

Treatment of Vertebral Compression Fractures

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Abstract

Vertebral compression fractures are burdensome to patients because of associated pain, decreased quality of life, and an increased mortality risk. Treatment options include conservative, non-operative care or vertebral body augmentation (VBA). Two types of VBA procedure exist: vertebroplasty and kyphoplasty. They involve the injection of polymethylmethacrylate bone cement into fractured vertebrae to stabilize the fracture fragments and thereby reduce the incidence of fracture progression and pain severity. While both VBA procedures are associated with high patient-satisfaction rates, cement leakage has been a major problem with classic vertebroplasties. Therefore, the Confidence Spinal Cement System™ (DePuy Spine Inc., US) has been developed to address the need for a system that can deliver high-viscosity cement with accuracy, precision, and control. In this way, the safety and efficacy of the vertebroplasty technique is enhanced.

Keywords

Osteoporosis, vertebral compression fracture, vertebral body augmentation, vertebroplasty, kyphoplasty, Confidence Spinal Cement System™

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Vertebral compression fractures (VCF) are associated with significant pain, loss of mobility and height, decreased quality of life, and an increased risk for mortality (see *Figure 1*).¹⁻³ There are an estimated 700,000 cases of VCF in the US every year,⁴ resulting mainly from osteoporosis and benign and malignant lesions. Treatment options include conservative or surgical care. The majority of fractures heal naturally, and therefore the initial treatment of VCF includes bed-rest, back-bracing, and analgesic medications. If conservative therapy is ineffective or intolerable, vertebral body augmentation (VBA) is considered. Vertebroplasty and kyphoplasty, two types of VBA surgery, are minimally invasive percutaneous procedures during which polymethylmethacrylate (PMMA) bone cement is injected into the fractured vertebral body to stabilize it, reducing the severity of pain and the risk for fracture progression (see *Figure 2*).⁵ A recent position statement from the American Society of Interventional and Therapeutic Neuroradiology (ASITN) indicates that early surgical intervention achieves rapid pain relief and patient mobilization. Such a strategy prevents long-term complications and offers improved patient quality of life.⁶ This article will discuss surgical techniques, treatment outcomes of VBA, and a new bone cement and cement delivery system that optimizes treatment and reduces complication risks.

Vertebral Body Augmentation— Surgical Approaches

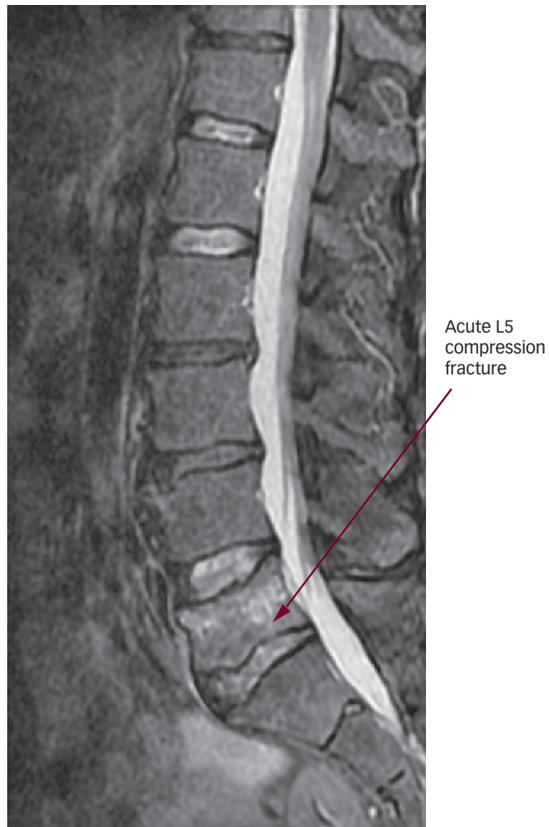
During VBA, percutaneous injection of bone cement into the fractured vertebrae usually occurs with patients under local anesthesia and

moderate sedation. The bone cement is prepared prior to cement injection by mixing a powder (polymethylmethacrylate [PMMA], X-ray contrast agent [e.g. barium sulfate]), and liquid methylmethacrylate monomer (MMA) to form a fluid mixture that solidifies over time. The 'working time' is described as the duration of time during which the surgeon can inject the cement of appropriate viscosity into the vertebral body. A higher-viscosity cement improves vertebral body filling and distribution and reduces the risk for bone cement leakage. Bone cement leakage into extra-osseous spaces can result in serious complications, such as spinal cord and nerve root compression,⁷⁻¹⁰ pulmonary embolism,^{11,12} and, possibly, death.¹³ Once the cement hardens, it provides mechanical reinforcement and stability to the weakened vertebrae.¹⁴⁻¹⁷

During the vertebroplasty procedure, a needle is percutaneously placed under fluoroscopic visualization into the cancellous bone of the affected vertebral body segment.¹⁸ Traditionally, a manually operated syringe was used to inject the standard low-viscosity PMMA bone cement because a delivery system was not available to generate the sufficiently high pressures required to infuse viscous, safer, bone cement.¹⁹

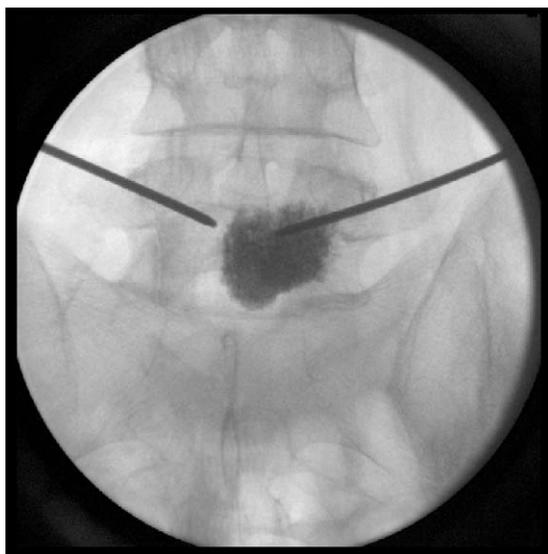
During a kyphoplasty,²⁰ a working cannula is inserted into the vertebral body, followed by a drill used to create a path for the inflatable balloon tamp. Once the balloon is introduced into the

Figure 1: Vertebral Column with L5 Compression Fracture



Magnetic resonance imaging (MRI) scan showing a pre-operative image of the vertebral column of a 45-year-old male with L5 compression fracture.

Figure 2: Injection of Bone Cement into Fractured Vertebrae



X-ray depicting a vertebral body augmentation procedure in progress. The patient was a 45-year-old male with L5 compression fracture. An X-ray image showing a vertebral body augmentation procedure in progress, with the needle being used to inject the bone cement (gray/black) into the fractured vertebral body.

vertebra, it is inflated to compress the cancellous bone, thereby creating a void in the fractured vertebra. The void is then filled with high-viscosity bone cement, KyphX® HV-R™ (Medtronic, US), under manual low pressure, reducing the risk for cement extravasation.^{21,22} Furthermore, the void created by the balloon is also intended to restore vertebral body height.

Treatment Outcomes with Vertebral Body Augmentation

The aim of VBA is to stabilize the fracture fragments in order to reduce pain and possibly restore vertebral body height to correct the kyphotic deformity. Patient satisfaction depends on the extent of pain reduction. Patients can be happy with the degree of pain reduction achieved

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without necessarily becoming pain-free. The clinical relevance of height restoration has not been evaluated adequately and so it is difficult to predict how much height restoration affects satisfaction. Both vertebroplasty and kyphoplasty have been shown to be effective in stabilizing vertebral fractures caused by osteoporosis, as well as malignancies, hemangiomas, and vertebral osteonecrosis,^{23,24} with patient satisfaction rates of up to 90% reported with both techniques. Significant reductions in pain and improvement in function have been reported for both techniques.^{18,20,25-38}

A meta-analysis that analyzed 69 studies (>1,500 patients) noted restoration of vertebral body height and sagittal alignment to be similar for both techniques (6.6% angle restoration in both cases).³⁹ Other studies have reported a better rate of height restoration with kyphoplasty than vertebroplasty.^{40,41} The meta-analysis also noted significantly lower leakage rates for kyphoplasty (9%) versus traditional vertebroplasty (41%), which is consistent with the use of an inflatable balloon and high-viscosity bone cement with the kyphoplasty technique. Cement leakage is a major problem with traditional vertebroplasty, with leakage reported in 20–73% of vertebroplasty procedures.^{9,18,42-44} Based on the available data,^{32,35,45-49} the ASITN and other US medical societies have concluded that the positive clinical response rate in individuals treated with kyphoplasty or vertebroplasty is equivalent and that there is no proven advantage of kyphoplasty over vertebroplasty in terms of pain relief or vertebral body height restoration.⁶

Strategies to Reduce Extravasation of Bone Cement

Bone cement leakage is a major concern with vertebroplasty procedures. Vertebral venography and gel-foam embolization have previously been utilized to reduce this problem,⁵⁰⁻⁵² but are found to be

relatively ineffective and cumbersome. High-viscosity cements have been shown in a pre-clinical experimental model to stabilize cement flow, enable uniform filling of the vertebral body, and reduce or completely prevent bone cement leakage.¹⁹ Bone cements have different working times and viscosities. A newer cement, the Confidence High-Viscosity Bone Cement™ (DePuy Spine Inc., US), has the most consistent working time and greatest viscosity of the available cements. The 10–12-minute extended working time allows the surgeon sufficient freedom to complete the procedure effectively. The high viscosity allows a predictable, uniform, and slow fill of the vertebral body, making it less likely for the cement to extravasate. This slow flow also encourages interdigitation into the vertebral bodies, thereby improving cement filling. The unique Confidence Spinal Cement System™ (DePuy Spine Inc.) enables the generation of high enough pressures to force the cement into the vertebral body in an accurate, precise, and controlled manner, thus reducing the leakage risk and improving the cement fill quality.

The Confidence Spinal Cement System

The Confidence Spinal Cement System is used to perform a vertebroplasty of a VCF. The kit includes the Confidence High-Viscosity Bone Cement, cement mixing and transfer tools, and the Confidence Bone Cement Delivery System (see *Figure 3*). The mixing and transfer tools allow the cement to be rapidly prepared and readily transferred into a reservoir within the cement delivery system. The cement reaches a uniform and highly viscous consistency after two minutes of mixing and remains at this consistency for about 10–12 minutes. This extended working time with a uniform cement is unique.

The delivery system (see *Figure 3*) is adapted to deliver the viscous Confidence Bone Cement. A saline-filled injector is triggered by manually rotating a handle. The injector is connected through a long tube to a piston that is, in turn, attached to a bone-cement-containing reservoir. The injector hydraulically activates the piston, resulting in a controlled flow of the cement into the needle and subsequently into the fractured vertebral body. Bevelled needles can also improve the

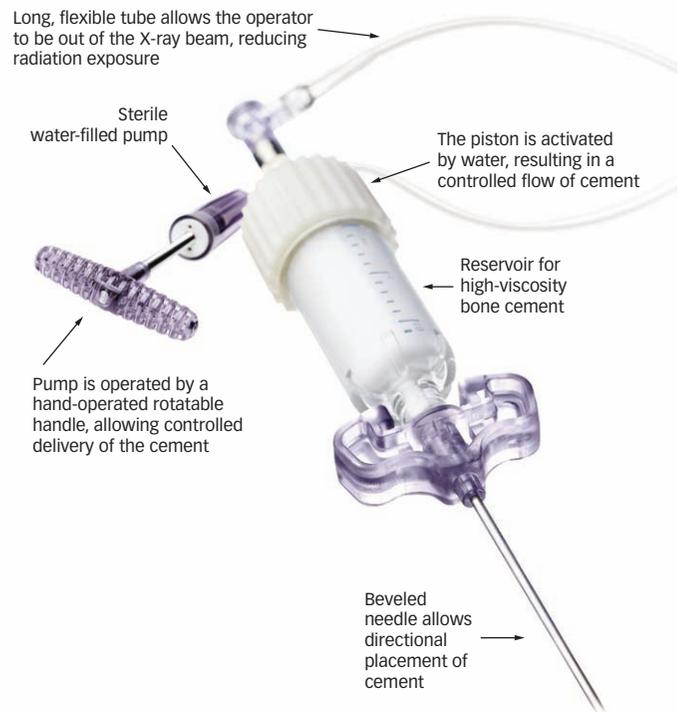
It is the ease of use and the significantly reduced cost of the Confidence vertebroplasty system that may make it a preferable procedure.

accuracy and precision of the fill because the cement stream can be directionally delivered to the right location within the vertebral body. This system enables carefully controlled delivery of cement flow with almost instantaneous start/stop capabilities.

Treatment Outcomes with the Confidence Spinal Cement System

Data from early clinical trials of the Confidence Spinal Cement System for the treatment of VCF are now available. One study assessed the

Figure 3: Confidence Cement Delivery System™



The Confidence Cement Delivery System™ (DePuy Spine Inc., US) is used to inject high-viscosity Confidence Bone Cement™ into the vertebral bone using a hydraulic-based delivery system. It has several features that allow accurate, precise, and controlled delivery of the cement into the fractured vertebral bone. Adapted from Anselmetti et al.²³ and Georgy.²⁵

incidence reduction of venous leakage in vertebroplasty cases using this novel approach.⁵³ The study cohort included 60 patients (52 female, mean age 72.2±7.2 years) with compression fractures due to osteoporosis, malignancy, or angiomas. The patients were randomized to a vertebroplasty with either Confidence Bone Cement or standard low-viscosity PMMA. Bone cement extravasation and radiological complications were detected using post-procedural computed tomography (CT) scans. In the Confidence High-Viscosity Cement group, eight of the 98 (8.2%) treated levels experienced asymptomatic leaks in the venous structures, while six of the 98 (6.1%) treated vertebral segments demonstrated leaks into the disc spaces. By contrast, low-viscosity treated vertebrae demonstrated venous leakage in 38 of 92 segments (41.3%) and discoidal leaks in 12 of 92 segments (13%). Therefore, it was evident that there was a significant reduction in asymptomatic venous extravasation in the high-viscosity group compared with the low-viscosity group ($p < 0.0001$), but no significant difference in discoidal leakage ($p = 0.14$). The authors concluded that it is safe to administer high-viscosity PMMA from the Confidence System because it offers a significant reduction in bone cement leakage compared with the standard low-viscosity cement.

Another study compared the incidence and pattern of cement leakage with the vertebroplasty technique using the Confidence System to the kyphoplasty procedure using the high-viscosity KyphX® cement.⁵⁴ Post-operative radiographs were used to retrospectively analyze the extent and incidence of cement leakage in the group of

65 patients. Forty-seven vertebral segments were treated with kyphoplasty and 58 levels with Confidence from T5 to L5, with an average vertebral body collapse of 26% in the Confidence group and 25% in the kyphoplasty group. There was no or minimal/mild extravasation in 91% of the Confidence-treated segments and 85% of the kyphoplasty-treated segments. While severe leakage was found in the disc space in some cases, no significant leakage requiring any surgical intervention was observed. Therefore, it appears that the extravasation rates for a vertebroplasty using the Confidence System and those seen after kyphoplasty are similar.

Future Investigation

As the Confidence System appears to improve the safety of the standard vertebroplasty by reducing extravasation rates, it may be informative to study whether the Confidence Bone Cement can enhance the safety and efficacy of kyphoplasty by further reducing bone cement leakage. There is also a need to investigate the effectiveness of the Confidence bone cement system on the restoration of vertebral body height and the correction of kyphotic deformities. Potential harmful effects of the viscous Confidence Cement System need to be analyzed further. Does the highly viscous cement penetrate the cancellous bone by breaking the existing trabecular structure and, if so, does this increase the risk for bone marrow emboli or negatively alter the structural integrity of the treated vertebral body segment? However, such adverse events have not been increasingly reported and so the system appears to be safe to use.

Summary and Future Treatment Strategies

Treatment options for VCF include conservative, non-operative modalities or surgical intervention with VBA. VBA is utilized when

patients do not respond favorably to the conservative approach, but there is a definite trend toward earlier surgical intervention because of such positive outcomes. Bone cement is injected into the fractured vertebral body during vertebroplasty and kyphoplasty procedures. This stabilizes the fracture fragments, reduces the pain severity, improves patient satisfaction, and sometimes restores vertebral body height. Nonetheless, extravasation of cement into extra-osseous spaces can cause complications when a low-viscosity bone cement is used. Therefore, the novel Confidence Spinal Cement System, comprising a high-viscosity, long-working-time bone cement, cement mixing and transfer tools, and cement delivery system, has been developed. This new vertebroplasty apparatus enables a viscous cement to be infused into a fractured vertebral body accurately. This improves the overall quality of the vertebral body fill while reducing the risk for cement leakage and possible resultant complications. A vertebroplasty with the Confidence System has been shown to result in a similar cement leakage rate compared with kyphoplasty. Although a Confidence vertebroplasty and kyphoplasty have similar safety and efficacy profiles, it is the ease of use and the significantly reduced cost of the Confidence vertebroplasty system that may make it a preferable procedure. ■



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