Double Cement–Application Cavity Containment Kyphoplasty: Technique Description and Efficacy

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Abstract

Kyphoplasty is an effective surgical treatment for the pain and deformity that can accompany vertebral compression fractures. In certain cases, however, defects or clefts in the vertebral body result either from the original fracture or from expansion of inflatable bone tamps (IBTs). Through such a defect, cement may extrude into the epidural space, paraspinal soft tissues, or disc space. In addition, by virtue of the dynamic nature of certain fracture configurations, the height restored by inflation of the bone tamps may be lost once the tamps are removed for cement placement, despite patient positioning.

In our modification of the kyphoplasty technique, we use 2 cement applications to minimize potential extravertebral cement extravasation and maintain the height restoration achieved with the IBTs. After 0.75 to 1.5 cm^3 of cement is deposited, the IBTs are reinserted into the fracture and inflated until the cement cures. Once the cement is cured, the IBTs are again deflated and removed, leaving a cement shell that seals the cracks and supports the endplates. Then, another batch of cement is mixed and is used to fill the cavities, as in the standard technique.

Results for our first 21 patients show a mean correction of more than 6° of kyphosis and no cement leaks into the spinal canal. We believe that this modification of the kyphoplasty technique is effective and safe for certain fractures.

Osteoporotic and osteolytic compression fractures can result in progressive kyphosis and chronic pain. The traditional treatment for these fractures is bed rest, analgesics, and bracing. Augmentation of vertebral compression fractures with polymethylmethacrylate (PMMA) bone cement, or vertebroplasty, has been used to treat pain[1-3] but does not restore the height of the collapsed vertebral body and is associated with higher rates of cement leakage.[2,4-6] Another technique, kyphoplasty, introduces inflatable bone tamps (IBTs) into the vertebral body.[7,8] Once inflated, the bone tamps restore the vertebral body back toward its original height while creating a cavity that can be filled with bone cement.

In certain cases, defects or clefts in the vertebral body result either from the original fracture[9,10] or from expansion of the IBTs. Through such a defect, cement may extrude into the epidural space, paraspinal soft tissues, or disc space. In addition, by virtue of the dynamic nature of certain fracture configurations, the height restored by inflation of the bone tamps may be lost once the tamps are removed for cement placement, despite positioning of the patient prone on a Jackson frame with upper thoracic and pelvic bolsters, which tend to have a lordosing effect on the spine.

In our modification of the kyphoplasty technique, we use 2 cement applications to minimize potential extravertebral cement extravasation and maintain the height restoration achieved with the IBTs when treating the more unstable fractures.

> **"The technique...allows for added control over cement application in cases in which vertebral body defects are known or suspected."**

Materials and Methods

Patient Population

From our institution's kyphoplasty database, we retrospectively reviewed and analyzed the cases of 21 consecutive patients who had undergone the double cement–application cavity containment modification. The decision to use this technique on each of these patients had been made during surgery on the basis of what happened to the vertebral endplates under fluoroscopy when the IBTs (Kyphon, Inc, Sunnyvale, Calif) were deflated after achieving the desired

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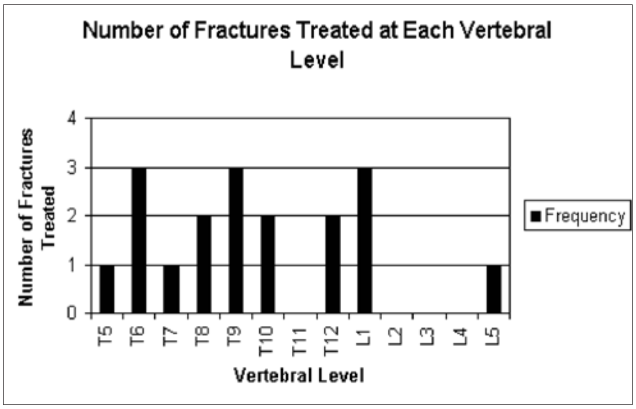

Figure 1. Number of fractures treated per level in the 15 patients with preoperative and postoperative standing radiographs available for review.

amount of expansion. When there was a visible loss of reduction under fluoroscopy with IBT deflation, then the double-cement application modification was used. Similarly, when the IBTs were noted as breaching an endplate or wall, then the technique was used to prevent the cement leakage that had been noted to happen in a similar group of patients in the past. All patients were under general anesthesia, except for 2 under local anesthesia because of poor pulmonary function that precluded a general anesthetic. All procedures were done with the patient in the prone position on a Jackson table with supports under the upper part of the chest, iliac crests, thighs, knees, and distal tibias.

The perioperative variables, including premorbid condition and fracture configuration, were analyzed. We also analyzed the intraoperative records and fluoroscopic images and postoperative variables to assess the outcome and any adverse effects of this technique. The radiographs were almost never centered on the affected level because they were standard, upright lateral radiographs of the entire thoracic spine and were often of poor quality because of the patient's osteoporosis. Therefore, endplate heights often could not be accurately measured—a problem documented in the literature.[11] However, because the goals of kyphoplasty are to restore spine alignment and to control pain, the local kyphosis angles were measured from preoperative and postoperative standing lateral radiographs. Depending on the quality of the images, the angles were measured off the endplates of the vertebral bodies above and below the fracture, or off the anterior or posterior walls of those adjacent bodies. The same technique was used on the preoperative and postoperative radiographs of all patients. The standing radiographs taken nearest the surgery date and the first available postoperative standing radiographs (usually 2-6 weeks) were used. Significance was measured with the Student *t* test.

Kyphoplasty Technique

IBT placement involves identifying an extrapedicular or transpedicular entry point into the vertebral body using a guide pin and biplanar fluoroscopy. The next step is placing a cannulated obturator over the guide wire. The obturator is then tapped into the bone over the guide wire. A working cannula is placed over the obturator and advanced until the tip of the cannula is seated in the posterior portion of the vertebral body. A hand-mounted drill bit is then used to ream a corridor through which the IBT will be passed. IBTs are ideally situated under the collapsed endplate on the lateral radiograph. Inflation is performed slowly, under fluoroscopy, as are guide wire, obturator, and cannula placement. An in-line pressure gauge is used to closely monitor the inflation pressure of the tamp during inflation. Inflation

Table. Patients Who Underwent the Double Cement–Application Cavity Containment Kyphoplasty Technique[a]

		Kyphosis Angle (°)						
Patient	Sex	Preoperative	Postoperative	Change	Level(s) Operated On	Fracture Configuration	Approach	Vertebral Body Breach
1	F	65	62.5	2.5	L5	Biconcave	Bilateral	Superior endplate
2	M	55	52	3	T5, T6, T8	Biconcave/wedge/planae	Bilateral × 3	—
3	F	27	22	5	T9, T10	Biconcave/wedge	Bilateral, unilateral	Endplate
4	M	39	20	19	T12	Wedge	Bilateral	Anterior wall
5	F	38	22	16	L1	Wedge/pseudo	Bilateral	—
6	F	25	18	7	T12	Wedge/pseudo	Bilateral	—
7	M	35	28	7	T6	Wedge	Unilateral	Lateral wall
8[b]	F	5	5	0	L1	Wedge	Unilateral	Endplate
9	F	22	18	4	T7	Wedge	Unilateral	Anterior wall
10[b]	F	34	31	3	T6	Wedge	Bilateral	Lateral wall
11[b,c]	F	10	6	4	T8	Wedge	Unilateral	Lateral wall
12	F	6	6	0	T10	Wedge	Bilateral	Endplate
13	F	26	10	16	L1	Wedge	Bilateral	—
14	F	8	6	2	T9	Wedge	Bilateral	—
15	F	11	5	6	T9	Wedge/pseudo	Bilateral	—
16[b]	F	—	—	—	T8	—	Unilateral	Endplate
17	F	—	—	—	T6, T11	—	Bilateral × 2	—
18	M	—	—	—	L1	—	Bilateral	—
19[b]	F	—	—	—	L4	—	Bilateral	Anterolateral
20	M	—	—	—	L4	—	Bilateral	—
21[c]	M	—	—	—	L1	Concave	Bilateral	—

[a]Only patients 1 through 15 had adequate preoperative and postoperative radiographs for review.
[b]Underwent cavity containment technique for significant breach, not for loss of reduction.
[c]Had multiple myeloma.

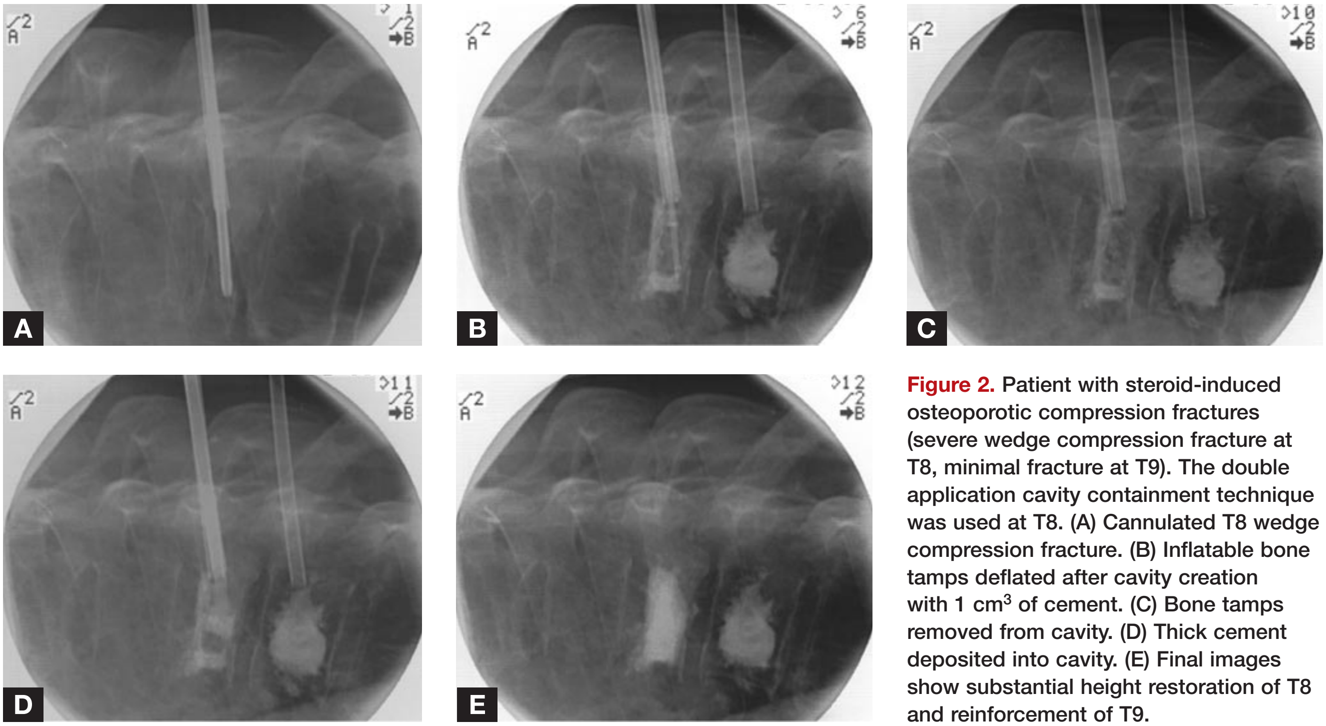

Figure 2. Patient with steroid-induced osteoporotic compression fractures (severe wedge compression fracture at T8, minimal fracture at T9). The double application cavity containment technique was used at T8. (A) Cannulated T8 wedge compression fracture. (B) Inflatable bone tamps deflated after cavity creation with 1 cm^3 of cement. (C) Bone tamps removed from cavity. (D) Thick cement deposited into cavity. (E) Final images show substantial height restoration of T8 and reinforcement of T9.

is continued up to a maximum pressure of 220 psi, or until the maximum balloon volume is reached. Inflation should also be stopped when the balloon abuts any of the cortical margins. When a suitable cavity has been prepared and the maximum possible reduction achieved, the PMMA, cement augmented with barium, is mixed. Smaller bone filler cannulae, which fit inside the working cannula, are filled with cement. Before application, the cement is allowed to thicken. A 2-cm^3 bolus of cement is repeatedly suspended from a wooden spatula, and, when the viscosity is such that the cement does not fall from the spatula, it is ready for injection. The IBT is removed, the bone filler cannula is advanced through the working cannula to the anterior vertebral body wall, and cement is slowly extruded using a stainless steel stylet, which acts as a plunger. Filling is performed under continuous lateral fluoroscopic guidance. Use of the stylet and bone filler cannula allows cement to be applied at considerably higher viscosity than is possible with injection through a 5-cm^3 syringe and an 11-gauge needle. Cement filling is stopped when the cement mantle reaches two thirds of the way back to the posterior vertebral body cortex on the lateral fluoroscopic images. How many bone filler cannulae need to be prepared is estimated from the final inflation volume achieved with the IBTs. Often the volume of cement applied is 0.5 to 1 cm^3 more than the final inflation volume, allowing cement from the central bolus to interdigitate with the surrounding bone. Once the cement has cured, the cannulae are removed.

Cavity Containment Modification

In vertebral bodies with clefts or defects in their walls or endplates, and in vertebral bodies that are so unstable that height restoration is lost on balloon removal, an initial batch of cement is mixed and prepared for application into the cavity. A bolus of 0.75 to 1.5 cm^3 of cement is deposited into the cavity and the IBT reinserted. The IBT is inflated to 1 cm^3 less than the volume achieved during initial inflation. The cement is allowed to fully cure or harden, as determined by the extra cement on the back table. Once cured, the IBTs are again deflated and removed, leaving a shell of cement that seals the cracks and supports the endplates. A second batch of cement is then mixed, and the cavities are filled with cement, as in the standard technique. The same procedure can also be accomplished with a large batch of cement instead of two smaller batches by placing cement-filled cannulae for the second phase in a cold water bath to retard the chemical reaction until the first phase is complete.

The PMMA cement does not adhere to the balloon, and the heat of polymerization does not damage the balloon, but care must be taken to ensure that no cement is forced back up the working cannula while the first batch of cement is curing. Cement in the working cannula may hinder smooth removal of the balloon. Should this happen, tapping the working cannula and advancing it into the shell will crack the thin layer of cement, and then the entire cannula with deflated balloon can be pulled out together. A new working cannula is then inserted into the tract, and the procedure is completed as described earlier.

Results

Twenty-one (15 female, 6 male) patients underwent the double injection procedure at 26 levels (Table). Of these 21 patients, 19 had either idiopathic or steroid-induced osteoporotic vertebral compression fractures, and 2 had multiple myeloma. The treated levels were L5 (n = 1), L4

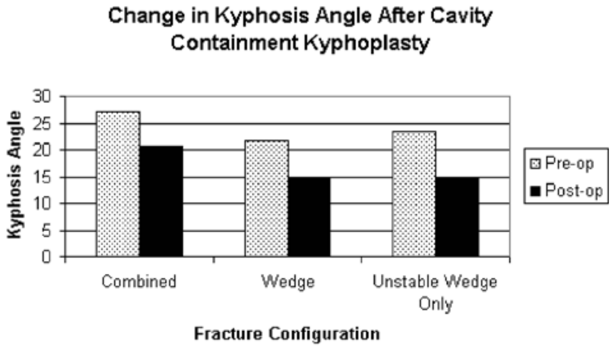

Figure 3. Reduction of kyphosis angle after double injection cavity containment modification for all fracture types combined, all wedge-shape fractures alone, and only wedge-shape fractures unstable after balloon deflation (*P*s = .001, .003, and .005, respectively).

(n = 2), L1 (n = 5), T12 (n = 2), T11 (n = 1), T10 (n = 3), T9 (n = 3), T8 (n = 3), T7 (n = 1), T6 (n = 4), and T5 (n = 1) (Figure 1). Twenty levels were treated using a bilateral approach, and 6 levels using a unilateral approach. At 24 levels, a double cement–application technique was used (Figures 2A–2E). At 2 levels, 3 cement applications were performed; the IBT was reinserted and reexpanded after the first 2 applications.

At 10 levels, the vertebral body was breached during initial IBT expansion. There were 2 anterior wall, 3 lateral wall, 1 anterolateral, and 3 endplate breaches. However, only 5 of these levels were stable after balloon tamp deflation. These levels underwent the cavity containment technique to prevent a leak rather than maintain the correction that had been achieved. There were 2 endplate and 3 lateral wall breaches. In no case was there evidence of cement leak into the spinal canal, and there were no complications resulted from this technique.

Height Restoration

Preoperative and postoperative standing radiographs were available for 15 of the 21 patients who underwent the double cement–application cavity containment technique at 18 levels: L5 (n = 1), L1 (n = 3), T12 (n = 2), T10 (n = 2), T9 (n = 3), T8 (n = 2), T7 (n = 1), T6 (n = 3), and T5 (n = 1). Thirteen levels were treated using a bilateral approach, and 5 levels using a unilateral approach. At 16 levels, the double cement–application technique was used. At 2 levels, 3 cement applications were performed; the IBT was expanded after the first 2 applications. In 1 case, this triple injection was used to maintain height restoration and progressively stabilize the vertebral body pseudarthrosis. In this subset of patients, there were 2 anterior wall, 3 lateral wall, and 3 endplate breaches with the balloon tamp. In this group of 15 patients, only 3 levels, in 3 separate patients, had the cavity containment procedure performed to treat the breach rather than to prevent loss of reduction.

Thirteen fractures were wedge-shape compression fractures, 3 were biconcave, and 1 was a true vertebrae planae. After the procedure was used to restore some of the lost anterior column height, the mean kyphotic angle decreased 6.3°, from 27.1° to 20.8°, after the double cement–application cavity containment technique (*P* = .001), when comparing the preoperative standing radiographs with the postoperative ones. When only the wedge-shape fractures were analyzed, the mean correction increased to 7.0°, from 14.6° to 21.6° (*P* = .003). When the 3 patients who underwent the cavity containment technique for a breach rather than for fracture instability were removed from the correction analysis, the mean correction for wedge-shape fractures increased to 8.6°, from 14.7° to 23.3° (*P* = .005) (Figure 3).

Discussion

The double cement–application cavity containment technique is an effective modification of the kyphoplasty procedure for maintaining vertebral height in the event that the height gained by IBT is lost with balloon deflation. Such height loss often occurs in unstable wedge-shape fractures, vertebrae planae, and compression fractures with a cleft and pseudarthrosis. We have shown that use of the double application technique can restore height and significantly reduce the preoperative kyphosis in these unstable fractures, despite sidewall or endplate defects. The double–application technique is also useful when sidewall cracks may lead to cement leakage. We acknowledge that it would have been desirable to have intraoperative images for all our patients documenting the height loss that occurred with IBT deflation in these unstable patterns. However, surgeons who often use IBTs and are well aware of the reduction loss and leaks that can occur will find our modification very useful.

McKiernan and colleagues[11] reported up to a 4-fold error when measuring apparent height restoration (depends on reporting method and fracture severity). In our study population, lateral radiographs were not centered on the levels in question; many of the patients were obese and had osteoporosis, making it difficult to visualize the endplates; many fractures were severe; and the endplates were uneven—all of which made it difficult to accurately measure how much each endplate was elevated. Therefore, we chose to measure local kyphosis angle as a way to assess for height restoration. We do not view this as a weakness of the study because one of the goals of kyphoplasty, in addition to pain control, is reduction of kyphosis and the return to normal sagittal anatomy. With improvement in the mechanical axis of the spine, there should be less pain secondary to muscle, joint, and ligament strain, as well as decreased incidence in further compression fractures compared with a more kyphotic spine.

Interestingly, some patients, such as the patient whose radiographs appear in Figure 2, had a very dramatic change in kyphosis angle on the operating table but lost much of the postural change on the follow-up radiograph, despite the lengthened anterior column. This may imply that posterior ligamentous laxity from prolonged, severe kyphosis may cause patients to retain much of their kyphotic angle even after the anterior column is improved, and that we should be correcting patients early in the course of their illness.

One weakness of this retrospective clinical series is that we did not have a control population of patients who had a noticeable loss of height with balloon deflation during the procedure and who did not later undergo the double cement–application cavity containment modification. Although having such a population would be desirable experimentally, it would be unethical for us to conduct a prospective, randomized study that denies our double cement–application modification to patients who incur collapse with balloon deflation, given the impressive differences in vertebral height under fluoroscopy before and after the procedure. It would also have been desirable to include preoperative and postoperative standing radiograph data for all 21 patients instead of only 15. In a busy, tertiary-care center, however, some patients were treated with initial radiographs from other institutions, and these radiographs did not always remain with the patients' records after treatment, or the patients did not travel long distances for follow-up and therefore were unavailable for data collection.

Conclusions

The double–application cavity containment kyphoplasty technique modification allows for added control over cement application in cases in which vertebral body defects are known or suspected. The modification also allows the surgeon to maintain height in cases in which the fracture configuration leads to a visible loss of correction under fluoroscopy on balloon tamp removal. The procedure appears safe, as we found no evidence of cement extravasation into the canal with this technique in our initial experience.

Authors' Disclosure Statement

Dr. Lieberman wishes to note the following: He is a founder, inventor, board member, and holds a management position with Merlot OrthopediX, Inc. He is a paid consultant, teacher, speaker, inventor, and member of the advisory committee and review panel for Axiomed Spine Corporation and Trans1, Inc. He is a paid consultant, inventor, and member of the advisory committee and review panel for CrossTrees Medical, Inc. He is a paid consultant, inventor, and member of the advisory committee and review panel for Mazor Surgical Technologies. He is an inventor with Stryker Spine. He is a laboratory investigator, mentor, and research supervisor with Medtronic, Inc., Baxano, Inc., and Orthovita, Inc.

Dr. DalCanto and Ms. Reinhardt report no actual or potential conflict of interest in relation to this article.

References

1. Galibert P, Deramond H, Rosat P, Le Gars D. Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty [in French]. *Neurochirurgie.* 1987;33(2):166-168.
2. Jensen ME, Evans AJ, Mathis JM, Kallmes DF, Cloft HJ, Dion JE. Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. *AJNR Am J Neuroradiol*. 1997;18(10):1897-1904.
3. Bai B, Jazrawi LM, Kummer FJ, Spivak JM. The use of an injectable, biodegradable calcium phosphate bone substitute for the prophylactic augmentation of osteoporotic vertebrae and the management of vertebral compression fractures. *Spine.* 1999;24(15):1521-1526.
4. Barr JD, Barr MS, Lemley TJ, McCann RM. Percutaneous vertebroplasty for pain relief and spinal stabilization. *Spine.* 2000;25(8):923-928.
5. Heini PF, Wälchli B, Berlemann U. Percutaneous transpedicular vertebroplasty with PMMA: operative technique and early results. A prospective study for the treatment of osteoporotic compression fractures. *Eur Spine J*. 2000;9(5):445-450.
6. Barr JD. In discussion of: Phillips FM, Todd Wetzel F, Lieberman I, Campbell-Hupp M. An in vivo comparison of the potential for extravertebral cement leak after vertebroplasty and kyphoplasty. *Spine.* 2002;27(19):2173-2178.
7. Lieberman IH, Dudeney S, Reinhardt MK, Bell G. Initial outcome and efficacy of "kyphoplasty" in the treatment of painful osteoporotic vertebral compression fractures. *Spine.* 2001;26(14):1631-1638.
8. Dudeney S, Lieberman IH, Reinhardt MK, Hussein M. Kyphoplasty in the treatment of osteolytic vertebral compression fractures as a result of multiple myeloma. *J Clin Oncol.* 2002;20(9):2382-2387.
9. McKiernan F, Faciszewski T. Intravertebral clefts in osteoporotic vertebral compression fractures. *Arthritis Rheum.* 2003;48(5):1414-1419.
10. McKiernan F, Jensen R, Faciszewski T. The dynamic mobility of vertebral compression fractures. *J Bone Miner Res.* 2003;18(1):24-29.
11. McKiernan F, Faciszewski T, Jensen R. Reporting height restoration in vertebral compression fractures. *Spine.* 2003;28(22):2517-2521.