Fracture Reduction Achieved by an Inflatable Bone Tamp During Kyphoplasty Under Simulated Physiological Load: Comparisons to Height Restored by Use of an Outer Sleeve

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Introduction

The loss of vertebral height after bone tamp removal and prior to filling the created cavity with bone cement is a problem that remains a concern with kyphoplasty. [1] An outer sleeve that surrounds the bone-tamp may help maintain height during the kyphoplasty procedure while filling the created cavity with bone cement on the contralateral side.

Methods

Twenty seven osteoporotic vertebral bodies (T11-L4) were sequentially assigned to one of three treatment groups: Group A, commercially available bone tamp I; Group B, commercially available bone tamp II; and Group C, bone tamp I with sleeve. Each vertebral body (VB) was compressed axially on an MTS Bionix 858 machine at a rate of 5mm/min until compressed by 40% of the initial anterior height (Figure 1). The fractured VBs then underwent kyphoplasty with cement augmentation (Figure 2). After the cement cured, augmented vertebral bodies were then recompressed. The anterior vertebral body height (mm) and wedge angle (degrees) were measured initially, after mechanically creating an anterior wedge fracture, and after repairing the compression fracture. Each vertebral body was subjected to 111N load to simulate in vivo physiologic loading during inflation and cement augmentation.[2] Failure loads were compared between intact and repaired VBs using a paired t-test ($p<0.05$).

The vertebral height, wedge angle, cement volume, and inflation pressure was compared between the treatment groups using an unpaired t-test ($p<0.05$).

Vertebral Compression

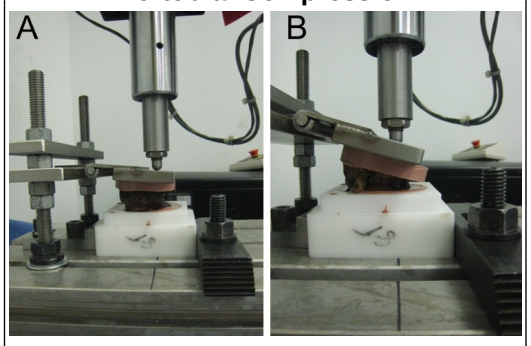

Figure 1: Each vertebra was seated in a loading fixture and axial load was applied by the test machine on the bonded superior endplate via a hinged-plate fixture to create an anterior vertebral compression fracture. A) Before compression. B) After compressing vertebral body by 40% of its initial anterior height.

Results

The average percentage of lost VB height restored in Group A,B,C was 29%, 30% and 56%, respectively (Figure 3). A similar trend was observed in the mean changes in vertebral body wedge angle. Average percentage increase in failure load was 218%, 241%, and 212% in Group A, B, and C, respectively. No significant difference in mean inflation pressures (Group A,B,C: 182 ±33 psi; 175 ±37 psi; 160 ±36 psi) and cement volume (Group A, B, C: 6.73 ±0.41cc;6.65 ±0.65cc;6.72 ± 0.56cc) was found among the three groups.

Procedural steps for Group C vertebral bodies

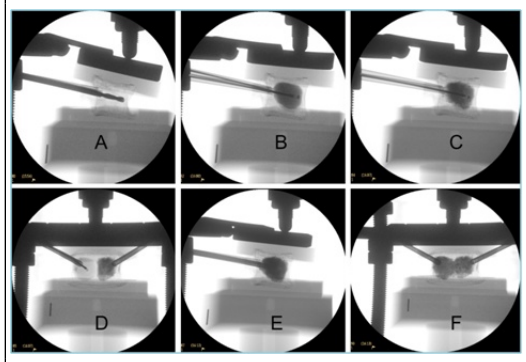

Figure 2: A) Bone tamps placed between anterior and posterior walls of the vertebral body through created drill channels. B) Lateral view of inflated bone tamps with sleeve on one side. C) AP view of the two inflated balloons. D) AP view showing cement injected through one channel while the inflated tamp with sleeve on the contralateral side maintain height. E) Lateral view of cement injection into the created cavity. F) AP view of the cemented vertebral body. All images show a 10mm calibration pin placed in the posterior vertebral body.

Conclusions

This in vitro study demonstrates that some height restoration was seen using traditional bone tamp in fractured vertebral bodies under simulated physiological load. This restoration corroborates clinically observed numbers, but is less than previous studies which neglected axial loads on the spinal column. The use of an outer sleeve significantly enhanced height restoration compared to the two inflatable bone tamps alone.

Verteral Height Comparison

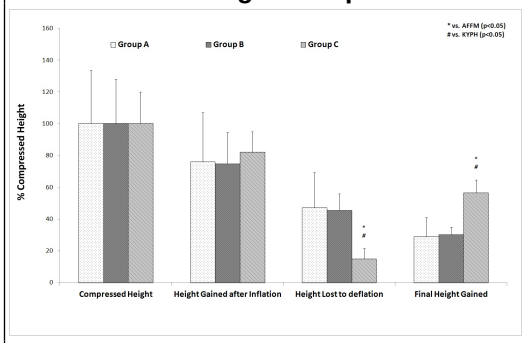

Figure 3: Normalized height at various technique steps compared to the compressed state.

References

1.Belkoff SM, Jasper LE, Stevens SS. An ex vivo evaluation of an inflatable bone tamp used to reduce fractures within vertebral bodies under load. Spine 2002; 27(15):1640-3.

2.Rotter R, Martin H, Fuerderer S, Gabl M, Roeder C, Heini P, Mittlmeier T. Vertebral body stenting: a new method for vertebral augmentation versus kyphoplasty. Eur Spine J. 2010; 19(6):916-23.

Disclosures

The device(s)/drug(s) that is/are the subject of this E-Poster is/are FDA-cleared/approved for this indication in the United States.