

# An *Ex Vivo* Evaluation of an Inflatable Bone Tamp Used to Reduce Fractures Within Vertebral Bodies Under Load

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**Study Design.** *Ex vivo* biomechanical study using osteoporotic cadaveric vertebral bodies.

**Objective.** To determine if fracture reduction could be achieved by the inflatable bone tamp (tamp) in vertebral bodies under simulated physiologic loads.

**Summary of Background Data.** Previous *ex vivo* biomechanical studies showed that kyphoplasty restored vertebral body height with vertebral body endplates under stress-free conditions.

**Methods.** Simulated compression fractures were experimentally created in 18 osteoporotic vertebral bodies alternatingly assigned to one of two treatment (tamp inflation) groups: low axial load (111 N) or high axial load (222 N). Each vertebral body was then placed between two platens in a special radiolucent loading fixture and subjected to the preassigned load to simulate *in vivo* physiologic loading. The tamps were inflated and post-reduction heights were measured fluoroscopically. The effect of applied load and condition on vertebral body height was checked for significance ( $P < 0.05$ ).

**Results.** Comparing the experimental conditions (initial, postcompression, postinflation), there were no significant vertebral body height differences between the load groups (low load vs. high load). However, vertebral body height differences between conditions within each load group were all significant. For the low-load and high-load groups, mean postinflation heights (24.4 and 24.4 mm) were significantly greater than mean postcompression heights (21.6 and 22.5 mm) but significantly less than initial vertebral body heights (26.6 and 26.3 mm), respectively. Initial heights were fully restored in 22% (two of nine) of vertebral bodies in both groups.

**Conclusion.** The inflatable bone tamp restored some of the height lost to compression fractures in vertebral bodies under simulated physiologic loads. [Key words: inflatable bone tamp, vertebroplasty, biomechanical evaluation, compression fractures, osteoporosis, kyphoplasty] **Spine 2002; 27:1640-1643**

Osteoporotic compression fractures of the vertebrae, which occur commonly in elderly women,<sup>17,18</sup> are often the source of pain and can lead to altered spinal mechanics, disability, and reduced pulmonary function.<sup>8,12,13,15,16,19,21</sup> Percutaneous transpedicular vertebroplasty, used clinically to stabilize compression fractures, provides pain relief and restores vertebral body (VB) strength and stiffness, but it does not fully reduce the fracture.<sup>3,5,6,10,11,22,23</sup>

Recently, a new procedure (kyphoplasty) has been developed that uses an inflatable bone tamp (tamp) as a means of restoring VB height.<sup>2,4,14</sup> The tamp is placed inside the compressed VB *via* a cannula and inflated, thus elevating the VB endplates. *Ex vivo* studies have indicated that kyphoplasty restores significant height to compressed VBs,<sup>2,4</sup> but those fracture reductions were obtained with the VB endplates under stress-free conditions. A preliminary study has suggested that kyphoplasty restores height in a most patients, yet 30% of the patients had no height restoration.<sup>14</sup> One possible explanation for the lack of height restoration is that the tamp may be unable to overcome the physiologic loads to which VBs are subjected *in vivo*.<sup>20</sup>

The purpose of the current study was to measure height restoration achieved by the tamp in VBs subjected to physiologic loads. The hypothesis was that there would be significantly greater height restoration in VBs subjected to the lower simulated physiologic load than in those subjected to the higher load.

## Materials and Methods

Eighteen VBs (T11-L4) from fresh spines were harvested from female cadavers (age range, 72-93 years) obtained from the Maryland State Anatomy Board. Bone mineral density (range, 0.42-0.79 g/cm<sup>2</sup>; t score range, -6.2 to -3.4) was measured using the Dual Energy Radiograph Absorptiometry method (Lunar DPX-IQ, Lunar Corp., Madison, WI) with rice bags placed along the spine to serve as surrogate soft tissue.<sup>4</sup> The vertebrae were disarticulated, their discs were excised, and the posterior elements were removed to more readily facilitate mechanical testing. The VBs were considered as paired specimens within a given donor. One of each pair was assigned to the low load (LL) group and the other to the high load (HL) group. Group assignment was alternated between specimens, thus distributing VBs from each spine equally between the two groups. 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. An impression of the endplates of each vertebra was made with a common epoxy resin (Fastray, Bos-

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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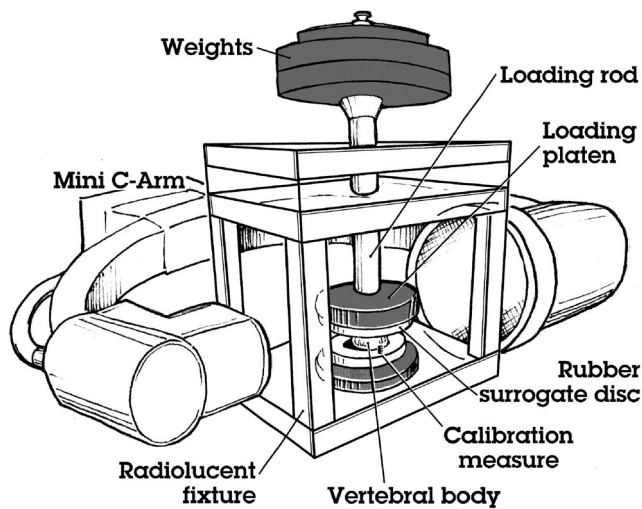


Figure 1. Experimental setup.

worth, Skokie, IL). The VBs were placed between two platens in a special radiolucent loading fixture, and a lateral image was obtained with a mini C-arm. VB heights were measured at the anterior and posterior aspects *via* a calibrated marker placed at the anterior surface of the specimen along the midsagittal plane.

Each VB was then seated between its respective impressions and placed between platens on an Instron materials testing machine (Instron, Canton, MA). A preload of 89 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<sup>22</sup> at a rate of 5 mm/min<sup>9</sup> until the VB was compressed by 25% of its average initial height (*i.e.*, average of initial anterior and posterior height). Force and deformation data were recorded at 10 Hz. The VBs were rewrapped in saline-soaked gauze, returned to their plastic bags, and returned to the refrigerator (4 C) until the time of testing (<24 hours later) to prevent dehydration and tissue degradation.

Each VB was then positioned in a special radiolucent loading fixture as follows: inferior platen, inferior surrogate intervertebral disc (custom-molded rubber), VB, superior surrogate intervertebral disc (custom-molded rubber), and superior platen (Figure 1). The VBs were then subjected to either a 111-N (LL group) or a 222-N (HL group) axial (superoinferior) load. These loads simulated the range of physiologic loads (108–212 N) calculated for young healthy volunteers (with normal spines) in the prone position.<sup>20</sup> Height measurements were made from anterior and lateral views obtained fluoroscopically with the mini C-arm, as outlined above. To provide measurement calibration, a 10-mm-long marker was placed at the anterior aspect of the VB midline for lateral views and at the lateral aspect of the VB midline for anterior views. The bone tamps were then inserted following the standard clinical procedure briefly outlined below.

Drill channels were created for placement of the tamps by passing a 3.2-mm-diameter bit (Kyphon Inc., Sunnyvale, CA) through each pedicle. An Inflatable Bone Tamp (size 15/3 or 20/3, Kyphon Inc.) was centered in each drill channel between the anterior and posterior walls of the VB. The tamps were inflated with radiopaque contrast medium in 0.5-mL increments; the inflation device was used to maintain similar vol-

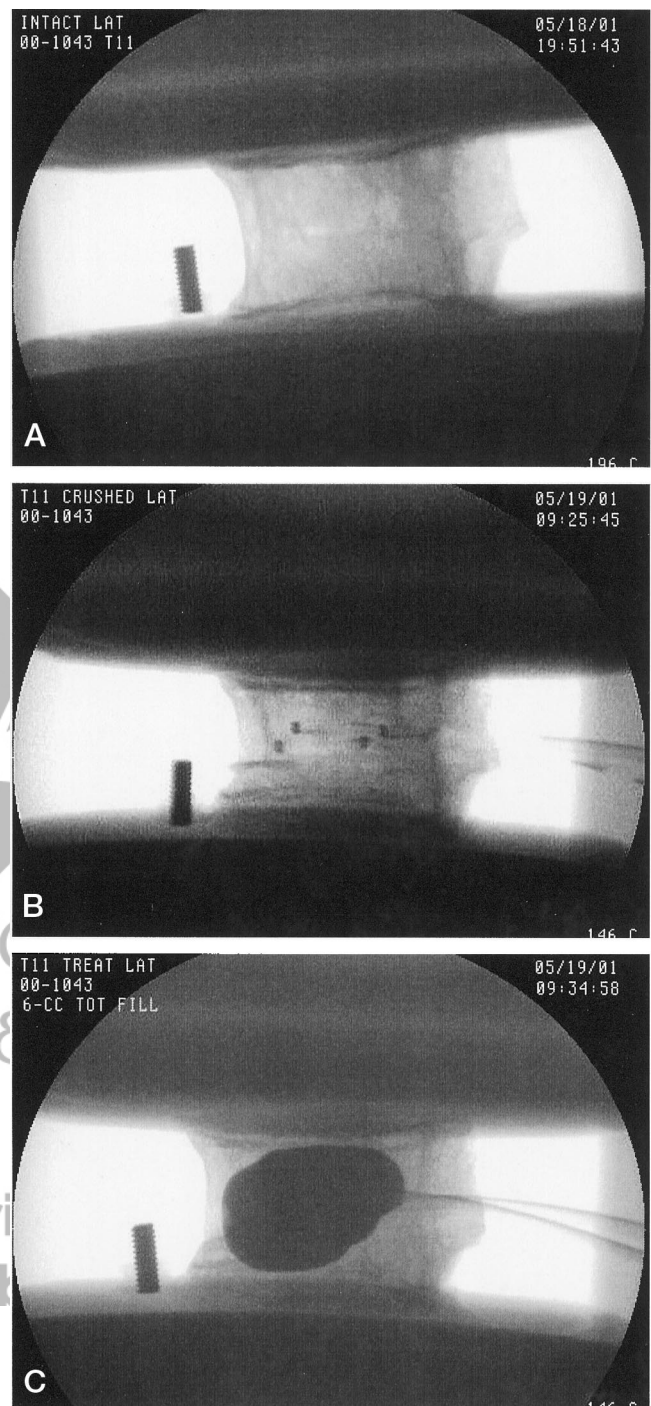


Figure 2. Lateral view of a VB (A) before creation of compression fracture, (B) after compression fracture and under simulated physiologic load (note the fiduciary markers of the uninflated tamps appear as radiodense dots), and (C) after reduction *via* bone tamp inflation. Note the calibration measure placed at the anterior aspect of the VB.

umes on each side and effect an *en masse* reduction (Figure 2). The maximum pressure was recorded at each increment of contrast volume injected. Inflation endpoints were based on the clinical endpoints of: 1) fracture reduction (height restoration) or 2) cortical contact. Postinflation heights were measured from the lateral C-arm scan as previously described. Average height lost and height restored were calculated as previously described.<sup>2,4</sup>

**Table 1. Average VB Height Measurements**

Experimental Condition	LL Group Height (mm)	HL Group Height (mm)
Initial	26.6 ± 0.4	26.3 ± 0.4
Postcompression	21.6 ± 0.4	22.5 ± 0.4
Postinflation	24.4 ± 0.4	24.4 ± 0.4

Values are mean ± SEM (n = 9).

The current authors checked for an effect of applied load on VB height by using a repeated-measures analysis of variance. The factors were treatment (LL *vs.* HL) and condition (initial *vs.* postcompression *vs.* postreduction). Differences were checked for significance using Tukey's post hoc test. Significance was set at  $P < 0.05$ , unless otherwise specified. Differences in inflation volumes and pressures between groups were checked for significance using Student's paired *t* test.

### ■ Results

Comparing the three experimental conditions, there were no significant differences in VB height between the two load groups (Table 1). However, VB height differences between conditions within each load group were all significantly different. For example, mean postcompression VB heights in the LL and HL groups were not significantly different, but within both the LL and HL groups the mean postinflation heights were significantly greater than mean postcompression heights. In both load groups mean postinflation heights were also significantly less than mean initial heights. Initial heights were fully restored in 22% (two of nine) of VBs in both groups. For the LL and HL groups the average percentage ( $\pm$  SD) of height lost to compression was  $19 \pm 5\%$  and  $14 \pm 6\%$  of initial height, respectively, and the average percentage of lost height restored was  $63 \pm 50\%$  and  $55 \pm 40\%$ , respectively.

Comparing groups, there was no significant difference in mean total balloon inflation volumes (LL,  $7.0 \pm 2.2$  mL; HL,  $7.0 \pm 2.6$  mL) or in mean inflation pressures (LL,  $185.9 \pm 22.6$  psi; HL,  $219.8 \pm 58.6$  psi). Inflation was suspended because of cortical contact in seven of nine VBs in both load groups.

### ■ Discussion

In the current study the authors measured fracture reduction (height restoration) achieved by the inflatable bone tamp in specimens under simulated physiologic loads. The results indicate that use of the tamp produced significant VB height restoration but did not fully restore height to the prefracture state in all VBs. Similar results have been reported previously for both *in vivo* and *ex vivo* studies.<sup>4,14,23</sup> Kyphoplasty has been shown to restore significantly more lost VB height (97%) *ex vivo* than standard percutaneous vertebroplasty (30%).<sup>4</sup> Mean height restored in that study was  $2.5 \pm 0.7$  mm. Interestingly, the height restoration achieved in that study was similar to the height restoration achieved in the current study, yet in the former the tamps were in-

flated in VBs whose endplates were stress free. A recent clinical study<sup>14</sup> also obtained height restoration (average, 2.9 mm) consistent with that in the current study. In the study by Lieberman et al,<sup>14</sup> patients with subacute and chronic fractures were divided into two subgroups: those who obtained height restoration (70%) and those who obtained none (30%). The average height restoration among fractures that were reduced was 47%. The current authors did not observe a bimodal distribution in VB height restoration. In the current study all VBs had some height restoration. On average, 63% and 55% of height was restored in the LL and HL groups, respectively.

The impetus for the current study was to investigate why some VBs experienced no height restoration in the earlier clinical study,<sup>14</sup> whereas nearly all lost height was restored in the *ex vivo* study.<sup>4</sup> One possible explanation was that the tamp could not overcome *in vivo* physiologic loads in some patients.<sup>14</sup> *In vivo* physiologic axial loads in the normal spines of young healthy adults in the prone position reportedly average 144 N.<sup>20</sup> The loads were calculated from intradiscal pressure measurements multiplied by the adjacent VB endplate surface area. The pressure measurements were made with the patients in various positions and under local anesthesia. In the current study the authors used 111-N and 222-N axial loads to approximate those calculated from the study by Sato et al.<sup>20</sup> Even under the simulated *in vivo* loads, the VBs in the current study had significant height restoration, suggesting that the tamp is capable of overcoming a range of *in vivo* loads. It should be noted that the simulated *in vivo* loads were calculated using data from L4 to L5 disc pressures of young (average age, 25 years; average weight, 73 kg) adults. *In vivo* loads may be expected to be lower in the more elderly, lighter-weight female population typically treated by kyphoplasty. Furthermore, loads would be expected to be less in the thoracolumbar area of the spine most often treated by kyphoplasty<sup>14</sup> than in the lower lumbar region from which the data of Sato et al were obtained.<sup>20</sup> Thus, the lack of height restoration in the subgroup studied by Lieberman et al<sup>14</sup> is likely related to other factors, such as age of fracture, amount of healing, bone remodeling, bone density, and the magnitude of paraspinal muscle tone. Patients experiencing painful muscle spasms at the level of the compression fracture would be expected to experience greater vertebral body loads. The magnitude of intravertebral loads in elderly patients with osteoporotic compression fractures is unknown. It is also unknown if the height restored during tamp inflation can be sustained once the tamp is removed. It is possible that muscle forces may decrease the apparent height restoration achieved with tamp inflation. The current *ex vivo* study departed from the clinical practice of kyphoplasty in that the experimental protocol was suspended before tamp removal and void filling. It was our original intention to determine if the bone tamp could reduce fractures in the presence of simulated *in vivo* loads. In retrospect, it

would have been interesting to see if fracture reduction would have been sustained after tamp removal and void filling. The role the above-mentioned factors play on fracture reduction needs to be determined to define which fractures are most likely to be reduced *via* the tamp. The effect of traction and postural position on fracture reduction also must be determined. One report indicated that mild axial traction and hyperextension also result in fracture reduction,<sup>1</sup> but the amount of reduction obtained and the consistency with which it was obtained are unknown.

Contrary to the original hypothesis, the current authors found no significant difference in height restoration between the two load groups in the current study. This result is likely related to the current study design, the magnitude of loads used, and the inflation endpoints used. The authors attempted to simulate clinical endpoints by suspending inflation when either height was restored or the tamp came in contact with the VB cortex in such a manner that further inflation would likely cause a cortical breach. There was no significant difference in inflation volumes between the two load groups. Although the HL group experienced higher inflation pressures than the LL group, the difference was not significant. Thus, it should not be surprising that the authors found no significant difference in height restoration between load groups and that the original hypothesis was rejected.

Another limitation to the current study was the simulated fracture model used. The authors created compression fractures in osteoporotic vertebral bodies using an axially applied load. It is unknown how applicable this model is to the various types of compression fractures.<sup>7</sup>

#### ■ Key Points

- In all VBs the inflatable bone tamp restored some height lost to compression fracture.
- Height was fully restored in 22% of VBs in both experimental groups.
- The magnitude of simulated physiologic load did not affect height restoration in this *ex vivo* model.

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