

An *Ex Vivo* Biomechanical Evaluation of an Inflatable Bone Tamp Used in the Treatment of Compression Fracture

Stephen M. Belkoff, PhD,* John M. Mathis, MD,† David C. Fenton, MS,*
Robert M. Scribner, BS,§ Mark E. Reiley, MD,¶ and Karen Talmadge, PhD§

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

Objectives. To determine if the inflatable bone tamp (tamp) restores height to compressed vertebral bodies and to compare the biomechanical properties of isolated, fractured osteoporotic vertebral bodies treated by kyphoplasty (tamp) or vertebroplasty.

Summary of Background Data. Previous biomechanical studies have shown that vertebroplasty increases vertebral body strength and restores vertebral body stiffness, but does not restore vertebral body height lost as a result of compression fracture.

Methods. Compression fractures were experimentally created in 16 osteoporotic VBs assigned to either the tamp or percutaneous vertebroplasty group. The tamp treatment consisted of inserting balloon-like devices into the vertebral body, inflating the bone tamp, and filling the void with Simplex P (Howmedica, Rutherford, NJ) bone cement. The percutaneous vertebroplasty treatment consisted of directly injecting Cranioplastic bone cement (CMW, Blackpool, UK) into the vertebral body. Pre- and posttreatment heights were measured, and the repaired vertebral bodies were recompressed to determine post-treatment strength and stiffness values.

Results. The tamp treatment resulted in significant restoration (97%) of vertebral body height lost after compression, whereas percutaneous vertebroplasty treatment resulted in a significantly lower restoration of lost height (30%) ($P < 0.05$). Both treatments resulted in significantly stronger vertebral bodies relative to their initial state ($P < 0.05$). The tamp treatment restored vertebral body stiffness to initial values, but the percutaneous vertebroplasty treatment did not ($P < 0.05$).

Conclusions. Tamp treatment resulted in significantly greater height restoration than did percutaneous vertebroplasty, without loss of vertebral body strength or stiffness. [Key words: biomechanical evaluation, compression fractures, inflatable bone tamp, kyphoplasty, osteoporosis, vertebroplasty] **Spine 2001;26:151-156**

women, occur in the United States each year.^{20,21} These fractures are the source of substantial pain and can lead to disability and poor quality of life.^{17,18,22,27} Until recently, treatment of these fractures has been by nonoperative means.¹⁷ In the mid-1980s, percutaneous transpedicular vertebroplasty (PVP) was developed in France⁹ and is now gaining acceptance in the United States. This technique consists of injecting cement into the cancellous bone of the fractured vertebral body (VB),^{5,9} presumably to stabilize the fracture.^{1,6,28} The procedure has not undergone prospective investigation, but findings in retrospective clinical studies indicate that it results in good pain relief and has a low complication rate.^{3,4,10,13} Although the technique increases strength and restores VB stiffness,^{1,2,28} it does not restore VB height. A new device, the inflatable bone tamp (referred to hereinafter as tamp), has been developed as a means of restoring height (Figure 1). Height restoration has the potential benefit of reducing postfracture kyphosis and its associated sequelae.^{15,16,18,26,27} The tamp is placed inside the VB under fluoroscopic guidance through a percutaneously introduced cannula. The tamp is inflated, thereby compressing the cancellous bone, creating a void, and concurrently lifting the end plates in an *en masse* reduction. After tamp removal, the void can be filled under lower pressure than that needed for PVP. This procedure has been termed kyphoplasty.

Little information exists about the biomechanics of kyphoplasty. In a recent report²⁹ the investigators suggest that kyphoplasty results in compliance reduction (*i.e.*, restoration of normal spine kinematics) similar to that achieved by PVP, but height restoration was not a primary focus of that investigation. The purpose of the current study was to determine whether the tamp restores VB height in simulated compression fractures and whether the procedure results in VB strength and stiffness values different from those obtained using PVP alone.

■ Methods

Sixteen VBs (T12-L1) from eight fresh spines harvested from female cadavers (average age at death, 84 ± 11 years; range, 60-96 years; Maryland State Anatomy Board, Baltimore, MD) were evaluated. Bone mineral density was measured by the dual-energy x-ray absorptiometry method (Lunar DPX-IQ; Lunar Corp., Madison, WI). Rice bags were placed beneath the

More than 200,000 symptomatic osteoporotic compression fractures of the vertebrae, primarily in elderly

From the *Orthopaedic Biomechanics Laboratory, Department of Orthopaedic Surgery, The University of Maryland at Baltimore, Baltimore, Maryland; the †Department of Neuroradiology, The Johns Hopkins Hospital, Baltimore, Maryland; §Kyphon, Inc., Santa Clara, California; and ¶The Berkeley Orthopedic Medical Group, Berkeley, California.

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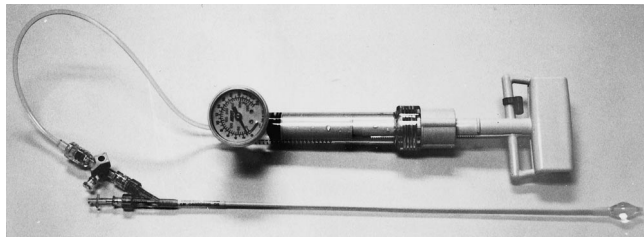


Figure 1. Bone tamp and inflation syringe.

spine to provide 16 to 18 cm of soft tissue surrogate (Lunar Corp., personal communication, 1999). The vertebrae were disarticulated, the 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 tamp group and the other was assigned to the PVP group, which served as the control. Group assignment was alternated between the T12 and L1 specimens. 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) 24 hours before testing. An impression of the endplates of each vertebra was made using a common epoxy resin (Fastray; Bosworth, Skokie, IL). The VB heights were measured at approximately 60° intervals around the VB longitudinal axis at the anterior center, right anterior, right posterior, posterior center, left posterior, and left anterior positions. Measurements were made using digital calipers accurate to 0.01 mm (Mitutoyo MTI Corp., Aurora, IL), and the values were averaged. Each VB was seated between its respective impressions, which were placed between platens on a 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 center²⁸ of the VB at a rate of 5 mm per minute⁸ until the average height of the VB was decreased by 25% of the average initial VB height. Force and deformation data were recorded at 10 Hz, and the initial strength and stiffness of the VB were measured. The following definitions were used: strength, the inflection point of the force *versus* deformation trace, and stiffness, the slope of the force *versus* deformation curve between 500 N and half the initial VB strength. This range was chosen, because it falls within the physiologic range of approximately one to two times body weight.

For the VBs in the PVP group, an 11-gauge Jamshidi biopsy needle (Manan; Medical Device Technologies, Inc., Gainesville, FL) was inserted by one investigator (JMM) under fluoroscopic guidance through each pedicle. Cranioplastic cement (CMW, Blackpool, England) was mixed and injected according to clinically practiced protocols, including the addition of barium sulfate (20% by weight) to increase radiopacity.¹³ A bolus of 5 mL of cement was then injected through each needle into the cancellous bone of each VB to result in a target total volume of 10 mL (Figure 2). In some instances, cement injection was suspended before the volume equaled 10 mL because of extravasation. In such cases, the total cement volume was noted. The pressure of cement injection was not measured.

The VBs in the tamp group were treated by one of the investigators (MAR) using the kyphoplasty clinical technique under fluoroscopic guidance. A drill channel was created for

placement of the tamp by passing a bit 3.2 mm in diameter (Kyphon, Inc., Santa Clara, CA) through each pedicle and ending medial and inferior in the VB. A size 15/3 tamp (Kyphon, Inc.) was centered in each drill channel between the anterior and posterior walls of the VB. The tamps were then inflated with radiopaque contrast medium in 0.5-mL increments using an inflation device (Basix25; Merit Medical Corp., Salt Lake City, UT) to maintain similar volumes on each side and effect an *en masse* reduction (Figure 3). The maximum pressure was recorded at each increment of contrast volume (using the gauge on the inflation device). Inflation endpoints were fracture reduction, cortical contact, maximum inflation volume (4 mL/tamp), or maximum inflation pressure (220 psi) without pressure decay. Cortical contact was an endpoint, because further inflation may have induced cortical fracture. The volume and pressure limits were based on the manufacturer's recommendations for safe use of the balloons.

The tamps were deflated and removed, and the void was filled with polymethylmethacrylate cement (Simplex P; Howmedica, Rutherford, NJ). The cement powder and monomer were chilled to 4°C at least 24 hours before mixing. To increase radiopacity, 5 g of BaSO_4 were mixed by hand into the standard 20-g dose of cement powder. The cement was then prepared using a vacuum mixer (Stryker Instruments, Kalamazoo, MI), according to the manufacturer's instructions. The cement was poured into three 5-mL syringes. The syringes were then attached by a Luer fitting to a 3-mm bone void filler nozzle (Kyphon, Inc.). The volume of cement injected through the void filler nozzles was matched to the final volume of each

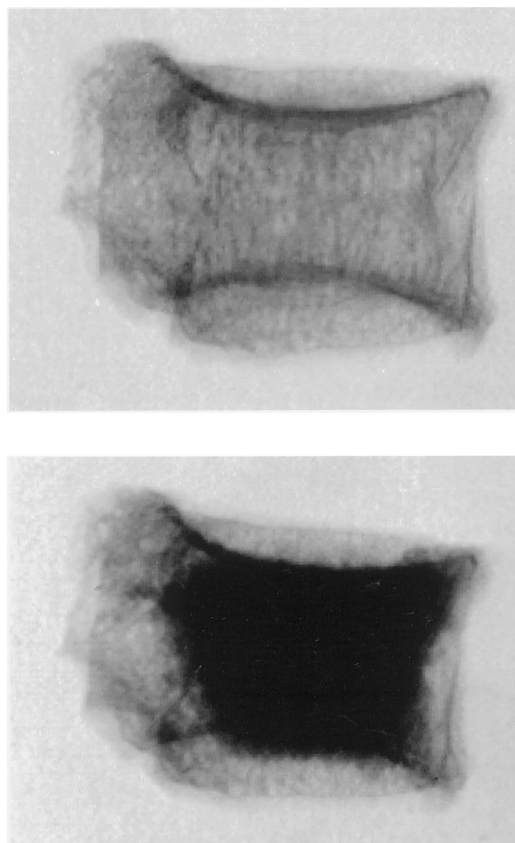


Figure 2. Lateral radiograph of a vertebral body after initial compression (top) and after percutaneous transpedicular vertebroplasty (bottom).

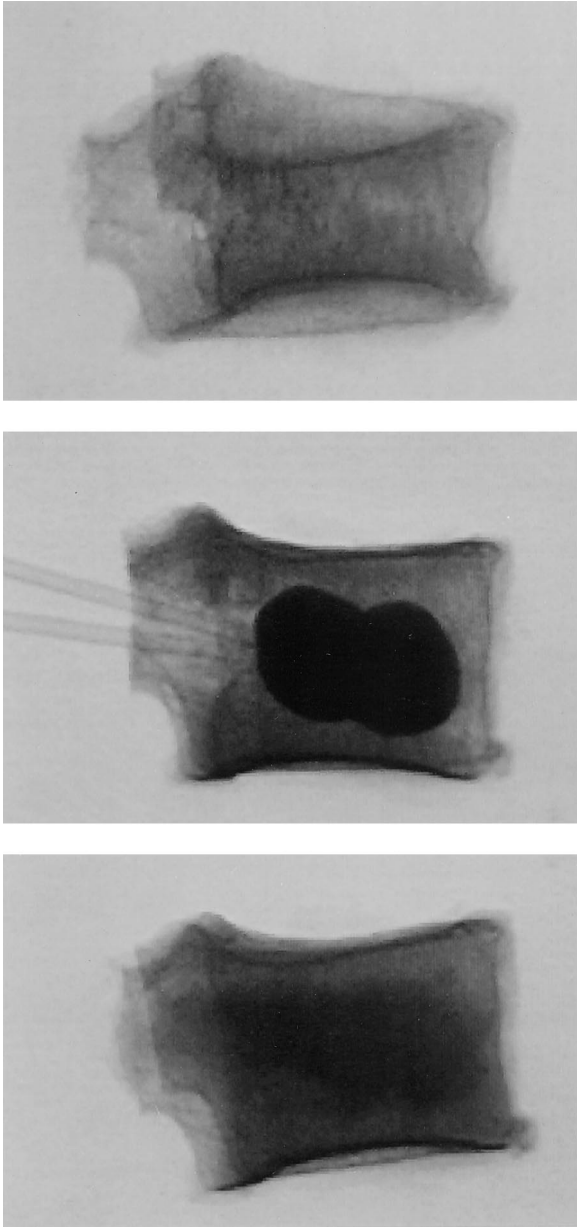


Figure 3. Lateral radiograph of a vertebral body after initial compression (top), after tamp inflation (middle), and after injection of cement (bottom).

cavity, as determined by the volume of contrast medium in each tamp at its final inflation point (Figure 3).

After injection, all VBs were rewrapped in saline-soaked

gauze, placed in sealed plastic bags to prevent dehydration, and stored at 4 C for 24 hours to allow complete polymerization of the polymethylmethacrylate before retesting. After 24 hours, but just before testing, height and width measurements were obtained for each VB. Each VB was then recompressed according to the initial crush protocol. Posttreatment strength and stiffness were measured as before. In some VBs injected with cement, load increased until the 8896-N (2000-lb) load limit of the test system was reached. For these specimens, a strength of 8896 N was recorded. Percentage of height lost for each VB was calculated as (average initial height minus average post-compression height)/average initial height. Percentage of height restored was calculated as (average posttreatment height minus average postcompression height)/(average initial height minus average postcompression height). Height lost was calculated as average initial height minus average postcompression height. Height restored was calculated as average posttreatment height minus average postcompression height.

According to results of Student's *t* test, the differences in height lost and height restored between the PVP and tamp specimens were evaluated. The current authors also evaluated for an effect of treatment on VB stiffness and strength, by using a repeated-measures analysis of variance (ANOVA). The factors were treatment (PVP *vs.* tamp) and condition (initial *vs.* posttreatment). Differences were checked for significance by Student–Newman–Keuls *post hoc* test. Significance was set at $P < 0.05$, unless otherwise specified.

■ Results

The *t* scores for the VBs ranged from -3.7 to -8.8 , with a mean of -5.3 ± 1.7 (\pm SD). The average bone mineral density was 0.56 ± 0.2 (\pm SD). Initially, VB strength for the tamp group (2117 ± 579 N) was similar to that of the PVP group (2138 ± 740 N). Although strength after treatment increased significantly in both groups (Table 1), VB strength after treatment was significantly greater in the PVP group than in the tamp group (Figure 4).

As was the case for initial VB strength, no significant difference was found in initial VB stiffness between the two groups; thus, the mechanical behavior of VBs in both treatment groups was similar initially. The VBs in the PVP group were significantly less stiff after treatment than they were in their initial condition. Posttreatment stiffness values for VBs in the tamp group were not significantly different than the initial stiffness values. There was no significant difference in posttreatment stiffness

Table 1. Comparison of Strength After Treatment in PVP and Tamp Groups

Group	Strength*† (N)		Stiffness‡§ (N/mm)		Height Change (%)	
	Initial	Treated	Initial	Treated	Lost	Restored
Tamp	2118	4792	1125	996	10.0	97.0
PVP	2138	7832	1239	904	11.2	30.5

* SEM, 653.

† All differences were significant ($P < 0.05$) except initial strength between tamp and PVP.

‡ SEM, 108.

§ Only the difference in stiffness between initial and treated specimens in the PVP group was significant ($P < 0.05$).

SEM = standard error of mean; PVP = percutaneous transpedicular vertebroplasty.

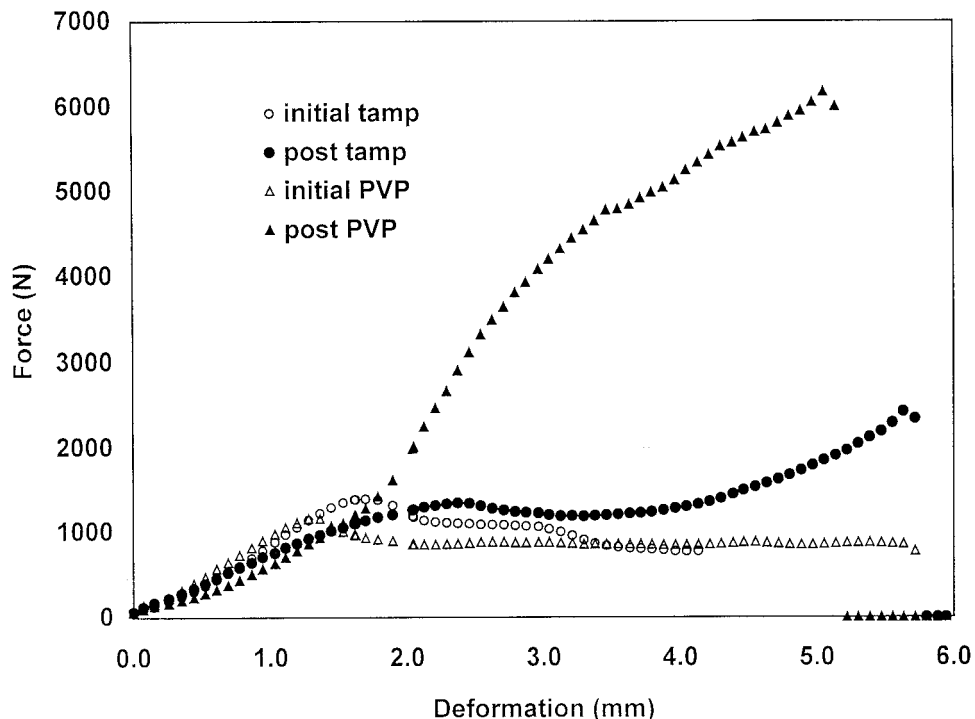


Figure 4. Typical force versus deformation response of vertebral bodies initially and after treatment with either standard vertebroplasty or the bone tamp.

between the VBs in the tamp group and those in the PVP group.

The average cement volumes for the tamp and PVP groups were 9.4 ± 3.5 mL and 9.4 ± 1.4 mL, respectively. This difference was not statistically significant. Cement extravasation (average, 0.6 mL) was noted in five of the VBs treated with PVP. No leakage was noted in the tamp group.

Initial heights for the tamp and PVP VBs were 25.7 ± 1.6 mm and 25.9 ± 2.0 mm, respectively. Postcompression height losses for the tamp and PVP groups were 2.6 ± 0.7 mm and 2.9 ± 0.9 mm, respectively. This difference was not significant. Height restored by the tamp treatment (2.5 ± 0.7 mm) was significantly more than that restored by the PVP treatment (0.8 ± 0.2 mm).

Discussion

In the current study, height restoration, strength, and stiffness were measured in VBs treated with tamp or PVP. Each VB was compressed to 25% of its initial height to create vertebral compression fractures with height loss consistent with clinical criteria. The average permanent height loss, measured immediately after the initial VB compression, was approximately 10%, which indicated some elastic height recovery resulting in an unassisted height restoration of 15%. Similar recovery phenomenon reportedly occurs *in vivo*.²³ It is not unreasonable to expect the study VBs to recover more height than VBs *in vivo* where muscle forces and body weight might prevent such recovery. The treated VB specimens exhibited permanent height loss below the radiographic criterion of 15%²¹ but on par with the less stringent criterion of 10%

used by others.²³ Presumably, the restorative effect of the tamp would be more pronounced in VBs with more height loss.

Some investigators suggest that pulmonary function decreases in patients with osteoporosis and vertebral compression fractures.^{15,16,26} A recent prospective randomized study¹⁴ showed that vertebral compression fractures are associated with increased primarily pulmonary-related mortality. The presence of one vertebral compression fracture indicates that the chance of experiencing a second vertebral compression fracture during the next 5 years increases by five times.²⁵ If multiple VBs were to succumb to compression fractures and lose height, it would be expected that the resultant progressive kyphosis would greatly affect normal spine function, pulmonary capacity, and activities of daily living.¹⁴ In such cases, restoration of VB height over several levels may have the most pronounced and desirable effect.

In the current study, the tamp treatment, followed by injection of Simplex P bone cement (Howmedica), resulted in stiffness restoration. Restoration of VB stiffness should prevent any stress-riser effects or altered kinematics that would be expected if the stiffness were significantly more or less than that in the initial condition, respectively. The result that VB stiffness is restored or nearly restored by augmentation (tamp or PVP) is supported by a complementary investigation of spinal segment compliance.²⁹

The result that VBs injected with Simplex P exhibited stiffness values similar to those in their initial conditions, whereas those injected with Cranioplastic (CMW) were significantly less stiff, is attributable in part to the respec-

tive mechanical properties of the cements.¹ In these studies, the stiffnesses of VBs injected with Simplex P, but without the use of the tamp, were restored to initial values. Furthermore, the material properties of Cranioplastic are diminished when the cement is mixed in accordance with procedures typically used in vertebroplasty.¹² That Cranioplastic used with PVP in bench-top studies results in VB stiffness values less than those in the intact state^{1,2,28} does not appear to be cause for concern. These cements are used clinically, and no report was found of complications related to insufficient stiffness restoration.

The result that VBs treated with direct injection of Cranioplastic were stronger than those treated with kyphoplasty and injected with Simplex P was unexpected. Simplex P is materially stronger than Cranioplastic¹⁹ and has been shown to result in stronger repairs *ex vivo*.¹ There was no significant difference between treatment groups in the volume of cement injected. Even so, the resultant kyphoplasty posttreatment strength was significantly greater (approximately twice as great) than the VB strength initially and was sufficient to withstand the mechanical demands of daily living.¹¹ No other report was found comparing the strength of VBs treated with the tamp *versus* those treated with PVP alone with which to compare results.

In the current study, different cements were chosen for the different treatments to be consistent with clinical practice. In the United States, clinicians performing PVP reportedly use Cranioplastic cement and alter the cement composition to increase radiopacity, increase working time, and decrease viscosity.^{7,12} Investigators engaged in clinical trials with the tamp more commonly use Simplex P. Simplex P is indicated for use in pathologic fractures (product insert, Stryker-Howmedica-Osteonics, Rutherford, NJ). Thus, in the current study, the ability to separate the effect of the tamp from the cement was traded for the ability to make the procedure consistent with clinical practice.

Extravasation of cement occurred in VBs in the PVP group, but not in VBs treated with the tamp. The VBs in the tamp group were each injected with a volume of cement equal to the volume of the void created by the tamp, whereas VBs in the PVP group were each injected with a predetermined volume of 10 mL, which in some cases exceeded the capacity of the VB and led to extravasation. Clinically, cement injection is stopped immediately when extravasation becomes radiographically apparent. Pulmonary embolism caused by the cement is also a potential complication,¹³ and a confirmed case has been reported recently.²⁴

In conclusion, treatment of simulated vertebral compression fractures by tamp and PVP resulted in increased VB strength relative to initial values. Only VBs treated by the tamp returned to initial stiffness values. Use of the tamp resulted in significantly greater height restoration than did PVP.

■ Key Points

- *Ex vivo* compression tests were conducted on osteoporotic cadaveric vertebral bodies that had been subjected to simulated compression fractures.
- The fractures were repaired with one of two treatments: kyphoplasty using an inflatable tamp or standard vertebroplasty.
- Use of the tamp resulted in significantly more height restoration than vertebroplasty.
- Both treatments increased strength, but only kyphoplasty restored stiffness.

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Address reprint requests to

Stephen M. Belkoff, PhD
c/o Elaine P. Bulson, Medical Editor
Department of Orthopaedic Surgery
Johns Hopkins Bayview Medical Center
4940 Eastern Avenue, 030
Baltimore, MD 21224-2780
E-mail: ebulson@jhmi.edu