CASE REPORT

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Clinical Experience with CONFIDENCE SPINAL CEMENT SYSTEM™ Single-level Case Report

Figure 1: Preoperative T2-weighted sagittal MRI showed evidence of bone marrow edema indicative of acute fracture at the L1 level (arrow).

Figure 2: Preoperative T1-weighted sagittal MRI confirming the L1 fracture observed in Figure 1.

This is the case of a 68 year-old male suffering from severe back pain since 3 months. The patient failed conservative treatment with high doses of analgesics. MRI was performed as shown in Figure 1 below. This T2-weighted image clearly revealed evidence of acute fracture with bone marrow edema at the L1 level.

The T1-weighted MRI image further confirmed the diagnostic of an acute fracture with edema, at the L1 level (Figure 2). Three treatment modalities can be considered for this type of fracture:

1. Conservative (non-surgical) care.

2. Surgical intervention with internal fixation device.

3. Percutaneous minimally invasive vertebral body augmentation.

1. Conservative Care: Impact on bone loss and quality of life

Conservative measures can be recommended for the first few weeks' post-injury, to allow for the natural healing of the vertebral body. In this case, however, the patient reportedly experienced pain for 3 months, and still showed signs of acute fracture with edema. Thus, healing had not occurred over this time frame.

Conservative care typically includes a combination of analgesics, bed rest and back braces.

Effective analgesics for this type of patient would most likely include a narcotic, which, when used long-term, may impact the patient's already deteriorated quality of life, as recently described[1].

Bed rest, while appropriate for a limited time span post-injury, can result in multiple physical and psychological side effects. Examples of significant clinical side-effects associated with bed rest are deep vein thrombosis (DVT) and pneumonia, both severe conditions for elderly patients. In cases of elderly patients, as seen herein, osteoporosis may be the cause of the initial fracture, and bed rest accelerates bone loss, which could have severe consequences on the other, still intact, spinal levels.

Back bracing may again be effective immediately post-injury, to help treat an acute fracture. In the case of a 3-month old fracture with edema, bracing may not be as effective. Bracing also affects quality of life and as such has low rates of compliance, as it is uncomfortable for the patient, potentially restricts proper breathing and is therefore poorly tolerated, especially by older patients.

2. Surgical Intervention with Internal Fixation Devices: High risk of post-op complications in compromised patients

Typical cases requiring surgical intervention with internal fixation are either showing signs of compromised spinal elements (i.e.; stenosis), misalignment of vertebral bodies (spondylolisthesis) and/or cases of intractable back pain unresponsive to conservative care, as observed in cases of advanced degenerative disc disease (DDD). In addition, young patients with vertebral fractures might be treated via corpectomy.

The operative trauma, however, can be avoided in older patients with vertebral fractures. These patients are often osteoporotic, and as such, may not have the appropriate bone stock for internal fixation devices. Their tolerance for operative trauma may be limited and thus result in a high rate of post-operative adverse events. In addition, these elderly

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Figure 3: Hydraulically-actuated delivery system for accurate and controlled delivery of high-viscosity cement in the vertebral body. The delivery system is provided sterile and ready to use.

Figure 4: The long built-in delivery tube allows physicians to remain out of the fluoroscopy field during the entire procedure.

patients may develop a so-called "dowager's hump" deformity following surgery with internal fixation.

Older patients with vertebral compression fractures, as seen in this case, do not show evidence of compromised spinal elements and are experiencing pain specifically because of the bone-on-bone motion within the fractured vertebral body. In these cases, the pain can be significantly alleviated by simply eliminating all motion at the fractured site. This can be accomplished by using vertebral body augmentation, a percutaneous minimally invasive procedure.

3. Vertebral Body Augmentation: A minimally invasive procedure for pain relief

Vertebral body augmentation, especially with high viscosity cements such as those provided by the CONFIDENCE SPINAL CEMENT SYSTEM™, represent a surgical option for treating older patients with vertebral body fractures.

Candidates for this procedure are patients that do not heal within 4-6 weeks post-injury and suffer significant pain, unresponsive to conservative care.

A recent study also showed that patients with extensive bone marrow edema (>50% of the entire vertebrae), observed on the preoperative MRIs (as seen in Figures 1 and 2), were particularly responsive to the injection of a vertebral body cement that would immobilize the fracture site[2].

Multiple types of cements are available for this type of procedure. A recent in vitro preclinical study has shown that high viscosity cements result in more uniform filling of the vertebral body with lower rates of leakage, as compared to low viscosity cements[3].

Methods
CONFIDENCE SPINAL CEMENT SYSTEM

The CONFIDENCE SPINAL CEMENT SYSTEM is a novel vertebral body augmentation system, designed to provide controlled delivery of a highly viscous cement with an extended working time.

The cement in the CONFIDENCE SPINAL CEMENT SYSTEM is dispensed into the vertebral body using a hydraulically actuated delivery system (Figure 3) that allows accurate placement of the cement in the fractured area. The delivery system also includes a long delivery tube to protect the surgeon or radiologist from exposure to fluoroscopy (Figure 4).

The cement adopts a dough-like consistency immediately after mixing, and does not require any wait time prior to implantation. This cement has an 9.5-minute working time and is radio-opaque (30.07% w/w BaSO4) for fluoroscopic monitoring.

Systems are available with 11-, 13- and 15-gauge diamond and 11- and 13-gauge beveled tip needles, as well as a new side hole needle design that provides a smooth and controlled delivery of the cement into the vertebral body.

Surgical Technique

Conscious sedation was given to the patient. The patient's heart rate, blood pressure and PO-2 were measured with electronic monitors throughout the procedure. The patient's level of consciousness was also monitored by the Special Procedures registered nurse.

The procedure was performed under strict antiseptic conditions and under intravenous coverage of antibiotic.

The patient was placed in the prone position. The L1 level was identified under fluoroscopy. The skin was then prepped and draped using standard antiseptic techniques. The periosteum was anesthetized using 1% lidocaine. A bipedicular

approach was used to access the vertebral body, using 13-gauge needles (Figures 5 & 6 below).

The cement in the CONFIDENCE SPINAL CEMENT SYSTEM was then injected. Approximately 5cc of cement was introduced in the vertebral body, filling the fracture area with controlled precision. The cement created a spherical fill pattern as seen in Figures 7 and 8 below. Interdigitation of the cement was clearly observed with the surrounding bony trabeculae.

The patient tolerated the procedure well with no complications. Successful internal fixation of the L1 level using the bipedicular approach with the high-viscosity cement in the CONFIDENCE SPINAL CEMENT SYSTEM was achieved.

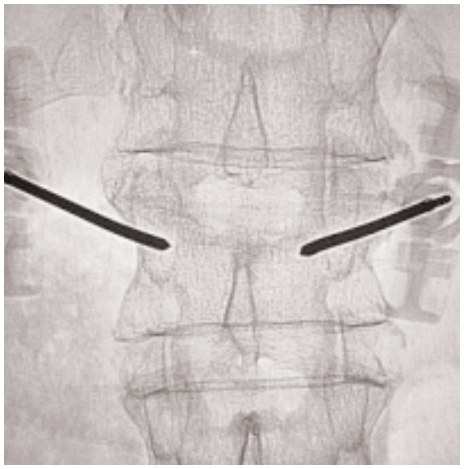

Figure 5: Bipedicular approach. The shadows above the needles are the outlines of the cement delivery system.

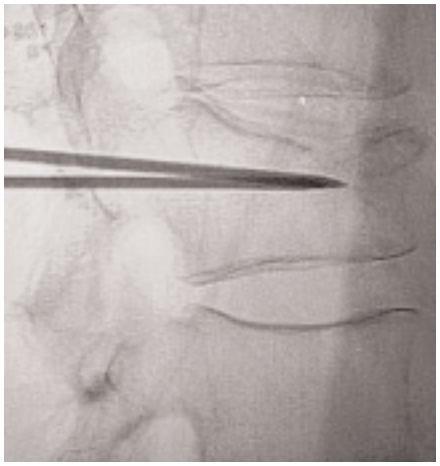

Figure 6: A lateral view confirms the correct location of both needles through the pedicles.

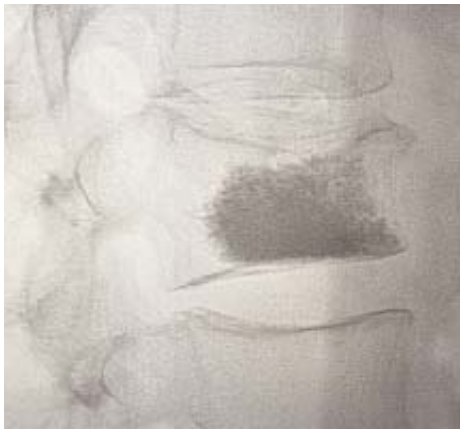

Figure 7: Lateral view of the L1 level after filling with the high-viscosity cement. No extravasion of the cement was observed.

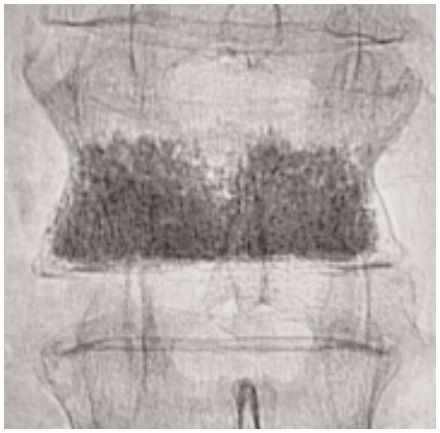

Figure 8: A/P view confirming fill of the vertebral body, with no cement extravasion.

Reference List

1. 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.
2. Mehbod A, Aunoble S, Le Huec JC. Vertebroplasty for osteoporotic spine fracture: prevention and treatment. European Spine Journal 2003;12:Suppl-62.
3. Tanigawa N, Komemushi A, Kariya S, Kojima H, Shomura Y, Ikeda K et al. Percutaneous vertebroplasty: relationship between vertebral body bone marrow edema pattern on MR images and initial clinical response. Radiology 2006;239: 195-200.

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.

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