Does Balloon Kyphoplasty Deliver More Cement Safely into Osteoporotic Vertebrae with Compression Fractures Compared with Vertebroplasty? A Study in Vertebral Analogues

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Abstract

Study Design A biomechanical and radiographic study using vertebral analogues.

Objectives Kyphoplasty and vertebroplasty are widely used techniques to alleviate pain in fractures secondary to osteoporosis. However, cement leakage toward vital structures like the spinal cord can be a major source of morbidity and even mortality. We define safe cement injection as the volume of the cement injected into a vertebra before the cement leakage occurs. Our objective is to compare the amount of cement that can be safely injected into an osteoporotic vertebra with simulated compression fracture using either vertebroplasty or balloon kyphoplasty techniques.

Methods Forty artificial vertebral analogues made of polyurethane with osteoporotic cancellous matrix representing the L3 vertebrae were used for this study and were divided into four groups of 10 vertebrae each. The four groups tested were: low-viscosity cement injected using vertebroplasty, high-viscosity cement injected using vertebroplasty, low-viscosity cement injected using balloon kyphoplasty, and high-viscosity cement injected using balloon kyphoplasty. The procedures were performed under fluoroscopic guidance. The injection was stopped when the cement started protruding from the created vascular channel in the osteoporotic vertebral fracture model. The main outcome measured was the volume of the cement injected safely into a vertebra before leakage through the posterior vascular channel.

Results The highest volume of the cement injected was in the vertebroplasty group using high-viscosity cement, which was almost twice the injected volume in the other three groups. One-way analysis of variance comparing the four groups showed a statistically significant difference ($p < 0.005$).

Keywords
- kyphoplasty
- vertebroplasty
- cement leakage
- compression fracture
- safety

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Conclusions High-viscosity cement injected using vertebroplasty delivers more cement volume before cement leakage and fills the vertebral body more uniformly when compared with balloon kyphoplasty in osteoporotic vertebrae with compression fractures.

Introduction

Vertebral compression fractures occur in up to 20% of patients over the age of 50, mostly due to osteoporosis.[1] Up to 1.4 million patients suffer from these compression fractures worldwide every year.[2] The most common cause of vertebral compression fractures is osteoporosis followed by trauma, tumor, and infection.[3] These fractures can cause marked acute pain and subsequent long-standing convalescence that can affect pulmonary function and diminish activities of daily living. Kyphoplasty and vertebroplasty are common procedures done for pain relief in these fractures due to either osteoporosis or cancer.[1,2,4–21] Nevertheless, cement leakage during these techniques can lead to major catastrophic morbidity or even life-threatening complications.[22] The literature shows an incidence of cement leakage up to 72% during vertebrae injection, when evaluated by postoperative computed tomography (CT) scan.[10,23] The most common directions of leakage are into the (1) epidural space, (2) disk space, or (3) segmental veins. The consequences of cement leakage range widely from asymptomatic leaks to leaks that cause paralysis, radiculopathy, or fatal pulmonary embolus, respectively.

Both kyphoplasty and vertebroplasty are used widely to treat these compression fractures and alleviate the pain but kyphoplasty promotes the ability to restore vertebral height better than vertebroplasty.[6,7,10,12,15,17,20,24] The advantage of height restoration in kyphoplasty relative to vertebroplasty is still debated.[7,8,10,12,15,17,24–26] One study has reported that the amount of the cement injected into the vertebral body may have an effect on the pain relief achieved by the procedure.[14] Some studies showed that the cement viscosity has also been identified to be an important factor in decreasing cement leakage, implying that high-viscosity cements can cause decreased cement leakage.[12,15,27]

With the lack of clear clinical superiority of one procedure over the other, it is important to know which procedure can provide a safer and more consistent cement volume injection while avoiding devastating complications caused by cement leakage. The purpose of our study was to measure the volume of cement that can be safely injected under low- and high-viscosity conditions using the vertebroplasty and the balloon kyphoplasty techniques.

Materials and Methods

This is a study determining the amount of cement that can be safely injected into a vertebral body before cement leakage, in a simulated osteoporotic vertebra with compression fracture. Artificial vertebral analogues (sawbones, Pacific Research Laboratories, Vashon, Washington, United States) made of polyurethane with osteoporotic cancellous matrix representing the L3 vertebrae were used for this study. Institutional review board approval was not required, as the study did not involve human or animal specimens. Forty vertebrae were used for the study and were divided into four groups of 10 vertebrae each based on a 2- × -2 experimental design protocol. The four groups tested were: (V1) low-viscosity cement injected using single pedicle entry vertebroplasty technique; (V2) high-viscosity cement injected using single pedicle entry vertebroplasty technique; (K1) low-viscosity cement injected using single pedicle entry balloon kyphoplasty technique (Kyphon, Medtronic Inc., Memphis, Tennessee, United States); and (K2) high-viscosity cement injected using single pedicle entry balloon kyphoplasty technique. Cement injection was stopped when the bone cement first leaked out of the posterior body simulated basivertebral vein defect.

A machine press using an eccentric load was used to create the compression fracture (►**Fig. 1**). The amount of the compression was standardized by fixing the degree of the machine press compression at 30%. The degree of the compression was measured using an electronic caliper before and after the compression. We found that the artificial vertebral analogues have the property to recoil back to the prefracture vertebral height, so we developed and attached a polycarbonate clip to the anterior vertebral body to maintain the 30% compression (►**Fig. 1**). The width of all clips was also standard at 20 mm and vertebral height was 29 (± 1) mm and the final average vertebral height after compression and clipping was 20 mm (i.e., 31% compression ranging from 30 to 32%).

We reviewed 10 CT scans of the lumbar spine to measure the average of the posterior channel for the basivertebral vein at the level of L3, and it was 4 mm (range 3 to 5.6). Each vertebra was prepared by drilling a vascular channel in the posterior wall that measured 4 mm in diameter through the posterior wall. To clear this hole and to trim the spinous process, we used a high-speed burr. The vertebral analogue, as shipped by the manufacturer, has six holes in the super and inferior end plates. To seal these potential leakage pathways, we coated all vertebral body surfaces, except the posterior wall, of the vertebral body with polyester resin (►**Fig. 2**).

Next, a custom-made targeting jig was used to achieve reproducible targeting of the trocars into the anterior middle portion of the vertebral analogue (►**Fig. 3**). The same trocar trajectory was used for kyphoplasty and vertebroplasty, with the sole difference being the depth of penetration of the trocar. By maintaining the trocar trajectories, we were able to eliminate the confounding effect of the trocar trajectory on

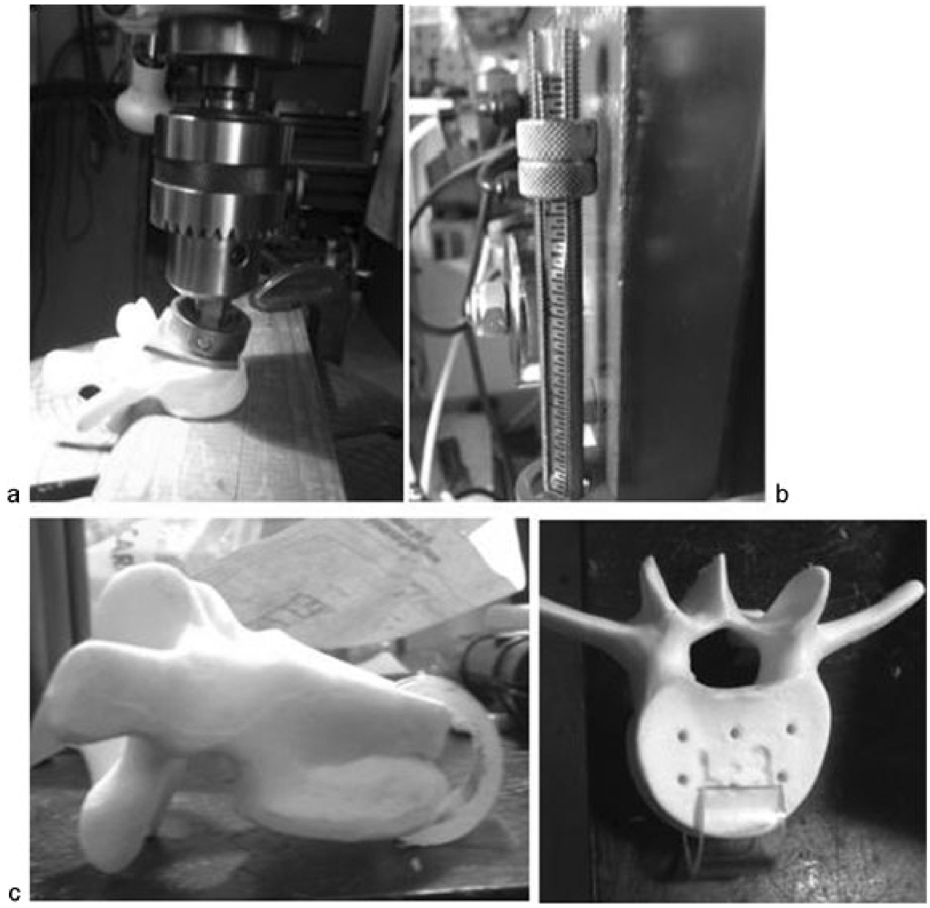

Fig. 1 (a) Press that was used to create the compression fracture model with a wide washer and a rubber pad to distribute the compression evenly without damaging the upper end plate. (b) The amount of compression was standardized by fixing the depth stop press at a point where 30% compression was achieved. (c) Polycarbonate clip maintains compression fracture position.

the cement leakage. The right pedicle was arbitrarily chosen as the trocar entry for all the vertebrae.

Vertebral bodies are filled with marrow and cellular elements.[1,28] Bone marrow is reported to have a viscosity ranging from 37.5 to 400 centipoise (0.037 to 0.4 Pascal seconds [Pa · s]).[29] These marrow elements are not present in sawbones vertebrae. To simulate bone marrow, we prepared several different concentrations of agarose gel ranging from 10.0 to 0.5% until we achieved a viscosity that was in the appropriate range. With the aid of a vacuum chamber, we filled each of 40 vertebrae in this study with a 0.75% agarose gel solution. The solution was subsequently allowed to gel.

The procedures were performed under fluoroscopic guidance using a mini C-arm machine to obtain axial images. A clamp was installed around the C-arm to hold the vertebra stable during the procedure in the prone position (►**Fig. 4**). For the balloon kyphoplasty groups, the kyphoplasty was performed using the Kyphon balloon kyphoplasty instruments under fluoroscopic control, with balloon inflation and balloon deflation, followed by cement injection. The balloon was inflated to a volume of 5 mL for each vertebra in the kyphoplasty groups.

For the vertebroplasty groups, cement injection was performed following trocar placement. The cement injected was

Fig. 2 Vertebral body after fiberglass resin coating. Note that the posterior wall of the vertebra is untouched in figure (b), but that the spinous process has been partially removed to create the sinuvertebral vein hole.

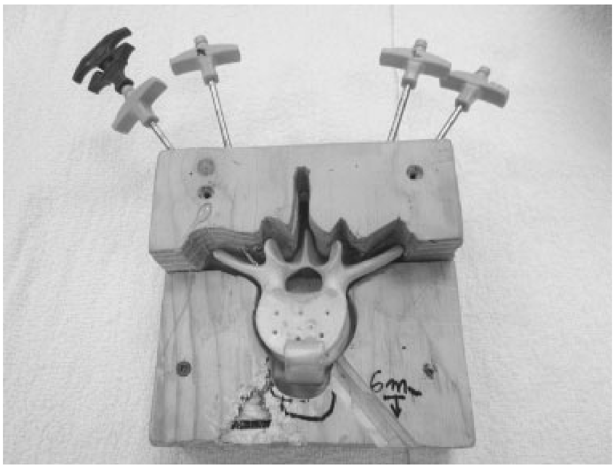

Fig. 3 Custom-made aiming jig to achieve reproducible targeting of the trocars into the anterior middle portion of the vertebral analogue.

Fig. 4 Vertebra held in a stable position with the aid of a clamp installed on the C-arm.

Simplex P, nonantibiotic, radiopaque cement (Simplex, Stryker, Mahwah, New Jersey, United States). The vertebrae in the V1 and K1 groups were injected with the cement in a low-viscosity state, whereas those in the V2 and K2 groups were injected with the cement in the high-viscosity state. The low-viscosity state is similar to the cement viscosity used in clinical practice. The high-viscosity cement is in a state where cement can only be ejected with significant force often requiring two hands. A custom load cell connected to the bone filler device (BFD) was used to ensure that the starting viscosity for the high- and low-viscosity cement, respectively, was uniform across the vertebrae being tested. We designated that the initial force needed to push the BFD was 10 N for low-viscosity cement and 40 N for high-viscosity cement. To estimate the viscosity of the cement, we loaded silicon oils with known viscosities of 65, 200, 400, and 800 Pa · s into the BFDs and ran them through the same load cell and flow rates. We estimate that these forces correspond to a starting viscosity of between 370 and 410 Pa · s for the low-viscosity group and between 1500 and 1600 Pa · s for the high-viscosity group.

The cement was injected into the vertebra under direct visualization and fluoroscopic guidance. Injection was stopped for all groups when the cement started protruding from the posterior vascular channel. The main outcome measured was the volume of the cement injected safely into a vertebra without leakage through the posterior wall defect. This volume was measured using two methods, and both results were recorded. In method 1, the vertebra was weighed before and after the cement injection. Using the change in weight of the vertebra (ΔW) and the density of the cement (D), the volume of the cement injected was calculated using the formula:

$$\text{Volume} = \frac{\Delta W}{D}$$

In method 2, the cumulative length (L) of the BFDs used to inject the vertebra was recorded and the inner diameter (d) of the BFDs was measured. The volume of the cement injected was then calculated using the formula:

$$me = \pi\left(\frac{d}{2}\right)^2 L$$

The filling patterns of the vertebral bodies in the different groups were also observed and recorded using pictures taken by a camera set up on a tripod.

Statistical differences between groups were analyzed using one-way analysis of variance followed by a post hoc Tukey test to further compare all group subjects with each other. A p value < 0.05 was considered as statistically significant.

Results

Calculation from Weight Measurement

All values recorded are the volume of the cement injected up to the point where cement leakage first occurs. The volume of the cement injected was highest in the vertebroplasty group using the high-viscosity cement (V2) with a mean of 4.9 mL. Followed by the kyphoplasty group using high-viscosity cement (K2) with a mean of 3.4 mL, vertebroplasty group using low-viscosity cement (V1) with a mean of 3.08 mL, and kyphoplasty group using low-viscosity cement (K1) with a mean of 2.5 mL. A significant difference was seen between groups with respect to the volume of the cement injected ($p = 0.005$). A post hoc Tukey test showed that all groups differ significantly in the volume of the cement injected ($p < 0.05$; ►**Table 1**).

Calculation from Bone Filler Device Measurement

The highest volume of the injected cement was in the vertebroplasty group using high-viscosity cement (V2) with a mean of 5.6 mL, followed by the kyphoplasty group using high-viscosity cement (K2) with a mean of 3.5 mL, the vertebroplasty group using low-viscosity cement (V1) with a mean of 3.4 mL, and finally the kyphoplasty group using low-viscosity cement (K1) with a mean of 2.9 mL. A significant difference was seen between groups with respect to the volume of the cement injected ($p = 0.0005$). A post hoc Tukey test showed that all groups differ significantly in the volume of the cement injected ($p < 0.05$; ►**Table 1**), except that there was no significant difference in the volume of the cement

Table 1 Results for volume of cement injected into the vertebrae

	Volume of cement injected (mL) calculated from weight measurement	Volume of cement injected (mL) calculated from BFD measurement
Kyphoplasty, low-viscosity	Average = 2.5 SEM = 0.41	Average = 2.9 SEM = 0.32
Kyphoplasty, high-viscosity	Average = 3.4 SEM = 0.40	Average = 3.5 SEM = 0.24
Vertebroplasty, low-viscosity	Average = 3.08 SEM = 0.49	Average = 3.4 SEM = 0.44
Vertebroplasty, high-viscosity	Average = 4.9 SEM = 0.50	Average = 5.6 SEM = 0.60
p	0.005	0.0005

Abbreviations: BFD, bone filler device; SEM, standard error of the mean.

injected between the high-viscosity kyphoplasty group and the low-viscosity vertebroplasty group.

Filling Patterns

The filling pattern for the low-viscosity vertebroplasty group is shown in ►**Fig. 5a**. The typical vertebra in this group appeared to fill diffusely but not densely with cement as it fingered through the cancellous pores in the anterior-to-posterior direction until it leaked out of the posterior wall defect. Demonstrated in ►**Fig. 5b** is the typical cavity created by the kyphoplasty balloon. The filling pattern of a vertebra in the low-viscosity balloon kyphoplasty group (►**Fig. 5c**) showed that the cement filled the cavity created by the balloon in the anterior-to-posterior direction until it protruded from the posterior vascular channel. Interestingly, there was a little spread of the cement into the vertebral body outside of the cavity created by the balloon.

The high-viscosity vertebroplasty group showed the most filling of vertebral body (►**Fig. 5d**). In this group, the cement diffusely and densely packed the entire vertebral body radiating out from the trocar tip until it leaked from the posterior wall of vertebral body. The high-viscosity balloon kyphoplasty group showed patterns similar to the low-viscosity balloon kyphoplasty group (►**Fig. 5e**). The cement filled the cavity created by the balloon in the anterior-to-posterior direction until it protruded from the posterior vascular channel, with little spread of the cement outside of the cavity created by the balloon. ►**Fig. 6** further illustrates these differences in the filling pattern by

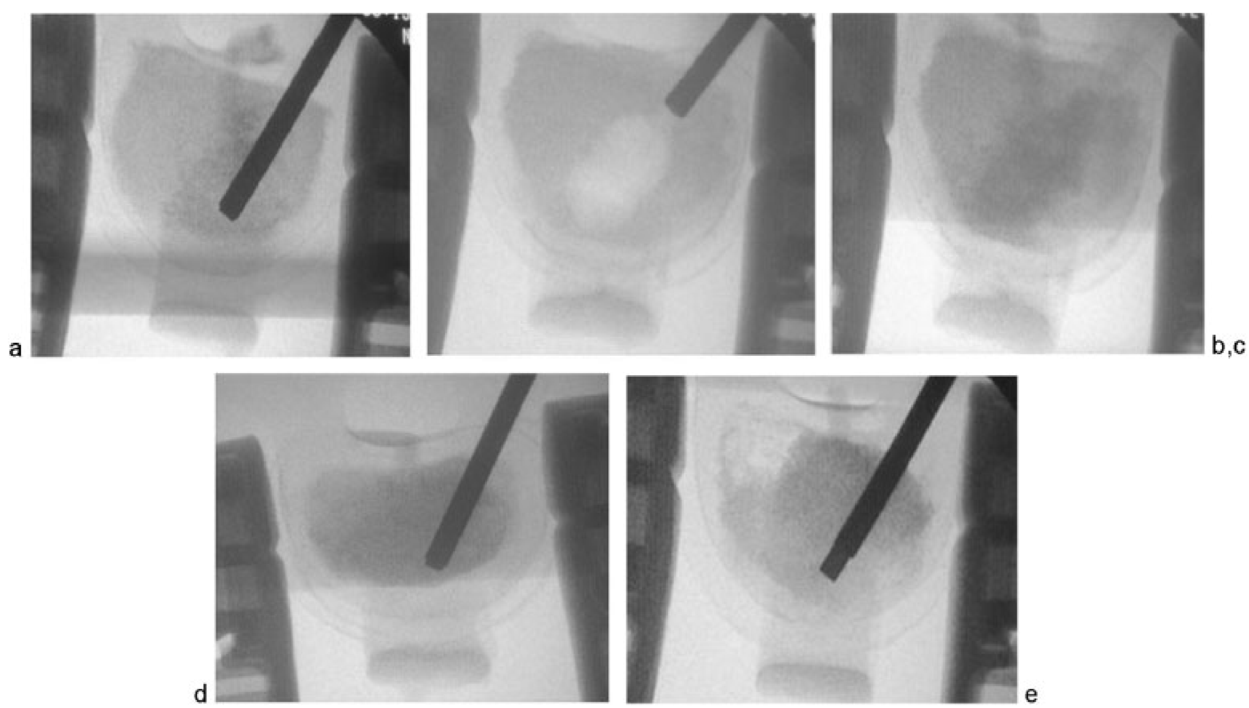

Fig. 5 (a) Filling pattern of a vertebral body being injected using the low-viscosity vertebroplasty technique. (b) The typical cavity created by the kyphoplasty balloon. (c) The filling pattern of a vertebra in the low-viscosity balloon kyphoplasty group. (d) The high-viscosity vertebroplasty group showing the most filling of vertebral body. (e) The filling pattern of high-viscosity balloon kyphoplasty group.

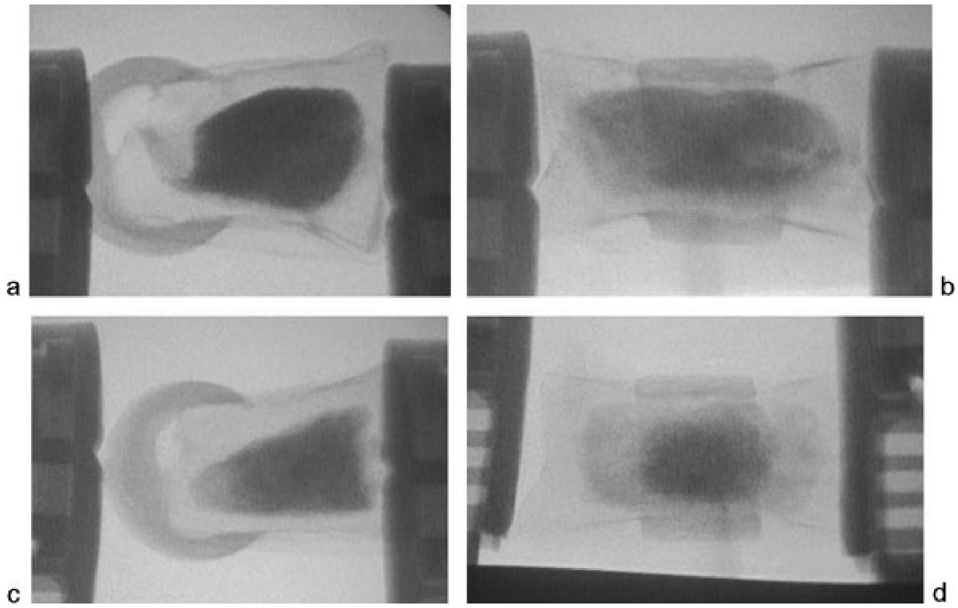

Fig. 6 Sagittal (a) and coronal (b) images showing the filling pattern of the high-viscosity vertebroplasty technique with cement filling most of the vertebral body uniformly. Sagittal (c) and coronal (d) images for the high-viscosity kyphoplasty technique, which demonstrates less vertebral filling with cement.

showing fluoroscopic images in the coronal and sagittal vertebral planes filled by either the vertebroplasty or kyphoplasty technique using high-viscosity cement. Note the greater cement fill for the high-viscosity vertebroplasty technique.

Discussion

Despite the fact that vertebroplasty and kyphoplasty are percutaneous procedures used to treat vertebral compression fractures, the complications secondary to cement leakage are common. One factor influencing cement leakage is the cement viscosity.[27] Gstöttner et al studied 37 patients (76 operated vertebrae) who had viscosity-controlled vertebroplasty and compared the results with a retrospective group of 31 patients (35 operated vertebrae) undergoing vertebroplasty without using a viscosimeter. They found that use of viscosity-controlled vertebroplasty led to a decrease in the leakage rate from 58.3 to 42.1% without any significant difference in the volume of the injected cement based on the imaging measurements.[27] One limitation of the study is that the researchers compared a retrospective group to a prospective group of patients. One might expect that the additional experience gained in the viscosity-controlled vertebroplasty might also have contributed to the lower cement leakage rate. Nieuwenhuijse et al showed that fracture severity and low-viscosity of polymethyl methacrylate bone cement are strong independent risk factors for cement leakage.[30] Other experimental and clinical studies showed that high-viscosity cement has less tendency to leak from the vertebral body.[31–33]

Our study showed that high-viscosity vertebroplasty delivers the biggest cement volume to the osteoporotic vertebral compression model before leakage through the posterior venous channel. The improved ability of high-viscosity vertebroplasty to prevent cement leakage is likely due to the tendency of the injected high-viscosity cement to expand in concentric uniform spheres without seeking low-resistance vascular flow pathways.[34] In contrast, we note that the inflation of a kyphoplasty balloon creates a cavity and hence a low-resistance flow path toward the posterior venous sinus, and in this way initiates earlier cement leakage than with vertebroplasty using the same cement.

The technique of kyphoplasty requires additional equipment and time to perform, generating additional costs to the health care system.[8,10] Based on our results, for any given volume of cement delivered, we believe that less cement leakage will occur in a vertebroplasty with high-viscosity cement than with any of the other techniques tested in this study. Given that there is no compelling data to demonstrate the clinical superiority of one technique over the other, vertebroplasty with high-viscosity cement is a good choice from the perspective of both cement leak safety and health care cost. Note that in our study, we were readily able to carry out vertebroplasty with high-viscosity cement using the BFDs from Kyphon. Sawbones are not made of bone and are, therefore, only vertebral analogues. Real vertebrae have unique geometries and trabecular structures that vary from one level to the next and from one individual to the next.[35,36]

To carry out adequate laboratory testing, there is a need for a vertebra that is identical from one specimen to the next in both geometry and internal architecture. To that end, the use of vertebral analogues that are identical externally, and that have identical internal architecture, have many distinct advantages. First, the variability related to both internal and external vertebral architecture is eliminated. Second, targeting jigs can be created that will permit highly reproducible targeting of the vertebroplasty and kyphoplasty trajectories. Third, the simulated bone marrow is mixed in one batch and uniformly fills all vertebrae equally with a material of identical composition. This uniform bone marrow replacement may serve to eliminate variability arising from patchy, fatty marrow replacement of bone marrow that occurs with age.[28]

The limitations of our vertebral fracture model include (1) the possible different behavior of in vivo real vertebrae from in vitro vertebral analogues; (2) the use of polycarbonate clips to maintain vertebral compression following fracture, which may decrease potential vertebral height restoration during cement augmentation but was felt to be necessary because of the tendency of sawbones to spring back to their prefracture height, as limited fracture height restoration may affect cement fill; (3) cement flow may be altered by the absence of blood flow and the absence of blood hemorrhage and clot that one would normally see in a fresh fracture. These factors taken together may make further study in vivo necessary.

Conclusion

Based on our model of an osteoporotic compression fracture, we conclude that high-viscosity cement injected using the standard vertebroplasty technique delivers significantly more cement before leakage and fills the vertebral body more uniformly when compared with balloon kyphoplasty cementing techniques with high- or low-viscosity cement or vertebroplasty using low-viscosity cement. Vertebroplasty with high-viscosity cement is less prone to leakage than kyphoplasty with high- or low-viscosity cement.

Disclosures
Fahad Abduljabbar, none
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