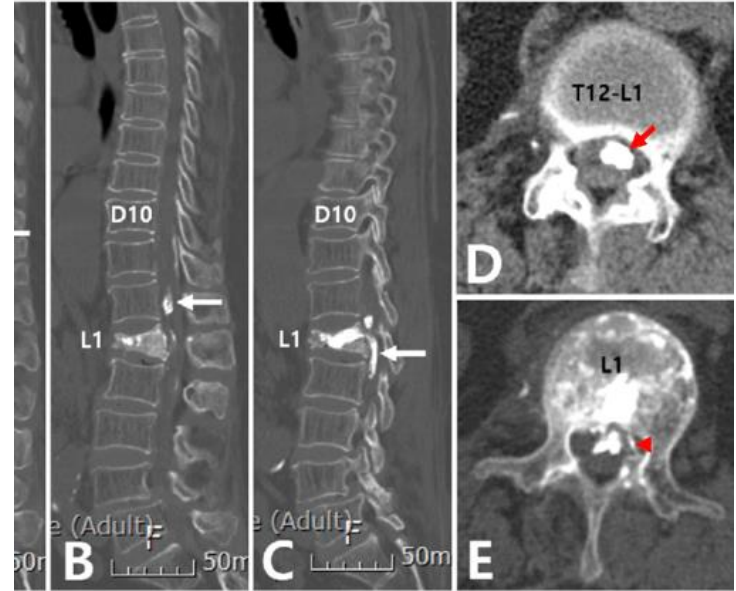
Functional Outcomes After Vertebral Augmentation

- Significant improvement in Oswestry Disability Index (ODI) [\[7\]](#)
- Improvements maintained through long-term follow-up [\[1,2,7\]](#)
- Enhanced mobility and self-care capabilities [\[7\]](#)
- Reduced days of limited activity and bed rest [\[7\]](#)
- EVOLVE Trial: Significant improvements in quality of life and activities of daily living at all time points [\[7\]](#)



Complications and Management

- **Cement Leakage (most common):**
- Typically asymptomatic (>90% of cases) [38]
- Management: Conservative if asymptomatic, surgical intervention rarely needed [22,23,24,25]



Complications and Management

Adjacent Level Fractures:

- Related to underlying osteoporosis rather than procedure [\[28,29,30\]](#)
- Management: Medical treatment of osteoporosis, consider augmentation if symptomatic [\[17\]](#)

Infection, Bleeding, Neurological Injury:

- Rare (<1%) [\[39\]](#)
- Management: Standard protocols based on complication type [\[22,23,24,25\]](#)

Summary

- Vertebral Augmentation is effective for both reduce mortality and improved quality of life
- Vertebral Augmentation DOES NOT result in increased incidence of adjacent level fractures
- Unipedicular technique is equal in outcomes to bipedicular technique
- Choice of cement directly corresponds to rates of cement extravasation
- Vertebra Plana can be successfully treated with SpineJack

Thank You



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