Original Article

Biomechanical Analysis of Range of Motion and Failure Characteristics of Osteoporotic Spinal Compression Fractures in Human Cadaver

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Abstract

Background: Vertebroplasty is a treatment for osteoporotic vertebral compression fractures. The optimal location of needle placement for cement injection remains a topic of debate. As such, the authors assessed the effects of location of two types of cement instillations. In addition, the motion and failure modes at the index and adjacent segments were measured. **Materials and Methods:** Seven human osteoporotic cadaver spines (T1-L4), cut into four consecutive vertebral segments, were utilized. Of these, following the exclusion of four specimens not suitable to utilize for analysis, a total of 24 specimens were evaluable. Segments were randomly assigned into four treatment groups: unipedicular and bipedicular injections into the superior quartile or the anatomic center of the vertebra using confidence (Confidence Spinal Cement System®, DePuy Spine, Raynham, MA, USA) or polymethyl methacrylate. The specimens were subjected to nondestructive pure moments of 5 Nm, in 2.5 Nm increments, using pulleys and weights to simulate six degrees of physiological motion. A follower preload of 200 N was applied in flexion extension. Testing sequence: range of motion (ROM) of intact specimen, fracture creation, cement injection, ROM after cement, and compression testing until failure. Nonconstrained motion was measured at the index and adjacent levels. **Results:** At the index level, no significant differences were observed in ROM in all treatment groups ($P > 0.05$). There was a significant increase in adjacent level motion only for the treatment group that received a unipedicular cement injection at the anatomic center. **Conclusion:** The location of the needle (superior or central) and treatment type (unipedicular or bipedicular) had no significant effect on the ROM at the index site. At the adjacent levels, a significant increase occurred with therapy through a unipedicular approach into the centrum of the vertebra at the treated segment.

Keywords: *Compression fractures, failure characteristics, osteoporotic human cadavers, range of motion, vertebroplasty*

MeSH terms: *Spinal cord injuries, cadaveric, bone cements, biomechanics*

Introduction

The optimal location of needle placement for cement injection into vertebrae with compression fractures remains controversial.[1,2] Much of this controversy stems from the debate that exists regarding the ultimate goal of vertebroplasty. Some studies have indicated that the objective of the procedure should be to fuse the fracture site while others advocate that the primary benefit is restoring the stiffness (and height) of the vertebral body (VB) toward the intact condition.[3,4] For instance, Graham *et al*. have suggested that augmenting the strength and stiffness of the treated segment yields better outcomes.[5] Injecting larger amounts of cement will increase the height and strength of the VBs;[3,6,7] however, this increase will likely surpass the inherent stiffness of the nearby intact levels. In turn, new fractures may be detected at the adjacent levels. Accordingly, several clinical and biomechanical studies have reported that the nontreated adjacent segments tended to fail after vertebroplasty treatment possibly due to the "over stiffening" of the augmented vertebra.[3,8-14]

There is no published study which has assessed the motion at the index level, as well as the adjacent levels after an assortment of vertebroplasty procedures, have been performed to the best of our knowledge. As such, the authors evaluate the effect of the Confidence perimeter system (Confidence Spinal Cement System®, DePuy Spine, Raynham, MA, USA and standard vertebroplasty on the range of motion (ROM) at both the index and the adjacent levels. This study also determines if the location of the needle at the time of cement insertion has an effect at the index and adjacent levels. Lastly

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the authors seek to compare the failure rates of adjacent segments to those of the index levels.

Materials and Methods

Seven osteoporotic thoracolumbar spines (T1-L4) were used for this study. The average age of the donors (2 males and 5 females) was 63.1 ± 8.7 years. The medical history of each donor was reviewed and excluded any specimens with malignancy or metabolic disease that might otherwise compromise the mechanical properties of the spine. Each spine was dual-energy X-ray absorptiometry (DEXA) scanned to eliminate unacceptable specimens and only specimens with lumbar spine T-scores < −2.5 were considered for this study. All the specimens were wrapped in ziplock airtight bags and stored at −20°C until the day of testing.

Specimen preparation

Before testing, all specimens were thawed at room temperature, and any musculature was removed. The ligaments, intervertebral discs, and bony tissues were left intact. Each spine was cut into four segments (T1-T4, T5-T8, T9-T12, and L1-L4). Each specimen was potted using a two-part epoxy resin (Bondo Body Filler Kit, 3M, St. Paul, MN, USA). To improve vertebra-bondo fixation, several 1.25-inch drywall screws were drilled in the cranial and caudal vertebrae during the potting process. The specimens were kept wrapped in saline-soaked gauze throughout testing to prevent dehydration. The third vertebra (T3, T7, T11, or L3) in each potted segment was designated as the index level and received the vertebroplasty treatment. The vertebra immediately rostral to the index segment was designated as the adjacent segment for testing purposes.

Each potted specimen was mounted onto a custom-made kinematic profiler base. Light-emitting diode plates were attached to each VB. To overcome the spine's viscoelastic effect, each specimen was preconditioned in all directions three times before data collection. During testing, nonconstrained, three-dimensional spinal movement at both the index and the adjacent levels was measured using an optical measurement system (Optotrak Certus; Northern Digital, Waterloo, Ontario, Canada). The specimens were subjected to nondestructive pure moments, using a system of pulleys and weights to simulate physiological extension (ext), flexion (flex), left lateral bending, right lateral bending, left axial rotation, and right axial rotation. A pure moment of 5 Nm was applied in increments of 2.5 Nm to each specimen. In addition, after completion of initial testing, a follower preload of 200 N was applied in flexion and extension only. After each load application, the system was allowed to stabilize for at least 30 s to minimize creep.

Follower preload

Using the follower load concept described by Patwardhan *et al*.,[15] a compressive preload of 200 N was applied to the osteoporotic specimens to simulate trunk muscle forces. This follower preload technique is validated only for flexion and extension, and thus, it was applied only in those two testing modes. The compressive preload was applied using the following construct: bilateral cables were attached to the cranial vertebra and passed freely through the cable guides attached to the VBs over the pulleys attached to the caudal vertebra. The path of each cable was adjusted to minimize the angular changes of the specimens' curvature on the application of the follower preload. Each specimen was tested in the following sequence: (1) ROM testing (intact); (2) fracture creation; (3) cement injection; (4) ROM testing postinjection; and (5) compression testing until failure.

All the specimens were initially tested intact. All six loading directions were tested without preload, and flexion extension was additionally tested with a follower preload of 200 N. The ROM at the index, and adjacent levels were recorded throughout the testing.

Fracture technique

To ensure a reproducible fracture at the index level, a defect (void space) was created on the anterior cortical surface of the third vertebra of each potted 4 vertebral segment (T3, T7, T11, or L3). The defect was created using a sagittal saw at the midsection of the vertebra. The defect was created to cover 25% of the total vertebral circumference centered at the anatomic midline anteriorly. The specimens were then mounted on an Enduratec machine (Bose Corporation, Eden Prairie, MN, USA). A compressive flexion load was applied to create fractures on each specimen. Radiographs were obtained to confirm the fracture was created appropriately.

Treatment types

Following exclusion of four spine segments, before testing, which were determined to be unsuitable for testing, the treatment cohort consisted of 24 spine segments that were randomly assigned into four different treatment groups.

a. Single perimeter mesh placed near the superior endplate centrally
b. Single perimeter mesh placed in the midpoint sagittally and coronally
c. Two perimeter mesh bags placed near the superior endplate centrally
d. Bilateral polymethyl methacrylate (PMMA) cement injection using standard vertebroplasty cement.

Cement injection

After simulating the compression fracture, a 13-gauge needle was inserted into the pedicle(s) under fluoroscopic guidance. Perimeter mesh was placed into the bone access needle. Cement was prepared as per the manufacturer's guidelines. Cement was injected into the perimeter mesh (treatment Groups A, B, and C). All the specimens

received cement calculated as 15% of the vertebral volume. The vertebral volumes utilized for these calculations were based on previously published data.[16]

Perimeter mesh system

Confidence Perimeter System® (Depuy Spine, Raynham, MA, USA) is used to complement the Confidence Spinal Cement System® through the use of a porous mesh bag. Use of a mesh bag creates a contained environment for the injected bone cement which yields an even distribution. The mesh bag is placed inside the bone access needle. As the injection is performed, forced movement of the bone cement by the hydraulic pressure system causes the mesh to extrude from the needle and into the injured VB. The bone cement expands the mesh bag and then oozes out of its pores. Once the required amount of cement was injected, the bone access needle(s) was removed from the pedicles along with mesh. Postinjection radiographs were taken to assess the cement distribution.

Cement injection– polymethyl methacrylate

PMMA was injected directly into the needle (treatment Group D). All the specimens received cement calculated as 15% of the vertebral volume. The vertebral volumes utilized for these injections were calculated based on previously published data.[16] Postinjection radiographs were taken to assess the cement distribution.

Postcement injection

After postinjection radiographs were completed, the injected specimens were again assessed in six degrees of freedom without a preload. For flexion and extension testing, motions of flexion and extension were also tested with a 200 N follower preload. ROM at the index and adjacent levels were recorded throughout the testing [Tables 1 and 2]. Specimens were then mounted on the Enduratec machine and compressive loads were applied to each specimen until failure. Most specimens failed well before the Enduratec maximum load limit of 5000 N. Radiographs were repeated to confirm fracture levels.

Results

Overall, no significant differences in the ROM at the index levels were observed ($P > 0.05$). Further analysis of the index levels indicated there were no significant differences in the ROM after cement injection either by unipedicular (treatment Groups A and B) or bipedicular approaches (treatment Groups C and D). Moreover, placement of the needle unipedicularly near the superior endplate (treatment A) or toward the center of the vertebrae (treatment B) did not demonstrate any significant differences with regard to the ROM.

There was a significant increase in the ROM at the adjacent level only for treatment Group B in extension without preload and flexion with and without preload ($P < 0.05$). There were no significant differences in the ROMs in the other three Groups (A, C, and D). The treatment groups consisted of specimens belonging to the different levels of the spine (T1-T4 through L1-L4). ROM varies depending on the level of the spine. Lumbar segments will have more motion compared to those in upper thoracic spine. This may be a possible explanation for the lack of any significant changes in the ROM in the treatment groups. Differences may have been suppressed or confounded by different ROM of the specimens within each treatment group.

During compression testing until failure, nine specimens had fractures at the adjacent level, and 13 had fractures at the index level. Index level fractures occurred either at the original fracture site, which was created with the sagittal saw or at a new location while most specimens failed well before the materials testing device maximum load limit of 5000 N, two specimens did not ultimately fracture.

Table 1: Normalized to the intact motion at the index level with and without preload

Treatment group	Extension	Flexion	LB	RB	LR	RR	Extension with preload	Flexion with preload
Intact	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
A	139.1	133.6	81.0	80.8	72.5	83.1	149.7	99.7
B	89.6	96.9	104.0	114.2	105.4	109.7	125.9	103.2
C	105.8	105.6	115.9	112.5	95.6	123.0	86.6	87.5
D	133.0	108.1	98.6	89.6	129.6	96.7	92.6	112.8

LB=Left lateral bending, RB=Right lateral bending, LR=Left axial rotation, RR=Right axial rotation

Table 2: Normalized to the intact motion at the adjacent level with and without preload

Treatment group	Extension	Flexion	LB	RB	LR	RR	Extension with preload	Flexion with preload
Intact	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
A	155.3	154.7	159.0	120.5	160.8	127.1	145.9	137.5
B	162.2	152.7	123.4	154.2	185.4	151.9	115.3	125.9
C	133.7	182.1	124.6	125.2	206.7	129.6	133.7	182.1
D	92.2	124.1	106.2	137.7	104.7	108.0	149.8	146.9

LB=Left lateral bending, RB=Right lateral bending, LR=Left axial rotation, RR=Right axial rotation

Discussion

This study compared the ROM of both the index and the adjacent vertebral levels following vertebroplasty using PMMA versus Confidence cement (with perimeter mesh). The results indicated that no significant increase in the ROM occurred (after the cement injection) at the implanted level in any of the treatment groups. Similar to our findings, Steinmann *et al*. reported that unipedicular kyphoplasty was comparable to bipedicular kyphoplasty in restoring the strength and stiffness of the VBs.[17] Moreover, Tohmeh *et al*. and Higgins *et al*. performed testing assessing the biomechanical efficacy of VBs after cement injection using both the unipedicular and bipedicular approaches. Their results showed that although the bipedicular approach was significantly stronger than the unipedicular approach, both groups were significantly stronger than intact.[18,19] Overall, as supported by the results of our study and a review of the literature, a unipedicular approach may be adequate to treat vertebral compression-related fractures and restore strength and stiffness to the index levels.

Numerous reports cite that the adjacent segments tend to fail after vertebroplasty treatment due to the "over-stiffening" of the augmented vertebra.[3,8-14] Boger *et al*. performed percutaneous vertebroplasty in a cadaveric study on functional spinal units (FSUs) using two types of PMMA (regular PMMA and low modulus PMMA).[20] Low modulus PMMA resulted in lower adjacent fractures compared with regular PMMA. It follows that the strength of the diseased spine could be preserved with low-modulus cement compared to regular cement. Uppin *et al*. and Fribourg *et al*. showed that fractures at the adjacent levels occur much sooner than at more remote nonadjacent levels.[13,21] Trout *et al*. followed 432 patients who were treated by percutaneous vertebroplasty, of which, 86 patients (19.9%) had 186 new vertebral fractures. Forty one percent of these new fractures occurred at the adjacent level. Consequently, the authors concluded that the relative risk of adjacent level fracture was 4.62 times to that of the more remote, nonadjacent levels.[22] In this study, we tested all the specimens in compression to see if the adjacent segment fails before the cemented segment. Of the 24 specimens tested, 9 specimens had new fractures at the adjacent level (37.5%), and 13 specimens (54.2%) had new fractures at the index vertebral site. The remaining 2 specimens (12.5%) did not fracture either at the index or adjacent levels.

Limitations of this study include limited sample size for both sample and interventions. This is due to the need to obtain osteoporotic specimens and confirm the diagnosis with DEXA testing. Given sample limitations, our methodology included comparisons of thoracic and lumbar spine ROMs. However, as noted above, the ROM varies depending on the level of the spine, and therefore, our ability to detect differences may have been affected. Similarly, with multiple intervention arms, a larger sample size could be employed in the future studies.

Conclusion

The optimal location of needle placement for cement injection into vertebrae has been an ongoing debate. In this study, the location of the needle (superior versus central) or unipedicular versus bipedicular had no significant difference in ROM at the index level. A significant increase in ROM was observed at the adjacent levels only for treatment Group B (unipedicular injections) in extension without preload and inflexion with and without preload. Therefore, the authors caution that adjacent levels may be affected with therapy instituted through a unipedicular approach into the centrum of the index segment.

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Conflicts of interest

There are no conflicts of interest.

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