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Engineering the extraordinary

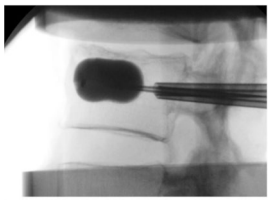
Sustaining height restoration: A comparison of three procedures

A Medtronic-sponsored cadaveric study evaluates bilateral vertebral augmentation systems for vertebral compression fractures

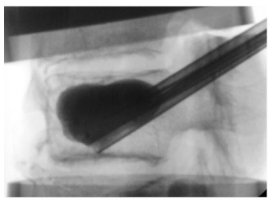
Treating VCF with BKP/BKP with Kyphon Assist™ directional cannula

A Medtronic-sponsored cadaveric study[1] evaluated three different bi-lateral procedures with respect to height restoration and sustainability post operatively[1]:

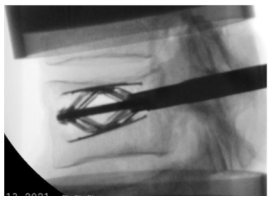
- BKP
- BKP with Kyphon Assist™ directional cannula (BKP w/KA)
- Titanium implantable vertebral augmentation device (TIVAD)



BKP



BKP w/KA



TIVAD

Methods

- Five osteoporotic female human cadaver thoracolumbar spines (age: 63 to 77 years, T-score: -2.5 to -3.5, levels: T7 to S1) were dissected into 30 two-functional spine units (2FSUs).
- Vertebral wedge compression fractures were created by reducing the anterior height of the vertebrae by 25%.
- Post-fracture, surgery was performed on each 2FSU. Surgeries included BKP, BKP w/KA, or TIVAD (n = 10 per treatment group).

Cyclic loading

Post-surgery, cyclic loading was performed on each 2FSU:

- 600 N loading: 10,000 cycles
  Representative activity: Walking
- 850 N loading: Additional 5,000 cycles
  Representative activity: Standing up/sitting down
- 1250 N loading: Additional 5,000 cycles
  Representative activity: Lifting a 5–10 kg weight from the floor

Anterior, central, and posterior heights were assessed based on fluoroscopic imaging and compared among treatment groups with ANOVA.

Limitations

- Although cyclic loading was performed for a total of 20,000 cycles, the study did not address long-term biomechanical performance.
- Wedge fracture was produced with static loading; cyclic fatigue loading may have better approximated a clinical setting.

Learn more.
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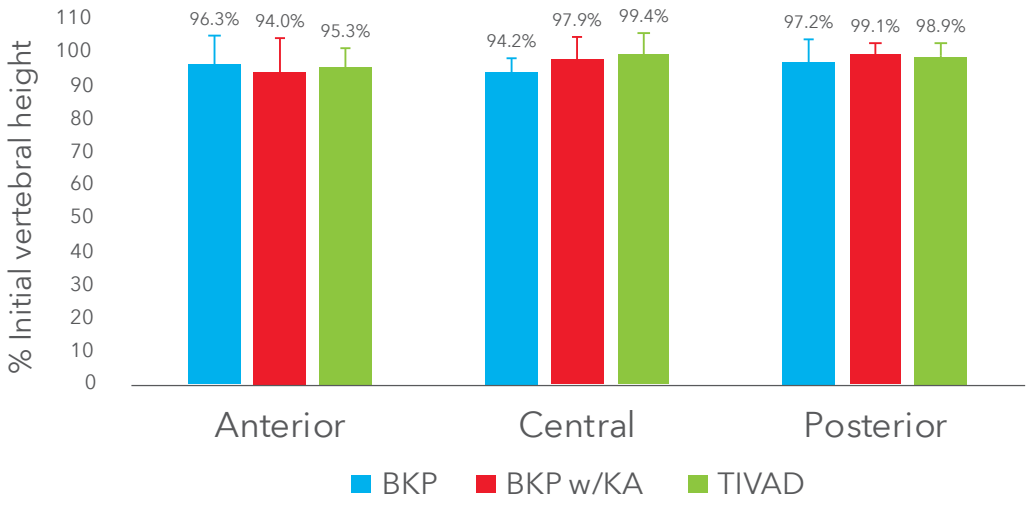
Height restored with BKP and BKP w/KA

All three treatments can restore height similarly after a vertebral compression fracture. At least 94% height restoration was attained with all treatments.[1]

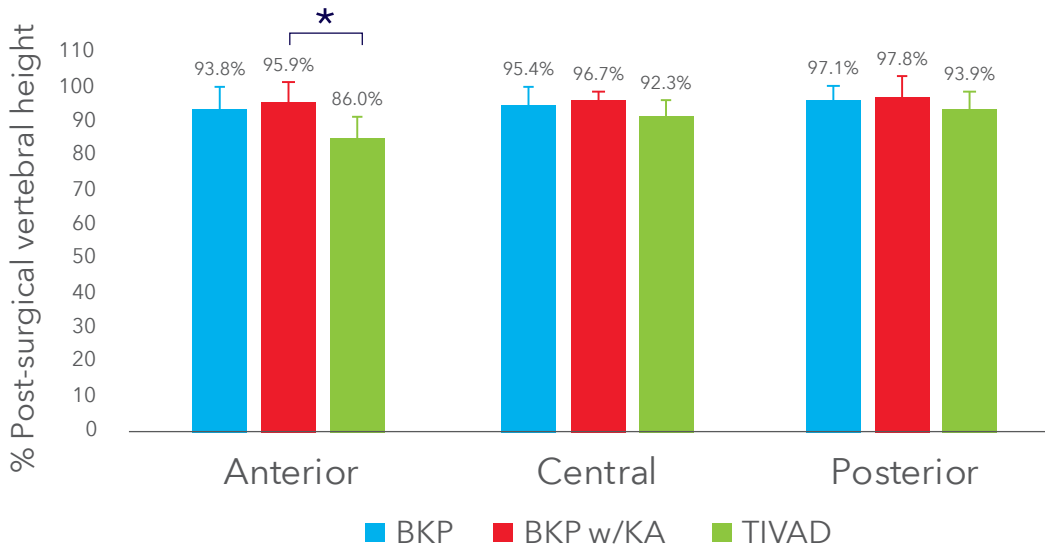


Compared to the initial height, post-surgery anterior height was 96.3 ± 8.7% for BKP, 94.0 ± 10.0% for BKP w/KA, and 95.3 ± 5.8% for TIVAD.[1]

No difference observed in height restoration among treatment groups (p = 0.72).[1]

Height sustained after highest loading with BKP w/KA

Less anterior height loss (~10%) following high-level 1250N cyclic loading **was observed in the BKP w/KA group compared to TIVAD** after highest level of loading.[1,11]



Anterior height decreased after 1250 N loading to 93.8 ± 6.8% of the post-surgery height for BKP, 95.9 ± 6.4% for BKP w/KA, and 86.0 ± 6.6% for TIVAD (p = 0.02).[1]

The mean anterior height loss between post-surgery and post-1250 N loading **was lower for BKP w/KA compared to TIVAD** (p = 0.02), but not when comparing BKP to TIVAD (p = 0.07).[1]

No difference in height sustainability at lower load levels (600 N (p = 0.76) and 850 N (p = 0.20)) was observed among treatment groups.[1]

The basic principles of fracture management include[12]:

1. **Fracture reduction** – Correct anatomical relationships with a goal of restoring height
2. **Fracture fixation** – Provide absolute or relative stability as the type of fracture, the patient, and the injury require
3. **Preservation** – Provide blood supply to soft tissues and bone
4. **Early and safe mobilization** – Address the injured part and the patient as a whole

For patients with VCFs, several previous studies[3,4] support bilateral BKP versus nonsurgical management (NSM), vertebroplasty (VP), and unilateral BKP as they pertain to items 2–4 above: fracture fixation, preservation, and early and safe mobilization.

And now, clinical research further confirms the role of bilateral BKP in item 1 above: fracture reduction and height restoration.

VCFs are serious

Even a single vertebral compression fracture (VCF) can lead to progressive[2]:

- Loss of height
- Increased kyphosis
- Severe and chronic back pain
- Reduced mobility
- Reduced pulmonary function

1.4 million people

are estimated to be affected by VCFs every year – worldwide.[3]

Why Medtronic?

As a market-leading healthcare solution provider, we support your practice or institution to help you thrive as a center of excellence. How? By listening to you, partnering with you, and providing solutions:

- **Portfolio** – Medtronic team expertise in a comprehensive portfolio, including balloon kyphoplasty market originator, vertebral augmentation therapy innovator and market leader, and metastatic bone tumor and nerve ablation market expanders
- **Partnerships** – Medtronic team expertise, supporting improved patient access, cost-effective solutions, research, and innovation
- **Patient access** – Medtronic team expertise, reducing barriers through therapy awareness programs, reimbursement advocacy, and established VCF clinical care pathways backed by powerful metrics and research
- **Powerful evidence** – Including mortality risk data[4–9] and clinically demonstrated swift pain relief for patients with VCF and painful metastatic lesions in the bone,[10] and with better VCF outcomes than nonsurgical management[3]
- **Predictability** – Evidenced in procedure and product performance
- **Progress** – Robust educator and committed, long-term investor in advancing the therapy

Medtronic Kyphon™ balloon kyphoplasty

- **Relieving VCF pain since 1998**
- **Backed by solid clinical evidence for 20+ years**
- **1.8+ million fracture levels treated**

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Balloon Kyphoplasty Indication and Risk Statement

Kyphon™ Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

The overall complication rate with the procedure has been demonstrated to be low. Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, cardiac embolism.

For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.

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