CASE REPORT

Dr. B. A. Georgy
Interventional Radiologist
Valley Radiology Consultants
Assistant Professor, UCSD
Dr. M. E. Majd
Orthopedic Surgeon, Spine Surgery
PSC, Louisville, Kentucky

Clinical Experience with CONFIDENCE SPINAL CEMENT SYSTEM™ in Single and Multi-level Cases - Retrospective Review of Four Cases

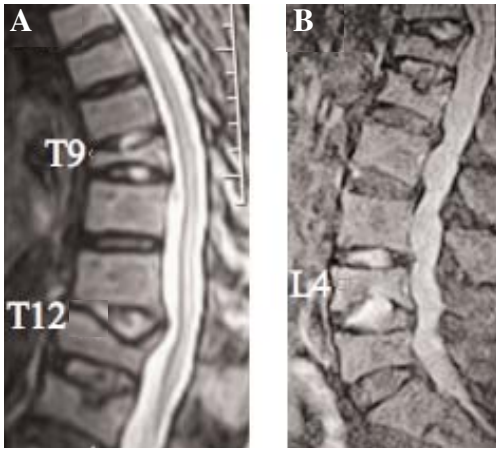

Figure 1: Preoperative T1-weighted MRI showing fresh fractures at T9, T12 and L4. A) Thoracic spine, with view of T9 and T12; B) Lumbar spine with view of L4.

Introduction

Osteoporosis is often defined as the epidemic of aging Western and Asian societies. In the spine, this condition can lead to vertebral body fractures (VBF), often associated with severe pain and disability[1]. An effective treatment to alleviate the pain of VBF consists of injecting polymethylmethacrylate (PMMA) bone cement to reinforce vertebral bodies and reduce fractures[2]. This procedure is percutaneous and minimally invasive.

There are currently two established modalities for vertebral body augmentation: 1) vertebroplasty and 2) kyphoplasty. Both have been shown effective to stabilize vertebral fractures caused by osteoporosis as well as malignancies, hemangiomas and vertebral osteonecroses[3;4]. These two procedures have also demonstrated similar rates of pain and disability relief.

The key difference between both procedures is the use of the inflatable balloon in kyphoplasty. This step is meant to reduce the fracture and create a path of least resistance for the PMMA, with the subsequent goal of restoring vertebral body height and decreasing risks of cement leakage beyond the fracture site[1;5].

To determine whether the balloon effectively achieves these goals, a recent review of 69 studies (>1500 patients) analyzed height restoration and leakage rates between vertebroplasty and kyphoplasty procedures[6]. While restoration of vertebral body height and sagittal alignment was found to be similar for vertebroplasty and kyphoplasty (6.6% angle restoration in both cases), lower leakage rates were observed for kyphoplasty (9%) vs. vertebroplasty (41%).

The CONFIDENCE SPINAL CEMENT SYSTEM™ includes a highly viscous cement capable of intricate interdigitation throughout bony trabeculae. This type of cement was shown in a preclinical study to spread uniformly within the vertebral body, thus reducing the potential for leakage[7]. In addition, a precision delivery system was created for the CONFIDENCE SPINAL CEMENT SYSTEM, to allow controlled delivery of this new cement in fracture sites. In this study, four clinical cases treated with the CONFIDENCE SPINAL CEMENT SYSTEM are presented and discussed.

Methods

Case #1

This 84 year-old female suffering from osteoporosis was admitted at the hospital due to severe back pain. X-ray imaging and MRI were performed, revealing acute fractures at T9, T12 and L4. Preoperative MRI are shown in Figure 1 left.

The procedure was performed under conscious sedation.

The patient was placed in the prone position. The T9, T12 and L4 levels were identified under fluoroscopy. A bipedicular approach was used for T9 and T12, while L4 was treated

Continued

using a unipedicular approach. An intra-operative photograph and fluoroscopic view are shown in Figure 2(A and B) below.

The cement was then injected. Approximately 3cc of cement was injected at T9 and L4, and 4cc at T12. The cement created a spherical fill pattern as seen in Figure 3 below. Interdigitation of the cement was clearly observed with the surrounding bony trabeculae. No extravasation of the cement was seen.

The patient tolerated the procedure well with no complications.

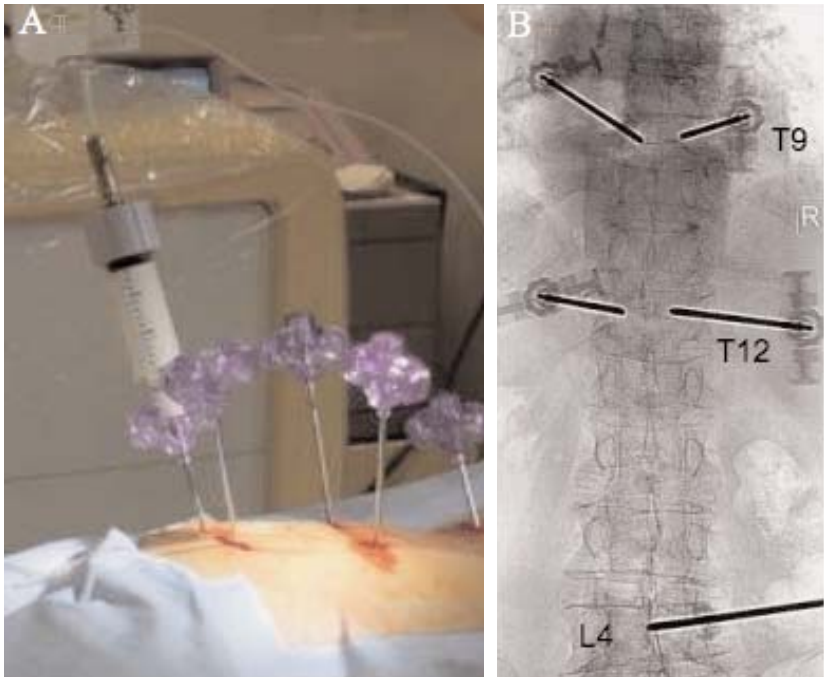

Figure 2: Intraoperative views: A) photograph, showing the bipedicular approach for the thoracic levels (T9 and T12), and the unipedicular approach at L4; B) fluoroscopic view of the needles inside the vertebral bodies, prior to injection of the cement.

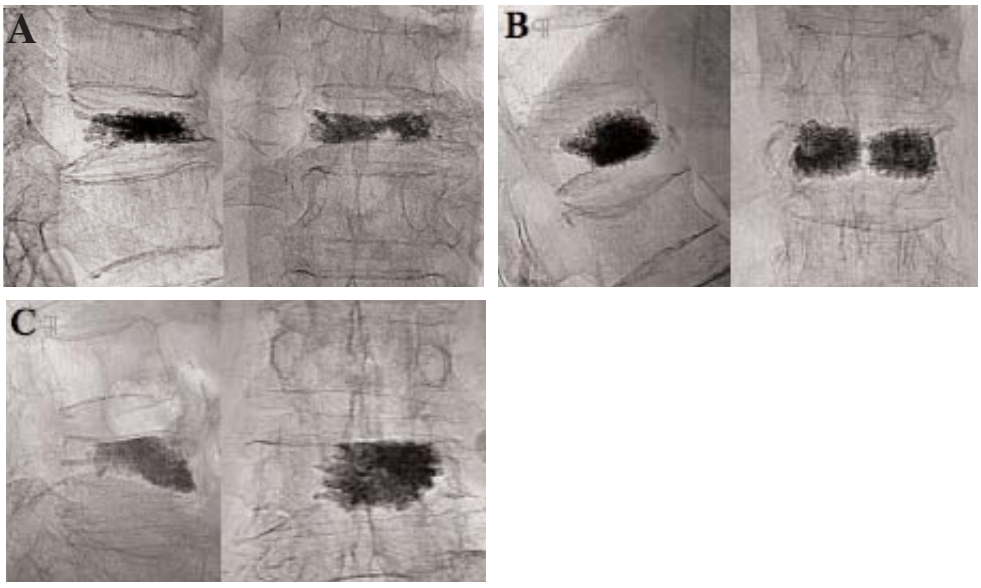

Figure 3: A/P and lateral views of the cement fill pattern after injection in the vertebral bodies; A) T9 after injection of 3cc; B) T12 after injection of 4cc and C) L4 after injection of 3cc.

Case #2

This 68 year-old male suffered from severe back pain since 3 months. The patient failed conservative treatment with high doses of analgesics. MRI was therefore performed and revealed the presence of a fracture at L1 with bone marrow edema. The T-1 and T-2 weighted MRI images are shown in Figure 4 right.

The same analgesics and surgical procedure were used for this patient as for Case # 1. The patient was placed in the prone position. The L1 level was identified under fluoroscopy. With the patient under conscious sedation, a bipedicular approach was used to access the vertebral body, using 13-gauge needles.

Approximately 5cc of cement was then introduced in the vertebral body. As in Case #1, interdigitation of the cement throughout the bony vertebrae was observed (Figure 5 below).

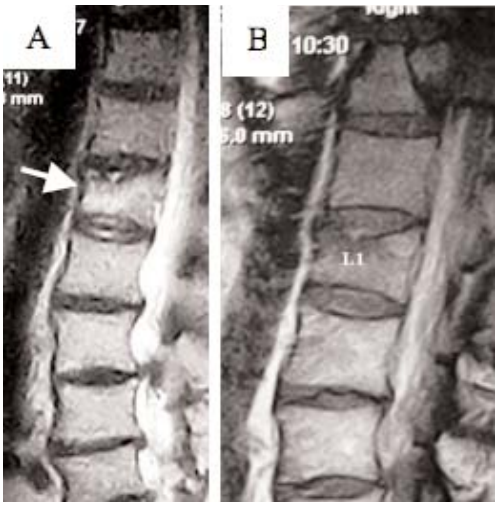

Figure 4: T-2 (A) and T-1 (B) weighted MRI, confirming a fracture with edema at the L1 level (arrow).

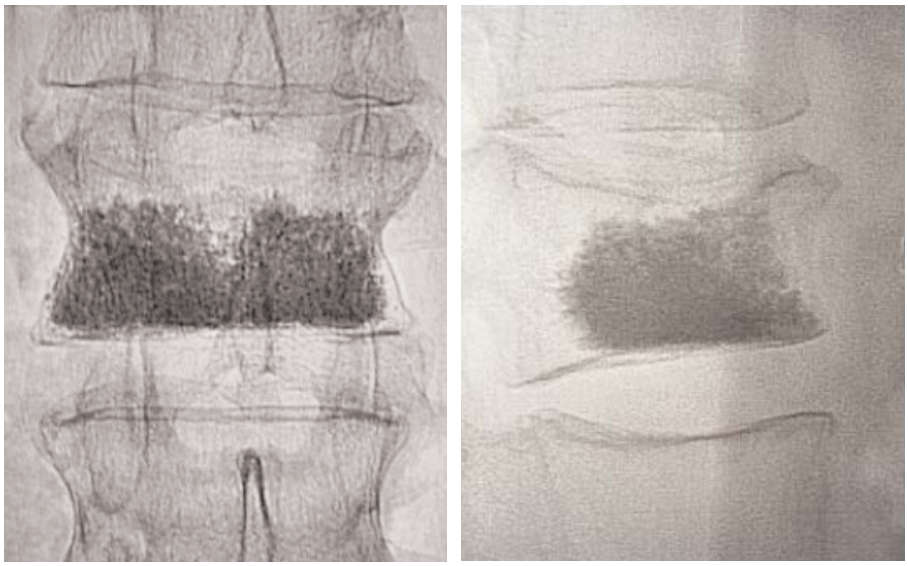

Figure 5: Lateral and A/P view of the L1 level after filling with the high-viscosity cement. No extravasation of the cement was observed.

Case #3

This 89 year-old female presented with difficulty walking and had a prior medical history of osteoporosis, lumbar and thoracic degenerative disc disease and hypertension, along with gastroesophageal reflux, bilateral hearing loss, right eye vision loss and Alzheimer's.

Preoperative radiographs and MRI revealed a compression fracture of T7 and inferior end plate fracture at the adjacent T6 level.

The procedure was performed under general anesthesia and the patient was placed in prone position. After routine prep, the skin and subcutaneous tissue were infiltrated with 0.5% marcaine and epinephrine. A 13-gauge needle was inserted into the medial wall of the T7 pedicle via extrapedicular approach. A similar procedure was performed through the left at the T6 level. Figure 6 right shows the intraoperative fluoroscopic views following insertion of the needles.

Approximately 5cc cement were then injected at T7 and 7cc at T6. The needles were removed and 0.5% epinephrine was injected at the level of the needles.

Intra-operative fluoroscopic views of the cement-filled vertebral body showed interdigitation of the cement with the bone vertebrae. No extravasation of the cement was observed, as seen in Figure 7 right.

The patient tolerated the procedure very well.

Continued

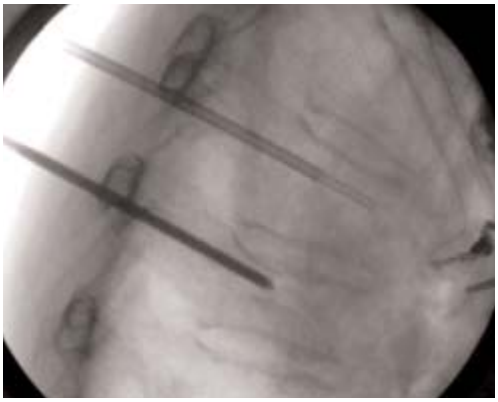

Figure 6: Intraoperative view after insertion of the needles at T6 and T7.

Figure 7: Cement fill of the T6 and T7 vertebral bodies, as seen in A/P and lateral views.

Case #4

This 85 year-old female had previously suffered from a compression fracture at L1 which had been treated by kyphoplasty. She had chronic degenerative disc disease at L3-L4. Her past medical history included diverticulosis, osteoarthritis, hip fracture, compression fracture, hyperlipiderma, coronary artery disease, cholecystectomy, cystoscopy, right wrist ganglionectomy and a tonsillectomy.

Her radiographic assessments indicated a fresh fracture at T11. She was treated under general endotracheal anesthesia. She was positioned in the prone position over two well padded rolls, her skin and subcutaneous tissues were infiltrated with 0.5% marcaine and epinephrine. A needle was inserted in the T11 vertebral body. The position was verified with AP and lateral fluoroscopy. The needle was then advanced towards the posterior wall of the vertebral body. The procedure was repeated on the other side, for a bipedicular approach. On the back table, the cement was prepared and when the viscosity was similar to a piece of clay, it was injected through both pedicles. Approximately 10cc of cement were injected into the fracture site. No leakage or extravasation was observed. Approximately 6mm of height restoration were obtained, from a 16 to 22mm vertebral body height. The patient tolerated the procedure well and with the needle taken out, was transferred to the recovery room.

Discussion

Vertebral body augmentation with the CONFIDENCE SPINAL CEMENT SYSTEM provides a treatment for patients with painful VBF. Patients with VBF due to osteoporosis cannot afford lengthy periods of bed rest, as inactivity may worsen their already altered bone quality and quality of life further deteriorates.

A recent position statement from the American Society of Interventional and Therapeutic Neuroradiology further discussed the issue of vertebral body augmentation vs. conservative care[8]. In this paper, the clinical consequences of conservative care, especially bed rest and inactivity, were evaluated. Authors concluded that vertebral body augmentation had "been shown to be more effective than continued medical treatment" and that "more of the same increases the chance of an adverse outcome associated with low mobility".

The four patients herein experienced immediate and significant pain relief. In addition, controlled placement and clear interdigitation of the cement throughout the vertebral body was observed in all four cases.

The CONFIDENCE SPINAL CEMENT SYSTEM differs from other modalities such as kyphoplasty, as it can be used either with a unipedicular or bipedicular approach, thus potentially reducing treatment time. This feature is particularly important in cases with compromised pedicles and/or other morphological conditions that may limit access to the vertebral body.

No extravasation was observed with cement. This observation is consistent with a previously-published pre-clinical bench study indicating that high-viscosity cements, such as that used in this system, fill cavities in a uniform manner and have lower risks of leakage than less viscous cements[7].

Conclusion

No extravasation of the cement was observed. In addition, interdigitation of the cement throughout the bony vertebrae was seen, and controlled delivery of the cement at the fracture site was also achieved.

Reference List

1. Heini PF et al. Kyphoplasty for treatment of osteoporotic vertebral fractures.[see comment]. [Review] [41 refs]. European Spine Journal 2004;13:184-92.
2. Heini PF. The current treatment–a survey of osteoporotic fracture treatment. Osteoporotic spine fractures: the spine surgeon's perspective. [Review] [48 refs]. Osteoporosis International 2005;16:Suppl-92.
3. Lieberman I, Reinhardt MK. Vertebroplasty and kyphoplasty for osteolytic vertebral collapse. [Review] [35 refs]. Clinical Orthopaedics & Related Research 2003;Suppl-86.
4. McGraw JK, Lippert JA, Minkus KD et al. Prospective evaluation of pain relief in 100 patients undergoing percutaneous vertebroplasty: results and follow-up. J Vasc.Interv.Radiol. 2002;13:883-6.
5. Coumans JV, Reinhardt MK, Lieberman IH. Kyphoplasty for vertebral compression fractures: 1-year clinical outcomes from a prospective study. J Neurosurg 2003;99:44-50.
6. Hulme PA, Krebs J, Ferguson SJ et al. Vertebroplasty and kyphoplasty: a systematic review of 69 clinical studies. [Review] [138 refs]. Spine 2006;31:1983-2001.
7. Baroud G, Crookshank M, Bohner M. High-viscosity cement significantly enhances uniformity of cement filling in vertebroplasty: an experimental model and study on cement leakage. Spine 2006;31:2562-8.
8. Jensen ME, McGraw JK, Cardella JF et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the american society of interventional and therapeutic neuroradiology, society of interventional radiology, american association of neurological surgeons/congress of neurological surgeons, and american society of spine radiology. J Vasc.Interv.Radiol. 2007;18:325-30.

Indications
The CONFIDENCE SPINAL CEMENT SYSTEM™ is intended for percutaneous delivery of CONFIDENCE Spinal Cements, which are indicated for fixation of pathological fractures of the vertebral body during vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancer, myeloma).

Contraindications
The use of CONFIDENCE High Viscosity Spinal Cement is contraindicated in patients presenting with any of the following conditions:

- Use of CONFIDENCE High Viscosity Spinal Cement for prophylaxis (such as in metastatic or osteoporotic patients with no evidence of acute vertebral fracture)
- Coagulation disorders, or severe cardiopulmonary disease.
- Haemorrhagic diasthesis.
- Non-pathological, acute, traumatic fractures of the vertebra.
- Patient clearly improving on medical therapy.
- Spinal stenosis (> 20% by retropulsed fragments).
- Compromise of the vertebral body or walls of the pedicles.
- Compromise or instability of vertebral fractures due to posterior involvement.
- Anatomical damage of the vertebra that prevents safe access of the needle to the vertebral body.
- Vertebral body collapse to less than 1/3 (33%) original height.
- Vertebral plana (collapse >90%)
- Active or incompletely treated infection.
- Coagulopathy or inability to reverse anti-coagulant therapy (both during and approximately 24 hours post-procedure).
- Severe pulmonary insufficiency.
- Allergic reaction to any of the components of the CONFIDENCE High Viscosity Spinal Cement.

DePuy Spine is a joint venture with Biedermann Motech GmbH.

DePuySpine™
a Johnson&Johnson company

PIONEERING WHAT MATTERS