

New Vertebral Fracture After Vertebroplasty

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Background: Because the complications of vertebroplasty are serious and can include new fracture, we retrospectively evaluated potential risk factors for new fracture after vertebroplasty. Our hypothesis is that thoracolumbar vertebrae adjacent to a vertebroplasty site have a higher incidence of new compression fracture than do other vertebrae.

Methods: Between March 2001 and December 2002, a total of 271 patients underwent vertebroplasty and a retrospective review of charts was performed. Patients reached 24 months of follow-up were included for analyses. Age, gender,

bone mineral density, the numbers of prior vertebroplasty procedures, cement volume, postoperative kyphotic angle, the vertebral level, and kyphotic changes were assessed in relation to surgical outcome.

Results: The 220 patients had a mean age of 72.7 years (range, 53–97 years) and a mean follow-up interval of 25.6 months (range, 24–36 months). A total of 15 patients had 18 new fractures, and 11 new fractures were at the thoracolumbar junction (T12–L1) ($p = 0.61$). New fractures were in vertebrae adjacent to a treated vertebra in 55.6% (10 of 18 cases) of cases. Analysis of potential predictors for new

vertebral fracture failed to identify statistically significant risk factors, despite a large sample size.

Conclusions: Overall, 6.16% (18 of 292) of all treated vertebra developed associated new vertebral fractures. Cranial vertebrae were most likely to fracture at the adjacent level, whereas thoracic vertebrae were least likely to fracture at the adjacent level. Additional risk factors for new vertebral fracture are poorly understood.

Key Words: New vertebral fracture, Vertebroplasty.

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Osteoporotic vertebral compression fractures typically cause functional deterioration, severe pain, and limited mobility. Conventional treatments of painful compression fractures include bed rest, administration of analgesics and muscle relaxants, bracing, and physical therapy.¹ Most patients respond to conventional treatment; however, patients who remain unresponsive to conservative therapy and suffer prolonged pain and immobility should be considered for vertebroplasty. The goals of vertebroplasty are to relieve pain,² to shorten recovery time, and to eliminate the need for extended nursing and rehabilitation care, thereby significantly reducing long-term care costs.³ Percutaneous vertebroplasty, developed by Galibert et al.,⁴ which uses acrylic cement injected under fluoroscopy into an affected vertebral body via a posterior transpedicular approach, is used to manage refractory vertebral compression fractures.^{4–7} Postmortem studies have shown that polymethylmethacrylate used in vertebroplasty can restore strength and stiffness to vertebral bodies.⁸

Complications of vertebroplasty identified in previous studies include pulmonary embolism, extravasations of cement, neurologic deficit or nerve root irritation, infec-

tion, hemorrhage, fracture of rib or posterior elements of the vertebrae, transient fever and unremitting pain, and pneumothorax.^{5,9,10} However, the most thoroughly documented complication of vertebroplasty is new vertebral compression fracture,^{9,11–23} which can cause neurologic deficit.²¹

Many risk factors for new fracture after vertebroplasty have been identified, including osteoporosis,^{9,19} prior vertebral fracture,^{12,15,17} proximity to the initial fracture site,^{2,9,11,13,16,17,23} cement leakage into the disk after treatment,^{11,14} old age,¹⁵ higher initial wedge angle or wedge angle change,^{18,23} vacuum clefts within the compression fracture,¹⁸ use of steroids,²⁰ and treatment of vertebrae at the thoracolumbar junction.²³ The purpose of this retrospective study was to analyze potential predictive factors for new vertebral fracture in a fresh cohort of patients treated with vertebroplasty. Our hypothesis was that T12–L1 vertebrae adjacent to a vertebroplasty site would have a higher incidence of new compression fracture than vertebrae elsewhere in the spine. This hypothesis was tested with a retrospective review of charts.

MATERIALS AND METHODS

Patients

Between March 2001 and December 2002, 271 consecutive patients were enrolled for study. All patients had osteoporotic vertebral compression fracture treated with percutaneous transpedicular vertebroplasty using bone cement augmentation of a total of 292 vertebrae. Exclusion criteria for this study were patients who were completely bedridden or who had stroke, limb weakness, preoperative neurologic deficits, senile dementia, cancer, or being followed up for less than 2 years. Before treatment, all patients

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had severe back pain that did not resolve after conservative treatment for at least 6 weeks. All vertebroplasty procedures were performed by two of the authors (W.-J.C., L.-H.C.).

All patients were asked to quantify their back pain on the Huskisson visual analog scale (VAS) (0 mm = no pain, 100 mm = most pain possible) before vertebroplasty. This measure was repeated on the first day postoperatively, 1 month after vertebroplasty, and on each subsequent follow-up visit. Patients were not allowed to see their previous score.

Prevertebroplasty Workup

A diagnosis of vertebral compression fracture was based on plain radiographic findings. Patient history and physical examination were analyzed to determine whether there was a correlation between location of pain and tenderness with levels of compression fractures, and to exclude the presence of focal neurologic deficits or myelopathy. Magnetic resonance imaging was used for all patients to analyze whether any significant spinal canal compromise existed, to assess posterior vertebral body walls, to identify whether the vertebral fracture was united, and to exclude other potential causes of back pain.

Surgical Procedure

Vertebroplasty was performed under local anesthesia. Patients were placed in a prone position. Using sterile technique under fluoroscopic guidance, an 11-gauge bone biopsy needle was inserted into the vertebral body using a posterior transpedicular approach. Forty grams of bone cement (Osteobond, Zimmer, Warsaw, IN) was mixed with 6 g of sterile barium sulfate powder (Barytgen, Fushimi, Kagawa, Japan), then poured into a plastic Luer-Lok syringe (PrecisionGlide, Becton Dickinson, Franklin Lakes, NJ). Under continuous fluoroscopic monitoring, the mixture was slowly injected into the vertebral body aided by a screw-syringe compressor (Bestcare Tech, Taiwan) until the cleft space was filled.²⁴ The procedure was typically performed using a unipedicle approach unless inadequate cross-filling of the vertebral body by the initial injection was observed.²⁵ The vertebral body was filled with cement as much as possible, and the procedure was stopped when cement filled approximately the posterior 25% of the vertebra. The total volume of injected cement was calculated by subtracting the remaining cement from the total amount mixed. Cement leakage was visualized by radiography 1 day posttreatment.

All patients were observed for a minimum of 24 hours after treatment, at which time most patients were able to stand and walk. Before discharge, patients were evaluated for pain relief, focal neurologic deficit, and respiratory problems. All patients were instructed to wear orthosis (Taylor brace) for at least 3 months postoperatively. The patient was followed monthly for 3 months postoperatively, then at a 3-month follow-up interval. If the patient complained of acute back pain again, an X-ray examination was performed immediately.

Statistical Procedures

Age, gender, number(s) of vertebroplasty procedures performed, cement volume, postoperative kyphotic angle, vertebroplasty level, and postoperative kyphotic changes were recorded. Age is reported as mean and standard deviation, whereas other variables are reported as median values with interquartile ranges in parentheses, or as categorical variables in frequencies with percentages in parentheses. Baseline comparisons used *t* tests, Wilcoxon rank sum tests, or Fisher's exact tests, depending on distributions. For example, patient VAS values before and at intervals after treatment were compared using a Wilcoxon signed rank nonparametric test. Time to adjacent vertebral fracture was evaluated using log rank test; we took a counting process approach when recurrent events were treated as identical. Data were analyzed using SAS 9.0 (SAS Institute, Cary, NC), and significance level was 0.05. The primary focus of our analysis was the occurrence of new fractures in subsequent follow-up visits. Risk factors for new fractures were analyzed using Pearson χ^2 test and Fisher's exact test.

RESULTS

A total of 220 patients (179 females and 41 males) who underwent vertebroplasty reached 24 months of follow-up and are included in this study. The mean age of these patients was 72.7 years (range, 50–97 years), and the average follow-up interval was 25.6 (range, 24–36). The mean age of 15 patients (2 males and 13 females) who developed new fracture(s) was 75.1 years, and the age of patients who had no new fractures was 72.5 years (Table 1). A total of 51 patients were excluded from analyses because of: had not reached at least 24 months of follow-up ($n = 28$), cardiovascular crash ($n = 5$), died of other disease ($n = 8$), lost to follow-up ($n = 8$), lacked complete records ($n = 2$). Thus, our rate of 2-year follow-up was 81% (220 of 271), and we specifically may have lost patients with serious underlying illness.

Of the 220 patients with complete data, the number of patients who received vertebroplasty at different vertebral levels is indicated in Table 2. The majority of patients had vertebroplasty performed at L1. Vertebroplasty for compression fracture was predominantly performed in the thoracolumbar junction (T12 and L1) where 54.09% (119 of 220) of all fractures occurred. The average total volume of injected cement was 4.5 mL (range, 0.5–18 mL).

Most patients experienced marked back pain relief. The VAS value decreased from 81 mm \pm 16 mm before treatment to 39 mm \pm 24 mm on the first day posttreatment, 37 mm \pm 28 mm at 1 month after vertebroplasty, and 31 mm \pm 19 mm at the time of the recent follow-up. The reduction in pain severity was significant at 1-month posttreatment ($p = 0.031$) and at the final follow-up ($p = 0.023$).

As shown in Table 1, complications of vertebroplasty were as follows: cement leakage (58 of 220 patients,

Table 1 Patient Characteristics

Variables	All Patients (N = 220)	No New Fractures (N = 205)	New Fractures (N = 15)	<i>p</i>
Age (yr)*	72.65 ± 8.2	72.46 ± 8.20	75.13 ± 8.25	0.1541
Male (%) [†]	41 (18.64)	39 (19.02)	2 (13.33)	0.7429
Injury to surgery (d) [‡]	80 (25 to 180)	80 (22.5 to 200)	80 (60 to 150)	0.5114
Operation time (min) [‡]	50 (39 to 71.5)	50 (39 to 73)	58 (40 to 68)	0.8715
Cement volume (mL) [‡]	5.0 (3.75 to 7.0)	5.0 (4.0 to 7.0)	2.0 (3.5 to 8.0)	0.9444
Bilateral (yes) [†]	106 (48.18)	100 (48.78)	6 (40.00)	0.5981
Cement leakage (yes) [†]	58 (26.36)	54 (26.34)	4 (26.67)	1.000
Preop kyphotic angle (degree) [‡]	20 (15 to 30)	20 (15 to 30)	25 (15 to 30)	0.7800
Postop kyphotic angle (degree) [‡]	20 (15 to 27)	20 (15 to 27)	20 (15 to 25)	0.6656
Delta (postdegree to predegree) [‡]	0 (0 to 0)	0 (0 to 0)	0 (-5 to 0)	0.7035
Restoration (yes) [†]	47 (21.36)	43 (20.98)	4 (26.67)	0.5173
Correction (yes) [†]	51 (23.18)	46 (22.44)	5 (33.33)	0.3536
Level [†]				0.1156
T5–T11	53 (18.15)	43 (17.55)	10 (21.28)	
T12–L1	153 (52.40)	132 (53.88)	21 (44.68)	
L2–L5	86 (29.45)	70 (28.57)	16 (34.04)	

* Mean ± SD, tested with *t* test.

[†] Number (%), compared with χ^2 tests or Fisher's exact test.

[‡] Median (interquartile range), compared with Wilcoxon rank sum test.

26.36%), new fracture (15 of 220, 6.82%), cement dislodgement (2 of 220, 0.9%), and infection (2 of 220, 0.9%). Besides, three patients had subcutaneous hematoma (3 of 220, 1.4%); and two patients had neurologic deficit (2 of 220, 0.9%). In patients who developed neurologic deficit subsequent to vertebroplasty, cement leaked into the spinal canal in one patient and the other patient suffered serious pyogenic spondylitis.²⁶

Bone mineral density (BMD) data were not available for all patients, as only 71 underwent the BMD screen. However, BMD was not related to the occurrence of new vertebral fractures. Neither was the volume of injected cement related to the occurrence of new fractures (Table 1), as has been reported.^{27,28} Finally, analysis of postoperative kyphosis angle showed no significant relationship to the occurrence of new fractures (Table 1).

Fifteen patients had 18 new fractures, and 11 new fractures were at the thoracolumbar junction (T12–L1). Mean

fracture-free interval was 55 days (range, 2–182 days) (Figs. 1–4). The site of index vertebroplasty was analyzed by dividing patients into three groups: initial fractures of T5–T11, T12–L1, and L2–L5. Only 10 new fractures were noted in 53

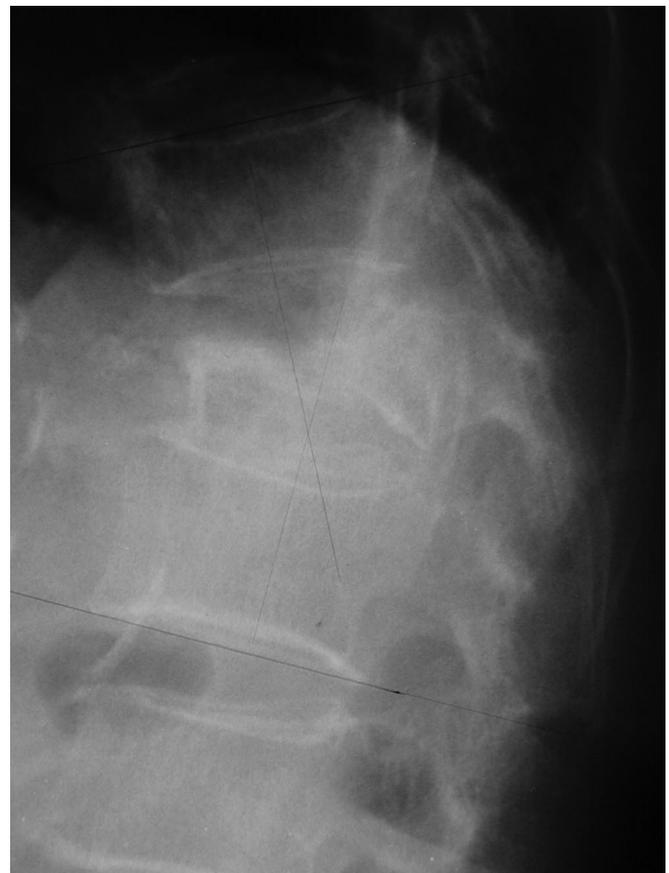


Fig. 1. Thoracolumbar roentgenogram lateral view of an 85-year-old woman showed T12 osteoporotic compression fracture.

Table 2 All Treated Vertebrae

Vertebral Level Treated	All Patients (N = 220)	No New Fractures (N = 205)	New Fractures (N = 15)
T6	3 (1.03)	2 (0.82)	1 (2.13)
T7	2 (0.68)	2 (0.82)	0 (0)
T8	3 (1.03)	2 (0.82)	1 (2.13)
T9	7 (2.40)	5 (2.04)	2 (4.26)
T10	11 (3.77)	8 (3.27)	3 (6.38)
T11	27 (9.25)	24 (9.80)	3 (6.38)
T12	73 (25.00)	60 (24.49)	13 (27.66)
L1	80 (27.40)	72 (29.39)	8 (17.02)
L2	51 (17.47)	41 (16.73)	10 (21.28)
L3	24 (8.22)	20 (8.16)	4 (8.51)
L4	11 (3.77)	9 (3.67)	2 (4.26)
Total level	292	245	47

Data pre presented with number (%).

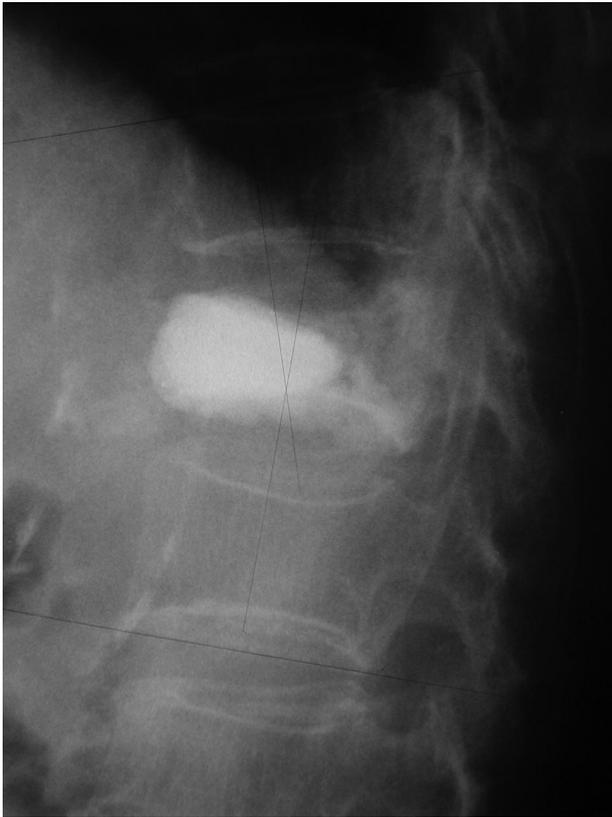


Fig. 2. Vertebroplasty of T12 was performed.

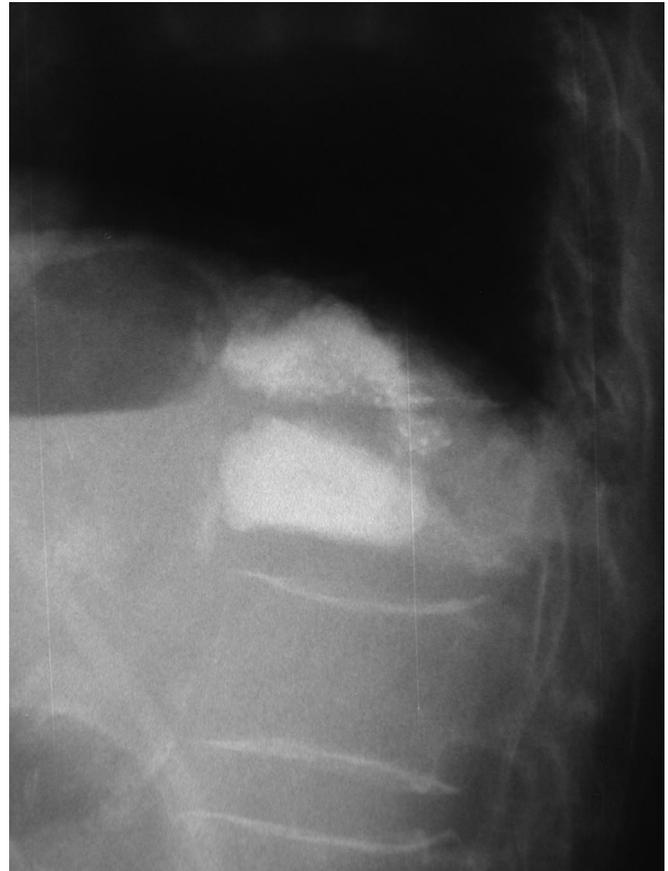


Fig. 4. T11 vertebroplasty was performed.



Fig. 3. Six weeks after T12 vertebroplasty, X-ray film showed new compression fracture of T11.

patients (18.86%) whose first fractures was in the range of T5–T11. The 153 patients whose first vertebroplasty was in the range of T12–L1 had 12 new fractures (7.84%), whereas the 86 patients whose first fracture was in the range of L2–L5 accounted for nine new fractures (10.46%) (Pearson χ^2 test, $p = 0.1156$) (Table 1).

A Kaplan-Meier analysis (Table 3) shows that the median time to fracture was shortest for T5–T11 vertebrae ($p = 0.0006$). The overall time to adjacent fracture is also presented in Figure 5. Detailed information is shown for the 15 patients who developed 18 adjacent new fractures (Table 4).

DISCUSSION

We have evaluated a range of risk factors that have been reported to predict new vertebral fracture after a prior

Table 3 Kaplan-Meier Analysis of Adjacent Segment Fractures on 18 Events

	T5–T11 (n = 2)	T12–L1 (n = 11)	L2–L5 (n = 5)	<i>p</i>
Median time to adjacent fracture (CI)	6 (2–10)	57 (40–73)	54 (23–182)	0.0006

Data are presented with median survival time and the product limit confidence interval.

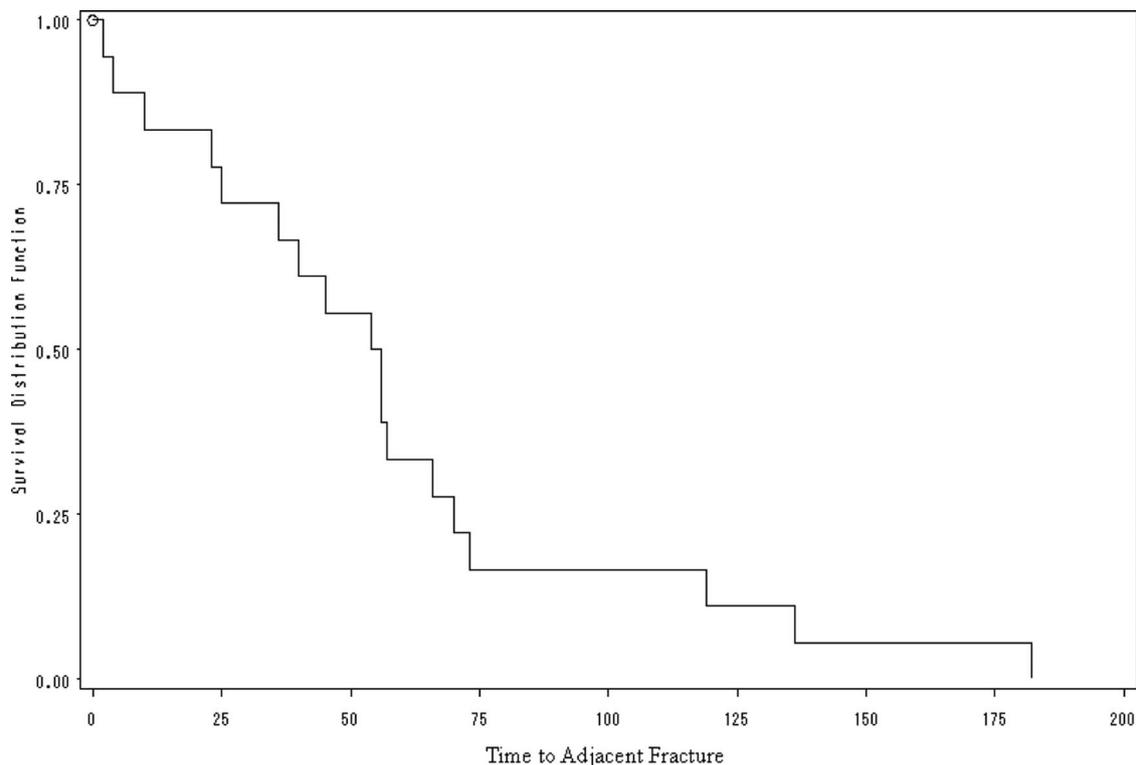


Fig. 5. Kaplan-Meier survival curve for overall adjacent fracture.

vertebroplasty.^{2,9,11-23} The only risk factor significantly related to new vertebral fracture in our sample of osteoporotic patients was proximity to a previous fracture (Table 1). Of 18 new fractures, 11 were at the thoracolumbar junction (T12-L1), consistent with our hypothesis that these vertebrae are more at risk of fracture. In current study, 18 new fractures occurred in 15 patients after vertebroplasty. Mean fracture-free interval was 1.8 (55 days, interquartile range, 25-70) months. 61.1% (11 of 18) of new fractures occurred at the

T12-L1, whereas 33.33% (6 of 18) were at the adjacent level above the previous vertebroplasty. On the other hand, 38.9% (7 of 18) new fractures were at the caudal vertebrae and three (16.7%) were located at the adjacent level below the old fracture site. So, we noted that there were 55.6% (10 of 18) new fractures found at the adjacent level, and the T12-L1 has the highest incidence (61.11%, 11 of 18) of developing new fracture after vertebroplasty.

Prior fracture is a stronger predictor of new fracture if the prior fracture was in a cranial vertebra; 38.9% of new fractures were adjacent to treated cranial vertebrae, whereas only 22% of new fractures were adjacent to treated thoracic vertebrae. We were unable to document that the risk of new vertebral fracture is related to patient age, patient gender, and bone mineral density, number of prior vertebroplasty procedures, cement volume, posttreatment kyphotic angle, or the kyphotic angle difference (Table 1). Our results contradict a number of earlier published studies, which implicated risk factors such as osteoporosis,^{9,19} prior vertebral fracture,^{12,15,17} cement leakage into the disk after treatment,^{11,14} old age,¹⁵ higher initial wedge angle or wedge angle change,^{18,23} vacuum clefts within the compression fracture,¹⁸ and use of steroids.²⁰ However, our findings strongly confirm other studies, which suggest that the risk of new fracture is highest in vertebrae close to the initial fracture site^{2,9,11,13,16,17,23} and in vertebrae at the thoracolumbar junction.²³ We note that our study included 222 patients, making it larger than most prior studies,^{2,9,11-14,17-23} so our sample size should yield good sensitivity to risk factors for vertebral fracture.

Table 4 Patients Who Developed New Fractures

ID/Age/Sex	Vertebral Level Treated	Days to New Fracture	Level of New Vertebral Fracture
1/80/F	T12	4	L4
2/88/M	T12	73	T11
2/88/M	T11	70	L1
3/74/F	T10	2	T12, L2
4/70/F	L1, L3	136	L2, T12
5/73/F	L1	66	T12
6/85/F	T12	57	T11
7/76/M	L2	23	L1
7/76/M	L1	36	T12
8/75/F	T12	25	L2
9/79/F	T12	40	T12
10/56/F	L1, L2, L3	119	T6
11/87/F	L4	56	L2, L3
12/71/F	L1	56	L2
12/71/F	L2	45	T9
13/70/F	T10, T12	10	T11, L1, L2
14/76/F	L2, L1, T12	182	T8, T9, T10
15/67/F	L2, L3	54	T12

The most frequent complication of vertebroplasty in our series was cement leakage, which affected 26% of patients (58 of 220). The incidence of this complication in our series is similar to that in other studies.^{29,30} The risk of cement leakage may be related to uncontrolled pressure during cement injection. The chance of inadequate cement filling and the risk of cement leakage are greater for compression fractures of vertebrae that lack a clear fracture cleft. Kyphoplasty is a procedure in which a balloon is inserted into a collapsed vertebra to elevate the end plates, forming a cavity for controlled cement placement.³¹ The incidence of cement leakage is generally less in kyphoplasty than in vertebroplasty because cement is injected at lower pressure and can be more viscous while injected. In our study, we did not use a balloon to do kyphoplasty, which may explain why the rate of this complication was 26% in our study.

Several previous studies have noted that vertebrae in close proximity to a prior fracture are at greater risk of new fracture. For example, among 25 patients with 34 treated vertebrae, the risk of adjacent fracture was 52% over an average follow-up period of 48 months (range, 12–84 months).²² This study concluded that the relative risk of fracture of the adjacent vertebrae was 2.27.²² Other risk factors in addition to proximity to a treated vertebrae include vertebrae at the thoracolumbar junction, and great degree of high angle restoration of the cemented vertebrae.²³

The time to new fracture tends to be short in patients who suffer this complication. We found that 7% of patients have a second fracture after vertebroplasty and the mean interval to new fracture was 1.8 months. Another study concluded that 12% of patients have a new fracture after treatment and 24 of 36 new fractures (67%) occurred within 30 days of vertebroplasty.⁹

Vertebral location is an important risk factor for new fracture. This result is consistent with a previous study, which found that the incidence of vacuum clefts is high at the thoracolumbar junction (T12, L1); 74% of 53 patients had fluid or air in compression fractures at this site.¹⁸

New vertebral compression fractures after an initial fracture are common in the natural course of osteoporosis.^{5,32} This result may be because the patients with osteoporosis have fragile bones and are highly susceptible to fracture.^{1,7,12–15,17} The strength of osteoporotic vertebrae was evaluated in cadaveric material, and bone cement increases the strength of osteoporotic vertebrae to more normal values.²⁸ Untreated vertebrae adjacent to treated vertebrae may therefore be exposed to higher stress than they encountered before adjacent vertebrae were treated. This suggests that the current practice of using the maximum amount of cement to restore vertebral stiffness and strength may increase the risk of fracture in adjacent, nonaugmented vertebrae³³ because biomechanical stresses are increased in adjacent vertebra after treatment.³⁴ A normal spine may be able to tolerate such an increase in force, but an osteoporotic spine may tolerate such alterations poorly.⁹

Multiple risk factors for new vertebral fracture after vertebroplasty were analyzed. We report that development of new fracture is not associated with factors such as patient age, patient gender, BMD, number of vertebroplasties performed simultaneously, the volume of cement, postoperative kyphotic angle, or kyphotic changes. However, the risk of new fracture is higher in adjacent vertebra, particularly if treated vertebrae are at or near the thoracolumbar junction.

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