SPINE Volume 25, Number 2, pp 158–165

1999 Young Investigator Research Award Runner-Up

Effect of Augmentation on the Mechanics of Vertebral Wedge Fractures

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Study Design. The effect of cement augmentation of wedge-fractured vertebral bodies on spine segment compliance was studied in 16 cadaver specimens.

Objectives. 1) To assess the mechanical effects of cement augmentation of vertebral wedge fractures. 2) To determine whether a new reduction/injection procedure has the same mechanical effects as the established direct injection procedure.

Summary of Background Data. Although wedge fractures cause pain and disability in hundreds of thousands of people, few effective treatments are available. Clinical studies have shown that cement augmentation, a new procedure, effectively relieves pain and restores mobility in patients suffering from weak or fractured vertebrae. However, only a few studies have examined the mechanics of vertebral augmentation.

Methods. A wedge fracture was created in the middle vertebra of 16 three-vertebra cadaver spine segments. Neutral and full-load compliance of each fractured spine segment in flexion/extension and lateral bending were assessed by measuring the relative rotation of the vertebral bodies in response to applied moments. Eight of the fractured vertebral bodies were then augmented using direct injection, while the remaining eight fractured vertebral bodies were augmented using a combined reduction/injection procedure. Compliance of the augmented segments was then assessed.

Results. Augmentation significantly reduced the neutral compliance (reduction of 25% ± 23%) (mean ± standard deviation) and the full-load compliance (reduction of 23% ± 20%) in flexion/extension ($P < 0.005$). Augmentation also significantly reduced the neutral compliance (reduction of 34% ± 20%) and the full-load compliance (reduction of 26% ± 17%) in lateral bending ($P < 0.0001$). No significant difference was found between the two procedures for compliance reduction.

Conclusions. Augmentation of wedge fractures using both direct injection and reduction/injection reduces spine segment compliance significantly. [Key words: fractures, osteoporosis, biomechanics, spine, spinal fractures, bone cements] **Spine 2000;25:158–165**

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This study was supported by a grant from Kyphon Inc.
Acknowledgment date: January 8, 1999.
First revision date: August 27, 1999.
Acceptance date: September 7, 1999.
Device status category: 1.

Vertebral compression fractures affect about 500,000 individuals annually in the U.S.[4] Compression fractures are characterized by a loss of height in the anterior, posterior, or central region of the vertebral body that is usually evident on a lateral or anterior/posterior (A/P) radiograph.[15] These fractures occur when the load transmitted by a vertebra exceeds its failure load.[21] It is widely accepted that the increased incidence of spinal wedge fractures in the elderly is directly associated with osteoporotic weakening of the bone that leaves it unable to support the loads of daily living. Recent studies estimate the prevalence of vertebral fractures in postmenopausal women to be 25%, and suggest that the prevalence of fractures in men may approach that in women of the same age group.[18] Fracture incidence rises dramatically with age,[18,19] with at least one fracture being the rule rather than the exception in octogenerians. The primary complication is acute pain: 84% of patients with radiographic evidence of a compression fracture reported associated back pain.[4] Other complications include kyphotic deformity, transient ileus or urinary retention, and, rarely, cord compression.[15] The pain, discomfort, and deformity associated with compression fractures often lead to significant physical, psychological, and functional impairments and frequently have a substantial impact on quality of life.[9,16]

Few effective, low-risk interventions are available for the treatment of vertebral compression fractures. Most research efforts have addressed the prevention of the underlying conditions that lead to compression fractures rather than their direct treatment. Attempts to reduce the risk of fracture have involved therapeutic strategies for strengthening bone including exercise, vitamin, and mineral supplements and antiresorptive agents such as estrogen, calcitonin, and bisphosphonates.[14] Once the fracture has occurred, however, treatment options are limited. Physical therapy, including strengthening of the paraspinal musculature and patient training to reduce the risk of fracture and pain during specific activities, is often recommended.[9,26] Surgery, which is complicated by osteoporosis,[10] is not currently indicated unless neurologic function is at risk or the deformity is substantial.[1] Bracing and analgesics may relieve pain but because immobilization can lead to further bone loss, bracing may actually increase the risk of further fractures.[2] Many

compression fractures currently go untreated due to the limitations of current approaches.

Cement augmentation of the vertebral body, a relatively new procedure, has been shown to relieve the pain and loss of mobility associated with weak and fractured vertebrae.[5,6,7,8,11,12,28] The procedure, sometimes known as vertebroplasty, has been used in France since 1984 and was first performed in the U.S. in 1995.[11] In this technique, acrylic cement is injected under pressure through a needle placed percutaneously through the pedicle into the anterior vertebral body. Several different vertebral augmentation techniques have been developed and shown to reduce pain when used to treat vertebral angiomas,[7,8] metastases,[5,7,8,12,28] and compression fractures due to osteoporotic weakening.[6,7,8,11] Pain relief was found to be sustained, although most studies report mean follow-up times shorter than 2 years. Augmentation was found to prevent further collapse of the treated vertebral bodies.[5] Treatment of as many as seven vertebrae in a single individual has been reported.[17]

It has been suggested that augmentation relieves pain by reducing the relative motion between fractured fragments of bone.[12] However, few studies have examined the effect of augmentation on vertebral mechanics. Mermelstein *et al*[20] showed that cement augmentation of thoracolumbar burst fractures stabilized with short-segment pedicle screw instrumentation increased spine segment stiffness in flexion/extension. However, this study did not examine the effect of augmentation on the uninstrumented segment. Galibert and Deramond showed that augmentation increased the axial stiffness of a small number of cadaver vertebral bodies.[7] Bostrom and Lane and Schildhauer *et al* found that augmentation increased the compressive force required to collapse cadaver vertebral bodies.[1,25] These studies are limited because only compressive loads were studied. For a more complete mechanical assessment of augmentation, relative motion of spine segment vertebrae in response to applied "pure" anterior/posterior and lateral bending moments must be determined.

A new method for augmenting fractured vertebrae, which includes a fracture reduction step, is emerging. In this reduction/injection technique,[1] an inflatable bone tamp (Kyphon Inc., Santa Clara, CA) is introduced percutaneously into the fractured vertebral body and expanded in an effort to compress cancellous bone to create a void. The tamp is then removed and the vertebral body is filled with acrylic cement. One potential advantage of this approach is that the cement can be introduced into the vertebral body at a lower pressure than it would be during direct injection, which may reduce the risk of cement leakage. However, it is not clear whether this procedure will have the same mechanical effect as direct injection.

The aim of the current study was to assess the mechanical effect of cement augmentation using both direct injection and reduction/injection on the fractured vertebral body. Compliance, the rotation of one vertebra in the segment relative to another in response to an applied load, was determined and compared to address two research questions:

1. In thoracolumbar spine segments in which a wedge fracture has been created, does augmentation of the fractured vertebral body with polymethylmethacrylate (PMMA) cement reduce segment compliance?
2. Does the reduction/injection technique of vertebral body augmentation reduce spine segment compliance as effectively as the direct injection technique?

These questions were studied by performing biomechanical tests on cadaver spine segments.

Methods

Specimens. Experiments were performed using 16 unembalmed three-vertebra spine segments (nine from T7–T9 and seven from T10–T12) obtained through the Harvard Anatomical Gifts Program (seven female donors; four male donors; age range 65 to 99 years; mean age 81). The upper and lower vertebrae of each segment were embedded in cylinders of PMMA cement. The bone mineral density of each donor's spine was assessed using a dual energy radiographic film absorptiometry (DXA) scan (QDR 2000+, Hologic Inc., Waltham, MA) of the vertebrae from L2 to L4.[22] The pool of specimens was divided into two treatment groups with eight segments each. To ensure that each group had a similar range of bone densities, the specimens from each level were sorted from highest to lowest density. For each level, the specimens were assigned to the two groups in an alternating sequence. The first group had four T7–T9 segments and four T10–T12 segments, while the second group had five T7–T9 segments and three T10–T12 segments. The mean Student's t score ($\pm$ standard deviation) describing bone density was -2.61 ± 0.98 in the first group and -3.04 ± 1.16 in the second group. A Student's t test showed that there was no significant difference between the bone mineral densities in each group ($P = 0.43$).

Fracture. To provide specimens for cement augmentation, a wedge fracture was created in the middle vertebra of each segment using a custom-built spine fracturing rig. This system, which has been described in detail previously,[29] applied a combined compression force and anterior flexion moment to the segment using two hydraulic pistons driven by a servo-hydraulic materials testing machine (Instron 1331, Canton, MA). Each specimen was mounted securely in the spine fracturing rig and then subjected to an increasing load until failure (characterized by a sudden increase in kyphotic angulation) was observed. Radiographs of the specimens were examined to confirm that wedge fractures had been created.

Height. Anterior and posterior wall heights of the fractured vertebrae in 12 specimens were assessed before fracture, 24 hours after fracture, and after cement augmentation. Radiographs of each specimen were taken using a protocol to align the sagittal plane of the specimen with the radiographic film and to ensure a uniform distance between the vertebra and the

[1]Kyphon Inc. calls this technique Kyphoplasty™.

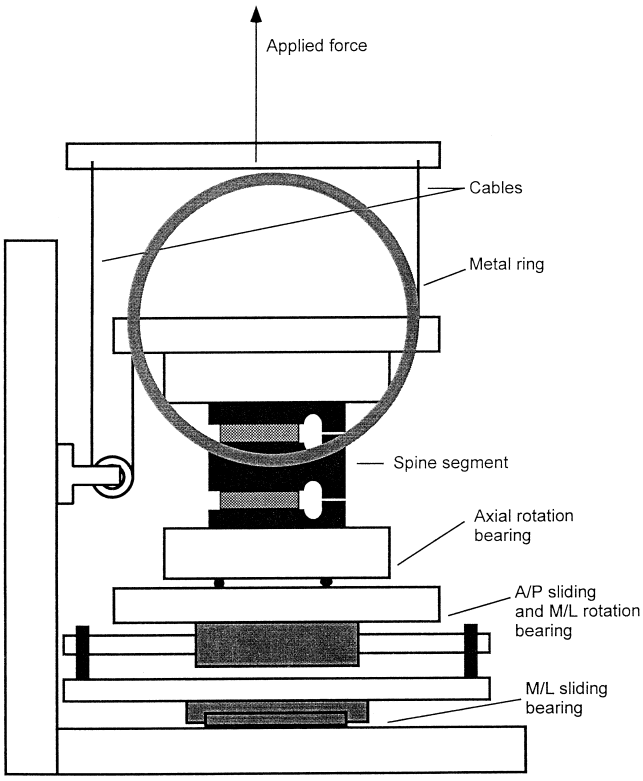

Figure 1. Stability test rig for applying moments to the spine segments.

film. The anterior (h_a) and posterior (h_p) wall heights were measured to the nearest millimeter on each radiograph. Two parameters were chosen to define vertebral geometry—the height ratio (h_a/h_p) and the average height ((hathp)/2).

Assessment of Compliance. Flexion, extension, and right and left lateral bending were applied to each specimen with a compliance testing rig (Figure 1) . This rig applies a moment to the upper vertebra using cables attached to torque wheels on the upper fixture and connected, using a system of pulleys and linkages, to the ram of a servohydraulic materials testing machine (Instron 1331, Canton, MA). The lower fixture secures the segment to the base of the materials testing machine using a four degree-of-freedom mechanism. Because the mechanism can resist only the applied moment and the weight of the apparatus and specimen, loading on the specimen consists only of a small compressive force and the applied "pure" moment. The direction of the moment is varied by rotating the segment within the rig fixtures. For each loading direction (flexion, extension, right lateral bending, and left lateral bending), a program of loading was applied to the specimen. This program consisted of three load cycles to 7.5 Nm at a rate of .25 Nm/s to precondition the specimen followed by the test load of 7.5 Nm, which was applied in three equal steps (2.5 Nm, 5.0 Nm, 7.5 Nm), each of which was held for 60 seconds. This type of sequence, with several preconditioning cycles followed by load application in equal steps, has been used in a number of previous studies in the literature.[24,30]

Kinematics. Relative movement of the upper and lower vertebrae of the three-vertebra segment was measured using a two-camera, video-based motion analysis system (MacReflex, Qualisys, Glastonbury, CT). The anterior/posterior, medial/lateral (M/L), and axial axes of the upper and lower vertebrae were aligned to corresponding axes marked on the fixtures that grip the specimen in the test rig. Throughout the loading cycle, the motion analysis system tracked the three-dimensional positions of 10 retroreflective spherical markers: five fixed to the upper fixture and five fixed to the lower fixture. The orientations of the axes of the upper and lower vertebrae were then calculated from these reference marker positions. Movement of the upper vertebra relative to the lower vertebra was represented using a gyroscopic coordinate system.[3] The principal axis (flexion, extension, right/left lateral bending) was fixed in the lower vertebra and corresponded to the anterior/posterior (for flexion/extension) or medial/lateral (for right/left lateral bending) axes. The axial rotation axis was fixed in the upper vertebra and corresponded to the axial axis of that vertebra. A third "floating" axis was defined as the cross product of the other two.

Augmentation. After the compliance of the fractured specimens was assessed, each fractured vertebral body was augmented using either direct injection or reduction/injection. Factors including specimen positioning, radiographic control, instruments, instrument placements, and cement preparation and injection corresponded to clinical protocols used by two of the authors (JMM and MAR). Motion segments were held to simulate the prone position, and all steps were controlled radiographically using a C-arm fluoroscope. The motion segments were rotated to change between medial/lateral and anterior/posterior views during inflatable bone tamp inflation, but remained in the equivalent of the prone position during cementing for both cement augmentation techniques.

Specimens in the first group were treated with direct injection. In this bilateral, transpedicular approach (described in Jensen *et al*),[11] an 11-gauge Jamshidi needle was placed into the center of each pedicle and advanced halfway into the vertebral body. Cranioplastic brand PMMA cement (Codman, Randolph, MA) was prepared by hand as described by Jensen *et al* and modified by Mathis *et al*.[17] Cement was poured into 1 cc syringes, which were attached to the Jamshidi needle and injected via each pedicle until approximately 75% of the vertebral body was filled (sparing the posterior wall) or leaks were observed. While cement volume varied from specimen to specimen, the mean volume was estimated to be 10 cc.

The second group of specimens was treated using reduction/injection. In this protocol, a posterolateral approach was effected by hand drilling with a 5 mm drill bit from the lateral inferior aspect of the pedicle across the middle vertebral body of the motion segment to the anterolateral side, stopping 3–5 mm from the anterior cortex. A 30 mm length inflatable bone tamp (Kyphon Inc., Santa Clara, CA) was positioned in the 5 mm drill channel, inflated with radiopaque contrast medium, deflated, and then removed from the drill channel, according to its instructions for use. Tamp positioning and inflation path were followed radiographically using A-P and lateral views, which were taken after the addition of each cc of inflation medium volume. Bone tamp inflation was ceased when the tamp reached any cortex. The average inflation volume, which is assumed to correspond to the cavity volume, was 5.0 cc (range 3.5–6.0 cc). Simplex P methylmethacrylate (Howmedica Inc., Rutherford, NJ) was mixed in a cement mixing system (Stryker Instruments, Kalamazoo, MI) and inserted into the void under radiographic control via a retrograde backfill

using a custom nozzle with a 4.8 mm outer diameter (to fit the drill channel). Cementing was stopped when the void was filled, as judged by lateral radiographic views. Cement volume exceeds cavity volume by about 20%, based on pre- and post-augmentation measurements of weight in other samples. This suggests that reduction/augmentation specimens received an average of 6.0 cc of bone cement. While this was smaller than the estimated volume of cement used in direct injection, the difference is not surprising given the substantial variation in volume from specimen to specimen described by Jensen *et al* (3–20 cc).[11] Average volumes from both procedures fall within this range. After augmentation, the compliance of each specimen was reassessed using the procedure described above.

Data Analysis. To assess segment compliance, two parameters were determined for flexion/extension and lateral bending—the neutral compliance and the full-load compliance. When loaded with a pure moment, spine segments display a primary rotation about the axis of the applied moment and coupled rotations about the other two axes. In the current study, the neutral compliance was defined as the primary rotation from the final unloaded (zero moment) position in the loading cycle in one direction to the final unloaded position in the opposite direction. The full-load compliance was defined as the primary rotation from the fully loaded position in the loading cycle in one direction to the fully loaded position in the opposite direction. These parameters correspond closely to Panjabi's definition of neutral zone and range of motion.[23] However, while Panjabi's parameters describe rotation from a "neutral" reference position to a position of interest on the loading cycle, our parameters describe the rotation between two positions of interest on the loading cycle. The advantage of the current approach is that definition of a "neutral" reference position, which can be difficult, is not required.

Two-way repeated-measures analyses of variance were used to test the following null hypotheses:

- Augmentation has no effect on the neutral and full-load compliance in flexion/extension and lateral bending.
- Reduction/injection has the same effect on neutral and full-load compliance in both directions as direct injection.
- Augmentation has no effect on the height ratio and average height of the fractured vertebral bodies.
- Reduction/injection has the same effect on height ratio and average height as direct injection.

Results

For all directions of loading and all conditions of augmentation (fractured, direct injection, reduction/injection), the primary component of vertebral rotation was in the direction of the applied moment. Although coupled rotations were observed (Figure 2), these were small relative to the primary rotations and are, therefore, not presented in this article.

Cement augmentation reduced the compliance of the wedge-fractured spine segments. Both the neutral and full-load compliance were reduced by augmentation for flexion/extension (Figure 3A, Table 1). Similarly, the neutral and full-load compliance were reduced by augmentation for lateral bending (Figure 3B, Table 1). Direct injection and reduction/injection had similar effects (Table 1): no significant differences ($P < 0.05$) were found between the two methods for either compliance parameter in either direction.

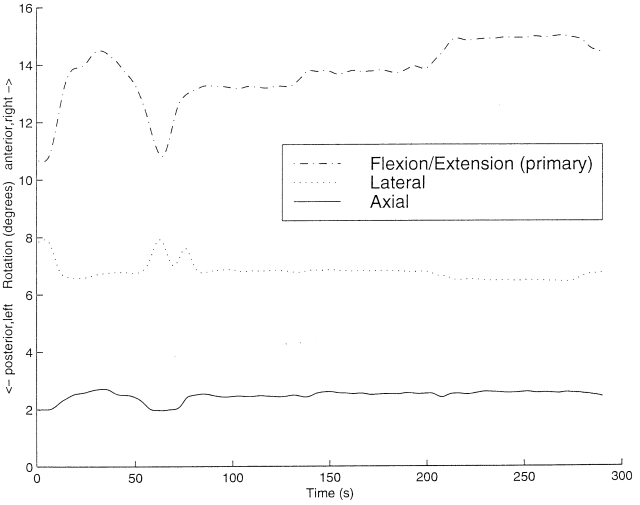

Figure 2. Rotations of the upper vertebral body relative to the lower vertebral body in a representative specimen. This plot shows the primary rotation and the two coupled rotations of the specimen loaded in flexion. The first peak of the primary rotation corresponds to the peak of the last cycle of preconditioning, and the subsequent plateaus correspond to loads of 2.5, 5.0, and 7.5 Nm.

Cement augmentation increased the height ratio and average height of the fractured vertebrae (Table 2). The height ratios of the fractured vertebrae increased by a mean of 0.1 ($P = 0.0016$) after treatment, and height ratios after augmentation were not significantly different from the intact values ($P = 0.1274$). The average height of the fractured vertebrae increased by a mean of 3.4 mm ($P = 0.0002$), although augmentation did not restore height to intact levels ($P = 0.0504$). No significant differences ($P < 0.05$) were found between reduction/injection and direct injection for height ratio increase or average height increase.

The pattern of fill for reduction/injection did not appear to be substantially different from the pattern of fill for direct injection. Lateral radiographs (Figure 4) and CT scans (Figure 5) of representative specimens chosen at random show that both procedures produced substantial filling of the vertebral body.

Discussion

In the current study, the effect of cement augmentation of wedge-fractured vertebral bodies on the compliance of cadaver spine segments was determined. Established guidelines for assessing spine segment compliance were followed.[23] The results of these experiments show that augmentation with acrylic cement reduced compliance in both flexion/extension and lateral bending and that reduction/injection reduced compliance as effectively as direct injection.

The current study has shown that augmentation reduced flexion/extension and lateral full-load compliance by 23% and 26%, respectively. The magnitude of

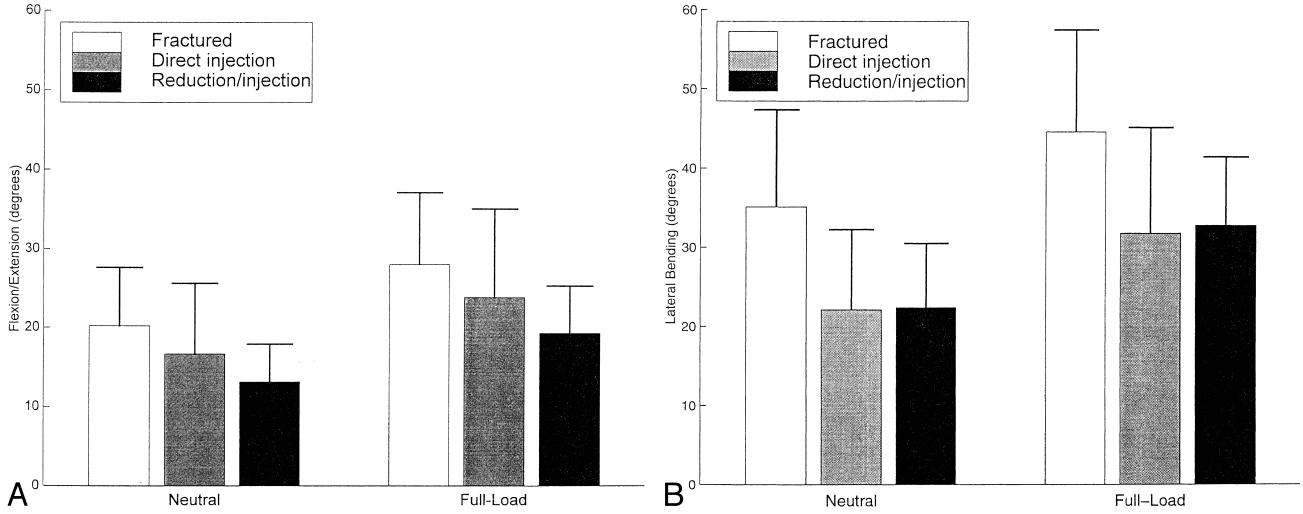

Figure 3. Compliance of the specimens before and after augmentation. Error bars show one standard deviation from the mean. **A,** In flexion/extension, augmentation (direct injection and reduction/injection) significantly reduced both the neutral ($P = 0.004$) and full-load ($P = 0.0025$) compliance significantly. **B,** In lateral bending, augmentation reduced both the neutral ($P < 0.00005$) and full-load ($P = 0.0001$) compliance significantly. No significant difference in compliance reduction was detected between the two procedures.

compliance reduction may be surprising because augmentation is likely to affect only the compliance of the bone by stabilizing the fracture fragments, while spine segment compliance is often attributed primarily to the intervertebral discs. The magnitude of compliance reduction required to achieve a clinical effect is not known. The results from the *ex vivo* study by Kifune *et al* can be extended to predict that restoration of spine segment compliance to normal after a wedge fracture was created would require a 34% decrease in the flexion/extension range of motion and a 34% decrease in the lateral range of motion.[13] This suggests that cement augmentation restores more than one-half of the spine segment stiffness lost due to wedge fracture and shows that the mechanical effect of augmentation is substantial. This partial restoration of normal compliance is not surprising—the soft tissues are likely also damaged when the fracture is produced. Mermelstein *et al*[20] also found that cement augmentation of fractured vertebral bodies had a significant effect on spine segment compliance. These authors studied transpedicular reconstruction of a vertebral body with calcium phosphate cement to reinforce a burst fracture initially stabilized using short segment pedicle screw instrumentation. They found that vertebral body augmentation increased initial stiffness in flexion/extension by 40%, but found no significant differences in torsional stiffness. In contrast with our results, Mermelstein *et al* also found that augmentation had no significant effect on lateral stiffness. This contrast is likely explained by the difference in fracture (burst *versus* wedge) and the fact that these authors tested a segment reinforced by pedicle screw instrumentation, which may have played a prominent role in stabilizing the structure in lateral bending.

In the current study, the compliance reduction provided by direct injection was not found to be significantly different from the compliance reduction provided by reduction/injection. Because the effect size and number of specimens are low, the power of the test to detect this result is too low to state that the effect of the two procedures is equivalent. Using the data from the current study as a predictor of effect size, a statistical analysis projects that results from 600 specimens would be required to show a statistically significant difference ($P < 0.05$, $power > 0.80$) between the two procedures for any one of the compliance parameters (PASS, NCSS, Kaysville, UT). However, the small effect size is unlikely to be clinically significant. The similar compliance reductions achieved with both techniques and the CT and radiographic images of the filled vertebral bodies suggest that the two techniques yield similar patterns of cement filling in the fractured vertebrae.

The improvements in vertebral body height and height ratio produced by cement augmentation suggest that this procedure will help to reduce the deformity associated with compression fractures. In a patient, an increase in vertebral body height ratio from the fractured condition similar to that observed in the treated specimens would reduce a kyphotic deformity. While average height was not restored completely in the tested specimens, this is not surprising and perhaps not desirable due to the extent of damage to the vertebral body caused by the fracture. While these data are promising, it should be noted that assessment of height restoration was not a primary aim of the current study. Further work using more accurate methods to measure vertebral body geometry is required to assess the effect of augmentation procedures on vertebral body height.

It is not clear whether the mechanical changes produced by vertebral augmentation explain the pain relief observed clinically. Kaemmerlen *et al*[12] proposed three hypotheses to explain how augmentation relieves pain:

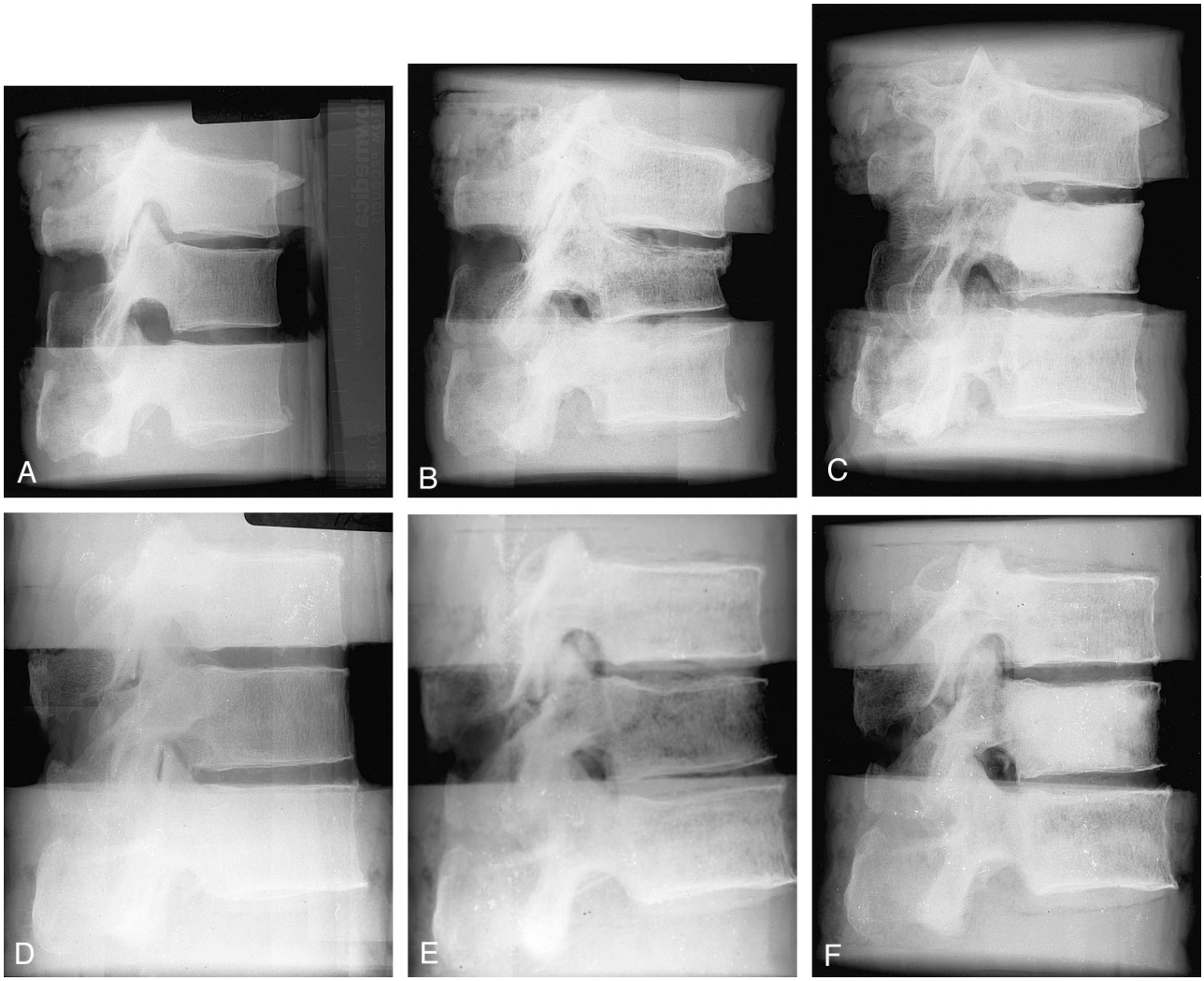

Figure 4. Radiographs of a specimen treated with direct injection: **A,** Intact; **B,** 24 hours after fracture; and **C,** After treatment. A specimen treated with reduction/injection: **D,** Intact; **E,** 24 hours after fracture; and **F,** After treatment.

1. Microfractures in the bone are immobilized by the cement.
2. The cement transmits part of the vertebral load, thereby reducing the load transmitted by healthy bone.
3. Sensory nerve endings in healthy bone are destroyed by the cementation procedure.

The first two hypotheses concern joint mechanics, while the third concerns neurologic function. It is possible that the reduced compliance after augmentation observed in the current study reflects a reduction of the relative movement of the fracture fragments in the augmented vertebra. Bostrom and Lane and Schildhauer *et al* [1,25] showed that augmented vertebrae were significantly stronger in compression than unaugmented specimens, which suggests that the cement transmits part of the compressive load in an augmented vertebral body. While the mechanical evidence does not disprove any of Kaemmerlen's hypotheses, it is not sufficient to prove any of them to be true.

Limitations of this study must be considered when interpreting the results. The full range of spinal loads could not be simulated in this *ex vivo* study. In the active human, the thoracolumbar vertebrae are generally loaded in combined compression and flexion/extension, lateral and axial bending. In this study, the cadaver specimens were loaded with separate "pure" flexion/extension and lateral bending moments. Although this is not a realistic simulation of *in vivo* spine loading, the application of a pure moment to the segment is the most reliable method for assessing compliance.[23] A second limitation of this study is that no axial compression was applied to the spine segments. Compressive load was not simulated because the flexion/extension of spine segments is very sensitive to small changes in the line of action of the compressive force.[27] We concluded during the design of the experiment that the line of action of the compressive force could not be controlled with sufficient accuracy to ensure that flexion/extension moments would not be applied. The omission of compressive load

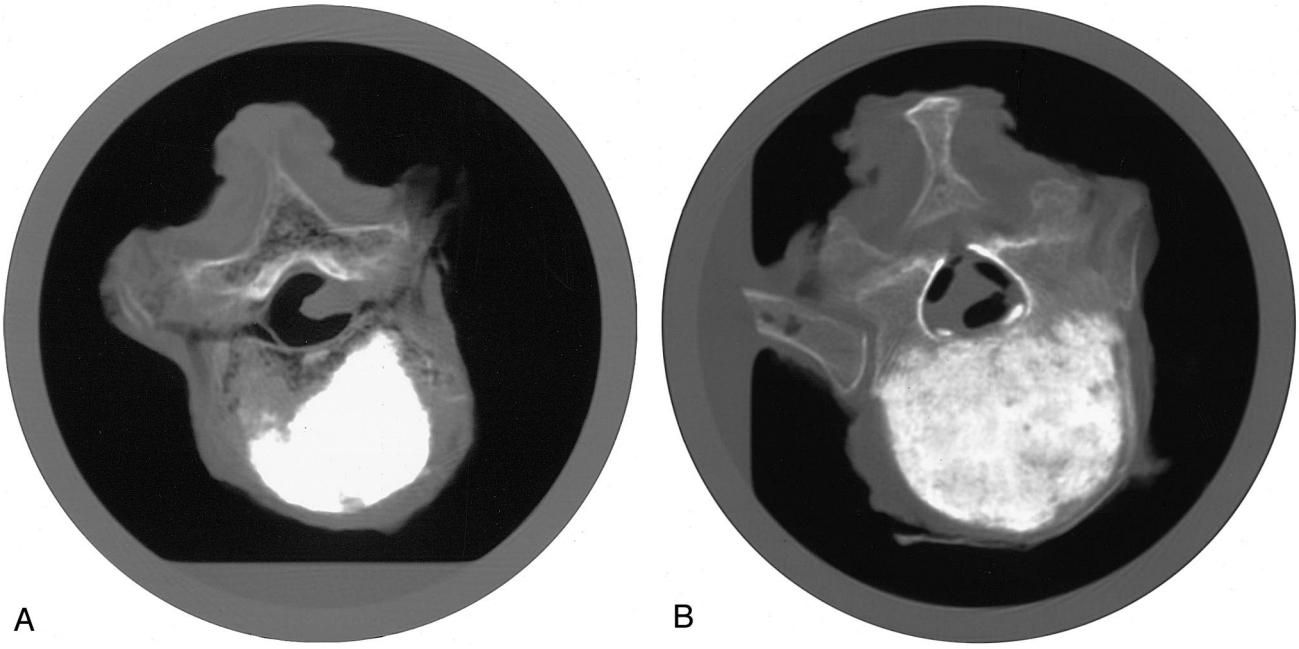

Figure 5. Computed tomography images of the augmented vertebrae: **A,** Central slice of a vertebra augmented using direct injection and **B,** A central slice of a vertebra augmented using reduction/injection.

was justified by Yamamoto *et al*,[30] who showed that spine movement in response to pure moments alone was not significantly different from spine movement in response to combined pure moments and axial compression. A further limitation of this study is that compliance was not assessed in axial rotation. However, because the changes observed in flexion/extension and lateral bending compliance are sufficient to show that augmentation significantly changes vertebral mechanics, this does not affect the conclusions of the study. An additional limitation is that compliance was not assessed in the intact, normal specimens. How closely the compliance of the augmented specimens matches their unfractured levels is not known. However, it may not be possible to assess the compliance of intact osteoporotic specimens due to the risk of fracturing them during loading. It is important to note that restoration of spine segment compliance to normal levels would not guarantee normal function or pain relief. It seems reasonable, in spite of these limitations, to expect that our results will provide insight into the performance of vertebral augmentation *in vivo*.

Additional considerations surround the clinical use of cement augmentation to treat vertebral wedge fractures. The procedure carries the risk of acute complications, including leakage from the vertebral body into the spinal canal during the augmentation process, which may lead to nerve irritation or injury. Leaks have been detected by fluoroscopy[11,28] and CT imaging.[5] Leaks into the epidural tissues, neural foramina, intervertebral disks, venous plexus, and paravertebral tissue are reported in 31% to 72% of clinical augmentation procedures.[5,11,28] However, the incidence of complications is lower. These complications include nondisplaced rib fractures in 2 out of 29 patients treated for osteoporotic compression fractures,[11] nerve root compression requiring decompressive surgery in 2 out of 37 patients, and transitory femoral neuropathy in 1 out of 37 patients treated for metastases and myeloma,[5] and sciatica in 3 out of 37 patients and difficulty swallowing in 2 out of 37 patients treated for metastases.[28] To minimize the risk of complications, the authors of these studies advise careful assessment of fracture severity before augmentation, fluoroscopic control during needle placement and cement injection to monitor leakage (and to immediately stop filling if a leak is detected), performing venography before cement injection, and careful control of cement viscosity.[5,11,28] All clinical results are for direct injection procedures. The reduction/injection procedure may reduce the risk of leakage by allowing the cement to be injected under lower pressure. Studies are underway to assess leakage risk during reduction/injection augmentation.

There are also potential late complications of the procedures. Certainly one of the chief concerns surrounding vertebral augmentation is that, because cement augmentation produces an exothermic reaction near bone, reduces fragment motion at the fracture site, and because cement flows into sites of potential repair, the procedure may hinder bone healing. Bioactive cements currently under development may be useful for augmentation and allow healing of the bone, which is the ultimate aim of fracture stabilization. Additional concerns are that stiffening of the fractured vertebra may put adjacent vertebrae at higher risk of subsequent fracture or degenerative change and that the added weight of material and the exothermic reaction of the curing polymethyl methacrylate (PMMA) may affect the spinal cord and nerve roots.[1]

To date, no clinical evidence of reduced healing, increased fracture risk in adjacent vertebrae, or nerve root or spinal cord damage due to added weight or heat has been reported. However, this area has not been studied extensively. Further studies are needed to determine whether cement augmentation affects bone healing and, if it does, which characteristics of the cement and the procedure have the most substantial effects. These studies, along with clinical investigations, are required to guide the evolving design of augmentation procedures and to minimize the risk of complications.

This study has shown that augmentation of wedge fractures using both direct injection and reduction/injection reduces spine segment compliance significantly, which suggests that both procedures will yield similar clinical benefits. The procedures should be evaluated further as a treatment for painful vertebral compression fractures.

Acknowledgment

The authors thank Jeanine Dulong for her assistance in manuscript preparation.

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