

Percutaneous Cement Injection into a Created Cavity for the Treatment of Vertebral Body Fracture

Preliminary Results of a New Vertebroplasty Technique

Ricardo Vallejo, MD, PhD, FIPP, Ramsin Benyamin, MD, DABPM, FIPP, Bonnie Floyd, PhD, Joseph M. Casto, PhD, Ninos J. Joseph, BS, and Nagi Mekhail, MD, PhD, FIPP

Objectives: Vertebral body fractures (VBFs) are the most common complication of osteoporosis. Minimally invasive placement of cement to stabilize VBFs results in significant pain reduction and improved performance of daily activities. The authors describe a modified percutaneous vertebroplasty (PV) procedure during which a cavity is created manually in the VBF, allowing the cement to be injected with less resistance.

Methods: Data were gathered from a retrospective chart review from 15 consecutive patients with acute compression VBFs who underwent 33 PV procedures with the Cavity Creation System. Mean follow-up was 30 weeks. Oral opiate intake, quality of life improvement, and visual analog pain scores (VAS) were measured before and 1 month after the procedure.

Results: All 15 patients exhibited a reduction in pain VAS (mean reduction 5.9 ± 2.5). Improvement in quality of life was demonstrated by lower (improved) FACIT scores in the General Activity, Enjoyment of Life, Mood, Normal Work Routine, and Sleep subscales. In addition, opioid use decreased in 10 of the 12 (83%) patients who were taking opioids before surgery. In eight (67%) patients, opioid use decreased by over 50%. Complications included extrusion of cement in two patients (an incidence of 5.7% of the levels operated) and two patients with intraoperative rib fractures. No postoperative neurologic deficits were noted.

Conclusions: The Cavity Creation System is a safe, cost-effective treatment of VBF resulting in good/excellent pain relief and an improved quality of life.

Key Words: percutaneous vertebroplasty, osteoporosis, pain relief, FACIT

(*Clin J Pain* 2006;22:182–189)

Received for publication September 29, 2004; revised February 27, 2005; accepted March 25, 2005.

From the Millennium Pain Center, the Central Illinois Neuroscience Foundation, Bloomington, IL; and the Department of Pain Management, Cleveland Clinic Foundation, Cleveland, OH.

Presented at the 20th Annual Meeting of the American Academy of Pain Medicine, Orlando, FL, March 4–7, 2004.

Reprints: Ricardo Vallejo, MD, PhD, Millennium Pain Center, 1015 South Mercer Avenue, Bloomington, IL 61701 (e-mail: vallejo1019@yahoo.com).

Copyright © 2006 by Lippincott Williams & Wilkins

Vertebral body fractures (VBFs) are the most common complication of osteoporosis, with 700,000 cases annually.¹ Minimally invasive placement of cement to stabilize these fractures results in significant pain reduction and improved performance of daily activities. Procedures to deliver cement into fractured vertebrae include both percutaneous vertebroplasty (PV) and kyphoplasty (Kyphon, Inc, Sunnyvale, CA). PV involves the injection of polymethylmethacrylate cement into an injured vertebral body via a needle that is placed percutaneously either using a transpedicular or extrapedicular approach. Pain relief is thought to be achieved via stabilization and reinforcement of the fractured vertebral body.¹ Because the cement must be forced into the cancellous bone matrix and because of the low viscosity of the injectate, incidences of cement extrusion range from 9.2% to 73%.^{2–4} Recently, Tomita et al⁵ have cast doubt on these assumptions by finding minimal pressure increases (9.4 ± 8.5 mm Hg) during direct injection of cement into ex vivo cadaveric osteoporotic vertebral bodies during PV.

We describe a modified PV procedure that employs the Cavity Creation System (CCS; Synthes-Stratec, Inc., Oberdorf, Switzerland) to manually create a cavity in fractured vertebral bodies under fluoroscopic guidance. This system consists of a disposable approach kit and a reusable hinged-tip curet set comprising varying lengths and sizes (Fig. 1). This modified procedure allows a more viscous cement to be injected with low resistance. Like conventional PV, this procedure is performed under monitored anesthesia care and local anesthesia and requires no hospital admission. We present our experience to date with the CCS to treat 33 VBFs in 15 patients.

METHODS

Data were gathered from a retrospective chart review of synchronized protocols from 15 consecutive patients (14 women, 1 man) with acute compression VBFs treated with the CCS. The patients ranged in age from 50 and 83 years (Table 1). A total of 33 VBFs were treated in these 15 patients. The number of VBFs treated per patient varied between one and five levels (Table 2).

Patient Selection Criteria

Patients considered for treatment using the CCS met all of the following inclusion criteria: acute or subacute diagnosis

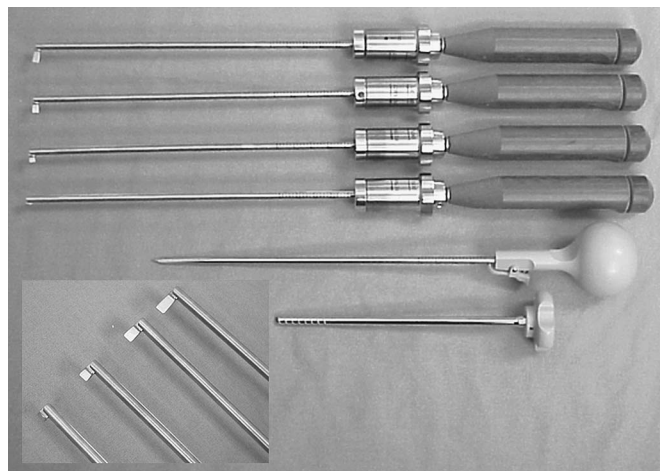


FIGURE 1. Cavity Creation System kit showing varying lengths of hinged curets.

of osteoporotic VBFs as evidenced by T2-weighted MRI; absence of retropulsed vertebral body fragment as evidenced by CT or MRI; skeletal maturity and age at least 18 years; and availability for follow-up and interval visits. Patients exhibiting one or more of the following exclusion criteria were not considered candidates for use of the CCS: coagulopathy or active anticoagulant medication intake; evidence of more than 50% vertebral height decrease; presence of pain with radicular symptoms that do not correspond to the area of the fracture; history of more than two previous open, posterior, lumbar spine surgical procedures at the involved level(s); already implanted with anterior or posterior instrumentation at the involved level(s); active localized or systemic infection; known allergy to polymethylmethacrylate; already treated with other devices for the same disorder (eg, electrical stimulation devices, pain control devices); VBF of malignant nature; and already participating in another clinical research study.

Preprocedural Evaluation

After the patients underwent a thorough history and physical examination and appropriate laboratory testing to determine their suitability for PV using the CCS, the selected patients’ subjective evaluation of preprocedural pain was elicited using a 0-to-10 visual analog scale (VAS), with 0 representing no pain and 10 representing the worst imaginable pain. In addition, the Functional Assessment of Chronic Illness

TABLE 1. Demographic Data Obtained During Preoperative History and Physical Examination

	Mean ± SD (Range)
Age	74.4 ± 8.2 (50–83)
Gender	
Females	14
Males	1
Height (cm)	158.3 ± 9.4 (53–68)
Weight (kg)	67.4 ± 12.5 (45–83)
BMI (kg/m ²)	27.3 ± 6.1 (18–44)

TABLE 2. Distribution of Vertebral Body Fractures (VBFs) Treated by Number of Levels Treated Per Patient

No. of Levels	Vertebral Body Fractures Treated
1 (n = 9)	T9, T11(2), T12(3), L1(2) & L3
2 (n = 1)	L1 & L2
3 (n = 1)	T12, L1 & L3
4 (n = 1)	T1, T11, T12 & L2
5 (n = 3)	T11, T12, L1, L2 & L4 L1, L2, L3, L4 & L5 T7, T9, L3, L4 & L5

n, number of patients.

Therapy (FACIT, FACIT.org, Elmhurst, IL) questionnaire was administered to gauge quality of life (QOL).⁶ This questionnaire includes subscales for General Activity, Enjoyment of Life, Mood, Work Routine, Sleep, and Walking. The FACIT Measurement System is a collection of QOL questionnaires targeted to the management of chronic illness. FACIT expands the FACT (Functional Assessment of Cancer Therapy) series of questionnaires into a broader, more encompassing evaluation. The measurement system, under development since 1987, has a generic core questionnaire called the Functional Assessment of Cancer Therapy-General (FACT-G Version 4). It is a 27-item compilation of general questions divided into four primary QOL domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being. It is considered appropriate for use with patients with any form of cancer and has also been used and validated in other chronic illness conditions. Validation of a core measure allowed for the evaluation of multiple disease, treatment, condition, and non-cancer-specific subscales. FACIT scales complement the FACT-G; they address relevant disease-, treatment-, or condition-related issues not already covered in the general questionnaire. Each FACIT scale is intended to be as specific as necessary to capture the clinically relevant problems associated with a given condition or symptom, yet general enough to allow for comparison across diseases and extension, as appropriate, to other chronic medical conditions.

Technique

Cefazolin 1 g IV (or clindamycin 600 mg IV in case of allergy) was administered 30 minutes prior to incision. In the procedure room, the patients received midazolam 1 to 2 mg and were carefully positioned to avoid new fractures. The patients were placed in the prone position on an operating table (Model 3100, Skytron, Grand Rapids, MI) over a Wilson frame with extra padding to avoid pressure points. Sedation was accomplished using fentanyl 1 to 2 µg/kg and propofol infusion at the discretion of the anesthesiologist to maintain adequate sedation.

Following site preparation and sterile draping, the fluoroscope was rotated to the oblique view until the pedicles of the VBFs were in a “Scottie dog” view. Skin and subcutaneous tissues were anesthetized using lidocaine 1% with epinephrine 5 µg/mL. Then a 0.5-cm stab skin incision was

made with a #11 blade scalpel. Under multidirectional fluoroscopic guidance, an awl-tipped probe was inserted through the incision and gradually advanced through the pedicle into the vertebral body (Fig. 2), using continuous anterior-posterior (AP) and lateral fluoroscopic views to ensure correct needle advancement. Once the awl-tipped probe was at the junction of the posterior third and the middle third of the vertebral body as confirmed by fluoroscopy, a 0.5 mm (OD) stainless steel threaded-tipped cannula was railroaded over the probe and rotated clockwise to advance the catheter into the cancellous bone, just past the cortical wall (Figs. 3 and 4). The probe was then removed, leaving the cannula in place. The same procedure was performed on the opposite side of the vertebral body to place a second cannula. Hinge-tipped curets, ranging in size from 8 to 16 mm, were inserted through the cannulas and then rotated into the vertebral body, under direct fluoroscopic view, to create and shape the cavity. To avoid injury to the cortical walls or the end-plates of the vertebrae, rotation of the curet was halted and the curet was repositioned if any resistance was felt. Using progressively larger-tipped curets, the cavity was enlarged. Curettage was limited to the anterior two thirds of the vertebral body (Fig. 5). Curets were then removed, leaving the cannulas in place. The cement mixture consisted of 40 mL powder methylmethacrylate (Slufyx, Winterthur, Germany) polymer mixed with 10 mL liquid methylmethacrylate monomer and 12 g barium sulfate (Biotrace, Bryan



FIGURE 2. Transpedicular approach using cannula.

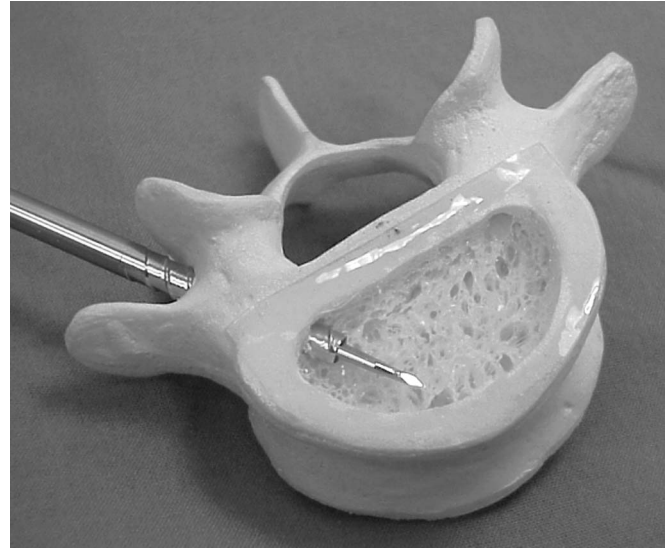


FIGURE 3. Introducer inserted into cannula.

Corp, Woburn, MA). The cement was allowed to reach the consistency of a thin paste (eg, like that of toothpaste) before transfer to a syringe. Using continuous fluoroscopic guidance, the cement was slowly injected into the cannula until the cavity was filled (Fig. 6). The same procedure was repeated in the opposite side. Injection was immediately discontinued if fluoroscopic evidence of cement extrusion was observed. In patients with extravasation of cement beyond the boundaries of the vertebral body, CT imaging was used to detect leakage into the epidural space or neural foramen.

One to five levels were treated during a single procedure, with a total amount injected per level of 2.5 to 5 mL of cement. The cannulas were then removed and the incision sites were closed with a single 3.0 polyglactin 910 stitch (Vicryl, Ethicon, Somerville, NJ). Total fluoroscopy time was 3 to



FIGURE 4. Curet inserted into cannula to create cavity.



FIGURE 5. Intraoperative fluoroscopic image showing curet within the vertebral body.

4 minutes per level treated. The patients were discharged after 3 hours of recovery, and close contact was maintained with them over the next 48 hours. Patients returned to the office 8 days later for suture removal and postoperative evaluation. At approximately 1 month the patients underwent a comprehensive neurologic examination, repeat VAS scoring of pain, assessment of analgesic requirement, and QOL assessment.

Statistical Analyses

Data were analyzed using the SPSS statistical package (Version 12.0, SPSS, Chicago, IL). The Student *t* test was used

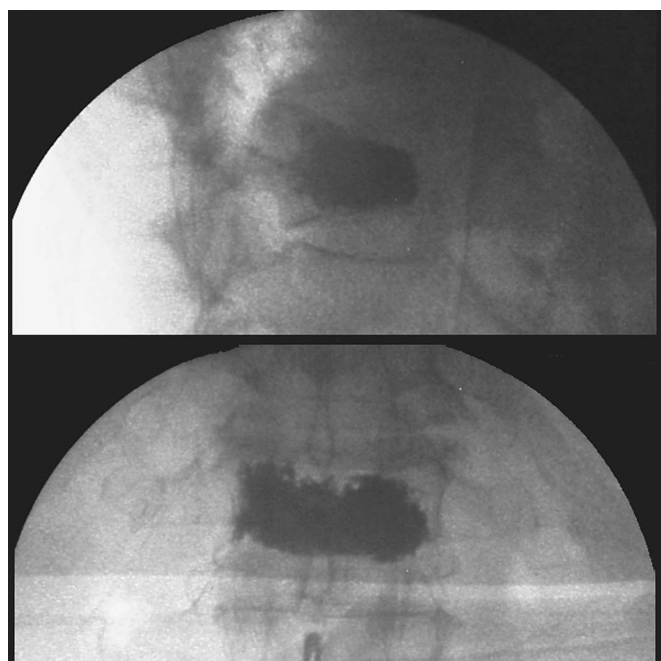


FIGURE 6. Postoperative lateral and AP fluoroscopic images.

to test for significant differences between preoperative and postoperative pain VAS and QOL subscales. A Bonferroni procedure was used to correct for multiple statistical comparisons and to maintain the overall study-wide criterion for significance at *P* < 0.05.

RESULTS

All 15 patients exhibited a reduction in pain VAS. Table 3 lists the mean maximum and minimum VAS recorded before and after surgery. The postoperative maximum and minimum values represented a significant reduction in pain at 1 month after surgery ($t_{13} = 8.63, P < 0.001$; $t_{14} = 9.43, P < 0.001$, respectively). The mean change (postoperative minus preoperative) in maximum VAS was 5.93 ± 2.52 (Fig. 7). This was accompanied by a decrease in opioid use in 10 of the 12 (83%) patients taking opioids preoperatively. In eight (67%) patients, this decrease in opioid use exceeded 50%. Significant improvement in QOL was shown by decreasing FACIT subscale scores for General Activity ($t_{14} = 9.22, P < 0.001$), Enjoyment of Life ($t_{14} = 8.38, P < 0.001$), Mood ($t_{14} = 11.21, P < 0.001$), Normal Work Routine ($t_{12} = 11.83, P < 0.001$), Walking ($t_{14} = 3.84, P < 0.002$), and Sleep ($t_{14} = 7.13, P < 0.001$). FACIT scores for General Activity, Enjoyment of Life, Mood, and Work Routine subscales improved in every patient. Improvement in the Sleep subscale was seen in 14 of the 15 patients and improvement in the Walking subscale in 12 of the 15 patients (Table 4). Mean scores for all FACIT subscales decreased postoperatively (Fig. 8). Complications related to the procedure included extrusion of cement confirmed by CT, which occurred in two patients, resulting in an incidence of 5.7% of the levels operated. In addition, two patients sustained iatrogenic rib fractures despite careful padding and positioning on the surgical frame. No postoperative neurologic deficits were noted in any of the patients undergoing this procedure.

DISCUSSION

The results of this retrospective pilot study suggest that the CCS can be effectively used to treat osteoporotic vertebral compression fractures of the thoracic and lumbar spine. Patients who underwent treatment routinely showed substantial relief of preoperative pain as evidenced by reduced VAS pain ratings and opioid use, as well as significant improvement in all QOL parameters assessed.

Vertebral compression fractures are associated with significant declines in health and functional activity. In the

TABLE 3. Mean Maximum and Minimum Visual Analog Pain Scores Recorded Preoperatively and Postoperatively in 15 patients Undergoing 33 Cavity Creation Percutaneous Vertebroplasties

	Mean ± SD Visual Analog Pain Score	
	Preoperative	Postoperative
Maximum	9.27 ± 0.96	3.33 ± 2.47*
Minimum	7.60 ± 2.50	2.80 ± 1.57*

*significantly different from preoperative value (*P* < 0.001).

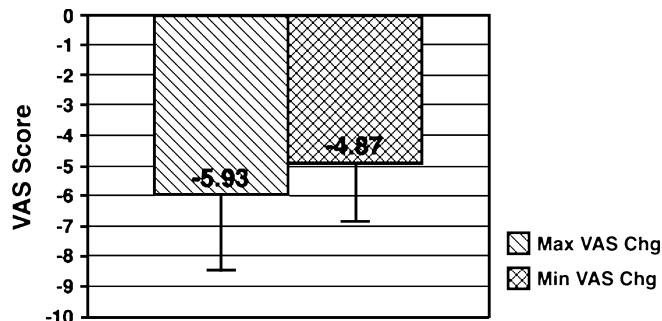


FIGURE 7. Mean maximum and minimum changes (preoperative vs. postoperative) in pain scores as measured using a VAS between 0 (no pain) and 10 (the worst imaginable pain).

United States, VBFs account for 150,000 hospital admissions, 161,000 physician office visits, and more than 5 million restricted activity days annually.⁷ The estimated prevalence of VBFs increases steadily with age, reaching 40% in 80-year-old women.⁸ Women with clinically diagnosed VBFs have a 15% higher mortality rate and are two to three times more likely to die of pulmonary causes.^{9,10} Osteoporotic VBFs also affect the musculoskeletal system, causing chronic pain, functional disability, changes of mood, and impaired QOL. Typically occurring at the anterior third of the vertebral body, where trabecular bone is more prominent, these fractures alter the biomechanics of the spine, making adjacent levels more vulnerable to fracture because of increased stress on the osteoporotic bone and surrounding musculature. When left untreated, progressive spinal deformity often ensues. Compression VBFs may also be secondary to tumor infiltration. The most frequent malignant lesions of the spine include osteolytic metastasis and myeloma. Although current cancer therapy prolongs life expectancy, there is an increased risk for these patients to develop metastatic vertebral involvement and collapse.

To date, three primary modalities are available for the treatment of VBFs: conventional medical management, reconstructive surgical intervention, and more recently developed minimally invasive procedures known as percutaneous vertebroplasty and kyphoplasty. In most cases, a course of conservative therapy is the first-line treatment of VBFs. Traditional therapeutic options include acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), opiate analgesics, bedrest, and bracing. Conservative therapy may be useful

TABLE 4. Comparison of Preoperative vs. Postoperative Quality of Life Using the Functional Assessment of Chronic Illness Therapy (FACIT) QOL Instrument

FACIT Subscale	Preoperative	Postoperative	Sig.
General Activity	3.65 ± 0.56	1.95 ± 0.78	P < 0.001
Enjoyment of Life	3.65 ± 0.62	1.76 ± 0.90	P < 0.001
Walking	3.44 ± 0.60	2.01 ± 1.30	P < 0.002
Mood	3.63 ± 0.60	1.38 ± 0.76	P < 0.001
Normal Work Routine	3.49 ± 0.68	1.47 ± 0.64	P < 0.001
Sleep	3.15 ± 1.04	1.20 ± 1.09	P < 0.001

Table entries indicate mean ± SD.

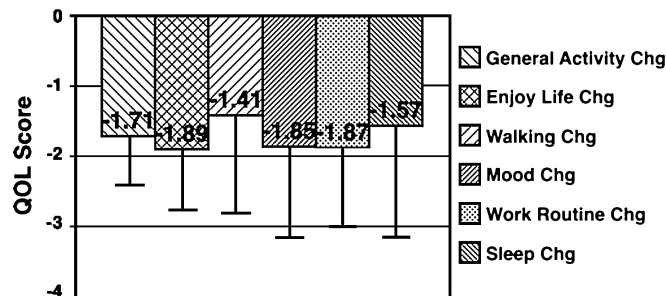


FIGURE 8. Mean changes in FACIT subscales.

in some patients, but it carries the risk of significant side effects related to the use of these medications in elderly patients. The added risk of protracted immobilization predisposes them to secondary complications such as atelectasis, pneumonia, and pulmonary embolus. Reconstructive surgical correction of these fractures is reserved for patients with neurologic deficits or deterioration, which occurs in approximately 0.05% of cases. Surgical intervention requires the use of anterior and posterior instrumentation. These extensive surgeries are often lengthy, are followed by prolonged hospitalization and recovery periods, and are not well tolerated by elderly patients with comorbid conditions.

Minimally invasive surgical procedures use acrylic bone cement to stabilize and treat painful vertebral compression fractures. In contrast to conventional management or surgical reconstruction, these procedures are particularly advantageous because of their brief surgical time, limited sedation, minimal recovery period, and short or no hospital stay. Follow-up care may include gentle physical therapy, but bracing is not required. Patients can return to their normal activities of daily living within a matter of days with 67% to 100% pain relief. The mechanism by which cement injection into the VBF produces pain relief remains unclear. Theories of analgesia include thermal necrosis, chemotoxicity of the intraosseous pain receptors, mechanical stabilization, and ablation of nociceptive fibers mediated by the monomer of the cement.^{11,12} More research is necessary to elucidate the means by which pain reduction is achieved. Neurologic sequelae are uncommon, and thermal injury to the neural structures does not appear to occur. Transient radiculopathy has been reported in 3% to 6% of patients and has been successfully treated in most cases with steroids and anti-inflammatory medications.¹³

Conventional PV was originally developed in response to limited results of medical and surgical modalities to stabilize and strengthen collapsed vertebral bodies.¹³⁻²⁰ Initial results of a Stanford University prospective randomized crossover trial comparing PV with medical therapy for acute osteoporotic VBFs have shown that PV offered significant improvement in measured outcomes.²¹ Significant benefits include reduced or eliminated fracture pain, less long-term pain or disability, prevention of further collapse, and an early return to mobility.²²⁻²⁴ Despite this impressive list of acknowledged benefits, conventional PV is associated with cement extrusion in 9% to 80% of patients, probably related to the low viscosity and the pressure required to inject cement into the

cancellous matrix of the vertebral body.²⁻⁴ There are many routes by which cement may leak from a vertebra: paravertebral leakage, venous leakage, or leakage into the spinal canal and intervertebral foramen.^{25,26} Leakage into the paravertebral muscles can cause severe localized pain due to the exothermic reaction during polymethylmethacrylate cement curing and the effect of the mass of cement on muscle motion. Leakage of cement into the venous circulation can produce generalized toxic reactions and, when entering the inferior vena cava, possibly life-threatening pulmonary embolization.²⁷⁻³² Leakage of cement into the epidural space canal may compress the spinal cord or nerve roots.^{17,25,26,33-35}

These disadvantages of conventional PV led to the development of an alternative method to deliver cement into fractured vertebrae, kyphoplasty. Kyphoplasty was also designed to address the kyphotic deformity associated with VBF, which has itself been associated with residual pain, a reduction in vital capacity,³⁶ and adverse effects on respiratory and gastrointestinal function.³⁷ Kyphoplasty involves the percutaneous insertion of an inflatable bone tamp into the fractured vertebral body. Inflation of the tamp elevates the end-plates, restoring the vertebral body toward its original height while creating a cavity to be filled with cement. In theory, this procedure should have a lower risk of cement extravasation compared with conventional PV since a more viscous (partially cured) cement is injected into the created cavity at a presumably lower pressure. Watts et al³⁸ completed a phase 1 efficacy study of 70 consecutive kyphoplasty procedures in 30 patients with painful progressive osteoporotic/osteolytic VBFs. They reported partial restoration (47%) of lost vertebral height in 70% of patients, improved QOL scores in bodily pain, physical function, and vitality, cement leakage in only 8.6% of patients with no directly related complications, and few complications overall. A more recent study showed that the height restoration averaged 4.6 and 3.9 mm in the anterior and medial columns, respectively.³⁹ The clinical significance of these height restorations is unknown. In addition, recent evidence indicates that the real pressures achieved during cement injection may not be as high as previously presumed.

Kyphoplasty is not without disadvantages. In May 2001, the cost of a patented kyphoplasty set comprising two inflatable balloon tamps, two inflation syringes, one introduction kit, six doses of cement, and one Jamshidi needle was approximately \$3,400. This is significantly higher in cost than the conventional or modified PV.⁴⁰ Recently, others have suggested that the real percentage of patients corrected and the degree of kyphotic correction might be considerably less than previously reported.⁴¹ Kyphoplasty is supposed to facilitate low-pressure injection of cement into the compressed vertebral body. However, measurements of injection pressures during cement administration have not been adequately addressed for kyphoplasty and investigated only *ex vivo* for conventional PV.^{5,42} Kyphoplasty is more labor-intensive than conventional PV, requiring 30 to 45 minutes per level in very experienced hands.⁴³ The average procedure time per level for conventional PV is 20 minutes. This longer time also translates into greater radiation exposure to the patient, operator, and assistants.⁴² Whereas conventional PV is usually performed as a same-day procedure, most kyphoplasties are performed under general

anesthesia and the patient is often admitted to the hospital. These factors compound the cost issues with kyphoplasty.⁴²

The modified PV technique described in the present study encompasses many of the claimed advantages of kyphoplasty as well as avoiding some of the disadvantages. We have shown that the technique is safe and effective in decreasing the pain associated with VBFs, decreasing the opiate requirement, and improving QOL. The incidence of cement extrusion was comparable to the lowest previously reported incidences of either conventional PV⁴ and kyphoplasty.^{4,44} This low incidence of extrusion was likely a consequence of using a "more-cured" polymethylmethacrylate cement, a small injectate volume, and gentle bilateral injection into a created cavity rather than unilateral injection into the dense bone matrix of a collapsed vertebra. Similarly, Fourney et al⁴ suggested that partially cured cement and small injectate volumes contributed to their low incidence of cement extrusion. Furthermore, when unilateral injection failed to yield the desired result, the contralateral side was cannulated to avoid exerting high pressures. In the current study, cavity creation required both sides to be cannulated, and therefore injection was bilateral in all patients. While we did not systematically monitor injection pressures, creating a cavity within the fractured vertebral body allows injection of more viscous cement bilaterally, presumably under the same low pressure as kyphoplasty, which has been anecdotally reported to be less than 10 psi in a cadaver model.⁴²

Cavity creation PV is considerably less costly than kyphoplasty. The CCS consists of a disposable approach kit that costs approximately \$1,175 and a reusable curet set. The procedure is performed under local anesthesia and sedation and thus requires minimal recovery area stay. Similar to conventional PV, patients are discharged home within 3 hours of the completion of surgery. Multiple levels can be treated during a procedure. We treated as many as five levels in a single procedure, but the small number of patients treated does not allow us to make any recommendations on the maximum number of levels that should be treated. The incidence of complications was low, even in inexperienced hands during this initial series of patients. Rib fracture during conventional PV or kyphoplasty has been previously reported.²⁶ The two intraoperative rib fractures (patients 7 and 10) in the present study occurred near the middle of the series of patients despite careful padding of the surgical frame and meticulous positioning. The two patients sustaining these fractures each had multiple levels treated (patient 7 had four levels and patient 10 had three levels treated). Intuitively, we would assume that treatment of multiple levels during a single procedure might increase the risk of iatrogenic fractures, but our data are insufficient to make such a determination. This assumption must be tempered with a hitherto unknown risk associated with multiple single-level cavity creation procedures.

However, cavity creation PV does have some limitations. Like conventional PV, cavity creation PV is not intended to treat the kyphosis associated with multiple VBFs, and thus it is unlikely to have any substantial effect on restoring lost vertebral height. The technique requires more experience than does conventional PV and probably the same as might be required for kyphoplasty. Cavity creation PV is more labor-intensive than conventional PV but less than that for

kyphoplasty, requiring on average 25 to 30 minutes per level treated. This is substantially longer than conventional PV and within the range of kyphoplasty. Cavity creation is performed with long curets inserted bilaterally. Their presence presents some risk of accidental advancement into the vertebral cortex, particularly when multiple levels are treated and a single uniplane C-arm is being continually rotated between AP and lateral views. Only patients with osteoporotic or osteolytic VBFs were recruited for this study. We hesitated to use this technique in patients with VBFs of cancerous origin, fearing that the curettage of the vertebral body might cause dissemination of cancerous cells.

Finally, this was not a case-controlled study, it was not randomized or blinded, and we reported on only 33 levels treated in 15 patients. However, the excellent results obtained, the low incidence of cement extrusion and total complications, and the low overall cost lead us to believe that more investigation is warranted, possibly a randomized, controlled, multicenter study.

In conclusion, despite efforts to prevent the development of osteoporosis with early intervention such as calcium, exercise, and various treatment regimens, compression fractures requiring pain control remain a major health problem. These fractures affect the musculoskeletal system, causing chronic pain and functional disability. The introduction of minimally invasive placement of bone cement to stabilize these fractures without a lengthy recovery period affords these patients an opportunity to quickly return to their activities of daily living and improve their overall QOL. Cavity creation PV appears to be a safe and effective treatment of patients with VBFs of osteoporotic or osteolytic origin. Further studies are indicated to substantiate these initial findings and to examine the applicability of this technique to a wider range of patients with painful VBFs following failed conservative therapy.

REFERENCES

1. Deen HG, Fenton DS, Lamer TJ. Minimally invasive procedures for disorders of the lumbar spine. *Mayo Clin Proc.* 2003;78:1249–1256.
2. Phillips FM. Minimally invasive treatments of osteoporotic vertebral compression fractures. *Spine.* 2003;28:545–553.
3. Yeom JS, Kim WJ, Choy WS, et al. Leakage of cement in percutaneous transpedicular vertebroplasty for painful osteoporotic compression fractures. *J Bone Joint Surg [Br].* 2003;85B:83–89.
4. Fourny DR, Schomer DF, Nader R, et al. Percutaneous vertebroplasty and kyphoplasty for painful vertebral body fractures in cancer patients. *J Neurosurg.* 2003;98:21–30.
5. Tomita S, Molloy S, Abe M, et al. Ex vivo measurement of intravertebral pressure during vertebroplasty. *Spine.* 2004;29:723–725.
6. Cella D, Webster K. Linking outcomes management to quality-of-life measurement. *Oncology (Huntington).* 1997;11A:232–235.
7. Phillips S, Fox N, Jacobs J, et al. The direct medical costs of osteoporosis for American women aged 45 and older. *Bone.* 1988;9:271–279.
8. Kado DH, Browner WS, Palermo L, et al. Vertebral fractures and mortality in older women. *Arch Intern Med.* 1999;159:1215–1220.
9. Leech JA, Dulberg C, Kellie S, et al. Relationship of lung function to severity of osteoporosis in women. *Am Rev Respir Dis.* 1990;141:68–71.
10. Schlaich C, Minne HW, Bruckner T, et al. Reduced pulmonary function in patients with spinal osteoporotic fractures. *Osteoporos Int.* 1998;8:261–267.
11. Bostrom MP, Lane JM. Future directions: augmentation of osteoporotic vertebral bodies. *Spine.* 1997;22:38S–42S.
12. Sappalainen AM, Rajaniemi R. Local neurotoxicity of methyl methacrylate among dental technicians. *Am J Ind Med.* 1984;5:471–477.
13. Chiras J, Depriester C, Weill A, et al. Percutaneous vertebral surgery: techniques and indications. *J Neuroradiol.* 1997;24:45–59.
14. Galibert P, Deramond H, Rosat P, et al. Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty. *Neurochirurgie.* 1987;33:166–168.
15. Mathis JM, Petri M, Naff N. Percutaneous vertebroplasty treatment of steroid-induced osteoporotic compression fractures. *Arthritis Rheumatism.* 1998;41:171–175.
16. Watts NB, Harris ST, Genant HK. Treatment of painful osteoporotic vertebral compression fractures with percutaneous vertebroplasty or kyphoplasty. *Osteoporos Int.* 2001;12:429–437.
17. Jensen ME, Evans AJ, Mathis JM, et al. Percutaneous methylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. *AJNR Am J Neuroradiol.* 1997;18:1897–1904.
18. Deramond H, Depriester C, Galibert P, et al. Percutaneous vertebroplasty with polymethylmethacrylate: technique, indications and results. *Radiol Clin North Am.* 1998;36:533–546.
19. Mathis JM, Barr JD, Belkoff SM, et al. Percutaneous vertebroplasty: a developing standard of care for vertebral compression fractures. *AJNR Am J Neuroradiol.* 2001;22:373–381.
20. Weill A, Chiras J, Simon JM, et al. Spinal metastases: indications for and results of percutaneous injection of acrylic surgical cement. *Radiology.* 1996;199:241–247.
21. Do HM, Marcellus ML, Weir RU, et al. Percutaneous vertebroplasty versus medical therapy for treatment of acute vertebral body compression fractures: a prospective randomized study. Proceedings of the ASNR 2002, and Proceedings of the AUR, 2002.
22. Do HM. Percutaneous vertebroplasty: rationale, clinical outcomes, and future directions. *Neuroimag Clin North Am.* 2003;13:343–363.
23. Alvarez L, Pérez-Higueras A, Quiñones D, et al. Vertebroplasty in the treatment of vertebral tumors: postprocedural outcome and quality of life. *Eur Spine J.* 2003;12:356–360.
24. Pérez-Higueras A, Alvarez L, Rossi RE, et al. Percutaneous vertebroplasty: long-term clinical and radiological outcome. *Neuroradiology.* 2002;44:950–954.
25. Ryu KS, Park CK, Kim MC, et al. Dose-dependent epidural leakage of polymethacrylate after percutaneous vertebroplasty in patients with osteoporotic vertebral compression fractures. *J Neurosurg (Spine).* 2002;96:56–61.
26. Mathis JM. Percutaneous vertebroplasty: complication avoidance and technique optimization. *AJNR Am J Neuroradiol.* 2003;24:1697–1706.
27. Vasconcelos C, Gailloud P, Martin JB, et al. Transient arterial hypotension induced by polymethylmethacrylate injection during percutaneous vertebroplasty. *J Vasc Interv Radiol.* 2001;12:1001–1002.
28. Scroop R, Eskridge J, Britz GW. Paradoxical cerebral arterial embolization of cement during intraoperative vertebroplasty: case report. *AJNR Am J Neuroradiol.* 2002;23:868–870.
29. Padovani B, Kasriel O, Brunner P, et al. Pulmonary embolism caused by acrylic cement: a rare complication of percutaneous vertebroplasty. *AJNR Am J Neuroradiol.* 1999;20:375–377.
30. Jang JS, Lee SH, Jung SK. Pulmonary embolism of polymethacrylate after percutaneous vertebroplasty. A report of three cases. *Spine.* 2002;27:E416–E418.
31. François K, Taeymans Y, Poffyn B, et al. Successful management of a large pulmonary cement embolus after percutaneous vertebroplasty: a case report. *Spine.* 2003;28:E424–E425.
32. Chen HL, Wong CS, Ho ST, et al. A lethal pulmonary embolism during percutaneous vertebroplasty. *Anesth Analg.* 2002;95:1060–1062.
33. Harrington KD. Major neurological complications following percutaneous vertebroplasty with polymethylmethacrylate. A case report. *J Bone Joint Surg [Am].* 2001;83A:1070–1073.
34. Shapiro S, Abel T, Purvines S. Surgical removal of epidural and intradural polymethylmethacrylate extravasation complicating percutaneous vertebroplasty for an osteoporotic lumbar compression fracture. *J Neurosurg (Spine).* 2003;98:90–92.
35. Phillips FM, Wetzel FT, Lieberman I, et al. An in vivo comparison of the potential for extravertebral cement leak after vertebroplasty and kyphoplasty. *Spine.* 2002;27:2173–2179.

36. Schlaich C, Minne HW, Bruckner T. Reduced pulmonary function in patients with spinal osteoporotic fractures. *Osteoporos Int.* 1998;8:261–267.
37. Silvermann SL. The clinical consequences of vertebral compression fractures. *Bone.* 1992;13(Suppl):23–25.
38. Watts NB, Harris ST, Genant HK. Treatment of painful osteoporotic vertebral compression fractures with percutaneous vertebroplasty or kyphoplasty. *Osteoporos Int.* 2001;12:429–437.
39. Rhyne A III, Banit D, Laxer E, et al. Kyphoplasty: report of eighty-two thoracolumbar osteoporotic vertebral fractures. *J Orthop Trauma.* 2004;18:294–299.
40. Hardouin P, Fayada P, Leclot H, et al. Kyphoplasty. *Joint Bone Spine.* 2002;69:256–261.
41. Alanay A. Point of view. *Spine.* 2003;28:2265–2267.
42. Ortiz AO, Zoarski GH, Beckerman M. Kyphoplasty. *Tech Vasc Interv Radiol.* 2002;5:239–249.
43. Theodorou DJ, Theodorou SJ, Duncan TD, et al. Percutaneous balloon kyphoplasty for the correction of spinal deformity in painful vertebral body compression fractures. *J Clin Imag.* 2002;26:1–5.
44. Phillips FM, Ho E, Campbell-Hupp M, et al. Early radiographic and clinical results of balloon kyphoplasty for the treatment of osteoporotic vertebral fractures. *Spine.* 2003;19:2260–2267.