

## Clinical and Radiographic Results of Unilateral Transpedicular Balloon Kyphoplasty for the Treatment of Osteoporotic Vertebral Compression Fractures

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**Objective:** Pain and kyphosis caused by osteoporotic vertebral compression fractures adversely affect quality of life and survival. Kyphoplasty involves the inflation of a balloon bone tamp, percutaneously placed in a fractured vertebral body, followed by deposition of bone cement into the resulting cavity. Most previous reports indicate that traditional bilateral kyphoplasty improves patient function and restores height of collapsed vertebral bodies, but limited data about the effects of unilateral kyphoplasty on clinical and radiological outcome are available. **Methods:** One hundred five patients with osteoporotic vertebral compression fractures who did not respond to medical therapy were treated by unilateral kyphoplasty between January 2004 and December 2006. These patients underwent 105 operations to treat 132 vertebral compression fractures between T8 and L5. Sagittal alignment was analyzed from standing radiographs (pre-and post kyphoplasty). Clinical outcomes were determined by comparison of preoperative and postoperative data from patient-reported indexes (pain assessment, pain medication usage and visual analogue pain scale (VAS) score for Back Pain). Radiographs were assessed as to percent vertebral collapse, vertebral height restoration and local kyphosis correction. **Results:** Mean length of follow-up was 15.3 months (range 3–36 months); improved height 2.3 and 4.0 mm in the anterior and medial columns, respectively ( $p > 0.05$ ); Cobb angle increased  $8.8^\circ$  ( $0-29^\circ$ ) ( $p < 0.05$ ), visual analogue pain scale score improved 7 points ( $p < 0.05$ ); no adverse medical or procedural complications; 6.8% (9/132) cement leakage rate. **Conclusion:** Unilateral transpedicular kyphoplasty improves physical function, reduces pain, and may correct kyphotic deformity associated with vertebral compression fractures. This result comparable to traditional bilateral kyphoplasty procedure. (J Kor Neurotraumatol Soc 2007;3:19-24)

**KEY WORDS:** Unilateral transpedicular kyphoplasty · Vertebral compression fracture · Osteoporosis · Kyphosis · Deformity correction.

### Introduction

Compression fractures lead to a loss of height of the vertebral segment, and the resulting spinal deformity can lead to a decrease in pulmonary capacity, malnutrition, decreased mobility, and depression. Kyphosis secondary to osteoporotic vertebral compression fractures is associated with a 2 to 3 times greater incidence of death due to pulmonary causes.<sup>5,10,12,14</sup>

Although usual treatment of an osteoporotic vertebral compression fracture consists of bed rest, analgesics, and bracing, some fractures go on to progressive deformity and debilitating pain. Techniques of vertebral body augmentation have been developed in an effort to treat these refractory cases. The technique of vertebroplasty uses a percutaneous transpedicular approach to introduce polymethylmethacrylate (PMMA) cement into the vertebral body. The cement reinforces the vertebral segment, prevents further collapse, and successfully provides pain relief. Limitations of this procedure include the lack of height restoration and a 30% to 70% incidence of cement extravasation into the surrounding soft tissue, epidural, or foraminal spaces, occasionally causing nerve root compression or even pulmonary embolus.<sup>4,6)</sup>

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Balloon kyphoplasty is a recently developed, minimally invasive surgical treatment for osteoporotic vertebral compression fractures (VCFs). It is designed to address the fracture-related pain and the associated spinal deformity. The deformity is purportedly corrected by the insertion and expansion of a balloon in a fractured vertebral body. After reduction of the fracture bone, cement is then deposited into the cavity created by the balloon to repair the fracture. Good clinical outcomes as well as restoration of vertebral body height have been reported with kyphoplasty.<sup>3,9,11)</sup>

The current standard technique for kyphoplasty involves cannulating both pedicles and placing 2 balloons into the vertebral body (bipedicular approach). Theoretically, an alternative unipedicular approach would reduce by 50% the risk associated with cannulation of the pedicles, while also reducing operative time, radiation exposure, and costs. There is a some technical report about the unilateral transpedicular approach, but limited data about the effects of unilateral transpedicular kyphoplasty on clinical and radiological outcome in large patients group is available.

We experienced 105 compression fractures patients and performed kyphoplasty in 132 levels via a unilateral transpedicular approach. The purpose of this study to describe the performance of a procedure known as inflatable bone tamp via a unilateral transpedicular approach and determine the efficacy of unipedicular transpedicular approach and the clinical and radiological outcomes.

## Material and Methods

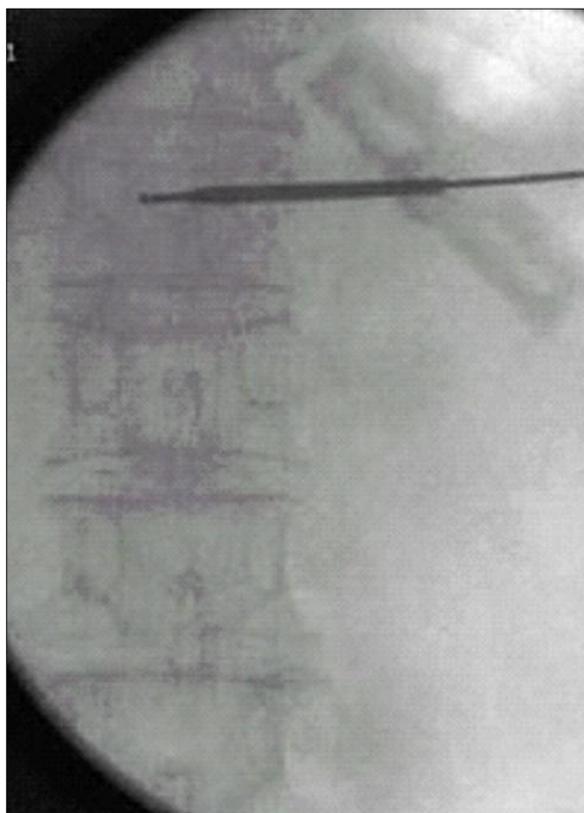
A consecutive series of one hundred thirty two osteoporotic VCFs were treated in 105 patients between January 2004 and December 2006 in our institute. Eighty (76%) patients were women and 25 (24%) were men. Mean patient age was 71.6 years (range, 49–85 years). The fractures occurred between T8 and L5. Ninety-five patients had a single vertebral fracture treated by kyphoplasty, and 10 patients had multiple vertebral levels treated by kyphoplasty (2–3 vertebrae).

Selection criteria for kyphoplasty were: 1) vertebral fracture pain, 2) sufficient pain to impair activities of daily living, 3) failure of reasonable medical therapy and time, 4) comprehensive medical evaluation of osteoporotic vertebral compression fractures, 5) technical feasibility, 6) sufficient medical stability to tolerate general anesthesia, 7) absence of contraindication, and 8) informed written consent.

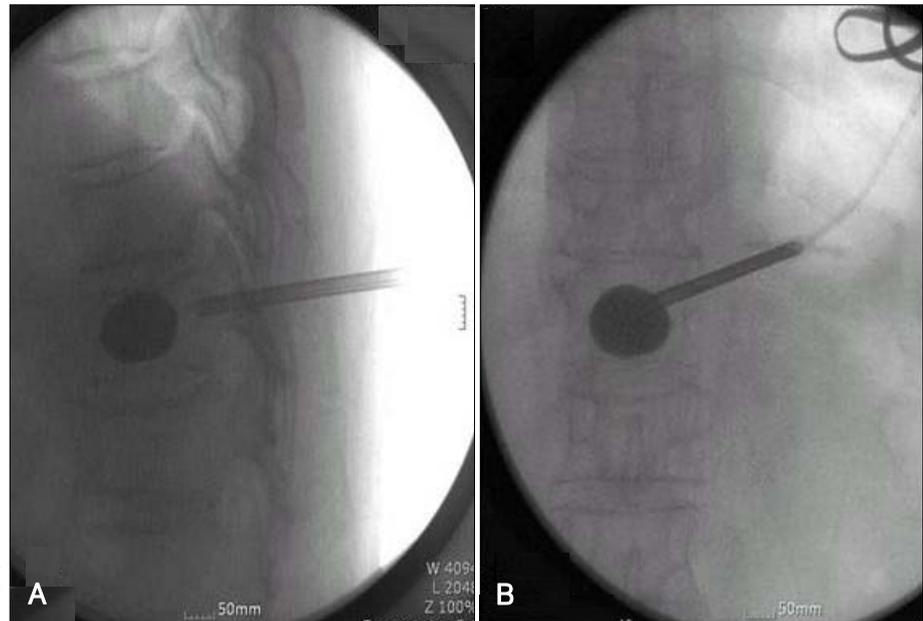
### Operative technique

Percutaneous kyphoplasty was performed using fluoroscopy via a unilateral transpedicular approach. After con-

scious sedation and the patient was carefully positioned prone on the fluoroscopy table. Using sterile technique, local lidocane was administered subcutaneously at entry site for the left-side pedicle which was localized by fluoroscopy. After incision of the skin, an 11-gauge Jamshidi needle was placed through the left-side pedicle into the posterior vertebral body. Special care was taken to achieve a medial trajectory of the needle and a final midline position of the needle tip in the vertebral body (Figure 1). The inflatable bone tamp (IBT) was then positioned within the vertebral body and expanded using direct fluoroscopy and manometric parameters. Inflation continued until vertebral body height was restored, the inflatable bone tamp contacted a vertebral body cortical wall, the IBT reached 250 psi, or the maximal balloon volume was reached. PMMA was prepared with additional barium sulfate. When satisfactory consistency was achieved, PMMA was injected using a commercially available cement delivery system kit under direct fluoroscopic visualization into the cavity in the vertebral body created by an inflatable bone tamp. Cement was administered which produced an excellent filling of the vertebral body cavity (Figure 2A, B). All instrumentation was removed at the end of the procedure.



**FIGURE 1.** Antero-posterior, image of inflatable bone tamp in the midline of the fractured vertebral body.



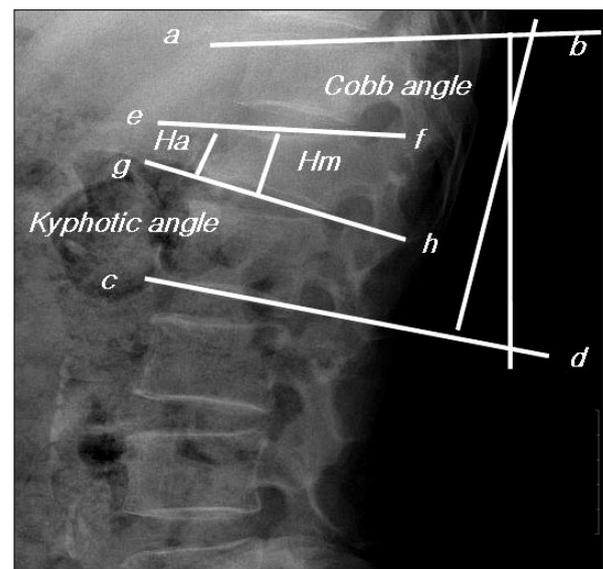
**FIGURE 2.** A: lateral, and B: anteroposterior fluoroscopic image of polymethylmethacrylate filling the cavity within the fractured vertebral body.

#### Assessment of kyphosis and vertebral body height

The fracture was detected in conventional preoperative standing anteroposterior and lateral radiographs centered on the fractured (index) vertebra. The radiographs were taken according to published standardized protocol and confirmed as the likely pain generator by correlating physical findings with the identification of edema in the fractured vertebra with spine MRI. The vertebral body kyphotic angle (Ka) [(Ka) was the angle in degrees defined by the intersection of lines ef and gh] was calculated using the Cobb technique. For determination of the Cobb angle measurements were taken from the superior endplate of the vertebra one level above the treated vertebra to the inferior endplate of the vertebral body one level below the treated vertebra (lines ab and cd). Vertebral height (H) of the fractured vertebra was the distance between identical points on the superior and inferior endplates at the middle (Hm) and anterior (Ha) location (Figure 3). Lateral radiographs were taken and analyzed at points preoperative standing lateral and postoperative standing lateral radiographs were taken after 3 month.

#### Outcome measure

Postoperative complications were recorded prospectively at surgery. Postoperative radiographs were also examined for the presence of leakage of cement. Cement leakage was recorded on the basis of position and correlated with any postoperative clinical symptoms. Patients rated their pain on a visual analogue scale of 0=no pain to 10=severe pain before surgery, and immediate postoperative 3rd day later when discharged.



**FIGURE 3.** Measurement of Cobb angle (line ab and cd), kyphotic angle (line ef and gh), height of fracture middle (Hm), and anterior (Ha) vertebral height.

#### Statistics

Statistical analysis including mean values and standard deviations, was performed using SPSS (version 13.0). Differences were considered as statistically significant for  $p$  values less than 0.05.

## Results

We performed unilateral transpedicular kyphoplasty in 105 osteoporotic compression fracture patients for 3 years at our institute. The fracture morphology was a wedge in

**TABLE 1.** Demographic of the patient group

Number of patients	105 patients
Age	71 years ( range 49–85 )
M/F	25 / 80
Duration of symptoms	4.5 weeks
No. of single level VCF*s	95 patients
Thoracic	32 patients
Lumbar	63 patients
Number of 2 levels	6 patients
Number of 3 levels	4 patients
Acute	94 patients
Chronic	11 patients
Wedged	101 patients
Bursting	4 patients

\*vertebral compression fracture

101 patients and burst in 4 patients. Fractures were classified as acute in 94 and chronic in 11 patients. The mean duration of symptoms was 4.5 weeks (range, 1–24 weeks) (Table 1). All fractures were considered active on T2-weighted chemical fat suppression or short tau inversion recovery MR sequences.

**Overall reduction of vertebral deformity**

For each treated level, separate Cobb angles were measured. The Cobb angle improved significantly from  $-14.8^{\circ} \pm 8.1^{\circ}$  before surgery to  $-11.8^{\circ} \pm 9.0^{\circ}$ . Every patient achieved at least a reduction of  $3^{\circ}$ . An improvement of at least  $5^{\circ}$  in sagittal alignment was achieved in 48 patients. Kyphotic angle improved significantly from  $-12.8^{\circ} \pm 6.1^{\circ}$  (range,  $-19.3^{\circ}$ – $-4.4^{\circ}$ ) before surgery to  $7.1^{\circ} \pm 4.7^{\circ}$  (range,  $-15.4^{\circ}$ – $5.8^{\circ}$ ) after surgery. Height of fractured body (Ha, and Hm) improved significantly from  $19.8 \text{ mm} \pm 0.24$  (range, 10.8–31.7) to  $22.1 \pm 0.16 \text{ mm}$  (range, 11.7–32) and from  $18.5 \text{ mm} \pm 0.18$  (range, 10.5–28.7) to  $22.5 \pm 0.15 \text{ mm}$  (range, 13.2–29.1) (Table 2). The average volume of cement applied to the cavities was 3.5 mL (range, 2–6 mL) and mean operation time was less than 35 minutes.

**Clinical outcome**

Evaluation of intraoperative and postoperative radiographs revealed extravertebral cement leaks in 9 of 132 vertebral fractures treated (6.8%). In 5 cases, cement leaked into the adjacent intervertebral disc and in 3 patients, cement leaked into paravertebral area. Cement leaked into the spinal canal in 1 patient, but no neurologic symptoms were developed. None of the cement leaks had any apparent clinical consequences, and no patients developed neurologic symptoms. No PMMA embolization was evident. Virtually all patients subjectively reported immediate relief of

**TABLE 2.** Cobb angle, kyphotic angle and vertebral body height (Ha, Hm) improved significantly after kyphoplasty procedure

	Pre-operative	Post-operative	Regain	
Cobb angle	$-14.8^{\circ}$	$-11.8^{\circ}$	$3^{\circ}$	20%
Kyphotic angle	$-12.8^{\circ}$	$-7.1^{\circ}$	$5.7^{\circ}$	44%
Average ant. Ht (Ha)	19.8 mm	22.1 mm	2.3 mm	7%
Average mid. Ht (Hm)	18.5 mm	22.5 mm	4 mm	13%

their typical fracture pain, and no patient complained of worse pain at the treated levels. The VAS score significantly improved from  $8.7 \pm 1.4$  (range, 2.9–10) before surgery to  $2.3 \pm 0.9$  (range, 0.3–4.2) 3 days after surgery.

**Discussion**

The results of the present study indicate that kyphoplasty is a minimally invasive procedure aimed at restoring strength, stiffness and is effective in reduction of spinal deformity and in short-term improvement of pain in selected patients with osteoporotic vertebral compression fracture.

The rationale of bilateral transpedicular approach is to achieve adequate endplate elevation with two inflatable bone tamp and to create a large enough cavity for maximal cement filling. With conventional needle trajectories, the inflatable bone tamp remain ipsilateral, thus necessitating bilateral inflatable bone tamp to cover the expanse of the vertebral body.

Previous studies have been suggested that unipedicular kyphoplasty might lead to unilateral wedging or that it would not be as effective in restoring vertebral body height.<sup>1,2,15)</sup> Steinmann et al in an ex vivo biomechanical study comparing a bipedicular approach to unipedicular approach in the treatment of vertebral compression fractures, found no significant lateral wedging associated with unipedicular injections.<sup>15)</sup> Our study found that the unipedicular approach is effective in restoring the vertebral height. In our cases, vertebral body height was successfully restored by unipedicular kyphoplasty to 96% of fracture levels. Furthermore, kyphoplasty by unipedicular approach markedly reduced pain and spinal deformity with osteoporotic vertebral compression fracture.

In the procedure that we describe, we perform a medially directed trajectory with the final destination of the inflatable bone tamp in the midline of the vertebral body. A midline-positioned inflatable bone tamp can be inflated to create a large enough cavity in the midline of the vertebral body.

Unilateral transpedicular approach has many advantages. This procedure reduced the risk associated with large needle

placement. These risks include pedicle fracture, medial transgression of the pedicle or transgression into the spinal canal, nerve injury, cement leakage along the cannula tract, and spinal epidural hematoma.

Even if complications of kyphoplasty are very rare, in previous studies, many authors reported such adverse complication. Coumans et al<sup>7)</sup> described a large series of 188 kyphoplasty procedures. There were five cases of complication such as, cement extravasation along the canal. Garfin et al retrospectively reviewed 2,194 vertebral compression fractures, finding 3 cases of instrument insertion through the medial pedicle wall, resulting in neurologic injury.<sup>8)</sup>

Nussbaum et al<sup>13)</sup> also reviewed complications associated with vertebroplasty and kyphoplasty as reported. Kyphoplasty may have an increased risk of pedicle fracture that can lead to spinal compression. It associated with breakage of the pedicle during insertion of the cannula. Theoretically, the incidence of such events may be reduced if unilateral rather than bilateral cannulas are placed. By cannulating only 1 pedicle, one can reasonably assume a considerable reduction in operative time, radiation exposure, and cannulation risks with the unipedicular kyphoplasty when compared to the bipedicular approach. In the procedure that we described, the time required for the procedure was less than 35 minutes and also save the cost about 30% compare to the bipedicular approach. Typically, when we have performed with bilateral approach, the total procedure time is close to one hour. We are sure that unilateral transpedicular approach has excellent clinical and radiographic outcome and is comparable to bipedicular approach.

The present study has several limitations. First, the number of patients and the number of compression fractures are limited and needs more long term follow up. Second, our data only presented in unipedicular approach. No data are available on studies providing a direct comparison of height restoration and deformity correction with bipedicular approach and unipedicular approach. Therefore, prospective randomized studies need to compare the result of bipedicular approach and unipedicular approach. Third, it is difficult and dangerous to perform the unilateral transpedicular approach in high thoracic level, particularly over the 6th thoracic vertebra, because of small pedicle size and narrow canal. In that case, extrapedicular approach is more safe and convenient. The surgeon is not satisfied with the inflatable bone tamp position or the extent of inflation or cavity created by using a unipedicular approach, a second contralateral balloon can be placed using the conventional technique. The key to the unilateral approach is the medial

trajectory of the needle and the final midline position of the balloon.

## Conclusion

Balloon kyphoplasty can be performed using a unilateral balloon tamp via a unilateral transpedicular pedicular approach for osteoporotic vertebral body compression fracture. Unilateral transpedicular pedicular kyphoplasty is comparable to bipedicular kyphoplasty in the restoration of vertebral body strength, stiffness, and height in vertebral compression fractures. There was no greater risk for lateral wedging in the unipedicular group. Given the advantages of a unipedicular approach with respect to vertebral pedicle cannulation risk, operative time, radiation exposure, and cost, this study would support the use of a unilateral transpedicular approach to kyphoplasty in the treatment of osteoporotic vertebral compression fractures.

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## Unilateral Transpedicular Balloon Kyphoplasty

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