

Height restoration and wedge angle correction effects of percutaneous vertebroplasty: association with intraosseous clefts

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Abstract

Objective To evaluate effects of vertebroplasty on restoration of vertebral body height and wedge angle and relief from pain in patients with osteoporotic compression fractures.

Methods A retrospective study of 156 patients (232 levels) who had undergone vertebroplasty was conducted. Treated vertebrae with cleft included 49 patients (49 levels) and that without cleft 107 patients (183 levels). Effects on restoration of vertebral body height and wedge angle, and pain scores between pre- and post-procedure were statistically analyzed by using a paired-sample *t* test, and Kruskal Wallis test.

Results The height and wedge angle of the fractured vertebral body, and pain score, improved significantly after vertebroplasty. On a vertebra-by-vertebra analysis, the vertebral body height and wedge angle in the cleft group, were statistically significantly better post-procedure ($P < 0.01$); in the non-cleft group, there was no significant improvement ($P > 0.05$). Pain relief was not statistically significant different between the two groups ($P > 0.05$).

Conclusion Most patients experienced pain relief after vertebroplasty. After vertebroplasty, the height and wedge angle were significantly improved in the cleft group ($p < 0.01$), with no significant improvement in the non-cleft group ($p > 0.05$).

Key Points

- *Vertebra with cleft is attributed to improvement of the spinal deformity*

- *Vertebra without cleft was not associated with improvement of the spinal deformity*
- *Vertebroplasty is an effective treatment strategy for osteoporotic compression fractures*

Keywords Percutaneous vertebroplasty · Compression fracture · Deformity · Restoration · Osteoporosis

Introduction

Vertebroplasty is a minimally invasive technique for treating painful osteoporotic vertebral fracture. Despite the benefit of the technique is still debated, numerous clinical studies have demonstrated that vertebroplasty is effective in relieving pain following vertebral fracture [1–4]. In clinical practice, height-restoration and kyphosis-correction have been noted following vertebroplasty [5–10]. The purpose of this retrospective study was to evaluate the effects of vertebroplasty on restoration of vertebral body height and wedge angle as well as pain relief in patients suffered from osteoporotic compression fractures with intraosseous cleft and without cleft.

Materials and methods

Patients selection

We performed a retrospective review of all patients treated with vertebroplasty at our hospital between March 2000, and December 2009. Three-hundred and sixteen patients were treated during this interval and all patients had previously consented to the use of their medical records

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for research purposes. Of 316 patients treated, 156 patients (232 levels) included 37 men and 119 women with mean age 64.4 ± 2.4 years (range, 59–78 years) were treated for vertebral fractures that were osteoporotic in nature and were selected for this analysis. In the earlier, vertebroplasties were performed on 72 patients who had no or minimally responded to a course of conservative medical treatment for at least 3 months [11–13], whereas, in recent years, vertebroplasties were offered early after fracture on 84 patients. Typically, these patients were referred from physicians who have clinical experience with vertebroplasty, had been extremely pleased with the outcomes, and would like to avoid the use of potent analgesics or immobilization in their elderly patients. We performed early vertebroplasty in these patients whose fracture age was less than 3 weeks. They no longer required a failure of medical therapy before the procedure.

Imaging assessment

For all patients, digital radiography and MR imaging were performed in 1–13 days preceding vertebroplasty. Patient records were reviewed for evidence of intraosseous cleft in the treated vertebrae which was identified with pre-procedural digital radiography, MR imaging and the cement filling pattern of cleft opacification. It traditionally radiographically appeared as a vacuum or airfilled cleft inside a vertebral body [14]. Variable MR imaging appearances of the radiographically detectable cleft had been described depending on whether gas or fluid filled the cleft [15] (Fig. 1). In a retrospective study, Lane et al. [16] assessed the detection of cleft during vertebroplasty as the visualization of a cavity filled with cement, which was different from the trabecular filling that was classically visualized (Fig. 2).

Of the 156 patients included in this study, 49 patients (49 levels) had an intraosseous cleft treated with vertebroplasty and was designated as the “cleft” group. The “non-cleft” group included 107 patients (183 levels) who were without intraosseous cleft.

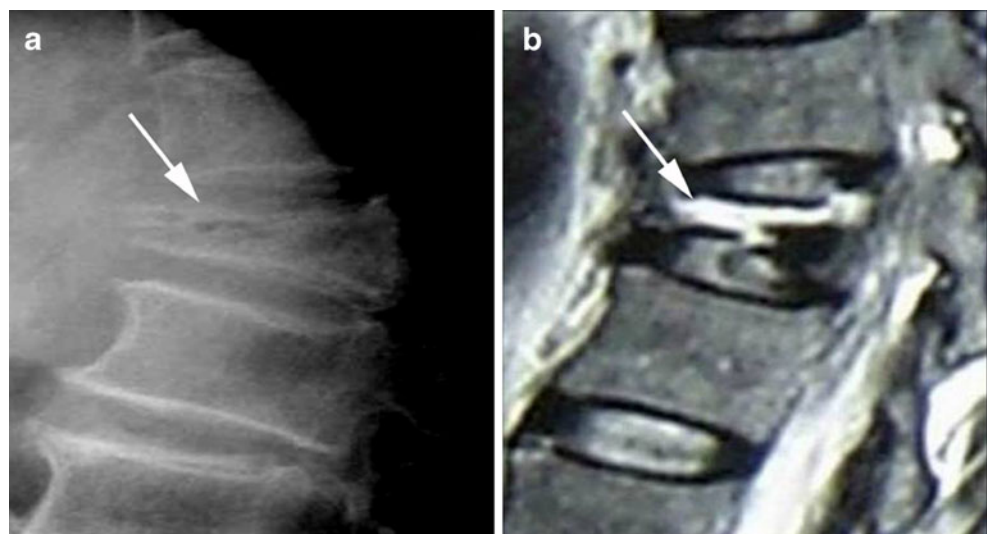
Vertebroplasty technique

Vertebroplasty was performed by staff radiologists who used a modified form of the method described by Jensen et al. [17]. The patient was placed in prone position on the table, and the skin overlying this area was prepared and draped. An 11- or 13-gauge needle was used to puncture the collapsed vertebral body via pedicle under local anaesthesia. The tip of the needle was placed in the anterior one-third of the collapsed vertebrate body without sign of intraosseous cleft. In collapsed vertebrate body with sign of intraosseous cleft, the needle tip was aimed for placement in the cleft for complete filling of the cleft with maximizing stabilization of the fracture fragments [16]. In most cases, a unilateral transpedicular approach was used. Cement was prepared as described previously and manually injected under fluoroscopic guidance [18]. The injection was stopped if the bone cement filled the vacuum cleft, reached the posterior quarter of the vertebral body, or leaked into the perivertebral veins or substantially into the disk space. The volume of injected cement was determined and recorded from the syringe graduation. No unique postural manoeuvre to retain the alignment was used before or during the procedure.

Measuring of vertebral body height and kyphotic angle

Fluoroscopic spot radiographs of the spine were reviewed. All the images were obtained with the patient placed in the prone position on the table immediately before and after vertebro-

Fig. 1 Intraosseous cleft inside a vertebral body. **a** Lateral radiograph obtained before vertebroplasty that showed cleft associated with compression fracture (*arrow*). **b** Sagittal T2-weighted MR image showed cleft in association with a vertebral compression fracture (*arrow*)



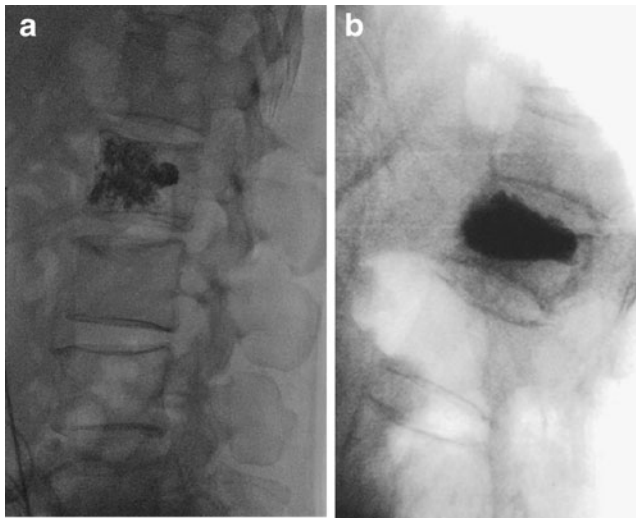


Fig. 2 Lateral radiographs show two patterns of opacification after bone cement injection. **a** Trabecular pattern of opacification represented by opaque cement distributed throughout the trabecular space. **b** Cleft pattern of opacification represented by opaque cement filling a large intraosseous cavity

plasty. The procedure was performed with the C-arm digitalized x-ray system (Angiostar, Siemens, Germany; Innova 4100, GE, USA) with a 40-cm field of view, and automatic adaptation of kV, mA and time of exposure. Before and after vertebroplasty fluoroscopic spot radiographs were exported to a workstation (Advantage Windows 4.0; GE, USA) and reviewed to measure the vertebral body height and wedge angle by a trained research assistant (X.L.) and then confirmed

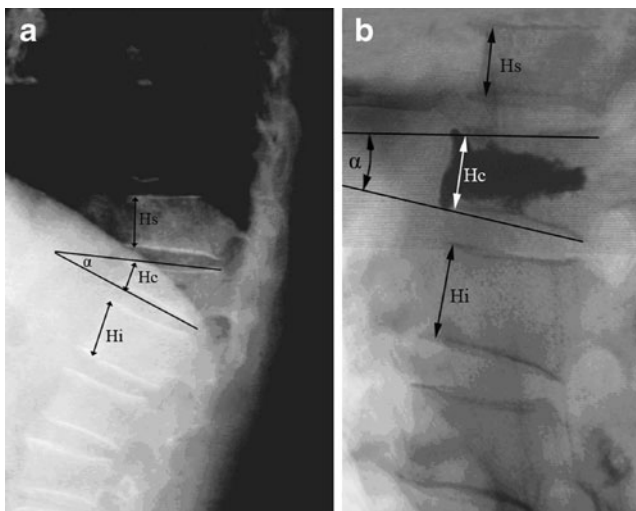


Fig. 3 Measurement of the collapsed vertebral body and reference line. Assessment of compressed vertebral body height : Most compressed vertical heights (H_c) were measured in the fractured vertebral body as compared to the same site of both nearest normal vertebral bodies (H_s and H_i) (The loss of most compressed vertical height of the vertebral body: $1 - [H_c / (H_s + H_i) / 2 \times 100\%]$). The loss of the vertical height of the vertebral body before vertebroplasty was 58.5% (**a**) and 15.0% after vertebroplasty (**b**). The wedge angle (α) in this case was 26° before vertebroplasty (**a**) and 13° after vertebroplasty (**b**)

by two experienced musculoskeletal radiologists (G.S, P.J. 25 and 16 years of experience in spinal radiology, respectively).

To correct the possible differences in the magnification ratio on the radiographs acquired from two C-arm system, we calculated the ratio of the most compressed vertical height of the collapsed vertebral body (H_c) compared to the same site of both nearest normal vertebral bodies (H_s and H_i) as a original height reference [19]. Local wedge angles were measured from the superior endplate and inferior endplate of the treated level (Fig. 3).

To illustrate the height of the vertebral body, the loss from fracture was the height before vertebroplasty (H_{pre}) and the height after vertebroplasty (H_{post}).

The loss of most compressed vertical height of the vertebral body due to the fracture before and after vertebroplasty was represented as follows: $H_{pre/post} = 1 - [H_c / (H_s + H_i) / 2 \times 100\%]$, where H_c is the most compressed vertical height of the collapsed vertebral body, H_s and H_i are the height of the same site of nearest superior and inferior normal vertebral bodies.

Thus, the restoration percentage of the height of the vertebral body was calculated as follows: $[(H_{post} - H_{pre}) / (1 - H_{pre})]$.

Similarly, the wedge angle due to the fracture before and after vertebroplasty was represented as: (wedge angle)_{pre}, and (wedge angle)_{post}.

Thus, the restoration percentage of the wedge angle was obtained from the following: $[(\text{wedge angle})_{pre} - (\text{wedge angle})_{post}] / (\text{wedge angle})_{pre}$.

Pain evaluation

The numerical rating scale, an 11-point scale with which patients subjectively rate their pain from 0 (no pain) to 10 (unbearable pain), was used and 1.5 as the minimal clinically important difference [3]. Numerical rating scale scores were established at initial evaluation and re-evaluated at 1 week, 1 month, 6 months, and 12 months after the procedure by telephone.

Statistical comparison before and after procedure

Data were analyzed using a commercially available statistical software package (SPSS for Windows, version 12.0. 2003; SPSS, Inc., Chicago, IL, USA). At a whole patient level analysis and a vertebra-by-vertebra level analysis, the effects of the changes in the vertebral body height and wedge angles between pre and post-procedure were statistically analyzed by using a paired-sample *t* test. The volume of injected cement was recorded. Pain scores between pre and post-procedure were statistically analyzed by using Kruskal Wallis test. For all statistical analyses, a *P* value less than 0.05 were considered statistically significant.

Results

In this study, the effects of vertebroplasty on the height restoration and kyphosis correction were evaluated in 156 patients (232 levels). We examined whether patients obtained the height-restoration and kyphosis-correction effects after vertebroplasty at a whole patient level analysis and vertebra-by-vertebra level analysis.

Amount of injected cement

The amount of cement injected per patient ranged from 2.0 to 7.0 mL, with a mean of 4.85 ± 1.71 mL. The amount of cement injected in the cleft group was 3.41 ± 1.23 mL in thoracic vertebrae and 5.55 ± 1.61 mL in lumbar vertebrae; in the non-cleft group, the injected cement was 3.37 ± 1.23 mL and 5.49 ± 1.67 mL in thoracic vertebrae and lumbar vertebrae, respectively. There was no statistically significant difference between two groups ($p=0.19$, and $p=0.16$).

Radiological results

Table 1 showed the changes in the height of the vertebral body and wedge angle from pre-procedure to post-procedure. A significant gain of most compressed vertical height rate ($9.7 \pm 19.0\%$; $P < 0.001$) and reduction in wedge angle ($1.2 \pm 3.4^\circ$; $P < 0.01$) were observed at a whole patient-level analysis. However, with a vertebra-by-vertebra level analysis, in the non-cleft group, both vertebral height and wedge angle showed no significant change when values of the pre-procedure were compared values of the post-procedure by using a paired sample *t* test ($P=0.11$, and $P=0.16$). A significant gain of the most compressed vertical height rate (45.4 ± 8.5 ; $P < 0.001$) and a reduction in wedge angle ($5.4 \pm 5.6^\circ$; $P < 0.01$) were observed in the cleft group.

Pain relief

Pain relief was observed in 94% (46/49) of patients with intraosseous cleft and 93% (100/107) of patients without intraosseous cleft at 1 week and continued to 12 months after vertebroplasty, respectively. No worsening of pain had been noticed. Numerical pain scores were displayed in the bar graph (Fig. 4). Baseline numerical pain scores were available for all treated patients (mean= 8.4 ± 0.6), and were available for 49 patients with clefts (mean= 8.5 ± 0.8) and 107 patients without cleft (mean= 8.4 ± 0.5) ($P=0.18$). Post-procedural pain levels were obtained for all treated patients (mean= 4.1 ± 0.6) at 1 week, (mean= 3.3 ± 1.1) at 1 month, (mean= 3.3 ± 1.1) at 6 months, (mean= 3.1 ± 1.2) at 12 months. Pain scores were available in the cleft group and non-cleft group (mean= 3.4 ± 1.0) and (mean= 4.2 ± 1.0) ($P=0.32$) at 1 week; (mean= 3.4 ± 1.1) and (mean= 3.9 ± 1.1) ($P=0.65$) at 1 month; (mean= 2.9 ± 1.2) and (mean= 3.3 ± 1.1) ($P=0.24$) at 6 months; (mean= 2.7 ± 1.2) and (mean= 3.2 ± 1.1) ($P=0.16$) at 12 months. Although there was a trend toward improved outcome in the cleft population alone, these differences were not statistically significant.

Discussion

Vertebroplasty is a minimally invasive procedure that provides pain relief and stability for osteoporotic compression fractures. Although the results are generally considered good or satisfactory by the patients and physicians, there has been no attempt to restore vertebral body shape and eliminate spinal deformity with vertebroplasty initially [6]. A modification of the technique, called “kyphoplasty”, has been reported to be an effective technique for achieving a better restoration of vertebral height and wedge angle

Table 1 Parameters of pre-procedure and post-procedure

Parameter	Pre-procedure	Post-procedure	<i>P</i> value ^a	Gain
Height^b				
Total levels (<i>n</i> =232)	55.6±25.6 (3.6, 90.0)	65.4±16.1(20.0, 94.8)	<0.001	9.7±19.0 (-4.6, 61.1)
Non cleft group (<i>n</i> =183)	65.7±17.7(19.6, 90.0)	65.9±17.5 (20.0, 90.4)	0.11	0.2±1.4 (-4.6, 10.1)
Cleft group (<i>n</i> =49)	17.8±10.7 (3.6, 82.6)	63.3±8.8 (25.2 94.8)	<0.001	45.4±8.5 (12.2, 61.1)
Wedge angle, °				
Total levels (<i>n</i> =232)	11.6±6.7 (3.3, 33.5)	10.4±6.1 (0.3, 27.1)	<0.01	1.2±3.4(-6, 27.4)
Non cleft group (<i>n</i> =183)	10.7±6.3 (3.3, 26.1)	10.6±6.2 (3.0, 26.1)	0.16	0.1±0.44 (-2.1, 1.3)
Cleft group (<i>n</i> =49)	15.1±7.0 (3.6, 33.5)	9.7±5.4 (0.3, 27.1)	<0.01	5.4±5.6 (-6, 27.4)

Data are the mean±SD. Data in parentheses are the minimum, maximum

^a For the comparison of pre-procedural and post-procedural values with the paired-sample *t* test

^b Heights were calculated as $H = [Hc / (Hs + Hi)] / 2 \times 100\%$

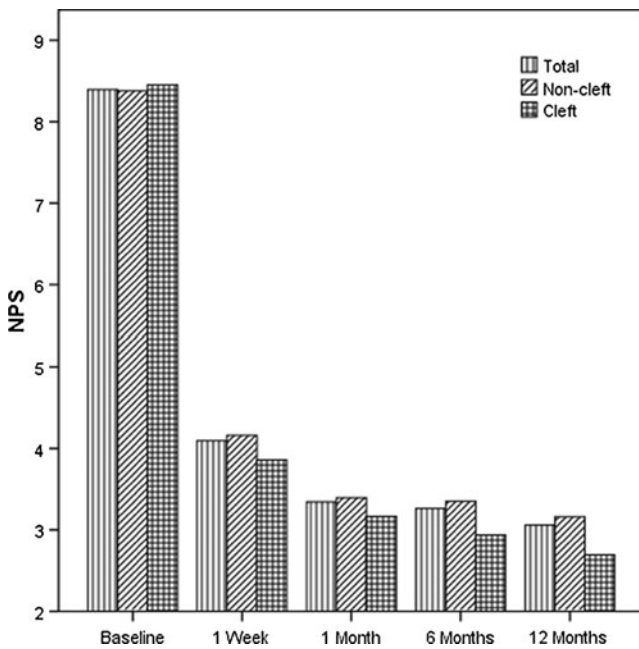


Fig. 4 Graph showed mean numerical pain scores recorded in all treated patients and groups with cleft or non-cleft at preprocedural baseline, 1 week, 6 months, and 12 months after vertebroplasty. *Strait line bars*, total treated patients; *Diagonal line bars*, non-cleft group; *Grid bars*, cleft group

[20–25]. Wang et al. [26] also reported that kyphoplasty achieved pain-relieving effects and some correction of the spinal deformity in vertebral compression fractures with cleft. Nevertheless, an *in vitro* study found that kyphoplasty achieved a better initial vertebral height restoration than vertebroplasty, the restored height was lost significantly during cyclic loading, and vertebroplasty specimens had higher compression stiffness and smaller height reduction [27].

In this study, it was analyzed that the effect of vertebroplasty on the restoration of height and on the reduction of the wedge angle for the collapsed vertebral bodies. Our results showed that performing vertebroplasty could restore some height of the collapsed vertebral bodies and correct some degree of the wedge angle due to compression fractures generally at a whole patient level analysis. However, at a vertebra-by-vertebra level analysis, the effects on the restoration of height and on the reduction of the wedge angle were observed only among patients in the cleft group.

McKiernan et al. noticed an intravertebral cleft was always present in mobile fractures and absent in immobile fractures. Postoperatively, in mobile fractures, average anterior vertebral height increased 106% compared with initial fracture height (absolute increase, 8.41 ± 0.4 mm), and kyphotic angle decreased 40%. However, fixed fractures exhibited no mobility had no appreciable height increase [5]. Several authors described techniques for postural reduction of vertebral body fracture height, some

used this technique with vertebroplasty, and others used that with kyphoplasty. Carrier et al. reported [8] that mobility in vertebral collapsed fracture was not always associated with a detectable intravertebral cleft. The result of the study showed that vertebroplasty with spinal hyperextension could correct some degree of localized kyphosis in cases of intravertebral mobility without intravertebral cleft. In the study reported by Cawley et al. [28], the patient was positioned prone with supports under the iliac crests and upper thorax to allow gravity to extend the spine. The positioning technique created a mean anterior height increase from 72% to 78% of the average height of the vertebrae. Balloon inflation did not significantly further increase anterior or posterior vertebral height, or Cobb angle.

In our study, pain relief was observed in 94% (46/49) of patients in the cleft group and 93% (100/107) of patients in the non-cleft group at 1 week and continued to 12 months after vertebroplasty. Although there was a trend toward more improved outcome in the cleft group, these differences were not statistically significant between two groups. However, some studies reported that pain relief following vertebroplasty was not substantially greater in patients with cleft, or in mobile fractures than in fixed [29, 30]. Two recent randomized controlled clinical trials found that the pain relief effect of vertebroplasty was no better than local anaesthetic [31, 32]. These data suggested that the mechanical and clinical effectiveness of vertebroplasty needed further investigation.

There is broad agreement that cleft is attributed to restore height and reduce wedge angle. However, most prior studies suggest that vertebroplasty can achieve some restoration of vertebral body height and/or improvement of wedge angle in collapsed vertebral bodies with and without cleft. To date, a few studies have looked into the effect of collapsed vertebral bodies with and without cleft on the improvement of the spinal deformity respectively. In a study by Teng et al. [7], the reduction of the kyphosis angle after vertebroplasty was greater in the cleft group than that in the non-cleft group, but the difference were not statistically significant. Vertebroplasty resulted in a gain in height at the anterior border, at the center, and at the posterior border, in both the cleft and non-cleft groups. However, Teng et al. did not explore that the relationship between the injection volume of cement and restoration of vertebral body shape and kyphosis angle [7]. Experiments on isolated cadaver vertebral bodies showed full restoration of vertebral body stiffness required injection volumes of approximately 4 mL in thoracic vertebrae and 6 to 8 ml in thoracolumbar vertebrae [33–35]. Restoration of vertebral body shape and kyphosis angle was also associated with increased in the injection volume of cement [36]. However, a large cement volume might not be advisable clinically as it increases the risk of cement leakage [37]. In our study, an

average injection volume of cement in the cleft group was (3.41 ± 1.23) mL in thoracic vertebrae and that was (5.55 ± 1.61) mL in lumbar vertebrae; An average injection volume of cement in the non-cleft group was (4.37 ± 1.23) mL in thoracic vertebrae and that was (5.49 ± 1.67) mL in lumbar vertebrae. There was no statistically significant difference between two groups ($P=0.19$, and $P=0.16$).

Our data suggested that only compressive vertebral body with treated cleft was associated with improvement of the spinal deformity. The difference in findings from other studies might be attributed in part to the following factors: a Early vertebroplasty was performed in part patients who no longer required a failure of medical therapy before the procedure, which might reduce the occurrence of potential intraosseous cleft; b No unique postural manoeuvre to retain the alignment was used before or during the procedure; and c Measurement of vertebral body height was the most compressed vertical height rather than the anterior, central, and posterior heights.

This study suffers several limitations. Most importantly, the study was retrospective in nature. In addition, following up radiographs were not obtained, the change of post-procedure vertebral height and wedge angle could not be determined. Finally, antecedent vertebral venography with contrast was not performed before injection of cement. Persistent contrast within a cleft might aid in the detection of clefts that might otherwise undetectable by MR images, CT images and conventional radiographs that might assist in predicting the effect of improvement of the spinal deformity with vertebroplasty in some kind of patient.

In conclusion, vertebroplasty seems an effective treatment strategy for osteoporotic compression fractures. Specifically, treatment of cleft-containing vertebrae with vertebroplasty is associated height restoration and the wedge-angle reduction in the fractured vertebral body. However, the effect of height restoration and wedge-angle reduction is not found in patients without cleft inside the fractured vertebral body. In appropriately patients selected, vertebroplasty may provide an opportunity for improvement of the spinal deformity, in addition to pain relief.

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