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The Spine Journal 7 (2007) 575–582

THE SPINE JOURNAL

Percutaneous vertebral augmentation: an elevation in adjacent-level fracture risk in kyphoplasty as compared with vertebroplasty

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Received 21 May 2006; accepted 29 October 2006

Abstract

BACKGROUND CONTEXT: Osteoporotic vertebral compression fractures (VCFs) are being increasingly treated with minimally invasive bone augmentation techniques such as kyphoplasty and vertebroplasty. Both are reported to be an effective means of pain relief; however, there may be an increased risk of developing subsequent VCFs after such procedures.

PURPOSE: The purpose of this study was to compare the effectiveness and complication profile of kyphoplasty and vertebroplasty in a single patient series.

STUDY DESIGN/SETTING: A clinical series of 36 patients with VCFs treated by vertebral augmentation procedures was retrospectively analyzed for surgical approach, volume of cement injected, cement extravasation (symptomatic and asymptomatic), the occurrence of subsequent adjacent level fracture, and pain relief.

PATIENT SAMPLE: Thirty-six patients with 46 VCFs underwent either kyphoplasty or vertebroplasty after failing conservative therapy. The mean patient age was not significantly different between the kyphoplasty group (70; range, 46–83) and vertebroplasty group (72; range, 38–90) ($p=.438$).

OUTCOME MEASURES: Outcomes were assessed by using self-report measures (a comparative pain rating scale) and physiologic measures (pre- and postoperative radiographs).

METHODS: Thirty-six patients with VCFs underwent 46 augmentation procedures (17 patients had 20 fractures treated via kyphoplasty, and 19 patients had 26 fractures treated via vertebroplasty). Seventeen patients in this series underwent kyphoplasty using standard techniques involving bone void creation with balloon tamps, followed by cement injection. Nineteen patients underwent a percutaneous vertebroplasty procedure using a novel cannulated, fenestrated bone tap developed to direct cement anteriorly into the vertebral body to avoid backflow of cement onto neural elements.

RESULTS: Pain improvement was seen in >90% of patients in both groups. Mean cement injection per vertebral body was 4.65 mL and 3.78 mL for the kyphoplasty and vertebroplasty groups, respectively ($p=.014$). Ninety-five percent of the kyphoplasty procedures were performed bilaterally, whereas only 19% of the vertebroplasty procedures required bilateral augmentation ($p<.001$). There was no cement extravasation resulting in radiculopathy, or myelopathy in either group. Asymptomatic cement extravasation was seen in 5 of 46 (11%) of the total series (3/20 [15%] and 2/26 [7.7%] of kyphoplasty and vertebroplasty, respectively) ($p=.696$). Within a 3-month period, there were 5 new adjacent level fractures seen in 3 patients who underwent a kyphoplasty procedure (5/20 [25%]) and none in the vertebroplasty group ($p<.05$).

CONCLUSIONS: Vertebroplasty appears to offer a comparable rate of postoperative pain relief as kyphoplasty while using less bone cement more often via a unilateral approach and without the attendant risk of adjacent level fracture.

Keywords: Osteoporosis; Spinal fracture; Polymethylmethacrylate; Vertebroplasty; Kyphoplasty; Adjacent-level fracture

FDA device/drug status: approved for this indication.

Authors acknowledge a financial relationship (Abbott Spine), which may indirectly relate to the subject of this research.

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1529-9430/07/$ – see front matter
doi:10.1016/j.spinee.2006.10.020

Introduction

In the United States, approximately 1.5 million fractures annually are attributable to osteoporosis with approximately 700,000 occurring in the spine [1]. Because of our aging population, the frequency of osteoporotic fractures is increasing necessitating improved preventative as well as safe and effective surgical strategies.

Vertebral fractures compression fractures (VCFs) can result in intractable pain [2], progressive deformity, reduced pulmonary function [3,4], sleep disorders [2], weight loss [2], impaired function, and decreased quality of life [5], ultimately resulting in increased morbidity and mortality [6]. As such, VCFs are being more aggressively treated with minimally invasive techniques using bone cement such as polymethylmethacrylate (PMMA) both with (balloon kyphoplasty) [7–14] and without (vertebroplasty) [7,15–26] attempts at fracture reduction.

The use of PMMA in balloon kyphoplasty and vertebroplasty must be done with caution because of a number of potential serious complications that may occur with intraosseous injection of bone cement. The risk of extraosseous PMMA leakage in various series ranged between 3% and 74% [17,19,25,27–31], with resultant neurological deficits such as radiculopathy and cord compression occurring in 0% to 3.7%, and 0% to 0.5%, respectively [32–35]. Additionally, there appears to be an increased incidence of adjacent-level fractures after PMMA vertebral body augmentation procedures, possibly related to an increase in the stiffness of treated vertebra [36,37] or some other poorly defined underlying etiology [38]. The risk of subsequent fracture occurrence appears to be greater in kyphoplasty [39,40] than vertebroplasty [41]; however, this question has not been previously addressed in a single series. Here we present a series of 36 patients with VCFs that underwent 46 augmentation procedures, 20 kyphoplasty and 26 vertebroplasty. Vertebroplasties were performed with a new technique for cement delivery, a fenestrated bone tap system. The technique, complications, and clinical results of each procedure are compared.

Materials and methods

Over a 3.5-year period, the clinical and radiographic results of 36 patients with osteoporotic compression fractures were reviewed. All patients had undergone a vertebral augmentation procedure by the senior author (BMF) as an outpatient procedure and were followed for a minimum of 6 months postoperatively. Plain X-ray films were obtained routinely at 1 and 3months postoperatively or if they developed new onset or worsening of back pain. Patients were taking alendronate, vitamin D, and calcium at the time of referral or were started shortly thereafter. The first 17 patients in this series underwent kyphoplasty (Kyphon, Sunnyvale, CA) using standard techniques described elsewhere [8,10,42–45]. The subsequent 19 patients underwent a percutaneous vertebroplasty procedure using the Pedestal fenestrated tap system (Abbott Spine, Austin, TX) (Fig. 1). Simplex Bone Cement (Stryker Instruments, Kalamazoo, MI) supplemented with additional barium sulfate powder for added radio-opacity was used in all 36 patients.

The vertebroplasty procedure is described as follows. By using standard operative techniques, a targeting needle was directed into appropriate pedicles using biplanar

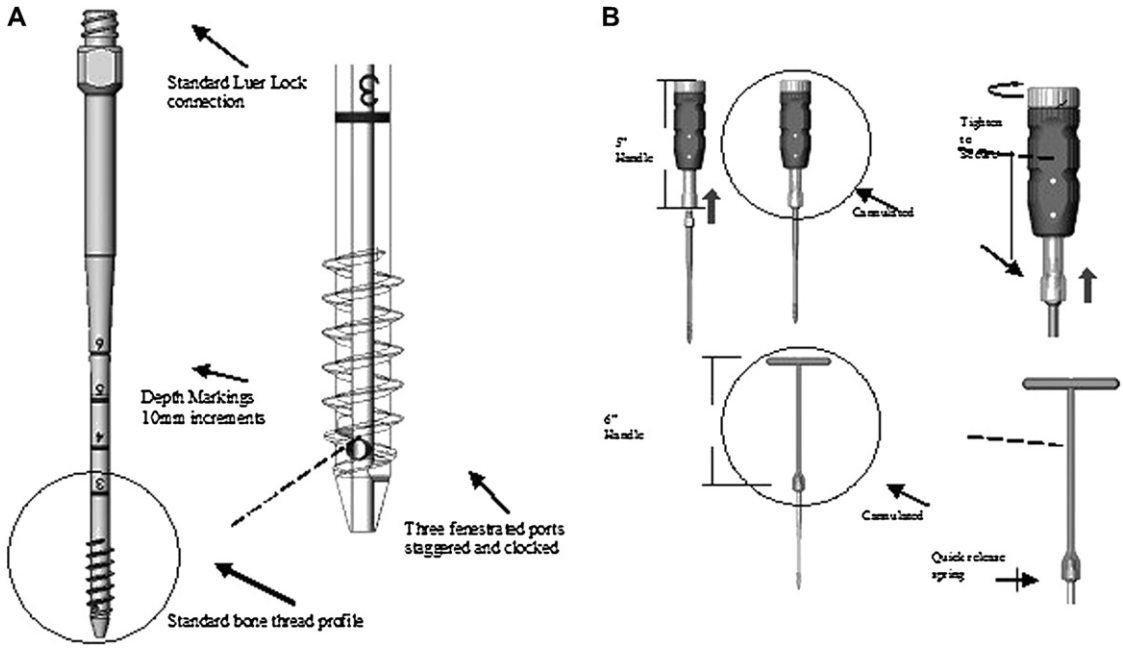

Fig. 1. Fenestrated bone tap (A) and tap handles (B) used for vertebroplasty.

fluoroscopy (OEC Workstation; GE, Chalfont, St. Giles, UK). A K-wire was subsequently placed and the targeting needle removed. Harmony serial tissue dilators (Abbott Spine, Austin, TX) were placed. The inner dilator was removed, leaving the smallest flanged dilator as the working port. The Pedestal bone tap was placed over the K-wire and threaded into the anterior one third of the vertebral body (Fig. 2). The K-wire was removed, and the bone tap was flushed with 3 to 5 mL of saline into the vertebral body. Bone cement supplemented with added barium was mixed according to the manufacturer's recommendations; 1.5 to 5 mLs of cement was injected by using a 10-mL Luer-Lok syringe (BD, Franklin Lakes, NJ), and monitored during continuous lateral fluoroscopy (Fig. 2). Cement was injected via a unilateral approach until filling across midline to the contralateral side was shown on spot anteroposterior (AP) fluoroscopy (Fig. 2). If there was no filling across midline, a tap was then placed into the contralateral side, and the procedure was repeated. The bone tap was then removed.

Outcome measures

Patient outcomes were assessed by using self-report measures (a comparative pain rating scale) and physiologic measures (pre- and postoperative radiographs). As previously suggested, a simple outcome assessment was used to quantify the impact of treatment on patients' lives instead of relying solely on numeric pain scales [46]. A comparative pain score, obtained 7 to 10 days after the procedure, was used to account for pre- and postoperative morbidity (pain score: 1=no pain/no analgesics, 2=reduced pain/taking analgesics, 3=no change in pain postoperatively, and 4=worse pain postoperatively). This simple outcome assessment was used because it has been suggested that this group of patients may have difficulty in reliably completing complex tests such as the McGill-Melzack questionnaire both before and after these procedures [19,46,47]. In addition, clinical data including pre- and postoperative X-ray films were reviewed for the quantity of bone cement used, cement extravasation, subsequent adjacent-level fractures, and neurological and systemic complications (Table 1).

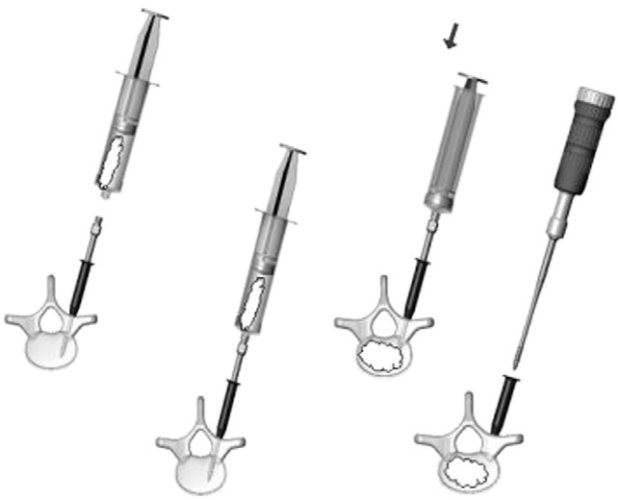

Fig. 2. Surgical technique showing injection of bone cement into vertebral body using the fenestrated tap system.

Statistical analysis

A *t* test was used to analyze age differences, unilateral versus bilateral procedures, and the amount of cement injected between the two groups. A Spearman rank order correlation was used to analyze the relationship between cement extravasation and the quantity of cement used, number of levels augmented, and location (thoracic or lumbar), as well as the association between either technique and the development of adjacent-level fractures.

Results

Thirty-six patients underwent a total of 46 vertebral augmentation procedures. These results are summarized in Table 1. Of these 36 patients treated, 17 patients had 20 fractures treated by kyphoplasty, and 19 patients had 26 fractures treated via vertebroplasty. The mean patient age in the kyphoplasty group was 70 (range, 46–83) and 72 (range, 38–90) in the vertebroplasty group. There were no significant differences in age between these groups (p=.4).

Vertebroplasty procedures were performed unilaterally if bilateral vertebral body fill was seen on AP fluoroscopy and bilaterally if unilateral fill was noted. In this series, a total of 21 of 46 (46%) procedures were unilateral and 24 of 46 (52%) bilateral. Nineteen of 20 (95%) of the kyphoplasty procedures were performed bilaterally, whereas only 5 of 26 (19%) of the vertebroplasty procedures required bilateral augmentation, a statistically significant difference (p<.001).

A total of 20 thoracic and 26 lumbar augmentation procedures were performed. Twenty-eight patients had one level treated (Fig. 3), whereas eight patients had two to three levels treated at once (Fig. 4). Mean cement injection per vertebral body was 4.65±.9 mL (range, 3.0–6.0 mL) for the kyphoplasty group and 3.78±1.3 mL (range, 2.0–7.0 mL) for the vertebroplasty group, a statistically significant difference (p=.01).

The mean postoperative pain score was 1.6±.8 (range, 1.0–4.0) for the kyphoplasty group and 1.3±.6 (range, 1.0–3.0) for the vertebroplasty group, a nonsignificant difference (p=.3). Complete pain relief (pain score=1) was 9 of 17 (53%) and 14 of 19 (74%) in the kyphoplasty and vertebroplasty groups, respectively. Patients improved by vertebral augmentation (pain Score=1 and 2 combined) was 16 of 17 (94%) and 18 of 19 (95%) in the kyphoplasty and vertebroplasty groups, respectively. Patients not helped by the augmentation procedure (pain Score=3 and 4 combined) was 1 of 17 (6%) and 1 of 19 (5%) in the kyphoplasty and vertebroplasty groups, respectively.

Table 1
Patient data for vertebral augmentation procedures

Pt (#)	Age	Procedure approach	Levels	PMMA level	Complications	Adj levels fx	Patients	PMMMA extravasation
1	67	Vert./Bil.	T12	L-1.5, R-3.0	None	None	1	No
2	46	Vert./Uni.	L5	L-2.0	None	None	2	No
3	68	Vert./Uni.	L2	R-5.0	None	None	1	No
4	38	Vert./Uni.	T7	R-2.5	None	None	2	No
5	78	Vert./Uni.	T12, L1, L3	L-3.0, L-3.0, L-5.0	None	None	1	Yes, L1 Asymp. inferior endplate
6	82	Vert./Uni.	T7	L-3.0	None	None	1	No
7	62	Vert./Uni.	L1, L5	L-5.0, L-5.0	None	None	2	Yes, anterior vein-Asymp.
8	90	Vert./Uni.	T11	L-3.0	None	None	1	No
9	68	Vert./Bil.	L3	L-3.0, R-3.0	None	None	2	No
10	88	Vert./Uni.	T12	L-4.0	None	None	1	No
11	79	Vert./Uni	L1, L2, L4	All-3.0 x 3	None	None	3	No
12	46	Kypho./Bil.	L2	2.5 each side	None	None	1	No
13	69	Vert./Bil.	L4	R-2.0, L-2.0	None	None	1	No
14	73	Kypho./Bil.	T11	R-3.0, L-2.5	None	None	1	No
15	78	Kypho./Bil.	L2	R-3.0, L-3.0	None	None	1	No
16	67	Kypho./Bil.	T7	R-3.0, L-1.5	None	None	1	No
17	83	Kypho./Bil.	T11	R-2.0, L-3.0	None	None	2	No
18	46	Kypho./Uni.	L1	R-4.5	None	None	2	No
19	78	Kypho./Bil.	L3	R-3.0, L-3.0	None	2 fx@L2&4	1	No
20	70	Kypho./Bil.	T6	L-1.5, R-1.5	Severe local pain	None	4	Yes, posterior soft elements
21	53	Kypho./Bil.	T8	R-3.0, L-3.0	None	None	1	No
22	79	Kypho./Bil.	T6	L-1.5, R-1.5	Rib fracture	None	2	Yes, anterior vein Asymp.
23	74	Kypho./Bil.	T7, T9	2.0 x 4	None	None	1	No
24	66	Kypho./Bil.	L1	R-2.5, L-2.5	None	None	1	No
25	79	Kypho./Bil.	T12	R-2.0, L-2.0	None	1 fx@T11	2	No
26	82	Kypho./Bil.	T12	R-3.0, L-1.5	None	None	2	Yes, T12 asymp. inferior endplate
27	69	Kypho./Bil.	T11	R-2.5, L-2.5	None	2 fx@T10&T12	1	No
28	75	Vert./Uni.	T12	L-6.0	None	None	1	No
29	67	Kypho./Bil.	L1, L2	L1-2.5/B; L2-1.5/B	None	None	2	No
30	80	Vert./Bil.	L4	R-3.0, L-3.0	None	None	1	No
31	73	Vert./Uni.	LI	L-3.0	None	None	1	No
32	83	Vert./Bil.-L4; Vert./Uni-L2	L2, L4	L4-L-5.0; R-2.0; L2-5.0	None	None	1	No
33	81	Vert./Uni.	L3	L3-3.0	None	None	1	No
34	77	Vert./Uni.	L3, L4	3.0@all levels	None	None	1	No
35	80	Kypho./Bil.	T11, 12	2.5@all levels	None	None	2	No
36	78	Vert./Uni	L2 burst	L2-2.0	None	None	1	No

Vert.=vertebroplasty; Bil.=bilateral; Uni.=unilateral; Kypho.=kyphoplasty; Asymp.=asymptomatic.

There was no cement extravasation resulting in radiculopathy or myelopathy using either technique. Asymptomatic cement extravasation was seen in 5 of 46 (11%) of the total series (3/20 [15%] and 2/26 [7.7%] of the kyphoplasty and vertebroplasty groups, respectively). This was not statistically significant ($p=.7$). Anterior cement extravasation into the external venous plexus was seen in two cases (one kyphoplasty and one vertebroplasty). Posterior retropulsion of cement into the posterior vertebral elements was noted on injection of cement into the contralateral side in one kyphoplasty case. In addition, two cases of asymptomatic cement extravasation through the inferior endplate into the disc space were seen (one kyphoplasty and one vertebroplasty). There was no posterior cement flow into the basivertebral or intervertebral veins in either group. There was no significant relationship between cement extravasation and the quantity of cement used ($p>.05$ for all comparisons), the number of levels augmented ($p>.05$ for all comparisons), and the location (thoracic or lumbar) ($p>.05$ for all comparisons).

Finally, the development of subsequent adjacent-level fractures after vertebral augmentation procedures was analyzed. There were 5 new adjacent-level fractures (Fig. 4) seen in 3 patients that underwent a kyphoplasty procedure (5/20, 25%). All were symptomatic and occurred within 3 months of the procedure. There were no new adjacent-level fractures seen after vertebroplasty procedures (Table 1). This represents a significant difference between the two treatment groups ($p<.05$).

Discussion

The use of PMMA in augmentation procedures must be done with caution because of a number of potential serious

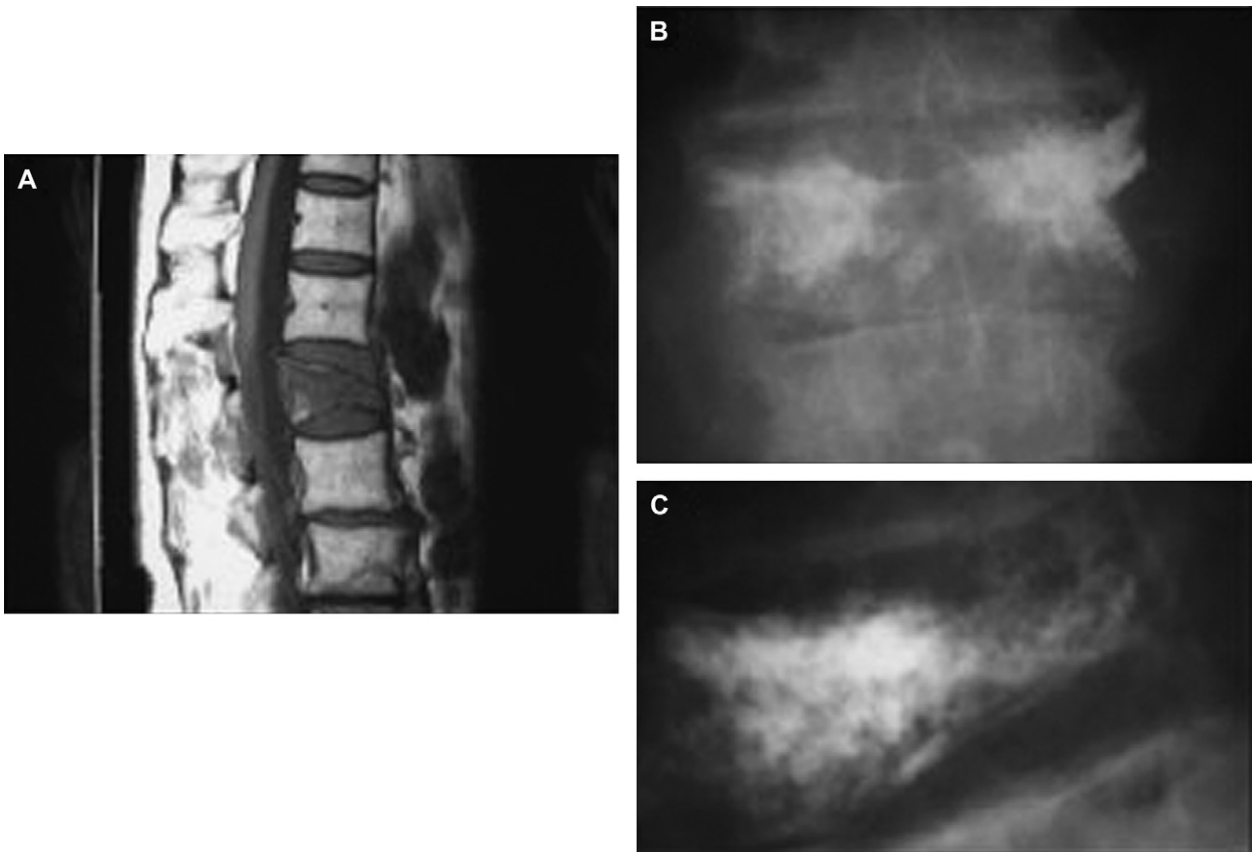

Fig. 3. Magnetic resonance imaging and X-ray films showing (A) pre- (B, C) and postoperative films of an L1 compression fracture. (A) Magnetic resonance imaging showing marrow edema in a subacute VCF. (B) AP and (C) lateral postoperative X-ray films showing a bilateral vertebroplasty.

complications that may occur with intraosseous injection of bone cement. The risk of cement extravasation in various series ranges between 3% and 74% [17,19,25,27–31], with resultant neurological deficits such as radiculopathy and cord compression occurring in 0% to 3.7% and 0% to 0.5%, respectively [32–35]. Similar to these studies, we report a low extravasation rate of 11% (15% and 7.7% of kyphoplasty and vertebroplasty procedures, respectively), without myelopathy (0%) and radiculopathy (0%).

The risk of epidural migration of PMMA has been reported to be minimized by the use of smaller volumes of bone cement, slow injection times under low pressures, and limitation of usage above T7 [29]. There was no significant correlation between cement extravasation and volume or number and location of levels augmented in this study. The use of antecedent venography is controversial and was not performed in this series. Its use is recommended by some authors, whereas others report no significant improvement in the effectiveness or safety of vertebroplasty procedures [28,48–52]. Regardless, there is no substitution for careful surgical technique using correct device positioning within the vertebral body with adequate AP and lateral fluoroscopy to image the extent and direction of PMMA injection by qualified, experienced surgeons. Any fluoroscopic demonstration of cement extravasation should immediately result in the termination of injection. Although the amount of PMMA injected in the vertebroplasty group was significantly less than in the kyphoplasty group, both were equally as effective in alleviating pain.

It appears that there is an increased risk of developing subsequent compression fractures after PMMA vertebral body augmentation procedures, possibly related to an increase in the stiffness of treated vertebra [36,37] or some other poorly defined underlying etiology [38]. Natural history data suggest that the incidence of subsequent vertebral fracture after experiencing an osteoporotic vertebral compression fracture is 19.2% when no surgical intervention is performed [40,53]. These data are taken from the placebo arms of large bisphosphonate trials and may not be directly applicable to patients undergoing vertebral augmentation procedures for several reasons. First, most patients with VCFs are on bisphosphonate therapy, which have been reported to reduce the risk of subsequent VCF by 50% [54]. Second, these studies report the incidence of all subsequent fractures, not just subsequent adjacent-level fractures, which are fewer in number and probably most relevant when looking at potential iatrogenic injury caused by PMMA injection. As a result, the risk of subsequent adjacent-level fractures is not known but should be probably significantly less than the 19.2% frequently quoted.

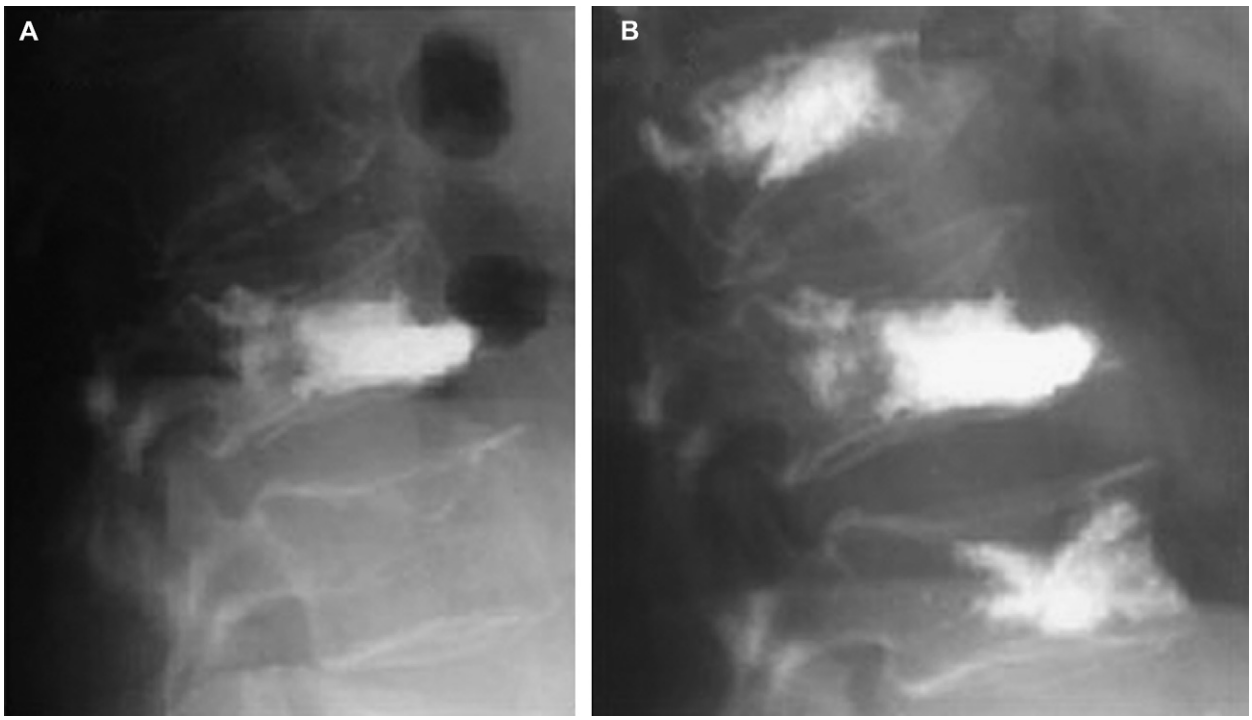

Fig. 4. X-ray films showing an L3 compression fracture treated via (A) kyphoplasty. The patient developed severe recurrent back pain at 3 months postoperatively. Adjacent-level fractures were noted at L2 and L4 and subsequently treated via (B) vertebroplasty.

According to the literature, the risk of subsequent adjacent fracture occurrence appears to be greater in kyphoplasty (75%–45%) [39,40,55,56] than vertebroplasty (0%–16%) [25,41,57–61]; however, this question has not been previously addressed in a single series. Our data are in agreement with these findings in that a significantly increased rate of adjacent-level fractures (25%) was seen in the kyphoplasty group as compared with the vertebroplasty group (0%).

This study has several weaknesses that may have resulted in our findings. Radiographic measurement data to determine the restoration of vertebral body height and kyphosis correction were not recorded nor were bone density measurements. Either of these factors may have resulted in significantly dissimilar populations for comparison. Additionally, this is a small retrospective study. Only a large randomized trial would have the power to sufficiently address whether or not subsequent adjacent-level fracture rates are higher in one group as compared with another. It is important for such a future study to be performed in order to determine the risk factors for developing subsequent adjacent-level fractures and whether or not they can be can be reduced using one technique or another.

Conclusions

Vertebroplasty appears to offer a comparable rate of postoperative pain relief as kyphoplasty while using less bone cement, more often via a unilateral approach, and perhaps with a lower attendant risk of adjacent-level fracture.

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