Clinical Evaluation of a New Kyphoplasty Technique With Directed Cement Flow

Baron Zarate, MD,* Jorge Gutierrez, MD,* Ajay K. Wakhloo, MD, PhD,† Matthew J. Gounis, PhD,‡ and Alejandro Reyes-Sánchez, MD*

Study Design: Prospective, single-center 2-year study.
Objective: The long-term clinical performance of a new cement-directing kyphoplasty system was evaluated for treatment of painful osteoporotic compression fractures.
Summary of Background Data: Cement leakage is a common clinical complication of vertebroplasty and kyphoplasty procedures. Balloon kyphoplasty restricts cement flow and reduces leakage by injection of high-viscosity cement into a compacted bone cavity. Biomechanical reinforcement of surrounding bone is limited, leaving the vertebral body vulnerable to continued collapse.
Methods: The patient population consisted of 20 patients at least 50 years of age with up to 3 painful osteoporotic vertebral compression fractures between T4–L5. The cement-directing kyphoplasty system procedure was performed unipseudically using a curved drill and reamer to create a central cavity. The cement-directing implant was positioned inside the cavity and cement was injected through it. A total of 37 levels were treated. Pain relief was assessed using a verbal pain scale. The Roland-Morris Questionnaire was used to evaluate disability. Cement leakage was determined from radiographs (anterior/posterior and lateral) obtained within 24 hours of the procedure.
Results: Significant pain relief was achieved immediately after the procedure, as shown by a decrease in the mean pain scores from 8.20 (±1.40) measured preoperatively to 2.85 (±2.13) measured postoperatively. Pain relief was sustained throughout the 2-year follow-up period. Mean Roland-Morris Questionnaire scores improved from 21.8 (±3.5) measured preoperatively to 11.6 (±5.6) measured 6 weeks postoperatively. The investigators reported 1 moderate cortical leak (2.7%) and an independent reviewer identified 8 additional minor segmental vein and cortical leaks (24.3%). None of the leaks was symptomatic.
Conclusions: Directed cement flow allows cement to fill the anterior vertebral body, stabilizing fractures and supporting biomechanical loading. Control of cement flow may help minimize the risk of posterior leakage into the basivertebral vein or spinal canal.

Key Words: vertebral compression fracture, osteoporosis, vertebroplasty, cement leakage

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There are an estimated 700,000 osteoporotic vertebral compression fractures (VCFs) annually in the United States, with approximately 26% of women over 50 years and 40% of women over 80 years of age reported to have sustained a VCF.1,2 As the population continues to age, the incidence of osteoporosis is expected to become increasingly prevalent. Acute VCFs are painful, but the severity of this pain is variable. Patients presenting to their physicians are typically offered conservative treatments such as pain medication, braces, and limitations on activity. However, at least one third of these fractures do not respond to nonsurgical treatment, remaining painful and debilitating.2 Surgical procedures such as vertebroplasty and balloon kyphoplasty (BKP) are used to treat unresponsive fractures through percutaneous injection of polymethylmethacrylate cement into the vertebral body to stabilize the fracture and relieve pain.

The vertebroplasty procedure was first proposed by Galibert et al3 for treatment of malignant and aggressive vertebral hemangiomas, and now it is used extensively in osteoporotic vertebral collapse. More recently, BKP was developed to improve fracture reduction, restore sagittal balance, and allow injection of high-viscosity cement. This technique involves the use of inflatable bone tamps to create a cavity through compaction of bone and marrow, followed by cement injection through bone filling cannulas. When large voids are present, multiple cannulas must be used to deliver a sufficient cement volume. Cement flow and interdigitation with the surrounding cancellous bone are limited to some extent by the compressed bone lining the cavity walls and by the cement viscosity. Similar to vertebroplasty, clinical studies have shown that BKP provides effective pain relief for osteoporotic VCFs.4 However, reproducible and clinically significant fracture reduction has not been clearly demonstrated.5,6

Cement leakage is a frequently reported clinical complication for vertebroplasty procedures. Leakage rates are highly variable and dependent on the subjective judgment of each investigator as well as the imaging method used. As
expected, more leaks are identified from computed tomography (CT) images, in comparison with postoperative anterior/posterior (AP) and lateral radiographs. Leakage has been reported to occur in 38%–72.5% of levels involving malignant collapse, and in 19%–87.5% of levels overall for vertebroplasty procedures. Cement may leak into a variety of anatomic compartments including the needle track, paravertebral soft tissue, spinal canal, intervertebral disk space, paravertebral veins, epidural veins, and lungs. Low-pressure injection of higher viscosity cement in BKP, in combination with compressed cancellous bone lining the cavity, are intended to restrict cement flow and reduce cement leakage. Despite these measures, leakage is reported in 7%–52% of levels treated with BKP.

Cement-directed kyphoplasty is a new procedure consisting of percutaneous unipedicular placement of a device within a cavity, which crosses the sagittal midline, to direct the flow of cement toward the anterior region of the vertebral body. This procedure offers the combined benefits of both kyphoplasty and vertebroplasty. More viscous cement can be injected, which causes the cement to flow into the vertebral body under greater directional control. The cement director guides cement in the anterior, superior, and inferior directions, and limits posterior flow. Cement is allowed to disperse into the spaces in the cancellous bone, along fracture planes, and toward the endplates of the vertebral body, interdigitating with the trabeculae. The cement ultimately serves to stabilize the fracture and provide long-term mechanical reinforcement. In this study, the first long-term clinical results for this novel minimally invasive technique to treat VCFs are reported.

MATERIALS AND METHODS

Study Design

A prospective, single-center, open-label study was conducted between November 2006 and September 2007. The patient population consisted of 20 patients, aged 50 or above, with a radiographically confirmed diagnosis of painful osteoporotic VCFs involving 1–3 levels between T4 and L5. All patients indicated a verbal pain score of 5 or above on a 10-point scale and were unresponsive to at least 6 weeks of conservative treatment before enrollment in the study. Fractures were limited to those with a loss of 15%–60% of vertebral height, as determined by radiographic evaluation of the height of an adjacent unfractured vertebral body. Exclusion criteria included vertebral collapse >60% of the original height, burst fractures, spinal canal compromise, uncorrectable coagulation disorder, active systemic or local infection, prior or current cancer treatment at the affected level, multiple myeloma, prior cement placement at the operative level, diabetes, and pregnancy.

Demographic and medical data, including age, sex, race, height, weight, smoking status, diagnosis, duration of symptoms, previous surgery, use of pain medication, and any prior treatments, were recorded during the enrollment process. Pretreatment clinical evaluation included assessment of back pain and disability using a 10-point verbal pain scale and a validated Spanish version of the Roland-Morris Questionnaire (RMQ), respectively. During the surgical procedure, the procedure time, implant location, observations of cement leakage, and postoperative pain medications were recorded. A postoperative pain assessment was performed within 24 hours after surgery. No RMQ was administered at this time.

AP and lateral radiographs were taken preoperatively and postoperatively. The procedure was conducted under fluoroscopic guidance to allow visualization of implant placement and cement filling. The intraoperative fluoroscopic images and postoperative radiographs were examined by the senior author (A.R.S.) for the presence of cement leakage. The postoperative radiographs were additionally examined for evidence of leaks by an independent interventional neuroradiologist (A.K.W., 20y of clinical experience). The leak locations and any clinical consequences were recorded. Cement leak locations were also categorized on the basis of the classification scheme developed by Yeom et al.

Patients were evaluated for 2 years after surgery at the following intervals: 6 weeks (± 7 d), 3 months (± 14 d), 6 months (± 30 d), 12 months (± 30 d), and 24 months (± 30 d). At each follow-up appointment, patients were asked to provide current pain and disability (RMQ) scores. Additional AP and lateral radiographs were obtained at 12 and 24 months to qualitatively evaluate the stability of the cement director and the surrounding cement mantle, and to assess the incidence of new fractures. Anterior vertebral body height was measured from the postoperative and 12-month radiographs and compared.

Operative Technique

The cement-directing kyphoplasty system (CDKS, manufactured by Soteira Inc., Natick, MA) consists of cavity creation instrumentation, a cement-directing implant, and a delivery device to insert the implant and deliver bone cement. The overall objective of this system is to position the cement-directing implant in the center of the vertebral body using a unipedicular approach and to direct the cement flow toward the anterior, superior, and inferior regions relative to the implant location. Cement is intended to fill the span between the endplates, flowing into cracks and voids and interdigitating with intact cancellous bone. The resulting cement mantle stabilizes the fracture and provides biomechanical reinforcement. Cement flow is physically limited in the posterior direction to prevent leakage into the spinal canal and the basivertebral vein.

The procedure was carried out under general anesthesia. The patient was placed prone on a radiolucent frame with the abdomen free and all bony prominences generously padded. C-arm fluoroscopy in the AP plane was used to identify the affected levels and pedicles. A Jamshidi needle was advanced through the pedicle, taking care not to cross the medial border of the pedicle until the junction between the pedicle base and the vertebral body was reached. The Jamshidi needle was subsequently advanced through the pedicle by gently tapping with a mallet, under fluoroscopic visualization in the AP and lateral planes.
Once the junction between the base of the pedicle wall and the vertebral body was reached, the Jamshidi needle was directed in a more medial manner. When the Jamshidi needle was positioned in the middle third of the vertebral body, a K-wire was inserted. The working channel instrumentation was inserted over the K-wire and the K-wire was subsequently removed. The distal tip of the working channel was located at least 5 mm beyond the posterior vertebral body wall, as viewed in the lateral fluoroscopic projection. The final position of the cement director is determined relative to the location of the working channel tip.

A cavity was formed in the cancellous bone, projecting anteriorly and medially from the tip of the working channel, using a curved drill and reamer. This cavity creation technique is designed to create a cavity of predictable size and shape. Drilling was performed manually, proceeding along a curved path starting from 1 pedicle, crossing the sagittal midline, and stopping within the contralateral anterior quadrant of the vertebral body (Fig. 1). A curved reamer was inserted fully within the previously drilled path. A pivoting blade was deployed at the distal end of the path and the reamer was counter-rotated along the curved path in a retrograde manner to create a 10-mm diameter cylindrical cavity. Once the length of the cavity was matched to the implant size, the reamer blade was retracted and removed.

The delivery system instrumentation was inserted through the working channel and locked in place. The cement-directing implant was then deployed under fluoroscopic guidance. The cement director is a non–load-bearing, hollow, cylindrical, self-expanding device 10 mm in diameter and 15 or 20 mm long (Fig. 2). It is designed to be impermeable to bone cement except at several openings specifically located on the anterior-superior and anterior-inferior surfaces. The implant was delivered in a collapsed state, and it was subsequently expanded within the prepared, centrally located cavity. At this point, Spineplex bone cement (Stryker Kalamazoo, MI) was mixed and injected into the interior of the implant. The cement was initially contained within the implant and then it was directed through the openings into the anterior, superior, and inferior regions of the vertebral body (Fig. 3). The final cement volume delivered was left to the discretion of the operating surgeon.

**RESULTS**

A total of 37 levels were treated with the CDKS for 20 patients (3 men, 17 women) with an average age of 69.1 (±8.1) years. The mean height of the patient population was 151.6 (±15.2) cm, and the mean population weight was 58.8 (±10.1) kg. In 45% of patients 1 level was treated, 25% were treated at 2 levels, and 30% received surgical treatment at 3 levels. The most frequent levels affected were L1 (19%), L2 (15%), T11 (11%), and T12 (11%). The mean duration of symptoms before surgery was 8.2 weeks (range, 6–11 wk).

The volume of cement injected per level ranged from 2.5 to 6 mL (mean 4.07 ± 0.87 mL). All patients were followed at least 6 weeks postoperatively. No serious adverse events related to the procedure and requiring medical intervention were reported at any follow-up interval. Four patients died before the study was completed from causes unrelated to the procedure (cancer, leukemia, and complications due to mitral valve replacement surgery).

**FIGURE 1.** Drilling and reaming along a curved path. The drill advances from its initial position (lateral view, left), crossing the sagittal midline until the contralateral anterior quadrant is reached (lateral view, middle). A 10-mm diameter cavity is then created by reaming along the same path in the retrograde direction (anterior/posterior view, right). Note: images were taken from a cadaver study to provide clearer imaging of the procedure.

**FIGURE 2.** Cement-directing implant. Cement fills the hollow, impermeable, self-expanding structure, and it subsequently flows evenly into the vertebral body through several holes fabricated at specific locations on the implant wall.
One of these patients provided verbal 24-month pain and RMQ scores, but was unable to return for the final radiographic evaluation. No other patients were lost to follow-up.

Substantial pain relief was achieved immediately after the procedure and pain relief was sustained throughout the 2-year follow-up period (Fig. 4). A significant decrease in mean pain scores was observed at all follow-up intervals, as compared with preoperative pain scores (Table 1). A similar improvement in RMQ disability scores was also reported at all follow-up visits (Fig. 5). A significant reduction in the mean disability scores was observed, as compared with the preoperative RMQ scores (Table 1).

Cement leakage was qualitatively evaluated by the senior investigator and an independent interventional neuroradiologist on the basis of their clinical experience and individual visual inspection criteria. The senior investigator reported 1 cortical cement leak (2.7%), considered moderate in volume, based on intraoperative fluoroscopy and examination of postoperative AP and lateral radiographs. In contrast, the independent reviewer examined only the postoperative radiographic images and identified a total of 9 leaks (24.3%). Five segmental vein leaks (type S) and 4 cortical leaks (type C) were detected, including the same cortical leak noted by the senior investigator (Fig. 6). With the exception of the moderate cortical leak, all leaks were characterized by the independent reviewer as minor or very minor in volume. None of the leaks was symptomatic and no medical intervention was required due to cement leakage.

The disparity in the leakage findings for the senior investigator and the independent reviewer was expected. Identification of cement leaks from radiographs has been previously shown to be variable due to a lack of standardized methods and limitations of imaging techniques, leading to only fair interobserver agreement within a study. The use of lateral and AP radiographs improves leak detection, although Schmidt and colleagues reported that only 48% of leaks were detected as compared with CT images. No posterior leaks through the basivertebral vein or into the spinal canal were detected by either observer in the present study, which may be attributed to a combination of more anteriorly directed cement flow and the limitations associated with identifying these leaks from radiographic views. AP and lateral radiographs have been shown to underestimate the occurrence of posterior type B leaks by an average of 50%, as compared with CT imaging. When they are detected, type B leaks are frequently misidentified.

Vertebral body height was maintained for at least 1 year after the procedure. The mean change in anterior vertebral body height at 12 months was 1.23% (±16.4%), relative to the postoperative height measured in the same anatomic location. At both 12 and 24 months, there was no evidence of movement of any cement director and the cement mantle was observed to be intact and stable for all levels examined. No refractures of any treated vertebral bodies were observed during the study and no new fractures at adjacent levels were reported.

**DISCUSSION**

Directed cement flow kyphoplasty combines the attributes of the vertebroplasty and BKP procedures. This
new treatment for osteoporotic VCFs provides controlled cement flow and extensive cement diffusion within the vertebral body bone, along with the ability to inject higher viscosity bone cement to further reduce the risk of leakage. Higher viscosity cement is predominantly used in BKP, but cement flow is limited to the compacted cavity created by the balloon and its immediate vicinity. In a quantitative study comparing cement interdigitation for cement-directed kyphoplasty and BKP, cement diffusion into the surrounding bone was greater for CDKS as compared with BKP (CDKS = 48.6% ± 20.6%, BKP = 16.7% ± 9.7%).

In some cases, inadequate biomechanical reinforcement is achieved with BKP, and continued collapse of the vertebral body occurs. Cement-directed kyphoplasty involves deployment of a self-expanding implant within a centrally located cavity, with the implant openings oriented toward the anterior of the vertebral body. Cement flows into the cement director, through the openings, and fills the anterior, superior, and inferior uncompacted bone spaces. Posterior cement flow is physically limited by the cement director, potentially reducing the risk of leakage into the basivertebral vein and spinal canal. The final cement distribution within the anterior vertebral body bone, which extends toward the endplate, stabilizes the fracture and maintains vertebral body height long term.

Kyphoplasty has the proposed advantage over vertebroplasty of reducing the risk of cement extravasation. In a systematic review of 69 clinical studies, Hulme et al reported a 9% incidence of cement extravasation overall, with a range of 0%–33.3% reported in the individual studies. In the present study, bone cement leakage was found in 9 of 37 levels treated (24%), as determined by a university professor of radiology who acted as an independent reviewer. None of these leaks were symptomatic and no further treatment was required. In addition to the surgical method for cement augmentation, other factors can affect the rate and clinical significance of cement leakage. In a recent study, Ren et al concluded that clinical factors such as cement viscosity, injected cement volume, and vertebral body wall incompetence were associated with the incidence of cement leakage. These investigators also found that patients with a history of pulmonary diseases were prone to lung-related complications.

Treatment with cement-directed kyphoplasty provides effective long-term pain relief for patients suffering from symptomatic VCFs. The sustained and significant improvement in pain scores (mean change of 6.06 ± 2.36) observed for this new procedure is comparable to previously

| TABLE 1. Change in Mean Pain and RMQ Scores Relative to Preoperative Levels |
|---------------------------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| No. Patients | Postoperative | 6 wk | 3 mo | 6 mo | 12 mo | 24 mo |
| Mean change in pain score (SD) | -5.35 (2.43) | -5.35 (2.58) | -5.16 (3.24) | -5.39 (3.68) | -5.88 (2.39) | -6.06 (2.36) |
| Pain score Wilcoxon signed-rank test† | < 0.0001 | < 0.0001 | < 0.0001 | < 0.0001 | < 0.0001 | < 0.0001 |
| Mean change in RMQ (SD) | NA | -10.2 (5.7) | -9.6 (7.7) | -10.9 (7.5) | -13.2 (3.6) | -13.9 (3.1) |
| RMQ Wilcoxon signed-rank test† | NA | < 0.0001 | 0.0003 | < 0.0001 | < 0.0001 |

*One patient provided verbal outcome scores, but expired before the final radiographs were obtained.
†Two-tailed Wilcoxon signed-rank test with pooled variances to assess whether the change is significantly different from 0.
NA indicates not applicable; RMQ, Roland-Morris Questionnaire.

![FIGURE 5. Mean disability scores by follow-up interval. An immediate decrease in the mean Roland-Morris Questionnaire score was observed postoperatively, and this improvement was sustained long term.](image-url)

![FIGURE 6. Cement leakage rates and classification of leaks by location. The investigator reported 1 cement leak, as compared with 9 leaks identified by the independent reviewer. All leaks were categorized according to location. No posterior leaks through the basivertebral vein were observed. Inset depicting leak locations. Reprinted with permission from Yeom et al.](image-url)
reported clinical outcomes for vertebroplasty and BKP procedures.\textsuperscript{9,12–14} In a meta-analysis report including 7587 vertebroplasty patients, Eck et al\textsuperscript{11} reported significant pain relief after vertebroplasty. The mean preoperative and postoperative visual analog scale (VAS) scores were 8.36 ($\pm$ 0.78) and 2.68 ($\pm$ 1.09), respectively ($P < 0.001$). The mean improvement in the VAS score was 5.68 ($\pm$ 1.24). In their review of the BKP literature, Hulme et al\textsuperscript{4} similarly reported a reduction in VAS pain scores in 183 combined patients from a preoperative mean of 7.15 ($\pm$ 0.55) to a postoperative mean of 3.4 ($\pm$ 0.70).

Timing of intervention for osteoporotic compression fractures may play a role in its ultimate effectiveness.\textsuperscript{20} In the present study, the average time between the onset of symptoms and intervention was 8.2 weeks. Similarly, 101 patients in a recent multicenter randomized trial were randomized in blocks to vertebroplasty or conservative treatment, with an average time from the onset of symptoms to treatment of 5.6 weeks.\textsuperscript{21} The results of this study demonstrated that surgical intervention had a clinical benefit as compared with conservative treatment for acute VCFs.

This is the first clinical study reported in which cement-directed kyphoplasty using a self-expanding implant has been performed for the treatment of painful osteoporotic compression fractures. The long-term clinical outcomes measured in this limited study are promising. Cement-directed kyphoplasty has the potential to reduce the risks associated with vertebral augmentation by providing better control of cement flow, cement mantle location, and a physical barrier to posterior cement flow. Additional prospective randomized studies are needed to compare CDKs with conventional vertebroplasty, BKP, and medical treatment alone.

REFERENCES