AN EX VIVO EVALUATION OF AN INFLATABLE BONE TAMP TO REDUCE FRACTURES WITHIN VERTEBRAL BODIES UNDER LOAD

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Introduction
Osteoporotic compression fractures of the vertebrae occur commonly in elderly women and can lead to altered spinal mechanics, disability, and reduced pulmonary function. Recently, a new procedure (kyphoplasty) has been developed that uses an inflatable bone tamp as a means of restoring vertebral body (VB) height. Ex vivo studies have indicated significant height restoration to compressed VBs after treatment with kyphoplasty, but fracture reductions were obtained with the VB endplates under stress-free conditions. It is unknown under what physiologic loads height can be restored.

The purpose of the current study was to measure the amount of height restored by the bone tamp used to reduce simulated compression fractures in osteoporotic vertebrae under two static axial loads. Our hypothesis was that there significantly greater height would be restored in VBs subjected to the lower simulated physiologic load than in those subjected to the higher load.

Materials and Methods
Eighteen VBs (T11-L4) were harvested from fresh female cadavers more than 65 years old. Bone mineral density was measured via the Dual Energy X-ray Absorptiometry (DEXA) method with rice bags placed along the spine to serve as surrogate soft tissue. The vertebrae were disarticulated, their discs were excised, and the posterior elements were removed to facilitate mechanical testing. Adjacent VBs (i.e., T1 & T2, L1 & L2, L3 & L4) were considered as paired specimens within a given donor. One of each pair was assigned to the high-load (HL) group; the other, to the low-load (LL) group. The VBs were wrapped in saline-soaked gauze, sealed in plastic bags, and stored frozen at -20°C until the day before testing.

All specimens were thawed at room temperature (~20°C) for 24 hours before testing. A custom-molded surrogate rubber disc was placed between the VB and each platen of the special radiolucent loading fixture. A lateral image was obtained with a mini C-arm, and VB heights were measured at the anterior and posterior aspects with a calibrated marker placed at the anterior surface of the specimen along the midsagittal plane. An impression of each endplate of each vertebra was made with a common epoxy resin. Each VB was then seated between its respective impressions and placed between platens on an Instron materials testing machine. A preload of 80 N was applied for 2 minutes. Immediately thereafter, compression was applied in stroke control, with the actuator acting along the vertical axis through the center of the VB. The factors were treatment (LL vs. HL) and age (18-65 vs. >65 years old). Bone mineral density was measured via the Dual Energy X-ray Absorptiometry (DEXA) method with rice bags placed along the spine to serve as surrogate soft tissue. The vertebrae were disarticulated, their discs were excised, and the posterior elements were removed to facilitate mechanical testing. Adjacent VBs (i.e., T1 & T2, L1 & L2, L3 & L4) were considered as paired specimens within a given donor.

Discussion
In the current study, we measured height restoration achieved by the inflatable bone tamp in specimens under a simulated physiologic load. The results indicated that use of the tamp produces significant VB height restoration but does not fully restore height to the prefracture state. Similar results have been reported previously for both in vivo and ex vivo studies. Kyphoplasty has been shown to restore significantly more VB height ex vivo than standard percutaneous vertebroplasty. Mean height restored in that study was 2.5 ± 0.7 mm, a value similar to that achieved in the current study. In vivo physiologic axial loads in the spine reportedly average 144 N and 240 N for the prone and lateral positions, respectively. In the current study, we used 111-N and 222-N axial loads to approximate those present in vivo and obtained height restoration consistent with that (2.9 mm) reportedly obtained clinically.

Table 1.

<table>
<thead>
<tr>
<th>Experimental Condition</th>
<th>Low Load Group</th>
<th>High Load Group</th>
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<tbody>
<tr>
<td>Initial</td>
<td>26.6 ± 0.4</td>
<td>26.3 ± 0.4</td>
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<tr>
<td>Postcompression</td>
<td>21.6 ± 0.4</td>
<td>22.5 ± 0.4</td>
</tr>
<tr>
<td>Postinflation</td>
<td>24.4 ± 0.4</td>
<td>24.4 ± 0.4</td>
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</table>

*Mean ± SEM, n = 9

Comparing groups, there was no significant difference in balloon inflation volumes (LL, 7.0 ± 2.2 ml; HL, 7.0 ± 2.6 ml) or in inflation pressures (LL, 185.9 ± 22.6 psi; HL, 219.8 ± 58.6 psi). Inflation was suspended because of cortical contact or impending cortical breach in 7/9 VBs in both load groups.

References

**Kyphon Inc., Sunnyvale, CA.**