

# Treatment of Osteoporotic Compression Fractures

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# Osteoporosis

- 54 million men and women have osteoporosis
- 2,000,000 men have osteoporosis
- 34,000,000 have osteopenia
- 1 in 2 white women and 1 in 4 men will experience an osteoporotic fracture in her lifetime.

# Osteoporosis

- Osteoporotic fractures cost \$18 billion annually
- Projected to cost \$50 billion by 2040
- Projected costs exceed the cost of stroke, breast CA, DM, or chronic lung disease

# Definitions

- Osteoporosis-Characterized by low bone mass leading to an increased fracture risk
  - WHO defines a bone mineral density (BMD) 2.5 standard deviations below the mean for healthy young women measured by dual energy x-ray absorptiometry (DEXA).
- Osteopenia-defined as BMD between 1-2.5 standard deviations below the mean.

# Primary Osteoporosis

- Primary Osteoporosis – bone loss related to the decline of gonadal function associated with aging.
- Increasing age
- Low body weight
- White or Asian
- Excessive alcohol and caffeine
- Low calcium and/or vitamin D intake

# Secondary Osteoporosis

- Low bone mass resulting from chronic disease, exposures, or nutritional deficiencies.
- Amyloidosis
- Ankylosing Spondylitis
- HIV
- IBD
- Severe Liver Disease
- Renal Failure
- Rheumatoid Arthritis
- SLE

# Endocrine and Metabolic disorders

- Athletic amenorrhea
  - Disordered Eating, Amenorrhea, Osteoporosis
- Cushing Syndrome
- DM type 1
- Hemochromatosis
- Hyperadrenocorticism
- Primary hyperparathyroidism
- Hyperthyroidism
- Hypogonadism
- Hypophosphatasia

# Medications

- Anticonvulsants
- Drugs causing hypogonadism
  - Progesterone, methotrexate, GRHA
- Glucocorticoids
- Heparin
- Immunosuppressants
  - Cyclosporine, tacrolimus
- Lithium
- Thyroid Hormone Excess

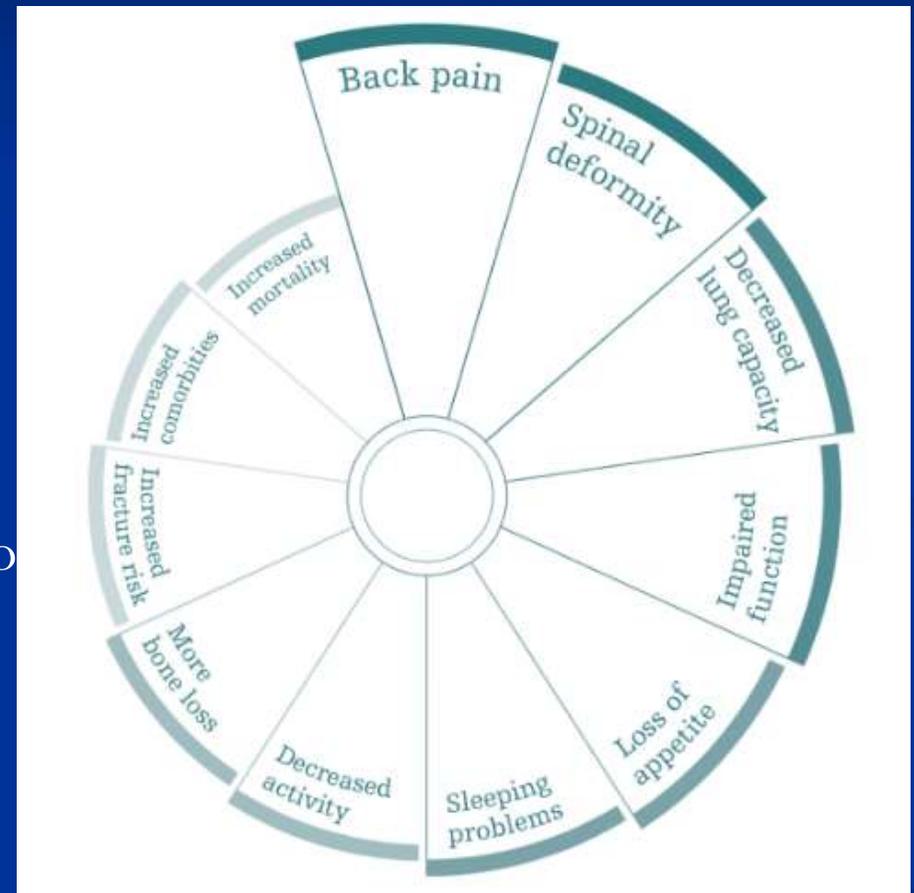
# Osteoporotic Fractures



# VCF Treatment Options vs Non-Surgical Management

- Non-surgical treatment options
  - Bed rest
  - Physical therapy
  - Bracing
  - Opioids

Non-surgical management may lead to adverse outcomes that, if left untreated, may begin a “downward spiral” in the health status of patients



# Bracing



# VCF Treatment vs Non-Surgical Management

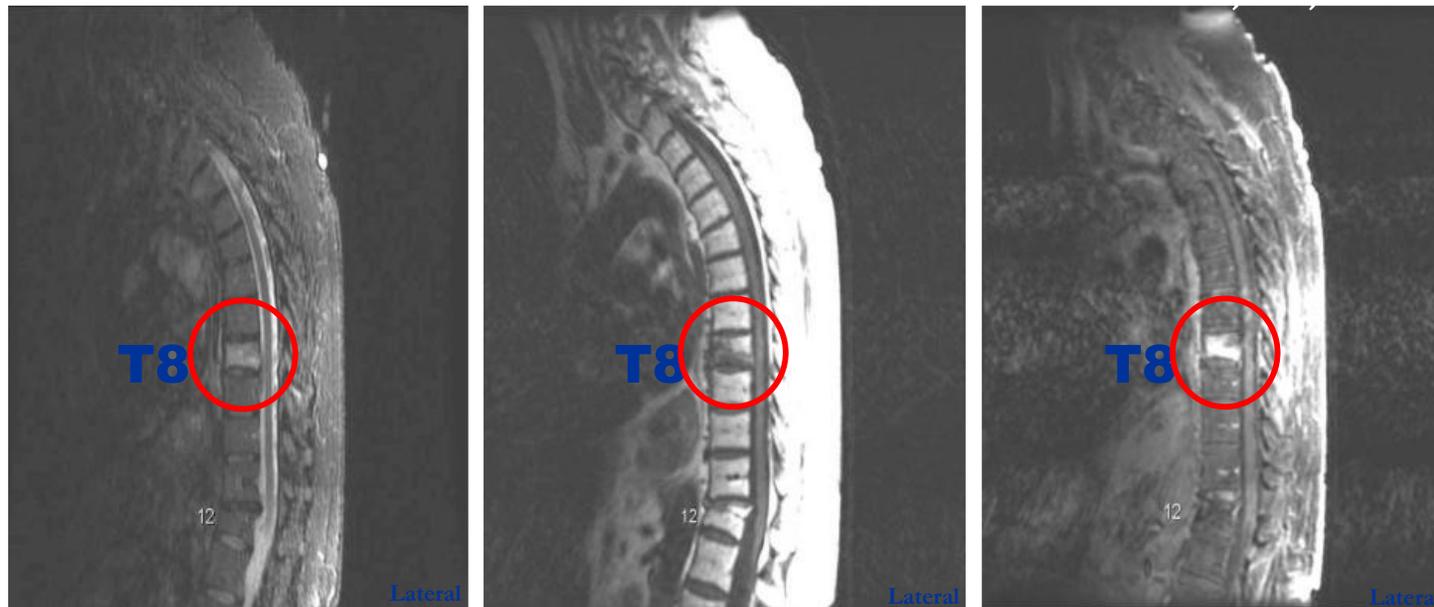
Significantly higher mortality risk with NSM vs BKP/VP	N-value	Years of follow-up	Key findings
Ong et al.* (Osteo Int 2018) <sup>3</sup> ✓	<b>2,077,944</b> BKP (n=261,756) VP (n=117,232) NSM (n=1,698,956)	<b>10+</b>	<b>NSM:</b> 55% and 24% higher mortality risk at 1 year and 10 years than BKP (Propensity adjusted: 95% CI: 23-24%; p<0.001). <b>NSM:</b> 30% and 8% higher mortality risk at 1 year and 10 years than VP. (Propensity adjusted: 95% CI: 8%-9%; p<0.001).
Edidin et al.* (Spine 2015) <sup>4</sup> ✓	<b>1,038,956</b> BKP (n = 41,343) VP (n = 75,364) NSM (n = 822,249)	<b>4+</b>	<b>NSM:</b> 55% higher mortality risk than BKP (AHR =1.55; 95% CI: 1.53–1.56) and 25% higher mortality risk than VP. After propensity matching, the Kaplan-Meier risk of mortality at 4 years was still found to be greater for the nonoperated cohort (AHR = 1.62; 95% CI: 1.60–1.64).
Edidin et al.* (JBMR 2011) <sup>5</sup> ✓	<b>858,978</b> BKP (n = 119,253) VP (n = 63,693) NSM (n = 676,032)	<b>4+</b>	<b>BKP:</b> 44% lower mortality risk than NSM (AHR = 0.56, 95% CI 0.55–0.57). <b>VP:</b> 24% lower mortality risk than NSM.
Chen et al.* (JBJS 2013) <sup>6</sup> ✓	<b>68,752</b> BKP (n = 22,826) VP (n = 7,700) NSM (n = 38,226)	<b>3+</b>	<b>BKP:</b> 32.5% lower mortality risk than NSM. <b>VP:</b> 15.5% lower mortality risk than NSM.
Lange et al.* (Spine 2014) <sup>7</sup> ✓	<b>3,607</b> BKP (n = 441) VP (n = 157) NSM (n = 3,009)	<b>5++</b>	<b>VP/BKP:</b> 43% lower mortality risk than NSM (AHR = 0.57; 95% CI: 0.48–0.70).

# Imaging

- X-rays – Allows for quick screening and identification of fractures
- CT – Allows for best imaging of bony anatomy
- MRI – Optimal imaging for judging fracture age, as it shows bony edema for an acute fracture
- Bone scan – Less commonly used imaging, but will show increased uptake in a fracture and may be done in conjunction with a DEXA scan

# Imaging

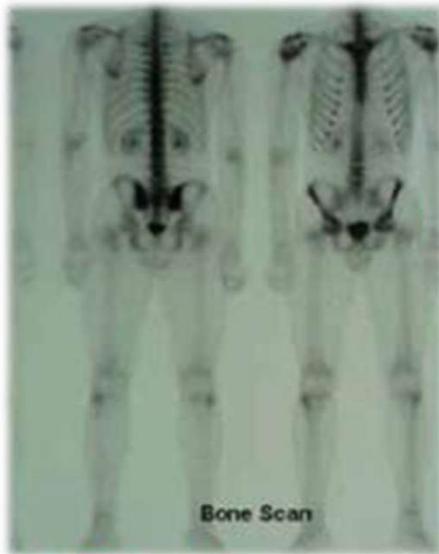
MRI with short T1-T2 inversion recovery (STIR)<sup>10</sup>



# Imaging

## **Bone scan<sup>3</sup>**

Allows for quick fracture evaluation from T4 to L4



## **CT scan<sup>3</sup>**

Demonstrates fracture through posterior wall of vertebra



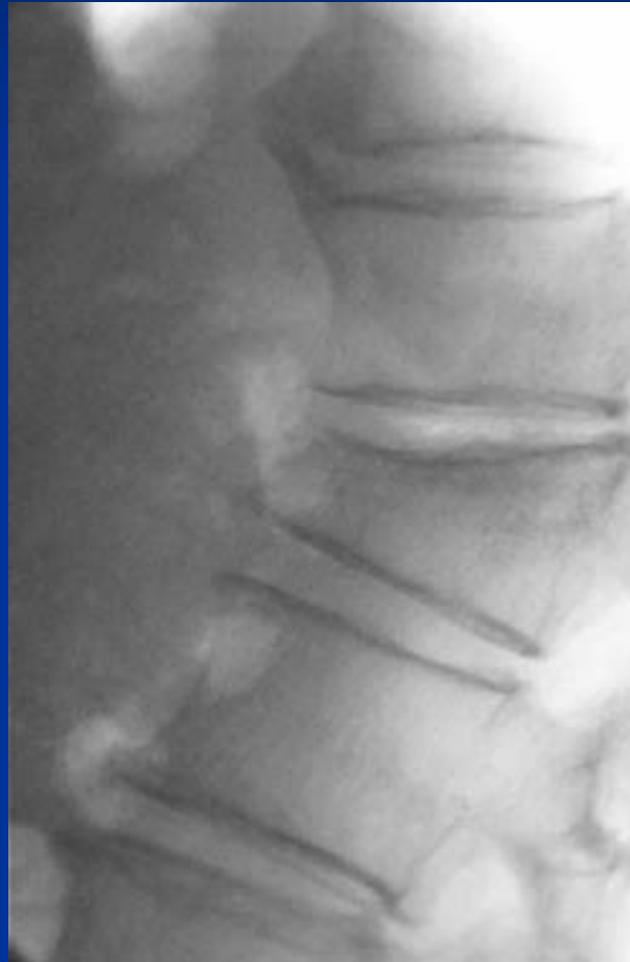
# Number Needed to Treat with Vertebral Augmentation to Save a Life

American Journal of Neuroradiology January 2020, 41 (1) 178-182; DOI: <https://doi.org/10.3174/ajnr.A6367>

- Why Treat: Number Needed to Treat with Vertebral Augmentation to Save a Life
- The purpose of this study was to calculate the number needed to treat (NNT) to save 1 life at 1 year and up to 5 years after vertebral augmentation.
- Pooled data from 10-year sample of US Medicare patients with vertebral compression fractures (VCFs) treated with nonsurgical management, balloon kyphoplasty, and vertebroplasty.
- Adjusted number needed to save 1 life saved for nonsurgical management versus kyphoplasty 14.8 at 1 year, 11.9 at 5 years; non-surgical management versus vertebroplasty ranged from 22.8 at 1 year, to 23.8 at 5 years.
- This large dataset analysis (>2 million patients) reveals that vertebral augmentation provides a significant mortality benefit over non-surgical management.

# Vertebral Compression Fracture

- Osteoporosis
- Neoplasm
- Hemangioma
- Myeloma
- Metastasis

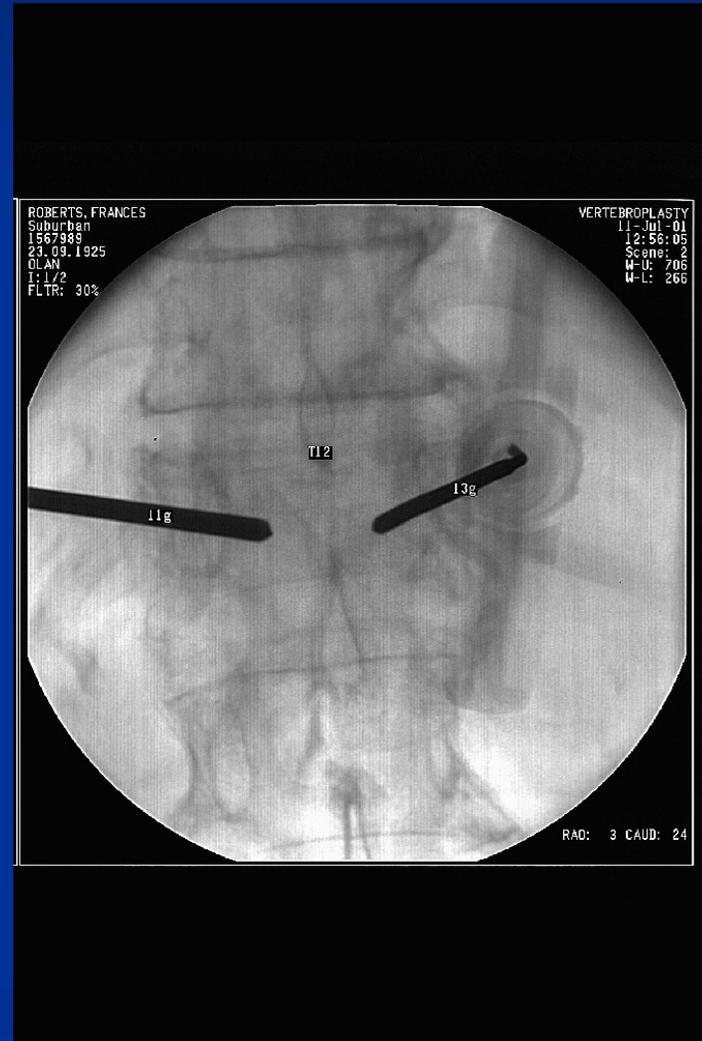
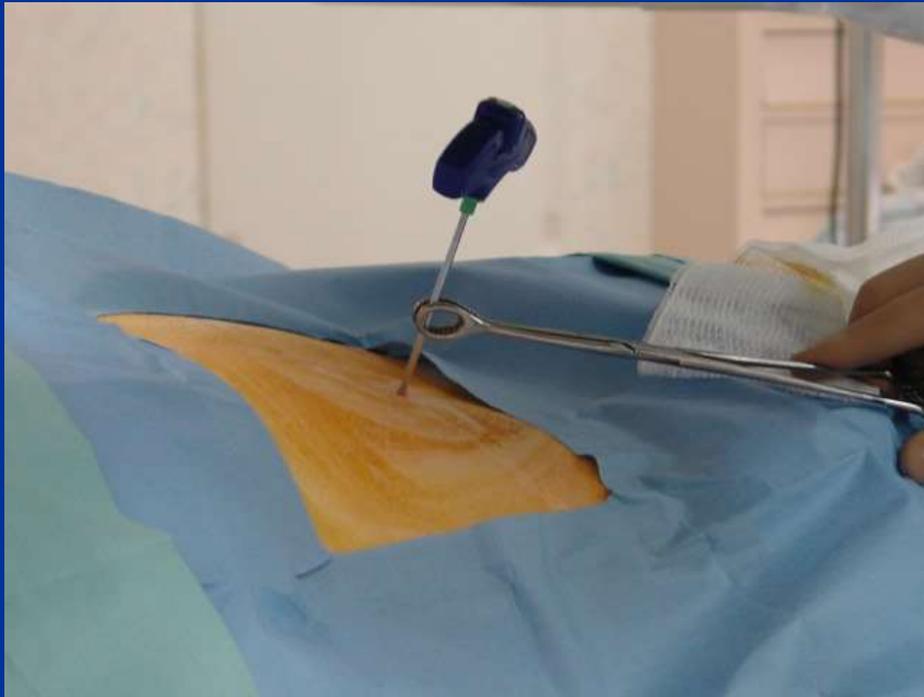


# Osteoplasty

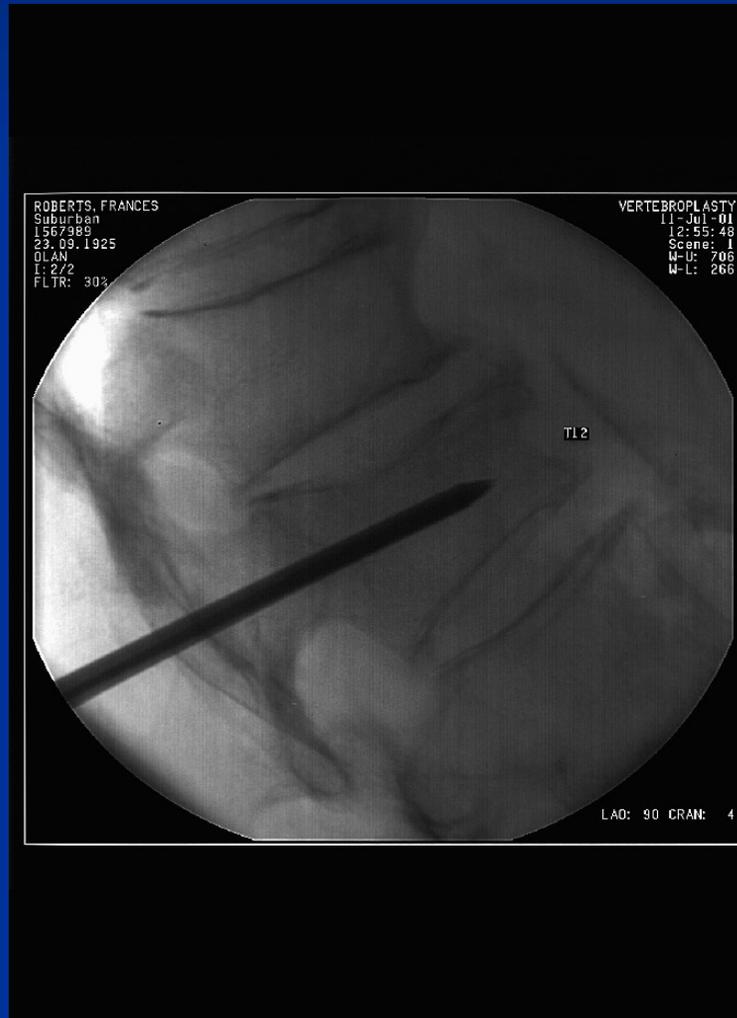
- A procedure for treatment of compression fractures.
- Promotes quicker return to activity.
- Originally not intended for treatment of traumatic fractures.
- Originally not intended for treatment in those less than 55 years of age.

Kyphoplasty and Vertebroplasty

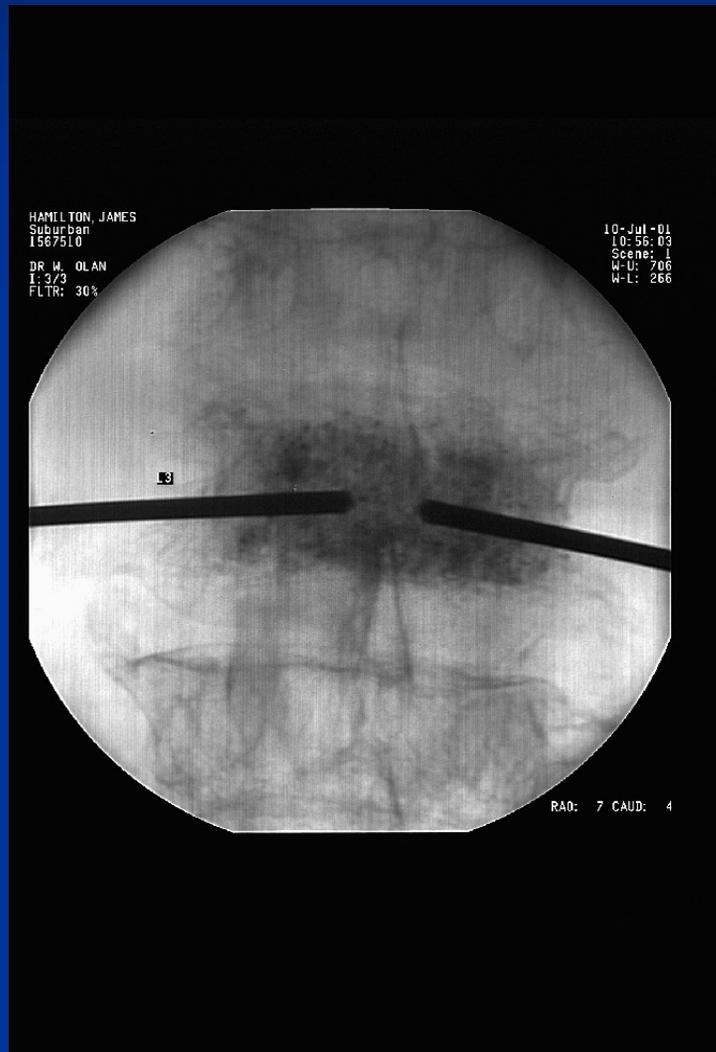
# Vertebroplasty



# Vertebroplasty

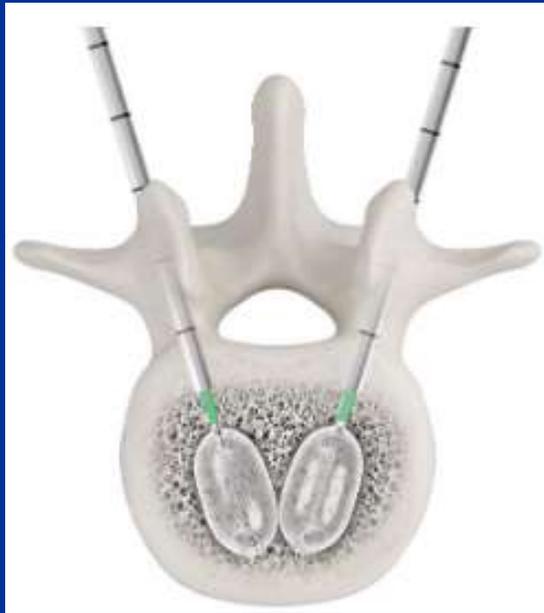


# Vertebroplasty



# New VCF treatment options

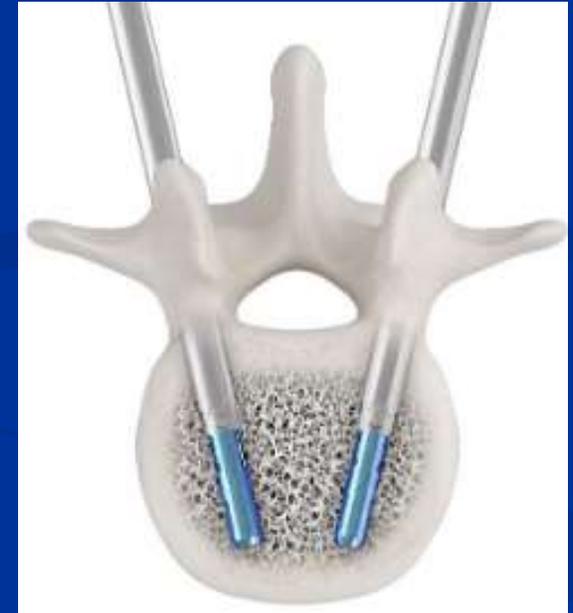
**Bi-Pedicular Balloon  
Augmentation**



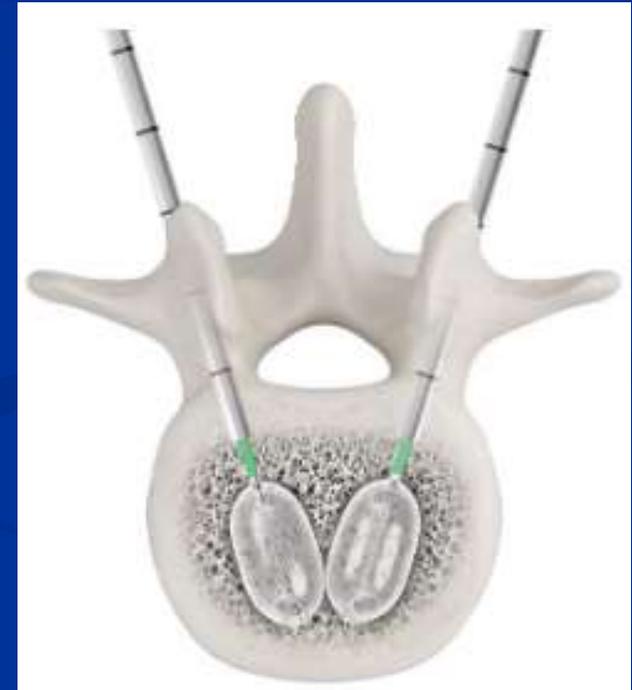
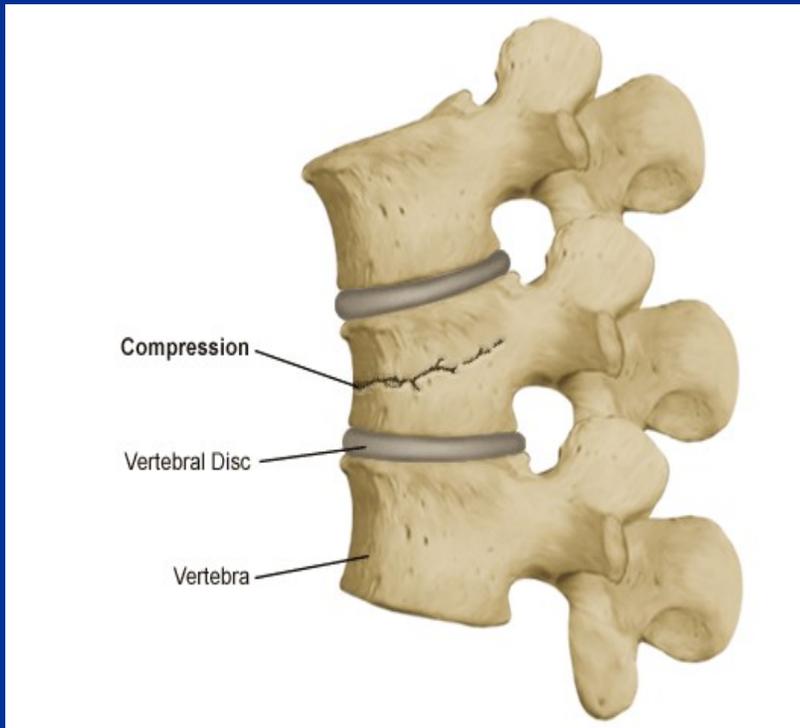
**Uni-Pedicular Balloon  
Augmentation**



**Spinejack Augmentation**



# Kyphoplasty



# Kyphoplasty



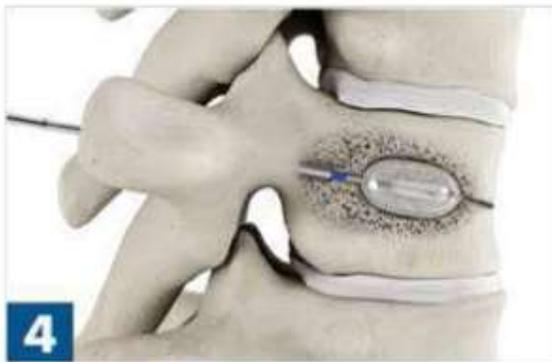
**1** Needle to posterior 1/3<sup>rd</sup>



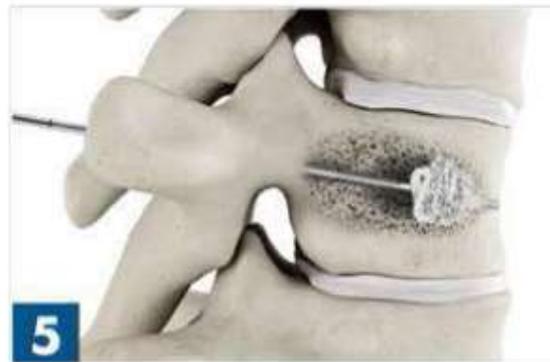
**2** Drill to anterior 1/3<sup>rd</sup>



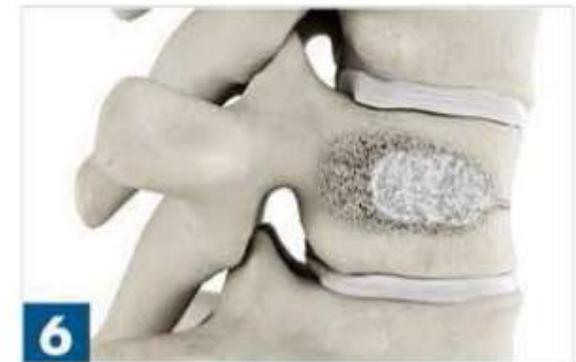
**3** Insert balloon



**4** Inflate balloon

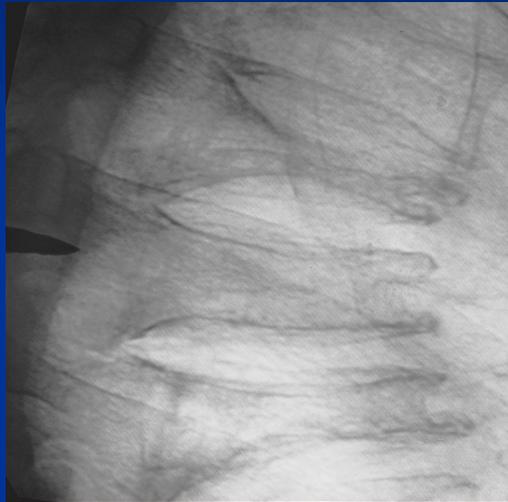


**5** Inject cement

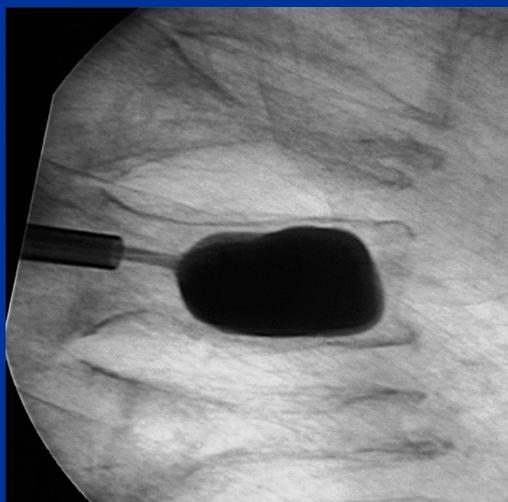


**6** Cement interdigitates

# The Procedure



**Pre-kyphoplasty**



**IBT Inflation**

- Minimally invasive (only 0.5 cm incision)
- General or local anesthesia
- Typically 15-20 minutes per treated fracture
- Adverse event risk due to bone cement leak very low (< 0.3% per patient)

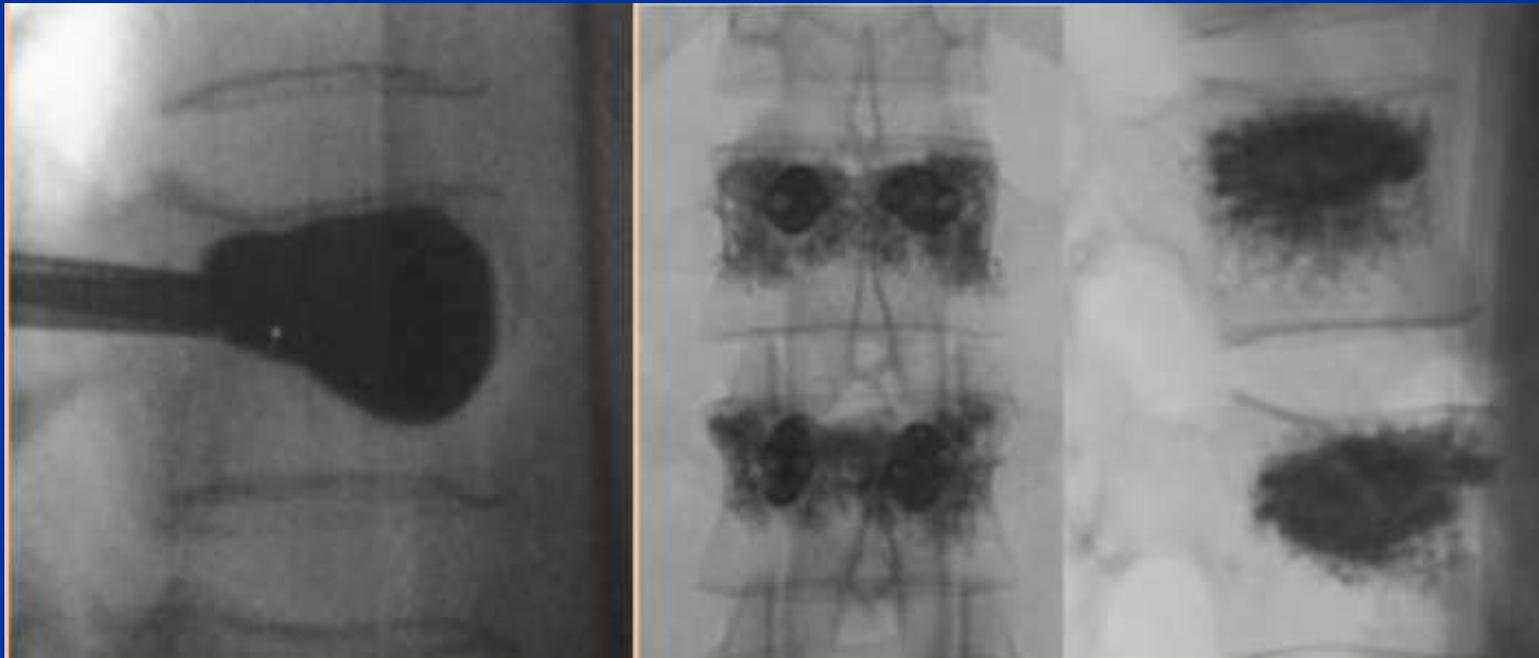
# Spine Jack



# Spine Jack in action



# Spinejack Difference



# Osteoporotic fracture

- Pre-operative situation:
  - Patient: 62, Female
  - Fracture type: Inferior Endplate

Level: L4

- Pre-op VAS: 10/10
- Post-operative situation:
  - 5.8mm Spinejack
  - Cement amount: 4-6 cc
  - Post-op VAS: 1/10



# Osteoporotic fracture

## ■ Pre-operative situation:

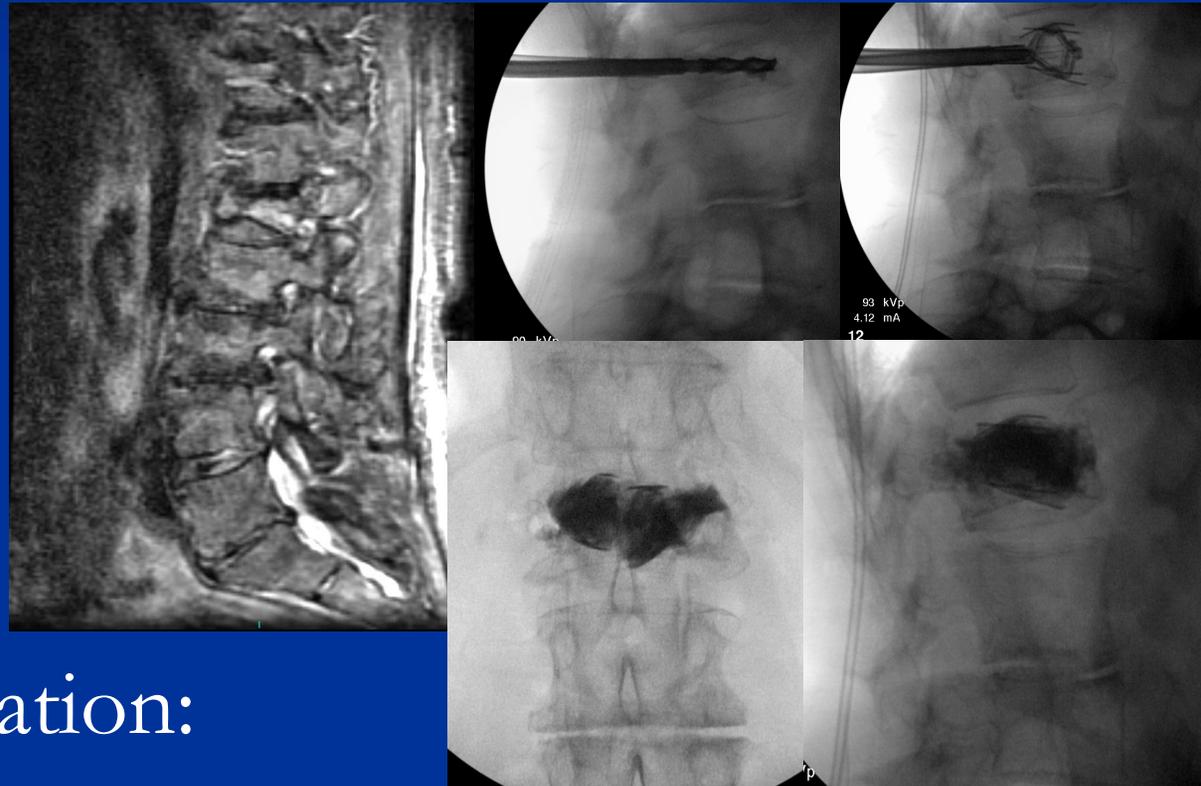
- Patient: 68 male
- Fracture type:
- 70% Compression

Level: L1

- Pre-op VAS: 9/10

## ■ Post-operative situation:

- 5.0mm Spinejack
- Cement amount: 7-8 cc
- Post-op VAS: 2/10



# Osteoporotic fracture

## ■ Pre-operative situation:

- Patient: 61 male
- Fracture type: 10% Compression
- Focus on less cement

Level: L2

- Pre-op VAS: 10/10

## ■ Post-operative situation:

- 5.0mm Spinejack
- Cement amount: 3-4 cc
- Post-op VAS: 2/10



# Osteoporotic fracture

## ■ Pre-operative situation:

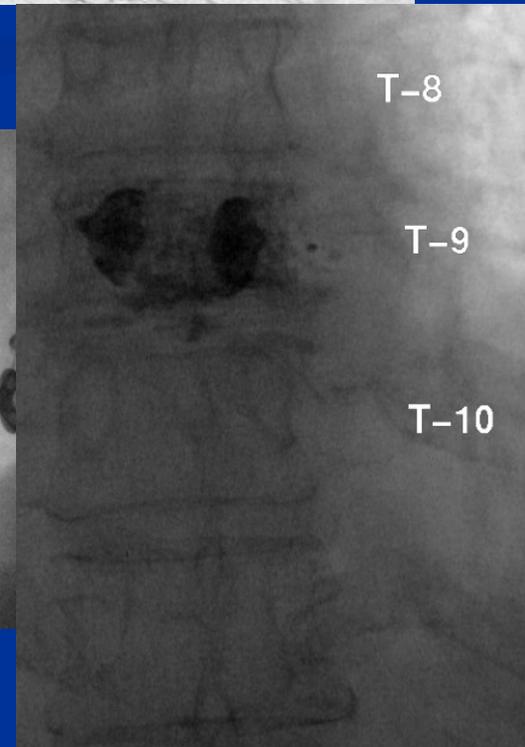
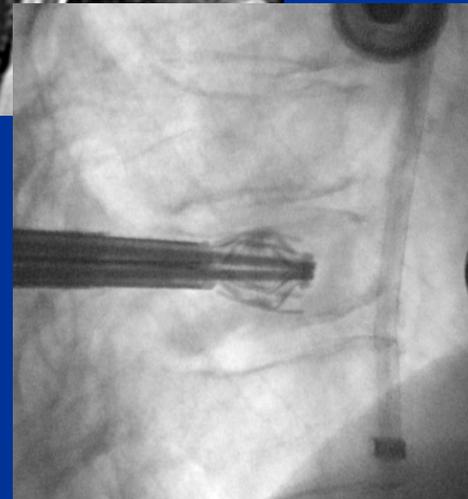
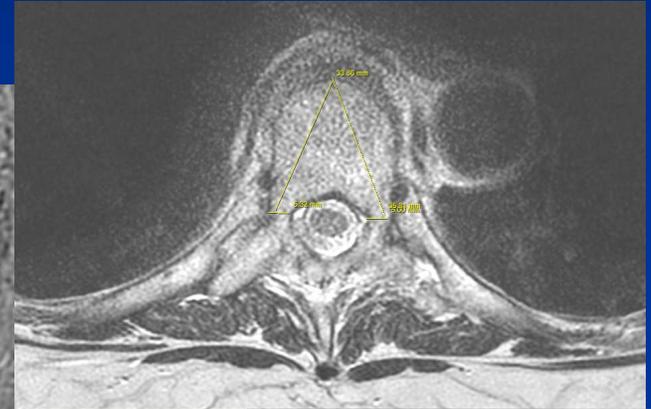
- Patient: 73 female
- Fracture type: 40%
- Compression

Level: T9

- Pre-op VAS: 10/10

## ■ Post-operative situation:

- 4.2mm Spinejack
- Cement amount: 5 cc
- Post-op VAS: 3/10



# Osteoporotic fracture

## ■ Pre-operative situation:

■ Patient: 66 Female

Levels: T10 & T11

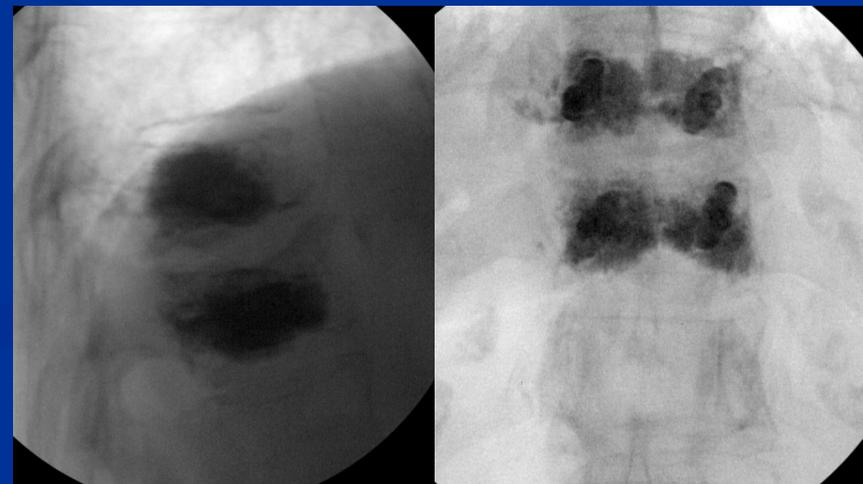
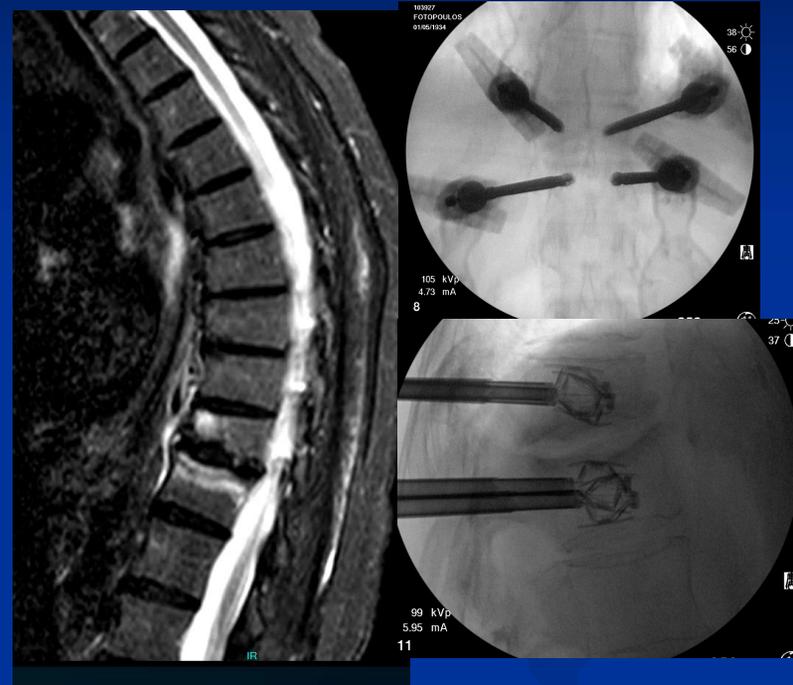
■ Pre-op VAS: 9/10

## ■ Post-operative situation:

■ 4.2mm Spinejack T10 & T11

■ Cement amount: 10cc Total

■ Post-op VAS: 2/10



# Spine Jack

- Correction of endplate deformity may help reduce the risk of adjacent level fractures
- In a study conducted by Edidin et al within a U.S. Medicare population from 2005-2009, VCF patients who received VA therapies experienced lower mortality and overall morbidity than VCF patients who received conservative management
- Significant pain relief
- Functional improvements
- Restoration of sagittal alignment

# Spinejack Additional Benefits

- • Greater midline VB height restoration
- • Significantly fewer adjacent level fractures than kyphoplasty
- • Results maintained over time in three-year follow-up
- • Fast and sustainable improvement in quality of life
- • Fracture reduction with ligamentotaxis leads to indirect central canal decompression

# SAKOS Clinical Study

## Mechanical vertebral augmentation

### SAKOS clinical study<sup>13</sup>

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

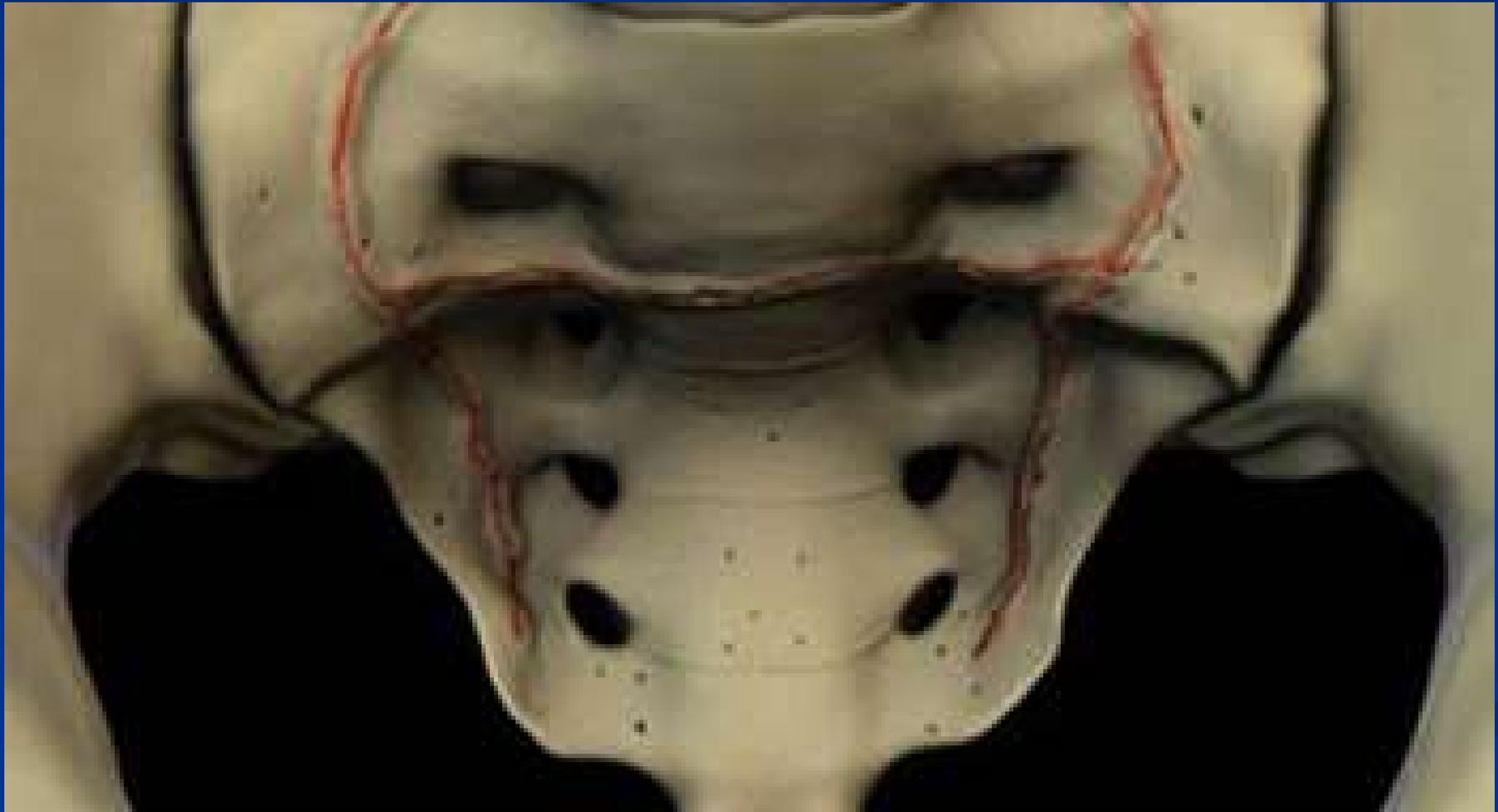
1 mo.  $p= 0.029$   
6 mo.  $p= 0.021$

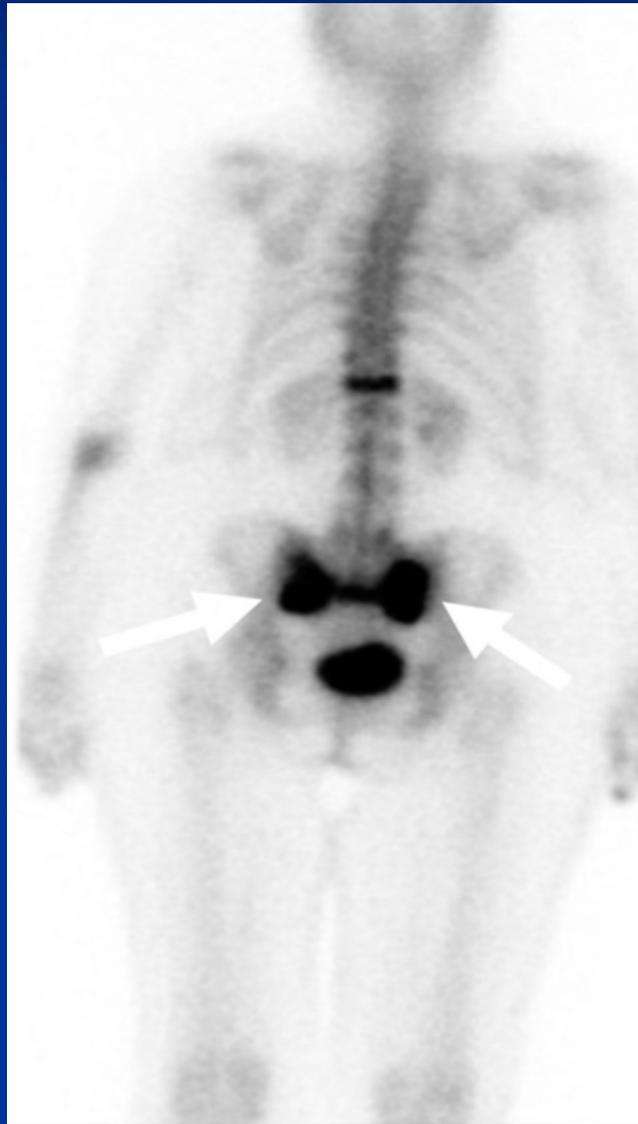
# Mechanical vertebral augmentation

## Additional SpineJack clinical data

SpineJack data	N-value	Follow-up	Key findings
<b>Bageac, D., &amp; De Leacy, R. *</b> (The Spine Journal 2020) <sup>8</sup>	<b>27 patients</b>	<b>6 month</b>	<ul style="list-style-type: none"> <li>Patients experienced an average vertebral height recovery of 74%</li> <li>Local kyphotic angle was reduced by an average of 50%</li> <li>33% of patients (n=9) achieved complete restoration of prefracture vertebral height</li> </ul>
<b>Crespo-Sanjuán J et al.*</b> (World Neurosurgery 2017) <sup>9</sup>	<b>178 patients</b>	<b>77 month</b>	<ul style="list-style-type: none"> <li>Adjacent fracture rate: 2.2% (4/178 cases)</li> <li>The mean total quantity of cement injected was 4.4 mL</li> <li>The leakage rate was 12.9%, and all of these occurrences were asymptomatic</li> </ul>
<b>Noriega D et al.*</b> (Pain Physician 2021) <sup>10</sup>	<b>44 patients</b>	<b>5+ years</b>	<ul style="list-style-type: none"> <li>Using SpineJack in the treatment of <b>fractures type A3</b> is a safe and effective method that allows marked clinical improvement, as well as anatomical vertebral body restoration</li> <li>Results were maintained over time, allowing a better long-term clinical and functional improvement</li> <li>The rate of cement leakage was lower than other reports</li> </ul>
<b>Renaud*</b> (Orthopaedics & Traumatology: Surgery & Research 2015) <sup>11</sup>	<b>77 patients</b>	<b>35 month</b>	<ul style="list-style-type: none"> <li>83 VCFs treated, 51 were due to <b>trauma</b> and 32 to <b>osteoporosis</b></li> <li>The pain score improvement was 77% at hospital discharge and increased gradually to 86% after 1 year</li> <li>The complication rate is similar to that seen with other vertebral expansion methods, whereas the risk of adjacent fractures is very low</li> </ul>
<b>Noriega D et al.*</b> (Turkish Neurosurgery 2016) <sup>12</sup>	<b>32 patients</b>	<b>12+ month</b>	<ul style="list-style-type: none"> <li>52 VCFs treated; 18 patients with <b>metastatic disease</b>, 14 patients with <b>hematologic disease</b> (9 multiple myeloma, 5 lymphoma)</li> <li>Statistically significant improvements in VAS pain and quality of life scores</li> <li>Statistically significant increase in average anterior VB height of 6.2 mm (31.6%) and central VB height of 5.8 mm (34.7%) resulting in significantly reduced kyphotic angle</li> <li>The SpineJack procedure may help reduce the complications associated with vertebral augmentation treatment of malignant VCFs, such as bone cement leakage, adjacent level fractures, and recollapse.</li> </ul>

# Sacral Insufficiency Fracture

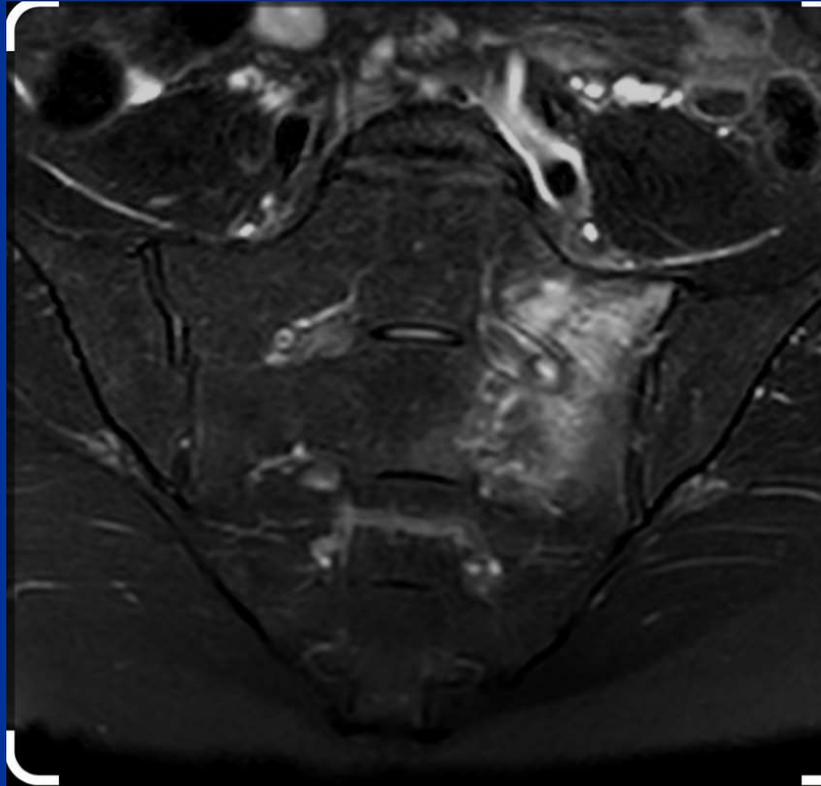




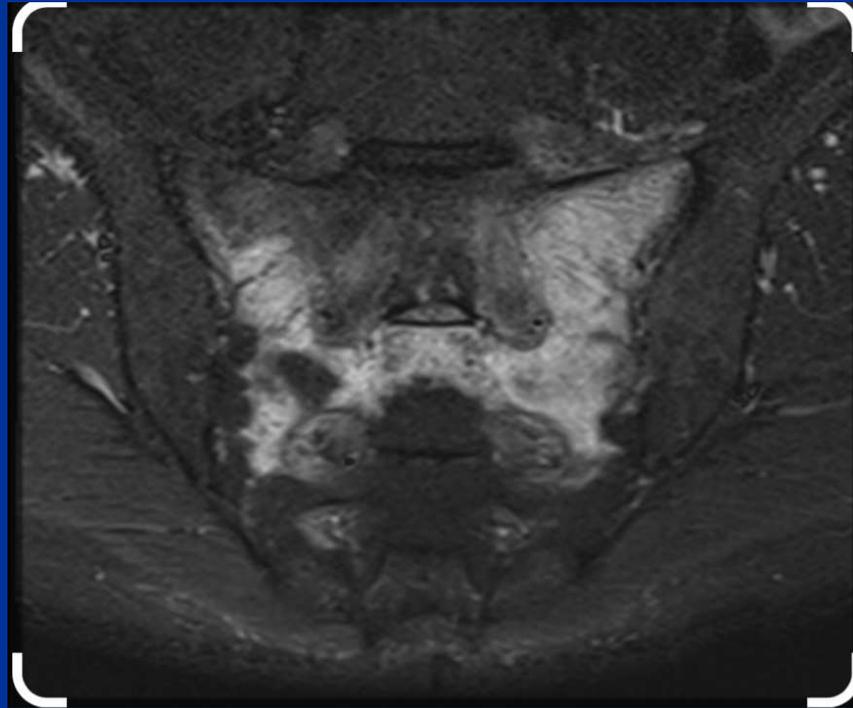
# Sacroplasty

- Sacral Insufficiency Fractures
- Known complication of Osteoporosis
- Until recently went untreated or poorly treated
- Newer treatment options have been developed
- Requires very high index of suspicion
- Sacroplasty

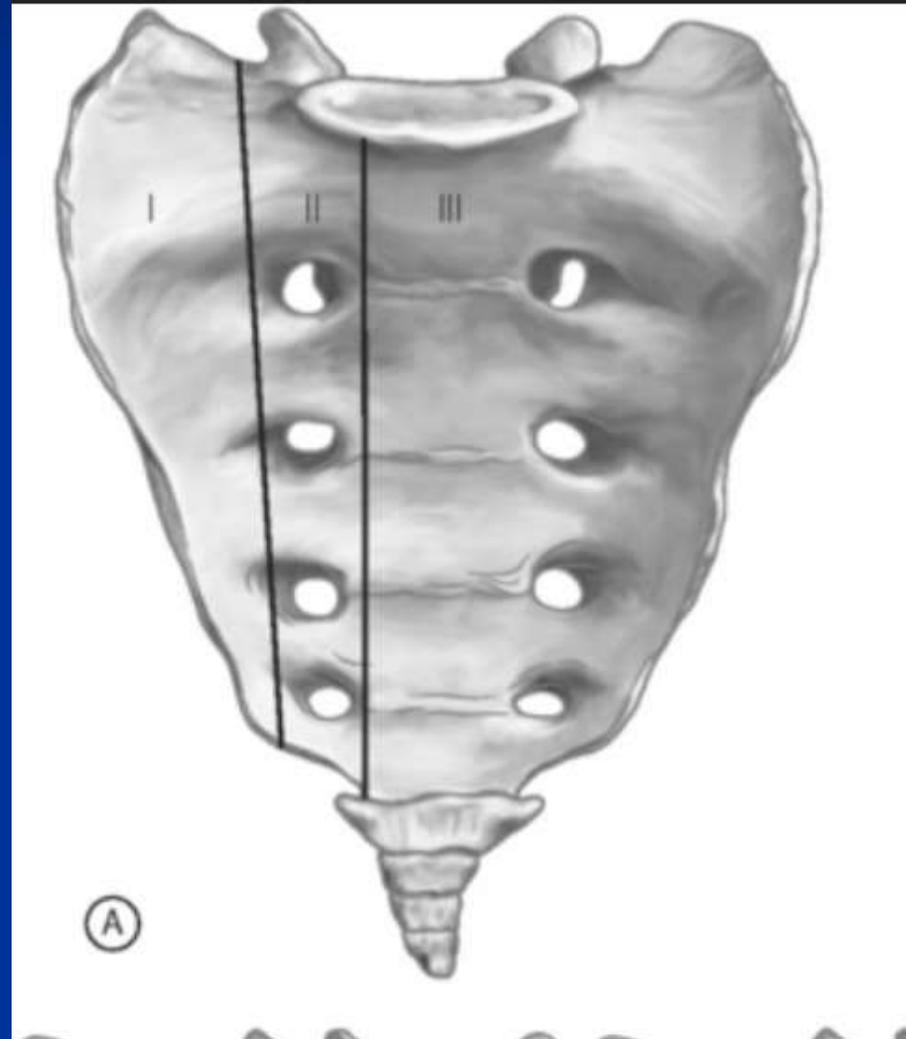
# Sacral Fracture



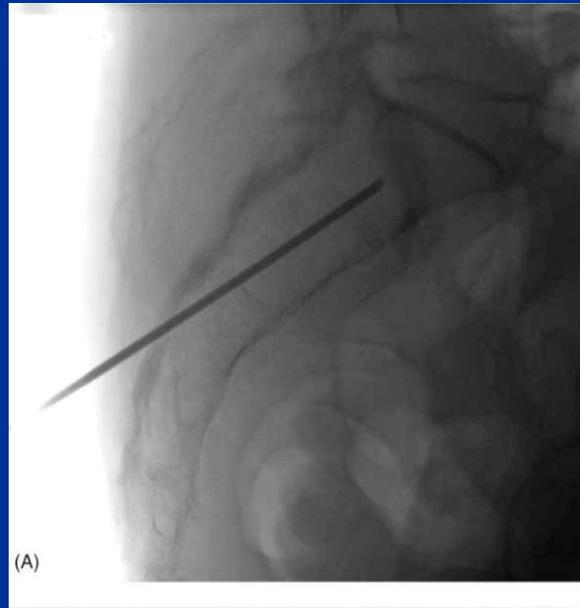
# Honda Sign



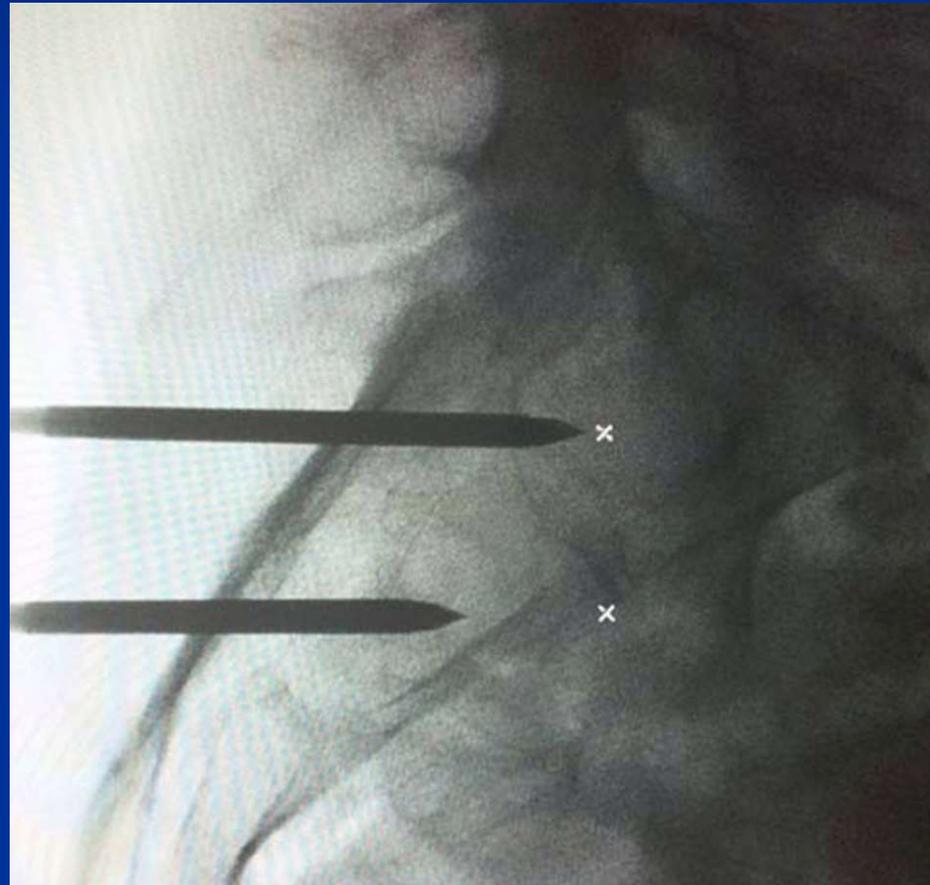
# Zones



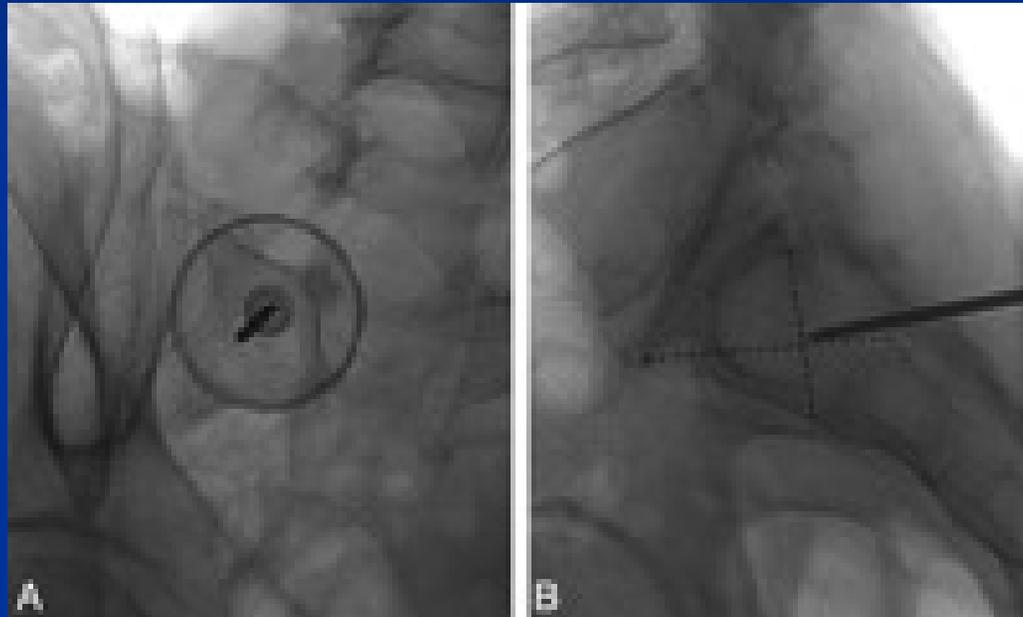
# Long Axis



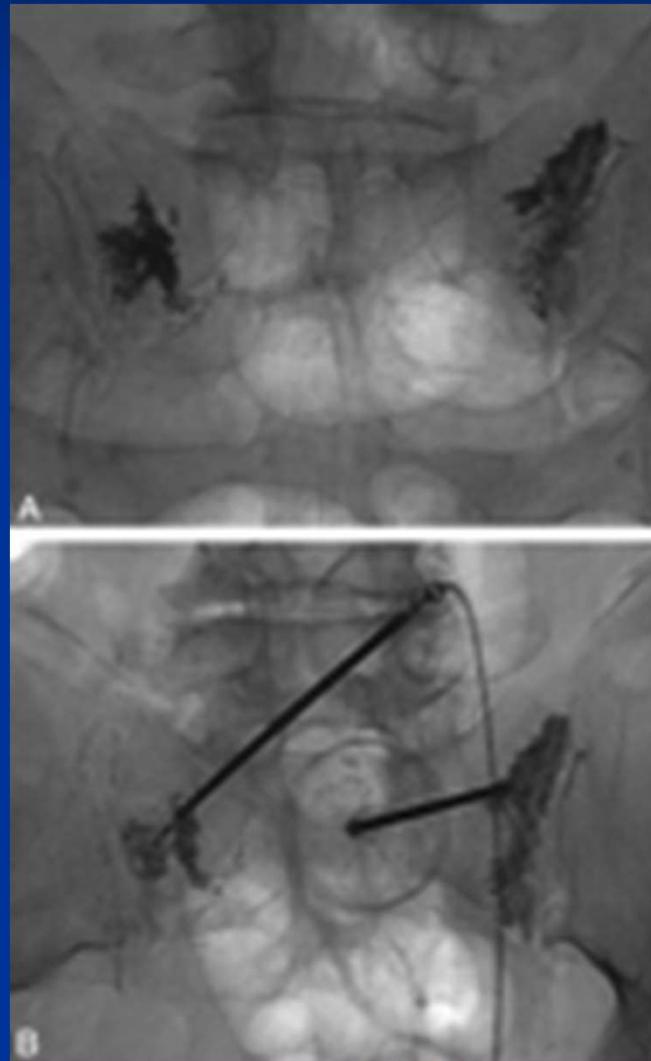
# Short Axis



# Sacroplasty



# Sacroplasty



# Conclusion

- Osteoporosis is a significant disease entity
- Diagnosis requires intervention and high level of suspicion
- Treatment is best done through prevention
- IF fracture suspected, recc Imaging and referral for Vertebral Augmentation.

