### Study Design

### Objectives
To evaluate the safety and efficacy of inflatable bone tamp reduction and cement augmentation, “kyphoplasty,” in the treatment of painful osteoporotic vertebral compression fractures.

### Summary of Background Data
Osteoporotic compression fractures can result in progressive kyphosis and chronic pain. Traditional treatment for these patients includes bed rest, analgesics, and bracing. Augmentation of vertebral compression fractures with polymethylmethacrylate, “vertebroplasty,” has been used to treat pain. This technique, however, makes no attempt to restore the height of the collapsed vertebral body. Kyphoplasty is a new technique that involves the introduction of inflatable bone tamps into the vertebral body. Once inflated, the bone tamps restore the vertebral body back toward its original height while creating a cavity that can be filled with bone cement.

### Patients and Methods
Seventy consecutive kyphoplasty procedures were performed in 30 patients. The indications included painful primary or secondary osteoporotic vertebral compression fractures. Mean duration of symptoms was 5.9 months. Symptomatic levels were identified by correlating the clinical data with MRI findings. Perioperative variables and bone tamp complications or issues were recorded and analyzed. Preoperative and postoperative radiographs were compared to calculate the percentage height restored. Outcome data were obtained by comparing preoperative and latest postoperative SF-36 data.

### Results
At the completion of the Phase I study there were no major complications related directly to use of this technique or use of the inflatable bone tamp. In 70% of the vertebral bodies kyphoplasty restored 47% of the lost height. Cement leakage occurred at six levels (8.6%). SF-36 scores for Bodily Pain 11.6 – 58.7, (P = 0.0001) and Physical Function 11.7 – 47.4, (P = 0.002) were among those that showed significant improvement.

### Conclusions
The inflatable bone tamp was efficacious in the treatment of osteoporotic vertebral compression fractures. Kyphoplasty is associated with early clinical improvement of pain and function as well as restoration of vertebral body height in the treatment of painful osteoporotic compression fractures. [Key words: kyphoplasty, vertebral compression fracture, osteoporosis, PMMA bone cement, vertebroplasty] Spine 2001;26:1631—1638

Osteoporosis is a systemic disease affecting more than 24 million Americans. It results in progressive bone mineral loss and concurrent changes in bony architecture, which leave the spinal column vulnerable to compression fractures, often after minimal or no trauma. There are an estimated 700,000 osteoporotic vertebral compression fractures (VCFs) in the United States each year, of which more than one third become chronically painful. Approximately 85% of these fractures are due to primary osteoporosis and the remainder due to secondary osteoporosis or malignancies. These VCFs lead to progressive sagittal spine deformity and changes in spinal biomechanics and are believed to contribute to a fivefold increased risk of further fracture by virtue of force transmission to weak vertebrae above or below. Whether the fracture is painful or not, the spinal deformity caused by two or more fractures dramatically impacts health, daily living, and medical costs through loss of lung capacity, loss of appetite, reduced mobility, chronic pain, and/or clinical depression. The adverse effect on activities of daily living is almost as great as that seen with hip fractures. The cost of managing osteoporotic VCF patients in the United States in 1995 was $746 million. Osteoporotic VCFs have been shown to be associated with up to a 30% age-adjusted increase in mortality not observed with osteoporotic distal radius fracture. It has been shown that there is a 9% loss in predicted forced vital capacity with each vertebral fracture, suggesting that the restrictive changes in thoracic anatomy are particularly harmful to patients with pre-existing lung disease. These patients frequently complain of the true loss of height because of the fractures and the apparent loss of height because of the compensatory hip and knee flexion posturing secondary to the progressive thoracic and lumbar kyphosis. In summary, osteoporotic VCFs pose a significant clinical problem including pain, spinal deformity, reduced pulmonary function and mobility, and an overall increase in mortality in this vulnerable group of patients.

Traditional treatment for patients with osteoporotic VCFs includes bed rest, analgesics, and bracing. This type of medical management obviously does nothing to restore spinal alignment, and the lack of mobility itself can increase the rate of demineralization. Because of the inherent risks and invasive nature, surgical treatment of osteoporotic VCFs has been limited to cases in which there is concurrent spinal instability or neurologic compromise. Reconstruction with structural bone graft and instrumentation may be performed from an anterior or...
posterior approach; however, the success of these techniques is limited by the patient’s poor bone quality and general medical condition.

Augmentation of VCFs with polymethylmethacrylate (PMMA), “vertebroplasty” was first described by Galibert et al in 1987 for use in vertebral body tumors. 8 It involves the forced injection of low viscosity PMMA cement into the closed space of the collapsed vertebral body. Intravertebral pressure is therefore required to enable low viscosity cement to infiltrate the compressed vertebral body. Although vertebroplasty is currently being used successfully for pain relief in VCFs,1,6,7,15 this technique makes no attempt to restore the height of the collapsed vertebral body. The principal limitation of vertebroplasty is cement extravasation, the rates of which are as high as 65% in metastases19 and 30% when used to treat osteoporotic fractures. 11

“Kyphoplasty” is a new technique with a number of potential advantages. This technique was conceived and developed by Dr. Mark Reiley (Berkley, CA). It involves the introduction of a cannula into the vertebral body, followed by insertion of an inflatable bone tamp (IBT) designed to reduce the vertebral body back toward its original height, while creating a cavity to be filled with bone cement. The cement augmentation is therefore done with more control into the low-pressure environment of the preformed cavity with viscous partially cured cement in an attempt to reduce the risk of extravasation.

In this Phase I study we aimed to evaluate the efficacy of using IBT reduction and cement augmentation, kyphoplasty, in the treatment of painful osteoporotic vertebral compression fractures. Our emphasis is on ease of application, positioning, and safety, of the IBT, and extent of fracture reduction. We also aimed to examine the rate of cement extravasation and early patient outcomes.

Methods

This study was designed as a single cohort study using consecutive prospectively gathered data examining early outcome and radiographic vertebral height restoration in no less than 20 patients after kyphoplasty for osteoporotic compression fractures. The end point of this Institutional Review Board-approved study was 3 months.

Patients Seventy consecutive kyphoplasty procedures were performed in 30 patients over 38 sessions from April 1999 to March 2000. The mean age was 68.6 years (range 48–86 years). The indications included painful primary (n = 19) or secondary (n = 5) osteoporotic vertebral compression fractures for a total of 24 patients unresponsive to nonoperative methods. A further six patients presented with painful compression fractures from multiple myeloma. The mean duration of symptoms was 5.9 months (0.5–24 months). Symptomatic levels were identified by correlating the clinical data with MRI findings of marrow signal changes consistent with compression fractures. MRI was also used to confirm the presence of a true wedge compression fracture and rule out burst-type injuries with retropulsed bone.

Kyphoplasty Technique IBT placement involves identifying an extrapedicular or transpedicular entry point into the vertebral body using a guide pin, with the use of biplanar fluoroscopy (Figures 1 and 2). This is followed by placement of a cannulated obturator over the guide wire. The obturator is then tapped into the bone over the guide wire. A working cannula is placed over the obturator and advanced until the tip of the cannula is seated in the posterior portion of the vertebral body. A hand-mounted drill bit is then used to ream a corridor for the IBT to be passed through. The IBTs are ideally situated under the collapsed endplate on the lateral radiograph. Inflation is slowly performed under fluoroscopy as are all stages of guide wire, obturator, and cannula placement. Inflation pressure of the IBT is monitored closely during inflation via an in-line pressure gauge. Inflation is continued up to a maximum pressure of 220 psi or the maximum size dependent balloon volume is reached. Inflation should also be stopped if the balloon abuts any one of the cortical margins. When a suitable cavity has been prepared and as much reduction is achieved as is possible, the PMMA cement augmented with barium is mixed. Smaller cement cannulas, which fit inside the working cannula, are filled with cement. Before its application the cement is allowed to thicken. A 2-cm³ bolus of cement is repeatedly suspended from a wooden spatula, and when the viscosity is such that the cement does not fall from the spatula, it is ready for injection. The cement cannula is advanced through the working cannula.