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Balloon Vertebroplasty with Calcium Phosphate Cement Augmentation for Direct Restoration of Traumatic Thoracolumbar Vertebral Fractures

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Study Design. A human cadaveric model was used to evaluate balloon vertebroplasty in traumatic vertebral fractures.

Objectives. To assess the feasibility and safety of balloon vertebroplasty followed by calcium phosphate cement augmentation to prevent recurrent kyphosis.

Summary of Background Data. Failure after short-segment pedicle-screw fixation for the treatment of vertebral fractures is probably caused by a redistribution of disc material through the fractured endplate into the vertebral body, causing a decrease in anterior column support. This lack of support can give rise to instrument breakage and recurrent kyphosis after removal of the instrumentation. Restoration of the endplate morphology could prevent these events.

Methods. Twenty-three traumatic fractures of thoracolumbar vertebrae were created. All fractures were distracted and fixated with short-segment pedicle screws and rods. Transpedicularly introduced inflatable bone tamps and subsequent injection of calcium phosphate cement were used to restore the endplates. Quantitative analyses of magnetic resonance images obtained at three time points were used to evaluate the morphology of the vertebral body and disc-space. After slicing all specimens, macroscopical examination was performed to detect leakage of cement or bone displacement in undesired directions.

Results. No technical problems were encountered during the study. The balloon vertebroplasty resulted in a significant (P = 0.0014) decrease of cranial endplate impression. No cement leakage or undesired bone displacement could be detected radiologically or macroscopically.

Conclusions. The present study suggests that balloon vertebroplasty may be a safe and feasible procedure for the restoration of traumatic thoracolumbar vertebral fractures. [Key words: balloon, cement, kyphosis, spine, trauma, vertebroplasty] **Spine 2002;27:543–548**

Traumatic thoracolumbar burst fractures needing surgical reduction are often treated by distraction and posterior fixation with short-segment, pedicle-screw instrumentation.[9,21] Notwithstanding the overall good clinical results following this procedure, failure defined as instrumentation breakage and/or loss of kyphosis correction after removal of the instrumentation have been reported as 0–45%.[16,21,24] A lack of anterior column support caused by a void in the vertebral body after height restoration is held responsible for these failures. The present authors' prospective magnetic resonance imaging study demonstrated a redistribution of intervertebral disc material into the fractured vertebral body and a subsequent collapse of the disc space causing instrumentation fatigue and recurrent kyphosis after removal of the instrumentation (Figure 1).[19] To prevent this event, several techniques have been developed to augment the anterior column. Anterior instrumentation and strut grafting have proven to be effective, but require a more invasive approach associated with prolonged operation time, bloodloss, and morbidity.[2,13] Transpedicular bone grafting has not been proven be advantageous, while it can be potentially dangerous if not placed carefully.[1,14,23,25] In this study, it was hypothesized that reconstruction of the intervertebral disc space by direct restoration of the vertebral endplates, after posterior reduction and stabilization, can restore the anterior column and prevent failure of the posterior construct. The void in the vertebral body that would result from reduction of the endplates could be filled by injecting a bone cement, effectively creating support for the cranial endplate and disc, thereby reducing the risk of recurrent kyphosis after removal of the instrumentation. The purpose of this investigation was to assess the feasibility and safety of balloon vertebroplasty with calcium phosphate cement (CPC) for the direct restoration and augmentation of the anterior column after distraction and posterior fixation of experimental high-energy thoracolumbar vertebral fractures in a human cadaver model.

Material and Methods

Eleven cadaveric spine specimens, without evident radiologic osteoporosis or other gross pathology, from T8–S1 were obtained (donor age, 55–80 years; mean age, 69 years; male/female ratio, 10:1). All soft tissue except the ligaments had been removed and the spines were divided at a high lumbar level to create 22 specimens. Both the cranial and caudal segments of each specimen were fixated in polyurethane cups with plastic foam, leaving the middle segment free. A specially designed and validated weight-dropping device was used for the creation of burst fractures of these segments.[20] All specimens were subjected to an axial impact (10–20 kg weight from 1.50 m height) until a macroscopic fracture was evident. All fractures were

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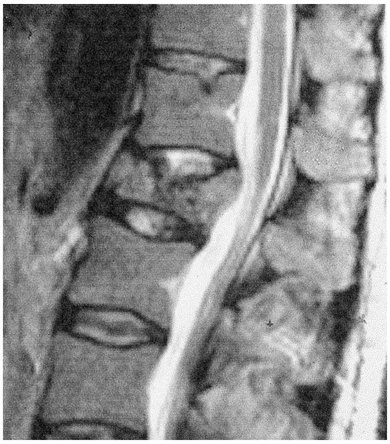

Figure 1. Detail of a sagittal MR-image of a thoracic spine demonstrating the kyphotic deformity as a consequence of disc-space collapse after intrusion of disc material through the fractured endplate in the vertebral body.

distracted and stabilized posteriorly (Figure 2A) by an experienced spinal surgeon (Dr. Oner) using titanium pedicle screws and rods (BWM-system, Stryker Howmedica, Allendale, New Jersey). The entrance of the pedicles of the fractured vertebra was identified and pierced with an orthopaedic awl. After probing the pedicles with a 4-mm pedicle probe inflatable bone tamps designed for the kyphoplasty procedure (KyphX, Kyphon, Inc., Sunnyvale, California), were inserted into both pedicles of the fractured vertebra and advanced until final paramedian localization in the anterior third of the vertebral body. Under fluoroscopic control, the position of the inflatable bone tamps below the fractured cranial endplate was confirmed. The bone tamps were inflated simultaneously by gradually forcing a radiopaque fluid from a pressure-gauge equipped syringe into the balloons. Both the volume and the pressure of the balloons were recorded carefully during the procedure. A fluoroscopic check was performed after each milliliter of added volume. Inflation was continued until satisfactory fluoroscopic reduction of the endplates was achieved as judged by the surgeon (Figure 2b). Indications to stop inflation were displacement of bone fragments into the spinal canal, exceeding the maximum inflation rate of the bone tamps or a build-up of pressure without an accompanying increase in balloon volume, displacement of the balloons, and insufficient visualization of the vertebral anatomy with the fluoroscopic device. Both balloons were actively deflated and retracted after optimal reduction of the endplates had been accomplished. The cement (BoneSource®, Stryker Howmedica Osteonics, Allendale, New Jersey) was prepared by mixing 20 g of calcium phospate, consisting of dicalcium phosphate and tetracalcium phosphate in equimolar amounts, with 6 mL of saline to form an injectable paste. The cement subsequently was transferred to 2 10-mL syringes with a 3-mm needle and injected transpedicularly, bilaterally, in the vertebral body. Injection continued until a complete filling of the defect was achieved fluoroscopically (Figure 2C). Indications to stop injection were leakage of cement outside the vertebral body, a build-up of pressure necessary to inject the cement, and poor visualization of the vertebral anatomy fluoroscopically. The total amount of injected cement was recorded for each specimen. After injection, the cement was allowed to harden at room temperature for 24 hours and the specimens were subsequently frozen to -20 C. Macroscopic examination of sagittal slices (sawed at 4-mm thickness using an electric bandsaw) of the frozen specimens was performed to assess the filling of the defect and to detect any leakage of cement.

During the study, plain radiographs (AP and lateral) and magnetic resonance images (T1- and T2-weighted, with a 0.5 Tesla Philips NT5 scanner) were obtained for all fractures at three time points: after creation of the fracture, after reduction and posterior stabilization, and after balloon vertebroplasty. Using both the plain radiographs and the MR images of t1, the fractures were classified according to the system described by Magerl et al.[18] The MR images of all time points were used for quantitative assessment of changes in vertebral body and disc-space morphology. The two central sagittal slices (distance, 3 mm) of each scan were digitized and all MR images were subsequently randomized. Dedicated software (NIH Image for Windows, Beta 4.0.2, Scion Corporation, Frederick, Maryland) was used to analyze the data by measuring the following

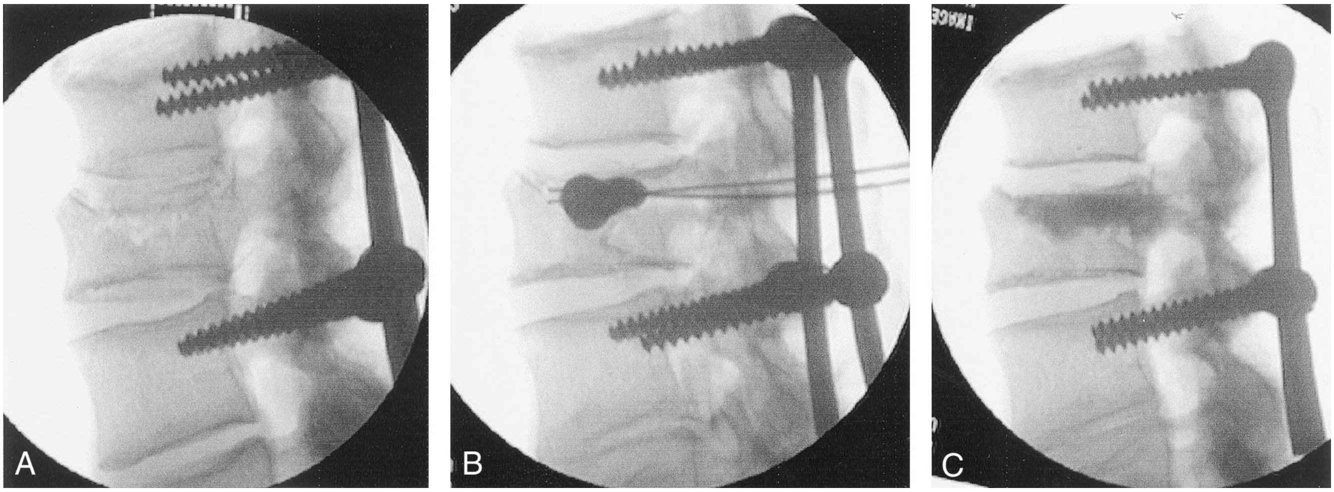

Figure 2. Sequence of fluoroscopic images demonstrating the balloon vertebroplasty procedure. **A,** Lateral fluoroscopy image of an instrumented vertebral fracture showing a central depression of the cranial endplate. **B,** Image of the same fracture as in Figure 2A with inflated balloons *in situ* after optimal reduction of the cranial endplate. **C,** Complete filling of the defect without evidence of extracorporal leakage after bilateral injection of CPC in the void.

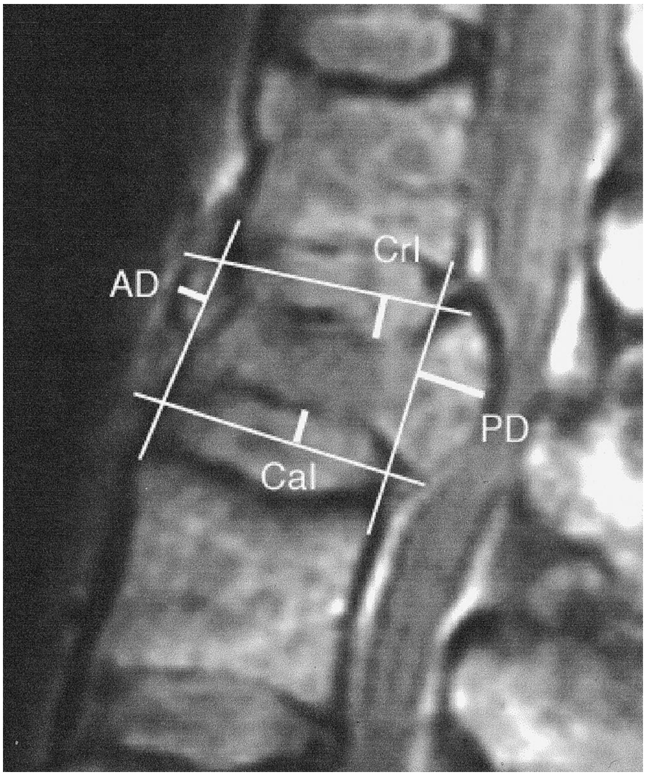

Figure 3. Graphical representation of the method used for assessing anterior displacement (AD), posterior displacement (PD), cranial impression (CrI), and caudal impression (CaI) projected on an MR image of a vertebral fracture.

parameters (Figure 3): anterior displacement (AD [the maximum displacement of bone fragments measured perpendicular to the line connecting the anterior margin of the adjacent cranial and caudal vertebral body), posterior displacement (PD [the maximum displacement of bone fragments measured perpendicular to the line connecting the posterior margin of the adjacent cranial and caudal vertebral body]), cranial endplate impression (CrI [the largest depression measured perpendicular to the line connecting the anterior and posterior superior margin of the vertebral body]), and caudal endplate impression (CaI [the largest depression measured perpendicular to the line connecting the anterior and posterior inferior margin of the vertebral body]). Multilevel analysis, designed to detect relative rather than absolute differences and taking into account spine number, fracture type, level of the fracture (thoracic or lumbar), was used to assess the differences ($P \leq 0.05$) for all four parameters between the baseline fractures (t1), the distraction/fixation (t2), and the balloon vertebroplasty (t3).

Results

In the 22 specimens, a total of 23 fractures was created, which were classified as 17 pure burst fractures (A3.3), four pincer fractures (A2.3), one impaction fracture (A1.3), and one rotation-burst fracture (C1.3) according to the AO classification by Magerl et al.[18] In all specimens, the posterior longitudinal ligament (PLL) was intact. The balloon vertebroplasty procedure was performed without technical difficulties in all fractured vertebrae. The maximum intravertebral pressure of the balloons varied between 50 and 200 psi (mean, 105 psi). These values were within the safe operating range for the balloons. The amount of injected CPC needed for fluoroscopically complete filling of the defect ranged from 6.0 to 22.1 g (mean, 14.3 g). Signs to prematurely stop inflation of the balloons or end cement injection, as mentioned above, were not encountered. In Figure 4A and 4B, the results of the effect of the experimental procedure on each of the four parameters are presented. Distraction of the specimens resulted in a reduction in displacement of both the anterior and posterior wall ($P = 0.0056$ and $P = 0.0013$, respectively) but no difference was detected for any of these parameters following the balloon vertebroplasty. As a result of the balloon vertebroplasty, the impression of the cranial endplate was significantly decreased ($P = 0.0014$). No difference in caudal impression was measured between any of the three time points. After individual judgment of the data, 11 specimens showed a positive (> 0 mm) PD of bone at t3. Of these 11 specimens, three exceeded 1 mm (Figure 5). The maximum PD measured was 1.3 mm. The investigators detected no cement leakage outside the vertebral body during the procedure and after macroscopical examination (Figure 6).

Discussion

Relying on the results of the study, the primary goals—to reconstruct the anatomic boundaries of the disc space and to provide information about the safety and feasibility of the procedure— have been achieved. Reduction of the impression of the endplate is, based on the authors' previous studies, a prerequisite to decrease the risk of intrusion of the disc in the vertebral body.[19] The technique to achieve reduction and augmentation resembles the 'kyphoplasty' procedure, in which inflatable balloons and injection of polymethyl methacrylate (PMMA) cement are used to correct the spinal deformity following osteoporotic vertebral compression fractures.[4,17] Severe complications, although rare, including pulmonary embolism and spinal cord compression caused by cement leakage, have been reported after classic vertebroplasty with PMMA cement for the treatment of osteoporotic vertebral compression fractures.[6,11,12,26] In the present study, the use of inflatable bone tamps facilitated endplate reduction and, by simultaneously creating a bone void, cement could be injected under low pressure, thereby decreasing the risk of leakage and undesired displacement of bone fragments. After individual judgment of the MRI data, it was concluded that no neurologic damage could have resulted from posterior displacement (PD) of bone fragments as a result of the balloon vertebroplasty. The intact PLL in all specimens may have contributed to this fact and also to the absence of cement in the spinal canal. Studies to evaluate the risks and indica-

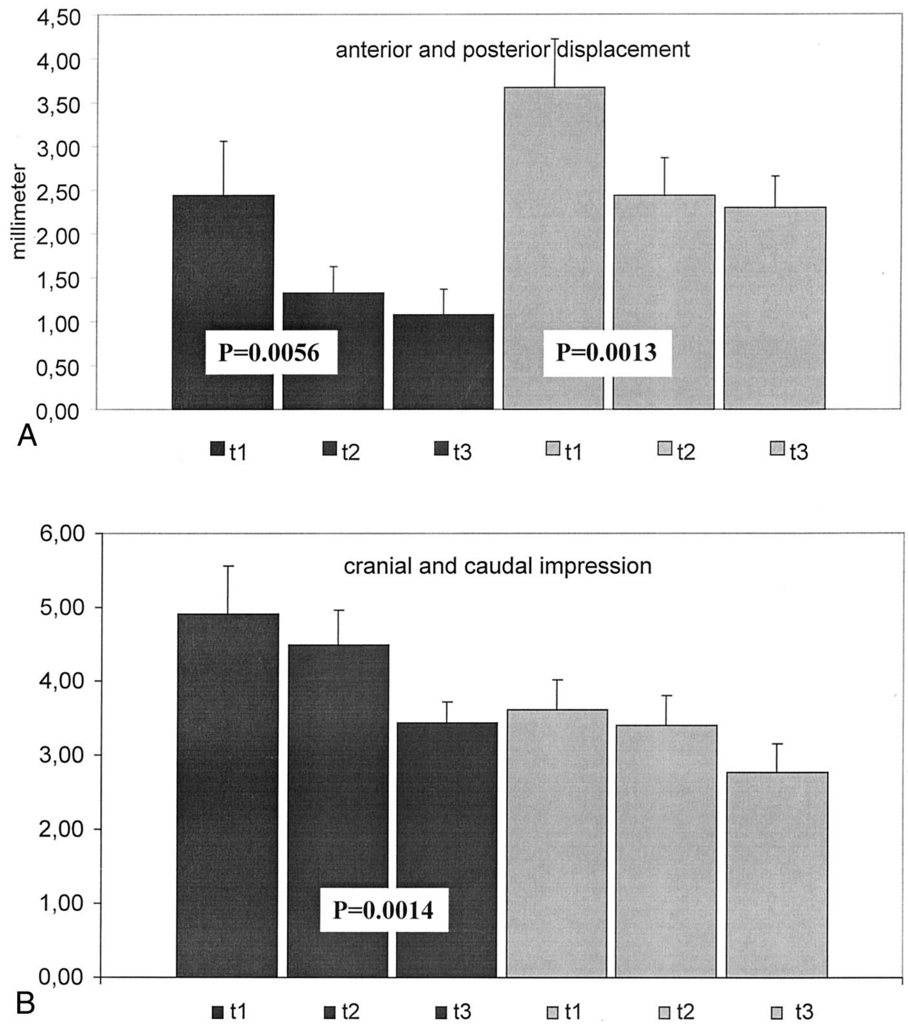

Figure 4. **A,** Chart showing the mean anterior (dark gray bars) and posterior (light gray bars) displacement and standard errors at t1 (after fracture), t2 (after reduction), and t3 (after balloon vertebroplasty). **B,** Chart showing the mean cranial (dark gray bars) and caudal (light gray bars) impression and standard errors at t1 (after fracture), t2 (after reduction), and t3 (after balloon vertebroplasty).

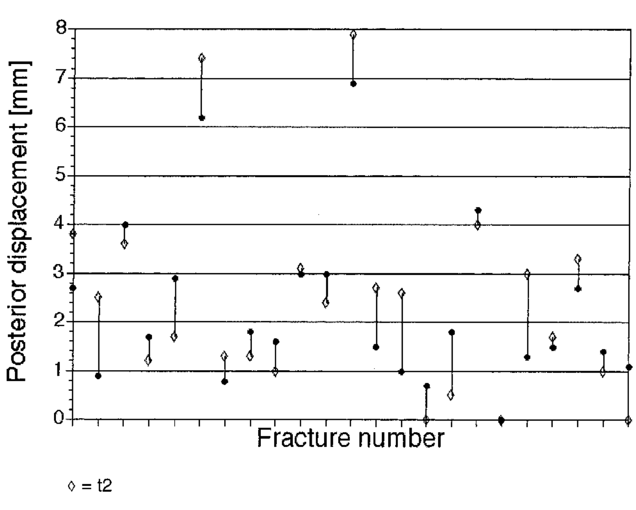

Figure 5. Chart demonstrating the individual data for posterior displacement (PD) at t2 (after reduction) and t3 (after balloon vertebroplasty).

Figure 6. Photograph of a sagittal slice of a frozen specimen after balloon vertebroplasty demonstrating a complete filling of the defect without evidence of cement leakage.

tions of balloon vertebroplasty for burst fractures with severely displaced or crushed bodies and fractures with associated PLL tears caused by an additional flexion/extension or rotational component (B- and C-type fractures), are currently under investigation.

Because PMMA cement is an inert material and hardens exothermally, which can cause tissue damage in case of cement leakage, it was rejected in favor of CPC for augmentation of the void. CPC has been demonstrated to be biocompatible, osteoconductive, and is slowly resorbed by creeping substitution because of osteoblastic and osteoclastic activity allowing for the deposition of newly formed bone.[3,5,8] In the event of CPC leakage, the damage to surrounding tissue most likely will be less compared with PMMA, by virtue of its isothermic properties during the setting phase.[7,15] Although the use of PMMA cement in vertebroplasty is widespread, no data on the long-term behavior of the material for spinal applications have been published. Because the majority of patients with traumatic vertebral fractures are aged between 20 and 50 years, the use of a more biocompatible bone cement is preferred.[10,22] Further studies are required to evaluate the rate at which CPC turns over into bone in intravertebral applications. The resistance to compressive forces of CPC has been demonstrated not to differ significantly from PMMA after *in vitro* vertebroplasty in human cadavers.[3] Although the brittleness of CPC represents a problem for weight-bearing applications, the authors believe that, because the pedicle-screw instrumentation remains *in situ* for an extended period of time in a clinical situation, the cement will not be under full load. The current investigation suggests that balloon vertebroplasty may be a safe and feasible procedure for the restoration and augmentation of the anterior column in traumatic thoracolumbar burst fractures. Clinical studies will be necessary to evaluate the usefulness of this technique and are currently under investigation by the authors.

■ Key Points

- Balloon vertebroplasty with calcium phosphate cement injection decreases the cranial impression of the fractured endplate in traumatic burst fractures after short-segment pedicle-screw instrumentation in a cadaveric model.
- No clinically relevant displacement of bone anteriorly or posteriorly could be detected after balloon vertebroplasty in the present study.
- No leakage of cement outside the vertebral body could be detected radiologically or macroscopically.

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Point of View

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Verlaan and coauthors have proposed a novel approach to the problem of anterior column reconstruction following thoracolumbar burst fractures. Their intervention is based on the evolving field of miniinvasive reduction and stabilization of vertebral body fractures using balloon vertebroplasty. Vertebroplasty and kyphoplasty (balloon vertebroplasty) are gaining in popularity as stabilization techniques for low-velocity osteoporotic compression fractures. Although nonrandomized studies[2,4] have shown both to be clinically efficacious in relieving pain in these patients, neither technique has been used in the setting of acute traumatic thoracolumbar fractures. The use of a balloon has potential advantages, including controlled fracture reduction capabilities, low cement insertion pressure, and some directional control of cement.[2] The low cement insertion pressure is associated with significantly lower cement extravasation[4] and neurologic complication rates[2] when compared to high-pressure vertebroplasty.[2,3,6]

Verlaan et al have explored the use of balloon vertebroplasty in a cadaver model of acute higher-energy thoracolumbar burst fractures. The study has shown that it is possible to augment the anterior column with cement following indirect reduction of the fracture using posterior short segment instrumentation. The authors suggest that the technique is also useful in reducing residual cranial endplate depression. The reduction achieved, while statistically significant, was actually small (1 mm on average). The biomechanical and clinical benefits of such a reduction require further investigation. It is unclear whether the anterior column augmentation achieved in this investigation has the desired biomechanical load sharing effect. A comparative biomechanical study is required to address this. Posterior vertebral body wall incompetence generally is regarded as a contraindication for both vertebroplasty and kyphoplasty. However, Verlaan et al have clearly shown that posterior cement extrusion did not occur when the posterior longitudinal ligament was intact. Posterior longitudinal ligament rupture, however, occurs in a proportion of thoracolumbar burst fractures and, as suggested by the authors, safety under these circumstances requires careful evaluation. Such studies must be cognizant of the fact that cadaver models vary from the normal clinical environment and cement extravasation patterns may differ between the two.

Calcium phosphate cement has certain theoretical advantages over polymethyl methacrylate (PMMA). It is more biocompatible, has osteoconductive properties with remodeling potential and hardens at physiologic temperatures. PMMA, however, has proven long-term efficacy in arthroplasty and for filling oncologic defects, most notably after curettage for giant cell tumor. PMMA used for both vertebroplasty and kyphoplasty is efficacious in reestablishing the normal load-bearing characteristics of the vertebral body.[1,5] There are still unresolved issues with both PMMA and calcium phosphate cement, including the biologic and mechanical sequelae over time in the vertebral column.

This study is an important first step in assessing the feasibility and safety of balloon vertebroplasty in acute spinal trauma, and the authors deserve credit for their instructive investigation.

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